

**Supporting women with mild to
moderate anxiety during
pregnancy; the development of an
intervention to be facilitated by
midwives.**

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Abstract

Aim: To develop an intervention that could be facilitated by midwives to improve symptoms of mild to moderate anxiety in pregnant women

Background: Many women experience symptoms of anxiety during pregnancy. Severe anxiety is associated with negative health outcomes for women and babies. Psychological interventions may be beneficial for pregnant women with mild to moderate symptoms of anxiety. Interventions require evaluation in pregnant populations to strengthen the evidence base.

Methods: An intervention was developed according to the Medical Research Council theoretical and modelling phases for developing complex interventions. The study comprised three phases: 1. systematic reviews exploring the effectiveness and acceptability of interventions for pregnant women with anxiety; 2. development of an intervention which comprised individual support from midwives, peer group discussion and self-help resources; 3. a feasibility study of the intervention. Data collection comprised baseline and post-intervention self-report anxiety measures and semi-structured interviews conducted post-intervention. Data analysis used descriptive statistics for the quantitative data and template analysis for the qualitative data.

Findings: Ten women participated in the feasibility study. Two midwife facilitators and two midwifery support worker co-facilitators were recruited and trained to facilitate the intervention. Women reported that the intervention was acceptable and beneficial. The findings highlighted how the intervention could be improved to maximise participant recruitment and improve the benefit derived by pregnant women with symptoms of anxiety. Facilitators provided positive comments about their involvement and said they felt prepared to deliver the intervention. Areas were identified where the

training of intervention facilitators, study manuals and use of self-help resources could be enhanced to improve performance and fidelity of the intervention.

Conclusions: Midwives have the potential to facilitate supportive interventions to enhance the current provision of emotional support in pregnancy. Minor refinements to the intervention are recommended prior to further testing. The next stage of development should be to conduct a randomised pilot trial. This should determine robust research methods and procedures for conducting a main trial to assess the effectiveness of the intervention on self-report symptoms of anxiety in pregnant women.

Outputs related to the research

Publications

- Evans, K., Spiby, H., & Morrell, C. J. (2015). A psychometric systematic review of self-report instruments to identify anxiety in pregnancy. *Journal of Advanced Nursing*. 71(9), 1986-2001.
- Evans, K., Morrell, C. J. & Spiby, H. (2016). Women's views on anxiety in pregnancy and the use of anxiety instruments: A Qualitative study. *Journal of Reproductive and Infant Psychology*. 6838(December), 1-14.
- Evans, K., Morrell, C. J. & Spiby, H. (2017). Systematic review and meta-analysis of non-pharmacological interventions to reduce the symptoms of mild to moderate anxiety in pregnant women. *Journal of Advanced Nursing*, Early View 2017; 00:1-21.
- Evans, K., Morrell, C. J., Spiby, H. (2015). Non-pharmacological interventions during pregnancy to reduce symptoms of anxiety: a systematic review of quantitative and qualitative evidence. PROSPERO: CRD42015017841/

Papers in preparation:

- Non-pharmacological interventions to reduce symptoms of mild to moderate anxiety in pregnant women. Systematic Review and Narrative Synthesis of women's views on the acceptability of and satisfaction with interventions.

Conferences

- An oral presentation of the feasibility study protocol was presented at the Institute of Mental Health research conference, May 2016, Nottingham.
- Systematic review of non-pharmacological interventions to reduce symptoms of mild to moderate anxiety in pregnant women. *International Confederation of Midwives, Toronto June 2017*. Poster presentation P1.045
- The development and feasibility testing of an intervention to reduce the symptoms of mild to moderate anxiety in pregnant women. *International Confederation of Midwives, Toronto June 2017*. Poster presentation P1.046

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Abbreviations

ANCOVA	Analysis of Co-Variance
APA	American Psychiatric Association
ASI	Anxiety Sensitivity Index
BAI	Beck Anxiety Inventory
BDI	Beck Depression Inventory
BMI	Body Mass Index
BP	Blood Pressure
CASP	Critical Appraisal Skills Programme
CBA	Cognitive Behavioural Approach
CBT	Cognitive Behavioural Therapy
CCG	Clinical Commissioning Group
CERQual	Confidence in the Evidence from Reviews of Qualitative Research
CG	Control Group
CI	Confidence Interval
CMW	Community midwife
COMP	Comparison Group
COREQ	Consolidated Criteria for Reporting Qualitative Research
CRD	Centre for Reviews and Dissemination
CRN	Clinical Research Networks
CTG	Cardiotocograph
DALYs	Disability Adjusted Life Years
DASS	Depression Anxiety Stress Scale
DOH	Department of Health
DSM-V	The Diagnostic and Statistical Manual of Mental Disorders version five
EPDS	Edinburgh Postnatal Depression Scale
GAD	Generalised Anxiety Disorder
GAD-2	Two-item Generalised Anxiety Disorder Scale
GAD-7	Seven-item Generalised Anxiety Disorder Scale
GDM	Gestational diabetes mellitus
GP	General Practitioner
HADS-A	Hospital Anxiety and Depression Scale - Anxiety
HADS-D	Hospital Anxiety and Depression Scale - Depression
HCP	Healthcare Professional
HRA	Health Research Authority
IAPT	Improving Access to Psychological Therapies
ICC	Intra Cluster Correlation
ICD-10	International Classification of Diseases version ten
IG	Intervention Group
IMD	Index of Multiple Deprivation
IPT	Inter-Personal Therapy
IQR	Inter Quartile Range
ITT	Intention to treat analysis
MAQ	Maternal Anxiety Questionnaire
MBCT	Mindfulness-Based Cognitive Therapy
MBSR	Mindfulness-Based Stress Reduction
MC	Mean Change
MCBT	Mindfulness cognitive based therapy
MMHA	Maternal Mental Health Alliance
MRC	Medical Research Council
MSW	Midwifery Support Worker
n	Numbers of ...

NCCMH	National Collaborating Centre for Mental Health
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NIHR	National Institute for Health Research
NMC	Nursing and Midwifery Council
NMRN	Nottingham Maternity Research Network
NR	Not Reported
OCD	Obsessive-Compulsive Disorder
ONS	Officer for National Statistics
OR	Odds Ratio
P	Significance value
PEOS	Participants, Exposure (or intervention), Outcomes, Study design
PHQ-12	Patient Health Questionnaire – 12 items
PICOS	Population, Intervention, Comparator, Outcome, Study design
PND	Postnatal Depression
PRA	Pregnancy Related Anxiety Scale
PRAQ-R	Pregnancy Related Anxiety Questionnaire - Revised
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSA	Pregnancy Specific Anxiety Scale
PSWQ	Penn State Worry Questionnaire
QALY	Quality Adjusted Life Year
QOL	Quality of Life
R&I	Research and Innovation
RCM	Royal College of Midwives
RCT	Randomised Controlled Trail
REC	Research Ethics Committee
SCID	Structured Clinical Interview for DSM criteria
SD	Standard Deviation
SE	Standard Error
SMD	Standardised Mean Difference
SMT	Senior Management Team
SOA	Super Output Areas
SR	Systematic Review
STAI	State Trait Anxiety Inventory
TAU	Treatment as Usual
TIDieR	Template for Intervention Description and Replication
TR	Therapeutic Relationship
UK	United Kingdom
US	United States of America
VASA	Visual Analogue Scale for Anxiety
WHO	World Health Organisation
YLD	Years Lived with Disability
α	Cronbach's Alpha

Chapter 1 Introduction and background

1.1.1 Definition of anxiety

Anxiety has been described as a future oriented mood state associated with preparation for possible negative events (Barlow 2002). Anxiety disorders are characterised by an elevated sensitivity to threat and a bias to interpret ambiguous information in a threat-relevant manner (Craske et al. 2009). Individuals with anxiety disorders have little or no control over their emotions which can be experienced as intense and overwhelming (Starcevic & Castle 2016). Lang (1968) classified the symptoms of anxiety into three categories of: worry (verbal-subjective); avoidance (overt motor acts); and muscle tension (somato-visceral activity). The Diagnostic and Statistical Manual of Mental Disorders version five (DSM-V) (American Psychiatric Association, APA 2013) and the International Classification of Diseases version ten (ICD-10) (World Health Organisation, WHO 1992) described the symptoms for anxiety disorders including the most prevalent conditions: generalised anxiety disorder; panic disorder; agoraphobia; obsessive compulsive disorder; specific phobias; and social anxiety disorder. To make a formal diagnosis, the anxiety disorder must be severe enough to be classed as interfering in an individual's everyday life.

Generalised anxiety disorder

Generalised anxiety disorder (GAD) is defined as excessive anxiety and worry which is difficult to control. Symptoms are experienced on most days over a period of at least six months. Symptoms include: feeling restless or on edge; being easily fatigued; difficulty concentrating; irritability; muscle tension and sleep disturbance (APA 2013). Excessive worry is "driven by a difficulty in coming to terms with uncertainty... which results in constant anticipation of further problems and no solution in sight" (Starcevic & Castle 2016, page 207).

Panic disorder

Panic disorder is characterised by the spontaneous occurrence of panic attacks. Panic attacks can occur in other anxiety disorders although in panic disorders the onset is unpredictable. Panic attacks are described as an abrupt surge of intense fear or intense discomfort that reaches a peak within minutes and are characterised by: palpitations; sweating and shaking; shortness of breath; chest pain; feelings of choking; nausea; feeling lightheaded; numbness; derealisation or depersonalisation; fear of losing control or fear of dying (APA 2013). To meet the criteria for panic disorder, panic attacks are followed by longer than one month of subsequent persistent worry about having another attack or consequences of the attack or significant maladaptive behavioral changes to avoid having another attack.

Agoraphobia

Agoraphobia refers to a fear of situations in which: 1. an individual feels it may be difficult to escape from, such as crowded or enclosed spaces; 2. an individual is alone or away from their safety zone. In these situations, an individual fears the onset of a panic attack or of being harmed. Individuals often become housebound to avoid such situations (Faravelli et al. 2008, Starcevic & Castle 2016).

Social anxiety disorder

Social anxiety disorder is defined as a "fear of social or performance situations in which the person is exposed to unfamiliar people or to possible scrutiny by others. The individual fears that he or she will act in a way that will be embarrassing and humiliating" (APA 2013). The individual is aware that the fear is unreasonable or excessive and will try to avoid these situations or will endure the situations with distress. Social anxiety disorder is a consequence of an individual having negative assumptions about themselves and the concern that

they will be humiliated, perform poorly or be rejected (APA 2013; Starcevic & Castle 2016).

Obsessive-Compulsive Disorder

The essential features of Obsessive-Compulsive Disorder (OCD) are recurrent, irrational, obsessional thoughts or compulsive acts. The thoughts are distressing to the individual who is unable to control or resist them. Rituals are carried out as a way of preventing an objectively unlikely event. The rituals often involve harm to or harm caused by the individual (WHO 2016).

Specific phobia

Individuals with specific phobias are excessively and irrationally afraid of particular objects, situations or phenomena which are considered as threatening or disgusting to the individual. Common phobias include needles penetrating the skin, fear of certain animals or air travel. Situations or objects are avoided or endured with marked distress to the individual, resulting in symptoms of anxiety or panic attacks (APA 2013; Starcevic & Castle 2016).

1.1.2 Prevalence of anxiety disorders

In general populations, anxiety disorders are very common and have been reported as the sixth leading cause of disability globally, in terms of Years Lived with Disability (YLD) and accounted for 390 Disability Adjusted Life Years (DALYs) per 100,000 persons in 2010 (Baxter et al. 2014). A high proportion of DALYs caused by anxiety disorders were experienced by females (65%) and DALY rates peaked for men and women in the 15–34 year age groups (Baxter et al. 2014). The worldwide lifetime prevalence rate for developing an anxiety disorder has been calculated at 16.6% (Somers et al. 2006).

Diagnostic criteria were designed to help clinicians describe common anxiety disorders in order to offer effective treatment. However, mild and moderate symptoms which may present at the start of a disorder or following effective treatment, may not meet the diagnostic criteria (Andrews et al. 2008). Symptoms of GAD below the diagnostic threshold (using DSM and ICD criteria), were found to increase the risk of developing co-morbid mental health problems and somatic disorders. Symptoms were associated with high levels of distress; poor perceived physical health; impairment in psychosocial functioning and more primary health care use than in non-anxious individuals (Haller et al. 2014). Haller et al. (2014) reported the median point prevalence rate of sub-threshold GAD symptoms was 4.4% in two general population studies (Angst et al. 2006, Kessler et al. 2005). In these studies, anxiety symptoms were assessed using structured clinical interviews:

- The Structured Psychopathological Interview and Rating of Social Consequences of Psychic Disturbances for Epidemiology (SPIKE, Angst & Dobler-Mikola 1985)
- The World Mental Health Composite International Diagnostic Interview (WMH-CIDI, Kessler & Üstün 2004).

The prevalence of sub-threshold anxiety symptoms in the general population were double the rate of the full disorder and subthreshold prevalence rates were higher for women than men.

1.1.3 Prevalence of anxiety in pregnancy

Reported prevalence of anxiety disorders in pregnancy varies from 10% to 16% (Goodman et al. 2014, National Institute for Health and Care Excellence (NICE) 2014, Rubertsson et al. 2014). The prevalence has been reported as 14.6% in a UK community sample of pregnant women at 18 weeks gestation (Heron et al. 2004), and 15.8% in a Canadian community sample of nulliparous and multiparous pregnant women (Fairbrother et al. 2016). A 'U-shaped curve' has been reported

for self-report anxiety which demonstrated a decrease in self-reported scores in the second trimester of pregnancy, with higher reported scores in the first and third trimesters (Öhman et al. 2003, Statham et al. 1997).

1.1.4 Presentation of anxiety in pregnancy

Anxiety disorders such as GAD in pregnancy have the same symptoms as anxiety disorders in non-pregnant populations (NICE 2014). Symptoms may include: feeling overwhelmed; angry and scared; ruminating thoughts; irritability; and being unable to relax (Highet et al. 2014, Staneva et al. 2015). During pregnancy, concerns over the wellbeing of the baby, the birth or parenting ability may present as predominant features (Staneva et al. 2015, Vythilingum 2009). There are suggestions that anxiety specific to pregnancy may be a distinct concept from general anxiety (Bayrampour et al. 2016). Pregnancy specific anxiety has been characterised by excessive concerns about the following: fetal wellbeing; childbirth; parenting; body image; financial issues; family and social support (Bayrampour et al. 2016).

Anxiety in pregnancy may be a normal adaptive process, helping the woman to take care of herself and her unborn baby. Anxiety symptoms become problematic when they consume a large proportion of a woman's time, when a woman is unable to focus on other tasks and when anxiety symptoms significantly interfere with everyday life (Guardino & Schetter 2014; Wenzel 2011). Women with a previous or existing mental illness, those who have poor social support or those who have had a previous negative experience of pregnancy or birth are especially vulnerable to developing symptoms of anxiety in pregnancy (Dahlen et al. 2015, Staneva et al. 2015). Pregnant women with anxiety have reported finding it difficult to concentrate, being incapable of making decisions and unable to look forward to the arrival of their babies (Bayrampour et al. 2016). Women have

also reported anxiety due to feeling a loss of control over their bodies and lacking knowledge and understanding of pregnancy and labour (Highet et al. 2014, Keeton et al. 2008, Staneva et al. 2015).

Some women may seek excessive reassurance about the wellbeing of their baby, such as obsessive counting of fetal movements, requesting additional ultrasound scans (Brockington et al. 2006) or frequent calls and visits to healthcare providers (HCPs). Women may delay disclosure of the pregnancy due to fear of miscarriage, especially following assisted conception or a previous pregnancy loss (Armstrong & Hutti 1998, Armstrong 2004, Côté-Arsenault & Donato 2011, Rowe & Fisher 2015, Staneva et al. 2015). Women may feel anxious if they think they are not having a 'perfect pregnancy', resulting in feelings of isolation, vulnerability and questioning their ability to be a 'good mother' (Evans et al. 2016, Highet et al. 2014, Rowe & Fisher 2015, Staneva et al. 2015).

1.1.5 Maternal and fetal consequences of anxiety in pregnancy

The effects of anxiety are often studied alongside depression because of the established co-morbidity (Glover 2014). Antenatal anxiety has been reported as a risk factor for developing postnatal depression. In a UK sample (n=246), antenatal GAD was reported to be a significant independent predictor of high Edinburgh Postnatal Depression Scale (EPDS) scores (EPDS 13 or more) at 24 months postnatal (Coelho et al. 2011). Anxiety disorders in pregnancy have been reported to predict postnatal depressive symptoms (EPDS 13 or more) at six weeks postpartum (n= 497, OR= 2.7, 95% CI 1.1–6.3, P= 0.03) (Sutter-Dallay et al. 2004), and at 8 weeks and 8 months postpartum (n= 8,323, OR= 3.22, P< 0.001) (Heron et al. 2004). Some of the effects on the children of women with

postnatal depression may have originated in antenatal anxiety (Coelho et al. 2011, Evans et al. 2001, Heron et al. 2004). Anxiety during pregnancy has also been associated with an increased use of pain relief in labour (Koelewijn et al. 2017) and with post-traumatic stress symptoms following childbirth (Czarnocka & Slade 2000; Iles et al. 2011). Pregnancy-specific anxiety has been reported as more strongly associated with poor health outcomes for women and infants than general anxiety (Blair et al. 2011, Kramer et al. 2009).

Elevated and prolonged anxiety has been associated with pre-term birth, fetal growth restriction (Ding et al. 2014, Littleton et al. 2007, Rich-Edwards & Gizzards 2005) and severe behavioural problems in developing children (Blair et al. 2011, Cardwell 2013; Davis & Sandman 2010, Glover 2014, Stein et al. 2014). Fetal overexposure to maternal cortisol, downregulation of placental barrier enzymes, increased fetal serotonin exposure and epigenetic changes due to increased maternal anxiety may be factors in fetal programming leading to adverse fetal and infant outcomes (Bonnin et al. 2011, Glover 2014, Herbert et al. 2006, Mairesse et al. 2007, Mueller & Bale 2008, Radtke et al. 2011). However, the underlying causal mechanisms are not yet established (Glover 2014).

1.1.6 Costs of anxiety in pregnancy

Bauer et al. (2014) valued the costs of additional use of public services, productivity losses and Quality Adjusted Life Year (QALY) losses for women with symptoms of anxiety in the perinatal period and continuing up to ten years after the birth of their baby. Based on reported prevalence rates and adjusting for anxiety co-existing with depression, costs were estimated at £35,000 per individual woman, £21,000 relating to the mother and £14,000 to the child (Bauer et al. 2014). However, the report was limited by the use of numerous self-report measures and different cut-off scores for anxiety disorders in the studies

included in the report. Limitations in the available data may have meant that a small degree of overlap between the costs of co-morbid mental health conditions remained (Bauer et al. 2014).

1.1.7 Identification of anxiety in pregnancy

The association between maternal anxiety and adverse health outcomes is not inevitable and in order to provide early prevention and treatment strategies it is important to identify women who are at an increased risk of adverse outcomes (Stein et al. 2014). 'Saving Lives, Improving Mothers' Care' (Knight et al. 2015) states that screening for the risk of, or presence of mental health disorders is the responsibility of all health professionals in contact with pregnant women. For at least 11% of pregnant and postnatal women who died by suicide, there was either no enquiry or inadequate enquiry about mental health at the antenatal booking appointment. Healthcare professionals (HCPs) have reported barriers to discussing emotional wellbeing and mental health with women due to time constraints during appointments, lack of training and lack of awareness of supporting services where women can be referred (Khan 2015; Russell et al. 2013). Psychological assessments are recommended as part of routine antenatal care to provide opportunities to offer support and identify women who require urgent psychiatric assessment (Austin et al. 2005, 2008; Austin 2003; Buist et al. 2006; Knight et al. 2015; NICE 2014).

Matthey (2005) suggested that routine assessment of antenatal anxiety does not occur only through formalised measures, but it also occurs when women are asked how they are feeling, if they have any worries or concerns about their pregnancy or after the birth of their baby.

Psychological instruments used alongside a general discussion about a woman's mental wellbeing may help midwives recognise mental health problems in pregnancy (NICE 2014; O'Hara 2009; Oates 2003). NICE (2014) recommended that screening questions for anxiety and depression should be asked during a woman's first contact with primary care, during the initial visit with a midwife and early in the postnatal period. To identify symptoms of anxiety the 2-item Generalised Anxiety Disorder scale (GAD-2) (Spitzer et al. 2006) was recommended. The GAD-2 questions are:

- During the past month, have you been feeling nervous, anxious or on edge?
- During the past month have you not been able to stop or control worrying?

Answers are scored on a 7-point scale; if a woman scores 3 or more on the GAD-2 scale or the HCP has other concerns, further assessment using the full GAD-7 scale or specialist mental health assessment is recommended.

The National Collaborating Centre for Mental Health (NCCMH, 2011) highlighted the limitations of using the GAD-2 self-report measure as it has not been validated for use in pregnancy or for other anxiety and phobic disorders. There is insufficient evidence to support the use of any single method of identification (Austin et al. 2008). Many of the instruments used during pregnancy were adapted from general health questionnaires and require validation in perinatal populations (Alderdice et al. 2012; Meades & Ayers 2011). Four recent literature reviews (Alderdice et al. 2012; Evans et al. 2015; Meades & Ayers 2011; Morrell et al. 2013) have highlighted the limited research investigating psychometric properties of pregnancy-specific anxiety measures. At present, due to incomplete psychometric data, a 'gold standard' self-report instrument for the identification of symptoms of anxiety in pregnancy has not yet been identified.

The NCCMH (2011) indicated that an assessment such as a Structured Clinical Interview for DSM criteria (SCID) by a mental health professional would be more likely to accurately identify symptoms of anxiety and appropriate treatment. However, the SCID has a higher cost than the GAD-7 as it requires specialist training for clinical interviewers and is more time consuming to administer in comparison to self-report measures.

A further limitation to psychological assessment is that women may not fully acknowledge their level of anxiety and use 'emotional cushioning', where women's emotions are held back until they have a greater certainty of maintaining a pregnancy or until they hold a live baby in their arms (Côté-Arsenault & Donato 2011). Emotional cushioning and other self-protective mechanisms, which women may use to cope during stressful pregnancies, highlight that women's anxiety in pregnancy might be underreported and underestimated (Côté-Arsenault & Donato 2011).

Criticisms of self-report measures of anxiety have highlighted the need for self-awareness and insight into the individual's own mental health. The use of self-report instruments are also susceptible to demand characteristics, that is where participants may be motivated to exaggerate or minimise their responses (Gerald & George 2010). Many women may worry about the consequences of disclosing their symptoms due to the perceived stigma surrounding mental health, lack of trust in HCPs and concerns that their baby may be taken away from them if they disclose a mental health problem (NICE 2007; Improving Access to Psychological Therapies (IAPT) 2013, Russell et al. 2013).

Vieten & Astin (2008) aimed to recruit anxious pregnant women into an intervention study but reported that women were reluctant to identify themselves as being anxious. However, when the authors presented the intervention as helping women

cope with stress and difficult moods, the recruitment rate improved.

1.1.8 Treatment of anxiety and current healthcare guidelines

Current mental health services for pregnant women in the UK are provided in a variety of settings depending on the range and severity of symptoms. These include: 1. specialist inpatient mother and baby units; 2. specialist perinatal community mental health teams; 3. adult mental health services (community and hospital based); 4. clinical psychology services linked to maternity care; 5. maternity services; 6. IAPT services; 7. General Practitioners; 8. health and social care organisations; 9. voluntary and self-help organisations (Joint Commissioning Panel for Mental Health 2012). Up to 90% of anxiety disorders in general populations are treated in primary care settings (NCCMH 2007).

Treatment recommendations

The treatment of anxiety disorders mainly focuses around alleviating the core symptoms such as worry, irritability, tension and fatigue (Lorenz et al. 2010). Treatment can be provided through pharmacological and/or non-pharmacological interventions (Anderson & Palm 2006; Borkovec & Ruscio 2001; Fisher 2006). The aim of interventions for pregnant women with symptoms of mild to moderate anxiety is to provide suitable and timely support and treatment to prevent an escalation of symptoms and improve a woman's ability to cope (NICE 2007; Maternal Mental Health Alliance (MMHA) 2013).

The maternal mental health pathway (Department of Health (DOH) 2012) stated that all women identified with mild to moderate mental health issues should have access to a range of support such as wellbeing advice, guided self-help, motivational

interviewing, Cognitive Behavioural Therapy (CBT) and medication (DOH 2012). Many women who take medication for anxiety stop taking it when they are pregnant (NICE 2014), due to the uncertainty surrounding the risk of teratogenicity (Baldwin et al. 2005). Non-pharmacological interventions are therefore recommended as the initial treatment option (NICE 2014). The Healthy Child Programme (DOH 2009) highlighted possible interventions to support women with anxiety in pregnancy, including social support, assisted self-help and CBT. The NICE guideline for perinatal mental health (NICE 2014) suggested that low intensity psychological interventions may benefit women with symptoms of mild to moderate anxiety which significantly interfere with personal or social functioning. Psychological interventions that have demonstrated effectiveness in non-pregnant populations with a GAD often include components of: psycho-education; early detection of anxiety cues such as physical symptoms (e.g. stomach pains) or avoidance of impulsive behaviours; monitoring of anxious responses; applied relaxation; guided imagery; coping skills rehearsal; and cognitive restructuring (Barlow 2002, Behar et al. 2009, Roemer & Orsillo 2002).

Availability of effective care for women with anxiety

Services to support women with symptoms of anxiety are not always readily available and need to be strengthened in order to provide suitable and timely support and treatment to help avoid illness (Independent Mental Health Taskforce 2016, MMHA 2013). However, the evidence of the effectiveness of interventions has not yet been determined (Bauer et al. 2016, Glover 2014, Howard et al. 2014, Ryan 2013). Further research is required to provide the evidence of the effectiveness of interventions to improve the symptoms of mild to moderate anxiety in pregnant women.

Acceptability of anxiety interventions

Four pilot studies have assessed women's views on self-help and group psychological interventions to improve symptoms of anxiety and stress in pregnancy. Most women reported the interventions to be enjoyable and helpful in enhancing their psychological wellbeing and developing coping skills (Cornsweet Barber et al. 2013; Dunn et al. 2012; Goodman et al. 2014; Woolhouse et al. 2014).

Timing of interventions in pregnancy

At present there is no consensus on the optimal timing for interventions to reduce the symptoms of anxiety in pregnancy. Glover (2014) highlighted that the adverse effects associated with antenatal anxiety are not all caused in the first trimester and although it is best to start interventions as early as possible, later interventions may also be beneficial.

1.2 Study rationale and research questions

There were 696,271 live births in England and Wales in 2016 (Office for National Statistics 2016). Applying a prevalence rate of 14.6% (Heron et al. 2004), it is possible that around 101,656 women may experience symptoms of anxiety during their pregnancy. It is considered that psychological interventions may be beneficial in reducing symptoms of anxiety in pregnancy. However, interventions need to be developed and evaluated in pregnant populations to strengthen the evidence base.

In the UK, midwives provide care for every pregnant woman and are ideally placed to identify mental health concerns (Oates 2003; O'Hara 2009) and support women's emotional wellbeing throughout pregnancy and the postnatal period (Alderdice & Lynn 2009; MMHA 2013).

The following research questions were developed following the initial review of the literature:

- *What non-pharmacological interventions have been reported for women with anxiety in pregnancy?*
- *How effective are these interventions for improving symptoms of anxiety in pregnancy?*
- *What are the strengths and limitations of these interventions?*
- *What further improvements can be made to interventions to enhance the acceptability for pregnant women with mild to moderate symptoms of anxiety?*
- *How can interventions be improved to enhance the feasibility specifically for facilitation by midwives in UK maternity care?*

1.3 Study aims and objectives

The overarching aim of the study was to develop an intervention that could be delivered by or facilitated by midwives to improve symptoms of mild to moderate anxiety in pregnant women.

Objectives:

1. To locate and assess research papers which report the effectiveness of non-pharmacological interventions to reduce the symptoms of mild to moderate anxiety in pregnant women.
2. To develop a protocol for a new intervention to test in a feasibility study.
3. To undertake a feasibility study.
4. To assess the acceptability of the intervention for women.
5. To assess the feasibility of the intervention for facilitators.
6. To identify where further developments and refinements can be made to improve implementation of the intervention by midwives in the context of UK maternity care.

7. To produce a report of the findings and a protocol for testing the new intervention in a pilot trial.

The study was developed in three distinct phases: 1. systematic reviews; 2. development of a new intervention and 3. a feasibility study of the newly developed intervention. The study design combined sequential and concurrent strands of data collection and analysis over the period of the study to address overarching aims and objectives. It is a framework often used in the development, adaptation, and evaluation of intervention programmes (Creswell & Clark 2011). Each phase involved concurrent qualitative and quantitative data collection and analysis, with the phases sequentially aligned to build on the findings from the previous phase. This design allowed a set of incremental research questions to be answered that advanced the central research objective.

The following chapter will report phase one of the study, undertaken to address the first research objective: to locate and assess research papers which report the effectiveness of non-pharmacological interventions to reduce the symptoms of mild to moderate anxiety in pregnant women.

Chapter 2 Systematic review

2.1 Introduction

In this Chapter, the conduct and findings from two systematic reviews (SR) will be reported. The reviews were conducted to locate and assess research papers which report the effectiveness and acceptability of non-pharmacological interventions to reduce the symptoms of mild to moderate anxiety in pregnant women. The SRs addressed the following research questions:

1. What non-pharmacological interventions to reduce the symptoms of anxiety in pregnant women have been tested?
2. How effective are non-pharmacological interventions in reducing the symptoms of mild to moderate anxiety in pregnant women?
3. How acceptable for pregnant women are non-pharmacological interventions for reducing the symptoms of mild to moderate anxiety?
4. How beneficial do pregnant women consider non-pharmacological interventions to be in reducing the symptoms of mild to moderate anxiety in pregnancy?

2.1.1 Scoping review

A scoping review was undertaken to identify appropriate parameters for the development of the PICOS (Population, Intervention, Comparator, Outcome, Study design) process for the systematic review (Centre for Reviews and Dissemination (CRD 2009). The scoping review followed the framework by Arksey & O'Malley (2005). The scoping review search was limited to four electronic bibliographic databases (Maternity & Infant Care, MedLine, PsychINFO and The Cochrane Library). Studies published in English over the previous ten years (2004 – 2014) were included. The following search terms were used:

'intervention or programme or trial' and 'anxiety' and 'pregnancy or antenatal'.

The scoping search identified 626 papers. The search results were sifted by reading the study titles and abstracts. Papers were excluded if they did not report outcomes from primary research, did not focus on pregnancy or intervention studies. Twenty-two papers were included in the scoping review. The papers included pilot studies, experimental and quasi-experimental studies, qualitative studies, systematic reviews and literature reviews (Appendix 2.1).

The interventions included in the scoping review were mapped into four main themes: mind-body interventions, psychological, supportive and educational. The scoping review also identified acupuncture and exercise interventions which could be included under a wider definition of non-pharmacological interventions. Interventions included women from general antenatal populations and women identified with symptoms of anxiety, depression or distress identified through structured clinical interviews, measurement scales, HCP referral and reported symptoms. The scoping review findings informed the mapping of inclusion criteria for the systematic review and the development of the search strategy.

2.1.2 Systematic review aims and objectives

Following the scoping review, it was decided to conduct two separate systematic reviews:

1. A systematic review and meta-analysis to assess the effectiveness of non-pharmacological interventions to reduce the symptoms of mild to moderate anxiety in pregnant women.
2. A systematic review and narrative synthesis to assess women's views on the acceptability of and satisfaction

with non-pharmacological interventions to reduce the symptoms of mild to moderate anxiety in pregnant women.

The following objectives were developed:

- To locate research papers which report non-pharmacological interventions to reduce the symptoms of anxiety in pregnant women.
- To assess the effectiveness of non-pharmacological interventions in reducing the symptoms of mild to moderate anxiety in pregnant women.
- To assess the acceptability for pregnant women of non-pharmacological interventions for reducing the symptoms of mild to moderate anxiety.
- To explore pregnant women's satisfaction with non-pharmacological interventions to be in reducing the symptoms of mild to moderate anxiety in pregnancy.

The methods and findings are presented and discussed separately (in sections 2.2 and 2.3). The findings were then integrated and used to draw overall conclusions which informed the design of a new intervention.

2.1.3 Systematic review framework

The systematic reviews were both conducted following the Centre for Reviews and Dissemination guidelines (CRD 2009). The review protocols were registered on the PROSPERO database at the CRD (Evans et al. 2015: CRD42015017841). Reporting followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement guidelines (Moher et al. 2009) and the narrative synthesis followed the guidelines by Popay et al. (2006).

2.1.4 Search strategy

A systematic search of the following 13 electronic databases was undertaken in January 2015 and updated in August 2016:

Medline (Medical Literature Analysis and Retrieval System Online), CINAHL (Cumulative Index to Nursing and Allied Health Literature), Maternity and Infant Care database from MIDIRS (Midwives Information and Resource Service), PsycINFO, The Cochrane Database of Systematic Reviews and The Cochrane Register of Controlled Trials (CENTRAL), EMBASE (Excerpta Medica Database), CRD (Centre for Reviews and Dissemination), SSCI (Social Sciences Citation Index), ASSIA (Applied Social Sciences Index and Abstracts), HTA Library (Health Technology Assessment Library), JBI (Joanna Briggs Institute) Evidence-Based Practice Database and AMED (The Allied and Complementary Medicine Database). Forward citation searches and visual scanning of reference lists from relevant primary studies and reviews identified three additional studies for inclusion. A full search strategy for the two reviews is included in Appendix 2.2. The studies had to be written in English and published since 1990, to reflect the time since non-pharmacological interventions were recommended to support women's mental health during pregnancy (DOH 1999).

2.2 Systematic review and meta-analysis of non-pharmacological interventions to reduce the symptoms of mild to moderate anxiety in pregnant women

The following PICOS parameters were developed to meet the review objectives and were refined in response to the findings of the scoping review.

2.2.1 Inclusion and exclusion criteria

	Inclusion	Exclusion	Rationale
Population	Studies with pregnant women of all parities across the three trimesters of pregnancy, from general antenatal populations and pregnant women with symptoms of mild to moderate anxiety	Studies with pregnant women with severe symptoms of anxiety and/or depression; under the care of specialist mental health services; less than 18 years of age; who lacked capacity to provide informed consent and pregnant women with complex social factors (NICE 2010)	Women with severe mental health concerns and complex social factors have established referral pathways to specialist services. There is limited support for women with mild to moderate symptoms of anxiety
Intervention	Studies of non-pharmacological interventions, including: physical; cognitive; behavioural and other complementary methods		Non-pharmacological interventions are recommended as the initial treatment option for symptoms of anxiety in pregnancy (NICE 2014) and are potentially feasible to be delivered or facilitated by midwives

Comparators	Studies with comparison groups which comprised any form of usual maternity care or other pharmacological or non-pharmacological interventions		The scoping search revealed that RCT interventions were compared with usual care, educational, mind-body and pharmacological interventions
Outcomes	Studies in which the primary or secondary outcome measure included symptoms of anxiety identified by various self-report measures or clinical interview measured at any time in the antenatal period prior to the onset of labour. Studies were included if the evaluation focused on the effects on symptoms of anxiety alone or anxiety and other psychosocial outcomes	Studies that did not include symptoms of anxiety as an outcome measure or where symptoms of anxiety were only measured in the intrapartum or postnatal period	The effects of anxiety are often studied alongside depression because of the established co-morbidity (Glover 2014).
Study design	Randomised Controlled Trials (RCTs) and pilot RCTs of non-pharmacological interventions, systematic reviews and meta-analyses	Non-randomised studies	

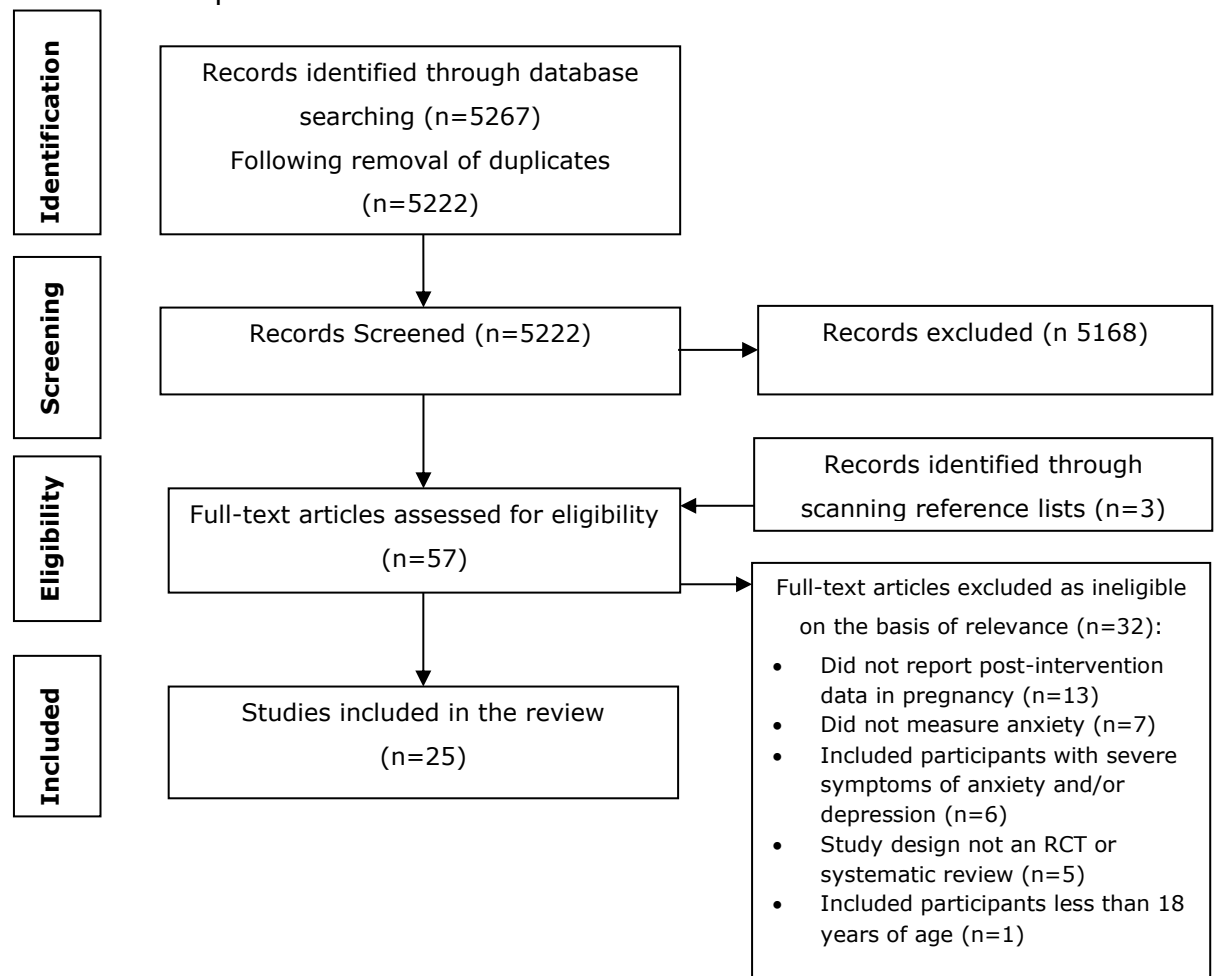
2.2.2 Search outcomes

After 45 duplicates were deleted, the search identified 5,222 potentially eligible papers which were individually assessed on the information provided in the study title and abstract. When the exclusion criteria were applied, 5,168 records were

excluded. Following the inclusion of three additional papers identified through scanning reference lists of relevant studies, 57 papers were retrieved for the full text assessment. From these, 32 papers were excluded and the remaining 25 papers were selected for inclusion. A research supervisor independently read the potentially relevant papers and the papers identified for inclusion were agreed with two disagreements resolved through discussion with a second research supervisor. The literature search and inclusion process are detailed in the PRISMA Flow Diagram in Figure 2.1 (Moher et al. 2009).

The twenty-five included randomised controlled trials were reported between 1992 and 2016 (Table 1) and were conducted in Australia, Belgium, Canada, Germany, Greece, India, Iran, New Zealand, Portugal, Switzerland, Taiwan, the UK and the US. Six studies were pilot Randomised Controlled Trials (RCTs). The total number of participants included in the 25 studies was 5,156. The sample sizes ranged from 25 participants (Côté-Arsenault et al. 2014) to 2,212 participants (Dodd et al. 2016).

Figure 2.1. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram of systematic reviews and randomised controlled trials included in the quantitative review.



2.2.3 Quality appraisal

Twenty-five included RCTs were independently assessed by two reviewers (researcher and academic supervisor). The studies were quality assessed using the Cochrane Collaboration's tool for assessing risk of bias (Higgins et al. 2011) to evaluate six domains: sequence generation; allocation concealment; blinding; incomplete data; selective outcome reporting; and other potential sources of bias.

2.2.4 Data extraction and synthesis

Data were extracted using a predesigned and piloted template which included the following headings: study design; intervention design; recruitment rate; number of participants; setting; outcome measures; control/comparators; results and comments. A data extraction table was produced to present the study characteristics, results and risk of bias. A narrative description of the data was conducted.

Where outcome data were available, the studies were assessed for methodological, clinical and statistical heterogeneity and considered for meta-analysis. Assessment of clinical heterogeneity was informed by the findings from the scoping review (CRD 2009), and considered the types of participants in the included studies (women with obstetric complications, general antenatal population, women with symptoms of or risk factors for mild to moderate anxiety), duration of interventions (single or multiple sessions), delivery of interventions (to individuals or groups) and types of intervention (psychological, mind/body, educational, supportive interventions).

To evaluate statistical heterogeneity, the Chi-squared test was performed to generate the Q-statistic and the I^2 statistic was calculated (CRD 2009, Higgins & Green 2011). A random effects model was considered to be the most appropriate method of analysis as the model involves an assumption that the effects being estimated in the different studies are not identical, but follow some random distribution (CRD 2009, Higgins & Green 2011). The standardised mean difference was used as the summary statistic for the self-report anxiety scores, with 95% confidence intervals and two-tailed p-values calculated for each outcome where possible. The criteria for conducting sub-group analysis were pre-specified in the review protocol: types of participants; timing of interventions; duration of interventions; and types of intervention.

2.2.5 Results

Quality of randomised controlled trials

One study was assessed as having an overall 'low risk of bias' (Faramarzi et al. 2015). One study was assessed as having an overall 'high risk of bias' (Korol & Von Baeyer 1992). Twenty-three studies were assessed as having an overall 'unclear risk of bias'. The risk of bias assessment summary for all included studies is presented in Figure 2.2.

Participants

In seven studies women were recruited from a general population of pregnant women and in four studies nulliparous pregnant women were included. In six studies, pregnant women with a history of mood concerns or elevated anxiety / depression scores were recruited. In the other studies, women were included who were not selected due to anxiety / depression symptoms but women who: had obstetric complications (high BMI, nausea, gestational diabetes mellitus); had social risk factors (single pregnant women or with unemployed partners); were African American pregnant women; were pregnant women attending for amniocentesis and pregnant women with a history of previous pregnancy loss.

Figure 2.2. Cochrane Risk of Bias summary judgements about each risk of bias item for each included RCT.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bastani 2005	?	?	?	?	+	+	?
Bastani 2015	?	?	?	?	+	+	?
Bittner 2014	+	+	?	?	?	+	?
Bogaerts 2013	?	?	?	?	+	+	+
Brugha 2015	+	+	?	+	?	+	?
Bullock 1995	+	?	?	?	+	+	?
Chang 2008	+	?	?	?	+	+	?
Cote Arsenault 2014	?	?	?	?	+	+	?
Davis 2015	+	?	?	?	+	+	?
Dodd 2016	+	?	?	?	+	+	?
Faramazri 2015	+	+	?	+	+	+	+
Guardino 2014	+	?	?	?	+	+	?
Jallo 2014	+	+	?	?	+	+	?
Knight 2001	+	+	?	+	+	+	?
Korol 1992	?	?	?	+	-	-	?
Milgrom 2015	+	+	?	?	+	+	?
Newham 2014	?	+	+	?	?	+	?
Satyaprigta 2013	+	?	?	+	+	+	?
Snaith 2014	+	?	?	?	+	+	+
Texiera 2005	?	+	?	?	+	+	?
Tragea 2014	+	?	?	?	+	+	?
Urech 2010	+	?	?	+	+	+	?
Ventura 2012	+	?	?	?	+	+	?
Vieten 2008	?	?	?	?	+	+	?
Woolhouse 2014	?	+	?	?	?	+	?

+ low risk of bias

? unclear risk of bias

- high risk of bias

Recruitment

A power calculation to determine the correct sample required to detect significant changes in the primary outcome was reported in 12 studies. The primary outcome was self-report measures of anxiety in seven of these studies.

In the included studies, pregnant women were mainly recruited from hospital antenatal clinics. Five studies recruited women from community locations (Bullock et al. 1995, Brugha et al. 2015, Côté-Arsenault et al. 2014, Davis et al. 2015, Newham et al. 2014). In most studies, a HCP approached potential participants during an antenatal clinic appointment. Pregnant women also self-selected into studies, study information was distributed: by posting flyers in clinic locations (Guardino et al. 2014, Vieten & Astin 2008, Woolhouse et al. 2014,); by midwives and HCPs during antenatal classes (Korol & Von Baeyer 1992, Vieten & Astin 2008, Woolhouse et al. 2014) and support groups (Côté-Arsenault et al. 2014), by HCPs at women's attendance at ultrasound scan (Snaith et al. 2014) and by HCPs during physiotherapy appointments (Woolhouse et al. 2014).

Symptoms checklists were used to assess participant eligibility in five studies:

- Bittner et al. (2014): STAI, BDI and PDQ followed by a diagnostic interview.
- Teixeira et al. (2005): STAI.
- Davis et al. (2015): STAI and EPDS.
- Guardino et al. (2014): PSA and PSS.
- Milgrom et al. (2015): EPDS and a Structured Clinical Interview for DSM-IV (SCID).

Interventions

Various types of interventions were tested in the included studies. For the purpose of the study, interventions have been categorised with reference to published definitions of mind-body (Wahbeh et al. 2008) and psychological interventions (Australian Psychological Society 2010).

1. Mind-body: hypnosis, meditation, yoga, biofeedback, tai chi, and visual imagery.
2. Psychological: CBT, motivational interviewing, psychotherapy.
3. Supportive: social, emotional or practical support provided by HCPs or peer groups.
4. Educational: health education and advice.

Categories were defined with reference to the main interventional approach reported in the included studies. Some studies included multiple components in the intervention design therefore a description of the interventions is included in Table 2.1.

- Fourteen studies evaluated mind-body interventions including:
 - relaxation (Bastani et al. 2005, Chang et al. 2008, Teixeira et al. 2005, Tragea et al. 2014, Ventura et al. 2012).
 - guided imagery (Jallo et al. 2014, Korol & Von Baeyer 1992, Urech et al. 2010).
 - mindfulness (Vieten & Astin 2008, Woolhouse et al. 2014, Guardino et al. 2014).
 - yoga (Newham et al. 2014, Satyapriya et al. 2013, Davis et al. 2015).
- Four studies evaluated psychological interventions including:
 - CBT (Bittner et al. 2014, Milgrom et al. 2015).

- CBA (Brugha et al. 2015).
 - MCBT (Faramarzi et al. 2015).
- Three studies evaluated supportive interventions, including:
 - telephone peer support (Bullock et al. 1995).
 - midwifery telephone support (Snaith et al. 2014).
 - home visits by nurses (Côté-Arsenault et al. 2014).
- Two studies evaluated educational interventions focused on health, diet and exercise (Bogaerts et al. 2012, Dodd et al. 2016).
- One study evaluated an acupuncture intervention (Knight et al. 2001).
- One study evaluated an acupressure intervention (Bastani et al. 2015).

First author Country Year	Intervention category (duration)	Intervention, control and comparison group. * Description of intervention ** Facilitator / facilitator training	Included women	Primary outcome (secondary outcome)	Gestation at start / post intervention. (weeks of pregnancy)	Analysed n= Post-intervention / baseline (method of analysis)	Main anxiety measure mean score: Baseline / post-intervention	Key anxiety results as reported in the included RCTs / pilot RCTs	Risk of bias assessed as:
Bogaerts Belgium 2013	Educational (4 group sessions)	IG: Motivational interviewing, CG: Standard care Comp: Brochures * Discussed energy intake and women's concerns in pregnancy ** Midwife / Motivational techniques	Pregnant women: BMI 29 or more	1. Maternal weight gain (Depression, anxiety, birthweight, prematurity)	<15 / (30-34)	IG: 76 / 78 CG: 63 / 63 Comp: 58 / 64 (Direct likelihood model)	STAI-S IG: 36.5 / 34.0 CG: 35.0 / 38.0 Comp: 35.9 / 37.6	RCT: reported STAI-S scores significantly decreased in the IG and increased in the CG post-intervention (p=0.02, n=141) (multivariate linear mixed effects model, time by group interaction)	Unclear
Dodd Australia 2016	Educational (5 individual sessions, 20-30 weeks)	IG: Diet / exercise education, CG: Standard care * Healthy eating advice; dietary and exercise goals and support with lifestyle changes. ** Dietician and research assistants / NR	Pregnant women: BMI 25 or more	1. Birthweight (Quality of life, depression, anxiety)	(12-17) / 36	IG: 1108 / 1108 CG: 1104 / 1104 (ITT analysis)	STAI short IG: 10.7 (SD 3.8) / 10.6 (SD 3.6) CG: 10.8 (SD 3.9) / 10.4 (SD 3.6)	RCT: reported no significant differences in STAI scores between groups post-intervention (p=0.51, n=2122) (multivariate linear mixed effects model, time by group interaction, 95% CI=0.19-0.38)	Unclear
Bastani Iran 2005	Mind body (7 group sessions)	IG: Relaxation, CG: Standard care * Discussion of and information on anxiety, stress and relaxation in pregnancy. Taught relaxation techniques. ** Instructor/ NR	Nulliparous pregnant women	1. Anxiety 2. Stress	18 (mean) / 25 (approximately)	IG: 55 / 55 CG: 55 / 55 (ITT analysis)	STAI-S IG: 37.2 (SD 5.4) / 22.7 (SD 7.4) CG: 38.6 (SD 6.5) / 38.5 (SD 5.7)	RCT: reported significant reductions in STAI-S scores for the IG compared with the CG post-intervention (p=0.001, n=110) († independent samples t-test, post-intervention between group scores)	Unclear
Chang Taiwan 2008	Mind body (daily exercises via audio CD, 2 weeks)	IG: Relaxing music, CG: Standard care * Audio CD (30 mins) with a choice of: classical music; nature sounds or crystal music performing Chinese children's songs. ** Audio CD / NR	General pregnant population	1. Anxiety 2. Depression 3. Stress	(18-34) / NR	IG: 116 / 120 CG: 120 / 121 (Analysis NR)	STAI-S IG: 37.9 (SD 9.8) / 35.8 (SD 10.9) CG: 37.1 (SD 10.0) / 37.8 (SD 12.1)	RCT: reported IG STAI-S scores were significantly different from the CG post-intervention (2.13 p=0.01). There was a significant between group difference in scores (values not reported, n=241) (ANCOVA, baseline scores as co-variables)	Unclear
Tragea 2014 Greece	Mind body (6 individual sessions)	IG: Relaxation / stress reduction, Comp: Educational materials * Audio CD (20 mins) with relaxation techniques and a healthy lifestyle brochure. ** Audio CD / NR	Nulliparous pregnant women	1. Anxiety 2. Stress 3. Locus of control	(14-21) / (21-28)	IG: 31 / 44 Comp: 29 / 41 (Per-protocol analysis)	STAI-S (median/IQR) 95% CI IG: 38.0 (35-42) / MC -3.5 [+/- 2.8] Comp: 40.0 (30-52) / MC -2.0 [+/- 2.9]	RCT: reported no significant difference for STAI-S scores between groups post-intervention (mean change= -1.5, 95%CI -2.7 to 1.7, n=60) (ANCOVA, baseline STAI-S score as co-variate)	Unclear
Teixeira UK 2005	Mind body (1 individual session)	IG: Active relaxation, Comp: Passive relaxation * Stress management: using imagination to induce feelings of comfort. Based on hypnotherapeutic methods. ** Stress management expert / NR	General pregnant population	1. Cortisol 2. Uterine artery resistance (Anxiety)	(28-32) / (28-32)	IG: 29 / 29 Comp: 29 / 29 (ITT analysis)	STAI-S (median/95% CI) IG: 38.5 (35-42) / 24.5 (23-27) Comp: 37.0 (32-42) / 27.5 (25-30)	RCT: reported both IG and Comp groups had reduced STAI-S scores, significantly greater in the IG (95% CI, p=0.0001, n=58) († independent samples t-test, comparison of deltas p=0.01, pre/post intervention between groups change score)	Unclear
Urech Switzerland 2010	Mind body (1 individual session)	IG: Active relaxation, CG: Passive relaxation Comp: Guided imagery * Monitored women's BP, attached to CTG and inserted a brachial vein catheter. Relaxation and guided imagery. ** Audio CD / NR	General pregnant population	1. Relaxation 2. Anxiety 3. Endocrine parameters 4. Cardiovascular responses	32 (mean) / 32 (mean)	IG: 13 / 13 CG: 13 / 13 Comp: 13 / 13 (ITT analysis)	STAI-S IG: 37.7 / 30.9 CG: 31.5 / 29.9 Comp: 30.9 / 28.1	RCT: reported no significant change of STAI-S scores from baseline to post-intervention. Anxiety scores decreased equally in all groups (d=0.38, p=0.030, F1,35=5.14, n=39) (mixed effect ANOVA, time by group interaction)	Unclear
Ventura Portugal 2012	Mind body (1 individual session)	IG: Relaxing music, CG: Sitting, Comp: Magazines * Relaxing music a choice of: light vocals; light instrumental; classical or vocal jazz. ** Audio CD / NR	Pregnant women attending for amniocentesis	1. Anxiety (Maternal cortisol levels)	17 / 17	IG: NR / 61 CG: NR / 47 Comp: NR / 46 (ITT analysis)	STAI-S IG: MD -7.6 (SD 8.3) CG: MD -4.5 (SD 5.7) Comp: MD -5.5 (SD 6.4)	RCT: reported STAI-S scores decreased in all groups (p=0.058). IG scores were significantly different from the comp and CG (F2,150=7.3, p=0.001, n=108) (ANCOVA, baseline STAI-S score as co-variate)	Unclear

