PAAM PROTOCOL

FULL/LONG TITLE OF THE STUDY

Accessibility and acceptability of perinatal mental health services for women from Ethnic minority groups (PAAM study)

SHORT STUDY TITLE / ACRONYM

Acceptability of perinatal mental health services for women from Ethnic minority (PAAM study)

PROTOCOL VERSION NUMBER AND DATE

Version 0.1 April 2019

RESEARCH REFERENCE NUMBERS

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KEY STUDY CONTACTS

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Funder(s)	NIHR
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STUDY SUMMARY

Short Title	Accessibility and acceptability of perinatal mental health services for women from Ethnic minority groups (PAAM study)
Methodology	WP1: Exploratory quantitative analysis of two large linked NHS databases (MHSDS and HES) WP2: Service evaluation of two perinatal mental health services in Birmingham and East London WP3: Qualitative interviews and analysis focusing on exploring experiences and views of women from South Asian and Black ethnic background who suffered from perinatal mental health problems (and comparing their views with views of White British women), of their partners/carers/family members, and of health professionals. WP4: Designing policy guidelines for the organisation of perinatal mental health services for women from ethnic minorities and dissemination of the study results
Research Sites	East London NHS Foundation Trust Birmingham Solihull NHS Foundation Trust We will also recruit participants (participant identification sites) (women with lived experience and their partner/carers/family members) from community organisations, primary care, maternity and health visiting services We will recruit health professionals from different NHS organisations
Objectives/Aims	WP 1. Establish the rates of women from ethnic minority groups who use mental health services in the perinatal period and assess whether rates vary by ethnicity WP 2. Identify pathways to accessing community and inpatient perinatal mental health services in two localities with large ethnic minority populations in the UK

	WP 3. Explore attitudes, expectations and experiences of women from South Asian and Black ethnic minority groups who experienced perinatal mental health problems, and of their partners/family members/carers and of the different health professionals WP 4. Disseminate the findings to a range of audiences and stakeholders
Number of Participants/Patients	WP3: Total N= 72 N= 42 South Asian/Black and N=6 White women with personal experience of perinatal mental health problems, N=10 partners/carers and N=15 health professionals
Main Inclusion Criteria	**Women with lived experience:** women from South Asian and Black ethnic minorities who experienced perinatal mental health problems **Carers**: partners/carers/family members of women we interviewed **Health professionals:** midwives, health visitors, obstetricians, social workers, specialist perinatal as well as general mental health professionals
Statistical Methodology and Analysis (if applicable)	Exploratory quantitative statistics for WP1 Content analysis and descriptive statistics for WP2 Qualitative analysis for WP3
Proposed Start Date	1 May 2019
Proposed End Date	1 July 2021
Study Duration	26 months Final dates dependent on REC approval

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
NIHR HS&DR - Project: 17/105/14	
NHS Trust- BSMHFT and ELFT NHS research/support costs	

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor and funder will not control the final decision regarding any of following aspects of the study (study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results).

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Oversight and management group- nominations have been submitted to the NIHR and further two nominations will be submitted

KEY WORDS:	Perinatal mental health service, ethnic minority, acceptability of mental health service, accessibility of mental health service

PROJECT PLAN GANT CHART (separate document)

STUDY PROTOCOL

Accessibility and acceptability of perinatal mental health services for women from Ethnic minority groups (PAAM study)

