



STUDY PROTOCOL

Perinatal **M**ental Health **A**ssessment and **T**reatment: An Evidence Synthesis and Conceptual Framework of Barriers and Facilitators to **I**mplementation (MATRIX)

Short Title	Perinatal mental health assessment and treatment
Acronym	MATRIX
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Chief Investigator	Prof Susan Ayers
Host Institution	School of Health Sciences, City, University of London
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Project duration	24 months

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:			
Chief Investigator:			
Susan Ayers	Chief Investigator	Date: 1 August 2019	

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KEY STUDY CONTACTS

Chief Investigator	Susan Ayers	Centre for Maternal and Child Health Research, School of Health Sciences, City, University of London, Northampton Square, London, EC1V 0HB. Telephone: 0207 040 5834 Email: Susan.Ayers@city.ac.uk
Research Fellow	Rebecca Webb	Centre for Maternal and Child Health Research, School of Health Sciences, City, University of London, Northampton Square, London, EC1V 0HB. Email: Rebecca.Webb.2@city.ac.uk
PPI Lead	Agnes Hann	National Childbirth Trust 30 Euston Square, London, NW1 2FB Agnes.Hann@nct.org.uk
Sponsor	City, University of London	Contact: Christopher Hull, Associate Dean for Research, School of Health Sciences, City, University of London, Northampton Square, London, EC1V 0HB Telephone: 0207 040 4317 Email: c.c.hull@city.ac.uk
Funder	NIHR HS&DR	University of Southampton, Alpha House, Enterprise Road, Southampton, SO16 7NS Telephone: 0238 059 7501 E-Mail: netspostawardsetup@nihr.ac.uk
Co-applicants	Helen Cheyne Judy Shakespeare Debra Salmon Simon Gilbody Abigail Easter Fiona Alderdice Elizabeth Ford	University of Stirling General Practitioner (retired) City, University of London University of York King's College London University of Oxford Brighton & Sussex Medical School
Collaborators	Evelyn Frame Camilla Rosan Clare Thompson Sally Hogg Elaine Clark Rose Coates Andrea Sinesi	NHS Greater Glasgow and Clyde University College London Maternal Mental Health Change Agents (MMHCA) Parent-Infant Partnership UK (PIP UK) Perinatal mental health clinical network for Scotland MAP Project, City, University of London MAP Project, University of Stirling

Project Oversight Committee	Members to be confirmed	Key contact: Nazihah Uddin Centre for Maternal and Child Health Research, School of Health Sciences, City, University of London, Northampton Square, London, EC1V 0HB. Telephone: 0207 040 5981 Email: Nazihah.Uddin.2@city.ac.uk
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SCIENTIFIC ABSTRACT

Background: Perinatal mental health problems affect up to one in five women, and the cost to the UK is estimated as £8.1 billion for every one-year cohort of births. Perinatal mental illness can have adverse effects on women, their infants and families. It is therefore important to identify and treat perinatal mental health problems quickly, yet it is estimated that half of women do not come to the attention of healthcare services and still fewer receive treatment.

Aim: The aim of this evidence synthesis is to identify the barriers and facilitators to perinatal mental health assessment, care and treatment for women, at individual, relational (e.g. woman-healthcare professional), organisational and systemic levels; and determine how these can be used to inform and improve perinatal mental healthcare services.

Methods: This evidence synthesis will be conducted in three phases. Phase 1 will determine the barriers and facilitators to implementing perinatal mental health assessment and treatment in different health and social care contexts. This will be achieved through a focused systematic review following PRISMA guidelines.

Phase 2 will identify factors that prevent women accessing treatment. This will be done through a meta-review of reviews. It will also enable us to evaluate the quality of the current evidence, map the geographical distribution of the evidence, and make recommendations for healthcare practice and research based on these findings.

Phase 3 will map the findings from phases 1 and 2 onto a conceptual framework developed by the research team. Phase 3 will be done in three stages. Firstly, overall concepts and themes from the literature will be identified from Phases 1 and 2. Secondly, reviews will be grouped at different levels (i.e. individual, interpersonal, organisational, social) and a detailed thematic analysis carried out to identify both existing and missed themes. Thirdly, the conceptual framework will be refined based on the themes and an expert stakeholder panel will assess its validity. The framework will then be revised based on their feedback. Recommendations to improve the chances of women being identified and accessing treatment will be formulated by the research team and expert stakeholder panel.

Anticipated impact: This evidence synthesis was developed through our partnerships with women who have experience of perinatal mental illness, health professionals and service managers. They identified this as a priority and will work with us through the project to ensure its relevance to women, their partners and families and the NHS. The anticipated impact is four-fold: (i) the evidence synthesis will provide recommendations to improve identification and access to appropriate care or treatment; (ii) improving access may reduce the morbidity and mortality associated with unidentified and untreated, or inappropriately treated, perinatal mental health problems; (iii) implementing recommendations from the evidence synthesis has the potential to improve service users' experience; and (iv) new knowledge will be generated in terms of a conceptual framework which will identify the multifactorial reasons why women do not access perinatal mental healthcare and/or receive appropriate assessment, care or treatment.

PLAIN ENGLISH SUMMARY

Mental health problems affect up to one in five women during pregnancy and the first year after birth (the perinatal period). These include anxiety, depression, stress-related conditions and adjustment disorders. Mental health problems can have a negative effect on women, their partners and their children. They are also one of the leading causes of maternal death. It is vitally important that women who experience mental health difficulties are identified quickly and get the care and treatment they need. However, only about half of women with perinatal mental health problems are identified by healthcare services and even fewer receive treatment.

This research aims to understand what factors increase or decrease the chances of women getting care or treatment, by pulling together the findings from existing research. The reasons may be to do with women's situation, background or behaviours (e.g. being isolated, feeling ashamed, not seeking help), with healthcare professionals (e.g. if they do not ask about women's mental health), or the relationship between women and healthcare professionals (e.g. poor communication, lack of trust). There may also be factors in the NHS and society that increase or decrease the chances of women getting treated, such as stigma around mental health, lack of training for health professionals or gaps in specialist NHS services.

There will be three stages to the research. In Stage 1, we will review the evidence from research studies to understand why it has been difficult to assess, care for and treat perinatal mental health problems in health and social care services. In Stage 2, we will look at all the factors that get in the way of women being able to get the care and treatment they need. This will be done by summarising the large reviews of research that have been done so far. In Stage 3, we will bring together an expert panel of women, healthcare professionals (such as GPs, midwives), and health service managers. This group of people will use the findings from Stages 1 and 2 to develop a clear overview of the factors that stop women getting the care and treatment they need. This overview will be shared with health services that support women during pregnancy and after birth, to help them improve their services.

This research was developed jointly between women who have experience of perinatal mental illness, midwives, health visitors and mental health professionals. They have told us that this is one of the most important issues affecting the care of these women and they will work with us on the project to make sure it is relevant to women, their families and the NHS. The research team includes midwives, health visitors, GPs, mental health professionals, and experts in research methods and health services.

This research has the potential to improve experiences for women and their families by helping us to understand the reasons why some women do not get treatment for perinatal mental health problems. We will use this to make recommendations for health services and staff to improve in order to ensure women get the support they need when they need it. Increasing the number of women who get treatment may help to prevent some of the negative effects of perinatal mental health problems on women, their partners, and their children. Better understanding of what stops women from accessing perinatal mental health support could also improve women's experience of care during pregnancy and after birth.

AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Section amended	Details of change

FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN
National Institute of Health Research University of Southampton, Alpha House, Enterprise Road, Southampton, SO16 7NS Telephone: 0238 059 7501 E-Mail: netspostawardsetup@nihr.ac.uk	Financial support

ROLE OF STUDY SPONSOR AND FUNDER

City, University of London, is the sponsor for this research and will assume overall responsibility for the initiation and management of the study. City, University of London, as research Sponsor indemnifies its staff, research participants and research protocols with public liability insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

The programme is funded by the NIHR Health Services & Delivery Research. The NIHR HS&DR will monitor progress and be informed of all changes to the protocol. The NIHR HS&DR will be sent all outputs at least 28 days before publication/dissemination. All published outputs will acknowledge funding and include the following disclaimer:

‘This project is funded by the National Institute for Health Research (NIHR) Health Services Delivery and Research programme (NIHR128068). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.’

All other decisions about the study design, conduct, data analysis and interpretation, manuscript writing and dissemination of results will be made by the Chief Investigator and study management group (see below) and will not be within the responsibility of the sponsor or funder.

ROLES AND RESPONSIBILITIES OF THE STUDY MANAGEMENT GROUPS

The trial is funded by the National Institute for Health Research (NIHR) Health Services Delivery and Research Programme (NIHR128068). City, University of London will be the project sponsor and the host organisation, with Ayers as the Chief Investigator. Subcontracts will be put in place between City, University of London, and other partner organisations, detailing the budget resources allocated, the responsibilities and the expected contributions of each party.

The Project Oversight Committee (POC) will provide independent oversight of the project on behalf of the sponsor. The POC will meet (in person) at least three times during the course of the project to advise on each of the three phases of the work. The POC comprises independent members to provide oversight of the project and ensure that the project is conducted to the standards set out in the Department of Health’s Research Governance Framework for Health and Social Care (79) and the Guidelines for Good Clinical Practice.

The core Project Management Group will comprise the project lead (Ayers), PPI lead (Hann), research fellow (Webb), specialist in implementation science (Easter) and the co-applicants who have been working on the conceptual framework (Shakespeare, Ford). The core project management group will meet 1 to 4 times a month to ensure smooth running of the project. Specialist input from other members of the research team will be available as and when needed.

The full research team will meet every 6 months to ensure milestones are achieved, oversee progress, trouble shoot if problems arise, plan the next stage and agree timelines. This steering group will include all co-applicants to ensure we have expertise and representation from disciplines including midwifery (Cheyne), general practice (Shakespeare), health visiting (Salmon), perinatal psychiatry (Gilbody), implementation science (Cheyne, Easter), perinatal psychology (Alderdice), methodology (Ford), systematic reviews (Alderdice, Ayers, Cheyne,

Ford, Gilbody) and meta-reviews (Alderdice). The project therefore has a clear management structure with the most appropriately qualified research team member taking responsibility for each aspect, and representation from key stakeholders.

Collaborators will be involved in full research team meetings and/or the expert stakeholder panel as required. Collaborators include the lead of the managed perinatal mental health network for Scotland (Frame), head of early years education at UCL (Rosan), representative for the MMHCA (Thompson), lead research fellows on the associated MAP project (Sinesi, Coates), and the strategic lead from PIP UK (Hogg).

The Chief Investigator has overall responsibility for the study and will oversee all study management. The data custodian will be the Chief Investigator. The project therefore has a clear management structure with the most appropriately qualified research team member taking responsibility for each aspect, and representation from key stakeholders.

GLOSSARY OF ABBREVIATIONS

AMSTAR	Assessing the Methodological Quality of Systematic Reviews
GP	General Practitioner
HCP	Health Care Professional
HS&DR	Health Services and Delivery Research
IAPT	Improving Access to Psychological Therapies
PIP UK	Parent Infant Partnership United Kingdom
MAP	Methods of Assessing perinatal anxiety Project
MMHSCA	Maternal Mental Health Scotland Change Agents
NCT	National Childbirth Trust
NIHR	National Institute for Health Research
OCD	Obsessive Compulsive Disorder
PIO	Population, Intervention, Outcome
POC	Project Oversight Committee
PPI	Patient Public Involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PTSD	Post-Traumatic Stress Disorder
RCGP	Royal College of General Practitioners
UK	United Kingdom
WP	Work Package

STUDY PROTOCOL

Background and Rationale

Perinatal mental health problems affect up to one in five women and the cost to the UK is estimated to be £8.1 billion for every annual cohort of women, with 72% of this cost attributable to the long-term impact on the child (1). Perinatal mental health problems commonly consist of anxiety, depression, post-traumatic stress disorder following a difficult birth, and stress-related conditions such as adjustment disorder. Many disorders are co-morbid (2, 3) and severe postnatal mental illness is one of the leading causes of maternal death (3).

Perinatal mental health problems are particularly important because of the potential negative impact on women, their partners, children and families. This impact varies according to the type of mental illness, severity and timing (e.g. whether pre- or postnatal; acute or chronic, pre-existing or new onset) but overall the evidence shows that perinatal mental health problems can have a severe and enduring impact on women and their children. For example, a study of 7,944 families in England found anxiety and depression in pregnancy was associated with the child being twice as likely to have a mental disorder (4). Perinatal mental health problems can also impact on child development, with research suggesting that perinatal mental illness can influence a child's cognitive development (5), language development (6), psychological outcomes (7) and behavioural outcomes (8).

It is therefore important to identify and assess perinatal mental health problems quickly so that women who need treatment are able to access it. However, it is estimated that half of women are not identified (9) despite regular routine contact with healthcare services, and still fewer receive treatment (1). For example, a study of postnatal depression suggested only 40% of women with postnatal depression were identified, 24% received treatment, 10% received adequate treatment, and only 3-6% of women recovered (10). This is likely to be due to a range of factors at individual, interpersonal, organisational and social levels, such as healthcare professionals not asking about mental health, lack of effective assessment, barriers to women seeking help or attending treatment, clinician barriers to diagnosis and treatment, lack of services to refer onto, or limited understanding of effective treatments.

Recognising the barriers and facilitators to identification and appropriate treatment of perinatal mental health problems is therefore important for health and social care services working with perinatal women. The need for this is evident in UK strategy and policy (11, 12), clinical guidelines (13, 14) and calls for research (15). Recent prioritisation of perinatal mental health and rapid expansion of specialist NHS services in this area, including development of perinatal mental health clinical networks across the UK, mean this research meets an urgent need which is likely to be sustained over the next 10 years. For example, the UK government pledged a significant investment of £365 million for improvements to specialist perinatal mental health services over 5-years from 2015/16. A key aim of the NHS England Five-year Forward View is that at least 30,000 more women each year will access evidence-based specialist mental health care during the perinatal period by 2020/21 (11). Similarly, the Scottish Mental Health Strategy aims to improve the recognition and treatment of perinatal mental health problems (14). Identifying barriers to women accessing treatment, as well as barriers to implementing perinatal mental health assessment and treatment in NHS services, is therefore important to inform these initiatives.

This evidence synthesis therefore aims to identify potential barriers and facilitators to assessment and treatment of perinatal mental health problems across the care pathway, both in terms of women accessing care or treatment, as well as in terms of NHS services implementing new assessment and treatment initiatives. This will be used to inform a

conceptual framework of barriers and facilitators to implementation that will inform healthcare services and practice, care pathways, and highlight where further research is needed.