<i>First author Country Year</i>	<i>Intervention category (duration)</i>	<i>Intervention, control and comparison group. * Description of intervention ** Facilitator / facilitator training</i>	<i>Included women</i>	<i>Primary outcome (secondary outcome)</i>	<i>Gestation at start / post intervention. (weeks of pregnancy)</i>	<i>Analysed n= Post-intervention / baseline (method of analysis)</i>	<i>Main anxiety measure mean score: baseline / post-intervention</i>	<i>Key anxiety results as reported in the included RCTs / pilot RCTs</i>	<i>Risk of bias assessed as:</i>
Korol Canada 1992	Mind body (group sessions, number NR)	IG: Guided imagery, Comp: Antenatal classes * Information about the birth process and relaxation techniques with visualisation. ** Instructor / NR	General pregnant population	1. Knowledge of childbirth (Anxiety, depression)	NR	IG: 30 / 30 Comp: 30 / 30 (Analysis NR)	STAI-S IG: 31.1 (SD 6.4) / 33.0 (SD 5.3) Comp: 37.0 (SD 9.9) / 36.9 (SD 10.0)	RCT: reported no significant difference between the STAI-S scores between the groups post-intervention (n=60) (values not reported)	High
Jallo US 2014	Mind body (daily exercises via audio CD, 12 weeks)	IG: Guided imagery, CG: Standard care * Relaxation; focused breathing and multisensory images to promote reduction of stress and anxiety and restore levels of energy. ** Audio CD / authored by a trained guided imagery instructor	Pregnant African American women	1. Stress (Anxiety, fatigue)	15 (mean) / (26-29)	IG: 36 / 36 CG: 36 / 36 (ITT analysis)	STAI-S IG: 39.6 (SE 2.3) / 36.4 (SE 2.4) CG: 39.4 (SE 2.2) / 34.4 (SE 2.3)	RCT: reported no significant differences in STAI-S scores between the groups post-intervention (p=0.606, n=72) (multivariate linear mixed effects model, time by group interaction)	Unclear
Vieten US 2008	Mind body (8 group sessions)	IG: Mindfulness, CG: Wait list (postnatal) * Mindfulness: meditation; Hatha yoga. Adaptations for pregnancy: awareness of the developing fetus and body; explanations and discussions about coping with anxiety in labour ** Psychologist / Mindfulness and yoga	Pregnant women: history of mood concerns	1. Stress 2. Depression 3. Anxiety 4. Positive / negative affect	25 (mean) / 35 (approximately)	IG: 13 / 15 CG: 18 / 19 (Analysis NR)	STAI-S IG: 43.8 (SD 12.4) / 35.4 (SD 9.1) CG: 35.6 (SD 10.9) / 35.6 (SD 8.4)	Pilot RCT: reported significantly reduced STAI-S scores in the IG in comparison to the CG post-intervention (F2,24=4.32, p=0.04, d=0.58, n=31), (ANCOVA, baseline STAI-S score as co-variate)	Unclear
Guardino US 2014	Mind body (6 group sessions)	IG: Mindfulness, Comp: Pregnancy book * Mindfulness meditation, lectures, discussions and sharing experiences. Guided meditations to use at home. ** Mindfulness instructor / Curriculum outlined in a standardised manual.	Pregnant women with elevated anxiety / stress scores	1. Mindfulness 2. Stress 3. Anxiety 4. Adherence	18 (mean) / 23 (mean)	IG: 24 / 24 Comp: 23 / 23 (ITT analysis)	STAI-S IG: 45.7 (SD 7.6) / 39.5 (SD 6.3) Comp: 44.4 (SD 10.9) / 37.4 (SD 11.5)	Pilot RCT: reported significant between group differences for the PSA and moderately significant for the PRA (p=0.01, p=0.07 respectively, n=47), no significant differences for STAI-S scores (multivariate linear mixed effects model, time by group interaction)	Unclear
Woolhouse Australia 2014	Mind body (6 group sessions)	IG: Mindfulness, CG: Standard care * 'MindBabyBody': breathing practice; body scan (communicating with babies); mindfulness of pain and thoughts; meditation; self-compassion; mindfulness skills in motherhood. ** Psychologist and Psychiatrist / Facilitation of mindfulness groups	General pregnant population	1. Stress 2. Depression 3. Anxiety	(11-34) / (17-40)	IG: 13 / 17 CG: 10 / 15 (Analysis NR)	STAI-S IG: 35.9 (SD 14.1) / 32.8 (SD 7.1) CG: 34.8 (SD 11.5) / 33.0 (SD 12.8)	Pilot RCT: reported significant changes on the DASS-21 anxiety subscale for the IG (Cohen's d=0.7). No significant between group differences for the IG and CG for the STAI-S or DASS-21 anxiety post-intervention sub-scale scores (values not reported n=23) (independent samples t-test)	Unclear
Satyapriya India 2013	Mind body (12 group sessions and daily home exercises, 16-18 weeks)	IG: Yoga, CG: Standard care * Integrated approach of yoga therapy (IAYT): physical postures; exercises; stretches; relaxation; breathing techniques and meditation. Audio cassette for home use. ** Trained yoga instructor / NR	General pregnant population	1. Anxiety 2. Depression	(18-20) / 36	IG: 51 / 53 CG: 45 / 52 (Analysis NR)	STAI-S IG: 35.7 (SD 7.1) / 30.1 (SD 5.7) CG: 36.4 (SD 6.0) / 39.7 (SD 6.8)	RCT: reported STAI-S and HADS-A scores reduced in the IG and increased in the CG with significant difference between groups post-intervention (p=0.001, n=105) (Mann-Whitney U test, post-intervention between group scores)	Unclear
Newham UK 2014	Mind body (8 group sessions)	IG: Yoga, CG: Standard care * Hatha yoga at each class. Sessions themed to aid common pregnancy ailments, optimal positioning of the fetus and stages of labour. ** Yoga instructor / British Wheel of Yoga	Nulliparous pregnant women	1. Pregnancy specific anxiety (Anxiety, depression)	21 (mean) / (29-30)	IG: 29 / 31 CG: 22 / 28 (Per-protocol analysis)	STAI-S (median/IQR) IG: 28.0 (24-42) / 27.0 (22-36) CG: 32.0 (24-37) / 34.0 (25-38)	RCT: reported no significant difference in STAI-S scores between the groups post-intervention (p=0.5, r=-0.09, n=51) (Mann-Whitney U test, post-intervention between group scores)	Unclear
Davis US 2015	Mind body (8 group sessions)	IG: Yoga, CG: Standard care * Ashtanga Vinyasa yoga modified for pregnancy. Video for home use. ** Yoga instructor / Experience in prenatal yoga	Pregnant women with elevated anxiety /	1. Depression 2. Anxiety 3. Positive and negative affect	21 (mean) / (28-29)	IG: 23 / 23 CG: 23 / 23 (ITT analysis)	STAI-S IG: 36.9 (SD 12.2) / 34.8 (SD 10.7) CG: 41.7 (SD 10.8) / 38.8 (SD 13.7)	RCT: reported no significant effect of group or the interaction between group and time, STAI-S scores decreased over time in both groups (p=0.05, 95% CI=0.96-0.47, n=46) (multivariate	Unclear

			depression scores	(satisfaction, adherence)				linear mixed effects model, time by group interaction)	
<i>First author Country Year</i>	<i>Intervention category (duration)</i>	<i>Intervention, control and comparison group. * Description of intervention ** Facilitator / facilitator training</i>	<i>Included women</i>	<i>Primary outcome (secondary outcome)</i>	<i>Gestation at start / post intervention. (weeks of pregnancy)</i>	<i>Analysed n= Post-intervention / baseline (method of analysis)</i>	<i>Main anxiety measure mean score: baseline / post-intervention</i>	<i>Key anxiety results as reported in the included RCTs / pilot RCTs</i>	<i>Risk of bias assessed as:</i>
Milgrom Australia 2015	Psychological (8 individual sessions)	IG: CBT, CG: Standard care * 'Beating the Blues Before Birth' based on 'Coping with Depression' (Lewinsohn et al. 1984): relaxation; behavioural activation before cognitive strategies; building support networks; partner sessions; preparation for parenthood; infant and relationship issues and anxiety. ** Psychologists with a background in CBT	Pregnant women with elevated depression scores	1. Depression 2. Anxiety (Infant outcomes)	20 (mean) / 29 (approximately)	IG: 27 / 27 CG: 27 / 27 (ITT analysis)	BAI IG: 22.4 (SD 10.1) / 10.4 (SD 7.6) CG: 20.6 (SD 10.7) / 17.4 (SD 7.9)	Pilot RCT: reported anxiety scores decreased in the IG but not in the CG. Between group differences for anxiety scores represented moderately large effect sizes post-intervention (p=0.006, d=0.67, 95% CI=0.33–1.01, n=54) (ANCOVA, baseline scores as co-variate)	Unclear
Bittner Germany 2014	Psychological (8 group sessions)	IG: CBT, CG: Standard care * CBT: coping strategies; self-assurance; problem solving; discussions around anxiety; prevention and treatment; future challenges. ** Psychologist / CBT Training	Pregnant women with elevated anxiety and depression scores	1. Depression 2. Anxiety (Fear of childbirth, social support)	16 (mean) / 24	IG: 21 / 80 CG: 53 / 80 (Analysis NR)	STAI-S IG: 38.0 (SD 6.1) / 35.0 (SD 7.0) CG: 38.0 (SD 6.2) / 36.9 (SD 7.7)	RCT: reported no significant difference between groups for the STAI-S scores post-intervention (p=0.246, $\eta^2=0.019$, n=74) (2-way repeated measures ANOVA)	Unclear
Faramarzi Iran 2015	Psychological Group MBCT (8 group sessions)	IG: MBCT, CG: Standard care * Integrated elements of MBSR, CBT and guided eating meditations. Pharmacological treatment for the IG and CG (pyridoxine hydrochloride) ** MBCT psychotherapist / MBCT methods within obstetric departments	Pregnant women with moderate nausea and vomiting	1. Nausea and vomiting (Anxiety, depression, distress)	8 (mean) / 11 (approximately)	IG: 43 / 43 CG: 43 / 43 (ITT analysis)	HADS-A IG: 11.3 (SD 4.4) / 6.2 (SD 3.1) CG: 10.1 (SD 3.7) / 10.1 (SD 3.8)	RCT: reported significant effect for group by time on HADS-A scores (p=0.001, d=0.53, n=86) (mixed effect ANOVA, time by group interaction)	Low
Brugha UK 2015	Psychological (up to 3 individual sessions, 22 weeks)	IG: Midwife psychological training, CG: Standard care * Midwife training: assessment of depressive symptoms; CBA; therapeutic relationships; Five Areas approach (Williams et al. 2008) ** Midwives / Based on training by Morrell et al. (2009) and adapted for pregnancy	General pregnant population	1. Depression (Anxiety and satisfaction)	22 / 34 (approximately)	IG: 118 / 165 CG: 94 / 133 (Pilot study – descriptive statistics)	STAI-S IG: NR / 38.2 (SE 0.9) CG: NR / 40.3 (SE 1.0)	Pilot RCT: Anxiety results not discussed in the paper	Unclear
Bullock New Zealand 1995	Supportive Interventions (individual sessions 10+ weeks)	IG: Telephone support, Comp: Leaflets * Discussions of women's feelings and concerns with questions about wellbeing in pregnancy. ** Peer volunteers / Healthy pregnancy, research and communication	Pregnant women who were single or with an unemployed partner	1. Depression 2. Anxiety 3. Stress 4. Social support	<20 / 34	IG: 59 / 65 Comp: 63 / 66 (Analysis NR)	STAI-S IG: 32.8 / 30.1 Comp: 34.3 / 34.1	RCT: reported no significant difference between the STAI-S scores between the groups post-intervention (p=0.05, n=122) (ANCOVA, baseline STAI-S score as co-variate)	Unclear
Snaith UK 2014	Supportive Interventions (3 individual sessions, 17 weeks)	IG: Telephone support / Doppler, CG: Standard care, Comp: Telephone support * Addressed the needs of the woman. Discussion guide: physical health; availability support; personal and fetal wellbeing. ** Midwife / Delivering the intervention	Nulliparous pregnant women	1. Number of antenatal visits (Anxiety)	20 / 36	IG: 170 / 275 CG: 159 / 283 Comp: 166 / 282 (ITT analysis)	STAI-S IG: 35.7 (SD 10.0) / 36.2 (SD 9.9) CG: 36.2 (SD 10.5) / 36.7 (SD 10.9) Comp: 36.9 (SD 10.9) / 37.1 (SD 10.3)	RCT: reported no significant difference between the STAI-S scores between the groups post-intervention (p=0.68, n=495) (one-way ANOVA)	Unclear
Côté-Arsenault US 2014	Supportive Interventions (approximately 5 individual sessions)	IG: Home visits, Comp: Booklets * Providing a safe, supportive environment. Encouraging use of pregnancy diary, teaching skills to reduce anxiety and depression and promote	Pregnant women with a history of at least one	1. Anxiety 2. Depression (Intervention evaluation)	14 (mean) / NR	IG: 12 / 13 Comp: 11 / 11 (Analysis NR)	NR	RCT: reported no significant difference between the STAI-S scores between the groups post-intervention (p=0.66, n=23) (multivariate linear mixed effects model, time by group interaction)	Unclear

	sessions, 20 weeks)	prenatal attachment. Based on the caring process (Swanson, 1993). ** Nurses with additional training / NR	spontaneous perinatal loss						
First author Country Year	Intervention category (duration)	Intervention, control and comparison group. * Description of intervention ** Facilitator / facilitator training	Included women	Primary outcome (secondary outcome)	Gestation at start / post intervention. (weeks of pregnancy)	Analysed n= Post-intervention / baseline (method)	Main anxiety measure mean score: baseline / post-intervention	Key anxiety results as reported in the included RCTs / pilot RCTs	Risk of bias assessed as:
Knight UK 2001	Other (4 individual sessions)	IG: Acupuncture, Comp: Sham acupuncture * Standardised acupuncture procedures. ** Midwife, experienced acupuncture practitioner / Integrated Chinese Medicine acupuncture college	Pregnant women with nausea	1. Nausea (Anxiety, depression)	8 (mean) / (9-14)	IG: 28 / 28 Comp: 27 / 27 (ITT analysis)	HADS-A (median/IQR) IG: 8.0 (6-9) / 7.0 (4-9) Comp: 10.0 (7-13) / 8.0 (5-9)	RCT: reported no significant difference for the HADS scores between the groups (p=0.20, n=57 (repeated measures ANOVA)	Unclear
Bastani Iran 2015	Other (3 individual sessions)	IG: Acupressure, Comp: Pressing at a sham point * Acupressure treatments: massage technique using fingers and palms with a certain amount of force to stimulate true acupoints and meridian lines on the surface of the skin. ** Nurse / Acupressure	Hospitalised pregnant women with GDM who expressed anxiety	1. Anxiety	18 (mean) / 25	IG: 28 / 30 Comp: 29 / 30 (Analysis NR)	MAQ IG: 37.3 (SD 5.9) / 33.3 (SD 4.3) Comp: 36.5 (SD 7.9) / 36.5 (SD 7.3)	RCT: reported significant decreases in the mean MAQ scores for the IG, scores remained unchanged in the comparison group (p=0.05, d=55, t=-1.96, n=57) (independent samples t-test, post-intervention between group scores)	Unclear
<p>ASI - Anxiety Sensitivity Index; BAI - Beck Anxiety Inventory; BMI - body mass index; BP - Blood pressure; CBA - Cognitive behavioural approach; CBT - Cognitive behavioural therapy; CG - control group; CI - confidence interval; Comp - comparison group; CTG - Cardiotocograph; DASS - Depression Anxiety Stress Scale; GDM - Gestational diabetes mellitus; HADS-A - Hospital Anxiety and Depression Scale; IG - intervention group; IQR - inter quartile range; ITT - Intention to treat analysis; MAQ - Maternal Anxiety Questionnaire; MBSR - Mindfulness-based stress reduction; MC - mean change; MCBT - Mindfulness cognitive based therapy; MD - mean difference; NR - Not reported; PRA - Pregnancy Related Anxiety Scale; PSA - Pregnancy Specific Anxiety Scale; SD - standard deviation; SE - standard error; STAI - State Trait Anxiety Inventory; STAI - short form; STAI-S - state anxiety; VASA - Visual Analogue Scale for the Severity of Anxiety.</p> <p>(For all self-report measures reported, a decrease in scores indicated an improvement in anxiety symptoms)</p> <p>† - test not clearly stated in the paper and has been inferred from the information provided</p>									

Theoretical basis

Authors described the theoretical basis for: CBT interventions (Bittner et al. 2014, Milgrom et al. 2015); psychological support / CBA interventions (Brugha et al. 2015, Côté-Arsenault et al. 2014); and mind-body interventions such as acupuncture (Bastani 2015), mindfulness (Guardino et al. 2014, Woolhouse et al. 2014, Vieten & Astin 2008), guided imagery (Jallo et al. 2014), yoga (Newham et al. 2014, Satyapriya et al. 2013) and relaxation (Bastani 2005, Chang et al. 2008, Teixeira et al. 2005, Tragea et al. 2014, Urech et al. 2010, Ventura et al. 2012).

Participation

Studies which reported that 40% or more of the eligible target population declined participation in interventions were the studies of:

- an educational intervention for pregnant women with a high BMI (Dodd et al. 2016): 60% (n=3262 / 5474) declined due to lack of interest, too busy to participate or were unable to be contacted.
- a CBT intervention (Milgrom et al. 2015): 56% (n=79 / 140) declined or could not be contacted to complete further SCID screening.
- a group CBT intervention (Bittner et al. 2014): following initial anxiety/depression screening 45% (n=209 / 467) declined further participation/screening or could not be contacted.
- a yoga intervention (Newham et al. 2014): 43% (n=44 / 103) declined or did not make further contact with the researchers.
- a telephone support intervention (Bullock et al. 1995): 41% (n=90 / 221) declined or could not be contacted.

Studies which reported that 80% or more of the eligible target population agreed and consented to participation included:

- a guided imagery intervention for pregnant African American women (Jallo et al. 2014): 97% (n=72 / 74) agreed.
- a mindfulness intervention for women with high pregnancy anxiety scores on the PRA and PSA scales (Guardino et al. 2014): 94% (n=47 / 50) agreed.
- a supportive intervention for pregnant women who had previously experienced pregnancy loss (Côté-Arsenault et al. 2014): 89% (n=24 / 28) agreed.
- an educational intervention for women with a high BMI (Bogaerts et al. 2012): 87% (n=205 / 235) agreed.

Interventions delivered to general populations of pregnant women which reported that 80% or more of the eligible target population agreed participation were:

- a relaxation intervention (Chang et al. 2008): 100% (n=136 / 136) agreed.
- a yoga intervention (Satyapriya et al. 2013): 86% (n=105 / 122) agreed.

Outcome measures and outcome time points

The State Trait Anxiety Inventory (STAI) (Spitzer et al. 2006) was the most commonly used outcome measure, utilised in 21 of the total 25 studies. Two studies included women with symptoms of nausea and conducted outcome assessments in the first trimester of pregnancy (Faramarzi et al. 2015, Knight et al. 2001).

Outcome measures were assessed in the second trimester of pregnancy in studies of five mind-body interventions (Bastani et al. 2005, Davis et al. 2015, Guardino et al. 2014, Tragea et al. 2014, Ventura et al. 2012), one study of a CBT intervention (Bittner et al. 2014) and one study of an acupressure intervention (Bastani 2015). All other studies which reported the timing of outcome assessments (n=15) collected post-intervention outcome data in the third trimester of pregnancy. Mid-point data

collection were collected in six studies (Bogaerts et al. 2012, Davis et al. 2015, Dodd et al. 2016, Jallo et al. 2014, Knight et al. 2001, Snaith et al. 2014). Data collection continued into the postnatal period in seven studies (Bittner et al. 2014, Bogaerts et al. 2012, Bullock et al. 1995, Dodd et al. 2016, Milgrom et al. 2015, Snaith et al. 2014, Vieten & Astin 2008).

Completion of the intervention

In four multi-session interventional studies, more than 20% of the IG did not complete all the intervention sessions (Bittner et al. 2014, Knight et al. 2001, Newham et al. 2014, Woolhouse et al. 2014).

Results of individual studies

Studies in which there were statistically significant differences in anxiety scores ($p < 0.05$) between the control group (CG) and intervention group (IG) post-intervention, reporting an improvement in anxiety scores for the IG, included:

- four relaxation interventions (STAI-S scores: Chang et al. 2008, $n=241$, Ventura et al. 2012, $n=108$, $p=0.001$, Teixeira et al. 2005, $n=58$, $p=0.01$, Bastani et al. 2005, $n=110$, $p=0.001$)
- two psychological interventions (Milgrom et al. 2015, $n=54$, BAI: $p=0.006$, Faramarzi et al. 2015, $n=46$, HADS-A: $p=0.001$)
- one educational intervention (Bogaerts et al. 2013, $n=141$, STAI-S: $p=0.02$)
- one mindfulness intervention (Guardino et al. 2014, $n=47$, PSA, PRA: $p=0.01$, $p=0.07$, no significant differences for STAI-S)
- one yoga intervention (Satyapriya et al. 2013, $n=105$, STAI-S: $p=0.001$).

The mindfulness intervention study by Vieten & Astin (2008) reported that the STAI state anxiety score were lower in the IG in comparison to the scores in the CG post-intervention (effect size, 0.85; $p < 0.05$) although the authors state the findings of the pilot study are limited by a small sample size ($n=34$) which did not present a socioeconomically or ethnically representative sample of the population.

The relaxation interventions which reported a significant difference between the IG and CG included two longitudinal interventions delivered by an instructor (Ventura et al. 2012), and by audio CD (Chang et al. 2008), and two single session relaxation interventions (Teixeira et al. 2005, Bastani et al. 2005).

The two psychological interventions which reported a significant difference between the IG and CG comprised eight intervention sessions, although the studies included women with different characteristics at different trimesters of pregnancy:

- A CBT intervention delivered to pregnant women with elevated depression scores in the second trimester of pregnancy (Milgrom et al. 2015)
- A MBCT intervention delivered to pregnant women with moderate nausea and vomiting in the first trimester of pregnancy (Faramarzi et al. 2015)

There was some evidence to support the effectiveness of group interventions. Positive results were reported in six out of eleven (55%) studies which evaluated group interventions. These studies reported significant between-group differences in one or more anxiety self-report measures, compared four out of 14 (26%) studies which evaluated interventions delivered to individual women.

2.2.6 Meta-analysis

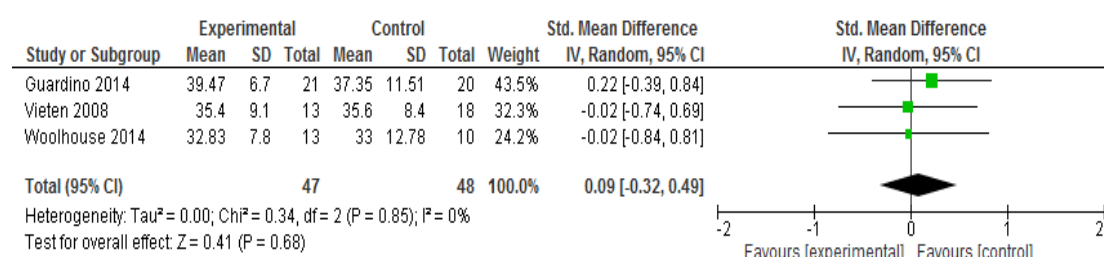
Different versions of the STAI were used (Spielberg et al. 1970, Spielberger et al. 1983) and other anxiety measures (HAD-A, BAI, MAQ, STAI-short) therefore the Standardised Mean Difference (SMD) was used as the summary statistic in the meta-analysis (Higgins & Green 2011).

In four studies (Knight et al. 2001, Newham et al. 2014, Teixeira et al. 2005, Tragea et al. 2014), anxiety scores were reported as median or as inter-quartile ranges (IQR) due to the non-normal distribution of the data. These studies were excluded from the meta-analysis.

A further four studies with insufficient details of post-intervention scores (Bogaerts et al. 2012, Bullock et al. 1995, Côté-Arsenault et al. 2014, Ventura et al. 2012) were excluded from the meta-analysis.

There were 1,928 IG participants in the 17 studies included in the meta-analysis and 1,914 CG participants. Pooling of results indicated considerable statistical heterogeneity among the studies ($I^2=92\%$; $p<0.001$). There was also clinical heterogeneity between the intervention type, timing and duration of the interventions and the characteristics of participants. Sub-group analyses were conducted on studies of interventions with similar characteristics, such as educational, mind-body, psychological and supportive interventions. Only interventions which included mindfulness group interventions were assessed as having sufficient clinical and statistical homogeneity to perform a meta-analysis (Figure 2.3) (Higgins & Green 2011).

Figure 2.3 Meta-analysis of mindfulness group interventions on self-report symptoms of anxiety



There was no observed beneficial effect in relation to the reduction of self-reported STAI state anxiety scores (MD=0.09; 95% CI=-0.32 to 0.49), with low statistical heterogeneity among the studies ($I^2=0\%$; $p=0.85$). However, the pooled number of participants in these three studies was small ($n=95$), all were assessed to have an unclear risk of bias and therefore the results of the meta-analysis should be interpreted with caution.

2.2.7 Discussion

The aim of the systematic review and meta-analysis was to identify and then assess the effectiveness of non-pharmacological interventions for pregnant women with symptoms of mild to moderate anxiety. A discussion of the findings from both systematic reviews will be presented in section 2.4.

Quality of the included RCTs

Most of the included studies were assessed as having an unclear risk of bias. Details of allocation concealment, blinding of study personnel, sampling methods and outcome assessors were not reported in many of the studies. Most of the included RCTs had relatively small sample sizes and thirteen studies did not include a sample size calculation. As a meta-analysis of post-intervention anxiety scores was only achievable for a small sub-group of studies the objective of the study to assess the effectiveness of interventions was only partially achieved.

Participants and eligibility screening

Studies which targeted women with obstetric complications or risk factors for anxiety, or where women could self-select into studies had higher percentages of women recruited from the sample population. Studies which had lower participation rates used anxiety and/or depression eligibility assessment measures or referral based on HCPs judgements of eligibility. Six studies reported using convenience sampling methods and six studies provided little information of the sample population and sampling methods. Without transparent reporting of the recruitment methods and characteristics of participants in each study, it would be difficult to assess whether the sample represent the target population and whether the results would be subject to change depending on the research context or with different populations of pregnant women (Sedgwick 2015). Therefore, detailed reporting of the recruitment process would assist the assessment of generalisability in future studies (Dzewaltowski et al. 2004, Tarquinio et al. 2014, Toerien et al. 2009).

Intervention components

Psychological, educational and mind-body interventions were evaluated in the review. Many interventions were complex and combined psychological or mind-body approaches with elements of education, discussion, professional support and peer support.

Intervention delivery

Details of intervention facilitators' professional background, experience or the training provided to prepare providers to deliver interventions were missing or underreported in the included studies. The Medical Research Council (MRC 2000) advised that variations in levels of skills across facilitators may affect delivery of the intervention and / or outcomes. The description of the training and of the practitioner skills required to deliver interventions in RCTs is valuable information for other

researchers, practitioners and service providers reviewing and delivering interventions.

Completion and concordance

Attrition rates of greater than 20% for the IG and/or CG were reported in five studies (Bittner et al. 2014, Knight et al. 2001, Newham et al. 2014, Tragea et al. 2014, Woolhouse et al. 2014) and only four studies indicated the numbers of sessions attended by participants (Bittner et al. 2014, Davis et al. 2015, Guardino et al. 2014, Milgrom et al. 2015). Delgadillo et al. (2014) found that non-pregnant participants in low intensity psychological interventions for anxiety and/or depression reported the highest attrition rates by session four, implying that sessions 1–3 are key periods to maximise engagement and retention. They suggested that at least four therapy sessions were required to achieve reliable and clinically significant improvement rates.

Outcome measures

Two studies solely focused on evaluating the effects of the intervention on symptoms of anxiety. Other studies included anxiety alongside other psychosocial outcomes.

2.2.8 Conclusion

The introduction of interventions to reduce symptoms of mild to moderate anxiety in pregnant women has the potential to improve health outcomes for pregnant women and their infants. The results of the review were inconclusive and need to be interpreted with caution as many of the included studies provided an inadequate description of their methods to allow a full assessment of methodological quality and the results of the review were predominantly based on small samples. Future RCTs should be adequately powered and reported in accordance with the CONSORT guidance (Schulz et al. 2010). Reporting the level of engagement and concordance with interventions and the

clarifying the criteria for completion will assist future researchers identify the optimal duration of interventions, balancing resources and the burden of participation for women with potential beneficial effects. The review found insufficient evidence to draw overall conclusions regarding the benefit of non-pharmacological interventions for pregnant women with anxiety and future studies are required to improve the current evidence base.

2.3 A systematic review and narrative synthesis of women's views on the acceptability of and satisfaction with non-pharmacological interventions to reduce the symptoms of mild to moderate anxiety in pregnant women

The study selection and eligibility criteria were developed using the PEOS (participants, exposure or intervention, outcomes, study design) framework (Khan et al. 2003).

2.3.1 Inclusion and exclusion criteria

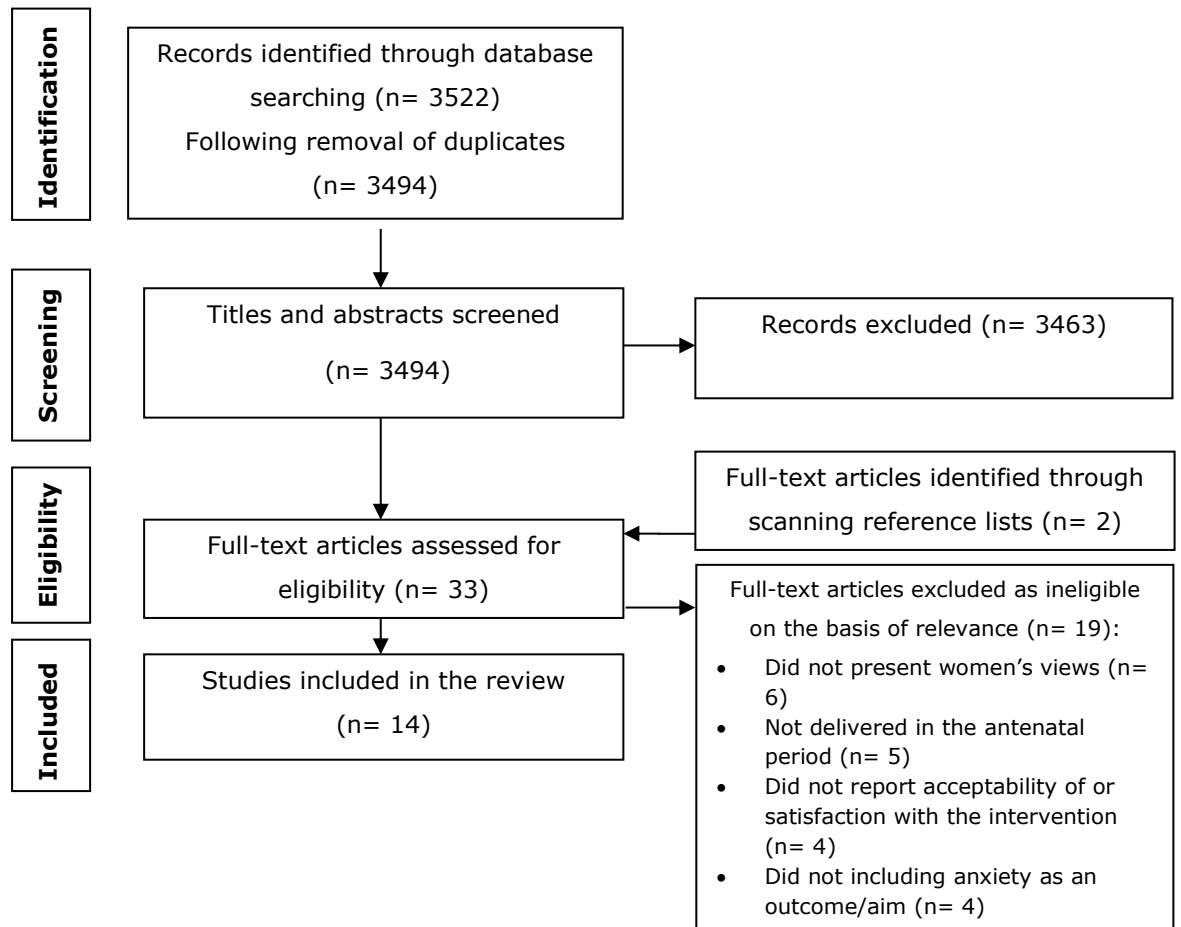
	Inclusion	Exclusion	Rationale
Population	Studies with pregnant women of all parities across the three trimesters of pregnancy, from general antenatal populations and pregnant women with symptoms of mild to moderate anxiety	Studies with pregnant women with severe symptoms of anxiety and/or depression; under the care of mental health services; less than 18 years of age; who lacked capacity to provide informed consent and pregnant women with complex social factors (NICE 2010)	Women with severe mental health concerns and complex social factors have established referral pathways to specialist services. There is limited support for women with mild to moderate symptoms of anxiety.
Intervention	Studies of non-pharmacological interventions, including: physical; cognitive; behavioural and other complementary methods		Non-pharmacological interventions are recommended as the initial treatment option for symptoms of anxiety in pregnancy (NICE 2014) and are potentially feasible to be delivered or facilitated by midwives.

Outcomes	Studies in which the primary or secondary outcome was women's views on the acceptability of and satisfaction with interventions. Studies were included if the evaluation focused on the effects on symptoms of anxiety alone or anxiety and other psychosocial outcomes		The effects of anxiety are often studied alongside depression because of the established co-morbidity (Glover 2014).
Study design	Quantitative or qualitative studies which assessed women's views on the acceptability of and satisfaction with an intervention		Focus groups, interviews or surveys may have been used alongside quantitative evaluations of interventions

2.3.2 Search outcomes

After 28 duplicates were deleted, the search identified 3,494 potentially eligible papers which were individually assessed on the information provided in the study title and abstract. From these 3,463 records were excluded using the inclusion and exclusion criteria. Following inclusion of two additional papers identified through scanning reference lists of relevant studies, 33 papers were retrieved and the full text assessed. From these, 19 papers were excluded and the remaining 14 papers were selected for inclusion. A research supervisor independently read the potentially relevant papers and the papers identified for inclusion were agreed, there were no disagreements between the reviewers. The literature search and inclusion process are detailed in the PRISMA Flow Diagram in Figure 2.4 (Moher et al. 2009).

Figure 2.4 The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram of qualitative and quantitative studies included in the review of women's views of interventions.



The 14 included studies, conducted in Australia, Canada, Germany, New Zealand, the UK and the US were reported from 2009 to 2015. There were 800 women in total in the included studies. For individual studies, sample sizes ranged from four women (Breustedt & Puckering 2013) to 298 women (Brugha et al. 2015). From the 800 participants of interventions, a sub-sample of 204 women provided their views about the interventions via questionnaires or qualitative interviews.

2.3.3 Quality assessment

The Critical Appraisal Skills Programme (CASP 2014) for assessing the methodological quality of qualitative studies and the Critical Appraisal Checklist for a Questionnaire Study (Boynton &

Greenhalgh 2004) were used to assess the quality of studies included in the review.

CERQual assessment

The Confidence in the Evidence from Reviews of Qualitative Research (CERQual) approach was used to assess the extent to which the review findings from the qualitative studies represented the phenomenon of interest (Lewin et al. 2015, The Cochrane Collaboration 2015). The GRADE-CERQual approach has been used in three recent systematic reviews (Glenton et al. 2013, Morrell et al. 2016, Rashidian et al. 2013). The process requires an individual assessment of the studies which contributed to a review finding. Assessment components included: methodological limitations; relevance to the review questions; adequacy of data and coherence (whether the finding was well grounded in data with a convincing explanation). After assessing each of the four components, an assessment of the overall confidence in each review finding was made. Each review finding was assessed as having a high, moderate, low or very low confidence rating (Lewin et al. 2015).

2.3.4 Analysis strategy

Data analysis and data synthesis followed the framework for conducting a narrative synthesis (Popay 2006), these are: tabulation (extraction) of the data; textual description of the studies; transforming and translating the data; data synthesis and assessment. Qualitative and quantitative studies which addressed the research questions were used to explore similarities and/or differences in the common themes (Popay et al. 2006). For example, where rates of acceptability were reported as percentages, these were described and included in the analysis. Each study was first described with reference to the context as intended by the original research (Jensen & Allen 1996). Secondly, a table of key concepts was produced to explore

the homogeneity of themes, noting any discordance. Themes emerged from the similarities and contradictions between the study findings (Walsh & Downe 2005). The next phase involved translating the study findings using concepts that could be applied to the relevant studies.

2.3.5 Results

Participants

In four studies women were recruited from a general pregnant population. In eight studies, pregnant women with a history of mood concerns or elevated anxiety or depression scores were recruited. Two studies included women with social risk factors and pregnant women with a history of previous pregnancy loss. Many of the studies used one of the self-report measures listed in Table 2.2 for participant assessment prior to inclusion.

Table 2.2 Anxiety self-report measures used to assess eligibility	
BAI	Beck Anxiety Inventory (Beck et al. 1988)
BDI	Beck Depression Inventory (Beck et al. 1988)
EPDS	Edinburgh Postnatal Depression Scale (Cox et al. 1987)
GAD-2	Generalised Anxiety Disorder – 2 items (Spitzer et al. 2006)
GAD-7	Generalised Anxiety Disorder – 7 items (Spitzer et al. 2006)
PDQ	Prenatal Distress Questionnaire (Yali & Lobel 1999)
PHQ-9	Patient Health Questionnaire – 9 (Kroenke et al. 2001)
PSWQ	Penn State Worry Questionnaire (Meyer et al. 1990)
STAI	State-Trait Anxiety Index (Spielberg et al. 1970)

Most women were recruited into studies while attending antenatal appointments in hospital and community locations. Women either self-selected into studies or were referred by HCPs such as midwives or GPs.

Interventions

The studies tested various types of interventions as indicated in Table 2.3, ordered by type of intervention.

Psychological interventions were evaluated in five studies:

- Cognitive behavioural therapy (CBT) (Bittner et al. 2014, Mcgregor et al. 2013, Milgrom et al. 2015)
- Cognitive behavioural approach (CBA) (Brugha et al. 2015)
- Psycho-educational and Inter-personal therapy (IPT) (Thomas et al. 2014)
- Psychological, practical techniques and social support to promote wellbeing (Breustedt & Puckering 2013)

Mind body interventions were evaluated in six studies:

- Hypnotherapeutic techniques and stress management (Goodman et al. 2014)
- Mindfulness-based cognitive therapy (MBCT) (Dunn et al. 2012)
- Mindfulness (Woolhouse et al. 2014)
- Mindful yoga and mindfulness-based stress reduction (MBSR) (Beddoe et al. 2009)
- Yoga (Davis et al. 2015)

A supportive intervention was evaluated in one study:

- Home visits by nurses (Côté-Arsenault et al. 2014)

One study considered how perinatal psychosocial assessment may act as an intervention (Darwin et al. 2013).

Most psychological and supportive interventions also included components of parent education, relaxation and/or social support (see table 2.3).

Outcomes

The included studies reported women's views and responses to questions about the level of satisfaction, perceived benefits, acceptability and relevance of the intervention and their experiences of anxiety in pregnancy.

Study Type

Qualitative and quantitative studies were included in the review.

- Four of the studies used qualitative interviews with pregnant women (Brugha et al. 2015, Cornsweet Barber et al. 2013, Darwin et al. 2013, Woolhouse et al. 2014).
- Two studies interviewed postnatal women about their participation during pregnancy (Breustedt & Puckering 2013, Dunn et al. 2012).
- Côté-Arsenault et al. (2014) interviewed women 6 to 19 months after birth of their babies to obtain their views on the usefulness of the skills learning during the antenatal intervention.
- Goodman et al. (2014) collected qualitative data during pregnancy from a post-intervention questionnaire.
- Six cross-sectional surveys were administered post-intervention during the second and/or third trimesters of pregnancy (Beddoe et al. 2009, Bittner et al. 2014, Davis et al. 2015, McGregor et al. 2013, Milgrom et al. 2015, Thomas et al. 2014).

Quality Appraisal

A summary of the quality assessment of the included studies is presented in Table 2.3. Most of the surveys reported limited details of the questionnaire design, psychometric properties, administration and data analysis. This may be because the surveys were sub-sections of larger quantitative evaluations. Results were presented as numbers and percentages with individual questionnaire item scores and brief descriptive statements of agreement or disagreement from participants.

GRADE-CERQual assessment

There were seven qualitative studies included in the review. The four CERQual components were used to assess the overall confidence in the findings of the review:

- Two studies were assessed as having moderate methodological limitations (Cornsweet Barber et al. 2013, Dunn et al. 2012). Five studies were assessed as low for methodological limitations.
- One study was assessed as having moderate coherence (the findings were moderately grounded in the data) (Cornsweet Barber et al. 2013). Six studies were assessed as being highly coherent.
- Two studies were assessed as being moderately relevant to the context of the review questions (Côté-Arsenault et al. 2014, Darwin et al. 2013). Five studies were assessed as being highly relevant.
- Six studies were assessed as being highly adequate: the authors provided detailed accounts of women's views and experiences and used the results to build theories and explanations (Popay et al. 1998). One study reported only a small number of examples of participant quotations to support the findings and was assessed as being moderately adequate (Cornsweet Barber et al. 2013).

Table 2.3 Data extraction from the studies included in the review

First author Country Year	Intervention category (duration)	Included women (n=)	Primary outcome (secondary outcome)	Gestation at start / post intervention (weeks of pregnancy)	Study type *Description of intervention **Facilitator / facilitator training	Method and timing of outcome measure: acceptability/ satisfaction/ beneficence (n=)	Quality assessment of the methods used to investigate the acceptability / satisfaction / beneficence of the intervention
McGregor Canada 2014	Psychologica I (6 individual sessions: 8 weeks)	Pregnant women: elevated depression scores (n= 42)	1. Depression 2. Anxiety 3. Healthcare/ medication utilisation (Intervention evaluation)	20 / 28	Pilot quasi-experimental trial * 10-minute CBT sessions: education and behavioural activation; cognitive restructuring; inter-connectedness of thoughts, feelings and behaviours ** Physicians / two-hour training session provided by a psychologist	Questionnaire Six weeks post-partum (n= 19)	No information provided on the development or the validity / reliability of the questionnaire. Questionnaires contained brief open and closed questions to assess women's experiences and satisfaction with the CBT intervention. The authors reported that content analysis was conducted on the open-ended questions, no further information provided
Milgrom Australia 2015	Psychologica I (8 individual sessions: 8 weeks)	Pregnant women: diagnosis of depressive disorder (n= 54)	1. Depression 2. Anxiety (Infant outcomes, satisfaction)	20 (mean) / 29 (approximat ely)	Pilot RCT * CBT sessions: 'Beating the Blues Before Birth' (Lewinsohn et al. 1984): relaxation; cognitive strategies; support networks; partner sessions; parenting skills; relationship issues and anxiety ** Psychologists / Trained in pregnancy-specific CBT	Questionnaire Post-intervention approximately 29 weeks (n= 19)	No information provided on the development or the validity / reliability of the questionnaire. Questionnaire contained six items on the helpfulness of and satisfaction with the intervention (Likert scale). Results presented as simple descriptive statistics
Bittner Germany 2014	Psychologica I (8 group sessions: 8 weeks)	Pregnant women: elevated depression, anxiety scores (n= 160)	1. Depression 2. Anxiety (Fear of childbirth, social support, intervention evaluation)	16 (mean) / 24	RCT * CBT sessions: coping strategies; self-assurance; problem solving; discussions about anxiety; prevention; treatment; future challenges ** Psychologist / CBT Training and supervision	Questionnaire Post-intervention – 24 weeks (n= 36)	No information provided on the validity / reliability of the questionnaire. Questionnaire contained items about participants' experience of and satisfaction with the intervention (Likert scale). The RCT had a high rate of attrition (46%). Results presented as simple descriptive statics
Thomas Australia 2014	Psychologica I / Educational (6 group sessions: 12 weeks)	Pregnant women with anxiety, depression or risk factors (n= 48)	1. Depression 2. Anxiety 3. Maternal attachment (acceptability, satisfaction)	26 (mean) / NR	Pilot study * Behavioural self-care; psycho-education; IPT (social support, communication, role transitions, mental health warning signs); parent-infant relationship ** Clinical psychologist and parent-infant mental health clinicians / experienced in CBT and IPT	Questionnaire Post-intervention – third trimester (n= 30)	The authors used a validated questionnaire, the CSQ-8 to assess satisfaction. There was no information on the development of the intervention feedback forms. Results were presented as simple descriptive statics
Goodman US 2014	Mind body (8 group sessions: 8 weeks)	Pregnant women: elevated anxiety scores (n= 26)	1. Anxiety 2. Depression 3. Self-compassion 4. Mindfulness Awareness (Intervention evaluation)	6-27 / NR	Pilot study * Stress management: using imagination to induce feelings of comfort. Based on hypnotherapeutic methods ** Stress management expert / NR	Questionnaire Post-intervention – second and third trimester (n= 23)	Open ended questions were used to elicit qualitative feedback concerning participation in the intervention. Qualitative content analysis was used to analyse the data with little further information provided. Quotations were presented to support the findings
Woolhouse Australia 2014	Mind body (6 group sessions: 6 weeks)	Pregnant women at risk of anxiety, stress, depression (n= 32)	1. Stress 2. Depression 3. Anxiety (Participants' experience)	11-34 / 17-40	Pilot RCT * 'MindBabyBody': breathing practice; body-scan; mindfulness of pain and thoughts; meditation; self- compassion; mindfulness skills in motherhood ** Psychologist and Psychiatrist / Training in facilitation of mindfulness groups	Qualitative Interviews Post-intervention – 17- 40 weeks (n= 4)	Qualitative interviews with a small self-selected sample of intervention group participants. Limited reporting of the data collection procedures. A detailed description Interpretative Phenomenological Analysis (IPA) procedure was reported and quotations were provided to support the findings
Beddoe US 2009	Mind body (7 group sessions)	General antenatal population (n= 16)	1. Stress 2. Anxiety 3. Pain 4. Cortisol levels 5. Acceptability	13-32 / NR	Feasibility study * Mindful yoga intervention combined elements of the Iyengar yoga, MBSR, relaxation and stress management ** Yoga MBSR instructor / experienced Iyengar yoga instructor with extensive training in MBSR	Questionnaire Post-intervention (n= 16)	The authors reported that the findings were limited by the inclusion of a small self-selected sample of women. No information provided on the validity / reliability of the questionnaire. Participants rated the acceptability of and satisfaction with the intervention. Results presented as simple descriptive statics
Davis US 2015	Mind body (8 group sessions: 8 weeks)	Pregnant women: elevated scores: anxiety, depression (n= 46)	1. Depression 2. Anxiety 3. Positive and negative affect (satisfaction, adherence)	21 (mean) / 28-29	RCT * Ashtanga Vinyasa yoga modified for pregnancy. Instructional video for home use ** Yoga instructor / Experience in prenatal yoga	Questionnaire Post-intervention (n= 23)	The questionnaire was completed by women in the intervention group. The authors used validated questionnaires, the CSQ-8 to assess satisfaction and a credibility scale questionnaire. The results were presented as simple descriptive statics

<i>First author Country Year</i>	<i>Intervention category (duration)</i>	<i>Included women (n=)</i>	<i>Primary outcome (secondary outcome)</i>	<i>Gestation at start / post intervention (weeks of pregnancy)</i>	<i>Study type *Description of intervention **Facilitator / facilitator training</i>	<i>Method and timing of outcome measure: acceptability/ satisfaction/ beneficence (n=)</i>	<i>Quality assessment of the methods used to investigate the acceptability / satisfaction / beneficence of the intervention</i>
Brugha UK 2015	Psychological (up to 3 individual sessions: 22 weeks)	General antenatal population (n= 298)	1. Depression (Anxiety and satisfaction)	22 / 34 (approximately)	Pilot cluster RCT * Care from midwives with additional training on: assessment of depressive symptoms; CBA; facilitating and maintaining therapeutic relationships; Five Areas approach (Williams et al. 2008) ** Midwives / Based on training by Morrell et al. (2009) and adapted for pregnancy	Qualitative interviews Post-intervention – approximately 34 weeks (n= 8)	A stratified subsample of intervention group women with EPDS scores of 12 or more and less than 12 were invited to take part in a qualitative evaluation of the pilot. Limited reporting of the methods of data collection. The authors described the data analysis method and provided quotations to support the findings
Breustedt Scotland, UK 2015	Psychological / Social support (8 group sessions)	Pregnant women: one or more social or psychological risk factors (n= 4)	1. Participants' experience of the intervention	NR	Qualitative study * 'Mellow Bumps' psychological and practical techniques to reduce anxiety and promote wellbeing in vulnerable pregnant women; encouraged women to make social connections, share information; addressed individual concerns	Qualitative interviews Post-partum period (n= 4)	Women who had completed the intervention and maintained contact participated. Authors state this may be related to positive experiences and non-attendees may hold different views. Authors included a description of the topic guide, data analysis method and participant quotations. A second researcher assessed for possible bias in the analysis process
Dunn Australia 2012	Mind body (8 group sessions: 8 weeks)	General antenatal population (n= 19)	1. Depression 2. Anxiety 3. Stress 4. Self-compassion 5. Mindfulness Awareness (Participants' experience)	12-28 / NR	Pilot quasi-experimental study * Based on MBCT programme (Segal et al. 2002): awareness of each moment; cognitive model; taking a wider perspective; fostering an attitude of acceptance; relating to negative thoughts; managing warning signs ** Psychiatrist, counsellor / accredited MBCT facilitators	Qualitative Interviews Six weeks post-partum (n= 10)	Qualitative interviews conducted with the intervention group participants. The authors employed a non-randomised design and reported that the intervention and control groups were unbalanced at baseline (history of anxiety/depression). Limited reporting of the methods of data collection and data analysis. Presented extensive examples of participant quotations
Cornsweet Barber New Zealand 2013	Mind body (Individual self-help material)	General antenatal population (n= 9)	1. Acceptability of the intervention and usability of the self-help material	Second and third trimesters of pregnancy / NR	Feasibility study * computerised self-help package using bio-feedback to teach relaxation and mindfulness skills ** self-help	Qualitative Interviews Post-intervention - Second and third trimester (n= 9)	The authors reported the findings were limited by the inclusion of a small self-selected sample of pregnant women. Limited reporting of the methods of data collection and qualitative data analysis. The authors presented a small number of examples of participant quotations to support the findings
Côté- Arsenault US 2014	Supportive (approximately 5 individual sessions: 20 weeks)	Pregnant women: history of at least one spontaneous perinatal loss (n= 24)	1. Anxiety 2. Depression (Intervention evaluation)	14 (mean) / NR	RCT * Supportive care for women pregnant after perinatal loss: pregnancy diary, information, skills to reduce anxiety and depression; prenatal attachment. Based on the caring process (Swanson, 1993) ** Nurses with additional training / NR	Qualitative Interviews Six to nineteen months post-partum (n= 12)	Qualitative interviews conducted with the intervention group participants. Limited reporting of the methods of data collection. The authors described the data analysis method and provided participant quotations to support the findings. Used member checking in the data analysis procedure
Darwin UK 2013	Other (individual psycho-social assessment)	Pregnant women with elevated depression, anxiety scores or risk factors for PND (n= 22)	1. Consider how perinatal psychosocial assessment may act as an intervention	18 (mean) / 25	Mixed methods study * Participated in a psychosocial assessment at the pregnancy booking appointment as part of routine clinical practice ** Midwives and HCPs	Qualitative Interviews Time 1: 10-12 weeks Time 2: 28-36 weeks Time 3: 7-13 weeks post-partum (n= 22)	Author employed sequential mixed methods sampling (cases where the most could be learnt in relation to the research questions). Women participated in up to 3 qualitative interviews. Field notes and a reflective diary were used to assist analysis. Presented a clear and transparent approach to the data collection process. Participant quotations presented to support the findings. A second researcher completed data analysis to reduce bias. The author described the use of prolonged engagement, member checking and searching for alternative explanations in the analysis procedure
CBA - Cognitive behavioural approach, CBT – Cognitive behavioural therapy, IPT – Inter-personal therapy, MBCT – Mindfulness-based cognitive therapy, MBSR - Mindfulness-based stress reduction, NR – Not reported, PND – Postnatal depression, RCT – Randomised controlled trial.							

2.3.6 Findings

Data analysis revealed five broad themes: Motivation and barriers to participating in studies; Acceptability of interventions; Satisfaction with components of interventions; Overall satisfaction with interventions; and Perceived benefit from participation (Table 2.4). The CERQual assessment of the confidence in the evidence contributing to the findings is presented in Table 2.5.

Motivation and barriers to participating in studies

Participants in studies of mindfulness interventions who had previous experience of anxiety and depression were motivated to participate (Dunn et al. 2012, Woolhouse et al. 2014). Women wanted to learn new ways to manage their symptoms, they considered that the intervention would help them achieve a positive experience of pregnancy. However some women who were identified or referred for inclusion by a HCP had concerns about participation (Breustedt & Puckering 2013, Darwin et al. 2013). They were uncertain about the reason for their selection and were concerned that disclosing their symptoms may lead to unwanted interference from HCPs and social care services.

Acceptability of interventions

Studies with reported attrition rates below 25% were those where interventions were provided to one-to-one (Brugha et al. 2015, Cornsweet Barber et al. 2013, Côté-Arsenault et al. 2014, Milgrom et al. 2015), and to participants in group yoga interventions (Beddoe et al. 2009, Davis et al. 2015). Rates of attrition greater than 45% were reported in studies of a group CBT intervention for women with elevated anxiety and depression scores (Bittner et al. 2014) and a psycho-social intervention for women with complex social factors (Breustedt & Puckering 2013). Women assessed as vulnerable or at risk of developing anxiety and depression initially felt uncomfortable attending group sessions and feared judgement or disapproval from the group (Breustedt & Puckering 2013, Woolhouse et al. 2014). Creating a

relaxed and non-judgemental atmosphere and visiting the women at home before the group began helped women to feel confident about attending and created a welcoming experience. Once the group was established, sharing time with other pregnant women was valued by most participants (Breustedt & Puckering 2013, Dunn et al. 2012, Woolhouse et al. 2014).

Satisfaction with components of interventions

Mcgregor et al. (2013) delivered a brief individual CBT intervention in ten-minute sessions, but reported that some women would have liked more time and in-depth discussions about their emotional difficulties. Having time to discuss emotional issues with HCPs was highlighted as an important component by Darwin et al. (2013). Research interviews provided women with an opportunity to talk, which for some had been the first opportunity to discuss their feelings.

A number of participants in the study by Darwin et al. (2013) felt that completing psychological questionnaires resulted in them being confronted by the reality of their anxiety and depressive symptoms but they felt left without any further support. Brugha et al. (2015) reported that many women found completing the EPDS important and helpful, although a few women found it difficult to discuss their emotions. Women felt apprehensive about the potential consequences resulting from elevated EPDS scores, such as the information being used by HCPs to raise child protection concerns.

Breustedt & Puckering (2013) discussed how the ending of the group left some participants with a sense of loss and signalled a period of adjustment. This was addressed by the provision of postnatal groups and reunions. Some women suggested that having partners included in at least one session would help support them with their new practices and would have welcomed

on-going support to continue developing mindfulness techniques (Goodman et al. 2014).

Some studies of mind-body interventions included homework exercises. Authors reported that participants did not complete some of the content (Cornsweet Barber et al. 2013) or at times, the homework had felt too much for the women to complete (Goodman et al. 2014). Certain exercises were reported as helpful to some women and unhelpful to others, however women did not feel any specific exercises should be omitted. Women welcomed the opportunity to learn a variety of relaxation and cognitive techniques, having the choice to participate in exercises which they enjoyed or found useful (Goodman et al. 2014, Woolhouse et al. 2014).

Overall satisfaction with interventions

Women who participated in psychological or mind-body interventions reported an overall satisfaction with the interventions. Mindfulness and CBT based interventions were described as enjoyable, valuable and beneficial and women said they would recommend the intervention to other pregnant women. Group interventions received positive comments from many participants in the included studies. Women were able to discuss their thoughts and experiences which they had found difficult to discuss with professionals or their family (Breustedt & Puckering 2013). Groups provided a supportive environment where they could make friends, which reduced feelings of social isolation. Knowing that others had similar thoughts and experiences helped women feel less alone and helped them develop an acceptance of their feelings (Breustedt & Puckering 2013, Dunn et al. 2012, Goodman et al. 2014).

Perceived benefit from participation

Some women felt they had derived benefit from learning practical breathing techniques and from developing an ability to reflect on

their thoughts and emotions which consequently had improved relationships with their children and partners (Cornsweet-Barber et al. 2013, Woolhouse et al. 2014). Women said that exercises such as the body scan (focusing awareness on different areas of the body) had helped them to sleep better.

Some participants in the studies of mindfulness and CBT interventions reported a greater understanding of the causes of stress and anxiety in their lives and greater self-awareness of their thought patterns. This helped them respond in a more positive way to situations and feelings, before negative thought patterns could escalate (Beddoe et al. 2009, Goodman et al. 2014, McGregor et al. 2013, Woolhouse et al. 2014). Some women who participated in studies which included psychological assessment also reported that they welcomed the self-reflection experienced through completing the assessments (Brugha et al. 2015, Darwin et al. 2013). Some women who participated in the CBT intervention (Goodman et al. 2014) stated that learning to recognise their feelings helped them to accept their anxious thoughts. Rather than becoming annoyed or frustrated, they had learned to be more gentle and kind to themselves. Some participants in the other studies of mindfulness and psychological interventions said that recognition and acceptance of anxious thoughts had helped them become more confident and positive about the future (Beddoe et al. 2009, Breustedt & Puckering 2013, Côté-Arsenault et al. 2014).

Table 2.4 Summary of data themes from included studies: recruitment; acceptability; satisfaction and perceived benefit.

First author Country, Year	Intervention description	Recruitment into studies	Acceptability of interventions	Satisfaction with interventions	Perceived benefit from participation
McGregor Canada 2014	Psychological Individual CBT		Reasons for withdrawing included not having time to complete homework. Some women would have liked more time and in-depth discussions with their physician about their mood difficulties.		Some women said the intervention helped them be aware of their moods and subsequently were able to change their mood in a positive direction.
Milgrom Australia 2015	Psychological Individual CBT			Most women were satisfied with the intervention.	Most women found the intervention effective and helpful
Bittner Germany 2014	Psychological Group CBT			Most women were satisfied with the intervention.	Most women found the intervention beneficial.
Thomas Australia 2014	Psychological / Educational Group, Behavioural, IPT, psycho- educational.	Reasons for declining to participate were: work commitments, unsuitable timing of sessions, childcare issues, lack of interest or clash with other antenatal appointments		Most women were highly satisfied, and the intervention had met their expectations.	
Goodman US 2014	Mind body Group mindful CBT		Women said the amount of home practice was sometimes too much. They suggested including partners in one session. Some would like ongoing support for their mindfulness practices.	Most women benefited from the experience and would recommend to friends.	Some women said they learnt different options to deal with anxiety. They developed acceptance of their feelings and were kinder to themselves. Interaction within a supportive group reduced their feelings of isolation.
Woolhouse Australia 2014	Mind body Group mindfulness	The opportunity to learn new skills was a common motivation for participation. Women wanted to learn ways to manage mental health challenges.	Some exercises were challenging. Women engaged in different ways, picking the best exercises for them. Group participation was initially uncomfortable, but ultimately enjoyable.		Mindfulness (Body Scan) helped some women to sleep. They valued developing an ability to reflect on their emotions. Some women reported improved relationships with family and colleagues. They felt able to respond to challenging situations.
Beddoe US 2009	Mind body Group mindfulness & yoga		Women who lived further away found sessions difficult to attend.	Most participants were satisfied and would recommend the intervention to other women	Most women felt more hopeful and confident after the intervention and said they were taking better care of themselves. They developed awareness about the sources of their stress which helped them to cope with stressful situations.
Davis US 2015	Mind body Group yoga	Women attended an average of 6 out of 8 classes. Reasons for missed classes included travelling and illness.		Most participants found the intervention to be highly credible and were satisfied with the intervention.	