BACKGROUND AND RATIONALE

Perinatal mental health problems are very common – associated with 20% of pregnancies (1). They cover a wide range of difficulties from adjustment and anxiety disorders to depression and psychotic illnesses such as postpartum psychosis. Several confidential enquiries into maternal deaths have shown that psychiatric disorders are one of the leading causes of maternal death in the UK. Women who experience mental health problems in the perinatal period often face a number of barriers in seeking help which are linked to personal factors (stigma, concerns about baby being removed etc.) (2) as well as factors related to the organisation of health services (difficulties in accessing services, long waiting times etc.). As a consequence, mental illness frequently remains untreated which leads to a significant negative impact on the mothers' health, the health of their children, on the wider family unit and on society as a whole. The estimated cost of perinatal mental health problems is £8.1 billion pounds per one year cohort of births in the UK, with almost three quarters of costs being related to adverse impacts on children (3). Barriers to accessing treatment in the perinatal period are likely to be even bigger for women from ethnic minority backgrounds, however there is little information available about the use of mental health services by women from ethnic minorities in the perinatal period. In one study minority ethnic women were twice as likely to have potentially missed being diagnosed with common mental disorders during the maternal period (4) and in a national survey non-white women were less likely to be asked about their mental health, to be offered treatment, or to receive support in the perinatal period (5). Furthermore, the Confidential Enquiry into Maternal Deaths showed that the rates of maternal mortality were higher in some ethnic minority groups than in others (6). Some evidence from 2010 suggests relatively low number of minority women accessing specialist perinatal mental health at Mother and Baby units (MBU) despite their disproportionate exposure to known psychosocial risks (7). Research is needed to explore this further. Overall in terms of perinatal mental health, the evidence base for women from ethnic minorities in the UK remains relatively poor. As a consequence it is difficult to advocate effectively for and/or implement the kind of services that would best meet the needs of ethnic minority women on the basis of evidence-based practice (7). Therefore, research is required to assess the accessibility and acceptability of perinatal mental health services for women from ethnic minorities in order to improve the care provided to them, to increase the likelihood of their illness being successfully treated and prevent long term negative consequences.. For this, we propose a mixed method research study with these objectives: 1. Establish the rates of women from ethnic minorities who use mental health services in the perinatal period; 2. Identify pathways to accessing community and inpatient perinatal mental health services in two localities with large ethnic minority populations in the UK; 3. Explore the attitudes, expectations and experiences of women from ethnic minorities who experienced perinatal mental health problems, their partners and family members/carers and of health professionals; 4. Disseminate the findings to a range of stakeholders. The research will be carried out in four steps and be supported by a Lived Experience Advisory Panel (LEAP). Additionally one member of our research team has lived experience of perinatal mental illness. In the first step WP1 (M1-M5) we will link and investigate two large national databases (Hospital Episode Statistics and Mental Health Service Data Set) in order to explore to what extent women from different ethnic minorities use perinatal and general mental health services during the perinatal period, what happens after a woman’s first contact with services and whether there is a difference in type of services, frequency of contact or admissions to psychiatric hospital amongst women from different ethnicities. In the second step WP2 (M6-M9), we will collect additional information from specialist perinatal mental health services in two areas with large ethnic minority populations - Birmingham and East London. We will assess the extent to which women from ethnic minorities do not attend appointments at specialist services and the pathways to admission to two Mother and Baby psychiatric hospital units. In the third step WP3 (M10-M23), we will carry out indepth qualitative interviews with women of South Asian and Black ethnic background who experienced perinatal mental health problems, with their partners and family members/carers, and with different health professionals about their attitudes, expectations and experiences. The interview questions will be informed by the findings the first two steps and will be developed in collaboration with LEAP. In the fourth step WP4 (M24-M26) we will discuss with different stakeholders (women with lived experience and their families, commissioners, different health professionals and community organisations) the best way to translate research results into policy guidelines and will then disseminate these results.

RESEARCH QUESTION/AIM(S)

The overarching aim of this study is to contribute to improving the care provided to women from ethnic minority backgrounds who experience mental health problems in the perinatal period. This will be achieved by exploring the acceptability of perinatal mental health services for women from ethnic minorities and the pathways they use to access them. Therefore specific objectives are to:

1. Establish the rates of women from ethnic minority groups who use mental health services in the perinatal period and assess whether rates vary by ethnicity
2. Identify pathways to accessing community and inpatient perinatal mental health services in two localities with large ethnic minority populations in the UK
3. Explore attitudes, expectations and experiences of women from South Asian and Black ethnic minority groups who experienced perinatal mental health problems, and of their partners/family members/carers and of the different health professionals
4. Disseminate the findings to a range of audiences and stakeholders

STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

The PAAM study contains four work packages using a mixed methods design. Quantitative analysis will be used in WP1 and WP2. WP3 will be a primary qualitative study. Mixed methods will allow the exploration of the complex and multi-layered aspects of the accessibility and acceptability of perinatal mental health services for women from different ethnic minorities.

