

BMJ Open RAPID-2 study protocol: a cluster randomised feasibility trial of a midwife facilitated intervention for pregnant women with symptoms of mild to moderate anxiety

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ABSTRACT

Introduction Many women experience symptoms during pregnancy. Elevated and prolonged anxiety can have negative effects on the woman and baby. The RAPID intervention aims to provide suitable, timely support for women with mild-moderate anxiety. The RAPID intervention is based on social support, relational continuity, psychological and relaxation response theory, and comprises midwife facilitated group discussions, one-to-one support and directed self-help materials.

Methods and analysis Four National Health Service Trusts in England that provide maternity care will be cluster randomised to the RAPID intervention plus usual care or usual care. At each intervention site, two midwives and two maternity support workers will facilitate the intervention over a 12-week period. Eligibility includes nulliparous women at 16–20 weeks of pregnancy (n=50) with self-report symptoms of mild-moderate anxiety. Community midwives will signpost women to the study. The aim of the study is to establish the feasibility of conducting a definitive trial to examine the effectiveness of the RAPID intervention in addition to usual care. The objectives are to assess recruitment and completion rates, and a qualitative assessment of women's and facilitators' experiences of participation. An estimation of change in the seven-item Generalised Anxiety Disorder scale will inform the sample size for a definitive cluster trial.

Ethics and dissemination Ethical approval was given by East Midlands—Derby Research Ethics Committee 14 March 2022 (REC Reference: 22/EM/0018). Findings will be made available through publication in peer-reviewed journals, conferences and to participants. A final report will be submitted to HEE/NIHR ICA awards committee for publication.

Trial registration number ISRCTN12834758.

INTRODUCTION

Anxiety disorders are reported as a leading cause of global health-related burden and are among the top three causes of disability-adjusted life years among females.¹ During the COVID-19 pandemic period, there has

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The intervention has been developed from current evidence and theory with sustained involvement from service user groups.
- ⇒ A mixed methods approach will be used to investigate the acceptability of the intervention and interpret the findings of the study.
- ⇒ The study is embedded within maternity care pathways and is facilitated by midwives and maternity support workers with brief additional training.
- ⇒ The study design is a cluster randomised controlled trial to minimise potential bias and contamination.
- ⇒ The study will be conducted in a single region in England which may limit the generalisability of the study findings.

been a reported increase in anxiety disorders.² Globally, the highest rise in incidence has been reported for women of reproductive age.²

Anxiety during pregnancy is common and burdensome. Many women experience anxiety and worry during pregnancy and the prevalence of anxiety symptoms has been reported as 22.9%. Prevalence of a clinical anxiety disorder diagnosis in pregnancy has been reported as 15.2% with generalised anxiety disorder reported as 4.1%. Prevalence in pregnancy is significantly higher than reported in a general adult population.^{3 4} The attributes of anxiety disorders in pregnancy are similar to anxiety disorders at other times, although women's concerns about their pregnancy may present as the predominant feature.^{5 6} Anxiety symptoms become problematic when they consume a large proportion of time, impact women's ability to focus on other tasks and when symptoms significantly interfere with everyday life.^{7 8} Anxiety during pregnancy has been reported

to have a negative impact on women's confidence in mothering, self-perceived quality of the relationship with their infants⁹ and predict post-traumatic stress disorder and depression in the postnatal period.^{4 10} Elevated and prolonged anxiety has been associated with preterm birth, fetal growth restriction and behavioural problems in developing children.^{4 11 12} Costs of additional use of public services, productivity losses and quality-adjusted life year losses for women with anxiety in the perinatal period and continuing up to 10 years after birth were estimated at £35 000 for the mother and child.¹³

The National Health Service (NHS) long-term plan¹⁴ identifies perinatal mental health as a priority area, aiming to support 30 000 more women each year to access evidence-based specialist mental healthcare. Priority areas include increasing access to evidence-based care including psychological therapies and mental health assessment. Women who are identified with mild to moderate anxiety should be offered a choice of support to meet their individual needs.¹⁵⁻¹⁷ However, services to support women's mental health are not always readily available and need to be strengthened.^{18 19} Many women with anxiety prefer psychological interventions to take medication during pregnancy, and non-pharmacological interventions are recommended as the initial treatment option.^{18 20} Non-pharmacological interventions developed specifically for pregnant women with anxiety symptoms are promising, although interventions have not been evaluated in definitive trials.²¹⁻²⁶ In England, midwives provide care for all women throughout pregnancy, thus midwives are ideally situated to identify mental health concerns and support women's emotional and psychological well-being.^{20 27 28}

