

**Informing the adaptation of a brief psychological intervention
for delivery by non-mental-health specialists for the treatment
of perinatal depression**

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Abstract

Behavioural activation (BA) is recommended by National Institute for Health and Care Excellence (NICE) guidelines for the treatment of perinatal depression; however, there is limited evidence about whether it is effective when delivered by non-mental-health specialists (NMHS) in a perinatal setting in the UK. This PhD aimed to adapt the BA intervention manual and guided self-help booklet intended for delivery by NMHSs for the treatment of perinatal depression.

A systematic review was conducted to examine the effectiveness of psychological interventions delivered by NMHSs for the treatment of perinatal depression. Thirteen randomised controlled trials (RCT) (N = 3040) were included in the review. The meta-analyses indicated that Cognitive Behavioural Therapy (CBT) delivered by NMHSs for postnatal depressive symptoms was superior to control at <6 months (SMD= -0.36; 95% CI -0.65 to -0.07; N = 500) and 6 to 12 months (MD= -1.32; 95% CI -2.09 to -0.56; N = 710). This review did not identify any trials of BA, indicating a knowledge gap.

Qualitative interviews with women and healthcare professionals (HCP) informed the adaptation process for the BA manual and booklet. Interviews with women (N = 15) and HCPs (N = 19) demonstrated that women who experience perinatal low mood or depression symptoms but do not fill the criteria for a referral to perinatal mental health services are not currently catered for. Interview findings suggested that this gap could be filled by NMHSs, such as Maternity Support Workers with appropriate training and supervision, by providing a brief talking therapy to these women.

Four co-design workshops with the involvement of women (N = 14) and HCPs (N = 3) helped to modify the BA documents for the specific needs of perinatal women. The results of this PhD provide the foundation to assess the effectiveness of the adapted intervention in a subsequent RCT.

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Author's Declaration

I declare that this thesis is a presentation of original work and I am the sole author. This work has not previously been presented for an award at this, or any other, University. All sources are acknowledged as References.

- The articles submitted from this thesis:

1) Chapter two has been submitted as a review article to Psychiatric Quarterly Journal. The authors are: Semra Pinar, Dean McMillan, Helen Bedford, and Steven Ersser.

2) Chapter four has been submitted as a primary research article to INQUIRY: The Journal of Health Care Organization, Provision and Financing. The authors are: Semra Pinar, Helen Bedford, Steven Ersser, and Dean McMillan.

3) Chapter five has been submitted as a primary research article to Behavioural and Cognitive Psychotherapy Journal. The authors are: Semra Pinar, Steven Ersser, Dean McMillan, and Helen Bedford.

Introduction

This PhD consists of three interrelated studies: an evaluation of the effectiveness of psychological interventions delivered by non-mental-health specialists (NMHS) for the treatment of perinatal depression; an exploration of women's experiences of perinatal low mood or depression and healthcare professionals' (HCP) experiences of providing support or care for women who have perinatal low mood or depression; and co-design workshops intended to inform the adaptation of a brief behavioural activation (BA) intervention manual and guided self-help booklet for delivery by NMHSs, such as maternity support workers (MSW) for the treatment of perinatal depression.

The first study element is a systematic review and meta-analysis of randomised controlled trials (RCT), in which the type of psychological interventions (including but not limited to BA), the groups of NMHSs, and the effectiveness of these interventions delivered by non-specialist groups, are examined. The findings of the systematic review showed limited evidence about the effectiveness of BA in a perinatal setting. This finding and the literature review informed the second and third study elements of the thesis: adapting a BA booklet intended for use by women with perinatal depression and a treatment manual intended for use by NMHSs, for example, MSWs delivering BA.

The second and third study elements are part of an experience-based co-design (EBCD) approach (O'Cathain et al., 2019a; Craig et al., 2013; Bate and Robert, 2007), underpinned by a symbolic interactionism (SI) theoretical perspective (Blumer, 1998). Qualitative data was collected through adopting an ethnographic approach (Hammersley and Atkinson, 2007), which then formed part of the first 'discovery phase' of the EBCD. The data was generated through face-to-face individual interviews with women and individual and focus group interviews with maternity HCPs. This was the starting point for the process of adapting the manual and booklet for women who experience perinatal depression symptoms.

The third study built on the first and second studies. In the third study, women and HCPs were introduced to the prototypes of the therapy manual and booklet and were invited to involve in the adaptation process through co-design workshops. The

adaptations were made iteratively as the co-design data emerged. The new prototypes of the manual and booklet were presented in every workshop and the co-designers commented on them and further changes were then made.

This PhD study provides a rich source of information to better understand the women's experiences of low mood and depression, and the potential challenges and enablers during the perinatal period, and to improve the provision of perinatal depression care, all of which informs the adaptation of BA intervention manual and booklet. It was carried out in the context of improving support for women with perinatal depression who may not need a referral to specialised mental health services but may need some form of talking therapy.

Chapter 1: Background

1.1 Introduction

This section provides an overview of mental health problems, particularly depression, in the perinatal period. It covers current approaches to the treatment of perinatal depression and highlights gaps in the evidence of treatment efficacy. These gaps are then linked to the focus of the thesis, which was to adapt a manualised BA intervention and guided self-help booklet suitable for delivery by NMHSs in a perinatal setting.

The chapter first defines key terms and then provides a summary of the prevalence and consequences of perinatal depression, including consequences for the mother, the child and other family members, as well as the economic costs. Treatments for perinatal depression, including pharmacological and psychological treatments, are discussed. A distinction is made between low- and high-intensity interventions.

While there are many different treatment options for perinatal depression, psychological interventions are widely preferred by women in the perinatal period (Dennis and Chung-Lee, 2006). From the available psychological interventions, BA differs from others in terms of its simplicity and cost-effectiveness; however, there is limited evidence about the effectiveness of BA in a perinatal setting (Chartier and Provencher, 2013).

The chapter then discusses the current policy and practice context of perinatal depression treatment, with a focus on the UK, before outlining the aims and objectives of the doctoral work.

1.2 Women's mental health in the perinatal period

The perinatal period encompasses pregnancy (antenatal period) and the first year after childbirth (postnatal period) (O'Hara and Wisner, 2014). Perinatal mental health problems are of critical importance because of the potential risks they represent to the woman and their family if they are not identified and left untreated (Howard and Khalifeh, 2020). A number of national guidelines for the detection and management of perinatal mood disorders have been published, including those for England, Scotland,

Australia, and the USA (National Institute for Health and Care Excellence, 2020; Scottish Intercollegiate Guidelines Network, 2012; Austin, Highet and the Expert Working Group, 2017; Yonkers et al., 2009 respectively). A number of authors have argued that more attention on perinatal mental health disorders is needed among healthcare professionals as adverse outcomes (e.g., prolonged morbidity or deterioration in symptoms) for women and other family members may occur if the diagnosis is delayed or the difficulty remains untreated or inadequately treated (Obe, 2015; Bauer et al., 2014; Joint Commissioning Panel for Mental Health, 2012; Scottish Intercollegiate Guidelines Network, 2012).

In addition, mental health problems are highly related to maternal deaths in the postnatal period. In 2015-17, mental health related deaths were the fifth most common cause of women's death during pregnancy or up to six weeks after childbirth, and suicide was the leading cause of death in the postpartum period in the UK (Knight et al., 2019).

A retrospective cohort study used electronic health records from nearly 10% of primary care settings in the UK to estimate the prevalence of children (aged 0-16 years) exposed to perinatal mental disorders in the UK from 2005 to 2017 (Abel et al., 2019). In total, 547,747 children and 381,685 mothers were included in the analysis. Maternal mental disorders were identified and analysed using routinely recorded data through ICD-10 categories (World Health Organisation, 1992). The findings suggest a small but significant increase in the prevalence of maternal mental disorders from 22.2% (95% CI 21.9 - 22.4) to 25.1% (95% CI 24.8 - 25.5) in the last decade (2007 to 2017) (Abel et al., 2019). It is important to consider some potential methodological issues when interpreting these findings. First, the data used in this study were collected from primary care, so the prevalence estimates may be inflated by the increased detection of mental health illnesses in primary care compared to wider population. Secondly, the changing prevalence may be related to destigmatising of mental health problems over the last decade. It is not clear, therefore, if there is a rise in the underlying prevalence or an increased willingness to report symptoms of mental health problems.

Perinatal mental illnesses comprise a wide spectrum of psychiatric disorders varying from mild depression to psychosis. These disorders are prevalent during pregnancy or in the postnatal period; however, they may present before pregnancy and recur during the perinatal period (Howard and Khalifeh, 2020). Table 1 displays the rates of perinatal mental health disorders per thousand maternities in the UK (Joint Commissioning Panel for Mental Health, 2012, p.6). Depression has relatively high rates relative to other perinatal mental health disorders. It is estimated that at least 1 in 10 women experiences depression in the perinatal period, and this is higher in low to middle-income countries than high-income countries and among socio-economically disadvantaged women (Woody et al., 2017; Fisher et al., 2012; Parsons et al., 2012; Gavin et al., 2005). Perinatal depression is, therefore, a substantial public health concern and the next section will discuss this in more detail.

Table 1: Rates of perinatal mental health disorders per thousand maternities in the UK (Joint Commissioning Panel for Mental Health, 2012, p.6)

Mental health problem	Rates per 1000
Postpartum psychosis	2/1000
Chronic serious mental illness	2/1000
Severe depressive illness	30/1000
Post-traumatic stress disorder	30/1000
Mild-moderate depressive illness and anxiety states	100-150/1000
Adjustment disorder and distress	150-300/1000

1.3 Perinatal depression

Depression is one of the most common mental health disorders in the perinatal period (Howard and Khalifeh, 2020). ‘Perinatal depression’ is regarded as a non-psychotic depressive episode that may occur in pregnancy or the year after childbirth (National Institute for Health and Care Excellence, 2020; Scottish Intercollegiate Guidelines Network, 2012).

One main classification tool for mental and behavioural disorders is the International Statistical Classification of Diseases and Related Health Problems, 10th Edition (ICD-10) (World Health Organisation, 1992); another common tool is the Diagnostic and Statistical Manual of Mental Disorders – Fifth Edition (DSM-V) (American Psychiatric Association, 2013).

According to ICD-10 (World Health Organisation, 1992), “depression” is classified on the basis of the following symptoms:

- 1- loss of interest and enjoyment
- 2- persistent sadness or low mood
- 3- fatigue or low energy, and associated symptoms
- 4- reduced concentration or attention
- 5- decreased self-esteem and self-confidence
- 6- disturbed sleep
- 7- diminished activity
- 8- poor appetite
- 9- feeling distress or agitation
- 10- suicidal thoughts or acts.

The ICD-10 diagnostic criteria for perinatal depression require the presence of five symptoms, one of which must be low mood or loss of interest/ pleasure commencing any time in pregnancy or within six weeks of birth, and continuing for at least two weeks (World Health Organisation, 1992, pp.119-124).

DSM-V has a broadly comparable list of depressive symptoms to ICD-10. It lists postpartum depression under ‘depressive disorder with peripartum onset’, described as starting any time in pregnancy or within the four weeks of childbirth (American Psychiatric Association, 2013).

Some women experience sub-clinical symptoms, which do not meet these diagnostic criteria but nevertheless lead to psychological distress, impairment of daily functioning and reduced quality of life (Milgrom and Gemmill, 2020). Sub-clinical depression is typically defined as having two to four symptoms, one of which must be low mood or loss of interest or pleasure (American Psychiatric Association, 2013; World Health Organisation, 1992). These symptoms can include fatigue, sleeping problems and changes in appetite, all of which can be experienced by most depressed and non-depressed pregnant and postpartum women (Boyd, Le and Somberg 2005; Runquist, 2007). Whether including somatic symptoms in depression severity measures would help to establish perinatal depression symptoms is not clear. For example, the Edinburgh Postnatal Depression Scale (EPDS) (Cox and Holden, 2003) explicitly excludes somatic symptoms of depression except for sleep difficulties (Boyd, Le and Somberg 2005); whereas other measure, such as the Patient Health Questionnaire (Kroenke, Spitzer and Williams, 2001), which is widely used in UK settings antenatally and postnatally, does include somatic symptoms.

Postpartum depression also needs to be differentiated from the 'baby blues'. The rapid decrease in oestradiol and progesterone levels is believed to lead to some changes in mood after childbirth (Wisner, Parry and Piontek, 2002). During the first a few days after giving birth, women may feel mood lability, confusion, anxiety and be tearful (National Health Service Choices, 2015b; O'Hara, 2009; Wisner, Parry and Piontek, 2002). This emotionally labile state is described as 'baby blues' (Scottish Intercollegiate Guidelines Network, 2012; Wisner, Parry and Piontek, 2002). Baby blues typically appears on the second or third day after giving birth and disappears by the tenth day (O'Hara, 2009; Wisner, Parry and Piontek, 2002). While the origin of 'baby blues' symptoms is physiological within a few days after childbirth, help and support may be needed if it continues for more than two weeks (National Health Service Choices, 2015b; Scottish Intercollegiate Guidelines Network, 2012). 15 to 84% of mothers report feeling weepy or tearful on the third day after giving birth (Henshaw, 2003). Other symptoms of baby blues are irritability, interpersonal hypersensitivity, insomnia and sometimes elation (O'Hara and Segre, 2008). It is important for women and HCPs to differentiate depression and these temporary changes in mood after giving birth, so

as to seek help earlier and provide support to women when they are potentially in a vulnerable period.

1.3.1 Prevalence of perinatal depression

Depression is a common mental health disorder during pregnancy and in the first year after childbirth. A systematic review (Gavin et al., 2005) and a large US epidemiological study (Vesga-Lopez et al., 2008) reported non-significant differences in the prevalence of depression between pregnant and similar aged nonpregnant women; however, the prevalence of depression was found to be significantly higher in the postpartum period than in aged 18-50 nonpregnant women (Vesga-Lopez et al., 2008).

A recent meta-analysis amongst perinatal women in low-, middle- and high-income countries showed that the estimated point prevalence of depression is in the range of 9% to 19% in the perinatal period, while being higher in low- and middle-income countries than higher income countries; however, there were no statistical differences between prevalence estimates of antenatal and postpartum depression (Woody et al., 2017). Almost 75% of included studies used self-administered screening tools rather than gold standard semi-structured diagnostic interviews to determine the prevalence of depression. The use of self-report screening tools may artificially inflate the prevalence estimates, because the cut-off selected for a screening tool may have a high false-positive rate. Most studies used the Edinburgh Postnatal Depression Scale for the measurement of severity of depression symptoms; however, the cut-off scores ranged from 10 to 15, which may explain the wide range of prevalence in addition to other factors, for example, design and settings. Definition of postpartum depression may also vary in the included studies as DSM-V and ICD-10 describes postnatal depression occurring within four and six weeks after delivery respectively, while self-administered scales may not impose the criteria of onset within four or six weeks (American Psychiatric Association, 2013; World Health Organisation, 1992).

The review conducted by Woody et al. (2017) indicated estimates of the prevalence of perinatal depression; however, other reviews provided detail about trimesters. An international systematic review amongst women in high-income countries showed that the prevalence of antenatal depression varies between 2.2-12.6% in the first trimester, 10.7-14.8% in the second trimester, and 7.4-16.7% in the third trimester

(Bennett et al., 2004). Other research indicates that the prevalence of postpartum depression, mostly in high-income countries, ranges from 7.4 to 11.0% in the first three months after delivery, 7.8 to 12.8% between three to six months, and 8.5 to 19.2% between six to nine months postnatally (Bauer et al., 2014; Banti et al., 2011; Gavin et al., 2005; Gaynes et al., 2005; Heron et al., 2004).

There is less data on the prevalence of sub-clinical depression. Gavin et al. (2005), however, reported a figure of 13% at three months post-partum. This suggests that sub-clinical depression may also be common in this period.

A US study, including 826 women who gave birth in an urban women's hospital, found that the majority of depression cases in the perinatal period have postpartum onset (within four weeks after delivery) (40.1%) compared to antenatal (33.4%) and before the antenatal period (26.5%) (Wisner et al., 2013). Whether onset is antenatal or postpartum, many depression cases may not be identified until much later (The National Childbirth Trust, 2017; Khan, 2015; Bick and Howard, 2010). This may result in unresolved ongoing problems which may have an impact on women's wellbeing, relationship with their partners and children, and their work-life (O'Hara, 2009).

1.3.2 Risk factors for perinatal depression

A risk factor is described as a measurable exposure that precedes the outcome, has an association with the outcome, and increases the likelihood of the outcome occurring (Kraemer et al., 1997). In order to demonstrate a characteristic is a risk factor: 1) the factor and the outcome should be defined clearly and measured validly and reliably; 2) the factor should occur before the outcome; 3) a statistically significant non-random association between the factor and the outcome should be established; 4) the effects of other variables in the outcome should be minimised; and 5) these criteria should ideally be assessed using a prospective cohort design (groups with and without the risk factor followed across time until the outcome occurs) (Kraemer et al., 1997).

Although a number of systematic reviews have been conducted to evaluate risk factors for perinatal depression (Howard et al., 2013; Beydoun et al., 2012; Fisher et al., 2012; Collins, Zimmerman and Howard, 2011; Villegas et al., 2011; Lancaster et al., 2010; Sawyer, Ayers and Smith, 2010; Vigod et al., 2010; Ross and Dennis, 2009; Robertson

et al., 2004; Beck, 2001), the primary studies included in the reviews were predominantly cross-sectional and case-control studies rather than cohort designs, which is typically needed to address the second criterion (temporal precedence) and does not meet the fifth (cohort design). While a small number of studies implemented gold-standard diagnostic interviews for the diagnosis of depression, the majority did not, so may not meet the first criterion (valid measurement). Although attempts were made in most studies to control statistically for other variables, it is unclear if all relevant variables were included or whether those included were measured in a valid and reliable way. This may limit the extent to which the fourth criterion is met (minimising impact of other variables). The majority of the evidence currently, therefore, speak mainly to the third criterion: the association between a putative risk factor and outcome.

On the basis of three reviews (Fisher et al., 2012; Lancaster et al., 2010; Sawyer, Ayers and Smith, 2010), risk factors with medium to strong statistically significant associations with antenatal depression include: domestic violence, prior history of psychopathology, life stress, low socio-economic status, and lack of social or partner support. Unintended pregnancy and being younger were found as risk factors with small associations with antenatal depression (Fisher et al., 2012; Lancaster et al., 2010; Sawyer, Ayers and Smith, 2010). A cross-sectional study including 1719 women conducted in Hungary found a history of unfavourable obstetric outcomes in a previous pregnancy as a risk factor for depressive symptoms during pregnancy (Dudas et al., 2012), which is consistent with one of the reviews previously mentioned (Sawyer, Ayers and Smith, 2010).

Ten systematic reviews (Howard et al., 2013; Beydoun et al., 2012; Fisher et al., 2012; Collins, Zimmerman and Howard, 2011; Villegas et al., 2011; Sawyer, Ayers and Smith, 2010; Vigod et al., 2010; Ross and Dennis, 2009; Robertson et al., 2004; Beck, 2001) and a large prospective study (n = 40,333) (Milgrom et al., 2008) looked at risk factors for postpartum depression. The common risk factors with medium to strong statistically significant associations with postpartum depression were: domestic violence, stressful life events, low social and partner support, depression or anxiety during or before pregnancy, previous nonpuerperal depression, low socio-economic status, migration status, and increased parity (Howard et al., 2013; Beydoun et al.,

2012; Fisher et al., 2012; Collins, Zimmerman and Howard, 2011; Villegas et al., 2011; Sawyer, Ayers and Smith, 2010; Vigod et al., 2010; Ross and Dennis, 2009; Milgrom et al., 2008; Robertson et al., 2004; Beck, 2001). Family history of any psychiatric illness and preterm birth and low birth weight were found as risk factors with small associations with postpartum depression (Fisher et al., 2012; Sawyer, Ayers and Smith, 2010; Vigod et al., 2010).

Although the majority of studies reviewed in the systematic reviews are case-control and cross-sectional designs, there are a number of longitudinal studies that have implemented gold-standard diagnostic interviews for the diagnosis of depression (Abiodun, 2006; Kersting et al., 2004; Rahman, Iqbal and Harrington, 2003; Chandran et al., 2002; Brugha et al., 1998). These studies found that poor social and family support (Abiodun, 2006; Rahman, Iqbal and Harrington, 2003; Chandran et al., 2002; Brugha et al., 1998), younger age (Abiodun, 2006), low income (Chandran et al., 2002), stressful life events (Chandran et al., 2002; Rahman, Iqbal and Harrington, 2003), being primigravida (Abiodun, 2006), having low birth weight infant (Kersting et al., 2004), and having undesired gender for their baby (Abiodun, 2006; Chandran et al., 2002) were risk factors for postpartum depression. These studies can better speak to criterion two (risk factor occurs before the onset of the outcome). More recent cohort studies established the similar risk factors; however, they used depression severity scales rather than diagnostic interviews (Rogathi et al., 2017; Tachibana et al., 2015).

In summary, there are a number of systematic reviews indicating a number of risk factors for antenatal and postpartum depression; however, many of the included studies had limitations in using appropriate study designs for establishing risk factors and controlling the third variables, and measuring the depression symptoms with gold standard semi-structured diagnostic interviews. These variables are, therefore, mostly associated with perinatal depression rather than being risk factors.

1.3.3 Consequences of perinatal depression

Whether experienced during pregnancy, in the postpartum period or before being pregnant, depression initiates challenging times for women, their children and the wider family. This section first outlines the consequences of perinatal depression on women. Secondly, its potential impact on physical, social, emotional, and cognitive

development of infants and children is discussed. Finally, the impact of perinatal depression on partners is described.

Women may struggle to admit and adapt to the physical changes occurring during pregnancy and some of them may experience medical complications (e.g. hyperemesis gravidarum) as well (O'Hara, 2009). Whilst it may be hard to cope with these substantial changes, depressed women also cope with depression symptoms which is an additional and unwelcome state for women and their partners as they move into a new phase in their lives of being parents.

The expectation that new parents will be joyful and celebrate the birth of the child, makes depression more poignant in the postpartum period (O'Hara, 2009). Moreover, the needs of newborns are considerably higher in the first a couple of months, for example, feeding and changing the baby at night, in addition to providing care all day. These challenges may make it harder for parents to adapt to the new life with a newborn who requires attention most of the time, even if they do not have a medical problem (e.g. jaundice). Other responsibilities such as caring for older children and pets, continuing daily household routines (e.g. cooking, laundry, washing up) and keeping up with normal self-care (e.g. having a bath, watching TV, reading) can be experienced as additional burdens regardless of whether a woman has depression or not. However, experiencing depression symptoms can be overwhelming for women, their partners and children (Milgrom and Gemmill, 2020). In addition, women may feel inadequate fearing that they are unable to meet the family's basic needs and this may lead to a worsening of their symptoms (Goodman and Brand, 2008).

Antenatal depression has other wider effects on women: it may reduce a woman's concentration and ability to make decisions about her own health and wellbeing, in addition to that of her foetus (e.g. diet, smoking, alcohol use and substance misuse) (Coverdale et al., 1996). This may result in poorer antenatal self-care and a range of obstetric complications (e.g. preeclampsia) and pregnancy outcomes (e.g. low birth weight and preterm delivery) (Milgrom and Gemmill, 2020; O'Hara, 2009).

Postpartum depression may impact mothers' breastfeeding behaviours. A review found an association between postpartum depression and breastfeeding (Chung et al., 2007). The findings showed that most mothers experienced depression before

cessation of breastfeeding. Chung et al. (2007) reported that women with depression were less likely to initiate or maintain breastfeeding in the postpartum period.

There is also a low but notable risk of self-harm and suicide which has been linked with perinatal depression (Lindahl, Pearson and Colpe, 2005). Women often stop antidepressant treatment in the perinatal period, which may lead to a rapid deteriorating their mood; as a result self-harm or suicide may occur (Khalifeh et al., 2016; Petersen et al., 2011). Some studies report that the risk of self-harm amongst women in UK settings varies between 6.8 - 10.2% during pregnancy (Lindahl, Pearson and Colpe, 2005; Taylor et al., 2016) and 4 - 5.4% in the postnatal period (Howard et al., 2011; Lindahl, Pearson and Colpe, 2005). Other figure suggests that suicidal ideation prevalence amongst women in the UK is 9% in the postnatal period (Howard et al., 2011). A UK-based study involving 4785 women found that approximately one in 50 suicides occurred in women aged 16-50, while one in 25 suicides occurred in perinatal women aged 20-35 (Khalifeh et al., 2016). Almost half of perinatal women and a third of non-perinatal women who died by suicide had a diagnosis of depression (Khalifeh et al., 2016). Younger age, depression diagnosis, being unmarried, having a low educational level, alcohol use, and psychosocial stress were found to be associated risk factors with antenatal suicidal ideation (Gressier et al., 2017; Zhong et al., 2016; Gavin et al., 2011). Low educational level, smoking during pregnancy, and having depression or psychiatric disorder were also reported as risk factors for suicidal ideation in the postpartum period (Gressier et al., 2017). As discussed before, suicide during pregnancy or within six weeks of the end of pregnancy is the second largest cause of direct maternal deaths in the UK and it is the leading cause of direct deaths in the postnatal period (Knight et al., 2019).

Remaining emotionally stable and engaging with infants' needs is important for infants' behavioural, emotional and cognitive development. Indeed, perinatal depression has implications for the physical, social, emotional and cognitive development of infants, children and adolescents (Milgrom and Gemmill, 2020; Murray, Fearon and Cooper, 2015; Goodman et al., 2011; Goodman and Brand, 2008).

A meta-analysis found a significant increased risk of preterm birth and low birth weight among women with depression in the antenatal period (Grote et al., 2010). The pooled

relative risk was calculated using diagnostic interviews and self-administered questionnaires separately, which was larger when dichotomous data was pooled. In addition to depression symptoms, other confounders, for example, smoking, substance use or abuse, previous preterm birth, ethnicity, socio-economic status, antidepressant use during pregnancy or medical complications may be predictive of preterm birth and low birth weight, all of which might not be easy to control in the analysis. Moreover, some studies reported an increased risk of sudden infant death syndrome with women who have experienced depression during pregnancy (Howard, Kirkwood and Latinovic, 2007) and in the postnatal period (Mitchell et al., 1992; Sanderson et al., 2002).

The most significant consequences of postpartum depression may be seen in the relationship between the woman and her newborn. For some women, it may be difficult to respond to their infants' emotional needs while experiencing loss of interest, flatness and sadness (Milgrom and Gemmill, 2020; Murray, Fearon and Cooper, 2015). This may lead to making less eye contact during feeding the baby, playing less and interacting less with the baby, giving a less positive response to them (O'Hara, 2009). Three meta-analyses demonstrated that postpartum depression is associated with a negative mother-infant relationship that involves maternal withdrawal and disengagement, all of which affect the synchrony of interaction behaviours between mother and the infant and increases the risk of avoidant and disorganised attachment pattern (Barnes and Theule, 2019; Martins and Gaffan, 2000; Lovejoy et al., 2000).

With regards to social outcomes, children of depressed mothers demonstrate social withdrawal (Field, 2011), and kindergarten-age children are frequently left out by peers (Cummings, Keller and Davies, 2005). With regards to emotional development, newborns of depressed mothers display less reactive to faces and voices, and less attentive to their own and other newborns' cry sounds. These delayed attention and slower processing are confirmed with their delayed heart rate deceleration (Field, Diego and Hernandez-Reif, 2009).

A meta-analysis, including 80,851 mother-child dyads and children aged 9 days to 20 years (mean = 7.13 years; SD = 5.08 years), showed significant association between

maternal depression and internalizing problems on children (particularly daughters) (Goodman et al., 2011). Other significant association was also reported between maternal depression and externalising problems and negative affect/behaviour (Goodman et al., 2011). These findings are consistent with other reviews (Goodman, 2019; Gentile, 2017; Sanger et al., 2015; Stein et al., 2014; Field, 2010).

Prospective longitudinal studies reporting the effects of perinatal (Pearson et al., 2013; Quarini et al., 2016) and antenatal depression (Capron et al., 2015) on children at 18 years of age show them to be at higher risk of depression. Although all these studies used the same data (Avon Longitudinal Study of Parents and Children), their analysis methods were different. There was a high attrition rate in the study which might affect the statistical power. Perinatal depression was measured through self-administrated questionnaires while their children's depression was assessed through a clinical diagnosis tool. There also might be other confounding factors affecting depression outcomes on children, for example, quality of parenting, severity of perinatal depression, persistence of perinatal depression, other mental disorders of parents, which might be predictors for depression in children.

The women's partners' health can also be affected by the depressive symptoms during the perinatal period (Milgrom and Gemmill, 2020); it is also possible that a mood disorder in one partner can exacerbate the mood of the other (Banker and LaCoursiere, 2014). This may put the couple's relationship and their children in a more vulnerable situation (Milgrom and Gemmill, 2020). The incidence of paternal depression was found to be between 1.2% to 25.5% in the community and 24% to 50% among men whose partners were experiencing postpartum depression (Goodman, 2004). Two meta-analyses found postpartum depression in the mother as the strongest predictor of paternal depression during the postpartum period (Goodman, 2004; Paulson and Bazemore, 2010). There was a moderate and positive correlation between maternal and paternal depression, which was relatively higher in the three to six months after birth (Paulson and Bazemore, 2010). Another systematic review also reported poor relationship satisfaction as an associated risk factor for depression in men (Wee et al., 2011). A literature review showed that children of depressive fathers are at risk of emotional and behavioural problems (Schumacher, Zubaran and White, 2008). The mental health needs of partners are as important as maternal depression

and require wider attention because of the consequences on a partners' ability to support women during this period (National Institute for Health and Care Excellence, 2020).

The consequences of perinatal depression for women, children and partners highlight the importance of addressing perinatal women's mental wellbeing in the perinatal period.

1.3.4 Economic cost

Perinatal depression also has an impact on the public sector and wider society services costs. It is estimated that perinatal depression, anxiety and psychosis cost £8.1 billion to society each year in the UK (Bauer et al., 2014). The average cost of one case of perinatal depression to society is around £75,728, of which £23,151 is associated with the mother and £52,577 is associated with the effects on the child (Bauer, Knapp and Parsonage, 2016). As discussed in section 1.3.3, exposure to perinatal depression increases the risk of emotional, behavioural and cognitive problems on children (ranged from 5% to 21%) and Bauer et al. (2015) argues that this is linked to economic cost via the increased need in special education for those children.

The potential risk of recurrence is another factor in increasing the economic burden. The evidence suggests that there is almost a 30 – 40% recurrence rate of depression in the perinatal period for women with a history of major depression (Di Florio et al., 2013; Goodman and Tully, 2009). Women with a history of postpartum depression symptoms are six times more likely to have recurrent depression symptoms four years after birth, compared with women without a history of postpartum depression (Josefsson and Sydsjö, 2007).

Effective treatment of perinatal depression is important not only for the woman herself and her family but also to decrease the detrimental economic costs to society.

1.3.5 Health Policy – Better Births, The National Maternity Review

Perinatal depression is a substantial public health concern because of its impact on women themselves, their children and partners, and also its costs to the family and the wider society (Bauer et al., 2014). The importance of perinatal mental health is

emphasised by the UK Government and a number of policy documents have been published in the UK in order to address this issue. A key document being implemented within England is the National Maternity Review, Better Births (National Health Service, 2016).

The National Maternity Review (National Health Service, 2016) summarises the gaps in the evidence regarding provision of perinatal mental health services, including the challenges of identifying perinatal depression, the need for education and training for HCPs with regards to identification and management of mental health disorders, and the challenges of providing perinatal mental healthcare and maintaining postnatal care. Other gaps include: insufficient duration of appointments; the challenges of providing evidence-based treatments for mental health; challenges of accessing specialist perinatal mental health services; and inadequateness of perinatal mental health services across England (National Health Service, 2016). The National Maternity Review also provides recommendations with regards to these gaps to improve the provision of perinatal mental health services (National Health Service, 2016). These include: training HCPs on the best practices to identify the risks and symptoms of perinatal mental health as early as possible to be able to offer personalised care plan at the right time; decreasing specialist perinatal mental healthcare variations across the country to ensure that women in all areas of the country receive the right care, closer to home, when they need it. Additional recommendations include: the need to review the mental health of women at every contact during pregnancy and after birth; spending sufficient time with women to build trust and get to know women better; and ensuring standardisation of the service provision across the country (National Health Service, 2016). According to these gaps and recommendations, the National Maternity Review suggested a number of action plans, one of which states that “There should be significant investment in perinatal mental health services in the community and in specialist care by 2020” (National Health Service, 2016, p. 106).

The Independent Mental Health Taskforce (2016) has also put forward similar recommendations with the National Maternity Review. In its five-year forward view for mental health report (The Independent Mental Health Taskforce, 2016, p.71) states that:

The NHS should invest to ensure that by 2020/21 at least 30,000 more women each year access evidence-based specialist mental health care during the perinatal period. This should include access to psychological therapies and the right range of specialist community or inpatient care so that comprehensive, high-quality services are in place across England.

The National Maternity Review strongly supports this statement (National Health Service, 2016, p. 60).

Other recommendations from a number of guidelines (National Health Service, 2016; Obe, 2015; Joint Commissioning Panel for Mental Health, 2012; Scottish Intercollegiate Guidelines Network, 2012) emphasise the need for HCPs to be given additional training regarding the emotional changes that occur during pregnancy and after childbirth and perinatal mental health issues. It is recommended that women have access to psychological or psychosocial interventions and Improving Access to Psychological Therapies (IAPT) services. Finally, organisations should invest in training new workforces and develop integrated care pathways (National Health Service, 2016; Obe, 2015; Joint Commissioning Panel for Mental Health, 2012; Scottish Intercollegiate Guidelines Network, 2012).

In the light of the current policy documents (National Health Service, 2016; The Independent Mental Health Taskforce, 2016) and their recommendations, a comprehensive literature review was conducted to further explore the gaps in the evidence with regards to the role of maternity services and HCPs including midwives, health visitors and general practitioners (GPs); screening, assessment and referral processes and available treatments for perinatal depression. These topics are discussed in the rest of the chapter, before the aims and objectives of the PhD study are outlined.

1.3.6 The role of maternity services

1.3.6.1 Screening and assessment

Early assessment of mental health is crucial to identifying antenatal or history of depression, providing support and making referrals to the appropriate services. As

indicated above, the National Maternity Review (National Health Service, 2016) recommended that HCPs ask women about their mental health regularly and review this at every contact during the perinatal period.

In the UK maternity services, midwives are typically the first point of contact in early pregnancy and lead carer during pregnancy, birth and the early postnatal period (first 28 days) (Nursing and Midwifery Council, 2021). The midwives have, therefore, the responsibility to detect women at risk of depression, ask about their current mental health, provide mental health support, advise women to see their GP or refer them to specialised perinatal mental health services (National Health Service, 2016; Obe, 2015; Royal College of Obstetricians and Gynaecologists, 2011). For perinatal care in England, the National Institute for Health and Care Excellence (NICE) (2020) advises HCPs to ask Whooley Questions at the first contact or booking visit, and during the early postnatal period.

The Whooley Questions (National Institute for Health and Care Excellence, 2020; Perinatal Institute, 2020; Perinatal Institute, 2019) used in practice are:

- During the past month, have you often been bothered by feeling down, depressed or hopeless? Yes / No
- During the past month, have you often been bothered by having little interest or pleasure in doing things? Yes / No

If a woman says yes to either of these questions, the NICE guidelines (National Institute for Health and Care Excellence, 2020; Perinatal Institute, 2020; Perinatal Institute, 2019) suggest offering self-reporting questionnaires such as Patient Health Questionnaire or EPDS. Although the National Maternity Review (National Health Service, 2016) recommends HCPs to review the women's mental health at every contact, the pregnancy notes and postnatal notes booklets have only two boxes for the recording of responses to the questions (Perinatal Institute, 2019; Perinatal Institute, 2020). These notes are widely used in NHS services in England but are not fully adopted nationally. Two different NICE guidelines provide two different views about when these two boxes should be completed. The recent guideline 'Antenatal and postnatal mental health: the NICE guideline on clinical management and service

guidance' (National Institute for Health and Care Excellence, 2020) suggests completing at the first appointment and during the early postnatal period, while another guideline 'Antenatal care for uncomplicated pregnancies: Clinical guideline' (National Institute for Health and Care Excellence, 2019) suggests completing at the first and before or at the 36-week appointments. Therefore, there appears to be potential confusion with regards to how regularly HCPs should ask about women's mental health and if they should be asking at every appointment, how they should record and do so except for re-using the Whooley questions. One of the objectives of this PhD study was, therefore, to investigate the process of identifying low mood or depression among perinatal women by interviewing women and HCPs.

The policy and implementation landscape related to perinatal mental health and depression is a fast-moving process and while undertaking the PhD study, the Institute of Health Visiting (2019) published their vision for the future, including their practice. According to this publication, health visitors should meet with women in late pregnancy (28 weeks) and then take over the care of the women from midwives in the postnatal period (within 14 days of birth) (Institute of Health Visiting, 2019). There are eight universal contacts (i.e. 1) from 24 weeks pregnancy; 2) new birth 10-14 days; 3) 3-5 weeks; 4) 6-8 weeks; 5) 3-4 months; 6) 9-12 months; 7) 2 years; 8) 3-5 year school readiness) and 15 high impact areas for health visiting services of which six contacts are in the perinatal period and two areas (i.e., 1) perinatal mental health including mothers, partners, and infant and 2) child mental health) are related to the mental health of the whole family (Institute of Health Visiting, 2019). The previous recommendations for health visiting services comprised six high impact areas including maternal perinatal mental health (Local Government Association, 2017). However, new recommendations address the vision of the National Maternity Review (National Health Service, 2016) and include not only perinatal mental health but also partner/fathers' and children's mental health, suggesting flexible additional visits and reviews that can be tailored to individual needs (Institute of Health Visiting, 2019).

Women are also advised to see their GP between 6 and 8 weeks postnatally. GPs should be checking the mother and the baby's wellbeing during the appointment and the women's mental health should also be reviewed (National Health Service, 2019a).

Although screening for depression is recommended to midwives, health visitors and GPs by NICE guidelines (2020) and written in the antenatal and postnatal notes booklets (Perinatal Institute, 2019; Perinatal Institute, 2020), according to a national survey of women's experiences of maternity care involving 16,606 women, more than one-third of women (33%) did not respond 'yes, definitely asked' about their mental health during pregnancy and more than one-third of women (37%) did not respond 'yes, definitely' to whether they were given information about perinatal mental health (Care Quality Commission, 2020). A previous study involving 1,738 women reported similar findings: more than one-thirds of women (38%) reported not being given any information or advice about mental health (Healthwatch, 2019). Early reports found that approximately one in five women had not been asked about their emotional and mental wellbeing by HCPs at the appointments and one in 10 women in the postpartum period (Redshaw and Henderson, 2015). It is also clear from the studies that three out of five women 'definitely' had not spent enough time talking about their mental health at the 6-week check-up with their GP (Care Quality Commission, 2020). A previous study similarly reported that half of the women said they were not asked about their emotional or mental health at the 6-week appointment with the GP (The National Childbirth Trust, 2017). Indeed, nearly half of all cases of perinatal depression could not be detected, despite routine appointments with HCPs during pregnancy and after childbirth (Bauer et al., 2014; 4Children, 2011). Early detection of perinatal depression is crucial in terms of providing the required support and treatment timely. Possible barriers have been compiled from the literature looking at the HCPs' views on managing perinatal mental health and women's help-seeking behaviour; however, these studies had insufficient information about the enablers or facilitating aspects of talking with women about their low mood or depression. One of the objectives of this PhD study was, therefore, to explore any perceived barriers and enablers to talking with perinatal women about their low mood or depression and to investigate the perceived barriers and facilitating aspects to disclosing women's feelings to HCPs.

1.3.6.2 Training needs of healthcare professionals

A survey of midwives' illness perceptions of antenatal depression, conducted in England and including 52 midwives, found that only 42% of midwives had received any training about antenatal depression, whereas 90% had received training about

postnatal depression (Jomeen, Glover and Davies, 2009). Of midwives who had received antenatal training, 46% attended the training during their pre-registration education (Jomeen, Glover and Davies, 2009). The authors conclude that health professionals need to have up to date knowledge and training about perinatal mental health issues so that they can detect, manage and refer to appropriate specialist support.

Rothera and Oates (2011) conducted a survey of health practitioners' views on managing perinatal mental health in the UK. The findings from 768 participants, including midwives, obstetricians and health visitors showed that health professionals lacked knowledge and/or skills to detect and manage perinatal mental health disorders, and most of them had not taken any specific pre-qualification or postgraduate training on this topic (Rothera and Oates, 2011).

Midwives' perceptions and experiences of caring for women who experience perinatal mental health problems were considered in an integrated review by Noonan et al. (2017). The review included 15 quantitative studies, six qualitative studies and one mixed-method study with a total of 3475 midwives (Noonan et al., 2017). From the included studies, six were England based. The study concluded that midwives have limited knowledge or skills, limited referral options, and require ongoing training to confidently support women with perinatal mental health problems (Noonan et al., 2017). The researchers also found that women needed support from health professionals but that this was reported as not possible because of workload (Noonan et al., 2017). This review is important in showing the challenges of requiring midwives to provide effective and comprehensive perinatal mental health care and the need for continuous development and support systems (e.g. clinical management guidelines and referral pathways) to meet the needs of perinatal women experiencing depression.

1.3.6.3 Women's discomfort on disclosing their feelings

The interaction between GPs and women with experience of common mental health problems in the perinatal period was considered in a study by Khan (2015). The author conducted a survey with 43 GPs and 1,547 women, and also collected data from interviews with three GPs and four mothers in the UK. The author found that the

biggest barrier for provision of care was the identification of need, as GPs lacked confidence in screening women and women did not tend to disclose their feelings (Khan, 2015). Khan concluded that what was needed was stigma reduction around mental health issues, since it was this stigma that was often the reason women refrained from talking about their feelings to professionals (Khan, 2015). The results of Khan's study were mainly generated from quantitative data and therefore lack the nuances that qualitative methods such as interviews can provide. Therefore, more qualitative studies are needed to hear health professionals' and women's own stories and understand their subjective experiences and views.

An international qualitative systematic review of 40 articles was conducted by Dennis and Chung-Lee (2006) examining postpartum depression, help-seeking barriers and maternal treatment preferences. They found that women do not tend to disclose their feelings and that they lack knowledge about the symptoms of depression (Dennis and Chung-Lee, 2006). The authors concluded that knowing what the barriers are to seeking help is important in order to strengthen the relationships between health professionals and women and to develop preventive and treatment approaches that are in accord with women's preferences and needs (Dennis and Chung-Lee, 2006).

The Royal College of Midwives (RCM) (2017a) published a report about the urgent need for understanding and caring for perinatal women with mental health problems. A total of 6989 individual comments left at Lucie Holland's Change.org petition, were collected. This petition was started by Lucie, after her sister died from postnatal depression, and was signed over 55,000 times. The Royal College of Midwives analysed all the individual comments; the themes to emerge from this data were lack of awareness among the general public, lack of specialist care, misunderstandings (stigma) about maternal mental health in society, and insufficient NHS mental healthcare (Royal College of Midwives, 2017a). The report concluded that poor identification of maternal mental illness, care and service provision have a critical impact on maternal mental health. It further argues for an approach that integrates health professionals' and women's experiences, to find appropriate ways to improve identification and care provision.

These findings confirm other studies that highlight the difficulties of identifying perinatal mental health problems, including depression. Because of the stigma of mental health issues, women may abstain from talking about their feelings to professionals (Forder et al., 2020; Button et al., 2017; Hannan, 2016; Khan, 2015; Bilszta et al., 2010). The other explanations are that the worry about the involvement of social care, which may result in loss of custody over the child (Dolman, Jones and Howard, 2013) and choosing to deal with depression themselves (Woolhouse et al., 2009).

As has been discussed, some health professionals experience difficulty in detecting depression because of limited knowledge or skills or confidence in talking about women's mental health or due to workload (Noonan et al., 2017; Boots Family Trust Alliance, 2013; Rothera and Oates, 2011; Jomeen, Glover and Davies, 2009). These findings highlight the importance of strengthening communication between HCPs and women. Knowledge and understanding about perinatal mental health are not enough if HCPs do not have the confidence to build a relationship within which to talk about signs and symptoms and provide effective care pathways (Forder et al., 2020; Henderson et al., 2018; Button et al., 2017; Hannan, 2016).

It is therefore crucial for HCPs to be knowledgeable about the signs of perinatal depression symptoms and referral systems, to be able to build a rapport with women and help them at the right time (National Health Service, 2016). One of the objectives of this PhD study was, therefore, to explore the HCPs' recent experiences of identifying, supporting, and caring for women with perinatal low mood or depression as well as exploring women's expectations of HCPs and provision of perinatal depression care, which was not explored before in this context.

1.3.6.4 Support and services

A range of policy (National Health Service, 2016; the Independent Mental Health Taskforce, 2016) and guidelines related to perinatal mental health and depression (NICE, 2020; Institute of Health Visiting, 2019; Obe, 2015; Joint Commissioning Panel for Mental Health, 2012; RCM, 2012; Scottish Intercollegiate Guidelines Network, 2012; Royal College of Obstetricians and Gynaecologists, 2011) are being implemented

across the UK. The available support and services relevant to this PhD thesis are discussed in the rest of this chapter.

The RCM (2012) published a good practice guide for midwives that includes a guideline on how midwives can support pregnant women with depression. The recommendations presented in the guide are: encouraging the woman to see her GP; listening to the woman's feelings and concerns and reminding her that recovery takes time but the treatment is also important for her and her baby; supporting women to use mindfulness techniques to increase the awareness of feelings and to concentrate the mind; encouraging women to contact local groups supporting pregnant women with depression (Royal College of Midwives, 2012). There is very little information in the literature presented in this guideline for midwives about giving practical advice to women that can help them relieve some of the symptoms of depression. The guideline is more about signposting women to the appropriate services according to the severity of symptoms. HCPs should provide additional support to women at risk of or experiencing depression and encourage them to seek help from their GP or specialised perinatal mental health teams (National Institute for Health and Care Excellence, 2020; Royal College of Obstetricians and Gynaecologists, 2011).

Specialist perinatal mental health midwives have a dual role: to ensure that women and their families receive the specialist mental health care and support; and to ensure that their maternity teams are supported and services provide the best feasible personalised care to these women and their families, to improve mental health (Maternal Mental Health Alliance, NCPCC, Royal College of Midwives, 2018; Royal College of Midwives, 2015). However, 73% of maternity services do not have a specialist mental health midwife in England (Hogg, 2013).

According to the new publication of the Institute of Health Visiting (2019), health visitors manage mild to moderate perinatal mental illness and refer women to specialist services when needed. The listening visits delivered by health visitors have been found to be beneficial for the treatment of postpartum depression (Obe, 2015; Morrell et al., 2009; O'Hara, 2009). Therefore, training health visitors and making advanced/ specialist lead health visitors accessible for every postcode, is suggested by national bodies (Health Education England, 2016). Some of the advice given by health

visitors to perinatal women is: trying to eat a healthy and balanced diet; doing regular and gentle exercise; not trying to do everything at once; making a list of things to do and setting realistic goals; making a wellbeing plan; doing meditation or mindfulness; talking about feelings and worries with family and friends; contacting local support groups; trying to have a rest in the day and aiming for regular sleep; not trying to be a super parent instead asking for help from family and friends (Institute of Health Visiting, 2020).

There are also specialist health visitors in perinatal and infant mental health who deliver low to medium intensity interventions to women and/or their families who need more specialist care; however, only a few health visiting services have specialist health visitors (Health Education England, 2016). Although the specialist health visitors in perinatal and infant mental health can manage mild disorders and deliver psychological based treatments, the specialist perinatal mental health midwives are not trained to deliver such interventions (Health Education England, 2016; Maternal Mental Health Alliance, NCPCC, Royal College of Midwives, 2018).

The support provided by midwives and health visitors varied in the literature and there was insufficient information about what support these HCPs provide to women experiencing perinatal low mood rather than depression. One of the objectives of this PhD study was, therefore, to explore the HCPs' experiences of supporting and caring for women with perinatal low mood and to explore women's experiences of low mood and support received from HCPs.

GPs can manage uncomplicated non-psychotic depression. They often prescribe medication or refer to IAPT. For complex disorders, they refer women to perinatal mental health services if they are available in the area. In their absence, they can refer to general psychiatry services (Obe, 2015).

If a woman experiences a complex or severe depression, she will usually receive care from specialist perinatal mental health services (NHS England, NHS Improvement, National Collaborating Centre for Mental Health, 2018). The phrase 'specialist perinatal mental health services' points out both specialist perinatal mental health community teams also inpatient mother and baby units where mum and baby receive health care together, when hospitalisation is needed (Joint Commissioning Panel for Mental

Health, 2012). The specialist mental health services specifically target perinatal mental health issues including depression. Yet around half the women in England have no access to these services (Bauer et al., 2014) and only 57% of mental health trusts have a perinatal mental health service (Hogg, 2013). Furthermore, less than half of these perinatal mental health services contains at least a specialist perinatal psychiatrist (Hogg, 2013). It is concluded that the majority of women living in England have no access to specialist maternal mental healthcare provision and that these services are insufficient (Royal College of Midwives, 2017a). The Government's recent investments in NHS Specialist Perinatal Mental Health and Maternity Services is very promising; however, many women will not meet the criteria for these services (Institute of Health Visiting, 2019; The Independent Mental Health Taskforce, 2016).

The IAPT programme was launched in 2008 to deliver psychological interventions and fill the gap in perinatal depression services in the UK. It aims to invest in evidence-based psychological therapies recommended by NICE (2009), mainly focussing on the training of para-professionals (i.e., mental health workers who are not qualified therapists) or peer supporters, in the delivery of low-intensity psychological interventions for the treatment of mild to moderate depression and anxiety (Rodgers et al., 2012; Obe, 2015). It is estimated that 27% of IAPT patients are pregnant and postpartum women (Hogg, 2013). Research focusing on the programme suggests that the content of training does not cover the physiological changes on mood and emotions, the changes in the dynamics of motherhood, parenting, mother-infant attachment, and interaction in the family after childbirth (Obe, 2015). Furthermore, Hogg (2013) highlights that there is no specialist perinatal mental health training for IAPT providers. Hence, there appears to be a need for a psychologically effective and low-cost intervention that can be tailored to the needs and/or wishes of women with perinatal depression.

The NICE (2020) guideline states that psychological treatment should be provided to women within one month of their first assessment. In a study by 4Children (2011), 81% of the 150 NHS Trusts (Mental Health Trusts, Foundation Trusts, Mental Health Partnership organisation, etc.) who replied said that they offered psychological intervention within six weeks. Five Trusts, however, said that the waiting times was more than three months and sometimes it was six months. The delays in the treatment

may result with adverse outcomes for women and their families. This PhD study, therefore, aimed to investigate the available services and treatments locally for women experiencing perinatal depression and to investigate the perceived barriers and facilitating aspects to receiving treatment for perinatal depression.

1.3.7 Treatment for perinatal depression

NICE (2020) highlights that psychological and pharmacological interventions are effective treatments for mental health problems. They also recommend psychological intervention or psychotropic medication for treating depression in the perinatal period (National Institute for Health and Care Excellence, 2020).

1.3.7.1 Pharmacological treatments for perinatal depression

In the case of severe depressive disorders and in special circumstances, antenatal and postnatal mental health clinical management and service guidelines published by NICE (2020) suggests psychotropic medications, which include tricyclic antidepressants (TCA), selective serotonin reuptake inhibitors (SSRI) or (serotonin-) noradrenaline reuptake inhibitor [(S)NRI], for the treatment of depressive symptoms. SSRIs are the most commonly prescribed medications by professionals in the treatment of perinatal depression (Bayrampour et al., 2020; Molenaar et al., 2020; El Marroun et al., 2014; Lattimore et al., 2005). An international systematic review showed that the prevalence of use of SSRIs amongst pregnant women ranges between 3% and 4.6%; use of SNRIs ranges between 0.6% and 0.7%; and use of TCAs ranges between 0.4% and 0.6% (Molenaar et al., 2020). However, another study suggested that one-third of women discontinue during pregnancy (Cohen et al., 2006). Two prospective studies including 201 and 132 pregnant women conducted in the USA and Spain, demonstrated that depression recurrence was seen in more than half of women over the course of their pregnancy who discontinued medication in the antenatal period (Cohen et al., 2006; Roca et al., 2013).

Most women stop taking antidepressants due to fear of adverse outcomes of medication on the infants (Dennis and Chung-Lee, 2006). A meta-analysis suggested that taking SSRIs during pregnancy may affect the foetus and newborn in terms of increased synthesis of serotonergic agents and withdrawal syndromes, in addition to

long-term effects on neurobehavior and performance (Lattimore et al., 2005). Furthermore, meta-analyses indicated that using antidepressants during pregnancy is associated with an increased risk of preterm birth (Eke, Saccone and Berghella, 2016; Huybrechts et al., 2014), cardiac malformations (Grigoriadis et al., 2013b), lower Apgar scores at 1 and 5 minutes (Ross et al., 2013), postpartum haemorrhage (Jiang et al., 2016), respiratory distress (Grigoriadis et al., 2013a; McDonagh et al., 2014), poor neonatal adaptation syndrome (Grigoriadis et al., 2013a), and tremors (Grigoriadis et al., 2013a). The included studies had methodological limitations as they were mostly from small observational and case-control studies because of the ethical reasons related to conducting randomised controlled trials for this question. The studies also mostly used prescription data, so it is unclear whether these women actually took the medication. The diagnosis of depression was not established in some studies, so it is unclear if antidepressants were used for anxiety or depression. While some studies compared depressed pregnant women exposed to antidepressants with depressed pregnant women unexposed to medication, other studies included pregnant women as a comparator without assessment of their depression symptoms. It is, therefore, unclear whether depression symptoms or using antidepressants leads to some of these outcomes.

Prescribing medication for perinatal women requires complex clinical decision-making (Patel and Wisner, 2011; Wisner et al., 2000). Before prescribing antidepressants in pregnancy or during lactation, the possible side effects have to be considered and discussed with the women and a careful risk-benefit analysis applied by professionals (National Institute for Health and Care Excellence, 2020; Eke, Saccone and Berghella, 2016; Scottish Intercollegiate Guidelines Network, 2012).

In moderate to severe perinatal depressive disorders, the recommendation is to combine antidepressant medication and a high-intensity psychological intervention such as cognitive behavioural therapy (CBT) (National Institute for Health and Care Excellence, 2020). While both medication and psychological approaches are recommended for treating perinatal depression, most women in the perinatal period have a preference for psychological interventions rather than medication (Goodman, 2009; Prins et al., 2008; Dennis and Chung-Lee, 2006; Ericksen et al., 2005; Sleath et al., 2005; Chabrol et al., 2004). This preference is due to stigma (Goodman, 2009); the

view of medication as addictive (Prins et al., 2008); the effects on breastmilk (Chabrol et al., 2004; Dennis and Chung-Lee, 2006); and the possible harmful side effects to the foetus (Dennis and Chung-Lee, 2006). Providing options to the women and involving them in decisions about their care is a valuable approach in the prevention of depressive relapse and recurrence (Dimidjian and Goodman, 2014). Listening to patient preferences is broadly acknowledged as a fundamental component of evidence-based practise in psychology (APA, 2006). Indeed, patients are more likely to engage in the treatment of depression if the provided treatment is their preference (Kwan, Dimidjian and Rizvi, 2010).

1.3.7.2 Psychological treatments for perinatal depression

Owing to the potential adverse effects of medications and the evidence on patient preference, non-pharmacological treatment options may be advantageous during the perinatal period (Dennis, Ross and Grigoriadis, 2007). In addition, there is some evidence that psychotherapeutic interventions may have a more sustained effect than pharmacological treatment (Hensley, Nadiga and Uhlenhuth. 2004).

Psychological interventions for depression include cognitive behavioural therapy (CBT), interpersonal psychotherapy (IPT), psychodynamic therapy, behavioural activation (BA) and behavioural couple therapy, facilitated by a qualified therapist (Dennis and Hodnett, 2007; National Institute for Health and Care Excellence, 2020). Previous meta-analyses showed that CBT (Sockol, 2015) and IPT (Bledsoe and Grote, 2006; Dennis, Ross and Grigoriadis, 2007) delivered in the antenatal period, and CBT (Sockol, 2015; Sockol, Epperson and Barber, 2011; Cuijpers, Brännmark and van Straten, 2008; Dennis and Hodnett, 2007; Bledsoe and Grote, 2006), IPT (Sockol, Epperson and Barber, 2011; Cuijpers, Brännmark and van Straten, 2008; Dennis and Hodnett, 2007), counselling (Bledsoe and Grote, 2006), and psychodynamic therapy (Bledsoe and Grote, 2006) delivered in the postpartum period significantly decreased the depression symptoms compared to control conditions. Although the assessment of depression symptoms and methodological quality of the studies (i.e. including pre and post-test designs without randomisation or including randomised controlled trials with high risk of bias) varies across the reviews, overall there is some evidence that psychological interventions are effective for the treatment of perinatal depression.

1.3.7.3 Low-intensity psychological treatments for perinatal depression

A distinction between “high-intensity” and “low-intensity” interventions is described in NICE (2020) guidelines. High-intensity interventions consist of psychological and psychosocial treatments that comprise one-to-one therapy with a trained mental health professional typically over an extended period of time (National Institute for Health and Care Excellence, 2020; Rodgers et al., 2012; National Institute for Health and Care Excellence, 2009). The majority of the evidence discussed above (section 1.3.7.2) is based on evaluations of high-intensity interventions.

A low-intensity intervention is recommended for mild to moderate perinatal depression cases (National Institute for Health and Care Excellence, 2020). If a low-intensity intervention is not beneficial to the patient, a high-intensity psychological intervention might then be offered (National Institute for Health and Care Excellence, 2020). The definition of low-intensity psychological treatments, however, is less clear.

In the NICE guidelines, a low-intensity intervention is referred to as “a psychological or psychosocial intervention delivered by a trained coach or facilitator (rather than a therapist) to enable the use of self-help materials” (2020, p.15). Although the NICE guidelines illustrate low-intensity psychosocial interventions, no detailed description of what comprises ‘low-intensity’ intervention is given. Richards and Whyte (2011, p.7) describe ‘low intensity’ in the IAPT handbook “as a lower dose of treatment techniques, often represents less support from a mental health worker in terms of duration or frequency of contact, and is often delivered in non-traditional ways such as by telephone or using the internet”. The most detailed definition of low intensity psychological treatments is provided in the Oxford Guide to Low Intensity CBT Interventions by Bennett-Levy et al. (2010): “Low-intensity” is defined in terms of four characteristics: the reduced duration of sessions (i.e., weekly contacts for five to eight sessions), the level of training and background of the providers (i.e., using peers or non-mental-health specialists), the complexity of the intervention (i.e., less intense content), and the mode of delivery (Bennett-Levy et al., 2010). Although the mode of delivery for low-intensity interventions is often referred to as telephone-based, web-based, email, groups or face-to-face, a recent systematic review of effectiveness of telephone-administered interventions for depression indicated that the number of

telephone sessions ranged between 6 and 21 with a mean number of 12, a mean that is more in keeping with high rather than low-intensity interventions (Castro et al., 2020). The mode of delivery may, therefore, not be an appropriate criterion to define low intensity treatments.

The Cochrane meta-analyses cited previously for high-intensity interventions, showed that low-intensity interventions (non-directive counselling) delivered by trained health visitors and nurses are effective in reducing postpartum depressive symptoms compared to control conditions (Dennis and Hodnett, 2007), while their effectiveness is not clear in pregnancy due to insufficient evidence (Dennis, Ross and Grigoriadis, 2007).

As stated above, low intensity interventions can be delivered by a trained coach or can be internet-based rather than involving a therapist, so may be a more cost-effective use of resources when compared with usual care (Rodgers et al., 2012). Morrel et al., (2009) conducted a cluster randomised trial with postpartum women in order to evaluate the effectiveness of health visitor training in cognitive behavioural therapy and counselling for depression. The study found that training health visitors was successful and that both approaches were effective in decreasing depressive symptoms at 6 and 12 months postpartum (Morrel et al., 2009). This study also highlights the applicability of low-intensity interventions by NMHSs for postpartum women with depression. Moreover, delivering psychological-based listening visits has been reported as an effective treatment for depression, as well as being effective in the prevention of depression (Morrell et al., 2016; Brugha et al., 2011). Health visitor training in the prevention of depression has also been found to be cost-effective (Henderson et al., 2019).

1.3.7.4 Implementation challenges

Although women receive antenatal and postnatal care from HCPs, validated screening tools exist and treatments are available, half the women in the UK remain undiagnosed for mental health problems (Bauer et al., 2014). An international review suggested that only 10-25% of the diagnosed cases receive adequate perinatal depression treatment and 30% of them achieve recovery (3% of all cases of perinatal depression) (Gavin et al., 2015). For these reasons, it is recommended that midwives, health visitors, GPs,

obstetricians and other professionals should pay attention to women's perinatal mental health and focus on multi-professional working to deliver personalised care for women and their families (National Health Service, 2016). According to Khan (2015), feedback from women is most positive when they receive personalised and integrated care, and when they feel they make decisions about their care. A meta-synthesis also found that women wish for good communication from caregivers, to be given important information, a respectful clinical environment with efficient care, to be able to participate in this care and have a sense of control (Renfrew et al., 2014). Integrated responses to perinatal mental health problems are crucial to the provision of personalised care, built around the needs of women (Bayrampour, Hapsari and Pavlovic, 2018; National Health Service, 2016).

Midwives are in a strong position, together with their colleagues in primary care, to address a woman's mental health problems as early as possible in the antenatal period, before her condition leads to deterioration (Renfrew et al., 2014). Indeed, midwifery is a vital solution in terms of providing high-quality care for mother and the baby (ten Hoop-Bender et al., 2014). Yet there is a scarcity of 3,500 full-time midwives to reach the optimum numbers in England (Royal College of Midwives, 2018). Owing to this, 40% of women see different midwives at every appointment during pregnancy (Hogg, 2013). Moreover, a report published as part of the NSPCC's All Babies Count campaign demonstrated that 41% of women said that their midwives or health visitors had never asked about depression in England (Hogg, 2013). The National Maternity Review (National Health Service, 2016) has found that across a large part of the England, perinatal mental health care is not sufficient.

Considering the high prevalence of perinatal depression (Woody et al., 2017) and its consequences on women, partners and children (O'Hara, 2009), the cost of perinatal depression to society (Bauer et al., 2014), the challenges with the identification of perinatal depression by midwives (Care Quality Commission, 2020) and the scarcity of midwives in England (Royal College of Midwives, 2018), it is very important to address depression in perinatal women and provide support and treatment. The stepped-care model of service delivery suggests "offering or referring for the least intrusive, most effective intervention first" (National Institute for Health and Care Excellence, 2018, p.16). Hogg (2013) comments that the available IAPT services for the treatment of mild

to moderate perinatal depression do not provide specialist training on perinatal mental health for IAPT providers. A survey conducted in the Primary Care Trusts in England showed that women experience delays in accessing psychological treatments (4Children, 2011). These delays may have potential outcomes for women and their families. On the other hand, the evidence shows the success of training health visitors to deliver psychological-based listening visits (Morrel et al., 2009) and the cost-effectiveness of training non-mental-health specialists in the delivery of brief psychological interventions (Ekers et al., 2011a).

Based on all the findings presented in this section, there is a case that a brief psychological intervention that promotes the mental health of women during pregnancy and in the postnatal period and a group of health workers who are non-specialists and can be trained and supported in the delivery of psychological treatment, could fill the gap in mental health provision during and after pregnancy.

1.3.7.5 Maternity Support Workers

The National Maternity Review is currently being implemented across NHS England via the Maternity Transformation Programme (National Health Service, 2019b). Currently, 10 workstreams are in progress, and one of them is transforming the workforce, led by Health Education England. It aims to establish a reconfigured maternity workforce with the right skills to perform the goals described in the National Maternity Review. This includes securing the supply of staff and developing midwifery training placements by 25% over four years, preparing multi-professional training packages, and publishing a competency framework for maternity support workers (MSWs) (National Health Service, 2019b; Royal College of Midwives, 2020).

In 2019, Health Education England also published a competency, education and career development framework for MSWs. MSWs are described as “assisting with caring for women, babies and their families throughout their maternity journey, working under the supervision and within agreed guidelines and protocols when providing care to women and their families” (Health Education England, 2019, p.7). According to the role descriptor of Band four MSWs, with appropriate training, MSWs can “use knowledge and understanding of common physical, mental and behavioural health conditions within maternity care to recognise signs of deterioration in women and babies”

(Health Education England, 2019, p.12). In addition they can “gather and interpret relevant information and form a judgement on the improvement or deterioration in the physical, mental or behavioural condition of women/babies” (Health Education England, 2019, p.12). Furthermore, they can liaise with psychologists and psychiatrists and provide support to women and families who have complex care and support needs (Health Education England, 2019). MSWs are a relatively new workforce in maternity care and with appropriate training, may fill the gap that exists in supporting and caring for women with depression during the perinatal period.

There is a need for personalised and integrated care for women, and MSWs can provide a bridge between the woman and registered HCPs. They can lessen role demands and pressures on midwives by working alongside (Royal College of Midwives, 2017b). The National Maternity Review (National Health Service, 2016) emphasises more multi-professional working and less miscommunication among midwives, obstetricians and other health professionals, to provide more evidence-based, and personalised care for women and their families. In this context, MSWs are an essential part of the maternity team and they can fulfil the goals of the National Maternity Review (National Health Service, 2019b). They could also decrease the demand for specialist mental health workers by delivering a brief low-intensity psychological intervention to women who demonstrate mild to moderate depression symptoms during pregnancy or afterwards.

In the perinatal period, the mental health needs of women should be met by the provision of the most effective and low-cost treatments. Behavioural activation (BA) is as effective as other psychological interventions (Mazzucchelli, Kane and Rees, 2009; Ekers, Richards and Gilbody, 2008; Cuijpers et al., 2007). It also offers the possibility of being more cost-effective because its simplicity means it can be delivered by non-specialists (Ekers et al., 2011a; Richards et al., 2016). BA is, therefore, a good candidate for the treatment of perinatal depression as a simple intervention that can be delivered by trained non-specialists (Veale, 2008). There is also some evidence that low-intensity forms of BA are effective for adults (Chartier and Provencher, 2013), though its effectiveness in the perinatal setting is inconclusive. BA, its clinical application and evidence base for depression and perinatal depression are described in the next section.

1.3.8 Behavioural Activation and its application in the treatment of perinatal depression

There has been a general interest among researchers in using Behavioural Activation (BA) for the treatment of depression over the past decade because of (1) its simplicity to teach providers who do not have a mental health background (Dimidjian et al., 2011; Ekers et al., 2011b; Veale, 2008; Cuijpers, Van Straten and Warmerdam, 2007); (2) cost-effectiveness of using non-specialists compared to qualified therapists (Ekers et al., 2011a; Richards et al., 2016); (3) effectiveness of BA compared to control conditions and medication (Uphoff et al., 2020); (4) and similar effectiveness of BA compared to other psychological interventions such as CBT (Uphoff et al., 2020; Mazzucchelli, Kane and Rees, 2009; Ekers, Richards and Gilbody, 2008).

In recent years, a considerable number of research activities on depression have used BA among different patient groups, for example, decreasing depressive symptoms in older people with mild depression (Gilbody et al., 2017: CASPER study); feasibility trial of community pharmacy staff delivered intervention for adults with long term conditions and sub-threshold depression (Littlewood et al., 2019: CHEMIST study); prevention of depression and loneliness among older people with long term conditions (Gilbody et al., 2021: BASIL study); treatment of depression in people with long term physical health conditions (MODS, 2021); comorbid depression treatment in non-communicable diseases (BEACON, 2021); treatment of depression among people with diabetes (DiaDeM, 2021); and treatment of depression in adults (Ruzickova et al., 2021). Almost all of these studies (except Ruzickova et al., 2021) have been coordinated at the University of York in partnership with other researchers from other universities, NHS Trusts or countries. In addition to the BA's simplicity to teach providers, cost effectiveness of using non-specialists, and gaps in the evidence according to the systematic review findings detailed in chapter two, these research activities at the University of York also inspired the decision for using BA for the treatment of perinatal depression in the beginning of the PhD.

1.3.8.1 Theoretical basis of BA

Behavioural Activation (BA) is rooted in the theoretical work of Skinner (1953) and the clinically application of Skinner's approach in the work of Ferster (1973) and Lewinsohn

(1974). Modern versions of BA, such as those outlined by Martell and colleagues (2001) and Lejuez and colleagues (2001a and 2001b), are variants or developments of these original accounts.

Behavioural approaches are described as distinct, structured psychological interventions, where the implementer and patient: work together to understand the impact of behaviours on mood, and endeavour to improve mood through behavioural tasks such as scheduling of activities and reducing avoidance behaviours (Dimidjian et al., 2011; Martell, Dimidjian and Herman-Dunn, 2010; Hopko et al., 2003).

BA is based on operant conditioning principles. Operant conditioning is described by Skinner (1938) as a method of learning through understanding the association between a specific behaviour and its consequence. It seeks to understand when and where behaviours happen (the context), and how those behaviours operate for people in that context (their function). If a behaviour is reinforced (i.e., the behaviour works in some way for the person), the prediction is that the behaviour will increase; however, if the behaviour leads to punishment for the person, then the prediction is that the behaviour will reduce.

Operant conditioning principles can be used to understand the development and maintenance of low mood or depression. People who experience difficult life events may struggle to adapt immediately to the new circumstances. They may stop doing things that are meaningful or valuable for them. This may lead them to feel low or depressed. In an effort to cope, they may avoid things or delay things until they feel better. This may be helpful for them in the short term; however, in the long term, it stops the person engaging in those activities that are meaningful or important for them. An example cycle is provided in Figure 1. This cycle is based on the CHEMIST booklet (see Appendix 20). This model was modified for the needs of perinatal women and used in this PhD study.

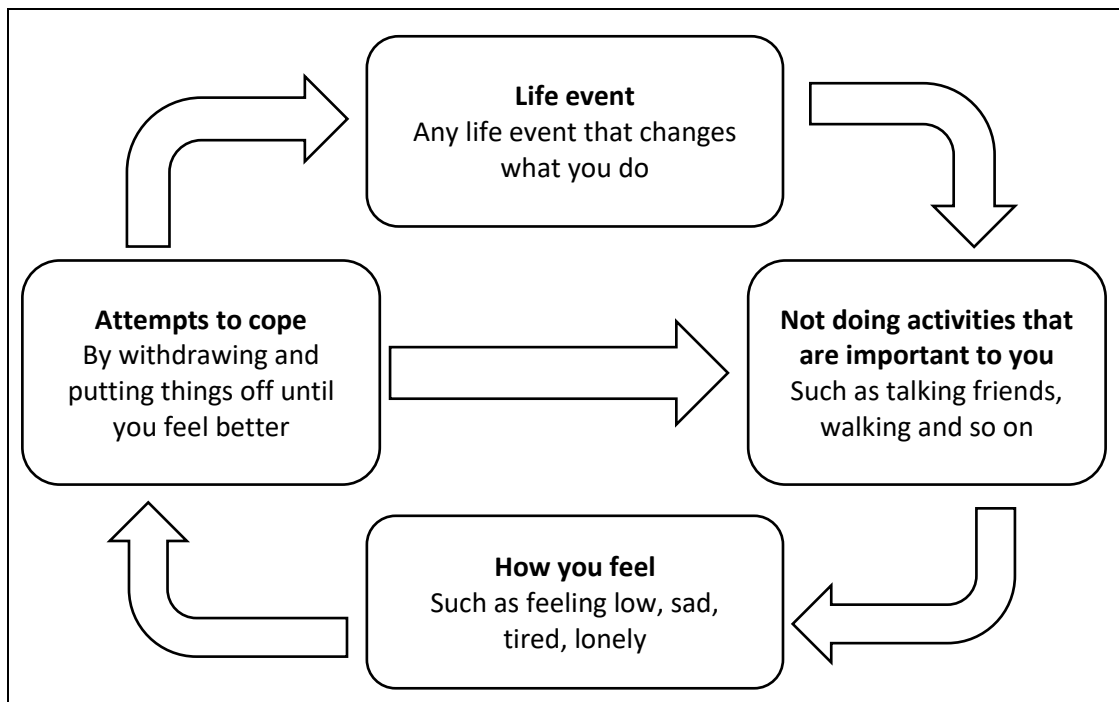


Figure 1: Behavioural activation cycle of low mood

On the basis of operant conditioning model, two treatment implications emerge for the treatment of depression. The first one is increasing activities that are meaningful and important to the person. The second one is reducing avoidance behaviours that work in the short term, but in the long term stop the person engaging in these meaningful and important activities.

1.3.8.2 BA treatment

According to Kanter et al. (2010), in their review of the literature on common behavioural activation techniques, BA starts with assessment techniques (activity monitoring and values assessment), then continues with activation techniques (activity scheduling and procedures targeting avoidance), and ends with a variety of action plans that are intended to maintain after the end of treatment the gains made during treatment.

A BA treatment is outlined in the training materials for IAPT practitioners (Richards and Whyte, 2011). The BA treatment described in these materials draws on the clinical methods developed by Martell, Addis and Jacobson (2001) and Hopko et al. (2003). According to this guidance, BA consists of six steps: 1- Explaining behavioural activation; 2- Identifying routine, pleasurable and necessary activities; 3- Making a

hierarchy of routine, pleasurable and necessary activities; 4- planning some routine, pleasurable and necessary activities; 5- implementing behavioural activation exercises; 6- reviewing progress (Richards and Whyte, 2011).

A similar BA intervention manual and guided self-help booklet have been adapted in this PhD research project, as discussed in chapter three (section 3.3.5).

1.3.8.3 Evidence base for BA for depression

In contrast to Cognitive Behavioural Therapy (CBT), BA is regarded as a simpler or more parsimonious treatment that focuses solely on changing behaviour, rather than both behaviour and cognition (Dimidjian et al., 2011; Ekers et al., 2011b; Veale, 2008; Cuijpers, Van Straten and Warmerdam, 2007). BA is also an evidence-based treatment for depression recommended by NICE guidelines. Although NICE (2009, p.22) guidelines state that the evidence for BA is less robust than for CBT, recent randomised controlled trials show that BA has no less effect than CBT in treating depression in adults (e.g., Richards et al., 2016) while being more cost-effective (Ekers et al., 2011a; Richards et al., 2016).

A meta-analysis of 17 studies demonstrated no statistically significant differences between CBT and BA in terms of post-treatment and follow-up symptom levels, in recovery rate or dropouts (Ekers, Richards and Gilbody, 2008). A subsequent meta-analysis, including 34 studies, also concluded that BA is as effective as other psychological interventions in the reduction of depressive symptoms (Mazzucchelli, Kane and Rees, 2009). Another review, including 23 RCTs, reported similar findings favouring BA compared with control conditions and medication (Ekers et al., 2014). A recent Cochrane review (Uphoff et al., 2020), including 53 RCTs, examined the effectiveness of BA in adults. They suggested that BA is more effective than medication and control conditions and as effective as other psychological interventions (Uphoff et al., 2020). It is important to note that although two reviews reported beneficial long-term (over a 2-year follow-up) effects of BA (Dobson et al. 2008, Gortner et al. 1998), more studies are needed to evaluate longer-term maintenance effects (Mazzucchelli, Kane and Rees, 2009; Uphoff et al., 2020).

BA may be particularly suitable for use as a low-intensity treatment. There is some evidence that BA can be effectively delivered as a low-intensity, guided self-help psychological treatment for mild to moderate depression (Chartier and Provencher, 2013). However, this review did not identify any perinatal depression trials. A summary of the current evidence base for BA is given in Appendix 1.

1.3.8.4 Evidence base for BA for perinatal depression

Two randomised controlled trials were found which trained a mixed group of specialists and non-specialists to deliver a 10-session BA therapy during pregnancy in the USA (Beck et al., 2014; Dimidjian et al., 2017). Both studies concluded that BA is an effective and feasible intervention for the treatment of depression during pregnancy and three-month postpartum.

A systematic review, which included low and middle-income country studies, demonstrated that psychological interventions delivered by trained, non-specialists, are feasible in the treatment of perinatal depression (Chowdhary et al., 2014).

However, this review did not identify any BA studies and the included studies were randomised and non-randomised study designs, which limits the conclusions that can be drawn about clinical effectiveness.

1.4 Outline of the thesis and overview of this doctoral project

1.4.1 Gaps in the evidence

As has been discussed in the previous section, BA is a structured, brief and effective psychotherapeutic approach that relies on changing behaviour through adaptive activities in the treatment of depression (Dimidjian et al., 2011; Martell, Dimidjian and Herman-Dunn, 2010; Ekers, Richards and Gilbody, 2008; Veale, 2008; Cuijpers, Van Straten and Warmerdam, 2007; Jacobson, Martell and Dimidjian, 2001). It is argued that BA is an uncomplicated intervention relative to other forms of psychotherapeutic interventions, such as CBT, and is therefore particularly suitable for adaptation as a low-intensity treatment that can be delivered by a non-specialist. (Dimidjian et al., 2011). Although there is evidence that BA is simpler than CBT and as effective as CBT,

when delivered in a low-intensity format by non-specialists, there is limited evidence about its effectiveness in the perinatal period.

Maternity services, community services and health visiting services comprise a diverse workforce. However, there is finite capacity in terms of allocating the role of delivering BA to perinatal women. For instance, because of their workload, lack of time and scarcity of numbers, training midwives to deliver BA treatment may not be viable. Therefore, it is crucial to identify a group of workers who are within the NHS and are in a close relationship with women in the antenatal period. This means they are in a good position to identify depression as early as possible and provide timely support and treatment. The role of maternity support workers already includes supporting women and providing complex care. They may be a suitable group to be trained in the delivery of BA for women in the perinatal period. By delivering a brief low-intensity treatment, such as BA, to women who experience mild to moderate depression symptoms during pregnancy or afterwards, they could also reduce the demand for specialist mental health workers and IAPT services.

There is at present an evidence gap for the effectiveness of low-intensity BA delivered by non-specialists for women experiencing depression in the perinatal period in a UK-setting.

1.4.2 Aims and objectives

This PhD research project consists of three interrelated study elements. The ultimate aim of this doctoral thesis was to adapt a manualised behavioural activation intervention manual and guided self-help booklet suitable for delivery in a perinatal setting by NMHSs, for example, MSWs. The specific objectives were:

1. To use systematic review methods to evaluate the effectiveness of psychological interventions, including but not limited to BA, when delivered by non-mental-health specialists for the treatment of perinatal depression.
2. To use qualitative methods to explore women's experiences of perinatal low mood or depression and any care that they may have received and healthcare professionals' experiences of providing support and care for women who have

perinatal low mood or depression, and to inform the third stage of the PhD study around what might be the opportunities, challenges and barriers to introducing the BA therapy, BA manual and BA booklet.

3. To use experience-based co-design to inform the adaptation of a manualised BA Therapist Manual intended for delivery by MSWs for the treatment of perinatal depression and a BA guided self-help booklet intended for the use of perinatal women.

1.4.3 Study design

This PhD research combines three study elements: a systematic review and meta-analysis, a qualitative study, and a co-design study. A quantitative systematic review of randomised controlled trials was conducted to assess the effectiveness of psychological interventions delivered by NMHSs for the treatment of perinatal depression.

The theoretical perspective of symbolic interactionism (Blumer, 1998) and the experience-based co-design approach (O’Cathain et al., 2019a; Craig et al., 2013; Bate and Robert, 2007) were used within the second and third study elements. The methodological design of ethnography (Hammersley and Atkinson, 2007) was deployed within the second study. Interviews were conducted with women who have experienced perinatal low mood or depression and interviews and focus groups were conducted with maternity HCPs who have experience of providing support and care for those women.

In the final element of the study, co-design workshops were conducted with the involvement of both women and HCPs. Thematic analysis was performed in the analysis of the qualitative data.

The next chapter presents the systematic review and meta-analysis of RCTs carried out regarding the effectiveness of psychological interventions delivered by NMHSs for the treatment of perinatal depression.

Chapter 2: Effectiveness of psychological interventions delivered by non-mental-health specialists for perinatal depression; systematic review and meta-analysis

2.1 Introduction

This chapter describes the methods employed to carry out a systematic review of evidence about the effectiveness of psychological interventions delivered by non-mental-health specialists (NMHSs) for the treatment of perinatal depression. This approach was used to provide new knowledge about what type of interventions are delivered by what range of NMHSs. The aim was to highlight the effectiveness of these interventions when delivered to perinatal women, underline any gaps in the evidence base and through this inform other study elements of the thesis. Chapter one highlighted the prevalence of perinatal depression, the limited access to psychological interventions recommended by NICE guidelines for perinatal depression, and the potential of NMHSs to address some of that gap. In order to respond to these challenges and provide an appropriate answer regarding the effectiveness of interventions delivered by NMHSs, the first step was to review all existing relevant evidence.

Previous systematic reviews show a significant reduction of depressive symptoms using psychological interventions in the treatment of antenatal and postpartum depression (Cuijpers, Brännmark and van Straten, 2008; Dennis and Hodnett, 2007; Dennis, Ross and Grigoriadis, 2007). These interventions were mainly delivered by qualified therapists or mixture of specialists and non-specialists. Evidence of the effectiveness of such interventions when delivered by NMHSs is as yet unclear.

One review (Clarke, King and Prost, 2013) reported beneficial outcomes for psychosocial interventions delivered by providers who are not mental health specialists in the treatment of perinatal common mental disorders in middle-income countries. In this review, depression was an outcome in 73% of the included trials; however, 13% of them were preventive interventions for depression, and 87% were health promotion interventions. Therefore, it is necessary to examine the effectiveness of interventions for the acute-phase treatment of depression.

Another review (Stephens et al., 2016) also reported outcomes for psychological interventions delivered by specifically trained personnel (e.g. nurses, health visitors, early childhood nurses, therapists with a nurse background, psychologists, trained researchers) in the treatment of postpartum depression; however, the review differs from the review conducted for this thesis in that it included studies using trained personnel including both specialists and non-specialists. Other limitations were that only studies published in the English language between 2000 and 2014 were included in the review. Including only English language studies may lead to language bias and an inflated effect size because positive results have been found to more likely be published in the English language (Egger et al., 1997). In addition, this review did not examine the efficacy of psychological interventions on infant outcomes and the mother-infant relationship, nor the long-term effects of interventions on maternal depression.

The review described in this chapter has a distinct focus: the identification and summarising of evidence from studies focusing exclusively on interventions delivered by NMHSs to women in the perinatal period with depressive symptoms. It also seeks to address some of the limitations of previous reviews. For example, there were no search restrictions in terms of country, language, date or setting and it used a comprehensive and sensitive search strategy. A systematic review was chosen over a narrative review because narrative reviews, in contrast to systematic reviews, have the following disadvantages (Egger, Smith and O'Rourke 2001; McKenzie et al., 2019):

- Narrative reviews are often subjective and may, therefore, lead to bias and error, in contrast to systematic reviews, which are objective and aim to minimise the bias through structured evidence appraisal methods
- Choosing studies similar to the views of the researcher is common, in contrast to systematic reviews, which aim to integrate all relevant studies objectively, using pre-defined eligibility criteria which can deal later with disagreements when the others support the opposite view
- Selecting studies that are frequently cited is often observed, in contrast to systematic reviews which systematically identify, examine and organise all relevant studies

- A standardised examination of the methodological quality of the studies is often lacking in narrative reviews, in contrast to systematic reviews, which aim to perform quality assessment tools for the included studies in the review
- The findings of narrative reviews often describe opposite views due to neglecting sample size, effect size and study design, in contrast to systematic reviews, which include small studies as well and consider their differences and their potential effect on the direction of the results.

Systematic reviews are crucial for researchers, healthcare professionals, public users, health decision-makers and policymakers who want to obtain high quality, relevant and up-to-date information on a topic (Egger, Smith and O'Rourke 2001; Lasserson, Thomas and Higgins, 2019). They endeavour to collect evidence that addresses pre-identified research questions and eligibility criteria in order to summarise them and provide further knowledge, using original studies or reviews (Chandler et al., 2019; Egger, Smith and O'Rourke 2001). In this review, randomised controlled trials meeting the criteria outlined below were used to gather evidence relevant to the research question.

Meta-analysis follows a structured and objective appraisal of the evidence through collecting and combining the data and reporting the enhanced estimation of the effectiveness of an intervention (Egger, Smith and O'Rourke 2001). Meta-analysis provides an estimate of overall treatment effects using data pooled from individual studies (Chalmers and Altman, 1995; Torgerson, 2003). In this review, the difference in perinatal women's depression symptom levels after receiving psychological intervention from NMHSs was pooled from the randomised controlled trials.

2.2 Development of the review question

Development of the review questions is the most important part of a systematic review to decide its scope (Thomas et al., 2019). Well-developed review questions often shape different parts of the review steps, for example, inclusion and exclusion criteria, search strategy, data extraction, planning data synthesis and presentation of findings (Oliver et al., 2017; Hedges, 1994; Cooper, 1984). The FINER criteria are recommended when developing a review question (Cummings, Browner and Hulley,

2007; Thomas et al., 2019). These criteria include the following points (Cummings, Browner and Hulley, 2007; Thomas et al., 2019):

- Asking *Feasible* questions to retrieve a manageable quantity of data
- Focusing on an *Interesting* field for the researcher to be able to continue and complete the work
- Finding a gap in the evidence and working on a *Novel* review
- Considering *Ethical* issues when formulating the research question
- Ensuring that the questions are *Relevant* to consumers, healthcare professionals, stakeholders and policymakers by engaging them in the process and writing the review in a way that it can be understandable by users.

2.2.1 Review question and objectives

After considering the FINER criteria and consulting the supervisory team, the review questions and objectives were determined. The review questions were:

- 1) How effective are psychological interventions delivered by NMHSs in the treatment of perinatal depression?
- 2) Which NMHS groups have delivered these treatments for perinatal depression?
- 3) What are the types of interventions delivered by NMHSs in the treatment of perinatal depression?

The secondary objectives were to assess the effects of psychological interventions, delivered by NMHSs on maternal anxiety, mother-infant relationship, cognitive and emotional development of the baby, and relationship with partners.

2.3 Review method

This review was conducted in accordance with the Centre for Reviews and Dissemination (CRD) guidance (University of York CRD, 2009) and was reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (The PRISMA Statement) (Moher et al., 2015). In addition, the Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al., 2019) was consulted on specific issues (e.g. calculation of missing data, risk of bias assessment). The review

protocol was registered with PROSPERO (Pinar 2017: CRD42017066000). Registering a protocol is important in terms of allowing other researchers to assess whether bias may be present if there are deviations from the approach outlined in the protocol (Booth et al. 2012).

After deciding the research questions, the next step was to translate the elements of the review questions into eligibility criteria, based on the study design and PICO elements (population, intervention(s), comparator(s) and outcome(s)) of the review question (McKenzie et al., 2019). Deciding on the PICO criteria before conducting the systematic review can prevent selection bias. These criteria are outlined in detail below.

2.3.1 Study design

The decision on what study design/s would be better to include in the systematic review should address the objectives of the research (Torgerson, 2003). Non-randomised designs can be preferred in the absence of randomised controlled trials (RCTs), for example, if it is impossible to randomise participants (McKenzie et al., 2019). For a systematic review, assessing treatment effects, including only RCTs, would be more appropriate than including non-randomised designs to prevent systematic differences between the groups in terms of confounders (McKenzie et al., 2019).

It is also important to include unpublished and grey literature, without date or language restrictions, to reduce the impact of reporting bias in systematic reviews (McKenzie et al., 2019). A preliminary scoping of the literature indicated that there were RCTs in which NMHSs had delivered the intervention; however, there was no systematic review of these. In this review, therefore, all published, unpublished, and ongoing RCTs, without language or date restrictions, were included to examine the treatment effect. Non-randomised controlled trials were excluded from the review.

2.3.2 Type of participants

The inclusion criteria for the type of participants should be broad enough to find a range of studies and narrow enough to find a meaningful answer when studies are considered together (McKenzie et al., 2019). A variety of factors, for example, evidence

from other interventions, may inform the decision on choosing participant characteristics to examine. In this review, the condition was perinatal depression and the types of participants were pregnant women or postpartum women. The postpartum period is often defined as the timescale starting with the delivery of the baby and ending after 12 months; therefore, only interventions delivered to women who were pregnant or in the postpartum period with a live birth, were included in the review. The reason for including only women with a live birth was the awareness of a need for special bereavement support for women after experiencing such a distressing event in their lives.

For inclusion in the review, studies had to establish the presence of depressive symptoms through a standardised diagnostic interview or a score above a recognised cut-off point on a validated depression severity measure.

2.3.3 Types of interventions

The important point in deciding the types of interventions is to identify the range of factors that can be related to the delivery of the intervention. For example, it is a useful practice to describe “what is delivered, who delivers it, how it is delivered, where it is delivered, when and how much is delivered, and whether the intervention can be adapted or tailored” (McKenzie et al., 2019).

In this review, interventions based on recognised psychological principles and delivered by NMHSs were included. Antenatal classes, intrapartum support, and peer-support interventions were considered as support interventions, rather than interventions based on recognised psychological principles; therefore, these interventions were excluded. The definition of ‘recognised psychological principles’ was based on Wampold’s (1997) description of ‘*bona fide psychotherapies*’. Of the three criteria outlined by Wampold, only the third criterion was used. The first criterion was related to the training of the therapist, but this review did not aim to include interventions delivered by mental health specialists. The second criterion was related to face-to-face meetings and individualisation of the treatment for the patient. This criterion may have excluded low-intensity psychological interventions, which non-specialists may be more likely to use, so again this criterion was not suitable. The third criterion states that to classify a treatment as *bona fide*, at least two of the following

criteria should be met (Wampold et al., 2002, p. 162; Wampold, 1997; Wampold et al., 1997):

- “A citation was made to an established school of or approach to psychotherapy
- A description of the therapy was contained in the article and the description contained a reference to a psychological process
- A manual for the treatment existed and was used to guide the delivery of the treatment
- The active ingredients of the treatment were identified and citations provided for those ingredients”.

Interventions delivered by mental health professionals or health workers with specialised training in the delivery of psychological treatments were excluded because this review aimed to include only interventions delivered by NMHSs.

2.3.4 Comparison groups

There are three commonly used types of comparison groups: intervention versus placebo; intervention versus control; and intervention A versus intervention B (Davey et al., 2011). In this review, it was not possible to include a placebo group because it is difficult to form and deliver a placebo psychological intervention that is not easily detected by patients (Hróbjartsson, 2002); therefore, studies were included if the comparator was either a control condition (e.g. treatment as usual, waiting list control) or other active psychological or pharmacological treatments.

2.3.5 Outcome measures

The review outcomes should be specified after deciding on the broad outcome (McKenzie et al., 2019). In this review, the primary outcome was depression as measured by standardised severity measures. Secondary outcomes were maternal anxiety, mother-infant relationship, cognitive and emotional development of the baby, and relationship with the partner. The time points were grouped as short-term (up to six months), medium-term (6 to 12 months), and long-term (12 months and above).

2.3.6 Information sources

The decision about which databases to search is important to ensure relevant citations are identified (Lefebvre et al., 2019). It is recommended to include at least three bibliographic databases (i.e., Cochrane Library Central Register of Controlled Trials (CENTRAL), MEDLINE and Embase) in addition to the other databases relevant to the aim and objectives of the review (Lefebvre et al., 2019); therefore, mental health databases (PsycINFO) and midwifery databases (Cumulative Index to Nursing and Allied Health Literature Plus (CINAHL Plus), Maternity and Infant Care (MIDIRS)) were searched in addition.

Excluding unpublished research from the meta-analysis is found overestimate the intervention effectiveness (Conn et al., 2003; McAuley et al., 2000). For this reason, it is crucial to consider searching for the grey literature where unpublished data can be identified (Lefebvre et al., 2019). ProQuest and Web of Science (Science Citation Index) were searched for dissertations, thesis and conference abstracts. Trial registries are also important sources for identifying ongoing trials that can be presented in a table and can be included in the review when the review is updated, and the findings are available. World Health Organization International Clinical Trials Registry Platform (ICTRP) was searched to identify ongoing trial registries.

The initial searches were conducted between 1 and 5 September 2017 (see Appendix 2 for search terms and the number of retrieved reports). It is important for systematic reviews to provide up-to-date information to the consumers, healthcare professionals, decision-makers and stakeholders. Reviews that are out of date may present misleading information because adding new studies and new data can significantly alter the findings of the review (Cumpston and Chandler, 2019). The changes in the evidence may require an update of the systematic reviews as reviews that are out of date may not be relevant to current evidence and practice; therefore, it was decided to update the searches and the systematic review. An update is described as “a new edition of a published systematic review with changes that can include new data, new methods, or new analyses to the previous edition” (Garner et al., 2016). The update was conducted on 15 and 16 April 2020 (see Appendix 2 and follow ‘update’ headings). The new data is indicated in the rest of the chapter using ‘update’ term or using ‘+’

sign, as appropriate. For updating the literature searches, update date field (University of York CRD, 2009) or specific search terms were used. For example, “2018\$.ed.” for MEDLINE database, as presented in the attachment (see Appendix 2).

The databases and date of searches are summarised below:

Electronic bibliographic databases: MEDLINE (Ovid) (date of inception to August Week 4 2017; update: date of inception to April 14, 2020), PsycINFO (Ovid) (date of inception to August Week 4 2017; update: date of inception to April Week 1 2020), CINAHL Plus (EBSCO) (date of inception to 31 August 2017; update: 1 September 2017 to 31 April 2020), EMBASE (Ovid) (date of inception to 30 August 2017; update: date of inception to 14 April 2020), MIDIRS (Ovid) (date of inception to July 2017; update: limit to year=“2017 –Current” (15 April 2020)), and CENTRAL (date of inception to 4 September 2017; update: 4 September 2017 to 15 April 2020).

Grey literature databases: ProQuest (date of inception to 5 September 2017; update: 5 September 2017 to 15 April 2020) and Web of Science Core Collection (date of inception to 2 September 2017; update: 2017 to 2020).

Trial registries: ICTRP (date of inception to 1 September 2017; update: could not be processed because of heavy traffic generated by the COVID-19 outbreak, which meant the website was not accessible).

Asking experts in the field can be helpful resource in identifying additional studies (Lefebvre et al., 2019). Julie Jomeen, a professor of midwifery with an interest in psychological interventions, was contacted to help identify potential additional trials in August 2018. She suggested two studies and one systematic review related to antenatal psychological group interventions; however, neither of the two primary studies met inclusion criteria and the systematic review did not yield any additional studies. Therefore, no additional trials were identified using this method.

2.3.7 Search strategy

The search terms combined three concepts “perinatal”, “depression”, and “psychological interventions”. The search terms were developed for MEDLINE database (see Table 2 for search syntax) and were then customised for other

databases. Some of the search terms (e.g. ‘ante-natal’, ‘ante natal’, ‘peri-natal’, ‘peri natal’) brought the same results in Medline and other databases; therefore, after checking the number of retrieved results, one of these terms was used, as presented in the appendix (see Appendix 2). MeSH terms in MEDLINE and thesauri terms in other databases, where available, were also used to widen the search scope. Search terms for all databases and the number of findings are listed in the appendices (see Appendix 2).

Table 2: Search syntax for MEDLINE

PICO heading	Syntax set
Population	exp Pregnancy/ OR *Peripartum Period/ OR *Postpartum Period/ OR antenatal.ti,ab. OR ante natal.ti,ab. OR ante-natal.ti,ab. OR antepartum.ti,ab. OR ante partum.ti,ab. OR ante-partum.ti,ab. OR perinatal.ti,ab. OR peri natal.ti,ab. OR peri-natal.ti,ab. OR peripartum.ti,ab. OR peri partum.ti,ab. OR peri-partum.ti,ab. OR postnatal.ti,ab. OR post natal.ti,ab. OR post-natal.ti,ab. OR postpartum.ti,ab. OR post partum.ti,ab. OR post-partum.ti,ab. OR pregnan*.ti,ab. OR prenatal.ti,ab. OR pre natal.ti,ab. OR pre-natal.ti,ab. OR prepartum.ti,ab. OR pre partum.ti,ab. OR pre-partum.ti,ab. OR puerper*.ti,ab.
Intervention	exp Counseling/ OR exp Psychotherapy/ OR BA.ti,ab. OR behavio* activation.ti,ab. OR behavio* therap*.ti,ab. OR CBT.ti,ab. OR cognitive behavio*.ti,ab. OR cognitive therap*.ti,ab. OR collaborative care.ti,ab. OR counseling.ti,ab. OR counselling.ti,ab. OR interpersonal psycho*.ti,ab. OR psychotherap*.ti,ab.
Outcome	exp Depressive Disorder/ OR *Depression/ OR depressed.ti,ab. OR depression.ti,ab. OR depressive.ti,ab.