In WP1 (M1- M5) an exploratory quantitative analysis will examine the use of mental health services by women of different ethnic groups in the perinatal period at a national level in collaboration with NHS Digital. We will use the linked Hospital Episode Statistics (HES) and Mental Health Services Dataset (MHSDS).

We propose to carry out the following exploratory analysis (which partly depends on the completeness of variables in datasets that have not been explored yet):

1) Identify an index cohort of women across England who became pregnant or gave birth during an appropriate 12 month period. This cohort will be identified using the national Hospital Episode Statistics (HES) inpatient and outpatient datasets based on the presence of either a birth episode or a first obstetric/midwifery outpatient attendance (this may exclude a small number of women from the analysis whose data would not be contained within the proposed datasets, specifically: those who miscarry prior to booking, those who receive private obstetric services, those who terminate pregnancy prior to booking and those who die before booking.) The perinatal period is defined as period from conception until 1 year postnatal.

2) Link the above cohort to the Mental Health Services Dataset (MHSDS) thereby identifying all women within the index cohort who had contact with or received care from mental health services.

3) Conduct an initial descriptive analysis to quantify and describe this cohort in terms of its demographic profile, specifically: age, ethnicity and deprivation

4) Stratification of the cohort into a number of groups relevant to the study based on the key demographic characteristics.

- Stratification based on ethnicity – the number and composition of the ethnic groupings will be agreed following discussion with relevant stakeholders and clinicians to identify appropriate subgroups but we anticipate a wider set of sub groups beyond the standard five subgroups (White, Black, Asian, Mixed and Other)
- Stratification based on deprivation (using index of multiple deprivation) – the number of deprivation groupings will be agreed following discussion with relevant stakeholders and clinicians.
- Stratification based on age groups
- Combinations of the above may also be included where it is considered to be of interest.

5) Carry out a detailed exploratory analysis to build a clear understanding of how use of mental health services by women in the perinatal period differs between the groups outlined above.

This analysis will identify and quantify some of the following elements:

For all services

- differences in the referral rates to mental health services
- differences in the diagnosis (care cluster)

For inpatient and HTT

- differences in inpatient admission rates (voluntary and involuntary) and difference between admissions to MBUs vs. general wards, differences between source of admission (and possibly when in perinatal period admissions occur), difference between admission length (voluntary and involuntary)
- differences in HTT admission rates (and possibly when in perinatal period admissions occurs)

For community services

- differences in service provision rates (e.g. access to psychology vs. nursing vs. medical)
- differences in the point of first contact/referral (i.e. time from conception)
- differences in type of mental health services accessed (e.g. specialist perinatal mental health or generic mental health services however this will be affected by availability of perinatal services which will vary by area)
- differences in attendance (non-attendance) rates and when disengagement occurs (early/late in treatment)
- differences in the frequency of contacts with mental health services
- differences in duration of care episodes

Data requirements

We propose to use the following datasets for this stage of the work:

National Hospital Episode Statistic (HES) Inpatient Dataset

National HES Outpatient Dataset

National Mental Health Services Dataset (MHSDS)

Mental Health - HES bridging file

The Strategy Unit (NHS Midlands and Lancashire Commissioning Support Unit) will carry out the analysis and a statistician will be involved in this analysis.

Data quality within the datasets is considered to be adequate for the purposes of this analysis. The initial review of the 2014/15 MHMDS identified that around 16% of cases had an ethnicity recorded as “Not Given” or “Not Stated”. Completeness of ethnicity data in HES is ca. 11% for birth episodes.

In order to account for the missing data we will take two approaches (one as our primary analysis and the other as a sensitivity analysis). The first approach will be to conduct the analysis on only the data where ethnicity was recorded (i.e. all records with missing ethnicity will be explicitly excluded from the analysis). This approach is based on the assumption that missing ethnicities are “missing at random”. However we recognise that this is unlikely to be the case and as such our second approach will be to impute missing ethnicities. We propose using K-Nearest Neighbours (KNN) imputation algorithm to replace the missing values. We will also explore potential methods to validate the results though comparisons with other datasets. Our outputs will consider the variation between the two approaches and we will highlight relevant and material implications of any differences in the results. In addition it is likely that the combination of the two independent datasets will result in a reduced level of missing values than are seen within each individual dataset.