First author Country, Year	Intervention description	Recruitment into studies	Acceptability of interventions	Satisfaction with interventions	Perceived benefit from participation
Brugha UK 2015	Psychological Psychological training of community midwives (psychological assessment and CBA)	Some women had not felt the need to share their feelings but felt they had the support if needed. Where women felt they would not have been able to share their feelings, it was attributed to the fact that they had not built a relationship with the CMW.	One woman offered CBA commented that two home visit sessions were sufficient for her needs. Women mostly found the EPDS helpful and important. A few women did not find it easy to discuss their emotions.	Most women valued the CMW exploring and discussing their feelings and welcomed the availability of support. Women were mainly positive about CMWs administering the EPDS.	For home visits, women mostly felt that CMWs were open, caring and supportive. Home visits offered reassurance and guidance. The EPDS increased women's awareness of their moods and anxiety. Women appreciated that support was available if required.
Breustedt Scotland, UK 2013	Psychological / Social Support Group Psychological, IPT, practical techniques	Some women were uncertain of the reason for referral to the intervention and felt pressured to attend. They feared judgement from other group participants.	Women described the groups created a relaxed, non-judgemental atmosphere. Home visits helped create a welcoming experience.		Some women described the groups as an accepting atmosphere to share experiences. They addressed issues difficult to discuss with others and reduced women's feelings of isolation.
Dunn Australia 2012	Mind body Group mindfulness	Women with a history of anxiety or depression had increased interest in and engagement with the intervention. They wanted to create a positive experience of pregnancy.		Most women valued group participation and forming new relationships.	Sharing experiences and stories with the group had the benefit of normalising women's own experience.
Cornsweet Barber New Zealand 2013	Mind body Individual mindfulness & relaxation		Women were initially frustrated with completing exercises, but it became easier. Some said the language used was confusing. One participant did not complete all of the content.	All women found the intervention enjoyable, would recommend to others.	Women said the exercises were helpful to do before sleeping. Some felt the exercises might be helpful during labour.
Côté-Arsenault US 2014	Psychological Individual supportive interactions		Home visits, pregnancy diary, relaxation and problem solving exercises received positive comments. Women found visualisation exercises somewhat difficult. Fetal movement counting was reassuring although women felt anxious until they felt their baby move. Some valued learning assertiveness techniques.	Most women found participation easy and the home visits were described as valuable. Women in the control group were disappointed that they did not receive an intervention but grateful that research was being done.	The women found the nurse non-judgmental, knowledgeable, and supportive. They reported reduced feelings of isolation, stress, anxiety and greater confidence. Women felt more positive about pregnancy and the intervention helped to normalise their anxiety. Completing the diary helped them reflect on their feelings over the pregnancy.
Darwin 2013 UK	Other Self-report psychological assessment	Some women were concerned that disclosing their distress may lead to interference by social services or HCPs. Other women were concerned that their feelings would be dismissed	Some women valued interactions where HCPs listened rather than psychosocial assessment being viewed a routine. Some felt confronted by their distress following assessments without the offer of further support. Assessment was often completed without discussion.		The interview enabled some women to reflect about their thoughts and feelings. For some it was the first opportunity to talk about their feelings and experiences. Some women embraced self-reflection through the questionnaires
CMW – Community midwife; CBA – Cognitive based approach; CBT – Cognitive based therapy; EPDS – Edinburgh postnatal depression scale (Cox et al. 1987); HCP – Healthcare professional; IPT – Inter-personal therapy.					

Table 2.5 GRADE-CERQual assessment of the themes			
Acceptability of and perceived benefit of interventions	Confidence in the evidence	Relevant papers	Explanation of confidence in the evidence assessment
Groups and individual home visits by HCPs provided an opportunity to discuss emotional issues which women found difficult to discuss with others. Discussions and supportive interactions reduced feelings of isolation	High confidence	(Breustedt & Puckering 2013, Brugha et al. 2015, Côté-Arsenault et al. 2014, Dunn et al. 2012, Goodman et al. 2014, Woolhouse et al. 2014)	In general the studies were moderately well conducted. The finding was seen across most studies and settings
Most women were satisfied with interventions which they found enjoyable and would recommend to others	High confidence	(Brugha et al. 2015, Cornsweet Barber et al. 2013, Côté-Arsenault et al. 2014, Davis et al. 2015, Dunn et al. 2012, Goodman et al. 2014, Milgrom et al. 2015, Woolhouse et al. 2014)	In general the studies were moderately well conducted. The finding was seen across most studies and settings
Initially women had concerns about disclosing their symptoms. They feared the judgment of others (in group interventions) and interference from HCPs	Moderate confidence	(Breustedt & Puckering 2013, Darwin et al. 2013, Woolhouse et al. 2014)	In general the studies were moderately well conducted. The finding was seen across several studies and settings
Mindfulness and CBT helped women to develop self-awareness and most women felt more positive and confident following the intervention	Moderate confidence	(Breustedt & Puckering 2013, Côté-Arsenault et al. 2014, Goodman et al. 2014, Woolhouse et al. 2014)	In general the studies were moderately well conducted. The finding was seen across several studies and settings
Women with history of anxiety/depression were motivated to participate in interventions	Low confidence	(Dunn et al. 2012, Woolhouse et al. 2014)	In general the studies were moderately well conducted. The finding was seen across a few studies and settings
Some CBT, mindfulness and relaxation exercises were initially challenging but became easier with practice	Low confidence	(Cornsweet Barber et al. 2013, Woolhouse et al. 2014)	In general the studies were moderately well conducted. The finding was seen across a few studies and settings
Women welcomed a choice of exercises and variety of techniques to practice	Low confidence	(Goodman et al. 2014, Woolhouse et al. 2014)	In general the studies were moderately well conducted. The finding was seen across a few studies and settings

2.3.7 Discussion

The review was conducted to evaluate women's views on the acceptability of and satisfaction with non-pharmacological interventions to reduce the symptoms of mild to moderate anxiety in pregnancy. A discussion of the findings from both systematic reviews are presented in section 2.4.

Fourteen studies from six countries were included which accessed women's views on interventions through qualitative interviews or questionnaires. Most of the included studies had small sample sizes ($n = 4-30$); many were feasibility studies or additional components to larger trials. Due to the limited reporting of the study methods in many of the included studies a full quality assessment was not always possible. Future studies should report in accordance with quality frameworks such as COREQ (Tong et al. 2007).

The review followed a narrative synthesis framework (Popay 2006) to assist the synthesis of qualitative and quantitative data and identify common themes across included studies. The use of the CERQual approach helped assess the confidence in the findings of the review. Themes assessed as having a high confidence were seen in six of the included studies, all of which were assessed as being moderately well conducted or better. The use of the CERQual tool helped assess the certainty of the findings. A narrative synthesis approach (Popay et al. 2006) contributed to the strength of the review as it involved a textual and thematic exploration of the data, identifying common themes, contradictions and highlighting where the evidence was absent (Lucas et al. 2007).

Quality of included studies

Only two of the seven studies included a survey with validated questionnaires to access participant feedback. Feedback from participants can be used to improve intervention design,

recruitment of and study retention in clinical trials. However, standardised surveys and benchmarks need to be developed to assess the experience of participation in clinical trials (Planner 2015). There was limited reporting of the methods of analysis in the survey studies. Two studies, which included open ended questions briefly reported the data analysis methods and included participant quotations to support the findings. In many of the studies, data were collected from all or a sub-section of participants who had successfully completed interventions which was a potential source of selection bias.

Recruitment and data collection methods were only described in three studies. Four of the seven studies which used qualitative interviews to access women's views provided detailed descriptions of the analytic method. All of the qualitative studies presented participant quotations to support the findings. Lewin et al. (2009) describe how increasing numbers of RCTs of complex interventions include qualitative components to explore participants' experiences of interventions. They found the quality of qualitative components were variable and often lacked a justification for the qualitative approach used. Improving the quality of studies, adequate reporting of study methods and recruiting appropriate sample sizes were reported as recommendations in many recent reviews of interventions focused on psychological health and emotion wellbeing in pregnancy (Fontein-Kuipers et al. 2014, Marc et al. 2011, Morrell et al. 2016, Ryan 2013).

Participants

Studies in the review which included women from general antenatal populations aimed to help women develop coping strategies to prevent the development of symptoms of anxiety/depression. Whereas, studies which recruited women with elevated scores or risk factors for anxiety and/or depression aimed to reduce women's existing symptoms.

Milgrom et al. (2015) reported that 54% of the initial study population declined to complete symptoms checklists, however most studies which conducted psychological eligibility assessment did not report the rates of consent (Bittner et al. 2014, Goodman et al. 2014, McGregor et al. 2013). Reporting the rate for agreeing to complete symptoms checklists and reasons for declining participation would help researchers to develop effective recruitment strategies (Williams et al. 2007). Williams et al. (2007) found that individuals who declined to participate in research often had misunderstandings about the aims of the research. Providing information and having verbal discussions early in the recruitment process may address concerns about psychological screening, fear of stigma and increase the likelihood of participation (Brintnall-Karabelas et al. 2012, NICE 2014). Women's apprehensions about joining group interventions may be eased by conducting welcome visits in order that women feel more confident to participate in group sessions (Breustedt & Puckering 2013).

Interventions delivery

Only three studies provided a detailed description of the facilitator training to deliver interventions. In most studies, women were not asked to provide their views on the acceptability or relevance of intervention facilitators. Such information could be helpful for researchers and service providers when considering the type and skill requirement of intervention facilitators, making efficient use of the resources available within maternity care provision.

Developing an awareness of the causes of anxiety and the ability to reflect on their thoughts and emotions was reported to be beneficial by women across all categories of interventions. Darwin et al. (2013) highlighted that some women felt distressed when confronted by their emotions. Self-reflection needed to be followed with further support and discussion. Facilitating time for women to discuss their feelings and experiences was highlighted

as an important component across many psychological mind-body and supportive, individual and group based interventions.

Discussions with HCPs was reported as helpful for women (Brugha et al. 2015, Côté-Arsenault et al. 2014, Darwin et al. 2013, McGregor et al. 2013). An opportunity to speak one-to-one with a HCP about their individual experiences was welcomed by the women with symptoms of or risk factors for mental illness. Group discussions were highlighted as a valued component of interventions in many of the included studies (Breustedt & Puckering 2013, Dunn et al. 2012, Goodman et al. 2014, Woolhouse et al. 2014). Three of the included studies reported that women often felt isolated and found comfort when they discovered other women had similar thoughts and experiences (Breustedt & Puckering 2013, Dunn et al. 2012, Goodman et al. 2014). Many studies of psychological and social support interventions included multiple components: psychological therapy; discussion sessions; parent education and /or social support. An investigation into the acceptability and satisfaction of each individual component was only reported in the studies using qualitative interviews, possibly because these studies were provided with greater scope to report in-depth qualitative findings.

Women indicated that the location of interventions and commitment required were important factors (Beddoe et al. 2009, McGregor et al. 2013). Women may have work commitments and other responsibilities which could restrict their ability to regularly attend sessions and complete additional homework between sessions. Most interventions were held during the daytime in hospital clinics, although some were also offered in community centres and during the evening which may have made it easier for women to attend.

2.3.8 Conclusion

The findings from this review are limited due to the small number of included studies, many with small sample sizes and limited reporting of methods. Women's views on the acceptability of and satisfaction with interventions were overwhelmingly positive. The review has highlighted the importance of creating a welcoming non-judgemental context for group interventions. Most women valued individual or group discussions about their symptoms of anxiety. Discussions helped women to feel supported and develop supportive networks.

Accessing women's views and experiences is important for developing interventions which are acceptable to women and can develop an understanding of how and why intervention components may contribute to outcomes. Many qualitative studies accessed the views of women who had successfully completed interventions and future RCTs are required to address potential selection bias. Accessing the views of women who did not participate or complete interventions will help to identify where further improvements could be made.

Researchers need to report the validity and reliability of evaluation questionnaires. Qualitative studies should follow guidance from quality frameworks and report the methodological approach, sample selection and analysis procedures. Studies should include a justification of the sample size required to address the research objectives. Researchers should consider the acceptability of eligibility screening and identify ways to effectively communicate the purpose of screening to potential participants. Further investigation into the acceptability, skills and training needs of intervention facilitators will help researchers balance resources with potential beneficial effects.

2.4 Discussion of the findings from both systematic reviews

The following paragraphs summarise the main findings from the two systematic reviews; this is further explored in the following chapter with reference to the design of the new intervention.

2.4.1 Strengths and Limitations

Strengths of the reviews

The comprehensive search strategy maximised the potential to identify relevant studies and the reviews used robust, independent and appropriate quality assessment method. The review assessed a wide range of non-pharmacological interventions to improve mild to moderate symptoms of anxiety in pregnancy and included different populations of pregnant women across the three trimesters of pregnancy.

Previous systematic reviews have reported evidence of the effectiveness of interventions to support women with symptoms of distress in pregnancy (depression, anxiety, stress, fear, self-efficacy and self-esteem) (Fontein-Kuipers et al. 2014), mind-body interventions for women with symptoms of anxiety in pregnancy (Marc et al. 2011) and pharmacological and non-pharmacological treatments for pregnant and postpartum women with a diagnosed anxiety disorder (Marchesi et al. 2016). To our knowledge, this is the only comprehensive review of women's views on the acceptability of and satisfaction with interventions to reduce the symptoms of mild to moderate anxiety in pregnancy.

A further strength of both systematic reviews was the consideration of the practical aspects of delivering non-pharmacological interventions within maternity care contexts including: 1. training needs for intervention facilitators; and 2. acceptable recruitment strategies.

Limitations of the reviews

Studies not published in English were not included which may have introduced bias into the review. It has been reported that authors were more likely to publish RCTs in an English-language journal if the results were statistically significant (Egger et al. 1997). In recent years, it has been reported that most studies publish in the English Language and the potential impact of studies published in languages other than English in a meta-analysis may be minimal (Higgins & Green 2011). Publication bias may have been introduced as the search strategy did not include grey literature, expert consultations, conference abstracts and table of contents searching. The quality assurance could have been improved by having two reviewers independently assess a portion of the papers identified in the initial search.

2.4.2 Inclusion criteria

The studies from both systematic reviews included women from general pregnant populations or pregnant women with obstetric complications, social risk factors or psychological symptoms or risk factors. There was insufficient evidence to draw conclusions about the effectiveness of targeted interventions compared to universal interventions.

Studies which reported an improvement in anxiety scores for the IG were: group mindfulness; MBCT; motivational interviewing; individual relaxation; and CBT interventions. There was some evidence to support the effectiveness of group interventions. However, the results were based on different types of intervention designs, many studies with small sample sizes ($n=32-197$), and need to be interpreted with caution.

Studies which included women with obstetric complications or risk factors for developing mental health conditions reported higher recruitment rates compared to studies which included women

from general antenatal populations. Some women with a history of mental health conditions reported that they were motivated to participate in studies as a way to develop coping strategies to manage their symptoms. The motivation for women with a history of anxiety or depression to participate in studies presents an important consideration for designing larger RCTs. Highly motivated women may be disappointed if they are allocated to a control group (Craig et al. 2006) and may be doubtful about the possibility of equipoise (Wade et al. 2017, Robinson et al. 2005, Kerr 2004). Highlighting women's motivations for and barriers to participation may help develop future recruitment strategies which need to be fully reported to help consider how this may be applied to different contexts.

However, some women were concerned that disclosing their symptoms may lead to unwanted involvement from health and social care services. Such concerns may partly explain the lower consent rates into studies based on HCP referral or psychological assessment. Therefore, the rationale for eligibility screening using symptoms checklists should be clearly communicated to potential participants within a supportive context so that women have a clear understanding of the purpose of the study and how the information will be used.

Women's apprehension about joining a group intervention may be addressed by pre-group contact to help communicate the purpose of the study, become familiar with the intervention facilitators and to encourage women to ask questions about what involvement would require for them.

2.4.3 Intervention components

The studies included in the reviews evaluated psychological, educational and mind-body interventions. Many interventions combined psychological or mind-body approaches with

components of education, discussion, professional support and peer support.

Studies which reported an improvement in anxiety scores for the IG were: group mindfulness; MBCT; motivational interviewing; individual relaxation; and CBT interventions. There was some evidence to support the effectiveness of group interventions. Positive results were reported in seven out of ten (70%) studies which evaluated group interventions. These studies reported significant between-group differences in one or more anxiety self-report measures, compared five out of 13 (38%) studies which evaluated interventions delivered to individual women. However, the results were based on different types of intervention designs, many studies with small sample sizes (n= 32-197).

In the review, developing an awareness of the causes of anxiety, the ability to reflect on their thoughts and emotions and facilitating time for women to discuss their feelings were reported as beneficial by women across all categories of interventions. An opportunity to speak face-to-face with a HCP was welcomed by the women with symptoms of or risk factors for mental health conditions. Group discussions were helpful to women who felt isolated in pregnancy. Some women found comfort when they discussed their thoughts and feelings with other women who had similar thoughts and experiences.

Women who have psychological or obstetric risk factors may feel especially isolated during pregnancy and may benefit from discussing their situation and feelings with HCPs if they are not able to access support from other women in similar circumstances. Women who are socially isolated may benefit from enhanced social support or interventions which act as a proxy for enhanced social support. The Boots Family Trust Alliance (2013) reported that women who experienced mental health problems in pregnancy stated the main causes were: 1. being isolated; and 2.

feeling unsupported. Morrell et al. (2016) identified the benefit of group based interventions for postnatal depression which provided women with access to a wide range of resources, compensated for limitations in formal care provision and provided additional social support.

Interventions delivered to pregnant women which combined education, professional support, peer support and psychological approaches are suggested as approaches to improve women's postnatal psychological outcomes and health outcomes for infants (Glover 2014, Marchesi et al. 2016, Morrell et al. 2016). The Acorn study is currently being conducted to evaluate a multi-component intervention delivered to pregnant women and consists of cognitive behavioural therapy principles, psycho-education and relaxation. The study will measure women's symptoms of anxiety during pregnancy (pre and post-intervention) with follow-up measures in the postnatal period (Wilkinson et al. 2016).

Qualitative studies can be used: 1. to explore how an intervention's components inter-relate; 2. identify critical components of interventions; and 3. understand how components relate to particular outcomes (MRC 2000, Moore et al 2015). In subsequent studies comparing the effects of different components can be approached by varying key elements or balancing components between arms of a trial (MRC 2000, Foster & Little 2012).

2.4.4 Completion of interventions

Most studies included in the reviews did not report the number or percentage of sessions attended by participants and five studies reported attrition rates of greater than 20% for the IG and/or CG. Women indicated that the location of interventions and commitment required were important factors when considering participating. Work commitments and other responsibilities may

restrict women's ability to regularly attend sessions and complete additional homework tasks.

2.4.5 Intervention delivery

In this review, psychological interventions were delivered by psychologists or HCPs who had received specialist training in relaxation techniques, mindfulness and cognitive based approaches. Mind-body interventions were delivered by mental health professionals or experienced instructors. In most studies, women were not asked to provide their views on the acceptability of intervention facilitators. Details of intervention facilitator skills and additional training provided to deliver interventions were underreported. Future evaluations of the acceptability of different types of intervention facilitator would be useful to assess the resources required to deliver interventions in maternity care (MRC 2000). Limited documenting of the skills and experience of intervention facilitators was also identified in a review by Marc et al. (2011) of mind-body interventions during pregnancy for women with anxiety. Variations in facilitator skills levels may have an effect on the fidelity of an intervention (Wight et al. 2015). Researchers need to standardise training to maintain fidelity in order to help other researchers to replicate the intervention in a clinical trial (Bellg et al. 2004, MRC 2000).

2.4.6 Outcome measures

In pregnancy, recognising the multidimensional psychosocial aspects is important in developing models of care to promote the psychological wellbeing (Jomeen 2004). This multidimensional approach was employed in six of the studies included in the quantitative SR which included anxiety alongside measures of depression, stress, positive and negative affect and social support. However, the presence of anxiety may have reduced the effectiveness of the treatment of depression or vice versa as interventions targeting one condition may not have been effective

for the other co-morbid condition (Garber & Weersing 2010). Interventions which aim to improve symptoms of anxiety and depression need to have a clear theoretical rationale before testing the mechanism by which an improvement in symptoms is likely to occur for each condition (Garber & Weersing 2010). Studies of interventions to prevent postnatal depression also require a sufficient one-year follow-up period to determine their medium-term effectiveness (Morrell et al. 2016).

2.4.7 Summary

The reviews indicate the effectiveness of, satisfaction with and acceptability of interventions to support women with anxiety in pregnancy has mainly been evaluated in small scale pilot or feasibility studies. In addition, studies have evaluated different intervention designs for different populations of pregnant women. The overall results were inconclusive regarding the effectiveness of interventions, and did not highlight a particular intervention design which could be directly recommended for clinical practice. The findings from the systematic reviews were used to inform the intervention design and are reported in Chapter 3, section 2. Synthesising the findings of the two reviews has helped to develop a greater understanding of why certain components of interventions may be more effective groups of pregnant women rather than one-to-one interventions and has helped identify elements which contribute to or detract from the acceptability of interventions. It also highlighted the types of interventions which may be more feasible to introduce within existing maternity care structures by considering the training needs of intervention facilitators.

Chapter 3 Developing a new intervention

3.1 Introduction

In this Chapter, the development and design of an intervention will be described. The stages of development followed the MRC framework for developing complex interventions (MRC, Craig et al. 2006) and were informed by: the findings from the systematic reviews; an exploration of the theoretical underpinnings of intervention approaches considered beneficial to improve symptoms of anxiety; and consultations with the study advisory group, service users and management teams from the local NHS trust.

Study Objective:

- *To develop a protocol for a new intervention for testing in a feasibility study.*

3.1.1 Medical Research Council framework for developing and evaluating complex interventions

It was considered that a new intervention would consist of several components which may operate within different locations and be delivered to different populations of pregnant women. The choice of intervention components involved consideration of how the mechanisms of change may function within the context of the study and how the mechanisms may have an influence on anxiety symptoms and other psycho-social outcomes. The Medical Research Council (MRC, Craig et al. 2006) described complex interventions as:

1. Including several interacting components
2. Sensitive to the context in which they are delivered
3. Having a causal chain linking the intervention to outcomes
4. Having a range of possible outcomes (Craig et al. 2006).

Therefore, the intervention was considered as 'complex' and the MRC framework was selected as an appropriate guide to inform the stages of development and testing of the intervention.

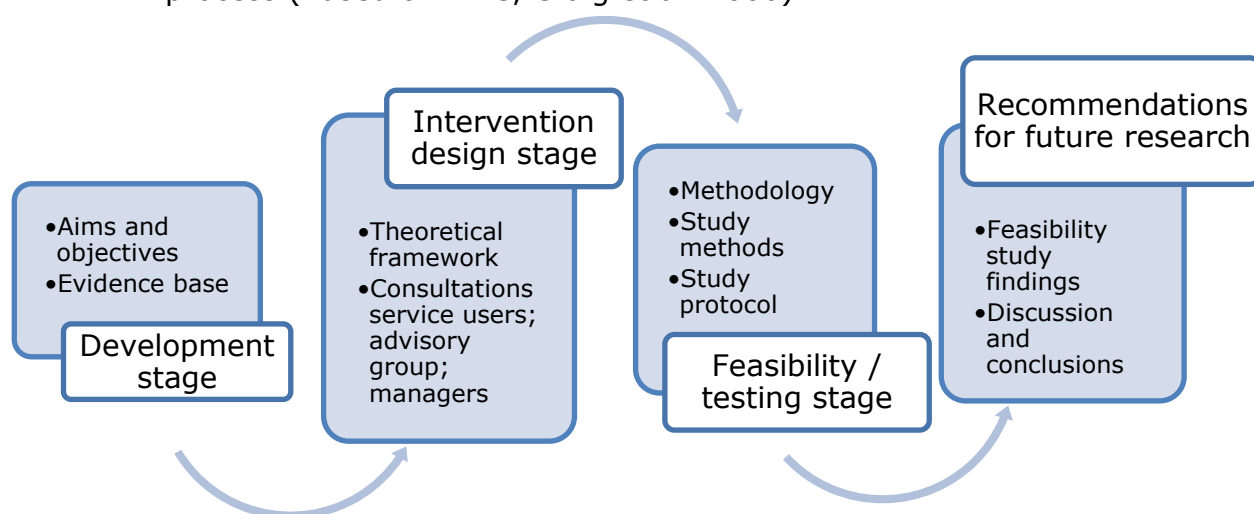
3.1.2 Stages of the development of the intervention

The MRC identified that complex interventions are systematically developed in an iterative process before testing in pilot and feasibility studies. These preliminary studies then test uncertainties in the intervention design which lead to successive modifications and refinements (Craig et al. 2006). Wight et al. (2015) provided further guidance on the stages of the development of a complex intervention:

1. Defining the clinical concerns, exploring current literature and considering the target population.
2. Exploring the contextual factors, how the intervention could operate within an existing system.
3. Defining the change mechanism by referring to theory, exploring the evidence and involving stakeholder groups.
4. Considering how the intervention would be delivered: available resources; training requirements; the location and context of delivery.
5. Testing the intervention through small scale studies to evaluate the acceptability, practicality and feasibility.

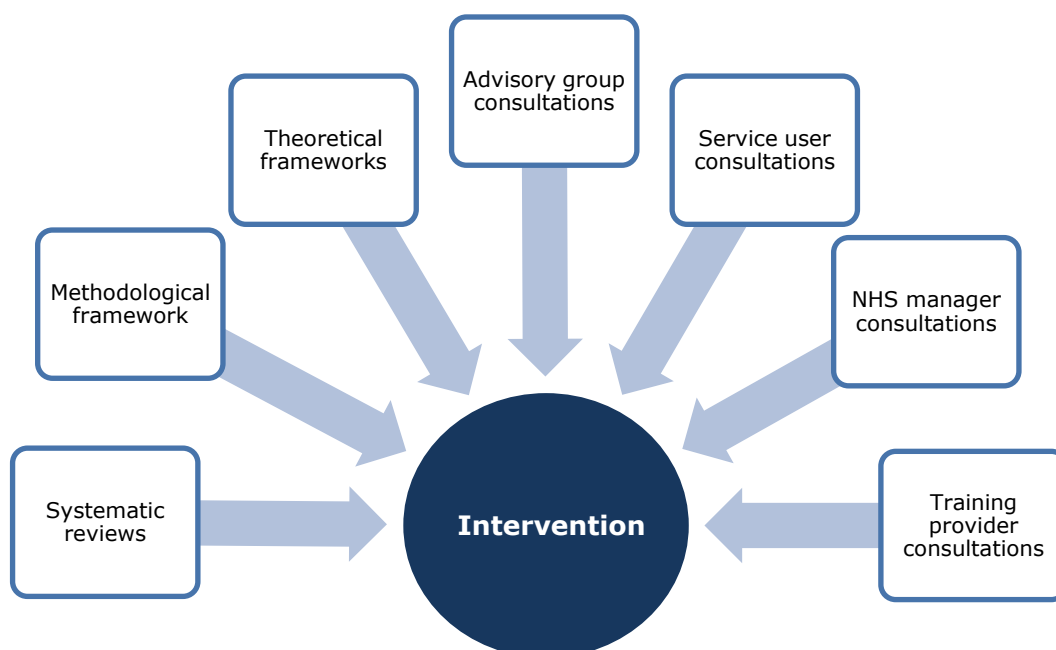
The stages of the intervention development followed the general principles outlined by the MRC theoretical and modelling phases for developing complex interventions (Craig et al. 2006) (Figure 3.1).

Figure 3.1 Key elements of the development and evaluation process (Based on MRC, Craig et al. 2006)



Each stage will be described in this Chapter with reference to the different sources of information, guidelines and frameworks for developing complex interventions which were considered appropriate for each developmental stage (Figure 3.2).

Figure 3.2 Stages of development of the intervention design



3.2 Theoretical framework for the intervention

3.2.1 Potential components identified from the literature

The main findings from the systematic reviews were summarised in Table 3.1. Although the systematic review did not find any strong evidence of the effectiveness of interventions for use during pregnancy, the findings provided some insight into potentially beneficial intervention components and aspects of research design which could be helpful.

Table 3.1 Summary of the findings from the systematic reviews – highlighting components to consider for the intervention design			
	Findings from Quantitative research	Findings from Qualitative research	Other considerations
Group and individual interventions			
Interventions delivered to groups of pregnant women	Some evidence of benefit for group interventions, 6 out of 11 studies reported significant differences in one or more anxiety measures between the IG / CG.	Most women benefitted from sharing experiences, reducing feelings of isolation, access to group support (n=5)	Whether to include both nulliparous and multiparous women in one group.
Interventions delivered to individual women	Limited evidence of overall benefit, 4 out of 14 studies which delivered interventions to individuals reported significant differences in one or more anxiety measures between the IG / CG. These five studies evaluated CBT or relaxation interventions.	Some women liked learning different techniques to manage their symptoms and having individual discussion with HCPs (n=2)	
Targeted or universal interventions			
Targeted interventions	Limited evidence of benefit, 7 out of 13 studies including women with medical, social or psychological risk factors reported significant differences on one or more anxiety measures between the IG / CG.	Some women were motivated to self-refer (n=2). However, some had concerns about disclosing anxiety symptoms and joining groups (n=3).	Highly motivated participants may become frustrated and withdraw from studies if allocated to a CG (Office of planning research and evaluation 2014).
Universal interventions	Limited evidence of benefit, 5 out of 12 studies which recruited from general antenatal populations reported significant differences in one or more anxiety measures between the IG / CG.		
Single or multi-session interventions			
Single sessions	Limited evidence of benefit for single-session relaxation intervention, enduring effects not evaluated (n=3).		
Multiple sessions	Some evidence of benefit for multi-session interventions, 10 out of 19 studies reported significant differences in one or more anxiety measures between the IG / CG.	Women identified group sessions as helpful once groups became established (n=5).	
Timing in pregnancy			
Gestation	Some evidence of benefit for interventions starting in 2 nd trimester, lasting until 3 rd trimester, 7 out of 13 studies reported significant differences in one or more anxiety measures between the IG / CG.		Only a few, small size studies (n=5) have evaluated the effectiveness interventions in the first trimester of pregnancy.
Intervention design			
Intervention type	Studies which reported an improvement in anxiety scores included group mindfulness and MBCT, group motivational interviewing, relaxation and CBT interventions.	Women welcomed interventions which presented options for managing their symptoms and included peer and HCP support.	No studies evaluated interventions delivered via web/ mobile phone applications (Apps).

3.2.2 Theory underpinning potential components

Interventions are more likely to be effective when researchers develop an awareness of the relevant theory underpinning intervention components (Craig et al. 2006). The rationale should include consideration of the process of change and how this relates to existing evidence and theory (Moore et al. 2015). The potentially beneficial components to consider for the new intervention were identified in Table 3.1. The next stage involved exploring the theory underpinning the different components, identifying the mechanisms which were considered to result in an improvement of anxiety symptoms (Table 3.2). The mechanisms were described, considering their usefulness for an intervention for pregnant women. This informed the conceptual framework for the study presented in Chapter 3, section 3.

Table 3.2 Summary of the findings from the systematic reviews and the theory underpinning the intervention components		
	Women's views on intervention components	Theory
Group and individual interventions		
Interventions delivered to groups of pregnant women	<ul style="list-style-type: none"> • Able to share experiences • Accessed group support • Reduced feelings of isolation • Helped to normalise women's experiences 	<ul style="list-style-type: none"> • Social support <ul style="list-style-type: none"> ◦ Experiential knowledge ◦ Social learning ◦ Social comparison ◦ Peer support
Interventions delivered to individuals	<ul style="list-style-type: none"> • Received support from HCPs • Provided reassurance and guidance 	<ul style="list-style-type: none"> • Therapeutic relationships <ul style="list-style-type: none"> ◦ Collaborative role theory ◦ Relational continuity ◦ Social influence
Intervention components		
Mind-body	<ul style="list-style-type: none"> • Provided options and coping strategies for managing anxiety symptoms • Learned breathing and relaxation techniques • Learned to recognise and accept anxious thoughts • Felt more positive about the future 	<ul style="list-style-type: none"> • Awareness, self-regulation and acceptance • Relaxation response
Psychological	<ul style="list-style-type: none"> • Developed an understanding of the causes of anxiety in their lives and self-awareness of their thought patterns. • Helped women respond in a more positive way to situations and feelings, before negative thought patterns could escalate. 	<ul style="list-style-type: none"> • Cognitive behavioural mechanisms

The theory underpinning the components of the interventions delivered to groups of women focused on social support mechanisms which encompassed:

- Experiential knowledge
- Social learning
- Social comparison
- Peer support

Interventions delivered to individuals were based on theoretical components of therapeutic relationships which included:

- Collaborative role theory
- Relational continuity
- Social influence

Mind body interventions were theoretically underpinned by:

- Awareness, self-regulation and acceptance mechanisms
- Relaxation response

Psychological interventions were underpinned by cognitive behavioural mechanisms.

3.2.3 Social support

Social support has been defined as an ability to access people who care and can act as a resource for an individual's psychological and practical needs (Salzer & Shear 2002). Social relationships which surround individuals and may serve various functions and provide supportive resources (Ferlander 2007). Social support is one function of social relationships and includes broad and overlapping categories including 1. emotional support; 2. instrumental support; 3. informational support and 4. appraisal support (House 1981). Social support is distinguished from other types of interactions within social relationships as it is always intended as helpful (from the perspective of the support provider) and respects the recipient's right to make their own choices (Heaney & Israel 2008). Social support can be provided by

various types of people through formal and informal networks. Family members and friends often provide long-term assistance to individuals and HCPs may offer short-term assistance and informational support at times of need or when people experience major life transitions (Thoits 1995).

The provision of psychological and material resources can help to buffer stress and improve an individual's ability to cope (Cohen 2004). Heaney & Israel (2008) have identified pathways in which social support may have a positive effect on mental and physical wellbeing, such as:

- Providing compassion, reassurance and a sense of self-worth.
- Providing access to new contacts and information to help develop problem solving skills.
- Reducing feeling of uncertainty and unpredictability and develop a sense of control.
- Providing instrumental support to reduce the frequency and duration of stressors.
- Influencing positive health behaviours.

Mechanisms within social support pathways include: experiential knowledge; social learning theory; social comparison theory and the helper-therapy principle (Salzer & Shear 2002).

Experiential knowledge, social learning and social comparison

Experiential knowledge has been described as a way individuals can resolve their problems through sharing their perceptions and experiences of mental illness with others who are experiencing similar problems or in similar situations (Shubert & Borkman 1994, Borkman 1999). Social learning and social comparison theory provide an explanation of the mechanisms within experiential knowledge that are considered beneficial for

improving symptoms of anxiety (Solomon 2004). Individuals can benefit by learning from others with similar experiences who have succeeded in managing their symptoms (Mancini 2007, Simoni et al. 2011). Individuals who have experienced mental health problems and are coping with illness are seen as credible role models for other group members with similar problems and are likely to inspire others to change their behaviours and become hopeful about their future. However, social comparison may be problematic if group members are too dissimilar. If there are role models in the group that individuals feel are too superior, they may present unattainable goals and may result in individuals feeling inferior or demoralised (Helgeson & Gottlieb 2000).

Peer support

Mental health peer support models identify the inter changeable helper-therapy roles (or help-seeker / help-provider) which aim to establish a mutually supportive pattern of behaviour (Brown & Lucksted 2010). A help-provider may share their experiences, feelings and insights to help other in the group, and as a result can feel empowered, gain social approval and a sense of increased self-efficacy (Skovholt & Thomas 1974, Solomon 2004). The help-seeker can benefit by sharing their problems, learning from others and receiving support from others through shared experiences (Brown & Lucksted 2010). This results in a reduced sense of isolation, normalisation of their feelings and an ability to develop coping strategies. The self-help model identifies that individuals who are group members can occupy both provider and seeker roles depending on the nature of the interaction.

Supportive exchanges within the helper/provider model are observed regardless of the types of participants (Brown & Lucksted 2010). However, under or over-populated groups may result in hierarchical groups (over-populated) or where participants feel 'over-burdened' (under-populated).

Peer groups may also help to develop an individual's interpersonal skills, talking and actively listening to others and building social networks (Skovholt & Thomas 1974). Groups which provide a warm, accepting atmosphere enable women to speak without fear of criticism and to create trusting, accepting and supportive relationships (Brown & Lucksted 2010). Family members and close friends may avoid talking about mental health and encourage women to be cheerful which can result in women feeling frustrated or belittled (Helgeson & Gottlieb 2000). The benefit from increased social support networks may be gained through a stress-buffering mechanism, enabling women to access a supportive network when required and knowing that support is at hand (Solomon 2004).

Self-help peer groups

Brown & Lucksted (2010) developed a conceptual framework which considers how individuals benefit from mental health self-help peer groups.

- Self-help groups need to be mutually supportive, where individuals can take on help-provider and help-seeker roles. This can be achieved through involving individuals who are likely to benefit or tailoring programmes to a particular setting.
- Women should be encouraged to develop relationships with other group members in order for them to move forward from being passive receivers of care
- Resources can be exchanged through giving and receiving empathy, information, esteem, access to services
- Groups should foster self-appraisal through social comparison and social learning
- Groups should build individuals interpersonal and critical thinking skills
- Transformation from help-seeker to help-provider roles should be supported

3.2.4 Therapeutic relationships and relational continuity

The central tenet of therapeutic relationship theory is the belief that the interaction between a HCP and service user can influence clinical and psychological outcomes, improve adherence and compliance to treatment interventions (McGuire et al. 2001).

Collaborative role theory

Collaborative role theory suggests that positive change occurs when both parties combine resources, share information and decision making to work towards a common goal. Although the roles of the professional and service user are separate, they are mutually validating and operate within a socially defined context (McGuire et al. 2001). Effective relationships require the professional and service user to agree on goals and tasks. HCPs need to have good communications skills and demonstrate positive regard and empathic understanding to encourage service users to explore their feelings and support their efforts to make positive changes to their behaviour (Norcross 2011). There remains some uncertainty to whether the therapeutic relationship itself brings about a positive change or improvement in symptoms or whether the relationship creates the interpersonal context required for other therapeutic approaches to function (Horvath 2005). Studies have identified that a collaborative approach between service users and providers of mental health services tends to be the preference of younger, more educated and healthier service users and those with less severe conditions (Adams & Drake 2006). A collaborative, shared decision-making approach is associated with a range of therapeutic approaches such as IPT and CBT and has been reported to improve health outcomes increase service user satisfaction and improve quality of life (Adams & Drake 2006, Joosten et al. 2008, McCabe & Priebe 2004, Schauer et al. 2007).

Collaborative relationships between women and maternity care providers is well established and the concept has been incorporated into the national maternity strategy in the UK since the Changing Childbirth report was published (DOH 1993). Collaborative therapeutic relationships enable pregnant women to feel physically and psychologically supported which facilitates confidence building and self-efficacy (Carolan & Hodnett 2007). Some studies have indicated that continuity of carer is required to develop effective midwife-woman relationships (Biró et al. 2003, Macpherson et al. 2016, Page 2003) while other studies suggest that women may value consistent, respectful and informative care above continuity of carer (Carolan & Hodnett 2007, Green et al. 2000). Debate also remains within mental health services, whether the beneficial mechanisms associated with TR and relational continuity can be achieved through multi-disciplinary teams or requires a single care provider.

Relational continuity

Relational continuity is defined as a therapeutic relationship between an individual and one or more healthcare providers across various healthcare events (Burge et al. 2011). It promotes a co-operative and co-ordinated approach which results in an increased knowledge of the individual, so care is provided which addresses their needs (Wierdsma et al. 2009). Care from a single provider 'continuity of carer' has been associated with positive health outcomes and increased satisfaction with care (Berry et al. 2008, Burge et al. 2011, Rodriguez et al. 2007). In maternity care, continuity of care from a midwife known to the woman throughout pregnancy and the intrapartum period has been associated with improved health outcomes for women and babies (Sandall et al. 2016). Benefits of the continuity of carer model for the woman include an increased sense of trust, choice and control. Care is provided based on the needs of the women rather than focused on the procedures governed by the institution (Sandall et al. 2016b).

Other studies have indicated that a team based approach reduces the risk of a breakdown in individual relationships due to personality clashes or unmet expectations (Bachrach 1981, Saultz 2003). A central theory in both individual and a team based approach to relational continuity is that the development of a trusting relationship between the individual and care providers leads to an accumulation of knowledge and understanding which produces beneficial effects. Benefit is also derived through care providers developing an increased sense of responsibility towards the individual. Therefore care provision is more consistent and planned to respond to an individual's needs and circumstances, providing care when it is needed (Burge et al. 2011, Haggerty et al. 2003, Wierdsma et al. 2009).

Social Influence theory

The role of social influence within TR requires consideration in relation to the treatment of anxiety disorders. Social influence theory recognises that the HCP may be seen a source of social power due to their access to information, resources and services. While this may be beneficial, it is also associated with negative outcomes if individuals are influenced or coerced into compliance to gain access to services or information. Excessive information seeking and reassurance seeking are common features of anxiety disorders and can have a negative impact on outcomes and the practitioner–service user relationship (Taylor & Asmundson 2004, Osborne & Williams 2013). Typically, the person seeking reassurance may find relief from their anxiety, but relief quickly diminishes, reassurance seeking returns and is reinforced (Williams 2012).

A pregnant woman with health anxiety may continually / excessively seek reassurance about fetal growth, the progress of their pregnancy and about the birth (Bayrampour et al. 2016). This has the potential to have a negative impact on the woman's symptoms of anxiety and leave the HCP feeling over-burdened.

HCPs need to be aware of possible service user motivations for seeking reassurance about their health and wellbeing and suggest strategies, such as CBT, to help modify negative behavioural patterns (Williams 2012). Service users may benefit from being referred to enhanced psychological services or supported to access CBT based resources.

3.2.5 Mind-body mechanisms

Self-regulation, awareness and acceptance

Self-regulation of attention has been described as a mechanism within mind-body approaches for improving emotional wellbeing. Self-regulation involves becoming aware of thoughts, feelings and sensations as they occur. Awareness of mind and body experiences enables an individual to direct their attention to their breathing or another object of focus, to prevent elaborative ruminative thought processing (Bishop et al. 2004, Brown et al. 2007, Gard et al. 2014, Hollis-Walker & Colosimo 2011, NurrieStearns & NurrieStearns 2013).

Acceptance involves a conscious decision to allow current thoughts, feelings and sensations with an attitude of openness and receptivity (Roemer & Orsillo 2002, Hayes-Skelton & Roemer 2013). It is theorised that acceptance of thought leads to a reduction in the use of cognitive and behavioural strategies used to avoid negative thoughts and reduce self-condemnation (Bishop et al. 2004, Hayes-Skelton & Roemer 2013, Hollis-Walker & Colosimo 2011).

Relaxation

Relaxation can be used as a stand-alone technique or used within other approaches such as yoga, stress reduction and meditation based approaches for improving symptoms of anxiety. The stress response is activated in challenging and stressful situations. Physiological, molecular pathways are activated when an

individual experiences stress or anxiety which result in a state of hyper-arousal or the fight-or flight response. This can lead to negative health outcomes if exposure to stress is elevated or prolonged. The relaxation response is thought to counteract the stress response of anxiety. Physiological mechanisms and 'adjustments' are activated when an individual engages in repetitive mental or physical activity and is able to passively ignore anxious thoughts (Esch et al. 2003, Manzoni et al. 2008).

3.2.6 Cognitive and behavioural mechanisms

CBT therapies incorporate both behavioural and cognitive interventions. In the treatment of anxiety disorders, the aim of CBT is to reduce anxious feelings by undoing prior learning or by providing new, more adaptive learning experiences, changing cognitive and behavioural responses to anxiety (Craske 1999, Williams & Garland 2002). Increasing an individual's awareness of unwanted emotions and behaviours is thought to generate a number of alternative responses. This helps the individual to decide on a course of action and monitor the outcome to re-enforce positive coping strategies (Brewin 1996).

Individuals with GAD can respond to many relatively harmless situations as a psychological and/or physical threat. The role of the CBT therapist is to gain information about an individual's reactions to these situations, draw attention to the individual's assumptions and challenge negative responses. This is thought to help distinguish situations that are "truly threatening from those which merely arouse the feeling of being threatened", changing cognition and behaviour (Brewin 1996, page 44). CBT for anxiety disorders may include components of:

- Psycho-education on the nature of fear/anxiety.
- Cognitive restructuring to challenge the truth of anxious thoughts and develop alternative thoughts to better reflect their experience.

- Behavioural exposure to help an individual to approach the feared stimuli and noting whether the expected disastrous result occurs (Brewin 1996).

3.2.7 Summary

A review of the underlying theories has identified that the different approaches share common features. For example, CBT techniques are often incorporated within TR approaches and can be accessed as a resource within peer support models. In summary, examining the theory underpinning interventions for pregnant women with anxiety has identified that positive change can occur through: 1. developing collaborative relationships with women which aim to promote women's choice and control over their care. 2. receiving support from professionals who both understand women's individual needs and can also help them access services; 3. accessing support and learning from other women who have experienced / are experiencing similar feelings or situations; 4. developing strategies to help women develop an awareness of their thought processes and learn techniques to improve the way they cope with anxiety.

3.3 Conceptual framework for the intervention

The next stage considered how the potentially beneficial components of interventions could be delivered as part of a new intervention. The evidence from and theory underlying existing interventions were considered, exploring how components could be delivered by midwives within the context of the study. Many of the interventions included in the systematic review had multiple components: education; relaxation; peer support; and professional support. This multi-component approach was reflected in the interconnected theoretical approaches which underpinned existing intervention components.

Professional and peer support

Within peer groups, it was considered that a midwife could facilitate the groups and be resource to the women. Having a midwife facilitate groups was thought to be more appropriate when groups were establishing, until women felt confident to contribute and lead the group themselves. Once groups were established, the midwife would need to become less active and enable the women to benefit from the beneficial effects of peer support (Brown & Lucksted 2010).

Women who feel isolated in pregnancy, or have poor social support may benefit from peer group approaches, however some women may not feel confident to share their situations or feelings within a group. Women may have additional pregnancy related or mental health concerns which they would prefer to discuss individually with a midwife who can provide support, advice and further signposting to services.

Coping strategies and techniques for managing anxiety

Mind-body and/or CBT approaches were considered as appropriate components of the intervention design. Further consideration about how CBT or mind-body interventions could be delivered were required:

1. How long would it take to train a midwife to deliver or facilitate CBT or mind-body interventions?
2. What alternative methods were available to deliver CBT or mind-body intervention components (i.e. co-facilitated sessions, self-help resources)?

Conceptual framework

Figure 3.3 illustrates the conceptual framework for the intervention design. The Figure displays the different approaches to improve symptoms of anxiety and the interconnected components which were considered beneficial for improving

symptoms of mild to moderate anxiety in pregnancy. Figure 3.3 also illustrates the components of interventions which midwives may have been able to deliver with additional training:



Could be facilitated / supported by a midwife with brief additional training



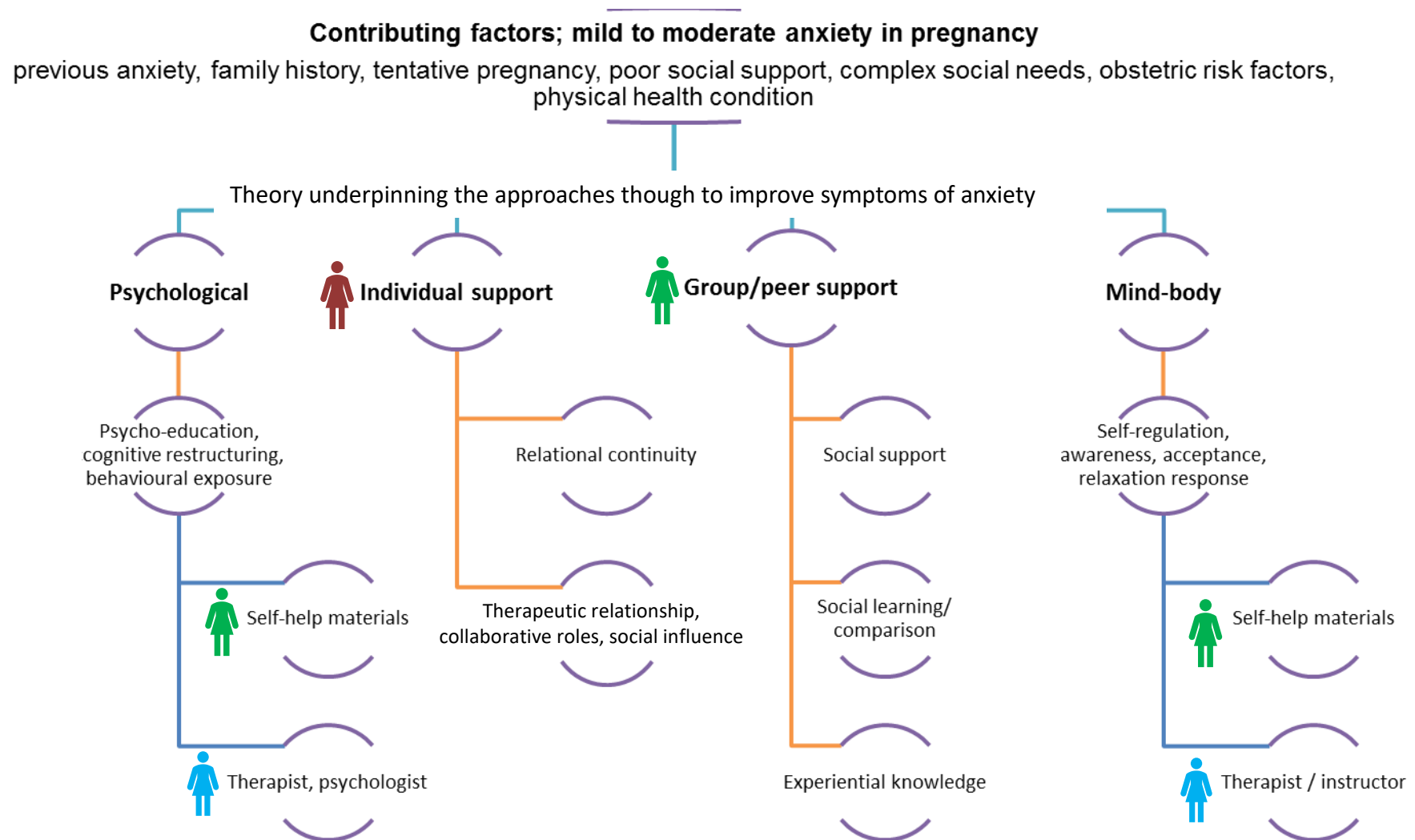
Could be provided by a midwife with brief additional training



Could be provided by a midwife with extensive additional training

The next stage involved accessing feedback from stakeholder groups to refine the intervention design and consider the practicality of conducting a feasibility study of the intervention within the current maternity care structure.

Figure 3.3 The conceptual framework for the intervention: mechanisms to improve symptoms of mild to moderate anxiety in pregnant women which could be delivered or facilitated by midwives



3.4 Consultations with stakeholders and healthcare professionals

The MRC (Craig et al. 2006) suggested that consultations with “stakeholders, i.e. those targeted by the intervention, or involved in its development or delivery” (Craig et al. 2006, Page 9), could help to identify the most appropriate theories for the intervention design. Stakeholder groups with relevant practical expertise can help define appropriate delivery options for the intervention and clarify the conditions and resources required (Wight et al. 2015). Accessing the views of stakeholders who are able to “take account of context and identify the elements relevant to decision-making such as benefits, harms and costs” will help to improve the intervention design (Craig et al. 2006, Page 13).

Consultations with stakeholders may be achieved through meetings, audit and local consensus processes. Information should be clearly presented, making recommendations as specific as possible to address the key options or clarify areas of uncertainty (Craig et al. 2006).

To further inform the intervention design consultation meetings were held between the researcher, academic supervisors and:

- The study advisory group
- Service users
- NHS Trust midwifery managers
- Training providers

The study advisory group consisted of the head of nursing and midwifery research at the local NHS trust, a community psychiatric nurse, a midwife manager, a service user and a consultant clinical psychologist.

3.4.1 The study advisory group

A meeting of the study advisory group was held on the 2nd October 2015. The background to the study and the findings of the systematic review were presented to the group. The group were then presented with options for the intervention design and asked to provide comments and feedback.

The group advised on the following aspects:

Introducing the study to pregnant women

The 16-week appointment would be an optimal time-point for the community midwife to discuss the study. Introducing the study would need careful consideration to overcome the barriers to seeking support for anxiety. Using phrases that would normalise symptoms of anxiety were recommended, such as: "In pregnancy there can be lots of things to think about and things that feel out of your control which can cause women to feel anxious".

Intervention facilitators / integration with maternity care

An intervention facilitated by a midwife within maternity care rather than mental health services may be more acceptable to women because of the stigma associated with mental health. They felt the intervention should be offered in local community locations to maximise participation.

Anxiety measures and eligibility screening

Using the GAD-2 (Spitzer et al. 2006) as part of eligibility screening was supported. The researcher would need to ensure the midwives were familiar with administering the GAD-2 and possibly provide the midwives with training if required.

Eligibility

Nulliparous women would be more likely to be interested and participate. Focusing on nulliparous women would facilitate the data analysis by reducing confounding factors, such as previous birth experience and postnatal mental health.

Training to deliver the intervention

Group members highlighted that the training to deliver CBT, and mindfulness based interventions was intensive, with training usually taking one year or more to complete. Also, readily accessible training courses were not focused on delivering interventions to pregnant women. Therefore, these approaches may not have been suitable for a midwife facilitated intervention. All the group members supported the use of anxiety self-help resources in addition to group support and discussion sessions as a possible intervention approach.

Comments from the advisory group were used to refine the intervention design. A draft plan of the intervention design and recruitment procedures was further developed and presented to the Nottingham Maternity Research Network (NMRN) service user group.

3.4.2 Service user perspectives

The Nottingham Maternity Research Network (NMRN) provided feedback on the draft intervention design on the 9th October 2015. The NMRN is supported by University of Nottingham maternal health researchers, members are generally local women who expressed an interest in maternity research.

The NMRN provided feedback as follows:

Eligibility screening

It was thought that eligibility screening for anxiety using the GAD-2 would be acceptable to pregnant women, however some women may not provide honest answers if there were concerns about how the information would be used by the midwife. There would need to be careful consideration of how the screening procedures were communicated to the women.

One-to-one initial visit with the midwife facilitator

The group commented that women might welcome an initial visit by the midwife facilitator in their own home, although some women could be anxious because of their situation at home and might prefer to meet at an alternative location. Ideally the midwife facilitator would be the women's named community midwife to enhance continuity of care/carer.

Discussion groups

The group felt there were benefits for face to face group discussions and on-line discussion forums. Face to face sessions would help women feel part of a group, normalising their experiences and building social support. The on-line sessions would provide women with a forum to seek support from the group whenever they needed it.

Self-help resources

The group supported the use of self-help computer packages, smart phone Apps, self-help books or audio formats. Some of the network members had experience of using Mindfulness Apps and had found them useful. Other group members, suggested that Apps would be useful for pregnant women to access because most women would have access to smart phones, and they would be flexible for women to use where and when they choose. The group felt it was important that women should have a choice of different formats of self-help resources, choosing format that would suit their needs. Women could share their experiences of the different resources during group discussions and encourage each other to access the resources.

3.4.3 NHS head of midwifery

The head of midwifery at the NHS Trust that would host the study was consulted in December 2016. The aim was to discuss the requirements in respect to the training and provision of midwife

intervention facilitators and of the involvement of community midwives in recruitment to the study. It was not feasible for two midwives to facilitate each group due to the impact on midwives' time (taking into account the current financial constraints of the Trust). Suggestions to include a midwifery support worker (MSW) to support the midwife and co-facilitate the intervention were discussed. It was agreed that the NHS Trust would support two midwives and two MSWs to undergo training to facilitate/co-facilitate the intervention.

The Royal College of Midwives (RCM) has produced guidance of the MSW role which states that MSWs should not make clinical judgements or decisions. However, with appropriate training and supervision MSWs can provide information, guidance, reassurance and support to women and families (RCM 2015b). Developing roles and skill mix across different maternity care professionals can result in a more developed contribution to prevention, public health and family wellbeing across integrated services and multi-disciplinary teams (RCM 2016). Sanders et al. (2016) identified a lack of research surrounding the contribution of the MSW in maternity care. The authors suggest that with appropriate training, knowledge and skills, MSWs can contribute to the maternity public health agenda.

3.4.4 Consultation with senior midwifery managers

The researcher and academic supervisors subsequently met with other senior midwifery managers (SMT) to discuss the recruitment of facilitators, the involvement of the community midwives in recruitment and to identify potential study sites.

Consultations with the SMT:

- Two locations for the study were identified.

- Some managers expressed concerns about the time required for midwives and MSWs to participate in the study due to recent staffing pressures.
- The timeline for completion of the study by August 2016 was agreed.
- Facilitators would be selected from different locations / clinical areas to reduce the impact on a single area.
- Facilitators would be recruited through expressions of interest and assessed by the researcher with the support of academic supervisors.
- Midwifery managers would have the final decision on the selection of facilitators.
- Recruitment advertisements for midwife facilitators and MSW co-facilitators would be circulated in the NHS Trust and details of the time of training workshops would be arranged and sent to managers in sufficient time to plan duty rotas.

3.4.5 Consultations with training providers

Two training providers were identified who were experts in peer group training for mental health and CBT therapies for HCPs. A meeting with the trainers was arranged in December 2015. The trainers agreed to develop and deliver a three-day training workshop to prepare midwives and MSWs to facilitate the intervention. The trainers indicated that for facilitating groups, two facilitators would be optimal for a group size of approximately ten women. Further details of the training plan, study manual and workshops will be presented in Chapter 5.

3.5 Self-help resources

To help identify self-help resources which would be suitable for the intervention, the researcher conducted a scoping exercise. This involved a search of NHS webpages, IAPT services, NHS mental health trusts, mental health charities and perinatal mental

health organisations. Self-help resources identified from the scoping exercise were evaluated by the researcher on the criteria developed by a panel of expert researchers and practitioners with experience in developing self-help resources (IAPT 2010).

The scoring method for the resources involved examining each resource against five criteria questions: 1. is the resource evidence based? 2. would the resource be acceptable to the target user groups? 3. would the resource be feasible to use by the target users and appropriate for the facilitators to support? 4. would the resource be easily accessible? 5. would the resource be cost-effective?

Each resource was scored (0 – 8) for each criterion. The scores were then added together and divided by 5 to assign each resource a total score. The evaluation of self-help resources was discussed with the trainers to confirm the most appropriate resources to use during the study. Table 3.3 summarises the evaluation of the self-help resources.