2.3.8 Selection of studies

The results of the searches were merged in the EndNote reference manager software programme (Analytics, 2016). Duplicates were removed using the 'find duplicates' command in EndNote. Study selection is one of the crucial stages of a systematic review and it is recommended to involve more than one reviewer to ensure the transparency of this stage (University of York CRD, 2009). The screening process, on the basis of titles and available abstracts, was conducted by the same researcher for pragmatic reasons. As a detailed search strategy was conducted and a high number of studies were captured, it would have been time-consuming for another reviewer to conduct the screening process for a PhD; therefore, one reviewer carried out the screening. After removing citations that did not meet the pre-specified inclusion criteria stated above, the full text of the remaining studies was assessed for inclusion.

2.3.9 Data extraction process

The data extraction form was prepared according to the Centre for Reviews and Dissemination (University of York CRD 2009) and the Cochrane Handbook for Systematic Reviews of Interventions recommendations (Higgins and Green, 2011). Also, the Cochrane data collection tool for RCTs was used as a guide (Cochrane Training, 2017). The data extraction form can be found in the appendix (see Appendix 3). The form was pilot tested on two RCTs and refined to meet the needs of the specific review.

The following data were extracted from the reports: title, authors, publication year, country of study, type of publication, source of funding, trial design, inclusion and exclusion criteria for participants, participant characteristics, screening tools for depressive symptoms and cut-off points, the profession of implementers, details of training given to implementers, types of psychological interventions, intervention duration, details of intervention and control conditions, the timing of assessments, sample size of groups in each assessment timing, attrition rates, analyses methods, results and available trial registries.

2.3.10 Risk of bias in individually randomised trials

The risk of bias was assessed using the Cochrane Collaboration's tool for assessing risk of bias in randomised trials (RoB 2) (Higgins et al., 2019a; Sterne et al., 2019). This tool helps in understanding how an individual result might be affected by bias arising from: the randomisation process; deviations from the intended interventions; missing outcome data; measurement of the outcome; and selection of the reported result (Higgins et al., 2019a). Each domain was assessed using the following answers: yes; probably yes; probably no; no; and no information (Higgins et al., 2019a). The decision was made by assigning the following judgements: low risk of bias; some concerns; or high risk of bias (Higgins et al., 2019a).

2.3.11 Risk of bias in cluster-randomised trials

Cluster RCTs were assessed for bias arising from: the randomisation process; the timing of identification and recruitment of participants; deviations from intended interventions; missing outcome data; measurement of the outcome; and selection of the reported result (RoB 2 Cluster) (Higgins, Eldridge and Li, 2019).

2.3.12 Summary measures and synthesis of results

Studies were grouped a priori by type of control conditions, type of interventions and timing of assessment. Standardised mean difference (SMD) was used in calculating individual effect sizes as the small sample bias-adjusted difference using Hedge's *g* (Higgins and Green, 2011). Mean differences (MD) and their associated 95% confidence intervals were calculated where all the studies in a group reported the same depression severity measure (Higgins and Green, 2011).

In one trial (Rojas et al., 2007), standard deviations (SD) were not reported; they were calculated from available confidence intervals using the following formula (Higgins, Li and Deeks, 2019):

$$SD = \sqrt{N} \times (\text{upper limit} - \text{lower limit}) / 3.92$$

One cluster trial (Morrell et al., 2009) was eligible for inclusion in the meta-analysis. A unit-of-analysis error may occur if cluster trials are combined with individually

randomised trials in the meta-analysis and this may lead to overestimation of the effect of a treatment (Higgins, Eldridge and Li, 2019). Reducing the sample size to its effective sample size is one of the methods that can be used for an approximately correct analysis (Higgins, Eldridge and Li, 2019). For this calculation, the number of clusters in each group, the number of individuals in each group, means, standard deviations and intraclass correlation coefficient (ICC) were extracted from Morrell et al.'s study (2009). Then the following formula was used (Higgins, Eldridge and Li, 2019):

$$\text{Design effect} = 1 + (M - 1) \times \text{ICC}$$

M is the average cluster size and can be calculated through:

$$M = (\text{Number of individuals in intervention group} + \text{number of individuals in control group}) / (\text{number of clusters in intervention group} + \text{number of clusters in control group}) \text{ (Higgins, Eldridge and Li, 2019).}$$

There might be variations between the studies in terms of sample sizes, duration of treatments, the NMHS groups, and content and components of treatments (clinical heterogeneity) or variations in the risk of bias and study design (methodological heterogeneity). These features of studies might lead to statistical heterogeneity. Statistical heterogeneity was estimated using the Chi-squared (χ^2) test and I-squared (I^2) statistic. For I^2 , heterogeneity was judged as follows: 0% to 40% might not be important, 30% to 60% may represent moderate heterogeneity, 50% to 90% may represent substantial heterogeneity, 75% to 100% represents considerable heterogeneity (Higgins and Green, 2011, section 9.5.2). A random-effects model was used to combine data rather than a fixed effect model, because of these variations between the studies.

Review Manager (RevMan) (Nordic Cochrane Centre, 2014) Version 5.3 was used to generate forest plots.

2.3.13 Publication bias

To reduce possible publication bias, the grey literature and trial registry databases were searched; however, publication bias was not investigated with a funnel plot or

associated statistical analyses because there were too few studies included in the meta-analysis to do so.

2.3.14 Additional analyses

The protocol specified a number of *a priori* subgroup analyses (healthcare professional, antenatal versus postpartum depression, intervention mode (e.g. individual or group bases)) (Pinar 2017: CRD42017066000); however, there were not sufficient studies to conduct a subgroup analysis for the type of health professional and antenatal versus postpartum depression. A subgroup analysis comparing individual and group interventions was conducted.

Sensitivity analysis may be performed to assess the robustness of results if the decisions for including studies is unclear (Higgins, Eldridge and Li, 2019). In this regard, a post hoc sensitivity analysis was undertaken to understand whether including the cluster randomised trial overestimated the effect size, despite calculating its effective sample size (Deeks et al., 2019).

2.4 Results

2.4.1 Study selection

A total of 13,824 (first search) + 3,689 (update) reports were identified. After removing duplicates using the 'find duplicates' command in EndNote, 11,286 + 2,922 reports remained. Figure 2 shows the PRISMA Flow Chart (Moher et al., 2015) for the selection of studies with reasons for exclusions. After title and available abstract screening process, 116 + 51 reports were left.

After the full-text screening, 98 + 49 reports were excluded for different reasons, as illustrated in Figure 2. Authors were contacted for clarification if the implementer's profession was unknown or only the trial registry was available. During this time, fourteen + five authors were sent emails with the following reasons: the profession of therapists was not clear (Zhao et al., 2017; Leung et al., 2016; Masood et al., 2015; Jiang et al., 2014; Ammerman et al., 2013; Mulcahy et al., 2010; Wiklund, Mohlkert and Edman, 2010; Grote et al., 2009; Scott, 2002; + Bleker et al., 2019; Stowe 2019; Lieshout, 2018; Mehri and Iravani, 2018; Jourabchi and Safaralinezhad, 2017); inclusion

criteria for women was not clear (Brock, O'Hara and Segre, 2017); and only protocol or trial registry was available (Ahmad, Silim and Aris, 2017; Nusrat et al., 2016; Lund et al., 2014; Dennis et al., 2012). Ten + one authors replied to the emails.

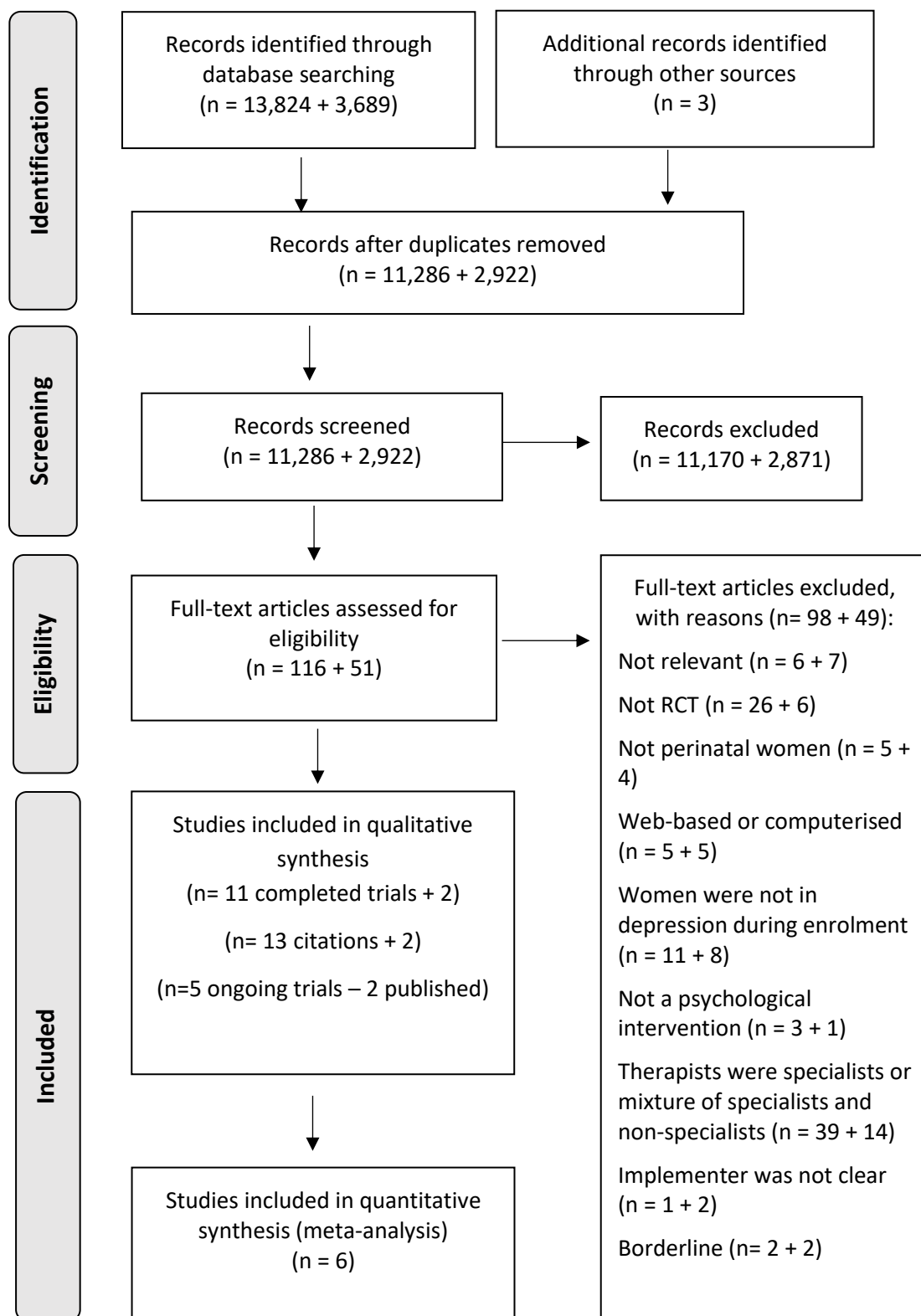


Figure 2: Flow diagram for the process of identification of studies

Two trials (Horowitz et al., 2013; Mulcahy et al., 2010) were discussed in detail with the supervisory team because it was not clear if they met the inclusion criteria. In one trial (Horowitz et al., 2013), the intervention had psychological underpinnings; however, it was not specifically for depressive symptoms; the main focus was on improving the interaction between mother and child. The trial, therefore, was excluded from the review. In the other trial (Mulcahy et al., 2010), the implementers were researchers who had undertaken 20 hours training followed by at least 6 months' supervision on individual cases, followed by eight hours training on the group intervention and supervision on pilot groups. This was considered to exceed training for a non-specialist; therefore, the trial was also excluded from the review. After updating the searches, there were two more borderline trials (Fuhr et al., 2019; Sikander et al., 2019) that used peers (laywomen) for the implementation of interventions to participants. The exclusion criteria in the protocol stated "peer-support interventions will be excluded" (Pinar 2017: CRD42017066000); therefore, these interventions were excluded from the study.

Results from two trials (Ngai et al., 2015; Rahman et al., 2008) were reported in more than one citation (Ngai et al., 2016; Maselko et al., 2015 respectively). Each of the two citations were treated as a single study. After updating the search, two of the trials that were originally ongoing had published reports; therefore, these trial registries are shown as "- 2" in the flowchart. Three ongoing trials were not included in the review, but, because they meet inclusion criteria, they are described in an appendix as an aid to future reviews in this area (see Appendix 4).

In total, 13 RCTs published between 1989 and 2020 were included in the review (N= 3,040). Table 3 summarises the characteristics of the studies.

Table 3: Details of included trials

Study	Participants and location	Interventions (n)	Profession of therapist and intervention duration	Assessment of depression for inclusion and outcome measures
Dennis et al., 2020	241 postpartum women; Canada	<p>Treatment -Telephone-based interpersonal psychotherapy (120)</p> <p>Comparison -Standard postpartum care (121)</p>	Nurses; 12 weekly sessions, 1 hour	<p>Assessment EPDS and SCID</p> <p>Outcome measures SCID, EPDS, STAI, DAS, Experiences in Close Relationships-Revised, Maternal Health Service Utilization and Cost of Care Questionnaire, and Maternal Satisfaction with IPT Questionnaire</p>
Holden, Sagovsky and Cox, 1989	50 postpartum women; UK	<p>Treatment -Non-directive counselling (26)</p> <p>Comparison -Control (24)</p>	Health visitors; 8 weekly counselling, at least ½ hour	<p>Assessment Goldberg's standardised psychiatric interview and EPDS</p> <p>Outcome measures Goldberg's standardised psychiatric interview and EPDS</p>
Honey, Bennett and Morgan, 2002	45 postpartum women; UK	<p>Treatment -Psychoeducational group intervention [educational, CBT techniques, teaching relaxation] (23)</p> <p>Comparison -Routine primary care (22)</p>	Health visitors; 8 weekly interventions, 2 hours	<p>Assessment EPDS</p> <p>Outcome measures EPDS, Duke-UNC Social Support Questionnaire, DAS, and Ways of Coping Checklist Revised</p>

Leung et al., 2016	164 postpartum women; China	<p>Treatment</p> <p>-Brief group CBT (82)</p> <p>Comparison</p> <p>-A booklet includes information and education material and a list of community resources (82)</p>	NMHSs; 6 weekly sessions, 2 hours	<p>Assessment</p> <p>EPDS and SCID</p> <p>Outcome measures</p> <p>EPDS, HADS, PSS, DMAS, Family APGAR, and DAS†</p>
Lund et al., 2020	384 antenatal women; South Africa	<p>Treatment</p> <p>-Psychological counselling (CBT)(psycho-education, problem solving, behavioural activation, healthy thinking, relaxation training, and birth preparation) (184)</p> <p>Comparison</p> <p>-Routine antenatal care and three monthly phone calls (200)</p>	Community health workers; 6 weekly sessions, 45 – 60 minutes	<p>Assessment</p> <p>EPDS</p> <p>Outcome measures</p> <p>HDRS, EPDS, MINI, A Health Care Utilization Questionnaire, Client Service Receipt Inventory, World Health Organization Disability Assessment Schedule 2.0, Cape Town Functional Assessment Instrument for Maternal Depression, Household Food Insecurity Assessment scale, Multidimensional Scale of Perceived Social Support, and Alcohol Use Disorders Identification Test</p>
Milgrom et al., 2011	68 postpartum women; Australia	<p>Treatment</p> <p>-GP management (23)</p> <p>-CBT from a nurse (an adjunct to GP management) (22)</p> <p>-CBT from a psychologist (an adjunct to GP management) (23)</p>	Nurses and psychologists; 6 weekly sessions	<p>Assessment</p> <p>EPDS and SCID</p> <p>Outcome measures</p> <p>BDI-II and DASS-21 SF</p>

Morrell et al., 2009	418 postpartum women; UK	Treatment -CBT or person-centred therapy (271) Comparison -Usual care (147)	Health visitors; 8 weekly sessions, 1 hour	Assessment EPDS Outcome measures EPDS, CORE-OM, STAI, SF-12 MCS, SF-12 PCS, and PSI-SF
Ngai et al., 2015 Ngai et al., 2016	397 postpartum women; China	Treatment -Telephone-based CBT (197) Comparison -Standard care (200)	Midwife; 5 weekly sessions, 30 minutes	Assessment EPDS Outcome measures EPDS and PSI-SF
Prendergast and Austin, 2001	37 postpartum women; Australia	Treatment - CBT (17) Comparison -Ideal standard care (20)	Early childhood nurses; 6 weekly sessions, 1 hour	Assessment EPDS and SCID Outcome measures EPDS, MADRS, DASS, and PSI
Rahman et al., 2008 Maselko et al., 2015	903 antenatal women; Pakistan	Treatment -Thinking Healthy Programme (CBT techniques) (463) Comparison -Routine care (440)	Community health workers; A total of 16 sessions: a session every week for four weeks in the last month of pregnancy, three sessions in the first postnatal month, and nine one-monthly sessions thereafter	Assessment SCID Outcome measures Hamilton Depression Rating Scale, Brief Disability Questionnaire, Global Assessment of Functioning Scale, Multidimensional scale for perceived social support, WPPSI-IV, SDQ, and SCAS

Rojas et al., 2007	230 postpartum women; Chile	Treatment -Multicomponent group intervention (psychoeducational group [information about symptoms and treatments, problem solving and simple behavioural activation and cognitive techniques], treatment adherence support, and pharmacotherapy if needed) (114). Comparison -Usual care (116)	Midwives and nurses; 8 weekly sessions, 50 minutes	Assessment MINI, SCID, and EPDS Outcome measures EPDS and SF-36
Wickberg and Hwang, 1996	41 postpartum women; Sweden	Treatment -Non-directive counselling (20) Comparison -Routine primary care (21)	Paediatric nurses; 6 weekly counselling, 1 hour	Assessment EPDS, MADRS, and SCID Outcome measures MADRS, and SCID
Wozney et al., 2017	62 postpartum women; Canada	Treatment -Telephone-based CBT (32) Comparison -Standard community care (30)	Paraprofessionals; 12 weekly telephone calls	Assessment SCID Outcome measures SCID, BDI-II, and EPDS

Beck Depression Inventory-II (BDI-II); Clinical Outcomes in Routine Evaluation-Outcome Measure (CORE-OM); Dyadic Adjustment Scale (DAS), Depression, Anxiety, Stress Scale (DASS); Depression Anxiety and Stress Scale-Short Form (DASS- 21 SF); Dyadic (Marital) Adjustment Scale (DMAS); Dysfunctional Attitudes Scale (DAS+); Edinburgh Postnatal Depression Scale (EPDS); Family Functioning in five dimensions: adaptation, partnership, growth, affection, and resolve (Family APGAR); Hospital Anxiety and Depression Scale (HADS); Mini

International Neuropsychiatry Interview (MINI); Montgomery and Asberg Depression Rating Scale (MADRS); Parenting Stress Index (PSI); Parenting Stress Index Short Form (PSI-SF); Perceived Stress Scale (PSS); Short Form 12 Mental Component Summary (SF-12 MCS); Short Form 12 Physical Component Summary (SF-12 PCS); Short Form-36 Health Survey (SF-36); Spence Children's Anxiety Scale (SCAS); State-Trait Anxiety Inventory (STAI); Strengths and Difficulties Questionnaire (SDQ); Structured Clinical Interview for DSM-IV Disorders (SCID); Wechsler Preschool and Primary Scale of Intelligence, fourth edition (WPPSI-IV).

2.4.2 Study design

Of the thirteen trials, eleven were individually randomised and two were cluster-randomised trials (Morrell et al., 2009; Rahman et al., 2008).

2.4.3 Setting

Three of thirteen trials were conducted in the UK; two in Australia; two in China; two in Canada; one in Chile; one in Pakistan; one in South Africa; and one in Sweden. Interventions were mostly delivered in healthcare settings (e.g. clinic, primary care, health centre) (Lund et al., 2020; Leung et al., 2016; Milgrom et al., 2011; Rojas et al., 2007; Honey, Bennett and Morgan, 2002; Prendergast and Austin, 2001; Wickberg and Hwang, 1996) or participants' homes (Lund et al., 2020; Morrell et al., 2009; Rahman et al., 2008; Wickberg and Hwang, 1996; Holden, Sagovsky and Cox, 1989).

2.4.4 Participants

The mean age of participants was 30.6 years. All participants were in the postpartum period (n= 1,753) except those in one individually randomised trial (n= 384) and one cluster trial (n= 903), who were pregnant at the time of the intervention (Lund et al., 2020; Rahman et al., 2008).

2.4.5 Interventions

Ten trials used Cognitive Behavioural Therapy (CBT) interventions (Lund et al., 2020; Wozney et al., 2017; Leung et al., 2016; Ngai et al., 2015; Milgrom et al., 2011; Morrell et al., 2009; Rahman et al., 2008; Prendergast and Austin, 2001); of which two trials used psycho-education principles from CBT (Honey, Bennett and Morgan, 2002; Rojas et al., 2007). Three trials used counselling interventions, of which two trials used Non-directive Counselling (Holden, Sagovsky and Cox, 1989; Wickberg and Hwang, 1996); and one trial used Person-Centred Therapy (Morrell et al., 2009). One trial used Interpersonal Psychotherapy (Dennis et al., 2020). The distinction between psychological and support interventions was made according to the *bona fide* classification as detailed above (Wampold et al., 2002). Non-directive counselling is sometimes used to refer to a sham psychological treatment with the intention of controlling for placebo effects. However, in the two trials (Holden, Sagovsky and Cox,

1989; Wickberg and Hwang, 1996) that used non-directive counselling, both cited an established approach and described the therapy; therefore, these studies were included in the review. Another two trials (Honey, Bennett and Morgan, 2002; Rojas et al., 2007) used psycho-education and the intervention was described as a CBT technique; therefore, these again met the inclusion criteria and were grouped with other CBT interventions in the meta-analysis.

The professions of the NMHSs were nurses (Dennis et al., 2020; Milgrom et al., 2011; Rojas et al., 2007; Prendergast and Austin, 2001; Wickberg and Hwang, 1996); health visitors (Morrell et al., 2009; Honey, Bennett and Morgan, 2002; Holden, Sagovsky and Cox, 1989); midwives (Ngai et al., 2015; Rojas et al., 2007); community health workers (Lund et al., 2020; Rahman et al., 2008); and not specified NMHSs or paraprofessionals (Leung et al., 2016; Wozney et al., 2017).

Information about the training of the NMHSs was provided in seven reports (Dennis et al., 2020; Lund et al., 2020; Ngai et al., 2015; Milgrom et al., 2011; Rojas et al., 2007; Wickberg and Hwang, 1996; Holden, Sagovsky and Cox, 1989). Duration of training varied between the reports: a half-day training (Milgrom et al., 2011); eight hours (Dennis et al., 2020; Rojas et al., 2007); 20 hours (Ngai et al., 2015); four half-day (Wickberg and Hwang, 1996); five days (Lund et al., 2020); and three weekly training sessions of two hours (Holden, Sagovsky and Cox, 1989).

Intended intervention duration varied between trials such that some delivered weekly sessions for five weeks (Ngai et al., 2015); for six weeks (Lund et al., 2020; Leung et al., 2016; Milgrom et al., 2011; Prendergast and Austin, 2001; Wickberg and Hwang, 1996); for eight weeks (Morrell et al., 2009; Rojas et al., 2007; Honey, Bennett and Morgan, 2002; Holden, Sagovsky and Cox, 1989); and for 12 weeks (Dennis et al., 2020; Wozney et al., 2017). There was one trial which intended to deliver 18 sessions at different time points during pregnancy and in the postpartum period (Rahman et al., 2008). One-to-one sessions were typically up to one hour and group sessions were mostly two hours long.

Three trials used a group format for delivery (Leung et al., 2016; Rojas et al., 2007; Honey, Bennett and Morgan, 2002). These interventions used CBT principles and were delivered by health visitors, midwives, nurses, and not specified NMHSs.

In three trials, CBT (2) and IPT (1) were delivered over the telephone (Dennis et al., 2020; Wozney et al., 2017; Ngai et al., 2015; respectively) by nurses, not specified paraprofessionals and midwives. One of the trials supported a telephone-based intervention with a handbook and corresponding videos (Wozney et al., 2017). The remainder seven trials used individually delivered face-to-face treatment.

2.4.6 Comparison group

In eleven trials, there was one intervention and one control group, while in two trials (Milgrom et al., 2011, Morrell et al., 2009), there were two active interventions and one control group. Comparison groups varied between trials. Although all of them referred to these groups as 'usual care' or 'routine care', the content of care was different. The distinction between active interventions and controls was made according to the authors' classification of them using the *bona fide* classification as detailed above (Wampold et al., 2002). For example, one trial (Prendergast and Austin, 2001) delivered the same number of sessions as were given to the intervention group using non-specific emotional support and referred to this as 'ideal standard care'. Non-specific emotional support cannot be classified as a psychological treatment according to the *bona fide* classification (Wampold et al., 2002); therefore, this group was included as a control arm in the review.

2.4.7 Outcome measures

Depression status at enrolment was identified in seven trials using the Structured Clinical Interview for Diagnostic and Statistical Manual (SCID) (APA, 2000; First et al., 2002); one used Goldberg's Standardised Psychiatric Interview (Goldberg et al., 1970); and one used Mini International Neuropsychiatry Interview (MINI) (Sheehan et al., 1994). In the remaining four trials, depression status at enrolment was defined using the Edinburgh Postnatal Depression Scale (EPDS) (Cox and Holden, 2003).

Outcome measures for depression were available at under six months in nine trials (Dennis et al., 2020; Lund et al., 2020; Wozney et al., 2017; Leung et al., 2016; Ngai et al., 2015; Milgrom et al., 2011; Rojas et al., 2007; Honey, Bennett and Morgan, 2002; Prendergast and Austin, 2001; Wickberg and Hwang, 1996; Holden, Sagovsky and Cox, 1989); between six and eleven months in nine trials (Dennis et al., 2020; Wozney et al.,

2017; Leung et al., 2016; Ngai et al., 2015; Morrell et al., 2009; Rahman et al., 2008; Rojas et al., 2007; Honey, Bennett and Morgan, 2002; Prendergast and Austin, 2001); and twelve months and above in four trials (Lund et al., 2020; Wozney et al., 2017; Morrell et al., 2009; Rahman et al., 2008).

Secondary outcomes were extracted for maternal anxiety, mother-infant relationship, cognitive and emotional development of the baby, and relationship with partners. A limited number of trials reported secondary outcomes. These included the effectiveness of psychological interventions on maternal anxiety (Dennis et al., 2020; Leung et al., 2016; Milgrom et al., 2011; Morrell et al., 2009); mother-infant relationship (Ngai et al., 2015); cognitive and emotional development of the baby (Ngai et al., 2015; Rahman et al., 2008); and relationship with partner (Dennis et al., 2020; Leung et al., 2016; Honey, Bennett and Morgan, 2002).

2.4.8 Risk of bias in individually randomised trials

2.4.8.1 Bias arising from the randomisation process

Sequence generation for randomisation was adequate in seven trials and they were assessed as having a low risk of bias (Dennis et al., 2020; Lund et al., 2020; Wozney et al., 2017; Ngai et al., 2015; Milgrom et al., 2011; Rojas et al., 2007; Prendergast and Austin, 2001). Four trials (Dennis et al., 2020; Lund et al., 2020; Wozney et al., 2017; Rojas et al., 2007) used a computer or web-based random number generator; two trials (Ngai et al., 2015; Prendergast and Austin, 2001) referred to a random number table; and one trial (Milgrom et al., 2011) generated a random sequence but it was not clear whether they used a random number table or a computer random number generator. In the remaining four trials (Leung et al., 2016; Honey, Bennett and Morgan, 2002; Wickberg and Hwang, 1996; Holden, Sagovsky and Cox, 1989), there was insufficient information to assess the risk of bias for random sequence generation.

Appropriate allocation concealment was achieved in six trials (Dennis et al., 2020; Lund et al., 2020; Wozney et al., 2017; Ngai et al., 2015; Milgrom et al., 2011; Rojas et al., 2007). Five trials (Dennis et al., 2020; Lund et al., 2020; Wozney et al., 2017; Milgrom et al., 2011; Rojas et al., 2007) used independent statistician or internet-based randomisation service providers to conceal allocation; one trial (Ngai et al., 2015) used

sequentially numbered, opaque and sealed envelopes which was considered as an adequate attempt to conceal the allocation. In the remaining five trials (Leung et al., 2016; Honey, Bennett and Morgan, 2002; Prendergast and Austin, 2001; Wickberg and Hwang, 1996; Holden, Sagovsky and Cox, 1989), there was insufficient information to permit judgement of high or low risk of bias.

Nine of eleven trials were considered as having a low risk of baseline differences because there were no major imbalances between intervention group sizes, compared with the intended allocation ratio and there was no significant difference between the groups in terms of baseline characteristics or baseline measures of outcomes variables (Dennis et al., 2020; Lund et al., 2020; Wozney et al., 2017; Leung et al., 2016; Ngai et al., 2015; Milgrom et al., 2011; Rojas et al., 2007; Honey, Bennett and Morgan, 2002; Holden, Sagovsky and Cox, 1989). In one study, baseline characteristics of women were not reported, the baseline MADRS score was slightly higher in the intervention group; therefore, this study was assessed as raising some concerns (Holden, Sagovsky and Cox, 1989). In another study, there was a statistically significant difference between the groups in baseline measures of EPDS. The baseline EPDS scores in the intervention group were higher compared with the control group and it was not clear if the imbalance was compatible with chance; therefore, this study was also assessed as raising some concerns (Prendergast and Austin, 2001).

2.4.8.2 Bias due to deviations from the intended interventions

The women and the NMHSs were aware of their assigned groups. It was not possible to blind participants and NMHSs because of the nature of the implemented psychological interventions, as mentioned earlier; therefore, outcome data was likely to be influenced by lack of blinding and all trials were assessed as having a high risk of bias.

In one study, although the control group intended to receive ideal standard care there was a contamination and almost 70% of the control group inadvertently received non-specific emotional support, which included some degree of problem-solving and pleasant event scheduling in their sessions; therefore, the outcomes might be affected

by inappropriate control conditions (Prendergast and Austin, 2001). This study was considered as having a high risk of bias.

2.4.8.3 Bias due to missing outcome data

Attrition rates varied between 9% and 28%. The loss to follow-up rates was low, balanced and comparable in seven trials (Dennis et al., 2020; Lund et al., 2020; Leung et al., 2016; Ngai et al., 2015; Rojas et al., 2007; Prendergast and Austin, 2001; Holden, Sagovsky and Cox, 1989). In one trial (Milgrom et al., 2011), attrition rates were balanced between the intervention and control groups; however, it was 28% at 8 weeks; therefore, this was regarded as unclear risk of bias. In another trial (Wozney et al., 2017), the attrition rate was 19% at 12 months; however, 69% of participants had complete data; therefore, this trial was also assessed as having unclear risk of bias. In the remaining two trials (Honey, Bennett and Morgan, 2002; Wickberg and Hwang, 1996), there was insufficient information to make a decision.

2.4.8.4 Bias in measurement of the outcome

Seven trials maintained blinding of outcome assessors (Dennis et al., 2020; Lund et al., 2020; Wozney et al., 2017; Ngai et al., 2015; Rojas et al., 2007; Wickberg and Hwang, 1996; Holden, Sagovsky and Cox, 1989). In six trials, an independent assessor carried out the outcome assessment, or the assessor was blind to the allocation (Dennis et al., 2020; Lund et al., 2020; Wozney et al., 2017; Rojas et al., 2007; Wickberg and Hwang, 1996; Holden, Sagovsky and Cox, 1989); and in one trial (Ngai et al., 2015), postal questionnaires were used. In the remaining four trials (Leung et al., 2016; Milgrom et al., 2011; Honey, Bennett and Morgan, 2002; Prendergast and Austin, 2001), there were insufficient details to assess the risk of detection bias.

2.4.8.5 Bias in selection of the reported result

The trial registry was available in five trials (Dennis et al., 2020; Lund et al., 2020; Ngai et al., 2015; Milgrom et al., 2011; Rojas et al., 2007) and all expected outcomes were reported. In the remaining five trials, the study protocol was not available; therefore, they were assessed as unclear risk of reporting bias (Wozney et al., 2017; Honey, Bennett and Morgan, 2002; Prendergast and Austin, 2001; Wickberg and Hwang, 1996;

Holden, Sagovsky and Cox, 1989). In the remaining one trial, analysis intentions were not reported to enable an assessment (Leung et al., 2016).

Table 4 displays the risk of bias assessment for the individually randomised trials.

Table 4: Risk of bias assessment for individually randomised trials

Risk of bias domains →	Bias arising from the randomisation process	Bias due to deviations from intended intervention	Bias due to missing outcome data	Bias in measurement of the outcome	Bias in selection of the reported result	Overall
Studies ↓						
Dennis et al., 2020	Low	High	Low	Low	Low	Low
Holden, Sagovsky and Cox, 1989	Some concerns	High	Low	Low	Some concerns	Some concerns
Honey, Bennett and Morgan, 2002	Some concerns	High	Some concerns	Some concerns	Some concerns	Some concerns
Leung et al., 2016	Some concerns	High	Low	Some concerns	High	Some concerns
Lund et al., 2020	Low	High	Low	Low	Low	Low
Milgrom et al., 2011	Low	High	Some concerns	Some concerns	Low	Low
Ngai et al., 2015	Low	High	Low	Low	Low	Low
Prendergast and Austin, 2001	Some concerns	High	Low	Some concerns	Some concerns	Some concerns
Rojas et al., 2007	Low	High	Low	Low	Low	Low
Wickberg and Hwang, 1996	Some concerns	High	Some concerns	Low	Some concerns	Some concerns
Wozney et al., 2017	Low	High	Some concerns	Low	Some concerns	Low

2.4.9 Risk of bias in cluster-randomised trials

2.4.9.1 Bias arising from the randomisation process

Both cluster-trials tried to avoid recruitment bias in different ways. In one trial, the randomisation was made using a table of random numbers by an independent researcher who was unaware of the clusters (Rahman et al., 2008). In the other trial, a computer randomisation programme was used by an independent statistician who generated the allocation sequence (Morrell et al., 2009). In both trials, the number of clusters were balanced between the groups.

2.4.9.1b Bias arising from the timing of identification and recruitment of participants

In one trial, the health workers were enrolled to participate in the study before randomisation (Rahman et al., 2008). In the other trial, the health visitors and general practitioners in each cluster signed a consent form before the random allocation (Morrell et al., 2009). In Morrell et al.'s trial, some women were identified prior to randomisation but recruited after the randomisation of clusters and in Rahman et al.'s study women were identified after the randomisation of clusters. There was insufficient information whether women were aware of cluster allocation; therefore, these studies were considered as raising some concerns.

2.4.9.2 Bias due to deviations from the intended interventions

In both studies, the NMHSs and women were aware of the assigned interventions; therefore, these studies were assessed as being at high risk of bias (Morrell et al., 2009; Rahman et al., 2008).

2.4.9.3 Bias due to missing outcome data

Although one of the trials (Morrell et al., 2009) lost one cluster from the control group and three clusters from the intervention group, attrition rate and the number of participants in each group were balanced. In the other trial (Rahman et al., 2008), there was no loss of clusters, but participants were lost to follow-up, which was again balanced in each arm.

2.4.9.4 Bias in measurement of the outcome

In one trial (Rahman et al., 2008), the outcome assessors were unaware of the allocation status of the women and in the other trial (Morrell et al., 2009), the outcomes were collected by postal questionnaires; therefore, both studies were considered as having a low risk of bias.

2.4.9.5 Bias in selection of the reported result

The trial registry was available in studies and both trials took clustering into account and the analysis was appropriate (Morrell et al., 2009; Rahman et al., 2008). In one trial (Morrell et al., 2009), there were two different intervention groups (CBT and counselling) and one control group. Although the women were allocated to three groups at a ratio of 1:1:1, in the analysis, intervention arms were reported together and compared with the control group. Therefore, the number of clusters in the CBT group was estimated by dividing the clusters in the intervention group by half.

Table 5 demonstrates the risk of bias assessment for the cluster-randomised trials.

Table 5: Risk of bias assessment for cluster-randomised trials

Risk of bias domains →							
Studies ↓	Bias arising from the randomisation process	Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation	Bias due to deviations from intended intervention	Bias due to missing outcome data	Bias in measurement of the outcome	Bias in selection of the reported result	Overall
Morrell et al., 2009	Low	Some concerns	High	Low	Low	Low	Low
Rahman et al., 2008	Low	Some concerns	High	Low	Low	Low	Low

The effects of interventions are reported according to a pre-planned comparison (Pinar 2017: CRD42017066000). First, active versus control interventions' effects on postpartum, antenatal and perinatal depressive symptoms are discussed depending on the types of psychological interventions (i.e., CBT, counselling, IPT). Then, active versus active interventions' (i.e., CBT vs. counselling; CBT from a nurse vs. CBT from a psychologist) effects are described. Finally, secondary outcomes are reported using the same structure. If a particular comparison is not reported it is because none of the included studies made that particular comparison.

2.4.10 Effects of interventions on depression symptoms

Thirteen studies reported depression outcomes, of which eleven examined depression in the postpartum period, one in the antenatal period and one in the perinatal period.

2.4.10.1 Effects of interventions on postpartum depression symptoms (active versus control)

Comparison 1: CBT versus control

Seven trials provided data on short-term (< 6 months) outcomes for CBT relative to control conditions, of which five reported sufficient data to be included in a meta-analysis. All trials used the EPDS, except one trial which used the BDI for the measurement of depressive symptoms; therefore, SMD was calculated. CBT delivered by NMHSs showed an improvement in the symptoms of postpartum women (N= 500) with depression (SMD= -0.36; 95% CI -0.65 to -0.07; P=0.01) (Figure 3). There was moderate heterogeneity ($I^2=53\%$).

Ngai et al. (2015) and Wozney et al. (2017) did not report sufficient data to be included in the meta-analysis, so the results of these two studies are summarised separately here. Ngai et al. (2015) (n=397) found that telephone-based CBT delivered by a NMHS was effective in decreasing minor and major depressive symptoms, compared with standard care at six weeks (EPDS=10-12; MD=1.90; 95% CI 0.72 to 3.08) (EPDS>12; MD=5.0; 95% CI 3.12 to 6.88). Wozney et al. (2017) (n=62) reported that postpartum women in the CBT group delivered by NMHSs were 1.5 times as likely to experience

recovery at three months (mid-intervention) compared to control group, which was not statistically significant ($p=0.742$).

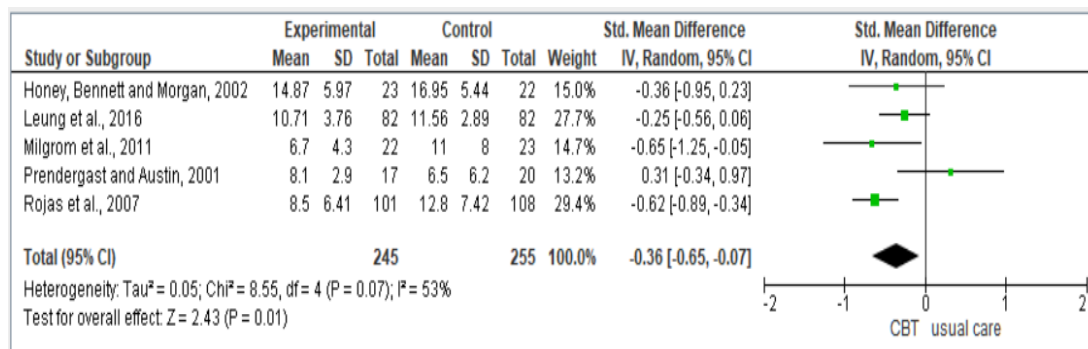


Figure 3: CBT versus usual care, short term (up to six months) outcomes in postpartum depression

Seven trials provided data on medium-term (6 to 12 months) outcomes, of which five could be included in a meta-analysis. The MD was calculated because all the trials used EPDS for the measurement of depressive symptoms. CBT delivered by NMHSs improved the symptoms of postpartum women (N= 710) with depression (MD= -1.32; 95% CI -2.09 to -0.56; P=0.0007) (Figure 4). There were low levels of heterogeneity (I²=13%).

Ngai et al. (2015) and Wozney et al. (2017) did not report sufficient data to be included in the meta-analysis, so the results of these two studies are summarised here. Ngai et al. (2015) (n=397) found that telephone-based CBT delivered by a NMHS was effective in decreasing minor symptoms (EPDS=10-12; MD=1.20; 95% CI 0.09 to 2.32) but not major symptoms (EPDS>12; MD=1.69; 95% CI -0.10 to 3.47) at six months. Wozney et al. (2017) (n=62) reported that postpartum women in the CBT group delivered by NMHSs were 1.54 times as likely to experience recovery at six months compared to control group, which was not statistically significant ($p=0.696$).

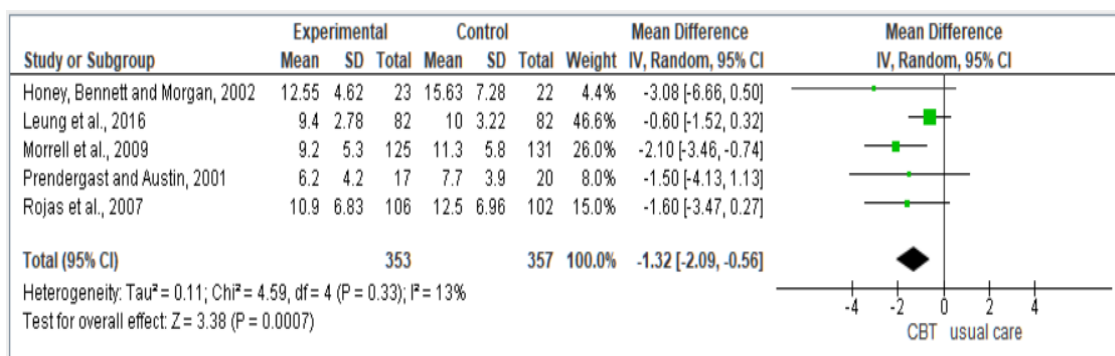


Figure 4: CBT versus usual care, medium term (6 to 12 months) outcomes in postpartum depression

One trial provided data on long-term (12 months and above) outcomes. Wozney et al. (2017) (n=62) reported that postpartum women in the CBT group delivered by NMHSs were 12.5 times as likely to experience recovery at 12 months (p=0.009) compared to control group.

Overall, taking the results of the meta-analyses and additional two studies not included in the meta-analysis, CBT delivered by NMHSs for postnatal depression symptoms was superior to control conditions, with some evidence of sustained effects.

Comparison 2: Counselling versus control

Two trials (Holden, Sagovsky and Cox, 1989; Wickberg and Hwang, 1996) (n=50; n=31 respectively) reported outcomes for the effectiveness of non-directive counselling delivered by health visitors and nurses, respectively. In the first trial (Wickberg and Hwang, 1996), 80% (12/15) of women with depression in the treatment group had fully recovered, compared to 25% (4/16) of women in the control group post-treatment (three months). The difference in recovery rate between the groups was 55%, which was statistically significant ($\chi^2=7.24$; P < 0.01). In the second trial (Holden, Sagovsky and Cox, 1989), 69% (18/26) of women in the non-directive counselling group had experienced diagnostic remission compared with 38% (9/24) in the control group post-treatment (six months). The difference in recovery rate between the groups was 31.7%, which was again statistically significant ($\chi^2=5.06$; P=0.03).

Comparison 3: IPT versus control

One trial (Dennis et al., 2020) (n=241) reported outcomes for telephone IPT delivered by nurses for the treatment of postpartum depression. In the short term (12-week post-randomisation), 10.6% (11/104) of women in the treatment group remained depressed in contrast to 35% (35/100) in the control group (OR=0.22; 95% CI 0.10 to 0.46). In the early medium term (24-week post-randomisation), 10.9% (11/101) of women in the treatment group and 33.7% (34/101) in the control group remained depressed (OR=0.24; 95% CI 0.11 to 0.51). In the late medium term (36 weeks), 10.9% (11/101) of women in the treatment group and 15.6% (15/96) in the control group remained depressed and there were no significant group differences (OR=0.66; 95% CI 0.29 to 1.52).

2.4.10.2 Effects of interventions on postpartum depression symptoms (active versus active comparator)

Comparison 1: CBT versus counselling

Morrell et al. (2009) reported that 33% (46/140) of women who received CBT intervention and 35% (46/131) of women who received counselling scored 12 or more on EPDS at six months. There were no significant differences between the groups (P=0.74) (the paper does not provide further details of the analysis).

Comparison 2: CBT from a nurse versus CBT from a psychologist

Milgrom et al. (2011) (n=45) reported eight-week post-treatment effects of CBT delivered by nurses (n=22) versus psychologists (n=23). The difference between the BDI-II scores of the groups was not statistically significant (the paper does not provide further details of the analysis).

2.4.10.3 Effects of interventions on antenatal depression symptoms (active versus control)

Comparison 1: CBT versus control

One trial (Lund et al., 2020) (n= 420) examined the effectiveness of CBT delivered by community health workers to women experiencing antenatal depression. This study

did not find a difference between the groups in the early short term (eight months gestation) (RR=1.10; 95% CI 0.72 to 1.68), late short term (three months postpartum) (RR=1.16; 95% CI 0.94 to 1.43), and long term (12 months postpartum) (RR=1.26; 95% CI 0.99 to 1.60). Although this study attempted to deliver the intervention during pregnancy, 27.7% of women received some or all sessions in the postnatal period. Of the women in the intervention group, 80% received at least one session and 53% completed all six intervention sessions. The outcomes, therefore, need to be interpreted cautiously, as this study demonstrated the effectiveness of CBT delivered in the perinatal period and only half the women completed all the intervention sessions.

2.4.10.4 Effects of interventions on perinatal depression symptoms (active versus control)

Comparison 1: CBT versus control

In one cluster trial (Rahman et al., 2008) (n= 903), CBT was delivered by community health workers to women during pregnancy and in the postpartum period. There was an improvement in depression symptoms (Hamilton Depression Rating Scale) in the medium term (six months) (n=818) (adjusted MD=-5.86; 95% CI -7.92 to -3.80) and long term (12 months) (n=798) (adjusted MD=-6.65; 95% CI -8.56 to -4.74) (Rahman et al., 2008).

2.4.10.5 Subgroup analyses

A number of *a priori* subgroup analyses were specified in the protocol (healthcare professional, antenatal versus postpartum depression, intervention mode (e.g. individual or group based)); however, there were sufficient data only for the comparison of individual versus group interventions. Six trials included relevant data: three trials delivered individual CBT by nurses and health visitors (Milgrom et al., 2011; Morrell et al., 2009; Prendergast and Austin, 2001) and three trials delivered group CBT interventions by health visitors, NMHSs, midwives and nurses (Leung et al., 2016; Rojas et al., 2007; Honey, Bennett and Morgan, 2002) in the postpartum period. Short term (up to six months) and medium term (6 to 12 months) outcomes were available and calculated. The overall short-term CBT treatment effect was close to conventional

levels of significance in group delivery format (MD= -2.36; 95% CI -4.83 to 0.12; P=0.06; I²=80%); however, it was not significant in individual delivery format (SMD= -0.18; 95% CI -1.13 to 0.77; P=0.71; I²=78%). There was substantial heterogeneity in both groups. Caution, therefore, is needed in interpreting the outcomes. Individual CBT intervention had a higher pooled effect size (MD= -1.97; 95% CI -3.18 to -0.77; P=0.001; I²=0%) than group intervention (MD= -1.03; 95% CI -2.03 to -0.03; P=0.04; I²=16%) in the medium term.

2.4.10.6 Sensitivity analysis

There was no pre-specified sensitivity analysis; however, a post hoc sensitivity analysis was undertaken to understand whether including the cluster randomised trial overestimated the effect size, despite calculating its effective sample size. It was assessed by removing the cluster-randomised trial from the meta-analysis which was conducted to examine the effectiveness of CBT delivered by NMHSs for the treatment of postpartum depression. After the sensitivity analysis, the heterogeneity was zero and the effect size was smaller; nevertheless, the overall effect favoured the CBT group (MD= -0.96; 95% CI -1.73 to -0.18; P=0.02; I²=0%), as illustrated in Figure 5.

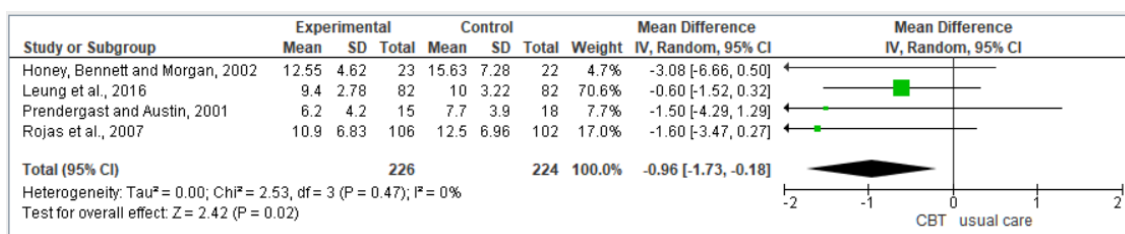


Figure 5: Sensitivity analysis: CBT versus usual care medium term (6 to 12 months) outcomes in postpartum depression

Overall, CBT, counselling and IPT delivered by NMHSs for postnatal and perinatal depression symptoms was superior to control conditions in the short and medium term. There were no statistically significant differences between the following groups: CBT versus counselling and CBT from a nurse versus CBT from a psychologist on postpartum depression symptoms. The subgroup analyses in group versus individual interventions showed inconsistent treatment effect sizes in the short and medium

term because of low number of trials included in the meta-analyses and substantial heterogeneity.

2.4.11 Effects of interventions on anxiety symptoms

Four studies reported anxiety outcomes, all of which examined anxiety in the postpartum period.

2.4.11.1 Effects of interventions on postpartum anxiety symptoms (active versus control)

Comparison 1: CBT versus control

Leung et al. (2016) (n=164) used the Hospital Anxiety and Depression Scale for the measurement of anxiety and reported non-significant group differences in the short term (three-month) (MD= 1.94; ANCOVA p=0.21) and medium term (six-month) (MD= 0.23; ANCOVA p=0.72).

Comparison 2: IPT versus control

Dennis et al. (2020) (n=241) used the State Anxiety Inventory (STAI) for the measurement of anxiety and reported that at the short-term (12 weeks) assessment, 40.4% (42/104) of women who received IPT by nurses, had an anxiety score >44 on the STAI, in contrast to 65% (65/100) in the control group, which was favourable to the IPT group (OR=0.36; 95% CI 0.21 to 0.65). Significant group differences were also maintained in the early medium term (24 weeks) (OR=0.20; 95% CI 0.11 to 0.37) and late medium term (36 weeks) (OR=0.47; 95% CI 0.26 to 0.85), favouring telephone IPT.

Comparison 3: CBT and counselling versus control

Morrell et al. (2009) used STAI to measure the effectiveness of both CBT and counselling delivered by health visitors. There was an improvement in the symptoms at six months (n=390) (MD=-3.8; 95% CI -6.6 to -1.0); and at 12 months (n=255) (MD=-4.3; 95% CI -8.1 to -0.7); but not at 18 months (n=131) (MD=-1.9; 95% CI -6.9 to 3.5).

2.4.11.2 Effects of interventions on postpartum anxiety symptoms (active versus active)

Comparison 1: CBT from a nurse versus CBT from a psychologist

Milgrom et al. (2011) (n=36) used the DASS 21 SF anxiety sub-scale for the measurement of changes in the symptoms of anxiety. There was no between group differences ($p>0.05$) in the early short term (three-week) and late short term (post-treatment eight-week) outcomes (no further information than this was reported in the paper).

2.4.11.3 Effects of interventions on antenatal anxiety symptoms

None of the trials fell into this category.

2.4.11.4 Effects of interventions on perinatal anxiety symptoms

None of the trials fell into this category.

2.4.12 Effects of interventions on mother-infant relationship

2.4.12.1 Effects of interventions on the postpartum mother-infant relationship (active versus control)

Comparison 1: CBT versus control

Ngai et al. (2015) published a separate paper (Ngai et al., 2016) for the outcomes of the Parenting Stress Index Short Form (PSI-SF). The PSI-SF consists of three subscales, one of which is the Parent-Child Dysfunctional Interaction (PCDI), which is related to parents' dissatisfaction with interactions with their children and the degree to which parents find their children unacceptable. There was a beneficial effect of CBT delivered by midwives on PCDI outcomes in the short term (six weeks) (MD=3.92; 95% CI 2.59 to 5.25) and medium term (six months) (MD=1.14; 95% CI 0.23 to 2.50) (n=397) (Ngai et al., 2016).

2.4.12.2 Effects of interventions on the antenatal mother-infant relationship

None of the trials fell into this category.

2.4.12.3 Effects of interventions on perinatal mother-infant relationship

None of the trials fell into this category.

2.4.13 Effects of interventions on the cognitive and emotional development of the infant

2.4.13.1 Effects of interventions on postpartum cognitive and emotional development of the infant (active versus control)

Comparison 1: CBT versus control

Two trials (Ngai et al., 2016; Rahman et al., 2008) reported outcomes for the effectiveness of CBT delivered by midwives and community health workers on the cognitive and emotional development of the baby. Ngai et al. (2016) (n=397) used PSI-SF, which uses a subscale of Difficult Child. It measures parents' perceptions of their children's self-regulatory abilities. There was a beneficial effect of CBT delivered by a midwife on Difficult Child outcomes in the short term (six weeks) (MD=2.78; 95% CI 1.28 to 4.27) and medium term (six months) (MD=0.95; 95% CI 0.45 to 2.36) (Ngai et al., 2016).

Rahman et al. (2008) reported CBT (delivered by community health workers) outcomes on children in a separate paper (Maselko et al., 2015). Children's cognitive and socioemotional development were assessed when the children were about seven years old. WPPSI-IV was used for cognitive development; SDQ for behavioural and emotional problems; and SCAS for the assessment of anxiety. They compared three groups: prenatally depressed intervention group (n=289); prenatally depressed control group (n=295); and prenatally non-depressed group (n=300). The results showed that the difference between prenatally depressed intervention and control groups was not statistically significant in terms of cognitive (adjusted MD=-0.01; 95% CI -2.09 to 2.07) and socioemotional development outcomes (adjusted MD=0.51; 95% CI -0.45 to 1.47); however, when these groups were compared with a sample of seven years old children whose mothers were not depressed in the antenatal period, those whose mothers had depression in the antenatal period had more socioemotional problems (adjusted MD=0.78; 95% CI 0.09 to 1.47), but there were no difference between the groups in

terms of cognitive outcomes (adjusted MD=0.73; 95% CI -0.80 to 2.27) (Maselko et al., 2015). This finding was not a pre-planned comparison in the registered protocol.

2.4.13.2 Effects of interventions on the antenatal cognitive and emotional development of the infant

None of the trials fell into this category.

2.4.13.3 Effects of interventions on perinatal cognitive and emotional development of the infant

None of the trials fell into this category.

2.4.14 Effects of interventions on relationship with partner

2.4.14.1 Effects of interventions on postpartum relationship with partner (active versus control)

Comparison 1: CBT versus control

One trial (Leung et al., 2016) reported CBT outcomes, delivered by NMHSs, using Family APGAR and Dyadic Adjustment Scale (DAS). The Family APGAR measures satisfaction with family functioning in five dimensions: adaptation, partnership, growth, affection and resolve. The DAS consists of four subscales: affectional expression; dyadic consensus; dyadic cohesion; and dyadic satisfaction. This study showed no significant group differences for family functioning in the short term (3-month) (MD=0.87; ANCOVA $p=0.69$) and medium term (6-month) (MD=1.22; ANCOVA $p=0.25$); and again no significant group differences for the relationship with the partner (DAS) in the short term (3-month) (MD= 0.02; ANCOVA $p=0.80$) and medium term (6-month post-intervention) (MD=0.33; ANCOVA $p=0.55$) (Leung et al., 2016).

Another trial (Honey, Bennett and Morgan, 2002) reported no significant medium term (six months) outcomes of CBT delivered by health visitors for the quality of the marital relationship as measured by DAS (ANOVA $p>0.1$).

Comparison 2: IPT versus control

One trial (Dennis et al., 2020) reported outcomes using the DAS. There was overall improvement on the quality of the partner relationship. Significant differences were found in the mean scores, favouring telephone IPT delivered by nurses in the short term (three months) ($t=2.98$; $p=0.003$) and early medium term (six months) ($t=2.74$; $p=0.007$) but fell short of conventional statistical significance in the late medium term (nine months) ($t=1.74$; $p=0.08$).

2.4.14.2 Effects of interventions on antenatal relationship with partner

None of the trials fell into this category.

2.4.14.3 Effects of interventions on perinatal relationship with partner

None of the trials fell into this category.

2.5 Discussion of review findings

2.5.1 Summary of findings

The systematic review sought to answer the following questions:

- How effective are psychological interventions delivered by NMHSs in the treatment of perinatal depression and on secondary outcomes (maternal anxiety, mother-infant relationship, cognitive and emotional development of the baby, and relationship with partners)?
- Which NMHS groups have delivered these treatments for perinatal depression?
- What are the types of interventions delivered by NMHSs in the treatment of perinatal depression?

This review summarises the outcomes of thirteen trials involving 3040 women, conducted in eight countries. The meta-analyses showed that CBT delivered by NMHSs may be effective for the treatment of postpartum depression, compared to control conditions in the short term (up to six months) with a small to medium effect size, and in the medium term (6 to 12 months) with a large effect size. There was also some evidence on the effectiveness of CBT for perinatal depression symptoms; however, its

effectiveness in the antenatal period was not statistically significant when compared to control conditions. There were fewer studies examining the other type of interventions' effectiveness, for example, counselling and IPT. However, there was some evidence that counselling and IPT for postpartum depression may be effective when delivered by NMHSs.

Although the review examined a whole range of secondary outcomes, there was extremely limited data on most of these. There was some evidence of the efficacy of IPT delivered by NMHSs on decreasing postnatal anxiety symptoms; CBT delivered by NMHSs on improving mother-infant relationship; and CBT delivered by NMHSs on the cognitive and emotional development of the infant in the short- (< 6 months) and medium-term (6 to 12 months).

In this review, the NMHS groups were nurses, health visitors, midwives and community health workers and the type of interventions were CBT, counselling and IPT.

2.5.2 Strengths and limitations

The strengths and limitations of the review and the primary studies within the review need to be considered before making conclusions about the findings. Although the overall methodological quality of studies was moderate, many of the trials had limitations in the reporting of information required to assess risk of bias. There is evidence that inadequate allocation concealment artificially inflates observed effects (Pildal et al., 2007; Wood et al., 2008). Allocation concealment was not reported in almost half of the trials, which might lead to selection bias. The trial registry was not available for half of the trials, which may lead to reporting bias. The participants were not blinded to the interventions, though this is difficult if not impossible to achieve in trials of psychological interventions. The size of the included trials was small in many studies, which might also influence treatment effect estimates (Dechartres et al., 2013). It was not possible to assess publication bias using funnel plots, because of the low number of studies included in the meta-analyses. Taken together, these factors may have led to an overestimate of the actual effect of interventions delivered by NMHSs for the treatment of perinatal depression.

In addition, few studies reported longer-term outcomes, so it is difficult to draw conclusions about the durability of the observed treatment effects. There were a limited number of trials available for many of the comparisons. The majority of the trials were conducted in high-income countries, which limits generalisability of the findings outside of these contexts. Overall, the results, therefore, should be interpreted with some caution.

The review has a number of strengths: (1) the FINER criteria (Cummings, Browner and Hulley, 2007; Thomas et al., 2019) were considered in developing the review questions; (2) the protocol was registered with PROSPERO before starting the review (Pinar 2017: CRD42017066000); (3) only RCTs were included in this review because they are known as the most rigorous methods to draw a conclusion on the effectiveness of treatments (McKenzie et al., 2019); (4) a detailed systematic review of all published, unpublished and ongoing RCTs, without language or date restrictions was conducted; (5) CRD (University of York CRD, 2009) and Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al., 2019) were followed while conducting the review; (6) and the PRISMA statement was followed in reporting the review.

Although all attempts were made to limit the researcher's bias on the systematic review, title and abstract screening and risk of bias assessment of the included studies were made by one reviewer, because of the large number of citations identified for screening. This may potentially affect the assessment of the methodological quality of this systematic review (Shea et al., 2007). There may have been value in conducting a more focused search, so that a second reviewer could feasibly have conducted an independent review of the titles and abstracts.

In summary, the key limitations of the review outcomes are as follows: (1) There was a clear and unavoidable problem with blinding women to assigned groups which might potentially exaggerate intervention effect estimates (Wood et al., 2008); (2) Allocation concealment was not reported almost half the trials which might lead to selective enrolment of women to the appropriate groups. There is evidence that the inadequate allocation concealment artificially inflates the observed effects (Pildal et al., 2007; Wood et al., 2008); (3) The size of the included trials was small, which might influence

treatment effect estimates (Dechartres et al., 2013). These considerations are likely to overestimate the actual effect of interventions delivered by NMHSs for the treatment of perinatal depression. In addition, it is unclear what impact the use of a sole reviewer had on the identified and coding of studies.

2.5.3 Interpretation of findings

The meta-analyses showed some evidence of the effectiveness of CBT delivered by NMHSs relative to control conditions in the treatment of postpartum depression symptoms in the short- (< 6 months) and medium-term (6 to 12 months). The review also found some evidence for other treatment modalities, including counselling and IPT. However, given the limitations discussed above, caution is needed in interpreting these results and further research is warranted. These findings are similar to a previous review that included postpartum women who were recruited in primary care or community settings and treated in community settings (Stephens et al., 2016). Only three trials from this review overlapped with Stephens et al. (2016) and the review described here differs in that it includes only interventions delivered by trained health workers.

There were too few trials to draw firm conclusions about the effectiveness of psychological interventions on the secondary outcomes: postpartum anxiety symptoms, mother-infant relationship, cognitive and emotional development of the baby and relationship with the partner. This may be related to the context of the interventions that focus only on the treatment of depression. There was some, though very limited, evidence of the effectiveness of: IPT delivered by NMHSs on decreasing postnatal anxiety symptoms; CBT delivered by NMHSs on improving mother-infant relationship; and CBT delivered by NMHSs on cognitive and emotional development of the infant in the short- (< 6 months) and medium-term (6 to 12 months).

In this review, the NMHS groups were nurses, health visitors, midwives and community health workers. The review shows the feasibility of training NMHSs for the treatment of perinatal depression, which may be helpful for settings in which there are an insufficient numbers of qualified therapists and high perinatal depression prevalence.

2.5.4 Implications for future research

In this systematic review, the range of psychological interventions delivered by NMHSs was limited to CBT (including psychoeducation), IPT, and counselling. Meta-analyses were possible only for CBT delivered in the postpartum period. There were too few trials of other interventions to draw firm conclusions about the effectiveness of these approaches. There are three ongoing trials, all of which are using CBT interventions, which again shows the need for the evaluation of other types of interventions.

Although some of the included studies briefly mentioned the training process of NMHS, these studies were limited because of the missing information about how interventions were adapted to address women's needs during pregnancy or in the postpartum period and specifically, how the NMHSs were trained and the interventions implemented. The next stages of this thesis provide detail about such an adaptation process.

As discussed in chapter one, BA is a good candidate for an intervention delivered by non-specialists because it is simple relative to other treatments; however, this review did not identify any BA studies delivered by NMHSs to women with ante- or post-natal depression. This finding has informed the scope of the second and third studies in chapters four and five, with the aim of adapting a BA intervention manual intended for delivery by NMHSs, potentially maternity support workers, for the treatment of perinatal depression.

From the included thirteen trials, only two of them delivered the intervention to women in the antenatal period and one further study continued the intervention in the postpartum period as well. Of the three trials that are currently underway, none of them include participants in the antenatal period. As was discussed in chapter one, there may be value in detecting depression as early as possible antenatally and then providing support to women during pregnancy and in the postpartum period. The BA intervention manual and booklet were adapted to respond to these gaps in the evidence and help support women experiencing depression during pregnancy and in the postpartum period.

With appropriate training, NMHSs could implement psychological interventions and the need for a qualified therapist may be compensated for in this way. Cost-effectiveness studies are, therefore, needed to draw conclusions on the benefits of using NMHSs for the treatment of perinatal depression rather than qualified therapists.

2.6 Conclusion

In summary, there is some evidence that psychological interventions delivered by NMHSs may be effective for postpartum depression compared to control conditions; however, there were some concerns about the methodological quality of the studies. More studies are needed to draw conclusions about the types of psychological interventions (i.e., IPT, counselling), time of delivery (i.e., antenatal, postpartum, perinatal); and cost-effectiveness of using NMHSs.

Although BA is a potentially simpler psychological intervention relative to alternative approaches, it has not as yet been delivered by NMHSs for perinatal depression. The aim of this PhD study is, therefore, to inform the adaptation of a BA therapy manual and guided self-help booklet, through listening to women's experiences of perinatal low mood or depression and exploring the practicality of using MSWs by asking women and healthcare professionals and involving them in the design of the manual and booklet. The next chapter describes the methodological considerations for the interrelated second and third studies of this PhD research.

Chapter 3: Theoretical framework, methodology and methods of sampling, data collection and analysis for the second and third study elements of the thesis

3.1 Introduction

This chapter outlines the theoretical framework, methodological considerations and sampling, data collection and analysis methods related to the research aims for the second and third study elements of the thesis. The main reason for combining these two study elements in one chapter is that they both fall within the qualitative tradition and the phases are sequential and interlinked, with one building on the other. The second study element of the thesis included individual interviews with women who have experienced perinatal low mood or depression and individual and focus group interviews with healthcare professionals (HCPs) who have experience of providing support or care for those women. The findings were used in the adaption of the behavioural activation (BA) intervention manual and booklet, intended for delivery by NMHSs, such as maternity support workers (MSWs) for the treatment of perinatal depression. The third study element of the thesis consisted of co-designed workshops in which the BA manual and booklet were improved with the involvement of women and HCPs.

A theoretical perspective of symbolic interactionism (SI) and the experience-based co-design (EBCD) approach were used within the second and third study elements and the methodological design of ethnography was deployed within the second study element of the thesis. This chapter discusses the planning stage and structure of the research design in detail, engaging with research sites, the challenges with recruitment and inclusion and exclusion criteria, the data collection period and reflexive notes, the analytic processes, and a detailed discussion of the methodological challenges and how they were addressed.

3.2 Developing the second and third study designs

Designing a research study requires outlining which research questions the study aims to answer, determining which research paradigm will be employed, organising where and from whom the evidence or data will be gathered, deciding how the evidence or

data will be processed and displayed, and planning how the report will be written (Creswell and Plano Clark, 2018; Kumar, 2019).

The starting point for designing the second and third studies was the literature review detailed in chapter one and the systematic review presented in chapter two. The literature review identified gaps in the evidence regarding women's experiences of perinatal depression, challenges in disclosing their feelings, the treatment options offered by HCPs and the received psychological interventions, if any. It also revealed gaps related to the HCPs' experiences of providing support and care for women who have perinatal low mood or depression, the screening process for perinatal depression, available treatment options, and the acceptance of them by women. The findings of the systematic review found gaps in the evidence about the effectiveness of BA as delivered by non-mental-health specialists for the treatment of perinatal depression. Thus, the second study was designed to explore women's experiences of perinatal low mood or depression and HCPs' experiences with those women and to inform the next stage of the PhD study around what might be the opportunities, challenges and barriers to introducing BA therapy. The 'low mood or depression' term is used throughout the thesis because women may not choose to seek help from HCPs and perinatal depression might not be diagnosed. The second study also explored the reasons behind this phenomenon. The third study element was designed to adapt the BA intervention manual intended for delivery by NMHSs, such as MSWs for the treatment of perinatal depression. Aims and objectives for the second and third study elements are detailed in section 3.3.1 'aim and objectives (second and third studies)' and also summarised in Table 6.

To address the research aims for the second and third study elements, a qualitative paradigm was chosen and a theoretical-methodological perspective of SI by Blumer (1998) was adopted within an EBCD approach as advocated by Bate and Robert (2007), which derives from an action research tradition. The theoretical perspective of SI is congruent with, and often employed within, the methodological design of ethnography; therefore, ethnography was used in the second study element in order to better understand women's lives, behaviours and interactions while experiencing low mood or depression and HCPs' caring practices for those women. These approaches were helpful to better understand the meaning of perinatal depression

and its influence on individuals' social actions and how these meanings and understandings are shared amongst the women and HCPs.

In the second study, face-to-face, semi-structured individual interviews with women and face-to-face semi-structured individual and focus group interviews with HCPs were planned to gather data from participants who were chosen with purposive and theoretical sampling methods, as detailed in section 3.3.3 'sampling technique (second and third studies)' in this chapter.

Table 6: A summary of aim and objectives and methodological design for the second and third study elements

Research Aim and Objectives	Methodological Design
<p>Second study (interviews with women and HCPs):</p> <p>a) To explore women's past experiences of perinatal low mood or depression in terms of; their management skills, perceived barriers and facilitating aspects of seeking help from HCPs, treatment preferences and expectations of HCPs and provision of perinatal depression care</p> <p>b) To explore HCPs' experiences of supporting women with perinatal low mood or depression in terms of; identifying, supporting, and caring for women with perinatal depression, available services and treatment options, and any suggestions to improve perinatal depression treatments and provision of care and services</p> <p>c) To inform the third stage of the PhD research around what might be the opportunities, challenges and barriers to introducing the BA therapy, BA manual and BA booklet</p>	<p>Ethnography (EBCD discovery phase)</p>
<p>Third study (co-design workshops):</p> <p>To inform the adaptation of a BA Therapist Manual intended for delivery by MSWs for the treatment of perinatal depression and a BA guided self-help booklet intended for the use of women with perinatal depression</p>	<p>EBCD co-design phase</p>

In the third study, co-design workshops were planned in the adaptation of the BA booklet and manual, with the involvement of women and HCPs who were selected with the same sampling strategy as adopted in the second study element of the thesis. Thematic analysis by Braun and Clarke (2006) was chosen for the analysis of data collected from the second and third study elements. Figure 6 illustrates the summary of the methodological considerations and sampling, data collection and analysis methods for each study element, which was adapted from Creswell and Plano Clark's (2018) framework.

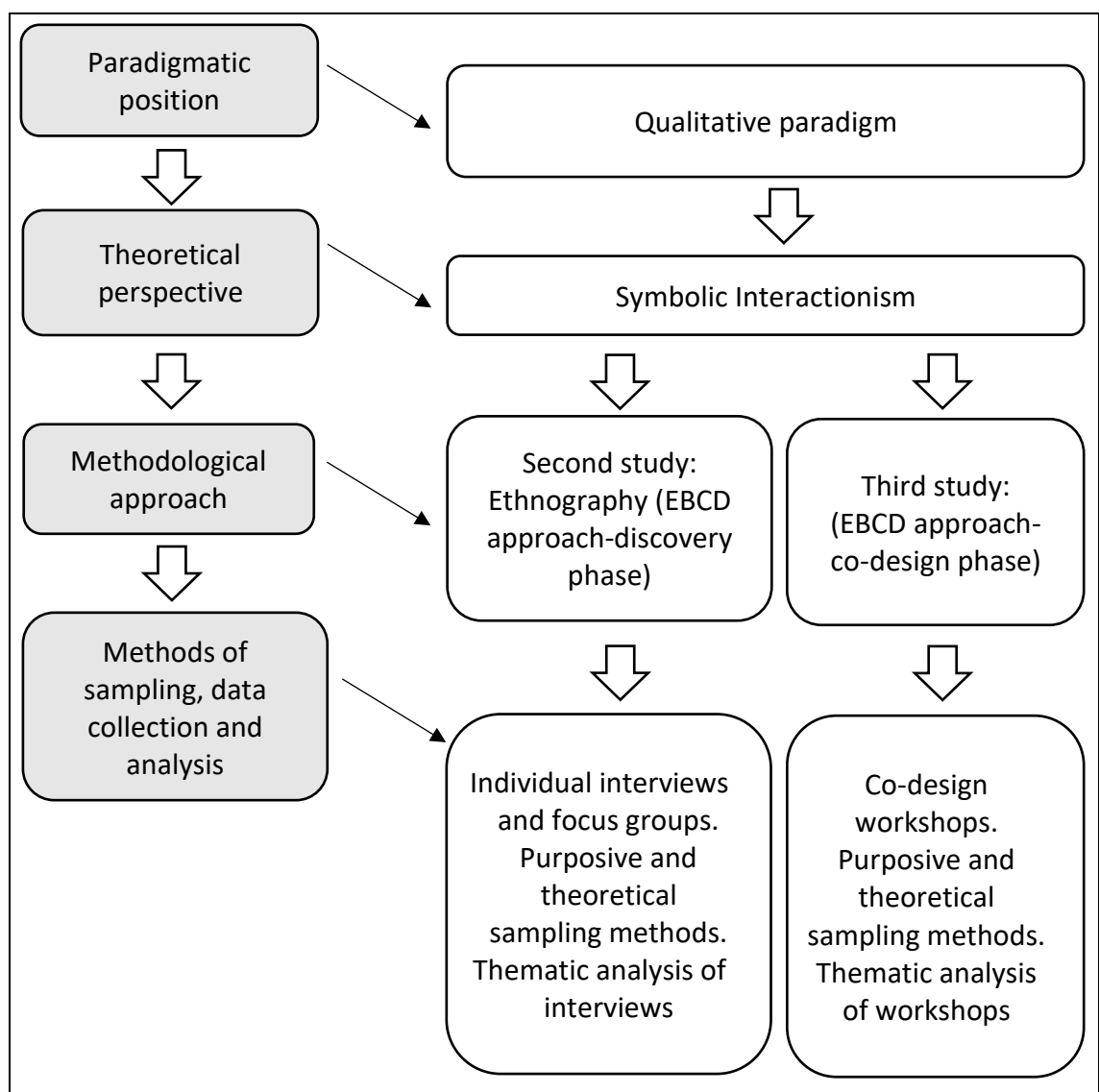


Figure 6: Application of Creswell and Plano Clark's (2018) framework for developing my research study

In the rest of this section, theoretical-methodological considerations and their rationales are discussed in detail. Specifically, the next section addresses how decisions were made about the research study design and discusses the strengths and weaknesses of each element.

3.2.1 Choosing a research paradigm for the second and third studies

A paradigm is defined as an approach to research, which consists of epistemological and ontological views, theoretical perspectives and methodological considerations, as illustrated above in Figure 6 (Creswell and Plano Clark, 2018; Barbour, 2014; Giacomini, 2010; Bowling, 2009). Different research paradigms can be used in varying forms of research enquiries to achieve different research goals (McNiff and Whitehead, 2011).

In answering a research question, there are two main paradigms 'qualitative and quantitative' and there is also a growing trend of combining both paradigms, referred to as 'mixed-methods' (Kumar, 2019; Creswell and Plano Clark, 2018; Flick, 2015; Patton, 2015). These paradigms are influenced by a variety of epistemological and ontological perspectives (Kumar, 2019; Creswell and Plano Clark, 2018; Patton, 2015) and these are discussed below, before discussing the paradigm chosen for this research study.

3.2.2 Ontological and epistemological assumptions

Ontology is related to ideas about the nature of reality and tries to understand if a social reality exists independent of human conceptions and interpretations and if common or multiple social realities exist (Ritchie et al., 2014). There are two major philosophical positions in this regard: realism and idealism. Realism asserts that reality exists independent of people's interpretations, so there is a division between reality and its interpretation by people. Idealism argues that reality is dependent on people's interpretations, so there is a relationship between reality and the human mind and socially constructed (shared) meanings (Barbour, 2014). Many qualitative researchers choose idealism while exploring the social world from the interior (the insider's view). Action researchers see people as part of their world where they are co-creating reality. Our social world consists of ourselves and our relationships with others in which we participate and co-create it (McNiff and Whitehead, 2011; Reason and Bradbury,

2001). We co-create the 'reality' with our feelings, perceptions and relationships with others (Reason and Bradbury, 2001).

Epistemology is concerned with the nature of knowledge and the ways of learning about reality (Patton, 2015). There are two fundamental ways of acquiring knowledge, inductive and deductive logic, which are crucial in a scientific enquiry (Barbour, 2014; Flick, 2015). Inductive reasoning involves building up ideas emerging from the data generated, while deductive reasoning is being done to collect data in order to test the ideas (Creswell and Plano Clark, 2018; Barbour, 2014; Ritchie et al., 2014; Bowling, 2009). Individuals' perspectives and the context of data generated play a key role in this study for the creation of ideas and statements, therefore an inductive approach was preferred for the research study.

There are different epistemological positions, for example, positivism, interpretivist/constructivist approaches, critical theory and action research. Positivism is often applied to quantitative paradigms and within this paradigm, reality is seen as objective and knowable via scientific methods without people's interpretation of it. In contrast, interpretivist/constructivist approaches are applied within qualitative paradigms and assume that there is no ultimate objective reality and knowledge, and that reality depends on subjectivity, people's interpretation of it and so how their constructed meaning arises from their experience (Barbour, 2014). Critical theory is based on divulging and challenging power relations to change the social circumstances that are seen as unacceptable (Ritchie et al., 2014). It includes different terms, for instance, social models of disability, critical race theory, queer theory and feminism, all of which claim that a variety of social and cultural factors affect people's lives (Ritchie et al., 2014). Of the critical theories, feminism has an important place in guiding the action research tradition. Feminist researchers opine that there is a strong difference in the roles and power of researchers and participants during the research process (Flick, 2014). This view helped to clarify the roles of the people involved in the research and the importance of the collaborative process (Ritchie, et al., 2014). Action research relates to critical theory, appeared after this stage and aimed to fill the gap between the researcher and the participant and encourage the active involvement of users (Ritchie, et al., 2014). While critical theory tries to understand the situation in order to

change it, action research goes beyond that and asks how it can be changed (McNiff and Whitehead, 2011).

In 1946, Kurt Lewin, a social psychologist, first introduced the concept of 'action research' as "comparative research on the conditions and effects of various forms of social action and research leading to social action" (Lewin, 1946, p. 35). Action research combines knowledge and experience and production for the aim of supporting learning with and among individuals and systems, in order to improve the situation of individuals involved (Bowling, 2009; Potvin, Bisset and Walz, 2010). It provides a bridge between the researcher, who has status and power, and the participant, who has knowledge and experience, creating a space to collaborate and coproduce meaningfully, values all perspectives and skills and builds and maintains a partnership between the researcher and the participant (Barbour, 2014; McNiff and Whitehead, 2011; Friedman, 2001). Participants are seen as co-researchers in action research, rather than subjects who share common goals with researchers, in order to achieve change through the co-creation of new knowledge or mutual learning, in a positive and respectful environment and democratic way for the benefit of the general public (Friedman, 2001). As a summary, the basic principle of action research is to reduce the gap between the researcher and participants and increase the involvement of service users, carers, patients and community members, for the purpose of understanding their needs and making the study findings more relevant to their needs (Kumar, 2019).

Although action research is a kind of knowledge-generating endeavour, this is a very limited explanation of what is actually being done in action research to create knowledge. It is important to understand the nature and forms of knowledge in action research, for instance, representational knowledge, relational knowledge and reflective knowledge, in order to understand the epistemological underpinnings that form action research (Park, 2001).

Representational knowledge consists of two subtypes: functional and interpretive forms (Park, 2001). The functional form lies in the description of an individual, an event or an experience and making predictions between the two events or experiences by demonstrating previous events and their probable consequences. This knowledge is

important in order to control events, by knowing their predictors; however, methodological frameworks for producing this type of knowledge in pure science requires the separation of researcher from the object of inquiry to minimize the effect of the researcher. In applied sciences and action research, this type of knowledge is also crucial to understand individuals and their behaviours because they use this form of knowledge in their daily routines, for instance, in trying to figuring out what causes sleeping problems, and this is only possible with trust and close relationship with participants, not separation. Interpretive forms of knowledge are about understanding meaning through understanding the participant as a whole, with their beliefs, thoughts, perceptions, past life, personal likes and dislikes, and re-presenting knowledge for interpretation. In action research, the researcher should be willing to listen to the participant and be open to the new information emerging from the discussion. Interpretation of knowledge enables the integration of information and builds a meaningful pattern, rather than breaking them down into two events, two variables (Park, 2001).

Relational knowledge facilitates people's connection with each other and makes them feel like they are part of a community, through understanding and sharing the feelings (empathy) and experiences of each other and 'knowing' one another (Park, 2001). Knowing one another does not mean knowing an objective thing, such as a fact or a theory. It is a subjective knowledge, which has relational meaning. Knowing each other as human beings who have fears, tears, experiences, moral values, unique features and stories and treating everyone equally, is an important part of action research (Park, 2001).

However, realising, understanding and knowing others or the world cannot be the only solution for the challenges people face in everyday life. Reflective knowledge is the other crucial feature of action research in both theory and practice that gives people the power of self-confidence to consider engaging in activities in order to change or improve the situation for the benefit of people (Park, 2001).

Action research is often small-scale and uses qualitative methods to produce data and knowledge and to set up and implement change (Barbour, 2014). Although action researchers heavily use qualitative methodologies to address research inquires, they

can also choose a quantitative methodology if the decision is made by the people involved (Lincoln, 2001; McNiff and Whitehead, 2011). In principle, researchers can adapt the methodological framework for their design which is appropriate for their research question, aims and objectives (Bourgeault, Dingwall and de Vries, 2010).

To address the overall research aims outlined at the start of the chapter, a qualitative approach was adopted since it enables researchers to explore the phenomenon from the subjective stance by asking 'why', and 'how' questions, and interpreting the answers in a naturalistic way, to gain a deeper understanding of people's own experiences and meanings (Pope and Mays, 2006; Ritchie et al., 2014). Qualitative methods are powerful in terms of exploring feelings and perceptions, how and why a situation occurs and producing detailed analysis of the target group; however, they often seem limited because of small number of participants included in the study. Therefore, generalizing findings to a large group is not possible. Furthermore, analysis of data requires a lot of time, and interpretation of the data is made by the researcher rather than a statistical analysis software, therefore relying on a rigorous research process and trustworthiness (Kumar 2019; Flick, 2015; Barbour, 2014; Flick 2014). On the other hand, while a quantitative approach has the strengths of demonstrating generalizable relations between variables and outcomes, it has pre-determined options or categories and it is limited in understanding the context or setting in which people talk (Braun and Clarke, 2013; Flick, 2015). A qualitative approach, by contrast, is not restricted to researchers' pre-existing knowledge of the field, so it can supply richer data (Braun and Clarke, 2013). Also, the voices of participants are not directly heard in quantitative research (Ritchie et al., 2014). Thus, qualitative approach was used in the second and third study elements of the thesis.

3.2.3 Theoretical perspective for the second and third studies

Theoretical perspectives are interpreted as a lens through which the researcher sees the world and interprets their observations (Bowling, 2009; Ritchie et al., 2014). It is important for the researcher to be aware of their theoretical perspectives because researchers from a different background may observe the same reality but their interpretation may be varied (Barbour, 2014). There are a couple of theoretical perspectives widely used in qualitative research approach. Symbolic interactionism (SI)

is one of the major movements in qualitative research (Ritchie et al., 2014). Within EBCD, I adopt the theoretical perspective of SI by Blumer (1998). Blumer is essentially a sociologist and one of the students of Mead who is seen as the founder of SI (Patton, 2015).

SI comes from the work of George Herbert Mead (1863-1931), who was a sociologist and professor of philosophy in the School of Philosophy at the University of Chicago (Flick, 2014). This school mainly taught pragmatism, which influenced Mead's ideas about the nature of truth and development of the SI perspective (Charon, 1998). The students of Mead collected his class notes after his death and published a book named *Mind, Self and Society* in his name.

Blumer was a student of Mead and was very interested in social interaction, symbols and their meanings, and put forward the term SI and Mead's description of it in a book titled "Symbolic Interactionism perspective and method" in 1969 (Patton, 2015).

'Symbolic' means that people live in a world that consists of objects (e.g. physical and social objects) which do not have natural meanings to people. Instead, the meaning of an object derives from the interaction with others and the interpretation of this action (Blumer, 1998). SI emphasises the importance of symbolism, how symbols, language and non-verbal symbols influence people's interaction. SI focuses on understanding interactions between people and the symbolic meanings that people attach to their social actions, interpretations and reactions to their environment (Patton, 2015; Flick, 2014; Ritchie et al., 2014; Bourgeault, Dingwall and de Vries, 2010; Blumer, 1998). The SI approach is essentially underpinned by the idea that meanings are constructed through the interaction of people and that meanings are shaped with action (Charon, 1998).

SI can be used to illustrate all social situations, as it is helpful in finding solutions for complex social problems (Charon, 1998). For the research study described here, the value of SI to qualitative inquiry is its well-defined emphasis on the power of symbols and the interpretative procedures, looking at people's perspective of the world, looking at the meanings that are constructed and shared amongst people, all of which are central to understanding human behaviour, because meanings and social actions are linked. It is also important to try to understand how the interactions between

people in the group are affected by their meanings. People will operate with different worldviews, perspectives and meanings but they have to come together for a purpose and the interesting thing is how they come together and negotiate the different understanding of meanings, all of which affect their interactions.

Choosing SI as a theoretical perspective for the purposes of this research had a number of advantages. First, it is related to philosophical assumptions that are the most appropriate way to explain a complex social world. Second, it focuses on how people describe their world and how that explanation shapes their action. This is important when exploring women's experiences of perinatal low mood or depression and its influence on their social actions, daily life, behaviour, thoughts, relationship with others and interaction and communication with the social world, all of which have crucial implications. When adapting a guided self-help booklet and therapy manual, it is crucial to understand the situations women act in, so as to better address their needs, change their behaviour for the better, alter their attitudes and make a better world for them. Third, SI emphasises that it is hard to change people in one direction because human beings are complex and they choose their own directions in communicating with others and within themselves. SI is the best choice in understanding these complexities and using knowledge generation, as explained before in this chapter, in order to understand the situation, making predictions between the two events and explaining how changing people may result, all of which informed the next stage of this study which was to adapt a talking therapy for the benefit of women. Fourth, within SI, people are viewed as free with their minds, symbols and perspectives, cooperating, communicating in their world and creators of their world. At the same time, society consists of people who interact with one another and living in a society has generalised rules to live by. Not accepting these rules may result in a society cutting off interaction with those individuals, which can be understood through SI. This may explain why mothers hide their true feelings about depression from their family and friends and HCPs, given the social pressure to 'be a good mum' and what that might mean. Fifth, SI tries to understand individuals' identities, how they define themselves and what they are supposed to do, which helps to understand HCPs in terms of who they are, how they describe their work, what are their roles, all of which provide a context for HCPs' experiences with women who have

experienced perinatal depression. In other words, SI brings in the world as seen from the angle of the HCPs. Sixth, SI highlights that communication, role-taking and realising common identities between people are important for cooperative action, which addresses the aim of co-design workshops in which HCPs and mothers develop common symbols, interact with each other and share equal power in designing the therapy manual and guided self-help booklet. Finally, SI has a logical relationship with the other methodological assumptions outlined in this chapter. For example, there is a tradition of drawing on symbolic interactionism within ethnography, which establishes harmony between data collection methods and interpretation of findings. In the rest of this section, SI is discussed in detail. Ethnography and its influence on the second study are explained in the following section.

“What common set of symbols and understandings have emerged to give meaning to people’s interactions?” (Patton, 2015, p.133). People come to understand the world while understanding the symbols, the words and the meaning. The central idea is that in social interaction, individuals make sense of the world with symbols and often with words. That interpretation of the world forms the basis for actions. In other words, actions are related to interpretation and meanings. Blumer (1998) underlines the importance of meaning and interpretation as necessary human activities. At the same time, people develop common meanings through their interactions with others and those meanings turn into their reality (Patton, 2015). SI is based on three simple premises (Blumer, 1998, p.2). Firstly, “human beings act toward things on the basis of the meanings that the things have for them”. These things could be: physical objects, such as a desk or a book; people, for example, a mother who is trusted or a thief who is not; the activities of others, for instance, their directives or appeals; and some situations that we come across during our daily life. Secondly “the meaning of such things is derived from, or arises out of, the social interaction that one has with one’s fellows”. The origin of meaning comes mainly from two views. One of them is the observation of an objective thing such as a cow is a cow itself, which reflects realism. The other view is the perception of a thing with feelings, sensations, ideas and attitudes, all of which consist of psychological elements that produce the meaning. SI has a different view of these two sources of meanings. SI views meaning as created during interaction between people. People describe a thing for the person and that

description emerges from and is shaped in the interaction. Thirdly, “these meanings are handled in, and modified through, an interpretative process used by the person in dealing with the things he encounters”. There is a common misunderstanding that the use of meaning by a person in an action is the implementation of other people’s perceiving of the meaning. Actually, the use of meaning by a person in an action is a result of a process of interpretation by the person. This interpretation process includes two steps: self-interaction and handling meaning in the direction of his action. These premises are summarised in Figure 7 (Charon, 1998).

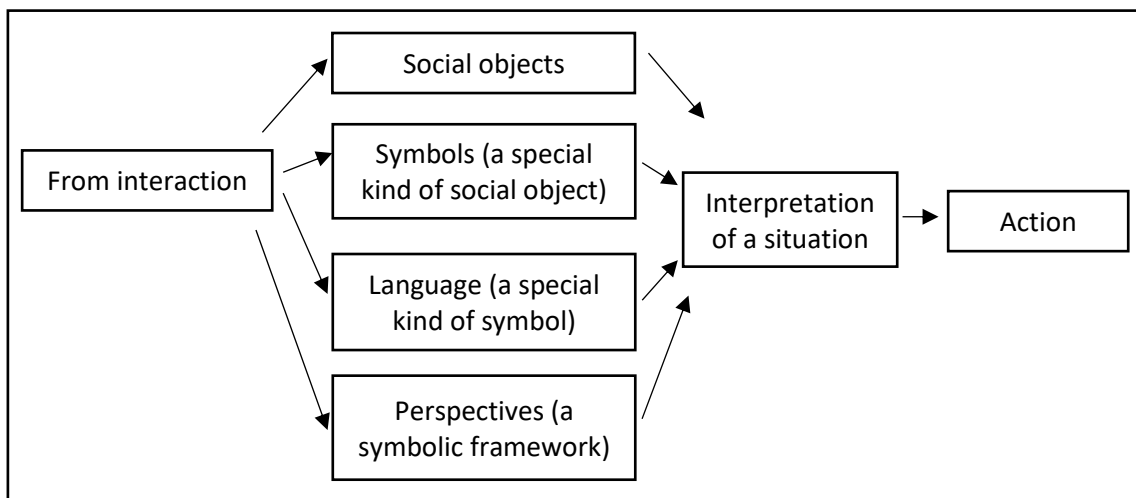


Figure 7: Illustrating human interaction and action points (Charon, 1998)

The perspective of SI is underpinned by four central ideas according to Charon (1998). First, SI concentrates on social interaction rather than on the individual or her/ his personality character. Societies consist of people who are actively interacting, communicating, shaping and sharing a common perspective through interaction with one another. Interaction within a society is therefore affected by each individuals’ actions and each individual takes into account others’ actions so that interaction also develops over time, depending on what others do in the situation. This does not mean that individuals are influenced by others; rather, it means that individuals’ actions influence each other in a dynamic cycle (Charon, 1998). Secondly, individuals’ actions are also influenced by their own interaction with themselves, in other words, through thinking. Individuals’ perspectives are highly affected by how they think and how they describe the situation (Charon, 1998). Thirdly, SI highlights that individuals’ actions are primarily influenced by their social interactions in the present, which means attitudes

that developed in the past do not influence present actions, unless individuals remember, reinterpret and apply it to the situation (Charon, 1998). Finally, SI describes individuals as complex human beings and although individuals are seen as free in their actions, their freedom depends on the choices that they make, upon assessing their and others' actions and redirecting their actions according to them, thereby limiting their freedom (Charon, 1998).

SI provides a useful approach to understanding the social world and it can be easily applied to all social situations, from understanding gender inequality and racism, to understand dating and parenthood. SI can also be helpful to understanding the processes and outcomes that are involved when women have perinatal low mood or depression symptoms, what having perinatal depression may lead to in women's lives, what it means to support a woman with perinatal depression (for HCPs) and what reconstruction of meanings and interpretations would be helpful in decreasing the effects of low mood or depression on women's lives.

3.2.4 Adopting a methodological approach for the second study

Qualitative methodologies refer to the "framework within which our research is conducted" (Braun and Clarke, 2013). Methodologies consist of methods and practices that show us the way of conducting research. Some examples of traditional methodological approaches within the qualitative paradigm are grounded theory, phenomenology and ethnography, which in turn will determine the choice of qualitative research methods (Bourgeault, Dingwall and de Vries, 2010). Grounded theory aims to explain social processes or actions in order to build theories from the experiences of participants (Ritchie et al., 2014). The phenomenological approach focuses on the lived experiences of humans and tries to understand how humans make sense of the world, aiming to see the world through people's perspective (Ritchie et al., 2014). Ethnography tries to understand social worlds or the culture of specific groups (Hammersley, 1998; Ritchie et al., 2014). Although all of them are used by health researchers, each position has its own tradition and has some strengths and limitations when applied to health research (Thorne, 2008).

In the second study, participants were approached from an ethnographic perspective which is a common approach in EBCD (Bate and Robert, 2007), and SI is congruent with

and often employed within, the methodological design of ethnography (Carter and Alvarado, 2019; Tan, Zhu and Wang, 2003; Rock, 2001). Ethnography involves understanding the social world of a particular group in which meanings, beliefs, behaviours, values and actions are shared (Hammersley, 1998; Ritchie et al., 2014). Ethnographic interviews are essential for learning about a particular group of people's needs, perspectives, work processes, preferences and activities, alongside the generation of descriptive data through prolonged fieldwork, acknowledging the researcher as the principal research instrument (Bate and Robert, 2007; Hammersley and Atkinson, 2007; Whitehead, 2004; Hammersley, 1998).

This perspective was helpful to better understand the meaning of perinatal depression and its influence on individuals' social actions and how these meanings and understandings are shared amongst the women and HCPs. Through interviews with participants, access to the participants' 'symbolic lifeworld' was gained in which their experiences were felt, heard, seen and reflected on from an outside-inside position (Bate and Robert, 2007).

Although ethnography involves fairly unstructured data gathering methods from diverse sources, with the stress on a small number of cases or a group of people, it is vital for researchers to pursue a systematic, structured research protocol and objectives (Hammersley, 1998; Hammersley and Atkinson, 2007). Additionally, the data needs to be analysed systematically and their connection and value explicitly interpret and presented. Prior to explaining the methods of data collection and analysis, participants, and recruitment processes, the next section focuses on the importance of Patient and Public involvement and the EBCD approach.

3.2.5 Importance of Patient and Public Involvement for the third study

Patient and Public Involvement (PPI) is another key aspect of the study approach that informed the decision making regarding methodology and design. The involvement and collaboration of the mothers who would receive the treatment, and the HCPs, who would deliver it, is a key element of this PhD research. In other words, it adopts a user-centred approach, which is broadly defined as research 'with' rather than 'on' people (Heron and Reason, 2001; Ritchie et al., 2014). The importance of PPI for the proposed

study, the impact of PPI on people and services and methodological considerations within PPI studies are discussed in detail below.

The importance of PPI in healthcare was emphasised in the UK government agenda: 'Equity and Excellence: Liberating the NHS' (Department of Health, 2010). Putting patients and public in the centre of care, personalising care according to their needs and involving them in decision making for their care, were some of the crucial targets of the UK government (Department of Health, 2010).

A comprehensive systematic review has explored the impact of PPI on the people involved in the process (Brett et al., 2014). In total, 65, 35 and 23 studies, written in the English language, were included in the review, with the outcomes of impact of PPI on service users, researchers and community patient groups respectively. Some negative impacts of PPI were reported by the people involved: for instance, not feeling valued by the researchers; feeling overloaded (from the service users' perspective); lack of funding and time to follow a rigorous process (from the researchers' perspective); creating conflict and power struggles within the community; increasing the time and cost burdens of the community organisations participated (from the community patient groups' perspective). However, the positive impacts of the research on people were dominant in the findings and these included: feeling valued and listened to, and increasing their knowledge of their condition (from the service users' perspective); gaining more knowledge about the area under study and development of more PPI focused research (from the researchers' perspective); greater awareness of the situation and a better understanding of research (from the communities' perspective) (Brett et al., 2014). This review shows that individuals' engagement in PPI research is important and valuable for them, for researchers and for the patient group community in order to better understand the condition. These findings were also important for the aim of the third study which was to understand women's perinatal low mood or depression experiences and HCPs' experiences with those mothers, and help shape the therapy documents for the benefit of women.