Evidence explaining why this research is needed now

Perinatal mental health is a priority for UK strategy and policy (11, 12), clinical guidelines (13, 14), research organisations (15), health professional organisations (16, 17) and third sector organisations (18). However, a great deal is still unknown about the best way to identify, treat or care for women with perinatal mental health problems, and evidence suggests half of women do not come to the attention of healthcare services (9) and still fewer receive treatment (1).

Reasons why women are not identified and treated are complex and multifaceted. They will include individual-level factors, healthcare professional (HCP) factors, interpersonal HCP-patient factors, organisational and social factors. In addition, these operate in healthcare services that are highly heterogeneous, with variation both within and between services. In some cases, care pathways and treatments are based on organisational factors or assumptions that are not evidence-based. For example, prior to 2016 some Clinical Commissioning Groups had never commissioned a perinatal mental health service and women were referred to mainstream adult psychiatry services (19). Furthermore, in 2010, fewer than 15% of localities in the UK had specialist services available at the level recommended by NICE; and more than 40% of localities had no specialist service at all (20).

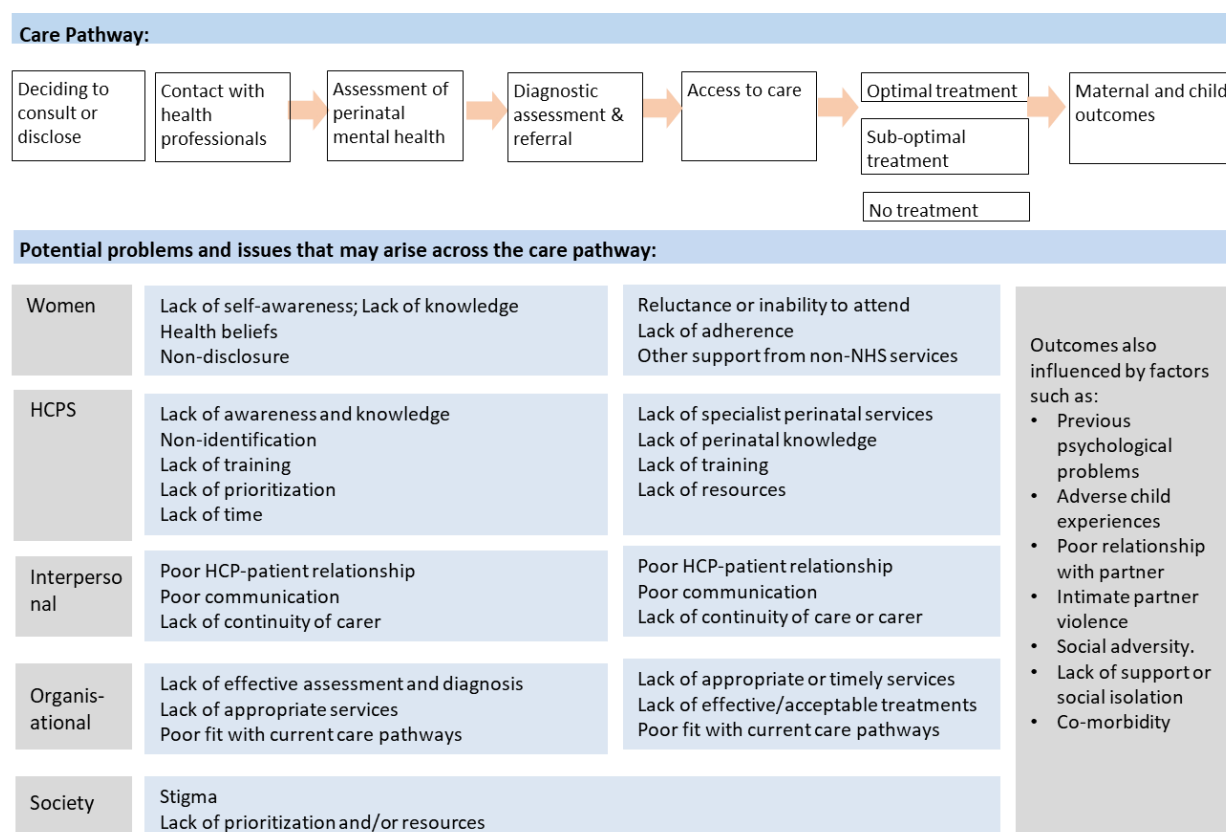
The literature on why women with perinatal mental health problems do not access care or treatment is varied and some areas are more clearly synthesised than others. At present, there is no clear overview and synthesis of how these factors may operate at different levels or interact with each other to prevent women being identified, assessed and accessing treatment. Figure 1 is a schematic diagram illustrating some of the possible barriers to identification and treatment that can occur across the care pathway at individual, relational, organisational and systemic levels.¹

At the individual level, several systematic reviews of qualitative literature have identified potential barriers and facilitators to women seeking help for their perinatal mental health problems. Barriers include a reluctance to acknowledge symptoms, and lack of support from partners, family members and HCPs; a lack of ability for women to talk about their feelings openly due to perceived social pressures and stigma, resulting in feelings of shame and fear of losing custody of their child; and a lack of knowledge of perinatal mental health problems among mothers, which hindered their ability to recognise and seek help for their symptoms (21-23). Valued aspects of support, such as therapeutic relationships, information and validation of difficult situations and symptoms were key facilitators to help-seeking behaviours. Other factors preventing women from seeking help include previous bad experiences of mental health care (24), feeling unable to share their feelings with health care professionals (22) and poor knowledge about perinatal mental illness (22, 25). Women also cite practical factors influencing their decision to seek help. For example, the cost of treatment, finding childcare, lack of health insurance and transport issues can influence women's help seeking behaviour (24, 26, 27).

¹ This has been depicted across a linear care pathway for ease, however the process of accessing treatment is multi-faceted and likely to be more complex and circular.

Similarly, HCP factors influence whether women access care or treatment. A review of GP's approach to diagnosis and treatment found that they consider perinatal mental health problems to be a psychosocial phenomenon so are reluctant to diagnose a disorder and medicalise distress. GPs tended to rely on their own clinical judgement more than guidelines. They also reported feeling isolated when dealing with perinatal mental health issues and often did not have timely access to appropriate psychological therapies (28). Furthermore, HCPs often do not have training in perinatal mental health, and just under a third of midwives and GPs report having had no training in perinatal mental health (29, 30).

Figure 1. Diagram illustrating some possible barriers to identification and treatment



This lack of training may be particularly critical given the importance of interpersonal factors in whether women seek help and access treatment. For example, women are more likely to seek help if HCPs are knowledgeable and experienced in perinatal mental health, and sensitive to women's needs (21, 26). A review of the qualitative literature into women's experiences of seeking help for postnatal depression found women valued the therapeutic relationship between the healthcare professional and themselves (31). Similarly, in qualitative studies of women's experiences of care, having a trusting relationship with a HCP and being helped to discuss feelings in an unrushed, conversational manner were associated with increased acceptability and disclosure (32-34).