The Lived Experience Advisory Panel (LEAP) will be involved in discussions of the results of this analysis and its` implications for the next stages of this research.

WP2 (M6- M9) will focus on extracting data from routinely collected information in local perinatal mental health services in Birmingham and East London which are areas with a large ethnic minority population. This will take the form of a service evaluation which will look at the following:

1) Rates of non-attendance at appointments in community perinatal mental health services in Birmingham and East London in 2018 and whether these varied by ethnic group. The analysis will include non-attendances at initial and follow-up appointments.
2) Also in order to explore further pathways to inpatient admission, RiO notes for all community patients during a period of 3 months will be reviewed to check if hospital admission was recommended and refused and what was a reason given for refusal. The same will be done for all patients who were under HTT within 12 month period – RiO notes reviewed to check if hospital admission was recommended and if it was whether it was accepted or refused (and a reason for refusal) and whether it was to the adult ward

or MBU. RiO notes will be searched for terms such as “admission”, “hospital”, “unit”, “ward”.

3) For a subset of community patients, pathways to care will be explored and following data collected :

- socio-demographic profile of the patients (age, gender, education, employment, marital status, number of children).
- Who referred the patient to perinatal services (e.g. midwifes, GP, etc.)
- Main presenting complain
- What were the main ICD-10 diagnoses of referred patients
- Duration of the onset of illness to access to psychiatric care
- The most frequently prescribed treatments (e.g. medication, psychological support, psychotherapy)

4) Pathways to admission for two inpatient psychiatric Mother and Baby Units in Birmingham and East London during 2018 and whether these varied by ethnic group. Routine clinical data (care records of all women admitted to two MBUs) will be reviewed in order to categorise pathways to admission and to explore whether pathways vary by ethnic group.

In WP3 (M10- M23) the quantitative analyses from WP1 and WP2 will be complemented by a qualitative study. The accessibility and acceptability of perinatal mental health services will be explored through qualitative, in-depth, semi-structured interviews with women from South Asian and Black ethnic minorities that experienced perinatal mental health problems. We will also interview their partners/carers/family members and health professionals working with women in perinatal period (midwives, health visitors, obstetricians, social workers, specialist perinatal as well as general mental health professionals). A semi-structured interview guide will be developed with input from the LEAP, considering results of WPs 1 and 2 as well as from existing literature.

In WP4 (M24- M26) we will finalise the development of guidelines and recommendations which will be followed by a targeted period of dissemination.

We will set up an Expert Reference Group (ERG) to develop the draft guidelines on the organisation of perinatal mental health services working with women from ethnic minority background based on the results from the research. This ERG will be constituted from members of our research team including those who have lived experience (e.g. service user co-applicant Tahir, peer researcher, feedback from LEAP) and who have clinical experience in this area. In addition a representative of partners/carers/family members will be part of this group as well as providers, commissioners and other health professionals that will be contacted through the regional Perinatal Mental Health networks. We will also invite a member of the national policy team from NHS England to contribute to the ERG. The ERG will prepare draft guidelines on the accessibility and acceptability of perinatal mental health services for women from ethnic minorities based on the results of the study (including barriers identified but also factors perceived as facilitating engagement with perinatal mental health services for this group). Draft guidelines with recommendations for implementation will be presented at a stakeholder meeting that will be facilitated by West Midlands Perinatal Mental Health Network. PAAM stakeholder meeting will be organised in M24 and will include women with lived experience of perinatal mental illness from ethnic minority backgrounds and their partners/carers/family members, commissioners, mental health professionals from perinatal and generic mental health services, health professionals from primary care, maternity and health visiting and community organisations working with women from ethnic minorities and their families. With this feedback from stakeholder meeting the ERG will finalise the guidelines.

The LEAP will take an active role in dissemination to ensure findings are accessible and meaningful to service users, carers and the public. Dissemination will target different stakeholders including mental health service commissioners, clinicians, women with experience of perinatal mental health problems and their families as well as academics.