A feasibility and acceptability study of the intervention (RAPID-1) was completed in 2017.²⁹ The aim of the intervention was to provide suitable, timely support and treatment to prevent an escalation of symptoms and improve women's ability to cope. To develop the RAPID-1 intervention, two systematic reviews were completed^{24 29 30} which concluded that interventions specifically designed to support women with mild to moderate anxiety in pregnancy have mainly been evaluated in small scale studies. No interventions which can be directly recommended for clinical practice were located. Synthesised findings identified three components which were likely to increase the effectiveness of the intervention: (1) social support; (2) relational continuity and (3) psychological and relaxation response theory. These components were used to develop a novel intervention, comprising midwife facilitated group discussions, one-to-one support and directed self-help materials with a choice of cognitive or mind-body resources (figure 1). The systematic reviews and development of the intervention have been fully reported in peer-reviewed journals.^{24 29 30}

Due to the COVID-19 pandemic, it was imperative to identify innovative ways to deliver safe, effective and equitable care. A systematic review was undertaken to identify and evaluate remotely delivered, digital or online interventions to support women with symptoms of anxiety

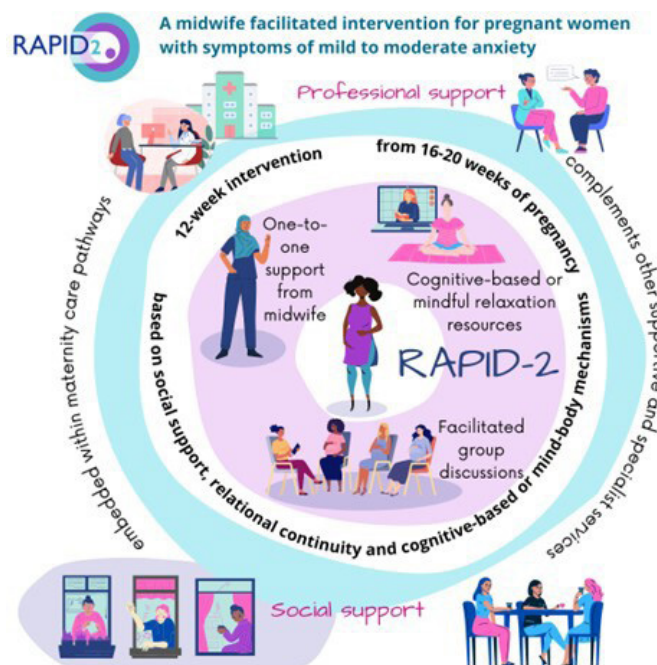


Figure 1 Components of the RAPID intervention.

in pregnancy.²⁵ There was limited evidence to suggest that pregnant women may benefit from remotely delivered interventions. Interventions may be more effective when women are motivated to maintain regular participation, and motivation can be enhanced by providing regular contact with care providers or providing peer support forums. Following a series of service user engagement sessions, a flexible, hybrid method of intervention delivery (face-to-face or online) was developed. In accordance with the Medical Research Council framework for the design and evaluation of complex interventions,³¹ this study advances to the next stage of development, by testing the processes that will be required in a definitive cluster trial.

METHODS AND ANALYSIS

Overview

A feasibility study, using a two-arm, parallel, open, pragmatic, cluster randomised controlled trial comparing usual care plus a midwife facilitated intervention for women with symptoms of mild to moderate anxiety to usual care alone. The trial protocol was developed according to the Standard Protocol Items: Recommendations for Interventional Trials guidelines.³² Clusters will be four NHS maternity services in the UK. The cluster design is appropriate because the intervention will be facilitated by midwives at the level of community-based midwifery teams. There could be a high risk of contamination in an individually randomised trial from midwife facilitators also providing midwifery care to control group (usual care) participants. The four maternity sites have community and hospital-based maternity care and provide midwife and obstetric led services. The study is

planned to start recruitment in September 2022 with a planned end date in January 2023.