In terms of organisational factors, research suggests that lack of referral pathways, lack of specialised services, and poor assessment influence whether women receive treatment (21, 26). Research on implementing specialist perinatal mental health services suggests key organisational barriers may be insufficient personnel, unclear protocols and referral pathways, lack of training (35, 36), and a lack of resource allocation to mental health treatment in general (37). This is illustrated in practice by research finding only 27% of maternity services have a

specialist mental health midwife, and 64% of primary care trusts have no perinatal mental health strategy (29). The impact of this lack of service provision is reflected in the fact that 41% of women report never being asked about depression by midwives or health visitors during the perinatal period (29).

Social or cultural factors are also important. Different cultural norms and healthcare systems will influence women and HCPs understanding of perinatal mental health as well as the availability of assessment and treatment. Attitudes towards mental health, such as stigma, may influence women's willingness to disclose their symptoms and seek help (21-23).

The evidence therefore highlights many factors at different levels that may influence whether or not women are identified and receive care or treatment for perinatal mental health problems. In some areas there is plenty of evidence and reviews have been conducted, such as in women's experiences of seeking help for perinatal mental health problems. In other areas there is evidence available but it is disparate and needs to be synthesised. There are also gaps in the evidence about what constitutes appropriate care or treatment for women, especially those with moderate or transient symptoms. Critically, there are no reviews on barriers and facilitators to implementing assessment and treatments for perinatal mental health in NHS or other healthcare services. In addition, no reviews have applied this knowledge to a multi-level framework such as the one outlined in Figure 1. This kind of meta-review and conceptual framework is important to inform healthcare services and practice, perinatal mental health care pathways, and highlight where further research is needed.

This research will be conducted in three phases. Phase 1 will determine the barriers and facilitators to implementing perinatal mental health assessment, care and treatment in different health and social care contexts. This will be achieved through a focused systematic review following PRISMA guidelines. Phase 2 will identify factors that prevent women accessing care or treatment. This will be done through a meta-review of reviews. Phase 3 will map the findings from phases 1 and 2 onto a conceptual framework using thematic analysis and feedback from an expert panel of stakeholders. This conceptual framework will be used to make recommendations for ways in which barriers to implementing services and women accessing care or treatment can be reduced in different healthcare settings.

The research team are well-placed to conduct this research. We have carried out numerous studies in this area, including research on women's experiences of perinatal mental health problems (33, 34, 38-42), healthcare professionals' perceptions of perinatal mental health needs and treatments (28, 43-45), assessment (46-52) and treatments (44, 53-62). We have conducted numerous systematic reviews, including barriers to women seeking help (21), GP and midwives' diagnosis and treatment of perinatal mental health (28, 45, 63, 64). Much of this research was conducted through a programme of work with the Royal College of General Practitioners' (RCGP) Perinatal Mental Health Champion (co-applicant Shakespeare) and a methodologist specialising in general practice (co-applicant Ford) to consider and outline the range of factors involved and develop a conceptual framework.

This application is also highly complementary to one recently funded by the NIHR on Methods of Assessing Perinatal Anxiety (MAP) (NIHR Ref: 17/105/16). Together these proposals form a broader programme of research into implementing assessment and treatment for perinatal mental health in healthcare practice. The MAP project is in response to the HS&DR commissioned call for research on perinatal anxiety. It aims to identify the most effective, acceptable and feasible method for assessing anxiety in pregnancy and after birth. Outputs include tailored implementation guides so the most effective and acceptable assessment measure can be easily implemented into NHS services across the UK.

The current evidence synthesis will identify key barriers and facilitators to implementing assessment, care and treatment for perinatal mental health problems in different health and social care settings. This is a complex literature so this evidence synthesis uses a focused review to determine barriers to implementing assessment, care and treatment in health and social care services, as well as a meta-review of reviews to determine the range of barriers to women accessing care or treatment. This will be used to refine a conceptual framework of barriers and facilitators to assessment and treatment at individual, interpersonal, organisational and social levels. This evidence synthesis and conceptual framework have the potential to inform the implementation of evidence-based perinatal mental health assessment, care and treatment generally, as well as being directly relevant to the implementation guides that will be produced by the MAP project.

RESEARCH QUESTION

What are the barriers and facilitators to perinatal mental health assessment, care and treatment at individual, interpersonal, organisational and social levels? How can these be used to inform and improve perinatal mental health care in different health and social care settings?

OBJECTIVES

1. Determine the barriers and facilitators to implementing perinatal mental health assessment, care and treatment in health and social care services (Phase 1)
2. Identify differences in barriers and facilitators across different health and social care settings (Phase 1 & 2)
3. Evaluate the quality of this evidence (Phase 1)
4. Extract recommendations for implementation practice and research based on the barriers and facilitators identified (Phase 1)
5. Determine the barriers and facilitators to women accessing perinatal mental health care or treatment (Phase 2)
6. Evaluate the quality of these reviews (Phase 2)
7. Map the geographical distribution of the evidence to establish generalisability and gaps in the evidence (Phase 2)
8. Map the findings from Phase 1 and 2 onto a conceptual framework, utilising a panel of expert stakeholders (Phase 3)
9. Conduct a consultation of the conceptual framework and recommendations with stakeholders (e.g. women, GPs, commissioners, 3rd sector organisations etc) (Phase 3).
10. Make recommendations for practice and future research for perinatal mental health assessment, care and treatment (Phase 3).

RESEARCH PLAN

This research uses a focused systematic review, a meta-review of reviews, conceptual framework and expert stakeholder panel to answer the research question. It will be carried out in three phases: Phase 1 is a focused systematic review of research into implementing assessment, care and treatment into health and social care services. Phase 2 is a meta-review of reviews into the range of barriers and facilitators to women accessing perinatal mental health care or treatment. Phase 3 will map the findings from phases 1 and 2 onto a conceptual

framework using thematic analysis and gain feedback from an expert panel of stakeholders. These phases are outlined in more detail below.

Definitions and scope

The literature on perinatal mental health, identification, assessment, care and treatment is complex so it is important to define the key terms and scope of this synthesis.

Perinatal mental health problems include common affective disorders experienced during pregnancy or the first year postpartum, such as depression and anxiety (e.g. Generalised anxiety disorder, phobias, panic, OCD), stress related disorders (e.g. acute stress disorder, PTSD), adjustment disorders, and other psychiatric disorders (e.g. psychosis, personality disorders). Symptoms can be mild, moderate or severe. In this project we will include the range of mental health disorders outlined above both in terms of type and severity. We will exclude substance misuse disorders because they raise unique challenges in terms of assessment and treatment that may not be generalisable to other disorders.

How assessment of perinatal mental health is conceptualised is important. In particular, the distinction between assessment and case identification is important because they have different implications in terms of barriers and facilitators to accessing care and treatment. Perinatal mental health assessment refers to identifying women who may be at risk for perinatal mental health problems, or who have perinatal mental health problems. Case identification uses psychiatric definitions of disorder, such as the American Psychiatric Association's Diagnostic and Statistical Manual (65), to identify women who fulfil diagnostic criteria for a disorder. Women who meet criteria (i.e. cases) are more likely to reach the threshold for onward referral and treatment. In this project we include both assessment and case identification to examine their implications in terms of barriers and facilitators to accessing care or treatment.