Table 3.3 Evaluation of self-help resources based on IAPT criteria	
Resource name Resources type Resources cost	Evaluation criteria
Headspace (Headspace UK 2016) App (Computer, Android & iPhone) 10 days free then £8.00 per month	Evidence based: Based on meditation and mindfulness techniques. Few studies have evaluated the effectiveness of mindfulness for women with anxiety. Qualitative studies reported that women found mindfulness enjoyable and helped them cope with their anxiety. Enables users to share experiences with others and track their progress through exercises.
	Acceptability: Users can choose longer or shorter exercises. Participants can also choose to focus on specific areas (i.e. anxiety). The app is not focused on pregnancy. Provided in 12 languages.
	Feasibility / Accessibility: Accessible to women with a computer or smart phone. It is considered that facilitators could support women by discussing their progress and experiences completing the exercises.
	Comments and overall score: Recommended within NHS organisations for use by service users and HCPs. Score 6/8
Mind the bump (Beyond Blue & Smiling Mind 2016) App (Android & iPhone) Free	Evidence based: Based on meditation and mindfulness techniques. Provides education on perinatal mental health. Currently, very few studies have evaluated the effectiveness of mindfulness for women with symptoms of anxiety. Qualitative studies have found that women found mindfulness techniques enjoyable and helped them cope with their anxiety symptoms. The website provides information about how mindfulness can help reduce stress and anxiety through simple animations. Users can rate how they are feeling before and after exercises and can track their progress.
	Acceptability: The App guides users through exercises for the three trimesters of pregnancy. Participants can also choose to focus on specific exercises for anxiety. Only available in the English language.
	Feasibility / Accessibility: Requires access to a smart phone. Users can choose different exercises depending on their available time. Facilitators could support women by discussing progress and experiences completing the exercises.
	Comments and overall score: Created by two large Australian mental health charities. Score 5/8
SAMapp (University of the West of England 2016) App (Android & iPhone) Free	Evidence based: Based on CBT techniques, intended as a psycho-educational tool for use with mild to moderate levels of anxiety. The website provides clear information about the nature of anxiety but little information about the theoretic underpinnings of the app. There are examples of how anxiety may present in individuals in the form of vignettes. The 'social cloud' is a discussion forum for users to access and contribute to discussion forums. Users can complete a rating scale about how they are feeling 'right now' and can track their progress using an 'anxiety tracker'.
	Acceptability: Users can choose exercises and access advice on a variety of topics: anxious thoughts; relaxation; meditation. Users can choose exercises depending on their available time and needs. Users can add favourite/beneficial exercises into a personalised toolkit. Only available in the English language.
	Feasibility / Accessibility: Accessible to women with access to a smart phone. Facilitators could support women by discussing their progress and experiences completing the exercises.
	Comments and overall score: Designed by psychologists from the University of the West of England and NHS practitioners. Reviewed by a panel of clinicians and endorsed by the NHS Health Apps Library. Score 6/8

Resource name Resources type Resources cost	Evaluation criteria
The Pregnancy & Postpartum Anxiety Workbook (Wiegartz & Gyoerkoe 2009) Book /e-book £12.00 - £21.00 (£14.24 kindle e-book)	<p>Evidence based: Based on CBT techniques with relaxation exercises, provides an overview of perinatal anxiety with reference to current research studies. Examples are provided as vignettes and sample answers to help the reader complete the exercises. There are various rating scales and self-assessment forms provided.</p> <p>Acceptability: The book is aimed at an American audience. Different chapters focus on specific anxiety symptoms and disorders. The book seems to be aimed at women with moderate to high levels of anxiety and covers topics on intensive therapy and anxiety medication. The book is only available in the English Language.</p> <p>Feasibility / Accessibility: Uses academic language and may not be accessible to all participants. However, some women may welcome this approach. Women will need to be advised to pace their progress through the book, breaking the sections down to smaller tasks. Helpful tips for are provided in the book for women who may have difficulty completing the exercises. It would be useful for the facilitators to complete the exercises themselves to have insight and provide support and feedback.</p> <p>Comments and overall score: Score 5/8</p>
Overcoming Anxiety (Kennerley 2009) Book £8.00 (approx.)	<p>Evidence based: Based on CBT techniques with relaxation exercises. Examples are provided throughout the book in the form of vignettes and examples of how to complete the exercises. There are various exercises to complete with self-rating scales.</p> <p>Acceptability: The text is aimed at an American audience and is not focused on pregnancy although the advice and techniques can be easily applied to different situations. The book appears to be aimed at individuals with mild to moderate symptoms of anxiety. The book is only available in the English language.</p> <p>Feasibility / Accessibility: Facilitators could support women by discussing progress and experiences.</p> <p>Comments and overall score: Overcoming anxiety is included in the NHS books on prescription scheme. Score 6/8</p>
Coping with anxiety during pregnancy and following the birth (Haring et al. 2013) Workbook Free to download	<p>Evidence based: Based on CBT with relaxation exercises. Sections of the book are clearly presented and explained. Aimed at pregnant women with sections for HCPs. Examples are provided throughout the book in the form of vignettes and examples of how to complete the exercises. There are various exercises to complete with self-rating scales.</p> <p>Acceptability: The information is clearly presented in a logical sequence and easy to understand for a non-professional reader. The book guides the reader through the relevant exercises. The text is aimed at a Canadian audience and is focused on pregnancy and the postnatal period. The advice and techniques can be easily applied to different situations. The book appears to be aimed at mild to moderate symptoms of anxiety, although does contain some information on more severe symptoms and anxiety medication. The book is only provided in the English language.</p> <p>Feasibility / Accessibility: The book can be read in short sections and is easy to access. Facilitators will need to be familiar with the exercises and problem-solving techniques in the book. Some of the exercises may be useful topics to discuss in group sessions. Handouts and worksheets are provided.</p> <p>Comments and overall score: The book is produced by BC Mental Health – an agency of the Provincial Health Services Authority, British Columbia, Canada. Score 7/8</p>

Five self-help resources were selected which were evaluated as relevant and appropriate for pregnant women with mild to moderate symptoms of anxiety. The Pregnancy and Postpartum Anxiety Workbook was not selected as it was evaluated as being too narrowly focused on a US maternity care model and focused on women with more severe symptoms of anxiety. The five self-help resources selected were:

- Headspace (Mindfulness based) Android/Apple/Computer App (Headspace UK 2016).
- Mind the Bump (Mindfulness based) Android/Apple App (Beyond Blue & Smiling Mind 2016).
- SAMapp (CBT based) Android/Apple App (University of the West of England 2016).
- Overcoming Anxiety – (CBT based) book (Kennerley 2009)
- Coping with anxiety during pregnancy and following the birth (CBT based) book (Haring et al. 2013).

These were introduced to the women during the first group by the facilitators.

Practitioners should be well acquainted with the selected self-help resources in order to provide appropriate support and guidance to the women who will be accessing them (IAPT 2010). Guided self-help has been reported as an effective intervention for depression and anxiety in general populations (Gellatly et al. 2007, Seekles et al. 2011) and has been used as a stand-alone intervention or alongside group interventions for pregnant women with anxiety, stress and depression (Breustedt & Puckering 2013, Cornsweet Barber et al. 2013, Guardino et al. 2014, Woolhouse et al. 2014). IAPT (2010) identified the following main elements of guided self-help:

- Engaging the person in guided self-help
- Identifying key problems and goals to work on
- Identifying appropriate self-help resources

- Supporting the person in their efforts to change
- Reviewing and assessing progress
- Identifying the need for further support and signposting to services

The training of facilitators to prepare them to support women accessing the selected self-help resources was be incorporated into the training workshops.

3.6 Rationale for the final intervention design

The previous sections in this Chapter have described how the intervention design was developed and refined in an iterative process through successive stages regarding: the evidence base; current policy and guidelines; theoretical approaches and consultations with stakeholder groups. All the sources of information were considered, and the final intervention design was agreed by the researcher and academic supervisors. Figure 3.4 provides an overview of the intervention components and the intended impact on and outcomes for women. Table 3.4 summarises the rationale for the intervention design.

Figure 3.4 Overview of the intervention components, intended impact on and outcomes for women with symptoms of mild to moderate anxiety in pregnancy.

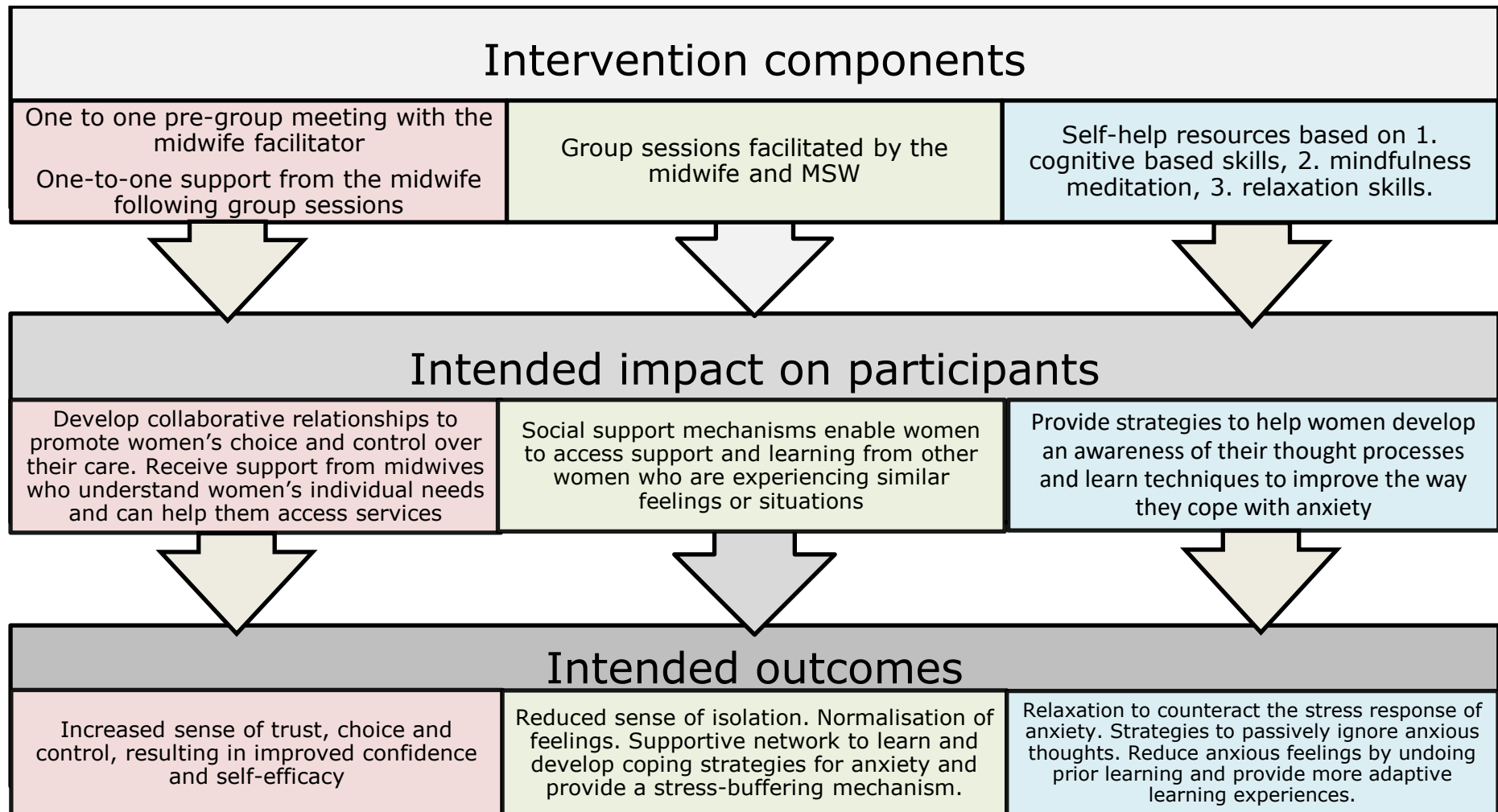


Table 3.4 Rationale for the final intervention design		
	Description	Rationale and source
Sample population	Nulliparous women attending for an appointment at approximately 16 weeks of pregnancy.	<p>Systematic review: most studies commenced in the second trimester of pregnancy (n=22).</p> <p>Advisory group suggested: recruitment at 16 weeks of pregnancy.</p> <p>Advisory group and service user group suggested: to focus on nulliparous women (facilitate data analysis and more likely to be interested and able to participate).</p>
Participant eligibility	<p>Inclusion criteria:</p> <ol style="list-style-type: none"> 1. Nulliparous pregnant women: 18 years or older. 2. Self- report mild-moderate anxiety (GAD-7 score 3-14). 3. Able to read, write, speak English. 4. Able to provide written consent. <p>Exclusion criteria:</p> <ol style="list-style-type: none"> 1. Receiving treatment for a severe and enduring mental health condition. 2. Complex social factors (NICE 2010). 	<p>Current clinical policy: women with severe mental health concerns and complex social factors have established referral pathways to specialist services. There is limited support for women with mild to moderate symptoms of anxiety.</p> <p>Pragmatic / financial considerations: for the feasibility study inclusion would be limited to women who were able to read and write and speak the English language and able to provide written informed consent. The provision of interpreters was not possible within the time and financial constraints of the study.</p>
Inclusion screening for potential participants	The GAD-2 will be administered by the CMW to indicate women who meet the cut-off score for anxiety (3 or more). Women who score 3 or more on the GAD-2 scale and have consented will be asked to complete the GAD-7 scale.	<p>Systematic review: rationale for applying inclusion criteria and referral should be clearly communicated to women within a supportive context.</p> <p>Advisory group suggested: midwives may require training in administering the GAD-2 if they were not familiar with its use.</p> <p>Current clinical policy: GAD-7 recommended as part of psychological assessment (NICE 2014)</p> <p>Service user feedback: inclusion screening would be acceptable; the midwife should be aware of concerns about being 'judged' and safeguarding implications.</p>
Intervention facilitator	The intervention will be facilitated by a midwife and co-facilitated by a MSW. They will receive training to deliver the intervention. Two midwives and two MSWs will be provided by the local NHS Trust.	<p>Systematic review: interventions were delivered by psychiatrists, psychologists, midwives, trained instructors, self-help and peer support volunteers.</p> <p>Advisory group suggested: women may be more willing to seek support from midwives than from mental health professionals. They supported a midwife facilitating the intervention.</p> <p>Service user feedback: the group supported the intervention being facilitated by a midwife.</p> <p>Consultations with trainers: two facilitators would be optimal to facilitate groups.</p> <p>Service Manager feedback: would not be feasible to deliver the intervention with two midwives (time and financial constraints). Suggestions to include an MSW to co-facilitate.</p>

Intervention components	<p>The intervention will be delivered in three components:</p> <p>Component 1: one to one pre-group meeting with the midwife facilitator.</p>	<p>Component 1:</p> <p>Systematic review: some women reported initial concerns about disclosing their symptoms and feared the judgment of others (in group interventions). Initial meetings with facilitators helped women feel more confident to join the group (n=3 studies).</p> <p>Advisory group: one to one meetings would provide an opportunity to discuss individual concerns, answer questions and inform discussion topics.</p> <p>Service user feedback: women may welcome a visit by the midwife facilitator.</p>
	<p>Component 2: Four sessions facilitated by the midwife and MSW. Sessions will take place fortnightly over an eight-week period. There will be two groups, each group consisting of eight to ten women. Sessions will be held in one of two community healthcare centres. Each session will last for 90 minutes (either early evening or weekends).</p>	<p>Component 2:</p> <p>Systematic review: discussion sessions were highlighted as an important and valued component (n=6 studies).</p> <p>Advisory group: self-help (relaxation, mindfulness, low level CBT) with discussion sessions supported as an option for the intervention. CBT and MBCT training is intense and takes a long time to complete, this may not be feasible for the study.</p> <p>Advisory group: support for community locations (i.e. Sure Start centres).</p> <p>Service user feedback: group discussion sessions would help women feel part of a group, normalising their experiences and building social support.</p> <p>Service user feedback: sessions should be offered outside daytime working hours.</p>
	<p>Component 3: Selected self-help resources to be completed between sessions. Resources will be selected for their relevance in a UK context, for anxiety in pregnancy and/or coping strategies for symptoms of mild to moderate anxiety. Women will have a choice of which resources to access. The self-help resources will be based on 1. cognitive based skills, 2. mindfulness meditation, 3. relaxation skills.</p>	<p>Component 3: Guided self-help resources</p> <p>Systematic review: some participants reported self-help interventions as challenging but also helpful (n=3 studies).</p> <p>Advisory group: self-help resources with discussion sessions was supported as an option for the intervention.</p> <p>Service user feedback: supported self-help resources between sessions; considered useful to pregnant women. Women should be able to choose different formats. Women sharing their experiences of the different self-help packages during group discussions would be beneficial and encouraging.</p>
<p>GAD-7 - Generalised Anxiety Disorder Scale (7-item); GAD-2 - Generalised Anxiety Disorder Scale (2-item); CBT - Cognitive Behavioural Therapy; MBCT - Mindfulness Based Cognitive Therapy</p>		

Chapter 4 Feasibility study

4.1 Introduction

In this Chapter, the design of the feasibility study will be discussed, describing the methodological approach and selection of study methods to address the overall study aims. The methodological approach was selected with reference to relevant frameworks to maximise the quality of the study conduct and reporting.

Study objectives:

- *To undertake a feasibility study*
- *To assess the acceptability of the intervention for women*
- *To assess the acceptability and feasibility of the intervention for intervention facilitators*

4.1.1 Feasibility studies of interventions

Feasibility studies are used to “determine whether an intervention is appropriate for further testing” (Bowen et al. 2010, page 4). Feasibility studies maximise the probability that the eventual implementation of the intervention is practical and potential threats to the validity of the study’s outcomes are identified and addressed before conducting evaluation studies (Tickle-Degnen 2013). There are a number of purposes of feasibility studies. These include:

- Assessing the acceptability of an intervention: uptake and attrition rates; participant satisfaction and perceived appropriateness.
- Assessing the demand for the intervention: expressed interest in participating; perceived demand for the intervention.
- Identifying whether the intervention can be implemented as planned: the success or failure of the execution of the intervention; the ability of participants to carry out intervention activities.

- Identifying the resources required to implement the intervention.
- Assessing how the intervention may need to be adapted for different contexts: the degree to which similar outcomes are obtained in different populations.
- Assessing how the intervention can be integrated into existing structures: the organisational 'fit' of the intervention, perceived sustainability: the cost to the organisation.

(Bowen et al. 2010)

Methodological components can also be tested which may include: the suitability and acceptability of data collection methods; timing of data collection; intervention fidelity and dose (Foster & Little 2012).

4.1.2 Pilot and feasibility studies

The distinction between a pilot study and a feasibility study has been described as a 'grey area' with some researchers using the terms interchangeably or applying the terms without a clear definition (Whitehead et al. 2014). Whitehead et al. (2014) suggest the term 'feasibility' may apply to all preliminary work prior to a main trial, however, the term 'pilot trial' should only be used for studies that mimic a definitive trial design (Charlesworth et al. 2013).

Pilot studies have the following characteristics:

- Follow strict study methodology (e.g. sample size justification).
- Conduct a smaller version of a main study (e.g. using a control group and randomisation).
- Ensure research methods and procedures are robust before conducting a main trial.

(Charlesworth et al. 2013, Whitehead et al. 2014)

Common problems in evaluation studies of interventions can be anticipated and addressed by conducting pilot and feasibility studies of interventions (MRC, Craig et al. 2006). Problems such as poor recruitment and retention, smaller than expected effect sizes and issues with the delivery and acceptability of the intervention, may be identified in the developmental stages of the intervention design. Qualitative and quantitative methods can be used to 'refine' the design of the intervention, before conducting full scale evaluations (Craig et al. 2006).

Feasibility studies are especially relevant:

- Where there have been very few published studies on a specific intervention design.
- Where existing interventions have been assessed in different settings to the one of interest.
- Where refined versions of an intervention may prove to be more successful (Bowen et al. 2010).

Because of the paucity of evidence surrounding interventions for pregnant women with symptoms of mild to moderate anxiety, and the limited time frame to conduct the study, it was decided that a feasibility study would be an appropriate study design for preliminary testing of the new intervention.

4.2 Feasibility study methods

Effective interventions must be acceptable to both participants and facilitators. Assessing acceptability prior to conducting definitive studies should highlight which components require modification to improve participation, adherence and clinical outcomes (Sekhon et al. 2017). Acceptable interventions are more likely to be implemented as intended, improving the overall fidelity and effectiveness. According to the MRC guidance, assessing acceptability in the feasibility and piloting stage of developing interventions can be achieved through quantitative approaches (measures of acceptability or satisfaction) or

qualitative methods to develop an understanding of how participants and facilitators interact with the intervention. (Craig et al. 2006; Moore et al. 2015).

However, the MRC guidance lacks a definition of acceptability and does not provide clear guidance on how acceptability should be measured (Sekhon et al. 2017). Existing definitions of acceptability refer to the suitability, convenience, adequacy and effectiveness of care to address a clinical concern (Sidani et al. 2009, Staniszewska et al. 2010). Sekhon et al. (2017) recognised that acceptability can be measured prospectively, concurrently or retrospectively to capture the changing experiences as participants progress through interventions.

The following seven components of the acceptability of interventions have been identified (Sekhon et al. 2017):

1. Feelings about the intervention.
2. Burden of participation (time, cost, effort).
3. Ethicality (whether the intervention reflects individual's values).
4. Understanding how the intervention works.
5. The cost to the individual of participating.
6. Perceived effectiveness of the intervention in achieving its purpose.
7. Participants' confidence in being able to perform the behaviours required to participate in the intervention.

4.3 Aims and objectives of the feasibility study

The aim of the feasibility study was to determine the acceptability and feasibility of the new intervention from the perspective of participants and intervention facilitators. The findings were to help determine whether the intervention should be recommended for further effectiveness testing.

The components of acceptability and feasibility identified in the previous paragraph informed the feasibility study objectives, which were:

- To calculate the proportion of eligible participants who agreed to be contacted by the researcher.
- To determine the proportion of participants, who following contact with the researcher, agreed to participate in the intervention.
- To assess women's reasons for declining participation in the intervention.
- To measure indicators of acceptability of self-report outcome measures (response rate, missing data, completion time).
- To determine women's views on the acceptability of the intervention.
- To determine women's views on the costs, if any, they incurred from the intervention.
- To determine women's views on the benefit, if any, they derived from the intervention.
- To determine intervention facilitators' views on the delivery of the intervention.

4.4 Data collection methods

4.4.1 Qualitative data

Qualitative methods such as focus groups and interviews can be used to conduct acceptability and feasibility research (Ayala & Elder 2011). Discussions conducted with intervention facilitators and participants could provide a deeper understanding of the factors which contribute to the overall acceptability and feasibility of interventions. Quantitative data can also be used to assess acceptability and feasibility, such as survey data on the uptake and retention rates to studies of interventions (Ayala & Elder 2011).

Qualitative semi-structured interviews were chosen as an appropriate method to determine women's views on the acceptability of the intervention. Psychological health is a sensitive topic and may involve women reflecting on their personal thoughts and feelings to respond to the interview questions. Semi-structured interviews can be used to guide participants through the different topics whilst being flexible to enable participants to elaborate on areas which are important to participants but may not have previously been considered by the researcher (Britten 2006).

Conducting semi-structured interviews with intervention facilitators would highlight the key areas of acceptability and feasibility identified during the study and identify the strengths and limitations of the intervention. Interview topic guides were developed which reflected the components of acceptability (Sekhon et al. 2017) (Appendix 4.1).

4.4.2 Quantitative data

In addition, quantitative data were utilised which related to women's acceptability of the intervention such as rates of eligibility, participation and retention and the indicators of acceptability of self-report outcome measures (response rate, missing data, completion time). This data would inform further refinements of the intervention design and help identify outcome measures which participants considered important to evaluate the effectiveness of the intervention in future studies.

4.4.3 Outcome measures

Study outcome measures were selected which:

1. Reflected clinical practice recommendations (NICE 2014).
2. Have been more extensively evaluated or used during pregnancy (Evans et al. 2015).

3. Women have said were relevant and acceptable to them (Evans et al. 2016).
4. Aim to capture the impact of anxiety on women's everyday life.

The outcomes measures selected for the study were:

The 7-item Generalised Anxiety Disorder scale

The 7-item Generalised Anxiety Disorder scale (GAD-7, Spitzer et al. 2006) was selected as it is recommended by NICE (2014) for consideration as part of antenatal psychological screening. However, the NCCMH (2011) highlighted the limitations of using the GAD-2 and GAD-7 self-report measures as they have not been validated for use in pregnancy. Scores of 5-9, 10-14 and 15 or more are reported as the cut-off points for mild, moderate and severe anxiety, respectively (Spitzer et al. 2006).

The Edinburgh Postnatal Depression Scale

The Edinburgh Postnatal Depression Scale (EPDS, Cox et al. 1987) is a 10-item questionnaire developed to identify postnatal depression. The EPDS has also been recommended as part of antenatal psychological screening (NICE 2014). Although the EPDS is mainly focused on depression with three anxiety items, factor analysis suggested that the EPDS includes a depression and anxiety sub-scale (Jomeen & Martin 2005) and may be used to assess both anxiety and depression in pregnant women (Brouwers et al. 2001). Internal consistency for the EPDS has been reported between $\alpha=0.80-0.85$ (Brouwers et al. 2001, Jomeen & Martin 2005). A score of 10 may indicate possible depression, whilst a score of 13 or more may indicate the woman is likely to be suffering from a depressive illness (Cox et al. 1987). Cut-off scores during pregnancy have been suggested between 14-15 for major depression (Murray & Cox 1990); cut-off scores for anxiety in pregnancy have not yet been established.

The State-Trait Anxiety Inventory

The State-Trait Anxiety Inventory (STAI) (Spielberger et al. 1983) is a widely used measure of anxiety in an adult population. It measures two types of anxiety: state anxiety, or anxiety at that moment and related to an event, and trait anxiety which is a characteristic of anxiety which endures over time. State and Trait subscales each consist of 20 items. Items are scored on a four-point scale (1-4), scores range from 20 to 80. Barnett & Parker (1985) have recommended cut-off scores of 40 or more to indicate high anxiety in a pregnant population. Cronbach's alpha values for the STAI were reported by two studies and demonstrated good internal consistency (Hall et al. 2009, state=0.93, Grant et al. 2008 state=0.95, trait=0.96).

The STAI and EPDS have been validated in general and postnatal populations, and currently present the best available instruments for use to identify self-report symptoms of anxiety in pregnancy.

The Pregnancy Related Anxiety Questionnaire

The Pregnancy Related Anxiety Questionnaire – Revised (PRAQ-R) (Huizink et al. 2004) consists of ten items rated on a 4-point scale. Internal consistency of the PRAQ-R has been reported as $\alpha=0.76-0.88$. Four recent literature reviews (Alderdice et al. 2012, Evans et al. 2015, Meades & Ayers 2011, Morrell et al. 2013) have highlighted the limited research investigating psychometric properties of pregnancy-specific anxiety measures. Psychometric testing of the PRAQ-R has been conducted in a single study of 230 nulliparous women (Huizink et al. 2004). However, other studies have indicated that the PRAQ-R performed well in predicting the duration of labour (Reck et al. 2013) and was able to differentiate between pregnancy specific anxiety and general anxiety (Huizink et al. 2014). In a previous study, women commented that they associated with the statements presented in the PRAQ-R which reflected their feelings and anxieties during pregnancy (Evans et al. 2016).

The 12-item Short-Form Health Survey

A quality of life (QOL) measure, the 12-item Short-Form Health Survey (SF-12) (Ware et al. 1996) was included as an outcome measure in order to assess how anxiety symptoms may impact women's feelings of wellbeing and women's QOL in pregnancy. The SF-12 contains 12 items over 2 sub-scales: a mental component summary (MCS) and physical component summary (PCS) (Ware et al. 1996). The SF-12 has been validated for use in general populations and has demonstrated good internal consistency (Cronbach's $\alpha \geq 0.82$ and 0.75 , PCS and MCS scale respectively) (Busija et al. 2011). Many health related quality of life measure have been designed for non-pregnant populations and there is little evidence on the psychometric properties of QOL instruments for use in pregnancy (Morrell et al. 2013).

4.5 Data analysis plan

4.5.1 Quantitative data

The objectives for the quantitative data analysis were developed to address the overall aims and objectives of the study.

The source documents, data collection and analysis methods were developed to meet the objectives (Table 4.1).

Table 4.1 Analysis plan for the quantitative data			
Study objective	Data collection method / source documents	Collected by	Data analysis
Number of women who are eligible or ineligible (with reasons)	Community midwives' data collection form	Community midwives	Numbers and percentages of eligible / ineligible participants (and documented reasons) from the total sample
Number of eligible women who agree/disagree to be contacted by the researcher	Community midwives' data collection form	Community midwives	Numbers and percentages of eligible participants who agree/disagree to be contacted
Proportion of participants, who following contact with the researcher, consent to participate in the intervention	Researchers contact log	Researcher	Numbers and percentages who consent to participate
Demographic data	Study form (collected pre-intervention)	Researcher	Numbers and percentages: age, gestation, ethnicity, employment status
Number of eligible women who would agree in principle to be allocated at random to the control group / intervention group	Baseline data collection form	Researcher	Numbers and percentages who agree/disagree in principle to being allocated at random to the control group / intervention group
Self-report anxiety and psychosocial instruments scores at baseline	Baseline data collection form: GAD-7, STAI, PRAQ(R), EPDS, SF-12	Researcher	Self-report scores: mean SD, median and IQR to describe the full range of data at baseline and post-intervention.
Self-report anxiety and psychosocial instruments scores post intervention	Baseline data collection form: GAD-7, STAI, PRAQ(R), EPDS, SF-12	Researcher	Self-report scores: mean SD, median and IQR to describe the full range of data at baseline and post-intervention.
To gauge whether the self-report outcome measures reach indicators of acceptability	Baseline data collection form: GAD-7, STAI, PRAQ(R), EPDS, SF-12	Researcher	Numbers and percentages: (number of returned measurement forms, item completion, completion time)
Rates of adherence and attrition to the intervention	Study form (collected post-intervention)	Researcher	Numbers and percentage of sessions attended

4.5.2 Qualitative data

Qualitative data from participant and facilitator interviews were collected by the researcher. Each interview lasted between 45-60 minutes.

The recorded interviews were transcribed prior to conducting template analysis (King 2004). Template analysis was selected as the method enables: 1. an interrogation of the data for themes/topics already identified in the literature review; and 2. an investigation of the data to identify new concepts. The first stage involved developing a coding "template", which summarised themes identified by the researcher as important in the data set, and organised them in a meaningful way (King 2004). Broad themes were then developed which encompassed successively narrower, more specific themes. In template analysis, the procedure often starts by defining some a priori codes, which identify themes strongly expected to be relevant to the analysis. Although researchers may begin with a pre-existing coding systems, these systems are modified in the course of analysis, or may even be discarded in favour of a new system, to ensure the best fit to the data (Sandelowski 2000).

Once a priori themes were defined, a sub-set of data was read through and marked with relevance to the research objectives (reported in Chapter 6). New themes which arose were defined to include the relevant material and organised into the initial template. The initial template was then applied to the whole data set, and modified in the light of careful consideration of each transcript (King 2004). An audit trail displaying successive versions of the template in its development and other resources such as notes and summaries were kept to present an overview of how the interpretations of the data were produced. Once a final version was defined, and all transcripts were coded using it, the template served as the basis for the interpretation of the data set. The stages of development of the analysis template were

discussed with academic supervisors and the final template was confirmed by the researcher and academic supervisors.

4.6 Guidelines for the study conduct and reporting

Evaluations of complex interventions should be reported in accordance with established guidelines to provide key information for replication studies, systematic reviews and guideline development (Craig et al. 2006). Although the aim was to conduct a feasibility study, standards and guidelines for RCTs and non-randomised evaluation studies of interventions were also applied to highlight where the quality of the feasibility study could be maximised and used to inform recommendations for conducting further effectiveness studies.

4.6.1 Evaluation of study process and conduct

The MRC stated that process evaluations complement evaluation studies and aim to develop an “understanding of the functioning of an intervention by examining the implementation, mechanisms of impact, and contextual factors” (Moore et al. 2015, page 8). They should address the question: if an intervention is effective in one context, what additional information would be required to be confident that another organisation would deliver it in the same way or that it would produce the same outcomes in new contexts? Alternatively, if an intervention was ineffective in one context, “was the failure attributable to the intervention itself or to poor implementation” (Moore et al. 2015, page 10). Process evaluations enable researchers conducting systematic reviews to assess whether they are comparing interventions which were delivered in the same way and develop an understanding as to why the same intervention may produce different effects in different contexts (Moore et al. 2015).

A process evaluation should address the following components (Moore et al. 2015):

- The fidelity and quality of implementation: whether the intervention was delivered as intended and anticipate factors which may undermine the fidelity of the intervention.
- Identify whether the hypothesised causal pathways operated as assumed. This may require qualitative and/or quantitative data to understand the complex pathways or identify unexpected mechanisms.
- Contextual factors: identify whether the recruitment was successful in reaching the target group and how the study population came into contact with the intervention.
- Describe how the intervention was tailored for the setting, how it might be replicated and how the intervention may need to be adapted for different settings.
- Describe the training and support of intervention facilitators.
- Report the communication and management structures within the study setting and consider how they interacted with researchers' attitudes and circumstances.
- Identify causes of a variation in outcomes between participants, study sites or timescales.

Studies of psycho-social interventions require a greater attention to issues of external validity because they are more likely "to be influenced by context, as different underlying social, institutional, psychological and physical structures may yield different causal and probabilistic relations between interventions and observed outcomes" (Mayo-Wilson et al. 2013, page 252). Researchers need to describe how the intervention operates in a particular context and consider how the results are likely to vary across time and place (Mayo-Wilson et al. 2013). Researchers need to have a good working relationship with all stakeholders involved in

the intervention development and implementation, yet need to maintain sufficient independence to critically observe and report the process (Moore et al. 2015). Transparent reporting of relationships between the researchers and other stakeholders, reflecting on how these may affect the evaluation is a critical quality component of process evaluations.

Feasibility studies should aim to capture the impact of the different influences that have an effect on the implementation of an intervention within existing healthcare systems (Bird et al. 2014). The SAFE (Structured Assessment of Feasibility) guidelines to evaluate complex interventions was developed by Bird et al. (2014). The guideline contains similar components of process evaluations described by Moore et al. (2015), although provides a more prescriptive checklist in the forms of specific questions surrounding the feasibility of implementation. The CONSORT group have also developed guidelines for reporting studies of social and psychological interventions (CONSORT-SPI) as they identified that RCTs of psychological and behavioural interventions were often poorly reported (Mayo-Wilson et al. 2013). The guideline identifies the importance of reporting a process evaluation of the study to help understand the mechanisms of the intervention and the study outcomes. It is recommended that the TIDieR framework (Template for Intervention Description and Replication) should also be used in conjunction with the CONSORT checklist or other relevant frameworks to when reporting intervention studies (The Consort Group 2017, Hoffmann et al. 2014). The TIDieR framework was designed to ensure intervention studies are reported with sufficient details to enable replication and provide a structured framework which makes the information usable to readers, reviewers and editors (Hoffmann et al. 2014).

To record the process of the feasibility study (Bird et al. 2014, Moore et al. 2015, Mayo-Wilson et al. 2013), a field diary was completed by the researcher. This documented information, observations and reflections which were not part of the formal data collection, but were considered important to inform an overall evaluation of the feasibility and acceptability of the intervention. The procedures of conducting the study will be reported and discussed in the Methods, Findings and Discussion Chapters.

4.6.2 The TREND statement checklist

The TREND statement is a 22-item checklist (DesJarlais & Lyles 2004) recommended by the MRC to guide the design and reporting of non-randomised evaluation studies. It was considered that many of the items in the checklist were applicable to the proposed feasibility study and were used to improve the design, quality and reporting of the study.

4.6.3 The COREQ checklist

For the qualitative interviews, the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist (Tong et al. 2007) was selected for use as framework. The COREQ checklist is appropriate for the reporting of focus groups and interviews and has been endorsed by peer reviewed journals (Booth et al. 2014). Although, due to the holistic nature of qualitative research, some authors recommend using the checklist as a prompt to address quality criteria as opposed to using COREQ as a prescriptive checklist (Booth et al. 2014).

Chapter 5 Methods

5.1 Introduction

The following Chapter presents a summary of the final study protocol which was submitted for governance reviews. The format of the full version of the protocol was developed in accordance with the IRAS submission guidelines. This Chapter will also report the study methods and procedures, providing a description of the study implementation and context. This will include details of the stages of the recruitment process; how the intervention was tailored for the setting; the training and recruitment of facilitators; amendments to the study protocol and the communication processes throughout the feasibility study. The process evaluation framework by Moore et al. (2015) and the TIDieR framework (Hoffmann et al. 2014) will be used as a guide for reporting the stages of the study.

5.1.1 Approvals to conduct the study

All permissions to undertake the study were received from The University of Nottingham (study sponsor), the Health Research Authority (HRA), East Midlands Research Ethics Committee (REC) and the NHS Trust Research and Innovation (R&I) department on the 17th March 2016 (REC reference: 16/EM/0041, R&I reference: 16OB001).

5.1.2 Access to and preparation of the study sites

Participants were recruited from one of two antenatal clinics held in community healthcare locations where midwifery care was provided by the local NHS Hospitals Trust.

The researcher contacted midwifery managers at the two study sites and attended team meetings to present an overview of the study and discuss the midwives' recruitment process. A letter

explaining the study and the involvement of the community midwives was distributed to all midwives working in the two community teams (Appendix 5.1). It was agreed that the researcher would be on site during the initial recruitment period to provide further support if required and ensure the midwives adhered to the study protocol. Reminders about the study were sent to both teams via email one week and one day before the start of the recruitment period. The researcher also attended weekly team meetings throughout the recruitment period to inform the team of the progress with recruitment and remind midwives to complete data collection forms for all women who met the initial inclusion criteria. Data collection forms were collected by the researcher at the end of each day from the community team offices. In this setting, the community midwives had a computer appointment system. The midwives decided to prepare recruitment forms for each potentially eligible woman prior to their appointment. This helped them to remember to approach women to assess their interest in the study.

5.2 Recruitment into the feasibility study

5.2.1 Population of interest

Participants were women attending community health centres for a routine antenatal appointment at approximately 16-25 weeks of pregnancy.

5.2.2 Eligibility criteria

Inclusion criteria

- Nulliparous pregnant women aged 18 years or older at the time of enrolment (no upper age limit)
- Self- report symptoms of mild to moderate anxiety (inclusion screening: score 3-14 on the GAD-7 scale)
- Able to read and write and speak the English language
- Able to provide written informed consent.

Exclusion criteria

- Pregnant women who were receiving treatment for a severe and enduring mental health condition
- Pregnant women who met the criteria for complex social factors (NICE 2010): women who misused substances (alcohol and/or drugs); women who were recent migrants; asylum seekers or refugees; women who experienced domestic abuse before or during pregnancy.

5.2.3 Sample size

The sample size of the feasibility study was not designed to have the statistical power to generate statistically meaningful data. A pragmatic decision was made to recruit 20 participants to the study. This was considered an appropriate number to facilitate an optimal number of participants to take part in two groups (maximum of 10 women per group), allowing for attrition.

5.2.4 Recruitment sites

Demographic information on the population living in the study sites was compiled from most recent data available (2015-2016) provided by local city council reports, local clinical commissioning group (CCG) reports and information from the midwifery community teams. The Index of Multiple Deprivation (IMD) information was collected by the Department for Communities and Local Government (2015). The data were based on small neighbourhood areas in England, known as super output areas (SOA) which were ranked from 1-32,844 (with 1 representing the most deprived area). Areas classified as highly deprived were rated in the lowest 10-20% of the index. IMD data on 326 larger district authority areas are ranked from 1-326 (with 1 representing the most deprived district). IMD considers: income levels; crime and disorder ratings; education and skills level;

employment rates; health and deprivation ratings; housing access and environmental ratings.

Location one

In this location, midwifery care was provided to five GP surgeries within the area which had 29,265 registered GP patients.

Typically, there were 40-48 pregnant women booking for maternity care per month, of which 18-21 were nulliparous. The area was located on the outer area of the City and was predominantly of White British ethnicity (81.4%). Most SOAs within the area were ranked amongst the 10% most deprived areas in England in terms of multiple deprivation, with high crime and high unemployment levels and low educational attainment and low health status.

Location two

The community midwifery team for this location provided care across two areas. Area one comprised a mix of urbanised, suburban and rural areas. The IMD rank was 319th out of 326 districts in England and was summarised as an area of very low deprivation with good overall health and good educational attainment. Over 70% of residents lived in areas of the lowest deprived quintile in England. Maternity care was provided to five GP surgeries with a total of 46,953 registered patients. The residents were predominantly of White British ethnicity (93%).

Area two formed part of a larger inner-city CCG. Midwifery care was provided to two GP surgeries with a total of 7,925 registered patients. The ethnicity of residents was reported as: 51% White British; 8% Mixed/Multiple ethnic group; 18% Asian/Asian British and 12% Black/African/Caribbean/Black British. The area was ranked amongst the 10% most deprived areas in England in terms of multiple deprivation.

In location two there were typically 68-80 pregnant women per month booking for midwifery care of which 30-36 were nulliparous.

5.3 Recruitment process

5.3.1 Recruitment and consent procedure: women

The initial approach to each individual woman was from the woman's community midwife (a member of the woman's usual care team).

The community midwife undertook the following roles:

1. Assessed women's eligibility for inclusion in the study in accordance with the guidelines.
2. Provided women who were interested in the study with a Participant Information sheet.
3. Administered the GAD-2 scale.
4. If a woman scored three or more on the GAD-2 scale and was interested, the midwife asked the woman's permission to collect contact information to be passed to the researcher.

The researcher undertook the following roles:

1. Collected contact details of potential participants from the community midwife in person.
2. Contacted each woman either in person or via email or telephone according to their preference.
3. Provided each woman with the opportunity to ask any questions about the study.
4. If a woman wished to take part in the study, the researcher arranged to meet with the woman at a time and location of the woman's preference.
5. Met each woman to gain informed written consent
6. Completed inclusion screening using the GAD-7 scale.

The researcher explained the details of the study and ensured the woman had a copy of the Participant Information Sheet (Appendix 5.3), ensuring that the woman had sufficient time to consider participating or not. The researcher answered any questions that the participant had concerning study participation. All participants provided written informed consent before completing the GAD-7 scale. The Informed Consent Form (Appendix 5.4) was signed and dated by the participant before they entered the study.

5.3.2 Recruitment procedures: midwives and MSWs

The midwife facilitators and MSWs co-facilitators were selected from the local NHS trust's existing workforce. It was considered that the criteria for selecting facilitators and co-facilitators would include:

- Experienced midwives
- MSWs: 1 years' experience working in the role of MSW
- Interest in antenatal anxiety / perinatal mental health
- Interest, experience or skills in group work

An email was distributed on the 3rd February 2016 via the NHS Hospital Trust internal email system with a letter outlining the study and the involvement of facilitators and co-facilitators (Appendix 5.5). Expressions of interest were received from six midwives and ten MSWs working in hospital and community areas. Expressions of interest were forwarded by the researcher to the senior management team who identified two midwives and two MSWs who they felt could participate in the study and attend the training workshops. Participant information sheets were provided to the midwives and MSWs and informed consent was sought prior to the start of the training.

5.3.3 Participants eligibility criteria

Participants with GAD-7 scores of 3 - 14 were invited to participate in the study. They were advised to contact their GP or community midwife if they felt they required further assessment and support (current practice guidelines NICE 2014).

Participants with a GAD-7 score of less than 3 were not be included in the study. They were thanked for their interest and advised that the type of intervention the study was aiming to develop may not be appropriate for them.

Participants with a GAD-7 score of 15 or more were excluded from the study. They were thanked for their interest and advised that the type of intervention the study was aiming to develop may not be appropriate for them. A score of 15 or more may have indicated severe anxiety (Spitzer et al. 2006) and these women were advised to contact their GP or community midwife for further assessment and support. The researcher offered to provide the woman with a letter for their GP / community midwife explaining the GAD-7 results and indicating the woman had requested further support.

Reporting concerns

If the researcher had any concerns that a woman may have been at risk of harm to themselves or others, the researcher would have had a duty of care to report those concerns (Nursing and Midwifery Council, NMC 2015) and inform the Chief Investigator within 24 hours. This information was detailed in the participant information sheet. Contingency arrangements were made for the researcher to discuss the concerns with the woman and seek further permission to contact the woman's lead care provider (GP, community midwife and/or obstetric team). If the woman did not provide permission, the researcher would have notified the Chief Investigator and would have sought the support of the on-call supervisor of midwives (available through the NHS Trust) to

follow the correct reporting procedure. The woman would have been fully informed of the intended actions.

A participant recruitment flow diagram will be presented in the following Chapter. This will outline the number of women who were approached about participating, women who agreed/declined to participate and women who attended and completed the intervention.

5.3.4 Ethical considerations related to inclusion screening

The process of psychological assessment provided the participant with new information and possible burdens that did not exist before (Palmer et al. 2011). For participants, screening tools can be seen to offer a definitive diagnosis and they may not consider the possibility for a false positive result (Jansen & de Bont 2010). In this study, the researcher informed the woman that self-report screening instruments do not provide a diagnosis of a disorder, but they highlight when women may benefit from further discussion about their psychological health with their GP. It is possible that during screening a woman may have scored in the severe anxiety category on the GAD-7 (Spitzer et al. 2006) and knowledge of this score had the potential to cause distress (Palmer et al. 2011). If this had occurred, the researcher would have followed current guidance and signposted women to additional sources of support which could have been accessed in a timely manner.

5.3.5 Participant baseline data collection

Participants were asked to complete self-report measures including the GAD-7, STAI, PRAQ-R, EPDS and SF-12. If the women scored above the recommended cut-off points for symptoms of depression (EPDS 10 or more) they were advised to

contact their GP or community midwife for further assessment and support.

5.3.6 Problems with recruitment and amendments to the recruitment process

The actual number of potential participants was lower than expected during the recruitment time frame due to some of the antenatal clinics being cancelled (staff illness and planned leave; bank holidays, staff training) and a lower than expected number of women accessing the service in the two locations during the recruitment period.

Following discussion with research supervisors, the following options to maximise the recruitment were considered:

- Continue with recruitment as planned in the two locations.
- Expand the recruitment sites from two to three community locations.
- Expand the gestational age of recruitment from 16 weeks of pregnancy to 16-25 weeks of pregnancy.
- Run a single group at a central hospital site for women in both community locations.
- Expand to multiparous women.
- Remove the inclusion screening process and offer the group sessions to all nulliparous women in the two locations.

5.3.7 Protocol amendments

A substantial amendment request was submitted on 19th April 2016 to the NHS REC and NHS Trust R&I to expand the gestational age of potentially eligible participants and to the NHS REC, NHS Trust R&I and the Health Research Authority (HRA) to expand the number of recruitment sites. The agreed amendments

did not compromise the rationale and theoretical framework of the study. The researcher met with midwifery managers to identify an additional community site which was in an adjacent geographical area to location one and could accommodate the additional workload from the recruitment process. The substantial amendment to expand the gestational period to 16-25 weeks of pregnancy received favourable opinion on the 29th April 2016. Due to delays in the HRA process, permissions to expand the recruitment sites was not received in time to operationalise during the recruitment time-frame. Progress with recruitment was discussed at each supervision meeting. One community location did not recruit sufficient participants to support group sessions. Following discussion with supervisors it was decided to proceed with one group and invite women from both locations to attend this group.

5.4 Recruitment and training of midwives and MSWs

5.4.1 Training needs assessment for midwives

The facilitators needed to be prepared to deliver components of the intervention: facilitating group discussion sessions and providing one-to-one support for women with symptoms of mild to moderate anxiety. In addition to the facilitators' existing clinical and communication skills demonstrated through their current roles, it was considered that training should ensure facilitators were working in accordance with current practice recommendations and to develop their skills in supporting women with symptoms of mild to moderate anxiety.

5.4.2 Training needs assessment for MSWs

It was considered that the MSW co-facilitators would benefit from attending the same training workshops as the midwives. This would help prepare them to co-facilitate the intervention and learn effective ways to support women with symptoms of mild to

moderate anxiety. It would also enable them to discuss with the midwives the MSW role in co-facilitating the intervention, acknowledging the role boundaries and responsibilities between the midwives and MSWs.

5.4.3 Training framework

The training framework referred to existing perinatal competency frameworks which were considered relevant to the role of the facilitators and co-facilitators within the study:

- The Perinatal Mental Health Curricular Framework (NHS Education for Scotland 2006).
- The Competency Framework for Professionals Working with Women who have Mental Health Problems in the Perinatal Period (NHS England & The Tavistock and Portman NHS Foundation Trust 2016).
- Caring for Women with Mental Health Problems: Standards and Competency Framework for Specialist Maternal Mental Health Midwives (RCM 2015).
- Training Framework for Perinatal Mental Health (Beyond Blue 2011).

It was considered that the midwives and MSWs training should cover the following domains:

- An overview of perinatal mental health: risk factors; impact of anxiety symptoms; assessment methods; role of the midwife.
- Identify ways to support women's mental health in pregnancy: one-to-one support; guided self-help; accessing other supportive services.
- Facilitating group discussions: peer-support mechanisms; group processes and dynamics; behaviours and qualities of effective facilitators in groups and identifying useful group resources.

- Adherence to the intervention protocol, safe working, accessing support, supervision and advice.

Table 5.1 reflects the training domains, possible resources and methods of delivery.

Table 5.1 Training domains, resources and method of training for intervention facilitators and co-facilitators		
Training Domains	Training resources and supporting documents	Possible methods of delivery for the training
Overview of perinatal mental health	<ul style="list-style-type: none"> Clinical guidelines: mental and perinatal mental health (NICE 2011, NICE 2014) Criteria for anxiety disorders (APA 2013, WHO 2016) Research papers: prevalence of mental health disorders in pregnancy (Heron et al. 2004) Health Education England: e-learning package: Introduction to perinatal mental health http://www.e-lfh.org.uk/programmes/perinatal-mental-health/open-access-perinatal-mental-health-sessions/ 	Training workshops with supporting resources and resources presented in a training booklet
Factors which impact on mental wellbeing in pregnancy	<ul style="list-style-type: none"> Risk factors associated with anxiety in pregnancy: Complex social needs, medical / obstetric risk factors, previous pregnancy loss, assisted conception, previous mental health concerns, family history of mental health concerns (NICE 2010, Hogg 2013, DeBackere et al. 2008, Côté-Arsenault & Donato 2011, Hjelmstedt et al. 2003, Henderson & Redshaw 2013, Rubertsson et al. 2014) NHS Education for Scotland. E-learning module: Understanding maternal mental health. http://www.knowledge.scot.nhs.uk/maternalhealth/learning/maternal-mental-health.aspx 	Training workshops with supporting materials and resources presented in a training booklet
Supporting women's mental health in pregnancy	<ul style="list-style-type: none"> Good practice guides (RCM 2012, DOH 2009) Resources for women: pregnancy wellbeing plan (Boots Family Trust 2013) Clinical guidelines (NICE 2014) Research papers: women's views and experiences (Evans et al. 2017, Boots Family Trust Alliance 2013) Health Education England: E-learning module: Interventions for perinatal anxiety and depression http://www.e-lfh.org.uk/programmes/perinatal-mental-health/open-access-health-visitor-sessions/ 	Training workshops with supporting materials and resources presented in a training booklet
Identification of the symptoms and risk factors for anxiety and other mental health disorders	<ul style="list-style-type: none"> Reports and research on assessing mental health in pregnancy (Cantwell et al. 2011, Jomeen 2004, NICE 2014) Self-report mental health questionnaires (Spitzer et al. 2006, Whooley et al. 1997) Health Education England: e-learning package. Module two: how to recognise perinatal anxiety and depression http://www.e-lfh.org.uk/programmes/perinatal-mental-health/open-access-health-visitor-sessions/ Maternal Mental Health Network: identifying women at high risk of severe mental illness: a learning programme for midwives http://www.app-network.org/what-is-pp/getting-help/midwives-on-line-tool/ 	Training workshops with supporting materials and resources presented in a training booklet

Signposting and referring to other supportive services	<ul style="list-style-type: none"> Local NHS Trust maternity mental health procedures and guidelines Local perinatal mental health supportive services and referral pathways: Nottinghamshire healthcare, Let's Talk Wellbeing, Trent PTS, Insight healthcare – referral procedures Social care agencies and referral procedures Professional standards (NMC 2015) NHS Education for Scotland. E-learning module: Maternal mental health, the woman's journey http://www.knowledge.scot.nhs.uk/maternalhealth/learning/maternal-mental-health.aspx 	<p>Training workshops with supporting materials and resources presented in a training booklet</p> <p>Local referral procedures are taught to all midwives as part of their annual mandatory training</p>
Self-help help resources	<ul style="list-style-type: none"> Good practice guidance on the use of self-help materials (IAPT 2010) Provide a copy of the selected self-help resources for the intervention 	Self-directed activity with discussion during training workshops
Group discussions	<ul style="list-style-type: none"> Research papers: support and peer groups (Crabtree et al. 2010, Owen et al. 2009) 	Training workshops
Practice within legal and professional policy frameworks	<ul style="list-style-type: none"> Professional standards (NMC 2015) Clinical guidelines and reports (NICE 2008, NICE 2014, Cantwell et al. 2011) Antenatal and postnatal mental health: clinical management and service guidance (NICE 2014) 	<p>Training workshops with supporting materials and resources presented in a training booklet and study manual</p> <p>Local referral procedures are communicated to midwives as part of mandatory training. Midwives complete regular validation to ensure they are aware of professional duties and responsibilities</p>
Intervention protocol: reporting and procedures	<ul style="list-style-type: none"> Research governance framework for health and social care (DOH 2005) Study protocol 	Discussions with the researcher and supporting materials and resources presented in a study manual

5.4.4 Training workshops and materials

The researcher discussed the training framework for the study facilitators (midwives and MSWs) with the training providers. Trainers agreed to deliver a training workshop over 3 days, spanning a 2-4 week period, to enable the facilitators time to complete homework exercises (such as reviewing the self-help resources) and reflect on the new information between training days. The trainers agreed to provide supporting resources to be included in a training booklet (Appendix 5.6).

The midwives and MSWs evaluated the training workshops: they said they would recommend the workshops to others; that it was worthwhile and achieved their learning outcomes. The trainers provided feedback to the researcher and said the workshops had been enjoyable, the facilitators were very motivated to learn about anxiety and ways to support women. They felt the facilitators were capable and prepared to deliver the intervention.

5.5 The intervention

The intervention was delivered in three components:

- Component 1: One to one pre-group meeting with the midwife facilitator.
- Component 2: Group sessions facilitated by the midwife and co-facilitated by the MSWs.
- Component 3: Selected self-help resources to be completed between sessions.

Component 1: One to one, pre-group meeting with the midwife facilitator

The pre-group meeting was planned to be a face-to face individual meeting between the midwife facilitator and the woman. The midwife facilitator would contact the woman to arrange a meeting time and location. The location was to be in a community healthcare centre and planned to last approximately 10 minutes. This purpose

of this session was to 1. enable the woman to meet the midwife before the first group session, 2. welcome the woman into the intervention and 3. help her feel more comfortable attending the groups (Breustedt & Puckering 2013).

Component 2: Group sessions

Four sessions were planned over an eight-week period (every fortnight). Each group was planned to consist of eight to ten women. The sessions would be facilitated by midwife and co-facilitated by a MSW. Sessions would be held in community healthcare centres. Each session was planned to last for 90 minutes (in the early evening). The purposes of the sessions were for women to access group support, to support and encourage women with accessing and completing the self-help resources and for women to have the option to discuss any concerns individually with the midwife. Following the sessions, each woman was allocated a 10-15 minutes individual meeting time if required to discuss any individual concerns or ask questions. This support from the midwives was provided within the scope of current midwifery practice (NMC 2015). During the first group session, the midwife discussed the ground rules for the session (asking participants to respect each other's point of view during the discussions and to keep confidential any sensitive information which may be discussed). The facilitators provided an overview of each self-help material and assisted participants to decide which format would suit their needs. Women were helped to access on-line resources during this time where necessary (i.e. locating and installing on-line applications).

In the following sessions (groups 2-4), facilitators agreed a discussion agenda with the women and discussed their progress with the self-help resources. Facilitators provided support and encouragement for the women using the self-help resources and promoted social support in groups.

Component 3: Guided self-help resources

Five self-help resources were provided and women had a choice which resources to access. Women were encouraged to access the self-help resources between groups and to discuss their progress with the group.

5.5.1 Ethical considerations

For some women, sharing their experiences and feelings in a group setting or with the midwife may be beneficial. However, discussing anxiety may be sensitive, embarrassing or upsetting for some women. The midwife facilitator was available following the groups to discuss any individual concerns.

5.5.2 Intervention locations

The researcher identified rooms at the two locations for the groups and adjacent rooms to provide the optional one-to-one support. The researcher met with the midwives and MSWs at the intervention site to familiarise facilitators with the rooms and facilities and discuss health and safety procedures.

5.5.3 Monitoring uptake and attendance

The researcher distributed the study manual and record form to all facilitators. This form contained details of the information for the facilitators to access and record: training sessions attended; record sheets to document participant attendance; an outline of the objectives for each meeting/group; management of risk procedures and contact information; additional comment forms and a timetable for the groups (Appendix 5.7).

5.5.4 Post-intervention follow-up

Data collection of participants self-report questionnaires

Participants completed a questionnaire set consisting of the STAI, GAD-7, PRAQ(R), EPDS and SF-12 post intervention, administered by the researcher prior to the research interview (Appendix 5.8).

Interviews with women, midwives and MSWs

All participants were then interviewed by the researcher about their experiences of the intervention. Women had the option to attend for interview at a community healthcare centre or in their own home. The midwife and MSWs were interviewed post-intervention by the researcher to determine their experiences on delivering the intervention. Interviews were held in hospital or community healthcare centres.