Patient and public involvement

Six advisory events were held between 2018 and 2020 with service users from the Nottingham Maternity Research Network and East Midlands Applied Research Collaboration Centre for Ethnic Health Research group. Meetings were held to help identify ways to improve the acceptability of and recruitment to the study. In response to the potential impact of the COVID-19 pandemic, three service user digital workshops were conducted 2020–2021 to identify acceptable methods of delivery of the intervention and to help develop public facing materials. Five service users have agreed to be actively involved throughout the study period. Involvement will include informing the protocol development (intervention delivery and recruitment processes), informing analysis of the qualitative data, assisting to interpret and disseminate the study findings.

Aims and objectives

The aim of the study is to test the feasibility of conducting a future definitive trial to examine the effectiveness for pregnant women with symptoms of mild to moderate anxiety of receiving the RAPID-2 midwife facilitated intervention plus usual NHS maternity care compared with usual care alone.

The primary objectives are to:

- ▶ Determine the number of women who are eligible and agree to participate.
- ▶ Assess the recruitment procedures.
- ▶ Determine retention rates for the intervention and control arms of the study
- ▶ Conduct a qualitative assessment of women's and facilitators' experiences.
- ▶ Investigate participant-related and service-level factors influencing outcomes.
- ▶ Assess the relevance and acceptability of data collection and outcome measures.

Secondary objectives:

- ▶ To estimate the parameters of the seven-item Generalised Anxiety Disorder scale (GAD-7)³³ to inform the sample size for a definitive cluster trial.
- ▶ To identify data collection tools for economic evaluation.

Eligibility criteria

Women will be at between 18 and 22 weeks of pregnancy at intervention start.

Inclusion criteria

- ▶ Nulliparous pregnant women aged 18 years or older at the time of enrolment.
- ▶ Accessing maternity care at one of the four cluster sites.
- ▶ Self-reported symptoms of mild to moderate anxiety.
- ▶ Able to read, write and speak the English language.

Exclusion criteria

- ▶ Pregnant women receiving treatment for a severe and enduring mental health condition.

Sample size

Four cluster sites (two in the intervention group and two in the control group) are deemed sufficient to highlight issues relating to intervention delivery. For feasibility studies, sample sizes of between 24 and 50 have been recommended to meet the objectives of the study: (1) estimating a parameter such as an SD which will be used in a sample size calculation for the full-scale trial; (2) estimating the rate (proportion) of eligible people who are willing to participate, of participants who drop out of the trial, or of participants who comply with their allocated intervention.^{34 35} The sample size has been chosen to balance practicalities with the need for reasonable precision in the estimation of effects to inform the sample size for a definitive trial. A decision has been made to recruit 50 participants to the study to estimate an SD of the GAD-7 measure to inform the sample size calculation for a definitive trial.³⁶ A sample size of 40–50 participants will enable a drop-out rate of 50% to within a 95% CI of $\pm 15\%$ to be estimated.³⁶

Control group

Control group participants will receive usual NHS maternity care.³⁷ The exact component of usual antenatal care varies across settings, but always includes routine midwife appointments to ensure that pregnant women are offered regular check-ups, information and support, and access to obstetric and specialist perinatal mental health services, as required. Components which may not be available in all sites include emotional or social support interventions and low-level psychological services.¹⁷

Intervention group

Participants in the intervention group will receive usual maternity care (as described for control group) plus the RAPID-2 intervention. The RAPID-2 intervention builds on the findings of the preliminary RAPID-1 study,²⁹ with refinements made to the method of delivery, including additional peer-led groups and flexibility to conduct groups face-to-face or online (table 1). The intervention comprises three components:

1. One-to-one pre-group introductory meeting with the midwife facilitator.
2. Group discussion sessions facilitated by a midwife and midwifery support worker. Four facilitated groups plus two peer-led groups will take place fortnightly over a 12-week period.

Groups will last approximately 90 min. Discussion topics will be suggested and agreed by the group. Facilitators will help to initiate discussions by asking women about their feelings and well-being during the week. Individual midwife support will be available before and after groups. Midwives and maternity support workers will provide care, support and guidance within their scope of practice. The role of facilitator in the groups is to cultivate peer support