Perinatal mental health interventions refer to any treatment or prevention strategy to reduce perinatal mental health symptoms. Services offering interventions vary widely. In primary care or maternity care GPs, midwives and health visitors may offer supportive care for women with mild or moderate perinatal mental health problems. Evidence suggests primary care is the main provider, with 90% of common mental disorders being managed in primary care (66). Specialist mental health services vary. For example, the NHS England specialist perinatal mental health services target the top 5% of women i.e. those with the most severe problems. These are likely to be women with severe postpartum depression, psychosis or other complex disorders, many of whom may require inpatient psychiatric treatment. In contrast, Improving Access to Psychological Therapies (IAPT) is a community-based out-patient service that predominantly treats moderate affective disorders such as anxiety, depression, PTSD and adjustment disorders. Increasing numbers of IAPT services now have a perinatal mental health specialist. In addition, there are increasing community services provided by third sector organisations, such as peer support services for women with moderate perinatal mental health problems. These different settings (primary care, maternity care, psychiatric and specialist perinatal mental health services) will have different barriers in terms of implementing services and women accessing treatment. In this project we therefore explicitly consider different health and social care settings throughout. We use the terms perinatal mental health 'care' and 'treatment' to recognise the difference between supportive care and specialist interventions.

Some services provide interventions focused on outcomes associated with poor perinatal mental health. These include parent-infant, couple or family interventions. In this project we focus on interventions for maternal mental health and exclude literature that focuses on mother-infant, couple or family interventions because these are aimed at associated outcomes

rather than perinatal mental health per se and raise different issues in terms of accessing services.

The scope of this project is also focused on women's perinatal mental health rather than partners. Although partner's perinatal mental health is important this is an area that requires research and evidence synthesis in its own right. Current research into men's perinatal mental health is sparse and there are likely to be differences in barriers and facilitators to assessment and accessing treatment for men.

Phase 1: Review of barriers to implementation in the NHS and other health and social care settings

Background: Given the negative impact of perinatal mental health problems on women and their partners and families, we need to understand what is preventing the implementation of perinatal mental health assessment, care and treatment in health and social care services. If we can understand what prevents or facilitates implementation, then suitable strategies can be put in place to overcome these barriers or encourage the facilitators. There is sufficient synthesised evidence from women's perspectives on reasons for not seeking perinatal mental health care or treatment (21, 22, 67). However, less is known from an implementation point of view about barriers to putting assessment, care and treatment for perinatal mental health into services. This phase addresses this by conducting a systematic review of barriers and facilitators to implementing assessment, care and treatment into health and social care services.

Aim: To identify the facilitators and barriers to implementing assessment, care and treatment for perinatal mental health problems into health and social care services.

Objectives are to:

1. Determine the barriers and facilitators to implementing perinatal mental health assessment, care and treatment into health and social care services.
2. Identify differences in barriers and facilitators across different health and social care settings.
3. Evaluate the quality of this evidence.
4. Extract recommendations for implementation practice and research based on the barriers and facilitators identified.

Design: A systematic review of facilitators and barriers to implementing assessment, care and treatment for perinatal mental health into health and social care services, conducted according to gold standard methods for systematic reviews (68, 69).

Search strategy: Systematic searches will be conducted through online databases such as: MEDLINE; PsycINFO; PsychARTICLES; PubMed; Cumulative Index to Nursing and Allied Health Literature (CINAHL); Gender Studies Database; EMBASE; Cochrane Library; Web of Science; Scopus. Other search strategies will include: tracking citations of key studies (forward searching); examining reference lists of key studies (backwards searching). When conducting the searches search terms will be combined using Boolean terms "OR" and "AND".

The following PIO parameters will be used:

- Population: NHS and other health or social care services for women in the perinatal period.
- Intervention: Implementing assessment, care or treatment interventions, programmes or protocols for perinatal mental health into health or social care services.
- Outcome: Implementation outcomes (e.g. acceptability, feasibility, barriers, facilitators)

Scoping searches on PubMed and PsychINFO returned between 4,016 and 6,950 abstracts. Search syntax for scoping searches was: (Perinatal OR postnatal OR postpartum OR antenatal OR antepartum OR peripartum OR pregnancy OR birth OR mother* OR father* OR parent*) AND (Mental health OR anxiety OR depression OR PTSD OR post traumatic stress OR trauma OR stress OR psych* OR mental illness OR affective symptoms OR mental disorder OR affective disorder OR mood disorder OR *phobia OR adjustment disorder) AND (Screening OR assessment OR treatment OR intervention OR medication OR therapy OR healing OR therapeutic* OR prevent* OR service* OR health service) AND (Implement* OR implementation science OR implementation practice OR application OR employ*)

Study selection: Studies will be selected in two stages according to PRISMA guidelines (68). In the first stage, titles and abstracts will be screened by one researcher for relevance to the topic. Studies that are clearly not relevant will be excluded. In the second stage, full texts for studies that appear to be relevant will be obtained and final selection made by the researcher and core project management team.

Inclusion and exclusion criteria: Studies will be included if they report primary research evidence that evaluates the implementation of perinatal mental health assessment, care or treatment into NHS or other health and social care services. Assessment refers to identifying women who may be at risk for perinatal mental health problems, or who have perinatal mental health problems. Care refers to supportive care or care pathways such as that provided by health visitors or specialist midwives. Treatment refers to any active intervention, programmes or protocols to reduce women's perinatal mental health symptoms. The perinatal period is defined as from conception to 1 year postpartum. Qualitative and quantitative research will be included.

Studies will be excluded if they are: non-English publications; non-empirical papers; reviews; not conducted on the target population (e.g. men/partners or children); examine interventions targeted at the parent-infant or family relationships; or focus on substance misuse which has unique challenges in terms of assessment and treatment.

Data extraction: Data will be extracted from eligible studies using a standard data extraction form in Excel. If information is missing corresponding authors will be contacted with a request for the information. If they do not respond within 2 weeks another request will be sent. If they do not respond within 4 weeks this data will not be included.

A range of data will be extracted to enable a comprehensive review. Key variables will include: Authors; Year; Country; Study design; Method; Health or social care service; Sample size and characteristics (healthcare provider, women); Type of assessment, care or treatment implemented; Outcome measures; Diagnostic interview or validated questionnaire; Methodological quality rating.

Quality assessment: Studies included will use different methodologies (e.g. cohort, RCT, cross-sectional, qualitative). Study quality will therefore be assessed using Joanna Briggs Institute checklists for methodological quality or risk of bias. One reviewer will conduct the quality assessments and reliability of these ratings will be checked by a second reviewer rating

a random selection of 25% of studies. If disagreements arise all papers will be double-rated and disagreements resolved through discussion and consensus. Where consensus cannot be reached the project management group will be consulted and make the final decision.

Data synthesis: It may be possible to conduct meta-analysis or meta-synthesis if there are enough studies with common methods (e.g. qualitative/quantitative), interventions and homogeneity. If this is not possible, papers will be narratively synthesised.

Outputs: Results of this phase will enable us to identify barriers to implementing perinatal mental health assessment, care and treatment into NHS and other health and social care services. This review will be published in a high impact peer reviewed journal. Specific recommendations about implementation of assessment, care and treatment in health and social care services will be extracted for review by the expert stakeholder panel (see Phase 3).

Phase 2: Meta-review of barriers to women accessing treatment

Background: Given that women accessing care or treatment might be important in preventing adverse outcomes for women and their families, we need to identify the wide range of factors that may prevent women from accessing these. Such factors will operate at individual, interpersonal, organisational and social levels and are likely to interact so need to be mapped into a conceptual framework to provide greater understanding (Phase 3).

Aim: To determine the individual, interpersonal, organisational and social factors that prevent women accessing care or treatment.