5.5.5 Participants time required to complete study components

Table 5.2 outlines the planned time involvement for the women during the various contact points over the study.

Table 5.2 Length of time, location and study personnel involved during the stages of the study.			
Components of the study	Study personnel	Location choice	Length of session
1. Complete Consent Form 2. Baseline measures 3. Demographic information	Researcher	home / community locations	45 minutes
One to one pre-group meeting	Midwife facilitator	Community healthcare centre	10 minutes
Group session 1	Midwife & MSW facilitators	Community healthcare centre	90 minutes plus 10 minutes optional
Self-help materials	Self-directed		
Group session 2	Midwife & MSW facilitators	Community healthcare centre	90 minutes plus 10 minutes optional
Self-help materials	Self-directed		
Group session 3	Midwife & MSW facilitators	Community healthcare centre	90 minutes plus 10 minutes optional
Self-help materials	Self-directed		
Group session 4	Midwife & MSW facilitators	Community healthcare centre	90 minutes plus 10 minutes optional
1. Conduct research interviews 2. Collect post-intervention self-report measures	Researcher	home / community locations	1 hour 30 minutes

5.6 Costs associated with the study

The tables below present an overview of the time (Table 5.3) and financial costs (Table 5.4) incurred during the study.

Table 5.3 Midwives and MSW facilitators' time for training and facilitating the intervention			
	Time component	Time to be taken	Total hours
Midwife facilitator – time (per midwife)			
Midwife facilitator training	3 days of training	6 hours per day	18 hours
Midwife facilitator pre-group meeting	10 women	10 minutes each	2 hours
Group sessions	4 weeks	1.5 hours per session plus set-up time	8 hours
Post group one-to-one sessions (optional)	4 weeks	1 hour per session	4 hours
Administration	4 weeks	15 minutes per session	1 hour
Total time for each midwife			33 hours
MSW co-facilitator – time (per MSW)			
MSW co-facilitator training	3 days of training	6 hours per day	18 hours
Group sessions	4 weeks	1.5 hours per session plus set-up time	8 hours
Administration	4 weeks	15 minutes per session	1 hour
Total time for each MSW			27 hours

Table 5.4 Resource costs for the study		
	Cost per session	Total
Training workshop for facilitators and co-facilitators	£1,490	£1,490 * two of the three days were in-house training – provided free of charge.
Room costs for the pre-meeting and group sessions	£70	£350
Total		£1840

5.7 Summary

The Chapter has presented the final study, methods and procedures. The qualitative and quantitative findings of the feasibility study will

be presented in the following Chapter. The process of conducting the study will be further explored in the Discussion Chapter to consider the feasibility of the intervention and identify where the processes may need to be refined before undertaking further testing.

Chapter 6 Feasibility study results and findings

In this chapter, qualitative and quantitative findings of the feasibility study will be presented. The rates of recruitment, and retention will be included alongside reporting of participants' demographic characteristics, baseline and post-intervention self-report anxiety measures and the findings from the analysis of participant and facilitator interviews.

The study findings and results presented in this chapter will follow the MRC guidance for developing and evaluating complex interventions (Craig et al. 2006) and the complex intervention process evaluation framework (Moore et al. 2015). The qualitative findings will be reported in accordance with the consolidated criteria for reporting qualitative research (COREQ) checklist (Tong et al. 2007). The intervention evaluation will be reported in accordance with the TREND statement checklist (DesJarlais & Lyles 2004).

6.1 Access and recruitment to the feasibility study

Study objectives:

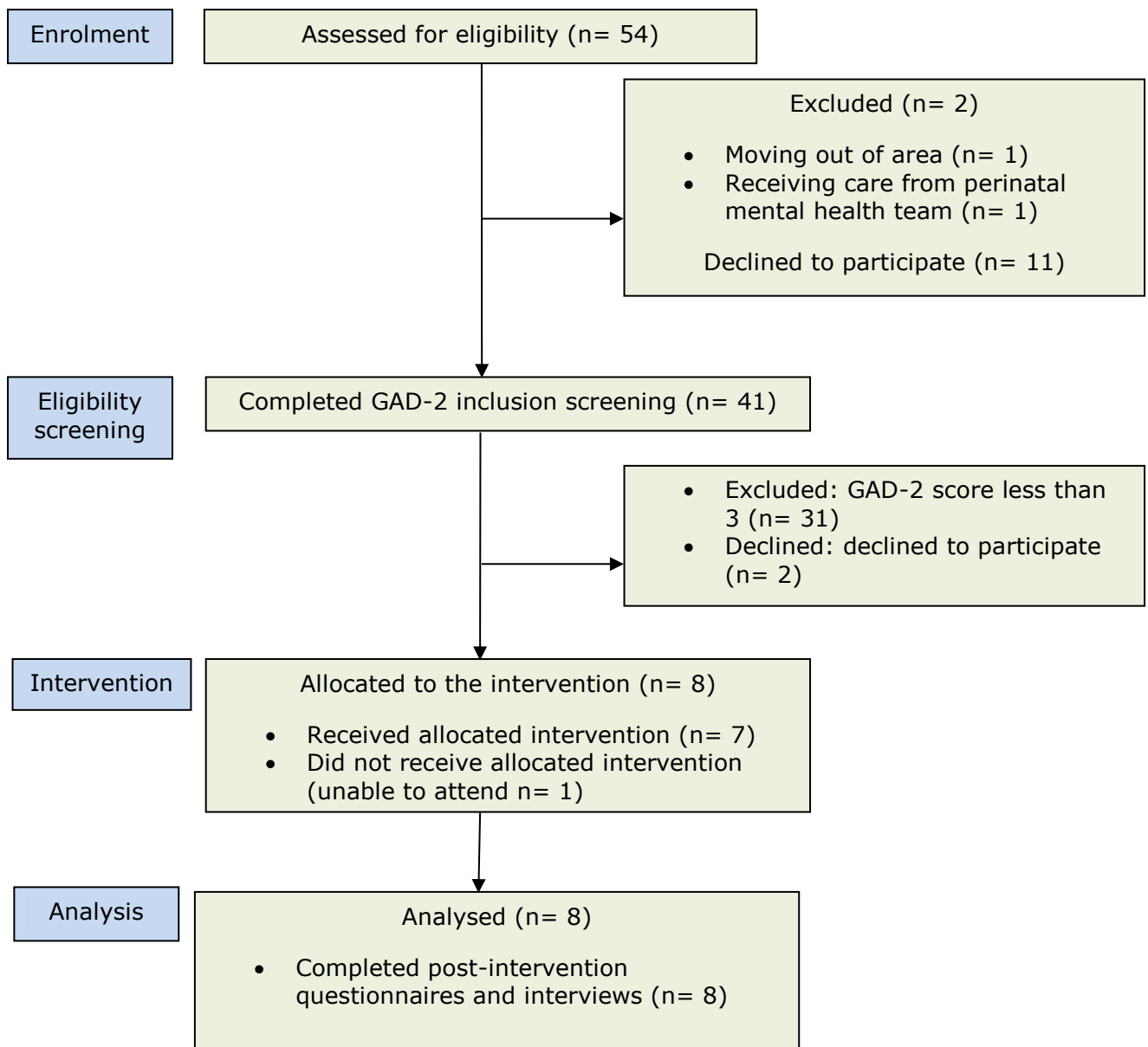
- *To calculate the proportion of eligible participants who agree to be contacted by the researcher*
- *To determine the proportion of participants, who following contact with the researcher, agree to participate in the intervention*
- *To assess women's reasons for declining participation in the intervention.*

From the 12th April - 26th May 2016, 54 nulliparous women between 16-25 weeks of pregnancy who met the initial eligibility criteria in the two locations were approached about their interest in participating in the feasibility study.

Over the study period, 76% of women (n= 41/54) were initially interested in the study. Ten women (19%), who scored three or more on the GAD-2 scale were eligible to participate and agreed to be contacted by the researcher. One woman did not reply to phone messages (P9) and one woman was unable to participate due to work commitments (P3).

Appointments were arranged individually with the remaining eight women (15%) to meet with the researcher to enable time for questions to be answered and obtain written consent prior to completing baseline measures. One woman could not attend the sessions due to work commitments but completed baseline and post-intervention questionnaires and interviews (P2). Seven women participated in the intervention. A participant flow diagram is detailed in Figure 6.1. During the study period, there were 60 scheduled appointments in the two locations for nulliparous women at 16 weeks gestation. Four women did not attend and two women were not asked about the study (midwife did not remember). From the number of women who attended their appointments, the midwife asked 96% about their interest in the study.

Figure 6.1: Participant flow diagram for the feasibility study



6.2 Uptake and attendance of the sessions

Five participants attended an individual pre-group meeting with the midwife facilitator on the 2nd June 2016. Each meeting lasted 10-15 minutes. Two women could not attend due to holidays and alternative arrangements were made: one woman requested a telephone conversation with the midwife prior to the first session; one woman chose to meet with the midwife 15 minutes prior to the first session (Table 6.1).

- **Group 1 (16th June 2016):** three women were unable to attend due to work commitments and planned holidays.
- **Group 2 (30th June 2016):** one woman was unable to attend due to work commitments.
- **Group 3 (14th July 2016):** three women were unable to attend due to work commitments and planned holidays.
- **Group 4 (28th July 2016):** one woman was unable to attend due to work commitments.

Table 6.1: Participant and facilitators attendance and uptake of the intervention sessions and components							
Participant	Baseline questionnaires	Attendance pre-group	Group 1	Group 2	Group 3	Group 4	Post-intervention interviews and questionnaires
P1	✓	✓	✓	✓	x	✓	✓
P2	✓	Did not attend: unable to get time from work					✓
P3	Did not attend: unable to get time from work						
P4	✓	✓	✓	X	✓	✓	✓
P5	✓	✓	X	✓	✓	✓	✓
P6	✓	✓	✓	✓	✓	✓	✓
P7	✓	✓	X	✓	x	x	✓
P8	✓	✓	✓	✓	✓	✓	✓
P9	Did not attend: did not respond to telephone messages						
P10	✓	✓	X	✓	x	✓	✓
Total	8	7	4	6	4	6	8
Facilitator							
MW1		✓	✓	✓	✓	✓	✓
MW2			✓				✓
MSW1			✓	✓	✓	✓	✓
MSW2				✓		✓	✓

Intervention facilitator attendance

One midwife facilitator and one MSW co-facilitator attended all four groups. A second midwife facilitator attended group one and a second MSW co-facilitator attended group two and four.

6.3 Baseline and post-intervention data collection

All eight women completed baseline questionnaires between the 3rd - 31st May 2016. Post-intervention questionnaires and research interviews were conducted between the 9th - 18th of August. Four facilitators participated in research interviews between the 1st and 15th August.

6.3.1 Demographic characteristics

Participant baseline demographic characteristics are presented in table 6.2.

Table 6.2: participant demographic characteristics	
Mean age in years (SD)	31 (6.2)
Mean gestational age in weeks at enrolment (SD)	17 (2.1)
Mean gestational age in weeks at intervention start (SD)	19 (1.9)
Mean gestational age in weeks at intervention end (SD)	27 (1.9)
Number of women employed (%)	7 (87.5%)
Number of women unemployed (%)	1 (12.5%)
Ethnicity	
White British (%)	8 (100%)
Household composition (%)	
Number of women living with partner	7 (87.5%)
Number of women living with others	1 (12.5%)

6.3.2 Participant's views on randomisation into studies

Women were asked to consider how they would feel about being randomly assigned to an intervention or control group of the intervention in future studies.

- Six women (75%) would have agreed in principle to be randomly assigned to either an intervention or control group, one woman was unsure and one woman would not have agreed.
- Five women (62%) would have been happy to continue in the study if they had been assigned to a control group, one woman was unsure and two women (25%) would not have been happy to continue.
- All of the women would have agreed to continue participation in the study if they had been assigned to an intervention group.

6.3.3 Baseline self-report anxiety, depression and quality of life questionnaires

Study objective:

- *To calculate the indicators of acceptability of self-report outcome measures (response rate, missing data, completion time)*

Burden of the questionnaires

The researcher noted that women took no more than 15 minutes to complete the five questionnaires and women did not require any further instructions above the information provided on the questionnaire form. All questionnaires were completed correctly and there were no missing data.

Questionnaire scores

Quantitative data from self-report measures were analysed, measures of mean and variance including confidence intervals (95%

CI) and standard deviation (SD) are presented to describe the full range of data at baseline and at post-intervention (table 6.3 and 6.4).

Table 6.3 Questionnaire scores: numbers and % of women who reported scores above thresholds for anxiety and/or depression	
GAD-7 score of 10 or more: number of women (%)	
Baseline	6 (75%)
Post-intervention	1 (12%)
*Lower GAD-7 scores indicate fewer reported symptoms of GAD	
STAI-S score of 40 or more: number of women (%)	
Baseline	5 (63%)
Post-intervention	4 (50%)
*Lower scores indicate fewer reported symptoms of anxiety	
EPDS score of 10 or more: number of women (%)	
Baseline	7 (88%)
Post-intervention	4 (50%)
*Lower scores indicate fewer reported anxiety/depression symptoms.	

Higher scores on the SF-12 questionnaire represent better reported physical and mental health status (Ware et al. 1996). Mean scores were higher for the mental component of the SF-12 at post-intervention compared to baseline, and lower for the physical component.

The PRAQ-R is ordered into three subscales: Fear of giving birth; Worries about bearing a physically or mentally handicapped child; Concern about own appearance (Huizink et al. 2004). Higher scores indicate strong agreement with the statements (a higher level of

pregnancy-related anxiety). When compared to baseline scores, post-intervention scores slightly increased for the 'fear of giving birth' sub-scale and slightly decreased for the 'worries about bearing a physically or mentally handicapped child' and 'concerns about one's own appearance' sub-scale.

Table 6.4: Questionnaire scores at baseline and post-intervention		
Self-report measure	Baseline mean score (SD) [95% CI] n= 8	Post-Intervention mean score (SD) [95% CI] n= 8
EPDS	12.5 (2.88) [10.51-14.49]	10.5 (3.85) [7.83-13.17]
GAD-7	10.37 (3.42) [8.01-12.75]	6.75 (3.45) [4.36-9.14]
PRAQ-R (fear of giving birth)	7.63 (2.33) [6.02-9.24]	8.13 (1.13) [7.35-8.91]
PRAQ-R (worries about bearing a physically / mentally handicapped child)	10.5 (3.96) [7.75-13.25]	9.63 (3.66) [7.09-12.17]
PRAQ -R (concern about own appearance)	6.63 (2.45) [4.94-8.32]	5.63 (2.0) [4.25-7.01]
STAI-S	44.87 (9.40) [38.36-51.4]	38.75 (5.72) [34.78-42.72]
STAI-T	55.75 (10.92) [48.18-63.32]	47.75 (9.65) [41.06-54.44]
SF-12 (physical component PCS)	49.51 (10.48) [49.9-56.0]	42.03 (13.2) [37.14-48.97]
SF-12 (mental component MCS)	31.84 (7.84) [27.44-36.67]	39.58 (8.59) [37.38-43.45]
* For the EPDS, GAD-7, PRAQ-R and STAI, lower scores indicate fewer reported symptoms * For the SF-12, higher scores indicate better reported health status		
EPDS: Edinburgh Postnatal Depression Scale; GAD-7: Generalized Anxiety Disorder 7-item scale; PRAQ-R: Pregnancy Related Anxiety Questionnaire (Revised); STAI: State Trait Anxiety Inventory; SF-12: 12-Item Short Form Health Survey.		

6.4 Participant interviews

Study objectives:

- *To determine women's views on the acceptability of the intervention*
- *To determine women's views on the costs, if any, they incurred from the intervention*

- *To determine women's views on the benefit, if any, they derived from the intervention*

Details of the development of the analysis template are presented in Appendix 6.1, which includes: pre-defined headings for the template and themes which emerged from the data with indications of supporting and refuting data of each theme. The findings are presented below and ordered into general theme headings which encompass more descriptive sub-theme headings. Theme and sub-theme headings are presented in Table 6.5.

Participant quotations are coded, for example: P1-P10 (Participant ID number). Participant quotations are presented to support the findings from the analysis. The use of ellipsis (...) at the start of the quotation indicates that the quotation is presented part way through a discussion. At the end of a quotation, ellipsis is used to indicate the participant had gone on talking about a topic. Ellipsis used part way through a quotation indicates that phrases have been taken out of the text, either due to repetition, hesitations or to help with understanding the response without altering its original meaning. Names of people or places have been omitted from quotations to maintain participant anonymity, these are indicated with square brackets []. To enhance readability, phrases such as 'ums', 'ers', 'I mean' and 'you know' have been omitted from quotations (Corden & Sainsbury 2006).

Table 6.5: Participant interview data themes and sub-themes	
Introducing the study	Women wanted the intervention to be offered to them by their midwife.
	Women initially thought the intervention may be of benefit to them but had some concerns about participating in the study.
	Women felt the intervention should have been available earlier in pregnancy.
	Meeting the midwife before the groups helped the women feel more confident about attending.
Group discussions	Women liked the fact that sessions were held in community centres.
	Attending was easier for women who had more flexible work patterns.
	Sharing experiences and receiving support from other women with similar feelings to them was helpful and reassuring.
	Some women found it difficult to join discussions and had anxiety about speaking in a group.
	Women preferred informal discussions to structured sessions.
	Groups took time to establish in order for women to feel confident to speak honestly and openly.
	Women said there should have been more than four groups and sessions needed to be longer.
	Most women preferred participating in smaller groups.
	Most women liked that the groups consisted of women who were all nulliparous and experiencing symptoms of anxiety.
	Women compared their own feelings and experiences with those of other women in the group.
Self-help materials	Women preferred self-help anxiety materials which were specific to pregnancy to more general anxiety materials.
Individual time with facilitators	Most women said individual support from facilitators was easy to access.
	Some women preferred to speak to facilitators before the start of the group rather than at the end.
Access to support	Women said there was little existing support for women with anxiety in pregnancy.
	Women said that being busy at work helped them cope with their anxiety.
Overall thoughts on participating in the study	It was important to the women that the intervention was facilitated by a midwife
	Some women were very comfortable talking about their anxiety with HCPs, but some women found it more difficult to talk about their anxiety and were

	worried about the potential consequences of disclosing their symptoms.
	Women wanted to meet with other pregnant women to help them feel less isolated.
	Most women said participating in the study was beneficial and enjoyable.
	Most women said they would recommend the intervention to other women.
Self-report anxiety measures may help women discuss their symptoms of anxiety with HCPs.	The EPDS was difficult to answer for women who felt their feelings varied from day to day.
	Women felt the items in the PRAQ felt relevant to them although some women wanted further opportunity to qualify their responses.
	Some women were confused about how to answer the SF-12, whether to relate the questions to pregnancy or their general health

6.4.1 Introducing the study

Women wanted the intervention to be offered to them by their midwife

Most of the women said they would not have self-referred to participate in the feasibility study. They considered they would not have self-referred into an anxiety intervention had it been available to them in pregnancy unless it was offered or introduced to them by their community midwife. They said that women may not always recognise that they have anxiety symptoms or that it could be difficult for women to disclose their anxiety symptoms to HCPs. When the study was introduced to them by their community midwife, the women felt assured that they would be suitable for inclusion. Women liked that the midwife had identified that they needed support for their anxiety without them having to ask the midwife for help. However, one woman was actively looking for help with her anxiety and would have self-referred into the study.

"... if I was invited I'd be more likely to go ... I'm not very good at helping myself ..." P1

"I didn't know why she introduced it to me.... I didn't know if I was selected ?.... I'm better if its presented to me ... one [poster] I did

see about exercise classes, but that's different, that appeals to me ... but if it's more like an anxiety help group ... I'm not sure if I would ..." P5

"... it felt quite useful that the midwife had identified a need, signposted me ... whether people always recognise it as anxiety or whether they think it's normal ... if you feel quite isolated by what you are going through you're not necessarily able to say ... that's what it is" P6

"... if you're personally invited, it makes you feel a bit more wanted and you know you're gonna fit into this, you meet the criteria ... if [midwife] hadn't mentioned it to me, I'd say it was probably unlikely that I would have gone" P8

"... some people might not recognise ... they might not have anxiety issues straight away, or might not feel comfortable to go off their own back and go to a session ... they might need someone to say actually I think you could really benefit from this ..." P10

"... it can be a bit scary sometimes ringing someone up and asking about this type of group ... when I talk about my anxieties I feel very vulnerable ..." P7

"Yes I would have done it [self-referred] ... I was excited because I'd looked for stuff like it where I could go and meet people and chat to people ... but not really found anything ..." P4

Women initially thought the intervention may have been of benefit to them but had some concerns about participating in the study.

"... it would be good to talk to other people and see how they are getting on in pregnancy" P1

"I was interested straight away ... because I knew I'd meet other first time mums ... I thought it would be beneficial ..." P5

"... getting involved with this was potential to be of benefit if I really, really needed it" P8

"... I think it's something that's needed ... anything that can help, I'll take" P7

Three women were initially concerned that listening to other women speak about their anxieties could have made them feel worse; that they would absorb other women's negative thoughts. Three women were worried about attending groups because they did not know what to expect. One woman discussed her initial concerns about fitting in with women from a different area.

"I don't want to be stereotypical, about [refers to location] women, you sort of have an idea in your head, that you don't feel good enough, but that was just one of my fears" P1

"... Cause [woman's partner] did say, is this not just gonna make you worse? Are you gonna go here and listen to all these things other people are worrying about and then worry yourself ..." P4

"... the only thing I had in my mind was making sure that I didn't get caught up in horror stories ... when you're quite anxious you can start to soak up other people's anxieties ..." P6

"... I didn't know whether talking about it would make me feel a little bit worse maybe, because it would submerge me into thinking about that a bit more than I possibly would have done on my own ... brought things up in conversation that I wouldn't have thought about ..." P10

"... as long as I can get through the door ... I have a fear of the unknown" P8

"Yes, I was nervous ... I didn't know what would happen in the sessions, what would be asked or if I would find it hard" P7

"... I just like to know exactly what I'm going to be walking into ... like role playing or something like that would be my nightmare" P2

Women felt the intervention should be available earlier in pregnancy.

Four women said they had felt very anxious in early pregnancy. From having their pregnancies confirmed to the time of the first ultrasound scan had felt like a long time. They were adapting to changes in their lifestyle and felt vulnerable. Knowing that the intervention was available to access at a later stage would have been helpful to them during the early stages of pregnancy. One woman found the timing of the intervention ideal. During the second trimester of her pregnancy she had less contact with her community midwife and felt overwhelmed by the amount of pregnancy information displayed on digital media sites. One woman considered the intervention would have been more beneficial to her had it continued in the third trimester when she might have been experiencing different anxieties and emotions.

"most of my anxiety about the pregnancy was at the beginning ... that's the most vulnerable" P1

"my really bad ones [anxieties] were in the first 12 weeks ... definitely a really bad time for me, when I kept buying scans ... I just felt like something was gonna go wrong, I think it was the unknown ... I started thinking that worrying will have an effect, it spiralled out of control ... even if it isn't available at 12 weeks, just knowing that it's there that you will go onto ..." P4

"maybe starting a little bit sooner because I felt that that's when I felt more anxious ... it was all so unknown at the beginning of the pregnancy, you're thrown into it all, it's a big change ... you might be full of questions and you might need a bit more guidance then" P10

"... having it confirmed that you're pregnant to you seeing the midwife, there's a bit of a gap ... your first few worries are sort of

great ... even if you can't go to it straight away, just knowing that there are services out there would help" P2

"... your first 12 weeks where it's quite an anxious time ... you get to 16 weeks and you've got that bit in the middle where not much happens ... it was nice to go to a group where you could talk about what you were experiencing ... the danger is, there's that may things to read out there, everybody's mind boggled ... I think that the timing was perfect" P5

"I think having them in the second tri [trimester] is really useful but I think understanding the effect of the third tri might be ... with a couple of the girls that were in their third tri, you can see their concerns and thought processes were different" P6

Meeting the midwife before the groups helped the women feel more confident about attending.

Women who attended the initial meeting with the midwife found it useful to get to know the midwife, familiarise themselves with the location and discuss any initial concerns. Following the meeting, women felt more confident to attend the group. One woman was unable to attend in person but had a telephone conversation with the midwife which she felt was appropriate. Another woman commented that although the face-to-face meeting was useful she felt it could have been conducted over the telephone. However, one woman stated that she felt anxious speaking on the telephone and found it helpful that she could get to know the midwife in person.

"It puts your mind at rest to know that the person that's running it is lovely and you can get on, because if she wasn't lovely I might not have gone ... just to know that there was trust there ... it might be a bit intimidating if we walked into a room where we didn't know anyone ... for me it was better face to face because I get anxiety talking over the phone ... I don't think you can trust someone by talking to them over the phone ..." P1

"... it was quite valuable, whether I needed to go all the way to [location] for it I'm not so sure, maybe she could have just told me on the phone" P5

"... you're not then walking into a strange room with people that you don't know, you know you've got somebody there to welcome you ..." P6

"... [facilitator] did call me to introduce herself so I wouldn't feel so anxious walking into a group of people that already knew each other ... that really did help and made me feel welcome" P10

"... the initial meeting with [midwife] ... she said we were gonna start off with saying a bit about yourself, so I said 'as long as I don't go first' ... she said 'I wonder if it would be better for us to go first?', and that really helped ... sometimes you need a model as to what to say, so you don't say the wrong thing ... if I didn't have that initial introduction, then I think it would have taken me a lot longer to get up the confidence to say something" P8

6.4.2 Group discussions

Women liked the location of the groups.

The time of the sessions was acceptable for women who had more flexibility with their work, but some women found it difficult to get time off work to attend. The location was suitable to women who lived close by and women who lived further away would have preferred the sessions to be more local to them. There was support for the sessions being held in community settings, they said the location was private and peaceful and it did not feel too clinical.

"... you know you're not going to see anything scary" P8

"... in a hospital it would have felt more like a medical thing" P10

Women found the groups helpful and reassuring.

Most women felt they benefitted from sharing experiences and receiving support from other women with similar feelings to them.

One woman said that hearing other women's stories about difficult situations helped her rationalise her own anxieties.

"... to know you've connected with other people who think the same as you ... it makes it easier to build those relationships ... something that you might fear that someone else is going through and then you can actually rationalise and go, it's not that bad ... it's OK" P4

"... I find that kind of mutual support really useful when people are able to ask for her help and people are able to give it" P6

"... being able to support each other and say actually I've felt exactly the same ... I think that was the most beneficial thing ... I could reflect off other people and realised that my experiences could help someone else and their experience could help me" P10

Most women said knowing that other women had the same thoughts and feelings provided reassurance that they were not 'crazy' (P1), 'weird' (P4) or 'abnormal' (P10) and helped the women feel less isolated.

"... it was nice to know I wasn't just going crazy on my own, there are other people out there ..." P1

"... it was nice to know that other people were thinking the same things or you're not weird for thinking that ... that we're not the only one who hid it [pregnancy] for ages and not wanted to tell anyone, cause I thought I was not normal for doing that" P4

"... it was such a big sigh when I thought that I'm not the only one that feels this" P8

"... realising that it wasn't just me thinking that, everyone else was thinking that as well, that I wasn't abnormal for having those thoughts ... I realised going there that I'm not silly ... things I was

thinking are quite normal and a lot of people think them as well"
P10.

Some women found it difficult to join discussions and had anxiety about speaking in a group.

Some women said they felt more comfortable listening to others than speaking in the groups. One woman felt 'angry' (P1) that she was unable to join in the discussion although this became easier as the groups progressed. Another woman initially thought that she would find it difficult to discuss her feelings but had found it a positive experience.

"... I just sometimes felt angry ... I felt anxious speaking ... you're expected to say something whereas it doesn't just come naturally ... the whole time when people are before me I can't really listen because I'm worried about what I'm gonna say, and after it's like a weights been lifted off my shoulders ... it's annoying cos I felt like I had a lot to say but didn't know how to say it" P1

"... it was a bit hard speaking up ... in front of people, that was a bit nerve-wracking" P7

Two women said they were not always able to relate to the other women's experiences. When one woman tried to talk about her anxiety about being in hospital and the birth, she felt other women tried to reassure her but she did not feel that they understood her. One woman felt her past experience was too distressing to share with the group and because she could not talk about it, she could not access group support.

"... I couldn't really relate to it ... I thought is there something wrong with me for not feeling the same as everyone ... I could obviously relate more to the people who'd had anxiety before ... when other people said oh like I've had CBT in the past, I felt happy about that because I have as well ... I'm quite happy with being

pregnant ... I did keep trying to say I'm worried about people jabbing needles in me and stuff, I just wanna be left alone while I'm in the birth, but I don't think that they could relate to it ... they were trying to reassure me which was nice but I don't think they really got what I meant" P1

"I know where my anxiety stems from, and it wasn't from a very pleasant experience, and I felt a bit like I couldn't say that at the groups, I didn't want to offer up this horror story ..." P7

Women preferred informal discussions rather than structured sessions.

During session two the facilitators conducted a more structured session where women had listed their anxieties and identified possible coping strategies. Two women commented that the structured session felt unresolved, they did not have sufficient time to explore the topic and were unsure of the purpose of the session.

Groups took time to establish in order for women to feel confident to speak honestly and openly.

Some women did not want to talk about things that they considered may cause distress or worry to other women. One woman wanted to discuss labour and birth but felt she could not introduce the topic in case she caused distress to the other women. One woman did not like participating in a discussion about fetal movements, whereas one woman wanted to discuss anxieties about fetal movements but was unsure about introducing this to the group.

"... one of the things I did want to discuss was the birth ... for me that would have been really beneficial ... I didn't really want to bring it up at all because in the beginning people said they don't wanna hear any birthing horror stories ... I don't wanna offend anyone" P1

"people were quite careful in what they were saying if it could affect someone else's thought processes ..." P4

"... I don't like talking about baby's movements ... because I did think, oh god, my baby doesn't move as much as theirs ... I did come home and think I'm not sure" P4

"I'd been feeling quite anxious about what normal baby movements are ... I wanted to raise in a way that was more about not getting everyone to be anxious about whether their baby's moving or not but about whether people are finding it difficult to worry about something like that" P6

One woman discussed how the setting of 'ground rules' resulted in her feeling worried about causing offence or distress to others. For another woman, establishing ground rules made her feel more confident that she would not hear other people's 'horror stories' (P6).

"They did stop me if I'm honest ... maybe we could not have called them 'ground rules' ... I'm not very good at not being able to talk about things cos then I get worried that I'm gonna offend people" P1

In the later groups they felt more comfortable with each other and were able to ask questions of each other and share their feeling more openly.

"I felt a difference, like a bit of a shift definitely in the last session where people were starting to be a bit more comfortable ... it felt a lot more open ... those barriers took a while to come down ... the last couple it felt like we had started to get to know each other, people were sharing a bit more and we were just more comfortable with one another" P4

"by the time you get to know people and start opening up it takes a few sessions for you to feel comfortable" P5

"session three and four then started to sort of demonstrate the strength of the group ... it takes a while to be honest about such sort of personal things ... the group got to a stage where we were asking more questions of each other, not in a sort of an overly challenging way but just to kind of elicit a little bit more discussion to help people say what they wanted to say ... that has been the most valuable thing" P6

"... [women] that had held back from being true and honest and the beginning ... everyone was only saying what they felt that they could say to each other being a little bit polite but then towards the end it was just like ... being completely honest and some people were getting a bit upset sometimes or felt a bit more emotional and that felt a bit more real ..." P10

Women said groups should be longer and there should be more than four sessions.

Towards the end of the intervention women had just started to feel confident to participate in the discussions. They said they had more questions and anxieties as they were approaching the birth of their baby. Two women indicated that later groups may not have needed to have been as frequent or structured.

"I think you need at least double that ... it's gonna take a while for you to talk, open up" P1

"coming up into the birth ... there's a lot more questions that are now starting to come to me ... it would have been nice for it to go on a little bit closer because I think that is when ladies will start to get a bit more, it becomes real" P4

"... everybody sort of ended the sessions saying we've really got to stay in touch, we really need to keep going, and I think that speaks volumes about how valuable it was becoming" P6

"Definitely could have done with more ... whether we needed all the team that was running it ... one person just to start things off,

initiate things ... it could have been more flexible ... where people can drop-in, carry on then once they've had the baby" P8

Most women said that the groups needed to be longer. By the time everyone had had an opportunity to speak the session time was almost over. Two women considered that the first group could be shorter but more time was needed to facilitate discussions in the later group when women felt more confident to speak, share experiences and seek the support of the other women.

Some women felt more comfortable in smaller groups or felt that with smaller groups there was more time to engage in discussions. However, one woman would have preferred a larger group with more time for discussion.

"I think you wouldn't want any more than ten in a group ... when there were more of us, I found it difficult ... I couldn't remember people's names and it became less personal and like I struggle in those situations when I don't really know people" P1

"I certainly wouldn't have gone more than that [eight women], the smaller the sort of the better ... just to try and form the bond and the trust amongst us, because we only had four weeks and I think we needed to be quite quick" P8

Most women liked the fact that the groups consisted of women who were all nulliparous and experiencing symptoms of anxiety.

Two women liked the fact that all the women were pregnant for the first time, they were all 'in the unknown' (P1). One woman could relate more to women who had had anxiety prior to pregnancy and felt more relaxed when she heard some of the other woman had accessed CBT in the past. One woman felt if the sessions were offered to all pregnant women, women may attend who were not

anxious which may have a negative effect on the group. For one woman, her anxieties were focused on the wellbeing of the baby and when other women talked about 'getting the birth they wanted' (P6) she could empathise with the other woman's feeling, but it was not important to her. One woman stated it was 'obvious' that other women in the group were anxious and felt she benefitted from the session because they all had that in common.

"I just think it's nice that we're all in the unknown and we can bond because of that" P1

"if you're not as anxious I don't think you quite place the same importance on things so I think it would make it more difficult for someone who is anxious to open up about it ... it would be like a drop-in and I think you'd lose that intimacy, that trust ... you'd get someone only coming once and I think you'd lose the effectiveness of it" P4

"... it was beneficial just because we're all in the same boat really ... I think if you'd had second or third time mums there giving their opinion ... I think they'd have lots of answers to give when I'm not sure if you're necessarily looking for an answer ..." P5

"... because of our worry that something would be wrong with the baby ... when you're in a group and somebody's saying I'm worried about not getting the birth I wanted on my birth plan, I think that you can definitely understand and empathise with that but for some of us that's almost ... I don't care" P6

Women compared their feelings and experiences with other women in the group.

"there's my anxious part that thinks like why aren't I feeling that way ... am I doing it right ... I know that women do compare themselves to others ... I wish I didn't but sometimes I do ..." P1

"it felt like there were definitely some people who were much more anxious than me" P4

"I would probably say I was the most stable ... I could relate things that they were talking about but my reaction, or my feelings weren't as strong as theirs ... it certainly gave me self-confidence" P8

6.4.3 Self-help materials

Women preferred self-help anxiety materials which were specific to pregnancy

One woman found it useful learning to use coping techniques and to use the materials to assess the severity of her symptoms. The workbook: 'Coping with anxiety during pregnancy and following the birth: A cognitive behaviour therapy-based self-management' Haring et al. (2013) was described as useful by three women because it was specific to pregnancy and they liked the examples and case studies presented. One woman had briefly looked at the materials and thought they would be a useful 'intermediate' step to access if she ever needed more support. Three women said they had not read the 'Overcoming Anxiety' (Kennerley 2009) book as it was too 'wordy' and not focused on anxiety in pregnancy.

"I've done CBT before ... some of it was new but a lot of it I knew ... it was still good to get other materials and things that are pregnancy related" P4

"...I found them quite useful cause I could learn about techniques and signs and also it made me feel, oh I don't feel like that and that's quite reassuring ... I knew where I stood, to know what level of anxiety I'd got ... I suppose you take things that are more relevant to you" P5

"I liked the [Haring folder] which was pregnancy related ... it really helped me ... you can relate to it cause that's what you're struggling with it's like - well I know how to calm my worries but it's these pregnancy specific ones that are just all new to me that I don't know

what to do and so that book was really helpful with the case studies and things" P4

6.4.4 Individual time with facilitators

Some women preferred to seek facilitator support before at the start of the group.

Most women said they felt the option to speak individually with the midwife facilitator was available to them if they needed it and thought this was beneficial. One woman had chosen to speak to the facilitators before the session to check if certain topics were appropriate to introduce in the session. One woman felt that she had needed some one-to-one support but felt there were other women who needed it more and time was limited.

"I think the opportunities were there if people needed them definitely ... it's nice just knowing where [midwife] is, obviously you don't wanna be messaging them all the time but it's nice to know if there is a time when I was really in a state and needed somebody that understood my worries who could talk to me ... it feels very personal to us which is nice, we've got that support on hand" P4

"... I think time beforehand is important ... when [MSW] texted us a reminder ... I went back to her and said can I pop I a few minutes early and just have a chat about something, so I think the ability to perhaps be able to flag up topics beforehand ..." P6

"... possibly I felt like I needed to but I didn't take part in that, maybe because there was so many other people there that wanted a little one on one time after ... they might need that more than I did ... maybe agree a separate time for you to speak to someone if you wanted it rather than, we've got a couple of minutes to talk now but I've got three other people waiting ... a follow-up phone call would be quite a good thing, it might then give someone that opportunity to speak to someone they might not have felt comfortable enough speaking about in the session" P10

6.4.5 Access to support

Women said, in general, there was little existing support for women with anxiety in pregnancy. In the past she had been advised to speak to her GP if she needed support with her symptoms of anxiety but she did find this acceptable. One woman had actively looked for help and had started CBT because she could not find any support that was related to pregnancy. One woman did not want to overburden her community midwife and was pleased this 'gap' (P4) in services had been identified. One woman was surprised that this intervention was not already established. She considered she could have used some CBT techniques she had learnt in the past but did not think she would have coped as well as she had with the groups. One woman who did not attend the sessions said the parent craft sessions at the hospital had helped 'calm' (P2) her.

"I don't think there's enough services that offer support for anxiety during pregnancy ... everyone just says go to your doctor if you're feeling low and I don't like my doctor so, so I wouldn't do that" P1

"... it's something that I thought that I wanted, I just wasn't sure how to get it and there was a point where I thought well obviously I'm not clinically bad enough for it, which at a point I thought, well I am, I just didn't know what else to do, cause I'd heard oh you can do this [Perinatal Mental Health Team] you can go here ... I thought well I've exhausted every option, I'm telling everybody that will listen that I'm really anxious so until this came along it was kind of a bit of a dead end" P4

"I think we all worry about over burdening our own midwife ... I feel really pleased that you and other people have identified that there is this gap" P6

"I can go to my GP, but I've not really found that to be the most useful source, stepping stone to getting help if I'm honest so ... I did

go to one of those day courses, learning about caring for your baby and that sort of calmed me down quite a bit" P2

Women discussed other coping strategies they had used to cope with their symptoms of anxiety.

Three women discussed how their busy lives distracted them from thinking about their anxious feelings; they were concerned that they would find it more difficult to cope during maternity leave from work. One woman discussed how she felt reassured following ultrasound scans to confirm fetal wellbeing but the reassurance would be short lived. One woman said her anxiety symptoms had become worse when she stopped taking medication for anxiety because she was pregnant. One woman knew she could not use her usual coping strategies (such as smoking).

"I just sort of go into run away mode ... I know that that's wrong and I know that sometimes I do have to face it, face whatever it is that's bugging me" P1

"...I'm finishing [work] with three weeks to go and that's enough for me ... not having my mind active, that's when I would go into overdrive ... I'm aware that I'm probably gonna have to ramp up my coping strategies in the next couple of months" P4

"the nature of my job it's always been quite fast paced, you're always in autopilot so you don't really get time to stop and think about how you're feeling ... I was thinking oh god, I'm gonna have so much time on my hands I'm gonna be going round in circles worrying and worrying" P5

"you have a scan and you think oh, ok that's really nice to see the baby and be reassured and that lasts for a certain amount of time and then you start thinking god, it's ages until my next scan ... and then you start getting closer to it again and then you start worrying about it so you really want the scan to come but then you're worried about it so you go through this kind of up and down" P6

"it's not surprising that we all have busy lives, because that's our way of coping ... when I slow down and I haven't got the structure ... that's when the anxiety is likely to hit the most" P8

"... I was on medication for a long time before I was pregnant and I came off it when I found out, and I think that's when my mood, it was up and down" P7

"...usual techniques that I might have gone to, I no longer can go to ... I might have started smoking again but I've got a baby so I'm not gonna do that" P2

6.4.6 Overall thoughts on participating in the study

It was important to the women that the sessions were facilitated by a midwife.

All of the women thought it was important for the sessions to be facilitated by a midwife. They valued the midwives' and MSWs' knowledge and experience and were able to ask questions and seek advice about minor symptoms of pregnancy and about birth. Women felt that they could trust the midwives' advice and felt safe with them.

"... if you just had a CBT therapist, they may not have understood some of our anxieties about birth as well, not just about birth about pregnancy" P1

"... I'm very much a person that likes reassurance from people that are in the know ... they've been there they understand it ... you can put your trust in them ..." P4

"... it gave you a feeling of security that you were speaking to somebody who'd had experienced so much ... if there was an alternative if it was perhaps somebody who was a psychologist or something like that I don't think it would have anywhere near the same effect ... there were some practical questions that popped up

as well along the way ... I'd say it's essential to have midwives there ..." P6

"...the midwife was there to reassure us that actually that's completely fine to feel like that ... to help us sort of understand that a bit more about why we might be feeling that ... when you do feel anxious about pregnancy, your anxieties relating towards having a baby, labour and everything, it's nice to have that reassurance, from someone who's experienced with it in lots of different ways" P10

Most women described the midwife facilitators and midwifery support workers as caring and friendly. Facilitators supported one woman with some difficulties she was having contributing to the group discussions. One woman appreciated the way the facilitators communicated with the group; she said they understood how 'off the cuff' (P4) comments could make them more anxious. The midwife also guided the group, checking that all group members were happy with the topics for discussion. One woman commented that the midwife was able to quickly understand her situation and both facilitators helped her to introduce topics for discussion.

"if someone else was saying something and I had a different opinion or view, then she would say 'what do you think about this' and then that's when I was able to ..." P1

"... they just understand a little bit more that we are worried about it and just the way they say things are different ... some off the cuff remark that a midwife may think is perfectly fine and probably is fine would make us think a lot more things than someone that's not anxious, so I think you can really tell in the way that they communicate that they're thinking about what they're saying and how they're saying it ... [midwife] is great at bringing stuff together to make sure that no one's saying anything that would adversely affect someone else" P4

"... she was very warm ... very adept at listening and you know picking up the salient points of what I was saying and grasping within a relatively short period of time, sort of where I was ... having [facilitators names] there has been very useful to have that backbone of experience" P6

"I could see how when we were discussing things how reassuring they were, not just what they were saying but also the way they said it, their body language, they genuinely cared, and wasn't just saying something for the sake of it ... 'Oh, you'll be fine, just get on with it', it was more than that, and that little bit more is what we need, as we suffer from anxiety" P8

Some women were very comfortable talking about their anxiety with HCPs, but some women found it more difficult and were worried about the consequences of disclosing their symptoms.

Two women had concerns that disclosing their symptoms of anxiety may lead to judgements from HCPs about their ability to care for their baby.

"I didn't want, obviously what I said to affect anything with my future child or anything like that ... I feel like I'm quite an open person and I didn't want to say the wrong thing ... say if I was just having one off day and something bad happened ... and then it was reported to social services or something so ... that was a worry, not that I'd do anything bad ..." P1

"...I think if you would have asked me right at the beginning do you suffer from anxiety, are you anxious right now, I'd have said no even though I did have a load of worries ... there is a bit of a fear that, if you talk about it, even though it might be a thought, that it would just be jumped on and that you know mental health would get involved and child services ... because I actually, like in my first, the first time I filled this in [GAD-2] ... I didn't answer that truthfully" P2

"...I was really scared about going to my doctor the first time to say I'm feeling like this ... that took me a long time to build up the confidence ... it was really hard for me at first" P7

Women wanted to meet with other pregnant women to help them feel less isolated.

Three women said that they welcomed the opportunity to meet other pregnant women. One woman felt that if she had not attended the group she would not have anybody she could have spoken to about her feelings in pregnancy. One woman felt there was an element of competition with 'new mums' (P6) in her area which could make her feel more isolated and 'inadequate' (P6), whereas the groups were helpful because the women had more in common with each other.

"...I'm going to be a mum and it would be nice to make mum friends ... that is one thing that causes me issues cos I never know if that's gonna happen." P1

"... at that point I was like I need to meet other people, pregnant people ..." P4

"... there's a huge amount of competition as you can imagine especially around [the area], and I knew that I wouldn't benefit from that at all, whereas actually this group of women we've got more in common because of how we feel about certain things ... I think you could have classes that could make you feel more isolated ..." P6

"I genuinely didn't think I'd have anyone to talk to ... I've not really got anyone else that I can speak to about that, so it was really helpful to meet up with other people that were in that situation as well" P10

Most women said participating in the study was beneficial and enjoyable.

"I think the benefit that we had the most was from listening to each other ... I do feel very fortunate to have been a part of the groups ... I have really enjoyed the sessions, I looked forward to going" P6
"being able to speak together as a group ... reflecting off each other and learning off each other, I thought was the most helpful ... it's been a really positive experience, everyone's been really lovely and supportive and I've been really surprised about how well I've emotionally connected to being able to speak to people about how I'd felt ..." P10

"it was definitely what I was looking for ... even if it was to go and have a chat about the week or what's been going on or what, it was really helpful" P4

"it gave me a lot of self-confidence about myself and got me thinking ... well, I'm not that bad ..." P8

Most women said they would recommend the sessions to other women.

"... at a consultant appointment, cause now I'm a bit more open about saying I'm really quite anxious about things ... so I have talked to them and said I'm part of the focus groups and some of them have been really interested in that and really identified with the need for it." P6

"I would highly recommend it ... I think I was in a fairly good place to start with ... but certainly if I had to be ... it would have been vital and would have stopped me from being referred back to [psychiatric team]" P8

"...some people might not deal with being in a group session rather than being in a one-to-one session" P10

Following the sessions some of the women said that although they still felt anxious, they were coping better with their anxiety. Two women said they wished the sessions were still running and that would help their anxiety as they were getting closer to the birth.

"I'm still anxious but that's always gonna be there ... sometimes I guess it would be nice to talk to someone ... when you see your own midwife you don't really get the time to talk so I guess yes, longer in group would be helpful ... a few sessions in I might have been able to talk" P1

"I'm less anxious at the moment than I was before ... I think it's a combination of everything ... whether this groups helped. I think we've had a lot going on in the house ... it will probably start to kick in a bit now when it's getting closer when I go on maternity leave but so far I'm managing to be ok ... to be honest I've done a lot better, so for example I had my blood test done the other week on a Friday [states test] and the midwife ran me back Tuesday or Wednesday but I just was able to put it in a box and put it to one side whereas before that would not have happened" P4

"... as its getting closer to delivery it would have been nice to still be meeting up and still talking about those things cause once the session were being run I just knew if I did have any questions, I'll wait till Thursday and I'll just ask it, when now I feel as though I don't have that ... I'm not saying my anxiety is worse but it was better when we were having the sessions" P5

"... it feels less isolating ... I feel more confident now that there are people that I can say certain things to and them absolutely get it ... it's not that anxieties about certain things have gone away, it's just that you're not the only one feeling it ... perhaps just sort of changed shape in that respect" P6

"I've had ups and downs recently, but I'd say it's at a steady level, but I'd say I'm still a bit anxious and I know I am, but it's definitely helped to have that reflective session with people" P10

"...I'm just about to be mum and it's just a bit scary, I'm excited for it but really scared about it at the same time ... it's a bit up and down, I think I'm talking about it more whereas I used to bottle it up" P7

6.4.7 Self-report anxiety measures may help women discuss their symptoms of anxiety with HCPs.

One woman referred to a previous experience using self-report questionnaires for CBT therapy and felt pressure to put the 'right thing' (P1). Two women thought the questionnaires may have helped women to discuss 'taboo' (P4) subjects which women may have found difficult to disclose to HCPs. One woman said the questionnaires were useful, but women had to be honest about their feelings in order to access help. Two women found the questionnaires helped them confront their feelings of anxiety.

"... I found the CBT was a lot more about scales at the end and how they've managed to improve me rather than how I've improved myself ... you get the impression that you need to tell them that you have improved, otherwise they're not happy about it ..." P1

"... sometimes people don't know what they're worried about and seeing it in black and white sometimes might help people ... it's such a taboo subject I think that sometimes people like to skirt around it ..." P4

"... when you have them written down ... it's an easier way of saying this is what I worry about than actually saying the word yourself ... it sounds a bit odd almost if you say a word out loud ..." P6

"... I think they're all valuable ... you've just got to be honest ... you've got to admit to yourself, hold your hands up, yeah I suffer from anxiety ... until you do that you're not going to get any better ..." P8

"... when you write it down on like a piece of paper, it makes you realise your feelings. When it's in your head you can just push it to the back of your mind ..." P10

The Edinburgh postnatal depression scale (EPDS) was difficult to answer for women who felt their feelings varied from day to day.

Two women found the EPDS difficult to answer as their emotions varied from day to day. One woman felt that the reason she had been crying was because she felt more emotional and not because she was unhappy but could not express this within the questionnaire. One woman felt the EPDS was more focused on the postnatal period. One woman discussed how she had not been honest when answering the EPDS (Q10) initially, she was afraid her answers may have led to unwanted interference from HCPs or social care.

"... I can have a really lovely day and my mind will be occupied one day and then the next day, like I feel emotionally exhausted and feel like I don't want to do anything and don't want to talk to anyone and I just want to stay in bed and not have to face the world so I think, like it's just difficult sometimes for me to fill out these forms ... in the past 7 days, within those days, I've probably had two really bad days but the other ones have been OK or good, so it's difficult" P1

"... I probably found this one the hardest really ... I suppose just relating the questions ... it says have you felt sad or miserable, I suppose this part of my pregnancy I've been a bit more emotional so I suppose things affect me a lot quicker than they would normally ... It says here 'have I been so unhappy that I have been crying' ...

I have been upset but it's not cause I've been unhappy really cause things emotionally get to you and I think where did that come from ..." P5

"...there is a bit of a fear that, if you talk about it, even though it might be a thought, that it would just be jumped on and you know, mental health would get involved and child services ... the first time I filled this in, I didn't answer that truthfully (Q10) ... and I don't know how you'd get around that" P2

Four women said the GAD-7 questionnaire was acceptable and relevant. One woman said it was a good starting point to then go on to discuss deeper feelings. One woman would have liked to qualify her responses with reasons for feeling the ways she did.

The women felt the items in the Pregnancy related anxiety questionnaire (PRAQ) were relevant to them.

Some women wanted an opportunity to qualify their responses.

"... the one [question] if your baby's stillborn, are you worried about it and I've put no, but obviously there is a part of me that is worried about it but in the back of my mind ... it's not a concrete thought I have every day like other things" P1

"Well I think them, so they don't freak me out or, I know they're quite, hard hitting, but I think that's actually the kind of things that run through my head so I think if they weren't you'd be shying away from it a little bit ... [in the group] I kind of said I'm worried about something going wrong at the birth but really in my head it's that the baby will be stillborn but I couldn't say it in that, so I think they're the things that I think people are still a bit guarded ... it's such a taboo subject" P4

"... I found easier to do ... it's more specific ... there were things in here that I wasn't worried about when I first filled it in but I was only 16-17 weeks where now I'm 30 weeks and there's things I'm thinking, oh god this is getting closer ... where's the stillborn one

[question] ... now it's closer I'm probably thinking oh god, is that going to happen and maybe this one [question] here, will I regain my figure after delivery, I was probably worried about that before but now I'm not so worried" P5

"... I think to a degree when you have them written down, to answer a question about them it's an easier way of saying this is what I worry about than actually saying the word yourself ... it sounds a bit odd almost if you say a word out loud ..." P6

"I think the pregnancy related one is vitally important because that is very specific to what we're experiencing at the moment and all the others are more of a general" P8

"... an extra column would have been like, it's crossed you mind ... [points to statement] I'm worried my baby will be ... or suffer from brain damage, so you want to say there ... it's crossed my mind ... I guess it's like prepare for anything ..." P7

"I felt a little bit bad because I wasn't worrying about some of these things ... I don't know if they could be a section to write what I would be worried about ... there a few about being unattractive, weight gain and things like that ... I don't really worry about those things" P2

Some women were confused about how to answer the Short Form 12 (SF-12), whether to relate the questions to pregnancy or their general health.

Four women said they did not feel the SF-12 was relevant to pregnancy. They were unsure whether to answer about their general health or the restriction to physical ability due to normal effects of pregnancy.

Two women who provided comment of the State-Trait Anxiety Inventory (STAI) felt it was helpful in the way it ran through different feelings. However, three women said the statements were

more difficult to answer. They felt they were contradictory and felt they needed to elaborate on or qualify some of their responses.

"... 'I feel content', you know I feel content in my marriage, in my home a ... but do I feel content specifically in my pregnancy related anxiety then no, so it's contradictory statements in there" P6

"... some of the questions were a little bit odd ... I feel pleasant ... I don't often think of myself as feeling pleasant ... some of them I almost wanted to add on ... I feel secure, it's because my partner makes me feel secure ..." P2

6.5 Facilitator interviews

Study objectives:

- *To determine intervention facilitators' views on the delivery of the intervention*

Details of the development of the analysis template is presented in Appendix 6.2, which includes: pre-defined headings for the template; modifications which were made to the themes during the analysis of transcripts and indications of supporting and refuting data of each theme. The findings are presented below and ordered into general theme headings which encompass more descriptive sub-theme headings. The interview findings are presented below and ordered into general theme headings with descriptive sub-theme headings. Theme and sub-theme headings are presented in Table 6.6.

Participant quotations are colour coded **M1-M2** (Midwife facilitator ID number) and **MSW1-MSW2** (Midwifery support worker co-facilitator ID number). Quotations are presented to support the findings from the analysis. The presentation of the quotations follows the same format as the participant interview data (section 6.4).

Table 6.6: Facilitator interview data themes and sub-themes	
Training to facilitate the intervention	Trainers introduced the facilitators to different approaches to supporting women with anxiety.
	The peer group training helped facilitators plan the practical running of the sessions and address some of their initial concerns.
	The delivery of the training enabled facilitators to have time to concentrate, discuss and reflect on the information and think about their approach the sessions.
Initial meeting with the midwife	The initial meeting gave women an opportunity to discuss their concerns about the group and share information which they felt was important for the midwife to know about them.
Group discussions	Women connected with each other on their experiences and anxious feelings.
	The community location was suitable for the sessions.
	Women wanted a greater number of sessions as the groups took time to establish.
	Group discussions enabled women to share their experiences and feelings and access the support of the group.
	Discussion groups were more successful when women had freedom to speak about what was important to them.
	The self-help materials were presented as an option for women to choose to access if they wanted to.
	Some women accessed individual facilitator support before groups.
	Facilitators joined in the discussions and encouraged some of the women to contribute.
Facilitating the intervention.	Facilitators would need to have an interest in supporting pregnant women's emotional wellbeing to facilitate the sessions.
	Facilitating the groups was an enjoyable and positive experience.
Suitability of the intervention in maternity care	There is a real need for the sessions and they would be welcomed by pregnant women.

6.5.1 Training to facilitate the intervention

Trainers introduced the facilitators to different approaches to supporting women with anxiety.

Training session one was described as outlining the different approaches used to diagnose and treat anxiety, which mainly focused on CBT.

".. the background to GAD ... how to use those resources and how to know their medical conditions and the background of it and around CBT" MW 1

"The first session was about CBT ... mental health in general, it's place within the NHS, that was really good, because nothing in my training had I ever learnt anything about that" MW 2

"... it was quite structured ... diagnosis based ... CBT ... there was always lot of rationale behind it ..." MSW 1

Training session two focused on peer support for women with anxiety and the facilitators described this approach as less formal than the approach in session one.

"... they didn't want to put a label on it, didn't want some diagnosis ... I'm experiencing this distress and I've wanted some sort of support from other people to get through it" MSW 1

One MSW co-facilitator found the two approaches were helpful, although another midwife facilitator found the two approaches caused her some confusion as to which approach to adopt when facilitating the sessions.

"... I felt the CBT approach and the peer approach, to me in my head they are just polar opposites ... I just got confused as to which approach to take ..." MW 2

"I thought they were a really good mix ... both of them [trainers] made it really clear what their approaches were. We were able to

use some of what [trainer 1] had said and see the benefits of peer support at the same time ...” MSW 1

The peer group training helped facilitators plan the practical running of the intervention sessions.

All of the facilitators commented that the training was interesting and enjoyable although one midwife facilitator said she did not feel she needed all of the additional information to prepare her for facilitating the sessions.

“... my knowledge as a midwife ... and the way I view how people work, was all I needed to bring to it ... I’m not sure I needed the two sessions about anxiety and what it does ... the [peer group training] that for me was the most useful ...” MW 1

This contrasts with the views of the other facilitators and co-facilitators who commented that it was not until the end of the training when they had got to know each other, and the information came together to enable them to prepare for delivering the intervention.

“because we’d had that time together ... I felt that we all kind of knew each other, we were gonna have each other backs so it was gonna be ok” MW 2

“... it all kind of came together ... until that point we were all a bit like, oh gosh, are we really gonna do this, we want somebody just to tell us how to do it, but neither [trainer] did that, they, with us not even realising, gave us the tools to be able to go on and know how to do it” MSW 1

“...we came back to the third session and again I think was very interesting and putting everything into practice” MSW 2

Most of the facilitators and co-facilitators found the peer support training (day two) the most useful and enjoyable; they described how the training addressed some of their concerns about facilitating the sessions. Three of the facilitators and co-facilitators were concerned that discussions would 'open up' (MW1) problems for the women, they would become very emotional and facilitators would not have the 'answers' (MSW1) the women required. The training helped them realise that it was acceptable for the women to become emotional. They learnt how to support the women by enabling them to speak freely, support each other and being able to signpost women for additional support if they needed it.