Table 1 Intervention group schedule of events

	Initial meeting with midwife facilitator	10–15 min
Week 1–2	Group 1 (face-to-face*) facilitated	90 min
	Additional one to one time	Optional 15 min
	Self-help resources	Participant choice
Week 3–4	Group 2 (online) facilitated	90 min
	Additional one to one time	Optional 15 min
	Self-help resources	Participant choice
Week 5–6	Group 3 (face-to-face*) facilitated	90 min
	Additional one to one time	Optional 15 min
	Self-help resources	Participant choice
Week 7–8	Group 4 (online) facilitated	90 min
	Additional one to one time	Optional 15 min
	Self-help resources	Participant choice
Week 9–10	Group 5 (group choice) peer-led	90 min
	Additional one to one time	Optional 15 min
	Self-help resources	Participant choice
Week 11–12	Group 6 (group choice) peer-led	90 min
	Additional one to one time	Optional 15 min
	Self-help resources	Participant choice

*Face-to-face groups will be offered to women depending on the COVID-19 situation. These will be held in community healthcare settings. Local and national guidelines will be followed. Alternative online sessions can be arranged if required or preferred by participants. GDPR guidance for each NHS study site will be followed for online group sessions with regard to the permitted platforms and recording of meetings.

by joining in rather than leading discussions and helping women introduce discussion topics they may find difficult to introduce themselves. Facilitators will also support women's well-being and signpost and support women to access specialist or supportive services where appropriate.

3. A choice of self-help materials to be accessed between groups. The choice of materials is based on service user preferences and relevance in a UK healthcare context. Materials include cognitive skill and mindfulness online resources.^{38–40}

Randomisation

Clusters will be randomly allocated to intervention groups and control groups. Randomisation will be performed by the statistical team at the Clinical Trials Support Unit.

Neither the participant nor the facilitator can be blinded to group allocation status.

Recruitment and baseline procedures

Intervention facilitators will be recruited from the two randomly selected intervention study sites and will be: (1) registered midwives who have completed a preceptorship period; and (2) midwifery support workers with a minimum of 1 year's experience in maternity care. Recruitment will be sought through expression of interest via an invitation email sent by a member of the midwifery senior leadership team at the NHS Trust site (for intervention groups only). Selection of facilitators will be agreed through discussion with the senior leadership team and the chief investigator. To allow for annual leave and unexpected absence in the intervention group sites, two midwives and two midwifery support workers will be recruited in each intervention site. One midwife and one midwifery support worker will be allocated as facilitators for a specific group and provide cover for other groups if required. Following procedures developed for RAPID-1,²⁹ training to facilitate the intervention will be delivered by perinatal mental health professionals who have developed a facilitator study workbook and a 2-day training workshop.

Potential participants will be signposted to a study webpage by community midwives during attendance at routine midwife appointment at approximately 16–20 weeks of pregnancy (figure 2). The community midwife will provide eligible women with an information leaflet about the study containing a webpage address, QR code and contact information. The study will also be promoted via social media platforms such as Facebook, Twitter, Instagram or distributed through online research participation websites. Posters will be placed in health service and community venues. The study webpage will contain information about the study, eligibility criteria, links to a participant information sheet and contact details (via email) for asking further questions and completing an eligibility assessment.

Eligibility screening will include an assessment of mild to moderate anxiety self-reporting symptoms using the GAD-7 scale. Women will be asked to complete the GAD-7 scale. Scores will be collated by a digital data management and capture system (REDCap) and women with scores of 3–14 will be advised they are suitable to participate in the study. Women will be advised to contact their general practitioner (GP) or community midwife if they feel they require further assessment and support (current practice guidelines). Participants with a GAD-7 score of 15 or more will be thanked for their interest and advised that the (type of) intervention being assessed may not be suited to them. A score of 15 or more may indicate severe anxiety³³; these women will be advised to contact their GP or community midwife for further assessment and support. Women with scores of less than 3 will be advised that the study is not suited to their needs and advised