The Guidelines will be disseminated through:

1. Dissemination workshops with local commissioning organisations responsible for designing and commissioning local perinatal mental health services. Workshops for CCGs, NHS Trusts and Service User organisations will be designed in collaboration with the LEAP to present the findings of the study. These will be offered as face to face workshops and as webinars.

2. Dissemination through presentations at National Perinatal Mental Health Clinical Networks Meetings and at the Executive Committee of Perinatal Section of the Royal College of Psychiatrists.
3. Dissemination through PAAM study Twitter account and websites of the participating organisations (two mental health trusts, The Strategy Unit, Action on Postpartum Psychosis etc.). Twitter account will be used to share progress throughout the study.
4. Presentations at national and international conferences
5. Scientific publications in high impact peer-reviewed journals to maximise dissemination and impact.

STUDY SETTING

WP3 – qualitative study

The interview guide with women who experienced perinatal mental health problems will address personal and cultural factors (e.g. attitudes, beliefs about mental illness and caring responsibilities, cultural stigma, pathways to care, fear of children being taken away and perceived role of social services, role of community organisations and religious beliefs, knowledge about services and support available, use of non-NHS services and preferences for other types of help for mental illness etc.), relationships with healthcare providers, and the perceived impact of receiving treatment on their parenting. Adopting an in-depth approach is important to allow for the exploration of differences between women from different ethnic minorities. Differing perceptions between women experiencing mental health problems and their partners/carers/family members and health professionals will also be explored in the analysis. We will use interpreters for women (or partners/carers/family members) who do not speak English.

Using purposive sampling, we will recruit women (and their partners/carers/family members) with experience of moderate-severe perinatal mental illness with different characteristics. We will purposively sample women with experience of perinatal mental health problems and use the following sampling criteria:

1. ethnicity: South Asian or Black
2. engagement with perinatal mental health services: accessed or not accessed perinatal mental health services

3. migration generation: first or second/third generation migrant

Given the exploratory nature of the study (and the absence of any specific hypotheses about differences between subgroups) we will focus on these core criteria and address each of them with sufficient material. In addition we will make every attempt to maximise the variability in terms of deprivation by targeting women from areas with different deprivation indices. This will be closely monitored during recruitment. We will then ensure that we include and explore during the interviews those factors that we know are indicative of levels of deprivation such as financial issues, education status and ability to read and write, employment, mobility in terms of access to transport, housing issues etc. When distinguishing deprivation from ethnicity, we will generate themes that are linked to those aspects of women's lives that are related to poverty, lack of education, accessibility of transport etc. Cultural issues will focus on the women's and the carers' beliefs and behaviour that are related to their cultural and religious background. Moreover, our analyses will aim to address the intersectionality of culture, deprivation, gender, disability and ethnicity. Yet, again, this will be an exploratory approach.

In addition, we will interview a small number of White British women to check whether categories identified in in-depth interviews with women from ethnic minorities differ from the ones that women from White British background mention.

In addition to two Research Assistants, interviews will be conducted by a peer researcher and by a bilingual researcher who speaks Asian language/s (Punjabi/Urdu/Bengali) as this is the largest ethnic group where interpreter may be needed for qualitative interviews (these interviews will be transcribed and then translated). In addition, for other community languages we will use interpreters. In order to ensure the validity of the qualitative interviews, the interpreters will receive training in interviewing techniques by the research team prior to qualitative interviews based on British Psychological Society guidelines.

We will recruit women who experienced mental health problems from 1) perinatal mental health services (both inpatient and community), both the ones who use services and the ones who did not attend their appointment and were discharged 2) primary care and maternity services, 3) health visiting services, and 4) wide range of community organisations working with women from ethnic minorities and women who experience perinatal mental illness. Women who experienced mental health difficulties in antenatal and early postnatal period will be recruited from primary care and maternity services whilst those whose mental health problems were prominent in postnatal period will be recruited through primary care and health visiting service. Women will be approached by health care professionals (mental health clinicians in perinatal mental health services, midwives and obstetricians in maternity services and health visitors in health visiting service) and by staff in community organisations. We will routinely offer to participants a possibility of having a spouse/partner/friend present during interviews. We will recruit through adverts at local radio and newspapers.