The impact of PPI on UK NHS healthcare was considered in another systematic review by Mockford et al. (2012). A total number of 28 studies were included in the review. Although the majority of included studies used qualitative methods to collect data,

questionnaires were also popular in examining the service users' feedback on the provided services. The following PPI activity areas were addressed in the included studies: 'Service planning and development, information development and dissemination, and changing attitudes of service users and providers' (p.30). Of these studies, five were related to the development of mental health services through patient experiences (Murie and Douglas-Scott, 2004; Perkins and Goddard, 2004; Crawford et al., 2003; Robert et al., 2003; Peck, Gulliver and Towel, 2002). Although there is insufficient evidence to draw conclusions about the impact of PPI on health and social care services, the authors maintained that using service user experiences and knowledge for the advantage of others is still important for policy-makers, service providers and researchers (Mockford et al., 2012). The methodological considerations for the included studies were not well established and often misrepresented with data collection methods, for instance, surveys, interviews and focus groups. Only two studies (Robert et al., 2003; Pickles, Hide and Maher, 2008) explicitly discussed how the methodological choices were suitable to address the research aims. These were 'action research' and 'experience-based design' respectively.

In terms of research leading to action, a recent scoping review grouped the types of patient experience feedback received in hospitals in the UK (Sheard et al., 2019) into four categories: 'Hospital-initiated surveys, patient-initiated qualitative feedback, feedback and improvement frameworks, and others' (Sheard et al., 2019). From the reviewed 39 studies, only five seem to go beyond the data 'collection' and take 'actions' based on the voices of staff and patients/ carers within 'feedback and improvement frameworks' category. Of the studies focused on both 'collection' and 'action', the following methodological approaches were referred to in the papers: action research (Baron, 2009); person-centred quality improvement method (NHS Education for Scotland, 2017); co-production model (NHS England, 2016); and accelerated EBCD (Locock et al., 2014). This review is important in terms of showing that a variety of action research traditions is being used in the field to understand the conditions and also take actions.

The Medical Research Council published a framework for developing and evaluating complex interventions (Craig et al., 2013). According to this framework, it is important for researchers to understand and use appropriate methods in the development of

interventions. There are four key elements in the development and evaluation process: 1- Development; 2- Feasibility/ piloting; 3- Evaluation; 4- Implementation (Craig et al., 2013). Although all the elements were outlined in the framework, the development phase, which is related to the aims of this PhD research, was only briefly described. O’Cathain et al. (2019a) published detailed guidance on how to develop interventions to improve health and healthcare, based on their previous study results (O’Cathain et al., 2019b) to fill this gap in the evidence. They categorised nine different approaches to intervention development: 1-Partnership; 2- Target population centred; 3- Theory and evidence based; 4- Implementation based; 5- Efficiency based; 6- Stepped or phased; 7- Intervention specific; 8- Combination; 9- Pragmatic (O’Cathain et al., 2019a). It was reported that “no research has shown that one of these approaches is better than another or that their use always leads to the development successful interventions” (O’Cathain et al., 2019a, p.5). The partnership category emphasises the importance of patient and public involvement throughout the research process and provides examples of approaches, for example, co-production, co-design, experience-based co-design and community-based participatory research (O’Cathain et al., 2019a).

According to Khan (2015), feedback from women was most positive when they received personalised and integrated care, and when they made decisions about their care. A meta-synthesis found that women wish for good communication from caregivers, be given important information, a respectful clinical environment with efficient care, being able to participate in this care and having a sense of control (Renfrew et al., 2014). Integrated responses to perinatal mental health problems are crucial to delivering personalised care built around the needs of women (National Health Service, 2016). The EBCD approach combines these elements and it is a great opportunity for engagement of patients and staff to collaborate in designing better services (Donetto et al., 2015; Donetto, Tsianakas, and Robert, 2014; Bate and Robert, 2007).

Therefore, in the second and third studies, in order to address the research aims indicated earlier in this chapter and detailed in section 3.3.1 ‘aims and objectives (second and third studies)’, an EBCD approach, as advocated by Bate and Robert (2007), was used. EBCD is derived from an action research tradition (Robert, 2013), which is argued to be the only method by which researchers can gain knowledge from

participants' actions and interpret within the social circumstances and contexts, design new actions and interpret their effects (Potvin, Bisset and Walz, 2010). Action research has the advantages of being flexible and creative in exploring patients' views and experiences with the services provided, patients' social circumstances and healthcare services in health service research (Morrison and Lilford, 2001). Co-designed research has the added benefit of improving the creative process for the service design project, better services for service users, and developing project management and longer-term effects for the organisations that are involved (Steen, Manschot and De Koning, 2011). Different approaches are used under the action research umbrella with different aims (e.g. participatory research, experience-based design, EBCD) (McNiff and Whitehead 2011; Schneider, 2013). Of these approaches, EBCD was identified as the most useful in terms of the aims of this PhD research.

3.2.6 The Experience-based co-design approach (EBCD) for the second and third studies

EBCD was originally called an experience-based design and later on, so as to emphasise the role of the partnership with patients and HCPs in the process, 'co' was added as a prefix to design (Bate and Robert, 2007). Bate and Robert (2007) developed the EBCD methodology inspired by participatory action research, user-centred design, learning theories, a narrative-based approach and working with the National Health Services Institute for Innovation and Improvement (Robert, 2013). It was first used in a Head and Neck Service in England (Bate and Robert, 2007) and afterwards, a toolkit was developed (The King's Fund, 2012). The EBCD approach has been applied in 59 projects in six countries, namely UK, Australia, New Zealand, Canada, Sweden and the Netherlands, in a variety of services, for instance, cancer care, mental health, neonatal and paediatric care and diabetes services, between 2005 and 2013 (Donetto, Tsianakas and Robert, 2014). It has also been widely used in robust studies, for example, feasibility trials of co-designed interventions, large-scale cluster randomised controlled trials and PhD projects (Donetto, Tsianakas and Robert, 2014).

EBCD involves two key elements of design thinking: experience design and participatory design; learning (the discovery) and action (the co-design). The EBCD is a process in which patients' experiences and knowledge combine with staff's

experiences and knowledge in order to improve their experiences and service provision (Bate and Robert, 2007). It comprises of a 'discovery' phase in which patient and staff experiences are explored in the first six months, and a subsequent 'co-design' phase, in which patients and staff act as co-designers of a product or service and share equal levels of power during the process in the second six months, as illustrated in Figure 8 (Robert, 2013). The whole project typically lasts 9 to 12 months (Donetto, Tsianakas and Robert, 2014).

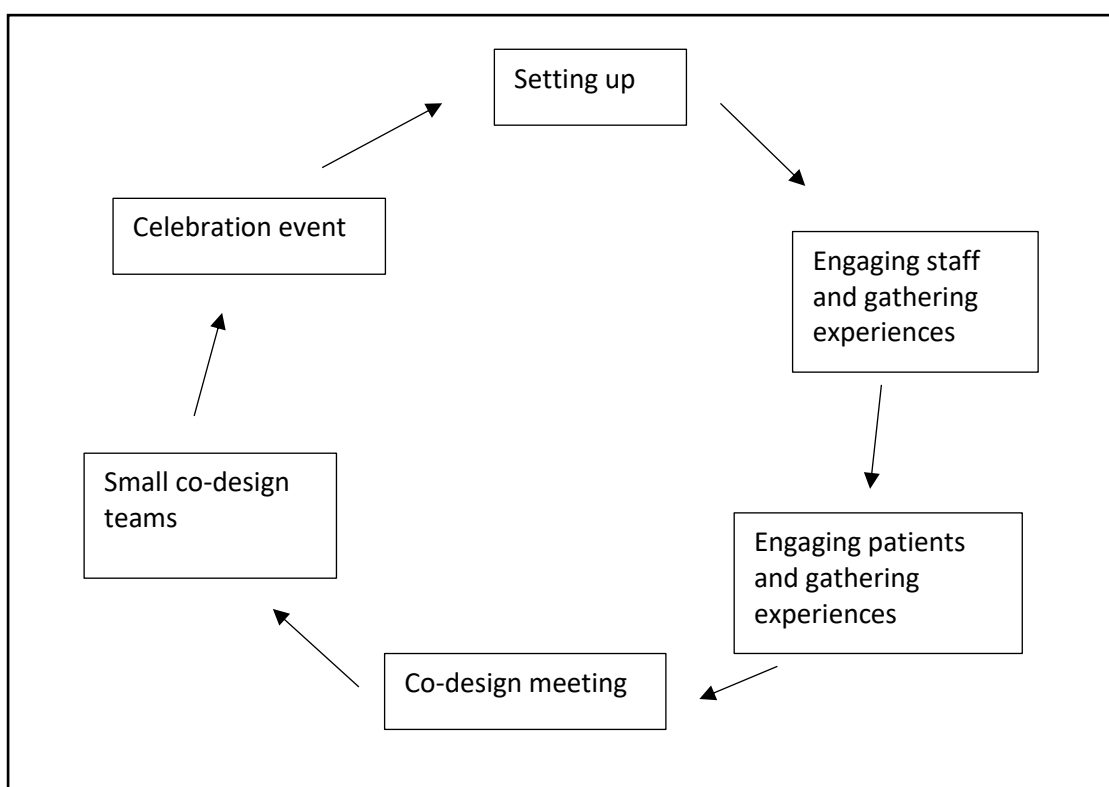


Figure 8: The EBCD cycle (Robert, 2013)

The EBCD adopted for the purposes of this PhD study involved a 'discovery' phase within the second study element when the women's and HCPs' experiences were explored, and the 'co-design' phase within the third study element, when the BA therapy manual and booklet were adapted, as illustrated in detail in Figure 9.

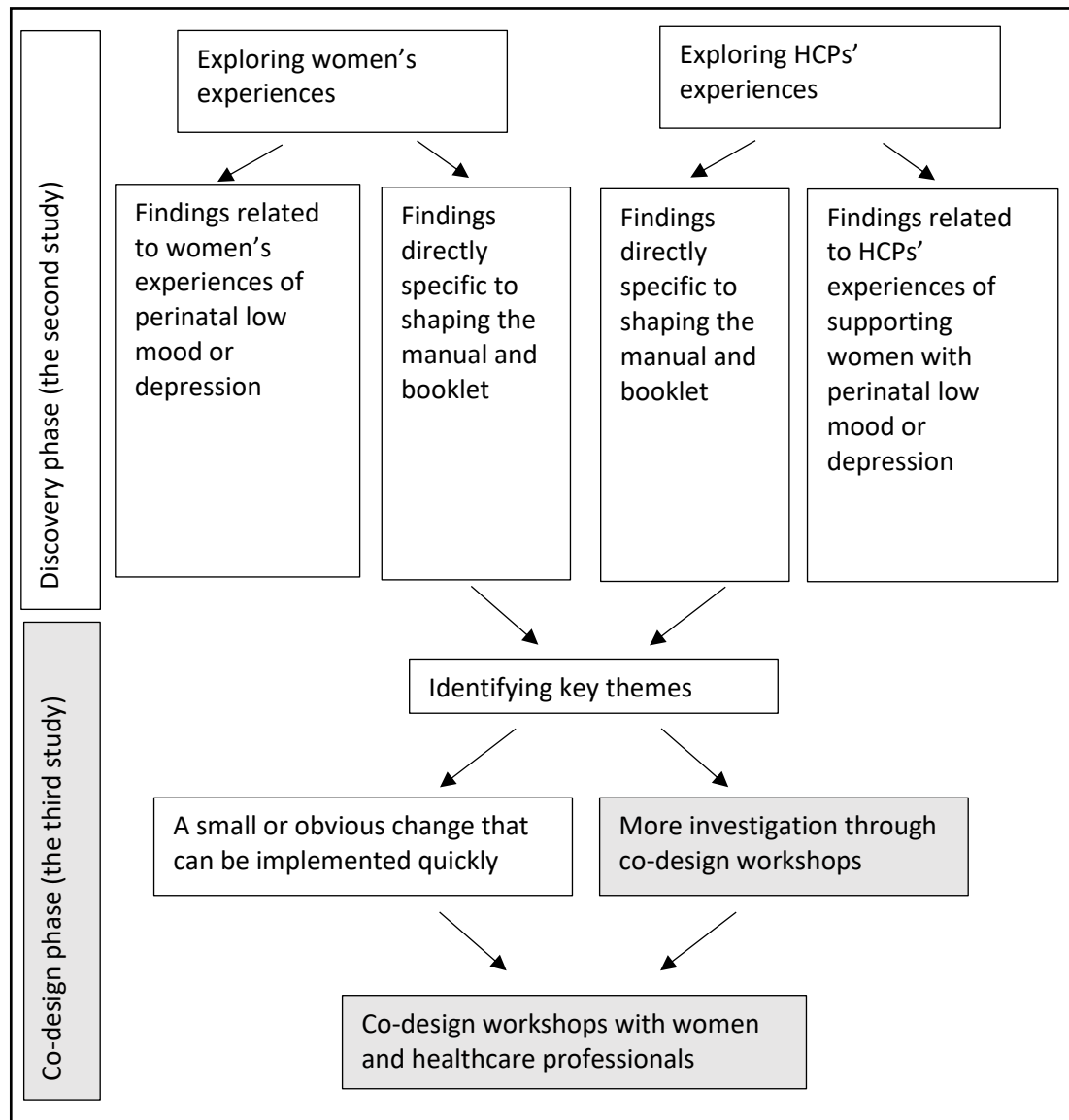


Figure 9: Stages of the EBCD approach in this PhD study (Bate and Robert, 2007)

There is a subsequent celebrating meeting for screening and evaluating the improvements and achievements in a service or product (Bate and Robert, 2007). Sometimes this celebratory meeting is held but it is optional and because of limited time and resources, it was not conducted in this PhD study.

The researchers and participants will also have their own assumptions, values, experiences and prejudices and for this reason, the researcher has to be open to a variety of knowledge and understanding during the process (Bate and Robert, 2007). This topic is discussed in detail in section 3.6 reflexivity, rigour and trustworthiness and in section 6.4.2 strengths and limitations of the EBCD studies.

Inevitably, the EBCD approach has its weaknesses. Although it really engages patients and HCPs and allows discussion in a positive environment, completing the circle is a lengthy process and therefore has time, funding and resource implications (Bowling, 2009; Donetto, Tsianakas and Robert, 2014).

3.3 The design of the second study (discovery phase) and the third study (co-design phase) elements

Sampling, data collection and analysis methods introduced in this chapter occurred both in the 'discovery phase', the second study, and the 'co-design phase', the third study elements. The main reason for combining these studies is that the phases were sequential and interlinked, with one building on the other.

3.3.1 Aim and objectives (second and third studies)

The second study: The main aims of the 'discovery phase' were to explore women's past experiences of perinatal low mood or depression in terms of perceived barriers to seeking help from HCPs and facilitating aspects; expectations of health service provision regarding perinatal depression care; HCPs' roles and experiences in terms of awareness of perinatal mood changes; perceived barriers and facilitating aspects to identification and treatment; and to inform the third stage of the PhD project around what might be the opportunities, challenges and barriers to introducing BA therapy.

Specific objectives:

For women:

- (i) To explore women's experiences of perinatal low mood or depression,
- (ii) To understand women's attitudes towards management of their mood changes,
- (iii) To explore women's psychological needs and concerns in the perinatal period,
- (iv) To understand the challenges that women face while experiencing perinatal low mood or depression,
- (v) To investigate the perceived barriers and facilitating aspects to disclosing their feelings to HCPs and receiving treatment for perinatal depression,

(vi) To investigate women's treatment preferences and the factors that influence their choices,

(vii) To explore women's expectations of HCPs and provision of perinatal depression care,

(viii) To inform the third stage of the PhD project around what might be the opportunities, challenges and barriers to introducing BA therapy, manual and booklet.

For HCPs:

(i) To investigate the process of identifying low mood and depression among perinatal women,

(ii) To explore the HCPs' experiences of identifying, supporting, and caring for women with perinatal low mood or depression,

(iii) To explore any perceived barriers or enablers to talking with perinatal women about their mood and mental wellbeing,

(iv) To investigate the available services and treatments locally for women experiencing perinatal depression,

(v) To understand the HCPs' duty and obligations of caring for women with perinatal low mood or depression,

(vi) To determine what, if necessary, would be helpful to improve perinatal low mood and depression treatments and provision of perinatal mental health care services,

(vii) To inform the third stage of the PhD project around what might be the opportunities, challenges and barriers to introducing BA therapy, manual and booklet.

The third study: The aim of the 'co-design phase' was to inform the adaptation of a BA guided self-help booklet intended for use by women with perinatal depression and the revision of a BA Therapist Manual for the treatment of perinatal women with depression, intended for delivery by MSWs.

Specific objectives:

(i) To facilitate exchanges of experience and knowledge between HCPs and women on the existing BA Therapist Manual and guided BA self-help booklet for application to perinatal women,

(ii) To enable continuity of the development process and a combination of the experiences obtained,

(iii) To find, confirm and describe key points where improvements might be made to the BA Therapist Manual and guided self-help booklet,

(iv) To set priorities for the adaptation of BA Therapist Manual and guided self-help booklet.

3.3.2 Study settings and participants (second and third studies)

Women and HCPs were recruited from three areas within Yorkshire and the Humber to seek representation beyond one geographical area.

Eligibility criteria (second and third studies)

Women participants were sought who had experienced low mood or depression during pregnancy and/or in the first year after childbirth in the last 5 years but who were not clinically depressed at the time of enrolment. In the first submission to the Health Sciences Research Governance Committee (HSRGC) for ethical approval, it was suggested to include mothers who were currently experiencing perinatal low mood or depression; however, this suggestion was considered risky for mothers who were pregnant or in the first year after childbirth as it might trigger difficult feelings during the interview or the interview questions might lead to a deterioration of their ongoing depression. Therefore, inclusion and exclusion criteria were changed according to HSRGC feedback. Mothers, who were pregnant, were in the postnatal period or were experiencing depression, were excluded from the study.

A range of HCPs was recruited from maternity services, primary care and community healthcare settings, with experience of care provision for perinatal low mood or depression and who had worked for at least three years. HCPs were chosen from these

settings because these services provide antenatal and postnatal care to women. They often have scheduled care points which recommend HCPs to see perinatal women regularly and on an individual basis.

Inclusion criteria (second and third studies)

For women:

- Female,
- Age 18> years,
- Who are able to read and speak fluent English,
- Who have the capacity to consent,
- Who either had felt or been diagnosed with low mood or depression during pregnancy or in the first year after childbirth (antenatal period or postnatal period or perinatal period),
- Whose youngest child is between 1 and 5 years old,
- Who had a live birth following their last pregnancy,
- Who had experienced perinatal low mood or depression within the last five years,
- Who scored between 0 and 9 on PHQ-9 (i.e. who did not have clinical depression),
- Who were living/receiving care in Yorkshire and the Humber.

For HCPs:

- Being a registered HCP (for example: midwife, health visitor, maternity service manager, perinatal mental healthcare specialist, or a GP etc.) or a maternity support worker working under the direction of a registered practitioner,
- Working in NHS Trusts, primary care or community healthcare settings in Yorkshire and the Humber geographical area for at least three years,
- Experience of planning or providing care for women who have perinatal low mood or depression.

Exclusion criteria (second and third studies)

For women:

- Under the age of 18,
- Lack capacity to consent,
- Episode of perinatal low mood or depression within the last year or over 5 years ago,
- Whose youngest child is under 1 year old or above 5 years old,
- Who had a stillbirth or late pregnancy loss in their last delivery or pregnancy,
- Who score 10 or above in PHQ-9 (clinical depression),
- Who were experiencing depression, severe mental illness, psychosis, or suicidal thoughts at the time of enrolment,
- Who lived outside of Yorkshire and the Humber,
- Non-English speaker.

For HCPs:

- No previous experience of caring for women who have perinatal low mood or depression,
- Less than 3 years professional experience.

3.3.3 Sampling technique (second and third studies)

Size of sample

The second study:

The sample size for a qualitative study depends on a variety of issues, for instance, the heterogeneity of the group, the inclusion and exclusion criteria, variety of data collection methods, and the funds available (Ritchie et al., 2014). For example, “Ethnography is intense, lengthy and ‘data-rich’, and it cannot and probably should not embrace too many people and too wide a field of activity” (Rock, 2001, p.14).

Ritchie et al. (2014) suggested that the reasons behind the small sample size of qualitative studies are: rise in the sample size does not necessarily contribute new

evidence; qualitative studies do not aim to provide estimates so there is no requirement to ensure a large sample size; and each sample supplies data rich in detail, so it is acceptable to have a small sample. However, it is crucial in a qualitative study to ensure that the sample size is not so small that key points may be missed or that lack of heterogeneity means that varying impacts of less common factors may be missed (Ritchie et al., 2014). It is also essential to know that much larger sample sizes than 50 may be complicated to deal with the quality of data collection and rigour of analysis (Ritchie et al., 2014).

Researchers have considered different sample sizes for individual interviews. Adler and Adler (2012) suggested 12-60 interviews while Ragin (2012) suggested 20-50 interviews. For focus groups, the recommended sample varies between 6 to 12 groups (Ritchie et al., 2014). It is suggested that a “mini-group” (4-6 participants in each group) can give more information than fuller groups (Greenbaum, 1998, p.2). The number of focus groups can also change if some of the invited participants change their minds and no longer wish to attend focus group interviews.

Theoretical saturation is referred to as the point at which no or little new information or themes are emerging from the analysis of data (Patton, 2015). According to Patton (2015, p.300 and 313), “sampling to the point of redundancy is an ideal, one that works best for basic research with unlimited timelines, and unconstrained resources”. Some researchers have proposed that six to 12 interviews (Ando, Cousins and Young, 2014; Guest, Bunce and Johnson et al., 2006) or five focus groups (Namey et al., 2016) would achieve data saturation. In this study, the sample sizes were not predictable, and the researcher’s time and resources were limited due to being a PhD student on a scholarship. Therefore, aiming for complete saturation was an impractical approach for this study; instead, the aim was to continue sampling until code saturation occurred. Therefore, the researcher planned to carry out sampling, transcribing and analysing iteratively until no or few new codes and themes emerged from the data.

Therefore, based on available resources and time frame of the PhD study, the aim was to recruit a maximum number of 30 women and 30 HCPs in the first submission to the Research Ethics Committee (REC) through Integrated Research Application System (IRAS). However, at the REC meeting, it was suggested to recruit a maximum number

of 15 women and 15 HCPs in the first instance and apply for another approval if these numbers did not achieve data saturation.

The third study:

Based on available resources and time frame of the study, it was anticipated that three co-design workshops would take place, with the involvement of both women and HCPs, one in each of the three research sites. Recruitment of participants was planned to continue until data saturation occurred.

Sampling technique (second and third studies)

A purposive sampling method was used to select HCPs and women. Bowling (2009, p.208) describes purposive sampling as “a deliberate non-random method of sampling, which aims to sample a group of people, or setting, with a particular characteristic, usually in qualitative research designs”. The aims of purposive sampling are to identify participants who have better experiences than others to provide more reliable information on the topic (Thorne, 2008) and to recruit a small number of people who represent a wider community in order to understand the main problem being studied (Patton, 2015).

A range of women were included so as to ensure diversity across age, ethnicity, socioeconomic status, experience of low mood (i.e., perinatal women might have experienced low mood for more than two weeks; however, they might not have chosen to seek help from professionals or may not have had a formal diagnosis of depression; the aim was to find out the reasons behind this phenomenon) or perinatal depression (i.e., antenatal depression, postpartum depression and perinatal depression), received psychological and/or pharmacological treatments for perinatal depression or none, duration of depression and depression severity. The representations in these categories were sought from each research sites through the demographics form.

In this study, a variety of HCPs (e.g. community midwives, antenatal midwives, perinatal mental health midwives, health visitors, antenatal clinical support workers, GPs) were sought to provide an overview in each geographical area. Diversity of

participants supplied rich data and different perspectives in terms of the experience of identifying depression, appropriate referral and treatment options, overall service provision, clinical pathways, views on BA booklet and manual etc. The demographics form for the HCPs was prepared for the purpose of the recruitment process.

3.3.4 The procedures for the recruitment of women and HCPs

Recruitment of women (see Appendix 47: study flowchart) (second and third studies):

Study advertisement posters (see Appendices 16 and 30) were displayed in healthcare and public settings (e.g. paediatric outpatients, accidental emergency paediatric waiting area, children's ward, and a university noticeboard) to inform women about the second and third studies. The contact details of the researcher were provided on the posters so that women who wanted to find out more information or participate could contact the researcher by email or telephone.

Online study advertisement posters were also used to invite women to participate in the second or third studies. A variety of charities and community groups were contacted through their websites, Facebook or Twitter accounts. After gaining the administrator or manager's approval or making payment (Mumbler), the study advertisement poster was posted on Mumbler, Mind and a university PhD network Facebook account. A number of people and groups also shared it with their friends on their profile on Facebook. Telephone and email addresses of the researcher were provided on the advertisement posters, so that women could contact the researcher to receive further information or participate in the second or third study.

When a woman called or sent an email, saying that they would like to get further information or take part in the study, the researcher gave them information about the study and explained the ethical considerations detailed in section 3.5. The women were then excluded if they were no longer interested in the study. The phone number and address of those wanting to participate in the study were then recorded on a spreadsheet of contact details and the information pack was sent out by post. Women sent their completed consent (see Appendices 15 and 28), demographics form (see Appendices 10 and 22) and contact detail sheet (see Appendices 11 and 24), to the researcher by mail.

If all the necessary information was provided on the forms (GP contact details for example), the Patient Health Questionnaire-9 (PHQ-9) (Kroenke, Spitzer and Williams, 2001) was then used over the telephone (see Appendix 48: study flowchart). This screening was part of the risk management strategy and used so as to only include women who had non-clinical depression severity scores (see section 3.5.1 assessment and management of risk).

PHQ-9 (see Appendix 32) is a validated instrument which monitors the severity of depression and has 92% sensitivity and 78% specificity when used in UK primary care, with a cut-off ≥ 10 (Gilbody, Richards and Barkham, 2007). It has nine items and each of them can be scored from 0 (not at all) to 3 (nearly every day). The overall score can range from 0 to 27. In this study, if 0 to 9 was scored, women were eligible for an interview or a co-design workshop.

The second study:

For the second study element, in total, 72 women expressed their interest in the study through sending a Facebook message (one woman), a text (two women), an email (66 women) and calling the researcher on the phone (three women). Fifteen women were excluded because of the following reasons: ongoing pregnancy, having a child below one year old and disclosing their ongoing depressive symptoms, all of which were disclosed by women in their first email to the researcher. Women who did not reply to the researcher's emails were also excluded from the study. Women, who wanted to receive further information, were asked for their postal address in order to send an information pack. In total, 30 information packs were sent to women and 19 consent forms were received. A selection process using a purposive sampling method, as detailed above, was applied. Four women were excluded from the study at this point because of the following reasons: only having low mood less than two weeks (2), not completing a demographics form and not answering the researcher's call and email (2).

A date and venue for an interview, with women who scored between 0 and 9, were quickly arranged by the researcher after the administration of PHQ-9. Interviews were completed with 15 women.

The third study:

For the third study element, 35 women sent emails to the researcher to show their interest in the study and two of them sent a text message to the researcher. Four of them were excluded from the study because of the following reasons: being pregnant, having a child under one-year-old and disclosing their ongoing depression in their first email to the researcher. 24 women sent their mail address to receive an information pack. 19 women sent back their completed consent forms, demographic form and contact details sheets to the researcher. They were called and asked the questions that comprise the PHQ-9. Their scores were below 10. Five of them did not show up so the third study was completed with 14 women. Five of them participated in both studies (the second and third studies).

Recruitment of HCPs (please see Appendix 56 study flowchart) (second and third studies):

After securing the required permission from the ethics committee (see section 3.5.2 research ethics committee), the researcher scheduled meetings with supervisors working in NHS Trusts and sent emails to GP Practice managers in order to discuss the recruitment process and expectations of them.

It was planned to visit the hospitals and primary care settings and deliver the research boxes to the gatekeepers (supervisors) at hospitals, (practice managers) in GP surgeries and Children's Services. These boxes contained a study advertisement poster and leaflets and information packs. The information packs consisted of participant information sheets, two consent forms, a demographics form, a contact details sheet and a pre-paid stamped-addressed return envelope. HCPs who wished to participate could take away an information pack, read the information sheets, sign the consent form, fill in the demographics form and contact details sheet and then put these in the envelope provided, to be sent to the researcher by mail.

The second study:

For the second study, two out of three NHS Trusts (research sites A and B) were visited by the researcher. In the first NHS Trust (research site A), the antenatal clinic and

perinatal mental health services were visited by the researcher and the gatekeeper, information about the study was provided and information packs were distributed to the HCPs who were interested to read more about the study. After initial contact with HCPs, four (a consultant obstetrician, an antenatal clinic midwife, a perinatal mental health midwife, a bereavement midwife) were interested in participating in the study and three of them said that they had some time for an individual interview on the same day, while one of them scheduled an interview for the upcoming week. When the researcher approached the NHS Trust the following week, one more HCP (an antenatal midwife) had expressed interest in participating on the same day and another one (antenatal clinical support worker) scheduled an interview for the day after. The day of the last interview, one more HCP (antenatal clinical support worker) expressed an interest. In total, seven HCPs were recruited from this NHS Trust. All the participants had their information packs before the individual interviews, so that they had enough time to read about the research and consider their participation (see section 3.5 ethical considerations).

In the second NHS Trust (research site B), the research boxes were left in the PANNEL ward, delivery suite and antenatal clinic when visiting with the gatekeeper. HCPs working in these services were encouraged to participate in the study. Information about the study was given verbally to staff and information packs were given to those HCPs who were interested to receive more information about the study. About two weeks after the visit to the hospital, an email containing information about the study, a leaflet and a participant information sheet was sent to the gatekeepers, which was then forwarded to the HCPs working in maternity services, community midwifery services and health visiting services. Two focus groups (involving four community midwives, a health visitor, an obstetrician) were completed in this Trust involving six HCPs in total.

In the third NHS Trust (research site C), information about the study was sent by email to the gatekeeper and she/he shared the study information with maternity services, community midwifery services and health visiting services. The researcher also shared the email with gatekeepers working in the community and they were asked to pass on the email to their colleagues working in NHS Services or GP Practices. HCPs working in different roles emailed the researcher requesting an information pack. The

information packs were sent to their postal address. In total, six HCPs (a GP, a lead midwife, a community midwife, a perinatal mental health midwife, two health visitors) were recruited through this approach.

For the recruitment of GPs from GP surgeries, three Clinical Commissioning Group (CCG) approvals were obtained and these letters were shared with 20 GP practices across the three research sites. However, only four of them replied and said that they did not have capacity to conduct the study in their practices and others did not reply to the email at all. The CCGs were contacted again and asked if they knew any GPs interested in perinatal depression studies, but no positive reply was received from the GPs contacted through this method.

The HCPs were asked to bring perinatal mental health guidelines, maternity pathways, or mental health provision guidelines, if possible, that they use in maternity services.

The third study:

For the third study, all the gatekeepers (R&D departments, supervisors, contacts in the community teams), who supported the recruitment of HCPs for the second study, were sent an email consisting of information about the third study and two attachments with a participant information sheet and an advertisement poster. Then, four HCPs who were interested in the co-design of the therapy manual and booklet sent an email to the researcher for more information about the study or to confirm their availability and attendance. HCPs who attended the second study were also sent an email to give information about the day, time and venue of the workshops in the area. One HCP did not show up. In research site C, two HCPs (a community midwife and a health visitor) participated in the workshop and in research site B, one HCP (a midwife) attended the workshop. Two of the HCPs attended both studies (the second and third studies).

3.3.5 Data collection methods

The second study:

It is vital for researchers to be careful on selected methods and to be aware of giving a rationale for choices (Ritchie et al.,2014). Researchers may prefer to adopt multiple

methods of data collection and analysis techniques into their study in order to address their proposed objectives (Patton, 2015). The use of multiple methods should take into account the practical implications of the study and should focus on running a study which best addresses the research question (Creswell and Poth, 2018). The second study element was designed around semi-structured face-to-face individual interviews with women and individual and focus group interviews with HCPs, which were then analysed separately but were interpreted together, using the thematic analysis process proposed by Braun and Clarke (2006).

Semi-structured individual Interviews

Interviews provide the opportunity to hear people's own stories, learn about their subjective experiences and views (Bowling, 2009). Semi-structured interviews are generally used if the interviewer knows the questions that she/he would like to ask, and in the nature of the conversation, there is flexibility to probe through the use of further questions -not in the list- if the interviewee's response requires more investigation (Morse, 2003). Semi-structured interviews also allow the order of questions to be changed if the interviewee has already answered some of them from the list (Barbour, 2014). Semi-structured interviews typically last between 30-60 minutes; however, in general, they are unique, individual and quite responsive within the individual interview and may only take 20 minutes. Crucially, the researcher should support the engagement of interviewees in the conversation (Braun and Clarke, 2013).

Semi-structured individual interviews were used to obtain women's experiences of perinatal low mood or depression. Individual interviews were planned for the women because if someone feels upset during a focus group interview, others might get distressed as well and it would be hard for the researcher to manage the group. Focus groups might be beneficial in terms of collecting rich data, but the risks were considered more than the benefits, so it was decided to collect data through individual interviews rather than focus groups. This decision was supported by the HSRGC when the research protocol was submitted in order to secure ethical approval.

Private interview rooms from four community centres, which were in a convenient place for the women, and provided privacy and confidentiality, were hired for the individual interviews with women. Nine women requested to be interviewed at their

home, one in her workplace and one in a private bookable room at a university. Eight individual interviews with HCPs were completed in their workplace, three in a private bookable room at a university and two at the HCPs' home. In this study, the duration of individual interviews with the 15 women ranged between 25 and 65 minutes, with an average of 40 minutes and the individual interviews with the 13 HCPs ranged between 15 and 60 minutes, with an average of 30 minutes.

Refreshments were provided for the individual interviews with women and HCPs. Although the aim was to reimburse reasonable travel expenses of HCPs and women, none of the participants requested a reimbursement. In recognition of the women's time and effort in the study, and as a thank you gift, the 15 women were given a One4all gift card worth £20 (not for HCPs). Women who had consented to participate received the gift card regardless of when they withdrew; however, none of the participants withdrew from the study.

Focus Groups

Focus group discussions are powerful tools in terms of bringing people together who have similar experiences on a topic, using group dynamics, exchanging ideas, generating new questions, exploring perspectives and building new knowledge about the phenomenon (Barbour, 2014; Bowling, 2009; Thorne, 2008; Pope and Mays, 2006). The typical duration for focus groups is around 60-90 minutes; however, each one is individual, and it might take a shorter time due to the depth of discussion, group dynamics and/or the researcher's ability to probe (Braun and Clarke, 2013).

Focus groups were primarily intended for HCPs to gain rich data; however, professionals have heavy workloads and a busy schedule and might be reluctant to participate in a focus group. To minimise this issue, interviewing preferences were given in demographics forms (see Appendix 5) and consent forms (see Appendix 6), so professionals could state their preference to be interviewed individually. The focus groups provided an opportunity to gain more information about HCPs' experiences of providing and planning care for women with perinatal low mood or depression. In this study, one focus group interview with two HCPs lasted 40 minutes and another focus group with four HCPs lasted 52 minutes. The focus groups were completed in HCPs'

workplace. Sandwiches, cakes and drinks were provided for the focus group interviews with HCPs.

Interviews and focus group discussions were conducted by the researcher, based on her experience of a completed Masters study (Pinar and Karacam, 2018) and “Qualitative Research in Health Sciences” Masters module at the University of York. She has also attended “Introduction to Focus Groups”, a one-day course, and “Introduction to Qualitative Interviewing”, a one-day course at Oxford University, in order to gain more knowledge about conducting qualitative research and doing interviews and focus groups. During the individual interviews and focus groups, the researcher’s role was to encourage participants to talk and to guide the conversation to make sure it addressed the purposes of the research (Burns and Grove, 2005).

Topic guides

For the purposes of the second study element, topic guides were developed for the individual interviews and focus group interviews through engaging with the literature and the recommendations of supervisors, who are experts in midwifery, nursing and clinical psychology and the recommendations of the Patient & Public Involvement (PPI), as explained in the section ‘Patient and Public Involvement for the development of the second study element and the study materials’ below. Separate topic guides were prepared for individual interviews (see Appendix 7) and focus group interviews with HCPs (see Appendix 8) and individual interviews with women (see Appendix 9). A practice interview was conducted with a friend who is a PhD student and also a mother and the flow of the questions were redesigned as a result. Another individual interview was conducted with a lecturer who works at a university and some changes were made after the interview.

During individual interviews with women, some themes, different from the content of the questions in the topic guide, emerged and these themes were explored in subsequent interviews. Examples of these themes were the content of the antenatal classes (if they include information about perinatal mental health), partner’s mental health (if it is affected by their mood), children’s mental health (if it is affected by their mood), the content of the CBT provided by IAPT (if the content covers perinatal

depression or general depression), and what was most helpful for recovery from low mood or depression.

The topic guide for HCPs was developed according to the themes that emerged from the interviews with women and the HCPs were asked those questions in the interviews, in addition to the questions in the topic guide: the content of antenatal classes, screening for paternal mental health, content of CBT delivered by IAPT and based on their own experiences, what kind of support do they think work best for women's low mood or depression symptoms.

Demographics form

The demographics form for women (see Appendix 10) was designed to include a number of different experiences in the study (e.g. low mood or depression during antenatal, postnatal or perinatal period, received support or none, psychological and/or pharmacological treatments or none, experience of other psychological challenges such as anxiety or none), and in order to collect descriptive data from participants, for example, age, education level, income, number of children, the age of youngest child etc.

The demographics form for HCPs (see Appendix 5) was prepared to include a variety of HCPs in the study (e.g. community midwives, health visitors, maternity support workers, specialist perinatal mental health midwives, GPs), so as to generate rich data and different perspectives.

Demographics forms for women and HCPs were developed through engaging with the literature and PhD supervisors and the PPI group, as explained below.

Contact details sheet

Contact details for women (see Appendix 11) and HCPs (see Appendix 12) were designed to be able to phone or email them in order to talk about arrangements for an individual interview or focus group, once the researcher received their consent form and demographics form by post. The recruitment strategy is explained in detail in the recruitment section below. A contact details sheet was also developed by liaising with PhD supervisors and the PPI group, as explained below.

Participant information sheets and consent forms

Participant information sheets (Appendices 13 and 14) and consent forms (Appendices 6 and 15) were produced using the principles within the Health Research Authority (HRA) website, the University of York guidelines, General Data Protection Regulation 2018, and through liaising with PhD supervisors, the sponsor for the university and the PPI group (see section 3.5 Ethical and regulatory considerations for details about the information sheet and consent procedures).

Patient and Public Involvement for the development of the second study element and the study materials

Study design and methods of data collection for both HCPs and women were developed through liaising with a research midwife and a research nurse who work in a Research and Development (R&D) department at an NHS Trust. The recruitment strategies for HCPs and women were shaped after this meeting.

All recruitment materials (poster and leaflets (Appendices 16 and 17), advertisements for electronic display, participant information sheets, consent forms, demographic forms and contact details sheets) for women and HCPs, were improved with the involvement of two mothers to better explain the study to future potential participants. For the purposes of PPI, an advertisement was published on the Mumbler website. Four mothers emailed the researcher and indicated their desire to be involved in designing the recruitment materials; however, only two were available at the time of the meeting. One of them was working in a health-related job and therefore, became involved in the design of the materials for the HCPs.

Prior to publishing an advertisement for PPI work on the Mumbler website, the researcher had attempted to find mothers through attending a mother and baby group with the help of a research midwife; however, none of the mothers was interested in designing recruitment materials, which prompted the decision to advertise on the Mumbler website.

The third study:

The co-design workshops were used to meet the study objectives of the third study element. Co-design is described as an equal partnership and shared leadership between researchers, service users and HCPs in the design or improvement of a service, product or organisation (Bate and Robert, 2007). Co-design groups enable researchers to consult patients (i.e. in this case women) and staff, to take advice on a particular issue, setting priorities and making decisions with equal involvement of patients and staff (Bate and Robert, 2006). The duration of the co-design workshops depends on the aims that are to be achieved at the end of the workshops.

In this study, these co-design workshops brought together women and HCPs face-to-face. In the adaptation of the BA booklet and manual, power was equally shared with the researcher, using women's and HCPs' experiences and previously collected data (second study). The typical content of a co-design workshop included (Bate and Robert, 2007): (1) giving information about the third study (this is revisiting/ reiterating information already provided to secure participation and consent); what is the aim of the project, why is this relevant to them, why are they invited to collaborate, expectations of participants in the process, what will be achieved at the end of the workshop; (2) going through the BA booklet and then manual, page by page while explaining the BA therapy, findings from the second study, and asking probing questions to identify, agree and define key points to change (see Appendix 18 for 'indicative questions to ask in the workshop'); (3) setting priorities for the adaptation of the BA booklet and manual: which points are important and urgent to change, how it would be modified to make the booklet and manual better for women experiencing perinatal depression and for MSWs, providing a BA intervention. Although using filming vignettes is a common approach in EBCD (Bate and Robert, 2007), because of limited resources, the researcher prepared PowerPoint slides to facilitate the communication with co-designers and understanding of the BA treatment by co-designers.

Each participant was asked in the workshops to read through the booklet first and then the manual and to write any comments directly on the documents. They were asked to comment on all features of the documents, for example, major changes; restructuring

the delivery of the BA therapy and booklet; the therapy stages and sections within the stages; adding information about something or removing irrelevant information; reordering the sections and stages; changing examples to make them more relevant to their situation and adding example activities; making minor changes on wording, pictures, tables, bullet points, and the size and colour of the booklet and manual. The researcher's role was to encourage women and HCPs to offer their suggestions and ensure that their voices were heard by everyone.

Four workshops in three different research sites were completed in three months, with two to three-week intervals, to give the researcher enough time to modify the BA booklet and manual after each workshop, within the time available to complete the PhD. Changes to the BA booklet and manual has been applied after each workshop and discussed within the supervisory team.

Women who participated in the second study were also informed about the time and venue of the co-design workshops in their area by email while recruitment was actively ongoing. Different women and HCPs attended each workshop. Private meeting rooms from the two churches and a university were hired for the workshops, which were convenient for everyone and provided privacy and confidentiality. Refreshments, sandwiches, cakes and fruit were provided. Travel expenses of seven women were reimbursed and the 14 women who attended the workshops were given a 20£ One4All gift card as a thank you gift and compensation for the time they spent in the workshops. It was expected that each workshop would not be longer than 90 minutes with the structure detailed above; however, all four workshops lasted longer than expected, between 110 to 145 minutes, with an average of 123 minutes.

Topic guide, Demographics form, Contact details sheet, Participant information sheets and consent forms

For the purposes of the third study, a topic guide (see Appendix 21) was developed for the workshops. It included detailed information about the structure of the workshops that are summarized above. Separate demographics forms (see Appendices 22 and 23), contact details sheets (see Appendices 24 and 25), participant information sheets (see Appendices 26 and 27) and consent forms (see Appendices 28 and 29) were produced for the women and HCPs. These forms were different from those used for

the second study element of the thesis but the same procedures were followed while preparing the forms, except for the PPI work which was not planned for this stage. Advertisement leaflets were also produced for the recruitment of women (see Appendix 30) and HCPs (see Appendix 31) for the third study.

Behavioural Activation guided self-help booklet

Detailed information about the BA therapy is provided in section 1.3.8 in chapter one. The BA booklet used in this research study was initially written by Deborah Hems with the help of Della Bailey and Dean McMillan at the University of York and used in previous sub-threshold depression research (CASPER study: Gilbody et al., 2017; Pasterfield, 2014). The booklet and the manual were then adapted by David Ekers, in partnership with a group of pharmacy customers, people who have experienced low mood and depression, people with physical health problems, and fellow researchers, for implementation by community pharmacy staff to people with sub-threshold depression and long-term conditions (The CHEMIST study: Littlewood et al., 2019). The manual and booklet from the CHEMIST study were used in this PhD research in the adaptation process (see Appendices 19 and 20). The decision to work with the BA manual and booklet that was used in the PhD study was made according to the availability of the materials for use with permission.

The booklet (see Appendix 20) includes an introductory page that stresses the importance of maintaining a healthy mood and then summarises the six stages to keep well. After that, it gives a summary of the factors that can lead to low mood and then goes into detail about the stages of BA therapy. These stages are: recognising symptoms of low mood; the value of keeping a diary; three types of activity; breaking jobs down into easier tasks and learning new ones; the benefit of your activities, finding other ways to be active; and spotting symptoms and making an action plan to stay well. The content of the booklet is summarised in Table 7. The self-help booklet was aimed to be used by women who are pregnant, are first time mothers and have more than one child and in the postnatal period. It was designed to address women's needs from pregnancy to the end of the first year after childbirth.

Table 7: The content and stages of BA therapy guided self-help booklet

The stages	The content
Stage 1: Recognising symptoms of low mood	Understanding what low mood is, so that the signs can be recognised
Stage 2: The value of keeping a diary	Looking at your own activities and recognising how they affect your mood
Stage 3: Three types of activity and planning to keep a balance	Planning routine, necessary and pleasurable activities
Stage 4: Breaking jobs down into easier tasks, and learning new ones	Making the tasks more manageable
Stage 5: The benefit of your activities Finding other ways to be active	What you get out of what you do
Stage 6: Spotting symptoms and making an action plan to stay well	What to do if you notice symptoms of low mood getting worse again in the future and planning to stay well.

Behavioural Activation therapy manual

The BA therapy manual (see Appendix 19) includes three sections: the first section describes the CHEMIST study details and overall principles of the intervention; the second section explains the structure of the sessions based on four principles: information gathering, information giving, shared decision making, and reporting and supervision and then presents information and a table to fill in on the contact sessions; the third section describes the Depression, Anxiety and Stress Scale (DASS21) Depression Subscale, risk protocol and provides the study team contact details. The content of the manual is summarised in Table 8. The BA manual was planned to be used by MSWs for the treatment of perinatal depression.

Table 8: The content and sections of the BA therapy manual

The sections	The content
Section A: Describes the CHEMIST study and provides details of the overall principles of the intervention	Gives information about the study structure, study team, depression and physical health problems, enhanced support intervention, management of risk
Section B: Outlines a session by session overview Contact session 1 Contact sessions 2-5 Contact session 6	Gives information about the session structure: information gathering, information giving, shared decision making. Action following contacts: reporting and supervision
Section C: Describes DASS21 Depression Subscale, Risk Protocol, and Study Team Contact Details	Outlines DASS depression symptom level assessment: scoring and reporting to supervisors. Risk protocol: identification, management and reporting of suicide or self-harm. Study team contact details: names, phone numbers and email addresses of study team.

3.4 Data management and analysis for the second study (discovery phase) and the third study (co-design phase) elements

All individual interviews, focus group interviews and workshops were audio-recorded by the researcher. A password-protected audio recorder was borrowed from the University of York, Department of Health Sciences IT services a day before each interview or workshop and returned a day after the interview or workshop.

Interviews from the second study were transcribed verbatim by the researcher or a professional transcriber. The professional transcriber was used because of the multiple tasks the researcher was juggling within a limited timeframe. This included advertising the study in three different NHS and CCG sites, recruiting women, calling women to ask PHQ-9, scheduling interviews, booking venues, preparing refreshments, conducting

interviews, listening to the recordings and transcribing, listening to them again so as to become familiar with the data, anonymising the name of the persons and places, coding and analysing, scheduling other interviews, and recruitment of HCPs. For the transcription of the recordings, a pedal was borrowed from the Health Sciences IT services and returned when all the interviews and workshops were completed.

The University of York supplies NVivo 11.3.2 qualitative data management software which supports users to organize and analyse the text-based information (IT Services, 2017). NVivo was used to manage and analyse the second study data. The researcher attended “Introduction to NVivo”, a one-day course at the University of York, and “Analysing Qualitative Interviews”, a two-day course at Oxford University, with the aim of learning how to manage and analyse qualitative data.

There is no accepted fixed method to analyse ethnographic data and researchers may customise their analysis method which addresses their needs (Angrosino, 2007).

Content analysis, framework analysis and thematic analysis are often used by researchers in the analysis of interviews, focus groups and documentary data (Barbour, 2014; Ritchie et al., 2014, Silverman, 2014). Content analysis is recommended for the analysis of documentary data, for example, policy documents and newspapers and it is stressed that to ensure the reliability of measures and validity of findings, data must be organised systematically into a structured framework (Silverman, 2014). In framework analysis, the data is systematically analysed and coding matrices are generated for each interviewee. Then each interviewee is assigned to a row and each column shows a subtheme. The interpretation of data is made by case and by subtheme (Ritchie et al., 2014; Smith and Firth, 2011). Framework analysis is a variant of thematic analysis (Barbour, 2014) and is often related to policy research (Smith and Firth, 2011).

Thematic analysis is in basic terms, the search for common patterns across the dataset in order to provide an illustration of the phenomena (Braun and Clarke, 2006). While stages of analysis until generating coding matrices are similar in both thematic analysis and framework analysis, framework analysis comprises descriptive analysis of the data, unlike thematic analysis that provides a rich and comprehensive understanding of the complex issues (Braun and Clarke, 2006; Smith and Firth, 2011). Therefore, thematic analysis was used in the analysis of interviews with women and HCPs within the second study element, and the analysis of workshops within the third study element of

the thesis. The analysis of interviews was enriched and supported with perinatal mental health pathways, referral guidelines and maternity notes booklet used in the research sites. The analysis of workshops was also supported by using participants' own comments on the draft BA booklets and manuals.

Thematic Analysis

Thematic analysis (TA) (Braun and Clarke, 2006) can be used in the analysis of a variety of data collection methods, for instance, individual interviews, focus groups, websites, magazines, articles and reports and across datasets (Braun et al., 2019) which support our data. TA was used to identify the commonalities that emerged from individuals' verbatim transcripts, using the field notes and was used in the analysis of interviews, focus groups and workshops. TA can also be applied to a variety of different theoretical and epistemological approaches (Braun and Clarke, 2006) and in this study, there was also an element of content analysis for the analysis of comments on the booklet and manuals. Data was also subjected to a process of comparison to generate the themes, which can also be facilitated by TA (Braun et al., 2019).

In TA, there are two main ideas that comprise the themes: domain summaries and shared meaning-based patterns (Braun et al., 2019). While domain summaries consist of the surface level of meaning and are based on the responses of participants to a specific question, shared meaning-based patterns comprise from the core and spread of meaning that are constructed from smaller meaning units (codes) (Braun et al., 2019). The analysis built from shared meaning-based patterns requires finding meanings that present more than one place, code combining and capturing and summarising clear ideas, as explained in detail below. Shared meaning-based patterns were used in the analysis of the transcriptions.

There are three types of TA which can be used for different purposes: coding reliability, codebook TA and reflexive TA approaches (Braun et al., 2019). Coding reliability comes from a post-positivist approach and aims to generate reliable and accurate codes and themes by using a codebook, which enables coders to label the data into prearranged themes (Braun et al., 2019). This analytic process is often done by more than one coder who have not collected the data and have no knowledge about the research being undertaken (Braun et al., 2019). Codebook TA lies between

coding reliability and reflexive TA and includes generating themes as domain summaries and using codebooks (Braun et al., 2019). The reflexive TA approach is underpinned by only qualitative philosophy and stresses that meaning is contextual, reality is multiple and the researcher is the main resource in the knowledge-generating process (Braun and Clarke, 2013), all of which are in a harmony with the chosen theoretical approach for the study. Coding using reflexive TA is an iterative process and not stabilised to predetermined codes. The initial codes can be merged with other codes and can be recoded or separated into other codes. The purpose of making these changes is to better capture the essence and the meaning lying under the surface (Braun et al., 2019).

Braun and Clark (2006) (Braun et al., 2019) describe six phases of TA: familiarisation with the data, generating initial codes, searching for themes, reviewing themes, defining and naming themes, and producing the report. These steps and how the analysis carried out for the second study are explained below.

The second study:

Familiarisation with the data

The first step of TA involves listening to the audio recording and reading and re-reading the transcriptions in order to see the whole picture, make notes about any interesting points that arise in each interview and in the whole dataset, all of which relate to the research questions (Braun et al., 2019).

To complete the first step, after listening to the recordings and reading the transcriptions to anonymise the names of the places and people and to check the accuracy of the transcriptions, audio recordings were listened to and transcriptions were read again with the aim of making notes about the interesting points. These emerging ideas were written in a word document that was separate from the field notes (see Appendix 33 for the first step. The field notes are not shared as participants could be identified).

Perinatal mental healthcare pathways, referral guidelines and the pregnancy notes booklet were read and important points were highlighted. Only one page of the

pregnancy notes booklet related to mental health is attached (see Appendix 34) because other documents included the name of the NHS Trusts, phone numbers to call for referral and regional help sources, all of which would break the anonymity of the participants in the study. The content of these documents supported the findings from the interviews with women and HCPs, as explained in the second study findings chapter.

Generating initial codes

The second step involves labelling data that contributes a meaning. In this stage, there are two types of coding: inductive and deductive. An inductive approach was chosen for identifying meaning because of the epistemological considerations detailed in section 3.2.2 ontological and epistemological assumptions. Another consideration in this stage is types of codes, for instance, semantic and latent codes. While semantic codes capture explicit meaning, latent codes consider the deeper or conceptual level of meaning (Braun et al., 2019).

Transcriptions were read line by line in NVivo and each transcript was given equal attention in the coding process. First, semantic codes were labelled; later latent codes were composed as illustrated with three examples below. In the given first example, a mother stated that she hid her feelings from the health visitor and this statement was coded as '*hiding feelings from HCPs*'. She described lying to the health visitor and described the reason behind her behaviour: '*fear of labelling as a bad mum*' and this became a latent code. In the second example, another mother expressed '*feeling ashamed*' so this was also a code. She then said '*if anyone knew that they would think that I wasn't capable of looking after the child*'. This was viewed as being a latent code, '*fear of labelling as a bad mum*'. Afterwards, '*stigma*' was coded as a latent code for each scenario as well. In the third quotation, an HCP explained the situation as '*stigma around mental health*'.

"...I did hide it from the health visitors. I said that I was tired when I used to cry, they did ask about my mood and things but I just thought that they would think I was a bad mum so I just hid it..."

“...I felt quite ashamed and definitely like if anyone knew that they would think that I wasn’t capable of looking after the child and I think one of the reasons that I denied it was that I was scared that someone would take her away like social services...”

“...I think stigma around mental health. I think it’s still quite a big thing for women. They don’t want to be labelled by that and they think that we’re going to take their baby away from them so yeah it’s just those sort of things really...”

For the codebook of this stage see Appendix 35.

Searching for themes (Constructing candidate themes)

The third step of TA involves generating candidate themes with the help of the codes generated in the previous step, using the research questions (what the researcher is looking for in the data) and reflexive notes written in the first step. Themes are generated by the researcher rather than fully emerging from the data (Braun et al., 2019). The codes may represent a wider theme or two or three codes may emerge and represent a broader theme. Separation or merging of codes can be helpful in this stage in order to go further in the analysis. Candidate themes can also be visualised with a thematic map (Braun et al., 2019).

After reviewing the codes and bearing in mind the research questions and reflexive notes, some codes were merged with others. For instance, codes similar to the expression of ‘feeling like a bad mum’ and ‘feeling not good enough’ were merged with other related codes and a broader theme was generated as ‘feelings in the postnatal period’. Another example would be that ‘feeling like a bad mum’ was merged with ‘feeling not good enough’, ‘fear of labelling as a bad mum’ and ‘stigma’ and represented as ‘reasons for not disclosing feelings’ (checking the direction of the conversation). Others were moved below the related themes, for example, reasons for depression before pregnancy and in the antenatal and postnatal periods were moved below the ‘triggers of low mood or depression’ theme. For the codebook for this stage, see Appendix 36 and the thematic map, see Appendix 37.

Reviewing themes (Revising themes)

The fourth step of TA aims to gather all the codes within relevant themes. It involves reviewing the candidate themes and all codes belonging to them, to see whether they are related to a shared meaning or concept (Braun et al., 2019). The thematic map can also be generated to illustrate the reviewed themes across the dataset if they encapsulate the whole story about the inquiry (Braun et al., 2019).

Candidate themes were reviewed to ascertain whether they represented the dataset and the whole story and changes were applied when needed (see Appendix 38: Thematic map).

Defining and naming themes

The aim of the fifth step is to “clarify the essence and scope of each theme” (Braun et al., 2019, p. 855). The researcher should answer the following questions: What is the theme about? Are there any relationship with the subthemes (if any) and main themes? What is the relationship between the main themes? (Braun and Clarke, 2006).

These questions were answered and the last version of the themes was created, presented as a thematic map (see Appendix 39). The coding process and thematic map were then evaluated by the consulting supervisors, with a sample of transcripts to ensure the rigour of the analysis and interpretation, and changes were applied when needed (Creswell, 2009).

For the analysis of interviews with HCPs, the same steps explained above were carried out by the researcher and a separate thematic map was produced (see Appendix 40).

Producing the report

In order to maximise the utility and practicality of qualitative health research results, they need to be written up and presented in a way that they can be understood by the target audience. The use of thematic sentences makes statements clear, and extracted quotations need to be meaningful and show explicitly the variations in statements across the dataset (Sandelowski and Leeman, 2012). The findings of the second study element, presented in chapter four and the third study element in chapter five, were

therefore written with this in mind and focus on the practical outcomes of the study so as to be directly useful, accessible and understandable for the intended readers.

HCPs' and women's transcripts were analysed separately and the analysis was collated in separate thematic maps (Appendices 39 and 40). However, the themes were then integrated (see Appendix 41: thematic map) and interpreted together (see chapter four). Only findings related to the adaptation of the BA booklet and manual were shared in the findings chapter, in order to avoid duplication of similar content and themes, to build a robust rationale for the proposed changes in the BA booklet and manual, while staying within the scope of the aims and word limit of the thesis. Other findings will be submitted as manuscripts after submission of the thesis. Themes are illustrated using sample codes and interview quotes, and making reference to interesting points. The interpretative process also draws on the existing literature (see sections 6.2.2; 6.2.3; and 6.3) and to ensure a rigorous analysis application, the 15-point checklist of criteria for good TA was used (Braun and Clark, 2006).

The third study:

The audio recordings were the main data sources used for the adaptation of the BA manual and booklet, in addition to co-designers' comments on the documents and the researcher's notes taken during the workshops with regards to the general direction of the improvements as identified by the group.

Audio recordings were transcribed and analysis of transcriptions, comments on the manual and booklet, and constant comparison of data across the datasets and workshops was done by using highlighters, colourful pens and sticky notes, page by page, stage by stage or section by section.

Thematic analysis

To avoid repetition within the chapter, the analytic process for the third study is described below without references.

Familiarisation with the data

The audio recording was listened to after each workshop and transcribed by the researcher. The transcription accuracy was checked, and all the names of the places and persons were anonymised. The recordings were listened to again and notes were made on a booklet and manual (see Appendix 42 for an example).

Generating initial codes

The coding process was carried out page by page from the transcription of the recordings and the co-designers' comments on the documents. For instance, in one workshop, one of the women suggested making changes to the key signs of depression. All the sentence was highlighted and was coded as 'sleeping page 6' because the participant was talking about one of the key signs (i.e., eating, sleeping, energy, behaviour and thinking) written on page 6 in the BA booklet. Another recommendation in the second quotation was again related to sleeping problems and was coded as 'sleeping page 6'.

"...A newborn baby's sleep pattern can be quite erratic. If you're unable to sleep when your baby sleeps, this could be a sign of low mood..."

"...Pregnancy problems can make sleep problems worse..."

The co-designers' comments on the booklet related to key signs were about making changes on wording, for example, adding 'losing motivation' in addition to 'losing interest' as a key sign of low mood (see Appendix 43 for example comments from co-designers).

The transcriptions were compared with the co-designers' comments on the documents and these changes were applied to the booklet and manual according to the decision of the majority and a new version of the documents was created. The decision on whether to amend the documents or not was a consensus decision-making process between women, HCPs and the researcher in the workshops by asking co-designers whether everyone is agreeing on the amendment or not.

Every comment made by co-designers was given attention in the coding process, even if the group did not agree on the suggested changes. In the subsequent workshop, the unresolved issue was brought to the co-designers' attention and their comments were compared with the suggestions of the previous group. For instance, in one workshop, a women suggested adding a few sentences to the booklet about information for partners or husbands on supporting their partners or wives. However, others in the group argued that the booklet was a very personal thing and that information for partners should not exist in the booklet. In the following workshop, the group also agreed that the booklet should not include information for partners.

Searching for themes (Constructing candidate themes)

Some of the codes were shaped into candidate themes while others were constructed into wider themes. For instance, in one workshop, it was suggested that information be added about 'baby blues and hormonal changes' as a major change in the booklet and this was added. However, after completing the four workshops and looking across the dataset, comparing the transcribed data and participants' comments on the documents, the theme was rephrased as 'changes in key signs' including changes in sleep, energy, eating, behaviour, thinking and hormonal levels (see Appendix 44).

Reviewing themes (Revising themes)

All the themes and sub-themes were reviewed after completing the four workshops and the representation of the whole story was explored across the datasets (see Appendix 45 for the thematic map).

Defining and naming themes

The last version of the themes was produced, and a thematic map was created (see Appendix 46).

After each workshop, the new versions of the booklet and manual were shared with supervisors. The last versions of the documents were also discussed within the supervisory team and changes were applied when needed.

Producing the report

The findings from the second study were used in the adaptation of the BA manual and booklet in the first instance. Chapter five first describes how the second study findings informed the third study and then findings from the third study are presented thematically. The themes are reported with example codes and quotations from the workshops.

3.5 Ethical and regulatory considerations (second and third studies)

Participant information sheets (Appendices 13, 14, 26 and 27) and consent forms (Appendices 6, 15, 28 and 29) were produced using the principles within the HRA website, the University of York guidelines and General Data Protection Regulation 2018. All potential participants were given or sent an information pack and they were able to read the participant information sheets before informed consent was sought and obtained. The researcher also fully explained the nature of the study when potential participants contacted her. When participants had any further questions, they were answered. Participants were asked to return one copy of their own completed consent form to be held by the researcher, whilst retaining a second copy for their reference. Only those who returned their signed consent form were considered.

A period of 24 hours was given to participants in order to allow them time to think about their willingness to take part in the study, after informed consent signed. After this 24-hour period, the participants were contacted and asked if they still wished to participate. Another 3 days were granted if they wanted to talk to their family or friends, as explained in the study flowcharts (Appendices 47 and 56).

There was no pressure on any of the participants to take part in the study. Participation was totally voluntary and it was made clear that individuals could withdraw at any time without giving a reason, even during the interview, focus group or workshop. Participants were told that if they chose to withdraw from the study, all data referring to them would be destroyed and would not be used in any way. However, if a participant chose to withdraw from the focus group interview or workshop, all the data collected until the time of withdrawal would be used in the

study because it was not possible to remove someone's contribution from a group discussion. Participants who chose to be interviewed individually could withdraw from the study within 48 hours after completion of the individual interviews. All data referring to them would then be destroyed and would not be used in any way. Should a participant choose to withdraw more than 48 hours after completion of the individual interview, her data would still be included in the analysis. After completing the focus group interviews and workshops, participants could still withdraw from the study but their data would be used in the analysis. This information was given on participant information sheets and consent forms for participants.

The participants were anonymised in all transcripts and their identity was kept strictly confidential. Their personal information, audio recordings, consent forms, demographics forms, and transcripts were accessible only by the researcher and the research team.

Data made publicly available was anonymised in accordance with the General Data Protection Regulation 2018. Participants will be referred to anonymously in publications arising from the study. No real names of people or places will be used in any presentations or publications resulting from the study or in the researcher's PhD thesis.

Quotations from the interviews, focus groups and workshops were used in reported findings from the research study. If anything that participants said appears in the quotation, it is made anonymous with a self-chosen false name or anonymous numbers so that they cannot be identified.

Consent forms

Consent forms were stored securely in the PhD supervisor's office at the University of York. It is within a restricted electronic key swipe area and the supervisor's office is a locked room which has two locked filing cabinets. Consent forms are accessible only by the researchers in the research team. Consent forms will be retained for up to 5 years from the end of the research to cover the period of the submission of the researcher's doctoral thesis and any publications arising from the study.

Spreadsheet of contact details

The spreadsheet of contact details was stored securely in the same locked cabinet with the consent forms. This was ensured to keep identifiable and non-identifiable data in separate cabinets. The spreadsheet of contact details were destroyed after 12 months.

Demographics forms

Demographics forms were stored securely in a different locked cabinet from the consent forms and spreadsheets of contact details. Demographics forms were destroyed after 12 months.

Audio recordings

The audio recordings of interviews, focus groups and workshops were stored on a password protected server on the researcher's University of York computer. Only the researchers in the research team had access to the audio recordings and they were deleted after 12 months.

Transcripts

The transcripts are stored on a password protected server on the researcher's University of York computer and managed in NVivo. Only the researchers in the research team have access to the transcripts. The transcripts will be stored for 10 years at the York research database and PURE, according to the University of York's policy. The transcripts will not be publicly available and only the research team will have access.

3.5.1 Assessment and management of risk

There were no anticipated disadvantages or risks for HCPs taking part in this study. However, the researcher was aware of their busy schedule and was as flexible as possible to suit their free days and time. Although the aim was to conduct focus group interviews with HCPs so as to gather a rich source of data, it was recognised that focus groups were more time-consuming than individual interviews, so professionals might prefer to be interviewed individually. To minimise this issue, interviewing preferences

were given in the consent form and demographics form, to suit their availability and there was no pressure for HCPs to take part in the study.

There were no perceived direct risks or burdens for women from taking part in the study. However, the researcher was aware that women who have experienced perinatal depression are potentially vulnerable people. The researcher was very aware that the mental health of women was of critical importance and that the potential participants would bring difficult life experiences to the interview situation. Individual interviews were chosen rather than focus group interviews for this reason so that the researcher could immediately respond if a participant became upset. It was also for this reason that only participants who deemed themselves 'recovered' were chosen rather than women in the perinatal period or women who were symptomatic at the time of the enrolment. The study aimed to include women who had experienced low mood or depression during pregnancy and/or in the first year after giving birth in the last five years, who were recovered at the time of enrolment, and whose youngest child was between one and five years old. The researcher recognises that this potentially raises another validity issue of data being limited over this time period. However, the researcher's understanding from talking to midwives and HCPs is that services have not changed radically in the last five years. This was also addressed through interviews with HCPs, which allowed any information from the women to be placed in the context of changing services.

Although it was clearly stated in the leaflets, posters, and participant information sheets that the study sought women who were recovered, there was the possibility that women who were experiencing depressive symptoms or who had suicidal thoughts might contact the researcher. To minimise the risk of including potentially vulnerable women, the researcher sent all women who showed an interest in the study, an information pack which comprised a participant information sheet, two consent forms, a demographics form, a contact details sheet, and a pre-paid stamped-addressed return envelope. Their GP's name and contact details were asked for in the contact details sheet. When the researcher received their envelopes, she checked their GP information. If women did not give their GP information, the researcher contacted them and explained that it is not possible to participate in an interview or a workshop unless they give their GP details. If women provided the details of their GP, the

researcher implemented the PHQ-9 over the telephone to make sure that they did not have ongoing depressive symptoms. If they scored between 0 and 9, they were eligible for an interview.

If they scored 10 or above, the researcher would have explained that they were not eligible to take part in the study because they might still be depressed. She would have recommended that they see their GP and would have asked them whether they wanted the research team to inform their GP. If they agreed, an email with a GP notification letter (see Appendix 55) would have been sent to their GP. If they did not agree, they would be reminded of available help and support sources. These details were also provided in the participant information sheets.

The PHQ question 9 was used to identify suicidal ideation. The plan was to use the 'Appendix 49: Self-Harm/suicide risk identified via telephone assessment', 'Exploring Risk Questions' (see Appendix 52) if the score was higher than 0. Responses were to be recorded verbatim and then a call was to be made to PhD supervisor Prof McMillan, who is a clinical psychologist who would then help determine the possible level of risk on 'Exploring risk questions guidance' (see Appendix 53) and decide whether or not the woman's GP should be contacted. If necessary, a 'GP notification letter' and 'Self-harm / suicide risk form' (Appendices 55 and 51) would be filled in and sent to the GP; however, none of the participants disclosed suicidal thoughts.

During the individual interview, if any concern regarding self-harm or suicidal risk arose, the researcher was to follow 'Appendix 50: Study flowchart 5: Self-harm / suicide risk identified via qualitative interviews or workshops'. During the workshops, this flowchart was to be followed after the end of the workshop, to ensure the privacy of the woman concerned; however, none of the participants disclosed self-harm or suicidal thoughts during the interviews or workshops. Available support sources were also included in participant information sheets and participants were reminded of these at the end of the interviews and workshops.

Unexpected disclosure of information by participants that could require notification or other follow-up action by the researcher would be shared within the research team in a way that protects the participant's anonymity and confidentiality but is bound by legal and ethical requirements (e.g. child protection concerns, risk to others, self-

neglect, domestic violence, alcohol or substance abuse). A decision would be made about actions required (e.g. contact duty social worker if child protection issues arise) and the decision and actions taken would be documented in 'Non-suicide risk form' (Appendix 54).

Women were invited to choose their preferred location for the interview in the demographics forms. It was expected that most of the women would choose to be interviewed at their home. There might be risks for the researcher when interviewing participants at their homes. The 'Lone working policy' was followed to anticipate and, therefore, diminish the risks to the researcher. All Lone Workers Contact Sheets (see Appendix 57) were destroyed after each fieldwork trip in order to safeguard the anonymity of the participants.

Interviewing in the home raised potential privacy issues for women. Women were told that the interview could be done only with them and that if her partner or other friends or relatives were present, the interview was possible only if a room was available that provided privacy. The researcher was aware that the participants had children. Unfortunately, the researcher's resources did not stretch to providing childcare. Therefore, women might be interviewed when children were around, and the conversation might also be interrupted by other people. The researcher endeavoured to secure a confidential interview but at times had to pause or terminate the interview if interruptions occurred.

3.5.2 Research Ethics Committee and other Regulatory reviews

The research protocol for the second study element was reviewed by the University of York's HSRGC and Research and Enterprise Directorate (Appendices 58 and 59) and the research passport application process started afterwards. The researcher made connections with each three NHS Trusts and CCGs and asked their R&D departments if they were happy to be involved in the study and seeing their names on the IRAS form and the research passport. Then, an IRAS submission (IRAS ID:237021) was made for the second study and the researcher and her PhD supervisor, Dr Helen Bedford, were invited to attend the REC meeting in Leeds. The REC members suggested revising some of the forms and decreasing the sample size from 30 women and 30 HCPs to 15 women and 15 HCPs. All the recommendations were applied after the meeting and

resubmission was made. The REC and HRA ethical approvals were granted (Appendices 60 and 61), and the approval letter and research passport were shared with three NHS Trusts and three CCGs. Each of the six R&D departments sent a Letter of Access and signed the research passport. One of the NHS Trusts required the researcher to complete the following online courses: Fire Safety - Level 1; Moving and Handling - Level 1; Health, and Safety and Welfare - Level 1. The researcher completed all required training and started recruitment in that NHS Trust afterwards.

For the purposes of gaining ethical approval for the third study, a substantial amendment form was filled in and all required recruitment forms were enclosed with the amendment form and sent by email to the HSRGC before sending to REC/HRA Yorkshire and Humber – Leeds West. Ethical approval for the third study was secured from the HSRGC (Appendix 62) and HRA (Appendix 63) and this information was shared with three NHS Trusts and three CCGs before starting recruitment for the third study element of the thesis.

3.6 Reflexivity, Rigour and Trustworthiness

Reflexivity is regarded as the researcher's awareness of her subjective experiences, backgrounds and interests which may influence the process of the research and includes acknowledgement of how the ideas of the researcher effectively co-builds the circumstances that they strive to study (Barbour, 2014; Potvin, Bisset and Walz, 2010; Krefting, 1991). The aim was to refrain from apparent, deliberate or any form of bias and to be as objective as possible during the research process, including data collection, analysis, interpretation of findings, knowledge-production process and writing process. However, this desire can never completely be achieved in a qualitative research and it is not possible to generate fully objective knowledge (Flick, 2014; Ritchie et al., 2014). Researchers cannot engage with the field as empty ideas and opinions but instead bring with them their own perceptions and assumptions (Barbour, 2014). Mirroring of the self during the research process and reflecting on feelings, impressions, preconceptions, beliefs, values, activities and observations in the field, clearly indicating each step of the process have critical importance in the interpretation of the outcomes. This is the basic principle of reflexive accounting.

The researcher of this PhD study is an overseas student conducting research in a foreign country, which presents both strengths and weaknesses. Although new to the National Health Services, the researcher has a midwifery background with eight months internship experience in Czechia, in addition to five years internship and education experience in her home country, Turkey. This experience was helpful in becoming familiar with a new health care system. Although she has no children and therefore has not experienced perinatal depression before, the researcher has been experiencing depression since 2012 and this insight helped in understanding women's experiences of it, their struggles with daily life, and the importance of support and awareness. When listening to the women's and HCPs' experiences, the researcher was mindful to being open-minded and empathic and strived to put aside any preconceptions, and pre-knowledge gained through reading about perinatal depression. This can be considered as having a positive and reinforcing impact on the interviews with mothers and HCPs. As a researcher doing ethnographic work, the main objective was to gain insight into the participants' symbolic life world and to endeavour to reflect on their experiences. The researcher believes that this objective was met through building trust and a sense of privacy with the women, which enabled them to be honest and open about their experiences. At the same time, the researcher found herself touched by the intense feelings that were expressed during the interviews and impressed by how these mothers endeavoured to deal with the challenges.

Co-designers' views and considerations were prioritised during the co-design workshops. At the same time, their struggles with their experiences were located within the wider PhD context and reiterated at the workshops. The researcher was careful to convey that the aim of the study related to their situation and that their involvement in the workshop would contribute to addressing women's needs who are in the same situation as them. The role of the researcher, as the person conducting all stages of the study, was made clear as was the process and the other elements of the research, such as how the previous workshop has worked, what actions had been agreed on, how the manual and booklet had been adapted and how the outcome of the workshop would be used in the next workshop. In terms of shaping the BA therapy manual and guided self-help booklet, the researcher endeavoured to ensure that the

voices of all the co-designers were heard equally, and co-designers were encouraged to listen to their own needs and also take into account others' needs in the group. Ideas were built up through discussion within the group with the aim of developing a consensus decision-making.

Rigour in a research study can be ensured by meticulous design: using features of scientific methods to address the research aims, conducting fieldwork properly, following research protocols, and generating trustworthy evidence that is grounded theoretically (Ritchie, et al., 2014). One way to achieve this, alongside reflexivity, was to be very explicit the entire research process, from the literature review and shaping the research questions, to the analysis and knowledge-generation process. Nonetheless, issues of validity and reliability of the research have to be acknowledged.

Validity, reliability and objectivity are important concepts when collecting and presenting data in order for the research to be considered robust and credible (Ritchie et al., 2014). Although these terms tend to be more associated with quantitative research, their application in qualitative research can be established through the researcher displaying trustworthiness, including credibility, transferability, dependability and confirmability (Shenton, 2004), all of which are explained in detail below.

Validity (internal validity, external validity and measurement validity) is concerned with the extent to which a finding is well-founded and accurately reflects the phenomena under study (Ritchie et al., 2014; Silverman, 2014). Internal validity in qualitative research focuses on how well and accurately participants' responses are captured and interpreted, which reflects credibility (Ritchie et al., 2014; Silverman, 2014). This can be ensured with participant validation, member validation and a triangulation approach. For participant validation, different methods can be used; for example, interview transcriptions can be returned to the participants and they can be asked to check the interpretation of the interview. Participants can also be asked to check the synthesized analysed data (Birt et al., 2016). However, participant validation was not considered feasible within the limited time of the researcher. Instead, in the second study, the coding process and thematic map were evaluated by the consulting PhD supervisors, with a sample of transcripts to ensure the rigour of the analysis and

interpretation, and changes were applied when needed (Creswell, 2009), as described in section 3.4 data management and analysis. In the third study, the outcome of the workshops was discussed after each workshop in supervision meetings with supervisors and the content of the next workshop was decided. This approach provided a rich and diverse analysis and strengthened confidence in the conclusions that were drawn (Silverman, 2014).

The triangulation process can consist of methods triangulation, triangulation of sources, triangulation through multiple analysts and theory triangulation (Patton, 2015). In this study, triangulation of sources was used in exploring available treatment and referral options: through collecting perinatal depression care pathways used across the three research sites; asking HCPs about the treatment and referral pathways that they often use in the community, hospital and health visiting services; through interviews and focus groups and asking women about the treatment options and referral process and if any had been offered to them by HCPs; through interviews, and in comparing these three sources during the data analysis process. In addition to this, findings across the three research sites and between two different participant population, women and HCPs, were compared and contrasted. Having a variety of HCPs working in nine different roles in NHS services, community services and GP services provided different perspectives, rich and varied data. In the third study, triangulation of sources was used in sharing and confirming with participants the key points emerging from the second study (which helped to adapt the BA therapist manual and guided self-help booklet) and again, after the first workshop, in comparing the outcomes of each workshop.

Reliability is regarded as the repeatability of the research, which reflects dependability in qualitative inquiry (Ritchie et al., 2014; Silverman, 2014; Shenton, 2004). Reliability in qualitative research can be problematic because of the nature of the research process, in that it cannot be replicated (Ritchie et al., 2014; Silverman, 2014; Shenton, 2004). Therefore, in this research, dependability was ensured through providing description of the methods and methodology, how they were planned and how they were used in the process. In addition, a reflective account was kept of the researcher's influence on the data analysis, interpretation process and attempts to reduce bias, all of which were reviewed and examined by the Thesis Advisory Panel members who

were outside of the supervision team (Ritchie et al., 2014; Silverman, 2014; Shenton, 2004; Krefting, 1991). Their objective views on the research process were taken into account at each stage of the research.

Confirmability is concerned with the objective analysis process, without the researcher's preconceptions or biases (Shenton, 2004). To ensure a rigorous analysis application, a 15-point checklist of criteria for good thematic analysis was used (Braun and Clark, 2006). In addition, the coding process and thematic map were evaluated by the consulting supervisors and all the stages of the analysis process are described in detail in the data management and analysis section (3.4) of this chapter, in the findings chapters and illustrated in the worksheets (see appendices 33, 34, 35, 36, 37, 38, 39, 40 and 41 for the second study; 42, 43, 44, 45, and 46 for the third study). The strengths and limitations of thematic analysis are also considered in the discussion chapter (see section 6.4.3).

Generalisability (external validity) is concerned with the extent to which the findings and conclusions of the study can be applied to the same population at large, which is referred to as transferability in qualitative research (Ritchie et al., 2014; Silverman, 2014; Shenton, 2004). Because the sampling strategy targeted a specific group of women and HCPs, it is hard to generalise the second study findings and conclusions to a larger population, as discussed in detail in section 6.4.2 strengths and limitations of the EBCD studies in the discussion chapter. However, the second and third study findings informed the adaptation of BA manual and guided self-help booklet, which can be tested in future research, in the treatment of perinatal depression.

3.7 Summary

In summary, this chapter has outlined the theoretical framework, methodological considerations and sampling, data collection and analysis methods related to the research aims for the second and third study elements of the thesis. The main reason for combining these two study elements in one chapter is that they are both within the qualitative tradition and the phases are sequential and interlinked, with one building on the other.

The aim of the second study was to explore women's experiences of perinatal low mood or depression and HCPs' experiences of providing care and support for women who have experienced perinatal low mood or depression. The data was collected through individual interviews with women and individual and focus group interviews with HCPs. The methodological approach of ethnography was used in the study and comprised of the 'discovery phase' of the EBCD approach.

The aim of the third study was to inform the adaptation of the BA manual and booklet, intended for delivery by MSWs for the treatment of perinatal depression. The data was collected through co-design workshops with the involvement of women and HCPs. This study comprised the 'co-design phase' of the EBCD approach.

A theoretical perspective of symbolic interactionism was used within the second and third study elements. Purposive and theoretical sampling methods and thematic analysis were used in the sampling and analysis processes.

The next chapter presents findings related to the second study element of the thesis: interviews with women and HCPs.

Chapter 4: Findings of the second study element of the thesis (discovery phase): Interviews with women and healthcare professionals

4.1 Introduction

This chapter outlines the findings related to the second study element of the thesis: women's experiences of perinatal low mood or depression and any care that they may have received and HCPs' experiences of providing support and care for women who have perinatal low mood or depression. Only findings related to the adaptation of the BA manual and booklet are shared in this chapter, to stay within the scope of the aims and objectives of the thesis; other findings will be published as manuscripts after thesis submission. This chapter draws on findings from the interviews with women and HCPs, the perinatal mental healthcare pathways and referral guidelines used by HCPs in different research sites, observations and field notes of the researcher. This avoids duplication of similar content and themes and helps build a robust rationale for the adaptation of the BA manual and booklet.

4.2 'Discovery' phase, the second study findings

4.2.1 Findings from the women's demographic forms

Fifteen women took part in individual interviews in 2019 (Table 9). All the women were white, aged 28 – 41 years (mean = 34.0 years; SD = 4.32). Over two-thirds of them (n = 11) were married or living with a partner and under one-third of them were single (n = 4). Over two-thirds of them had completed graduate study (11 = graduate; 2 = left full time education aged 16; 2 = postgraduate) and nearly all of them (n = 13) were working in a part-time job (1 = full time; 1 = not working). Two-thirds of women (n = 10) had one child (five had two children) and the youngest child was aged 1 – 4 years old. The mean age of these children was 2.3 years (SD = 1.23). Women's scores on PHQ-9 varied between 0 and 6 (n = 15), and the mean score was 2.07.

Table 9: Characteristics of women participated in interviews

Participant number	Research sites	Age	Deprivation score ¹ , 2019	PHQ-9 score	Age of youngest child	Number of children
W A 1	A	31	1,458	5	1	1
W A 4		35	24,324	2	3	1
W A 10		28	11,591	1	1	2
W A 11		30	11,300	6	3	1
W A 14		30	6,904	1	1	2
W B 9	B	36	26,356	0	2	1
W C 3	C	33	17,329	0	4	1
W C 6		-	29,202	2	1	1
W C 7		41	26,120	1	3	1
W C 8		28	17,024	3	4	1
W C 13		37	29,684	2	3	1
W C 15		38	13,045	2	1	2
W C 5		41	25,922	2	1	2
W C 16		35	20,541	1	3	1
W C 17		34	28,981	3	4	2

¹Public Health England, Index of multiple deprivation: A score of 1 reveals the most deprived area and 32,844, the least deprived.

Over half the women (n = 8) reported experiencing *perinatal* low mood or depression and the other half (n = 7) had experienced only *postnatal* low mood or depression symptoms. From those who had experienced *perinatal* low mood or depression, six had been diagnosed with it; of these, two received only psychological treatment (one had been offered medication but refused to take it due to ongoing pregnancy and received only therapy), one received only medication after giving birth and three received both medication and therapy in the antenatal and/or postnatal period. The psychological treatments received were CBT (IAPT), private counselling and counselling from a charity (based on one area) (its name is not provided here to maintain the participant confidentiality). This charity gives support and counselling for postnatal depression. Two women did not have a diagnosis of perinatal depression, nor had received any treatment. One woman described struggling to disclose her feelings to the GP because they did not ask about her feelings outright. The other woman expressed disclosing her feelings to the midwife, but it did not make a difference, and therefore, did not ask for help from other HCPs afterwards.

The reported duration of perinatal depressive symptoms varied from two months to three and a half years (n = 8). For a woman, the depression symptoms during pregnancy were occasional and did not appear after giving birth until a few months later.

Half the women (n = 7) reported experiencing only *postnatal* low mood or depression. Five had a diagnosis of postnatal depression through their GP; two received only psychological treatment (they were being offered medication but refused to take it because of continuing breastfeeding in one case and giving priority to resolving childhood issues through therapy in another case), and three received both psychological and medical treatments. The psychological treatments received were IAPT CBT, occupational health services counselling, Let's Talk CBT and a well-being course. Two women did not have a diagnosis of postnatal depression, nor receive any treatment. One of them stated disclosing her feelings to the health visitor, but they did not say anything. She also attended a GP appointment, but they only checked the baby and did not ask her about how she was feeling, therefore, she could not find an opportunity to talk about her low mood. Other woman described having the fear that social services would remove the child from her care, therefore, she did not disclose to the HCPs about her low mood or depression. She also stated trying to talk to her GP, but they said it is normal to feel like that and so she did not go further and seek help.

The duration of postnatal depression symptoms ranged from five months to three years (n = 7).

Over one-third of women (n = 6) described experiencing anxiety at some point during pregnancy and/or in the postnatal period because of the following reasons: feeling anxious about a potential miscarriage during pregnancy (n = 2); feeling anxious about going out with the baby (n = 2); feeling anxious about leaving the baby and going back to work (n = 2); and feeling anxious about being judged by people when going out (n = 1). A small number of women (n = 2) were prescribed medication for both anxiety and depression symptoms in pregnancy (n = 1) and the postnatal period (n = 1).

Almost two-thirds of women (n = 9) stated in the interviews experiencing depression (n = 3), low mood (n = 2), anxiety (n = 1), low mood and anxiety (n = 1), depression and anxiety (n = 1) and an eating disorder (n = 1) at some point in their life before their

pregnancy or in their previous pregnancy; however, over one-third of them (n = 6) did not state these problems in their demographics form, which shows the advantage of conducting interviews compared to asking participants to complete surveys.

4.2.2 Findings from the HCPs' demographic forms

Nineteen HCPs participated in the study (Table 10). Over half of them (n = 11) were midwives; 15% (n = 3) were health visitors; 10% (n = 2) were obstetricians; 10% were maternity support workers (n = 2); and 5% were GPs (n = 1).

Table 10: Characteristics of HCPs participated in interviews

Participant number	Research sites	Job role
H A 1	A (individual interviews)	Consultant obstetrician
H A 2		Specialist perinatal mental health midwife
H A 3		Antenatal clinic midwife
H A 4		Antenatal clinic midwife
H A 5		Bereavement midwife
H A 6		Antenatal clinical support worker
H A 7		Antenatal clinical support worker
H B 9	B (focus groups)	Community midwife
H B 10		Community midwife
H B 11		Health visitor
H B 12		Community midwife
H B 13		Community midwife
H B 14		Registrar Obstetrician
H C 8	C (individual interviews)	General practitioner
H C 15		Lead midwife
H C 16		Community midwife
H C 17		Perinatal mental health midwife
H C 18		Health visitor
H C 19		Health visitor

4.2.3 Findings from the interviews with women and HCPs

After analysing the transcripts thematically (Braun and Clarke, 2006, Braun et al., 2019) within NVivo 12.1 software, using field notes and collected pathways and referral guidelines, the following nine themes emerged from the data, which were the most

frequently highlighted patterns related to the adaptation of the BA manual and booklet: 1) triggers of perinatal low mood and depression; 2) recognising the signs of low mood and depression; 3) breaking the barriers to help women to disclose their feelings; 4) hidden face of perinatal low mood and depression; 5) needing attention while providing support and care for perinatal low mood and depression (by HCPs, friends and groups in social media, partners and parents); 6) helpful strategies in recovery; 7) women’s messages for improving perinatal low mood and depression care and services, for HCPs, and for other women who might be feeling as they have felt; 8) HCPs’ messages for improving perinatal low mood and depression care and services, and for women who are experiencing low mood and depression; 9) women’s and HCPs’ views on Behavioural Activation and maternity support workers (MSWs).

Figures 10 and 11 demonstrate the thematic map. These themes were generated using the original thematic maps (see Appendix 39 and 40) which include all the findings not only related to the adaptation of the BA manual and booklet but also those related to the perinatal low mood or depression experiences of women and caring and supporting experiences of HCPs.

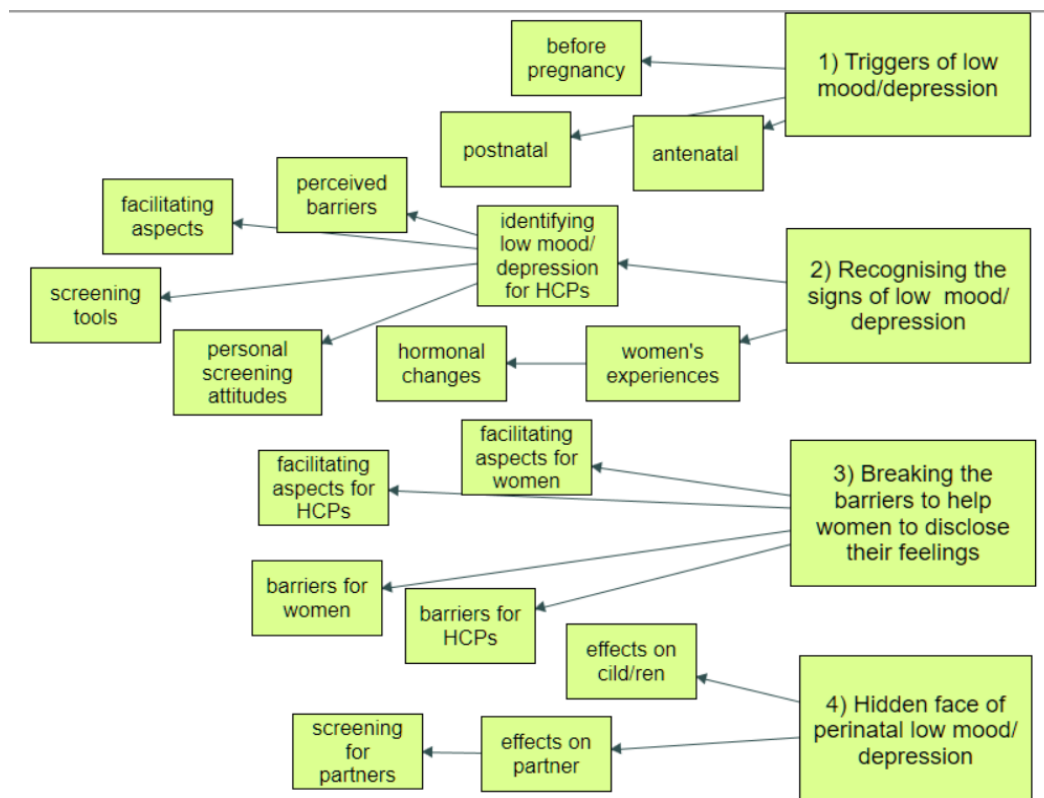


Figure 10: Thematic map for the second study element of the thesis (discovery phase) (continued the next page)

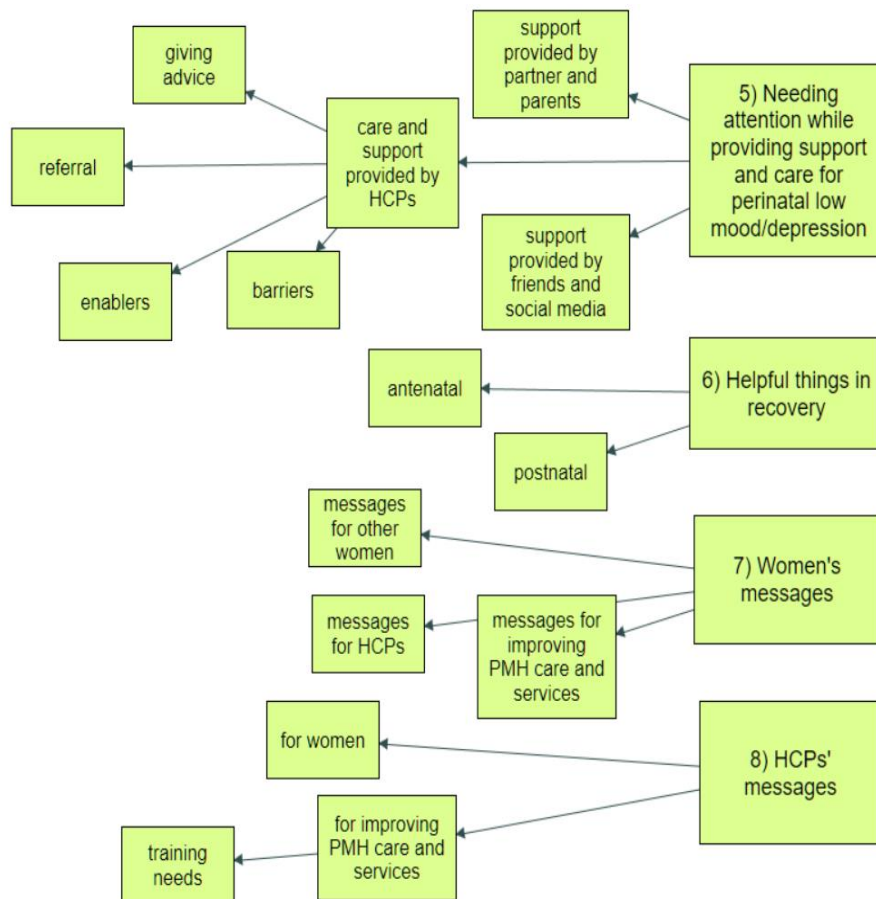


Figure 11: Thematic map for the second study element of the thesis (discovery phase)

1) Triggers of perinatal low mood or depression

The women described having some triggers in their lives as the major reason for their antenatal and postnatal low mood or depression experiences. The reported triggers of *antenatal* low mood or depression were: history of low mood or depression and/or anxiety; pregnancy-related symptoms (e.g. morning sickness, hyperemesis, tiredness, sleeping problems); history of infertility or having miscarriages; lack of support from their partner, family or friends; being unhappy with the partner; and major life events in their lives (e.g. marriage, unplanned pregnancy).

“...I didn’t have any support or anybody and I was shopping for things on my own, all the baby clothes and I wanted somebody to share things with and there was nobody there so that sent me depressed really. No friends or anything. My family could have come but they were too far away...” (W C 15)

The reported triggers of *postnatal* low mood or depression were: struggling to get used to a new life with a newborn (e.g. sleep deprivation, problems with breastfeeding, changes in their roles, finding hard to manage housework and personal care) or struggling in transition to be a parent; physical birth-related complications (e.g. tear, haemorrhage and kidney infection); hormonal changes and baby blues; and lack of information and emotional support from HCPs at hospital.

“...I had a third degree tear... it was like 5 hours in total and I hadn’t seen him, so that was like traumatic anyway and then I felt fine like the first week maybe and then it like hit me like a ton of bricks and I felt like he didn’t love me. That always upset me for some reason. I felt like he didn’t like me at all and I was doing everything wrong... I think it was from the trauma of the birth and it just spiralled so quickly... I was feeling depressed...” (W A 10)

One woman described going back to work as a trigger of low mood or depression and anxiety after maternity leave, while other woman described it as having her identity back and feeling normal again. They reported feeling anxious about starting work and worried about its potential effect on bonding with the baby.

“...I got a letter from work telling me I had to arrange my hours for going back to work and I just felt like a weight of anxiety about leaving him. It sort of affected my bond with him. I felt I like, how am I ever going to leave my baby and it was sort of from then on really. Probably for a few months after that I started feeling quite low...” (W C 5)

2) Recognising the signs of low mood or depression

Women reported experiencing difficult situations before getting pregnant, during pregnancy or in the postpartum period, as explained above and developed low mood or depressive symptoms with/without anxiety as a result of that. The most commonly used words to describe their feelings *during pregnancy* were feeling low, depressed, down, tired, exhausted, sick, emotional, worried, anxious, awful, rubbish and isolated. Most women expressed not feeling excited about the baby and a few did not want to carry on the pregnancy and did not want to become pregnant again. They reported being unwilling to go out, to socialise with other people, to talk to someone and to do

anything; therefore, there was a decrease in their activities and communication within the family and with others. Women's other descriptions were crying without any reason, having poor appetite or eating too much and having sleeping problems.

"...I think going from a normal happy quite, I was crying a lot, sleeping a lot and just generally horrible... a couple of times I even had a conversation with my husband to think about ending the pregnancy because I just couldn't cope with feeling that sick anymore..." (W C 3)

The feelings of women in the *postpartum period* and their description of it was slightly different from those in the antenatal period. Common feelings of women in the postnatal period were feeling low, depressed, exhausted, emotional, tired, lonely, sad, upset, worried, stressful, anxious and guilty. Women expressed wanting to be alone, to isolate themselves and not to go out, not to see people and not to talk to anyone, because of their low mood, depression or anxiety (a few cases). They reported having feelings of not being good enough or not being a good mother and thoughts of 'everyone would be judging them'. They expressed experiencing a lack of energy and lack of motivation to do anything and as a result of that, the desire to stay in bed and not want to do cleaning, cooking or washing the dishes. Some women stated experiencing poor appetite, sleeping problems, constant crying and bonding problems with the baby. A few women reported having thoughts that they were 'going to feel like that forever'.

"...I just started to just like have no motivation to do anything. I really struggled to get dressed. I'd just sit and watch TV and I remember one day we went out for a walk and I just couldn't even walk home... I was crying. I didn't really know why..." (W C 13)

Most women were aware that due to hormonal changes, they might experience baby blues after giving birth, while one of them reported never hearing about it before. They described baby blues as starting on the third, fourth day or a week after giving birth and feeling low most of the time. Almost all of them were expecting this to occur and they expressed it as normal and hormonal. However, low mood symptoms continued for weeks and constant crying for no reason started afterwards and they reported that it was not normal to feel like that at that point. As one woman stated,

“...You assume that it’s just part of it because you’re so tired hence overwhelming and then afterwards I felt it more... People say you get the baby blues. Normal. But I knew it wasn’t normal because it just wasn’t. It wasn’t just sadness, it was complete misery...”
(W A 11).