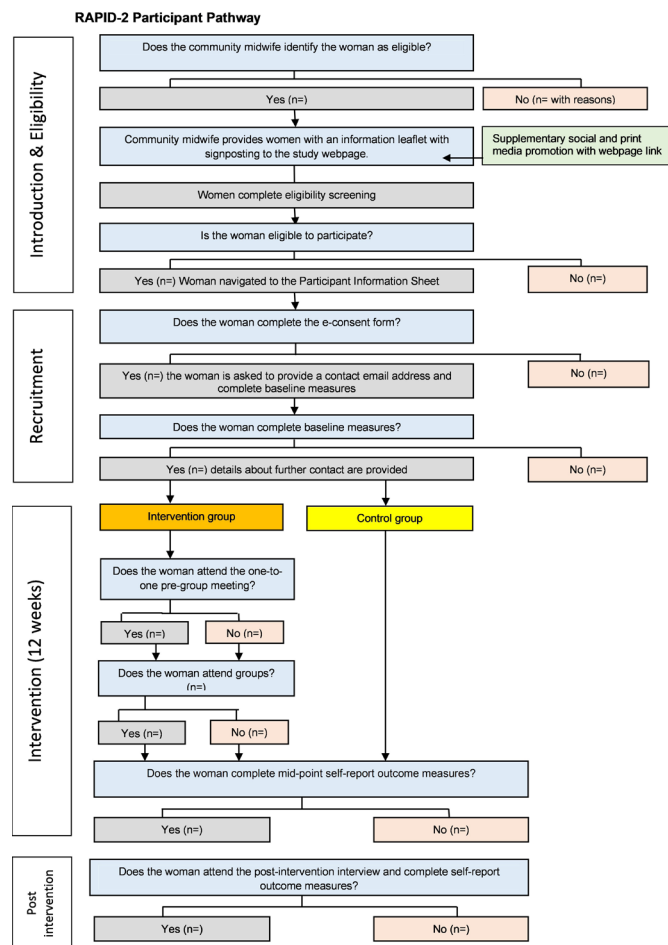


Figure 2 Participant pathway for the RAPID-2 study.

to contact their midwife if they feel they need further support.

Informed consent will be sought from women who are interested and eligible to participate. After completing eligibility screening and reading the Participant Information Sheet, a potential participant will be asked to complete paper or online consent (online supplemental appendix 1). Potential participants will be asked to provide a valid email address or phone number or postal address to enable the collection of online baseline and outcome data and receive information from facilitators about attending groups (for intervention group participants). If participants agree to complete the consent form, the data will be captured on the REDCap system and the participant will be enrolled. Informed consent will be collected from each participant before they undergo any interventions (including baseline data collection) related to the study. Participants will not receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this study. The chief investigator and study sponsor will have access to the full dataset.

Women in the intervention group will need to start the intervention no later than 22 weeks of pregnancy. To minimise the time between study entry and starting the intervention (1) facilitators will be trained in advance of the participant recruitment period; (2) study promotion

activities will be conducted with community midwives in advance of recruitment; (3) two to three groups will be held at each intervention site consisting of 4–10 participants.

If a participant wishes to withdraw from the study they can contact the study team via phone, email or through the contact website page. They will be advised that no further identifiable information will be collected. If they withdraw consent from the study at any time, their data up until the point of withdrawal, will remain on file and will be included in the final study analysis. Participants in the intervention group who do not attend any or all of the group sessions will not be withdrawn from the study and outcome measures will be sent as planned. Non-attendance will be reported to meet the study objectives.

Outcomes

Data will be collected to assess: (1) the number of women accessing the site and completing eligibility screening, (2) the number of eligible women and (3) the number of women who consent to participate. A qualitative evaluation will focus on women's and facilitators' views on participating in the intervention and assess the acceptability and experiences of random allocation to a usual care group.

Secondary outcomes

- Self-reported symptoms of anxiety, pregnancy related anxiety and fear of childbirth.
- Self-reported levels of social support and QoL.
- Self-reported standardised measures of service and support use.

Measures

Self-report measures include:

1. The GAD-7,³³ recommended for consideration as part of antenatal psychological screening.¹⁷
2. The Edinburgh Postnatal Depression Scale, a 10-item questionnaire mainly focused on depression with an anxiety subscale.^{41–43}
3. The 10-item Pregnancy Related Anxiety Questionnaire-Revised.⁴⁴
4. The 12-item Short-Form Health Survey,⁴⁵ a quality of life (QoL) measure with two sub-scales: a mental component and physical component summary.
5. The 12-item Multidimensional Scale for Perceived Social Support, measures perceptions of support from three sources: family, friends, and significant other.⁴⁶
6. The Fear of Childbirth Questionnaire 20-item fear of childbirth questionnaire.⁴⁷
7. Economic evaluation: developed for the study and based on the Client Service Receipt Inventory.^{48 49}

A subsection of participants (n=6 from the intervention group and n=6 from the control group) and all facilitators will be interviewed about their experiences of the intervention. Face-to-face semi-structured interviews will be conducted. Purposive sampling will identify cases where the most could be learnt in relation to the objectives.⁵⁰

A semi-structured interview guide has been developed for intervention and control group participants and for facilitators. Topics have been developed using predefined themes from the literature and designed to facilitate emergent data to be collected⁵¹ (online supplemental appendix 2).