Objectives are to:

1. Determine the barriers and facilitators to women accessing perinatal mental health care or treatment.
2. Identify differences in barriers and facilitators across different health and social care settings.
3. Evaluate the quality of these reviews.
4. Map the geographical distribution of the evidence to establish generalisability and gaps in the evidence.

Design: A systematic meta-review of reviews to identify barriers and facilitators to women accessing perinatal mental health care or treatment, conducted according to gold standard methods (68-69).

Search strategy: Systematic searches will be conducted through online databases such as: MEDLINE; PsycINFO; PsychARTICLES; PubMed; Cumulative Index to Nursing and Allied Health Literature (CINAHL); Gender Studies Database; EMBASE; Cochrane Library; Web of Science Scopus. Other search strategies will include: tracking citations of key papers (forward searching); examining reference lists of key papers (backwards searching). When conducting the searches search terms will be combined using Boolean terms “OR” and “AND”.

Study selection: Papers will be selected in two stages according to PRISMA guidelines (69). In the first stage, titles and abstracts will be screened by one researcher for relevance to the topic. Papers that are clearly not relevant will be excluded. In the second stage, full texts for papers that appear to be relevant will be obtained and final selection made by the researcher and project management group.

The following PIO parameters will be used:

- Population: Women in the perinatal period (conception to 1 year postpartum).
- Intervention: Assessment, care or treatment for perinatal mental health.
- Outcome: Barriers and facilitators, women's experiences, health and social care professionals' experiences.

Scoping searches on MEDLINE and PsychINFO returned between 7,651 to 8,665 and abstracts. Search syntax for scoping was: (Perinatal OR postnatal OR postpartum OR antenatal OR antepartum OR peripartum OR pregnancy OR birth OR mother* OR father* OR parent*) AND (Mental health OR anxiety OR depression OR PTSD OR post traumatic stress OR trauma OR stress OR psych* OR mental illness OR affective symptoms OR mental disorder OR affective disorder OR mood disorder OR *phobia OR adjustment disorder) AND (Screening OR assessment OR treatment OR intervention OR medication OR therapy OR healing OR therapeutic* OR prevent* OR service* OR health service AND Access* OR implement* OR help seeking OR seeking OR decision OR application OR employ OR treatment seeking OR treatment engagement OR service use) AND (Barriers OR drawbacks OR obstacles OR issues OR challenges OR difficulties OR factors) AND (Review of literature OR literature review OR meta-analysis OR systematic review OR review OR meta-review OR meta review)

Inclusion and exclusion criteria: Papers will be included if they are systematic reviews, meta-syntheses, meta-analyses, or meta-reviews about access to mental health care or treatment by women in the perinatal period. Assessment refers to identifying women who may be at risk for perinatal mental health problems, or who have perinatal mental health problems. Care refers to supportive care or care pathways such as that provided by health visitors or specialist midwives. Treatment refers to any active intervention, programmes or protocols to reduce women's perinatal mental health symptoms. The perinatal period is defined as from conception to 1 year postpartum. Mental health measures need to be gold standard clinical interviews or validated self-report questionnaires.

Papers will be excluded if they are: non-English publications; primary research; include people outside the target population (e.g. men/partners or children); include interventions targeted at the parent-infant, couple or family relationships; or focus on substance misuse which has unique challenges in terms of assessment and treatment.

Data extraction: Data will be extracted from eligible reviews using a standard data extraction form in Excel. If information is missing, corresponding authors will be contacted with a request for the information. If they do not respond within 2 weeks they will be contacted again. If they do not respond within 4 weeks missing data will not be included.

A range of data will be extracted to enable a comprehensive meta-review. Key variables will include: Authors; Year; Country; Review design; Method; Sample size and characteristics (of parents, of health care provider); Mental health problem; Outcome measures; Type of intervention(s); Methodological quality rating.

Quality assessment: Quality will be assessed using assessed using the AMSTAR checklist which is a reliable and valid measure for assessing the methodological quality of systematic reviews (70). One reviewer will conduct the quality assessments and reliability of these ratings will be checked by a second reviewer rating a random selection of 25% of papers. If disagreements arise then all papers will be double-rated and disagreements resolved through

discussion and consensus. Where consensus cannot be reached the project management group will be consulted and make the final decision.

Data synthesis: We will follow a similar strategy to McNeill et al (2012) (64). Firstly, a table summarising the findings will be presented. Within this table we will include the following information: authors/year; aim; search strategy; number of studies included; total number of participants; results (i.e. key barriers and facilitators identified); quality rating. We will then perform a narrative synthesis of the reviews identified, discussing both barriers and facilitators to perinatal mental health assessment, care and treatment.

Outputs: Results of this phase will identify barriers and facilitators to women accessing perinatal mental health care or treatment, as well as indicate which factors may overlap or interact with one another. Results will form the basis for Phase 3 and enable us to extract recommendations for healthcare practice and research, including which countries have a sparsity of data and recommendations for quality improvement in research methods.

Phase 3: Mapping onto conceptual framework

Background: A conceptual framework can be defined as a “network, or a plane, of interlinked concepts that together provide a comprehensive understanding of a phenomenon or a phenomena” (71). A conceptual framework of potential barriers and facilitators for perinatal mental health assessment, care and treatment is important because it can highlight areas for improvement and provide an empirical basis for recommendations for future practice and research (72). There are currently no conceptual reviews of barriers and facilitators of perinatal mental health assessment, care and treatment. We have been working with the former RCGP perinatal mental health champion (co-applicant Shakespeare) and a methodologist specialising in general practice (co-applicant Ford) to develop a conceptual framework of barriers and facilitators to women accessing treatment. The work in Phase 3 will map the evidence onto this framework to develop and refine it in consultation with an expert panel of stakeholders.

Aim: To develop a conceptual framework of barriers and facilitators to perinatal mental health identification, assessment and treatment that will inform healthcare services and practice, care pathways, and highlight where further research is needed.

Objectives are to:

1. Map the findings from Phase 1 and Phase 2 onto a conceptual framework, utilising a panel of expert stakeholders.
2. Conduct a consultation of the conceptual framework and recommendations with stakeholders (e.g. service managers, women, GPs, commissioners, 3rd sector organisations etc).
3. Make recommendations for practice and future research for perinatal mental health assessment, care and treatment.

Design: Evidence synthesis of data collected in Phases 1 and 2 to develop a conceptual framework for barriers to identification, assessment and treatment of perinatal mental health.

Sampling: Following the approach of Leamy et al. (72), a panel of expert stakeholders will be consulted about the preliminary design of the conceptual framework. The panel will include women and their partners, as well as representatives from the NHS (e.g. service managers,

GPs, nurses, midwives, health visitors) and 3rd party organisations that represent perinatal women with and without lived experience (e.g. NCT, Maternal Mental Health Change Agents).

Data Collection: Data will have been collected in Phases 1 and 2.

Data Synthesis: We will follow a similar method to that used by Leamy et al (72) in their development of a conceptual framework for personal recovery in mental health. This has three stages of synthesis:

Stage 1: developing a preliminary synthesis. The results from Phases 1 and 2 will be used for the preliminary synthesis. The main overarching themes and subthemes from the reviews will be identified using inductive open coding techniques. Open coding includes labelling concepts, defining and developing categories based on their properties and dimensions (73). This analysis will be conducted using specialist software NVIVO to identify key themes. We will then use vote counting (i.e. counting the number of times each theme appears) to identify which themes appear most frequently. Based on these themes a preliminary conceptual framework will be drawn up. Gaps in the literature will also be identified and included.