HCPs were asked in the interviews about what signs they look for to identify low mood or depression. They reported looking for body language (e.g. look sad, tearful, quiet, subdued, look away and not holding eye contact, not talking or engage the conversation), women’s description of their hopes and fears about pregnancy and the baby, whether having sleeping problems, eating or drinking problems or bonding problems with the baby, if they feel low, depressed, overwhelmed or worried about going out, not wanting involvement with the baby, isolating themselves, not wanting to engage in their usual activities or appointments, not wanting to leave the house, not having people around supporting them, not having a shower and/or staying in their pyjamas in the afternoon.

3) Breaking the barriers to help women to disclose their feelings

While some of the women reported sharing their feelings with their partner, close friends, friends from social media, mother, GP, midwife, health visitor, mother and baby group friends and occupational health services, others expressed hiding it from HCPs and a few of them hid it from their partner and family as well while struggling with low mood or depression in the antenatal or postpartum period.

Women who disclosed their feelings to anyone, reported finding it very helpful in improving their mood and feeling relieved after sharing. As one woman stated, *“...once you start talking and you meet other mums who’ve experienced similar things like that you realise how normal it is and yeah that helps...”* (W C 13).

“...I can’t be this way, something has to happen, I have to talk to people. I have to be more open. I have to ask for help. I’m not an island...” (W A 11)

A few women expressed seeking help from HCPs due to pressure from their partners who recognised the mood changes of the woman and supported her to ask for help from professionals such as midwives, health visitors and/or GPs. This finding shows the

importance of support from the partner for the woman in accessing services and seeking for help.

The women reported the aspects that facilitated their disclosure of their feelings to the HCPs (i.e., midwives, health visitors and GPs). Table 11 illustrates the factors that helped women to disclose their feelings. These findings show that in addition to being honest to HCPs, HCPs' approach to women, seeing the same HCP, spending considerable time, building trust and rapport, have the biggest impact on women's disclosure of their feelings to the HCPs.

Table 11: The factors facilitating women's disclosure of their feelings

<p>Disclosure to the midwives</p> <ul style="list-style-type: none">• awareness that the conversation with the midwife would remain confidential• feeling safe to open up to them• trust in midwives that they are trained professionals who can give the correct advice <p><i>"...I knew it was all confidential so I felt safe telling them [midwives] anything so I knew they were trained to give me the correct advice so I felt safe with them..." (W C 15).</i></p>
<p>Disclosure to the health visitors:</p> <ul style="list-style-type: none">• being honest about their feelings• seeing the health visitor at home which is a natural environment for the woman• knowing that they are there 50% to check the baby and 50% to check the woman• feeling that the health visitor is not in a hurry and she has enough time to talk to• seeing the same health visitor each time and feeling comfortable talking to them and having a rapport with them• spending at least 30 minutes with the woman to let her come out of the mask she may be hiding behind• picking up on signs that the woman seems sad• asking direct questions to check the woman's mood

- scheduling extra visits to the woman's home

"...I'd met her a couple of times before, but it was hard sort of sharing something so personal with somebody you don't know but she [health visitor] did everything she could to put me at ease. Like I say, she had a cup of tea, she sat and we had a really long chat. She gave me her time when I needed it. She probably didn't have a lot of it. So it was difficult but she did.. she was absolutely lovely and she made it quite easy in that situation..." (W A 4)

"..that was a much more natural meeting and much more natural environment [at home]. It just felt much more at ease to say anything.." (W A 1)

Disclosure to the GPs:

- being honest about their feelings
- the non-judgmental approach of GP to the woman
- the GP to be knowledgeable about the sign of depression and help and support sources and referral processes and explaining this information to the woman clearly

"...I think my GP was very non-judgemental and knew what I needed to do, knew who I needed to see and he was the one who arranged for me to see my midwife in the first instance... and then the mental health midwife came and spoke to me as well so. And I think they were very good at explaining to me that to have a healthy baby you have to have a healthy mum..." (W B 9)

The HCPs reported using certain enablers to encourage women to talk about their mood and disclose their true feelings: asking Whooley questions for the screening of low mood and anxiety and making clear that asking these questions are part of their job and that they ask every women; asking PHQ-9 and GAD-7 for further exploration if they suspect depression or anxiety; generalising depression in conversation with women by saying that *"you know what, depression affects 1 in 4 people and it can be fleeting"* (H A 1); building a rapport with individual women and getting to know them quite well; seeing women at their home environment. They mentioned other indirect enablers, such as: extensive professional experience of HCPs; increased awareness of perinatal mental health on public; experiencing depression in the past (personal

experience); sharing a personal story; talking about things like adjustment to parenting; telling women that they have got enough time to listen to them; explaining to women very clearly that they are there to support them; and encouraging women to be open about their feelings.

“...We’re asking these questions not because we’re judging you, not because we’re going to you know, we’re not going to take the children away if you answer in the wrong way or you know we just want to offer support. If you say that even before you ask the question and you let them know why you’re asking the questions, I think you’re more likely to get an honest answer or more likely to get a sort of opening up about things...” (H B 10)

Some of the women described hiding their feelings from their family and friends because of the following reasons: finding it hard to admit it; finding it hard to open up to someone about it; fear of being judged by others and thinking it as a failure. As one woman stated, *“...I think it’s hard to admit that you’ve got a problem in the first place. For me anyway. It’s hard to say that you’re struggling I think sometimes. When you see like you see other mums and babies and they seem so happy and you see social media and it seems everyone is having a great time and I think it’s hard to admit to people that you’re not...” (W C 5).*

Some women described the barriers that prevented them from disclosing their feelings to the HCPs. Table 12 collates these barriers as identified by the women. The highlighted patterns in most women’s transcriptions were: not being asked about their mood or how they were feeling outright by HCPs; not being honest about how they were feeling when they were asked about their mood or were given a questionnaire to fill in; being dismissed or neglected by HCPs when they talked about their feelings; fear that social services would remove the child from their care; fear of being labelled as a bad mum; and not being able to think rationally while experiencing low mood or depression and giving irrational decisions.

Table 12: Barriers stopping women from disclosing their true feelings

Related to women themselves:

- not being honest about how they were feeling when they were asked about their mood or were given a questionnaire to fill in
- thinking that the HCPs do not care about how they are feeling
- fear that social services would remove the child from their care
- fear of being labelled as a bad mum
- not being able to think rationally while experiencing low mood or depression and giving irrational decisions

"...People like me won't want to divulge their true feelings in fear of it being escalated to other services to protect their child and I think that's a barrier that needs to be broken down. It's like the mother and the baby come together..." (W C 6)

Disclosure to the midwives:

- seeing different midwives each time and could not develop a rapport with them
- time constraints of the midwives
- being dismissed or neglected by midwives when they disclosed their feelings
- the midwives thinking that it is hormonal and normal

"...I remember speaking to the midwife and saying, "I've had depression in the past, I know I'm at risk of postnatal depression, I'm really struggling" and she was just like, "oh it's baby blues, you'll be fine". Never mentioned it. I never saw her again..." (W C 3)

"...So quite often when I went to the midwife for check-ups they were like, "How are things?" "How are you doing?" "How are you feeling?" but I don't think it ever went into how is your mood, you know, how are you coping..." (W A 1)

Disclosure to the health visitors:

- feeling like the health visitor was there for the baby not for the woman
- being dismissed or neglected by health visitors when they disclosed their feelings

"...when the health visitor came at the ten months check, I told her how I'd been feeling and I said that I get quite frustrated when she's not feeding properly and I said that that's affecting my mood. I said that it affects me... but she didn't say anything... She didn't advise me on anything..." (W A 14)

Disclosure to the GPs:

- thinking that the GPs do not care about how they are feeling
- the GP saying it is normal to feel like that
- the GP's approach to the woman that 'you can't come in here and get a 10-minute appointment and expect to talk about everything that is wrong with you'

"...going to the GPs was horrible because I just, felt like, like I said, they weren't listening to me, I had to go in with an agenda each time and say, I had to prepare, I knew I had to be prepared to say I don't want the medication so, that was quite uncomfortable, quite upsetting and anxiety provoking when you're already feeling quite low anyway..." (W A 4)

HCPs reported the perceived barriers that prevented women from disclosing their feelings to them as: not recognising the signs in themselves; not feeling ready to disclose their feelings; wanting to deal with it themselves; not having a relationship with the HCPs because of time constraints or seeing different midwives at each appointment (no continuity of care); not being alone at the appointment with the HCP; feeling guilty that they are not as happy as they thought; thinking "*that people might judge them to be not very good mothers*" (H B 11); women's fear that social services would remove the child from their care; and misleading information in the media about social workers. Some HCPs expressed their frustration that not disclosing low mood in the antenatal period could lead to deterioration in the postnatal period.

"..it can be very frustrating when you're sure there is something wrong with somebody but they won't disclose it. So all you can do then is sort of speak very generically. Saying some ladies feel like this and it's normal to feel like this at

some point you may feel like this and then if you do we're here to support you with this and this..." (H C 17)

"...so the other thing is a time thing that we have 20 minute appointments for women and we've got to do all this and all the other things and if someone's fine and doesn't have any problems, that's great. If someone is not well and needs more support I am very aware that other people are waiting to see me. I always try and give the women the time they need but sometimes we just don't physically have the time to give them the support they need..." (H C 16)

4) Hidden face of perinatal low mood and depression

Most women expressed having problems with bonding with the baby after giving birth and two cases reported having thoughts of giving the child for adoption. Women described not enjoying taking care of the baby but nevertheless doing it in a mechanical way and feeling like they were losing their identity with the baby, who was dependent on them all the time. They described having a block between them and thoughts about the baby not liking them:

"...I think for the first four weeks I found it difficult because I just looked at her like she didn't like me. She hated me. She preferred other people. That made me sad...the first month was really bad. I didn't connect with her at all..." (W A 11)

Four of five women who had two children expressed that their older child was aware of their low mood or depression. As the first woman stated, *'the first one, if I cry, she cries. She can see that I'm upset'*. The second woman expressed pretending to be excited for the older child when he told her something; however, she felt that the child could see through this pretence. The third woman reported that she did not want to play with her child when she felt low in mood. The fourth woman described how, because of her low mood, she could not respond to the older child's needs properly.

"...I did feel quite a lot of anger and frustration with her and her behaviour. But I think I couldn't always respond to her very well because I was feeling so low and it was hard to try and respond positively to her sometimes..." (W C 5)

“...if I was feeling really tired and not wanting to play with her and things like that..” (W C 7)

Two women reported not coping with postpartum depression and having suicidal thoughts; however, no one expressed the intention to harm themselves.

“...I thought this is ridiculous. I can't function. I can't do things. I have to really sort things out. It's either do something or do nothing and throw myself under a bus...” (W A 11)

“...I said to her my thoughts are not good. They've gone from being, I want to run away, to I want to die...” (W C 17)

Twelve women expressed that depression affected their relationship with their partners and some partners also experienced low mood or depression symptoms and some level of anxiety as well. In one case, the partner started taking antidepressants as a result of the woman's depression and in another case, the partner went for marriage guidance counselling. Women described having conflicts with their partners due to: poor communication between them; struggles both of them faced in getting used to a new life with the baby; and partner's concerns about the wellbeing of the woman and putting pressure on her to seek help from HCPs. Other challenges related to partners included: thoughts that the partner does not understand her needs; the partner goes back to work after two weeks paternal leave and the mother struggles with taking care of the children and pets on her own, in addition to cooking, cleaning and washing the dishes, without any support from the partner or family and friends. Many women felt resentful towards their partner. This was exacerbated where the partner was perceived as unsupportive and where there were conflicts within the wider family.

“...I think he felt very sad for me and he was very fearful because he thought that I was going to kill myself. Yeah he was very anxious at that time...” (W C 8)

Some women were aware that there was a lack of proper mental health and support services for partners who experienced mental health problems in the perinatal period, and they noted that HCPs did not ask how partners were doing.

From the professional perspective, HCPs concurred that there was no formal screening for partners regarding their mental health in the perinatal period but that this *was* now on the agenda. HCPs also stated that at the first booking appointment they asked the woman if there was a family history or partner history of mental illness. HCPs stated that if the partner had a mental illness and presented at the appointment, they would give support she/he needed, would also ask GAD-7 and PHQ-9 to be given to their partner and make a referral to the IAPT or GP if appropriate. They pointed out that *“it’s more a bit of a supportive role rather than a huge amount of responsibility for it”* (H B 9).

“...it’s becoming bigger on the agenda as a recognized problem. Postnatal depression in men. I do ask dads about their mental health and their mental wellbeing, especially, well I ask them all, but especially when it’s dads that have witnessed a traumatic birth, for example..” (H C 18)

5) Needing attention while providing support and care for perinatal low mood or depression

a) Attention from HCPs

Women described the mental healthcare provision and support from some of the midwives, health visitors and GPs as not meeting their expectations and some women expressed a lack of emotional or psychological support by these HCPs during pregnancy, at hospital and in the postnatal period.

Reports regarding midwives asking pregnant women about their mood or how they were feeling varied. Some women reported them not asking about their feelings antenatally or being given a questionnaire to fill in, while others expressed being given a questionnaire to fill in and/or being asked verbally how they were feeling.

“...Yeah, the nurses and the midwives suspected that something wasn’t right but they didn’t act on it. They didn’t do anything. They just sort of kept trying to bring [name- the baby] to me and I just didn’t want her. I didn’t want to have her near me...” (W C 8)

Women who received support from their midwives expressed being given advice to attend groups specific for pregnant women, making an appointment with their GP, calling the talking therapy services, and calling the midwives if they needed.

The majority of women expressed that the health visitors asked about their mood verbally or gave them a questionnaire to fill in, while a few of them stated that the health visitors did not ask about their mood and did not give appropriate advice when they sought help from them. As one woman stated, *"...I remember it was all very much focused on how's the baby doing, what size is the baby. Is the baby growing as it should be. Focused on measurements and scans. No there was not really a focus on asking how I was at all..."* (W B 9).

Many women stated that their health visitors were good at giving practical advice on how to deal with postpartum low mood or depression and giving advice on other professional help sources that would be helpful. The reported practical advice given by most health visitors included: talking to partner, family and friends about it; asking for physical help from family and friends on housework; not putting too much pressure on themselves; attending mother and baby groups; going out of the house for whatever reason; eating and drinking healthily and sleeping properly; and having time for themselves. The reported advice on professional help and support sources given by the health visitors included: making an appointment with their GP; calling IAPT or Let's Talk services for receiving talking therapy; and providing information to women about starting medication and its side effects in the first couple of weeks. Other advice provided to women included: supporting the mother in dealing with older child's behaviour and dealing with the child's sleeping problems.

"...We had a really nice health visitor who came out who weighed my daughter, asked about mood, asked about feeding, things like that..." (W C 7)

The HCPs who participated in the study described the support and care that they provide to women who experience perinatal low mood or depression. Their advice to women was: to seek support from family; to eat and drink regularly; quality sleeping; to attend activities; to attend antenatal and postnatal classes and groups; to exercise; to get outside in the fresh air; to do yoga or mindfulness; to walk; and *"making sure you're not trying to carry on at your 100 percent life style working full time doing*

everything else and coping with this and just accepting that you need to slow down a little bit to look after yourself” (H C 16). Other advice included: using social media to find support groups; suggesting Pandas, Mood Juice, Mind, Papyrus, Home Start, Samaritans and other locally available charities supporting women with postnatal depression (names omitted here to maintain confidentiality).

“what I tend to say to people is... if you have a physical injury, like you broke your leg, you might need surgery, you’d probably need painkillers, you might need antibiotics, you might also need some physiotherapy, you might also need some support from somebody to help run you around and it’s a similar thing where there’s lot so different layers of treatment that all complement each other, or they should. But you know there’s not one single thing that’s going to usually fix it, it’s usually a combination of different things that will start to make you feel a bit better“ (H C 15)

Some women stated feeling like they were surrounded by healthcare professionals who work in maternity services and health visiting services and that this made it a lot easier to receive information about perinatal low mood or depression. Easy accessibility of healthcare professionals (e.g. health visitors, GPs), medication and psychological therapy services (e.g. Let’s Talk, IAPT) were other factors that facilitated reaching out to these services. The personal characteristics of individual healthcare professionals and their approach to women were mentioned as important in building a relationship and trust, all of which affected their treatment preferences.

Some women identified factors that affected their choice of treatment and facilitating aspects of receiving medication and talking therapy. Table 13 illustrates these facilitating aspects. The most frequently mentioned was being given information about the available treatment options, their pros and cons and potential effect on the foetus or breast milk.

Table 13: Facilitating aspects of receiving treatment for women

Factors affecting women's treatment choice/s and facilitating aspects

- the HCPs explaining the treatment options clearly and their pros and cons, which helped them to make a decision and start medication and/or talking therapy
- some GPs had supportive attitudes towards women to taking medication, which affected women's decision to take them
- a few women found it easier to take medication every day at the same time, rather than going somewhere for a talking therapy
- some women found it easier to understand the underlying cause of their depression through talking therapy
- the phone number of Let's Talk was written in the given Personal Child Health Record (the red book).

"...I've seen that number all over anyway because when you get given their red book which is for the measurements and stuff, it has it at the front, Let's Talk and the number. So it's easily like accessible and it wasn't that long..." (W A 10)

All 15 women who participated in the study expressed some concerns about perinatal mental health care services and support provided by midwives and/or health visitors and/or GPs, expressed dissatisfaction and/or stated that the provided treatment options by HCPs did not meet their expectations. Table 14 shows the barriers to women receiving support and/or treatment. Most women described the barriers as related to themselves (i.e. not admitting the illness, not disclosing/ hiding their feelings due to stigma and fear of social services), related to HCPs (i.e. not being asked about their mood; their approach to them, such as being neglected or dismissed when asked for help or saying it is normal and hormonal) or related to services (i.e. not enough options to choose from and long waiting list).

Table 14: Barriers to receiving support and/or treatment

<p>Related to women themselves:</p> <ul style="list-style-type: none">• not admitting the illness• not disclosing their feelings to the HCPs due to stigma• fear of social services involvement• women’s fear of medication contaminating breast milk and its potential harmful effect on the baby• women’s fear of becoming addicted to the medication
<p>Related to HCPs:</p> <ul style="list-style-type: none">• not asking outright how the woman is feeling• not paying attention to the women’s needs when women disclosed their feelings• being neglected or dismissed by HCPs when asking for help• thoughts that HCPs will dismiss the feelings as normal and hormonal• being asked to self-refer to IAPT/ Let’s Talk which women felt was not possible in that mind space• not being informed about the support and treatment options and their pros and cons
<p>Related to services:</p> <ul style="list-style-type: none">• not having enough options to choose from except medication and IAPT/Let’s Talk• finding attending a face-to-face talking therapy impractical with a baby• long waiting list in IAPT• finding the content of IAPT unhelpful and unrelated to postpartum depression <p><i>“...Well there was the waiting times and then there was the fact that it didn’t feel, the IAPT didn’t feel targeted to postnatal depression. It just felt like a very broad-spectrum kind of like a talking therapy that wasn’t pin-pointed to unravelling why someone was feeling like that. It was very clinical. It was not very emotional or comforting. It was just very clinical...” (W C 8)</i></p>

When asked about the referral process, a few HCPs brought with them the perinatal mental healthcare pathways documents that they use and the researcher took photos of the pathway and guidance (with permission from the staff), showing the referral process seen on the noticeboard at a hospital. The pathway for perinatal mental health consists of asking Whooley questions and then PHQ-9 and GAD-7 if needed. Then, advice, support, extra visits and self-help sources are offered if the risk is low (mild symptoms), women are referred to IAPT, Let's talk, counselling services or GP if the risk is moderate (moderate symptoms), and are referred to perinatal mental health midwife (if one exists), specialist perinatal mental health team (if available), crisis team, or Accident & Emergency if the risk is high (moderate or severe symptoms). The pathways were similar across the different research sites.

The HCPs described how the electronic referral process made it easier to refer someone (in one research site). The reported barriers for referral were difficulties in finding the forms on the hospital computer system, reluctance of women to self-refer and non-engagement with the services provided as a result.

b) Attention from friends and groups on social media

Apart from professional care and support from HCPs, women reported receiving support from their friends, social media, partner and parents.

Most women found talking about their feelings with their friends and seeing them face to face helpful in improving their mood. As one woman stated, *"...I found that actually trying to be proactive and even if it was just going and meeting a friend for a coffee with the babies helped me to maybe lift out of the low mood a little bit. So I think having support networks is really important to people. Even if you don't talk about how you're feeling you can kind of just have a little bit of time off from thinking about how you're feeling, if that makes sense..."* (W C 6)

Some women stated finding it easier to talk about their feelings with their friends on social media. Women expressed that talking to other women who had experienced the same feelings and receiving advice and support based on their experiences, was very important for them. Other women expressed needing a face to face conversation rather than online chatting. As one woman stated, *"...all my friends on Facebook who*

live miles away, I messaged them and they told me what to do and gave me advice. I shared it with people but not face to face. I needed that face to face I think so that was what made me more depressed because I didn't have the support around me..." (W C 15).

c) Attention from partners and parents

While half the women described that their *partners* were very supportive and helpful with looking after the child or children, doing the housework, making decision of seeking help from HCPs, waking up in the night and taking care of the baby, looking after the children when the mother went out to socialise, the other half described their partners as unsupportive and as not understanding their needs, which led to conflict between them. Women also stated that it was sometimes hard to express their needs properly to their partners while struggling with low mood or depression and their partners were not supportive in talking about their low mood or depression, helping with housework, looking after the children, deciding to seek help; most importantly, partners did not understand women in terms of their illness, what low mood or depression is, the nature of the illness and how to support a mother with depression.

"...I tried to talk to my partner about it but I don't think he appreciated what I was trying to say. He's always focused more on the little things that were getting me down like not being able to do wash a mug or pick up a wrapper that was on the floor. So I was saying to him, I need a bit more help with that sort of thing and he took it a little bit...well he took it as a criticism of he's not doing enough which that's not how it was meant but that was the only way that I could express it. That's the only way I could ask for help was in terms of asking for physical help in doing things..." (W A 1)

Most of the women were supported by their *parents* in terms of looking after the child, advising woman based on their own experiences with depression or anxiety, and supporting them to make an appointment with the GP and talk about their feelings to the health visitors. However, a few women did not receive support because of poor communication in the family, parents' lack of interest, parents' pressure on the woman

to have a baby or pressure put on them by some parents to stay at home and look after the child and not to go to work.

“...I had to phone my mum to come and like walk home with us. I was crying. I didn't really know why.... Nobody said anything but I think my mum. My mum suffered as well so I think she maybe recognised and would help me with things come and do housework around the house for me and things like that...” (W A 13)

6) Helpful strategies in recovery

a) Antenatal period

Women expressed that apart from professional help sources (e.g. taking medication and attending CBT sessions), other sources were also helpful in improving their low mood or depression in the antenatal period. The most mentioned helpful strategies were talking with friends, having support networks and taking time for themselves. Other sources are listed in Table 15. Some of these coping strategies (e.g. antenatal classes, having support networks) were recommended by the midwives while others were the women's personal coping strategies.

“...in the early hours of the morning when everyone's asleep, you've got that group of friends, this group of contacts that you can just message on your phone...are you awake? Yes I'm awake. How are you doing? You know, that sort of thing was really useful...” (W B 9)

b) Postpartum period

In addition to professional help sources (e.g. medication, occupational counselling and CBT), the following strategies were helpful for most women in recovering from postpartum low mood or depression: talking to people about their feelings; going out of the house for whatever reason (e.g. shopping, walking, seeing friends and family, attending mother and baby classes); and scheduling activities that they like (e.g. having a bath, going for a walk, going for shopping, reading a book, watching a film). Other helpful strategies in recovery are listed in Table 15.

Table 15: Helpful strategies in recovering from antenatal and postpartum low mood or depression

Antenatal low mood or depression	Postpartum low mood or depression
<ul style="list-style-type: none"> • joining antenatal classes (e.g. breastfeeding, caring for the baby, first aid, yoga) • exercising (e.g. swimming, doing yoga) • talking with friends and having support networks • taking time for themselves 	<ul style="list-style-type: none"> • attending mother and baby groups (e.g. baby massage, baby music, baby sensory) • meeting with friends • going out of the house for whatever reason (e.g. shopping, walking, seeing friends and family, attending mother and baby classes) • asking people to look after the child and/or for physical help on housework • eating and drinking healthily • quality sleeping • exercising (e.g. yoga, Pilates, walking) • scheduling activities that they like (e.g. having a bath, going for a walk, going for shopping, reading a book, watching a film) • talking to people about their feelings • finding support groups from social media who have experienced perinatal low mood or depression and/or anxiety and sharing their experiences and giving support to each other • taking time for themselves (e.g. having a bath, doing make-up, hairdressing) • putting less pressure on themselves.

“...Talking out, expressing it. Knowing that there was professional help but also like friends and family that would help as well. That just changed everything I think. Just expressing it. Telling my mum. Telling the health visitor and then telling like a few friends. It did just change everything. It made everything so much easier...” (W A 1)

“...Reaching out to other people, asking for help looking after her so that I could do other things and looking after myself, so having baths, reading a book, watching a film, whatever it is, to make myself feel normal and treating myself...” (W C 7)

7) Women’s messages

a) Messages for improving perinatal low mood and depression care and services

Women expressed their messages for improving perinatal low mood and depression care very clearly. The most frequent messages were: the need to improve perinatal mental healthcare services, their availability and accessibility for perinatal women; informing women about locally available services, updating HCPs’ knowledge about the available help and support sources and referral processes; updating knowledge of the HCPs so that they picked up on signs of perinatal low mood or depression; and increasing the length of the antenatal midwifery appointments. Women’s messages are listed in Table 16.

“...a woman won’t really open up and tell you how she’s feeling, I certainly wouldn’t, because I thought I’ve only got 5 minutes. I’ll be blubbing. I’ll be in floods of tears. I can’t get myself together in 5 minutes to leave and go out into the waiting area so I think just be aware of just how fragile the human mind can be especially when it’s pumped full of lots of pregnancy hormones and yeah, don’t make assumptions that a woman’s okay just because she looks to be okay outside...” (W B 9)

“...when you’re in the hospital, they give you a little pack about baby and feeding and things like that, maybe put a pack in there about mood and things like that...” (W C 15)

Table 16: Women's messages for improving perinatal low mood or depression care and services

- Improving perinatal low mood or depression services
 - the diversity of talking therapies
 - the mode of delivery (e.g. face-to-face, group sessions, internet-based, telephone-based)
 - their availability and accessibility for perinatal women
 - decreasing waiting times for therapies
- including perinatal mental health and transition to parenting topics to the content of antenatal classes and National Childbirth Trust (NCT) groups
- launching antenatal and postnatal classes for women having mental health challenges
- improving IAPT content and including treatment of perinatal depression and anxiety
 - grouping women who have experienced perinatal depression or anxiety with each other in the group therapies rather than people with general depression or anxiety
- improving psychological support in the hospitals for women who had miscarriages, stillbirth or neonatal deaths or had traumatic births
- making locally available services known to the women (e.g. providing them a leaflet in the pregnancy pack including mood changes and support sources)
- making referral or self-help processes easier for the women
- updating knowledge of HCPs about the available help and support sources and referral processes and to pick up on signs of perinatal low mood or depression
- increasing the length of the antenatal midwifery appointments
- involving partners in the antenatal appointments and the midwife to give them information about the importance of maternal and paternal mental wellbeing
- routinely checking the women's and partner's mood at every appointment
- extending the postnatal period from 12 months to 24 months or more
- seeing the same midwife and the health visitor during pregnancy and after giving birth to build a rapport with them, which is crucial for women in building trust and disclosing true feelings to the HCPs.

b) Messages for HCPs

Women were asked in the interviews if they would like to say anything to the HCPs. The messages in Table 17 were extracted from the women's transcripts related to the HCPs. The most highlighted messages were: women's desire to being asked outright about their mental health at every appointment; HCPs to improve their communication skills and be knowledgeable about the help and support sources and providing this information to women; HCPs to do the referral on behalf of women; and HCPs to respect women's decisions if women do not want to breastfeed or take medication for depression.

c) Messages for other women

All the women who participated in the study highlighted the importance of talking about their feelings with someone who is good at listening, for example, partner, family, friends, midwives, health visitors and GPs, and the importance of seeking professional help from HCPs as soon as possible when they realise that there is something wrong with their mood or thoughts. They also added that it could take time to find the right help and support sources but to never give up and keep asking for it. Some women noted the stigma around perinatal mental health, and they recommended that women not to feel ashamed, not to be embarrassed, not to feel like a failure or a bad mum and not to hide their feelings, because the majority of women experience similar feelings but not everyone is open to sharing them.

"...It would be having postnatal depression it doesn't mean that you're not a good mum. It doesn't mean that you are a bad person. It happens to anyone and it happens to people who least expect it and if you are open and honest from the start, you can get better quicker. You can have that time back with your child and you're not going to feel like that forever..." (W C 8)

Table 17: Women's messages for healthcare professionals

- HCPs to update their knowledge on the difference between the baby blues and postpartum low mood or depression and the signs, specifically that just because a woman is dressed and wearing make-up does not mean they are not experiencing depression
- HCPs to ask every woman outright how their mood is and how the pregnancy is going
- HCPs to improve their communication skills: listen to the woman, what they are experiencing and how they are experiencing the pregnancy
- HCPs to respond to the woman if she says she is feeling low and HCPs to not leave the conversation there if a woman feels down, checking-in again sooner and not leaving a gap until the next appointment
- HCPs to not see the woman as a number, to make eye contact with the woman and to not eye roll
- not to expect the woman to self-refer to a mental health service but to do it on behalf of the woman
- if there is a birth complication, HCPs to be aware of its potential psychological effects on the woman and to give support before discharging from the hospital
- HCPs to decrease the poor communication and misinformation in the hospital
- HCPs to not put much pressure on the woman to breastfeed the baby if the woman does not want to
- HCPs to not put pressure on women if they do not want to take medication for depression

“...sometimes you sort of say, “how are you doing?” “Yeah I’m fine” and you say it when you’re not fine just because you feel like it’s quite a light-hearted conversation. Whereas I think if someone sort of gave you eye contact and said, “no actually really how are you feeling?” and made it look like they had time to speak to you and wanted to know the answer, I think that would be how I would open up and if I wanted to ask someone else, that’s what I’d try to do...” (W C 3)

8) HCPs' messages

a) Messages for improving perinatal low mood and depression care and services

The HCPs were asked if they had any messages for improving perinatal mental health care and services. The messages in Table 18 were mentioned in the interviews. The most frequently mentioned messages were: willingness to spend more time with women to support them psychologically; women to be able to see the same HCP (i.e. consultant and midwife) at every visit; filling in the gap, the grey area where a woman has got low to moderate depression who does not need a referral but support from the HCPs; more training for HCPs about basic suggestions that they can offer women with low mood.

"...there's always often a grey area where, somebody has not got a severe depression, hasn't got a psychosis and there's no risk, no formal psychological help there for mothers. So something that fills that gap cos we're obviously there for general support and most of the mental health care needs but there's just not that sustained psychological input therapy for that grey period where there is no risk, there's no urgent need for the mental health team..." (H C 8)

The HCPs were asked if they needed any training on perinatal mental health. Some of the HCPs stated not receiving any training about perinatal mental health after graduating from the university or medical school, while others in different research sites expressed receiving training on perinatal mental health regularly (i.e., every year). The common source of training was through the Institution of Health Visiting (IHV) or staff training in hospitals. The majority of HCPs described needing for more training on managing low to moderate perinatal depression that does not need referral but requires support from the HCPs, updating their knowledge on available help and support sources, what these sources provide for women and how the self-referral process works if a woman chooses to self-refer to these services.

"...One I think is my lack of training. We really don't get a lot of training on perinatal mental health and the different treatments available and the options so I'm very much signposting people to somebody else who knows better..." (H C 16)

Table 18: Healthcare professionals' messages for improving perinatal low mood and depression care and services

- willingness to spend more time with women to support them psychologically and women to be able to see the same HCPs at every visit
- more investments in the risk assessment and triage system to *“utilise resources or identify resources to meet the needs of women”* (H A 1)
- investment in more Mother and Baby Units and specialist perinatal mental health services as they are not available for every postcode and the capacity of the units is very low
- more training for the HCPs about the single point of access (this service is available for HCPs to report women with perinatal mental health problems and seek advice and make the referrals quickly) *“because they are taking from there you don’t actually understand what happens after that”* (H A 3)
- improving counselling services for miscarriages, stillbirths and neonatal deaths
- having a specialist perinatal mental health midwife in the service on a permanent basis who can provide the psychological support to women
- filling in the gap, the grey area where a woman has got low to moderate low mood or depression and does not need a referral but support from the HCPs
- *“more training for us midwives about those basic suggestions of things we can do for the increasing number of people with low mood rather than to diagnose depression”* (H C 16)
- *“being able to be consistent in the messages that we give and the treatments that we offer, more training on mental health”* (H C 15),
- *“antenatal classes need to be more honest”* (H C 17) in preparing women realistically for the delivery and postpartum period
- the content of National Childbirth Trust (NCT) classes and other free classes should be consistent and the NCT classes should be accessible by every woman for free.

b) Messages for women

HCPs also had some messages for women who are experiencing perinatal low mood or depression. HCPs stated that women should be honest about their feelings, talk to HCPs, their partners, family and friends about how they are feeling, seek help as early as possible and not to feel alone, not to feel guilty or ashamed as it is very prevalent and can happen to anybody. As one HCP stated, “We’re here to try and help you, we’re not here to judge you” (H B 13).

“I would just say that the chances are that whatever you say to somebody wouldn’t shock a midwife, wouldn’t shock your GP, it wouldn’t be a surprise to say I’m feeling really low. It would not surprise most people because it is so common and also it is really highly treatable, it’s very treatable and so just to feel, and even if you don’t get the right response first time and you might speak to somebody and you don’t have any faith in them and they haven’t, you know you think you might not get an appointment like you’re supposed to get an appointment but just to keep talking about it I think” (H C 15)

“If you’re diabetic you take insulin. If you’ve got an infection you take antibiotics. If you’ve got a mental health problem why do you think you need to manage it by yourself?” (H C 16)

9) Women’s and HCPs’ views on Behavioural Activation and Maternity Support Workers

Most women expressed that anyone with appropriate training within the maternity or health visiting team would be an appropriate staff member to deliver BA to women who have perinatal low mood or depression. They also pointed out that there should be continuity of care after giving birth and MSWs should be easily accessible whenever women needed. Other recommendations made by the women were: MSWs should receive appropriate training on how to pick up on signs of perinatal low mood and depression symptoms as well, because some women are very successful in hiding their feelings and scoring low in the PHQ-9 intentionally. Also, they believed that MSWs should have good communication skills and be willing to work together with perinatal women. They could provide women with a direct phone number to talk to or for online

chatting; they could have an office in the Children's Centre and/or in the hospital where women can pop in and talk confidentially during pregnancy and in the postpartum period. While some women expressed that they would prefer to go anywhere other than their home to receive care and support, other women preferred to receive it at their home.

"...sometimes you just need somebody to listen to you. That can help a lot I think. I think that's..when I spoke to the GP and the counselling it was just getting it all of my chest so for a maternity support worker, that would be a good role.. I think they would need quite a lot of extra training to deliver that..."
(W C 5)

"...I think any support you can get when you're ill is a good support... Any form of support or talking to someone... so if it is a continual one person and that you had that trust then yes I think they could do it and I don't think it matters who it is. A midwife supporter would be just fine because you got to know them and they know you enough..." (W C 17)

"...I think it would be good to have some consistency in who you see rather than seeing a lot different people because when you have a baby you feel like you're seeing this person and this person and this person and you don't feel like you really get a connection with someone and I think if it was like your midwife or somebody like that who you could talk to and they were trained in that and they could offer some support I think that could be really useful. I think that could make you feel quite empowered that it's the same person you're speaking to and you can see that going through. I think that could really help..." (W C 13)

Some women considered that everyone is different, and that BA can only be one of the options to offer women, rather than delivering it to every woman who experiences perinatal low mood or depression in the same format. Women also stated that the number of sessions and the content of sessions should be optimized for the needs of women.

A few women thought that BA should be delivered by professionals who have a mental health background so as to be able to recognise other problems that women might

have, for example, post-traumatic stress disorder, anxiety, personality disorder or schizophrenia.

HCPs who participated in the study pointed out that midwives and health visitors have so many responsibilities; therefore, MSWs would be appropriate staff members to deliver BA. However, they highlighted that MSWs should be trained very well. They should receive appropriate clinical support from a psychiatrist or a psychologist and be confident in recognising other mental health problems as well, because there might be something lying behind depression. According to the HCPs, support workers should assist the continuity of care in the postpartum period as well.

“...I think there’s a really big opportunity for MSWs across aspects of maternity and they quite often are in a good position to build up that relationship with the women. It sounds terrible but because we have so many responsibilities and boxes we’ve got to tick and sometimes you do feel like you’ve lost that time that you’d like to have to be with them. So to have someone else who can provide that constant relationship, yeh, if there’s an appropriate training package for them that they’re interested in doing it could be a really good thing for the MSWs and the women...” (H B 9)

“Yes as long as the correct training is given, I wouldn’t have thought that would be a problem at all, I would have thought they would be ideal people to do it” (H C 8)

“Yes, I think it would be great. I really really do. Lots of women will say that nobody prepares you and nobody tells you about this stuff. And nobody said this would happen. We hear a lot of those kinds of things. So I think especially because the Maternity Support Workers would be mostly at the beginning I think they are definitely well placed” (H C 18)

“I would imagine so yes. Just thinking, we have one Maternity Support Worker in our team and she runs the time and space group for younger pregnant women but also for women with low level mental health and she is fantastic because she has more time to spent with them and she gets to know them really well and she can go and see them at home, she can see them in the clinic,

just to talk to them. She can see them in a group setting and she already does very well just getting along with people. Again I think it's probably an individual personality thing, just like anything, so one woman might get on really well with an MSW, someone else might not but certainly our MSWs are already fulfilling that role and I suspect have had even less training than we have" (H C 16)

Some HCPs discussed MSWs and BA in a focus group and a few of them stated a preference for giving this role to midwives or health visitors. One of them pointed out the importance of recognising the need as early as possible, for example, in the antenatal period, by midwives who would be appropriate staff members for women to build a rapport with and access the treatment quickly without delay and deterioration in mood. However, others in the group discussed the role definition of the midwives who disappear after giving birth, suggesting that it would be more appropriate for health visitors to do, given that they take care of the family longer than the midwives and can book more listening visits if the woman needs. At the end of the discussion, the group decided that health visitors cannot do it either because they do not see the women antenatally; therefore, they thought it should be done by someone who sees the woman while she is pregnant but who will not disappear after a short time period. MSWs, therefore, would be an appropriate staff to deliver the BA intervention to women experiencing depressive symptoms.

Two antenatal clinical support workers who participated in the interviews expressed their desire to be more involved in the low mood or depression care of perinatal women.

"...I think that would be a brilliant service for the woman yes. And obviously, I would be happy to do that. It would expand our role and you would get continuity with the lady which I think is really important..." (H A 6)

A health visitor stated that she had received BA training before as part of her professional development and had found it very simple to learn. She also described using it with women who have low mood and finding it useful for some women who have a decrease in their activities. As she stated, *"it's quite nice and simple. And it's easier for people to work on because it's more like a plan of what to do rather than the CBT type things that have more about changing thoughts and I think it's quite difficult*

to do. I think it's good but I think it's difficult and I think as a health worker who isn't a mental health practitioner, sometimes it's easier to have something simpler to work through with somebody than that" (H C 19).

"...I know there was somebody I used it with where it just worked brilliantly, gave her confidence and motivation and everything that she hadn't had and she went from practically lying on the sofa all day to completely changing her life..."
(H C 19)

4.3 Summary

This chapter has presented the findings from the second study (discovery phase) findings related to the women's experiences of perinatal low mood or depression and HCPs' experiences of providing support and care for those women. It has discussed in detail the main themes that emerged in relation to the adaptation of the BA manual and booklet. The following chapter focuses on how the second study findings were used in the adaptation process and on the findings related to the third study element of the thesis (co-design workshops). In the discussion chapter, these findings are summarized and interpreted and discussed in relation to the pre-existing literature (see section 6.2.2). Strengths and limitations of the research (see sections 6.4.2 and 6.4.3) are acknowledged and implications for policy, practice and research (see section 6.5) are considered.

Chapter 5: Findings of the third study element of the thesis (co-design phase): co-design workshops with the involvement of women and HCPs

5.1 Introduction

Following on from chapter four, which described the findings from the interviews with women and healthcare professionals (HCP), this chapter describes the findings related to the third study element of the thesis: this involves co-design workshops with the involvement of women and HCPs to inform the adaptation of the Behavioural Activation (BA) intervention manual and guided self-help booklet intended for delivery by maternity support workers (MSW) for the treatment of perinatal depression. The chapter first discusses how the second study findings, interviews with women and HCPs were used in the adaptation process and then describes the third study findings.

5.2 Using the second study findings in the adaptation of the BA manual and booklet

The identified themes and the relevant context from the second study were used in the adaptation process, although not every finding presented in chapter four was worthy of implementing in terms of changes to the manual and booklet. The findings that were deemed relevant or important enough to apply in amending the manual and booklet, are presented below. This decision was made by the researcher, taking into account the context, stages and aim of the BA treatment and their relevance to the findings.

1) Triggers of perinatal low mood or depression

The triggers of low mood or depression reported by women in the interviews were compared with the literature and then shared with co-designers (women and HCPs) in the workshops and added to the BA manual (p. 5) (see Appendix 65) *“recognising the symptoms of low mood and the changes in actions during pregnancy and after childbirth”* and BA booklet (p. 4) (see Appendix 64) *“some factors that can lead to low mood”*. As stated in the booklet (p. 4):

- *Previous depression or anxiety*
- *Financial difficulties*

- *Domestic violence*
- *Stressful life events, such as lack of partner or daily hassles for example work hassles*
- *Lack of support from partner, family and friends*
- *Pregnancy problems, such as morning sickness*
- *Complications after the birth, such as bleeding*
- *Newborn problems, such as infant crying*

2) Recognising the signs of low mood or depression

Women's feelings in the perinatal period were considered as the key signs of low mood or depression and they were compared with the literature and then were shared with co-designers in the workshops and added to the manual (p. 5) "*recognising the symptoms of low mood and the changes in actions during pregnancy and after childbirth*" and booklet (pp. 4, 5, 6, 7 and 27) "*recognising symptoms of low mood*".

One of the key signs, as reported by women who participated in the second study, was a decrease in their activities due to a lack of motivation and energy, which led them to isolate themselves and avoid more activities. This cycle was also shared with co-designers in the workshops and developed afterwards, as demonstrated in the booklet (pp. 8 and 9), because 'realising how they avoid or put off things when they have low mood and reducing the avoidance and increasing the activities that are meaningful or valuable to them' are the main aims of the BA intervention (Manual, p. 4).

3) Breaking the barriers to help women to disclose their feelings

Women who disclosed their feelings, regardless of recipient, reported finding it very helpful in improving their mood and feeling relieved after sharing. Therefore, in the booklet, women were encouraged to talk about their feelings with their family and friends. As stated in the booklet (p. 2), "*It is very common for mothers and expectant mothers to experience low mood and it is hard to admit sometimes. It is okay to share your feelings with your friends, family, midwife, health visitor, general practitioner and support worker. We are here to help and support you*".

Some of the women described hiding their feelings from their family and friends because of the following reasons: finding it hard to admit it; finding it hard to open up to someone about it; fear of being judged by others and thinking it as reflecting failure. These findings were added to the booklet (p. 5) *“Some mothers or expectant mothers are reluctant to share their true feelings with friends and family and hide it from healthcare professionals. As a result, low mood is often not recognised or treated in women. Not addressing this aspect of women’s health can affect the general wellbeing of the women and their family”*.

The interviews with women demonstrated that it is important for HCPs to: be knowledgeable about the signs of low mood or depression; have good communication skills so as to build a rapport with women; ask women outright about their feelings and spending considerable time with women to learn more about their feelings and give appropriate support. These findings were shared with MSWs in the manual (p. 5) *“How to approach women in the contacts?”*.

Using the Whooley questions and PHQ-9 and/or GAD-7 were found to be enablers in terms of women disclosing their true feelings to the HCPs. The screening process is also a crucial part of the BA support, to check if there is an improvement in mood or deterioration, so as to seek timely help from specialists. The scale used in the original manual was the depression subscale of the Depression, Anxiety and Stress Scale (DASS21). Therefore, this was changed to the PHQ-9 which is a well-known, widely used questionnaire in maternity services and health visiting services, and a validated and reliable source of screening women for perinatal depression, as detailed in chapter three (see section 3.3.4).

4) Hidden face of perinatal low mood and depression

The findings demonstrated that women may experience thoughts of harming herself and difficulty with bonding with their baby. This information was compared with the literature and then shared with co-designers in the workshops and added to the BA booklet (p. 6) *“It can also include thinking about ending your life or harming yourself or others”*. Activities about taking care of the baby and reading and playing with the baby were also added to the booklet (pp. 11, 13, 14, 17 and 19) to support bonding and increase time spent with the baby.

The second study findings showed that perinatal low mood or depression might affect women's partners and their children in some way. This information was compared with the literature and then added to the booklet as follows: *"Not addressing this aspect of women's health can affect the general wellbeing of the women and their family... This booklet, with help from your support worker, aims to help you learn how to manage your mood and lessen the impact it has on you or your family's health"*. These statements were then removed according to the feedback received from co-designers, as explained in 'to differentiate what is common and not common to feel in the perinatal period' theme below.

5) Needing attention while providing support and care for perinatal low mood and depression

a) Attention from HCPs

Undoubtedly, midwives are in a crucial position to recognise the symptoms as early as possible in the antenatal period and give appropriate support and advice. However, the findings showed that the midwives did not ask women the Whooley questions at every appointment. Instead, they asked two times at the first appointment and in the 28-week check, which led to overlooking women who developed symptoms during pregnancy. Some midwives tried to ask about women's feelings at every appointment in a natural conversation. But women did not necessarily see this question as asking about their mood and this led to missing women who were experiencing low mood or depression. The pathways for perinatal mental health were collected from the HCPs and these pathways supported the finding, suggesting that HCPs should ask Whooley questions at the first booking appointment and then ask again only if women say "yes" to one of the two Whooley questions. The 'pregnancy notes' booklet Whooley questions section also demonstrated a similar finding, which had two boxes to tick at the first appointment and later, during pregnancy or early in the postpartum period.

It was also clear from the interviews with midwives that not every midwife had knowledge of giving practical advice to women who do not need referral but might need support. There is an urgent need for a member of maternity staff to fully support women from the beginning and cover the postnatal period as well. This staff member should be easily accessible and in a good relationship with women, as findings in

chapter four suggest. MSWs are in a good position to fill this gap. The two antenatal clinical support workers interviewed in this research and most of the HCPs, also supported the idea of training MSWs to support women with perinatal depression. BA is a good candidate to serve as a simple psychological intervention for non-mental-health specialists to learn, with appropriate training as detailed in chapter one. Women's and HCPs' views on BA and MSWs are discussed below.

b) Attention from friends and groups on social media

Most women found talking about their feelings with their friends face to face or online, helpful in improving their mood. In the booklet (pp. 2, 9, 11, 13, 14, 17, 20, 22, 25 and 28), women were encouraged to talk to or meet with their friends, to attend pregnancy classes and mother and baby groups to socialise with others, and to find groups on social media who are experiencing similar feelings to them. For example, the following statements were added to the booklet: *"Over the next week, schedule into your diary or calendar when you are going to spend time with your family and friends and attend an antenatal class. Remember, it does not need to be done all in one day"* (p. 20); *"Joining antenatal classes, mother and baby groups"* (p. 25); and *"Telephone, email or use social media to chat with friends and family"* (p. 25).

c) Attention from partners and parents

Half the women described that their partners and parents supported them with looking after the children, doing the housework and encouraged them to disclose their true feelings to the HCPs, all of which were helpful in maintaining their daily routines and self-care. Accordingly, women were encouraged to talk to their family about their feelings and spend time with them in the booklet (pp. 2, 13, 14, 17, 19, 20, 25 and 28). For example, (Booklet, p. 28), *"Call friends and family and talk to them about how you are feeling"*.

6) Helpful strategies in recovery

Women described their coping strategies with perinatal low mood and depression as: joining antenatal classes and mother and baby groups; meeting and talking with friends and family and having support networks; exercising, going out of the house for

whatever reason; asking people to look after the child and for physical help on housework; eating and drinking healthily; promoting quality sleep; finding support groups from social media for perinatal low mood or depression and/or anxiety; and taking time for themselves. These findings inspired all the activities in the booklet (pp. 9, 11, 13, 14, 17, 19, 20, 22, 28) and the “*Finding other ways to be active and improve your mood*” section in the booklet (p. 25), as presented in Table 19. This table was then improved with the help of co-designers in the workshops.

7) Women’s messages

a) Messages for improving perinatal low mood and depression care and services

The second study findings demonstrated that women need more treatment options for low mood and depression; personalised care to address their needs and continuity in care to build a rapport with the same person who would support women during pregnancy and after childbirth. These findings support the idea of delivery of BA by MSWs. Women’s care and support preferences, as explained in chapter four, were used in the adaptation of the BA manual.

Women would be able to choose the place for the treatment; at home or a Children’s Centre or hospital, whichever is the most convenient venue for them, and also the frequency and number of contacts with MSWs. The length of the contact sessions was decided according to the second study findings. This information was added to the manual (p. 6) “*Treatment contacts are organised via 6 appointments; however, the number of sessions, frequency of appointments, delivery mode (face to face or telephone) and the support place (home, Children’s Centres or hospital) should be decided through talking with the women and listening to their needs and demands. Contacts last 45 – 60 minutes, although session one is sometimes longer*”.

Table 19: List of strategies to improve mood (Booklet, p. 25)

- joining antenatal classes, mother and baby groups
- exercise, walking or getting fresh air
- yoga, mindfulness or meditation
- personal time
- working in a job and not bringing work home
- asking people to look after the baby
- asking people to help in housework
- delivery home or going for shopping
- having a shower
- drinking water, eating healthily
- sleeping or taking naps
- reading or watching TV
- inviting a friend to home
- going out of the house for whatever reason
- meeting with friends in a café
- moving baby to her or his own room after 6 months
- putting less pressure on yourself
- using social media sensibly, finding other mums experiencing low mood and sharing experiences
- telephone, email or use social media to chat with friends and family
- getting support from family, friends and healthcare professionals
- baking cake and cooking
- hobbies specific to the person; for example, gardening, painting, crafts, playing a musical instrument, colouring, jigsaws
- watching movies, TV series, or listening to music
- praying or religious activities.

b) Messages for HCPs

Women were asked in the interviews if they would like to say anything to the HCPs who provide care and support for women during the perinatal period. Their responses were merged with the findings from the section “breaking the barriers to help women to disclose their feelings” and were shared in the manual (pp. 5 and 6) “How to approach women in the contacts?”. As it is stated in the manual, *“Findings from the interviews with women who have experienced perinatal low mood or depression suggested that women would welcome being asked outright by the MSWs how they are feeling and how the pregnancy or motherhood is going; to listen to what they are experiencing and how they are experiencing it; to respond if a woman says she is feeling low and to check-in again sooner and not to leave a gap until the next contact; to make eye contact with them and to build a rapport with them; if there is a birth complication, to be aware of its potential psychological effects on the woman and guide them to seek help from appropriate services, before being discharged from the hospital; to be knowledgeable about the difference between the baby blues and postpartum low mood and depression; to update their knowledge about the signs of perinatal low mood and depression, specifically they should not make assumptions that just because a woman is dressed and wearing make-up she is not experiencing depression; to decrease the poor communication and misinformation with their colleagues and to report women to the appropriate specialists or services if they experience a deterioration in their mood; they want MSWs to carry out the referral process on behalf of the woman rather than expecting the woman to self-refer to a GP or a specialist mental health service; they would want MSWs to continue contact sessions after making the referral, unless requested otherwise by the woman”*.

c) Messages for other women

Women highlighted the importance of talking with friends, family and HCPs about their feelings and seeking help from HCPs as soon as possible. This message was also highlighted in the appropriate pages of the booklet, for example, *“It is okay to share your feelings with your friends, family, midwife, health visitor, general practitioner and support worker. We are here to help and support you”* (p. 2) and *“As you can see, there*

are many reasons meeting with friends helps to keep this mum well. It has many benefits and it covers all three activity types, which in turn helps her stay well” (p. 22).

8) HCPs’ messages

a) Messages for improving perinatal low mood/depression care and services

Apart from the HCPs’ demand on improving perinatal mental health services and psychological therapy options, they identified the need for filling the grey area for women who do not need a referral but support from the HCPs. Training MSWs would potentially fill this gap and be helpful for the women experiencing depression and their families who are likely to be affected by them.

b) Messages for women

The HCPs’ messages for women who experience low mood or depression were similar to women’s messages for other women, therefore, women were encouraged to talk with family, friends and HCPs about their true feelings in the booklet (p. 25).

9) Women’s and HCPs’ views on Behavioural Activation and Maternity Support

Workers

The findings from the interviews with women and HCPs have shown that MSWs could be an appropriate support role to deliver BA, with appropriate training, and BA could be one of the options to recommend women with perinatal depression. This is also discussed at bullet point 5a above.

The MSWs have 22 different role names for example; ‘maternity support worker’ and ‘clinical support worker’ (Griffin, 2017), therefore, they were referred to as ‘support worker’ in the booklet. As it is stated in the booklet (p. 2), *“We hope that working through it with your support worker will help you to learn how to improve your mood, as this is important to your health and wellbeing. Support workers play an active role in maternity services and community services and have regular contact with midwives, health visitors and other healthcare professionals”.*

The second study findings, interviews with women and HCPs, and their role in the adaptation of the BA manual and booklet, are summarised above using relevant

examples and texts from the BA manual and booklet where is appropriate. The third study findings, co-design workshops with the involvement of women and HCPs (i.e., co-designers), are presented in the rest of this chapter using themes, relevant data quotations from co-designers, and text extracted from the BA manual and booklet.

5.3 'Co-design' phase, the third study findings

5.3.1 Findings from the women's and HCPs' demographic forms

In total, 14 women and three HCPs took part in four co-design workshops across the three research sites in 2019 (Table 20). Two of the HCPs were midwives and one of them was a health visitor. Four-fifth of women ($n = 11$) were white British, one-fifth ($n = 3$) were other Asian backgrounds, and aged 31 – 45 years (mean = 36.8 years; SD = 4.26). All of them were married or living with a partner. Over half of them completed graduate study (8 = graduate; 1 = left full time education aged 18; 4 = postgraduate; 1 = other - qualification) and half were working in a part-time job (7 = part time; 4 = full time; 3 = not working). Two-thirds of women ($n = 10$) had one child (four had two children) and the youngest child aged 1 – 5 years old. The mean age of these children was 2.5 years (SD = 1.29). Women's scores on PHQ-9 varied between 0 and 9 ($n = 14$), and the mean score was 2.71 (SD = 2.70).

Almost three-fifth the women ($n = 8$) reported experiencing perinatal low mood or depression, one-fifth of women ($n = 3$) experiencing only postpartum low mood or depression symptoms and one woman experiencing only antenatal low mood in the demographic forms (two left it blank). From those who experienced perinatal low mood or depression ($n = 8$), six had a diagnosis of it; of these four received only psychological treatment and two received only medication. Two of them did not have a diagnosis of perinatal depression and did not receive any treatment. The reported duration of perinatal low mood or depressive symptoms varied from five to 21 months ($n = 8$).

Table 20: Characteristics of women and HCPs participated in workshops

Participant number	Research sites	Age	Deprivation score ¹ , 2019	PHQ-9 score	Age of youngest child	Number of children
W C 1	C (first workshop)	45	29,202	2	2	1
W C 3		41	26,120	0	3	1
W C 6		41	25,922	1	2	2
H C 18		Community midwife				
H C 19		Health visitor				
W A 9	A (second workshop)	34	32,568	2	4	1
W A 13		31	12,261	1	3	1
W A 14		37	22,650	9	1	1
W A 15		33	19,168	2	1	1
W A 16		33	21,534	0	1	1
W B 10	B (third workshop)	40	31,365	1	4	1
W B 12		36	26,356	3	2	1
H B 20		Midwife				
W C 4	C (fourth workshop)	39	26,925	2	1	2
W C 17		31	31,263	3	3	2
W C 21		40	31,263	4	3	2
W C 22		35	31,263	8	5	1

¹Public Health England, Index of multiple deprivation: A score of 1 reveals the most deprived area and 32,844, the least deprived.

All three women who reported experiencing only postpartum depression had a diagnosis of it; one received only psychological treatment and one received only medication while the third one did not receive any treatment. The duration of postpartum depression symptoms ranged from 12 to 18 months (n = 3).

For one woman who experienced low mood during pregnancy was occasional and disappeared after giving birth.

One-fifth of women (n = 3) stated in the demographic forms experiencing anxiety at some point in their life before their pregnancy.

5.3.2 Findings from the co-design workshops

After analysing the recording transcripts and the women's and HCPs' notes taken on the booklet and manual provided to them, the following five themes emerged from the data, which were the most frequently highlighted developments related to the adaptation of the BA booklet and manual in the workshops: 1) To differentiate what is common and not common to feel in the perinatal period (risk factors and signs of perinatal low mood and depression) and other adaptations to the content; 2) illustration of mood cycles and suggested activities with examples (breaking the low mood cycle, activities for women, planning manageable activities, example action plan, example diary); 3) using quotations from the second study; 4) highlighting that "BA may not work for you" (other help sources are available); and 5) minor modifications on format or text (using bullet points, highlighting important text, choosing brighter and natural pictures, reordering some sections, removing repetitions and unnecessary information, improving the clarity of the texts and scale to use for mood, and deciding the size of the manual and booklet).

Figure 12 illustrates the thematic map which emerged from the four workshops in three different research sites. The decision on whether to amend the documents or not was a consensus decision-making process between women, HCPs and the researcher. The decision was made in the workshops by asking co-designers whether everyone agreed with the amendment or not. The adaptation was made according to the majority's opinion. The adapted version of the BA booklet (see Appendix 64) and manual (see Appendix 65) can be found in the appendix.



Figure 12: Thematic map reflecting the findings from the co-design workshops involving women and HCPs

1) To differentiate what is common and not common to feel in the perinatal period

The first main adaptation recommended by co-designers were to differentiate what is common to feel in the perinatal period and what is not common as some symptoms are common when you have depression and are pregnant or have a newborn baby, for example, feeling tired and sleeping problems. As one woman stated, *“It is common to have sleeping problems in pregnancy”* (W A 14). Therefore, the priority was developing the booklet and the manual in terms of the signs of depression and difference between common and non-common feelings and the ‘baby blues’. For example, in the text below, it is emphasised that it is common to feel emotional around the fourth day after giving birth, however, if it continues for a few weeks or more, it can be more of a sign of depression.

“Around the 4th day after giving birth, hormonal changes in your body can lead to emotional mood swings commonly known as the ‘baby blues’.

- *Most mothers become emotional during these days and it might be hard to differentiate it from low mood*
- *If the signs carry on for a few weeks or more, it can be more of a sign of depression*
- *It is important to deal with the symptoms of low mood as early as possible before they get worse”* (Booklet, p. 7).

Sleeping problems are common during pregnancy and after giving birth regardless of having depression. As one woman stated in the workshop, *“Not being able to sleep when your baby’s asleep”* (W B 10) could be the difference between the common and non-common sleeping pattern. This example was used in the booklet as follows:

“Changes in sleeping: Some women with low mood sleep much more than usual. Other women find getting to sleep much more difficult or wake up much earlier than normal and struggle to get back to sleep. It is common to have sleep problems in pregnancy due to pregnancy symptoms, so this can make sleep problems worse. A newborn baby’s sleep pattern can be quite erratic. If you are unable to sleep when your baby sleeps, this may be a sign of low mood” (Booklet, p. 6).

Some of these symptoms were shared in the manual too, as a reminder for the MSWs.

Sleep disturbances may be the leading factor for depression for some women as one woman stated, *“Poor sleep has an effect on your mood”* (W B 10). Therefore, this factor was added to the booklet along with the other factors.

“Some risk factors have been listed below. There may be other risk factors, for example, hormonal changes, sleep disturbances, social isolation, changes in routines and roles, and life-changing events, or there may be no risk factors and it can be the factor of coming to terms with pregnancy and motherhood”
(Booklet, p. 4).

Co-designers feedback on the risk factors pages on the booklet was very positive. As one woman stated, *“I wish I’ve been told this by somebody”* (W C 17). As other woman stated, *“I’d agree with all those and more probably”* (W C 21).

There were some concerns between the co-designers about the symptoms that not everyone shows the same signs as one woman stated, *“Everyone could show the signs in a different way”* (W A 9). Therefore, the following statement was added to the booklet.

“Not everyone will have all of these signs, but some are likely to be there and noticing them is the first step to staying well” (Booklet, p.6).

Another adaptation suggested by co-designers was about the cooking food as one woman stated, *“You’ve got to have the motivation to cook something nutritious and if you’re feeling low you just can’t bother”* (W B 12), therefore, the following statement was added to the booklet (p. 6).

“Changes in eating: Some women lose their appetite or do not have the motivation to cook healthy meals when they feel low in mood. Other women eat much more, even at night”.

Another content-related adaptation was made to the booklet and manual about the effect of maternal depression on partners and children. The second study findings and the literature have shown that perinatal depression can affect the partners and

children in some way, therefore, this finding was written in the booklet and manual. However, after two workshops, this information was removed because the women were not happy by seeing the potential negative consequences of depression on their partner and children. They stated that while it was hard to take care of themselves how they would take the responsibility of the whole family, it might increase the pressure and stress on them. As one woman stated, *“it would make more pressure on me... I would think I am a bad mum affecting the whole family”* (W A 13). As other woman stated, *“I think it would almost make a mum feel like to happen to be a superwoman and pick up the whole family”* (W A 15). Therefore, this information was removed from the manual but kept on the booklet (p. 5) as follows: *“...Not addressing this aspect of women’s health can affect the general wellbeing of the women and their family”*. The co-designers were happy with this statement.

Lack of support for partners was another finding and this issue was raised in the first workshop. The co-designers were asked if they would like to see text about ‘information for partners struggling with paternal low mood or depression’; however, they expressed their thoughts as not willing to include information for partners because this is a personal booklet aiming at women. One woman suggested to include information for partners about how to support women with perinatal low mood in a box with bullet points; however, others in the workshop disagreed with the woman; therefore, no information included to the booklet or manual after the first workshop. In the other workshops, the same issue was asked to the co-designers, but again their response was negative. As one woman stated, *“I wouldn’t share this with my husband because this is a very personal booklet”* (W A 16) and the other replied as *“yeah, I wouldn’t let him read my notes”* (W A 15).

2) Illustration of mood cycles and suggested activities with examples

The second main adaptation suggested by co-designers was modifying the examples and activities in the booklet and manual by considering three groups of women; pregnant women, first-time mothers and mothers who have more than one child. They also highlighted that activities and examples should be from those women’s daily routines, for example, feeding the baby, changing the baby and bathing the baby.

According to this feedback, the examples in the manual were developed, as below.

- *“a woman may no longer be able to walk longer than 20 minutes due to tiredness in the last months of pregnancy. In this case, the woman may be able to find alternative routes, including benches where she can sit and have a rest for 10-15 minutes and then continue her walking”* (Manual, p. 10).
- *“a woman is no longer able to visit their friends and family due to feeling overwhelmed with caring for a newborn baby. The MSW should encourage the woman to find other ways to get in touch with them, such as talking to them online or on the phone”* (Manual, p. 10).

Other adaptations were made to the examples in *“the cycle of reduced activities and low mood”* in the booklet (pp. 8 and 9). According to the suggestions from the co-designers, activities in the *“break the cycle”* box (p. 9) were modified and written as *“You can break the cycle by setting small goals for yourself, for example, attending a pregnancy class, eating at least one healthy meal in a day and drinking more water”*. The other suggestion on the cycles was writing a note for women that their low mood will not suddenly disappear, but it will get better day by day. The women and HCPs’ suggestions can be found below.

“...Adding something like you can feel better again because you have felt that before...” (W A 9)

“...It is not going to go away suddenly but you will feel better day by day...” (W B 12)

“...It is not something that suddenly happens, it is something that gradually builds, gradually deteriorates...” (H B 20)

According to the comments above, the following statement was written to the booklet (p. 9), *“Your mood has gradually deteriorated; therefore, it will gradually get better. It is important to take time for yourself”*.

The original cycle was in a circular shape, however, some co-designers suggested to use a downward flowchart. As one woman stated in a workshop, *“Downward spiral can be used rather than a cycle”* (W C 3) and as the other woman stated in the other workshop *“I found it a little bit confusing. Maybe you can show it with a flowchart”* (W A 14). After creating a flowchart, the co-designers involved in the subsequent

workshop stated that they liked the flowchart. As one woman stated, *"I did love the cycle, it's easy to read"* (she means the flowchart) (W C 17).

Another suggestion was providing examples for each of the exercises in the booklet, for example, the cycle of reduced activities and low mood (example cycle was provided on p. 9), example diaries for a pregnant woman and a mother (p. 11), examples of routine, necessary and pleasurable activities (p. 14), an example diary (p. 17), examples for breaking things down to make them easier to manage (p. 19 and 20), an example for benefits of activities (p. 22), examples for finding other ways to be active (p. 25), examples for spotting symptoms of low mood (p. 27), and an example action plan (p. 28). A couple of them were explained in detail below.

Examples of three types of activities were modified by co-designers (Booklet, p. 13). They interpreted the routine activity as 'have to do every day', necessary activity as 'do not have to do but necessary' and then they reordered the examples in the right places. Their suggestions were listed below.

Routine activity examples: *"...feeding, changing, bathing the baby and the other children, eating healthily, drinking..."* (W C 3)

Necessary: *"...attending appointments, classes..."* (H C 18)

Pleasurable: *"...having a nice bath, swimming, reading, watching tv, seeing friends, gardening, cooking, hobbies, spending time with partner, children, family, friends..."* (W C 1)

Placing an example diary was one of the suggestions of co-designers and they helped to create the example in the workshops (Booklet, p. 17). According to their comments below, the example was created.

"...walking with the dog for 15 min, ringing a friend, really small and realistic things, to get dress before lunch time, eating, showering, drinking..." (W A 9)

"...include some information about the importance of drinking and eating healthily..." (H C 19)

"...try to take one nap..." (W B 10)

“you can add something like this is only an example, you may not be able to do all the things. You can miss an activity and that is absolutely normal for the first a couple of weeks” (W C 4)

Providing two separate examples; one for a pregnant woman and one for a mother was another recommendation of the co-designers for the *“stage 4 breaking things down to make them easier to manage”* in the booklet (pp. 19 and 20). As one woman stated, *“The activities could be different in pregnancy and afterwards so it would be good to give separate examples for both pregnancy-related and postpartum-related”* (W C 3). Examples suggested by co-designers were listed below.

“...at work make sure you take a break through the day, plan your shopping so healthy snacks are available, use your freezer, schedule into your diary when you are going to spend time with your family and friends, that is for pregnancy...” (W C 6)

“...it would be hard to manage everything so ask for help when you have a newborn baby about shopping, cleaning, preparing food...” (W C 3)

“...try to eat at least one nutritious meal in a day...” (H C 18)

“...delete home delivery option from the example because grocery shopping is a good activity for many women...” (W A 9)

“...went to midwifery appointment, you have been in work whole day, you came home, you cooked a healthy tea, eating healthily, you spent time with your family and friends in the evening. People would be realise that it is just the basic stuff. Eating properly, drinking properly, having a bottle of water to remind you to drink, have a nap while the baby’s sleeping...” (H C 19)

After applying changes, the co-designers in the following workshop liked the examples as one woman stated, *“Yeah, really good examples”* (W B 12).

The co-designers made comments to modify the activities in the *“finding other ways to be active and improve your mood”* section in the booklet (p. 25). Some of them suggested other activities to add in the list while others made comments on the

usefulness of the list as one woman stated, *"I think it's a really good idea because when you're feeling low and tired you can't think... it's like reminding... the examples are really useful"* (W C 17). Other suggestions added to the list are provided below.

"...Self-care, even if it is like painting your nails or putting your earrings in..." (W A 16)

"...Gardening is helpful..." (H B 20)

"...be mindful when you're accessing these online forums maybe adding something like using social media and internet wisely..." (W C 4)

Other small suggestion was for the circumstances in which women can no longer do an activity they used to do. The co-designers suggested to include financial problems, childcare issues/difficulties and backache to the text (Booklet, p. 24).

3) Using quotations from the second study

Women's experiences of perinatal low mood or depression and HCPs' experiences of providing support and care for those women were used in the adaptation of the BA manual and booklet; however, their quotations were not used directly in any documents. In the first workshop, the co-designers suggested using experiences of real people in the booklet to make it more meaningful and attractive for the readers; therefore, a couple of quotations were placed to the relevant places in the booklet. In the second workshop, the co-designers found them really good, as one woman stated, *"I do think these quotes work very well. I do like that"* (W A 13). They requested to use more quotations almost on every page of the booklet.

In the last two workshops, the researcher observed two co-designers who were reading only quotations in the booklet until the end instead of reading the booklet page by page as requested by them. When they were asked if they liked the quotations, their answers were very positive as follows.

"I think it's wonderful" (H B 20)

"Good quotes, really really good" (W C 22)

The quotations were chosen on the basis of their relevance to the content and stages in the booklet. At the beginning of the interviews, women were asked for choosing a false name for themselves and these false names have been used in the quotations. Although it was attempted to include quotations from all 15 women participated in the second study, it was not possible practically; therefore, only quotations from 10 women which match with the content in the stages were chosen. For example, one of the risk factors for postnatal depression was delivery complications (Booklet, p. 4), therefore, a quotation matching with this risk factor was chosen to use in the booklet as follows.

"...I was taken back into surgery ... for bleeding ... and because I didn't have the close time with her during those early days, I felt like the bond was lost immediately and I just started feeling very, very depressed. I didn't know it was postnatal depression until several months later. I just thought it was normal to feel that way after such a medical crisis..." (Louise, first time mother) (Booklet, p. 4)

Another example would be about 'making plans to maintain a healthy mood' section in the booklet (p. 16). A quotation related to supporting women to attend activities was chosen for this section as follows:

"...but in the meantime I would force myself out the house. I would go to the mother and baby groups, even though I didn't really feel like it, I'd make myself go because I knew that getting out the house and being with other mums and babies that would help and it did. Definitely help me. So again, even though I felt awful I was strong enough to make myself do things even though I didn't want to...."(Katie, first time mother) (Booklet, p. 16)

At the end of the booklet (pp. 29 and 30), women's and HCPs' messages for women were shared within quotations. Two examples are shared below.

"...having postnatal depression doesn't mean that you're not a good mum. It doesn't mean that you are a bad person. It can happen to anyone and it happens to people who least expect it. If you are open and honest from the start, you can get better quicker. You can have that time back with your child

and you're not going to feel like that forever...."(Louise, first time mother)
(Booklet, p. 29)

"...I would like to say that not to be ashamed and not to feel on your own because you are absolutely not on your own and that postnatal depression doesn't stereotype. It can happen to anybody, it doesn't matter who you are or what your job is, it can happen to anybody so I think it's really important that we keep talking about it and it's not a taboo subject that people feel awkward about because it's really really prevalent and it's happening all the time so I think the more we talk about it and the more we realize we should all support each other and try and get that community feel back..." (a health visitor)
(Booklet, p. 30)

At the end of the workshops, co-designers were asked about their thoughts on the booklet and manual and their feedback was really positive about the content and usefulness of the documents.

"It's been quite helpful working it through page by page cause obviously anything new is like overwhelming but actually working through it page by page is really make sense" (H C 19)

"I think it's really good" (W A 15)

"I liked the way the whole booklet's progressed until the stage 6 spotting symptoms.. it flows really nicely" (W B 10)

"I'd really like to see booklet when it's finished. I want to give it to mums" (H B 20)

"it's fantastic and it's been done and I'm pleased to be able to help a little bit in the process" (W C 4)

"anything given as a booklet would be helpful for women" (W C 17)

Some co-designers suggested giving this booklet to every pregnant woman within their maternity packs. As one woman stated, *"I think it should be in the maternity pack because knowledge is power and also it highlights that there could be an issue and if*

there is you can start to read through it and I think it also helps starting conversation with the midwife as well if I had all these I probably would have talked to my midwife about it” (W B 12). Other woman suggested the same as follows, “I am thinking whether all women should have this” (W B 10).

4) Highlighting that “BA may not work for you”

Another common thought about the adaptation of the booklet and manual was although it seems like the majority of women with perinatal depression have limited activities and prefer to stay home because of feeling tired, overwhelmed or anxious, there are many other women who continue their daily routines and activities as usual but feel depressed inside. The co-designers suggested the need to highlight this point in the manual and booklet; therefore, the following statement was added to the manual (p. 4) *“There is always other help available if this booklet does not work for women and there are a variety of things that can be tried, as written on the last page of the manual and booklet”.*

The similar information was added to the booklet (p. 2) as follows: *“Working with you and tailoring the guidance in this booklet to your specific situation, is one of several tools available to help you. There is other help available if this booklet does not work for you and there are a variety of things that can be tried. You can find contact details for a few of these support sources in the last page of this booklet. For locally available sources please ask your support worker”.*

5) Minor modifications on format/ text

The fifth adaptation suggested by co-designers was improvements on the design of the BA booklet and manual pages, for example, using bullet points, highlighting important texts, choosing brighter and natural pictures (for the booklet), removing unnecessary repetitions or information, improving clarity of the texts and scale to use for mood, and deciding on the size of the manual and booklet. These points are discussed in detail below.

The first point suggested by co-designers was on using bullet points and highlighting important texts. As one woman stated, *“there is a lot of texts there, is it possible to*

highlight the bottom ‘don’t wait to feel better to do things, do things to make you feel better?’” (W C 3). According to the feedback received from the co-designers, an attempt was made to write important tips in colour other than black to emphasise the critical points and to write texts in bullet points where possible as in the example below.

“Some mothers or expectant mothers:

- are less likely to recognise symptoms of low mood*
- may think that how they are feeling is part of being pregnant or baby blues*
- are reluctant to share their true feelings with friends and family and hide it from healthcare professionals. As a result, low mood is often not recognised or treated in women. Not addressing this aspect of women’s health can affect the general wellbeing of the women and their family. ”*
(Booklet, p 5).

The second adaptation was on the pictures to use more natural, brighter and mood-boosting ones. As one woman stated, *“...maybe a picture because it looks more academic kind of you know very dissertation style kind of.. so maybe a picture or something like that to make it brighter and happier...” (W A 14). As other woman stated, “I want to see pictures of real women not models because models are not real life” (W A 15). After changing pictures, the co-designers’ feedback was more positive. As one HCP stated in the other workshop, “I did like the picture with a coffee” (H B 20), and other woman stated, “the pictures are fine” (W C 22). They also commented on the photo on the last page of the booklet. As one woman stated, “it’s a nice picture. It’s really nice to see the researcher, makes it feel a lot more personal” (W B 12).*

Other minor suggestions were; reordering some sections, removing unnecessary repetitions or information and improving clarity of the text and scale to score their mood daily and deciding on the size of the manual and booklet. There were some repetitions in the booklet, for example, in the introductory page and in stage 1 as follows.

Introductory page: *“It is very common for mothers and expectant mothers to experience low mood because of changes in routines, lifestyles and hormones and having health problems in pregnancy or in the postpartum period”*.

Stage 1: Some factors that can lead to low mood: *“It is quite common to experience low mood when you are pregnant or have a baby. About one in four of us will have some symptoms in our life, and one in five of us in pregnancy or after childbirth. Some risk factors have been listed below. There may be other risk factors for example sleep disturbances, social isolation, changes in roles and life-changing events, or there may be no risk factors and it can be the factor of coming to terms with pregnancy and motherhood”*.

These repetitions were determined in a workshop and then they were fixed by the researcher for the other workshop. In another workshop, it was asked co-designers if there are any repetitions or things breaking the flow of the therapy stages. As one woman stated, *“actually it is flowing very well I think, it is actually it’s really good, really useful isn’t it”* (W B 10) and the other woman and HCP confirmed, *“yeah”* (W B 12), *“yeah, it’s really good”* (H B 20) respectively. The content of the booklet was also asked co-designers if it is too much wordy. Their responses were negative, and they were happy with the content. As one woman stated, *“no. I think it is just explanations. It was clear, it was not difficult to read”* (W B 12) and as one HCP confirmed, *“no. Easy to read”* (H B 20).

Another adaptation was made to the scale to score mood daily on the booklet. The scale (p. 10) was for the aim of scoring mood to recognise how women feel by doing or not doing things during the day. The original scale was from 1 to 10 and the co-designers suggested to change it to a 1 to 5 scale and using emojis to describe the numbers’ meaning. As one woman stated, *“The mood score is quite long 1 to 10. The scale could be smaller like 1 to 5 or 0 to 5”* (W C 6). As one HCP stated, *“What would 4 mean or 3 mean? I can’t see the difference between 2 and 3 or 6 and 7”* (H C 19). The scale was changed afterwards, and a 1 to 5 scale was developed using emojis to describe the meaning of the numbers.

The co-designers were asked in the workshops about the size of the booklet and the manual whether they prefer a smaller or bigger size. Women described preferring the

same size of the booklet provided them which was 21 x 21cm. As one woman stated, *“Definitely not bigger.. the size is good”* (W B 10). As other woman stated, *“The size is okay. People may not want to disclose the booklet, having this size would be good”* (W C 1). The HCPs expressed their preference for the size of the manual as A4, which seems like a formal document for the MSWs.

5.4 Discussion

Fifteen women who have experienced perinatal low mood or depression and 19 HCPs who have experience of providing support and care for those women participated in the second study. The findings from the interviews with women and HCPs indicated that there is limited support available for women who experience depression symptoms and not meet the criteria for a referral to specialist perinatal mental health services. Therefore, the women and HCPs supported the idea of delivery of a brief psychological intervention, Behavioural Activation, by MSWs for the treatment of depression in perinatal women. Other findings helped to understand women’s life with perinatal low mood or depression and HCPs’ experiences of caring those women, all of which guided the adaptation of the BA manual and booklet for perinatal women with depression. These adaptations are presented in this chapter with findings emerged from the second study and examples of adapted texts from the booklet and manual. The context of these themes fit well with the principles of BA treatment explained in section 1.3.8 (Hollon and Dimidjian, 2009; Martell, Dimidjian and Herman-Dunn, 2010; Murrell et al., 2008; Jacobson, Martell and Dimidjian, 2001) and associated and consistent with the BA manual and booklet described in section 3.3.5. However, this study also underlines a number of factors facilitating women’s help seeking behaviour from HCPs and treatment preferences, all of which are unique for this study phase and may be useful to MSWs in approaching women and offering BA treatment.

A previous qualitative study conducted in the USA aimed at modifying the CBT for perinatal depression (O’Mahen et al., 2012). The authors conducted qualitative interviews with 23 perinatal women, and they modified the CBT manual according to the themes emerged from the interviews. The decrease in women’s activities, their struggles in managing their daily routines and isolating themselves from the social activities were found related to behavioural component of the CBT (O’Mahen et al.,

2012) and these findings were consistent with the second study findings. This PhD study differs from O'Mahen et al.'s study methodologically. Uniquely, in this study, in addition to the interviews, co-design workshops were conducted with the involvement of women and HCPs who shared equal power with the researcher in the adaptation process for the BA manual and booklet instead of CBT as in the O'Mahen et al.'s (2012) study.

In total, 14 women and three HCPs (selected by the same sampling method and recruitment strategy with the second study) involved in four co-design workshops in three different research sites within the third study element of the thesis. The findings from the workshops, that guided the adaptation of the documents, were presented with five main themes (i.e., 1) To differentiate what is common and not common to feel in the perinatal period and other adaptations to the content; 2) Illustration of mood cycles and suggested activities with examples; 3) Using quotations from the second study; 4) Highlighting that "BA may not work for you"; and 5) Minor modifications on format or text.

Two randomised controlled trials reported outcomes of BA treatment delivered by a mixture of specialists and non-specialists during pregnancy and at three-month postpartum (Beck et al., 2014; Dimidjian et al., 2017). However, these studies did not provide information on how the BA treatment was adapted for the specific needs of pregnant women. The Medical Research Council recommends researchers to acknowledge and use appropriate methods in the development of interventions (Craig et al., 2013). The EBCD is one of the methods that can be used in the development of interventions (O'Cathain et al., 2019a). Choosing a co-design approach for the adaptation of the BA manual and booklet empowered the relationship between the researcher and the women and HCPs, established an opportunity to work and produce material collaboratively, and created a respectful environment to value their knowledge, views and expertise in perinatal low mood and depression. Therefore, this PhD study has critical importance in using appropriate methods in the adaptation process for the BA intervention manual and booklet to meet the specific needs of perinatal women.

Although co-design established these strengths in the modification of the BA manual and booklet, it has constraints of being tokenistic by researchers who continue holding power and not valuing co-designers' experiences in the development process (Boylan et al., 2019; Ritchie et al., 2014). In spite of the fact that outcomes can also be affected by co-designers' unpredictable feelings, thinking, volition, social circumstances and dynamic interactions with others, tokenism can be overcome by including more and diverse co-designers, avoiding dominant part and letting everyone's voice to be heard during the co-design workshops and balancing involvement of the researcher in the process (Beresford, 2019; Locock and Boaz, 2019).

Adaptation process for the BA manual and booklet has the advantages of using inputs from women and HCPs, not for the 'performative logics and practices' (Paylor and McKeivitt, 2019), but for improving the content of the documents for the benefit of women. This was achieved by collaboratively working with women who will receive the BA support and with non-mental health specialists who will deliver the intervention (for example MSWs) and be part of the collaborative care (midwives, health visitors, obstetricians and GPs).

Current policy strongly emphasises the need for more investment in perinatal mental health services, psychological therapies and new workforces to support implementing the five-year forward plans for better births and five-year forward view for mental health within the current ambition of the government (National Health Service, 2019b; National Health Service, 2016; National Health Service and DoHaS 2016; the Independent Mental Health Taskforce, 2016). The NHS England was launched the Maternity Transformation Programme to implement the vision set out in the National Maternity Review. One of the workstreams was 'transforming the workforce' that aimed to ensure the right workforce with the right skills to establish the objectives detailed in the National Maternity Review and develop a competency framework for MSWs according to this (National Health Service, 2019b). The Health Education England published this framework in 2019. According to the role descriptor of level four MSW, MSWs can "provide specialist support to women and families with complex needs" (2018, p. 12) with appropriate training. Therefore, the study findings are highly related to the current policy and the role description of the MSWs, and highly

important in terms of filling a gap in the evidence by adapting a psychological intervention for the needs of women.

5.5 Conclusion

In this chapter, the second study findings, interviews with women and HCPs are briefly presented by explaining its role in the adaptation of the BA manual and booklet. Relevant texts were extracted from the manual and booklet to illustrate the adaptive changes that have been made according to second study findings. Then, the third study findings, co-design workshops with women and HCPs are discussed using themes, related quotations from co-designers and example texts from the manual and booklet. In the following discussion and conclusions chapter (chapter six), these findings are summarized and interpreted, discussed in more detail in relation to the pre-existing literature (see sections 6.2.2 and 6.2.3) and theoretical perspective (see section 6.3), acknowledged the strengths and limitations (see section 6.4.2), and considered implications on policy, practice and research (see section 6.5).

Chapter 6: Discussion and conclusions

6.1 Introduction

This thesis began by identifying the psychological interventions that are delivered by non-mental-health specialists (NMHS) for the treatment of perinatal depression and by reviewing the evidence of their effectiveness. It discussed the different types of psychological interventions that were delivered and the variety of non-specialist groups trained in the delivery of these interventions. A gap was identified in terms of interventions suitable for treating perinatal depression by NMHSs and, accordingly, the study aimed to adapt a behavioural activation (BA) intervention manual intended for delivery by NMHSs, for example, maternity support workers (MSW) and a guided self-help booklet for use by women experiencing perinatal depression through an experience-based co-design approach (EBCD). Women's experiences of perinatal low mood or depression and any care that they may have received and healthcare professionals' (HCPs) experiences of providing support and care for women with perinatal low mood or depression were explored, and this study element also informed the adaptation process of BA intervention manual and booklet.

In this chapter, the key findings of the three elements of the thesis research are presented. The findings are then interpreted in relation to the theoretical perspective of symbolic interactionism to understand perinatal depression experiences of women and HCPs meaningfully. Additionally, the methodological strengths and weaknesses of each study element as well as the research design as a whole and the chosen method for analysis of qualitative data are discussed. Finally, the implications of findings for policy, practice and future research are presented in the light of considering these strengths and weaknesses.

6.2 Key findings

Three interrelated studies were conducted, and each of the findings of these studies is summarised in this section.

6.2.1 Findings of the systematic review: effectiveness of psychological interventions delivered by NMHSs for the treatment of perinatal depression

The systematic review and meta-analysis aimed to evaluate the type of psychological interventions delivered by NMHSs, the range of NMHS groups delivering the interventions and the effectiveness of these interventions. The main findings of the systematic review are summarised in Table 21.

Table 21: Summary of findings for the systematic review of psychological interventions delivered by NMHSs for the treatment of perinatal depression

<ul style="list-style-type: none">• The types of psychological treatments that had been delivered by NMHSs were identified as cognitive behavioural therapy (CBT; including psycho-education), counselling (including non-directive counselling and person-centred therapy), and interpersonal psychotherapy (IPT)
<ul style="list-style-type: none">• The NMHS groups were mostly nurses, health visitors, midwives and community health workers
<ul style="list-style-type: none">• The meta-analysis showed that CBT delivered by NMHSs was effective in the treatment of <i>postpartum</i> depression in the short (up to six months) and medium-term (6 to 12 months)
<ul style="list-style-type: none">• Counselling and IPT delivered by NMHSs were also found to be beneficial in decreasing postpartum depression symptoms in the short and medium-term
<ul style="list-style-type: none">• CBT delivered by NMHSs for <i>perinatal</i> depression was also beneficial in decreasing depression symptoms in the medium and long-term (12 months and above)
<ul style="list-style-type: none">• There was some limited evidence of impact on secondary outcomes for some of the interventions (including postpartum anxiety, mother-infant relationship, and cognitive and emotional development of the baby)
<ul style="list-style-type: none">• These results need to be interpreted in the light of the methodological strengths and limitations of the primary studies and the review (discussed in section 6.4.1).

Although CBT and BA are recommended in NICE guidelines (2009 and 2020) for the treatment of perinatal depression, this review did not identify any evaluations of BA interventions delivered by NMHSs in perinatal settings.

The literature review in chapter one demonstrated that BA is a good candidate as a simple intervention, which can be delivered by people without an extensive background in mental health or specialist training in psychotherapeutic treatment (Veale, 2008). It is as effective as other psychological interventions (Mazzucchelli, Kane and Rees, 2009; Ekers, Richards and Gilbody, 2008; Cuijpers et al., 2007) and cost-effective when delivered by NMHSs (Ekers et al., 2011a; Richards et al., 2016). These features may make BA more attractive for services, particularly as there is growing evidence on the effectiveness of BA in different age groups, a range of populations and settings, comorbid health conditions and a variety of delivery formats (Dimidjian et al, 2011).

Findings of the systematic review on the effectiveness of a variety of psychological interventions delivered by NMHSs for the treatment of perinatal depression showed a gap in the evidence regarding the effectiveness of BA in perinatal settings. This gap informed the development of the second and third study elements of the thesis, which set out to by adapt the BA manual and booklet intended for delivery by NMHSs, for example, MSWs for the treatment of perinatal depression.

6.2.2 Findings of the second study element of the thesis: qualitative interviews with women and HCPs

Interviews were conducted with women and HCPs to explore women's past experiences of perinatal low mood or depression in terms of: perceived barriers to receiving treatment and facilitating aspects; expectations of health service provision regarding perinatal depression; HCPs' roles and experiences in terms of awareness of perinatal mood changes; perceived barriers and facilitating aspects to identification and treatment; and to inform the third stage of the PhD project around what might be the opportunities, challenges and barriers to introducing BA therapy. These specific aims were addressed as detailed in chapter four, and the key points were captured which then helped in adapting the BA manual and booklet within an experience-based co-design approach (Bate and Robert, 2007) as detailed in chapter five. The themes

summarised in Table 22 emerged from the data and were used in the adaptation process of the BA manual and booklet (see Appendices 64 and 65). Other key findings are presented below.

Table 22: Summary of qualitative interview findings that were used in the adaptation process of the BA manual and booklet

Second study findings: thematic areas	Adaptive changes made to the BA manual and booklet according to the second study findings
1) Triggers of perinatal low mood/depression	<ul style="list-style-type: none"> • BA manual (p. 5): Recognising the symptoms of low mood and the changes in actions during pregnancy and after childbirth • BA booklet (p. 4): Some factors that can lead to low mood
2) Recognising the signs of low mood/depression	<ul style="list-style-type: none"> • BA manual (p. 5): Recognising the symptoms of low mood and the changes in actions during pregnancy and after childbirth • BA booklet (pp. 4, 5, 6, 7, 8, 9 and 27): Recognising symptoms of low mood
3) Breaking the barriers to help women to disclose their feelings	<ul style="list-style-type: none"> • BA manual (p. 5): How to approach women in the contacts • BA booklet (p. 2 and 5): It is okay to share your feelings. We are here to help and support you
4) Hidden face of perinatal low mood/depression	<ul style="list-style-type: none"> • BA booklet (pp. 6, 11, 13, 14, 17 and 19): It can also include thinking about ending your life or harming yourself or others
5) Needing attention while providing support and care for perinatal low mood or depression (by HCPs, friends and groups in social media, partners and parents)	<ul style="list-style-type: none"> • BA booklet (pp. 2, 9, 11, 13, 14, 17, 19, 20, 22, 25 and 28): Call friends and family as well as the HCPs and talk to them about how you are feeling
6) Helpful strategies in recovery	<ul style="list-style-type: none"> • BA booklet (pp. 9, 11, 13, 14, 17, 19, 20, 22, 25 and 28)
7) Women's messages (for improving perinatal low mood or depression care and services, for HCPs, for other women)	<ul style="list-style-type: none"> • BA manual (pp. 5 and 6): Treatment contacts are organised via 6 appointments; however, the treatment should be personalised for women • BA booklet (pp. 2 and 22): There are many reasons why meeting with friends helps
8) HCPs' messages (for improving perinatal low mood and depression, and care and services, for women)	<ul style="list-style-type: none"> • BA booklet (p. 25): List of strategies to improve mood
9) Women's and HCPs' views on Behavioural Activation and MSWs	<ul style="list-style-type: none"> • BA booklet (p. 2): We hope that working through it with your support worker will help you to learn how to improve your mood

Women's feelings of low mood in the perinatal period led to a significant decrease in their social activities and communications with their family and friends. They reported a desire to be alone, not to talk to or see anyone, not to do housework or cook for themselves or have a shower. These outcomes showed consistency with the findings of another UK study regarding older women's (aged 30 or above) experiences of postpartum depression (Hannan, 2016). The findings of this PhD study included a range of experiences, for instance, antenatal or postpartum low mood or depression, and described the negative effect of depression on perinatal women's daily routines and activities. The symptoms of depression may be improved through behavioural activation therapy, adapted to the specific needs of perinatal women (Barrera and Castro, 2006).

Some women described reaching out and seeking help from HCPs while others reported hiding it even from their partners and family members. A few of them ticked the lower score boxes intentionally when given a depression measure to fill in by HCPs. The HCPs described suspecting that something was not right but the women were reluctant to share their true feelings with them. These outcomes are consistent with previous study findings: from the UK which reported that women did not tend to disclose their feelings with the HCPs (Khan, 2015); from Australia which reported that one-fifth of perinatal women had not responded honestly when HCPs asked them about their mental health (Forder et al., 2020) and more than three-fifth of postnatal women were reluctant to share their true depressive feelings with HCPs (Woolhouse et al., 2009); also from an international systematic review which reported that women do not tend to seek help from HCPs (Dennis and Chung-Lee, 2006). However, the PhD study described here also highlights a number of approaches that HCPs could use to help women to disclose their feelings to them. Specifically, women indicated it may help if HCPs ask every woman in a direct way how they are feeling with regard to their mood or mental health specifically and how they are coping at every contact. Consistent, high quality communication skills would also support effective care; therefore, it may help to make eye contact and make women feel they are being listened to. Having enough time to listen to and respond to a woman if she discloses her feelings was also identified as important, and not to leave the conversation incomplete or unfinished if a woman expresses that she is feeling down. It may help if

HCPs checked-in again soon with the woman and not leave too big a gap until the next routinely scheduled appointment. It was also clear from the interviews from HCPs that though they wanted to spend more time with women, their role demands within their working hours made this challenging.

Interviews with women showed that the provision of help and support sources varied between the midwives and health visitors. For women with the moderate and severe depression, there was consistency between the midwives and health visitors in signposting women to the appropriate mental health services. For women with low mood or mild depression, where referral may not be needed but support is, there were variations in the provision of practical help and support. The same finding emerged from interviews with midwives and health visitors. Most of the health visitors were knowledgeable about providing practical recommendations for women with postpartum low mood or mild depression. For instance, talking to family and friends, asking for physical help from them with housework, going out of the house for whatever reason, attending mother and baby groups, eating and drinking healthily and sleeping properly, and having time for themselves. However, the midwives barely mentioned these activities in the interviews, except for advising women to attend pregnancy groups and have support networks. Previous studies have also reported similar concerns. In these studies, HCPs stated that they had received insufficient training about managing perinatal mental health difficulties and lacked the confidence to talk about perinatal mental health with women (Noonan et al., 2017; Boots Family Trust Alliance, 2013; Rothera and Oates, 2011; Jomeen, Glover and Davies, 2009). Uniquely, in this PhD study, the midwives expressed their desire for more training about the basic suggestions that they could make in cases of low mood or mild depression. A GP also indicated that there may be a grey area in provision of mental health services where women do not need a referral to specialist perinatal mental health services but need support.

All the women who participated in the study stated their dissatisfaction with perinatal mental healthcare services and support provided by HCPs or stated that the treatment options did not meet their needs. They stated that there were not enough options to choose from; they were either offered medication or referred to the IAPT services. A broader, recent review (Bayrampour, Hapsari and Pavlovic, 2018) of the barriers to

addressing perinatal mental health issues in midwifery settings, identified some of the findings observed in this study, including the scarcity of available referral options. However, this review did not provide detail on women's expectations of psychological treatments. In this PhD study, this gap was filled by asking women about their expectations from psychological treatments. The women expressed willingness to receive psychological support from their maternity team or health visiting team that they are familiar with. However, they highlighted that there should be more treatment options for low mood or depression. For example, there should be face-to-face, group or telephone-based treatment options and continuity of care from pregnancy to the end of the postnatal year or two years postnatally. In addition, the provider should be easily accessible and there should be a direct phone number to access them. When they were asked whether they would like to go somewhere to receive the talking therapy or they would prefer the HCP to visit them at home, some women preferred the latter while others stated that the HCP should have an office at hospital or within a Children's Centre, where they can call in and talk about their mood confidentially. In addition, women stated that the therapy sessions should include information specific to perinatal depression.

Lack of continuity of care was also reported in the review previously mentioned (Bayrampour, Hapsari and Pavlovic, 2018). The review highlighted that development of the scope of help and support and collaborative care are central in the management of perinatal mental health problems (Bayrampour, Hapsari and Pavlovic, 2018). The findings of this PhD study shed further light on the existing problem and contribute to the literature by adapting BA for perinatal depression. The MSWs, who are part of the maternity team would be appropriate staff to deliver BA to perinatal women in collaboration with midwives, health visitors and GPs. The interview data from women and HCPs, including two MSWs, shows that both groups see MSWs as appropriate staff to deliver BA, with appropriate training and supervision.

The strategies women identified as helpful when recovering from perinatal low mood or depression, other than professional help sources (i.e., psychological therapies and medication) are listed in Table 15 in section 4.2.3. All the items in this list can be achieved through activity scheduling, using the BA booklet within a BA treatment. Indeed, these specific useful suggestions for women in recovery from perinatal low

mood or depression can be used in treatment adaptations in order to engage women more effectively, thereby enhancing the success of the psychological treatment (Barrera and Castro, 2006). Further, the use of written materials (e.g. BA booklet) would be beneficial in the discussion of perinatal mental health of women (Boots Family Trust Alliance, 2013).

6.2.3 Findings of the third study element of the thesis: co-design workshops with the involvement of women and HCPs

The co-design workshops were conducted with the involvement of women and HCPs (i.e., co-designers) to inform the adaptation of the BA manual and booklet, intended for delivery by MSWs for the treatment of perinatal depression. This aim was achieved by adapting the documents (see Appendices 64 and 65) for the specific needs of women in the perinatal period. The outcomes of these workshops are summarised in Table 23. The key findings are provided below.