All women with experience of perinatal mental illness will be asked whether they would ask their partners/cares/family members if they would agree to speak to a researcher about taking part in the study. We aim to include purposive sample with sampling criteria of partners/cares/family members of women who have received and those who have not received mental health treatment and of different ethnic groups (South Asian and Black). If we do not recruit enough partners/cares/family members in this way, we will expand recruitment to include asking women who have not been approached to take part in the study but are of South Asian or Black ethnic background and from settings described above (1. perinatal mental health services, 2. primary care and maternity services 3. health visiting services, and 4. community organisations working with women from ethnic minorities and women who experience perinatal mental illness) and who have experienced perinatal mental health problems to ask their partners/cares/family members if they would agree to speak to a researcher about taking part in the study.

We will include a purposive sample of health professionals and the sampling will be stratified by professional background (for example midwives, health visitors, obstetricians, social workers, perinatal and general psychiatrists, perinatal and general psychiatric nurses). We will interview approx. 42 women with personal experience of perinatal mental health problems from ethnic minority background, 6 White British women with personal experience of perinatal mental health problems, 10 partners/carers and 15 health professionals. Interviews will be recorded, transcribed and coded.

Interviewed will be conducted face-to-face, audio recorded, transcribed and de-identified by research assistants. A thematic analysis will be conducted through an iterative process by the multi-disciplinary research team with strong involvement from the LEAP. They will be coded by research assistant following discussion with Chief Investigator and co-investigators and qualitative data analysis software may be used.

SAMPLE AND RECRUITMENT

Women with lived experience of perinatal mental illness

1. Black or South Asian ethnic minority (and White British for a small subsample)
2. Female gender
3. Able to provide informed consent for participation in the study
4. Aged over 18 years
5. Have experienced mental health problems in perinatal period of moderate-severe intensity (for women who received mental health treatment the severity will be based on health professional's judgment, and for women who did not receive treatment, severity will be based on self-assessment)

Partner/Family member/Carer

1. Has experience of supporting a women of Black or South Asian ethnic minority (who gave consent for them to be interviewed) with perinatal mental health problems
2. Aged over 18 years
3. Able to provide informed consent for participation in the study

Health professionals

1. Have experience of working with women who experienced mental health difficulties in perinatal period
2. Aged over 18 years
3. Able to provide informed consent for participation in the study
4. Fluent in English

Exclusion Criteria WP3

1. No specific exclusion criteria if meets inclusion criteria

Sampling

We will purposively sample women with experience of perinatal mental health problems and use the following sampling criteria:

- ethnicity: South Asian or Black (and White British for a smaller subgroup)
- engagement with perinatal mental health services: accessed or not accessed perinatal mental health services
- migration generation: first or second / third generation migrant

Given the exploratory nature of the study (and the absence of any specific hypotheses about differences between subgroups) we will focus on these core criteria and address each of them with sufficient material. In addition we will make every attempt to maximise the variability in terms of deprivation by targeting women from areas with different deprivation indices. This will be closely monitored during recruitment.

In addition a small group of women from White British background who experienced perinatal mental health problems will be interviewed.

All women with experience of perinatal mental illness will be asked whether they would ask their partners/cares/family members if they would agree to speak to a researcher about taking part in the study. We aim to include purposive sample with sampling criteria of partners/cares/family members of women who have received and those who have not received mental health treatment and of different ethnic groups (South Asian and Black). If we do not recruit enough partners/cares/family members in this way, we will expand recruitment to include asking women who have not been approached to take part in the study but are of South Asian or Black ethnic background and from settings described above (1. perinatal mental health services (both inpatient and community), 2. primary care and maternity services to 3. health visiting services, and 4. community organisations working with women from ethnic minorities and women who experience perinatal mental illness) and who have experienced perinatal mental health problems to ask their partners/cares/family members if they would agree to speak to a researcher about taking part in the study.

We will include a purposive sample of health professionals and the sampling will be stratified by professional background (midwives, health visitors, obstetricians, social workers, perinatal and general psychiatrists, perinatal and general psychiatric nurses).