Stage 2: exploring relationships within and between studies, we will group the reviews by their main topic (i.e. women's experiences, HCPs experiences) and thematically analyse the groups separately. Emergent themes will then be compared with the preliminary conceptual framework. At this stage the thematic analysis will use a more fine-grained approach, going through the reviews in a line-by-line manner. The aim of this grouping of reviews and more fine-grained analysis is to identify additional themes, as well as identifying any similarities and differences between these new themes and the preliminary conceptual framework.

Stage 3: assessing robustness of the synthesis: The preliminary conceptual framework will be sent to our expert panel of stakeholders. The panel will include women and their partners, representatives from the health and social care services (e.g. service managers, GPs, nurses, midwives, health visitors) and 3rd sector organisations that include women with and without lived experience of perinatal mental health problems (e.g. NCT, Maternal Mental Health Change Agents). Experts will be asked to comment on positioning of the concepts, any important areas that may have been omitted, modification of the framework for different healthcare settings (e.g. primary care, maternity and mental health services), and any general observations. The preliminary conceptual framework will then be revised based on these comments to produce the final conceptual framework.

Following the development of the conceptual framework, recommendations for clinical practice and research will be identified and refined. The expert stakeholder panel will be invited to a half-day workshop to be consulted again and get their feedback on the recommendations proposed.

Outputs: Results from Phase 3 will provide a framework for understanding barriers and facilitators to women being identified, assessed, and accessing care or treatment for perinatal mental health problems. This framework will provide the basis for evidence-based recommendations to ensure that perinatal mental health assessment, care and treatment is implemented in the best way to reduce barriers and ensure more women with perinatal mental health problems access appropriate care or treatment.

PATIENT AND PUBLIC INVOLVEMENT (PPI)

This project has been developed with PPI representatives from the NCT in England (Hann) and the MMHCA, a group of women with lived experience of perinatal mental ill health in

Scotland (collaborators). We also work closely with the PPI Research Advisory Group (RAG) at the Centre for Maternal and Child Health Research, City University (advisors).

These organisations will continue to ensure we have PPI input from perinatal women generally as well as those affected by perinatal mental health problems. The research team have collaborated with the NCT and MMHCA for a number of years so have very good, productive and valuable relationships. Representatives from the NCT and MMHCA will co-ordinate PPI input throughout the research and will be very involved in the Dissemination of each phase of the project. PPI members have been, and will continue to be involved in the project at every step including input into research processes, analysis and interpretation of the data, and dissemination.

DISSEMINATION AND IMPLEMENTATION

Outputs

This research programme will provide syntheses of the evidence on barriers and facilitators to accessing care or treatment as well as to implementing assessment, care and treatment in NHS and other health and social care services. It will provide recommendations on key barriers that may prevent women in the perinatal period getting the care they needed, and possible ways to overcome these.

Impact

The impact of this research and its outputs will be significant in terms of timely identification and evidence-based care or treatment for women with perinatal mental health problems. Results will inform clinical practice and guidelines for overcoming barriers and therefore maximising the likelihood that perinatal mental health problems are identified and women access care or treatment. Limitations and gaps in the research reviewed, such as the sparsity of evidence for ethnic minority populations, will inform research and practice in the future.

Improved access to perinatal mental health care: Research suggests there are a variety of reasons women may not access perinatal mental services (24, 25, 27, 35-37, 67). Synthesising these reasons in a systematic way and creating a conceptual framework will enable us to identify key barriers and provide recommendations for changing practice and implementing assessment, care and treatment. This should contribute to more women having better access to perinatal mental health assessment, care and treatment.

Preventing morbidity and mortality: Current research suggests that improving access to assessment, care and treatment has the potential to reduce negative health outcomes for women and children (18, 74, 75). Untreated perinatal mental health problems may become chronic and enduring, or may have been chronic prior to pregnancy so it is important to identify them and provide appropriate care and treatment. In terms of infant morbidity, anxiety in pregnancy is associated with increased risk of preterm birth, which can result in severe morbidity or mortality (74).

Improved service user experience: Understanding the reasons women do not access perinatal mental health care or treatment will enable us to provide a better experience for service users. We will utilise research evidence and feedback from an expert panel, including women themselves, to provide recommendations. Implementing these recommendations has the potential to improve the service users' experience because potential barriers which prevented women from accessing care or treatment will be identified and potentially reduced in the future.

New knowledge: This research addresses gaps in knowledge and the lack of a synthesised overview of the evidence on why women do not access perinatal mental health care or

treatment. It will provide new knowledge of how to best implement perinatal mental health care into services to minimise barriers and ensure women are identified and get the care and treatment they need. It will also provide useful information for training healthcare professionals working with perinatal women on, for example, best practice to facilitate a conversation regarding mental health. It will therefore be of interest to researchers, healthcare services and policy nationally and internationally. It is consistent with the Five Year Forward View aim for the UK to be a world leader in the development and application of new mental health research (11) as well as the NHS Long-Term Plan (2019) to ensure 30,000 women get specialist perinatal mental health support by 2020/21 and an additional 24,000 women per year access perinatal mental health support by 2023/24 (76).

Dissemination and Implementation plans

Phase 1 and Phase 2 involve systematic reviews and evidence syntheses. **Phase 3** involves the development of a conceptual framework, implications and recommendations for practice and research in collaboration with an expert stakeholder group. The research team has a good track record of dissemination to other researchers through conferences and publishing in high-impact psychology, midwifery, obstetric, general practice and other journals. Results from each phase will be published in open access journals to ensure maximum reach and impact. Results will be disseminated at national and international conferences and through university webpages, press releases and blogs. These dissemination strategies will ensure the research results and recommendations are widely disseminated to the NHS, wider public and researchers; and that the recommendations are implemented into services.

Results will be disseminated to **health researchers** in multiple ways. Review protocols will be registered on PROSPERO. Results of each phase will be written up and published in high-impact peer reviewed open access journals, such as the British Medical Journal, to ensure they will be freely available online so that services and individuals can access them. Results will be presented at two large key international conferences e.g. the International Marcé Society Conference in 2020 in the USA, and the World Congress of Women's Mental Health in 2021. Results will also be presented at conferences that research team members attend in other roles (e.g. the Society of Reproductive and Infant Psychology).

Results will be disseminated to **the public** through dissemination streams led by our PPI co-applicant (Hann, NCT) and collaborator (Thompson, MMHCA). These include the NCT's website (6.5 million views/year), digital magazine [NCT Matters](#) and [Research Blog](#), and MMHCA's work in Scotland. The findings will also inform NCT's face-to-face support services for expectant and new parents, including 100,000 parents accessing antenatal education each year and their free-to-access local branch activities across the UK. Press releases will be made by press offices at City, University of London, and Stirling University and other partner organisations. The research team is well placed to ensure dissemination throughout the wider population, The NCT and MMHCA have active and successful campaigns for perinatal mental health (e.g. the NCT's [Hidden Half campaign](#)) so are very experienced at disseminating information and raising public awareness. Applicants will also disseminate the results through professional and personal social media channels.