The co-designers commented on the booklet and manual in the workshops. Changes were made according to the view of the majority of co-designers in the workshops. These changes were then discussed in subsequent workshops for confirmation or refutation and information was added or removed accordingly. Final decisions were made based on the outcomes of two or three workshops in that the views of the majority were applied.

Following feedback received from women, the examples in the documents were enriched by taking into account a broad spectrum of women; for instance, pregnant women, first-time mothers and mothers with more than one child. The appropriateness of examples was a key point to emerge in all four workshops. The women also wanted to see an example for each activity before being asked to do it. The women pointed out that it can be a struggle to think clearly when experiencing low mood. Having examples would help them to see what the possibilities might be before creating their own diary sheets or tables of activities. This point was congruent with the views of HCPs in the workshops.

Table 23: Summary of findings for the third study element of the thesis (co-design workshops involving women and HCPs)

<p>1) To differentiate what is common and not common to feel in the perinatal period and other adaptations to the content</p>	<ul style="list-style-type: none"> • feeling tired • feeling emotional • having sleeping problems • not bothering cooking nutritious food • clarification of the risk factors and other signs of perinatal low mood and depression • other content related adaptations
<p>2) Illustration of mood cycles and suggested activities with examples</p>	<ul style="list-style-type: none"> • considering example activities for <ul style="list-style-type: none"> • pregnant women • first-time mothers • mothers who have more than one child • providing pregnancy and postpartum-related examples to the cycle of low mood • providing examples for manageable activities • providing an example action plan and example diary
<p>3) Using quotations from the second study</p>	<ul style="list-style-type: none"> • placing relevant quotations to the appropriate pages using women-chosen pseudonyms
<p>4) Highlighting that “BA may not work for you”</p>	<ul style="list-style-type: none"> • other sources of help that may be helpful for some women
<p>5) Minor modifications</p>	<ul style="list-style-type: none"> • using bullet points • highlighting important text • choosing brighter and natural pictures • reordering some sections • removing repetitions or unnecessary information • improving the clarity of the text • improving mood scale by using emojis • deciding the size of the manual and booklet and font size of the content

Another improvement was made to the content of the booklet and manual in response to the second study findings and the literature review. The study findings and the literature review showed that perinatal depression potentially has an impact on children and partners. This information was added to the documents; however, both

the women and HCPs asked them to be removed. They argued that including this information might reinforce a woman's fears that she is a bad mum and that emphasising the effect of her mood on the whole family puts additional pressure on her. Another finding from the second study was the lack of support for partners. The co-designers were asked if they wanted information to be added for partners about help and support sources that they can try if they are experiencing low mood. The women anticipated that they would be reluctant to share the booklet with their partners. Another rationale given was not wanting to imply that the mood of the mum can detrimentally impact on the mood of the partner. One woman asked if information for partners could be included about how they can support the woman with depression. However, other women in the group and in the subsequent workshops did not want this information to be included because they insisted on keeping the booklet personal for women. The consensus among the women was that they did not want to share the booklet with their partners.

The co-designers reported being confused about the signs of perinatal depression initially presented in the booklet. They pointed out that having sleeping problems, changes in appetite, feeling exhausted and feeling emotional, may be experienced by non-depressed mothers as well during pregnancy or in the postpartum period, especially around the fourth day after giving birth. Therefore, it was important to differentiate these feelings with depression and ensure a clear distinction was made in the BA booklet between what is common experience and what is not. For sleeping problems, it was emphasised that not being able to sleep when the baby is asleep *may* be a sign of depression. For changes in appetite, it was added that not prioritising or having the motivation to cook food *may* be a sign of depression. In the same vein, in relation to emotions, the booklet stresses that due to hormonal changes around the fourth day after giving birth, women can feel emotional and it is common to feel like that. It then goes on to say that if it continues for more than a few weeks, then it can be a sign of depression.

Using relevant quotations from the second study element of the thesis was one of the suggestions of the co-designers. According to their recommendations, a few quotations were used in the booklet and as a result of the very positive feedback in the following workshop, more quotations were added. Later, quotations were placed

almost on every page in the booklet. These quotations were chosen according to their relevance to the content of the text and represented with women-chosen pseudonyms.

Although BA aims to increase women's engagement with activities, the co-designers also pointed out that a considerable number of women continue their daily routines and attend activities, including mother and baby groups, but do not get enjoyment from them and feel depressed. The consensus among the co-designers was that a statement should be added for these women stating that BA is just one of the options that can be tried and that other help is available if this booklet does not feel right for them. This statement is critically important as it encourages women not to give up and that there are always other treatment options if one does not work.

6.3 Interpretation of findings in relation to theoretical perspective and within the context of the wider literature

Symbolic interactionism (SI) was chosen as the theoretical perspective for the second and third studies because it argues that the meaning of the social world for people is linked with their interactions and interpretations of these social exchanges. SI can be viewed, therefore, as a useful theoretical perspective to understand the social world, people's interactions with one another and how these shape a common understanding and the social actions that follow from that understanding (Charon, 1998).

In the second study, SI facilitated understanding each woman's perspective who had experienced perinatal low mood or depression and how the meaning of depression and their interactions with others formed their actions. The latter included for example, changing in their daily routines, behaviours, relationships and communication with family and friends, changing roles within the family and transition to motherhood and parenthood.

One example related to this would be understanding what it can feel like to experience postpartum depression, and what having depression may lead to in the lives of new parents. The parents' definition of 'us' may change when having a baby and with increasing interaction with other parents, the previous definition of being a parent will be renewed (Charon, 1998). Some people may have the expectation from new parents

that they should be happy because of having a new member of the family. This puts pressure on women to appear happy and demonstrate that they are the perfect mum even though they feel sad or depressed (Hannan, 2016; O'Hara, 2009). Whilst getting used to a changed identity of being a parent (transition to parenthood) is difficult, having depression and responding to the effects of depression on the mother, the needs of the newborn and the pressure from other people, can make the transition more difficult. This can result in conflict within the family which exacerbates the challenge for women, their partners and children (Milgrom and Gemmill, 2020). Women may feel ashamed or inadequate (Goodman and Brand, 2008) or see themselves as failures and may stigmatise perinatal depression (Button et al., 2017; Hannan, 2016; Khan, 2015; Bilszta et al., 2010), which then informs their future actions. These actions may include withdrawing from their family and friends, not seeking help from HCPs, and in some cases self-harm or suicide (Hannan, 2016; Lindahl, Pearson and Colpe, 2005).

This example illustrates how the perspective of SI helps to understand the challenges women face in the transition to parenthood while experiencing postpartum depression and their actions in their new situation. Having depression may lead to undesirable consequences for women, their partners and children; it is therefore crucial to understand their world with depression to be able to provide appropriate help and support sources. BA interventions during the perinatal period can draw on understanding generated by research such as this. More generally, it should be informed by work around a range of culturally supported beliefs about the significance of changing roles within the family, the influence of having a baby on a woman's life and her capacity to maintain and attend in previously engaged and worthwhile activities. Addressing women's needs (Bayrampour, Hapsari and Pavlovic, 2018) and adaptation of the interventions to the circumstances in which women live and will be treated, are also recommended (Howard et al., 2014). Successfully adapted interventions may be beneficial for the engagement of users (e.g. recruitment, enrolment, participation and treatment satisfaction) and improve their symptoms of low mood (Barrera and Castro, 2006).

In the third study, SI assisted in understanding the cooperative actions of the women and HCPs and the common symbols and meanings that were developed during the

workshops. All the co-designer women had experienced some level of depression, but in different ways, and all the HCPs had the experience of supporting women with depression, but their roles were different. They came together for the same purpose but bringing with them their different understandings and perspectives of perinatal depression and treatments. Using SI for the third study, therefore, helped the co-designers to understand the importance of sharing their knowledge with other co-designers in the group, and in so doing, helped each other to reinterpret their experiences and knowledge. This encounter of a range of understandings formed the basis of the process of negotiating and reaching consensus regarding the changes that were made to the BA materials.

6.4 Strengths and limitations of the thesis

6.4.1 Strengths and limitations of the systematic review: effectiveness of psychological interventions delivered by NMHSs for the treatment of perinatal depression

This is the first systematic review that has examined the effectiveness of psychological interventions delivered by NMHSs for the treatment of perinatal depression. The chosen design, a systematic review and meta-analysis of randomised controlled trials, is a robust and established method for evaluating the effectiveness of such psychological interventions (McKenzie et al., 2019).

Previous systematic reviews assessed the effectiveness of psychological interventions for the treatment of antenatal or postnatal depression (Stephens et al., 2016; Cuijpers, Brännmark and van Straten, 2008; Dennis and Hodnett, 2007; Dennis, Ross and Grigoriadis, 2007); however, they did not specifically report their effectiveness for depressive symptoms when delivered only by NMHSs. One review described the content and delivery of psychological interventions delivered by NMHS in low- and middle-income countries for perinatal depression (Chowdhary et al., 2014), but the effectiveness of these interventions was not assessed in that review. Another review examined the effectiveness of psychosocial preventive and treatment interventions delivered by peers or NMHSs to pre-pregnant, pregnant or postnatal women (Clarke, King and Prost, 2013). However, only studies conducted in middle-income countries were included in the review, limiting generalisation to other countries, and 10 of 11

studies were preventive interventions, limiting the treatment advice for women with clinical levels of perinatal depression. The systematic review detailed in chapter two, therefore, specifically examined the effectiveness of psychological treatments delivered by NMHSs for perinatal depression. Building on the previous reviews, it included: antenatal, postpartum and perinatal depression; maternal anxiety; mother-infant relationship; cognitive and emotional development of the infant; and relationship with the partner. By including only randomised controlled trials without date, language, setting or country restrictions, as well as conducting a highly sensitive search strategy, a comprehensive review of existing trials was achieved.

There are some potential limitations of the review and the primary studies included in the review that need to be discussed before interpreting the outcomes. Many of the trials had limitations in the reporting of information required to assess risk of bias. Allocation concealment was not reported almost half the trials, which may artificially inflate observed effects and might lead to selection bias (Pildal et al., 2007; Wood et al., 2008). The trial registry was not available for half of the trials, which may lead to reporting bias. The participants were not blinded to the interventions, which might potentially exaggerate intervention effect estimates (Wood et al., 2008). The size of the included trials was small in many studies, which might also influence treatment effect estimates (Dechartres et al., 2013). It was not possible to assess publication bias using funnel plots, because of the low number of studies included in the meta-analyses. Taken together, these factors may have led to an overestimate of the actual effect of interventions delivered by NMHSs for the treatment of perinatal depression.

The screening of database search outcomes and the risk of bias assessment of the included studies were made by one reviewer, which may potentially limit the reliability of the decisions made and may, therefore, limit replicability (Shea et al., 2007).

6.4.2 Strengths and limitations of the experience-based co-design studies: qualitative interviews with women and HCPs, and co-design workshops with the involvement of women and HCPs

This is the first study to apply experience-based co-design (EBCD) to the adaptation of the BA manual and booklet, intended for delivery by NMHSs, such as MSWs for the treatment of perinatal depression in England. The design chosen was congruent with

the Medical Research Council's framework for the processes of developing and evaluating complex interventions (Craig et al., 2013) and O'Cathain et al.'s (2019a and 2019b) guidance on how to develop interventions to improve health and healthcare (as discussed in section 3.2.5). This thesis also systematically captured insights into, and reflections of, women's experiences of perinatal low mood or depression and any care that they may have received. It also captured HCPs' experiences of providing support and care for women who have experienced perinatal low mood or depression. Women and HCPs' experiences helped to inform the adaptation process for the BA booklet and manual, all of which may be helpful to increase engagement in treatment and, through this, improvement in mood (Barrera and Castro, 2006).

One criticism of patient and public involvement studies has been that the greater part of the involvement activities in healthcare are at the level of receiving feedback about a service rather than designing it or influencing the decision-making process (Ocloo and Matthews, 2016). The EBCD approach, which derives from an action research tradition, maintains a bridge between the researcher and the co-designers; it enables an environment in which people can work and design together expressively, creatively and collaboratively; it values the skills and respects the ideas, perspectives and knowledge of all; it intends to build a rapport between the researcher and the co-designers (Bate and Robert, 2007).

Action research approaches have been criticised for leading to tokenism ["asking for involvement but not taking it seriously or enabling it to be effective" (Ocloo and Matthews, 2016, p. 628)], an imbalance in the involvement of participants, and not pursuing equality (Locock and Boaz, 2019; Paylor and McKeivitt, 2019; Ritchie et al., 2014). Additionally, co-design has been criticised as involving simplistic tasks that are separated from the financial, bureaucratic and community contexts in which they may function (Beresford, 2019; Paylor and McKeivitt, 2019). Furthermore, some factors might be inadvertently excluded by researchers when using approaches that use the involvement of the patient/service user and the public, and they may undermine the quality and credibility of the research (Beresford, 2019; Ocloo and Matthews, 2016). Examples of these factors include: (during recruitment) exclusion of people with regards to where they live (e.g. homeless, travellers, in residential services), and exclusion of people with communication issues (e.g. deaf, blind, people for whom

English is not their first language, unwanted voices) or poor health literacy (e.g. their access to healthcare is important). In the involvement process itself, there might be a lack of sexual and racial equality and other forms of discrimination (e.g. gender, ethnicity, belief, disability and socio-economic status). In the meetings, the researcher might not value or listen to what people say, might discourage people to say more, may behave like they do not want people to be involved, and might not use incentives for the compensation of their time spent in the study, all of which might affect some peoples' effective involvement in the study and their performance, thereby impacting on the rigour and trustworthiness of the research (Beresford, 2019; Locock and Boaz, 2019; Ocloo and Matthews, 2016; Ritchie et al., 2014).

There is still uncertainty in the literature about EBCD approaches about how to improve the involvement of the patient/service user and the public and how best to involve a greater variety of people, rather than a small number of selected people (Ocloo and Matthews, 2016; Tritter and McCallum, 2006). Ocloo and Matthews (2016) suggest that balancing the power between the researchers and patient/service user and the public, supporting empowerment, variety and equality, and promoting assessment of findings and the impact can help in avoiding tokenism. These suggestions may be ensured through providing practical help and opportunities to facilitate people's involvement in the study. These might include: offering different methods to reach more and hard to reach groups (e.g. using surveys; workshops; written and verbal skills; supportive, attractive, inclusive and enjoyable activities; encouraging networking; informal venues; a safe environment; free refreshments); being open to people's assumptions, experiences, knowledge and understanding; and supporting people's skills and expertise and building confidence, trust and rapport with them. The researcher facilitating the process should: speak clearly and slowly; repeat important points and check people's understanding; support them to ask questions; provide written materials and supporting visual materials (Beresford, 2019; Ocloo and Matthews, 2016; Bate and Robert, 2007).

As explained in section 3.6 on reflexivity, rigour and trustworthiness, during the recruitment and data collection for the second and third study elements of the thesis, one of the researcher's roles was scheduling interviews with women and HCPs according to their availability, whilst adhering to the risk assessment protocol. This

included booking a convenient venue for the interviews and workshops that provided privacy, a safe environment, was close to the participant's home or at a central location for everyone, with free car park option and a room that was pushchair and wheelchair accessible. The researcher also took care to ensure that refreshments were provided in the interviews and a light meal in the workshops. Fruit, coloured pencils and paper were available for the children. Women were reimbursed for the time spent in the interviews and workshops by offering them gift cards and travel expenses. In addition, hanging room location identifiers on the walls and doors were used where possible to make it easier for them to find the meeting room. The researcher aimed to always be polite and kind to them and their children, guiding them to find the toilets if necessary. During the interviews and workshops the researcher aimed to ask questions without judgemental thoughts or behaviours and avoided asking questions that may be difficult or embarrassing in a sensitive manner. She endeavoured to talk slowly and clearly, repeating the key messages and encouraging the women throughout the process to raise any point or to ask any questions, including if anything the researcher said was not clear. Additionally, post-it notes, colourful pens, pencils, highlighters, blank sheets, presentation outputs, and BA booklets and BA manuals were provided for every co-designer to work with. The participants were encouraged to share their ideas about how to improve the BA manual and booklet, in order to develop them and make them useful for other women who may share similar experiences to theirs. The researcher described the BA therapy to co-designers verbally before going through the BA manual and booklet page by page. Although a PowerPoint presentation was prepared to facilitate the communication, because of limited equipment in the rooms hired, printed copies of the presentation outputs were shared with co-designers so that they could follow the information from the worksheets and take notes. Finally, the researcher tried to respect their knowledge and experiences and emphasise that they were experts in this work. She conveyed that this was an opportunity for them to help other women by using their experiences, allowing everyone to share their thoughts, and was mindful not to take over the conversation by talking more than others, thereby balancing the researcher's power in the process.

In the second and third study elements of the thesis, attempts were made to recruit a variety of women, including different age groups, ethnicity, socioeconomic status, and

experience of low mood or with a diagnosis of depression antenatally, postnatally, or perinatally. The intention was to also recruit women with different treatment experiences, including those who had received psychological or pharmacological treatment and those who had received neither. Another criterion was the duration of depression and depression severity (i.e., mild, moderate, severe). However, only few of these criteria were not achieved. The sample size of women involved in the second study was relatively small (n = 15), all of them were older than 28 years, and all were white British, thereby limiting the transferability of the findings to younger women or ethnic minorities. Fourteen women were involved in the third study and all of them were older than 31 years. Although the majority were white British, a small number of women (n = 3) were from other Asian backgrounds. Some inference may be made therefore regarding the utility of BA support for ethnic minorities in England, though this is, of course, very limited. The spread of women in the other categories (i.e., socioeconomic status, the experience of low mood or with a diagnosis of depression antenatally, postnatally, or perinatally, received psychological treatment or not, received pharmacological treatment or not, duration of depression and depression severity) was reasonable in both of the studies as discussed in section 4.2.1 and section 5.3.1.

The women involved in the studies were also limited to mothers who had experienced perinatal low mood or depression in the last five years, and whose youngest child was between 1 and 5 years. The reasons for the inclusion and exclusion criteria are detailed in the assessment and management of risk section in section 3.5.1. Although the priority was to include women who had recently experienced perinatal low mood or depression, the youngest child was 2.3 (second study) and 2.5 (third study) years, which potentially raises the issue of the data being limited over this time period. However, the literature review and interviews with HCPs supported the study findings that perinatal low mood and depression is an ongoing problem and available help and support sources remain limited. It was identified as an issue that needed to be addressed a matter of urgency, as detailed in section 6.5 'recommendations for policy, practice and future research'.

Another challenge in terms of recruiting women with a range of experiences was the inclusion criteria regarding women who scored less than 10 in PHQ-9, as detailed in

section 3.3.2 'study setting and participants' and section 3.5.1 'assessment and management of risk'. This information was provided in the emails sent to women who had expressed an interest. As a result, more than half the women who had showed an interest initially, did not respond. It is anticipated that women continue to experience depression after the end of the postnatal period but the inclusion criteria did not allow them to participate in the study, which was due to ethical considerations for the study as discussed in section 3.5.1. Their experiences, therefore, cannot be assumed to be similar to those women who were involved in the second and third study elements of the thesis.

Finally, the recruitment criteria excluded women under 18 years because it was felt that the experiences of adolescents might be different because of their younger age. According to Lieberman, Le and Perry (2014), psychological interventions need to be adapted for specific populations. Therefore, a separate adaptation process would be needed for adolescent groups.

With regards to the recruitment of HCPs for interviews and workshops, using gatekeepers might have limitations as well as advantages. The gatekeepers might be selective in informing their colleagues about the study and only send emails to specific staff (Ritchie, et al., 2014). Although in this research using gatekeepers was advantageous in reaching community midwifery teams and health visiting services who are not based in hospitals, using advertisement leaflets and posters was a challenging and impractical approach. In the event, personal contact through the researcher visiting the service and introducing herself to the staff was more effective than using advertisement channels. This was also important as it provided an opportunity to get to know each other and build confidence, trust and rapport.

The aim was to include a variety of HCPs from NHS Trusts, primary care and community healthcare settings and this was achieved in the second study, with the involvement of 19 HCPs from nine different job roles, as explained in section 4.2.2. However, the recruitment of GPs was challenging (McKinn et al., 2015; Patel et al., 2017); only one GP participated in the study. This was despite the researcher's efforts to inform 20 GP practice managers across the three research sites and ask them if they

could inform their GPs about the study or allow a visit to the surgery to introduce the research to the GPs.

Participation of maternity service managers, head of midwifery teams, lead midwives, specialist perinatal mental health midwives and psychological wellbeing practitioners was also valuable for the second study in terms of understanding their management of perinatal depression cases and exploring the potential of MSWs to provide a brief talking therapy to women; however, some of these professionals did not show an interest in the study while others (i.e., psychological wellbeing practitioners) were not the target group during recruitment.

Three HCPs from three different job roles participated in the third study element of the thesis. Some of the HCPs needed to know the date at least one month before the meeting so that they could arrange their working times. Although the date of the workshops was decided at least one month before the workshops, informing the gatekeepers and then the HCPs about the workshops delayed the process. The decision taken regarding the date of the workshops arose from different factors. For instance, because of the inclusion and exclusion criteria for women, only a small number of them met the criteria. Therefore, women were asked about their availability by phone and the date was chosen according to the date the majority could attend. The BA booklet was the main document to be worked on during the workshops because it included the therapy stages, activities and diaries for use by the women as well as the MSWs during the therapy sessions. Women's participation was therefore crucial. Initially the idea was to schedule separate workshops for HCPs, according to their availability; however, after four workshops, the remaining time to finish the PhD was limited, and the cost of the four workshops, 28 individual interviews and 2 focus groups in three different research sites, already exceeded the researcher's resources to fund the study.

Finally, it is acknowledged that the IAPT services provide BA treatment for depression; therefore involvement of psychological wellbeing practitioners in the co-design workshops would be highly valuable. However, because of the funding and time implications as mentioned above, very limited number of HCPs involved in the co-design workshops.

6.4.3 Strengths and limitations of thematic analysis

In undertaking qualitative research, the analysis of the data is the most complicated step (Thorne, 2000). The findings of qualitative research were intended to fill a gap in the evidence not only for understanding the phenomena and taking action, but also for the efficacy of findings (what works in research) and its effectiveness (what works in practice) (Sandelowski, 2004). The researcher, therefore, should be aware of their assumptions and their impact on the analytic process, what they are doing and why they are doing it, and their strengths and limitations, all of which affect the trustworthiness of the research and analysis (Nowell et al., 2017).

One of the limitations of symbolic interactionism is that there are no fixed procedural rules about how to analyse the study (Charon, 1998; Barbour, 2014). In the absence of distinct guidance on how to analyse the data generated within SI, thematic analysis (Braun and Clarke, 2006 and 2019) was employed in the second and third studies. While to some extent, aspects of the data could have been analysed and interpreted through ethnography, the researcher decided that, given the wide range of data generated in the research, thematic analysis would be the most useful.

Reflexive thematic analysis was adopted to analyse the qualitative data that emerged from the second and third study elements of the thesis. Coding within a reflexive thematic approach allowed the researcher to engage in an iterative process, going backwards and forwards between the data and the codes. Data within the codes and between the codes was constantly compared. Codes were merged, separated or renamed throughout the process in order to capture shared meaning-based patterns (core meaning) as well as differences among the participants and across the workshops (Braun et al., 2019).

Thematic analysis is a distinct method and has the following advantages: it is relatively simple to learn and the analytic steps are straightforward; it is a widely used method by researchers who have no or little previous experience of conducting qualitative research; it is a theoretically flexible method that can be used within a range of epistemological assumptions; it is a practical method for using with study designs involving the public and patients in particular. Also, thematic analysis is a useful method for producing key features of data collected from a great number of

participants. It is effective in emphasising the similarities as well as the differences of the data set and is flexible in terms of generating unexpected insights. Finally, it allows interpretation of data with regards to social factors as well as psychological factors and produces data analysis that can inform policy development (Braun and Clarke, 2006 and 2019).

Despite these advantages, interpretation of the data might be descriptive rather than interpretative if thematic analysis is not used within a theoretical framework (Braun and Clarke, 2006). In this regard, SI was employed so this particular limitation was avoided. Thematic analysis has also been criticised for lacking in transparency and not being sufficiently rigorous, as most of the literature focuses on how to conduct a qualitative study rather than on how to conduct a rigorous thematic analysis (Nowell et al., 2017; Smith and Firth, 2011; Braun and Clarke, 2006). To address this issue, Braun and Clarke (2006) provide a 15-point checklist of criteria for good thematic analysis, enabling researchers to use this as a guide when verifying if the thematic analysis has been properly conducted. All the steps of the thematic analysis described in Braun and Clarke (2006) were carried out during the analysis process and the checklist of criteria for good thematic analysis was also used.

In qualitative research, credibility can be ensured through collecting multiple perspectives, using varied sources of data, and comparing findings from different sources (Patton, 2015). As discussed in section 3.6 on 'reflexivity, rigour and trustworthiness' in the methodology chapter, triangulation of data sources was achieved through: collecting perinatal depression care pathways used in the research sites; interviewing HCPs about the treatment and referral pathways that they used; interviewing women about the treatment options and referral process, if any, offered by HCPs; and by sharing and confirming the second study findings with co-designers in the workshops and comparing the outcomes of each workshop. In addition, multiple perspectives were collected from women who had experienced antenatal or postpartum or perinatal low mood or depression, and a variety of health professionals who have experience of providing support and care for those women (i.e. community midwives, antenatal clinic midwives, obstetricians, maternity support workers, health visitors, specialist perinatal mental health midwives and GP). Moreover, comparison of

findings with different sources (i.e., between women and HCPs) was used in the EBCD, all of which enhanced the quality, accuracy and credibility of the studies and findings.

6.5 Recommendation for policy, practice and future research

6.5.1 Implications for policy and practice

The current policy 'Better Births' the National Maternity Review (National Health Service, 2016), underlines the importance of perinatal depression and recognises that it is an ongoing problem that affects not only the women themselves but also their children, partners, and the economy of the family and wider society. Although perinatal depression is a recognised problem, the provision of perinatal mental health services is insufficient across a large part of the country (Royal College of Midwives, 2017a). Improving the provision of perinatal depression treatments is in the Government's agenda and this is one of the action plans of the National Maternity Review, as detailed in section 1.3.5. As a result, evidence-based psychological therapies are receiving investment (National Health Service, 2016). The adaptation of the BA therapy manual and booklet directly addresses this government target and fills a gap in the evidence. Additionally, using MSWs in the delivery of treatment addresses the Government's other target which is to transform the workforce (National Health Service, 2019b).

In practice, it is crucial for HCPs to detect perinatal low mood and depression as early as possible to be able to provide help and support timely and avoid deterioration, all of which may result in reduced severity of symptoms and may reduce need for expensive secondary care interventions and costs of treatments (4Children, 2011; Stubbs, O'Shea and Durcan, 2018). Nearly 50% of all instances of perinatal depression go undetected, in spite of regular appointments with HCPs during pregnancy and after childbirth (The National Childbirth Trust, 2017; Bauer et al., 2014; 4Children, 2011). The midwives, health visitors and GPs have critical importance in the early identification of need for mental healthcare due to their positions where they have intimate contact with women at the beginning of their pregnancy, intrapartum and in the postpartum period (Schumacher, Zubaran and White, 2008). Indeed, HCPs', especially midwives' awareness and knowledge about perinatal mental illnesses can catalyse the processes of identification, management and treatment of depression and could be helpful for

women and their wider family (Hauck et al., 2008). In this regard, the recommendations of the researcher to HCPs and the specific implications of findings at the policy level are as follows:

- There is some evidence that psychological interventions delivered by NMHSs may be effective in the treatment of perinatal depression. Using NMHSs instead of therapists may have broader benefits in decreasing the cost of specialised perinatal mental health professionals. Policymakers may want to consider the potential benefits of training maternity and other relevant staff. Brief, low-intensity interventions delivered by this workforce may provide timely help and support and may be effective in decreasing perinatal depression symptoms, which may decrease the demand for high-intensity treatments provided by therapists, and the need for referrals to specialised perinatal mental health services in the longer term. It also means there would be better integration of care rather than 'outsourcing' care and treatment for mental health difficulties.
- The second study findings, interviews with women and HCPs, indicated that though there is an increase in awareness of perinatal depression among women and HCPs, women may still be reluctant to disclose their true feelings and seek help because of stigma and the potential involvement of social services. The HCPs may need to make it clear that women might be worried about their feelings; however, the HCPs are there to provide help and support for them to overcome their feelings, and mental health challenges do not automatically result in concerns about parenting which would warrant child protection concerns. Asking women's mood at every visit may also be helpful. Although the routine screening of postnatal depression has not yet been found to be a factor in changing the help-seeking behaviour of women, the HCPs' attitudes have the biggest impact on women disclosing or refraining from disclosing their feelings (Newman, Hirst and Darwin, 2019). This is also important in building trust and a friendly relationship not only with the woman but also with their wider family (Forder et al., 2020; Schumacher, Zubaran and White, 2008).

- Finally, the second study findings showed a gap in care for women experiencing low mood or depression and who do not need a referral but would benefit from support from the HCPs for perinatal low mood or depression. Indeed, the NHS has been criticised for not providing care to decrease the incidence and the effect of perinatal mental illness on women and their families (Maternal Mental Health Alliance, NCPCC, Royal College of Midwives, 2018). In this regard, HCPs may be trained in managing perinatal low mood or depression that does not need a referral but require support from the HCPs. BA delivered by MSWs for the treatment of perinatal depression may also help fill this gap.

6.5.2 Implications for future research

This study contributes to the literature on the delivery of psychological treatments by NMHSs and to the best of the researcher's knowledge, this is the first to look at adapting BA therapy manual and booklet intended for delivery by this workforce for the treatment of perinatal depression, guided by an EBCD, which derives from the action research tradition. The study included three phases: a systematic review and meta-analysis, in which the effectiveness of psychological interventions delivered by NMHSs for the treatment of perinatal depression was examined; a discovery phase, in which perinatal depression experiences of women and HCPs were explored; and a co-design phase, in which women and HCPs acted as co-designers of the BA therapy manual and booklet. The co-design phase built on the discovery phase. Future research could replicate the discovery phase in different geographical areas, including minority groups, teenager or younger women, women for whom English is not their first language and a variety of psychologists or mental health professionals. Such research would contribute to understanding these variations, for both women and HCPs. If similar outcomes are reported, this suggests that the problems identified in this study are widespread and would increase the transferability of its findings.

Further studies are also needed to evaluate the feasibility of BA interventions delivered by NMHSs, such as MSWs for the treatment of perinatal depression. These studies would need to explore the willingness of MSWs to deliver the treatment, the willingness of pregnant and postpartum women to participate and be randomised to BA intervention, willingness of MSWs, midwives, health visitors and other HCPs to

recruit participants, number of eligible women, features of the outcome measures that will be used in the study, follow-up rates and adherence rates (Arain et al., 2010).

Other specific recommendations for future research:

- More methodologically rigorous RCTs with adequate random sequence generation and allocation concealment, preregistered protocols, reports of reasons for missing data, larger sample sizes and longer follow-up periods are needed to be able to draw firmer conclusions about the effectiveness of psychological interventions delivered by NMHSs for the treatment of perinatal depression. The impact of these psychological interventions on maternal anxiety, mother-infant relationship, children's cognitive and emotional development and in the relationship with partners, need to be examined.
- A recent RCT suggested that the NMHSs may be less expensive to train and employ than psychological therapists (Richards et al., 2016). There is a gap in the evidence regarding cost-effectiveness of psychological interventions delivered by NMHSs for the treatment of perinatal depression; therefore, further studies are needed to evaluate cost-effectiveness of specific interventions when delivered by NMHSs compared to interventions delivered by therapists.
- Finally, little evidence was found with regards to adaptations of psychological treatments for perinatal women experiencing depression (O'Mahen et al., 2012). More adaptation studies are, therefore, needed to improve adherence and outcomes and evaluate the feasibility and effectiveness of adapted interventions for this specific group of women in other countries or regions, with different population groups (i.e., perinatal teenagers), and using NMHSs.

6.6 Conclusion

This thesis research aimed to inform the adaptation of the BA manual and booklet intended for delivery by MSWs for the treatment of perinatal depression. A systematic review and meta-analysis guided the process at the beginning, which was conducted to examine the effectiveness of psychological interventions delivered by NMHSs for the

treatment of perinatal depression. This review identified a gap in the evidence regarding the effectiveness of BA delivered by NMHSs in a perinatal setting.

A second qualitative study was aimed to explore women's experiences of perinatal low mood or depression and HCPs' experiences of providing support and care for those women. It was also aimed to inform the adaptation of the BA manual and booklet. This study identified a gap in provision, where women experiencing low mood or depression who do not need a referral but simply support, fall through the gap. This study supports the idea of MSWs delivering BA treatment and has demonstrated their suitability for this role. Perinatal low mood or depression experiences of women and HCPs played a key role in the adaptation process.

A third study further aimed to develop the adaptation of the BA manual intended for delivery by MSWs and booklet for use by women experiencing perinatal low mood or depression. This manual and booklet were adapted with the involvement of women and HCPs by working collaboratively with them in co-design workshop cycles.

The fundamental contribution of this research is firstly that it is a rigorous, adaptation of an evidence-based psychological intervention, Behavioural Activation, recommended by national, evidence-based guidelines (NICE, 2009; NICE, 2020), for the treatment of perinatal depression. It used an EBCD approach with the involvement of women who have experienced perinatal low mood or depression and HCPs who have provided support and care for those women, which established a balance between the Medical Research Council's framework for the processes of developing and evaluating complex interventions (Craig et al., 2013) and O'Cathain et al.'s (2019a and 2019b) guidance on how to develop interventions to improve health and healthcare. Although the effectiveness of the adapted BA manual and booklet was not evaluated in this thesis, these documents could be used in a future feasibility study and a related randomised controlled trial.

Appendices

Appendix 1: Current evidence base for BA

Study	Methods and Participants	Aim/ Interventions	Outcomes	Notes
Cuijpers, Van Straten and Warmerdam, 2007 (mixed of intensity, delivered by mostly mental health specialists to adult participants)	A meta-analysis of RCTs Adults, 16 studies (N = 780)	Effectiveness of activity scheduling-a behavioural treatment of depression	The differences between activity scheduling and cognitive therapy at follow-up were non-significant	Activity scheduling is an attractive treatment for depression, and it is effective
Ekers, Richards and Gilbody, 2008 (mixed of intensity, delivered by mostly mental health specialists to adult participants)	A meta-analysis of RCTs Adults, 17 trials (N = 1109)	Effectiveness of BA	A random-effects meta-analysis of symptom-level post-treatment showed behavioural therapies were superior to controls, brief psychotherapy, supportive therapy and equal to CBT	Behavioural therapy is an effective treatment for depression with outcomes equal to that of the current recommended psychological intervention
Mazzucchelli, Kane and Rees, 2009 (mixed of intensity, delivered by mostly mental health specialists to adult participants)	A meta-analysis of RCTs Adults, 34 studies (N = 2055)	Effectiveness of BA	No differences in effectiveness between BA and CBT were found	BA may be considered a well-established and advantageous alternative to other treatments of depression
Chartier and Provencher, 2013 (Effectiveness of low-intensity BA, only two studies included)	A systematic review Adults (50 years and older) 3 studies	Effectiveness of low-intensity BA		BA could be a viable option as a low-intensity guided self-help psychological treatment for mild to moderate depression

Beck et al., 2014 (USA) (High-intensity, perinatal depression, mixed of specialists and non-specialists)	RCT Pregnant women (N=163)	BA (N=85), usual care (N=78)	BA group had a 50% or greater reduction in PHQ-9 scores	BA is effective and feasible treatment for depressed pregnant women
Dimidjian et al., 2006 (USA) (High-intensity, perinatal depression, mixed of specialists and non-specialists)	RCT Adults with major depressive disorder (N=172)	BA (N=36), cognitive therapy (N=39), antidepressant medication (N=56), and placebo (N=41)	BA was comparable to antidepressant medication, and both significantly outperformed cognitive therapy	BA is comparable in efficacy to antidepressant medication, and more efficacious than cognitive therapy, among more severely depressed participants
O'Mahen et al., 2013 (UK)	RCT Postpartum women (N=343)	Internet-based BA (N=181), usual care (N=162)	Fewer exceeded the depression cut-off in the BA group compared to usual care	Internet-based BA is feasible to deliver and an effective treatment for postnatal depression
Richards et al., 2016 (UK)	RCT Adults (N=221) with major depressive disorder	BA (N=185), CBT (N=195)	BA, a simpler psychological treatment than CBT, can be delivered by junior mental health workers with less intensive and costly training, with no lesser effect than CBT	BA can be delivered without the need for costly and highly trained professionals

Appendix 2: Search history of databases

The following electronic bibliographic databases were searched:

- MEDLINE (Ovid),
- EMBASE (Ovid),
- PsycINFO (Ovid),
- Maternity and Infant Care (MIDIRS) (Ovid),
- Cumulative Index to Nursing and Allied Health Literature Plus (CINAHL Plus) (EBSCO),
- Cochrane Library CENTRAL.

The following sources of grey literature were searched:

- ProQuest,
- Science Citation Index (SCI) Web of Science Core Collection.

The following source of ongoing trial registry was searched:

- World Health Organization, International Clinical Trials Registry Platform (ICTRP) Search Platform.

Database: Ovid MEDLINE(R) <1946 to August Week 4 2017>

Searched on: 4th September 2017

Records retrieved: 1364

Search terms	Number of findings
1. exp Pregnancy/	848019
2. *Peripartum Period/	390
3. *Postpartum Period/	12445
4. antenatal.ti,ab.	26704
5. ante natal.ti,ab.	384
6. ante-natal.ti,ab.	384
7. antepartum.ti,ab.	4918
8. ante partum.ti,ab.	354
9. ante-partum.ti,ab.	354
10. perinatal.ti,ab.	58341
11. peri natal.ti,ab.	152
12. peri-natal.ti,ab.	152
13. peripartum.ti,ab.	3336
14. peri partum.ti,ab.	128
15. peri-partum.ti,ab.	128
16. postnatal.ti,ab.	87673
17. post natal.ti,ab.	5855
18. post-natal.ti,ab.	5855
19. postpartum.ti,ab.	40277
20. post partum.ti,ab.	9602
21. post-partum.ti,ab.	9602
22. pregnan*.ti,ab.	417109
23. prenatal.ti,ab.	76125
24. pre natal.ti,ab.	883
25. pre-natal.ti,ab.	883
26. prepartum.ti,ab.	1853
27. pre partum.ti,ab.	274

28. pre-partum.ti,ab.	274
29. puerper*.ti,ab.	10715
30. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29	1018709
31. exp Depressive Disorder/	99824
32. *Depression/	60187
33. depressed.ti,ab.	84528
34. depression.ti,ab.	251261
35. depressive.ti,ab.	83972
36. 31 or 32 or 33 or 34 or 35	363421
37. exp Counseling/	40968
38. exp Psychotherapy/	183111
39. BA.ti,ab.	19212
40. behavio* activation.ti,ab.	1360
41. behavio* therap*.ti,ab.	15361
42. CBT.ti,ab.	6852
43. cognitive behavio*.ti,ab.	19012
44. cognitive therap*.ti,ab.	2314
45. collaborative care.ti,ab.	1470
46. counseling.ti,ab.	50130
47. counselling.ti,ab.	20232
48. interpersonal psycho*.ti,ab.	851
49. psychotherap*.ti,ab.	34857
50. 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49	304512
51. 30 and 36 and 50	1364

Database: Ovid MEDLINE(R) <1946 to April 14, 2020> UPDATE

Searched on: 15th April 2020

Records retrieved: 287

Search terms	Number of findings
1. exp Pregnancy/	885977
2. *Peripartum Period/	533
3. *Postpartum Period/	13246
4. antenatal.ti,ab.	30147
5. ante natal.ti,ab.	417
6. ante-natal.ti,ab.	417
7. antepartum.ti,ab.	5206
8. ante partum.ti,ab.	373
9. ante-partum.ti,ab.	373
10. perinatal.ti,ab.	63446
11. peri natal.ti,ab.	162
12. peri-natal.ti,ab.	6449
13. peripartum.ti,ab.	3874
14. peri partum.ti,ab.	152
15. peri-partum.ti,ab.	152
16. postnatal.ti,ab.	94443
17. post natal.ti,ab.	6449
18. post-natal.ti,ab.	6449
19. postpartum.ti,ab.	45508
20. post partum.ti,ab.	10352
21. post-partum.ti,ab.	10352
22. pregnan*.ti,ab.	448309
23. prenatal.ti,ab.	83509
24. pre natal.ti,ab.	1001
25. pre-natal.ti,ab.	1001
26. prepartum.ti,ab.	2054
27. pre partum.ti,ab.	303
28. pre-partum.ti,ab.	303
29. puerper*.ti,ab.	10809
30. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29	1069829
31. exp Depressive Disorder/	107746
32. *Depression/	71014
33. depressed.ti,ab.	86273
34. depression.ti,ab.	280658
35. depressive.ti,ab.	96878
36. 31 or 32 or 33 or 34 or 35	398525
37. exp Counseling/	43419
38. exp Psychotherapy/	193493
39. BA.ti,ab.	23961
40. behavio* activation.ti,ab.	1560
41. behavio* therap*.ti,ab.	17819
42. CBT.ti,ab.	8349
43. cognitive behavio*.ti,ab.	22182
44. cognitive therap*.ti,ab.	2544
45. collaborative care.ti,ab.	1808

46. counseling.ti,ab.	56286
47. counselling.ti,ab.	22808
48. interpersonal psycho*.ti,ab.	973
49. psychotherap*.ti,ab.	37089
50. 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49	331010
51. 30 and 36 and 50	1562
52. 2020\$.ed.	283867
53. 2019\$.ed.	973764
54. 2018\$.ed.	900093
55. 201712\$.ed.	74312
56. 201711\$.ed.	69222
57. 201710\$.ed.	79895
58. 201709\$.ed.	78462
59. 52 or 53 or 54 or 55 or 56 or 57 or 58	2458615
60. 51 and 59	287

Database: PsycINFO <1806 to August Week 4 2017>

Searched on: 4th September 2017

Records retrieved: 944

Search terms	Number of findings
1. *ante partum period/	14
2. *perinatal period/	1668
3. *postnatal period/	2891
4. exp pregnancy/	22259
5. antenatal.ti,ab.	2852
6. ante natal.ti,ab.	48
7. antepartum.ti,ab.	278
8. ante partum.ti,ab.	10
9. perinatal.ti,ab.	8683
10. peri natal.ti,ab.	61
11. peripartum.ti,ab.	234
12. peri partum.ti,ab.	7
13. postnatal.ti,ab.	17391
14. post natal.ti,ab.	934
15. postpartum.ti,ab.	9691
16. post partum.ti,ab.	1040
17. pregnan*.ti,ab.	40124
18. prenatal.ti,ab.	15837
19. pre natal.ti,ab.	216
20. prepartum.ti,ab.	241
21. pre partum.ti,ab.	28
22. puerper*.ti,ab.	744
23. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22	74151
24. *"depression (emotion)"/	18674
25. *postpartum depression/	3543
26. depressed.ti,ab.	44108
27. depression.ti,ab.	208681
28. depressive.ti,ab.	89469
29. 24 or 25 or 26 or 27 or 28	257566
30. *cognitive therapy/	10938
31. exp Counseling/	73226
32. exp Psychotherapy/	202178
33. BA.ti,ab.	2688
34. behavio* activation.ti,ab.	1681
35. behavio* therap*.ti,ab.	27368
36. CBT.ti,ab.	10987
37. cognitive behavio*.ti,ab.	35152
38. cognitive therap*.ti,ab.	5947
39. collaborative care.ti,ab.	1047
40. counseling.ti,ab.	65438
41. counselling.ti,ab.	10085
42. interpersonal psycho*.ti,ab.	1762
43. psychotherap*.ti,ab.	99935
44. 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43	339525

Database: PsycINFO <1806 to April Week 1 2020> UPDATE

Searched on: 15th April 2020

Records retrieved: 146

Search terms	Number of findings
1. *antepartum period/	60
2. *perinatal period/	2026
3. *postnatal period/	3204
4. exp pregnancy/	41387
5. antenatal.ti,ab.	3413
6. ante natal.ti,ab.	55
7. antepartum.ti,ab.	334
8. ante partum.ti,ab.	12
9. perinatal.ti,ab.	10071
10. peri natal.ti,ab.	65
11. peripartum.ti,ab.	329
12. peri partum.ti,ab.	12
13. postnatal.ti,ab.	19491
14. post natal.ti,ab.	1068
15. postpartum.ti,ab.	11386
16. post partum.ti,ab.	1190
17. pregnan*.ti,ab.	45690
18. prenatal.ti,ab.	17978
19. pre natal.ti,ab.	234
20. prepartum.ti,ab.	258
21. pre partum.ti,ab.	35
22. puerper*.ti,ab.	791
23. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22	94734
24. *"depression (emotion)"/	19690
25. *postpartum depression/	4058
26. depressed.ti,ab.	47284
27. depression.ti,ab.	237670
28. depressive.ti,ab.	103987
29. 24 or 25 or 26 or 27 or 28	292772
30. *cognitive therapy/	11455
31. exp Counseling/	76925
32. exp Psychotherapy/	201211
33. BA.ti,ab.	3023
34. behavio* activation.ti,ab.	2013
35. behavio* therap*.ti,ab.	31635
36. CBT.ti,ab.	13371
37. cognitive behavio*.ti,ab.	40318
38. cognitive therap*.ti,ab.	6479
39. collaborative care.ti,ab.	1288
40. counseling.ti,ab.	70364
41. counselling.ti,ab.	11327
42. interpersonal psycho*.ti,ab.	2000
43. psychotherap*.ti,ab.	106787
44. 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43	365862

45. 23 and 29 and 44	1139
46. 2020*.up.	46523
47. 2019.up.	155395
48. 2018*.up.	155107
49. 201712*.up.	18830
50. 201711*.up.	21418
51. 201710*.up.	16033
52. 201709*.up.	16780
53. 46 or 47 or 48 or 49 or 50 or 51 or 52	430086
54. 45 and 53	146

Database: Embase <1974 to 2017 August 30>

Searched on: 1st September 2017

Records retrieved: 2827

Search terms	Number of findings
1. *Perinatal Period/	4042
2. *Puerperium/	12080
3. exp Pregnancy/	675781
4. antenatal.ti,ab.	40369
5. ante natal.ti,ab.	694
6. antepartum.ti,ab.	6697
7. ante partum.ti,ab.	485
8. perinatal.ti,ab.	81325
9. peri natal.ti,ab.	305
10. peripartum.ti,ab.	5276
11. peri partum.ti,ab.	288
12. postnatal.ti,ab.	113666
13. post natal.ti,ab.	9132
14. postpartum.ti,ab.	54680
15. post partum.ti,ab.	14313
16. pregnan*.ti,ab.	557212
17. prenatal.ti,ab.	101415
18. pre natal.ti,ab.	1351
19. prepartum.ti,ab.	2082
20. pre partum.ti,ab.	342
21. puerper*.ti,ab.	11627
22. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21	1066931
23. exp Depression/	401622
24. depressed.ti,ab.	108387
25. depression.ti,ab.	374790
26. depressive.ti,ab.	125690
27. 23 or 24 or 25 or 26	629682
28. exp Counseling/	139934
29. exp Psychotherapy/	230799
30. BA.ti,ab.	28644
31. behavio* activation.ti,ab.	1817
32. behavio* therap*.ti,ab.	25399
33. CBT.ti,ab.	11982
34. cognitive behavio*.ti,ab.	30696
35. cognitive therap*.ti,ab.	4079
36. collaborative care.ti,ab.	2197
37. counseling.ti,ab.	72871
38. counselling.ti,ab.	34147
39. interpersonal psycho*.ti,ab.	1161
40. psychotherap*.ti,ab.	53347
41. 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40	442776
42. 22 and 27 and 41	2827

Database: Embase <using update search terms> UPDATE

Searched on: 15th April 2020

Records retrieved: 1003

Search terms	Number of findings
1. *Perinatal Period/	5113
2. *Puerperium/	12215
3. exp Pregnancy/	654524
4. antenatal.ti,ab.	48532
5. ante natal.ti,ab.	767
6. antepartum.ti,ab.	7646
7. ante partum.ti,ab.	501
8. perinatal.ti,ab.	93030
9. peri natal.ti,ab.	344
10. peripartum.ti,ab.	6813
11. peri partum.ti,ab.	384
12. postnatal.ti,ab.	128117
13. post natal.ti,ab.	10623
14. postpartum.ti,ab.	66423
15. post partum.ti,ab.	16267
16. pregnan*.ti,ab.	622748
17. prenatal.ti,ab.	116458
18. pre natal.ti,ab.	1555
19. prepartum.ti,ab.	2359
20. pre partum.ti,ab.	416
21. puerper*.ti,ab.	11065
22. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21	1105078
23. exp Depression/	464254
24. depressed.ti,ab.	116588
25. depression.ti,ab.	447816
26. depressive.ti,ab.	152223
27. 23 or 24 or 25 or 26	729259
28. exp Counseling/	163770
29. exp Psychotherapy/	246044
30. BA.ti,ab.	41089
31. behavio* activation.ti,ab.	2228
32. behavio* therap*.ti,ab.	31101
33. CBT.ti,ab.	15744
34. cognitive behavio*.ti,ab.	38087
35. cognitive therap*.ti,ab.	4712
36. collaborative care.ti,ab.	3007
37. counseling.ti,ab.	89716
38. counselling.ti,ab.	41943
39. interpersonal psycho*.ti,ab.	1368
40. psychotherap*.ti,ab.	56780
41. 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40	504231
42. 22 and 27 and 41	3343
43. 2020\$.ew.	956762
44. 2019\$.ew.	2647603
45. 2018\$.ew.	1668353

46. 2017\$.ew.	1774067
47. 43 or 44 or 45 or 46	7046785
50. 42 and 47	1003

Database: Maternity & Infant Care Database (MIDIRS) <1971 to July 2017>

Searched on: 4th September 2017

Records retrieved: 505

Search terms	Number of findings
1. Postnatal.de.	14
2. Postnatal period.de.	2212
3. Postpartum.de.	8
4. Postpartum Period.de.	26
5. Pregnancy.de.	57846
6. Puerperium.de.	3431
7. antenatal.ti,ab.	14024
8. ante natal.ti,ab.	151
9. antepartum.ti,ab.	2241
10. ante partum.ti,ab.	55
11. perinatal.ti,ab.	17852
12. peri natal.ti,ab.	18
13. peripartum.ti,ab.	870
14. peri partum.ti,ab.	19
15. postnatal.ti,ab.	10606
16. post natal.ti,ab.	618
17. postpartum.ti,ab.	12309
18. post partum.ti,ab.	1717
19. pregnan*.ti,ab.	80170
20. prenatal.ti,ab.	15680
21. pre natal.ti,ab.	125
22. prepartum.ti,ab.	113
23. pre partum.ti,ab.	13
24. puerper*.ti,ab.	1283
25. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24	123411
26. Depression.de.	964
27. Postnatal depression.de.	1686
28. depressed.ti,ab.	997
29. depression.ti,ab.	5855
30. depressive.ti,ab.	1658
31. 26 or 27 or 28 or 29 or 30	6924
32. Cognitive therapy.de.	30
33. Counseling.de.	2
34. Counselling.de.	1414
35. Collaborative care.de.	310
36. Postnatal depression-therapy.de.	144
37. Psychotherapy.de.	62
38. BA.ti,ab.	98
39. behavio* activation.ti,ab.	6
40. behavio* therap*.ti,ab.	105
41. CBT.ti,ab.	42
42. cognitive behavio*.ti,ab.	208
43. cognitive therap*.ti,ab.	14
44. collaborative care.ti,ab.	55
45. counseling.ti,ab.	2772

46. counselling.ti,ab.	2629
47. interpersonal psycho*.ti,ab.	32
48. psychotherap*.ti,ab.	245
49. 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48	6932
50. 25 and 31 and 49	505

Database: Maternity & Infant Care Database (MIDIRS) <limit to yr="2017 -Current">
UPDATE

Searched on: 15th April 2020

Records retrieved: 104

Search terms	Number of findings
1. Postnatal.de.	17
2. Postnatal period.de.	2712
3. Postpartum.de.	7
4. Postpartum Period.de.	27
5. Pregnancy.de.	59702
6. Puerperium.de.	3437
7. antenatal.ti,ab.	16817
8. ante natal.ti,ab.	166
9. antepartum.ti,ab.	2570
10. ante partum.ti,ab.	65
11. perinatal.ti,ab.	21504
12. peri natal.ti,ab.	22
13. peripartum.ti,ab.	1116
14. peri partum.ti,ab.	26
15. postnatal.ti,ab.	12928
16. post natal.ti,ab.	752
17. postpartum.ti,ab.	15647
18. post partum.ti,ab.	2111
19. pregnan*.ti,ab.	95933
20. prenatal.ti,ab.	18801
21. pre natal.ti,ab.	139
22. prepartum.ti,ab.	128
23. pre partum.ti,ab.	15
24. puerper*.ti,ab.	1433
25. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24	145164
26. Depression.de.	1033
27. Postnatal depression.de.	1823
28. depressed.ti,ab.	1006
29. depression.ti,ab.	7332
30. depressive.ti,ab.	2149
31. 26 or 27 or 28 or 29 or 30	8597
32. Cognitive therapy.de.	32
33. Counseling.de.	2
34. Counselling.de.	1462
35. Collaborative care.de.	65
36. Postnatal depression-therapy.de.	144
37. Psychotherapy.de.	69
38. BA.ti,ab.	118
39. behavio* activation.ti,ab.	8
40. behavio* therap*.ti,ab.	138
41. CBT.ti,ab.	54
42. cognitive behavio*.ti,ab.	262
43. cognitive therap*.ti,ab.	21
44. collaborative care.ti,ab.	358

45. counseling.ti,ab.	3555
46. counselling.ti,ab.	3134
47. interpersonal psycho*.ti,ab.	36
48. psychotherap*.ti,ab.	292
49. 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48	8407
50. 25 and 31 and 49	604
51. limit 50 to yr="2017 -Current"	104

Database: The Cochrane Library via Cochrane Central Register of Controlled Trials (CENTRAL) < – 4 September 2017>

- Cochrane Central Register of Controlled Trials: Issue 8 of 12, August 2017

Searched on: 4th September 2017

Records retrieved: 540

Search terms	Number of findings
1. (antenatal OR ante natal OR ante-natal OR antepartum OR ante partum OR ante-partum OR perinatal OR peri natal OR peri-natal OR peripartum OR peri partum OR peri-partum OR postnatal OR post natal OR post-natal OR postpartum OR post partum OR post-partum OR pregnan* OR prenatal OR pre natal OR pre-natal OR prepartum OR pre partum OR pre-partum OR puerper*) in Trials	58317
2. (depressed OR depression OR depressive) in Trials	65694
3. (BA OR behavio* activation OR behavio* therap* OR CBT OR cognitive behavio* OR cognitive therap* OR collaborative care OR counseling OR counselling OR interpersonal psycho* OR psychotherap*) in Trials	99086
#1 AND #2 AND #3	540

Database: The Cochrane Central Register of Controlled Trials (CENTRAL) < 4 September 2017 – 15 April 2020> UPDATE

- Cochrane Central Register of Controlled Trials: Issue 4 of 12, April 2020

Searched on: 15th April 2020

Records retrieved: 424

Search terms	Number of findings
1. (antenatal OR ante natal OR ante-natal OR antepartum OR ante partum OR ante-partum OR perinatal OR peri natal OR peri-natal OR peripartum OR peri partum OR peri-partum OR postnatal OR post natal OR post-natal OR postpartum OR post partum OR post-partum OR pregnan* OR prenatal OR pre natal OR pre-natal OR prepartum OR pre partum OR pre-partum OR puerper*) in Trials	69453
2. (depressed OR depression OR depressive) in Trials	78628
3. (BA OR behavio* activation OR behavio* therap* OR CBT OR cognitive behavio* OR cognitive therap* OR collaborative care OR counseling OR counselling OR interpersonal psycho* OR psychotherap*) in Trials	119820
#1 AND #2 AND #3 with Publication Year from 2017 to 2020, in Trials	424

Database: CINAHLPlus via EBSCO <1937 – 31 August 2017>

Searched on: 1st September 2017

Records retrieved: 1739

Search terms	Number of findings
1. (MH "Postnatal Period+")	8738
2. (MH "Pregnancy+")	150201
3. AB antenatal	6993
4. AB ante natal	82
5. AB ante-natal	76
6. AB antepartum	999
7. AB ante partum	25
8. AB ante-partum	20
9. AB perinatal	10322
10. AB peri natal	30
11. AB peri-natal	21
12. AB peripartum	636
13. AB peri partum	20
14. AB peri-partum	18
15. AB postnatal	8635
16. AB post natal	492
17. AB post-natal	485
18. AB postpartum	10344
19. AB post partum	1083
20. AB post-partum	1080
21. AB pregnan*	59654
22. AB prenatal	12784
23. AB pre natal	307
24. AB pre-natal	253
25. AB prepartum	86
26. AB pre partum	37
27. AB pre-partum	9
28. AB puerper*	878
29. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28	185281
30. (MH "Depression+")	80589
31. AB depressed	9787
32. AB depression	63697
33. AB depressive	23731
34. 30 or 31 or 32 or 33	117700
35. (MH "Counseling+")	27603
36. (MH "Multidisciplinary Care Team+")	41261
37. (MH "Behavior Therapy+")	30547
38. (MH "Behavior Therapy (Iowa NIC)+")	24
39. (MH "Cognitive Therapy+")	20739
40. (MH "Psychotherapy+")	137050
41. (MH "Psychotherapy, Group+")	23013
42. (MM "Depression, Postpartum/TH")	350
43. (MM "Psychotherapy, Brief")	767
44. (MM "Psychotherapy, Psychodynamic")	190
45. AB BA	1523

46. AB behavio* activation	566
47. AB behavio* therap*	7999
48. AB CBT	2953
49. AB cognitive behavio*	12436
50. AB cognitive therap*	6903
51. AB collaborative care	2329
52. AB counseling	17194
53. AB counselling	7316
54. AB interpersonal psycho*	912
55. AB psychotherap*	6898
56. 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54	190526
57. 29 and 34 and 49	1739

Database: CINAHLComplete via EBSCO <20170901-20200431> UPDATE

Searched on: 16th April 2020

Records retrieved: 531

Search terms	Number of findings
1. (MH "Postnatal Period+")	2931
2. (MH "Pregnancy+")	27985
3. AB antenatal	3113
4. AB ante natal	25
5. AB ante-natal	21
6. AB antepartum	340
7. AB ante partum	4
8. AB ante-partum	2
9. AB perinatal	4152
10. AB peri natal	12
11. AB peri-natal	5
12. AB peripartum	344
13. AB peri partum	17
14. AB peri-partum	14
15. AB postnatal	3283
16. AB post natal	239
17. AB post-natal	236
18. AB postpartum	4620
19. AB post partum	504
20. AB post-partum	504
21. AB pregnan*	24592
22. AB prenatal	4684
23. AB pre natal	240
24. AB pre-natal	205
25. AB prepartum	27
26. AB pre partum	25
27. AB pre-partum	8
28. AB puerper*	419
29. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28	42915
30. (MH "Depression+")	18589
31. AB depressed	2075
32. AB depression	23463
33. AB depressive	9173
34. 30 or 31 or 32 or 33	31004
35. (MH "Counseling+")	5795
36. (MH "Multidisciplinary Care Team+")	6732
37. (MH "Behavior Therapy+")	6210
38. (MH "Behavior Therapy (Iowa NIC)+")	0
39. (MH "Cognitive Therapy+")	4679
40. (MH "Psychotherapy+")	33352
41. (MH "Psychotherapy, Group+")	2774
42. (MM "Depression, Postpartum/TH")	86
43. (MM "Psychotherapy, Brief")	156
44. (MM "Psychotherapy, Psychodynamic")	96
45. AB BA	580

46. AB behavio* activation	294
47. AB behavio* therap*	3051
48. AB CBT	1265
49. AB cognitive behavio*	4472
50. AB cognitive therap*	2918
51. AB collaborative care	896
52. AB counseling	5973
53. AB counselling	2617
54. AB interpersonal psycho*	322
55. AB psychotherap*	2720
56. 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54	55096
57. 29 and 34 and 49 Published date: 20170901-20200531	531

Database: Web of Science Core Collection via Web of Science, Thomson Reuters <1900 – 02/09/2017>

- Science Citation Index Expanded (SCI-EXPANDED) --1900-present
- Social Sciences Citation Index (SSCI) --1956-present
- Arts & Humanities Citation Index (A&HCI) --1975-present
- Conference Proceedings Citation Index- Science (CPCI-S) --1990-present
- Conference Proceedings Citation Index- Social Science & Humanities (CPCI-SSH) --1990-present
- Emerging Sources Citation Index (ESCI) --2015-present

Searched on: 4th September 2017

Records retrieved: 2432

TS=(depressed or depression or depressive) AND TS=(antenatal or ante natal or ante-natal or antepartum or ante partum or ante-partum or perinatal or peri natal or peri-natal or peripartum or peri partum or peri-partum or postnatal or post natal or post-natal or postpartum or post partum or post-partum or pregnan* or prenatal or pre natal or prepartum or pre partum or puerper*) AND TS=(BA or behavio* activation or behavio* therap* or CBT or cognitive behavio* or cognitive therap* or collaborative care or counselling or counseling or interpersonal psycho* or psychotherap*)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years
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Findings: 2432

Database: Web of Science Core Collection via Web of Science, Thomson Reuters <2017 – 2020> UPDATE

Searched on: 15th April 2020

Records retrieved: 1,109

TS=(depressed or depression or depressive) AND TS=(antenatal or ante natal or ante-natal or antepartum or ante partum or ante-partum or perinatal or peri natal or peri-natal or peripartum or peri partum or peri-partum or postnatal or post natal or post-natal or postpartum or post partum or post-partum or pregnan* or prenatal or pre natal or prepartum or pre partum or puerper*) AND TS=(BA or behavio* activation or behavio* therap* or CBT or cognitive behavio* or cognitive therap* or collaborative care or counselling or counseling or interpersonal psycho* or psychotherap*)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=2017-2020
--

Findings: 1,109

Database: ProQuest <1716 – 05/09/2017>

- Applied Social Sciences Index & Abstracts (ASSIA) (1987 – current)
- British Nursing Index (1994 – current)
- ProQuest Dissertations & Theses: UK & Ireland (1716 – current)

Searched on: 5th September 2017

Records retrieved: 2886

```
((SU.EXACT("Perinatal") OR SU.EXACT("Antenatal") OR SU.EXACT("Postpartum women") OR SU.EXACT("Pregnancy") OR antenatal OR antepartum OR perinatal OR postnatal OR postpartum OR pregnan* OR prenatal OR puerper*) AND (SU.EXACT("Depression") OR SU.EXACT("Depressed") OR SU.EXACT("Puerperal psychosis") OR depression OR depressed OR depressive) AND (SU.EXACT("Cognitive therapy") OR SU.EXACT("Psychotherapy") OR SU.EXACT("Psychosocial therapy") OR behavio* activation OR behavio* therap* OR cognitive behavio* OR cognitive therap* OR collaborative care OR counselling OR counseling OR interpersonal psycho* OR psychotherap*)) NOT (fdb(1007595 1007594 1007593 1007590 1007592 1007589) AND subt.exact(("pregnancy" OR "mental depression" OR "mothers" OR "mental disorders" OR "women" OR "mental health" OR "womens health" OR "depression" OR "social support" OR "postpartum depression" OR "psychotherapy" OR "stress, psychological" OR "depression, postpartum" OR "postnatal depression" OR "mental health care" OR "intervention" OR "treatment outcome" OR "depressive disorder" OR "postpartum period" OR "counseling" OR "clinical trials" OR "education" OR "prenatal care") NOT ("child" OR "children & youth" OR "socioeconomic factors" OR "domestic violence" OR "child psychology" OR "prevalence" OR "qualitative research" OR "sexual behavior" OR "child abuse & neglect" OR "genetic counseling" OR "life change events" OR "obesity" OR "risk assessment" OR "substance-related disorders"))))
```

Findings: 2886

Database: ProQuest <05/09/2017 – 15/04/2020> UPDATE

Searched on: 15th April 2020

Records retrieved: 85

(Perinatal OR Antenatal OR Postpartum women OR Pregnancy OR antenatal OR antepartum OR perinatal OR postnatal OR postpartum OR pregnan* OR prenatal OR puerper*) AND (Depression OR Depressed OR depressive) AND (Cognitive therapy OR Psychotherapy OR Psychosocial therapy OR behavio* activation OR behavio* therap* OR cognitive behavio* OR cognitive therap* OR collaborative care OR counselling OR counseling OR interpersonal psycho* OR psychotherap*)

Findings: 85

Database: World Health Organization, International Clinical Trials Registry Platform-
Search Platform <2005- 01/09/2017>

<http://apps.who.int/trialsearch/AdvSearch.aspx>

- Australian New Zealand Clinical Trials Registry (ANZCTR)
- Brazilian Clinical Trials Registry (ReBec)
- Chinese Clinical Trial Register (ChiCTR)
- Clinical Research Information Service (CRIS), Republic of Korea
- ClinicalTrials.gov
- Clinical Trials Registry - India (CTRI)
- Cuban Public Registry of Clinical Trials (RPCEC)
- EU Clinical Trials Register (EU-CTR)
- German Clinical Trials Register (DRKS)
- Iranian Registry of Clinical Trials (IRCT)
- ISRCTN.org
- Japan Primary Registries Network (JPRN)
- Pan African Clinical Trial Registry (PACTR)
- Peruvian Clinical Trials Registry (REPEC)
- Sri Lanka Clinical Trials Registry (SLCTR)
- Thai Clinical Trials Register (TCTR)
- The Netherlands National Trial Register (NTR)

Searched on: 1st September 2017

Records retrieved: 587

Search terms		
In the condition	In the title	Findings
Depression	antenatal	36
Depression	antepartum	4

Depression	perinatal	55
Depression	peripartum	0
Depression	postnatal	76
Depression	postpartum	223
Depression	pregnan*	160
Depression	prenatal	23
Depression	prepartum	0
Depression	puerper*	10
Total		587

Database: World Health Organization, International Clinical Trials Registry Platform-
Search Platform <01/09/2017- > UPDATE

Searched on: 16th April 2020

Records retrieved: "Due to heavy traffic generated by the COVID-19 outbreak, the
ICTRP Search Portal is not accessible from outside WHO temporarily. Please subscribe
to the ICTRP listserv if you wish to be notified when the search portal is working again.
Information on how to subscribe can be found on the same page below."

Search terms		
In the condition	In the title	Findings
Depression	antenatal	
Depression	anteartum	
Depression	perinatal	
Depression	peripartum	
Depression	postnatal	
Depression	postpartum	
Depression	pregnan*	
Depression	prenatal	
Depression	prepartum	
Depression	puerper*	
Total		

Appendix 3: Data extraction form

DATA EXTRACTION FORM

1. General Information

Study ID (First Author and year):
Title:
Country of study:
Type of publication: <input type="checkbox"/> Journal article <input type="checkbox"/> Abstract <input type="checkbox"/> Other....
Funding source of study:
Potential conflict of interest from funding? Y / N / Unclear

2. Study Eligibility

<input type="checkbox"/> Randomised Controlled Trial (RCT) INCLUDE
<input type="checkbox"/> Cluster Randomised Controlled Trial (cluster RCT) INCLUDE
<input type="checkbox"/> Profession of implementer: midwives, nurses, health visitors, GPs, and occupational therapists. INCLUDE
<input type="checkbox"/> Profession of implementer: health workers with specialised training in the delivery of psychological treatments: clinical psychologists, cognitive behavioural therapists, psychiatrists. EXCLUDE
<input type="checkbox"/> Psychological interventions: e.g. CBT, BA, IPT, counselling. INCLUDE
<input type="checkbox"/> Psychological interventions: e.g. antenatal classes, intrapartum support, and peer-support. EXCLUDE
Does the study design meet the criteria for inclusion? Yes <input type="checkbox"/> No <input type="checkbox"/> → Exclude Unclear <input type="checkbox"/>

3. Study details

Aim of intervention:
Aim of study:

4. Ethical issues

Ethical approval: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear
Informed consent: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear

5. Participants

Antenatal Postpartum Perinatal

Inclusion criteria:

Exclusion criteria:

Baseline number of participants: Intervention= Control=

Age (median, mean and range if possible):

Baseline social economic status:

Baseline education:

Baseline ethnicity:

Health problems:

Stage of illness:

Co-morbidity:

6. Intervention group(s)

Number of clusters: Number of people per cluster:

Number of individual patients:

Lost to follow-up:

Type(s) of intervention:

How is the intervention applied: individual group

face-to-face telephone online

Number of sessions:

Duration of intervention:

Frequency of sessions:

Profession of implementer:

Number of implementers:

Duration of training of implementer:

Concurrent pharmacology:

7. Comparison group(s)

Number of clusters: Number of people per cluster:

Number of individual patients:

Lost to follow-up:

Type(s) of intervention:

How is the intervention applied: individual [group](#)

face-to-face telephone online

Number of sessions:

Duration of intervention:

Frequency of sessions:

Profession of implementer:

Number of implementers:

Duration of training of implementer:

Concurrent pharmacology:

Balanced with intervention group Imbalanced

8. Outcomes

Maternal outcomes: Depression Anxiety Mother-infant Relationship

Infant outcomes: Cognitive and emotional development

Family outcomes: Marital relationship

Statistical summary of outcomes:

9. Dichotomous outcome

Outcome measure:

Diagnostic criteria:

Timepoint:

Missing participants:

Intervention		Comparison	
Depressed	Not depressed	Depressed	Not depressed

10. Continuous outcome

Outcome measure:

Time point:

Missing participants:

Intervention			Comparison		
Mean	SD (or <u>other</u> variance)	No. participants	Mean	SD (or <u>other</u> variance)	No. participants

11. Risk of bias assessment (Higgins et al., 2011)

Domain	Source of bias	Review authors' judgement*	Description	Page/ Para/ Figure #
Selection bias	Random sequence generation	Yes / No / Unclear		
	Allocation concealment	Yes / No / Unclear		
Performance bias	Blinding of participants and personnel	Yes/No/Unclear		
Detection bias	Blinding of outcome assessment	Yes/No/Unclear		
Attrition bias	Incomplete outcome data	Yes / No / Unclear		
Reporting bias	Selective reporting	Yes / No / Unclear		
Other bias	Anything else, ideally prespecified	Yes/No/Unclear		

Appendix 4: Details of ongoing trials

Study	Participants and location	Intervention and comparator (n)	Profession of therapist and intervention duration	Assessment and outcome measures
Ahmad, Silim and Aris, 2017	54 postpartum women; Malaysia	<p>Treatment -Brief cognitive behavioural therapy (CBT) and standard management based on Clinical Practice Guideline</p> <p>Comparison -Standard management based on Clinical Practice Guideline</p>	Nurses and Medical Officers; 6 weekly sessions	<p>Assessment EPDS and MINI</p> <p>Outcome measures BDI and ATQ</p>
Lieshout, 2018	100 postpartum women; Canada	<p>Treatment -Group CBT</p> <p>Comparison -Postnatal care as usual</p>	Public health nurses; 9 weekly sessions	<p>Assessment EPDS and MINI</p> <p>Outcome measures EPDS, MINI, Ages and Stages Questionnaires, Corticolimbic Brain Function: EEG-Based Frontal Lobe Asymmetry, Early Child Behaviour Questionnaires, Face-to-Face Still Face Paradigm, Infant Behaviour Questionnaire-Revised, Maternal and Infant Healthcare Utilization, Parasympathetic Nervous System Functioning: Heart Rate Variability, Parent-Child Early Relational Assessment,</p>

				Penn State Worry Questionnaire, Postpartum Bonding Questionnaire, Salivary Cortisol, and Social Provisions Scale
Nusrat et al., 2016	36 postpartum women; Pakistan	Treatment -Group CBT Comparison -Treatment as usual	Traditional Birth Attendants; 8 sessions	Assessment EPDS Outcome measures EPDS, PHQ-9, and World Health Organization Quality of Life scale

Automatic Thought Questionnaire (ATQ), Beck's Depression Index (BDI), Edinburgh Postnatal Depression Scale (EPDS), Hamilton Depression Rating Scale (HDRS), Mini International Neuropsychiatric Interview (MINI), Patient Health questionnaire (PHQ-9).

Appendix 5: Demographics form for healthcare professionals (second study)



An exploration of women's experiences of perinatal low mood/depression and health professionals' experiences of providing care for women who have perinatal low mood/depression

Researchers: Semra PINAR, Dr Helen BEDFORD, Dr Dean McMILLAN, Prof Steven ERSSER

Demographics Form for Health Professionals

The information provided here will be kept anonymous and confidential. Before conducting an interview/focus group, we would like to learn about you. This will help us to choose a range of health professionals from different backgrounds for an interview/focus group.

Anonymous identifier	
Your age	Prefer not to state <input type="checkbox"/>
In which NHS Trust or GP surgery do you currently work?	
What is your current role?	
For how long have you been working in that role?	
Please state your professional qualifications.	
Please could you write your available days and time for an interview/focus group? (e.g. Mondays pm, Thursdays am)	
Where would you like to be interviewed individually? <input type="checkbox"/> NHS premises <input type="checkbox"/> Other place where is in a convenient and confidential location and provide privacy (e.g. a community centre)	Where would you like to attend a focus group? <input type="checkbox"/> NHS premises <input type="checkbox"/> Other place where is in a convenient and confidential location for everyone and provide privacy (e.g. a community centre)

Thank you for taking the time to fill in this demographics form. Please put this form together with one of your signed consent forms and contact details sheet into the stamped-addressed return envelope and send it to the researcher.

Semra Pinar, Research Centre for Social Sciences, 6 Innovation Close, University of York, Heslington, York, YO10 5ZF

Tel: 07729 070393 Email: sp1365@york.ac.uk

Date: 15/06/2018
Version:1.0
IRAS ID: 237021

Appendix 6: Consent form for healthcare professionals (second study)

UNIVERSITY of York
The Department of Health Sciences

Participant Consent Form for Healthcare Professionals

An exploration of women's experiences of perinatal low mood/depression and health professionals' experiences of providing care for women who have perinatal low mood/depression

	Please confirm agreement to the statements by putting your initials in the boxes below
I have read and understood the participant information sheet [date: 05/02/2019, version: 2.0].	
I have had the opportunity to ask questions and discuss this study.	
I have received satisfactory answers to <u>all</u> of my questions.	
I have received enough information about the study.	
I understand my participation in the study is voluntary and that I am free to withdraw from the study: 1 At any time, even during the individual interview/focus group interview. 2 Without having to give a reason for withdrawing. 3 Should I choose to withdraw from the study before the end of the individual interview, all data referring to me will be destroyed and will not be used in any way. However, should I choose to withdraw during a focus group interview, all the data collected until that time will be used in the study because it is not possible to remove my contribution from a focus group discussion. 4 Should I choose to withdraw more than 48 hours after completion of the individual interview, I understand that my data will still be included in the analysis. After completing the focus group interview I can still withdraw from the study, however, my data will still be included in the analysis.	
I understand that my individual interview/focus group interview will be audio-recorded.	
I understand that my data collected during the study may be looked at by the research team. I give permission for these individuals to have access to my data.	
I understand that any information I provide, including personal details, will be kept confidential, stored securely and only accessed by those carrying out the study.	
I understand that any information I give may be included in the researcher's PhD thesis, peer-reviewed journals and/or conference presentations but all information will be anonymised.	
I understand that any quotations from my interview or focus group discussion may be used in reporting the study findings (If anything that you have said is quoted, it will be made anonymous so that you cannot be identified).	
I agree to take part in a face-to-face interview with the researcher.	
I agree to take part in a focus group interview with the researcher, a moderator and approximately 4-6 other healthcare professionals.	
I agree to take part in this study.	
I would like to receive a summary of the results from the study.	
Participant Signature	Date:
Name of Participant:	
Researcher Signature	Date:
Name of Researcher:	

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Appendix 7: A topic guide for individual interviews with healthcare professionals (second study)

An Example of a Semi-Structured Interview Topic Guide for Health Professionals

An exploration of women's experiences of perinatal low mood/depression and health professionals' experiences of providing care for women who have perinatal low mood/depression

Stage 1: Introduction and context setting

- Introduction to researcher, PhD study and funder
- Study topic and explanation of the aims and objectives of the study
- Explanation of confidentiality and anonymity
- Explanation of recording, length (up to one hour) and the nature of the interview, outputs/reporting and data storage issues
- Reminder participant of reimbursement of travel expenses
- Going through consent issues explaining that she/he may withdraw at any time from interview as whole, and does not have to answer any questions she/he would prefer not to
- Checking whether she/he has any questions
- Choosing pseudonym to call her/him during the interview
- Ask if any changes to the demographics

Stage 2: Opening questions; more surface level. Background and contextual information-preliminary information. Definitional/conceptual questions

Awareness –generic questions

- Can you tell me how do you describe perinatal low mood?
 - Perinatal depression?

Stage 3: Core part of interview-questioning and discussion is in more depth. Move from circumstantial to attitudinal/evaluative/explanatory questions. Move from general to more specific coverage

Roles and management

- Please, can you describe your role in assessing/screening women regarding their mental health in the perinatal period?
- How do you identify perinatal low mood?
 - Perinatal depression?
- Please, could you tell me about the process of screening for women regarding depression in the perinatal period?
- What guidelines are used to implement perinatal depression care in antenatal period and postnatal period? Is it different?
 - Have you brought an example of that?
 - Could you tell me more about the guidelines?
 - What is the process of referral?
 - What are the enablers of the process of referral?
 - What are the challenges/barriers of the process of referral?

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- How have maternity services changed in terms of identifying women, if at all, supporting, and giving care in recent times?
 - Within last 3-5 years

Perceived barriers and enablers

- What sort of challenges/barriers do you experience while discussing about women's mental health status?
 - Do you experience any difficulty to leading or approaching women who you think may be experiencing perinatal low mood/depression?
- How about any enablers that might help you to talk about women's mental health status?
 - What sort of things help you to talk about women's mental health status?
 - Which words do you use while talking to women who may experience perinatal depression?
- What sort of difficulties/barriers do you face while providing care/support for women with low mood/perinatal depression?
- What sort of things help you/what are the enablers to deal with these difficulties?
- Do you think you are knowledgeable and well educated to support women with perinatal low mood/depression?
 - Could you tell me more about that?
 - Existing education?
- Do you have any additional education or training needs?
 - Could you tell me more about that?

Treatment options

- Which treatments are available locally for women with antenatal low mood/depression?
 - Postnatal low mood/depression?
- How acceptable do you feel are these treatments for women?
- One of the things that this study will potentially be looking at the next stage is to see if some form of a talking therapy that is used for the treatment of perinatal depression can be delivered by maternity support workers. Do you think if maternity support workers receive appropriate training for delivering a psychological intervention and deliver it to women who are in depression or at risk of depression, would this be helpful for women and continuity of maternity care?
 - Do you think maternity support workers would be an appropriate staff to deliver a psychological intervention with appropriate training?

Stage 4: Winding down. Questions looking to the future, suggestions. Summarising. Information about what happens next

Recommendations

- What, if anything, do you think would be helpful for improving provision of perinatal mental healthcare?
- What, if anything, do you think would be helpful for improving perinatal depression treatments?

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Closing

- Okay, at the end of the focus group we normally ask people if they have any messages for service planners/providers with your own experiences.
- Do you have some other thoughts or views you would like to share?
- Thanking the participant for her/his time. Reiterating that the interview will remain confidential. Telling her/him that she/he is welcome to contact members of the study team to ask questions at a later date if she/he wishes.

ENDING RECORDING

Giving the participant travel expenses if needed.

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Appendix 8: A topic guide for focus group interviews with healthcare professionals (second study)

An Example of a Focus Group Topic Guide for Health Professionals

An exploration of women's experiences of perinatal low mood/depression and health professionals' experiences of providing care for women who have perinatal low mood/depression

Stage 1: Scene-setting and ground rules

- Thank participants for coming and welcome them
- Introducing the moderator and explanation of confidentiality
- Offering refreshments
- Indication of expected roles
- Introduction to researcher and study
- Study topic and funder
- Explanation of the aims and objectives of the study
- Explanation of confidentiality and anonymity
- Explanation of recording, length (up to one and a half hours) and the nature of the focus group, outputs/reporting and data storage issues
- Reminder participant of reimbursement of travel expenses
- Going through consent issues explaining that they may withdraw at any time from the focus group however all the data collected until that time will be used in the study, and they do not have to answer any questions they would prefer not to
- Checking whether they have any questions

Stage 2: Individual introductions

- Choosing pseudonym to call them during the focus group, giving name badges

Stage 3: The opening topic

Awareness – generic questions

- Can you tell me how do you describe perinatal low mood?
 - Perinatal depression?

Stage 4: Discussion

Roles and management

- Please, can you describe your role in assessing/screening women regarding their mental health in the perinatal period?
 - Ask to every member in the group because they may be in different positions in the healthcare system
- How do you identify perinatal low mood?
 - Perinatal depression?

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- Please, could you tell me about the process of screening for women regarding depression in the perinatal period?
- What guidelines are used to implement perinatal depression care in antenatal period and postnatal period? Is it different?
 - Have you brought an example of that?
 - Could you tell me more about the guidelines?
 - What is the process of referral?
 - What are the enablers of the process of referral?
 - What are the challenges/barriers of the process of referral?
- How have maternity services changed in terms of identifying women, if at all, supporting, and giving care in recent times?
 - Within last 3-5 years

Perceived barriers and enablers

- What sort of challenges/barriers do you experience while discussing about women's mental health status?
 - Do you experience any difficulty to leading or approaching women who you think may be experiencing perinatal low mood/depression?
- How about any enablers that might help you to talk about women's mental health status?
 - What sort of things help you on talking about women's mental health status?
 - Which words do you use while talking to women who may experience perinatal depression?
- What sort of difficulties/barriers do you face while providing care/support for women with low mood/perinatal depression?
- What sort of things help you/what are the enablers to deal with these difficulties?
- Do you think you are knowledgeable and well educated to support women with perinatal low mood/depression?
 - Ask to every member in the group
 - Existing education?
- Do you have any additional education or training needs?
 - Ask to every member in the group

Treatment options

- Which treatments are available for women with antenatal low mood/depression?
 - Postnatal low mood/depression?
- How acceptable do you feel are these treatments for women?
- One of the things that this study will potentially be looking at the next stage is to see if some form of a talking therapy that is used for the treatment of perinatal depression can be delivered by maternity support workers. Do you think if maternity support workers receive appropriate training for delivering a psychological intervention and deliver it to women who are in depression or at risk of depression, would this be helpful for women and continuity of maternity care?
 - Do you think maternity support workers would be an appropriate staff to deliver a psychological intervention with appropriate training?

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Stage 5: Ending the discussion

Recommendations

- What if anything, do you think would be helpful for improving provision of perinatal mental healthcare?
- What if anything, do you think would be helpful for improving perinatal depression treatments?

Closing

- Okay, at the end of the focus group we normally ask people if they have any messages for service planners/providers with your own experiences.
- Do you have some other thoughts or views you would like to share?
- Thanking the participants for their time. Reiterating that the focus group interview will remain confidential. Telling them that they are welcome to contact members of the study team to ask questions at a later date if they wish.

ENDING RECORDING

Giving the participants travel expenses if needed.

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Appendix 9: A topic guide for individual interviews with women (second study)

An Example of a Semi-Structured Interview Topic Guide for Women

An exploration of women's experiences of perinatal low mood/depression and health professionals' experiences of providing care for women who have perinatal low mood/depression

Stage 1: Introduction and context setting

- Introduction to researcher, PhD study and funder
- Study topic and explanation of the aims and objectives of the study
- Explanation of confidentiality and anonymity
- Explanation of recording, length (up to one hour) and the nature of the interview, outputs/reporting and data storage issues
- Reminding participant of £20 gift voucher as thank you for her time and help
- Reminding participant of reimbursement of travel expenses
- Going through consent issues explaining that she may withdraw at any time from interview as whole, and does not have to answer any questions she would prefer not to
- Checking whether she has any questions
- Choosing pseudonym to call her during the interview
- Ask if any changes to the demographics

Stage 2: Opening questions; more surface level. Background and contextual information-preliminary information. Definitional/conceptual questions

- Why are you interested in taking part in this study?

Stage 3: Core part of interview-questioning and discussion is in more depth. Move from circumstantial to attitudinal/evaluative/explanatory questions. Move from general to more specific coverage

Experience of perinatal low mood/depression

- Okay so if you'd like to start from when you began feel that you may have had low mood or depression and what happened?
 - When did it start? -before pregnancy -antenatal -postpartum
 - How did you recognise the changes in your mood?
 - What kind of feelings did you have?
 - What was that like?
 - Can you give me an example of that?
 - The symptoms
 - Did anybody around you recognise it?
 - For how long have you experience it?
 - How did it affect your daily life? (during pregnancy and/or postpartum period)
 - Impact on relationship with partner
 - Impact on relationship with child/children and wider family
 - Impact on social life
 - Impact on work life

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- How did you cope with that?
- What is it like when you feel or know that you have some mental health challenges?

Psychological needs and concerns

- What were your concerns while experiencing low mood and/or perinatal depression?
 - about you, your baby, your family
- What challenges did you face while experiencing low mood and/or perinatal depression?
- What was the most difficult thing while experiencing antenatal/postpartum depression and being pregnant/having a baby?
- What helped you to deal with these challenges/low mood/perinatal depression?

Seeking help

- What did you do when you first realised the symptoms?
 - Did you seek help?
 - Why/Why not?
 - From who?
 - What advice did you received?

Maternity services

- Did you go for regular care or appointments to maternity services?
 - What was the frequency of your appointments, if you can remember?
- Did someone ask you questions about your mood in maternity services?
 - Who asked?
 - Did you find her/him quite knowledgeable?
- How did you find her/his approach to you?
 - Was she/he trying to do her job? Or trying to listening to you and trying to help?
- Do you think you were offered support that was right for you?
 - Did you feel enough support from your caregiver?
 - Did you find it helpful?

Disclosing feelings

- Did you share your true emotions and mood with others?
 - Why did you share/did not you share?
 - If yes, with whom?
- What the triggers were to the decision to seek advice/help?
- How did you feel while sharing your mood?
- How was their approach to you?
 - Did you feel any barriers to disclosing your feelings to health professionals?
- What helped you to disclosing your feelings to health professionals?
- What aspects supported talking about your feelings and mood with health professionals?

Treatment and care options

- What was their advice to you? -referral? -treatment options? -psychosocial support? -peer-support?

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- How did you feel about it?
- Did you feel enough support from your caregiver?
- Could you tell me more about that?
- How acceptable were the treatments that recommended to you?
 - Changes in their expectations or views about the different options on offer
- What was your choice of treatment(s)?
 - What was that consist of?
 - Did you have regular checks and monitoring?
- What factors did affect your choice of treatment?
 - Factors which contribute towards making particular decisions
- What were the barriers to receiving treatment?
- What were the facilitating aspects of receiving treatment?
- Did you find the treatment useful?
 - Which aspects were most useful?
 - How satisfied were you with services provided?
- What was good about what they were doing?
- So how long did it take to recover after that?
- One of the things that this study will potentially be looking at the next stage is to see if some form of talking therapy that used for the treatment of perinatal depression can be delivered by maternity support workers. Do you think if maternity support workers receive appropriate training for delivering a psychological intervention and deliver it to women who are in depression or at risk of depression, would this be helpful for women and continuity of maternity care?
 - Do you think maternity support workers would be an appropriate staff to deliver a psychological intervention with appropriate training?

Stage 4: Winding down. Questions looking to the future, suggestions. Summarising. Information about what happens next, or help and support available

Recommendations

- Based on your experiences, is there something that maternity services could support women experiencing low mood/perinatal depression?
- What do you think would be helpful for improving perinatal mental healthcare for women?
- Where and from whom do you prefer to receive advice/support/treatment for perinatal depression?
- What factors affect your preferences?

Closing

- Okay, at the end of the interview we normally ask people if they have any messages for other women based on your own experiences, maybe somebody who's recently been diagnosed with perinatal depression or who is not quite sure how to deal with it and seek help?
 - What advice would you give to other women who have experienced low mood and/or depression during pregnancy and/or after childbirth?
- What about messages for maternity services/provisions/health professionals? Have you got anything you'd like to say to them?

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- Is there something that we haven't spoken about in the interview that you'd like to tell me about your perinatal low mood/depression?
- Do you have some other thoughts or views you would like to share?
- Thanking the participant for her time. Reiterating that the interview will remain confidential. Telling her that she is welcome to contact members of the study team to ask questions at a later date if she wishes.
- Reminding available help and support. She might choose to contact with her GP or speak to National Childbirth Trust, Mind, PANDAS Foundation or Samaritans.

ENDING RECORDING

Giving the participant a £20 One4all gift card.

Giving the participant travel expenses if needed.

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Appendix 10: Demographics form for women (second study)



An exploration of women's experiences of perinatal low mood/depression and health professionals' experiences of providing care for women who have perinatal low mood/depression

Researchers: Semra PINAR, Dr Helen BEDFORD, Dr Dean McMILLAN, Prof Steven ERSER

Demographics Form for Women

The information provided here will be kept anonymous and confidential. Before conducting an interview, we would like to learn about you. This will help us to choose a variety of women with different background and experiences for the research study.

Anonymous identifier			
1) Your age	2) The first part of the postcode		
3) Ethnicity <input type="checkbox"/> White <input type="checkbox"/> Black <input type="checkbox"/> Asian <input type="checkbox"/> Mixed <input type="checkbox"/> Other Please state.....	4) Current marital status <input type="checkbox"/> Single <input type="checkbox"/> Married or living with partner <input type="checkbox"/> Married but living without partner <input type="checkbox"/> Divorced <input type="checkbox"/> Widow/widower <input type="checkbox"/> Other Please state.....	5) Highest level of education <input type="checkbox"/> Left full time education aged 16 <input type="checkbox"/> Left full time education aged 18 <input type="checkbox"/> Graduate <input type="checkbox"/> Postgraduate study <input type="checkbox"/> Other Please state.....	
6) Employment status <input type="checkbox"/> Working full time <input type="checkbox"/> Working part time <input type="checkbox"/> Not working <input type="checkbox"/> Other	7) Approximate household income per year <input type="checkbox"/> <£15,300 <input type="checkbox"/> £15,300-£26,400 <input type="checkbox"/> £26,401-£35,600 <input type="checkbox"/> £35,600-£49,200 <input type="checkbox"/> £49,200> <input type="checkbox"/> Prefer not to say	8) Number of children <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 or more	9) Age of youngest child <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
10) When did you start feeling low mood/depression? (You can choose more than one options) <input type="checkbox"/> Before pregnancy <input type="checkbox"/> Some point during pregnancy <input type="checkbox"/> In the first year after childbirth			
11) When did you experience low mood/depression? <input type="checkbox"/> During pregnancy <input type="checkbox"/> During the first year after childbirth <input type="checkbox"/> Both during pregnancy and the first year after childbirth			

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<p>12) Were you been diagnosed with depression during pregnancy and/or in the first year after childbirth?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Unsure</p>
<p>13) For how long had you been suffering from low mood/depression?</p> <p>.....</p>
<p>14) Did you receive any psychological treatment (e.g. counselling, CBT, peer-support) for your low mood/depression during pregnancy and/or the year after childbirth?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>
<p>15) Were you prescribed medical treatment for your low mood/depression during pregnancy and/or the year after childbirth?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>
<p>16) Have you been diagnosed with a psychological or mental health illness other than depression during your pregnancy and/or the year after childbirth? If yes, please could you write it/them below?</p> <p><input type="checkbox"/> Yes.....</p> <p><input type="checkbox"/> No</p>
<p>17) Have you been diagnosed with any psychological or mental health illnesses other than depression in the past?</p> <p>.....</p>
<p>18) Please, could you write your available days and times for the interview with the researcher? (e.g. Mondays am, Thursdays pm)</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>19) Where would you like to be interviewed?</p> <p><input type="checkbox"/> A place in a convenient and confidential location for you which provides privacy (e.g. a private room in a community centre)</p> <p><input type="checkbox"/> Your home</p>

Thank you for taking the time to fill in this demographics form. Please put this form together with one of your signed consent forms and contact details sheet into the stamped-addressed return envelope and send it to the researcher.

Semra Pinar, Research Centre for Social Sciences, 6 Innovation Close, University of York, Heslington, York, YO10 5ZF
 Tel: 07729 070393 Email: sp1365@york.ac.uk

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Appendix 11: Contact details sheet for women (second study)

UNIVERSITY of York
The Department of Health Sciences

Contact Details Sheet for Women

An exploration of women's experiences of perinatal low mood/depression and health professionals' experiences of providing care for women who have perinatal low mood/depression

Please write your contact details below so the researcher can contact you when she receives your envelope.

Name details:	
My telephone number :	
My email address (optional) :	
My home address :	
My General Practitioner's contact details: (If as part of the research you disclose risks to yourself or others, then a member of the research team may pass this information on to a relevant health or social care professional)	GP Name:
	GP Telephone number:
	GP Practice name:
	GP Practice address:

Thank you for taking the time to fill in this contact details sheet. Please return this sheet with one of your signed consent forms and demographics form into the stamped-addressed return envelope and send it to the researcher.

Semra Pinar, Research Centre for Social Sciences, 6 Innovation Close, University of York, Heslington, York, YO10 5ZF

Tel: 07729 070393 Email: sp1365@york.ac.uk

Date: 15/06/2018

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Appendix 12: Contact details sheet for healthcare professionals (second study)

UNIVERSITY *of York*

The Department of Health Sciences

Contact Details Sheet for Healthcare Professionals

An exploration of women's experiences of perinatal low mood/depression and health professionals' experiences of providing care for women who have perinatal low mood/depression

Please write your contact details below so the researcher can contact you when she receives your envelope.

I wish to be contacted by telephone email

Name details:	
My telephone number :	
My email address :	
My work address:	

Thank you for taking the time to fill in this contact details sheet. Please return this sheet with one of your signed consent forms and demographics form into the stamped-addressed return envelope and send it to the researcher.

Semra Pinar, Research Centre for Social Sciences, 6 Innovation Close, University of York, Heslington, York, YO10 5ZF

Tel: 07729 070393 Email: sp1365@york.ac.uk

Date: 15/06/2018

Version: 1.0

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Appendix 13: Participant information sheets for women (second study)

UNIVERSITY *of York*

The Department of Health Sciences

An exploration of women's experiences of perinatal low mood/depression and health professionals' experiences of providing care for women who have perinatal low mood/depression

Researchers: Semra PINAR, Dr Helen BEDFORD, Dr Dean McMILLAN, Prof Steven ERSSER

PLEASE KEEP THIS INFORMATION SHEET AND A SIGNED COPY OF THE CONSENT FORM FOR YOUR RECORDS

You are being invited to take part in a research study. Before you decide whether to participate, it is essential for you to understand why the research is being conducted and what it will involve. If there is anything you do not understand, or if you want more details, please ask the researcher Semra Pinar. Her contact details are at the end of this sheet. Please take the time to read the following information carefully.

What is the purpose of this study?

Nearly one in ten women suffers from depression during pregnancy or after childbirth. Depression during this period (known as the perinatal period) can affect not only the woman herself but also her partner and children. Evidence suggests that although women are advised to have regular contact with health professionals, perinatal low mood and/or perinatal depression is not always recognised. Where such conditions are detected and treated, treatment is rarely evidence-based. According to the literature, there are some challenges at the level of women in seeking help from health professionals. Considering the problems associated with perinatal depression that can affect women and their children and partners, it is a very important issue to address. Therefore, the aim of the study is to explore women's experiences of perinatal low mood and/or perinatal depression and health professionals' experiences of providing care for women who have perinatal low mood and/or perinatal depression.

Who is doing the study?

The researcher, Semra Pinar, is a PhD student in the Department of Health Sciences at the University of York. Semra is a qualified midwife and this research is part of her PhD thesis. The researcher has three supervisors in her research team, Dr Helen Bedford (midwifery), Dr Dean McMillan (clinical psychologist) and Prof Steven Ersser (clinical nursing), from the Department of Health Sciences. This study is being funded by the Ministry of National Education, Turkey.

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Who is being asked to participate?

The project seeks to recruit women who fit the criteria below:

- Are 18 years and over;
- Able to read and speak fluent English;
- Have the capacity to give consent;
- Have felt or have been diagnosed with low mood and/or depression during pregnancy and/or in the first year after childbirth;
- Have experienced low mood or depression within the last five years (whose youngest child is between 1 and 5 years old);
- Had a live birth following their last pregnancy;
- No longer experience low mood or depressive symptoms;
- Living in [REDACTED]

Do I have to take part?

You do not have to take part in the study. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign two copies of the consent form (one copy is for you to keep). If you decide to take part you will still be free to withdraw without giving a reason, even during the interview itself.