Procedures

A process evaluation will follow the framework developed by Grant *et al*⁵² to explore the recruitment of clusters, the delivery of the intervention, recruitment and reach within each cluster, intervention fidelity, maintenance, context, unintended consequences and theory of change. Data reporting the number of groups attended, engagement with individual support and self-help resources will be recorded by facilitators. Intervention fidelity will be established through a structured notes review including a summary of any individual discussions and the topics covered in the groups. Group sessions will be audio recorded and analysed to describe group content and assess fidelity between groups. The degree of completion for self-report forms will be assessed and reported to meet the objectives of the study.

Quantitative data from the self-report measures will be collected at three time points: baseline (first week following enrolment at 16–20 weeks of pregnancy), mid-point (6 weeks after baseline at 22–28 weeks of pregnancy) and postintervention (14 weeks after baseline at 30–34 weeks of pregnancy). Participants will be offered a choice of completing self-report measures by hand (via post), via telephone with the researcher or through an online data entry. Participants preferred method of completion will be established at enrolment. Study data will be collected and managed using REDCap electronic data capture tools hosted at the sponsor site. Participants selecting to complete measures via the online system will be sent automated emails at enrolment (baseline), at 6 weeks and 14 weeks after baseline, the email will contain a link for completing online forms. Two reminders will be sent at 1-week interval. Participants choosing to complete measures by hand or via the telephone will be either sent forms in the post or telephoned at the three timepoints by the researchers. Data from hand completed and online forms will be entered into the electronic case report form and checked for accuracy by the chief investigator.

Data analysis

Participant baseline characteristics will be summarised using means (SD) or median (IQR) if the data were continuous or counts, respectively, or frequency (percentage). The unit of analysis will be the individual participant and the primary analysis performed using intention to treat. Outcome data will be collected from all participants, whatever their level of subsequent engagement with the allocated intervention programme. Descriptive analyses will be conducted for all of the study outcome measures. All continuous variables will be summarised using mean, SD or median and IQR as appropriate. Exploratory analysis

will use independent samples t-test for the GAD-7 measure, with analysis of covariance to analyse the change in scores while controlling for baseline imbalance. To account for the cluster randomisation, mixed-effects modelling will be used for continuous outcomes to compare the two groups on self-report outcome data. Baseline measures of the outcome variables (where appropriate) will be included as individual-level covariates in the models for outcome data.

Qualitative data

Template analysis⁵¹ will be used to explore interview data for predefined themes outlined in the topic guide and themes generated from the data.

Protocol amendments

Any changes to the study protocol outlined in this paper will be approved by East Midlands—Derby Research Ethics Committee. This will be in agreement with the sponsor.

ETHICS AND DISSEMINATION

Ethical approval was given by East Midlands—Derby Research Ethics Committee 14 March 2022 (REC Reference: 22/EM/0018). It is considered unlikely that participants will be at risk during the study. The study website will provide information on the limitations of self-report measures: measures 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. If the participant in the intervention arm of the study is considered by midwife facilitator as being at risk of harm to themselves or others, they have a duty of care to report those concerns as per usual practice at the study sites.⁵³ Facilitators will also be directed to inform the chief investigator within 24 hours of risk being identified. This information is detailed in the participant information sheet. Women in both the intervention and control arm of the study will access usual maternity care and will be able to access perinatal mental health services and/or psychological therapies as per usual care.

Monitoring

A Trial Steering Committee and Data Monitoring Committee will not be required for this feasibility study. A Trial Management Group will be convened and will comprise the chief investigator, and a sponsor and Clinical Research Network representative who will meet regularly to ensure all practical details of the study are progressing well and working well and everyone within the study understands them. This will include a regular review of recruitment and retention to the study.

Dissemination

Following completion of the study, the data will be analysed, and a Final Study Report prepared for submission to the HEE/NIHR ICA awards committee. The report will be published on the NIHR website. Dissemination will

include written reports, briefings, executive summaries and presentations to healthcare providers, Local Maternity Systems, Integrated Care Alliances, local and national perinatal mental health networks, national and international health charities (ie, King's Fund, Mind, Beyond Blue), Royal Colleges (ie, GPs, psychiatrists, midwives). Papers will be prepared for academic and clinical conferences and peer-reviewed journals. Participants will be offered a summary of findings to be sent via email or post.

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