"... the whole point is that they're discussing things and find answers out themselves. Cause I was very worried that I didn't have the answers to somebody's anxiety ..." MW 2

"we were worried about if you open up problems for people ... we learnt how to deal with that, that you'd refer back and it was OK for them to bring problems out ..." MW 1

Other aspects of the training that the facilitators found useful were the review of the self-help materials and hearing the experience of the service user.

"... it did make you realise that the tools were really useful and simple to use ..." MW 2

"... I particularly enjoyed the part where we had a service user come in and give her account ... that gave us a great understanding of how, actually of how some women can really feel and how overwhelming it can be ..." MSW 1

The training enabled facilitators to have time to concentrate, discuss and reflect on the information and think about their approach the sessions.

Although facilitators commented the training days were long, they needed a full day to concentrate on the information and get to know each other. The facilitators used the time between the training sessions to discuss and reflect on the training and review the self-help materials.

At the end of the training most facilitators and co-facilitators felt they were well prepared to deliver the intervention although anxious about running the first group. However, one midwife felt that specific tasks had not been adequately delegated to particular facilitators. She felt this gave the women the initial impression the facilitators were unprepared.

"... I was emotionally anxious about it but I knew what I was going to do ... we had spoken as a group before, we made a plan to come together so we all were doing the same thing, but we did all approach it very differently ... but then the sessions ran themselves"
MW 1

"... I felt comfortable and confident that it was going to work, cause I thought honestly before the sessions, is a group of anxious people together just gonna make them more anxious ... I don't think I felt overly confident that I knew precisely what I was gonna say ... we'd not really got together, and said, I'll do the introduction and then you introduce the homework and then I'll do that ... it did come across to the women there at the beginning that we didn't really know what we were doing" MW 2

"[the trainers] gave us all the knowledge and then we were able to say, oh right so were gonna do this and we'll approach it like that ..." MSW 1

6.5.2 Initial meeting with the midwife

All facilitators said the initial meeting was important and beneficial for the women. Women familiarised themselves with the location of the group and met the midwife which gave them more confidence to attend the groups. One midwife said the meeting also provided women with an opportunity to discuss their initial concerns; things they may find difficult in the group and identify strategies for addressing their concerns. Some women helped the midwife to develop the 'ground rules' for the groups. All facilitators felt the initial meeting could have been conducted by the MSW co-facilitator, however, one MSW said that she would need to make it clear to the women that she may need to share any information with the midwife. The facilitators who did not attend the initial meeting felt they would also have benefitted from meeting the women before the groups to have a first-hand account of women's individual concerns and needs. By meeting women in person, the information would have been easier to retain.

"we sort of got a few hints from people of how people would want to be treated in the groups ... one [woman] ... she shared something, like, 'there's bound to be ice-breakers I know there is ... I never want to be first'. So actually that made us build in that ... we always joined the check-in and it was one of us first and one of us last, so it took any anxiety away ..." MW 1

"I think there were two [women] that I don't think would have come to the group if they'd not met somebody first ... a lot of them did share a lot of themselves with me in that 10 minutes ... they almost felt like they needed to do that" MW 1

"... [MW] did meet me before the class and tell me about the women and things to look out for ... but then I couldn't put the names to the face and what the problem was, so I didn't absorb it very well ..." MW 2

"... they were able to have a face that they knew when they walked through the door. I would think if you didn't have that it could be quite daunting to make that step into that room" MSW 1

"... I think as a MSW I could do that ... there does need to be some good boundaries between midwives and MSWs and you know and if they asked something that I didn't think I would really know, or I was out of my depth I would just say, 'oh, thank you for sharing that with me, it's not something I've come across before, I would like to discuss that with the midwife before I say anymore' ..." MSW 2

6.5.3 Group discussions

Women connected with each other on their experiences and anxious feelings.

One MSW initially thought that there may be social barriers between women from different areas and/or different ages but found that the women connected on their shared experiences and feelings. The facilitators said that although the women had things in common, they were different characters which helped the women to look at the same problems/anxieties from different perspectives. One MSW commented that the all of the participants and facilitators were White British ethnicity. She felt that recruitment from other ethnic groups may be improved if the intervention became a normal part of care and other women's experiences would 'trickledown' (MSW 2) by word of mouth within in their local communities. One midwife felt this type of intervention would be beneficial for multiparous women. However, they would need to have a separate group because multiparous women may want to discuss a previous birth experience which may heighten the anxiety of nulliparous women.

"... maybe in an ideal world it would be good to have a group of professional middle aged women together and then a group of teenagers together but I don't think that will ever be achievable and actually you might get benefit from mixing everyone together and

*everybody coming at the same problem from different perspectives”
MW 2*

“[participant name], she asked if there would be other young people there ... whether or not a young persons’ group would be a good thing to do for somebody like her ...” MW 1

“I think there’s a need for it for parous ... but I’d worry about mixing the two just because if you’ve got a woman who’s anxious about giving birth because she’s not done it before and then somebody who’s there because she had a traumatic time before, I’d worry about how those two people would get on together or whether it would heighten some anxiety, so I think ... maybe a separate session” MW 2

“...I naively thought it might cause a bit of a barrier but actually they seemed to connect more on the shared experiences, shared feelings rather than their general day to day life ...” MSW 1

“... the whole diversity of getting people engaging would need to be addressed, if just getting one sector of society, wouldn’t really be ideal ...” MSW 2

Two facilitators considered that the initial anxiety screening was important to identify mild to moderate anxiety as women with severe anxiety may not benefit from the intervention. Three facilitators commented that because the women knew that all of the women participating were anxious, that helped them share their feelings with each other. Two facilitators also acknowledged that some women may not identify their feelings as anxiety or may not want to admit they are anxious so the sessions could be introduced at the initial booking visit in a more informal way.

“I don’t think it’s appropriate for women who are tremendously finding it difficult to deal with their anxiety ... I think it’s more support than that they need ... it was appropriate for them to have filled in the GAD (questionnaire) ... it made them aware of how they

were feeling ... gave them a title to be free to talk about ... were allowed to talk about it ...” MW 1

“... I think women could be experiencing anxiety issues without wanting to put a label on it, or if they’re asked by their community midwife – do they have anxiety they’re not gonna want to say yes, whereas if you just open it up to everyone ... you’re probably gonna access a lot more people. But I would just worry about ... there was just something quite bonding about the group, for people to say, I’ve been diagnosed with this or I’ve had CBT before or I know I’ve got this issue, I just felt that everybody there identified with each other instantly because they all knew why they were there and the issues they all had.” MW 2

“... some people can be quite anxious and not know they are anxious ... some people I suppose don’t even want to come out and say, oh I’m anxious ... it might be worth discussing with them at booking in a bit more of a relaxed way” MSW 1

The community location was suitable for the sessions.

Facilitators said some of the women had anxieties about hospitals and it was good to be away from a hospital environment. However, one midwife said that holding some of the sessions at the local hospitals would help the women address their anxieties with the support of the facilitator. She said that some women had requested a hospital tour at the end of the sessions.

“I liked it where it was, it had the space to be relaxed ... hospital tour has become something that was talked about and concerns around how it would feel being in the hospital ... maybe if one of the sessions could be a tour with anxious women ... I think it would still be as useful in the hospital” MW 1

“... they don’t have to go to a hospital and it doesn’t make them feel like there’s something wrong ... if your anxiety is about going to

hospital, maybe being in labour and that's what's got you scared it's good to be away from that ..." MW 2

"... the location worked ... it makes it feel a little more low key, than ... gosh I'm so poorly I need to go to the hospital once a fortnight for a session ..." MSW 2

Women would benefit from having a greater number of sessions as the groups took time to establish.

Most facilitators felt that the sessions needed to be longer and suggested two hours. One MSW said women needed around 15-20 minutes each to speak in the groups and the session time should reflect the numbers in the group. However, one midwife was concerned that two hours may seem too long for women who had been to work all day. Facilitators felt the groups worked well with 4-7 women; larger groups would be more difficult to facilitate everyone having time to talk.

All facilitators said they felt the women wanted and would benefit from having more sessions. They felt the groups were progressing to a point where women were able to be more open and provide support to each other.

Midwife facilitators identified that it took a number of sessions for women to start opening up to each other and access the support of the group. Women were initially careful not to distress others and as a consequence, felt that their anxiety was more severe than the other group members.

"... I felt like they were all masking their anxiety because they didn't feel like an anxious bunch of women at all to start off with, with and then the more they felt comfortable, the more it came out ... I definitely felt that they were ... being careful together, then feeling more relaxed together then being able to talk together and that very last session they were able to cry together ... that's where the trust

in the group built and led them to a point where they could share ... we had to encourage them that the others were thinking the same way that they were" MW1

"Because at the beginning they were just kind of individual people and they were quite shy ... but by the end of it, I remember we had coffee and that seemed to be the turning point ... then some just started talking" MW 2

Group discussions enabled women to share their experiences and feelings and access the support of the group.

"that's exactly what this was about ... they were there for each other, they shared themselves completely with each other, and that's what they needed because they know they're anxious and they trust each other ... They were able to cry together and they were all very strong women but they were able to be vulnerable together ... talking to people who feel the same to feel safe" MW 1

"... no question whatsoever that they've all benefitted ... they all looked so much more at ease with themselves at that last session. Now whether or not that's something that happened during that or not, whether it would have happened or not, I'm not sure" MW 1

"I think they got benefit from it, and even from that first session, I think you could tell the difference from the beginning of the class and the end of it" MW 2

"... having those other women to discuss their anxiety with really seemed to help them move forward ..." MSW 1

"... every single one of them expressed that they'd found it really beneficial ... they all offered so much support and said we are here for you ... we're gonna be here to support you in this" MSW 1

Facilitators said the women felt relieved when they knew that other women had similar thoughts and the women benefitted from knowing they were not alone.

"...I think they all got a lot from that knowing that they weren't the only one ..." MW 2

"...when they all said 'we've all thought that as well' ... that look of relief came over her face" MSW 1

"... the normalising of their anxiety that they weren't on their own ..." MSW 2

Discussion groups were more successful when women had freedom to speak about what was important to them.

Facilitators structured the second group around flip chart work as a way to open up discussions but they felt it was too structured and groups were more successful when the women had freedom to speak about what they wanted.

Two facilitators said the 'check-in' (they asked women to talk about something they had done for themselves that week) opened up the discussions. One MSW said the 'check-out', making sure everyone was OK to leave the group and felt safe was an important part of the groups.

"... the check-in ... that gave them the chance to say ... this is what I've done ... and these are my thoughts ... feeling relaxed enough to say what they wanted to say, so the check-in itself created the group, the trust within the group ..." MW 1

"... the third week we found that by doing that 'check-in', just saying how are you, how have you been for the last two weeks, that kind of just led the session ... letting them talk actually worked really well ... then at the end just a really brief check-out to make sure everyone was OK quite happy to leave and feeling quite safe ...

if anyone had got anything that they needed to discuss further ... we identified that in the training as being a really important part to see how everyone was at the start of the session and to check how everyone was leaving the session” MSW 1

One midwife commented that some women wanted to talk about the birth but there was not enough time to discuss all of the suggested topics in four sessions.

The self-help materials were presented as an option for women to access, but it was not a requirement.

One MSW said the pregnancy specific CBT workbook (Haring et al. 2013) appeared to be the most popular with the women. Facilitators said that although materials were not used by all women it helped some in the group and provided a resource to refer back to between sessions. They felt the number of materials could be reduced as the choice could be overwhelming. One midwife said she led an exercise from one of the 'Apps' to introduce the materials and give the women some experience with the materials. One midwife found the different approaches in the training created some conflict to how they should introduce the self-help materials. She was uncertain whether to set homework tasks or leave it free for the women to choose if they wanted to look at the materials.

“... they [materials] were there in case they needed something for them to get through anxiety ... I think giving them all them at the beginning isn't required but knowing they're there as a resource ... MW 1

“... I just remember CBT being very much like, this is homework, you need to do it, if you're not gonna do it then you're not gonna get any benefit ... whereas the other one was very much like don't call it homework, that's a bit of an intimidating word, people should do what they want to do ...” MW 2

"I don't think all of them used it there were certain ones who said I'd had a bit of a rough week last week so actually I'd made the decision to sit down and read the modules ... I think that's really important because there is a two week gap, it kind of gives them something to refer back to ..." MSW 1

... just to draw down how much were giving them really because if you give them a lot it can be a little bit overwhelming ... we made it very clear early on that they're there to use if you want to use them and if you want to discuss anything you've used from group that's absolutely fine ..." MSW 1

"... some had been quite diligent ... we didn't want it to be the question, have you done your homework, what homework have you done because we were saying that could tip people in another direction if they hadn't managed to access stuff" MSW 2

Some women accessed individual facilitator support before groups.

Facilitators said the women did not access individual time at the end of the groups when they mainly chose to speak to each other. However, some women requested time before the session to discuss whether certain topics would be appropriate to introduce in group discussions and asked facilitators help to raise those topics. Facilitators considered it was easier for the women to access one-to-one time before groups because it was not obvious to the whole group that they needed additional support. One midwife said the women did not feel comfortable enough to access the one-to-one time until the last session when she was mainly asked pregnancy-related questions.

"... I don't think any of them felt confident to peel off to have that discussion ... on the very last session there were very comfortable, you felt they were just coming to you and talking separately ... they chatted to me about specific midwifery questions ... [participant name] didn't know whether to talk in the group about [obstetric

complication], so she came early to talk to both of us about whether or not she should bring it to the group because she didn't want to alarm and upset the group ... maybe sometime before the actual session ... then you're not doing an obvious breaking off to go and talk to somebody at the end ..." MW 1

"... you've still got to have some confidence to hang back when everybody else is leaving ... if you could have the one-to-one session before ... then it not obvious that they've been having that one-to-one time ..." MW 2

"... we did get a couple of requested to come in early and speak to us, which I think may work better because if they had things they wanted to talk about but they weren't sure about if they felt overly comfortable with discussing in the session ... that bit where the session ended ... where they do that peer support with each other and talk about what they were gonna do in the coming weeks was really beneficial" MSW 1

Facilitators joined in the discussions and encouraged some of the women to contribute.

Facilitators described the approach they took to create a calm and supportive environment where they were part of the group. They chose not to wear uniforms and joined in the conversations when appropriate. They also gave the women time to speak to each other. One MSW said they wanted the women to feel they were doing this alongside them rather than being 'parachuted in' (MSW 2) to help.

"we were encouraging them to say things and share their thoughts ... we had to encourage them that the others were thinking the same way that they were" MW 1

"we chose not to be in uniform so there were no sort of barriers ... I think that was really important to create that sort of calm, rather homely environment rather than a clinical environment ... we joined in the conversations when it felt appropriate ... we also made a

conscious effort in all of the sessions to ... give them space without us to chat ...” MSW 1

“I think it was helpful not wearing uniform and it was helpful joining in the ice breakers ... we were doing alongside the women as well ... we weren’t sort of parachuting in help ...” MSW 2

One MSW felt the combination of the midwife / MSW worked well, each facilitator could bring a different perspective to the group. One midwife said the women had lots of questions about pregnancy which she felt needed to be answered by a midwife who could give accurate advice. One midwife said maybe for the women it was important to have a midwife facilitator, but she did not feel she contributed anything to the groups that the support worker did not. One MSW felt the groups needed two facilitators as they all picked up on different things and were able to recognise different women’s responses in the groups. The MSW felt that MSWs could offer continuity as midwives’ time was often stretched but they would need the support of a midwife and work as a team.

“they need to believe the person that they are asking, who they’re opening themselves up to has got the knowledge to be able to be true in what their saying to them ... they had questions, what would happen around the pregnancy” MW 1

“I don’t think it is important there’s a qualified midwife there, I think maybe ... for some women it makes them feel a bit ... safer ... more official to have a midwife there because that’s the person they go to, they see a midwife regularly in pregnancy ... but I don’t think I brought anything that a support worker who was there didn’t” MW 2

“... from a learning perspective we all felt that we came from this from very equal places, so actually I wouldn’t really make much difference if it was the midwife or the MSW because actually we just shared the support equally ... you can look at things from different perspectives ... I think that the midwife, support worker

combination works really well ... because they are pregnant, they do come with some pregnancy related questions as well ... to have that midwife who's able to talk to them on that level is really beneficial"
MSW 1

"... there were some kind of medical questions ... perhaps that's something that would require midwives' knowledge and skill because I can empathise but I haven't got that background ... I think it would be far better to have a midwives' presence to work a team ... You absolutely must not in any circumstances leave one person running a group like that ... there is too much going on ... it's having somebody observing, are the other women coping with this ... things that I had not observed, somebody sitting at the other side of the room might see different with their own, sort of perspective, not just from their physical perspective but ... from their professional perspective as well ..." MSW 2

A facilitator and co-facilitator said they were initially worried that the women would not speak to each other or that they would become very emotional, although these situations did not occur. During the training they had learned that it was acceptable for participants to leave the groups with things to think through. The women could access the self-help resources between sessions if they needed some additional support or they could contact their community midwife.

"... if they did become very emotional about anything, that actually that was OK cause I was worried that ... in the training we asked the questions it was OK for them to go away with that ... to use the tools we had given them to get through what they were thinking and hopefully come back saying that they'd managed because of the resources that we'd given them" MW 1

"... nobody said anything that I felt I couldn't answer or nobody put me on the spot ..." MW 2

"... one big worry for us was that ... nobody would speak or we'd get this whole overflow of emotions ... there were parts where people did get upset ... but I was all quite manageable, we were able to deal with it, give them support, it wasn't overwhelming" MSW 1

6.5.4 Facilitating the sessions.

Facilitators would need an interest in supporting pregnant women's emotional wellbeing to facilitate the sessions.

All facilitators thought that midwives and MSWs needed to have experience or an interest in mental health to facilitate the sessions. They felt that midwives and MSWs could be recruited from different areas of practice. Asking for 'expressions of interest' would help identify midwives and MSWs with an interest in emotional wellbeing.

"... it links to who I am as a person, that emotional level of midwifery" MW 1

"... you want midwives who are very passionate about it because I think it's important these women get a good service ..." MW 2

"... who have a bit of a passion for it because you are dealing with people's emotions for the whole session and actually them sharing their anxieties is something quite huge for them" MSW 1

One midwife said when women asked her questions specifically about their pregnancy (i.e. test results, care plans), that she could not provide individual advice as she did not have access to the woman's medical notes. She considered whether having contact with the women's community midwife or access to the medical notes would be more beneficial to the women but was unsure whether the women would have wanted facilitators to have access to their notes.

Facilitating the sessions was an enjoyable and positive experience.

A facilitator and co-facilitator said their care for women with anxiety had improved due to the training and consequentially having a

greater insight into mental health in pregnancy. All facilitators said they would be very interested to facilitate the sessions in the future.

"... these women knowing they're anxious are thinking about how to deal with it and taking every helpful step to go there, so yes very glad to be involved" MW 1

"... I felt it was just good to see people ... a bit happier really and know that you've facilitated that. It was enjoyable ... it's made me a lot more open to just asking people whether they feel they've got issues with anxiety which is good because I've had some people say yes, which means we can discuss it more and try and deal with their anxiety in some way and make sure they are getting proper help ... and also it's made me aware of the mental health system we've got in maternity, how dire it is really ... so yes it's been good" MW 2

"... I absolutely adored every moment of it ... It was such a positive thing for the women involved ... but I think it was such a positive thing for us as well as healthcare professionals. It gave us so much more of an insight and I think it's something we would be able to take forward, just doing our normal role ... MSWs get very little emotional or mental health training and just to have some sort of awareness would help them do their job even better ... we all left feeling really positive actually this has really been of benefit to everyone involved ..." MSW 1

6.5.5 Feasibility of the intervention in maternity care

All facilitators thought the intervention was necessary and would be feasible to deliver within maternity care structures. They said the intervention would be welcomed by many pregnant women.

Facilitators said they did not think the women would have accessed support for their anxiety if they had not participated in the study. One midwife doubted whether HCPs would have identified women's

anxiety symptoms and commented that there were no existing services to which women could have been signposted.

One midwife said it would have been easy to implement the intervention into maternity care. The intervention had not taken up too much additional time to plan and administer. One MSW commented that the sessions could free up midwives' time from having additional appointments with anxious women. The coping techniques and strategies learnt may help women in other areas such as labour. Staffing and funding pressures were identified by facilitators as potential barriers to implementing the intervention.

"... I get the feeling that the other women just wouldn't have done anything ... keep struggling along, nobody's gonna identify a problem and I think as midwives, were not really trained to identify it ... we've got no services to refer them to" MW 2

"... there's a real need for it ... a lot of them said 'oh I feel so lucky that this has happened and having been able to take part in it ... other women at the moment don't have that facility and I think it would absolutely be a service that would be utilised" MSW 1

6.6 Summary

This chapter has included the findings from the quantitative and qualitative data to assess the feasibility of the intervention.

Scores from the self-report anxiety and quality of life questionnaires indicated that the questionnaires reached pre-agreed indicators of acceptability (number of returned forms, item completion, completion time) and may be considered for use as outcome measures in future testing of a similar experimental intervention.

Analysis of the participant interviews suggested that the women found the intervention acceptable and beneficial. The findings highlight areas for consideration to maximise participant attendance

and improve the benefit that could be derived by anxious pregnant women.

Findings from the facilitator interviews provided useful information to further develop the training, support and resources required to effectively deliver the intervention in maternity care. The next chapter will discuss how the findings from the study addressed the study aims and objectives, with reference to existing literature and methodological issues. The qualitative and quantitative findings will be synthesised to explore the components of the intervention and consider how these components may influence outcomes and how they could be evaluated in a future pilot trial.

Chapter 7 Discussion

7.1 Introduction

In this Chapter, the findings of the study will be discussed, referring to the results of the systematic review and make comparisons to published research. This Chapter will be structured following the process evaluation framework by Moore et al. (2014). The mechanisms underpinning the intervention components will be referenced to develop a greater understanding of the findings. Methodological approaches which have been used to evaluate previous research will be compared to the feasibility study methods to inform the proposal for conducting a pilot trial of the intervention. The findings will be discussed alongside current policy and contemporary practice to consider how the intervention could be developed and identify the strengths and limitations of the study.

The feasibility study was conducted to inform the protocol for a pilot trial of the intervention, therefore the chapter will conclude by summarising key recommendations for conducting a pilot trial.

7.1.1 Study preparations

Study objectives:

To determine intervention facilitators' views on the delivery of the intervention

To identify where further developments and refinements can be made to improve implementation of the intervention

In this Chapter, the term 'facilitators' has been used as a general reference to the midwives and MSWs who facilitated / co-facilitated the intervention. Distinction between the roles of midwives and MSWs facilitators will be discussed where relevant.

7.1.2 Recruitment of facilitators

An essential stage of the feasibility study involved engaging with NHS organisations to secure an agreement on the number of

facilitators who could be supported. Although recruitment of facilitators was sufficient for the feasibility study, it is likely that more midwives and MSWs would need to be recruited into a future pilot study to facilitate the intervention and manage unanticipated dropout (Bellg et al. 2004). Implementing contingency plans at the beginning of the study would reduce the likelihood of conducting hurried recruitment and training which would lead to skills differences between facilitators and performance differences between the intervention groups (Bellg et al. 2004).

Concerns with recruitment from an NHS perspective are as follows:

- Single organisations may not be able to release the number of staff required to facilitate the intervention.
- HCPs can be reluctant to engage in research studies due to: having limited time to undertake additional duties; a reluctance to take on new roles; concerns for patients; and a lack of skills and experience in research (Birken et al. 2017, Stuart et al. 2015).

Enhancing a research culture by having on-site experienced HCP researchers has been identified as a way to improve HCP involvement in research (Birken et al. 2017, Pighills et al. 2013, Stuart et al. 2015). For a future pilot trial, the support of midwives with research experience within the organisation could help promote the study across clinical areas and support recruitment. Additionally, it may be possible to access support from research midwives employed by National Institute for Health Research (NIHR) local clinical research networks (CRN). CRN research midwives were introduced specifically to increase recruitment into trials and to undertake research related duties. However CRN research midwives are not available in some UK regions and NHS trusts (Stuart et al. 2015).

7.1.3 Facilitator training

Facilitators who volunteered to participate expressed an interest in perinatal mental health. Enabling facilitators to self-select into interventions can improve engagement by appealing to their interest, meaning they are more likely to adhere to the study protocol (Mazzucchelli & Sanders 2010). However highly motivated facilitators may not represent all staff who may facilitate the intervention if it were implemented in clinical practice. To enhance the fidelity of a study, it is essential facilitators receive appropriate training to prepare them to deliver the intervention as planned (Bellg et al. 2004). Training packages need to account for different baseline levels of education and clinical experience to prepare facilitators to deliver the intervention in the same way (Bellg et al. 2004). For the feasibility study, it was decided to provide shared training workshops as it was anticipated that midwives and MSWs would benefit from discussing ideas and developing a shared plan for their approach to the groups. The following sections considers how training packages can be improved for future studies.

7.1.4 Training workshops

Group skills

Midwives require additional training and support as they transition to group facilitators (Novick et al. 2013, Svensson et al. 2009). Active learning strategies such as discussing video recorded interactions, practicing techniques and receiving feedback from each other and the trainers can help facilitators prepare for their new role (Forehand et al. 2010). One midwife in the feasibility study felt the practical skills for facilitating peer groups was the only training she needed. However, different groups of women may present a variety of challenges and facilitators need to feel adequately prepared to deal with emerging situations.

Mental health training

Midwives can feel uncomfortable when women disclose mental health concerns as they feel they lack expertise to respond

appropriately and can be unsure of the actions they should take (McGlone et al. 2016). In this study, the facilitators anticipated similar concerns which were addressed through practical skills and guided role-play activities, for example techniques to manage potentially difficult situations and signposting women to further supporting services. All facilitators said they had developed an understanding that they were not required to provide all of the answers to address women's concerns (Repper & Carter 2011). Pre-registration midwifery education programmes in England are now required to include a perinatal mental health module with further provision in post-registration training (DOH 2014). Therefore, the future midwifery workforce should feel more confident to provide support for pregnant women with mental health concerns.

Training providers

The training was delivered by the two different training providers. This caused some initial confusion for the midwives and MSWs regarding the different options to support women with anxiety: a cognitive based therapy approach and a peer support approach. In a future pilot trial, a single training provider to discuss the theoretical approaches that underpin all the intervention components would provide a more integrated programme.

Self-help resources

Facilitators rarely referred to the use of self-help resources during the interviews. It appeared that supporting and guiding the use of self-help resources was a low priority for trainers and/or facilitators, possibly because they felt that training was not required to deliver this component. However, this was not fully explored during the interviews. In a future pilot study, a post-training evaluation of the skills and competencies required to deliver all intervention components should be included. For the feasibility study, facilitators completed a brief evaluation to assess whether the training met their overall learning needs. A more structured and detailed

evaluation could be developed using the training components identified in the training needs assessment (Chapter 5, section 4).

7.1.5 Developing a training workbook

Training manuals for complex interventions should be informative without being too prescriptive and encourage facilitators to reflect on how the information can be used to anticipate and respond to situations which may arise during the groups (Forehand 2010). Incorporating flexibility in training programmes can: 1. enable facilitators to use their creativity and meet the individual needs of the women; 2. provide opportunities early in the training to experiment while receiving supervision and feedback from trainers; 3. allow early opportunities for learning the importance of tailoring the intervention to meet the needs of the woman (Forehand et al. 2010, Novick et al. 2013). The training manual used for the feasibility study could be developed into a workbook to encourage facilitators to reflect on how different supportive techniques could be used to respond to situations which may arise during the study.

7.2 Study conduct

Study objectives:

To determine the feasibility of the recruitment process.

To calculate the proportion of eligible participants who agreed to be contacted and participate.

7.2.1 Eligibility criteria and recruitment strategies

To recruit women into the feasibility study, various recruitment strategies were considered, namely:

- Conduct eligibility assessment using a self-report anxiety measure (GAD-2).
- Recruitment based on midwives' appraisal of women's symptoms and risk factors for anxiety disorders.

- Invitation to all pregnant women in the study location to 'opt-in' to the study.

It was decided to target the intervention on nulliparous women with symptoms of anxiety to: 1. consider the effective use of limited NHS resources; and 2. consider the theory underpinning interventions. For example, social comparison and learning theory identifies that women need to be able to connect on shared experiences and feelings to benefit from peer support mechanisms (Shubert & Borkman 1994, Borkman 1999, Brown & Lucksted 2010). There were concerns that potentially eligible women may be missed if midwives did not recognise women's symptoms and that the use of GAD-2 questionnaire may help to address this.

Most of the women in the feasibility study commented that providing the intervention to all pregnant women could be beneficial for women who may not have self-awareness about their symptoms or who have hidden these because of concerns regarding disclosure. However, there were concerns that inclusion of non-anxious women may have been detrimental to the dynamics of the group and would pathologise normal experiences in pregnancy. The inclusion of women who did not share a similar experience (nulliparous women with symptoms of anxiety), would undermine the peer support mechanism of the intervention where women are able to seek reassurance and support from other women in similar circumstances (Helgeson & Gottlieb 2000). This was identified by the women who participated in the study who said that sharing a common experience of anxiety and not knowing what to expect about labour and birth had helped them connect as a group.

The recruitment process involved community midwives introducing the study to potentially eligible women and conducting initial eligibility assessment. This resulted in 76% of the sample population (n= 41/54) expressing interest and agreeing to complete the GAD-2 questionnaire. The potential problems with this approach are

discussed in the following paragraphs and include the risk of introducing selection bias and variation in the way the study was introduced.

The findings of the feasibility study revealed that the women wanted the intervention to be offered to them by their midwife. Women were pleased that their midwife had identified their needs without them having to ask for help and this helped women feel assured that they would be suitable. However, it is of interest that the women in the study perceived that they had been specifically selected to take part which raises questions about selection bias and the midwives' state of equipoise. It is possible that the midwives were more persuasive in encouraging women to participate if they felt particular women were more suitable or would benefit (Street & Luoma 2002; Stuart et al. 2015). However, some women would be missed if they did not reveal their true feelings or the midwives did not have the skills to recognise their symptoms.

Gatekeeping

'Gatekeeping' has been described as the process by which an individual's capacity to be invited into a research project, or to make an informed decision regarding research participation, is inhibited by others (Hudson et al. 2005). Access to mental health services can depend on value judgements made by HCPs as to which individuals they feel are more deserving (Hughes & Griffiths 1997; McEvoy & Richards 2007). Levy (2006) reported that midwives acted as gatekeepers, releasing information to guide women towards courses of action that midwives perceived as safe and relevant to women's circumstances. Midwives avoided giving women information which they considered would cause undue worry but also as a way to protect themselves from getting into difficult situations (Levy 2006). Value judgements of HCPs can also determine whether approval is given to a researcher to contact an individual to participate in a research study, for example:

- Perceptions of an individual's medical and psychosocial characteristics
- Judgements about the suitability of an individual to participate in a research study
- HCP's own personal biases and treatment preferences
- Protecting individuals from the perceived burden of research participation which they feel would offer no or little benefit

(Gurwitz et al. 2001, Borschmann et al. 2014, Stuart et al. 2015, Tromp & Vathorst 2015)

Strategies such as effective communication with HCP's about the purpose of the study (Borschmann et al. 2014) and having research staff on-site (such as CRN midwives) to support care providers can improve recruitment into a trial. Gatekeeping can be eliminated if the researcher can have direct access to participants (e.g. in waiting rooms). This can also improve recruitment into studies by enabling individuals to "see that research has a friendly face" (Borschmann et al. 2014, page 10). However, this approach can compromise participant confidentiality as potential research participants are often regarded as vulnerable. NHS ethical approval for a study often requires the researcher to access potential participants through their main care providers (Patterson et al. 2011).

In the feasibility study, the researcher felt that access to the sample was not restricted by the community midwives and this may have been due to prolonged engagement with the teams: regularly attending team meetings and being on-site during the recruitment phase to support community midwives. This enabled the midwives to ask questions about the study and for the researcher to reinforce the recruitment and eligibility assessment processes. The researcher was also a clinical midwife working at the NHS Trust which hosted the study. The familiarity of the researcher as a colleague may have helped secure access to the sample population. This approach needs to be considered in a future pilot trial as it would not be possible to

achieve the same level of involvement in a larger study. Accessing support from CRN midwives, developing recruiter training materials and enhanced study promotion using various media forms should be considered (Frew et al. 2014).

7.2.2 Eligibility screening

Recruitment into studies can be enhanced when eligibility assessments utilise methods which are used in routine clinical practice (Borschmann et al. 2014). With recommendations for midwives to complete routine assessment of anxiety symptoms in pregnancy (NICE 2014), they should become more experienced in administering psychological screening measures and develop better ways to communicate the purpose of screening. Current clinical recommendations provide little guidance surrounding either the use of screening tools or the context for psychological screening. Therefore, in a future pilot trial, brief training materials to support midwives in communicating and administering the GAD-2 scale could enhance recruitment into the study and improve the acceptability of eligibility screening measures.

This study and previous research has identified limitations to applying psychological assessment criteria. Women may not fully acknowledge their level of anxiety, avoid disclosing the symptoms as a way of coping and have concerns about the consequences of disclosure (Côté-Arsenault & Donato 2011, Darwin et al. 2013). It can be seen as unethical to identify anxiety and depression symptoms without providing women with timely access to supportive services (Evans et al. 2016, IAPT 2013, Kopelman et al. 2008, NICE 2007).

The stigma of mental health concerns, lack of trust about the nature of the research, concerns about confidentiality and reluctance to accept a mental health diagnosis have been reported as barriers to participation in mental health research (Woodall et al. 2010). Individuals can minimise their responses to assessment

questionnaires to avoid a mental illness diagnosis (Gerald & George 2010). In pregnancy and the postnatal period, women worry about the consequences of disclosing anxiety or depression symptoms which they fear could result in being referred to children's social care services due to HCPs child protection concerns (Russell et al. 2013). Two of the women in the feasibility study revealed similar concerns about providing honest answers to the self-report anxiety questionnaires. Pregnant women may also be reluctant to disclose mental health concerns because of the pressure to conform to social norms which portray pregnancy as a time of joy, especially when their true feelings are inconsistent with their expectations of pregnancy (Biaggi et al. 2016, Evans et al. 2016).

During the initial stages of the development of the intervention, the study advisory group highlighted that the way the study was introduced to pregnant women would need careful consideration. Phrases that normalise symptoms of anxiety may be reassuring to women, such as: "In pregnancy there can be lots of things to think about and things that feel out of your control which can cause women to feel anxious". Vieten & Astin (2008) reported an increase in uptake to their study when they amended their study literature to present the intervention as helping women cope with stress and difficult moods rather than requiring women to identify themselves as being anxious. The NIHR have produced guidance to indicate how service user involvement can improve the quality and relevance of research studies and strengthen research ethics committee submissions (INVOLVE 2009; INVOLVE 2012). Although the views of the advisory group and service users were considered when developing the information materials, in a future trial, service users should be more involved in the development, writing and reviewing of study materials to improve the clarity and acceptability of the literature.

Diversity of participants

Minority ethnic groups are often under-represented in health research, which could limit the generalisability of research findings (Sheikh et al. 2009). Cultural barriers to research participation can have an impact on ethnic minority groups due to the stigma associated with mental health. Individuals from ethnic minority groups can experience racial discrimination outside and within mental health services in addition to the public and internalised stigma of mental health concerns (Gary 2005). In addition, research studies will have increased costs of translating research materials and providing interpreters to meet the language needs of diverse ethnic groups (Sheikh et al. 2009, Woodall et al. 2010). A larger study would need to consider the cultural appropriateness of the intervention and recruitment strategies for minority ethnic groups of women to improve the reach of the intervention across diverse cultural groups. Service users, local healthcare and community groups should be involved in designing the protocol and materials for cultural relevancy and in promoting the study in ethnically different communities (Borrelli 2011, Craig et al. 2006, Sheikh et al. 2009).

7.2.3 Prevalence of anxiety symptoms

In the feasibility study, from the 41 of 54 eligible women who expressed an interest in the study, 19% (10/41) scored three or more on the GAD-2 scale. However, the prevalence of anxiety symptoms needs to be interpreted with recognition of the small sample size. The MRC advise that preliminary study results should be interpreted cautiously when making assumptions about the required sample size for a main trial as "response rates are often lower when the intervention is rolled out across a wider range of settings" (Craig et al. 2006, page 10). Other studies have reported the prevalence of anxiety disorders from 12% to 16% although studies used a variety of anxiety measures at different times in pregnancy, for example:

- Fairbrother et al. (2016) found the prevalence to be 11.7% across all trimesters of pregnancy using a diagnostic interview (SCID)
- Heron et al. (2004) found the prevalence to be 14.6% at 18 weeks of pregnancy using the Crown–Crisp experiential index (Crisp et al. 1978)
- Rubertsson et al. (2014) found the prevalence to be 15.6% at 8-12 weeks of pregnancy using the HADS-A (Zigmond & Snaith 1983)

Considerations to inform the sample size for a pilot trial will be discussed further (sections 7.5).

7.2.4 Uptake and attendance

Study objectives:

To assess women's reasons for declining participation

Barriers to recruitment

Lack of transport, financial considerations and the inconvenience of attending sessions are factors which impact on an individual's willingness to participate in mental health research (Kaminsky & Roberts 2003, Woodall et al. 2010, Zullino et al. 2003). In the UK, women have legal rights to take paid time off for antenatal care, which includes antenatal or parenting classes if they have been recommended by a doctor or midwife (UK Government Employment Rights Act 1996 section 55). However, a recent survey reported that 10% (334 / 3,245) of a sample of pregnant women said they were discouraged from attending antenatal appointments by their employer (Adams et al. 2016). Women reported negative employment experiences related to their pregnancy, such as receiving lower pay rises than their peers, a lack of promotion or training opportunities while pregnant and denied requests for flexible working. In the UK workforce, complaints about unfair treatment during pregnancy have amplified over the last decade

of economic austerity (Trade Union Congress 2015). Women working on casual contracts, women with long-term mental or physical health conditions, women from ethnic minorities and single women were more likely to report that their pregnancy had a negative impact on their job security and status (Adams et al. 2016b). Pregnant women in the US minimised the amount of time they had to miss from work for medical appointments due to fear of being devalued and discriminated against by their employer (Little et al. 2015). Other studies have reported a 'lack of time due to work commitments' is often presented as a socially acceptable excuse for non-attendance in research and suggest this may mask deeper reasons such as social disadvantage and a lack of perceived value (Attwood et al. 2016, Currie et al. 2015, Cvijovic et al. 2010). However, it should be considered that some women will be reluctant to take time from their employment to attend the groups for their own reasons. Requesting time off work could also increase women's symptoms of anxiety if they feel that such requests could have a negative impact on their employment.

To address such concerns, conducting the groups in the early evening may have increased participation and minimised the amount of time women had to take off work to attend. However, the women in the feasibility study did not reach consensus on the ideal time for the groups which may reflect the views of women in a future study. It was of interest that when asked about the timing of the groups, all the women commented with reference to their ability to attend the groups outside working hours. A possible solution for a future pilot study would be to offer alternative times of day for the groups over various study sites which all of participants could choose to access. Previous studies have identified the need to offer a choice of intervention session times to increase participation (Guardino et al. 2014, Woolhouse et al. 2014). Outlining the exact time requirements of participation

in the study information may also help improve recruitment (Attwood et al. 2016). Travel expenses to attend antenatal appointments have an important financial impact on resources in low-income households (Henderson et al. 2002). A woman's financial situation should not preclude her from having the opportunity to participate therefore a future pilot trial should reimburse any incurred costs for all participants (Frew et al. 2014).

The National Maternity Review report 'Better Births' (2016), identified the importance of delivering antenatal care in community locations to improve women's access to services. Six of the women in the study reported one reason they liked the location for the groups was that it was either close to their home or had good transport links with adequate parking facilities. During the study, three women worked in different geographical areas and the travel time from their place of work impacted on their ability to attend. In a future study, some women may prefer to attend classes which are closer to their place of employment or participate in groups offered at alternative times. It is possible that some women may also want to participate in groups outside their local community to maintain confidentiality.

7.2.5 Location of the intervention sessions

Enabling group members to support each other is a key function of peer support mechanisms (Brown & Lucksted 2010). The way in which women in the feasibility study used the time at the end of the groups to continue their conversations with each other should be fostered. A future pilot trial would provide women access to a room to continue their conversations if they wish without being in the presence of the facilitators.

7.2.6 Sessions attended and amount of exposure to the intervention

Researchers need to consider the theoretical effective dose of an intervention prior to definitive testing. The duration and frequency of intervention sessions and amount of time engaged in research activity needs to be defined in research protocols. The actual dose received can then be assessed during the study (Voils et al. 2014). The burden of participation for individuals needs to be balanced with efforts to achieve the desired outcomes. RCTs can be used to evaluate the most effective dose parameters by varying the intervention duration/frequency in different arms of the trial, for example four sessions compared to six sessions, and observing the between group difference on the primary outcome (Voils et al. 2014). Currently there are no guidelines to suggest the optimal number of sessions required to achieve reliable and clinically significant improvement rates for low intensity psychological interventions (Delgadillo et al. 2014). In the feasibility study women would have preferred more than four groups. This is further discussed in the following sections (section 7.5).

The data collection forms completed by the facilitators were effective in capturing information on attendance and amount of exposure, 'dose received'. In addition, a future pilot trial could explore the optimal dose of the intervention by using various quantitative data collection points alongside a qualitative evaluation of how women respond to the intervention as they progress through the study (Moore et al. 2014).

7.3 Intervention design

Study objective:

To determine women's views on the acceptability of the intervention.

To determine women's views on the costs, if any, they incurred.

To determine women's views on the benefit, if any, they derived.

7.3.1 Pre-group meeting

For some women, it was important that they met with the midwife in person and familiarise themselves with the location of the groups. Other women considered that a telephone call would have been sufficient. For future studies, employing a flexible approach, providing women with the choice of a face-to-face meeting or telephone conversation should be adopted.

7.3.2 Initial concerns about participating in groups

Support groups are often required when individuals are in new situations where they are uncertain about their feelings and unsure how to react. Contact with peers exposes group member to different coping strategies and enables them to validate their feelings by accessing a collective opinion (Helgeson & Gottlieb 2000). Individuals can be inspired by others (upward comparisons) or feel that others are worse off than themselves (downward comparisons) (Solomon 2004). Some of the women in the study described how they compared their symptoms of anxiety with those shared by other women. This either provided reassurance that other women had worse symptoms of anxiety or resulted in a reluctance to disclose symptoms of anxiety for women who considered themselves to be more severe than the other women in the group.

Individuals must feel able to disclose their personal feelings and circumstances in order to connect with others in the group and benefit from group support (Helgeson & Gottlieb 2000). However, an individual is at risk of having their feelings invalidated if other group members do not share their experiences or understand their situations. Previous studies have reported that during the first few sessions of group interventions, women felt uncertain about why they had been selected to participate and feared judgement or disapproval from other group members (Breustedt & Puckering 2013, Woolhouse et al. 2014). This was evident in the women's

responses about the earlier groups where women reported they found it difficult to understand other women's concerns if they were different to their own. Peer groups take time for individuals to get to know each other and have the confidence to speak openly (Helgeson & Gottlieb 2000), and by the end of the groups women in the feasibility study said that they understood each other better. It is important that a future pilot study maintains a longitudinal intervention design to enable women to fully benefit from peer support.

Women in the study described the vignettes and personal stories in the self-help workbook (Haring 2013) as useful, enabling them to compare and assess their experiences and symptoms. Good practice guidance on the use of self-help materials (IAPT 2010), highlighted that the inclusion of personal narratives in self-help materials can be beneficial. In future studies facilitators could use the workbook examples in earlier group sessions to help women contribute to discussions without feeling vulnerable about disclosing personal information.

7.3.3 Normalising women's symptoms of anxiety

Individuals develop bonds with other group members based on providing and receiving experiential knowledge of experiences and health conditions, enabling individuals to feel understood, accepted and validated in their feelings (Coatsworth-Puspoky et al. 2006, Repper & Carter 2011). Women with anxiety symptoms in pregnancy have reported that they would have welcomed the opportunity talk to other women who were going through similar experiences in pregnancy (Evans et al. 2016). They felt this would help them accept it was normal to feel anxious, and that other women understood those feelings. Most of the women in the feasibility study reported that sharing experiences with other women provided reassurance that they were not abnormal for feeling the way they did, as a result they reported feeling less isolated in their experiences during pregnancy.

Women's feelings of isolation and failure are often reported in different types of supportive interventions for pregnant and postnatal women (Dennis 2010). Women with symptoms of anxiety and depression question why their experience is different from others and feel as if they have failed to live up to the idealised societal depiction of a perfect pregnancy or a good mother (Evans et al. 2016, Highet et al. 2014, Jones et al. 2014, Rowe & Fisher 2015, Staneva et al. 2015). Peer support acknowledges that these idealised depictions do not exist and serve to help women by identifying that not being perfect is acceptable. This realisation "overcomes isolation, mediates guilt and seemingly facilitates recovery, through the realisation that the experience of being a mother is different for all women" (Jones et al. 2014, page 469).

Peer Support

Women in postnatal mental health peer group interventions have identified the benefits of being able to normalise their parenting concerns (McLeish & Redshaw 2017). This enabled them to challenge their self-perception that they were abnormal or inadequate by validating their feelings and experiences with other members. This was particularly beneficial for women "who struggled with a sense of profound failure when they compared themselves with other women who appeared to be succeeding effortlessly at motherhood" (McLeish & Redshaw 2017, Page 10). In maternity care, peer groups for breastfeeding support, antenatal care and women with PND have been reported as beneficial, enabling women to feel understood, share common experiences and challenges, reduce feelings of isolation and develop self-confidence (Andersson et al. 2012, Hoddinott et al. 2006, Letourneau et al. 2007, McLeish & Redshaw 2017).

Sharing experiences within an accepting and supportive context was identified as beneficial in the feasibility study and should be acknowledged as an essential feature in future studies. However, peer support can result in negative effects if other group members

minimise or belittle individuals problems and concerns in an attempt to normalise their own situation (Dennis 2010). The presence of a HCP to facilitate group sessions and having one-to-one support available to women can help to address individual concerns and guide group discussion and should therefore be maintained in a future pilot study.

7.3.4 Group facilitators

The key drivers in developing an intervention which could be facilitated by midwives were the recent publications highlighting the important role midwives could fulfil in supporting women's emotional wellbeing (Bauer et al. 2016, Knight et al. 2015, MMHA 2014, NICE 2014, RCM 2015). The decision that midwives should facilitate the intervention was supported by service users and advisory group members who considered it was appropriate for midwives to offer support to women with mild to moderate symptoms of anxiety. In addition, they felt women would be more likely to seek help from maternity services than mental health providers because of the stigma associated with mental illness. The feasibility study findings revealed that all the women supported the role of midwife to facilitate the intervention. They identified therapists and psychologists as alternative intervention providers/therapists but felt they would not have been as suitable as the midwife was able to offer information and advice focused on their anxieties about pregnancy. The role of facilitator was also acceptable to the midwives and MSWs who described participating in the intervention as enjoyable and rewarding.

The interchangeable role of help-provider and help-seeker which underpin social support theory aims to empower individuals to move forward from being passive receivers of care (Finfgeld-Connett 2005, Brown & Lucksted 2010). It could be argued that having a midwife as the group facilitator could counteract this mechanism. Repper & Carter (2011, page 395) state "reciprocity is integral to the process of peer-to-peer support as distinct from expert worker

support", based on experience rather than professional expertise to develop equal reciprocal relationships. The role of the professional in peer groups should not interfere with the potential benefits derived when group members help others in the group (Brown & Lucksted 2010). Many self-help groups include a degree of professional involvement which can be effective as long as professionals do not dominate the functioning, goals, and direction of the group (Solomon 2004). In maternity care, the role of the HCP in breastfeeding support groups has been reported to "normalise or counteract extreme views and help women to distinguish between fact, anecdote and myth" (Hoddinott et al. 2006, page 143). This resonates with the feedback from the women in the groups who trusted the midwives' experience and knowledge of pregnancy and birth.

Facilitators in the study reported how they enabled peer-support mechanisms by joining in rather than leading discussions and helping women introduce discussion topics they found difficult to introduce themselves. In a group based antenatal care study (Andersson et al. 2012), women welcomed midwives who were less structured in their approach to facilitating group sessions. They appreciated midwives contributing their expertise in antenatal care and helping to address topics women found difficult to introduce. In future studies, facilitator training should continue to emphasise the role of the facilitator in supporting peer support mechanisms. However, to maximise the benefit of social learning mechanisms (Repper & Carter 2011), women may benefit from hearing the experiences of other women who have been through similar experiences who can share their success stories and inspire hope (Davidson et al. 2012, Miyamoto & Sono 2012, Repper & Carter 2011).

Peer support volunteers

The MSW co-facilitator was acceptable to the women and the MSWs in the feasibility study and will be maintained in a future pilot trial.

However further feasibility studies could evaluate the potential role of a peer support volunteer to co-facilitate groups. Peer support volunteers can act as liaisons between the staff and individuals, demonstrating the abilities of individuals with anxiety disorders and breaking down stigmas (Gates & Akabas 2007). However, there may be boundary issues as peer support volunteers may feel that taking on a more coordinating role conflicts with their unique perspectives as consumers of care (Moll et al. 2009). Peer support volunteers are often asked to disclose personal experiences in order to help others, therefore it is important they receive adequate mental health support, professional supervision and training (Davidson et al. 2012; Repper & Carter 2011). Peer supporter volunteers and professional staff have reported ambiguity about the role of peer support volunteer and clear role descriptions needed to be defined and communicated (Miyamoto & Sono 2012). Further preliminary testing would be required to explore the acceptability and feasibility of a peer support volunteer co-facilitating the intervention alongside a midwife facilitator. Support from perinatal mental health services and peer educators would be required to assist with recruitment and training of peer support volunteers and to develop programmes of supervision programmes.

7.3.5 Continuing and ending the groups

Several recent studies have identified that ending group interventions can be challenging, especially when the support is offered during an emotionally intense life transition such as during pregnancy (McLeish & Redshaw 2017, Spiby et al. 2015). Volunteer doulas during pregnancy and birth and reported that women felt a sense of loss when the intervention had come to an end (Spiby et al. 2015). Although doulas understood the need to end the period of support, to hand over to further supportive services and allow doulas to support other women, they felt the ending caused tension with the women. Strategies for ending the period of support were suggested which included arranging informal catch-ups or the

opportunity for doulas to receive an update from the women about the family's progress (Spiby et al. 2015). McLeish & Redshaw (2017) reported that peer support volunteers providing emotional support for pregnant women often remained informally in contact with the women after the end of the study which for some women had evolved into an enduring friendship.

All of the women in the feasibility study wanted more than four group sessions and suggested groups should continue until the birth of their baby or into the postnatal period. Three women indicated that further sessions would not need to be as structured and suggested a reduced role for the facilitator. It would be possible to provide further group sessions with a reduced role of the facilitator who could contribute by organising the group timetables and be contactable if further support was required. The women were on average 27 weeks of pregnancy on completion of the study (SD 1.9), therefore an additional 2-3 groups could be scheduled for women to access in pregnancy. However, a formal ending to the groups would need to be acknowledged at some stage. Although not part of the formal data collection, since the end of the study one midwife facilitator has reported that she has maintained contact through a social media group which was initiated by the women. One MSW discussed this with her supervisor and decided not to participate as this could have resulted in her feeling over-burdened. Potential challenges in managing the ending of the groups was not anticipated during the planning of the study and therefore not addressed in the training. Future studies need to identify strategies to help facilitators effectively end the groups. This should draw on the findings of the existing research and may include facilitators helping women identify ways they can maintain the groups themselves if they wish and highlight the positive and negative aspects of facilitators maintaining informal contact.

7.3.6 Individual support

Most women who accessed individual support from midwives and MSWs chose to speak before the groups to ask advice before they raised discussion topics. The facilitators felt it was more discreet for the women to seek support before the sessions and that women often chose to speak to each other after the groups. In future studies, a more flexible approach to the accessibility of individual support will be outlined, offering women time before and/or after the groups and enabling the women to continue their discussions with each other at the end.

Some of the women identified that they had sought reassurance from the midwife about the minor symptoms of pregnancy and asked the midwife to explain certain test results. In order to support the women with their individual concerns, one midwife felt she could have provided the women with more individual advice if she had access to the women's pregnancy notes. This may reflect the midwife's approach to care in her day-to-day role, making clinical decisions and providing specific guidance based on the woman's individual circumstances. However, none of the women reported that they required specific advice and all women were positive about the role of the midwife in the study.

In the design stage of the intervention, the service user group consultation suggested that the women's community midwife would be the ideal facilitator for the intervention as this would promote continuity. Although the intervention did not enhance women's 'continuity of carer' in relation to their overall maternity care (Biró et al. 2003, Page 2003, Macpherson et al. 2016), the continuity the women received from facilitators appeared to meet their needs. Future models of midwifery care as outlined in 'Better Births' (National Maternity Review 2016) set out to improve continuity through structuring maternity care via small teams of midwives who provide care for local women. It is important to consider how the intervention would perform within this care structure. In future

studies, as well as continuing the provision of local group settings, it may be possible for one member of a community team to facilitate groups to enhance the benefits associated with improved continuity of carer (Burge et al. 2011, Sandall et al. 2016, Wierdsma et al. 2009).

7.3.7 Self-help resources

In a future pilot study, women should be presented with a choice of resources to access as this was supported by the women and facilitators in the feasibility study. However, the amount of resources was described as overwhelming by the facilitators who suggested the amount of resources could be paired down. The women used and favoured the resources which were specific to pregnancy, identifying the workbook (Haring et al. 2013) and pregnancy related 'apps' (Beyond Blue & Smiling Mind 2016) as beneficial. It is therefore important that these two resources are further evaluated in pilot testing.

7.3.8 Developing the intervention for different groups of women

Research has highlighted the association between anxiety symptoms in pregnant women with a history of pregnancy loss (Ali et al. 2012, Gong et al. 2013, Chojenta et al. 2014, Armstrong & Hutti 1998, Bergner et al. 2008, Fisher et al. 2013). However the role of parity on the risk of developing symptoms of anxiety in pregnancy is ambiguous, receiving very little research attention (Biaggi et al. 2016). One study reported that nulliparous women are more at risk than multiparous women (women who have had at least one previous birth) (Ali et al. 2012), while other studies report no significant association between parity and antenatal anxiety symptoms (Faisal-Cury & Rossi Menezes 2007, Glazier et al. 2004). To amend the intervention for multiparous women it is anticipated that a similar format to the nulliparous groups would be designed. The main reason for restricting participation to nulliparous women

for the feasibility study was based on an assumption that multiparous women may want to discuss their previous birth experiences during the groups which may provide some comfort to nulliparous women but also had the potential to cause distress. Although this assumption was supported by the advisory and service user groups and in the feasibility study findings, there is little existing evidence to support this view.

Although multiparous women with symptoms of anxiety may have had previous positive experiences of pregnancy and birth, it has to be considered that some of the women may report a negative or traumatic previous birth experience. Qualitative studies highlight that women who are pregnant following a previous traumatic birth experience symptoms of fear, panic and anxiety which can continue and escalate in pregnancy (Beck & Watson 2010, Fenech et al. 2014). Individual support from midwives has been identified as therapeutic and beneficial in helping women to gain an understanding about their previous experiences; cope with uncertainty about their forthcoming birth; or to develop birth plans to help them feel more in control during labour (Thomson & Downe 2010; Beck & Watson 2010). Although no studies have evaluated group or peer support interventions for pregnant women with previous traumatic birth experiences, qualitative studies have reported that women benefit from having their stories listened to and validated by HCPs. Validation accessed through sharing similar experiences is the core theoretical construct underlying peer support (McLeish & Redshaw 2017). Therefore, a group intervention may be of potential benefit for multiparous women with previous traumatic birth experiences. However, the acceptability of the intervention would need to be explored in a feasibility study for this target group prior to further testing.

7.4 Data collection

7.4.1 Qualitative evaluation

Study objective:

To determine women's views on the acceptability of the intervention.

To determine intervention facilitators' views on the delivery of the intervention

Feasibility studies are used to increase the chances of developing and evaluating the optimum intervention design using the most appropriate and efficient methods (O'Cathain et al. 2007).

Qualitative methods used alongside quantitative methods monitor the acceptability and feasibility of complex interventions prior to definitive testing to understand the mechanisms which bring about change (Craig et al. 2006, Lewin et al. 2009). The qualitative data in the feasibility study enabled a deeper understanding of how the intervention functioned, which was then compared to findings from existing studies of antenatal anxiety interventions and to the underlying theory. Qualitative interviews identified areas of the study which would not have been revealed through quantitative methods. These include: women's motivations for and barriers to participation which has identified where future improvements to recruitment strategies can be made; women's feedback on the intervention delivery which has helped to develop an understanding of the role of the midwife to promote peer support mechanisms; the changing support needs of the women as they progress through the intervention, helping to identify how groups may progress to become self-supporting.

The use of template analysis assisted in identifying common themes as they emerged while concurrently exploring the data in relation to a priori assumptions informed from the existing research. This explored the a priori assumption that peer support could be beneficial for women with anxiety symptoms in pregnancy and

revealed the reasons as to why group interventions take time to establish and produce benefits for the women.

Qualitative research within RCTs tends to focus on the intervention group (IG) but can also help to understand the control group (CG) such as the acceptability of random allocation to a CG, how the trial may change or influence usual care provision, and explore the provision of usual care across different contexts (O’Cathain et al. 2007). Differences within and between the intervention and control group will have implications for the effectiveness of the intervention, such as provider effect and usual care provision in different NHS trusts. These factors may impact the transferability of findings to other contexts (O’Cathain et al. 2007).