What will be involved if I take part in this study?

If you fill in and sign the consent forms, the demographics form and contact details sheet, and send one of your consent forms, demographics form and contact details sheet in the pre-paid stamped-addressed return envelope by mail to the researcher, you will have a chance to take part in the study.

Once the researcher receives your consent and completed forms, the researcher will call you and ask a small number of questions over the telephone to ensure that you are now recovered from depression. It is not possible to check your current mood without your consent, and your GP's name and contact details. If your answers to the questions indicate depressive symptoms and we think that you are still experiencing depression symptoms, the interview will not be conducted with you.

The study aims to include women with different experiences of low mood/depression and from different geographical regions. Therefore, the information you provide on the demographics form is important for us to choose you for an interview. If there are more than three women in the same category, we may not arrange an interview with you.

If you are eligible to take part, a convenient date, time and venue for the interview will be arranged between yourself and the researcher. You can say whether you prefer to be interviewed at your home or another convenient location providing privacy (e.g. private room in a community centre). The interview will be audio-recorded and will take up to 60 minutes. The interview will be like having a conversation with the researcher. The researcher will ask you questions about your past experience with low mood and/or depression during pregnancy and/or the year after childbirth.

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What are the advantages/benefits and disadvantages/risks of taking part?

There are no anticipated disadvantages/risks to taking part in this study. However, during or after the interviews, you may feel upset because of talking about your experiences of low mood/depression during pregnancy and/or in the first year after childbirth. If this happens, we would suggest that you contact your own GP. Also, please take advantage of the available support below.

NHS Choices: (111) - Free NHS helpline service for urgent care services. For mental health helplines; <https://www.nhs.uk/conditions/stress-anxiety-depression/mental-health-helplines/>

Mind: (0300 123 3393) - information on a range of mental health topics; <https://www.mind.org.uk/>

Samaritans: (116 123) (24 hour helpline-free) - a charity aimed at providing emotional support to anyone in emotional distress, struggling to cope, or at risk of suicide; <https://www.samaritans.org/>

SANE: (0300 304 7000) – for emotional support, information and guidance for people affected by mental illness, their families and carers; <http://www.sane.org.uk/>

Your participation in the research will contribute to a better understanding of the problems and potentially help improve the provision of care and treatment for perinatal depression. The findings will also contribute to the chief investigator's PhD project in terms of tailoring a psychological intervention for the treatment of perinatal depression. Your participation and sharing your story may help others in the future.

The researcher will be sensitive to all issues raised during the interview, but if you do not want to continue the interview, you can stop the conversation at any time.

If you decide to take part in an interview and choose to be interviewed in a private room other than your home, your travel expenses will be reimbursed in person, in exchange for original travel tickets.

Also, as a thank you gift for the time you spend in an interview, a £20 One4all gift card will be presented.

Can I withdraw from the study at any time?

You do not have to answer any questions that you do not want to answer. During the interview, you can stop the conversation with the researcher at any time without giving a reason. You can withdraw from the research at any time, even during the interview itself. If you withdraw from the study during your interview or within 48 hours after completion of the interview, we will destroy your data and will not use it in any way. If you choose to withdraw more than 48 hours after completion of the interview, your data will still be included in the analysis.

Will the information I give be kept confidential?

University of York is the sponsor for this study based in United Kingdom. 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. We will retain your contact details for 12 months for undertaking this study and a copy of the signed consent form for five years from the end of the research to cover the period of the submission of thesis and any publications arising from the study. Your personal information will be stored separately from the research data which will be retained for 10 years following the end of the research. The information will be stored securely at the University of York in password protected files and locked filing cabinets that only the named researchers have access to, in line

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with the General Data Protection Regulation 2018. Your spreadsheet of contact details and consent form will be stored separately with your demographics form to ensure confidentiality.

Your name and any personal identifiable information will be anonymised in all audio recordings and transcripts (the interview will be typed up into a transcript by the researcher or a professional transcriber who will be subject to a confidentiality contract) with a self-chosen false first name and your identity will be kept strictly confidential. No real names of people or places will be used in any presentations or publications resulting from the study or in the researcher's PhD thesis. Your personal information, recordings, consent form, demographic form and transcript will be accessible only by the researchers in the research team.

Quotations from your interview may be used in reported findings from the research study. If anything that you have said appears in quotation, it will be made anonymous so that you cannot be identified. Your recording will be destroyed 12 months after the study. Your anonymised transcripts will be stored on the York research database and PURE (database to store research data safely) for 10 years according to the University of York's policy. Transcripts will not be publicly available and only the research team will have access.

Confidentiality can only be broken, if as part of the research you disclose risks to yourself or others. In this case, a member of the research team may pass this information on to a relevant health or social care professional and also for this reason your GP may be informed about your participation in this study.

What will happen to the results of the study?

The results of the study will be published in the researcher's PhD thesis. Also, the researcher intends to present the results at conferences and publish in academic journals.

Who has reviewed this study?

This study has been reviewed and approved by Research Ethics Committee Yorkshire and Humber – Leeds West.

Who do I contact in the event of a complaint?

If your complaint is related to the study, you can contact Prof Tracy Lightfoot (Deputy Head (Postgraduate)), Department of Health Sciences, University of York, email: tracy.lightfoot@york.ac.uk; Tel: 01904 32 1881. If it is an NHS care issue, you are advised to contact relevant Patient Advice and Liaison Service (PALS) in your location.

If you agree to take part, please fill in and sign the consent forms, the demographics form and contact details sheet, put one of your signed consent forms, demographics form and contact details sheet in the pre-paid stamped-addressed return envelope and send the envelope by mail to the researcher.

If you would like more information or have some questions or concerns about the study please contact the researcher Semra Pinar, Tel: 07729 070393, Email: sp1365@york.ac.uk
Address: Research Centre for Social Sciences, 6 Innovation Close, University of York, Heslington, York, YO10 5ZF.

Thank you for taking the time to read this information sheet.

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Appendix 14: Participant information sheets for healthcare professionals (second study)



An exploration of women's experiences of perinatal low mood/depression and health professionals' experiences of providing care for women who have perinatal low mood/depression

Researchers: Semra PINAR, Dr Helen BEDFORD, Dr Dean McMILLAN, Prof Steven ERSSER

PLEASE KEEP THIS INFORMATION SHEET AND A SIGNED COPY OF THE CONSENT FORM FOR YOUR RECORDS

You are being invited to take part in a research study. Before you decide whether to participate, it is essential for you to understand why the research is being conducted and what it will involve. If there is anything you do not understand, or if you want more details, please ask the researcher Semra Pinar. Her contact details are at the end of this sheet. Please take the time to read the following information carefully.

What is the purpose of this study?

Nearly one in ten women suffer from depression during pregnancy or after childbirth. Depression during the perinatal period affects not only the woman herself but also her partner and children. Evidence suggests that although women are advised to have regular contact with health professionals, low mood and/or perinatal depression is not always recognised. Where such conditions are detected and treated, treatment is rarely evidence-based. According to the literature, health professionals are not always able to recognise, screen and provide appropriate care and referral for women who have perinatal depression. Considering these problems, the high prevalence of perinatal depression and devastating outcomes associated with perinatal depression for women, children and partners, it is a very important issue to address. Therefore, the aim of the study is to explore women's experiences of perinatal low mood and/or perinatal depression and health professionals' experiences of providing/planning care for women who have perinatal low mood and/or perinatal depression.

Who is doing the study?

The chief investigator, Semra Pinar, is a PhD student in the Department of Health Sciences at the University of York. Semra is a qualified midwife and this research is part of her PhD thesis. The researcher has three supervisors in her research team, Dr Helen Bedford (midwifery), Dr Dean McMillan (clinical psychologist) and Prof Steven Ersser (clinical nursing), from the Department of Health Sciences. This study is being funded by the Ministry of National Education, Turkey.

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Who is being asked to participate?

The project seeks to recruit health professionals who have experience of providing and/or planning care for women who may have perinatal low mood and/or perinatal depression. We would like to hear your experiences through face-to-face interview with the researcher or through group discussion with other health professionals. We are contacting registered health professionals (e.g. midwives, health visitors, GPs, service managers, specialist maternal mental healthcare providers) and maternity support workers who have been working in NHS maternity services in Yorkshire and the Humber for at least 3 years, and have experience of providing and/or planning perinatal low mood and/or perinatal depression care.

Do I have to take part?

You do not have to take part in the study. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign two copies of the consent form (one copy is for you to keep). If you decide to take part you will still be free to withdraw without giving a reason, even during the interview/focus group itself.

What will be involved if I take part in this study?

A convenient date, time and place for the interview or focus group discussion will be arranged between yourself and the chief investigator. You can say whether you prefer to take part in a face-to-face interview with the researcher or a group discussion with other 4-6 health professionals, the researcher, and a moderator. You will be asked to bring examples of any local perinatal mental health provision guidelines or pathways that you use in maternity services for discussion in the interview.

The face-to-face interview will take place at a time convenient to you, in a location that you are comfortable with and that provides privacy. The interview will be audio-recorded and will take up to 60 minutes. The interview will be like having a conversation with the researcher. The researcher will ask you questions about your experiences of providing care for women who have perinatal low mood/depression.

In the focus group, you will be sharing your experiences with other health professionals who have similar experiences. The researcher will ask questions about your experiences of providing care for women who have perinatal low mood and/or perinatal depression and wants you to engage with the conversation with others. Participants will need to maintain confidentiality of others in a focus group. Focus group discussions will last for approximately 60-90 minutes. There will be a moderator who will listen to everyone and take notes. The moderator will also maintain confidentiality. The focus group discussion will take place in a private and convenient place for all participants.

The individual interviews and focus group discussions will be recorded on a digital audio recorder.

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What are the advantages/benefits and disadvantages/risks of taking part?

There are no anticipated disadvantages/risks to taking part in this study. By taking part in the research, you will contribute to understanding the problems faced by professionals and improving the provision of perinatal low mood and/or perinatal depression care in maternity services. Your participation and sharing your experiences will help us to tailor a psychological intervention for the treatment of perinatal depression.

If you decide to take part in a focus group/interview, your travel expenses will be reimbursed in person, in exchange for original travel tickets. Also, refreshments will be available during the interview/focus group.

Can I withdraw from the study at any time?

You can refuse to answer any questions. During the interview, you can stop the conversation with the chief investigator at any time without giving a reason. You can withdraw from the research at any time, even during the interview/focus group. If you withdraw from the study during your individual interview, all data referring to you will be destroyed and will not be used in any way. However, if you choose to withdraw from the focus group interview, all the data collected until the time of withdrawal will be used in the study because it is not possible to remove your contribution from a focus group discussion.

If you choose to be interviewed individually, you can withdraw from the study within 48 hours after completion of the individual interview. All data referring to you will be destroyed and will not be used in any way. If you choose to withdraw more than 48 hours after completion of the individual interview, your data will still be included in the analysis.

After completing the focus group interview, you can still withdraw from the study, however, your data will be used in the analysis.

Will the information I give be kept confidential?

University of York is the sponsor for this study based in United Kingdom. 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. We will retain your contact details for 12 months after undertaking this study and a copy of the signed consent form for five years from the end of the research, to cover the period of the submission of thesis and any publications arising from the study. Your personal information will be stored separately from the research data which will be retained for 10 years following the end of the research. The information will be stored securely at the University of York in password protected files and locked filing cabinets that only the named researchers have access to, in line with the General Data Protection Regulation 2018. Your spreadsheet of contact details and consent form will be stored separately with your demographics form to ensure confidentiality.

Your name and any personal identifiable information will be anonymised in all audio recordings and transcripts (the interview will be typed up into a transcript by the researcher or a professional transcriber who will be subject to a confidentiality contract) with a self-chosen false first name and your identity will be kept strictly confidential. No real names of people or places will be used in any presentations or publications resulting from the study or in the researcher's PhD thesis. Your personal

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information, recordings, consent form, demographic form and transcript will be accessible only by the researchers in the research team.

Quotations from your interview may be used in reported findings from the research study. If anything that you have said appears in quotation, it will be made anonymous so that you cannot be identified. Your recording will be destroyed 12 months after the study. Your anonymised transcripts will be stored on the York research database and PURE (database to store research data safely) for 10 years according to the University of York's policy. Transcripts will not be publicly available and only the research team will have access.

What will happen to the results of the study?

The results of the study will be published in the researcher's PhD thesis. Also, the researcher intends to present the results at conferences and publish in academic journals.

Who has reviewed this study?

This study has been reviewed and approved by Research Ethics Committee Yorkshire and Humber – Leeds West.

Who do I contact in the event of a complaint?

If your complaint is related to the study, you can contact Prof Tracy Lightfoot (Deputy Head (Postgraduate)), Department of Health Sciences, University of York, email: tracy.lightfoot@york.ac.uk; Tel: 01904 32 1881.

If you agree to take part, please fill in and sign the consent forms, fill in the demographics form and contact details sheet, put one of your signed consent forms, demographics form and contact details sheet in the stamped-addressed return envelope and send the envelope by mail to the researcher.

If you would like more information or have any questions or concerns about the study please contact the chief investigator Semra Pinar, Tel: 07729 070393, Email: sp1365@york.ac.uk, Address: Research Centre for Social Sciences, 6 Innovation Close, University of York, Heslington, York, YO10 5ZF.

Thank you for taking the time to read this information sheet.

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Appendix 15: Consent form for women (second study)

UNIVERSITY of York
The Department of Health Sciences

Participant Consent Form for Women

An exploration of women's experiences of perinatal low mood/depression and health professionals' experiences of providing care for women who have perinatal low mood/depression

	Please confirm agreement to the statements by putting your initials in the boxes below
I have read and understood the participant information sheet [date: 05/02/2019, version: 2.0].	
I have had the opportunity to ask questions and discuss this study.	
I have received satisfactory answers to all of my questions.	
I have received enough information about the study.	
I understand my participation in the study is voluntary and that I am free to withdraw from the study: 1 At any time, even during the interview. 2 Without having to give a reason for withdrawing. 3 Should I choose to withdraw from the study before the end of the interview, all data referring to me will be destroyed and will not be used in any way. 4 Should I choose to withdraw more than 48 hours after completion of the interview, I understand that my data will still be included in the analysis.	
I understand that my interview will be audio-recorded.	
I understand that my data collected during the study may be looked at by the research team. I give permission for these individuals to have access to my data.	
I agree to my GP being informed of my participation in the study.	
I understand that if as part of the research I disclose risks to myself or others, then a member of the research team may pass this information on to a relevant health or social care professional.	
I understand that any information I provide, including personal details, will be kept confidential, stored securely and only accessed by those carrying out the study.	
I understand that any quotations from my interview may be used in reporting the study findings. (If anything that you have said is quoted, it will be made anonymous so that you cannot be identified).	
I understand that any information I give may be included in the researcher's PhD thesis and/or peer-reviewed journals and/or conference presentations but all information will be anonymised.	
I agree to take part in an interview with the researcher.	
I agree to take part in this study.	
I would like to receive a summary of the results from the study. Please provide contact details if you wish to be informed of the results of the study:	
Participant Signature	Date:
Name of Participant:	
Researcher Signature	Date:
Name of Researcher:	

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Appendix 16: Study advertisement leaflet and posters for women (second study)

Study Advertisement Poster



Have you experienced low mood or depression during pregnancy or in the first year after childbirth? (within the last 5 years)

I would like to hear your recent experiences of low mood or depression during pregnancy or in the first year after childbirth, and following any care that you may have received

This study aims to understand the provision of care for women with perinatal low mood or depression and help them to explore the use of a talking therapy for treatment

Your participation and sharing your story may help others in the future



Who can take part in the study?

Women:

- Aged 18+
- Have felt or have been diagnosed with low mood or depression during pregnancy or in the first year after childbirth
- Whose youngest child is between 1 - 5 years old
- Who no longer experiences depression symptoms
- Living in [REDACTED]

You will be asked to take part in an interview, which would be audio recorded and last for no more than 60 minutes

Your participation would be anonymous and your identity will be kept strictly confidential

You can choose a convenient and private location for the interview

Reasonable travel expenses will be reimbursed and as a thank you gift for your time, a £20 gift card will be presented

For more information or to take part, please contact *PhD student Semra Pinar*


Tel: 07729 070393 or

Email: sp1365@york.ac.uk

This study, 'An exploration of women's experiences of perinatal low mood/depression and health professionals' experiences of providing care for women who have perinatal low mood/depression', has been reviewed and approved by REC Yorkshire and Humber - Leeds West. IRAS ID: 237021 Version 1.0 [18/03/2019].
Version 2.0 ; Date: 05/02/2019

Appendix 17: Advertisement leaflet and poster for healthcare professionals (second study)


Are you a health professional supporting women with perinatal low mood or depression?



I would like to invite you to participate in a PhD study to hear your experiences of caring for women who have perinatal low mood or depression.

This study aims to improve the provision of perinatal depression care in maternity services.

Your participation will help to inform effective care and potentially tailor a psychological intervention for the treatment of perinatal depression.



Who can participate in the study?

- ✓ Any registered health professionals (e.g. midwives, health visitors, service managers, perinatal specialists, or general practitioners) or maternity support workers working in NHS maternity services, community services or GP practices in [REDACTED] for at least three years;
- ✓ With experience of caring for women with perinatal low mood or depression.

Participation in this study is completely voluntary. Your participation will be anonymous and your identity will be kept strictly confidential.

You can choose an individual interview (maximum 60min, with the researcher) or a focus group interview (maximum 90 min, with other 4-6 health professionals, the researcher and a moderator) in a private and convenient location to you. The interviews will be audio recorded.

If you would like to find out more information or take part, please take an information pack from the research box or contact *PhD student Semra Pinar*, and she will send you an information pack.

PhD student Semra Pinar Tel: 07729 070393 Email: sp1365@york.ac.uk

This study, 'An exploration of women's experiences of perinatal low mood/depression and health professionals' experiences of providing care for women who have perinatal low mood/depression', has been reviewed and approved by REC Yorkshire and Humber – Leeds West. IRAS ID: 237021 Version 1.0 [18/03/2019]. The photos in this image (Carlisle Hospital Walk-in centre staff in work.) CC BY 2.0 (<https://creativecommons.org/licenses/by/2.0/>), via iStockphoto.com

Version: 1.0 ; Date: 22/10/2018

Appendix 18: Indicative questions list for the workshops (third study)

Indicative questions to ask at the 1 st workshop		
Yes/no in each section	Superficial changes in wording	Probing for some substantive changes
is this a good idea to add an introduction before stage:1 or not	<ul style="list-style-type: none"> -Would it be better to give information in a table with bullet points as in the p.2? -Would you like to see any pictures? -Would you like to make any changes in wording? 	<ul style="list-style-type: none"> -Do you have any suggestions for what kind of information/content an introduction might contain? -Would you like to read information about the proportions of people getting better from this treatment? -information about its effects on children and other family members - information about dealing with stigmatising during this period - information about dealing with being worried about a social worker that taking away your kids - what would you expect to see in introduction information - <i>what is missing in there and what would you add</i> -this manual will be used through pregnancy and after childbirth so how can we make this appeal to a whole range of women who might be in different stages
is this a good idea to add stage:1 Recognising symptoms of low mood or not	<ul style="list-style-type: none"> -Do you think tables look fine about the symptoms? -Would you like to make any changes in wording? 	<ul style="list-style-type: none"> - do you think this section is going to work for anyone to recognise the symptoms of low mood? -<i>what is missing and should be in there?</i> - do you think the cycle on p.6 is clear? Should it be different in some way? Would you like to add another part to the cycle? - Would you like to see any information for partners? For example, bullet points in a table for recognising your partner's mood if s/he is affected by your mood? Or help and support sources for partners -how about domestic violence, child abuse, sexual abuse type of things?
stage:2 The value of keeping a diary is a key stage in BA treatment	<ul style="list-style-type: none"> - Do you think given examples on p.8 match your activities during pregnancy and in the postnatal period? Would you like to change some of them? - Do you think the table might be in a different structure? -Would you like to make any changes in wording? 	<ul style="list-style-type: none"> -<i>what is not here that should be?</i> -Do you feel it is a good idea to score your mood? Cooking is a routine or necessary activity, but it might be an unpleasant activity for you. <u>So</u> if you were to score this activity as 3, would you stop cooking next week? What would your advice be here? Should we write any suggestions for unpleasant but necessary activities?
stage:3 three types of activity and planning to keep a balance is a key stage in BA treatment	<ul style="list-style-type: none"> -do you think given examples match your activities during pregnancy and in the postnatal period? - Do you think the table might be in a different structure? 	<ul style="list-style-type: none"> - do you think there should be an activity scheduling table as on p. 9? -where it should be? -<i>what is missing and should be in there?</i>

<p>is this a good idea to add stage:4 breaking jobs down into easier tasks, and learning new ones or not</p>	<p>-would you like to see on p.13 an example day routine of a pregnant lady and a new mum? -Would you give me an example of your daily routine when you were pregnant? And after having your baby? -Would you like to change the examples on p.14? -would you like to change the wording in the table on p.15?</p>	<p>-What would you like to see at this stage? <i>-what is not here that should be?</i> -Do you think this stage should come within the third stage? Or is it fine as a separate stage? What would your advice be? -do you think the table on p.16 is necessary and relevant to the stage? Would it be different in some way?</p>
<p>is this a good idea to add stage:5 the benefit of your activities or not</p>	<p>-Would you like to make any changes in wording? -Would this example be helpful and relevant for women? -Would you like to make any changes in tables on pages 18 and 19? -would it be beneficial to add pictures on p.20? -Would you like to give some examples that we can add on p.21? -would like to make any changes in the table on p.22?</p>	<p>-What would you like to see at this stage? <i>-what is not here that should be?</i> -some mothers may experience physical health problems during pregnancy or in the postpartum period for example hip problems/pelvic floor health/pelvic girdle pain/backache which may need an operation. Would it be helpful to keep the information on p.20 and maybe adding more information about physical health problems that women may experience during pregnancy or in the postpartum period? What would be your advice on this?</p>
<p>is this a good idea to add stage:6 spotting symptoms and making an action plan to stay well or not</p>	<p>-Would you like to make any changes in wording? -would you like to add anything in the table?</p>	<p><i>-what is not here that should be?</i> -would action plan be useful if your mood is getting worse? -would you like to change or add anything to the useful tips box? -the last two pages are for keeping notes. Would you think it would be useful?</p>
<p>Design, size and colour of the manual</p>	<p>-Would you like it handbag size smaller than this or like an A4 size notebook? Maybe an electronic copy? -Would you like it to be in different colours? -Every stage is in a different colour. Would you like to change it?</p>	<p>-What would you like to see on the cover page and the last page? -Do you want it to be personalised in some way? -confidentiality</p>



Community Pharmacy Mood Intervention Study

The CHEMIST Study

Enhanced Support Intervention Manual

Introduction

This manual contains guidelines for delivering the enhanced support intervention (ESI) within the CHEMIST study. It is for use by those who have received training in the intervention and who are receiving ongoing supervision from the study team.

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Section A Describes the CHEMIST Study and details the overall principles of the intervention.	4
Section B Outlines a session by session overview. Contact Session 1 Contact Sessions 2-5 Contact Session 6	15 22 26
Section C Describes DASS21 Depression Subscale Risk Protocol Study Team Contact Details	31 33 40

Section A
The CHEMIST Study

**Principles and Practice of
Enhanced Support for
Sub Threshold
Depression**

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CHEMIST ESI Manual V3 8/3/17

The CHEMIST Study

About 30% of the UK population have long term physical health problems. In those that do, depression is 2-3 times more common than in the general population. Depression alongside long term physical health problems can worsen health outcomes, quality of life and double healthcare costs. People with these conditions are more likely to live in poorer areas, contributing significantly to health inequalities.

For most people with milder depression their symptoms will go undetected/untreated alongside physical health problems. This is disappointing as treatments can help and improve quality of life. One treatment, we recently tested in the UK, in people over 65, with mild depression (most with long term health problems), called collaborative care, was acceptable and effective. It reduced depression symptoms at 4 and 12 months and nearly halved progression to major depression, compared to usual primary care. The intervention was delivered by people with no professional healthcare qualification, but who were trained/supported by experts in the approach. It included a psychological self-help treatment called behavioural activation supported by structured phone/face to face sessions, regular use of a mood measurement questionnaire and liaison with the person's GP if needed.

As nine out of 10 people live within 20 minutes' walk of a pharmacy, we think they may provide an excellent public health setting for such an intervention, having a strong presence in poorer communities. Pharmacies are well placed to offer opportunistic psychological support to people with long term physical problems who attend their pharmacy for a range of health related services. In CHEMIST we aim to adapt our existing collaborative care intervention and see if it can be delivered by suitably trained community pharmacy staff to adults with mild depression and long term health problems. If beneficial in this setting the intervention could reach many people who remain untreated.

We will conduct two phases of research to test if a larger definitive study would be possible. In 'phase one' we will train a small number of pharmacy staff to test our proposed study recruitment, intervention and data collection processes. We plan to recruit 20-30 people via pharmacies, community settings or local GP practices. By using interviews with participants and pharmacy staff and observing recruitment, intervention acceptance and data completion rates we will refine our research approaches/intervention. In 'Phase two' we will run a randomised controlled trial 'in miniature' with 100 people testing our intervention against 'usual care'. By observing how many people we need to approach, screen and assess to recruit this number and by

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observing how well we can treat people and collect those data we need, we will be able to decide if a larger study is possible. We will collect a range of questionnaires at the start and at 4 months. We will also conduct detailed interviews with 10 participants and a range of pharmacy staff and GPs to get an in depth understanding of our procedures. If we are successful in meeting our aims we will seek separate funding to run a larger study to reliably answer the question 'does enhanced support in pharmacies work for less severe depression, can it prevent progression to major depression and does it represent value for money'?

Local pharmacy networks, pharmacy user groups and local authorities have worked with us in developing the study.

Your work in delivering the intervention is central to the study's success. We thank you for your help in this process and look forward to working with you over the next 28 months.

The Study Team

Name	Role	Organisation
Co-applicants		
Dr David Ekers	Chief Investigator	Durham University
Professor Simon Gilbody	Co-Investigator	University of York
Dr Dean McMillan	Co-Applicant	University of York
Professor Catherine Hewitt	Co-Applicant	University of York
Dr Shehzad Ali	Co-Applicant	University of York
Ms Ada Keding	Co-Applicant	University of York
Professor Clare Bamba	Co-Applicant	Durham University
Dr Cate Whittlesea	Co-Applicant	Durham University
Dr Adam Todd	Co-Applicant	Durham University
Professor Carolyn Chew-Graham	Co-Applicant	Keele University
Mrs Claire Jones	Co-Applicant	Durham County Council
Mr Jay Badenhorst	Co-Applicant	Whitworths Chemists
Non-Co-applicants		
Della Bailey	Clinical Supervisor	University of York
Dr Liz Littlewood	Trial Manager	University of York
Rose McNulty	Trial Administrator	Tees, Esk & Wear Valleys NHSFT

Enhanced Support Intervention (ESI)

What is ESI?

ESI consists of a **structured management plan** whereby facilitators give participants information on a psychological intervention known as Behavioural Activation and help them to use it. In addition, they monitor depression symptom levels during the intervention in discussion with the participant and take action if there are signs of deterioration. The aim is to help people to learn to 'stay well' psychologically despite the challenges their long term health problem brings.

Treatment contacts are **scheduled** and organised via 4-6 (mainly telephone) appointments over up to 12 weeks.

The approach is part of a **multi-professional approach to participant care** whereby ESI facilitators can contact participants' GPs as needed, based upon intervention protocols. Supervisors provide ESI facilitators support and guidance on their management plan and communication to GPs.

Where does ESI happen?

Most contacts will be phone based from the pharmacy. Occasional face to face contact in the consultation room is possible if preferred by the participant using the local pharmacy protocols for using the rooms.

How often do ESI contacts happen?

Initial contact should be as soon as possible after notification that a participant has been allocated, generally within 4 working days (Monday – Friday). As far as possible subsequent telephone or face to face contacts will be on a weekly basis. Contacts last 15-20 minutes although session one sometimes is longer.

How often should ESI Facilitators try to contact participants?

ESI Facilitators should try to make contact with participants until they are successful in reaching the participant or until supervisors deem that further attempts are unlikely to be successful. If repeated attempts by phone and letter have been unsuccessful then the GP should be contacted by the study team to find out whether there has been a change in the participant's health status or contact details.

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ESI facilitator support

Facilitators do not work alone. Supervision is provided from the study team and there is always a mental health specialist available to consult in event of any concerns. The GP remains the person who will hold clinical responsibility for the participant's care.

Summary: Roles in the CHEMIST study**The GP**

The GP retains all clinical responsibility for the treatment of trial participants.

The ESI facilitator

Support participants in their treatment choices for sub threshold depression.

Deliver support for the use of the BA self-help workbook.

Monitor depression symptom levels.

Communicate with the GP as needed.

Have contact with study team for supervision and support.

The Supervisors

Provide regular support to ESI facilitators via telephone.

Initiate regular, scheduled reviews of participants and help ESI facilitators to problem solve any difficulties and assist case communications with GPs if needed.

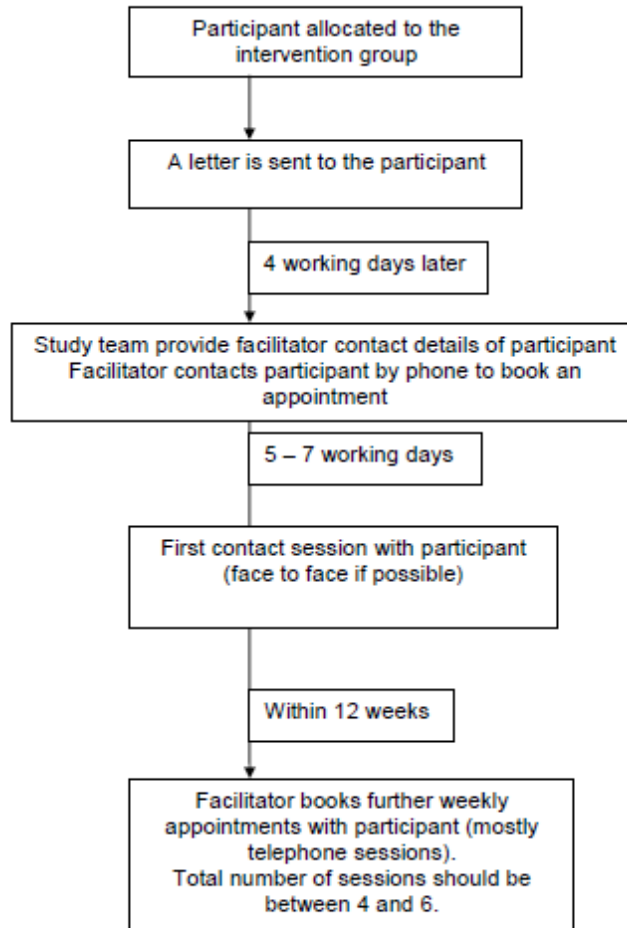
The Researchers

Assess participants for suitability for the trial.

They will interview suitable participants at the beginning of the trial and send them follow-up questionnaires 4 months later to collect outcome measures and for informing ESI Facilitators of participant contact details once randomisation has taken place.

The York Trials Unit is responsible for the random allocation of participants to each arm of the trial (pilot phase).

**CHEMIST study
Time Table**



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Assessing and Managing Risk

Participants who are actively suicidal at the start of the trial are not eligible for inclusion. However, some participants may experience deterioration in their mental state during the trial. Each contact, therefore, should always include a risk assessment. No ESI facilitator should be managing participants at significant risk of suicide, self-harm or harm to others. Where participants express such ideas, facilitators should follow the CHEMIST risk management protocol (see section C for the Guide to Assessing & Reporting Risk).

Communicating with GPs

Regular communication with GPs is an essential aspect of collaborative care. If ESI facilitators are concerned about any aspect of a participant's healthcare they should contact the participant's GP. All contacts with the GP should be logged and discussed with the supervisor.

Section B

**Enhanced Support
Intervention: A
Session by Session Guide**

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Enhanced Support Session by Session Guide

General Session Structure

All sessions should adopt the following structure:

1. Information Gathering
2. Information Giving
3. Shared Decision Making
4. Action Following Contacts: Reporting and Supervision

1. Information Gathering

The depth of information gathering depends on which stage participants are currently at in the ESI process. For example, the first contact requires a more in-depth assessment in order to get to know the participant and any problems they may be having. Later contacts will gather information in a more focussed way around progress. In all contacts there will be assessment of:

- Symptoms of depression using the DASS depression subscale
- Progress using the self-help workbook
- Response to ESI support

2. Information Giving

Again, the level of input will vary from session to session. It is likely that in the early contacts, input will be highest. However, information giving may be required at all stages to help participants take decisions about their treatment. Behavioural activation information based upon the self-help workbook is also likely to be given in more detail during the early contact sessions.

3. Shared Decision Making

ESI facilitators should develop a collaborative relationship with participants. Participants are in charge of their own decisions. Facilitators collaborate in these decisions by helping participants weigh up their options regarding possible behavioural activation activities etc.

Decisions will include discussion of behavioural activation targets and exercises. Negotiated activities should be realistic and achievable and should be based on participants' own identification of things they do to keep themselves well, or things they may have stopped doing recently.

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Other decisions will be about the frequency of contacts, time of next contact etc. Finish the contact with a clear understanding of what the participant has decided to do between this and subsequent contacts and get feedback from participants on their shared understanding of the next steps.

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Basic principles

Below are some things that facilitators should bear in mind throughout the sessions.

Participants in the CHEMIST study have been diagnosed as experiencing sub threshold depression; however they may not recognise themselves as having a problem with mood or activity levels. Facilitators should take this into account during sessions and work collaboratively and sensitively with the participant to enable them to undertake behavioural activation

Behavioural Activation principles

- 1) Experiment - "Let's try it out"
 - o Try out different behaviours to find out what is meaningful for the participant.
 - o A wide and diverse range of healthy activities for people tends to bring the best results
- 2) Participants will often find when they start to do activities it is very hard. Remind them that this is normal. The treatment is not about just getting on with it, it helps them understand how low mood can impact on activity. It then helps people understand how to target certain activities to help them feel better.
- 3) Remind participants of the 'outside – in' rationale.
 - o i.e. rather than wait to feel ready to do things that are good for you, do things to make you feel ready.
 - o Support them to start doing things, despite difficult feelings and thoughts they may have, in a way that reconnects them with things that were previously good for them.
- 4) Functionally equivalent activities. It is the benefit of the behaviour rather than what the behaviour is.
 - o Some participants may not be able to do things they used to enjoy due to physical health problems, financial problems or changes in their role.
 - o If this is the case, ask the participant what it was about the activity they found rewarding, what else it offered them and what made them keep doing it. It may be that the activity served a social function, gave a sense of achievement, helped the person feel useful, or provided time to think or reflect. This information can be used to help them to think of alternatives or adaptations.
 - o Examples:

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- a participant may no longer be able to play golf due to physical health restrictions, however, it may be that this activity also served an important social function for the person. In this case the participant may be able to meet with their golf friends for coffee or lunch instead.
- a participant is no longer able to visit their friends and family due to mobility restrictions, the facilitator could encourage alternative ways of being in touch like 'Skype' or telephone.

5) Grading activities

- Start small and break activity down into stages.
- For example, a participant may have previously enjoyed going for walks but since having an operation on their hip has not been doing this. In this case, the participant could start off with short walks (e.g. to the end of the road) and build these up over time. They could also ask someone to accompany them on walks at first until they feel they are able to go on their own.

Questioning style

Facilitators use an open discovery orientated fashion. This involves asking open questions such as:

- Can you give me an example of that?
- What do you think causes...?
- What would happen if...?
- What are the strengths and weaknesses of...?
- How does ... fit with what we learned before?

Help the participant to come to their own decisions.

Contact Session 1

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ESI Facilitator contact Checklist
(photocopy additional copies as required)

Tick when
Complete

Introduction self, study and contact length-double check speaking to right person	
---	--

1.0 Information Gathering	
1.1 Review of problem areas	
1.2 Assessment of depression symptom level DASS depression subscale	score
1.3 Risk assessment	
1.4 Brief summary BA and link to main problems (if any) the person has at the moment that led them to volunteer for the study and current scores/risk	
Notes on Information gathering	

2.0 Information Giving	
2.1 Depression information	
2.2 Material on behavioural activation	
Notes on Information giving	

3.0 Shared Decision Making	
Agree action goals for behavioural activation and hand out materials	
Negotiate the next contact session	
Discuss participant initiated contact	
Notes on shared decision making	

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Contact Session 1

1.0 Information Gathering

1.1 Review of problem areas

The facilitator should spend 5 minutes speaking with the participant about how they feel at the moment and what were the things that led them to volunteer for the study (how is their mood, what are the main problems they have at the moment, what is hard for them to do at the moment that used to be important to them).

1.2 Formal symptom assessment

The facilitator should use the DASS to measure depressive symptoms and discuss scores with the participant and that this will be done at each contact to see how they are doing in a consistent way (much like taking blood pressure does) (see section C).

1.3 Assessment of Risk

The facilitator should ask the risk screening question, and follow risk assessment protocol if positive (see section C).

1.4 Review of Behavioural Activation Support Programme

The facilitator should discuss the BA model and how in the following 6 contacts they will aim to help them use the self-help booklet to understand the link between low mood and health problems. That this is done in a step by step fashion and they are keen to try to help the person apply what is in the booklet to themselves. The aim of this is to help with any current problems if they have them, and/or to keep well in the future. That this is important as the link between low mood and health problems is clear, and if you can maintain a healthy mood, it helps you deal with the health problems you have.

Using the DASS

"In order to measure your progress through the treatment, I would like to ask you some standard questions from a questionnaire at each appointment. There are 7 questions and they relate to the last week. The aim is to give us a quick idea about how you've been feeling in the past week. You can find a blank copy of this in your participant pack"

Run through the questions in order.

Quickly add up the score.

Give the participant feedback on what the score indicates. Be honest with the scoring and ask, *"How does this fit for you?"* in terms of the way the participant is currently feeling.

"So now we have a baseline measure we'll continue to do this every week to monitor your scores"

Remind the participant there is a blank copy of the questionnaire in their participant pack which they can use to answer this questionnaire in future appointments, especially if they are over the phone.

2.0 Information Giving-using the BA workbook.

The participant will be given the BA self-help workbook and extra exercise sheets.

In the contact it is important to ask the person how they find the booklet and if they have any issues in using it.

Briefly explain the following in session 1.

2.1 Depression or low mood

The facilitator should explain to the participant that as a participant in this trial they have been screened as experiencing some symptoms of low mood. This is very common in people with long term conditions, and the aim of the study is to give them information and some things they can do to stop that getting worse. It should be noted that many people with long term health problems have problems with feeling low and if this gets too bad it can have a negative impact on their overall health. This project aims to nip such problems in the bud and help people stay well.

Use the information gathered about the participants' views and the words they use to describe their mental health to approach this subject.

2.2 Behavioural Activation

Introduce the self-help workbook and state that in the sessions you will go over them step by step with the person to help them use them.

Contact Session 1 Information Giving

In this first session I have quite a lot of information to give you so it'll feel like I'm talking quite a lot. Just stop me if you feel you need me to repeat anything. All of this information is in your pack so you can look through it in your own time.

Contact Session 1 Information Giving: Behavioural Activation Workbook

In this session we will focus on stage 1. We have already looked at some of the symptoms of low mood you have, now we want to think about what keeps them going

Review the mood symptoms

The cycle of low mood (workbook stage 1, page 6)

Our mood is linked to how we engage with the world around us, so what we do impacts considerably on how we feel. In other words, what we do impacts on how we feel.

Sometimes things happen in life that mean we can't do the things we used to do that helped us feel ok. This is particularly common in people with health difficulties. The more we are cut off from the things that used to make us feel OK, we start feeling bad.

The problem is that sometimes when we feel bad we withdraw more to cope, because it all feels too much. This further isolates us from those things that were good for us.

This is shown in the cycle in the workbook on page 6, being aware of this is really important in people with health problems as it can help you 'nip this cycle in the bud' before it gets too bad. This is what the workbook is aimed at helping you do.

Can we think about how the cycle relates to you?

Spend 5 mins with the participant reviewing the cycle

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Behavioural activation is a simple treatment that is focused on:

- re-establishing our daily routines
- increasing contact with the activities you value
- dealing with issues that may be making this difficult

The purpose of this is to help us to do things that we find rewarding or meaningful by gradually starting to do more of the things we have stopped doing since feeling low. There is good evidence that this treatment can help us overcome low mood. We understand this is very hard when you feel low, which is why we work together to try to make sure what you do gives you the most benefit. The workbook aims to help you do this, I can help you use the workbook.

NOTE: If you're fairly active and managing to do the routine, enjoyable and necessary activities you would like to, the focus will be on helping you to keep doing these as we know it is a good way of preventing people's mood getting worse.

In the next contact we will move onto stage 2 and 3 of the workbook. Between now and then how can you use what we have covered today?

- Review cycle for yourself
- Think about possible signs of low mood
- Think about those things that may have been dropping out of daily routines

Arranging the Next Contact

The facilitator should negotiate the next contact session with the participant.

This will normally be within a week of the initial session and be conducted by telephone.

Contact Sessions 2-5

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Facilitator's Checklist for Session Number 2-5
(photocopy additional copies as required)

Tick when
Complete

Session number	Please record
1.0 Information Gathering	
1.1 Summary of last session Review last session and action plan	
1.2 Formal symptom assessment DASS	Write scores here
1.3 Assessment of Risk	
1.4 Review of Behavioural Activation Support Programme BA worksheets	
Notes on information gathering	
2.0 Information Giving	
Information about the next stage/stages of the programme (see P25 for an example session structure for sessions 2-5)	
Notes on information giving	
3.0 Shared Decision Making	
Specific behavioural activation plans	
Negotiate the next contact session	
Notes in shared decision making	

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Contact Sessions 2-5

Introduction

The facilitator should confirm that they are speaking to the participant, remind the participant of who they are and describe the objectives and time scale for the contact.

1.0 Information Gathering

1.1 Confirmation of Summary from last session

The facilitator should remind the participant about the summary of the last contact and ascertain whether there have been significant changes.

1.2 Formal symptom assessment

The facilitator should use the DASS to re-measure symptoms and confirm the assessment information.

1.3 Assessment of Risk

The facilitator should ask the risk screening question, and follow risk assessment protocol if positive.

1.4 Review of Behavioural Activation Support Programme

The facilitator should discuss the previous behavioural activation activities negotiated during the last session. In session 2 this will usually involve reviewing the cycle and asking the participant if they have read the workbook and thought more about how it possibly applies to them. This should lead to open discussion.

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Information Giving

The facilitator should clarify or go over any information given in the participant pack, as appropriate. Use the type of conversation style outlined above in session 1, and remain open and collaborative, helping the participant come up with solutions. Go back to the cycle of depression at each session and help the participant understand how it relates to them.

Remember Behavioural activation is aimed at:

- *re-establishing our daily routines*
- *increasing contact with the activities you value*
- *dealing with issues that may be making this difficult*

Using an 'outside in' approach.

Below is an example session structure of sessions 2-5. The section of the workbook covered will vary on person by person basis, but ideally is;

Session 2: Workbook stages 2 the values of keeping a diary and first section of stage 3 the three types of activity

Session 3: Second section of stage 3 keeping a balance and stage 4 Breaking jobs down

Session 4: Workbook stages 5 the benefits of activity and 6 finding other ways to be active

Session 5: Workbook stages 7 spotting symptoms of depression and stage 8 what to do if you notice symptoms of low mood.

Contact Session 6

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Facilitators Checklist for Session Number 6
(photocopy additional copies as required)

Tick when
Complete

Introduction	
1.0 Information Gathering	
1.1 Review of feedback from previous contacts	
1.2 Review and re-confirmation of BA approach	
1.2 Formal symptom assessment DASS	Write scores here
1.3 Assessment of Risk	
1.4 Review of Behavioural Activation Support Programme Recap on sessions 1-6	
Notes	
2.0 Information Giving	
Future research contact	
Notes	

Contact Session 6

Introduction

The facilitator should confirm that they are speaking to the participant, remind the participant of who they are and describe the objectives and time scale for the contact.

It should be noted this is the final appointment

1.0 Information Gathering

1.1 Confirmation of Summary statement

The facilitator should remind the participant about the summary of the last contact and ascertain whether there have been significant changes.

1.2 Formal symptom assessment The facilitator should use the DASS to re-measure symptoms and confirm the assessment information with the participant.

1.3 Assessment of Risk

The facilitator should ask the risk screening question, and follow risk assessment protocol if positive.

1.4 Review of Behavioural Activation Support Programme

This is the main focus of session 6. The facilitator should discuss the previous behavioural activation activities negotiated during the treatment and how the participant has found them.

It is important to identify if there are any areas the participant has found particularly difficult, and if so use the session to review these.

A summary of the BA rationale, including the cycle and the idea of working from the 'outside in' should be undertaken with the participant. This then should be linked to the types of activities they have scheduled, and how this can be used in the future.

It should be emphasised this is self-help, and by using the workbook and keeping going with activities, they are much more likely to stop problems with low mood in the future. Note that this is important as research shows, low mood with physical health difficulties is common and worsens health outcomes.

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Finally review the spotting signs of depression and action plans.

2.0 Information Giving

a. Last session

Remind the participant this is the last of the 6 sessions, and thank them for being part of the research.

Encourage them to keep using the workbook and those approaches described in it.

Inform them that the researchers will be sending them the final questionnaire pack in the post and that it is important to complete this as it helps us evaluate the support sessions from the pharmacy. Remind them that all information they provide is confidential and won't be shared with the pharmacy or anyone else. All research reports are anonymous and they cannot be identified from it.

Point out if they think things are deteriorating with their mood, to use the approaches in the workbook and seek additional support via their GP if they feel this is needed.

Section C

DASS questionnaire Risk assessment Team contact details

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DASS depression symptom level assessment

DASS 21 (dep subscale) Participant Number: _____ Date: _____

Please read (if on phone 'consider') each statement and select a number 0, 1, 2 or 3 which indicates how much the statement applied to you over the past week. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:

- 0 Did not apply to me at all - NEVER
- 1 Applied to me to some degree, or some of the time - SOMETIMES
- 2 Applied to me to a considerable degree, or a good part of time - OFTEN
- 3 Applied to me very much, or most of the time - ALMOST ALWAYS

						FOR OFFICE USE		
		N	S	O	AA	D	A	S
1	I couldn't seem to experience any positive feeling at all	0	1	2	3			
2	I found it difficult to work up the initiative to do things	0	1	2	3			
3	I felt that I had nothing to look forward to	0	1	2	3			
4	I felt down-hearted and blue	0	1	2	3			
5	I was unable to become enthusiastic about anything	0	1	2	3			
6	I felt I wasn't worth much as a person	0	1	2	3			
7	I felt that life was meaningless	0	1	2	3			
TOTALS								

Score	Severity band
0-4	No / few symptoms
5-10	Mild to moderate
11-13	Severe
14 or above	Extremely severe

Briefly discuss with participant (e.g., discuss change in scores)

If scores remain the same or improve reflect on this and continue with programme of support

If scores worsen slightly but remain in same category discuss possible reasons with participant and monitor closely, advise supervisor at next contact.

If scores worsen and move across to next severity range discuss with supervisor as soon as possible

If scores move into severe or extremely severe category discuss with participant about going to see their GP to review their mood, and discuss with supervisor as soon as possible

Briefly summarise to supervisor scores collected across sessions and the participant's view on this.

SUPERVISOR MAY ADVISE ACTION IF:

Participant moves into severe or extremely severe range

Participant 'goes up' one or more severity banding and remains there for two consecutive contacts

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Risk Protocol

Whilst we do not anticipate significant risk in CHEMIST we must be aware there is a possibility people may develop self harm/suicidal ideas during contact with us. Therefore we have an ongoing responsibility to assess this and act if we notice it. This protocol guides you through appropriate assessment and action.

The risk protocol has been devised to provide guidance for ESI Facilitators for instances where a participant's mental wellbeing causes them concern, specifically when they present with risk of self-harm or suicidal ideation/suicide. ESI Facilitators are part of a system of collaborative care. They do not work alone, but receive regular supervision and support from their clinical supervisor. If ESI Facilitators are in any way concerned about a participant's wellbeing they are obliged to ensure that this information is shared with the clinical lead or participant's GP. If participants express any thoughts of self-harm or suicide, ESI Facilitators must enact the risk protocol.

Below provides a summary of the risk protocol. Please ensure you have read the full guidance document on assessing and reporting risk (see 'ESI Facilitators Guide to Assessing & Reporting Risk').

Checking for and assessing risk of self-harm / suicide

- During EACH treatment session, ESI facilitators must check for risk by asking participants the following question:

"In the last two weeks / since we last spoke, have you had thoughts of harming yourself or wished that you were dead?"

- If the participant indicates that they have NOT had such thoughts, the ESI Facilitator should continue with the treatment session
- If the participant indicates that they HAVE had such thoughts, the ESI Facilitator must enact the Risk Protocol below.

Questions to ask & protocol if risk has been identified:

- If risk of self-harm / suicide is identified, advise the participant:

"I see that you've said / you mentioned that..... These are thoughts / feelings that people can have from time to time, but it's important to make sure you are receiving the right kind of support. So if it's OK, I would now like to ask you some more questions that will explore these feelings in a little more depth."

- Ask the participant the six Exploring Risk Questions on next page.
- Use a blank sheet to record participant responses (Appendix 3a).
- Make sure you document **verbatim** the participant's responses to the probing question **and** each of the six exploring risk questions to aid in establishing level of risk.

Details of disclosed thoughts (please record verbatim as far as possible)	
Now ask the following six questions	
Plans	
1. Do you know how you would harm yourself or try to end your life? If Yes – details	Yes / No
2. Have you made any actual plans to harm yourself or end your life? If Yes – details	Yes / No
Actions	
3. Have you made any actual preparations to harm yourself or end your life? If Yes – details	Yes / No
4. Have you ever attempted to end your life in the past? If Yes – details	Yes / No
Prevention	
5. Is there anything stopping you harming yourself or attempting to end your life at the moment? If Yes – details	Yes / No
6. Do you feel that there is any immediate danger that you would act on these ideas about harming yourself or ending your life? If Yes – details	Yes / No

➤ The six Exploring Risk Questions are to be used following any indication of risk from responses to the risk question, or any other indication that risk may be present.

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- Look at the participant's answers to the six Exploring Risk Questions to determine Level of Risk - A B or C (see Appendix 3b):

Gaining participant's consent for GP contact (Level of Risk = B or C):

- **Level B Risk:** For Action B, where the ESI Facilitator should arrange for a letter to be sent to the participant's GP, the participant should give their permission for this to be done. If the participant does not give their permission for this action, the ESI Facilitator must inform them that this may still be done if the clinical lead thinks it is appropriate. The ESI Facilitator should discuss this with the designated risk contact/clinical lead who will advise whether they should inform the GP or not.
- **Level C Risk:** Action C should be undertaken immediately, with or without the participant's permission.

Participant responses to Exploring Risk Questions

Actions by ESI Facilitator

All answers 'NO' apart from Q5 'YES':

Explain to the participant:



LEVEL A RISK

I can see that things have been very difficult for you, but it seems to me these thoughts about death are not ones you would act on – would this be how you see things? (if they say yes) I would advise you to make an appointment to see your GP to talk about these feelings.

ACTION: Discuss the participant's responses to the Exploring Risk Questions at your next supervision session. If there is anything you are unsure on or would like to discuss things further you may telephone the clinical lead for advice.

Participant responses to Exploring Risk Questions	Actions by ESI Facilitator
<p>Answers 'YES' to any <u>one</u> of Qs1-4; plus 'YES' for Q5 and 'NO' for Q6</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">LEVEL B RISK</p>	<p>Explain to the participant:</p> <p><i>Things seem to be very hard for you right now and I think it would help if you were to speak to your GP about these feelings. <u>We (study team) will be writing to your GP to tell them that you have been here today and have been having some troubling thoughts (check that they are happy for us to write to their GP – see above – and confirm their GP details). I would also advise you to make an appointment to see your GP to talk about these feelings.</u></i></p> <p>ACTION: Contact the clinical lead by telephone immediately following the session (see below)</p>

<p>Answers 'NO' to Q5 or 'YES' to Q6</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">LEVEL C RISK (ACTIVELY SUICIDAL)</p>	<p>Explain to the participant:</p> <p><i>I am very concerned about your safety at this moment, advise the participant that you are going to contact your clinical lead and their GP / the emergency services to let them know they have been experiencing these thoughts and feelings and to arrange for them to receive immediate help.</i></p> <p>ACTION: <u>Contact the clinical lead by telephone IMMEDIATELY. If the clinical lead does not answer the phone, the researcher should leave a voice message, and then immediately contact the clinical supervisor or the trial manager. The clinical lead will then respond when available. The ESI Facilitator should then follow the 'Actions to take in the case of immediate risk' below.</u></p>
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Reporting risk

Actions to take following identification of a Level B Risk:

- Following the participant treatment session, the ESI facilitator should contact the clinical lead by telephone to advise them of the risk of self-harm / suicide, the participant's responses to the exploring risk questions, and the associated level of risk (following the above guidance).
- The clinical lead will advise/confirm whether a letter needs to be sent to the participant's GP.
- The ESI facilitator should then complete the 'Reporting Risk Form'.
- The ESI facilitator should sign and date the Exploring Risk Questions and the Reporting Risk Form.
- The Reporting Risk Form should then be faxed, along with a copy of the completed Exploring Risk Questions, to the trial manager on 01904 321651.
- On receipt a completed Reporting Risk Form and Exploring Risk Questions form, the study team will send a letter to the participant's GP.

Actions to take in case of IMMEDIATE RISK (LEVEL C RISK):

- If the level of risk has been identified as Level C, then the participant requires immediate help – do not leave the participant alone, or if on the telephone, do not hang up, if possible.
- Contact the clinical lead by telephone **IMMEDIATELY** in order to involve a supervisory clinician right away.
- The clinician will discuss with the ESI Facilitator the necessary actions to take, which are likely to include one or more of those listed below
- If the clinical lead does not answer the phone, the researcher should leave a voice message. If the clinical lead does not respond immediately, the ESI Facilitator should take one of the actions listed below.

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Actions if unable to contact the clinical lead:

- Contact the participant's GP / Out of Hours GP
- If with the participant: call a taxi to take the participant to A&E. The ESI Facilitator should accompany the participant to A&E and should not leave the participant until a clinician has taken responsibility for their care.
- If the session is being conducted over the telephone: call an ambulance.

Reporting Level C Risk to Study Team

- Following the treatment session, the ESI facilitator should complete the 'Reporting Risk Form'.
- The ESI facilitator should sign and date the Exploring Risk Questions and the Reporting Risk Form.
- The Reporting Risk Form should then be faxed, along with a copy of the completed Exploring Risk Questions, to the trial manager on 01904 321651.

Study Team Contact Details

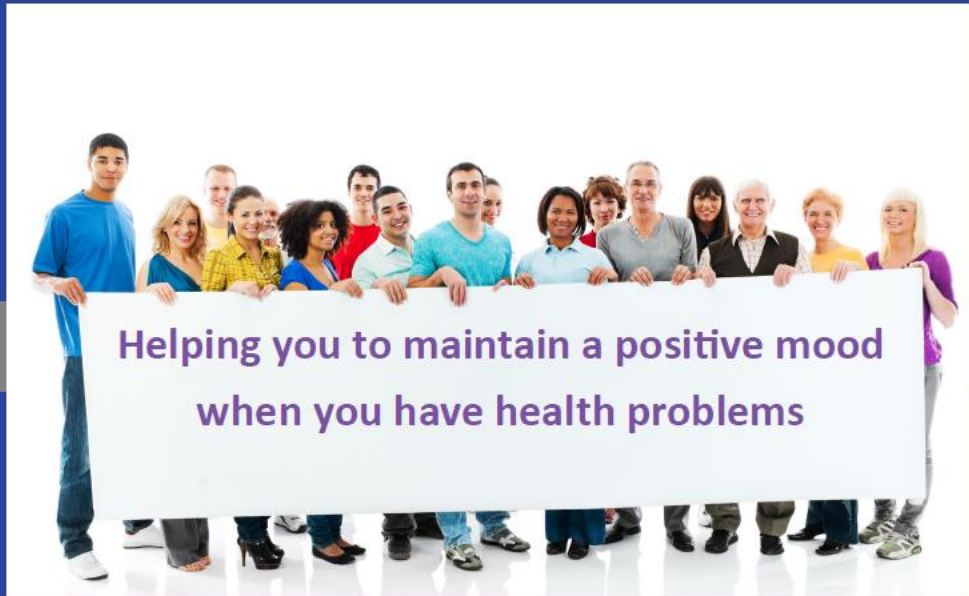
Name	Role	Contact Details
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Liz Littlewood	Trial Manager	T: 01904 321828 F: 01904 321651 Liz.littlewood@york.ac.uk
Dean McMillan	Clinical Supervisor	T: 07967 537883 F: 01904 321651 dean.mcmillan@york.ac.uk
Della Bailey	Clinical Supervisor	T: 01904 321686 07919 293083 F: 01904 321651 della.bailey@york.ac.uk
Rose McNulty	Trial Administrator	T: 01642 451596 rose.mcnulty@nhs.net

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A Self Help Workbook

David Ekers



UNIVERSITY *of York*
The Department of Health Sciences

NHS
Tees, Esk and Wear Valleys
NHS Foundation Trust

A 6-stage plan to help you keep a healthy mood when you have long term health problems

This workbook is about maintaining mental wellbeing for people who are experiencing ongoing physical health problems. We hope that working through it will help you to learn how to manage your mood, as this is important to your overall health and wellbeing. The booklet is divided into six stages. It may be helpful to work through each stage to understand how what we *do* can have an impact on how we *feel*.

This workbook:

- Provides information about low mood
- Encourages you to make links between what you do and how it makes you feel
- Offers guidance on how to recognise low mood symptoms and prevent them getting worse
- Provides a way of managing your wellbeing

It is very common for people with health problems to experience low mood because health problems can change the way we are able to live our lives. Spotting signs of low mood is important, as having persistent low mood is a risk factor for people's health, both physical and mental, to get worse.

Some people with long term health problems:

- are less likely to recognise symptoms of low mood
- may think that how they are feeling is part of the physical illness.

As a result, low mood is often not recognised or treated in people with long-term health conditions. Not addressing this aspect of people's health can worsen their general wellbeing and recovery.

This workbook, with help from your pharmacy support worker, aims to help you learn how to manage your mood and lessen the impact it has on your health. It will help you to recognise any signs of low mood you may have and learn how to manage it in a way that research has shown can improve how people feel.

Low mood can have a negative impact on our overall health and result in increased visits to the GP and possibly more prescribed medication. Using this self-help booklet with support from your pharmacy support worker aims to help you nip any such problems in the bud.

Your Pharmacy plays an active role in health promotion in your community and has regular contact with people with a range of health concerns. Working with you, using approaches in this booklet in a way that suits your specific needs, is one of these health promotion activities. We hope you find it useful.



The stages to keeping well

Stage 1 (page 5)

Recognising symptoms of low mood

Understanding what low mood is, so that it doesn't get worse in the future

Stage 2 (page 8)

The value of keeping a diary

Looking at your own activities and recognising how they affect your mood

Stage 3 (page 10)

Three types of activity...

...and planning to keep a balance

Stage 4 (page 13)

Breaking jobs down into easier tasks, and learning new ones

Stage 5 (page 17)

The benefit of your activities

What you get out of what you do

Finding other ways to be active...

...if you can no longer do the things you used to do

Stage 6 (page 23)

Spotting symptoms and making an action plan to stay well

What to do if you notice symptoms of low mood getting worse again in the future and planning to stay well.

Factors that can lead to low mood

Many people experience the symptoms of low mood from time to time; it is much more common than you may think. In fact about one in four of us will have some symptoms in our life, and one in ten of us at any given time.



Particular life events can make it much more likely to experience these symptoms such as:

- Medical problems including diabetes, heart disease or other long term health conditions.
- Difficulty in doing the things you used to be able to do, for example getting out and about to see other people, doing jobs about the house and so on.
- Loss of your usual role, changes in your circumstances, or loss of independence.

If any of the above apply to you, then thinking about how these events may have impacted on your mood is important, because it is the first step in taking control of how you feel.

Stage 1: Recognising symptoms of low mood

Understanding what low mood is, so that the signs can be recognised.

Key signs that your mood may be worsening include feeling down or losing interest or pleasure in doing things. While we all feel low from time to time, if these feelings are there most of the time and carry on for a few weeks then it may be a sign that these problems need working on to make them better. When this is the case there may be a number of other signs that can be present. Not everyone will have all of these signs, but some are likely to be there and noticing them is the first step to staying well.

Eating: Some people lose their appetite and start to lose weight when they feel low in mood. Other people eat much more and put on weight.

Sleeping: Some people with low mood sleep much more than usual. Other people find getting to sleep much more difficult, or wake up much earlier than normal and struggle to get back to sleep.

Energy: Some people with low mood feel they have much less energy than usual or they feel tired all the time.

Behaviour: Some people are much more restless and agitated than usual when they feel in a low mood.

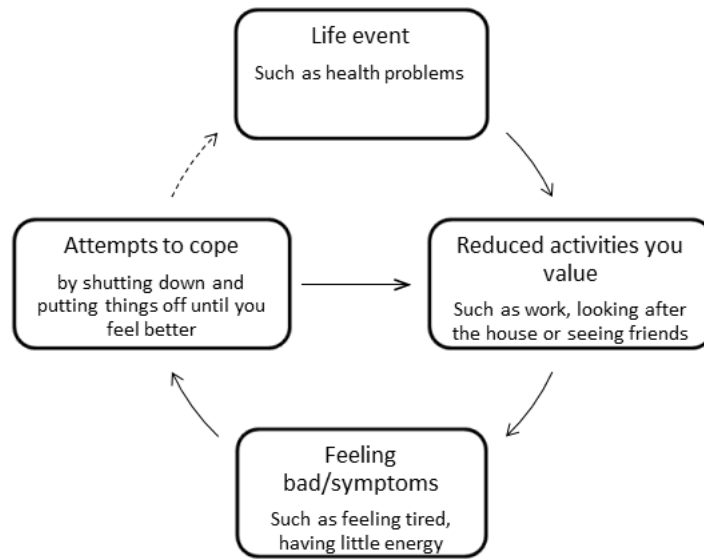
Thinking: The way people think also changes when their mood drops. These changes can include feeling worthless or guilty. This may include finding it much more difficult to concentrate or to make decisions. It can also include thinking about ending your life or harming yourself.

Sometimes people have just a few of these signs. However, if these signs carry on for a few weeks or more, it makes it more likely that a person's mood will drop and could become more difficult to manage. Low mood can also worsen the physical problems someone has and how well treatment works for them. Therefore it is important to deal with the symptoms of low mood as early as possible so they do not lead to other problems.

The aim of this booklet with the support from your pharmacy is to help you deal with the problems.

To do this we first think about what keeps these symptoms of low mood going, this can be described as a vicious cycle.

The vicious cycle of health problems and low mood



Life events

Often things happen in life that are out of our control, but they can have a considerable impact on what we do and how we are able to go about our life. For example development of a physical health problem can mean you can't get out as much.

Stopping or reducing doing things that are important

As a result of these life changes we sometimes stop or reduce certain activities that are good for our mental wellbeing. For example going to work, playing sport, seeing friends or even more routine things like housework.

Feeling bad

When people become cut off from things in life that are important to them, they feel bad, or low. This can take the form of feeling tired or low in energy, or just not enjoying things as much.



Attempts to cope

Sometimes when people feel bad they attempt to cope by shutting down from the world and waiting until they feel better to do things. This shutting down can help in the short term, as everything can feel too much to face. Unfortunately it removes you further from the things that improve your mental wellbeing, so worsens the problem in the long term.

An example might be avoiding people when feeling tired. In the short term there is some relief, because you don't have to face people. In the long term, however, you see less of your friends and this may make you feel lonely and low. This then feeds back into the cycle, removing you further from the things in your world that are positive for you, and can often lead to more life events (like work, money or relationship problems). This is shown in the diagram on the previous page.

All areas in the cycle feed into the next one and form a vicious circle, maintaining low mood. In this approach, therefore, we try to break the cycle focusing on *one key area*, because changing this will have a knock-on effect on the others.

Our research has shown that gradually changing what you do (your behaviours) in small steps can have a great benefit on how you feel. The trick, however, is doing this in a way that is helpful for you. The following exercises in this workbook and talking it through with your pharmacy support worker will help you do just that.

Stage 2: The value of keeping a diary

Looking at your own activities and recognising how they affect your mood

If you are suffering with symptoms of low mood and recognise a vicious cycle, there are things you can do.

- It is possible to break the cycle by changing some of your behaviours.
- Research shows that if a change is made to one part of the cycle, what you do being the easiest, this can have a positive effect on the whole negative cycle.
- This means gradually bringing back into our lives those things you have been doing less or avoiding. This will hopefully lead to a greater sense of achievement and motivation and will eventually bring interest back into your life.

When you have low mood, it is unlikely you will have stopped doing all activities. Some people find that keeping a diary of their activities each day for one week is really useful. It helps you think about what you are doing and, by noting down your mood level, identify how it affects your wellbeing.

A good scale to use is:

0 ←————→ 10

0 (sad mood) to 10 (good/happy mood)

Keeping a diary and noting your mood each day for one week will give you a pattern of your activities and how they are making you feel. People sometimes comment that keeping a diary has given them a better understanding of their mood patterns. We rarely connect what we are doing with how we are feeling, so if you notice an unhelpful pattern you can make changes to your behaviour which may improve your mood.

Use the diary chart on the next page to monitor your activity and mood over the next week to see if you can identify any unhelpful patterns. An activity is anything you are doing, for example housework, reading, washing up, watching TV, walking, gardening, bowling, golf, etc. Even if you think you are not doing anything, just sitting, rate how you are feeling.

	Monday Date:	Tuesday Date:	Wednesday Date:	Thursday Date:
AM	Eg: washing up after breakfast - mood score 5			
PM			Eg: gardening - mood score 8	
Eve				
	Friday Date:	Saturday Date:	Sunday Date:	Instructions:
AM				Rate your mood: Please enter a number from 0 to 10 to rate your mood for each activity that you do 0 (low mood) to 10 (good mood/happy)
PM				
Eve		Eg: watching TV - mood score 7		

Stage 3: Three types of activity, and planning to keep a balance

There are three different types of activity. If we have a balance of all three in our lives we are more likely to keep well. Not doing one or more of these types of activity can affect our mental wellbeing.



Some of your activities may fit into more than one type; for example, cooking may be both routine and pleasurable.

Everyone is different and what one person sees as necessary, another may see as pleasurable.

Routine

These are activities such as washing up or loading the dishwasher, cleaning the car, cooking, shopping and gardening, to name but a few.

Necessary

These are activities like opening post, paying bills, checking finances, decorating, cleaning the car and household repairs.



Pleasurable

This is any activity that brings you pleasure or a sense of achievement. It could be reading, gardening, watching TV, walking, swimming, shopping, cooking, etc.

Keeping a balance

To see if you have a balance of these three activity types in your life, have a go at filling in the columns on the next page. List your routine, necessary and pleasurable activities.

Look back at the diary you completed last week, if you notice an imbalance between the types of activity it may give you an idea of changes you might make to help you manage your mood.

Routine

For example, washing up; supermarket shopping

Necessary

For example, opening post; dealing with paperwork

Pleasurable

For example, going to the cinema; doing crosswords

Making plans to maintain a healthy mood

As can be seen in the cycle of low mood in stage one of this booklet, it is easy to become cut off from those things that are important to us due to life events, like becoming unwell. This can result in feelings of low mood, and sometimes to cope with such feelings we put off, or avoid doing things 'until we feel better'. This is understandable as it is hard to keep going with things when we feel down. In the longer term however this can mean we are further cut off from those things that are important to us. This is the cycle you will have looked at and discussed with your pharmacy support worker.

In order to break the cycle it is important to plan activities that reconnect, or maintain your connections with things in your world that are healthy for you. We call this planning to maintain a healthy mood. This is particularly important for people who have physical health problems to help them stay well.

To do this look over the three types of activity and your diary and see what activities are linked to you feeling in a more positive mood, and where certain types of activity are missing. Then use the diary sheets, or any other diary to plan these into your days for the coming week. Start small, over the coming weeks you can gradually build this up. Your pharmacy support worker can help you do this in the sessions you have.

This breaks the cycle with the aim of maintaining your contact with those things in your world that are important to you. In our research we have found this to be an excellent way of managing low mood. We call it working from the 'outside in'. That is not waiting to feel better inside to change what you do on the outside, but plan what you do on the outside to make those inside feelings better. In simple terms 'don't wait to feel better to do things, do things to make you feel better'.

The following sections of this booklet help you do this, as regular planning of 'healthy activities' is key to breaking the cycle and maintaining a 'positive mood'.

Stage 4: Breaking things down to make them easier to manage

Sometimes we stop doing things because they have become too difficult or too big a task to manage. Alternatively, we may find things harder to manage owing to the symptoms of our physical health problem.

Here are two examples showing how you might break jobs down or perhaps share jobs. These are examples from other people. Your pharmacy support worker will discuss this with you to help you think how to apply this to your own particular situation.

Example One: Friday's routine

- you washed clothes, ironed them and put them away in the bedroom cupboard
- you vacuumed and dusted the bedroom

Recently you have noticed this is getting more difficult and by the time you have finished you are exhausted. So you may have started to neglect these jobs, but are feeling low because the bedroom is not as clean and tidy as it used to be. It now seems like a huge task to get it back into shape.

Example Two: Saturday's routine

- You went to the allotment and dug over the vegetable patch
- You picked the vegetables that were ready to eat
- You watered the vegetable patch

Recently you have found yourself too tired to sort out the allotment. This has led to you missing Saturdays and when you now go to the allotment it all seems too much to face, you don't feel you can get it done. You also miss chatting with your friends there and worry about what they will be saying about your patch. This upsets you so you avoid going there at the moment.

Steps to making the task more manageable

Thinking about the last two examples, here are some smaller steps that people use to make the tasks more manageable.

Example one:

1. Tidy dirty clothes and put in laundry bin on day one.
2. Over the next week, schedule into your diary or calendar when you are going to wash the clothes and do some ironing. If you feel okay, take the ironed clothes and put them away.
3. Use the same approach for dusting and vacuuming, each day plan in your diary a room to do, for a time you can manage (such as Friday at 10 in the morning 'vacuum and dust the lounge for 20 mins').

Remember, it does not need to be done all in one day, often when you have health problems doing too much in one go is very exhausting. This can lead to feeling overwhelmed and then not doing other things that you like doing.

Example two:

1. List the jobs that need attending to at the allotment.
2. Discuss the list with friends or close relatives if possible, see if anyone would give you a hand to get back on top of it.
3. Plan to go to the allotment and dig over the patch in short bursts of one hour each, decide which area to start with and get that done.
4. Pick a small carrier bag of vegetables, enough for one or two meals, and bring home for cooking.
5. Speak to your friends at the allotment each time you go, even if it means a bit less time working there.

The above are examples and they may not be useful for your particular activities, but they show how breaking things down can help you to keep going with those activities that are helpful in maintaining a healthy mood. The cycle helps us to see that if we get too tired and then stop doing things it can get on top of us. Breaking things down and planning how they can be spread across a week helps to make sure you don't get exhausted and helps you keep up with those things that are healthy for your mood and your body.

Discuss this with your pharmacy support worker to think how it applies to you. Sometimes things are no longer possible to do especially when you have long term health issues. Stage 5 includes information to help you think about how to replace those activities with others that are manageable and that give you a similar sense of purpose.

Make a list of jobs you have noticed, if any, that are getting too much for you to do all in one go. Or use this space to list jobs you may like to start sharing.

Use the table below. Take one job at a time. Try to break it down into manageable or shared tasks. If you find this useful, you may wish to repeat it with an alternative job on a separate piece of paper.

Which job has become, or is becoming, too much to do all in one go?

1. Is this job essential? Does it need doing all at once?

2. How can you break this down into more manageable or shared steps?

3. Timetable the new steps into your diary and see if this helps.

4. Do you need help to complete this job? How can you get that help?

Stage 5: Keeping the benefits of your activities when you have health problems

What you get out of what you do

Why do the things we do keep us well? The answer is they have benefits. Research shows it is not only the individual activity that keeps us well. It is what that activity gives us that is important, the benefits we gain from doing it. Here's an example...

Activity: Supermarket shopping

Some benefits of supermarket shopping:

1. I like the drive out in the car
2. I pay some bills at the Post Office located in the store
3. I meet a friend in the café for a coffee and a chat
4. I walk down all the aisles, so it gives me some exercise
5. I buy clothes as well as food
6. I meet different people as I walk around and I have a chat with the checkout person

As you can see, there are many reasons why supermarket shopping keeps this person well. It has many benefits and it covers all three activity types, mentioned on page 10, which in turn help you stay well.



What activities do you do that help to keep you well?

List a range of activities you do below...

Choose one of the activities you listed on page 18 and write it here:

Now list the benefits of this activity, as shown by the example on page 17.

Benefits:

If you find this useful, you may wish to repeat it with an alternative activity on a separate piece of paper.

Finding other ways to be active if you can no longer do an activity you used to do

If the activities I have listed are keeping me well, what if I can't do them anymore?

This is a good question, particularly for people coming to terms with physical health problems. The idea is that it is the benefit you get from these activities that keeps you well, not always the particular activity itself.

So, if you can no longer do a certain activity, think about what you can do instead, to retain the benefits you get from it.

You may need to consider two or more activities to replace the one you are unable to do.



It may be you are unable to do an activity in the short term, due to an operation or brief worsening of your health. However, the reason could also be due to a long term change in your health. In both cases, thinking about how to find new things to do in order to maintain the benefits you got from the old activity is important.

Think about any activities you are no longer able to do, the benefits you got from those activities. Then think about what other things you might be able to do that could bring similar benefits. Discuss this with your pharmacy support worker at your next session.

Finding other ways to be active

If we go back to our example on page 17 of supermarket shopping, you may have had an operation on your knee and are unable to go to the supermarket during the recovery period. Finding alternatives for this temporary period may help to maintain your mental wellbeing. This in turn will help with your physical recovery.

Benefits:

1. I like the drive out in the car
2. I pay some bills at the Post Office located in the store
3. I meet a friend in the café for a coffee and a chat
4. I walk down all the aisles, so it gives me some exercise
5. I buy clothes as well as food
6. I meet different people as I walk around and I have a chat with the checkout person.

Alternative activities to maintain benefits:

1. A drive out as a passenger
2. Pay bills over the telephone, by post, or on the internet
3. Ask a friend to visit your home for a chat and coffee
4. A walk in the garden, or local park, physiotherapy or chair exercises
5. Shopping via the internet, neighbour/friend/family member doing some shopping for you
6. Telephone, email or use social media to chat with friends or family.

Looking at your own activity on page 19 and the benefits listed. What alternative activities can you think of in order to keep these benefits in your life? Use the times you talk to your pharmacy support worker to discuss this.

Alternative activities:

Stage 6: Spotting symptoms of low mood and making an action plan to stay well

Now you know what keeps you well, it may be worth considering what to look out for if you were becoming low, so hopefully you can seek help quickly.

Think about yourself. Using the boxes below to help you, list the symptoms which may signal that you are becoming increasingly low in mood.

Page 5 may help you to recognise symptoms which some people report when suffering with mood problems.

Physical symptoms: e.g. Changes in sleep or appetite

Thoughts: e.g. 'I can't be bothered'

Behaviours: e.g. No longer going out or seeing friends

Action Plan

What to do if you notice symptoms

We hope you now have more of an understanding of what low mood is, how it is maintained, and how activities can affect your mood. If you spot these symptoms and think they are getting worse, what do you think you could do about it?

Action Plan:

Action Plan continued:

Useful tips:

1. Look at your activities. Have you stopped doing anything?
2. Do you still have a balance of all three types of activity?
3. Use your diary to reintroduce the activities you have stopped doing, by planning them into your week.
4. Try not to isolate yourself. Call friends and family and talk to them about how you are feeling.
5. Make an appointment to see your GP and talk about your symptoms.

Notes

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Notes

We hope that completing this workbook and discussing it with your pharmacy support worker has been useful and given you a better understanding of how your activities can help you maintain a positive mood, even with the difficulties of ill-health. We hope it has been useful to work through it and the activities you have found helpful can be used in the future to help you maintain your mental wellbeing.

Useful organisations

If you require additional help, information or support, please speak to your GP. In addition the following resources may be helpful to you.

Mind www.mind.org.uk t: 0300 123 3393
Mind Infoline, Unit 9, Cefn Coed Parc, Nantgarw, Cardiff, CF15 7QQ

Additional Self Help Guides - Self Help Guides produced by Northumberland, Tyne and Wear NHS Foundation Trust covering a range of mental health issues can be found at:
www.ntw.nhs.uk/pic/selfhelp



David Ekers is a nurse consultant in the NHS and a researcher working with the University of York. His research investigates accessible and effective ways of helping people with low mood and depression. He is the chief investigator of the CHEMIST study. This workbook has evolved through the idea that using self-help materials can aid recovery and they may also be helpful to prevent depression. It was initially written by Deborah Hems with the help of Della Bailey and Dean McMillan at the University of York for use on the CASPER Study. David Ekers, in partnership with a group of pharmacy customers, people who have experienced low mood and depression, people with physical health problems and fellow researchers, has adapted this workbook for use in the CHEMIST Study.

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The Department of Health Sciences

Appendix 21: Topic guide (third study)

Co-design Workshop Topic Guide

Development and adaptation of a Behavioural Activation intervention manual intended for delivery by non-mental-health specialists for the treatment of perinatal depression

Stage 1: Scene-setting and ground rules

- Thank participants for coming and welcome them
- Introducing the moderator and explanation of confidentiality
- Offering refreshments
- Indication of expected roles
- Introduction to researcher and funder
- Introduction to study topic, aims and objectives
- Explanation of confidentiality and anonymity
- Explanation of recording, length (up to one and a half hours) and the nature of the co-design workshop, outputs/reporting and data storage issues
- Reminder participant of reimbursement of travel expenses
- Going through consent issues explaining that they may withdraw at any time from the workshop however all the data collected until that time will be used in the study, and they do not have to answer any questions they would prefer not to
- Checking whether they have any questions

Stage 2: Individual introductions

- Including choosing pseudonyms to be used during the workshop and giving name badges

Stage 3: The opening topic

- Noting everyone's experiences are really important, everyone has different perspectives and they all need to be heard. Everyone will learn from each other.
 - Researcher outlines what the workshop is about
 - Why it is relevant
 - Introduce the BA intervention manual
 - And note its importance
- Introducing the aims of the workshop.
 - Why they are invited to work together
 - my expectations of them
 - their expectations from me
 - What will be achieved at the end of the workshop
- Introduce Behavioural Activation therapist manual including guided self-help booklet.
 - Researcher outlines what the manual is about (introducing every section in detail)
 - Why it needs to be adapted

Date: 23/04/2019

Version: 1.0

IRAS ID: 237021

Stage 4: Discussion

- Providing brief results from data collected in the previous phase
 - Showing thematic map for women
 - Showing thematic map for healthcare professionals
 - Comparison of maps
 - Discussing how women's and healthcare professionals' experiences have been used to produce prototype of the manual
- Giving time to make them familiar with the Behavioural Activation therapist manual and guided self-help booklet
 - Answering their questions
- Identifying key touch points
 - Where improvements are needed for the treatment manual (ensure everyone use papers and pencils)
 - How to improve women's and healthcare professionals' experiences using the formula: If you want to achieve Y in situation S, something like X might help
 - How these identified touch points would be helpful for the development of the manual?
- Agreeing key touch points
 - Summary of identified key touch points
 - Asking everyone if they all agree on the touch points and if someone would like to add something
- Defining key touch points
 - *This* point would be helpful to achieve *this* in *that* situation
 - *This* point would be helpful to achieve *this* in *that* situation...
- What are the priorities for the development of the manual?
 - (cross tabulation) Important ones
 - (cross tabulation) Urgent ones

Stage 5: Ending the workshop

- Summary of the workshop
 - What has been achieved in this workshop
- Future work
 - What am I going to do with the data collected today
 - how the manual including guided self-help booklet will be developed to make it better for women experiencing perinatal depression and for non-mental-health specialists providing BA intervention
- Asking their suggestions or thoughts about the workshop
- Thanking the participants for their time. Reiterating that the workshop will remain confidential and that they have agreed to maintain confidentiality. Telling them that they are welcome to contact members of the study team to ask questions at a later date if they wish.

ENDING RECORDING

Giving the women a £20 One4all gift card. Giving the participants travel expenses if needed.

Date: 23/04/2019

Version: 1.0

IRAS ID: 237021

Appendix 22: Demographics form for women (third study)



Development and adaptation of a Behavioural Activation intervention manual intended for delivery by non-mental-health specialists for the treatment of perinatal depression

Researchers: Semra PINAR, Dr Helen BEDFORD, Dr Dean McMILLAN, Prof Steven ERSSER

Demographics Form for Women

The information provided here will be kept anonymous and confidential. Before taking part in a co-design workshop, we would like to learn about you. This will help us to involve a variety of women from different backgrounds and with different experiences for the research study. |

Anonymous identifier (for researcher to use)		1) Your age		2) The first part of the postcode	
3) Ethnicity <input type="checkbox"/> White – British <input type="checkbox"/> White – Irish <input type="checkbox"/> White – any other White background <input type="checkbox"/> Mixed – White and Black Caribbean <input type="checkbox"/> Mixed – White and Black African <input type="checkbox"/> Mixed – White and Asian <input type="checkbox"/> Any other Mixed background <input type="checkbox"/> Asian or Asian British <input type="checkbox"/> Any other Asian background <input type="checkbox"/> Black or Black British <input type="checkbox"/> Any other Black background <input type="checkbox"/> Other Ethnic Groups Please state.....		4) Current marital status <input type="checkbox"/> Single <input type="checkbox"/> Married or living with partner <input type="checkbox"/> Married but living without partner <input type="checkbox"/> Divorced <input type="checkbox"/> Widow/widower <input type="checkbox"/> Other Please state.....		5) Highest level of education <input type="checkbox"/> Left full time education aged 16 <input type="checkbox"/> Left full time education aged 18 <input type="checkbox"/> Graduate <input type="checkbox"/> Postgraduate study <input type="checkbox"/> Other Please state.....	
6) Employment status <input type="checkbox"/> Working full time <input type="checkbox"/> Working part time <input type="checkbox"/> Not working <input type="checkbox"/> Maternity leave <input type="checkbox"/> Other Please state.....	7) Approximate household income per year <input type="checkbox"/> <£15,300 <input type="checkbox"/> £15,300-£26,400 <input type="checkbox"/> £26,401-£35,600 <input type="checkbox"/> £35,600-£49,200 <input type="checkbox"/> £49,200> <input type="checkbox"/> Prefer not to say	8) Number of children <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 or more	9) Age of youngest child <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5		

Date: 05/08/2019
Version: 1.0
IRAS ID: 237021

<p>10) When did you start feeling low mood/depression? (You can choose more than one options)</p> <p><input type="checkbox"/> Before pregnancy</p> <p><input type="checkbox"/> Some point during pregnancy</p> <p><input type="checkbox"/> In the first year after childbirth</p>
<p>11) During what period did you experience low mood/depression?</p> <p><input type="checkbox"/> During pregnancy</p> <p><input type="checkbox"/> During the first year after childbirth</p> <p><input type="checkbox"/> Both during pregnancy and the first year after childbirth</p>
<p>12) Were you diagnosed with depression during pregnancy and/or in the first year after childbirth?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Unsure</p>
<p>13) For how long did you experience low mood/depression?</p> <p>.....</p>
<p>14) Did you receive any talking treatment (e.g. counselling, CBT, peer-support) for your low mood/depression during pregnancy and/or the year after childbirth?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>
<p>15) Were you prescribed medication for your low mood/depression during pregnancy and/or the year after childbirth?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>
<p>16) Have you been diagnosed with a psychological or mental health illness other than depression during your pregnancy and/or the year after childbirth? If yes, please could you write it/them below?</p> <p><input type="checkbox"/> Yes.....</p> <p><input type="checkbox"/> No</p>
<p>17) Have you been diagnosed with any psychological or mental health illnesses other than depression in the past? If yes, please could you write it/them below?</p> <p><input type="checkbox"/> Yes.....</p> <p><input type="checkbox"/> No</p>
<p>18) Please, could you write your available days and times for a co-design workshop? (e.g. Mondays am, Thursdays pm)</p> <p>.....</p> <p>.....</p>

Thank you for taking the time to fill in this form. Please put this form together with one of your signed consent forms and contact details sheet into the stamped-addressed return envelope and send it to the researcher.

Semra Pinar, Research Centre for Social Sciences, 6 Innovation Close, University of York, Heslington, York, YO10 5ZF
 Tel: 07729 070393 Email: sp1365@york.ac.uk

Date: 05/08/2019
 Version: 1.0
 IRAS ID: 237021

Appendix 23: Demographics form for healthcare professionals (third study)



Development and adaptation of a Behavioural Activation intervention manual intended for delivery by non-mental-health specialists for the treatment of perinatal depression

Researchers: Semra PINAR, Dr Helen BEDFORD, Dr Dean McMILLAN, Prof Steven ERSSER

Demographics Form for Healthcare Professionals

The information provided here will be kept anonymous and confidential. Before conducting a co-design workshop, we would like to learn about you. This will help us to choose a range of health professionals for the co-design workshop.

Anonymous identifier (for researcher to use)		
Your age		Prefer not to state <input type="checkbox"/>
In which NHS Trust or GP surgery do you currently work?		
What is your current role?		
For how long <u>have you</u> been working in that role?		
Please state your professional qualifications.		
Please could you write your available days and time for a co-design workshop? (e.g. Mondays pm, Thursdays am)		
Where would you like to attend a co-design workshop? (You can tick more than one option)		
<input type="checkbox"/> NHS premises		
<input type="checkbox"/> Other place where is in a convenient and confidential location for everyone and provide privacy (e.g. a community centre or hotel)		

Thank you for taking the time to fill in this form. Please put this form together with one of your signed consent forms and contact details sheet into the stamped-addressed return envelope and send it to the researcher.

Semra Pinar, Research Centre for Social Sciences, 6 Innovation Close, University of York, Heslington, York, YO10 5ZF

Tel: 07729 070393 Email: sp1365@york.ac.uk

Date: 23/04/2019
Version: 1.0
IRAS ID: 237021

Appendix 24: Contact details sheet for women (third study)

UNIVERSITY *of York*
The Department of Health Sciences

Contact Details Sheet for Women

Development and adaptation of a Behavioural Activation intervention manual intended for delivery by non-mental-health specialists for the treatment of perinatal depression

Please write your contact details below so the researcher can contact you when she receives your envelope.

My name:	
My telephone number :	
My email address (optional) :	
My home address :	
My General Practitioner's contact details: (If as part of the research you disclose risks to yourself or others, then a member of the research team may pass this information on to a relevant health or social care professional)	GP Name:
	GP Telephone number:
	GP Practice name:
	GP Practice address:

Thank you for taking the time to fill in this contact details sheet. Please return this sheet with one of your signed consent forms and demographics form into the stamped-addressed return envelope and send it to the researcher.

Semra Pinar, Research Centre for Social Sciences, 6 Innovation Close, University of York, Heslington, York, YO10 5ZF

Tel: 07729 070393 Email: sp1365@york.ac.uk

Date: 23/04/2019
Version: 1.0
IRAS ID: 237021

Appendix 25: Contact details sheet for healthcare professionals (third study)

UNIVERSITY *of York*
The Department of Health Sciences

Contact Details Sheet for Healthcare Professionals

Development and adaptation of a Behavioural Activation intervention manual intended for delivery by non-mental-health specialists for the treatment of perinatal depression

Please write your contact details below so the researcher can contact you when she receives your envelope.

I wish to be contacted by telephone email

Name details:	
My telephone number :	
My email address :	
My work address:	

Thank you for taking the time to fill in this contact details sheet. Please return this sheet with one of your signed consent forms and demographics form into the stamped-addressed return envelope and send it to the researcher.

Semra Pinar, Research Centre for Social Sciences, 6 Innovation Close, University of York, Heslington, York, YO10 5ZF

Tel: 07729 070393 Email: sp1365@york.ac.uk

Date: 23/04/2019
Version: 1.0
IRAS ID: 237021

Appendix 26: Participant information sheet for women (third study)



Development and adaptation of a Behavioural Activation intervention manual intended for delivery by non-mental-health specialists for the treatment of perinatal depression

Researchers: Semra PINAR, Dr Helen BEDFORD, Dr Dean McMILLAN, Prof Steven ERSSER

PLEASE KEEP THIS INFORMATION SHEET AND A SIGNED COPY OF THE CONSENT FORM FOR YOUR RECORDS

You are being invited to take part in a research study. Before you decide whether to participate, it is essential for you to understand why the research is being conducted and what it will involve. If there is anything you do not understand, or if you want more details, please ask the researcher Semra Pinar. Her contact details are at the end of this sheet. Please take the time to read the following information carefully.

What is the purpose of this study?

Nearly one in ten women suffers from depression during pregnancy or after childbirth (perinatal period). The mental health needs of women should be met by providing the best available and most cost-effective treatments. Behavioural Activation (BA) is an uncomplicated and promising talking therapy for the treatment of depression in adult patients. This study is seeking to understand how BA could be modified to meet women's psychological needs and expectations during the perinatal period. BA may be particularly suitable for use as a low-intensity treatment for perinatal depression when delivered by non-mental-health specialists (for example maternity support workers who work under the supervision of registered midwives). Therefore, the aim of the study is to conduct workshops where women and healthcare professionals can discuss the development of a BA therapist manual and guided self-help booklet and share decision making equally throughout the process.

Who is doing the study?

The researcher, Semra Pinar, is a PhD student in the Department of Health Sciences at the University of York. Semra is a qualified midwife and this research is part of her PhD thesis. The researcher has three supervisors in her research team, Dr Helen Bedford (midwife), Dr Dean McMillan (clinical psychologist) and Prof Steven Ersser (clinical and research nurse), from the Department of Health Sciences. This study is being funded by a PhD studentship from the Ministry of National Education, Turkey.

Who is being asked to participate?

The project seeks to recruit women who fit the criteria below:

- Are 18 years and over,
- Able to read and speak fluent English,
- Have the capacity to give consent,
- Have felt or have been diagnosed with low mood and/or depression during pregnancy and/or in the first year after childbirth,
- Have experienced low mood or depression within the last five years (i.e. whose youngest child is between 1 and 5 years old),
- Had a live birth following their last pregnancy,
- No longer experience depressive symptoms,
- Live in [REDACTED]

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Do I have to take part?

You do not have to take part in the study. If you do decide to take [part](#) you will be given this information sheet to keep and will be asked to sign two copies of the consent form (one copy is for you to keep). If you decide to take part you will still be free to withdraw without giving a reason, even during the co-design workshop itself.

What will be involved if I take part in this study?

To take part in the study, simply fill in and sign the consent forms, the demographics form and contact details sheet, and send one of your consent forms, demographics form and contact details sheet in the pre-paid stamped-addressed return envelope by mail to the researcher.

Once the researcher receives your consent and completed forms, the researcher will telephone you and ask a small number of questions to ensure that you are now recovered from depression. It is not possible to check your current mood without your consent, and your GP's name and contact details. If your answers to the questions indicate depressive symptoms and we think that you are still experiencing depression symptoms, you will not be able to attend a co-design workshop.

The study aims to include women with different experiences of low mood/depression and from different geographical regions. Therefore, the information you provide on the demographics form is important for us to choose you for a workshop.

If you are eligible to take part, the researcher will contact you to seek your available days and times for the co-design workshop. The workshop will be held on a convenient date, time and private place (e.g. meeting room in NHS premises, a community centre or hotel) for you and other participants (the researcher, a moderator, 10-12 health professionals and 10-12 women who have also experienced low mood/depression in the perinatal period). The workshop will be audio-recorded and will take up to 90 minutes. In the workshop, you will be asked to be involved in the development of a BA Therapist Manual including a guided self-help booklet for women to treat perinatal depression. You do not need to know anything about BA - your experience of perinatal low mood/depression will help you to be involved in the process.

Everyone taking part in the workshop will need to maintain confidentiality of others. There will be a moderator who will listen to everyone and take notes. The moderator will also maintain confidentiality.

What are the advantages/benefits and disadvantages/risks of taking part?

There are no anticipated disadvantages/risks to taking part in this study. However, during or after the workshop, if you feel upset, we would suggest that you contact your GP. Also, you could take advantage of the available support sources below.

NHS Choices: (111) - Free NHS helpline service for urgent care services. For mental health helplines; <https://www.nhs.uk/conditions/stress-anxiety-depression/mental-health-helplines/>

Mind: (0300 123 3393) - information on a range of mental health topics; <https://www.mind.org.uk/>

Samaritans: (116 123) (24 hour helpline-free) - a charity aimed at providing emotional support to anyone in emotional distress, struggling to cope, or at risk of suicide; <https://www.samaritans.org/>

SANE: (0300 304 7000) – for emotional support, information and guidance for people affected by mental illness, their families and carers; <http://www.sane.org.uk/>

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Your participation in the research will assist and inform the adaptation and development of BA intervention manual for the treatment of perinatal depression, and findings will also contribute to the researcher's PhD project. Your participation may help you and others in the future.

The researcher will be sensitive to all issues raised during the workshop, but if you do not want to continue in the workshop, you can leave at any time.

If you decide to take part in a workshop, your reasonable travel expenses will be reimbursed in person, in exchange for original travel tickets. As a thank you gift for your time, a £20 One4all gift card will be presented. Also, pizza and refreshments will be available during the workshop.

Can I withdraw from the study at any time?

You do not have to answer any questions that you do not want to answer. You are free to withdraw from the study at any time, even during the co-design workshop without having to give a reason for withdrawing. If you choose to withdraw from the study before the commencement of the workshop, all data referring to you will be destroyed and will not be used in any way. However, if you choose to withdraw from the study during a workshop, all the data collected until that time will be used in the study because it is not possible to remove your contribution from a group discussion. After completing the co-design workshop, you can still withdraw from the study, however, your data will still be included in the analysis.

Will the information I give be kept confidential?

University of York is the sponsor for this study based in United Kingdom. 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.

The University of York uses personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

When you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. 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. To safeguard your rights, we will use the minimum personally-identifiable information possible. The only people in the University of York who will have access to information that identifies you will be people who need to contact you to manage your participation in the research study or to check that the research study is being conducted appropriately. 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.

We will retain your contact details for 12 months after undertaking this study and a copy of the signed consent form for five years from the end of the research to cover the period of the submission of thesis and any publications arising from the study. Your personal information will be stored separately from the research data, which will be retained for 10 years following the end of the research.

The information will be stored securely at the University of York in password protected files and locked filing cabinets that only the named researchers have access to, in line with the General Data Protection Regulation. Your spreadsheet of contact details and consent form will be stored separately with your demographics form to ensure confidentiality.

Your name and any personal identifiable information will be anonymised in all audio recordings and transcripts (the workshop will be typed up into a transcript by the researcher or a professional transcriber who will be subject to a

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confidentiality contract) with a self-chosen false first name and your identity will be kept strictly confidential. No real names of people or places will be used in any presentations or publications resulting from the study or in the researcher's PhD thesis. Your personal information, recordings, consent form, demographic form and transcript will be accessible only by the researchers in the research team.

Quotations from discussions in the workshop may be used in reported findings from the research study. If anything that you have said appears in quotations, it will be made anonymous so that you cannot be identified. Your recording will be destroyed 12 months after the study. Your anonymised transcripts will be stored on the York research database and PURE (database to store research data safely) for 10 years according to the University of York's policy. Transcripts will not be publicly available and only the research team will have access.

Confidentiality can only be broken if, as part of the research, you disclose risks to yourself or others. In this case, a member of the research team may pass this information on to a relevant health or social care professional **and also** for this reason your GP may be informed about your participation in this study.

What will happen to the results of the study?

The results of the study will be published in the researcher's PhD thesis. Also, the researcher intends to present the results at conferences and publish in academic journals.

Who has reviewed this study?

This study has been reviewed and approved by Research Ethics Committee Yorkshire and Humber – Leeds West.

Who do I contact in the event of a complaint?

If your complaint is related to the study, you can contact Prof Tracy Lightfoot (Deputy Head (Postgraduate)), Department of Health Sciences, University of York, email: tracy.lightfoot@york.ac.uk; Tel: 01904 32 1881. If it is an NHS care issue, you are advised to contact relevant Patient Advice and Liaison Service (PALS) in your location.

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).

The University of York's Data Protection Officer can be contacted at dataprotection@york.ac.uk.

If you agree to take part, please complete and sign the consent forms and the demographics form and contact details sheet. Put one of your signed consent forms, your demographics form and contact details sheet in the pre-paid stamped-addressed return envelope and send the envelope by mail to the researcher.