Results will be disseminated to **healthcare professionals** in a number of ways and will be used to inform national training for existing healthcare professionals through ongoing work by members of the research team who contribute to training programmes for the Royal College of Psychiatrists, Royal College of Obstetricians and Gynaecologists, and Royal College of General Practitioners. The research team has a strong clinical background with significant roles in local and regional healthcare services. Each member of the team will ensure the

results are disseminated within their own hospital, trust or specialism. Results will also directly inform education of student healthcare professionals that members of the research team are involved in, including undergraduate and postgraduate courses on midwifery, health visiting, adult nursing, practice nursing, child and neonatal nursing. Results can also be included in the Institute of Health Visiting online good practice points and RCGP online perinatal mental health tool kit which reach a wide number of Health Visitors and GPs.

In terms of **policy and practice**, the research team are well connected with professional, third sector, and policy organisations so will use these connections to ensure wide-spread dissemination e.g. NHS England perinatal mental health team; National Managed Clinical Networks for Perinatal Mental Health; Maternal Mental Health Alliance; relevant Royal Colleges (Psychiatrists, GPs, Obstetricians, Midwives); the Institute of Health Visiting and others. For example, results and outputs will be disseminated through the clinical networks for perinatal mental health in England and Scotland; and sent to the perinatal mental health team at NHS England and other relevant stakeholders.

At the end of the programme we will have additional dissemination outputs and events to ensure that the conceptual framework, implications and recommendations for practice are widely and appropriately disseminated. Public-facing outputs using infographics, animation and short PDF reports will be created. These will be disseminated by the NCT, City University and Stirling University and research team via press releases and social media. It will directly inform the NCT's continued campaign focus on perinatal mental health (e.g. [Hidden Half Campaign](#)), which aims to raise awareness of mental health issues and promote early identification. In addition, applicants and collaborators have relationships with many organisations through the Maternal Mental Health Alliance and the 1001 Critical Days Parliamentary movement which have professional newsletters, blogs and social media channels we can utilise to share key messages with the public and professionals. Creating public-facing outputs like a bitesize report and infographics will make it easier for us to create appropriate and engaging content to disseminate through these different channels.

Engagement activities will be put on to facilitate discussion and implementation of the recommendations into practice. This will include circulating the public-facing outputs to all key stakeholders and putting on a half-day dissemination event at City, University of London, for up to 90 stakeholders. City, University of London, will provide the venue (at no cost) and people will be invited from key stakeholder organisations, including NHS England, perinatal mental health networks, CCGs, Institute of Health Visiting, Maternal Mental Health Alliance, Royal Colleges, and Maternity Voices Partnerships (England) or Maternity Services Liaison Committees (Scotland).

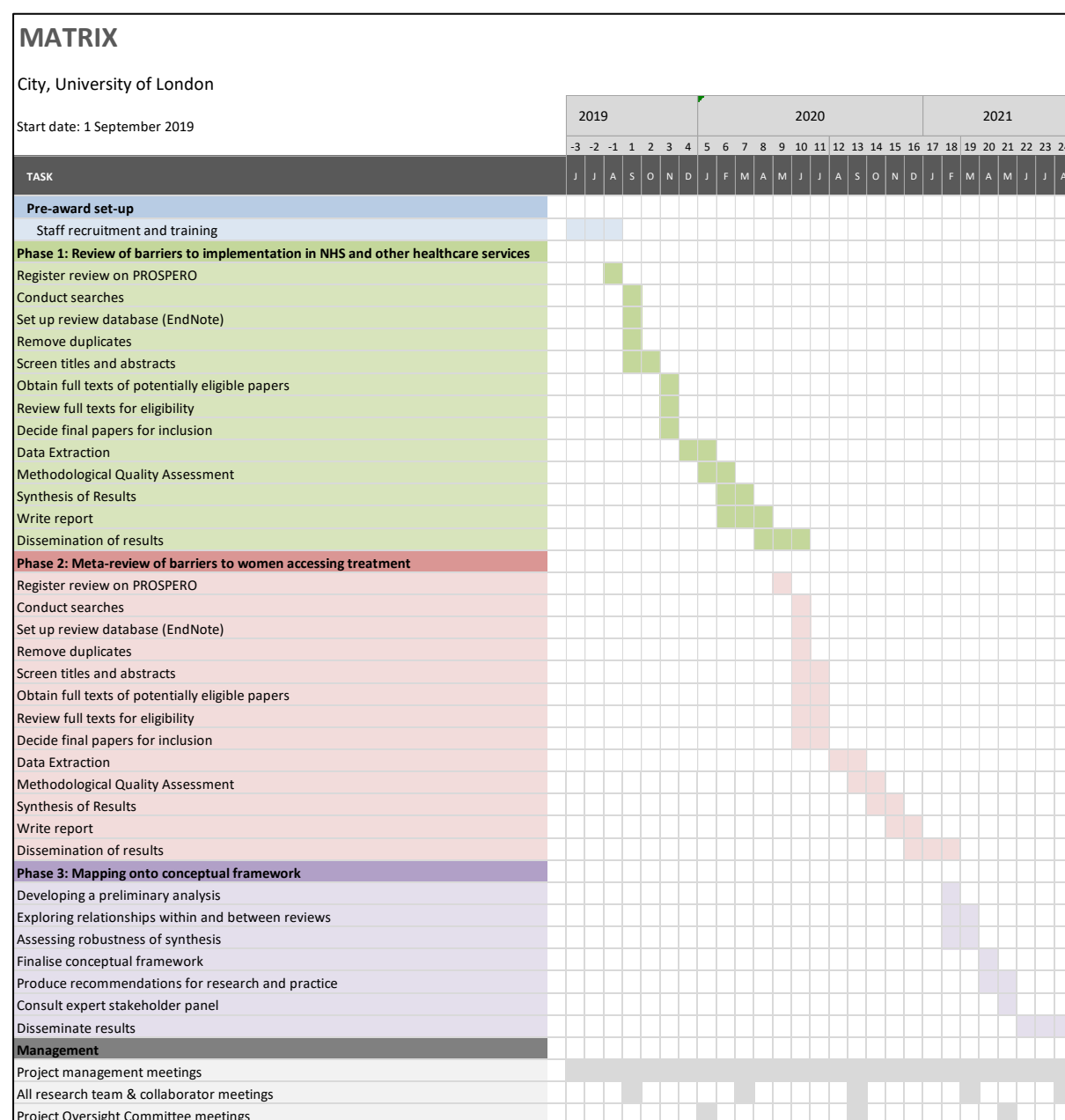
These dissemination strategies will ensure the results and recommendations are widely disseminated to health services, the wider public and researchers; and that the recommendations are implemented into services.

Possible barriers to implementation identified by this research may be individual, interpersonal, organisational or social. It may be hard to change or overcome organisational or social barriers in practice. For example, systemic factors such as stigma will be more challenging to overcome as they are socially embedded. Certain healthcare services or individuals may be reluctant to replace existing procedures, especially if there are implications for time and resources. The research team will work closely with clinical networks, key stakeholders and service managers to identify and mitigate against potential organisational and individual barriers.

RESEARCH TIMETABLE

The project will take 24 months. The timeline and progression points are shown in Figure 2. A 3-month pre-award period has been factored in to set up the study e.g. approving contracts, recruiting staff and obtaining approvals. Phase 1 will be completed from months 1-10 and phase 2 from months 11-20. Phase 3 work will begin in month 19 and be completed by month 24. Time for disseminating results has been included.

Figure 2. Research timetable (start date 1 September 2019 for 24 months)



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