Qualitative data in process evaluations

Qualitative methods are also used in RCTs as part of process evaluations and fidelity monitoring (Lewin et al. 2009). For complex interventions, qualitative data can help explain the function of the intervention in different contexts, which is especially important in cluster or pragmatic trials which are evaluated across routine clinical settings. Developing an explanation of why particular outcomes occurred in a trial will help future researchers understand the generalisability of the intervention in different settings (Lewin et al. 2009, Moore et al. 2014, Oakley et al. 2006).

Process evaluations need to be fully integrated into a trial design, process data collection methods and research questions should be specified prospectively and include a strategy for integrating the process and outcome data (Oakley et al. 2006). However, qualitative approaches are often poorly reported alongside RCTs which can be enhanced by the use of process evaluation frameworks and checklists (Moore et al. 2015, Tong et al. 2007). The qualitative data collection and analysis in the feasibility study were time-consuming activities. For a future pilot study, adequate time, resources and expertise required to conduct a qualitative evaluation

of the intervention process and outcomes will need to be included in the research protocol.

7.4.2 Quantitative outcome measures

Study objective:

To calculate the acceptability of self-report outcome measures

Overall, the anxiety and depression self-report questionnaires were acceptable to the women in the feasibility study. The quality of life measure, SF-12 (Ware et al. 1996) received the most negative feedback as it did not feel relevant to women's experiences or concerns in pregnancy. For future studies, a quality of life measure which has been specifically designed and validated for use in pregnancy should be evaluated (Morrell et al. 2013). The GAD-2, GAD-7 (Spitzer et al. 2006) and Edinburgh Postnatal Depression Scale (Cox et al. 1987) are suitable for use in antenatal care (NICE 2014), therefore midwives may be more familiar with the administration process and scoring methods for these measures. This would facilitate the community midwives' undertaking eligibility screening in a future pilot trial. The STAI (Spielberg et al. 1970) would be useful to include as an outcome measure as it has been more widely validated in pregnancy compared to other anxiety measures (Evans et al. 2015). Most of the studies in the SR included the STAI as an outcome measure for anxiety and therefore it would facilitate the pooling of outcomes into future meta-analysis. Most women in the feasibility study reported the PRAQ (Huizink et al. 2004) represented their anxieties in pregnancy and other women have found the PRAQ helpful to voice their concerns (Evans et al. 2016). Therefore, the PRAQ should be specified as an outcome measure in future studies.

Responder bias

Discussing mental health can be a sensitive topic during pregnancy and women's reluctance to disclose their symptoms has been discussed in previous sections of this chapter. In psychological and

behavioural research 'demand characteristics' may influence how participants behave and self-report their experiences (McCambridge et al. 2012). Although this type of bias is considered to impact on behavioural research studies, there is very little research studying the effect of demand characteristics (McCambridge et al. 2012, Orne & Whitehouse 2000).

Social desirability bias is the effort made by participants to present a good image of themselves (Bowling 2005). This can result in the over-reporting of desirable behaviours, and under-reporting of undesirable behaviours, "confounding associations between variables by attenuating, inflating or moderating relationships" (Bowling 2005, page 285). Social desirability bias has been considered as a potential source of bias in PND studies as women may not disclose their true symptoms because of the pressure to conform to social or cultural norms of being a 'good mother' (Chi et al. 2016, Rich-Edwards 2006). Social desirability bias can be reduced by providing responders with assurances of confidentiality and anonymity and enabling questionnaires to be administered without the need for interaction with the researcher (Bowling 2005, Evans et al. 2004, Heerwegh 2009). For a future pilot study of the intervention, women could complete the self-report measures in their own time and send the completed forms via the post rather than hand them directly to the researcher. Data collection methods could be evaluated in a future pilot study by reporting the response rates and levels of completion of the questionnaires.

7.4.3 Economic evaluation

Economic evaluations (EE) are conducted to provide evidence on clinical and economic outcomes to inform decisions about clinical practices and health care resource allocations (McIntosh & Luengo-Fernandez 2006). While the design of an EE of the intervention was beyond the scope of this study, testing the data collection methods to use in a future EE should be explored in the pilot study. There are various analytic techniques used for EE in healthcare including:

cost-benefit analysis, cost-effectiveness analysis, cost-utility analysis and cost-consequences analysis. For mental health interventions, a cost-utility analysis (CUA) is widely used as it considers broad measures of wellbeing (Luyten et al. 2016). A primary outcome measure used in CUA are quality-adjusted life-years (QALYs), which measure health as a combination of the duration of life and the health-related quality of life. CUAs evaluate the cost per QALY which is the difference in the expected cost of two interventions, divided by the difference in the expected QALYs produced by the two interventions (McCabe 2009). This allows comparisons to be made across different health care interventions in different clinical areas (McIntosh & Luengo-Fernandez 2006). QALYs are normally calculated using health status instruments such as the EQ-5D or the SF-6D (McCabe 2009). However, it can be difficult to meaningfully quantify very specific health effects (e.g. anxiety symptom severity) into broad and generic outcome measures (i.e. QALYs) and difficult to capture the value that society attaches to healthcare interventions (Luyten et al. 2016, McCabe 2009). The results of a CUA are often compared with incremental cost-effectiveness ratio (ICER) thresholds. The threshold ICER is the 'willingness to pay' for health gain, which is designed to reflect differences in the value society attaches to health gain depending on the characteristics of the individuals who receive it (McCabe 2009). For the intervention, data to inform a CUA may include calculating/evaluating:

- Direct costs: midwives' and MSW facilitator costs, costs of training, resources and facilities.
- Indirect / societal costs: opportunity costs of women, for example losing working time by being unwell verses participating in an intervention. This may also include service costs for women in both intervention and control groups (additional appointments with midwives, obstetricians, GPs, mental health services)

- Patient costs: borne by patients (women) and their families and include transport costs, out of pocket expenses
- Future costs: costs that are directly related to the condition (e.g. increased risk of developing PND or adverse infant outcomes) (Luyten et al. 2016)

Testing data collection methods for a future EE requires further consideration and expert advice prior to pilot testing.

7.5 Study design for a future pilot trial and main trial

Study objective

- *To produce a report of the findings and a protocol for testing the new intervention in a pilot trial*

7.5.1 Study manual

To maximise the consistency of an intervention study, all of the components and processes need to be planned, operationalised and described in the study manual (Ruggeri et al. 2013). However, Hawe et al. (2004) discussed that the current view about the level of standardisation required to conduct RCTs was “at odds with the notion of complex interventions” (Hawe et al. 2004, page 328). For complex interventions to be adapted for different contexts, the crucial question is what should be standardised. Process evaluations set out to describe and define individual components and processes within an intervention, whereas what should be defined are the mechanisms and functions of components (Hawe et al. 2004).

Defining the potentially beneficial mechanisms within interventions will result in an intervention which can be flexible to different contexts while achieving the same objective. Whereas process fidelity defines and describes the skills and strategies employed by the intervention facilitators which are required to support the function of the intervention, content fidelity aims to standardise the

intervention delivery in terms of the duration, frequency and resources (Novick et al 2013). Interventions which adhere more closely to the underpinning theory have reported larger treatment effects (Novick 2013, Resnick et al. 2005). Study protocols should answer the question 'What must be maintained to achieve fidelity and effectiveness for the participants' (Chorpita & Daleiden 2009; Chorpita et al. 2007). Ensuring facilitators adhere to the theory underpinning intervention components will enable a degree of flexibility of the delivery and techniques (Forehand et al. 2010). Evaluating the level of standardisation and potential flexibility of an intervention are included as components in the Structured Assessment of Feasibility (SAFE) guidelines. SAFE guidelines are used to assess the feasibility of implementing a complex intervention within NHS mental health (Bird et al. 2014). Incorporating SAFE ratings into studies of interventions ensures researchers acknowledge aspects that might hamper or facilitate successful implementation in practice (van der Krieke et al. 2015).

Future studies of the intervention would need to be conducted in a variety of settings and delivered to women with different characteristics. Therefore, identifying the process and functions of components would help to achieve the study objectives while enabling flexibility within different contexts. Table 7.1 outlines the components, functions and training requirements of each component of the intervention, providing useful information for developing a future study protocol and study manual.

Table 7.1 Standardising the form and function of the intervention components (based on Hawe et al 2004)			
	Types of standardisation		Training standards
Principle of the intervention	By component	By function	Skills and awareness
To provide access to individual support for pregnant women with symptoms of mild to moderate anxiety	<p>Facilitate individual time for women to speak with the facilitator. Access to a private room away from the groups. Provide information about further supportive services which women can access.</p> <p>Document the number of women accessing individual support and summarise any further actions.</p>	Promote a safe supportive environment where women feel confident to discuss their concerns.	Develop skills in fostering therapeutic and collaborative relationships. Acknowledge that women may have concerns about disclosing their symptoms. Identify ways to support women to disclose their symptoms and seek support. Discussing the importance of working within professional guidelines and identify other supporting services and referral pathways.
To enable pregnant women to provide and receive peer support and build social support networks	<p>Hold four group meetings, one every 2-weeks. Midwife and MSW facilitators work in collaboration with women to develop group agendas and ground rules.</p> <p>Document attendance and summarise the topics of conversation.</p>	Promote a safe supportive environment where women can talk about topics important to them. Encourage women to share experiences and offer and receive support from other group members.	Develop an understanding of the beneficial mechanisms which underpin peer support: experiential knowledge, social learning and comparison, help-seeker / help-provider. Explore the role of the facilitator in peer groups through active learning approaches. Work within professional guidelines. Develop strategies for formally ending groups.
To guide women in accessing and completing self-help resources to improve their symptoms of anxiety	Facilitators to provide an overview of the self-help resources and encourage women to feedback about their progress with the resources.	Self-help resources can help develop coping mechanisms for symptoms of anxiety. Women should be offered a choice of approaches and formats.	During the training, facilitators will familiarise themselves with the self-help material and acknowledge the mechanisms which underpin each resource (relaxation, mind-body and cognitive behavioural approaches)

7.5.2 Random allocation

In a future study, the intervention should be piloted and tested in a RCT. RCTs are recognised as providing the definitive method of ascertaining treatment effects (Howard & Thornicroft 2006), with random assignment of participants to intervention and control arms acknowledged as the 'gold standard' for clinical studies (Corrigan & Salzer 2003). Randomisation minimises systematic factors differentiating treatment groups which may explain the observed between-group differences in outcomes (Sibbald & Roland 1998). Clinical equipoise is when there is no agreement within the research and clinical community as to the preferred treatment or the effectiveness of the intervention being compared with usual activities (Binik et al. 2011). The SR highlighted the lack of evidence to support the effectiveness of interventions to improve symptoms of anxiety in pregnancy, therefore the principle of clinical equipoise could be used to justify the process of random allocation of women into an IG and CG in future trials. Previous studies have highlighted concerns regarding an individual's understanding and acceptance of random allocation which can impact on the ethical principle of attaining informed consent (Skingley et al. 2014, Busby-Grant et al. 2009). Participants express doubts about the possibility of equipoise and remain convinced that they will be given the best possible treatment (Wade et al. 2017, Robinson et al. 2005, Kerr 2004).

Women in the feasibility study required additional explanation from the researcher about the meaning of random allocation and what this would imply for them. Only five women (50%) would have been happy to continue in the study if they had been assigned to a CG. Previous studies have reported participants' feelings of resentful demoralisation when allocated to a CG which is associated with higher rates of attrition (Lindström et al. 2010, Petersen et al. 2015, Skingley et al. 2014, Corrigan & Salzer 2003, Howard & Thornicroft 2006).

The altruistic act of participating in RCTs, and the willingness to help others in the future, can be a major driver for potential participants and should be identified in the participant literature and discussions in a future pilot trial (Robinson et al. 2005, Jenkins et al. 2013). Providing combinations of written and oral information about the reasons for randomisation and helping participants to reflect on the aim of study can also be beneficial and will be included in the study literature (Robinson et al. 2005).

7.5.3 Control groups

RCTs of complex interventions can be undermined by a neglect by researchers to model for the influences of potential mediators or confounders (e.g. the effect of undertaking eligibility screening, receiving attention from researchers) and moderators (baseline characteristics such as level of family support) (Ruggeri et al. 2013). The use of a CG to address the effect of potential confounding variables provide greater confidence that the intervention mechanisms are responsible for any observed difference between the IG and CG (Street & Luoma 2002). Control groups help to determine whether the effects of an intervention exceed the effects of nonspecific factors. Nonspecific factors include processes that are presumed to underpin numerous therapeutic approaches such as relational continuity and therapeutic alliance (Safer & Hugo 2006).

Control groups are also used to “ascertain that changes in outcome are not caused primarily by patient expectancies about getting well or beliefs about the treatment for a particular problem” (Street & Luoma 2002, page 7). This may include a woman’s motivation to improve her symptoms of anxiety, the credibility of the intervention and the woman’s preference for one type of intervention over another. These factors can affect how well an individual will respond to the intervention being tested, regardless of the specific components (Street & Luoma 2002). The paragraphs below consider the strengths and limitations of various control group designs for a future pilot trial and main trial.

Waiting list control groups

Waiting list controlled studies randomise participants to either receive the intervention immediately or after some time delay during which participants receive usual care. This design enables the researcher to recruit participants with the guarantee of receiving the experimental intervention. However, this type of design is generally viewed as weak (Lindquist et al. 2007). The guarantee of receiving the experimental intervention may infer that the researchers are not in equipoise about the intervention. Another problem with this type of non-treatment control may occur if an individual is assigned to a waiting list for several months and during this time receives other treatments or interventions from which they may benefit. In addition, asking individuals who have a condition for which there are effective treatments, to go for a period of time without receiving treatment or receiving usual care, may result in suffering and harm for the individual (Lindquist et al. 2007). This design is especially unsuitable for research including childbearing women due to the need to complete participation before the end of the antenatal period and because of women's changing support needs during pregnancy.

Non-specific control groups

RCTs designed with a non-specific control aim to balance as many nonspecific factors across the intervention and control groups as possible. Non-specific control interventions may comprise patient education about a disorder or aspects of the intervention not thought to be associated with the therapeutic outcomes. Control group designs reported in ten studies in the SR (n=25) used a placebo or non-specific control group, including: antenatal classes; educational material; passive relaxation or sham acupuncture / acupressure. Criticisms of non-specific control interventions highlight that it is not possible to balance all common and non-specific factors across the experimental and control groups and it can be very difficult to separate the specific and non-specific effects of a

complex intervention (Lindquist et al. 2007, Paterson & Dieppe 2005).

Component control designs

A component control design involves breaking an intervention into its various components, for example, individual support, group support and assisted self-help. The aim is to attempt to isolate the essential active mechanisms of action (Lindquist et al. 2007). The MRC highlight that once the effectiveness of an intervention has been established further studies should aim to fine-tune the intervention, or deliver it more efficiently. This can be approached by “allowing one key element of the intervention to vary, while balancing the other elements between arms of a trial” (Craig et al. 2006, page 7). It is acknowledged that intervention facilitators may have treatment preferences or be more skilled in delivering certain components of interventions which needs to be considered when undertaking component control designs (Street & Luoma 2002).

Treatment as usual

To evaluate the effectiveness of an intervention (whether the intervention works in everyday practice), the appropriate comparison will usually be with treatment as usual (TAU) control groups (Craig et al. 2006). It can be difficult to define TAU across larger maternity care trials as the constituents of usual antenatal care may vary across settings. For example, emotional or social support interventions may be available in one setting as part of standard care but not in another. This may be addressed in smaller trials through the process of minimisation, where groups can be balanced on certain characteristics considered important to the trial (Altman & Bland 2005).

Fourteen studies (n=25) included in the SR comprised trials with a TAU control group, however none of the studies reported sufficient details of what ‘standard antenatal care’ involved. A future pilot trial, employing a TAU control group would follow the CONSORT

checklist recommendations which state that authors should describe the constituents of TAU in sufficient detail to allow future researchers to know how to administer the intervention as evaluated (Schulz et al. 2010; Mayo-Wilson et al. 2013). Participants in the TAU group will usually have contact with researchers which may have some additional therapeutic benefits. The amount and nature of researcher contact with the control group needs to be described when analysing the difference in outcomes between the IG and CG (Lindquist et al. 2007; Schwartz & Ph 2012).

Improving Access to Psychological Therapies (IAPT) services are becoming more widely available in the UK for pregnant women with mild to moderate mental health concerns. Depending on the availability of IAPT services at the time of the pilot study it may be useful to compare the intervention with perinatal IAPT services, particularly if IAPT services become the accepted 'standard treatment' for pregnant women with mild to moderate anxiety. The mental health taskforce report for NHS England (2016) has set a target to provide at least 30,000 more women with access to evidence-based psychological therapies by 2020/21. However, currently there is considerable variation in IAPT service provision and availability in the UK (Independent Mental Health Taskforce 2016) and IAPT services have not yet been tailored or evaluated for pregnant women with anxiety.

7.5.4 Pragmatic and cluster trials

The MRC (Craig et al. 2006) identified that the contamination of the CG, leading to biased estimates of effect size, is often cited as a drawback of RCTs of population level interventions. For example, midwives working within the study setting who have been trained to facilitate the intervention cannot be expected to ignore the supportive techniques they have learned when they provide care to women in the CG. One possible solution is to conduct a cluster randomised trial where, for example, women are allocated into groups based on their location or care provider (clusters). The

groups or clusters are randomly assigned to the experimental or a control intervention. Although cluster random allocation can help to avoid contamination of care providers, it also has limitations (Ryan et al. 2013). Individuals within any one cluster are likely to be more alike than those across clusters and therefore it is difficult to determine whether the results are due to baseline differences between clusters, rather than to the intervention itself. Therefore, cluster trials require larger sample sizes than individual RCTs “to adjust for the clustering effect, and the analysis should be undertaken at the cluster level and using specific analytic techniques” (Ryan et al. 2013, page 23).

The conduct of conventional RCTs has been criticised for disrupting clinical-decision making and engagement with patients. Results are often considered by clinicians as inapplicable or irrelevant to real clinical practice because the trials are conducted on selective participants within tightly controlled settings (Dunn 2013, Ruggeri et al. 2013, Schwartz & Lellouch 1967). Pragmatic trials offer a compromise between observational studies (with good external validity but compromised internal validity) and conventional RCTs (with good internal validity but compromised external validity) (Ruggeri et al. 2013). Pragmatic designs evaluate intervention effectiveness in as realistic circumstances as possible (heterogeneity among trial participants and heterogeneity in the way the intervention is delivered). This aims to improve the external validity of the findings which are considered generalisable to other populations and settings represented in the study population. Many pragmatic trials are cluster trials as they do not aim to test interventions under ideal conditions and often use natural clusters of participants within real world settings (Eldridge & Kerry 2012).

A pragmatic cluster trial has the potential to address many of the methodological challenges for evaluating the intervention in a future pilot trial (minimising contamination of the usual care provider and demoralisation of the CG) (Donner & Klar 2000). However, RCTs of

psychological interventions in real-world healthcare settings are challenged by the complexity and heterogeneity of healthcare provision (Harvey et al. 2011).

7.5.5 Intervention fidelity

Ensuring participants receive the full intervention as planned will optimise the statistical power of the study (Resnick et al. 2005). If a study deviates from the stated protocol, then the internal validity will be compromised as the results may be due to variations in the implementation of the intervention. The external validity would also be threatened as it would be impossible to replicate the study if 1. the facilitator training and 2. the implementation of the intervention is not standardised and adhered to (Resnick et al. 2005).

Fidelity monitoring of complex interventions is used to form an outcomes assessment of the study which can provide a transparent report to help other researchers to replicate the trial. Gold standard fidelity monitoring strategies including audiotape or videotape analysis and professional supervision can be challenging to implement, costly and not appropriate for all types of interventions (Bellg et al. 2004). Audio and video recording can also be intrusive and may affect the dynamics of group interventions (Borrelli 2011).

Less costly approaches can include participant questionnaires; facilitators self-administered checklists and observations; facilitator and participant interviews. However self-regulatory frameworks can be less reliable and have low correlations with other objective measures (Borrelli 2011). Previous studies of complex interventions have used a combination of observational (i.e. non-participant observation, video and audio recording) and self-report methods (surveys, diaries, qualitative interviews) as part of fidelity assessment strategies (Ruggeri et al. 2013, Spillane et al. 2007). Mars et al. (2013) developed fidelity evaluation criteria based on: 1. adherence to key intervention components; 2. competence of facilitators to create a supportive group environment; 3. the extent

to which the aims and objectives were achieved. The researchers reported practical and methodological difficulties in measuring subjective concepts. For example, facilitators did not always deliver the prescribed components, yet positively responded to emerging situations and achieved the overall aims and objectives. Mars et al. (2013) recommended that adherence and competence criteria should be based on the theoretical underpinnings and overall aims of the intervention. This enables fidelity assessment tools to be developed which are sensitive to the complexity of the underlying theory and account for the contextual variables that influence it. Methods of fidelity monitoring should be considered during the intervention design, used to inform facilitator training and incorporated into study manuals. Researchers evaluating fidelity require a sophisticated understanding of the intervention and training should be provided. Intervention fidelity may vary over time and should be assessed throughout the study (Mars et al. 2013).

For a future pilot trial, the form and function of the intervention components identified in table 7.1, could be used to form evaluation criteria to monitor intervention fidelity. It would be feasible to audio record the groups although participants would need to provide consent and the acceptability of audio recording would need to be explored. Reflective records completed by facilitators could also form part of the fidelity monitoring and be used to cross-check against audio data to confirm the content and function of the groups. The extent to which the aims and objectives of the groups were achieved, from the perspective of facilitators and participants, could be assessed through post-intervention qualitative interviews. It is important that fidelity monitoring also incorporates the CG. Recording the amount and the nature of the interactions can be used to assess whether any interactions could have produced a therapeutic effect which could have reduced the difference in outcomes between the IG and CG (Spillane et al. 2007).

7.5.6 Evaluating intervention facilitator effect

Complex interventions present a range of options for analysis which should be tested in pilot studies (Craig et al. 2006, page 16).

Variation in outcomes may occur when there are hierarchical structures (e.g. women attending different intervention groups in different locations with different facilitators), in which case multi-level models for hierarchically structured data can be used as a method of inference (Craig et al. 2006). When group interventions are selected because of the theorised beneficial effects of groups, researchers should pay attention to group characteristics in any model for treatment effectiveness (Novy & Francis 1989).

Hierarchical linear models or mixed models are typically used with continuous variables (i.e. anxiety scores) and can simultaneously examine effects of individual and group level variables and their interactions on an individual-level outcomes (Cleary et al. 2012). Hierarchical linear models can analyse the variation in outcomes between the sub-groups (i.e. the different intervention groups women attended) and may indicate the effect of the different intervention facilitators or other group characteristics.

7.5.7 Data analysis in a future pilot trial

In future studies the effectiveness of the intervention on self-report anxiety scores (as continuous variables) between the IG and CG would be analysed using an independent samples t-test. Analysis of co-variance (ANCOVA) would also be performed to analyse the difference between anxiety scores while controlling for baseline imbalance (using baseline self-report anxiety score as a co-variate) (Vickers & Altman 2001). Hierarchical linear models would be used to examine effects of individual and group level variables and their interactions on outcomes (Cleary et al. 2012).

Data from pilot trials may be pooled into a main trial if the design and methods are the same (Charlesworth et al. 2013). It is possible that a future pilot trial would meet the criteria to be integrated into a main trial which could have financial and ethical benefits. A checklist has been developed to assist researchers to decide whether pilot data can be carried forward to the main trial dataset without compromising the trial integrity (Charlesworth et al. 2013).

7.5.8 Sample size calculations

Sample size in a future main trial

To conduct a RCT, the sample size required to attain the required power for the specified significance criterion and hypothesised effect size would need to be calculated. The statistical power of a significance test is the probability of rejecting the null hypothesis given the effect size and sample size (Cohen 1992). The value for power is recommended as 0.9 as a smaller value would present too greater risk of type 2 error (accepting null hypothesis) (Eldridge et al. 2016, Whitehead et al. 2016). The significance criterion (the risk of rejecting null hypothesis: type 1 error) is generally taken as $\alpha = 0.05$ (5% probability that the difference between the groups is due to chance). The effect size is calculated from the standard mean difference between two groups:

$$\frac{\text{mean of the IG} - \text{mean of the CG}}{\text{standard deviation (SD)}}$$

Effect sizes can be estimated based on the result of existing studies. If the effect size is large between the study groups then the sample size required will be smaller, conversely if the effect size is small, a larger sample size will be required (Coe 2002). Studies included in the SR which evaluated anxiety scores for different types of group interventions reported various effect sizes from small to large effects ($d=0.23 - d=2.39$), although the interventions were heterogeneous in their designs and study populations. Calculations based on these results would indicate that to detect small, medium or large

differences between two independent sample means on the primary outcome ($\alpha = 0.05$) sample sizes of $n=393$, $n=64$, or $n=26$ would be required in each group (Cohen 1992). The large variation reflects the paucity of evidence currently available to base a robust sample size calculation and a more accurate prediction of the SD of outcome scores is required to perform a more precise sample size calculation. This can be achieved by undertaking a pilot trial to anticipate what could be observed in the main trial (Whitehead et al. 2016).

Sample size pilot trial

Sample size formulae are not usually applicable to pilot trials, however there should be a sample size justification (Eldridge et al. 2016, NIHR 2014). It may not be possible to know the standardised effect size prior to the pilot trial and the sample size may need to be based on pragmatic decisions (Eldridge et al. 2016). Whitehead et al. (2016) presented some general guidelines "For a main trial designed with 90% power and two-sided 5% significance, we recommend pilot trial sample sizes per treatment arm of 75, 25, 15 and 10 for standardised effect sizes that are extra small (0.1), small (0.2), medium (0.5) or large (0.8), respectively" (Whitehead et al. 2016, page 1057). A large pilot trial is able to more precisely estimate the variance, meaning a smaller inflation factor would be applied to the main study sample size, which may in turn lead to a smaller main trial (Whitehead et al. 2016). An estimated sample size of 15 - 25 participants per treatment arm (based on small to medium effect sizes) may be sufficient to predict the sample size for definitive trials. This would mean conducting 2-4 IG groups (4-8 women per group). The sample population in the feasibility study included 54 women of whom 8 women were eligible and agreed to participate (15%). Therefore, based on the results of the feasibility study, a total sample population of 200-334 women may be needed to meet the requirements of a pilot trial.

The intervention would be constrained by the need to complete the study during pregnancy. This means that achieving the required

numbers of participants could not be approached by simply increasing the recruitment timeframe. The number of study sites would need to be considerably expanded, at least four times the sample size of the feasibility study. Caseloads for the study sites need to be calculated to inform the number of study sites. In the feasibility study, the actual number of eligible women was much lower than the estimated number of eligible women. This information was based on midwife team leaders records of average caseload numbers in their community areas and more robust data would need to be accessed to accurately determine the sample size for a pilot trial. Recruiting from community teams with larger caseloads would be easier to manage: less time travelling between community teams; more midwives accessing a central administration point where study information can be disseminated.

Cluster RCT sample sizes

Standard sample size calculations (based on individual randomisation) do not account for the between-cluster variation, therefore using standard sample size formulae for cluster trials will result in sample size estimates that are too small, resulting in under-powered studies (Campbell et al. 2004). A variance inflation factor should be applied to sample size calculations to account for the clustering effect. To calculate the value of the inflation factor, the intra cluster correlation (ICC) needs to be defined. ICC equals:

$$\frac{\text{variance between clusters (primary outcome)}}{\text{variance between clusters} + \text{variance within the clusters}}$$

(Donner & Klar 2000)

Pilot studies should not be used to estimate the ICC for main cluster trials because estimates lack precision and can potentially cause downward bias in estimates of between-cluster variation (Eldridge & Kerry (2012)). More reliable methods to identify the ICC can be sought from existing research (Eldridge & Kerry 2012). Due to the

limited number of studies which have evaluated anxiety interventions in pregnant women, estimates from general population studies may need to be used. For example, Adams et al. (2004) identified an ICC of 0.03-0.04 based on a review of cluster based studies assessing anxiety and depression scores in primary care.

7.6 Strengths and limitations

Strengths

This is the first study to design and evaluate the feasibility and acceptability of an intervention for pregnant women with mild to moderate anxiety which is facilitated by midwives. The intervention design, which had little direction from existing research, drew on theorised beneficial components and guidance from stakeholder and professional groups. This resulted in the development of an innovative intervention which is potentially feasible for implementation in UK maternity care and other countries with similar midwifery care provision. There is increased focus on improving pregnant women's mental health and the important role of the midwife has been highlighted. The study aimed to explore ways in which women with mild to moderate anxiety symptoms could be supported by midwives. This is also the first study which has incorporated MSWs in the provision of an intervention for pregnant women with mild to moderate anxiety.

The feasibility study identified that this novel intervention could be provided by midwives and MSWs and that it was acceptable to women. Clinical effectiveness will require evaluation in a full RCT. Prior to that a pilot study is required to determine study procedures to inform a main trial design. Conducting high quality trials is expensive and in response to the number of interventions that fail to demonstrate effectiveness, or were unable to be translated into real-world contexts, the use of feasibility and pilot studies has been strongly recommended (Bugge 2013, Collier 2009, Cooksey 2006, Craig et al. 2006). The feasibility study highlighted which

components performed well and where modifications were required. The feasibility study also informed the methodological approach for a pilot trial and identified ways to reduce potential bias and assess the fidelity of the intervention.

The study followed established research frameworks for developing complex interventions and included quality assessment tools relevant for the different methodological components (Craig et al. 2006, DesJarlais & Lyles 2004, Moore et al. 2015, Tong et al. 2007). This enhanced the methodological rigour of the study and the quality of reporting.

The study was undertaken by a researcher, who is a practising midwife working in the NHS organisation where the study was conducted. The influence of the dual role of midwife / researcher was considered throughout all stages of the study. Discussions with research supervisors, service users and the advisory group, the use of quality frameworks and reflective contemporaneous notes helped to identify potential and emerging role conflicts and develop strategies to improve the rigour of the study.

Limitations

There are key aspects of the study where the role of the researcher had the potential to introduce bias in the conduct of the study. For example, researcher bias in proposing a midwife facilitator for the study, facilitated access to the study site and potential influence on the data collection and analysis process. For a future pilot trial, professional research staff could assist with participant recruitment and data collection. This will help to reduce confounding factors associated with additional researcher attention being paid to the IG and will retain the blinding of data collection and analysis.

The background of the researcher can influence what questions are asked during interviews and how the information is interpreted (Kacen & Chaitin 2006). Participants may be more willing to share

their experiences with researchers who they view as sympathetic to their situations (Berger 2015). The researcher's clinical knowledge and experience may have improved the richness of the data, enabling a greater depth of understanding of the issues encountered by the women and facilitators. However, the validity of the study can be threatened when researchers are over involved in the subject under study, making incorrect assumptions and misinterpretation of the data (Jootun et al. 2009). To address the potential for bias, reflexivity was used throughout the qualitative data collection and analysis to enhance the rigour of the study (Berger 2015). Data analysis was undertaken by a single researcher, although the development of the analytic template was discussed at key stages with academic supervisors and the final template was confirmed by the researcher and academic supervisors. Reflexive journals, audit trails and feedback from advisory group consultations were used to consider the tension between involvement and detachment of the researcher and explore alternative interpretations of the data. In future studies, the rigour of qualitative data analysis could be improved by involving service users in the analysis and interpretation of data (INVOLVE 2012).

Diversity of sampling is more important in feasibility studies than the number of participants or interviews (O'Cathain et al. 2007). A diverse sample of participants will help identify a wide range of problems likely to be faced by the populations for which the intervention is intended. Including a diverse range of study sites can reduce the chance of refining an intervention to only work within a single centre. The original proposal set out to conduct a feasibility study with two groups of women in two community locations. This was not achieved, and a single group was conducted which included women from both study locations. This limited the evaluation of the acceptability of the intervention, however, the decision to include women from both locations maximised the potential to access a diverse a range of views as possible within the time constraints.

The anxiety and depression measures were selected in response to clinical recommendations and the current psychometric evidence. However, many of the measures require further psychometric evaluation for use with pregnant women. Future studies will need to consider any emerging research demonstrating psychometric performance to ensure the most appropriate and robust anxiety measures are selected.

7.7 Next stages

The MRC state that pilot work is used to test the procedures to inform a main trial design, estimating recruitment and determining the required sample size (Craig et al. 2006). RCTs that are underpowered are considered unethical and have limited use (Whitehead et al. 2016).

To secure funding for a pilot trial, a robust case needs to be made for the plausibility of the intervention and clinical importance of the study. This includes having a clear plan for a main trial in the near future (NIHR 2017). It is concerning that many studies included in the SR (15/39) were pilot or feasibility studies that have not progressed into main trials. Kaur et al. (2017) reviewed pilot and feasibility studies published in the *Clinical Rehabilitation Journal* and found that only 12% of pilot and/or feasibility studies (often the terms were used interchangeably) were followed by a definitive clinical trial. The authors recommended that to progress pilot studies into main clinical trials, researchers should:

- Label Pilot and feasibility studies correctly and follow CONSORT reporting guidelines (Eldridge et al. 2016).
- Address process, resources and management issues to facilitate the development of a competitive trial proposal.
- Justify the rationale for pilot sample size.

- Report descriptive statistics, point estimates, and CI for the effect observed. Data for effect size estimation should be reported as this can indicate the potential for efficacy.
- Justify the need for a further trial. Pilot studies may not progress to a main trial if it is not ethical to offer the control condition. Authors have reported a lack of funding or change in personnel have hindered progression to a main trial.
- Provide sample size estimates for a main trial using the pilot data. Small datasets can yield imprecise effect size estimates and need to be interpreted with caution. (Kaur et al. 2017)

A future pilot trial would follow the principles outlined by the MRC feasibility and modelling phases for complex interventions (Craig et al. 2006) and would be conducted in accordance with CONSORT standards for pilot trials (Eldridge et al. 2016).

Table 7.2 below highlights the refinements and developments to the existing study design as informed by the findings of the feasibility study. This table provides a summary of the main issues identified in the Discussion Chapter.

Table 7.2: Refinements and developments of the intervention and study design to consider for a pilot trial					
Intervention components / processes	Consultations / actions	Assumptions	Other considerations	Resources	Outcomes / process evaluation
Recruitment of study facilitators and access to study sites	<p>Agreement with NHS managers at proposed study sites:</p> <p>Availability of staff required to train and facilitate the intervention</p> <p>Agreements for the involvement of community midwives to recruit women and conduct initial eligibility screening</p>	<p>Facilitators required for 3-4 groups</p> <p>Possible sample size: 202-337 nulliparous women at 16-25 weeks gestation: calculate the numbers booked for care different study locations.</p>	<p>NHS research ethical approval and Health Research Authority permissions</p> <p>Availability of support from CRN midwives / research midwives</p>	<p>Study information and engagement activities with community midwives working at the study sites</p> <p>Community midwives' recruitment form (as per the feasibility study)</p> <p>Brief training tools to support community midwives administering the GAD-2</p>	<p>Number of staff willing to participate</p>
Facilitator training	<p>Single training provider to present an integrated overview of the intervention mechanisms</p> <p>Joint training for facilitators to foster shared ownership and discuss role boundaries</p> <p>Action learning strategies, group skills, supporting women's mental health</p>		<p>Identify strategies for formally ending groups, signposting to services and facilitator support</p>	<p>Develop a reflective workbook for facilitators highlighting where techniques and approaches could be applied in different situations</p>	<p>Facilitator evaluation of training to assess preparedness to deliver all components of the intervention</p>
Recruitment of participants	<p>Strengthen service user involvement: developing study literature (consider women's concerns about disclosing anxiety)</p> <p>Liaise with community leaders and HCPs to improve the acceptability of the intervention for women within their local communities</p>	<p>Proposed sample size: 202-337 nulliparous women at 16-25 weeks gestation</p>	<p>Translating study materials and translator services (demographics of the study locations)</p> <p>Availability of support from CRN midwives / research midwives</p>	<p>Participant information sheet (revised and including random allocation information)</p> <p>Consent form as developed for the feasibility study</p>	<p>Number of women interested in the study</p> <p>Number of women agreeing to participate</p>

Intervention components / processes	Consultations / actions	Assumptions	Other considerations	Resources	Outcomes / process evaluation
Random allocation	Random allocation procedures and blinding of study personnel		Consider cluster trial Availability of CRN support	Consort guidelines Involvement of accredited Clinical Trials Unit	
Baseline / post intervention quantitative measures	Identify pregnancy related quality of life measure		Consider postal data collection methods for questionnaires. Consider outcomes for an economic evaluation.	Baseline anxiety, depression and demographic questionnaires (as per the feasibility study)	Anxiety, depression and QOL scores Questionnaire completion and return rates
Intervention group: Pre-group meeting	Offer pre-group meeting as a face-to-face individual meeting or telephone meeting				Participant uptake of the pre-group meeting
Intervention group: groups	Community based location with good access and adequate facilities for group and individual discussion Assist with travel (costs) to the location Based on peer support models (as per the feasibility study) Increase the number of groups, planning later session with a reduced role of the midwife facilitator Provide one to one support before and/or after the groups		Groups in different locations to run groups at different times to provide women a choice as to which group to attend Explore peer-supporters to co-facilitate groups (liaise with perinatal mental health services)	Facilitators to make use the workbook examples / vignettes with the early groups sessions	Facilitators data collection sheets as per the feasibility study and facilitators reflective diaries used for fidelity monitoring Audio recording of groups assessed against fidelity monitoring criteria Post-intervention qualitative interviews to identify women's experiences of participating in groups and the acceptability of the intervention

Intervention components and processes	Consultations / actions	Assumptions	Other considerations	Resources	Outcomes / process evaluation
Intervention group: self-help resources	Reduce the amount of self-help resources offered to the women but provide choice between different formats		Refer to women's preference in the feasibility study for the anxiety workbook and CBT / relaxation 'apps'		Post-intervention qualitative interviews to identify use and potential benefits (if any) of accessing resources
Control group			Consider 'treatment as usual' for the control group Explore and define the provision of usual antenatal care in the study settings, particularly the availability of emotional support		Qualitative interviews to assess the acceptability of random allocation to a CG and how women interacted with the study personnel. Retention rates of the CG participants
Data analysis	Analysis strategy for a main trial to be tested: Independent samples t-test for primary outcome: anxiety symptoms scores Hierarchical linear models to analyse group and individual outcomes Analysis of co-variance (ANCOVA) to analyse the change in scores while controlling for baseline imbalance.		Data used to calculate sample size for a main trial. Inflation factor for cluster RCT / pilot trial	Support from statistician	

7.7.1 Draft structured summary of a pilot study design

Study objective:

To identify where further developments and refinements can be made to improve implementation of the intervention.

In a future pilot trial, the key uncertainties to be addressed include: the acceptability of random allocation; women's views of participating in the refined intervention; the acceptability of fidelity monitoring methods; data analysis strategies; and collection of outcome data to inform the sample size of a main trial. The section provides a brief structured summary of the pilot study design following the consort checklist for pilot and feasibility studies (Eldridge et al. 2016). This is not a comprehensive protocol but focuses on the main issues for developing the feasibility study protocol to a pilot trial protocol. The protocol will be further refined to reflect advances in maternity and perinatal mental health provision and contextual factors of potential future study sites.

Aims and Objectives

The research aim for the pilot study is to test the trial procedures and provide data to estimate the parameters required to design a definitive RCT. The objectives of the pilot randomised study are:

1. To assess how many women are eligible and recruited.
2. To test the methods used to generate the random allocation sequence and cluster random allocation procedures.
3. To assess retention for the intervention and control group.
4. To identify robust data collection methods and data analysis procedures to measure the efficacy of the intervention within a definitive trial.
5. To collect and synthesise data, from which the sample size of a definitive cluster RCT could be estimated.

Secondary objectives:

1. To assess the competence and preparedness of facilitators to deliver all components of the intervention.
2. To determine optimal methods of eligibility assessment.
3. To evaluate the feasibility and acceptability of audio recording of groups for the purpose of fidelity monitoring.
4. To evaluate the acceptability and potential benefits (if any) of participating in the refined intervention.
5. To evaluate how women in the CG interact with the study.

Methods

The study will be a pilot, pragmatic, two-arm parallel, cluster RCT in community healthcare locations where midwifery care is provided by a NHS Hospitals Trust.

The intervention

The intervention will be delivered in three components: a pre-group face-to face or telephone meeting with the midwife; groups facilitated by the midwife and co-facilitated by the MSW; access to selected self-help resources.

Four facilitated groups (4-8 women) will take place over an eight-week period. Women will be able to access individual support from the midwife either before or after the groups. An additional 2-3 groups with a reduced facilitator role will be provided.

Control group

The control group will receive usual antenatal care which will be fully described and include the amount and nature of researcher contact.

Sample size

The study will aim to recruit 15-25 women per treatment arm. This would mean conducting 2-4 intervention groups (4-8 clusters).

Randomisation

Community midwifery teams will be randomised using computer-generated random numbers stratified by the size of the midwifery team caseload in the ratio 1:1 to continue to offer usual care or usual care plus the intervention. The study statistician will be blinded to the community midwifery team allocation.

Data collection and analysis

Outcomes will include: demographic details of participants, self-report anxiety, depression and QOL measures collected at baseline and post-intervention. A statistical analysis plan will be developed and approved by the trial statistician prior to the final analysis.

Descriptive summaries will report the number of IG and CG participants who were eligible, recruited and completed participation. Withdrawals (and where possible, reasons for withdrawals) will be reported. Baseline demographic, clinical and obstetric characteristics of participants will be compared and scrutinised for imbalances in observable baseline variables. Since this is a pilot trial, imbalance between participants in each of the study arms on one or more baseline characteristics is anticipated.

Descriptive analyses will be conducted for the anxiety self-report outcomes. All continuous variables will be summarised using mean, SD, median and IQR as appropriate. To test the analysis strategy for a future main trial exploratory analysis will be conducted, including:

- independent samples t-test for the primary outcome of anxiety symptoms scores
- hierarchical linear models to analyse group and individual outcomes.
- analysis of co-variance (ANCOVA) to analyse the change in scores while controlling for baseline imbalance.

The pilot data will provide information on the parameters needed for a realistic sample size calculation for a future, main cluster RCT. Previous research has estimated the intra-cluster correlation coefficient (ICC) to inform a main trial.

Qualitative evaluation will focus on women's and facilitators' views on the refinements made to the intervention design and assess the acceptability and experiences of random allocation to a usual care control group. The nature of 'usual care' will be reported. Pre-defined criteria will be used to assess the fidelity of the intervention, this will evaluate data from audio recordings of the groups and facilitators' reflective records.

Chapter 8 Conclusion

8.1 Introduction

The study was conducted to develop an intervention that could be facilitated by midwives to improve symptoms of mild to moderate anxiety in pregnant women. A novel intervention was developed and the acceptability and feasibility demonstrated. Objectives were developed to help identify where further refinements could be made prior to further testing in a pilot trial. This chapter will present the overall conclusions of the study and suggest recommendations for researchers and clinical practice.

8.2 Importance of the study

Policy and research recommendations highlighted the important role for the midwife in identifying women with symptoms of anxiety in pregnancy, supporting women's emotional wellbeing and signposting women to further supportive services (DOH 2012, Glover 2014, Knight et al. 2015, MMHA 2014, NICE 2014, RCM 2015). However, the role of the midwife in supporting women's psychological wellbeing needs to be strengthened. Midwives are restricted in their current role by a lack of appropriate training and support, time constraints due to busy services, a focus on physical wellbeing and a lack of awareness of the availability of supportive services to signpost women (Knight et al. 2015, McGlone et al. 2016, Russell et al. 2013). The study set out to provide training for midwives and MSWs to help them support women with symptoms of mild to moderate anxiety. The study also strived to develop an intervention which could be delivered within midwives' scope of practice, with minimal additional resources and which could be integrated into existing community based midwifery services.

The introductory chapter identified the burden of the problem: prevalence rates for anxiety in pregnancy reported as 10-16% of the pregnant population and the associated negative health

outcomes for women and babies (Goodman et al. 2014, NICE 2014, Rubertsson et al. 2014). The midwives' function in providing support for women with mild to moderate anxiety was considered as helping women develop coping strategies and to prevent an escalation of anxiety symptoms. However, at the start of the study it was unclear whether women with symptoms of mild to moderate anxiety would benefit from receiving an intervention facilitated by midwives or whether other HCPs would be better placed to deliver this service. Consultations with service users, mental health and maternity care professionals endorsed a midwifery facilitated intervention and this was further explored in the feasibility study.

Existing research forewarned of the barriers and limitations to identifying pregnant women with symptoms of anxiety and this was an important consideration when deciding the eligibility criteria for the study. The decision to limit eligibility to women reporting anxiety symptom scores in the mild to moderate range acknowledged the sphere of midwifery practice and the need for services to make efficient use of NHS resources, focusing on women who were most likely to benefit. The intervention was tested within a NHS maternity care service which highlighted how the intervention would perform within existing care pathways.

8.3 Main findings

Conducting the feasibility study helped to develop an understanding of the particular concerns women face when questioned about their mental health. The women supported the introduction of the study by a community midwife, although qualitative findings uncovered the potential to introduce selection bias in the recruitment process. Ways in which the acceptability of eligibility screening could be improved were identified: brief training packages to enhancing midwives' confidence and skills in undertaking assessments; involvement of research professionals; and by involving services users to developing clear study information and literature.

The women in the study overwhelmingly supported having a midwife to facilitate the intervention. An understanding of the role of the midwife facilitator suggested that women benefitted from professional guidance about their pregnancy alongside being supported with their anxiety symptoms. The training workshops, which were developed for the study, helped midwives and MSWs gain confidence in their ability to provide support for women with anxiety. Synthesising the study findings with existing literature identified that the training and study manuals should be developed to enable flexibility in the delivery of the intervention to respond to emerging situations. However, to promote fidelity in the intervention components, essential training skills, underlying mechanisms and processes were identified and reported. The findings of this study illuminate the usefulness of feasibility studies to identify, define and monitor theorised beneficial mechanisms within complex interventions.

The findings from the SR were considered alongside the underlying theory of approaches to support women with symptoms of mild to moderate anxiety. This identified that peer support could be helpful for pregnant women with anxiety. Assumptions about the potential benefit of peer support were assessed in the feasibility study which received a positive evaluation from the women who participated. The women reported the main benefit of participation was achieved through sharing feelings and experiences with other women with anxiety. Potential barriers for individuals benefitting from peer support mechanisms were identified from existing theoretical literature. The study findings highlighted how such concerns emerged for this particular group of pregnant women. This included women's fears about upsetting others through sharing stories and an initial lack of confidence to join in discussions. The findings supported a longitudinal intervention as women's initial concerns were overcome with time as they progressed with the groups. For future implementation of the intervention, enhanced continuity as recommended by the National Maternity Review (2016) has the

potential to reduce barriers for women disclosing their symptoms of anxiety. Local peer groups, facilitated by a midwife already known to the woman, could further strengthen the therapeutic and relational continuity intervention mechanisms.

Conducting the feasibility study enabled the methodological approach for further testing to be considered. The women in study expressed some reluctance about the possibility of being assigned to a control group in future randomised trials. A cluster randomised controlled trial was suggested as an appropriate study design for a future pilot trial to overcome potential problems associated with selection bias, contamination and attrition in the control group.

8.4 Summary

With recognition of the limitations of feasibility studies, the aim and objectives of the study were achieved. The intervention design appeared to be acceptable and beneficial for this group of women, midwives and MSW facilitators. There was no evidence of harm to the women or facilitators who participated. The components identified as requiring revision or further development mainly surrounded the study processes (recruitment strategies, number of groups, flexibility in the provision of individual support).

Methodological processes which would need to be developed for testing in a pilot trial (data collection methods, random allocation and fidelity monitoring) were identified and progressed to a stage where a future protocol for pilot testing could be planned. The supportive mechanisms which underpinned the intervention performed well in this small study when evaluated against the study objectives.

8.5 Implications and recommendations

Although these findings were limited to the small number of women and facilitators participating in the study, findings from existing

research have been discussed and compared to help researchers consider how the intervention could be progressed and how it may operate in different contexts. Although the effectiveness of the intervention has not yet been evaluated, the findings are useful for maternity care professionals interested in developing ways to improve midwives' discussion about mental health. Midwives should acknowledge that for some women it helped that midwives opened discussions and recommended supportive services. To maximise the potential benefits from anxiety screening, midwives need to communicate the purpose of mental health questionnaires and develop skills in their administration. Further research is required to evaluate the effectiveness of interventions to improve symptoms of mild to moderate anxiety in pregnancy. Services for women with mild to moderate anxiety symptoms need to be strengthened. Establishing evidence based interventions delivered within maternity care structures will present women with a choice of effective services to access which appeal to them and best suit their needs.

Conclusion

This study highlights the potential for midwives to facilitate supportive interventions to enhance the current provision of emotional support for women with anxiety symptoms in pregnancy and address the current gap in services. The intervention is potentially feasible for introduction into clinical practice with minimal additional resources. Furthermore, the intervention would be well placed within current strategic recommendations for maternity and perinatal mental healthcare provision. The intervention was acceptable, considered beneficial and did not cause harm to the women who participated. This novel intervention was based on the theory and current evidence from existing interventions to improve symptoms of anxiety and has the potential to be evaluated in a RCT. The next stage is to undertake a pilot trial to inform a main trial to determine the effectiveness of the intervention.

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Appendices

Appendix 2.1 Studies included in the scoping review

Appendix 2.1 Studies included in the scoping review										
Primary research studies included in the scoping review										
First Author	Year	County	Intervention	Intervention delivered by	Study design	n=	Participants	Gestation (weeks)	Outcomes	
Alder	2011	Switzerland	Relaxation and guided imagery	Midwife	RCT	39	Healthy pregnant women	32-34	Self-report anxiety, negative affect, maternal blood pressure, endocrine analysis, birth outcomes (gestation, weight), use of analgesics, induction, obstetric complications	
Barber	2013	New Zealand	Mindfulness & relaxation	Self-help computer program	Pilot (cohort)	7	Healthy pregnant women	36-38	Maternal heart rate, respirations and galvanic skin response. Fetal heart rate. Women's satisfaction with the intervention. Self-report: anxiety, stress, self-confidence	
Bastani	2005	Tehran	Applied relaxation	Not stated	RCT	110	Nulliparous pregnant women	14-28	Self-report anxiety and perceived stress	
Beddoe	2009	US	Mindfulness based yoga	Mindfulness, yoga instructor (Nurse)	Pilot	17	Nulliparous pregnant women	12-32	Self-report perceived stress, pregnancy stress, anxiety, pain. Cortisol markers. Women's satisfaction with the intervention.	
Dunn	2011	Australia	Mindfulness MCBT	Mindfulness instructor (psychiatrist & counsellor)	Pilot (control trial)	11	General antenatal population	12-28	Self-report anxiety, depression, self-compassion. Women's satisfaction and perceived benefit of the intervention	
Field	2013	US	Peer support group and IPP	Trained IPP therapist	Quasi - experimental	44	Pregnant women with symptoms of depression	20-24	Symptoms of depression, self-report anxiety and anger	
Field	2013 b	US	Tai-chi and yoga	Trained yoga instructor	Quasi – experimental	92	Pregnant women with symptoms of depression	22-34	Symptoms of depression, self-report anxiety and sleep-disturbance	
Guardino	2014	US	Mindfulness	Mindfulness instructor	Pilot	47	Pregnant women with symptoms of anxiety	10-25	Self-report stress and anxiety	

First Author	Year	County	Intervention	Intervention delivered by	Study design	n=	Characteristics of participants	Gestation	Outcomes measured
Guerreiro	2007	Brazil	Acupuncture	Trained practitioner	Quasi - experimental	51	Pregnant women with mild to moderate emotional complaints	15-30	Self-report emotional distress, infant birthweight and APGAR score
Lara	2010	Mexico	Educational (psychological strategies)	Trained facilitators (HCP's)	RCT	337	Pregnant women with symptoms of depression	Less than 27	Self-report: depression, anxiety, clinical interview: depression
Miquelutti	2013	Brazil	Birth preparation program	Physiotherapists	RCT	197	Low risk pregnant women	18-24	Self-report: anxiety, exercise, lumbopelvic pain, urinary incontinence. Infant APGAR score
Newham	2014	UK	Yoga	Trained yoga teacher	RCT	59	Low risk nulliparous women	21 (mean)	Self-report: anxiety, depression, fear of childbirth
Snaith	2014	UK	Telephone support	Midwife	RCT	840	Low risk nulliparous women	20	Number of antenatal visits. Uterine artery doppler screening, self-report: anxiety, social support, satisfaction with care. Maternal hypertension. Birthweight
Thome	2012	Iceland	Family nursing intervention	Midwife	Quasi - experimental	39	Distressed pregnant women	2nd and 3rd trimester	Self-report: anxiety, depression, distress, adjustment, self-esteem
Urech	2005	Switzerland	Relaxation	Assisted self-help audio CD	RCT	39	Healthy pregnant women	32-34	Fetal heart rate, endocrine measurement. Self-report: relaxation, anxiety
Vieten	2008	US	Mindfulness MBSR, MCBT	Clinical psychologist	Pilot	34	Pregnant women with self-report history of mood concerns	12-30	Self-report: depression, anxiety, positive and negative effect, mindfulness
Woolhouse	2014	Australia	Mindfulness, 'mind-baby-body' program	Psychologist/psychiatrist with mindfulness training	Pilot	20 & 32	Pregnant women at risk of mental health disorders (identified by midwife) & general antenatal population	11-34	Self-report: stress, depression, anxiety.

Appendix 2.2 Search strategy

Search strategy for MEDLINE:

1	Intervention Studies/ or intervention*.mp
2	study.mp
3	clinical Trial/ or trial.mp
4	randomi*ed controlled trial.mp
5	Randomized Controlled Trial as topic/ or rct.mp
6	review.mp
7	meta analysis.mp/or Meta-Analysis/
8	meta sysnthesis.mp
9	narrative synthesis.mp
10	systematic review.mp
11	Anxiety Disorders/ or anx*.mp or Anxiety/
12	pregnan*.mp
13	Pregnancy/ or childbearing.mp
14	Peripartum Period/ or periprt*.mp
15	perinatal.mp or Perinatal Care/
16	antenatal.mp or Prenatal Care/
17	ante-natal.mp
18	ante-partum.mp
19	ante-partum.mp
20	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
21	12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
22	11 and 20 and 21
23	Limit 34 to (English Language and female and humans and last 25 years)

1	Intervention Studies/ or intervention*.mp
2	study.mp
3	clinical Trial/ or trial.mp
4	randomi*ed controlled trial.mp
5	Randomized Controlled Trial as topic/ or rct.mp
6	review.mp
7	meta analysis.mp/or Meta-Analysis/
8	meta sysnthesis.mp

9	narrative synthesis.mp
10	systematic review.mp
11	Anxiety Disorders/ or anx*.mp or Anxiety/
12	qualitative.mp or Qualitative Research/
13	survey.mp
14	Patient Satisfaction/ or satisfaction*.mp
15	accept*.mp
16	perception*.mp
17	experience*.mp
18	attitude*.mp
19	view*.mp
20	Interview/ or interview*.mp
21	Focus Groups/ or focus group*.mp
22	findings.mp
23	pregnan*.mp
24	Pregnancy/ or childbearing.mp
25	Peripartum Period/ or periprt*.mp
26	perinatal.mp or Perinatal Care/
27	antenatal.mp or Prenatal Care/
28	ante-natal.mp
29	antepartum.mp
30	ante-partum.mp
31	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
32	12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22
33	23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
34	11 and 31 and 32 and 33
35	Limit 34 to (English Language and female and humans and last 25 years)

Appendix 4.1 Participant and facilitator interview guides

Participant interview guide	
<p>What did you think when you first heard about this study?</p> <p>What did you feel about participating in the study?</p>	<p><i>What did you think about the way the study was introduced?</i></p> <p><i>What did you think about the length of the sessions?</i></p> <p><i>How easy was it for you to attend?</i></p> <p><i>What would have made it easier for you to attend?</i></p> <p><i>What did you think but the number of sessions?</i></p> <p><i>What could we improve?</i></p>
<p>What aspects did you find beneficial? (discussion, self-help)</p> <p>What aspects did you find difficult / unhelpful?</p>	<p><i>How useful was it to meet the midwife before the groups?</i></p> <p><i>How did you think about the self-help materials?</i></p> <p><i>Which materials did you use? How often?</i></p> <p><i>How did you find the sessions?</i></p> <p><i>To what extent was it helpful to have the sessions facilitated by a midwife?</i></p>
<p>How would you describe your anxiety now?</p> <p>How do you feel about coping with your anxiety these days?</p>	<p><i>What types of things have changed for you since you completed the study?</i></p> <p><i>To what extent did the sessions help you cope with your anxiety, if at all?</i></p>
<p>How relevant were the anxiety rating questionnaires used in the study?</p>	<p><i>How easy were they to understand / complete?</i></p> <p><i>How did they reflect your experiences of anxiety in pregnancy?</i></p>
<p>To what extent do you think other women would find this support useful?</p> <p>What comments if any would you would like to share about the study?</p>	<p><i>To test the method of support further we may randomly select women: some would receive the support and others would receive their usual care. How do you feel women who would be selected to not receive the support would feel?</i></p> <p><i>Can you think of anything that would make not receiving the support more acceptable to those women?</i></p>

Facilitator interview guide	
What are your overall thoughts about delivering or facilitating the sessions?	<p><i>How helpful or unhelpful were the training workshops and study manual? How could we improve?</i></p> <p><i>How comfortable were you facilitating the sessions?</i></p> <p><i>How prepared did you feel to facilitate the sessions?</i></p> <p><i>What did you think about the length of the discussion sessions? Number in group?</i></p>
<p>What aspects of the sessions did you think were beneficial to women?</p> <p>What aspects did you find difficult?</p>	<p><i>How useful did you think the pre-group sessions were?</i></p> <p><i>What did you think about the number/ location of sessions?</i></p> <p><i>How important or unimportant was it that the sessions were facilitated by a midwife?</i></p> <p><i>What did you think worked well?</i></p> <p><i>What situations, if any, did you find difficult to deal with?</i></p> <p><i>What did you think about targeting the sessions for women with mild to moderate anxiety?</i></p> <p><i>What could we improve?</i></p>
What are your thoughts on the self-help resources women accessed?	<p><i>What type of feedback did the women give you about the materials?</i></p> <p><i>How do you think the use of the materials contributed to the discussions, if at all?</i></p>
Do you feel the intervention sessions would be feasible to introduce into practice?	<p><i>How feasible would it be to introduce the sessions across the service?</i></p> <p><i>What are the barriers/facilitators to developing this type of service?</i></p> <p><i>How do you think we should recruit/identify other midwives /MSWs to facilitate the sessions in the future?</i></p> <p><i>How much training do you think midwives/MSWs would need to deliver the sessions?</i></p> <p><i>How interested would you be in continuing to facilitate the sessions?</i></p>

Appendix 5.1 Community midwives letter



An evaluation of the feasibility and acceptability and of an intervention for pregnant women with symptoms of mild to moderate anxiety.