If you would like more information or have some questions or concerns about the study please contact the researcher
Semra Pinar, Tel: 07729 070393, Email: sp1365@york.ac.uk
Address: Research Centre for Social Sciences, 6 Innovation Close, University of York, Heslington, York, YO10 5ZF.

Thank you for taking the time to read this information sheet.

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Appendix 27: Participant information sheet for healthcare professionals (third study)

UNIVERSITY *of York*
The Department of Health Sciences

Development and adaptation of a Behavioural Activation intervention manual intended for delivery by non-mental-health specialists for the treatment of perinatal depression

Researchers: Semra PINAR, Dr Helen BEDFORD, Dr Dean McMILLAN, Prof Steven ERSSE

PLEASE KEEP THIS INFORMATION SHEET AND A SIGNED COPY OF THE CONSENT FORM FOR YOUR RECORDS

You are being invited to take part in a research study. Before you decide whether to participate, it is essential for you to understand why the research is being conducted and what it will involve. If there is anything you do not understand, or if you want more details, please ask the researcher Semra Pinar. Her contact details are at the end of this sheet. Please take the time to read the following information carefully.

What is the purpose of this study?

Nearly one in ten women suffers from depression during pregnancy or after childbirth (perinatal period). The mental health needs of women should be met by providing the best available and most cost-effective treatments. Behavioural Activation (BA) is an uncomplicated and promising talking therapy for the treatment of depression in adult patients. This study is seeking to understand how BA could be modified to meet women's psychological needs and expectations during the perinatal period. BA may be particularly suitable for use as a low-intensity treatment for perinatal depression when delivered by non-mental-health specialists (for example maternity support workers who work under the supervision of registered midwives). Therefore, the aim of the study is to conduct workshops where healthcare professionals and women can discuss the development of a BA therapist manual and guided self-help booklet and share decision making equally throughout the process.

Who is doing the study?

The researcher, Semra Pinar, is a PhD student in the Department of Health Sciences at the University of York. Semra is a qualified midwife and this research is part of her PhD thesis. The researcher has three supervisors in her research team, Dr Helen Bedford (midwife), Dr Dean McMillan (clinical psychologist) and Prof Steven Ersser (clinical and research nurse), from the Department of Health Sciences. This study is being funded by a PhD studentship from the Ministry of National Education, Turkey.

Date: 23/04/2019
Version: 1.0
IRAS ID: 237021

Who is being asked to participate?

The project seeks to recruit health professionals who have experience of providing and/or planning care for women who may have perinatal low mood and/or perinatal depression. We are contacting registered health professionals (e.g. midwives, health visitors, GPs, service managers, specialist maternal mental healthcare providers) and maternity support workers who have been working in NHS maternity services, community services or GP Surgeries in [REDACTED] for at least 3 years, and have experience of providing and/or planning perinatal low mood/depression care.

Do I have to take part?

You do not have to take part in the study. If you do decide to take [part](#) you will be given this information sheet to keep and will be asked to sign two copies of the consent form (one copy is for you to keep). If you decide to take part you will still be free to withdraw without giving a reason, even during the co-design workshop itself.

What will be involved if I take part in this study?

A convenient date, time and private place (e.g. meeting room in NHS premises, a community centre or hotel) for the workshop to take place will be arranged between yourself, the researcher, a moderator, 10-12 other healthcare professionals and 10-12 women who have experience of perinatal low mood/depression. The workshop will be audio-recorded and will take up to 90 minutes.

In the workshop, you will be asked to be involved in the development of a BA Therapy Manual including a guided self-help booklet for the treatment of perinatal depression. You do not need to know anything about BA - your professional experience of providing care for women who have perinatal low mood/depression will help you to take part in the process.

Participants will need to maintain confidentiality of others in the workshop. There will be a moderator who will listen to everyone and take notes. The moderator will also maintain confidentiality.

What are the advantages/benefits and disadvantages/risks of taking part?

There are no anticipated disadvantages/risks to taking part in this study. By taking part in the research, you will contribute to tailoring a psychological intervention (BA) for the treatment of perinatal depression. Your participation will also contribute to the researcher's PhD project.

The researcher will be sensitive to all issues raised during the workshop, but if you do not want to continue to the workshop, you can leave at any time.

If you decide to take part in a workshop, your reasonable travel expenses will be reimbursed in person, in exchange for original travel tickets. Also, pizza and refreshments will be available during the workshop.

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Can I withdraw from the study at any time?

You can refuse to answer any questions. You are free to withdraw from the study at any time, even during the co-design workshop without having to give a reason for withdrawing. If you choose to withdraw from the study before the commencement of the workshop, all data referring to you will be destroyed and will not be used in any way. However, if you choose to withdraw from the study during the workshop, all the data collected until that time will be used in the study because it is not possible to remove your contribution from a group discussion. After completing the co-design workshop, you can still withdraw from the study, however, your data will still be included in the analysis.

Will the information I give be kept confidential?

University of York is the sponsor for this study based in United Kingdom. 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.

The University of York uses personally-identifiable information to conduct research to improve health, care and services. As a [publicly-funded](#) organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. Health and care research should serve the public interest, which means that we [have to](#) demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

When you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. 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. To safeguard your rights, we will use the minimum personally-identifiable information possible. The only people in the University of York who will have access to information that identifies you will be people who need to contact you to manage your participation in the research study or to check that the research study is being conducted appropriately. 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.

We will retain your contact details for 12 months after undertaking this study and a copy of the signed consent form for five years from the end of the research, to cover the period of the submission of thesis and any publications arising from the study. Your personal information will be stored separately from the research data, which will be retained for 10 years following the end of the research.

The information will be stored securely at the University of York in password protected files and locked filing cabinets that only the named researchers have access to, in line with the General Data Protection Regulation. The spreadsheet of contact details and consent form will be stored separately with your demographics form to ensure confidentiality.

Your name and any personal identifiable information will be anonymised in all audio recordings and transcripts (the workshop will be typed up into a transcript by the researcher or a professional transcriber who will be subject to a confidentiality contract) with a self-chosen false first name, and your identity will be kept strictly confidential. No real names of people or places will be used in any presentations or publications resulting from the study or in the researcher's PhD thesis. Your personal information, recordings, consent form, demographic form and transcript will be accessible only by the researchers in the research team.

Date: 23/04/2019
Version: 1.0
IRAS ID: 237021

Quotations from discussions in the workshop may be used in reported findings from the research study. If anything that you have said appears in quotation, it will be made anonymous so that you cannot be identified. Your recording will be destroyed 12 months after the study. Your anonymised transcripts will be stored on the York research database and PURE (database to store research data safely) for 10 years according to the University of York's policy. Transcripts will not be publicly available and only the research team will have access.

What will happen to the results of the study?

The results of the study will be published in the researcher's PhD thesis. Also, the researcher intends to present the results at conferences and publish in academic journals.

Who has reviewed this study?

This study has been reviewed and approved by Research Ethics Committee Yorkshire and Humber – Leeds West.

Who do I contact in the event of a complaint?

If your complaint is related to the study, you can contact Prof Tracy Lightfoot (Deputy Head (Postgraduate)), Department of Health Sciences, University of York, email: tracy.lightfoot@york.ac.uk; Tel: 01904 32 1881.

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).

The University of York's Data Protection Officer can be contacted at dataprotection@york.ac.uk.

If you agree to take part, please complete and sign the consent forms and fill in the demographics form and contact details sheet. Put one of your signed consent forms, your demographics form and contact details sheet in the stamped-addressed return envelope and send the envelope by mail to the researcher.

If you would like more information or have any questions or concerns about the study please contact the researcher Semra Pinar, Tel: 07729 070393, Email: sp1365@york.ac.uk, Address: Research Centre for Social Sciences, 6 Innovation Close, University of York, Heslington, York, YO10 5ZF.

Thank you for taking the time to read this information sheet.

Date: 23/04/2019
Version: 1.0
IRAS ID: 237021

Appendix 28: Consent form for women (third study)

<p>UNIVERSITY of York The Department of Health Sciences</p> <p>Participant Consent Form for Women</p> <p>Development and adaptation of a Behavioural Activation intervention manual intended for delivery by non-mental-health specialists for the treatment of perinatal depression</p>	
	<p>Please confirm agreement to the statements by putting your initials in the boxes below</p>
I have read and understood the participant information sheet [date: 23/04/2019, version: 1.0].	
I have had the opportunity to ask questions and discuss this study.	
I have received satisfactory answers to all of my questions.	
I have received enough information about the study.	
<p>I understand my participation in the study is voluntary and that I am free to withdraw from the study:</p> <p>1) At any time, even during the co-design workshop.</p> <p>2) Without having to give a reason for withdrawing.</p> <p>3) Should I choose to withdraw from the study before the commencement of the workshop, all data referring to me will be destroyed and will not be used in any way. However, should I choose to withdraw during a workshop, all the data collected until that time will be used in the study because it is not possible to remove my contribution from a group discussion.</p> <p>4) After completing the co-design workshop, I can still withdraw from the study, however, my data will still be included in the analysis.</p>	
I understand that my co-design workshop will be audio-recorded.	
I understand that my data collected during the study may be looked at by the research team. I give permission for these individuals to have access to my data.	
I agree to my GP being informed of my participation in the study if necessary.	
I understand that if as part of the research I disclose risks to myself or others, then a member of the research team may pass this information on to a relevant health or social care professional.	
I understand that any information I provide, including personal details, will be kept confidential, stored securely and only accessed by those carrying out the study.	
I understand that any quotations from my participation in a co-design workshop may be used in reporting the study findings. (If <u>anything</u> that I have said is quoted, it will be made anonymous so that I cannot be identified).	
I understand that any information I give may be included in the researcher's PhD thesis, peer-reviewed journals and/or conference presentations, but all information will be anonymised.	
I agree to take part in a co-design workshop with the researcher, a moderator and approximately 10-12 other people (healthcare professionals and women).	
I agree to take part in this study.	
<p>I would like to receive a summary of the results from the study.</p> <p>Please provide contact details if you wish to be informed of the results of the study:</p> <p>.....</p> <p>.....</p>	
Participant Signature	Date:
Name of Participant:	
Researcher Signature	Date:
Name of Researcher:	
<p>Date: 23/04/2019 Version: 1.0 IRAS ID: 237021</p>	

Appendix 29: Consent form for healthcare professionals (third study)



Participant Consent Form for Healthcare Professionals


Development and adaptation of a Behavioural Activation intervention manual intended for delivery by non-mental-health specialists for the treatment of perinatal depression

	Please confirm agreement to the statements by putting your initials in the boxes below
I have read and understood the participant information sheet [date: 23/04/2019, version: 1.0].	
I have had the opportunity to ask questions and discuss this study.	
I have received satisfactory answers to all of my questions.	
I have received enough information about the study.	
I understand my participation in the study is voluntary and that I am free to withdraw from the study: 1) At any time, even during the co-design workshop. 2) Without having to give a reason for withdrawing. 3) Should I choose to withdraw from the study before the commencement of the workshop, all data referring to me will be destroyed and will not be used in any way. However, should I choose to withdraw during a workshop, all the data collected until that time will be used in the study because it is not possible to remove my contribution from a group discussion. 4) After completing the co-design workshop, I can still withdraw from the study, however, my data will still be included in the analysis.	
I understand that my co-design workshop will be audio-recorded.	
I understand that my data collected during the study may be looked at by the research team. I give permission for these individuals to have access to my data.	
I understand that any information I provide, including personal details, will be kept confidential, stored securely and only accessed by those carrying out the study.	
I understand that any information I give may be included in the researcher's PhD thesis and/or peer-reviewed journals and/or conference presentations, but all information will be anonymised.	
I understand that any quotations from my participation in a co-design workshop may be used in reporting the study findings (If anything that I have said is quoted, it will be made anonymous so that I cannot be identified).	
I agree to take part in a co-design workshop with the researcher, a moderator and approximately 10-12 other people (healthcare professionals and women).	
I agree to take part in this study.	
I would like to receive a summary of the results from the study.	
Participant Signature	Date:
Name of Participant:	
Researcher Signature	Date:
Name of Researcher:	

Date: 23/04/2019
Version: 1.0
IRAS ID: 237021

Appendix 30: Advertisement leaflet and poster for women (third study)

Study Advertisement Poster / Leaflet




- ✓ **Have you experienced low mood or depression during pregnancy or in the first year after childbirth? (within the last 5 years)**
- ✓ **Would you like to take part in a co-design workshop to help shape care for women?**

You are invited to participate in a co-design workshop for the development of a simple talking treatment, called Behavioural Activation, for the treatment of depression during pregnancy and after childbirth

In the workshop, you would be supported to discuss the manual with other women and healthcare professionals

You do not need to know anything about the Behavioural Activation treatment, your experiences of low mood/depression are all that you need



You will be asked to take part in a co-design workshop, which would be audio recorded and last for no more than 90 minutes

Your participation would be anonymous and your identity will be kept strictly confidential. The workshop will be held in a private and convenient location to everyone

Light meal will be available. Reasonable travel expenses will be reimbursed and as a thank you gift for your time, a £20 gift card will be presented

For more information or to take part, please contact PhD student Semra Pinar
Tel: 07729 070 393 or
Email: sp1365@york.ac.uk

Who can take part in the study?
Women:


- ✓ Aged 18+
- ✓ Have felt or have been diagnosed with low mood or depression during pregnancy or in the first year after childbirth
- ✓ Whose youngest child is between 1-5 years old
- ✓ Who no longer experience depressive symptoms
- ✓ Living in [REDACTED]

This study, 'Development and adaptation of a Behavioural Activation intervention manual intended for delivery by non-mental-health specialists for the treatment of perinatal depression', has been reviewed and approved by REC Yorkshire and Humber – Leeds West. IRAS ID: 237021 Version 2.0 [13.08.2019].

Version: 1.0; Date: 05/08/2019

Appendix 31: Advertisement leaflet and poster for healthcare professionals (third study)

Study Advertisement Poster / Leaflet




- ✓ Are you a healthcare professional supporting women with perinatal low mood or depression?
- ✓ Would you like to take part in a co-design workshop to help shape care for women?

You are invited to participate in a co-design workshop for the development of a simple talking treatment, called Behavioural Activation, for the treatment of depression during pregnancy and after childbirth

In the workshop, you would be supported to discuss the manual with other health professionals and women

You do not need to know anything about the Behavioural Activation treatment - your experience will help you in the development of the manual



You will be asked to take part in a co-design workshop, which would be audio recorded and last for no more than 90 minutes

Your participation would be anonymous and your identity will be kept strictly confidential. The workshop will be held in a private and convenient location to everyone

Light meal will be available and reasonable travel expenses will be reimbursed

For more information or to take part, please contact *PhD student Semra Pinar*

Tel: 07729 070393 or
Email: sp1365@york.ac.uk

Who can take part in the study?

- ✓ Any registered health professionals (e.g. midwife, health visitor or general practitioner) or maternity support workers working in NHS maternity services, community services or GP practices in [redacted] for at least three years
- ✓ With experience of caring for women with perinatal low mood or depression

This study, 'Development and adaptation of a Behavioural Activation intervention manual intended for delivery by non-mental-health specialists for the treatment of perinatal depression', has been reviewed and approved by REC Yorkshire and Humber – Leeds West. IRAS ID: 237021 Version 2.0 [13.08.2019].

Version: 1.0; Date: 05/08/2019

Appendix 32: Patient Health Questionnaire-9 (second and third studies)

Patient Health Questionnaire-9 for women participants

PATIENT HEALTH QUESTIONNAIRE - 9 (PHQ-9)				
Over the <u>last 2 weeks</u> , how often have you been bothered by any of the following problems? (Use "✓" to indicate your answer)				
	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
FOR OFFICE CODING <u>0</u> + + + =Total Score: _____				
If you checked off <u>any</u> problems, how <u>difficult</u> have these problems made it for you to do your work, take care of things at home, or get along with other people?				
Not difficult at all ...	Somewhat difficult ...	Very difficult ...	Extremely difficult ...	

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

Appendix 33: The first stage of thematic analysis familiarisation with the data: Interesting points and emerging ideas (second study)

Notes

Interviews with women

HCPs should be aware of the fact that not all mothers are brave enough to disclose their real feelings to them, therefore, mothers should be encouraged to speak about their mood and hcp's should be in a right body posture and eye contact not to make mothers feel like that they are doing their job and completing forms, but in a way that they are really listening to and caring them.

No follow up by GPs.

All the mothers are actually very strong mentally and they do not want their mood to affect their children.

(08): IAPT does not cover perinatal mood, it is for general depression.

Women get pressure from their family and friends about having children and this makes on them more pressure to be a good mum. They focus on making others happy with being pregnant and having a child, but they are not happy at all.

They found activities very helpful for improving their mood. Some of them forced themselves to go out and attend activities which they believed helped them to feel better.

Time, work, family commitments, fear of being judged, do not know about services, stigma, fear of social services taking away the baby, denial, don't want to be on psychiatric medications, lack of support from husband/partner, too much responsibilities, lack of knowledge, lack of support, low self-esteem.

Is there a difference between the past and present years in terms of asking women about their mental health?

Is there a regional difference in terms of HCPs asking women their mood?

Is there a difference between the research sites in terms of the available treatment options?

Mothers feel anxious about starting work.

Midwives should ask mothers mental health at every appointment during pregnancy and also HV and GPs should do it.

Breastfeeding check from the data?

Discuss in the discussion part of the thesis that there is a shortage of staff in the NHS, mothers feel social services as a threat for themselves so do not want to discuss their mental health challenge with HCPs. Would be judged for not being a good mum. Mothers who thought they lost their identity with giving birth (e.g. breastfeeding all the time) they found starting work helps to improve their mood, however, other mothers feel anxious to start working and feel separated from their child.

Mothers feel like they lost their identity after giving birth because of breastfeeding and caring for the baby and making his needs prior at all times and they feel exhausted.

Mothers do not want to breastfeed their babies due to depressive mood and hcps do not understand this and force them to breastfeed.

Midwives ask about their mental health in the first appointment, then they do not ask about it, and there are no follow up questions afterwards if you do not disclose anything.

Mothers who have one child said that they do not want another child because they do not want to experience all things again and again.

We are child prepared for labour and birth rather than actually this lifelong change in parenting and change in overall lifelong.

Lack of motivation is really important.

Postnatal classes for mental health would be useful. Partners would also be involved in these classes.

Mothers don't like to burden people with their problems so suffer in silence.

"Screen everyone, screen early, screen regularly"

"Leading cause of disability depression. Nothing about me, without me" what helped you to get better? Personalised, tailored, targeted interventions"

Schedule some ME TIME : What they used to do before pregnancy?

This is an overview of the women interviewed. This is not a representation of the overall UK population.

Current experience of postnatal depression could not be recruited so it is as recent as we expect...

Interviews with HCPs

How frequently do midwives and HVs ask mood questions?

Midwives do not ask the Whooley questions directly. They try to integrate the questions in a natural conversation.

Partners should be integrated into maternity care.

The content of the antenatal classes and NCT classes should be investigated in terms of whether they include information about the mental health of woman, partner and older chil/dren in transition to parenting

MSWs should be trained appropriately in the delivery of BA.

Lack of options for the treatment of perinatal depression especially for low mood

There is no way for some women to make them disclose their real feelings even if you know that there is something wrong.

Fear of social services, TV series do not show the reality about social workers

Every hcp should be trained on giving practical advice to women for depression and anxiety

Referral process should be explained clearly to hcps

In every NHS Trust, there should be an SPMH midwife and they should work at the hospital every day for permanent bases.

There are only 8 beds in the mother and baby unit close to this area. Because of lack of services women have to travel far away from their home to stay in other units with their babies but women often choose to stay in psychiatric wards (which is close to their home) without their babies and kitchen facilities.

HVs check the house if it is tidy or not also check the woman if she is in pyjamas in the afternoon, eat breakfast or not and look moody

Lack of specialist perinatal mental health services in every city

Appendix 34: Pregnancy notes booklet

Mental Health (Complete this assessment page 14 and management plan page 15)

Pregnancy and having a baby can be an exciting but also a demanding time. This can result in pre-existing symptoms getting worse. It's not uncommon for women to feel anxious, worried or 'down' at this time. The range of mental health problems women may experience or develop is the same during pregnancy and after birth as at other times in her life, but some illnesses/ treatments may be different. Some women who have a mental health problem stop taking their medication when they find out they are pregnant. This can result in symptoms worsening. **You should not alter your medication without specialist advice from your GP, mental health team or midwife.**

Women with a severe mental illness such as psychosis, schizophrenia, schizoaffective disorder or bipolar disorders are more likely to become unwell again than at other times. Severe mental illness may develop more quickly immediately after childbirth and can be more serious requiring urgent treatment.

At your 1st appointment you will be asked how you are feeling now and if you have or have had any problems with your mental health in the past. You will be asked about your emotional wellbeing at your appointments during pregnancy and after the birth of your baby. These questions are asked to every pregnant woman and new mother. The healthcare team supporting you during pregnancy and after birth may identify that you are at risk of developing a mental health problem. If this happens they will discuss with you options for support and treatment. You may be offered a referral to a mental health team/specialist midwife/obstetrician.

If you are concerned about your thoughts, feelings or behaviour, you should seek help and advice.

Further information can be found about mental health including medication in pregnancy and breastfeeding via:
www.medicinesinpregnancy.org
www.nice.org.uk/guidance/cg192/1p/chapter/about-this-information

1st Assessment. Have you ever been diagnosed with any of the following:		No	Yes
Psychotic illness, bipolar disorders, schizophrenia, schizoaffective disorder, post-partum psychosis		<input type="checkbox"/>	<input type="checkbox"/>
Depression		<input type="checkbox"/>	<input type="checkbox"/>
Generalised anxiety disorder, OCD, panic disorder, social anxiety, PTSD		<input type="checkbox"/>	<input type="checkbox"/>
Eating disorder e.g. anorexia nervosa, bulimia nervosa or binge eating disorder		<input type="checkbox"/>	<input type="checkbox"/>
Personality disorder		<input type="checkbox"/>	<input type="checkbox"/>
Self-harm		<input type="checkbox"/>	<input type="checkbox"/>
Is there anything in your life (past/present) which might make the pregnancy/childbirth difficult? e.g. tokophobia, trauma, childhood sexual abuse, sexual assault		<input type="checkbox"/>	<input type="checkbox"/>
Help received (current or previous):			
GP/Midwife/Health visitor support		<input type="checkbox"/>	<input type="checkbox"/>
Counselling/cognitive behavioural therapy (CBT)		<input type="checkbox"/>	<input type="checkbox"/>
Specialist perinatal mental health team		<input type="checkbox"/>	<input type="checkbox"/>
Hospital or community based mental health team		<input type="checkbox"/>	<input type="checkbox"/>
Inpatient (hospital name) <input type="text"/>		Date(s) <input type="text"/>	
Psychiatrist <input type="text"/>		Psychiatric nurse/care coordinator <input type="text"/>	
Medication (list current or previous) drug name, dose and frequency			
<input type="text"/>			
Partner		No	Yes
Does your partner have any history of mental health illness?		<input type="checkbox"/>	<input type="checkbox"/>
Family History		No	Yes
Has anyone in your family had a severe perinatal mental illness? (first degree relative e.g. mother, sister)		<input type="checkbox"/>	<input type="checkbox"/>
Depression identification questions		1st No	2nd No
During the past month, have you often been bothered by feeling down, depressed or hopeless?		<input type="checkbox"/>	<input type="checkbox"/>
During the past month, have you often been bothered by having little interest or pleasure in doing things?		<input type="checkbox"/>	<input type="checkbox"/>
If yes to either of these questions, consider offering self-reporting tools e.g. PHQ 9			
Anxiety identification questions		No	Yes
During the past 2 weeks, have you been bothered by feeling nervous, anxious or on edge?		<input type="checkbox"/>	<input type="checkbox"/>
During the past 2 weeks, have you been bothered by not being able to stop or control worrying?		<input type="checkbox"/>	<input type="checkbox"/>
Do you find yourself avoiding places or activities and does this cause you problems?		<input type="checkbox"/>	<input type="checkbox"/>
If yes to any of these questions, consider offering self-reporting tool e.g. GAD 7			

6 GAD - General Anxiety Disorder; GP - General Practitioner
 OCD - Obsessive Compulsive Disorder; PHQ - Patient Health Questionnaire
 PTSD - Post Traumatic Stress Disorder
 * Signatures must be listed on page 30 for identification

Name
 Unit No
 NHS No

Appendix 35: The second stage of thematic analysis generating initial codes: The codebook for women (second study)

Perinatal depression - views of women

Nodes

Name
anxiety
barriers to seek help
delivery type
caesarean
vaginal
depression started after giving birth
depression started before pregnancy
depression started during pregnancy
disclosing feelings
disclosing on facebook
disclosing to a friend
disclosing to a GP
disclosing to a midwife
disclosing to HV
disclosing to mother
disclosing to mother and baby group facilitator
disclosing to occupational health
disclosing to partner
feelings
after giving birth

Name
baby blues
hormonal changes
being concerned
criticising her ability to parent
crying
denial of situation
eat take away
fear of being judged by others
fear of social services
feeling alone
feeling annoyed
feeling anxious
feeling ashamed
feeling bad
feeling conscious
feeling depressed
feeling dreadful
feeling embarrassed
feeling emotional
feeling exhausted
feeling frustrated
feeling guilty
feeling helpless

Name
feeling hysterical
feeling inadequate
Feeling like a bad mum
feeling like everyone is judging me
feeling like he did not love me
feeling like letting everyone down
feeling like losing control
feeling like screaming out for help
feeling like someone will take the child away
feeling like wasnt coping
feeling lonely
feeling low
feeling not good enough
feeling not great
feeling overwhelmed
feeling relief after giving birth
feeling robotic
feeling sad
feeling shattered
feeling stifling
feeling stressful
feeling stuck at home
feeling suicidal

Name
feeling tied
feeling tired
feeling upset
feeling weepy
feeling worry
felt in shock
felt like could not talk to anyone
felt like doing everything wrong
felt like he didnt love me
felt useless
felt withdrawn
hiding feelings
horrendous
ignoring
just sit and watch TV
lack of energy
lack of identity
lack of motivation
looks gaunt
looks ill
losing weight
low confidence
low self-belief

Name
misery
no one understands me
nobody wants to know about you
not brushing hair
not cook food
not doing cleaning
not feeling happy
not feeling like a mum
not feeling too great
not having a proper shower
not having time to do things
not looking after herself
not want husband to go to work
not want to contact people
not want to do anything
not want to exercise
not want to get dressed
not want to go out
not want to play with the child
not want to see any people
not want to take care of the child
not want to talk to anyone
not want to walk

Name
not washing dishes
OCD
parenting is hard
poor appetite
sleeping problems
stigma
struggling to feed
struggling to looking after pets
they want to know about the child
thinking of giving the child for adoption
thought going to feel like that forever
want to die
wants to be alone
wants to stay in bed
before pregnancy
anxiety
depression
feeling bad about herself
feeling pressure from family and friends to have a baby
low mood
stress
worrying
difference between ante and postnatal low mood depression

Name
difference between the two birth experiences
during pregnancy
crying
deterioration on mood
did not want to carry on pregnancy
feeling anxious
feeling ashamed
feeling awful
feeling daunted
feeling depressed
feeling desperate
feeling disappointment
feeling down
feeling dreadful
feeling embarrassment
feeling exhausted
feeling frightened
feeling frustrating
feeling guilt
feeling horrible
feeling ill
feeling isolated
feeling like an incubator for the baby

Name
feeling like cannot cope with this feeling
feeling like nobody want me
feeling low
feeling overweight
feeling panicky
feeling poorly
feeling rubbish
feeling shame
feeling snappy
feeling terrified
feeling tired
feeling ugly
feeling uncomfortable
feeling very pleased
feeling worried
hiding feelings
if anything does happen it is my own fault
ignoring the reality
lack of energy
lack of motivation
lack of support about pregnancy losses
no one understands me
not being able to do activities

Name
not feeling exciting
not having quality time with family and partner
not like being on her own
not want to be pregnant again
not want to do anything
not want to go out
not want to work
poor appetite
pretend to be happy
sickness
sleeping problems
struggling with her breathing
trying not to get attached baby and the pregnancy
messages for HCPs
messages for improving perinatal mental health care
messages to other mothers
reasons for depression after giving birth
bullying at job
haemorrhage
hip problem
hormonal
jaundice
kidney infection

Name
<u>moving house</u>
OCD
partner starts a new job
third degree tear
too much responsibilities
work issue
reasons for depression before pregnancy
anxiety
broken relationship with partner
depression
fertility issues
pregnancy losses
problems with hips
reasons for depression during pregnancy
anaemic
being pregnant
bleeding
bullying at job
emesis
first pregnancy
gaining weight
high blood pressure
hip problem

Name
lack of support from friends and family
lack of support from HCPs
late pregnancy related to fertility issue <u>n</u> pregnancy losses
long labour
miscarriage
tokophobia
work issue
reasons for not disclosing feelings
denying
fear of social services
hiding
judgement as a bad mum
thinking it is as a failure
thinking it is normal hormonal
would be removed from her care
reasons for not seeking help from HCPs
conflicting information between the professionals
related to child
bonding problem
bottle feeding
breast feeding
thinking of another child
related to consultant

Name
related to friend
after giving birth
pregnancy
related to GPs
after giving birth
before pregnancy
Did GP ask you ques about your mood antenatally
Did GP ask you ques about your mood postnatally
during pregnancy
thoughts about his approach
related to HVs
after giving birth
Did HV ask you ques about your mood postnatally
thoughts about her approach
related to midwives
after giving birth
staying in hospital due to bleeding
Did midwife ask you ques about your mood antenatally
Did midwife ask you ques about your mood postnatally
during pregnancy
thoughts about her approach
related to paediatrician
related to parents

Name
after giving birth
support from mother
related to partner
after giving birth
other
paternal low mood depression
supportive partner
unsupportive partner
during pregnancy
related to pharmacist
related to SPMH midwife
timing of appointments with HCPs
treatments suggested by GPs
crisis team
hospitalised
medication
mental health team
occupational health through work not the GP
counselling
other
psychological treatment
counselling
----- (anonymised) counselling from a charity

Name
IAPT
CBT
----- (anonymised) counselling from a charity
Let's Talk
----- (anonymised) counselling from a charity
thoughts about recommended treatment
views about talking therapy and MSWs
what factors affect your preferences
what helped them
after giving birth
activity scheduling
after winter season
asking people to look after the baby
baking cake
delivery to home - shopping
doing routine activities like shower
drinking water, eating well, sleeping well
exercise
go for shopping
going out for whatever reason
hospitalised
ignoring
inviting a friend to home

Name
medical treatment
meeting with friends with the babies
mother and baby groups
baby massage
baby music
baby sensory
moving child to her own room
not bringing work at home
overeating
personal time
psychological treatment
putting less pressure on herself
realising the reality
sleeping, reading, watching
social media and internet
support from a charity
support from friends
support from HV
support from mother family
support from partner
talking out
trips
walking

Name
working in a job
yoga
during pregnancy
antenatal classes
breastfeeding
caring for baby
first aid
baking cake
exercise
mother groups
NCT groups
personal time
working in a job
where and from whom do you prefer to receive advice and support
working in a job or not

Appendix 36: The third stage of thematic analysis searching for themes: The codebook for women (second study)

Perinatal depression - views of women

Nodes

Name
1 triggers of low mood depression
antenatal
anaemic
being pregnant
bleeding
bullying at job
emesis
first pregnancy
gaining weight
high blood pressure
hip problem
lack of support from friends and family
lack of support from HCPs
late pregnancy related to fertility issue <u>n</u> pregnancy losses
long labour
miscarriage
tokophobia
work issue
before pregnancy
anxiety

Name
broken relationship with partner
depression
fertility issues
pregnancy losses
problems with hips
postnatal
bullying at job
haemorrhage
hip problem
hormonal
jaundice
kidney infection
<u>moving house</u>
OCD
partner starts a new job
third degree tear
too much responsibilities
work issue
2 feelings
antenatal
crying
deterioration on mood
did not want to carry on pregnancy

Name
feeling anxious
feeling ashamed
feeling awful
feeling daunted
feeling depressed
feeling desperate
feeling disappointment
feeling down
feeling dreadful
feeling embarrassment
feeling exhausted
feeling frightened
feeling frustrating
feeling guilt
feeling horrible
feeling ill
feeling isolated
feeling like an incubator for the baby
feeling like cannot cope with this feeling
feeling like nobody want me
feeling low
feeling overweight
feeling panicky

Name
feeling poorly
feeling rubbish
feeling shame
feeling snappy
feeling terrified
feeling tired
feeling ugly
feeling uncomfortable
feeling very pleased
feeling worried
hiding feelings
if anything does happen it is my own fault
ignoring the reality
lack of energy
lack of motivation
lack of support about pregnancy losses
no one understands me
not being able to do activities
not feeling exciting
not having quality time with family and partner
not like being on her own
not want to be pregnant again
not want to do anything

Name
not want to go out
not want to work
poor appetite
pretend to be happy
sickness
sleeping problems
struggling with her breathing
trying not to get attached baby and the pregnancy
before pregnancy
anxiety
depression
feeling bad about herself
feeling pressure from family and friends to have a baby
low mood
stress
worrying
difference between ante and postnatal low mood depression
difference between the two birth experiences
postnatal
baby blues
hormonal changes
being concerned
criticising her ability to parent

Name
crying
denial of situation
eat take away
fear of being judged by others
fear of social services
feeling alone
feeling annoyed
feeling anxious
feeling ashamed
feeling bad
feeling conscious
feeling depressed
feeling dreadful
feeling embarrassed
feeling emotional
feeling exhausted
feeling frustrated
feeling guilty
feeling helpless
feeling hysterical
feeling inadequate
feeling like a bad mum
feeling like everyone is judging me

Name
feeling like he did not love me
feeling like letting everyone down
feeling like losing control
feeling like screaming out for help
feeling like someone will take the child away
feeling like <u>wasnt</u> coping
feeling lonely
feeling low
feeling not good enough
feeling not great
feeling overwhelmed
feeling relief after giving birth
feeling robotic
feeling sad
feeling shattered
feeling stifling
feeling stressful
feeling stuck at home
feeling suicidal
feeling tied
feeling tired
feeling upset
feeling weepy

Name
feeling worry
felt in shock
felt like could not talk to anyone
felt like doing everything wrong
felt like he <u>didn't</u> love me
felt useless
felt withdrawn
hiding feelings
horrendous
ignoring
just sit and watch TV
lack of energy
lack of identity
lack of motivation
looks gaunt
looks ill
losing weight
low confidence
low <u>self belief</u>
misery
no one understands me
nobody wants to know about you
not brushing hair

Name
not cook food
not doing cleaning
not feeling happy
not feeling like a mum
not feeling too great
not having a proper shower
not having time to do things
not looking after herself
not want husband to go to work
not want to contact people
not want to do anything
not want to exercise
not want to get dressed
not want to go out
not want to play with the child
not want to see any people
not want to take care of the child
not want to talk to anyone
not want to walk
not washing dishes
OCD
parenting is hard
poor appetite

Name
sleeping problems
stigma
struggling to feed
struggling to looking after pets
they want to know about the child
thinking of giving the child for adoption
thought going to feel like that forever
want to die
wants to be alone
wants to stay in bed
3 effects on child
bonding problem
bottle feeding
breast feeding
thinking of another child
3 effects on partner
after giving birth
other
paternal low mood depression
supportive partner
unsupportive partner
during pregnancy
4 care and 5 support from HCPs

Name
consultant issues
GP issues
after giving birth
before pregnancy
Did GP ask you ques about your mood antenatally
Did GP ask you ques about your mood postnatally
during pregnancy
thoughts about his approach
treatments suggested by GPs
crisis team
hospitalised
medication
mental health team
occupational health through work not the GP
counselling
other
psychological treatment
counselling
house of light
IAPT
CBT
----- (anonymised) counselling from a charity
Let's Talk

Name
----- (anonymised) counselling from a charity
thoughts about recommended treatment
HV issues
after giving birth
Did HV ask you ques about your mood postnatally
thoughts about her approach
midwife issues
after giving birth
staying in hospital due to bleeding
Did midwife ask you ques about your mood antenatally
Did midwife ask you ques about your mood postnatally
during pregnancy
thoughts about her approach
paediatrician issues
pharmacist issues
SPMH midwife issues
timing of appointments with HCPs
where and from whom do you prefer to receive advice support
anxiety
copng strategies
after giving birth
activity scheduling
after winter season

Name
asking people to look after the baby
baking cake
delivery to home - shopping
doing routine activities like shower
drinking water, eating well, sleeping well
exercise
go for shopping
going out for whatever reason
hospitalised
ignoring
inviting a friend to home
medical treatment
meeting with friends with the babies
mother and baby groups
baby massage
baby music
baby sensory
moving child to her own room
not bringing work at home
overeating
personal time
psychological treatment
putting less pressure on herself

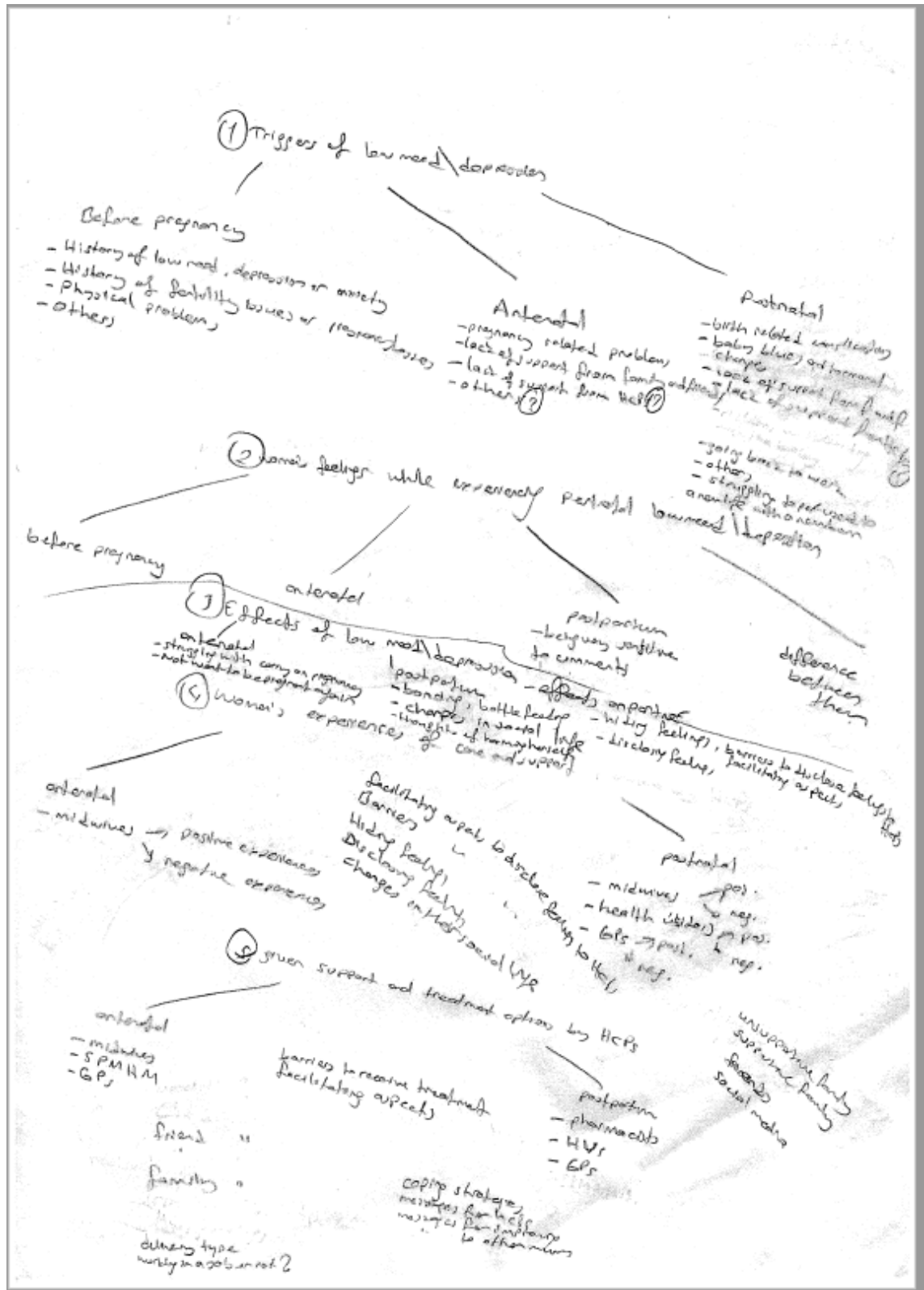
Name
realising the reality
sleeping, reading, watching
social media and internet
support from a charity
support from friends
support from HV
support from mother family
support from partner
talking out
trips
walking
working in a job
yoga
during pregnancy
antenatal classes
breastfeeding
caring for baby
first aid
baking cake
exercise
mother groups
NCT groups
personal time

Name
working in a job
delivery type
caesarean
vaginal
disclosing or hiding real feelings
barriers to seek help
disclosing feelings
disclosing on <u>facebook</u>
disclosing to a friend
disclosing to a GP
disclosing to a midwife
disclosing to HV
disclosing to mother
disclosing to mother and baby group facilitator
disclosing to occupational health
disclosing to partner
reasons for not disclosing feelings
denying
fear of social services
feeling like a bad mum
feeling not good enough
hiding
judgement as a bad mum

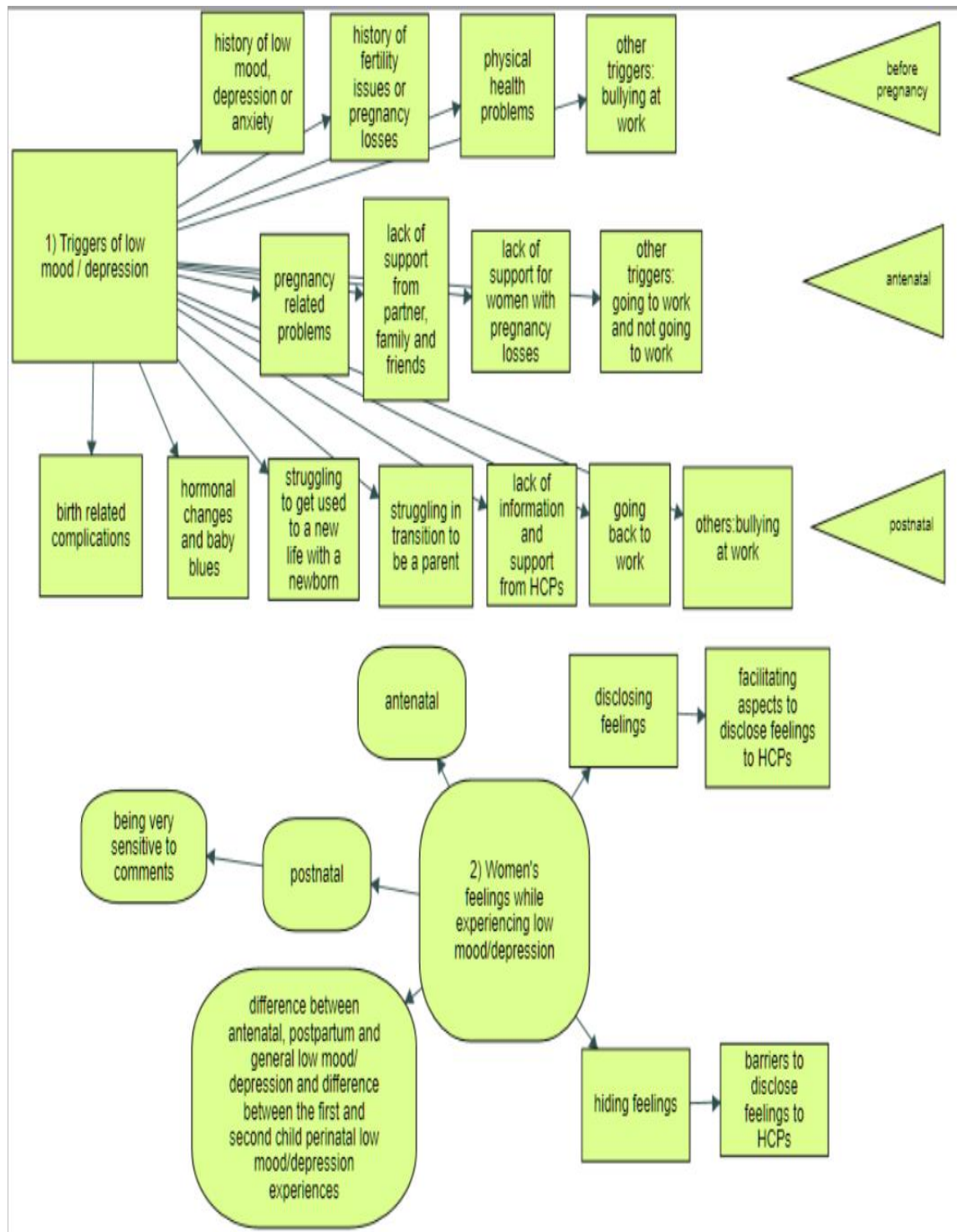
Name
stigma
thinking it is as a failure
thinking it is normal hormonal
would be removed from her care
messages for HCPs
messages for improving perinatal mental health care
messages to other mothers
onset of low mood depression
antenatal
before pregnancy
postnatal
reasons for not seeking help from HCPs
conflicting information between the professionals
support from <u>parents</u> partners and friends
friend issues
after giving birth
pregnancy
parent issues
after giving birth
support from mother
partner issues
after giving birth
other

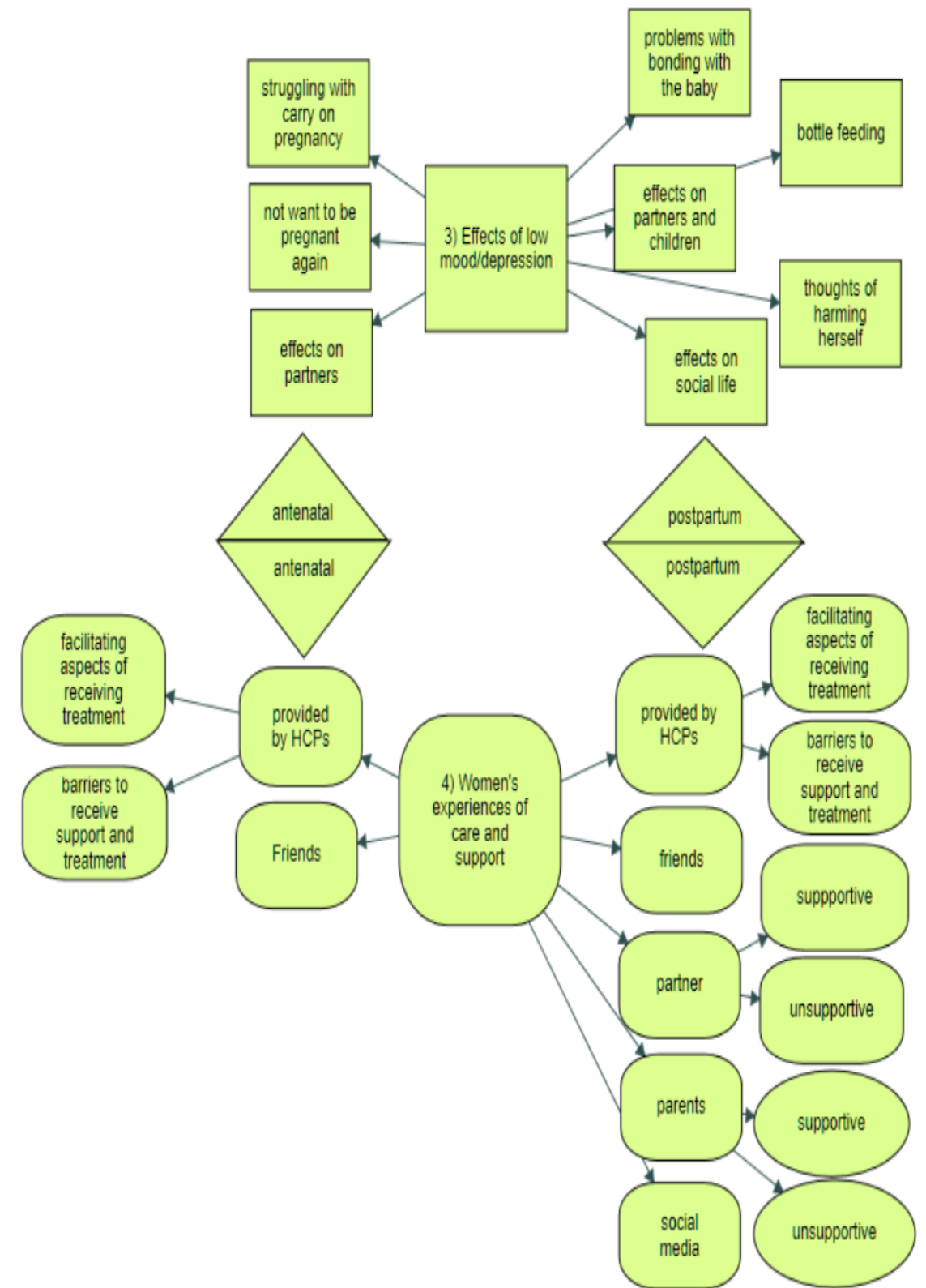
Name
paternal low mood depression
supportive partner
unsupportive partner
during pregnancy
views about talking therapy and MSWs
what factors affect your preferences
working in a job or not

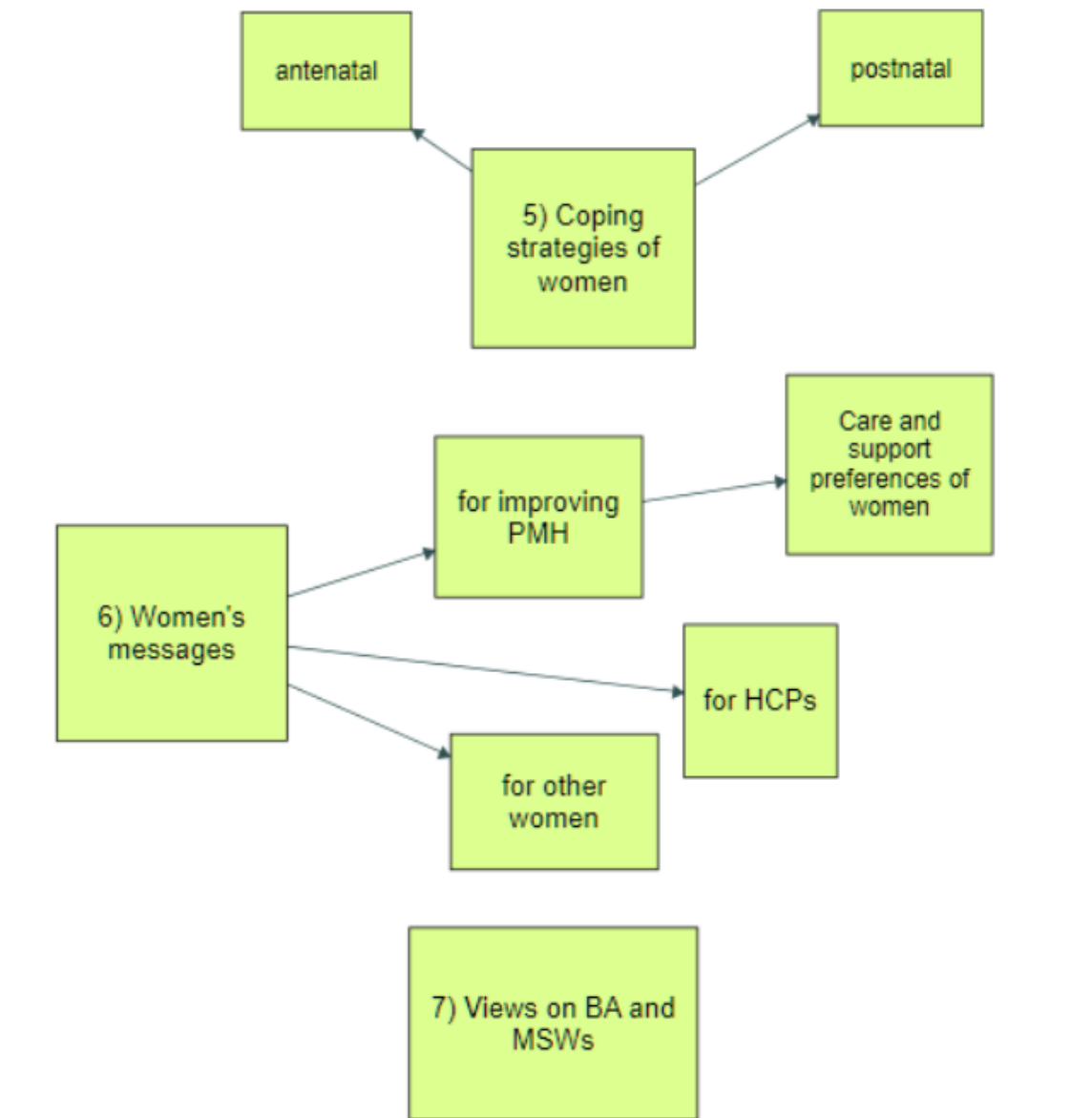
Appendix 37: The third stage of thematic analysis searching for themes: Thematic map for women (second study)



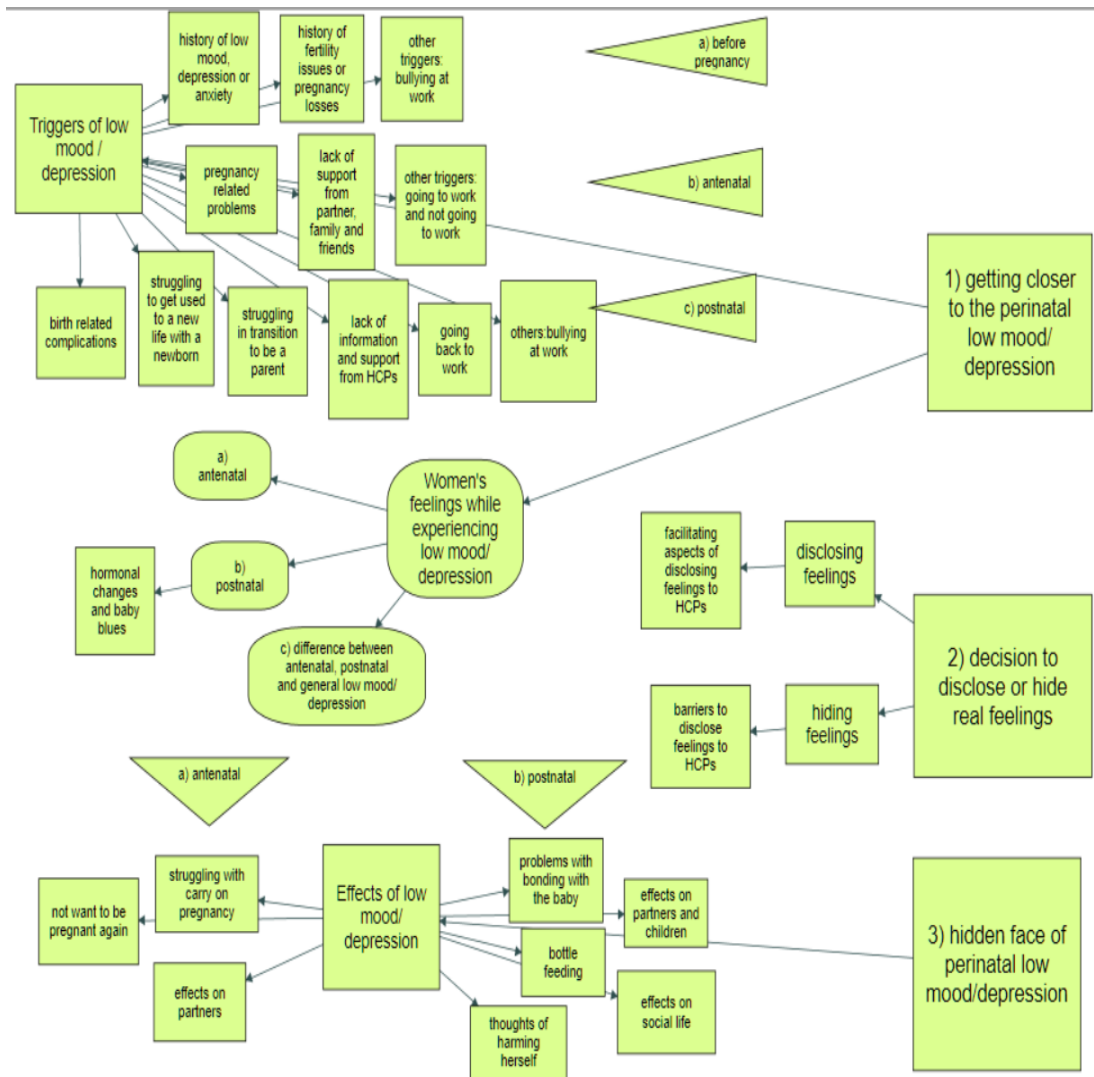
Appendix 38: The fourth stage of thematic analysis reviewing themes: Thematic map for women (second study)



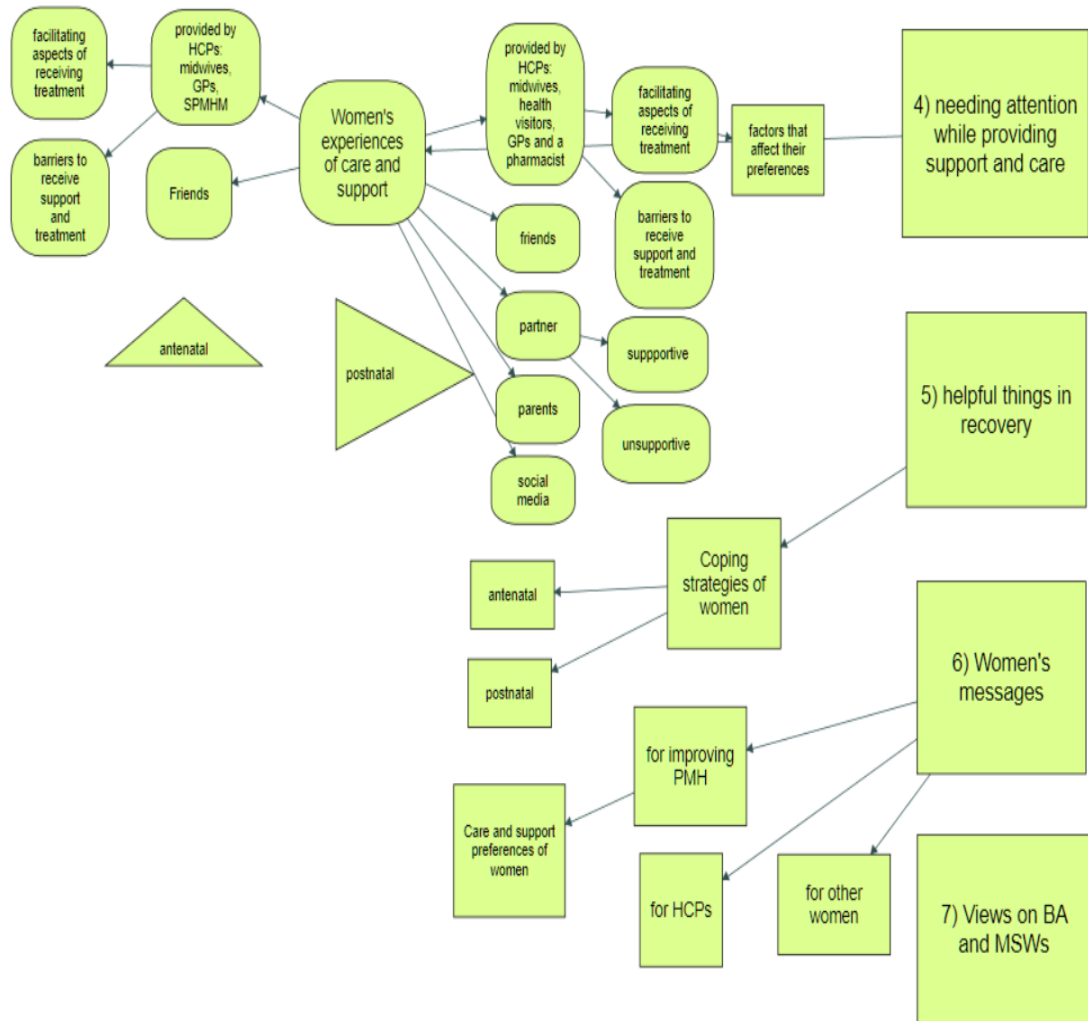




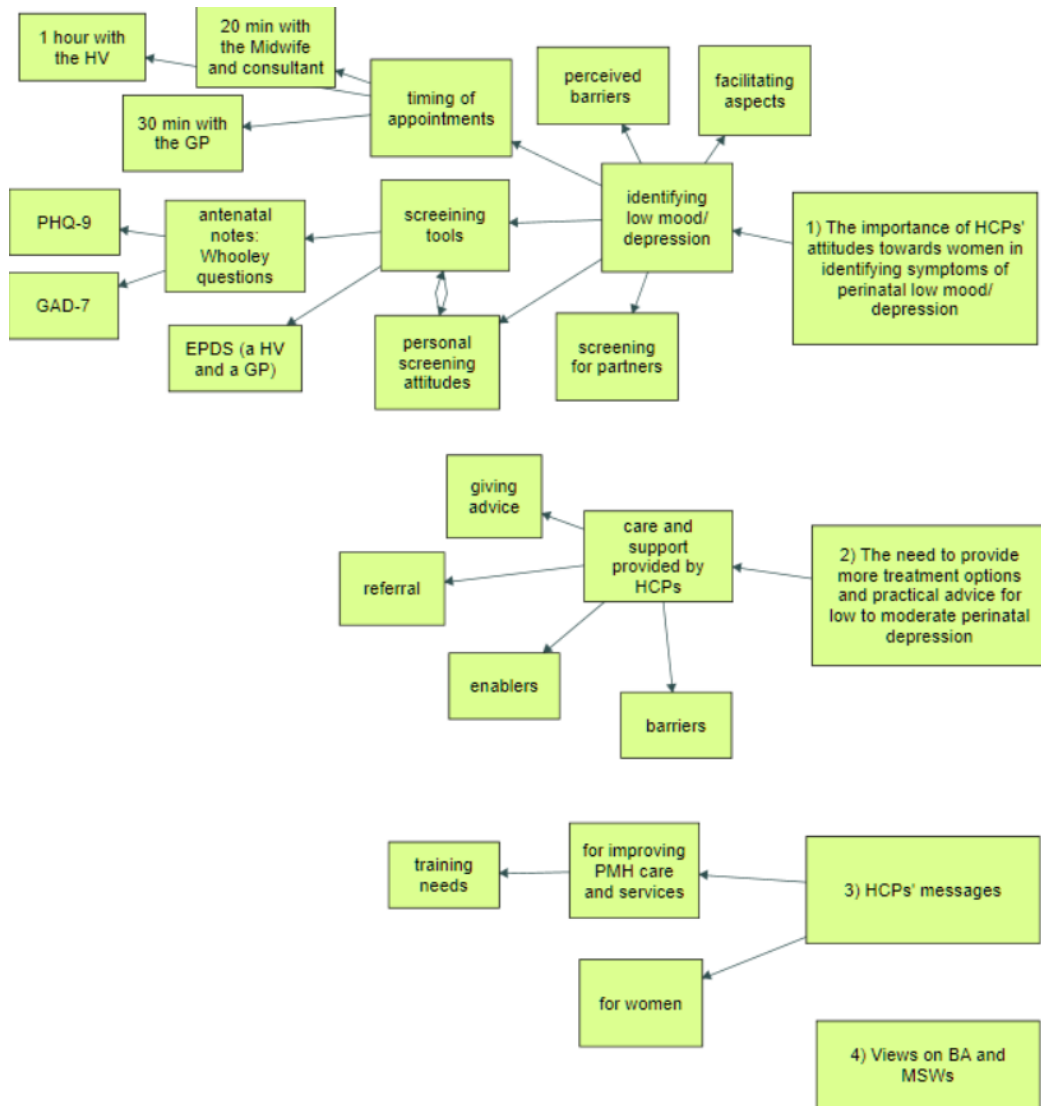
**Appendix 39: The fifth stage of thematic analysis defining and naming themes:
Thematic map for women (second study)**



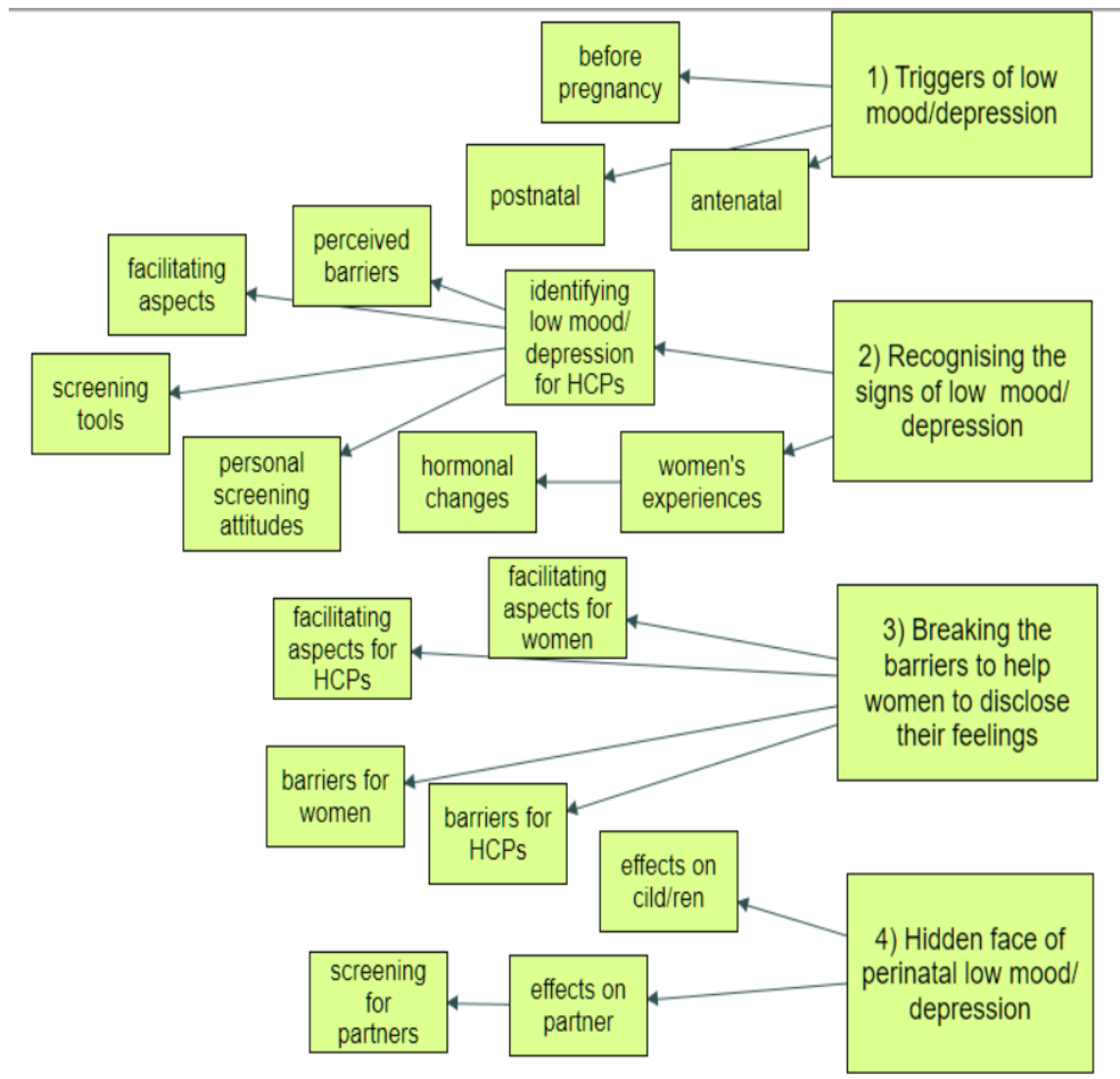
Continued the next page

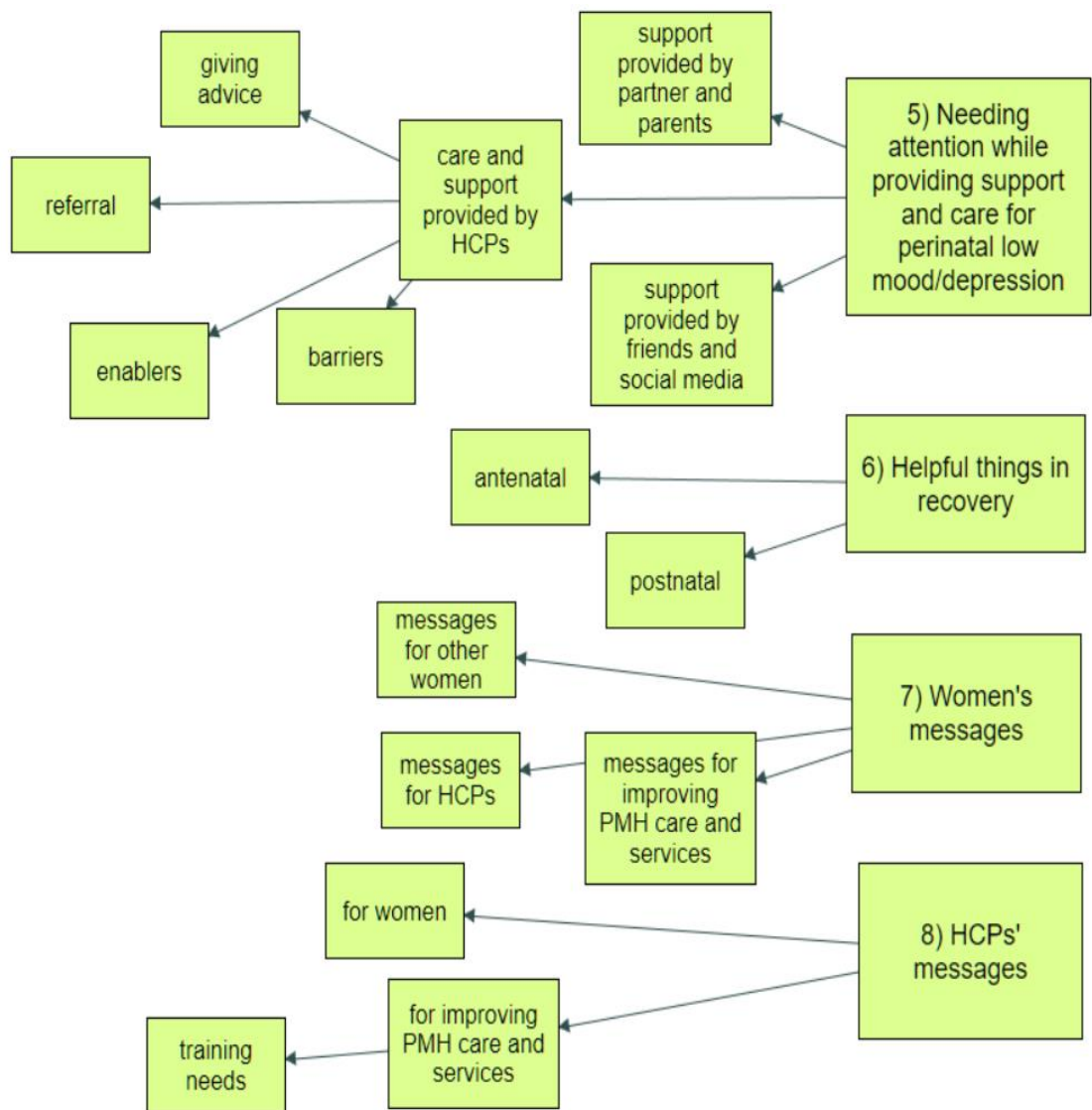


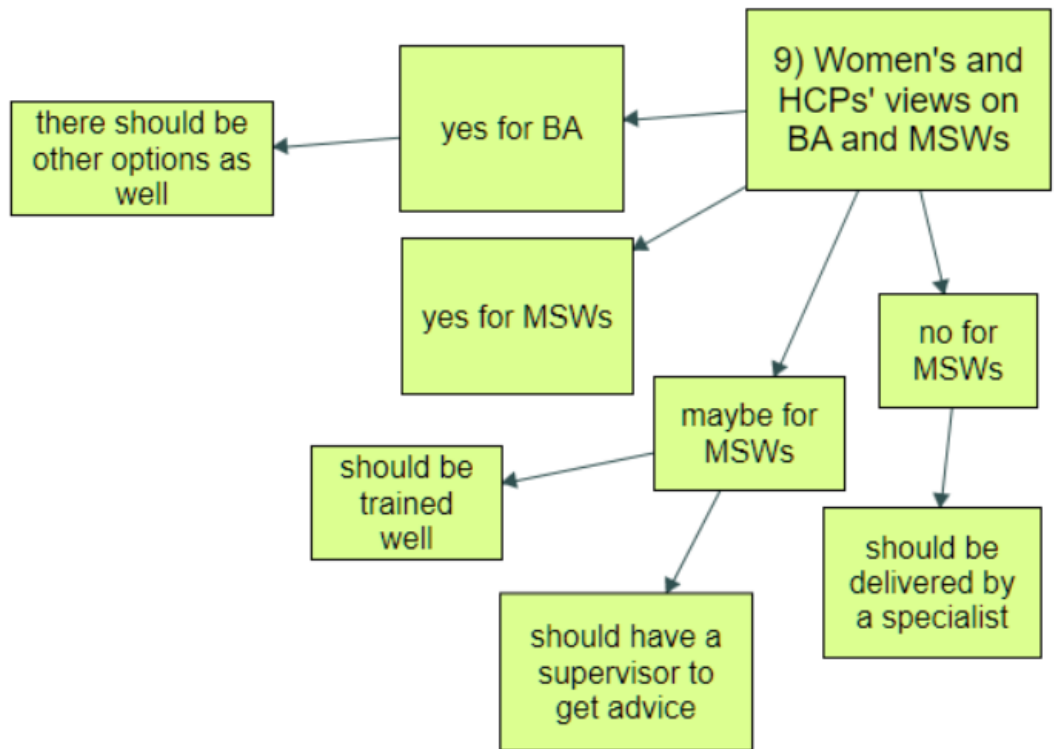
**Appendix 40: The fifth stage of thematic analysis defining and naming themes:
Thematic map for healthcare professionals (second study)**



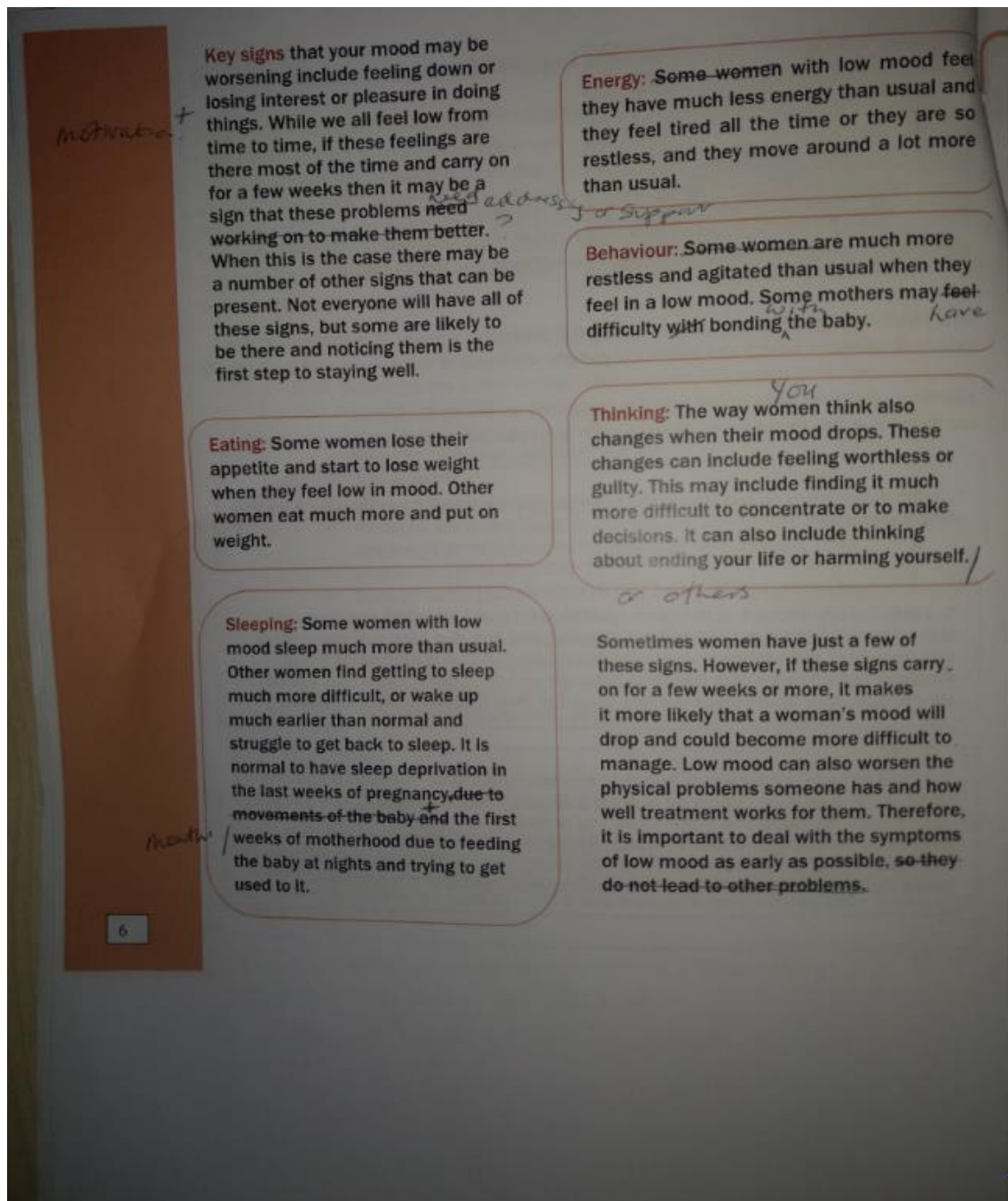
Appendix 41: Thematic map including interviews with women and healthcare professionals for the second study findings related to the adaptation of the manual and booklet (second study)







Appendix 43: The second stage of thematic analysis generating initial codes: Example comments from co-designers' booklets (third study)



^{low}
Key signs that your mood may be worsening include feeling down or losing interest or pleasure in doing things. While we all feel low from time to time, if these feelings are there most of the time and carry on for a few weeks then it may be a sign that these problems need ^{addressing} ~~working on to make them better~~. When this is the case there may be a number of other signs that can be present. Not everyone will have all of these signs, but some are likely to be there and noticing them is the first step to staying well.

Eating: Some women lose their appetite and start to lose weight when they feel low in mood. Other women eat much more and put on weight.

Sleeping: Some women with low mood sleep much more than usual. Other women find getting to sleep much more difficult, or wake up much earlier than normal and struggle to get back to sleep. It is normal to have sleep deprivation in the last weeks of pregnancy due to movements of the baby and the first weeks of motherhood due to feeding the baby at nights and trying to get used to it.

Energy: Some women with low mood they have much less energy than usual. They feel tired all the time or they are restless, and they move around a lot more than usual.

Behaviour: Some women are much more restless and agitated than usual when they feel in a low mood. Some mothers may find difficulty with bonding the baby.

Thinking: The way women think also changes when their mood drops. These changes can include feeling worthless or guilty. This may include finding it much more difficult to concentrate or to make decisions. It can also include thinking about ending your life or harming yourself.

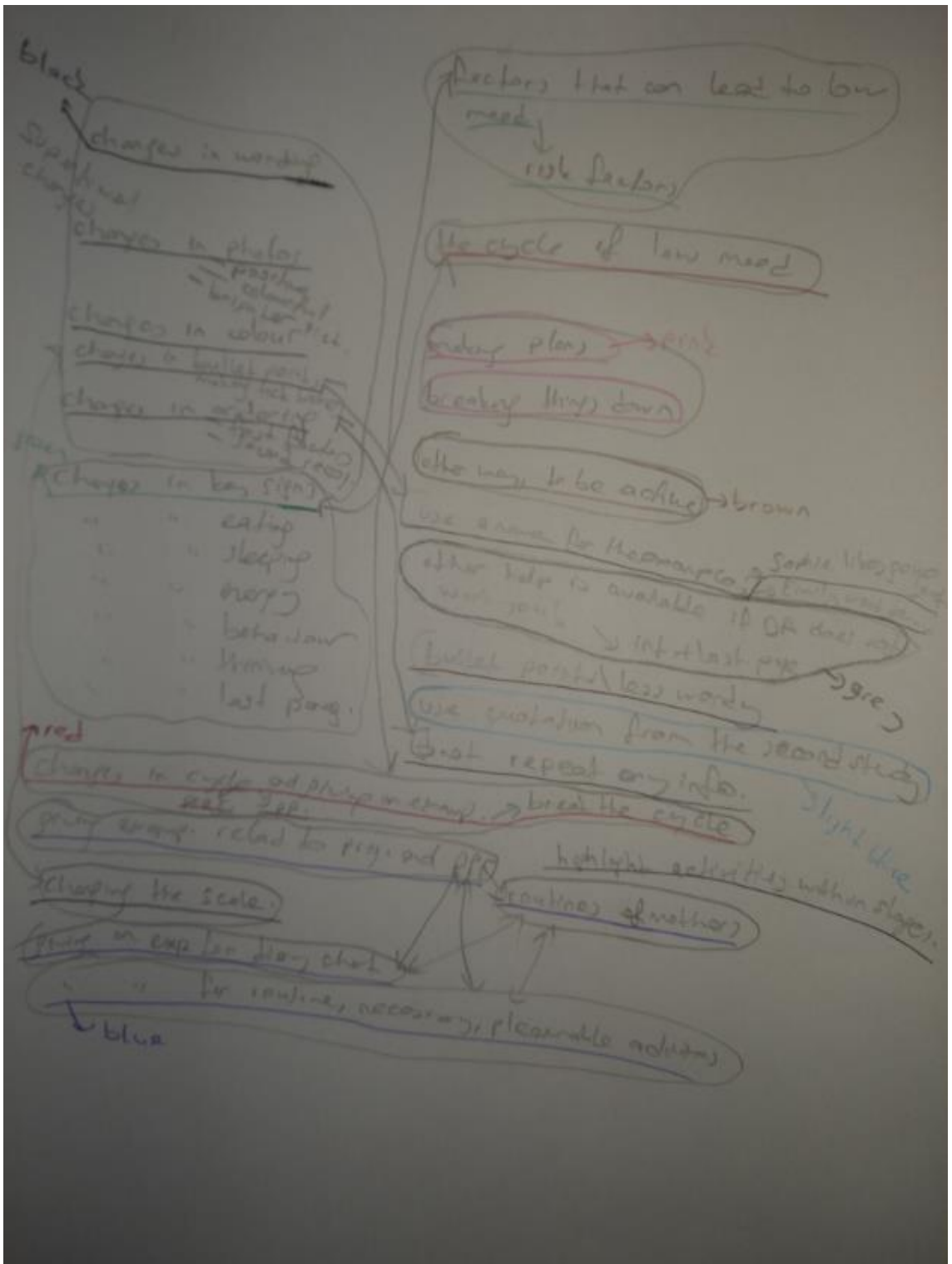
Sometimes women have just a few of these signs. However, if these signs carry on for a few weeks or more, it makes it more likely that a woman's mood will drop and could become more difficult to manage. Low mood can also worsen the physical problems someone has and how well treatment works for them. Therefore, it is important to deal with the symptoms of low mood as early as possible, so they do not lead to other problems.

6

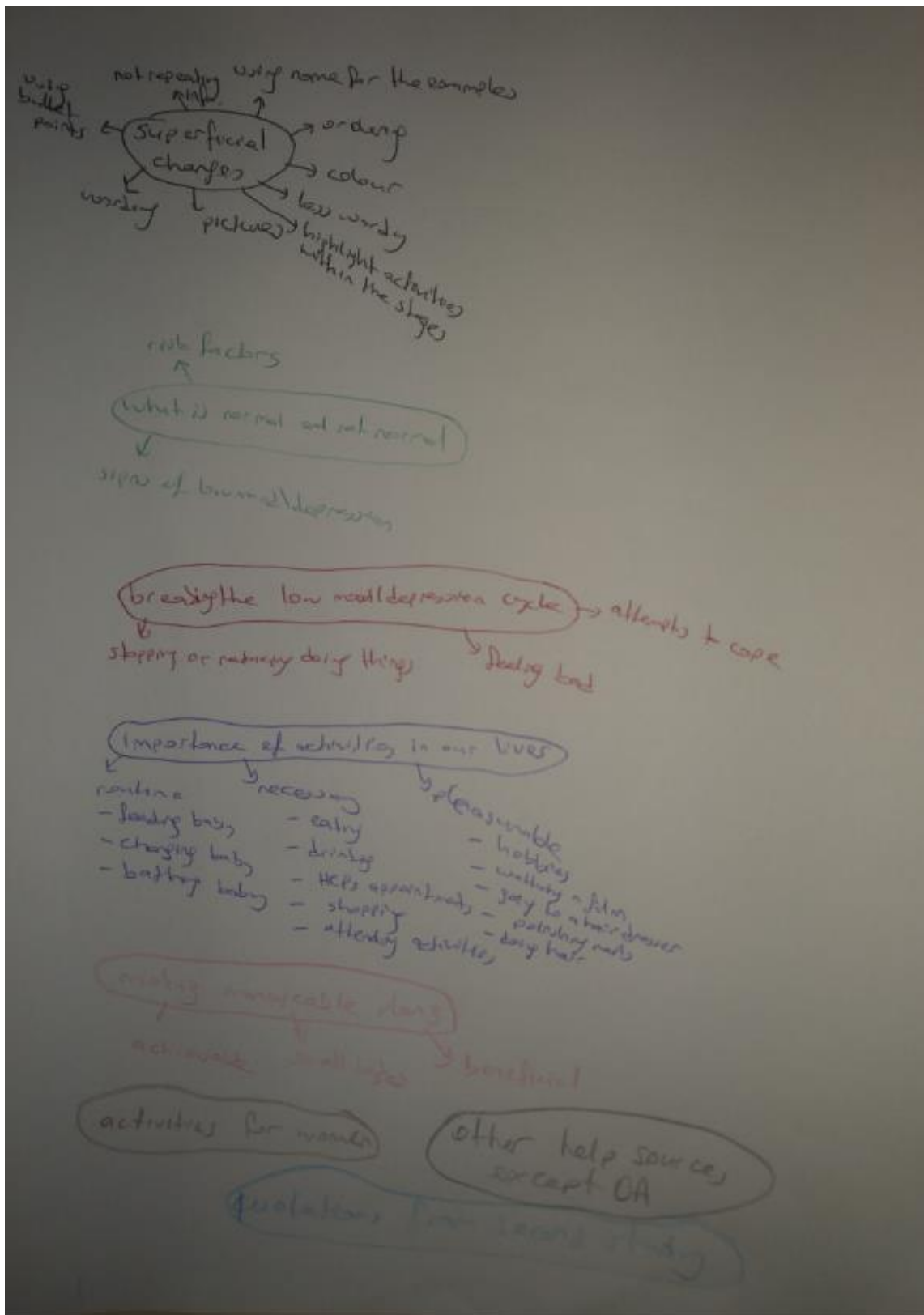
months

year

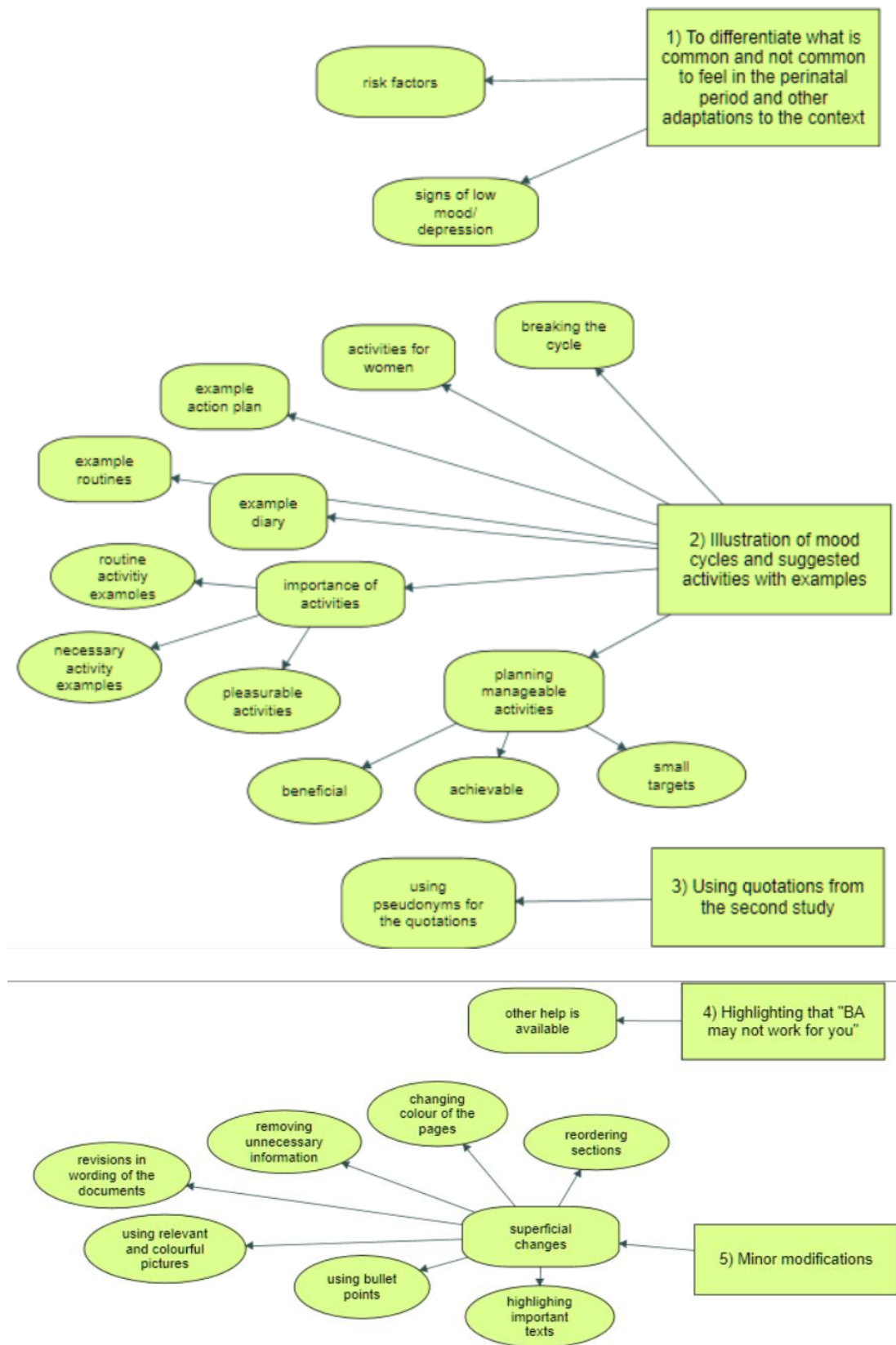
Appendix 44: The third stage of thematic analysis searching for themes (third study)



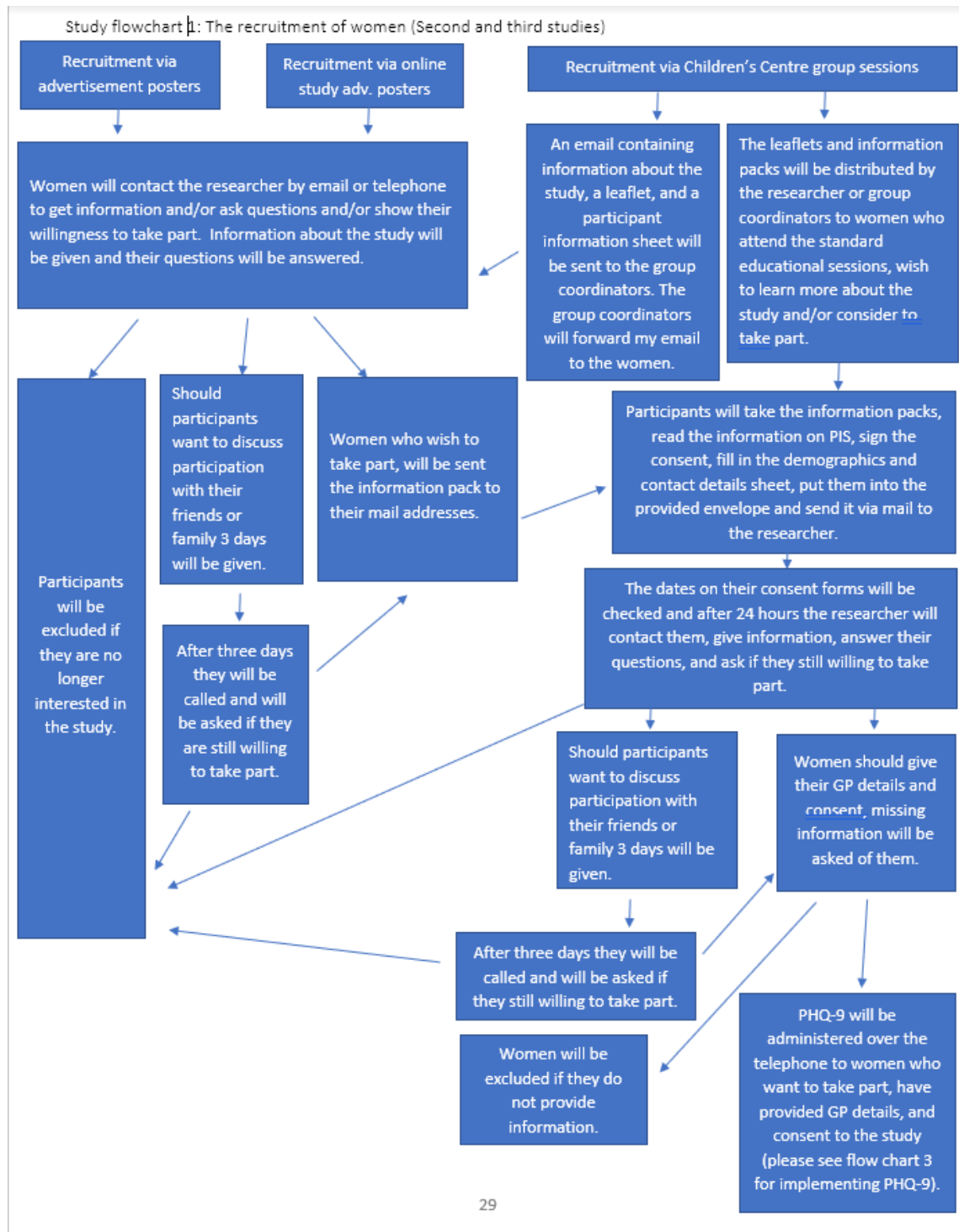
Appendix 45: The fourth stage of thematic analysis reviewing themes (third study)



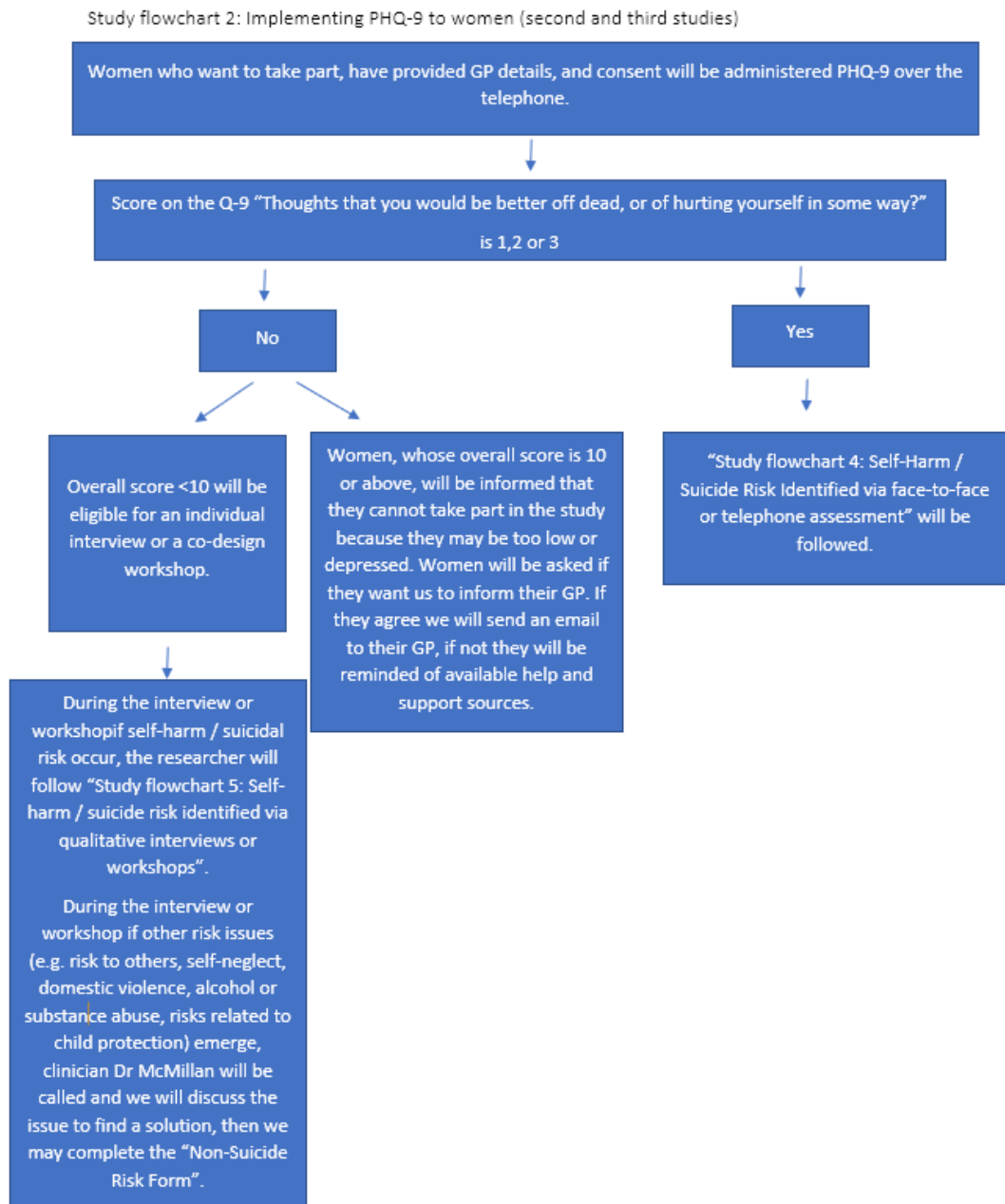
Appendix 46: The fifth stage of thematic analysis defining and naming themes (third study)



Appendix 47: Study flowchart for the recruitment of women (second and third studies)

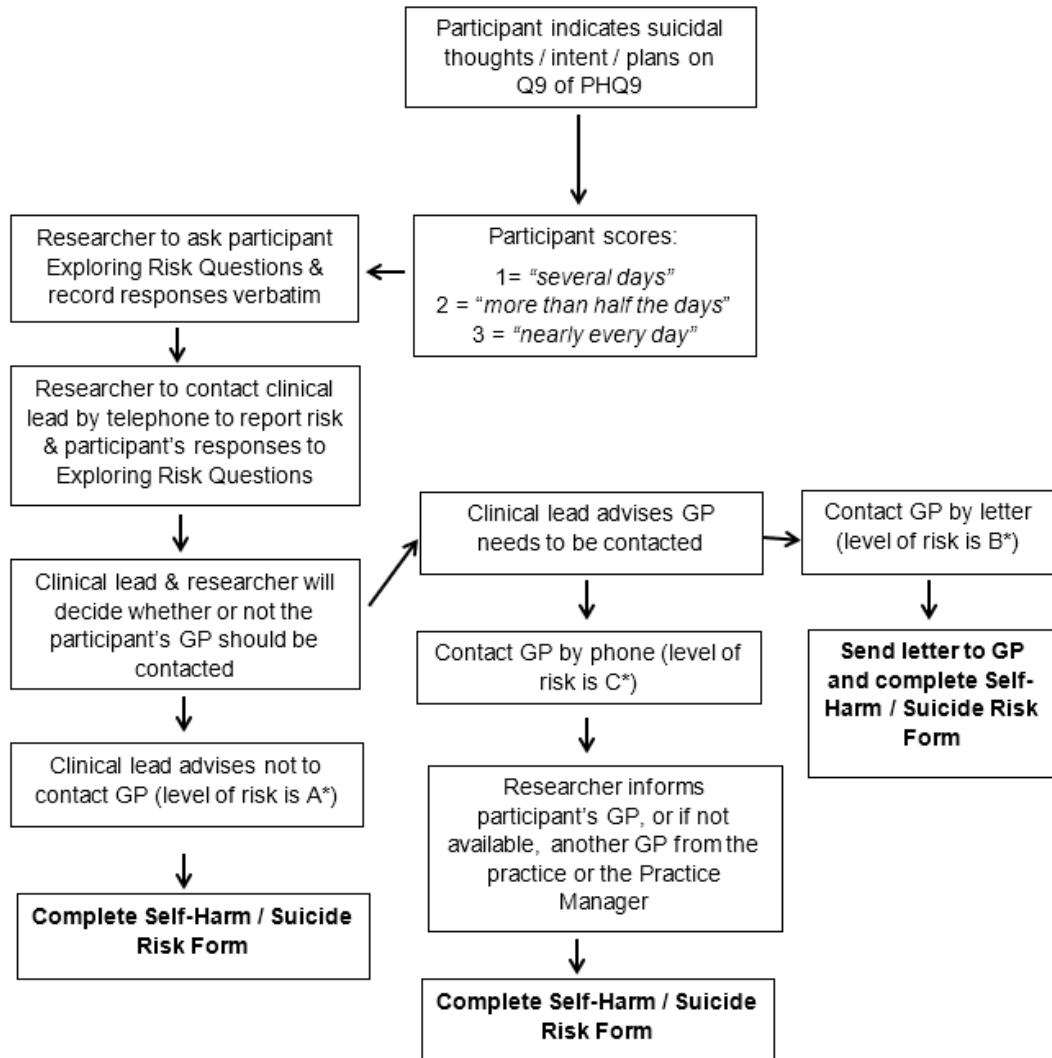


Appendix 48: Study flowchart for the implementation of PHQ-9 to women (second and third studies)



Appendix 49: Self-harm / suicide risk identified via telephone assessment (second and third studies)

Study flowchart 4: Self-harm / suicide risk identified via telephone assessment

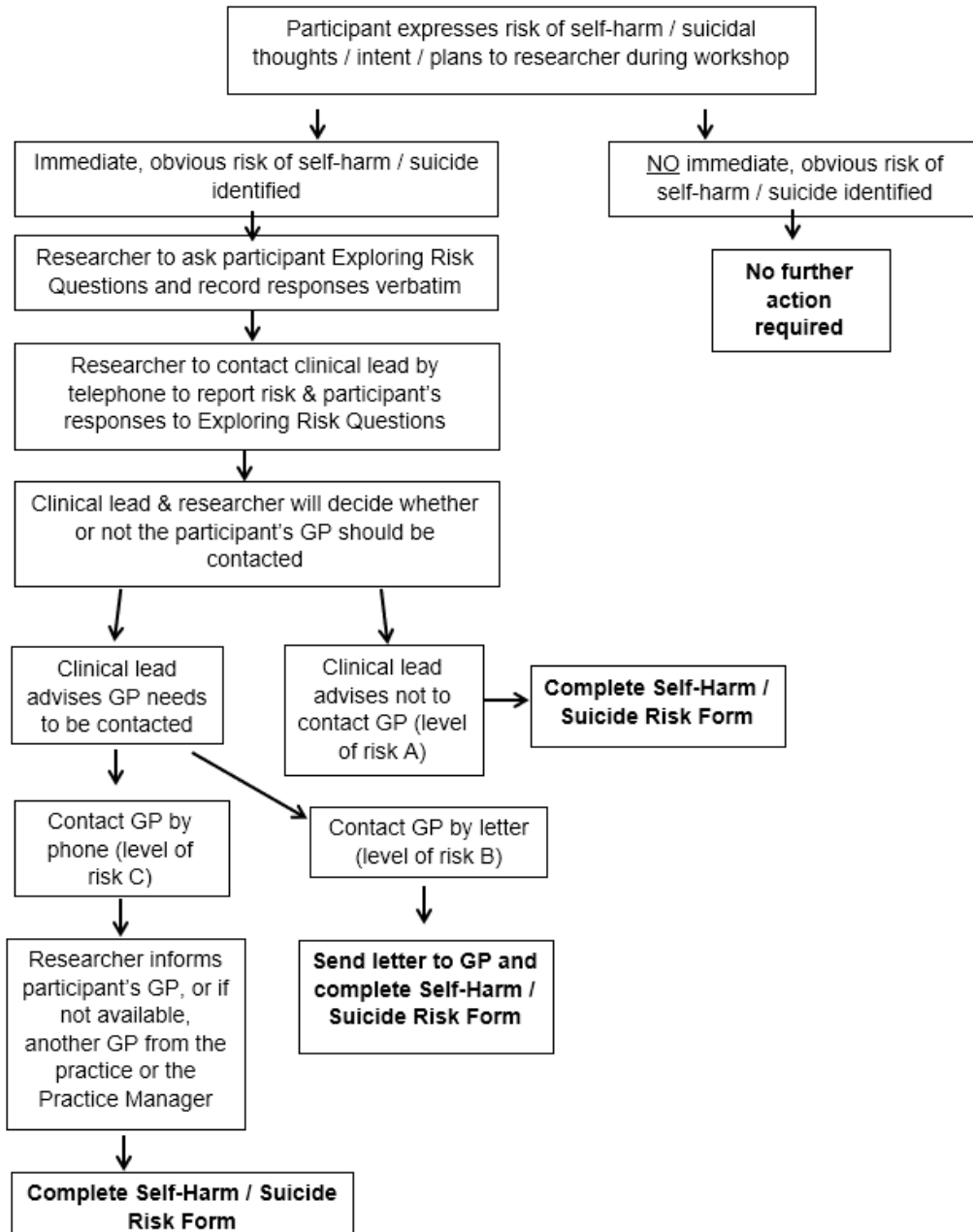


*Exploring risk questions guidance-level of risk

Date: 23/04/2019
Version: 1.0
IRAS ID: 237021

Appendix 50: Self harm / suicide risk identified via interviews / workshops (second and third studies)

Study flowchart 5: Self-harm / suicide risk identified via interviews / co-design workshops



Date: 23/04/2019
Version: 1.0
IRAS ID: 237021

Appendix 51: Self-harm / suicide risk form (second and third studies)

Self-Harm / Suicide Risk Form

The patient below has expressed thoughts of suicidal intent /self-harm on the PHQ-9 during an assessment or during an interview / co-design workshop.

Participant's Name:

Date of Assessment: / /

Risk of suicide / self-harm identified from:

Telephone assessment	PHQ9	<input type="checkbox"/>
Interviews /Co-design workshop		<input type="checkbox"/>

Has the participant been advised to contact their GP? Yes No

Has the GP been sent the Notification of Risk letter? Yes No as advised by clinical lead

Summary of how suicide risk protocol was implemented:

(Which clinician gave advice, what advice was given, was risk judged as passive or active? If advised to contact GP – name of practice, name of GP spoken to, date of contact)

Researcher Name:

Research Signature: Date:

Name of Clinical Contact:

Clinical Contact Signature: Date:

Appendix 52: Exploring risk questions (second and third studies)

Exploring Risk Questions

<p>PHQ- 9: "Can you tell me more about why you answered ("several days" / "more than half the days" / "nearly every day") to the question 'Thoughts you would be better off dead or hurting yourself in some way'?"</p> <p>Details of disclosed thoughts (please record verbatim as far as possible)</p>	
Plans	
1. Do you know how you would kill yourself? If Yes – details	Yes / No
2. Have you made any actual plans to end your life? If Yes – details	Yes / No
Actions	
3. Have you made any actual preparations to kill yourself? If Yes – details	Yes / No
4. Have you ever attempted suicide in the past? If Yes – details	Yes / No
Prevention	
5. Is there anything stopping you killing or harming yourself at the moment? If Yes – details	Yes / No
6. Do you feel that there is any immediate danger that you will harm or kill yourself? If Yes – details	Yes / No

Researcher name:

Researcher signature:

Date:

Date: 23/04/2019

Version: 1.0

IRAS ID: 237021

Appendix 53: Exploring risk questions guidance (second and third studies)

Exploring Risk Questions Guidance

This guidance is to be used to determine the level of risk, A B or C, based on the participant's responses to the six Exploring Risk Questions.

Participant's responses to Exploring Risk Questions

Advise the participant

All answers 'no' apart from Q5 'yes':



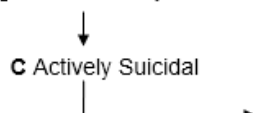
I can see that things have been very difficult for you, but it seems to me these thoughts about death are not ones you would act on – would this be how you see things? (if they say yes) I would advise you to make an appointment to see your GP to talk about these feelings.

'Yes' for any **one** of Qs 1-4; plus 'yes' for Q5 and 'no' for Q6



Things seem to be very hard for you right now and I think it would help if you were to speak to your GP about these feelings. I will be writing to your GP to tell them that you have been here today and have been having some troubling thoughts. I would also advise you to make an appointment to see your GP to talk about these feelings.

Scoring 'no' to Q5 or 'yes' to Q6



I am very concerned about your safety at this moment, I am going to make some telephone calls to your GP/ the emergency services to let them know how you are feeling and to arrange for you to receive immediate help.

Date: 23/04/2019
Version: 1.0
IRAS ID: 237021

Appendix 54: Non-suicide risk form (second and third studies)

Non-Suicide Risk Form

The participant below has been identified as being a risk other than self-harm/ suicide during an interview / co-design workshop.

Participant's Name:

Date of Assessment: / /

Risk identified and how:

Summary of how risk protocol implemented:

(Which clinician gave advice, what advice was given, was risk judged as passive or active? If advised to contact GP – name of practice, name of GP spoken to, date of contact)

**Researcher
Name:**

.....
Research Signature: **Date:**

Name of Clinical Contact:

Clinical Contact Signature: **Date:**

Date: 23/04/2019

Version: 1.0

IRAS ID: 237021

Appendix 55: GP notification letter (second and third studies)

Notification of risk letter to General Practitioner |

Dear Dr XXX/Practice Manager

Re:

An exploration of women's experiences of perinatal low mood/depression and health professionals' experiences of providing care for women who have perinatal low mood/depression

OR

Development and adaptation of a Behavioural Activation intervention manual intended for delivery by non-mental-health specialists for the treatment of perinatal depression

Your patient, XXX, is taking part in the above study. As part of this study, we assess the women's depressive symptoms using the Patient Health Questionnaire-9.

I am writing to let you know that responded with a score of "XXX" on Question 9 "Thoughts that you would be better off dead or of hurting yourself in some way" on the PHQ-9. Her overall score on the PHQ-9 was XX.

In response to further questioning, the patient stated "XXXXXXXXXX".

I have recommended that she make an appointment to come and see you and discuss this further.

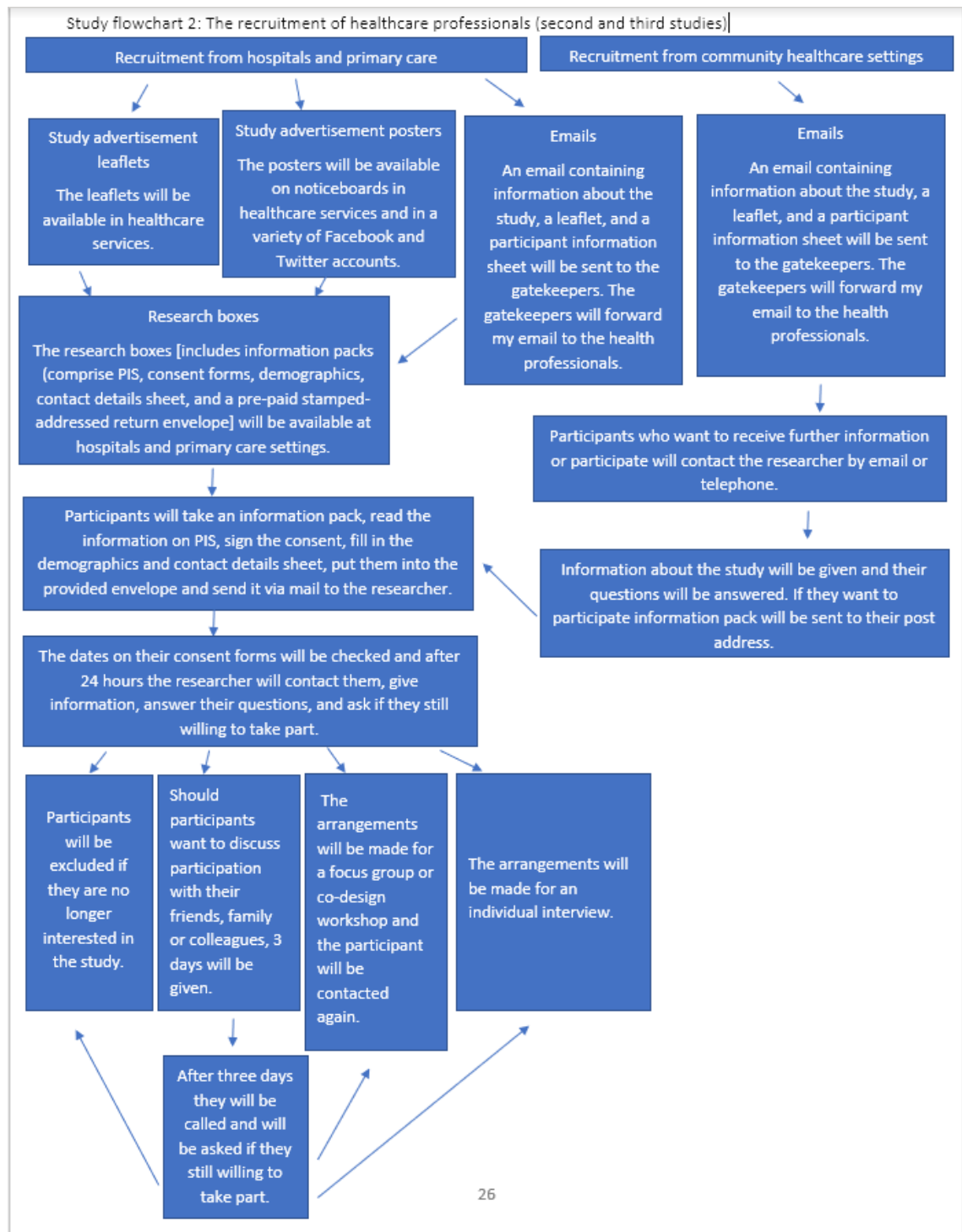
As ever, the clinical management of this patient remains your responsibility, but it is part of our study protocol to inform you of any suicidal thoughts disclosed to ourselves so that you can take account of them in your clinical management of this patient.

Yours sincerely,

The chief investigator
PhD Student Semra Pinar

Clinical Lead
Dr Dean McMillan

Appendix 56: Study flowchart for the recruitment of healthcare professionals (second and third studies)



Appendix 57: Lone working contact sheet for interviews at home (second study)

LONE WORKING CONTACT SHEET

Researcher's details

Researcher's name:

Researcher's mobile numbers:

Researcher's home number and address:

Personal/home details of contact person

Name:

Mobile number:

Home number:

Academic supervisor contact

Name:

Mobile number:

Interview details

Date of lone working:

Names of research participants (interviewees):

Full address of participant (or interview location if not interviewee's home):

Travel plans and transport arrangements:

Mobile contact number during interview:

Estimated time of departure from home:

Estimated time of arrival (at interview location):

Estimated time of departure (from interview location):

Estimated time of arrival at home (from interview location):

Appendix 58: Health Sciences Research Governance Committee approval (second study)



DEPARTMENT OF HEALTH SCIENCES

c/o Department of Philosophy
Heslington
York YO10 5DD

Telephone (01904) 323253
Fax (01904) 321383

Chair, Health Sciences Research
Governance Committee

www.york.ac.uk/healthsciences

6 July 2018

Miss S Pinar
University of York
Department of Health Sciences
York
YO10 5DD

Dear Semra

Perinatal depression – views of women and healthcare professionals

Thank you for resubmitting the above project to the Health Sciences Research Governance Committee for review. Your application was considered by the committee at its meeting on 2 July 2018.

I am pleased to report that the committee approved the project being sent out for NHS REC review.

I was asked to feedback the following points, which you must take up with your supervisors.

- It is important that documents do not state that that the study 'has gained ethical approval from the Department of Health Sciences Research Governance Committee, the University of York' (e.g., Information Sheet). The HSRGC has not approved the study; rather, the HSRGC has approved sending the study through IRAS, so it's the NHS REC that should be named as providing ethical approval.
- The committee weren't sure whether the phone number on the Information Sheet – 07729 070393 – is a personal number, so reiterated that only work contact details, not personal contact details, are to be provided.
- The committee raised two points about withdrawal from the study. (i) The Consent Form states, 'After completing the interview my withdrawal from the study would not be permitted', and the Information Sheet states, 'after completing the interview your withdrawal from the study would not be permitted'. These should be reworded to clarify that it means that data from participants who withdraw will still be included in the analysis. (ii) The study documents state, '... and it is not possible to receive a gift card in withdrawals.' The committee's view is that it's fine to withhold the gift card if the

participants withdraw before the end of interviews, but participants who withdraw after the interview should still receive a gift card.

- The main point of discussion centred on the inclusion criteria for the study. The IRAS form states, 'if the women's PHQ-9 score is between zero and nine, they will be eligible for an interview. If they score ten or above, it will be explained that their current level of symptoms means they will not be able to take part in the study'. But women who score between 5 and 9 on the PHQ-9, though not clinically depressed, are experiencing low levels of depression. So the committee suggest you think about whether you want the exclusion criterion to be clinical depression (in which case, the form can stay as it is) or clinical and low-level depression (in which case, the exclusion criterion on the form should change from 'PHQ-9 score between zero and nine' to 'PHQ-9 score between zero and five'). Both criteria can be justified; the point is to be really clear as to which will be applied on the form.

Please send us the NHS REC approval for our records, when you receive it. In the meantime, if you have any queries regarding this decision or feedback, or make any substantial amendments to the study, please contact me.

Yours sincerely

██████████

██████████████████

Chair: HSRGC

cc: Dr Helen Bedford, Dr Dean McMillan, Prof Steven ~~Exssg~~

Appendix 59: Research and Enterprise directorate approval (second study)



RESEARCH & ENTERPRISE DIRECTORATE

University of York
RCH/120, Ron Cooke Hub
Heslington
York YO10 5GE

Contracts & Sponsorship Manager:

Telephone +44 1(0)1904 328693
Email:

Ms Semra Pinar
Department of Health Sciences
University of York

12 November 2018

Dear Ms Pinar,

Project title: An exploration of women's experiences of perinatal low mood/depression and health professionals' experiences of providing care for women who have perinatal low mood/depression (the "Study")

Chief Investigator: Ms Semra Pinar

IRAS Project ID: 237021

The University of York (the "Sponsor") confirms that it shall act as the sponsor of the Study within the meaning of the UK Health Departments' Policy Framework for Health and Social Care Research (v3.3, November 2017) (the "Framework") and will fulfil such responsibilities as set out in the Framework, including, without limitation:

- Establishing proportionate, effective arrangements to conduct, monitor and report on the Study in accordance with the conditions of the research ethics committee favourable opinion and all other relevant approvals
- Ensuring that there are in place appropriate insurance arrangements
- Ensuring that the Study has obtained a favourable ethical opinion and all other relevant approvals before the research starts

Reporting and other conditions

- Starting the research only when the Sponsor has confirmed that everything is in place for it to begin
- Throughout the course of the Study you are required to make the following notifications:
 - Notify the Sponsor of amendments to the Study prior to submission for ethical or other relevant approval body review
 - Notify the Sponsor of suspected serious breaches of the research protocol or breaches of confidentiality or data security
 - Notify the Sponsor of adverse events exhibited by participants directly arising from the conduct of the Study
 - Submit annual and end of study reports to the ethics committee and other relevant approval bodies, notifying the Sponsor of the submission of such reports and providing copies
 - Within 90 days of the end of study, notify the ethics committee, other relevant approval bodies and the Sponsor of the end of the Study

Yours sincerely,



Sponsor Representative

Cc: Dr Helen Bedford, Dr Dean McMillan, Professor Steven Ersser

Research Sponsor Letter_v1.3, 01/11/2018

Project Ref: RE18_041_237021

Appendix 60: Health Research Authority Approval (second study)



Ms Semra Pinar
Research Centre for Social Sciences
6 Innovation Close, University of York
Heslington
YO10 5ZF



Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

18 March 2018

Dear Ms Pinar

**HRA and Health and Care
Research Wales (HCRW)
Approval Letter**

Study title:	An exploration of women's experiences of perinatal low mood/depression and health professionals' experiences of providing care for women who have perinatal low mood/depression
IRAS project ID:	237021
Protocol number:	N/A
REC reference:	19/YH/0004
Sponsor	University of York

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should formally confirm their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a 'green light' email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed [here](#).

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see [IRAS Help](#) for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to [obtain local agreement](#) in accordance with their procedures.

What are my notification responsibilities during the study?

The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The [HRA website](#) also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?

You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Ms Semra Pinar


Email: sp1365@york.ac.uk

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is 237021. Please quote this on all correspondence.

Yours sincerely


HRA Assessor

Email: 

Copy to:  University of York, (Sponsor Contact)
 NHS Foundation Trust,
(Lead NHS R&D Contact)

Appendix 61: Research Ethics Committee approval (second study)



Health Research
Authority

Yorkshire & The Humber - Leeds West Research Ethics Committee
NHSBT Newcastle Blood Donor Centre
Holland Drive
Newcastle upon Tyne
NE2 4NQ

Telephone: 0207 104 8086

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

18 March 2019

Ms Semra Pinar
Research Centre for Social Sciences
6 Innovation Close, University of York
Heslington
YO10 5ZF

Dear Ms Pinar

Study title:	An exploration of women's experiences of perinatal low mood/depression and health professionals' experiences of providing care for women who have perinatal low mood/depression
REC reference:	19/YH/0004
Protocol number:	N/A
IRAS project ID:	237021

Thank you for your letter of 19th February 2019, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Alternate Vice Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

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

Conditions of the favourable opinion

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

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

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at <http://www.rdforum.nhs.uk>.

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

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

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

Registration of Clinical Trials

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

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

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

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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

Ethical review of research sites

NHS sites

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

Approved documents

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

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Leaflet for healthcare professionals]	Version 1	22 October 2018
Copies of advertisement materials for research participants [Poster for healthcare professionals]	Version 1	22 October 2018
Copies of advertisement materials for research participants [Leaflet for women]	Version 1	22 October 2018
Copies of advertisement materials for research participants [Advertisement for electronic display- for women]	Version 1	22 October 2018
Copies of advertisement materials for research participants [Poster for women]	Version 2	05 February 2019
Covering letter on headed paper [Cover letter as a response to the provisional opinion letter]	1	05 February 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Evidence of insurance]		23 July 2018
GP/consultant information sheets or letters [GP notification letter]	Version 1	22 October 2018
Interview schedules or topic guides for participants [Focus groups topic guides for healthcare professionals]	Version 1	22 October 2018
Interview schedules or topic guides for participants [Individual interviews topic guides for healthcare professionals]	Version 1	22 October 2018
Interview schedules or topic guides for participants [Individual interviews topic guides for women]	Version 1	22 October 2018
IRAS Application Form [IRAS_Form_19022019]		19 February 2019
Letter from funder [Funding letter from Turkish Government]		23 June 2016
Letter from sponsor [Sponsorship letter]		12 November 2018
Non-validated questionnaire [Demographics form for healthcare professionals]	Version 1	15 June 2018
Non-validated questionnaire [Contact details sheet for healthcare professionals]	Version 1	15 June 2018
Non-validated questionnaire [Contact details sheet for women]	Version 1	15 June 2018
Non-validated questionnaire [Demographics form for women]	Version 2	05 February 2019
Other [Letter from sponsor to support the Chief Investigator]		13 December 2018
Participant consent form [Consent for healthcare professionals]	Version 1	22 October 2018
Participant consent form [Consent for women]	Version 2	05 February 2019
Participant information sheet (PIS) [Participant information sheet for women-online]	Version 1	22 October 2018
Participant information sheet (PIS) [Participant information sheet for healthcare professionals]	Version 2	05 February 2019

Participant information sheet (PIS) [Participant information sheet for women]	Version 2	05 February 2019
Referee's report or other scientific critique report [University of York Health Sciences Research Governance Committee report]		06 July 2018
Referee's report or other scientific critique report [University of York Health Sciences Research Governance Committee decision on changes]		01 November 2018
Research protocol or project proposal [Research protocol]	Version 2	05 February 2019
Summary CV for Chief Investigator (CI) [CV]		02 November 2018
Summary CV for student [CV-Ms Semra Pinar]		02 November 2018
Summary CV for supervisor (student research) [CV-Dr Helen Bedford]		13 June 2018
Summary CV for supervisor (student research) [CV-Dr Dean McMillan]		11 June 2018
Summary CV for supervisor (student research) [CV-Prof Steven Ersser]		13 June 2018
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flowchart of protocol]	Version 1	22 October 2018
Validated questionnaire [The Patient Health Questionnaire for women]		

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form

available on the HRA website:
<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:
<https://www.hra.nhs.uk/planning-and-improving-research/learning/>

19/YH/0004	Please quote this number on all correspondence
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With the Committee's best wishes for the success of this project.

Yours sincerely


pp


Alternate Vice Chair

Email: nrescommittee.yorkandhumber-leedswest@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to:  University of York

Appendix 62: Health Sciences Research Governance Committee approval (third study)



**DEPARTMENT OF
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Chair, Health Sciences Research
Governance Committee

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7 December 2018

Ms S Pinar
University of York
Department of Health Sciences
York
YO10 5DD

Dear Semra

Development of Behavioural Activation intervention manual

Your study was reviewed at the meeting of the HSRGC on Tuesday 4 December 2018. The committee approved the study to go forward to the NHS REC.

- I was asked to point out that only work, not personal, mobile phone numbers should be included in study documents.

If you have any queries regarding the decision or feedback, or make any substantial amendments to the study, please contact me. Finally, if you intend to submit this letter or any other correspondence from the HSRGC as part of your assessed work (e.g., to demonstrate that your study has ethical approval) please make sure you edit the letter so as to maintain anonymity.

Yours sincerely

[REDACTED]

[REDACTED]

Chair: HSRGC

cc. Dr Dean McMillan, Dr Helen Bedford, Prof Steven Exser

Appendix 63: Health Research Authority approval (third study)



Health Research Authority

Yorkshire & The Humber - Leeds West Research Ethics Committee

NHSBT Newcastle Blood Donor Centre
Holland Drive
Newcastle upon Tyne
NE2 4NQ

Tel: 0207 104 8018

13 August 2019

Ms Semra Pinar
Research Centre for Social Sciences
6 Innovation Close, University of York
Heslington
YO10 5ZF

Dear Ms Pinar,

Study title:	An exploration of women's experiences of perinatal low mood/depression and health professionals' experiences of providing care for women who have perinatal low mood/depression
REC reference:	19/YH/0004
Protocol number:	N/A
Amendment number:	Substantial Amendment 1, 23/04/2019
Amendment date:	23 April 2019
IRAS project ID:	237021

The above amendment was reviewed the Sub-Committee in correspondence.

Summary of Amendment

The first phase of my PhD project involved a systematic review of psychological interventions delivered by non-mentalhealth specialists for the treatment of perinatal depression. I found a gap in the evidence regarding the effectiveness of Behavioural Activation (BA) for the treatment of perinatal depression. This led me to seek to consider modification of BA to meet the specific psychological needs of perinatal women with the involvement of women and healthcare professionals.

The second phase of my project is an experience-based co-design approach which has two phases. In phase 2a, I have planned to explore women's experiences of perinatal low mood/depression and healthcare professionals' experiences of providing care for women who have perinatal low mood/depression. This will help me to shape the prototype of the BA intervention manual and guided self-help booklet. The protocol for phase 2a has been reviewed and approved. In phase 2b, I will use the outcomes from phase 2a to inform the development and adaptation of a BA intervention manual and guided self-help booklet intended for delivery by non-mental health specialists for the treatment of perinatal depression. The protocol and submission for phase 2b are congruent with previous submission, phase 2a. All the process will be the same as the phase 2a. The only difference is the data collection method which will be codesign workshops involving both women and healthcare professionals. In the research protocol, I aimed not to duplicate information which has been provided before, but only provide information related to phase 2b using 'track changes'.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Copies of advertisement materials for research participants [HP - Study Advertisement Leaflet]	1	23 April 2019
Copies of advertisement materials for research participants [Women - Study Advertisement Poster]	1	23 April 2019
Copies of advertisement materials for research participants [HP - Study Advertisement Poster]	1	23 April 2019
Copies of advertisement materials for research participants [Study Advertisement Information]	1	05 August 2019
Copies of advertisement materials for research participants [Study Advertisement Poster / Leaflet - HCP]	1	05 August 2019
Copies of advertisement materials for research participants [Study Advertisement Poster / Leaflet - Women]	1	05 August 2019
Covering letter on headed paper [Covering Letter]		
GP/consultant information sheets or letters [Notification of risk letter to General Practitioner]	1 - Highlighted	05 August 2019
Interview schedules or topic guides for participants [Co-design Workshop Topic Guide]	1	23 April 2019
Non-validated questionnaire [Patient Health Questionnaire-9 for women participants]	1	23 April 2019
Notice of Substantial Amendment (non-CTIMP) [Notice of Substantial Amendment]	Substantial Amendment 1, 23/04/2019	23 April 2019
Other [Contact Details Sheet for Healthcare Professionals]	1	23 April 2019
Other [Contact Details Sheet for Women]	1	23 April 2019
Other [Study Flowcharts]	1 - Highlighted	23 April 2019
Other [HSRGC Decision Letter]		07 December 2018
Other [Organisation Information Document]	2	18 July 2019
Other [Schedule of Events]	2	23 April 2019
Other [Demographics Form for Women]	1 - Highlighted	05 August 2019
Participant consent form [Participant Consent Form for Healthcare Professionals]	1	23 April 2019
Participant consent form [Participant Consent Form for Women]	1	23 April 2019
Participant information sheet (PIS) [HP - Participant Information Sheet]	1	23 April 2019
Participant information sheet (PIS) [Women - Participant Information Sheet]	1	23 April 2019
Research protocol or project proposal [Protocol]	3 - Tracked Changes	23 April 2019

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

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

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

19/YH/0004:	Please quote this number on all correspondence
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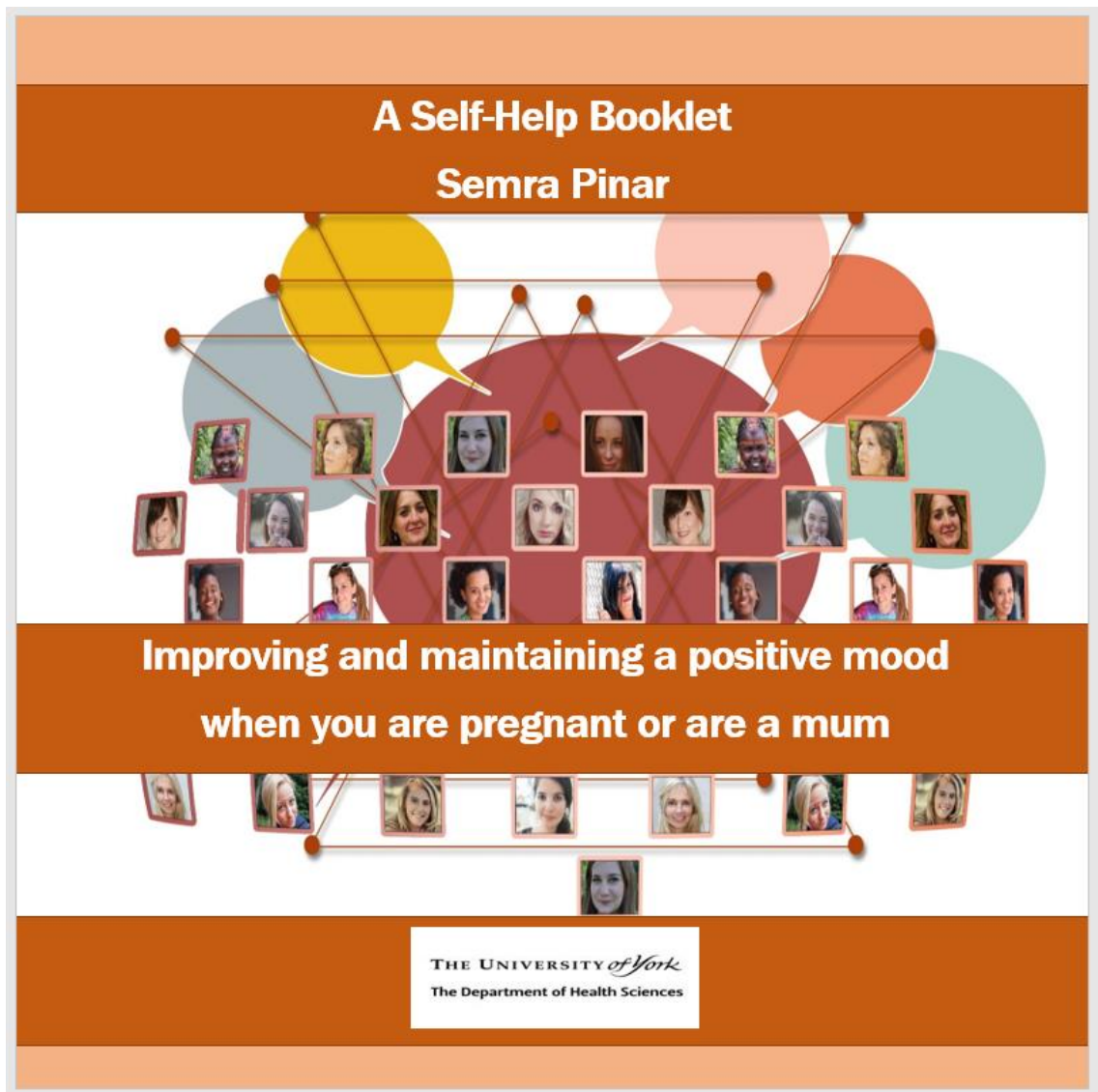
Yours sincerely

PP

A redacted signature consisting of several black circles of varying sizes arranged in a pattern that suggests a name, but the text is obscured.

Chair

E-mail: nrescommittee.yorkandhumber-leedswest@nhs.net



A 6-stage plan to help you keep a positive mood when you are pregnant or are a mum

It is very common for mothers and expectant mothers to experience low mood and it is hard to admit sometimes. It is okay to share your feelings with your friends, family, midwife, health visitor, general practitioner and support worker. **We are here to help and support you.**

This booklet is about improving low mood for women who are pregnant or mums with a child under a year. We hope that working through it with your support worker will help you to learn how to improve your mood, as this is important to your health and wellbeing.

Support workers play an active role in maternity services and community services and have regular contact with midwives, health visitors and other healthcare professionals. Working with you and tailoring the guidance in this booklet to your specific situation, is one of several tools available to help you.

There is other help available if this booklet does not work for you and there are a variety of things that can be tried. You can find contact details for a few of these support sources in the last page of this booklet. For locally available sources please ask your support worker. If you cannot cope with your feelings or need urgent care, you can call 111, a free NHS helpline service.



Some mothers, who have experienced low mood during pregnancy or in the first year after childbirth, have been interviewed about their experiences of low mood and their related experiences have been extracted and used in this booklet. We hope you find them helpful. Many other women experience similar feelings that you have been experiencing so far. **You are not alone!**

“...you're not alone. It can feel quite isolating and overwhelming. I think if you're brave enough to talk about it you will find out that lots of other people are also feeling the things that you're feeling and thinking the things that you're thinking. So I just think it's be brave and talk to people...”(Katherine, first time mother)

The booklet is divided into six stages. It may be helpful to work through each stage to understand **how what you do can have an impact on how you feel.**

This booklet:

- Provides information about low mood
- Encourages you to make links between what you do and how it makes you feel
- Offers guidance on how to recognise low mood symptoms and prevent them getting worse
- Provides a way of managing your wellbeing



The stages to keeping well

Stage 1 (page 4)

Understanding risk factors and recognising symptoms of low mood

Understanding what low mood is, so that you can start to manage it

Stage 2 (page 10)

The value of keeping a diary

Looking at your own activities and recognising how they affect your mood

Stage 3 (page 13)

Three types of activity...

...and planning to keep a balance

Stage 4 (page 19)

Breaking things down to make them easier to manage

Stage 5 (page 22)

Keeping up your activities when you become pregnant or have a baby

What you get out of what you do

Finding other ways to be active and improve your mood

...if you can no longer do the things you used to do

Stage 6 (page 27)

Making an action plan to stay well

What to do if you notice symptoms of low mood getting worse again in the future and planning to stay well

Stage 1: Understanding risk factors and recognising symptoms of low mood

Some factors that can lead to low mood

It is quite common to experience low mood when you are pregnant or have a baby. About one in four of us will have some symptoms in our life, and one in five of us in pregnancy or after childbirth.

Some risk factors have been listed below. There may be other risk factors, for example, hormonal changes, sleep disturbances, social isolation, changes in routines and roles, and life-changing events, or there may be no risk factors and it can be the factor of coming to terms with pregnancy and motherhood.



Risk factors for low mood during pregnancy or in the first year after childbirth:

- Previous depression or anxiety
- Financial difficulties
- Domestic violence
- Stressful life events, such as lack of partner or daily hassles for example work hassles
- Lack of support from partner, family and friends
- Pregnancy problems, such as morning sickness
- Complications after the birth, such as bleeding
- Newborn problems, such as infant crying.

“...I was taken back into surgery ... for bleeding ... and because I didn't have the close time with her during those early days, I felt like the bond was lost immediately and I just started feeling very, very depressed. I didn't know it was postnatal depression until several months later. I just thought it was normal to feel that way after such a medical crisis....” (Louise, first time mother)

Recognising symptoms of low mood

Some mothers or expectant mothers:

- are less likely to recognise symptoms of low mood
- may think that how they are feeling is part of being pregnant or baby blues
- are reluctant to share their true feelings with friends and family and hide it from healthcare professionals. As a result, low mood is often not recognised or treated in women. Not addressing this aspect of women's health can affect the general wellbeing of the women and their family.



Therefore, spotting signs of low mood is important, as having persistent low mood is a risk factor for your health, both physically and psychologically.

"...I didn't recognise depression in the beginning or low mood. I just thought it was sleep deprivation..." (Marie, first time mother)

"...I didn't really notice it at the time, I just thought that I was tired and obviously I was pregnant and I was tired and not sleeping very well. But I felt very down then and didn't have much energy but I guess some of that is normal for being pregnant but when it's your first time pregnant you don't really know how you're supposed to feel. So that was the first time. But then it became more obvious..." (Lisa, first time mother)

"...I used to feel very embarrassed by it and I do think there used to be quite a lot of stigma around it. But the more people you are honest with, the more you explain how you're feeling, I've had really positive responses too and I have found myself picking up on signs that someone else isn't right and having a chat with them and then being able to tell them how I felt and share that experience, so I'm no longer embarrassed about it. It is what it is..." (Katie, first time mother)

Key signs of low mood

Key signs that your mood may be worsening include **feeling down or losing interest, motivation or pleasure in doing things.**

While we all feel low from time to time, if these feelings are there most of the time and carry on for a few weeks, then it may be a sign that these problems need addressing to help you feel better. When this is the case there may be a number of other signs that can be present.

Not everyone will have all of these signs, but some are likely to be there and noticing them is the first step to staying well.

- ✓ **Changes in eating:** Some women lose their appetite or do not have the motivation to cook healthy meals when they feel low in mood. Other women eat much more, even at night.
- ✓ **Changes in behaviour:** Some women isolate themselves and lose contact with family and friends. Other women continue their routines without enjoyment and experience difficulty bonding with the baby.
- ✓ **Changes in thinking:** Some women feel worthless or have upsetting thoughts. This may include forgetfulness, finding it much more difficult to concentrate or to make decisions. It can also include thinking about ending your life or harming yourself or others.
- ✓ **Changes in sleeping:** Some women with low mood sleep much more than usual. Other women find getting to sleep much more difficult or wake up much earlier than normal and struggle to get back to sleep. It is common to have sleep problems in pregnancy due to pregnancy symptoms, so this can make sleep problems worse. A newborn baby's sleep pattern can be quite erratic. If you are unable to sleep when your baby sleeps, this may be a sign of low mood.
- ✓ **Changes in energy:** Some women with low mood feel they have much less energy than usual and they feel tired all the time or are very restless and need to move around a lot more than usual.



6

“...I've never known such complete disorientation, everything that was my normal had just disappeared...” (Katie, first time mother)

Key signs of low mood during pregnancy and after childbirth

Being pregnant or having a newborn baby can make it much more likely to experience these symptoms, such as:

- ✓ Feeling morning sickness, tired, overwhelmed, useless, lack of energy or lack of sleep
- ✓ Difficulty in doing the things you used to be able to do, for example getting out and about to see other people, doing jobs about the house and so on
- ✓ Loss of your usual role, changes in your work life and daily routines, changes in your body image, or loss of independence and identity.

Around the 4th day after giving birth, hormonal changes in your body can lead to emotional mood swings commonly known as the 'baby blues'.

- ✓ Most mothers become emotional during these days and it might be hard to differentiate it from low mood
- ✓ If the signs carry on for a few weeks or more, it can be more of a sign of depression
- ✓ It is important to deal with the symptoms of low mood as early as possible before they get worse.

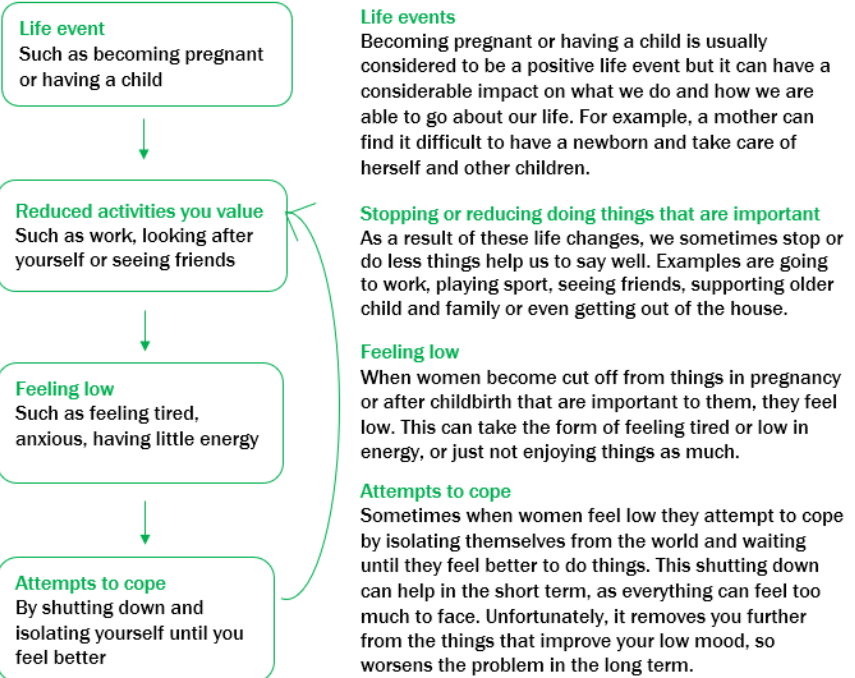
If any of the above apply to you, then thinking about how these events may have impacted on your mood is important, because it is the first step in taking control of how you feel.

"...I was crying quite a lot and I thought it was a little bit more than I expected, so I knew that I'd get the baby blues and you feel a bit low sometimes but that happened and it was okay and I could recognise what was going on and I felt alright dealing with it. But a little bit later I thought it was too much and I couldn't talk myself out of it and it was about silly things like, not being able to open a tin of tuna or, you know, really little things..." (Ollie, first time mother)

"...I think motivation to do things to go out and do things. Like I say, I didn't take very good care of myself. I lost my appetite. I wasn't eating properly. I lost a load of weight. I looked ill, I looked gaunt. What else? I wasn't bothering with brushing my hair. I would have a wash but I wouldn't have a proper shower or a bath, I would literally have a quick wash because it was so difficult trying to do anything with a baby that wants my attention all the time so I didn't look after myself very well. Like I say, I didn't really want to leave the house ..." (Katie, first time mother)

The cycle of reduced activities and low mood

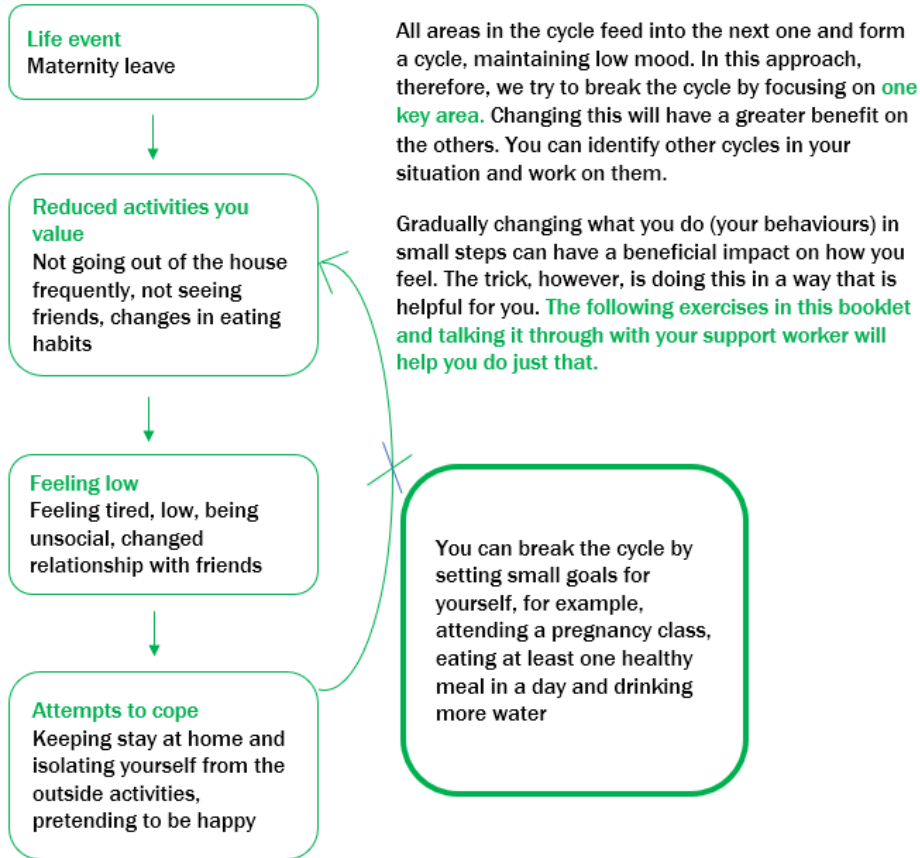
The flowchart below describes what keeps the symptoms of low mood going.



"...lack of sleep, struggling to eat, struggling to drink, not being able to do any of my normal activities and then having work taken away from you as well, which was a good distraction, those last few weeks, that's when I really started to lose the plot a little bit..." "...Very much isolated myself. didn't want to go out. I felt low. I had to pretend to be happy about things..." (Katie, first time mother)

The cycle of reduced activities and low mood

An example is given below. The cycle summarises the aim of this booklet



Your mood has gradually deteriorated; therefore, it will gradually get better. It is important to take time for yourself.

Stage 2: The value of keeping a diary

Looking at your own activities and recognising how they affect your mood

If you are experiencing low mood and recognise a cycle, there are things you can do:

- It is possible to break the cycle by changing some of your behaviours.
- If a change is made to one part of the cycle, what you already do being the easiest, this can have a positive effect on the whole negative cycle.
- Gradually bringing back into your life those things you have been doing less or avoiding will hopefully lead to a greater sense of achievement and motivation. It will eventually bring interest back into your life.



When you have low mood, it is unlikely you will have stopped doing many or all activities. Some people find that keeping a diary of their activities each day for one week is really useful.

Keeping a diary and noting down how you are feeling by doing or not doing activities and their effects on your mood, will help you to manage your low mood.

Keeping a diary and noting your mood each day for one week will help you to monitor your activities and how they are making you feel. People sometimes comment that keeping a diary has given them a better understanding of their mood patterns.

We rarely connect what we are doing with how we are feeling, so if you notice an unhelpful pattern, you can make changes to your behaviour which may improve your mood.



A scale to use on scoring your mood level

“...I think one of the problems that I actually had was going out. So when you're about to have a baby you sort of told that leaving the house is really difficult because you've got to make sure you've got everything and the baby will need changing before you going and all these things happen but actually leaving the house and being out was really easy...” (Ollie, first time mother)

Use the diary chart on the next page to monitor the activities you could or could not do and your mood over the next week to see if you can identify any patterns. An activity can be anything you do, for example meeting with friends, going out for a walk, shopping, reading, working, watching TV, having a shower, sleeping, feeding baby, playing with baby, washing up, doing laundry, etc. Even if you think you are not doing anything, just sitting, rate how you are feeling. An example diary is given below.

An example diary of Alexandra (24 weeks pregnant)

What did you do or did not do and how do you feel?	Monday Date: 7 Oct	Tuesday Date: 8 Oct	Wednesday Date: 9 Oct	Thursday Date: 10 Oct
Morning	Couldn't sleep – mood 2	Woke up two times at night – mood 3	Woke up one time at night – mood 4	Woke up two times – mood 2
Afternoon	Working – mood 3	Working and feeling exhausted – mood 2	Working – mood 4	Working and feeling sleepy – mood 2
Evening	Cooked – 4 Had a shower – 4	Could not eat -2 Watched TV-4	Laundry – mood 3	Cooked and washed up - 2
Night	Read a book - 4	Ate a cake – mood 2	Had a shower – mood 4	Went to bed early - 4

An example diary of Sophia (a new mum)

What did you do or did not do and how do you feel?	Friday Date: 11 Oct	Saturday Date: 12 Oct	Sunday Date: 13 Oct
Morning	Woke up three times at night – mood 3	Feeling exhausted – mood 2	Slept until afternoon – mood 4
Afternoon	Ate two slices of a loaf – mood 2	Ate pancakes – mood 3; couldn't do laundry mood 2	Had a full breakfast – mood 4
Evening	Went for a shopping – mood 4	Met with friends – mood 4	Couldn't do laundry – mood 3 Played with baby - 4
Night	Had a shower – mood 4	Feeding, changing, bathing the baby – 3	Watched TV – mood 4



My diary:

What did you do or did not do and how do you feel?	Monday Date:	Tuesday Date:	Wednesday Date:	Thursday Date:
Morning				
Afternoon				
Evening				
Night				

What did you do or did not do and how do you feel?	Friday Date:	Saturday Date:	Sunday Date:
Morning			
Afternoon			
Evening			
Night			



Stage 3: Three types of activity, and planning to keep a balance

There are three different types of activity. If we have a balance of all three in our lives, we are more likely to keep well. It is important to not give priority to pleasurable activities all the time. **It should be balanced with routine and necessary activity types.**

Some women may get help from their partners and family while others may be living alone with their children. Everyone is different and what one person sees as necessary, another may see as pleasurable.



Routine

These are activities such as eating healthily, having a shower, feeding the baby, changing the baby, bathing the baby, looking after other children, cooking, to name but a few.

Necessary

These are activities like going to GP, midwife or healthcare appointments, attending antenatal groups, mother and baby groups, washing up or loading the dishwasher, laundry, shopping, gardening, opening post, paying bills, checking finances and household repairs.



Pleasurable

This is any activity that brings you pleasure or a sense of achievement. It could be reading, watching TV, walking, seeing friends, having a bath, spending time with family, hobbies, etc.

“...starting taking my son to the park. And then the next step was to come inside into the cafe for a drink afterwards. And then we built upon it...And I thought, I can do this. And that was the point where I realised that I could and that I wasn't the illness anymore...”(Gemma, second time mother)

Keeping a balance

To see if you have a balance of these three activity types in your life, have a go at filling in the columns on the next page. List your routine, necessary and pleasurable activities. An example is given below.

It seems like pleasurable activities can be increased in the given example. Ayeshe could ask her partner, friend or family to help her do the housework so she can spend more time on the third activity type.



Example activities of Ayeshe:

Routine

- 1) Going to work
- 2) Having a shower
- 3) Sleeping
- 4) Eating healthily
- 5) Feeding baby
- 6) Changing baby
- 7) Bathing baby
- 8) Cooking

Necessary

- 1) Taking a nap
- 2) Laundry
- 3) Washing up
- 4) Grocery shopping
- 5) Going to midwife or GP appointment
- 6) Vacuuming
- 7) Paying bills
- 8) Attending pregnancy or mother and baby classes

Pleasurable

- 1) Watching TV
- 2) Reading
- 3) Meeting with friends

My activities:

Routine

Necessary

Pleasurable

Look back at the diary you completed on page 12; if you notice an imbalance between the three types of activities this may give you an idea of changes you might make to help you manage your mood.

15

Making plans to maintain a positive mood

As can be seen in the cycle of low mood in stage one of this booklet, it is easy to become cut off from those things that are important to us due to life events. This can result in feelings of low mood, and sometimes to cope with such feelings, we put off or avoid doing things 'until we feel better'. This is understandable as it is hard to keep going with things when we feel down. In the longer term, however, this can mean we are further cut off from those things that are important to us.



In order to break the cycle, it is important to plan activities that reconnect or maintain your connections with things in your world that are important or meaningful to you. We call this planning to maintain a positive mood. This breaks the cycle with the aim of maintaining your contact with those things in your world that are important to you.

This is a useful way of managing low mood. It is called working from the 'outside in'. That is, not waiting to feel better inside to change what you do on the outside, but plan what you do on the outside to make those inside feelings better. **In simple terms; 'don't wait to feel better to do things, do things to make you feel better'.**

Look over the three types of activity on page 15 and your diary on page 12 and **see what activities are linked to you feeling in a more positive mood, and where certain types of activity are missing.** Then use the diary sheets on page 18, or you can make your own table if you wish, to plan these into your days for the coming week. **Start small and over the coming weeks; you can gradually build this up.** You can find an example of a completed diary on the following page.

"...I used to go for a lot of walks and I think in part it gave me something to do so I wasn't thinking so much but also being out in public helped because even if you weren't socialising you were still seeing other people at least..."(Katherine, first time mother)

"...but in the meantime I would force myself out the house. I would go to the mother and baby groups, even though I didn't really feel like it, I'd make myself go because I knew that getting out the house and being with other mums and babies that would help and it did. Definitely help me. So again, even though I felt awful I was strong enough to make myself do things even though I didn't want to..."(Katie, first time mother)

An example of Ruby's diary:

This is only an example. You may not be able to do all the things. You can plan your week on the following page to meet your own needs.

	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
Morning	Getting dress before lunch time	Feeding, changing and bathing the baby	Getting dress before lunch time	Having a nutritious breakfast	Sleeping, resting	Getting dress before lunch time	Having a nutritious breakfast
Afternoon	Going out for grocery shopping	Tidy dirty clothes and put in the basket	Attending a mother and baby group	laundry	Reading, playing with the baby	Meeting with friends at a cafe	Spending time with family
Evening	Calling a friend to talk	Having a nutritious meal	Taking a nap when the baby sleeps	Drinking a cup of tea	Going out for a 15 min. walk	Feeding, changing, bathing the baby	Spending time with family
Night	Spending time with family	Having shower - self care	Watching favourite TV series	Spending time with family	Having shower	Relaxing	Watching favourite TV series

My diary:

	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
Morning							
Afternoon							
Evening							
Night							

Stage 4: Breaking things down to make them easier to manage

Sometimes we stop doing things because they have become too difficult or too big a task to manage. Alternatively, we may find things harder to manage because of being pregnant or having a new baby.



Here are two examples showing how you might feel overwhelmed with all the jobs.

An example of Izabel's Tuesday routine (24 weeks pregnant)

- Izabel went to work, came home and prepared the evening meal
- She loaded the dishwasher, she washed the clothes
- She spent time with family and had a shower

Recently Izabel has noticed this is getting more difficult and by the time she has finished, she is exhausted. So she may have started to neglect these jobs, but is now starting to feel low because of this. There is a pile of dirty clothes waiting to be washed. It now seems like a huge task to get things back in shape.

An example of Laila's Tuesday routine (a new mum)

- Laila went to the mother and baby group, went to a grocery store
- She fed the baby, changed the baby, bathed the baby, played with the baby
- She prepared the meal, washed the dishes

Recently Laila has found herself too tired to prepare a meal for herself, drink enough water or wash the dishes. This has led to her neglecting her own needs. It all seems too much to face; she doesn't feel she can get it done. She also misses spending quality time with her family. This upsets her so she avoid going outside for baby groups and shopping.

"...it made me feel more tired I think when I was low I was really tired and had no energy at all. That was the most challenging thing, to get moving. To do things really. To keep on top of jobs like the housework. It was all too much really...."(Tina, second time mother)

Steps to making the task more manageable

An example of Izabel's Tuesday routine (24 weeks pregnant)

1. Gather all the clothes together after coming home from work
2. Tomorrow, load the washing machine
3. Ask partner for help with drying of the clothes



Over the next week, schedule into your diary or calendar when you are going to spend time with your family and friends and attend an antenatal class. Remember, it does not need to be done all in one day.

An example of Laila's Tuesday routine (a new mum)

1. Make a shopping list and schedule shopping into diary
2. When cooking, make extra portions and freeze
3. Ask other people to help with the housework such as laundry, washing the dishes, dusting and vacuuming



Breaking things down and planning how they can be spread across a week helps to make sure you don't get exhausted and helps you keep up with those things that are good for your mood and your body.

"...whenever I spoke to other mums in those sort of first year or two and even still now sometimes, they were all saying, oh big pile of washing, the house is a mess and we'd all just say, yeh but we've got a baby so it's not that important so I think the housework did take a bit of a back seat. The washing was always done. The laundry was always done. But the cleaning and the hoovering probably took quite a back seat but I think that's probably the same with a lot of new mums..."(Lisa, first time mother)

An exercise to break the jobs down into manageable tasks

Make a list of jobs you have noticed, if any, that are getting too much for you to do all in one go. Or use this space to list jobs you may like to start sharing.

- 1)
- 2)
- 3)
- 4)
- 5)

Use the questions below. Take one job at a time. Try to break it down into manageable or shared tasks. If you find this useful, you may wish to repeat it with an alternative job on a separate piece of paper.

Which job has become, or is becoming, too much to do all in one go?

.....
.....

Is this job essential? Does it need doing all at once?

.....
.....

How can you break this down into more manageable or shared steps?

.....
.....

Timetable the new steps into your diary and see if this helps.

.....
.....

Do you need help to complete this job? How can you get that help?

.....
.....

Stage 5: Keeping up your activities when you become pregnant or have a baby

What you get out of what you do

Why do the activities we do keep us well? The answer is they have benefits. It is not just the individual activity that keeps us well. It is what that activity gives us that is important, for example, the benefits we gain from doing it. Here's an example...

Activity: Meeting with friends

Some benefits of meeting up with friends:

- I like walking there with the pushchair, so it gives me some exercise and I get some fresh air
- I meet other mums and have a chat. This helps me and my baby to socialise with others
- I buy some food from the grocery, so healthy snacks are available. If needed I pop into the post office and pay some bills

As you can see, there are many reasons meeting with friends helps to keep this mum well. It has many benefits and it covers all three activity types, which in turn helps her stay well.



"...but I found that actually trying to be proactive and even if it was just going and meeting a friend for a coffee with the babies helped me to maybe lift out of the low mood a little bit. So I think having support networks is really important to people. Even if you don't talk about how you're feeling you can kind of just have a little bit of time off from thinking about how you're feeling, if that makes sense...."(Ann, first time mother)

"...I really liked walking around in the dark, even though it was 5 o'clock and I liked the fact that I was out in the fresh air but nobody could actually see me. But yeh that definitely helped when I made myself go out and it has always made me feel better...." (Marie, first time mother)

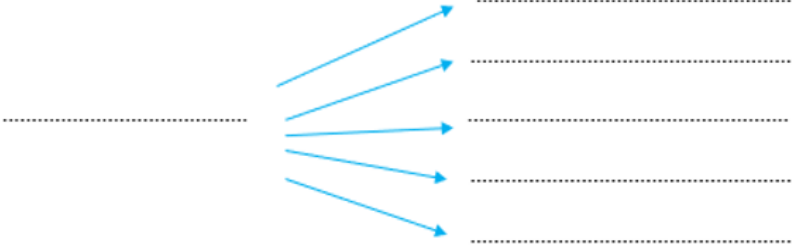
What activities do you do that help to keep you well?

List a range of activities you do and their benefits to you below...

My Activity

Its benefits to me

.....



.....



Finding other ways to be active if you can no longer do an activity you used to do

If the activities I have listed are keeping me well, what if I can't do them anymore?

This is a good question, particularly for women coming to terms with physical health problems such as pelvic floor pain, backache, or who are unable to do activities due to financial reasons or childcare difficulties. The idea is that it is the benefit you get from these activities that keeps you well, not always the particular activity itself.

So, if you can no longer do a certain activity, think about what you can do instead, to retain the benefits you get from it. You may need to consider two or more activities to replace the one you are unable to do.



It may be you are unable to do an activity in the short term. For example, you may be feeling very tired because your child has not been sleeping well recently. Thinking about how to find new things to do in order to maintain the benefits you got from the old activity, is important.

Think about any activities you are no longer able to do, the benefits you got from those activities. Then think about what other things you might be able to do that could bring similar benefits.

"...in the early hours of the morning when everyone's asleep, you've got that group of friends, this group of contacts that you can just message on your phone...are you awake? Yes I'm awake. How are you doing? You know, that sort of thing was really useful..." (Katie, first time mother)

Finding other ways to be active and improve your mood

Here are some examples from women who have experienced depression during pregnancy and after childbirth. Although everyone is different and what works for one person may not work for another.

List of strategies to improve mood:

1. Joining antenatal classes, mother and baby groups
2. Exercise, walking or getting fresh air
3. Yoga, mindfulness or meditation
4. Personal time
5. Working in a job and not bringing work home
6. Asking people to look after the baby
7. Asking people to help in housework
8. Delivery home or going for shopping
9. Having a shower
10. Drinking water, eating healthily
11. Sleeping or taking naps
12. Reading or watching TV
13. Inviting a friend to home
14. Going out of the house for whatever reason
15. Meeting with friends in a cafe
16. Moving baby to her or his own room after 6 months
17. Putting less pressure on yourself
18. Using social media sensibly, finding other mums experiencing low mood and sharing experiences
19. Telephone, email or use social media to chat with friends and family
20. Getting support from family, friends and healthcare professionals
21. Baking cake and cooking
22. Hobbies specific to the person; for example, gardening, painting, crafts, playing a musical instrument, colouring, jigsaws
23. Watching movies, TV series or listening to music
24. Praying or religious activities

Stage 6: Spotting symptoms of low mood and making an action plan to stay well

Hopefully, this booklet has helped you to know a bit more about keeping well. If you feel low again in the future, you can use this booklet and start again. The stages are the same.

Think about yourself. Using the boxes below to help you, list the symptoms which may signal that you are becoming increasingly low in mood.

Pages 6 and 7 may help you to recognise symptoms which some women report when experiencing mood problems.

Changes in appetite: for example, 'The sign I know I am starting to feel depressed is when I start ordering pizza at 11 pm'

.....
.....

Changes in sleeping: for example, 'struggling to get to sleep and waking up early'

.....
.....

Changes in energy: for example, 'not finding the energy to dress, prepare the baby and go out for a walk'

.....
.....

Changes in behaviours: for example, 'not going out or see my friends'

.....
.....

Changes in thoughts: for example, 'I can't be bothered'

.....
.....

Action Plan

What to do if you notice symptoms

We hope you now have more of an understanding of what low mood is, how it is maintained, and how activities can affect your mood. If you spot these symptoms and think they are getting worse, what do you think you could do about it? Please read the useful tips below and the example and write your own action plan on the following page.

Useful tips:

- Look at your activities. Have you stopped doing anything?
- Do you still have a balance of all three types of activity?
- Use your diary to reintroduce the activities you have stopped doing, by planning them into your week.
- Try not to isolate yourself. Call friends and family and talk to them about how you are feeling.
- Make an appointment to see your GP and talk about your symptoms.

An example of a completed Action Plan:

Normally, I like baking a cake and trying new recipes. I'm aware that if I feel low in mood, I won't have the motivation to bake a cake, so my action plan in this situation is as follows:

Day 1. I can choose an easy recipe that I can do really well

Day 2. I can buy the ingredients

Day 3. I can bake the cake and invite my friends for a coffee as a reward for managing the baking.



Here, you can find some messages from healthcare professionals for you...

“...I would like to say that not to be ashamed and not to feel on your own because you are absolutely not on your own and that postnatal depression doesn't stereotype. It can happen to anybody, it doesn't matter who you are or what your job is, it can happen to anybody so I think it's really important that we keep talking about it and it's not a taboo subject that people feel awkward about because it's really really prevalent and it's happening all the time so I think the more we talk about it and the more we realize we should all support each other and try and get that community feel back...”

(a health visitor)

“...making sure you're not trying to carry on at your 100 percent lifestyle, working full time, doing everything else and coping with this and just accepting that you need to slow down a little bit to look after yourself...”

(a midwife)



“...If you're diabetic you take insulin. If you've got an infection you take antibiotics. If you've got a mental health problem why do you think you need to manage it by yourself?...”

(a midwife)

“...if you have a physical injury, like you broke your leg, you might need surgery, you'd probably need painkillers, you might need antibiotics, you might also need some physiotherapy, you might also need some support from somebody to help run you around and it's a similar thing where there's a lot so different layers of treatment that all complement each other, or they should. But you know there's not one single thing that's going to usually fix it, it's usually a combination of different things that will start to make you feel a bit better...”

(a midwife)

NOTES:

31

NOTES:

32

NOTES:

We hope that completing this booklet and discussing it with your support worker has been useful and given you a better understanding of how your activities can help you maintain a positive mood. We hope it has been useful to work through it and that the activities you have found helpful can be used in the future to help you maintain your wellbeing.

Useful organisations:

If you require additional help, information or support, please speak to your GP.

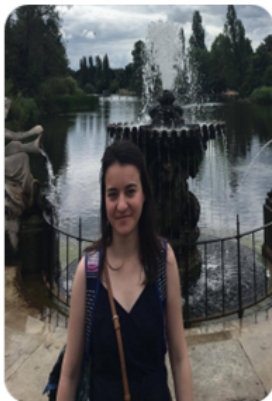
In addition, the following resources may be helpful to you.

NHS t: 111 Free NHS helpline service for urgent care services if you cannot cope with your feelings

PANDAS t: 0843 28 98 401 Pre and postnatal depression advice and support (9am to 8pm, Monday to Sunday)

Mind t: 0300 123 3393 the mental health charity

Samaritans t: 116 123 a charity aimed at providing emotional support to anyone in emotional distress, struggling to cope, or at risk of suicide (Free 24-hour helpline)



THE UNIVERSITY of York
The Department of Health Sciences

Semra Pinar is a PhD student in Health Sciences at the University of York. This booklet has been developed as part of a PhD study with the involvement of women who have experienced perinatal low mood or depression and healthcare professionals who have experience of providing care and support for those women. It is adapted from booklets developed for the CASPER and CHEMIST studies.

UNIVERSITY *of York*
The Department of Health Sciences

**Behavioural Activation Support
Intervention Manual Intended for
Delivery by Maternity Support Workers
for the Treatment of Perinatal
Depression**

Support Intervention Manual

Date: 02/12/2019
Version: 6.0

Introduction

This manual contains guidelines for delivering the Behavioural Activation (BA) support intervention by maternity support workers (MSW) for the treatment of perinatal depression.

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Section A

Principles and Practice of the BA Support for Perinatal Depression

BA intervention manual

This manual was adopted from the CHEMIST study manual (Community Pharmacy Mood Intervention Study), through listening to women's experiences of perinatal low mood or depression and healthcare professionals' experiences of providing support and care for those women, and involving both women and healthcare professionals in co-design workshops where improvements were made to the manual.

This manual consists of a structured management plan whereby MSWs give women information on a psychological intervention known as BA and help them to use it. In addition, the MSWs monitor depression symptom levels during the intervention, in discussion with the women, and **take action** if there are signs of deterioration. The aim is to help women to learn to 'stay well' psychologically by using the BA booklet and with the support from their MSWs, despite the challenges they may experience during pregnancy or in the first year after giving birth.

There is always other help available if this booklet does not work for women and there are a variety of things that can be tried, as written on the last page of the manual and booklet.

What is BA?

BA in basic terms is a set of strategies based on behaviour theory for helping people with low mood and depression. It aims to help women to understand the relationship between their actions (activities) and how they feel.

How does BA work?

BA helps women to re-establish their daily routines and increase activities that they find meaningful or valuable. BA support includes 6 stages as detailed in the booklet. It starts with understanding the risk factors for perinatal low mood and depression and recognising the symptoms (Booklet p. 4). The cycle of reduced activities and low mood (Booklet pp. 8 and 9) aims to help women to realise how they avoid or put off things when they have low mood. Keeping a diary (Booklet p. 10) aims to reduce the avoidance and increase the activities that are meaningful or valuable to them. Some women may find it very hard to start doing activities. Even getting dressed herself before lunchtime might be very challenging. It is important to set achievable and

small goals in the beginning and make it very simple to complete. Breaking things down into easier tasks can also be beneficial (Booklet p.19 and 20) to achieve success in the planned activities. Realising the benefits of activities for them can be helpful to find the motivation to continue their activities (Booklet p. 22). The list of things to improve their mood is provided in the Booklet (p. 25) which were suggested by women who have experienced perinatal low mood or depression.

Recognising the symptoms of low mood and the changes in actions during pregnancy and after childbirth

Women who have low mood or depression during pregnancy or in the postnatal period, might reduce their interactions with friends and family and activities that they may have previously enjoyed. This may be due to medical problems, changes in their personal or social circumstances, a pre-existing low mood or depression or there may be no risk factors and it can be the factor of coming to terms with pregnancy and motherhood. Some women are reluctant to share their true feelings with friends and family and hide it from healthcare professionals because they feel ashamed of how they are feeling or do not want to admit it. It is vital for MSWs to be knowledgeable about the signs of low mood and depression, having good communication skills to build a rapport with women, asking women outright about their feelings and spending considerable time with women to learn more about their feelings so as to be able to give appropriate support.

How to approach women in the contacts?

Findings from the interviews with women who have experienced perinatal low mood or depression suggested that women would welcome being asked outright by the MSWs how they are feeling and how the pregnancy or motherhood is going; to listen to what they are experiencing and how they are experiencing it; to respond if a woman says she is feeling low and to check-in again sooner and not to leave a gap until the next contact; to make eye contact with them and to build a rapport with them; if there is a birth complication, to be aware of its potential psychological effects on the woman and guide them to seek help from appropriate services, before being discharged from the hospital; to be knowledgeable about the difference between the baby blues and postpartum low mood and depression; to update their knowledge

about the signs of perinatal low mood and depression, specifically they should not make assumptions that just because a woman is dressed and wearing make-up she is not experiencing depression; to decrease the poor communication and misinformation with their colleagues and to report women to the appropriate specialists or services if they experience a deterioration in their mood; they want MSWs to carry out the referral process on behalf of the woman rather than expecting the woman to self-refer to a GP or a specialist mental health service; they would want MSWs to continue contact sessions after making the referral, unless requested otherwise by the woman.

Where and how often do the contacts happen?

Treatment contacts are organised via 6 appointments; however, the number of sessions, frequency of appointments, delivery mode (face to face or telephone) and the support place (home, Children's Centres or hospital) should be decided through talking with the women and listening to their needs and demands. Contacts last 45 – 60 minutes, although session one is sometimes longer.

Section B

Behavioural Activation Support Intervention: A Session by Session Guide

BA Support Session Structure

All sessions should adopt the following structure:

- 1. Information Gathering**
- 2. Information Giving**
- 3. Shared Decision Making**
- 4. Action Following Contacts: Reporting and Supervision**

1. Information Gathering

The depth of information gathering depends on which stage women are currently at in the support process. For example, the first contact requires a more in-depth assessment in order to get to know the woman and any problems she may be having. Later contacts will gather information in a more focussed way around progress. In all contacts, there will be assessment of:

- symptoms of depression using the PHQ-9 depression scale
- progress using the self-help booklet
- response to BA support
- assessing and managing risk (see section C for the guide to assessing and reporting risk).

2. Information Giving

Again, the level of input will vary from session to session. The aim of information giving is to take the woman through the relevant stage of the booklet for that session. It is likely that in the early contacts, input will be highest. However, information giving may be required at all stages to help women take decisions about their treatment. BA information based upon the self-help booklet is also likely to be given in more detail during the early contact sessions.

3. Shared Decision Making

MSWs should develop a collaborative relationship with women. Women are in charge of their own decisions. MSWs collaborate in these decisions by helping women weigh up their options regarding possible BA activities etc.

Decisions will include discussion of BA targets and exercises. Negotiated activities should be realistic and achievable and should be based on women's own identification of things that they do to keep themselves well, or things they may have stopped doing recently.

Other decisions will be about the frequency of contacts, time of next contact etc. The contact session should end with a clear understanding of what the

woman has decided to do between this and subsequent contacts and with getting feedback from the woman on their shared understanding of the next steps.

Basic Principles

Below are some things that MSWs should bear in mind throughout the sessions.

Women who have been diagnosed as experiencing sub threshold perinatal depression may not recognise themselves as having a problem with mood or activity levels. MSWs should take this into account during sessions and work collaboratively and sensitively with the woman to enable them to undertake BA.

BA Principles

1) Experiment - "Let's try it out"

- Try out different behaviours to find out what is meaningful for the woman.
- A wide and diverse range of healthy activities for women tends to bring the best results.

2) Women will often find it very hard when they start to do activities. Remind them that this is normal. The treatment is not about just getting on with it; it is about helping them to understand how low mood can impact on activity. It then helps women understand how to target certain activities to help them feel better.

3) Remind women of the 'outside – in' rationale.

- i.e. rather than wait to feel better to do things that may help you, do things to make you feel better.
- Support women to start doing things, despite difficult feelings and thoughts they may have, in a way that reconnects them with things that were previously good for them.

4) Functionally equivalent activities. It is the benefit of the behaviour rather than what the behaviour is.

- Some women may not be able to do things they used to enjoy, owing to being pregnant or having a baby.
- If this is the case, ask the woman what it was about the activity that they found rewarding, what else it offered them and what made them keep doing it. It may be that the activity served a social function, gave a sense of achievement, helped the woman feel useful, or provided time to think or reflect. This information can be used to help them to think of alternatives or adaptations.

- Examples:
 - a woman may no longer be able to walk longer than 20 minutes due to tiredness in the last months of pregnancy. In this case, the woman may be able to find alternative routes, including benches where she can sit and have a rest for 10-15 minutes and then continue her walking.
 - a woman is no longer able to visit their friends and family due to feeling overwhelmed with caring for a newborn baby. The MSW should encourage the woman to find other ways to get in touch with them, such as talking to them online or on the phone.

5) Grading activities

- Start small and break activity down into stages.
- For example, a woman may have previously enjoyed going for walks but since having a baby has not been doing this. In this case, the woman could start off with short walks with the baby (e.g. to the end of the road) and build these up over time. They could also ask their family or friends to accompany them on walks at first until they feel they are able to go on their own with the baby.

Questioning Style

MSWs should use an open discovery orientated approach. This involves asking open questions such as:

- Can you give me an example of that?
- What do you think causes...?
- What would happen if...?
- What are the strengths and weaknesses of...?
- How does ... fit with what we learned before?

Help the woman to come to their own decisions.

Contact Session 1

MSW contact Checklist (details can be found on the next pages)
(photocopy additional copies as required)

Tick when
Complete

Introduction self and contact length-double check speaking to right person	
--	--

1.0 Information Gathering	
1.1 Review of problem areas	
1.2 Assessment of depression symptom level PHQ-9 depression scale	score
1.3 Risk assessment	
1.4 Brief summary BA and link to main problems (if any) the woman has at the moment and current scores/risk	
Notes on Information gathering	

2.0 Information Giving	
2.1 Depression information	
2.2 Material on BA	
Notes on Information giving	

3.0 Shared Decision Making	
Agree action goals for BA self-help booklet	
Negotiate the next contact session	
Discuss woman initiated contact	
Notes on shared decision making	

Contact Session 1 (supporting information)

1.0 Information Gathering

1.1 Review of problem areas

The MSW should spend 15 minutes speaking with the woman about how they feel at the moment (how is their mood, what are the main problems they have at the moment, what is hard for them to do at the moment that used to be important to them).

1.2 Formal symptom assessment

The MSW should use the PHQ-9 to measure depressive symptoms and discuss scores with the woman and that this will be done at each contact to see how they are doing in a consistent way (much like taking blood pressure does) (see section C).

1.3 Assessment of risk

The MSW should ask the risk screening question, and follow the risk assessment protocol if positive (see section C).

1.4 Review of BA support

The MSW should discuss the BA model and how in the following 6 contacts they will aim to help them to use the self-help booklet to understand the link between low mood and actions. They should explain that this is done in a step by step fashion and that the MSWs are keen to try to help the women apply what is in the booklet to themselves. The aim of this is to help with any current problems such as not going outside, feeling tired and overwhelmed if they have them, and/or to keep well in the future. If they can maintain a positive mood, it helps them deal with the other symptoms.

Using the PHQ-9

"In order to measure your progress through the treatment, I would like to ask you some standard questions from a questionnaire at each appointment. There are 9 questions and they relate to the last two weeks. The aim is to give us a quick idea about how you've been feeling in the past two weeks.

Run through the questions in order.

Quickly add up the score.

Give the woman feedback on what the score indicates. Be honest with the scoring and ask, *"How does this fit for you?"* in terms of the way the woman is currently feeling.

"So now we have a baseline measure we'll continue to do this every week to monitor your scores"

Remind the woman there is a blank copy of the questionnaire with you which they can use to answer this questionnaire in future appointments, especially if they are over the phone.

2.0 Information Giving-using the BA booklet.

The woman will be given the BA self-help booklet and extra exercise sheets.

In the contact, it is important to ask the woman how they find the booklet and if they have any issues in using it.

Briefly explain the following in session 1.

2.1 Depression or low mood

The MSW should explain to the women that they have been screened as experiencing some symptoms of low mood. This is very common in pregnancy or in the postpartum period, and the aim of the support is to give them information and some things that they can do to improve their mood. It should be noted that many women who are pregnant or in the postpartum period have problems with feeling low and if this gets too bad, it can have an impact on the whole family. This manual aims to nip such problems in the bud and help women stay well.

Use the information gathered about the women's views and the words they use to describe their mental health to approach this subject.

2.2 Behavioural activation

Introduce the self-help booklet and state that in the sessions you will go over them step by step with the woman to help them use it.

Contact Session 1 Information Giving

In this first session I have quite a lot of information to give you so it'll feel like I'm talking quite a lot. Just stop me if you feel you need me to repeat anything. All of this information is in your pack so you can look through it in your own time.

Contact Session 1 Information Giving: BA Booklet

In this session we will focus on stage 1. We have already looked at some of the symptoms of low mood you have. Now we want to think about what keeps them going.

Review the mood symptoms

The cycle of low mood (booklet stage 1, page 8)

Our mood is linked to how we engage with the world around us, so what we do impacts considerably on how we feel. In other words, what we do impacts on how we feel.

Sometimes things happen in life that mean we can't do the things we used to do that helped us feel ok. This is particularly common during pregnancy and in the postpartum period. The more we are cut off from the things that used to make us feel ok, the more likely we are to start feeling bad.

The problem is that sometimes when we feel bad, we withdraw more to cope, because it all feels too much. This further isolates us from those things that were good for us.

This is shown in the cycle in the booklet on pages 8 and 9. Being aware of this is really important for women who are pregnant or have a baby, as it can help 'nip this cycle in the bud' before it gets too bad. This is what the booklet is aimed at helping you do.

Can we think about how the cycle relates to you?

Spend 5 mins with the woman reviewing the cycle

BA is a simple treatment that is focused on:

- re-establishing our daily **routines**
- increasing contact with the activities you value
- dealing with issues that may be making this difficult

The purpose of this is to help us to do things that we find rewarding or meaningful by gradually starting to do more of the things that we have stopped doing since feeling low. There is good evidence that this treatment can help us overcome low mood. We understand that this is very hard when you feel low, which is why we work together to try to make sure that what you do gives you the most benefit. The booklet aims to help you to do this and I can help you use the booklet.

NOTE: If you're fairly active and managing to do the routine, enjoyable and necessary activities you would like to, the focus will be on helping you to keep doing these, as we know it is a good way of preventing women's mood getting worse.

In the next contact we will move onto stage 2 and 3 of the booklet. Between now and then how can you use what we have covered today?

- Review the cycle for yourself
- Think about possible signs of low mood
- Think about those things that may have been dropping out of daily routines

Arranging the Next Contact

The MSW should negotiate the next contact session (within one or two weeks, depending on the woman's needs) with the woman.

Contact Sessions 2-5

MSWs Checklist for Session Number 2-5 (details can be found on the next pages)
(photocopy additional copies as required)

Tick when Complete

Session number	Please record
1.0 Information Gathering	
1.1 Summary of last session Review last session and action plan	
1.2 Formal symptom assessment PHQ-9	Write scores here
1.3 Assessment of Risk	
1.4 Review of BA Support BA worksheets	
Notes on information gathering	
2.0 Information Giving	
Information about the next stage/stages of the support (see P 21 for an example session structure for sessions 2-5)	
Notes on information giving	
3.0 Shared Decision Making	
Specific BA plans	
Negotiate the next contact session	
Notes in shared decision making	

Contact Sessions 2-5 (supporting information)

Introduction

The MSW should confirm that they are speaking to the woman, remind the woman of who they are and describe the objectives and time scale for the contact.

1.0 Information Gathering

1.1 Confirmation of summary from last session

The MSW should remind the woman about the summary of the last contact and ascertain whether there have been significant changes.

1.2 Formal symptom assessment

The MSW should use the PHQ-9 to re-measure symptoms and confirm the assessment information.

1.3 Assessment of risk

The MSW should ask the risk screening question, and follow the risk assessment protocol if positive.

1.4 Review of BA support

The MSW should discuss the previous BA activities negotiated during the last session. In session 2, this will usually involve reviewing the cycle and asking the woman if they have read the booklet and thought more about how it possibly applies to them. This should lead to an open discussion.

Information Giving

The MSW should clarify or go over any information given in the booklet, as appropriate. Use the type of conversation style outlined above in session 1, and remain open and collaborative, helping the woman to come up with solutions. Go back to the cycle of depression at each session and help the woman understand how it relates to them.

Remember that BA is aimed at:

- re-establishing our daily **routines**
- increasing contact with the activities you value
- dealing with issues that may be making this difficult

Using an 'outside in' approach.

Below is an example session structure of sessions 2-5. The section of the booklet covered will vary on a person by person basis, but ideally is:

Session 2: Booklet stage 2, the value of keeping a diary and first section of stage 3, the three types of activity;

Session 3: Second section of stage 3, keeping a balance and stage 4, breaking jobs down;

Session 4: Booklet stage 5, the benefits of activities and finding other ways to be active;

Session 5: Booklet stage 6, spotting symptoms of depression and what to do if you notice symptoms getting worse again.

Contact Session 6

MSWs Checklist for Session Number 6 (details can be found on the next pages) (photocopy additional copies as required)

Tick when Complete

Introduction	
1.0 Information Gathering	
1.1 Review of feedback from previous contacts	
1.2 Review and re-confirmation of BA approach	
1.2 Formal symptom assessment PHQ-9	Write scores here
1.3 Assessment of Risk	
1.4 Review of BA Support Recap on sessions 1-6	
Notes	
2.0 Information Giving	
Notes	

Contact Session 6 (supporting information)

Introduction

The MSW should confirm that they are speaking to the woman, remind the woman of who they are and describe the objectives and time scale for the contact.

It should be noted this may be the final appointment (confirm with the woman)

1.0 Information Gathering

1.1 Confirmation of summary statement

The MSW should remind the woman about the summary of the last contact and ascertain whether there have been significant changes.

1.2 Formal symptom assessment

The MSW should use the PHQ-9 to re-measure symptoms and confirm the assessment information with the woman.

1.3 Assessment of risk

The MSW should ask the risk screening question, and follow the risk assessment protocol if positive.

1.4 Review of BA support

This is the main focus of session 6. The MSW should discuss the previous BA activities negotiated during the treatment and how the woman has found them.

It is important to identify if there are any areas that the woman has found particularly difficult, and if so, use the session to review these.

A summary of the BA rationale, including the cycle and the idea of working from the 'outside in', should be undertaken with the woman. This then should be linked to the types of activities they have scheduled, and how these can be used in the future.

It should be emphasised that this is self-help, and by using the booklet and keeping going with activities, they are much more likely to prevent problems with low mood occurring in the future.

Finally, review the 'spotting signs of depression' and action plans.

2.0 Information Giving

a. Last session

Remind the woman this is the last of the 6 sessions.

Encourage them to keep using the booklet and those approaches described in it.

Point out that if they think things are deteriorating with their mood, to use the approaches in the booklet and seek additional support via their GP or midwife or health visitor, if they feel this is needed.

Section C

**The PHQ-9
Risk assessment
Key people contact details**

PHQ-9 depression symptom level assessment

Woman number:

Date:

**PATIENT HEALTH QUESTIONNAIRE - 9
(PHQ-9)**

Over the last 2 weeks, how often have you been bothered by any of the following problems?

(Use "✓" to indicate your answer)

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

FOR OFFICE CODING 0 + _____ + _____ + _____
=Total Score: _____

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

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
...

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Score	Severity band
0 - 4	Minimal
5 - 9	Mild
10 -14	Moderate
15 -19	Moderately severe
20 - 27	Severe

Briefly discuss with woman (e.g., discuss change in scores)

If scores remain the same or improve reflect on this and continue with BA support

If scores worsen slightly but remain in same category discuss possible reasons with woman and monitor closely.

If scores move into moderately severe or severe category discuss with woman about going to see their GP to review their mood as soon as possible.

Risk Protocol

Whilst we do not anticipate significant risk during the support sessions, we must be aware there is a possibility women may develop self-harm /suicidal ideas during contact with MSWs. Therefore, we have an ongoing responsibility to assess this and act if we notice it. This protocol guides you through appropriate assessment and action.

The risk protocol has been devised to provide guidance for MSWs for instances where a woman's mental wellbeing causes them concern, specifically when they present with risk of self-harm or suicidal ideation/suicide. MSWs are part of a system of collaborative care. If MSWs are in any way concerned about a woman's wellbeing they are obliged to ensure that this information is shared with the woman's GP. If women express any thoughts of self-harm or suicide, MSWs must enact the risk protocol.

Below provides a summary of the risk protocol. Please ensure you have read the full guidance document on assessing and reporting risk (see 'MSWs Guide to Assessing & Reporting Risk').

Checking for and assessing risk of self-harm / suicide

- During EACH treatment session, MSWs must check for risk by asking women the last question of PHQ-9:

"In the last two weeks / since we last spoke, have you had thoughts that you would be better off dead, or of hurting yourself in some way?"

- If the woman indicates that they have NOT had such thoughts, the MSW should continue with the treatment session
- If the woman indicates that they HAVE had such thoughts, the MSW must enact the Risk Protocol below.

Questions to ask & protocol if risk has been identified:

- If risk of self-harm / suicide is identified, advise the woman:

"I see that you've said / you mentioned that..... These are thoughts / feelings that people can have from time to time, but it's important to make sure you are receiving the right kind of support. So if it's OK, I would now like to ask you some more questions that will explore these feelings in a little more depth."

- Ask the woman the six Exploring Risk Questions on next page.
- Use a blank sheet to record woman responses.
- Make sure you document **verbatim** the woman's responses to the probing question **and** each of the six exploring risk questions to aid in establishing level of risk.

Details of disclosed thoughts (please record verbatim as far as possible)

Now ask the following six questions	
Plans	
1. Do you know how you would harm yourself or try to end your life? If Yes – details	Yes / No
2. Have you made any actual plans to harm yourself or end your life? If Yes – details	Yes / No
Actions	
3. Have you made any actual preparations to harm yourself or end your life? If Yes – details	Yes / No
4. Have you ever attempted to end your life in the past? If Yes – details	Yes / No
Prevention	
5. Is there anything stopping you harming yourself or attempting to end your life at the moment? If Yes – details	Yes / No
6. Do you feel that there is any immediate danger that you would act on these ideas about harming yourself or ending your life? If Yes – details	Yes / No

➤ The six Exploring Risk Questions are to be used following any indication of risk from responses to the risk question, or any other indication that risk may be present.

- Look at the woman's answers to the six Exploring Risk Questions to determine Level of Risk – A, B or C.

Gaining woman's consent for GP contact (Level of Risk = B or C):

- **Level B Risk:** For Action B, where the MSW should arrange for a letter to be sent to the woman's GP, the woman other should give their permission for this to be done. The MSW should discuss this with the designated risk contact who will advise whether they should inform the GP or not.
- **Level C Risk:** Action C should be undertaken immediately, with or without the woman's permission.

Women responses to Exploring Risk Questions

Actions by MSW

All answers 'NO' apart from Q5 'YES':



LEVEL A RISK

Explain to the woman:

I can see that things have been very difficult for you, but it seems to me these thoughts about death are not ones you would act on – would this be how you see things? (if they say yes) I would advise you to make an appointment to see your GP to talk about these feelings.

ACTION: Discuss the woman's responses to the Exploring Risk Questions at your next supervision session. If there is anything you are unsure on or would like to discuss things further you may telephone the risk contact for advice.

Woman responses to Exploring Risk Questions	Actions by MSW
<p>Answers 'YES' to any <u>one</u> of Qs1-4; plus 'YES' for Q5 and 'NO' for Q6</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">LEVEL B RISK</p>	<p>Explain to the woman:</p> <p><i>Things seem to be very hard for you right now and I think it would help if you were to speak to your GP about these feelings. I will be writing to your GP to tell <u>them that you have been here today and have been having some troubling thoughts (check that they are happy for us to write to their GP – see above – and confirm their GP details). I would also advise you to make an appointment to see your GP to talk about these feelings.</u></i></p> <p>ACTION: Contact the risk contact by telephone immediately following the session (see below)</p>
<p>Answers 'NO' to Q5 or 'YES' to Q6</p> <p style="text-align: center;">↓</p> <p style="text-align: center;">LEVEL C RISK (ACTIVELY SUICIDAL)</p>	<p>Explain to the woman:</p> <p><i>I am very concerned about your safety at this moment, <u>advise the woman that you are going to contact your risk contact and their GP / the emergency services to let them know they have been experiencing these thoughts and feelings and to arrange for them to receive immediate help.</u></i></p> <p><u>ACTION: Contact the risk contact by telephone IMMEDIATELY. The MSW should then follow the 'Actions to take in the case of immediate risk' below.</u></p>

Reporting risk

Actions to take following identification of a Level B Risk:

- Following the woman treatment session, the MSW should contact the risk contact by telephone to advise them of the risk of self-harm / suicide, the woman's responses to the exploring risk questions, and the associated level of risk (following the above guidance).
- The risk contact will advise/confirm whether a letter needs to be sent to the woman's GP.
- The MSW should then complete the 'Reporting Risk Form'.
- The MSW should sign and date the Exploring Risk Questions and the Reporting Risk Form and then send a letter to the woman's GP.

Actions to take in case of IMMEDIATE RISK (LEVEL C RISK):

- If the level of risk has been identified as Level C, then the woman requires immediate help – **do not leave the woman alone, or if on the telephone, do not hang up, if possible.**
- Contact the risk contact by telephone **IMMEDIATELY** in order to involve a specialist right away.
- The specialist will discuss with the MSW the necessary actions to take, which are likely to include one or more of those listed below
- If the specialist does not answer the phone, the researcher should leave a voice message. If the specialist does not respond immediately, the MSW should take one of the actions listed below.

Actions if unable to contact the specialist:

- Contact the woman's GP / Out of Hours GP
- If with the woman: call a taxi to take the woman to A&E. The MSW should accompany the woman to A&E and should not leave the woman until a clinician has taken responsibility for their care.
- If the session is being conducted over the telephone: call an ambulance.

Key People Contact Details

Name	Description	Contact details
NHS	Helpline service for urgent care services	111 (free)
PANDAS	Pre and postnatal depression advice and support	0843 28 98 401 (9 am to 8 pm, Monday to Sunday)
MIND	The mental health charity providing advice and support to empower anyone experiencing a mental health problem	0300 123 3393 (9 am to 6 pm, Monday to Friday)
SAMARITANS	A charity aimed at providing emotional support to anyone in emotional distress, struggling to cope, or at risk of suicide	116 123 (free 24-hour helpline)

Abbreviations

BA: Behavioural activation

CBT: Cognitive behavioural therapy

CCBT: Computerised cognitive behavioural therapy

EBCD: Experience-based co-design

EPDS: Edinburgh Postnatal Depression Scale

HCP: Healthcare professional

HRA: Health Research Authority

HSRGC: Health Sciences Research Governance Committee

IAPT: Improving Access to Psychological Therapies

IPT: Interpersonal psychotherapy

IRAS: Integrated research application system

MSW: Maternity support worker

NICE: National Institute for Health and Care Excellence

NMHS: Non-mental-health specialist

PHQ-9: Patient Health Questionnaire-9

R&D: Research and Development

RCT: Randomised controlled trial

REC: Research ethics committee

SI: Symbolic interactionism

TA: Thematic analysis

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