Chief Investigator: [name] Academic supervisor: [name] Researcher: [name]

Information for the Community Midwife

Dear Midwife

My name is [name], I am a midwife at [NHS Trust] and I am currently undertaking a PhD at the University of Nottingham to test the feasibility and acceptability of a group intervention for pregnant women with mild to moderate symptoms of anxiety. I would like you to help me recruit women into this study. The study has the following permissions / approvals:

Sponsorship from the University of Nottingham (2.3.16)

NRES ethical permissions (2.3.16)

R&I approval (17.3.16)

The [NHS Trust] Head of Midwifery [name] (23.12.2015)

Recruitment and eligibility

I aim to recruit 20 women from two community locations. The sample population will be nulliparous women attending for an appointment at approximately **16-25 weeks of pregnancy**.

Inclusion criteria

- Nulliparous pregnant women aged 18 years or older at the time of enrolment
- Self- report symptoms of mild to moderate anxiety
- Able to read and write and speak English and provide written informed consent

Women will not be included if they:

Are receiving treatment for a severe and enduring mental health condition or who fit the criteria for complex social factors (NICE 2010): (substances misuse, recent migrants, asylum seekers or refugees, women who experience domestic abuse before or during pregnancy).

How you can help

When nulliparous women who meet the above inclusion criteria attend for their 16 or 25 weeks appointment - your role would be to do 4 things:

1. Provide the Participant Information Sheet
2. Ask the GAD-2 anxiety assessment questions (Document 1)
3. Ask women with scores of 3 or more if they would be interested in taking part in the study.
4. Ask permission to pass on their contact details to [researcher name] (Document 1)

What participation would involve for the women

1. I would contact the woman, with their permission and explain the study

2. Gain consent from the women wanting to participate
3. Answer a further anxiety questionnaire (GAD-7) to assess the criteria of mild to moderate anxiety

If a woman scores more than 15 on the GAD-7 scale, this indicates severe anxiety and the woman will not be eligible to participate. She will be advised to contact her GP and/or midwife for further assessment and support. I will offer to provide her with a GP/community midwife letter explaining the GAD-7 results.

If women take part, they would:

1. Be invited to attend four group sessions, facilitated by a NUH midwife who has undertaken training.
2. Encouraged to use pre-selected publicly available self-help packages which consist of coping skills and relaxation exercises.
3. Be invited to take part in an interview to ask about their experience in participating in the sessions.

Thank you for reading this letter. If you have any questions please contact: [name and contact information]

Appendix 5.2 Community midwives' data collection form



The University of
Nottingham

UNITED KINGDOM • CHINA • MALAYSIA

Document 1 - Community Midwives Data Collection Form

Date of clinic:

Location:

Section 1: Eligibility	Insert ✓	insert X
approximately 16 - 25 weeks gestation (+/- 1 week)		
Nulliparous		
aged 18 years or older		
able to read and write and speak in English		
able to provide written informed consent		
Not receiving treatment for a severe and enduring mental health condition		
Not meeting the criteria for complex social factors (NICE 2010)		
<ul style="list-style-type: none"> • substance misuser (alcohol and/or drugs) • recent migrant, asylum seeker or refugee • experience of domestic abuse before / during pregnancy 		

If all the eligibility criteria are met, please provide a copy of the participant information form and proceed to ask permission to ask the GAD-2 questions.

<p>Section 2: Provide study introduction and seek permission to ask GAD-2 questions.</p> <p><i>[researcher name] is registered for her PhD at the University of Nottingham to look at the acceptability of a method of support for pregnant women with mild to moderate anxiety.</i></p> <p><i>The method of support consists of talking alone with a midwife then attending a group discussion session with other women, once a fortnight and accessing support to complete a self-help package such as relaxation exercises and coping skills.</i></p> <p><i>If you are interested in taking part in the study I need to ask you two questions to see if the package of support may be appropriate to you, if you agree.</i></p>

If the woman agrees, please ask the GAD-2 questions. If not, please ask no further questions.

Section 3: GAD-2 questions				
Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
Feeling nervous, anxious or on edge	0	1	2	3
Not able to stop or control worrying	0	1	2	3

Please total the score

Score of 0, 1, or 2 NOT ELIGIBLE	The scores suggest the woman does not have mild anxiety. The method of support is not suited to their needs at this time. The woman may discuss any future concerns she may have about her anxiety with her midwife or GP.
Score of 3, 4, 5, 6 ELIGIBLE	The scores suggest the woman may be eligible to participate in the study. If the woman is interested <i>[researcher name]</i> would like to make contact to discuss the study further. If the woman agrees, please ask her to complete the contact information overleaf.

If the score is 0, 1, or 2, please ask no further questions.

If the score is 3 or more, please ask for permission for *[researcher name]* to contact.

Section 4: Contact details			
Do you give your permission for [researcher name] to contact you? Please tick your answer	Yes	No	Maybe*
If yes, how would you like to be contacted?			Please tick
in person (following this appointment if researcher is available)			
in person at a time of your convenience (if you agree, please supply a contact number for the researcher [name] to contact you to arrange a meeting)			
by mobile telephone			
by land line telephone			
by text			
by email			

*If you need more time to think about the study please ask your midwife for a copy of the Participant Information Sheet. If you then decide you are interested in finding out more, you can contact [researcher name and contact details]

Please complete the following relevant contact information:	
Name:	
Mobile number:	
Landline number:	
Email address:	

Have you been provided with a copy of the Participant Information Sheet (please tick your answer)	Yes	No
If not - please ask your midwife for a copy		

This form will be treated as a confidential document and held securely in accordance with regulations. All study staff and investigators will adhere to the Data Protection Act, 1998. The form should be handed to the researcher in person at the end of the clinic. All study forms will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the study staff and investigators and relevant regulatory authorities.

Appendix 5.3 Participant information sheet



Participant Information Sheet (Final Version 1.5 Date: 24.2.15)

An evaluation of the feasibility and acceptability of an intervention for pregnant women with symptoms of mild to moderate anxiety.

Name of Researcher(s):

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

The purpose of the study is to test a way of providing support for women with anxiety in pregnancy. The support includes attending group sessions supported by a midwife and using self-help packages which consist of coping skills and relaxation exercises. The study will test the acceptability and practicality of the methods of support for pregnant women.

Why have I been invited?

We want to include you in this study because your midwife has found that you are experiencing some symptoms of anxiety in your pregnancy. We feel that your views and experiences would be important for the research.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

If you are happy to take part, the researcher would contact you using the contact details that you gave to your midwife. You would be asked to answer some questionnaires about anxiety. If your replies to the anxiety questions indicate that the support we are developing may be suited to your needs, we would invite you to take part in the study and your GP will be notified of your participation. First, you would meet one-on-one with the research midwife. Then, you would be invited to attend four group sessions, one per fortnight. There would be at most ten women in the group. The group would support you with accessing and using anxiety self-help materials. The self-help materials have been evaluated and selected for use with pregnant women with symptoms of anxiety and are based on coping skills, meditation and relaxation. The study would last up to 12 weeks and would be located in community healthcare centres.

At the end of the study you would be asked to complete some questionnaires about anxiety and take part in an interview with the researcher to ask about your experience of taking part in the group sessions and your experience of the self-help materials. The interview would be audio recorded to help analyse the interview but nothing that could identify you as an individual would be discussed outside the research team. Your name would not appear in the transcript or in any research findings. When we write up the findings we might use direct quotes from the interviews but we would ensure that the quotes that we use would not identify you as an individual.

If the questionnaires indicate that you are experiencing more severe symptoms of anxiety you will be advised to contact your GP and community midwife for further assessment and support. We will provide a GP letter detailing the questionnaire scores.

Expenses and payments

Participants will not be paid to participate in the study.

What are the possible disadvantages and risks of taking part?

We think that it is unlikely that there would be any drawbacks in taking part, although women may sometimes feel upset when discussing their feelings. We ask that during the group you only share something that you are comfortable to share. The midwife leading the group would be available to discuss any concerns with you at the end of the group.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help other women in the future.

What happens when the research study stops?

Information may be published in peer reviewed academic journals; presented at professional conferences or local seminars. The study is being conducted for Kerry Evans doctoral study and the results would be submitted as part of a final thesis.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet.

If you remain unhappy and wish to complain formally, you can do this by contacting the **Patients Advice and Liaison Service (PALS)**: [contact details]

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty. All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, telephone number) will be kept for 6-12 months after the end of the study so that we are able to contact you about the findings of the study (unless you advise us that you do not wish to be contacted). All other research data will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data. If any information was revealed during the study which could indicate a risk of serious harm to yourself or others, the research team would have a duty of care to report this information to your healthcare providers and the Chief Investigator.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis. A decision to withdraw at any time, or a decision not to take part, would not affect the quality of care you receive.

What will happen to the results of the research study?

Information may be published in academic journals; presented at professional conferences or seminars. The study is being conducted for [researcher name] doctoral study and the results would be submitted as part of a final thesis. Should you wish to see a summary of the study report please ask the researcher to forward a copy.

Who is organising and funding the research?

This research is being organised by the University of Nottingham. The study is part of [researcher name] doctoral study which is funded by a Wellbeing of Women & Royal College of Midwives Doctoral Fellowship Training award.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the NHS East Midlands Research Ethics Committee.

Further information and contact details

You are encouraged to ask any questions you wish, before, during or after the study. If you have any questions about the study, please speak to [researcher name]

[name and contact information]

Appendix 5.4 Study consent form

CONSENT FORM (Final Version 1.5 date: 24.2.15)

An evaluation of the feasibility and acceptability of an intervention for pregnant women with symptoms of mild to moderate anxiety.

REC ref: 16/EM/0041

Name of Researcher:

Name of Participant:

Please initial box

1. I confirm that I have read and understand the information sheet version number 1.5 dated 24.2.15 for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that relevant sections of the data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I understand that the interview will be recorded and that anonymous direct quotes from the interview may be used in the study reports. ☐
5. I understand that if the researchers have concerns that I may be at risk of harm to myself or others, they have a duty of care to report the concerns and I would be fully informed of the researchers' intended actions. ☐
6. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

Appendix 5.5 Intervention facilitators recruitment letter

University of Nottingham, School of Health Sciences



An evaluation of the feasibility and acceptability and of an intervention for pregnant women with symptoms of mild to moderate anxiety.

Chief Investigator: [name] Co-Investigators: [names]

Recruitment of Midwife and Midwifery Support Workers

Dear Midwife / Midwifery Support Worker

My name is [name], I am a midwife at [NHS Trust name] and I am currently undertaking a PhD at the University of Nottingham. I am conducting a study to test the feasibility of an intervention for pregnant women with mild to moderate symptoms of anxiety. The study aims to assess the acceptability of the intervention from the perspectives of pregnant women and the practicality of delivering the intervention from the perspectives of midwives and midwifery support workers providing the intervention. I would like to recruit midwives and midwifery support workers to be trained to deliver the intervention.

What will this involve?

A midwife and a midwifery support worker will work in a group to deliver an intervention to a group of ten pregnant women. The intervention includes:

- The midwife meeting the women on an individual basis to welcome them to the group sessions.
- The midwife and midwifery support worker facilitating 4 group sessions, once every 2 weeks, each lasting up to 90 minutes.
- The midwife providing optional time following the sessions for women to discuss any individual concerns on a one-to-one basis.

The group sessions will include providing access and encouragement to women who are going to use the self-help packages for their symptoms of anxiety. Group sessions will be located in community settings.

Will I receive any training?

There will be a 3-day training programme to support you in delivering the intervention. The training programme will involve attending 3 sessions (lasting 6-7 hours each) over a three-week period. The training will include:

- Overview of perinatal mental health
- Supporting mental health in pregnancy and identifying the symptoms of anxiety
- Appropriate signposting and referral for women with severe anxiety
- The role of the professional in the group sessions, qualities of effective facilitators
- Groups as a vehicle for accessing support and promoting wellbeing
- Managing conflict and difficult behaviour in the group
- Adherence to the intervention protocol, safe working and accessing support, supervision and advice

What are the requirements for midwives?

Midwives will be selected for their interest in perinatal mental health, interpersonal skills and clinical knowledge (demonstrated through their current practice requirements in a community or hospital setting). Midwives will need to have:

- Band 6 midwives
- Interest in antenatal anxiety / perinatal mental health
- Interest or skills in group work

What are the requirements for midwifery support workers?

One midwifery support worker will be selected from each clinical area (QMC, CHN and Community teams). Midwifery support workers will be selected for their interest in perinatal mental health, interpersonal skills and experience working in the role of a midwifery support worker. Midwifery support workers will need to have:

- One years' experience working as a midwifery support worker
- Interest in antenatal anxiety / perinatal mental health
- Interest or skills in group work

When will the study take place?

Subject to receiving all appropriate permissions, the study will take place between [dates]. Training will take place between [dates]. Definite dates will be provided when all permissions have been received. We will ensure you have sufficient time to arrange duty rotas with your manager.

How much time is involved?

The training will be delivered in 3 sessions, each lasting 6-7 hours.

Delivering the intervention will take around 16 hours in total:

- 2-3 hours to contact the women individually (10 minutes discussion with each participant, 10 participants per midwife)
- 1.5 hours to facilitate the group sessions (x4 sessions)
- Up to 1 hour to provide individual support following the groups (x4)
- Additional preparation and administration time

The training will contribute to your revalidation requirements and your personal portfolio. You will need to agree participation with your manager. It has been agreed by [manager name] that you will be provided with a total of [number of hours] clinical time for training and to deliver the intervention.

Who is sponsoring the study?

The University of Nottingham will act as sponsor to the study and the study has received permissions from the National Research Ethics Service (NRES) Committee East Midlands, the Research & Innovation department of [NHS Trust] and the University of Nottingham.

Contact for further information

If you have any questions about the study, or would like an informal chat about participating please speak to the study researcher: [name and contact information]

Appendix 5.6 Training workbook for facilitators



Supporting Women with Anxiety in Pregnancy

An evaluation of the feasibility and acceptability of an intervention for pregnant women with symptoms of mild to moderate anxiety

Training Workbook for Midwife and Maternity Support Worker Facilitators

Training workshop dates	Page ...
Day 1: Overview and supporting materials	Page ...
Day 2: Overview and supporting materials	Page ...
Day 3: Overview	Page ...
References	Page ...

Training workshop dates
The training sessions will be held over 3 days: Day 1: Location: Day 2: Location: Day 3: Location:

Training Day 1

Aims and objectives

- Provide an overview of common mental health conditions in pregnancy including anxiety disorders
- Identify the impact of anxiety to women and infants
- Identify the prevalence of anxiety in general and pregnant populations
- Discuss the causes and risk factors for developing anxiety symptoms in pregnant women
- Discuss how the symptoms of anxiety are identified, including the use of anxiety measurement tools
- Discuss the treatment aim of supporting women with mild to moderate symptoms of anxiety
- Identify the methods of support (therapeutic approaches / mind-body approaches / group sessions / self-help materials) for treating anxiety disorders

Information to support the learning objectives

Common mental health disorders in the perinatal period

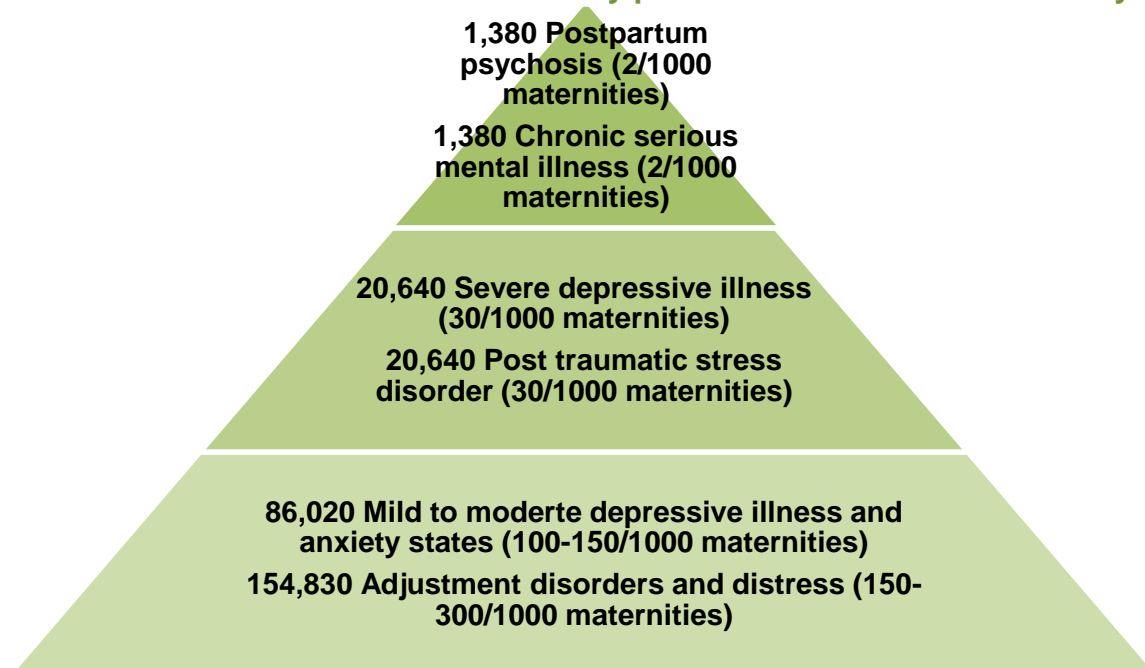
The NSPCC report, Prevention in mind. All Babies Count: Spotlight on Perinatal Mental Health (Hogg 2013) stated the incidence of many mental health disorders does not change in the perinatal period, however the effects of these illnesses are likely to be more significant at this time.

The NICE guideline for antenatal and postnatal mental health (National Institute for Health and Care Excellence 2014) reported depression and anxiety as the most common mental health problems during pregnancy:

- 12% of women experience depression during pregnancy
- 13% experience anxiety during pregnancy
- many women will experience both (co-morbid)
- depression and anxiety affect 15-20% of women in the first year after birth.

In the perinatal period, anxiety disorders, including panic disorder, generalised anxiety disorder (GAD), obsessive-compulsive disorder (OCD), post-traumatic stress disorder (PTSD) and tokophobia (an extreme fear of childbirth), can occur on their own or can coexist with depression. Psychosis can re-emerge or be exacerbated during pregnancy and the postnatal period. Postpartum psychosis affects between 1 and 2 in 1000 women who have given birth. Women with bipolar I disorder are at particular risk, but postpartum psychosis can occur in women with no previous psychiatric history (NICE 2014).

Estimated numbers of women affected by perinatal mental illnesses each year



From: Hogg (2013) Prevention in mind, all babies count: Spotlight on perinatal mental health NSPCC

Overview of Anxiety Disorders

The Diagnostic and Statistical Manual of Mental Disorders (DSM-V) (American Psychiatric Association (APA) 2013) provide a description of the categories of anxiety and obsessive-compulsive disorders:

Anxiety Disorders

Separation Anxiety Disorder
 Selective Mutism
 Specific Phobia
 Social Anxiety Disorder (Social Phobia)
 Panic Disorder
 Panic Attack (Specifier)
 Agoraphobia
 Generalized Anxiety Disorder
 Substance/Medication-Induced Anxiety Disorder
 Anxiety Disorder Due to Another Medical Condition
 Other Specified Anxiety Disorder
 Unspecified Anxiety Disorder

Obsessive-Compulsive and Related Disorders

Obsessive-Compulsive Disorder
 Body Dysmorphic Disorder
 Hoarding Disorder
 Trichotillomania (Hair-Pulling Disorder)
 Excoriation (Skin-Picking) Disorder
 Substance/Medication-Induced Obsessive-Compulsive and Related Disorder
 Obsessive-Compulsive and Related Disorder Due to Another Medical Condition
 Other Specified Obsessive-Compulsive and Related Disorder
 Unspecified Obsessive-Compulsive and Related Disorder

Diagnostic Criteria for Anxiety Disorders

GENERALISED ANXIETY DISORDER

- excessive anxiety or worry, occurring for the majority of the time, difficult for the individual to control
- symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning
- excessively apprehensive about the outcome of routine activities, often anticipate a catastrophic outcome.
- often unsubstantiated worry
- muscle tension; gastrointestinal discomfort or diarrhoea; irritability; fatigue; edginess; restlessness; sleep difficulties (APA 2013).

PANIC DISORDER

- intermittent apprehension and panic attacks to situations or with no apparent cause
- a period of intense fear or discomfort
- symptoms develop abruptly and reach a peak within ten minutes
 - palpitations and accelerated heart rate; sweating and shaking; sensations of shortness of breath or feeling of choking; chest pain; nausea; feeling dizzy or faint; derealisation (feelings of unreality); depersonalisation (being detached from oneself); fear of losing control or dying; numbness and chills or hot flushes (APA 2013, NICE, 2011).

OBSESSIVE-COMPULSIVE DISORDER

- recurrent and persistent thoughts, impulses or images
- thoughts are intrusive, unreasonable, inappropriate: cause anxiety/distress.
- obsessions and compulsions are time consuming and significantly interfere with the person's normal routine, occupational functioning, social activities or relationships.
- Common obsessions:
 - contamination from dirt, germs, viruses; fear of harm; excessive concern with order or symmetry; body / physical symptoms; religious or sexual thoughts; an urge to hoard useless possessions; thoughts of violence or aggression
- Common compulsions: checking, cleaning, washing, repeating acts, repeating special words in a set manner, ordering, symmetry, collecting and counting
- Perinatal OCD: obsessions and compulsions are more likely to focus on the baby.
(APA 2013, Lochner & Stein 2003, NICE, 2011)

POST TRAUMATIC STRESS DISORDER

- develops in response to one or more traumatic events such as deliberate acts of violence, severe accidents, disasters or military action.
- involuntarily re-experience aspects of the traumatic event in a vivid and distressing way.
- characterised by hyper-vigilance for a perceived threat, exaggerated startle responses, irritability, difficulty in concentrating, sleep problems and avoidance of trauma reminders.
- symptoms of emotional numbing, making efforts to avoid thoughts, activities, people or conversations associated with the trauma
 - an inability to recall important aspect of the trauma; diminished interest in activities; feelings of detachment from others; a sense of a foreshortened future
(APA 2013, NICE, 2011).

TOCOPHOBIA

- an intense fear of childbirth, which may be primary, usually originating in adolescence or secondary following a previous traumatic childbirth experience.
- associated with anxiety and depressive disorders (Hofberg & Brockington 2000)
- For certain serious mental illnesses (postpartum psychosis, severe depressive illness, schizophrenia and bipolar illness). the risk of developing or experiencing a recurrence increases after childbirth.

NHS e-learning for Healthcare package: Module One: Perinatal depression and other maternal mental health disorders (click on the PMH logo to access)



Impact of anxiety in pregnancy

Baxter et al. (2014) identified anxiety disorders as the sixth leading cause of disability globally, in terms of Years Lived with Disability (YLD). While there are no specific data for anxiety disorders in pregnancy, Baxter et al. (2014) found that females accounted for about 65% of the Disability adjusted life years (DALYs) caused by anxiety disorders, with the highest burden experienced by those aged between 15 and 34 years.

A systematic review by Haller et al. (2014) explored the prevalence and impact of GAD below the diagnostic threshold using DSM and ICD criteria. The prevalence for sub-threshold GAD symptoms was twice that for the full disorder. The median prevalence rate in a general population was reported as 4.4%. Sub-threshold symptoms of GAD were found to cause considerable impairment in psychosocial functioning; work functioning; benzodiazepine use; and more primary health care use than in non-anxious individuals. Sub-threshold symptoms were also found to increase the risk for developing a range of co-morbid mental health and somatic disorders. In the management of sub-threshold symptoms of anxiety, the aim is to prevent an escalation of symptoms and improve a woman's ability to cope (NICE 2014).



The costs of perinatal mental health problems

Annette Bauer, Michael Parsonage, Martin Knapp, Valentina Lemmi & Bayo Adelaja

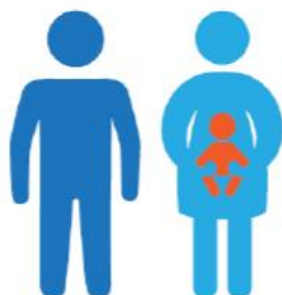


Table 3: Costs of perinatal anxiety, impact on mothers, £ per case

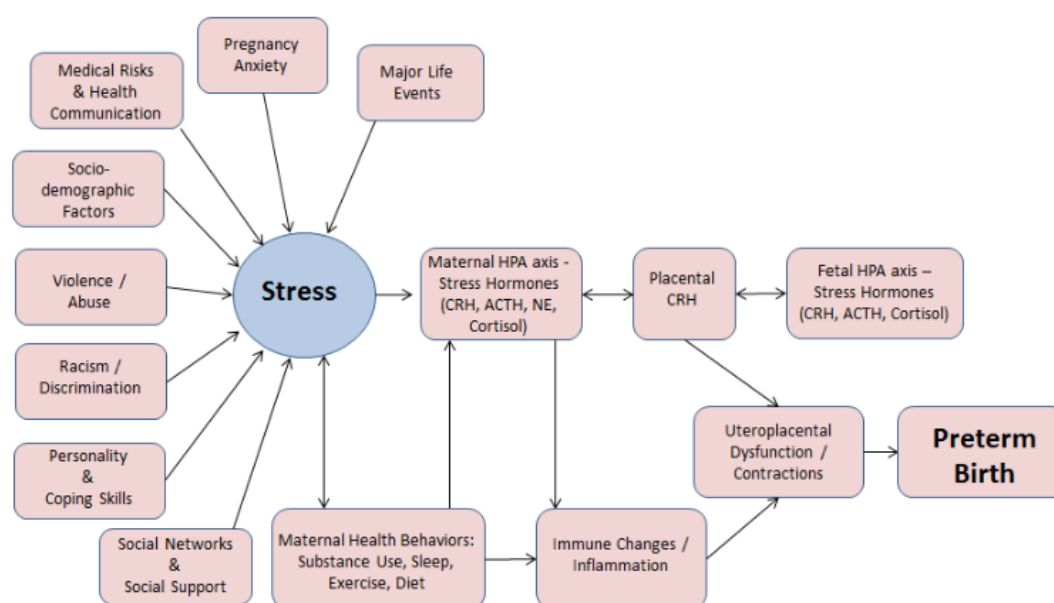
Public sector	Wider society			Total
Health and social care	QALY losses	Productivity losses	Other	
4,320	10,975	5,499	-	20,794

Table 4: Costs of perinatal anxiety, impact on children, £ per case

	Public sector			Wider Society			Total
	Health and social care	Education	Criminal justice	QALY losses	Productivity losses	Other	
Pre-term birth (incl. cognitive impairment)	2,435	13	-	1,044	54	34	
Emotional problems	273	176	-	535	440	-	
Conduct problems	236	-	558	960	508	2,105	
Chronic abdominal pain	1,531	140	-	-	736	2,239	
Total	4,475	329	558	2,539	1,738	4,378	14,017

Bauer et al. (2014) valued the costs of additional use of public services, productivity losses and quality adjusted life year (QALY) losses for women with symptoms of anxiety in the perinatal period and continuing up to ten years after birth. Based on reported prevalence rates and adjusting for anxiety co-existing with depression, costs were estimated at £35,000 per case, £21,000 relating to the mother and £14,000 to the child (Bauer et al. 2014).

Elevated and prolonged anxiety in pregnancy has been associated with pre-term birth, fetal growth restriction and severe behavioural problems in developing children (Hansen et al. 2000, O'Connor 2002, Rich-Edwards & Grizzard 2005).



Masho & Cha (2013) modified from Dunkel Schetter (2011)

O'Connor et al. (2002) identified a strong link between maternal anxiety and behavioural problems in children at four years. Mild to moderate psychological distress can be extremely debilitating for pregnant women (Furber et al. 2009) and can affect a woman's general functioning and the development of her infant.

Anxiety during pregnancy has been reported to have a negative impact on women's confidence in mothering and satisfaction with their infants (Reece & Harkless 1998) and to predict post-traumatic stress disorder and depression in the postnatal period (Czarnocka & Slade 2000, Iles et al. 2011, Reece & Harkless 1998).

Factors which impact on mental health during pregnancy

Vulnerability to Anxiety

Personality and coping styles



Reported relationship between symptoms of anxiety and dysfunctional attitudes, inferential style, dependence on other people (sociotrophy) and autonomy (Sutton et al. 2011)

Genetic



Individuals with GAD are reported to be more likely to have family members with anxiety problems (McLaughlin et al. 2008)

Traumatic life events



Traumatic or abusive life-experiences strongly predict higher levels of anxiety and depression (Kinderman et al. 2013)

Overprotective parenting



Overprotective and over critical parenting linked to a low internal locus of control and a vulnerability to anxiety (Bennet & Stirling, 1998, Chorpita & Barlow 1998)

Social support



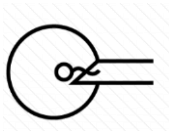
The relationship between good social support and mental wellbeing and poor social support and mental health problems is reported in numerous studies and populations (Resick 2001)

Previous pregnancy loss



Emotional cushioning (attempting to hold back emotions) reported as a complex self-protective mechanism used by women to cope with the anxiety, uncertainty, and sense of vulnerability experienced in subsequent pregnancies (Côté-Arsenault & Donato 2011)

Assisted conception



Women who experience IVF pregnancies are reported to be highly anxious about the possibility of loss of the pregnancy (Hjelmstedt et al. 2003)

Identification of anxiety symptoms in pregnancy

The report 'Saving Lives, Improving Mothers' Care' (Knight et al. 2015) states that screening for the risk of, or presence of mental disorders is the responsibility of all health professionals in contact with pregnant women. This report documents that for at least 11% of antenatal and postnatal women who died by suicide there was either an inadequate or absence of enquiry made at antenatal booking about mental health history or current mental ill health.

Psychological assessments are recommended as part of routine antenatal care (Austin et al. 2005, Buist et al. 2006, NICE 2014). This would provide an opportunity to offer support to women with symptoms of anxiety (Austin et al. 2008, Austin 2003, NICE 2014) and help identify women who require urgent senior psychiatric assessment (Knight et al. 2015).

Midwives are well-placed to identify many risk factors and symptoms of mental health problems during pregnancy (Oates 2003; O'Hara 2009; National Institute for Health and Care Excellence 2008). Psychological instruments can be used alongside a general discussion about a woman's mental wellbeing to help midwives recognise mental health problems in pregnancy (NICE 2014).

The National Institute for Health and Care Excellence (NICE) (2014) recommend that screening questions for anxiety and depression should be asked during a woman's first contact with primary care, during the initial visit with a midwife and early in the postnatal period. To identify symptoms of anxiety the 2-item Generalised Anxiety Disorder scale (GAD-2)(Spitzer et al. 2006) is recommended. The GAD-2 questions are: During the past month, have you been feeling nervous, anxious or on edge? During the past month have you not been able to stop or control worrying? Answers are scored on a 7-point scale; if a woman scores 3 or more on the GAD-2 scale or the health care practitioner has other concerns, further assessment using the GAD-7 scale or specialist mental health assessment is recommended.

NHS e-learning for Healthcare package. Module Two: How to recognise perinatal anxiety and depression (click on the PMH logo to access)



Supporting women's mental health in pregnancy

The maternal mental health pathway (Department of Health 2012) states that all women identified with mild to moderate mental health issues should be offered a range of support tailored to the needs of those women.

The treatment of anxiety disorders mainly focuses around improving the core symptoms such as worry, irritability, tension and fatigue (Lorenz et al. 2010). Treatment can be provided through pharmacological and/or non-pharmacological interventions (Anderson & Palm 2006, Borkovec & Ruscio 2001, Fisher 2006). Many women who take medication for anxiety stop taking it when they are pregnant (NICE 2014), due to the uncertainty surrounding the risk of teratogenicity (Baldwin et al. 2005). Non-pharmacological interventions are therefore recommended as the initial treatment option (NICE 2014).

Psychological interventions that have demonstrated effectiveness in non-pregnant populations with a GAD often include components of psycho-education, early detection of anxiety cues such as physical symptoms (e.g. stomach pains) or avoidance of impulsive behaviours, monitoring of anxious responses, applied relaxation, guided imagery, coping skills rehearsal and cognitive restructuring (Behar et al. 2009, Roemer & Orsillo 2002).

The Healthy Child Programme (Department of Health 2009) highlighted possible interventions to support women with anxiety in pregnancy, including social support, assisted self-help and CBT. The NICE guideline for perinatal mental health (NICE 2014) suggested low intensity psychological interventions may benefit women with symptoms of mild to moderate anxiety which significantly interfere with personal or social functioning.

Education for Scotland E-learning resources Maternal Mental Health (click on the picture to access)



The Boots Family Trust Alliance conducted a survey with 1,500 women and 2,000 health professionals on the topic of perinatal mental health. (Boots Family Trust Alliance 2013). Many women were reluctant to disclose symptoms of

mental health problems as they considered that this was a sign of failure. Almost a third (30%) had never told a health professional that they were unwell. Women's reasons for hiding their feelings included feeling embarrassed, they didn't feel ready to talk, they thought professionals wouldn't be able to help and because they were concerned their baby might be taken away. Boots Family Trust Alliance have developed a wellbeing plan to help raise awareness of the possible emotional challenges during pregnancy and in the postnatal period.

<http://www.bftalliance.co.uk/wp-content/uploads/2014/02/wellbeing-plan-with-NICE-and-RCGP.pdf>

Training Day 2

During the training day two you will take part in interactive skills based workshops with experienced mental health professionals and peer support education consultants. The training aims to:

- Understand the benefits of groups from multiple perspectives
- Reflect on the implications of self-management models and how to apply these in supporting groups to set up and establish themselves
- Build self-confidence when working with common challenges
- Consider helpful approaches in dealing with problems which may arise
- Identify resources for making the best use of groups

The topics covered include:

- Definitions of mutual aid and social capital in group settings
- The stages of group development and common reasons for closing
- The role of professionals
- Groups as vehicles for personal recovery, surviving and sustaining change
- Psychological perspectives of groups

The Peer Support Training Team have produced a film to highlight the concept of the shared journey of peer support. Click on the picture below to access:



Management of risk identified relating to the intervention

If the participant is considered by the midwife intervention facilitator as being at risk of harm to themselves or others, the midwife has a duty of care to report those concerns (NMC 2015) and inform the Chief Investigator within 24 hours. This information is detailed in the participant information sheet.

Should this situation arise, the midwife facilitator will discuss the concerns with the woman and seek further permission to contact the woman's lead care provider (community midwife or obstetric team). If the woman does not provide permission, the researcher will notify the Chief Investigator and will seek the support of the on-call supervisor of midwives (available through the NHS Trust) to follow the correct reporting procedure ensuring all relevant healthcare professionals are informed (National Institute for Health and Care Excellence 2014). The woman will be fully informed of the intended actions. Contact details for the researcher, Chief Investigator, community team leaders and supervisor of midwives is detailed below.

Emotional distress during participation in the study

For some women, sharing their experiences and feelings in a group setting or with the midwife may be beneficial. However, discussing anxiety may be sensitive, embarrassing or upsetting for some women. The midwife facilitator will be available following the discussion sessions to discuss any individual concerns.

Contact information:

- Researcher [name and contact details]
- Chief Investigator [name and contact details]
- Mental health link midwife [name and contact details]
- On-call supervisor or midwives: [contact details]
- Community co-ordinator number [name and contact details]

Training Day 3

During training day three you will discuss and feedback on the self-help materials you have accessed. A service user has kindly agreed to discuss her experience of anxiety she experienced during her pregnancy and how she benefitted from receiving psychological support. You will take part in a role play scenario of a peer discussion group. This will help you prepare for the groups, address any concerns, ask questions and agree your approach and format of the groups.

Appendix 5.7 Study manual and records

An evaluation of the feasibility and acceptability and of an intervention for pregnant women with symptoms of mild to moderate anxiety.

Study manual and study records for intervention facilitators: Midwives and MSWs

Study Documents

Facilitator name	Facilitator information sheet [date sent]	Study protocol [date sent]	Timetable for groups [date agreed]	Consent form [date signed]	Training workbook [date sent]	Study manual [date sent]

Contents

1.	General information regarding the completion of study forms
2.	Data Protection
3.	Pre-group meeting with midwife facilitator
4.	Group 1 – Group 4
5.	Management of risk identified relating to the intervention
6.	Contact information
7.	Additional record sheets
8.	Timetable of groups, locations and facilitators

1. General information regarding the completion of study forms

Each participant will be assigned a study identity code number, allocated at consent for use on study forms, other study documents and the electronic database. The documents and database will also use their initials (of first and last names separated by a hyphen) and recruitment site. Study forms will be treated as confidential documents and held securely in accordance with regulations. All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated.

2. Data protection

All study staff and investigators will endeavour to protect the rights of the study participants to privacy and informed consent, and will adhere to the Data Protection Act, 1998. The study form will only collect the minimum required information for the purposes of the study. Study Forms will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the study staff and investigators and relevant regulatory authorities (see above). Computer held data including the study database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one-way encryption method).

Information about the study in the participant's hospital notes will be treated confidentially in the same way as all other confidential medical information. Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

3. Pre-group meeting with midwife facilitator

The pre-group meeting will be a face-to face individual meeting between the midwife facilitator and the woman. The midwife will contact the woman to arrange a meeting time and location. Contact details will be passed to the midwife by the researcher. The meeting will last approximately 10 minutes. This purpose of this session will be to 1. enable the woman to meet the midwife before the first group session, 2. welcome the woman into the intervention and 3. help her feel more comfortable attending the sessions.

The researcher will meet the midwives in the study sites before the pre-group meeting to familiarise the midwives with the room locations and highlight health and safety procedures in the study sites.

Please complete the table below with the participant code to plan and record pre-group sessions

Pre-group meeting		
Date / time	Participant code	Attended YES/NO

Following the meeting the midwife will provide the woman with details of the timing and location for the groups

4. Group sessions

Four groups will take place over an eight-week period. There will be one group, each group consisting of eight to ten women. Sessions will be held in the community healthcare centre. Each session will last for 90 minutes. The purposes of the sessions are to support and encourage women with accessing and using self-help materials and for women to have the option to discuss any concerns individually with the midwife. Following the group sessions, each woman will be allocated 10-15 minutes individual meeting time if required to discuss any individual concerns or ask questions. This support shall be provided within the scope of current midwifery practice (Nursing and Midwifery Council 2012).

Group 1: During the first group the facilitators will discuss the ground rules for the session (asking participants to respect each other's point of view during the discussions and to keep confidential any sensitive information which may be discussed). The facilitators will provide an overview of each self-help material and assist participants to decide which resource would suit their needs. Women will be helped to access on-line materials during this time if necessary (i.e. locating and installing on-line applications).

Please complete the table below to record attendance at group 1

Midwife name:

Maternity support worker name

Group 1		date:	time:
Participant Initials	Attended YES/NO	Participant Initials	Attended YES/NO

Please indicate the number of women requiring additional individual meeting time

Group 2-4: The midwife and MSW will agree a discussion agenda with the women and discuss their progress with the self-help materials. The midwife and midwifery support worker will provide support and encouragement for the women using the self-help materials and promote social support in group discussions.

Please complete the table below to record attendance at group 2

Midwife name:

Maternity support worker name

Group 2 Date: Time:		Group 3 Date: Time:		Group 4 Date: Time:	
Participant code	Attended YES/NO	Participant code	Attended YES/NO	Participant code	Attended YES/NO

Please indicate the number of women requiring additional individual meeting time:

5. Management of risk identified relating to the intervention

If the participant is considered by the midwife intervention facilitator as being at risk of harm to themselves or others, the midwife has a duty of care to report those concerns (NMC 2015) and inform the Chief Investigator within 24 hours. This information is detailed in the participant information sheet.

Should this situation arise, the midwife facilitator will discuss the concerns with the woman and seek further permission to contact the woman's lead care provider (community midwife or obstetric team). If the woman does not provide permission, the Co-investigator will notify the Chief Investigator and will seek the support of the on-call supervisor of midwives (available through the NHS Trust) to follow the correct reporting procedure ensuring all relevant healthcare professionals are informed (National Institute for Health and Care Excellence 2014). The woman will be fully informed of the intended actions. Contact details for the researcher, Chief Investigator, community team leaders and supervisor of midwives is detailed below.

Emotional distress during participation in the study

For some women, sharing their experiences and feelings in a group setting or with the midwife may be beneficial. However, discussing anxiety may be sensitive, embarrassing or upsetting for some women. The midwife facilitator will be available following the discussion sessions to discuss any individual concerns.

6. Contact information:

- Researcher [name and contact details]
- Chief Investigator [name and contact details]
- On-call supervisor or midwives: [contact details]
- Community coordinator number [name and contact details]

7. Please use this space to record any actions taken related to the study or other relevant information. If the following pages contain any confidential or identifiable information, please arrange for this form to be stored securely in accordance with the study protocol. Contact: the researcher (using the contact information on page 6). Please initial and date each entry.

	Location	Date	Time	Midwife name	MSW name
Training				All	All
Training				All	All
Training				All	All
Pre-group					
Group 1					
Group 2					
Group 3					
Group 4					

Appendix 5.8 Post intervention self-report measures

University of Nottingham, School of Health Sciences



An evaluation of the feasibility and acceptability and of an intervention for pregnant women with symptoms of mild to moderate anxiety.

Chief Investigator: [name] Co-Investigators: [names]

Post-intervention self-report measures

Participant Number:

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Date:

--	--	--	--	--	--

GAD-7	Page ...
State Trait Anxiety Inventory	Page ...
Pregnancy Related Anxiety Questionnaire (Revised)	Page ...
Edinburgh Postnatal Depression Scale	Page ...
12-Item Short Form Health Survey (SF-12)	Page ...

GAD-7 Inclusion screening

Over the <u>last 2 weeks</u> , how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3
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 <input type="checkbox"/>	Somewhat difficult <input type="checkbox"/>	Very difficult <input type="checkbox"/>	Extremely difficult <input type="checkbox"/>	

- Spitzer, R. L., Kroenke, K., Williams, J. B. W., & Löwe, B. (2006). A brief measure for assessing generalized anxiety disorder: the GAD-7. *Archives of Internal Medicine*, 166(10), 1092–7.

State Trait Anxiety Inventory (State anxiety Y1)

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel right now, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feeling best.	Not at all	Somewhat	Moderately so	Very much so
1. I feel calm	1	2	3	4
2. I feel secure	1	2	3	4
3. I am tense	1	2	3	4
4. I feel strained	1	2	3	4
5. I feel at ease	1	2	3	4
6. I feel upset	1	2	3	4
7. I am presently worrying over possible misfortunes	1	2	3	4
8. I feel satisfied	1	2	3	4
9. I feel frightened	1	2	3	4
10. I feel comfortable	1	2	3	4
11. I feel self-confident	1	2	3	4
12. I feel nervous	1	2	3	4
13. I am jittery	1	2	3	4
14. I feel indecisive	1	2	3	4
15. I am relaxed	1	2	3	4
16. I feel content	1	2	3	4
17. I am worried	1	2	3	4
18. I feel confused	1	2	3	4
19. I feel steady	1	2	3	4
20. I feel pleasant	1	2	3	4

State Trait Anxiety Inventory (Trait anxiety Y2)

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you generally feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel.	Almost never	Sometimes	Often	Almost always
21. I feel pleasant	1	2	3	4
22. I feel nervous and restless	1	2	3	4
23. I feel satisfied with myself	1	2	3	4
24. I wish I could be as happy as others seem to be	1	2	3	4
25. I feel like a failure	1	2	3	4
26. I feel rested	1	2	3	4
27. I am 'cool, calm and collected'	1	2	3	4
28. I feel like difficulties are piling up so that I cannot overcome them	1	2	3	4
29. I worry too much over something that really doesn't matter	1	2	3	4
30. I am happy	1	2	3	4
31. I have disturbing thoughts	1	2	3	4
32. I lack self confidence	1	2	3	4
33. I feel secure	1	2	3	4
34. I make decisions easily	1	2	3	4
35. I feel inadequate	1	2	3	4
36. I am content	1	2	3	4
37. Some unimportant thought runs through my mind and bothers me	1	2	3	4
38. I take disappointments so keenly that I can't put them out of my mind	1	2	3	4
39. I am a steady person	1	2	3	4
40. I get in a state of tension or turmoil as I think over my recent concerns and interests	1	2	3	4

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Published by Mind Garden Inc, 1690 Woodside Road, Suite 202, Redwood City, CA 94061.

Pregnancy Related Anxiety Questionnaire (Revised)

	Very true	True	Not true	Certainly not true
1. I am afraid the baby will be mentally handicapped or will suffer from brain damage	4	3	2	1
2. I am afraid our baby will be stillborn, or will die during or immediately after delivery	4	3	2	1
3. I am afraid that our baby will suffer from a physical defect or worry that something will be physically wrong with the baby	4	3	2	1
4. I am worried about the pain of contractions and the pain during delivery	4	3	2	1
5. I am worried about the fact that I shall not regain my figure after delivery	4	3	2	1
6. I sometimes think that our child will be in poor health or will be prone to illnesses	4	3	2	1
7. I am concerned about my unattractive appearance	4	3	2	1
8. I am anxious about the delivery because I have never experienced one before	4	3	2	1
9. I am worried about not being able to control myself during labour and fear that I will scream	4	3	2	1
10. I am worried about my enormous weight gain	4	3	2	1

Edinburgh Postnatal Depression Scale

As you are pregnant or have recently had a baby, we would like to know how you are feeling. Please check the answer that comes closest to how you have felt IN THE PAST 7 DAYS, not just how you feel today. Here is an example, already completed.

I have felt happy

- X **Yes, all of the time** This would mean 'I have felt happy most of the time' during the past week.
 Yes, most of the time
 No, not very often
 No, not at all Please complete the other questions in the same way

In the past 7 days:

1. I have been able to laugh and see the funny side of things

- ☐ As much as I always could
☐ Not quite so much now
☐ Definitely not much now
☐ Not at all

2. I have looked forward with enjoyment to things

- ☐ As much as I ever did
☐ Rather less than I used to
☐ Definitely less than I used to
☐ Hardly at all

3. * I have blamed myself unnecessarily when things went wrong

- ☐ Yes, most of the time
☐ Yes, some of the time
☐ Not very often
☐ No, never

4. I have been anxious or worried for no good reason

- ☐ No, not at all
☐ Hardly ever
☐ Yes, sometimes
☐ Yes, very often

5. *I have felt scared or panicky for no very good reason

- ☐ Yes, quite a lot
☐ Yes, sometimes
☐ No, not much
☐ No, not at all

6. * Things have been getting on top of me

- ☐ Yes, most of the time I haven't been able to cope at all
☐ Yes, sometimes I haven't been coping as well as usual
☐ No, most of the time I have coped quite well
☐ No, I have been coping as well as ever

7. * I have been so unhappy that I have had difficulty sleeping

- ☐ Yes, most of the time
☐ Yes, sometimes
☐ Not very often
☐ No, not at all

8. * I have felt sad or miserable

- ☐ Yes, most of the time
☐ Yes, quite often
☐ Not very much
☐ No, not at all

9. * I have been so unhappy that I have been crying

- ☐ Yes, most of the time
☐ Yes, quite often
☐ Only occasionally
☐ No, never

10. *The thought of harming myself has occurred to me

- ☐ Yes, quite often
☐ Sometimes
☐ Hardly ever
☐ Never

Source: Cox, J.L., Holden, J.M., and Sagovsky, R. 1987. Detection of postnatal depression: Development of the 10-item Edinburgh Postnatal Depression Scale. *British Journal of Psychiatry* 150:782-786

12-Item Short Form Health Survey (SF-12)

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer each question by choosing just one answer. If you are unsure how to answer a question, please give the best answer you can.

1. In general would you say your health is
☐ Excellent (1) ☐ Very good (2) ☐ Good (3) ☐ Fair (4) ☐ Poor (5)

The following two questions are about activities you might do during a typical day. Does YOUR HEALTH NOW LIMIT YOU in these activities? If so, how much?

2. MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf:
☐ Yes, Limited A Lot (1) ☐ Yes, Limited A Little (2) ☐ No, Not Limited At All (3)
3. Climbing SEVERAL flights of stairs:
☐ Yes, Limited A Lot (1) ☐ Yes, Limited A Little (2) ☐ No, Not Limited At All (3)

During the PAST 4 WEEKS have you had any of the following problems with your work or other regular activities AS A RESULT OF YOUR PHYSICAL HEALTH?

4. ACCOMPLISHED LESS than you would like:
☐ Yes (1) ☐ No (2)
5. Were limited in the KIND of work or other activities:
☐ Yes (1) ☐ No (2)

During the PAST 4 WEEKS, were you limited in the kind of work you do or other regular activities AS A RESULT OF ANY EMOTIONAL PROBLEMS (such as feeling depressed or anxious)?

6. ACCOMPLISHED LESS than you would like
☐ Yes (1) ☐ No (2)
7. Didn't do work or other activities as CAREFULLY as usual:
☐ Yes (1) ☐ No (2)
8. During the PAST 4 WEEKS, how much did PAIN interfere with your normal work (including both work outside the home and housework)?
☐ Not at all (1) ☐ A little bit (2) ☐ Moderately (3) ☐ Quite A Bit (4) ☐ Extremely (5)

The next three questions are about how you feel and how things have been DURING THE PAST 4 WEEKS. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the PAST 4 WEEKS –

9. Have you felt calm and peaceful?
☐ All of the Time (1) ☐ Most of the Time (2) ☐ A Good Bit of the Time (3) ☐ Some of the Time (4) ☐ A Little of the Time (5) ☐ None of the Time (6)
10. Did you have a lot of energy?
☐ All of the Time (1) ☐ Most of the Time (2) ☐ A Good Bit of the Time (3) ☐ Some of the Time (4) ☐ A Little of the Time (5) ☐ None of the Time (6)
11. Have you felt downhearted and blue?
☐ All of the Time (1) ☐ Most of the Time (2) ☐ A Good Bit of the Time (3) ☐ Some of the Time (4) ☐ A Little of the Time (5) ☐ None of the Time (6)
12. During the PAST 4 WEEKS, how much of the time has your PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with your social activities (like visiting with friends, relatives, etc.)?
☐ All of the Time (1) ☐ Most of the Time (2) ☐ A Good Bit of the Time (3) ☐ Some of the Time (4) ☐ A Little of the Time (5) ☐ None of the Time (6)

Appendix 6.1 Analysis template: participant interview transcriptions

General themes/topics: pre-defined headings themes added/amended from transcriptions Themes: support (✓) / refute (x)	P1	P4	P5	P6	P8	P10	P7	P2
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Recruitment

Women with anxiety are motivated to self-refer to manage their symptoms	x	✓	x	x	x	x		
Women were reluctant to self-refer - prefer to be invited to participate by their midwife	✓	x	✓	✓	✓	✓	✓	✓
Women may be reluctant / find it difficult to disclose symptoms of anxiety to HCPs	✓	x	x			✓	✓	✓
Women were open about disclosing their symptoms	x	✓		✓		x	x	x
Women had initial concerns about participating	✓	✓		✓	✓	✓	✓	✓
Women thought the intervention may benefit them		✓	✓		✓		✓	✓

Other sources of support

There is limited support available for women with mild to moderate symptoms of anxiety	✓	✓		✓		✓		✓
Women identified existing anxiety coping strategies		✓	✓		✓			✓
Women felt isolated / limited social support		✓	✓			✓		

Length / timing of sessions

Some evidence of benefit for interventions in the 2nd - 3rd trimester			✓	✓				
Women wanted more than four intervention sessions	✓	✓	✓	✓	✓	✓		
Women were more anxious in early pregnancy	✓	✓				✓		✓
Intervention sessions needed to be longer		✓	✓	✓	✓	✓		

Intervention components

Women valued materials which gave them options / coping strategies for managing their symptoms			✓	✓	✓		✓	
Women were initially guarded and didn't want to distress other women	✓	✓		✓			✓	
Meetings intervention facilitators before the groups help women to feel welcome and confident to attend.	✓	✓	✓	✓	✓	✓		
Women preferred pregnancy related materials		✓	✓	✓		✓		
Women identified topics they would have liked to discuss / found difficult to discuss	✓	✓		✓	✓			
Women preferred unstructured group sessions			✓	✓				

Group discussions

Women benefit from sharing experiences and accessing group support.		✓	✓	✓	✓	✓		
Women feel more comfortable and derived greater benefit when groups had time to establish.	✓	✓	✓	✓		✓		
Sharing experiences help women feel less isolated.	✓	✓	✓		✓	✓	x	✓
Women felt anxious about speaking in groups	✓				✓		✓	
Women had difficulty relating to others in the group	✓	x	x	x	x	x	✓	

Individual discussions

Women welcomed the option to access individual support from midwife facilitator	✓	✓	✓	✓	✓	✓		
---	---	---	---	---	---	---	--	--

Facilitators

Support for an intervention delivered by a midwife which can be integrated into maternity care.	✓	✓	✓	✓	✓	✓	✓	✓
Women accessed individual support from facilitator	✓	✓		✓		x		

Group location, time, size, characteristics

Location of the intervention sessions is an important component. Support for community locations		✓	✓	✓	✓	✓		
The intervention should be offered outside daytime working hours	✓	✓	✓		✓	✓	✓	✓
Women preferred smaller groups	✓		x	✓	✓	✓		
Women liked being in groups with other women with similar feelings / experiences	x	✓	✓	✓	✓			

Benefits / satisfaction

Anxiety symptoms improved after the intervention	✓	✓	✓	✓	✓	✓		
Women identified the main benefit they derived from participating in the intervention	✓	✓		✓	✓	✓		
Would recommend the intervention to other women	✓	✓	✓	✓	✓	✓	✓	✓
The intervention was enjoyable / positive experience		✓	✓	✓		✓		

Self-report forms

SF-12 did not feel relevant to pregnancy		✓	✓			✓		
EPDS was difficult for some women to complete	✓		✓	✓			✓	✓
PRAQ reflected women anxieties	✓	✓	✓	✓	✓	✓	✓	x
GAD-7 felt relevant to women			✓	✓				✓
STAI helpful to some women			✓	x		✓		x
Help women discuss their symptoms of anxiety		✓	✓	✓	✓		✓	

Appendix 6.2 Analysis template: facilitator interview transcriptions

General themes/topics: pre-defined headings themes added/amended from transcriptions Themes: support (✓) / refute (x) / uncertain (?)	MSW 1	MW 1	MW 2	MSW 2
--	-------	------	------	-------

Training

Training general thoughts/comments		✓	✓	✓
Conflict between two approaches / providers	x		✓	
Training day 1 comments discussed	✓	✓	✓	✓
Training day 2 comments discussed	✓	✓	✓	✓
Training day 3 comments discussed	✓		✓	✓
Training was the right length of time	✓		✓	
Useful to have a gap between training days	✓		✓	
Enjoyed the training	✓		✓	
Suggested improvements to the training		✓		✓
Training: felt prepared to facilitate	✓	✓	?	✓

Length / timing of sessions

Needed more sessions	✓	✓		✓
Needed longer sessions	✓	✓	✓	✓

Intervention components

Meetings intervention facilitators before the groups help women to feel welcome and confident to attend	✓	✓	✓	✓
Support for self-help packages for use between sessions	✓	✓	✓	✓
Discussion topics		✓		
Impact of missing sessions	✓			
Structured sessions were less successful	✓	✓		

Group discussions

Women valued shared experiences, helping others and access to group support	✓	✓		
Women feel more comfortable and derived greater benefit when groups had time to establish		✓		
Sharing experiences help women feel less isolated	✓		✓	✓
Women did not want to distress others		✓		
Helped women access/question maternity care		✓		

Individual discussions

Women welcomed the option to access individual support from midwife facilitator	✓	✓	✓	✓
---	---	---	---	---

Facilitator

Support for an intervention delivered by a midwife which can be integrated into maternity care	✓	✓	✓	✓
Facilitators approach: welcoming, being part of the group	✓	✓		✓
Initial worries about facilitating the groups	✓	✓	✓	✓

Group location, time, size, characteristics

The location of the intervention sessions is an important component. Support for community locations	✓	?	✓	✓
Group size (groups should not have more than 6-7 participants)	✓	✓		
Group characteristics: differences/similarities worked well	✓	✓	✓	?
Group characteristics: support for the group to be targeted at women with mild/moderate anxiety	✓	✓	?	

Women continued the groups informally	✓	✓		✓
What worked well (views provided)	✓	✓		✓
What we could be improved (views provided)		✓	✓	✓

Benefits / satisfaction

Happy to be involved in the future	✓		✓	✓
Benefit for the women	✓	✓	✓	
Facilitating: positive experience	✓	✓	✓	
Recruiting facilitators: through expressions of interest	✓	✓	✓	✓

Knowledge of other sources of support

There is limited support available for women with mild to moderate symptoms of anxiety	✓	✓	✓	
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Feasibility

Feasible to introduce the intervention in maternity care	✓	✓	✓	✓
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