Size of sample

Recommendation is that 25–30 participants is the minimum sample size required to reach saturation and redundancy in grounded theory studies that use in-depth interviews. This number is considered adequate for publications in journals because it (1) may allow for thorough examination of the characteristics that address the research questions and to distinguish conceptual categories of interest, (2) maximizes the possibility that enough data have been collected to clarify relationships between conceptual categories and identify variation in processes, and (3) maximizes the chances that negative cases and hypothetical negative cases have been explored in the data (8).

We will interview approx. 48 women with personal experience of perinatal mental health problems, 10 partners/carers and 15 health professionals.

Sampling technique

Purposive sampling

Recruitment

Women will be approached by health care professionals (mental health clinicians in perinatal mental health services, midwives and obstetricians in maternity services and health visitors in health visiting service) and by staff in community organisations. Women who DNA-ed appointments in perinatal mental health teams will be contacted via post and offered to be contacted to take part in the study.

All women with experience of perinatal mental illness who take part in the study will be asked whether they would ask their partners/cares/family members if they would agree to speak to a researcher about taking part in the study. We aim to include purposive sample with sampling criteria of partners/cares/family members of women who have received and those who have not received mental health treatment and of different ethnic groups (South Asian and Black). If we do not recruit enough partners/cares/family members in this way, we will expand recruitment to include asking women who have not been approached to take part in the study but are of South Asian or Black ethnic background and from settings described above (1. perinatal mental health services, 2. primary care and maternity services to 3. health visiting services, and 4. community organisations working with women from ethnic minorities and women who experience perinatal mental illness) and who have experienced perinatal mental health problems to ask their partners/cares/family members if they would agree to speak to a researcher about taking part in the study.

Health professionals will be approached through local collaborators from specialised perinatal mental health teams and asked if they wish to participate in the study.

Information that will be collected about participants who we conduct in depth interviews with

Women with lived experience
Age, ethnicity, diagnosis (if known), which pregnancy

Family members/partners/carers
Age, gender, ethnicity of woman with lived experience/their, relationship with a woman with lived experience, diagnosis of a woman with lived experience (if known)

Health professionals
Age, gender, ethnicity, professional background

Consent

Informed consent will be obtained prior to the participant undergoing any activities that are specifically for the purposes of the study.
In all cases, the study researchers will explain to participants what will be expected of them and how long they would be in the study for. The researchers would also ensure they are aware of their right to decline participation at any stage of the research and clarify that declining to participate will not result in any consequences whatsoever on patient treatment.

All participants will receive a written information sheet. All women with lived experience of perinatal mental illness, their partners/cares/family members and health professionals will be given the option to have the contents of the sheet read aloud to them by the researchers. All participants' questions about study participation will be answered by the researchers prior to proceeding with the study. Written (signed) consent will be taken from all participants on the day of participation. Two copies of a written consent form will need to be signed by the participant and a member of the research team in order to proceed with study participation. The participant will keep one copy and the research team will keep the other. A photocopy will be made for the patient's medical notes and handed to a clinician in their care team. Research team members will assess each person's level of understanding at the time of reading them the information sheet and answering any questions they might have. If there are any doubts about the person's capacity to consent, this will need to be resolved before proceeding with study participation. If any doubts about their capacity emerge during the recruitment process, or capacity to consent appears to change during the research assessments, their capacity to consent will be re-evaluated before proceeding with study participation.

ETHICAL AND REGULATORY CONSIDERATIONS

Potential risk is that participants may get distressed when discussing experience of perinatal mental illness. However a clear procedure will be in place as to how to deal with these situations.

Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from a NHS REC for the study protocol (WP3), informed consent forms and other relevant documents e.g. advertisements.

Approval or service evaluation for WP2 will be sought separately from respective NHS Trusts (ELFT and BSMHFT)

For WP1, The Strategy Unit has confidentiality agreements for use of the above stated databases hence a separate approval for that is not required.

For NHS REC reviewed research

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC of the end of the study.
- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance. Different arrangements for NHS and non NHS sites are described as relevant.

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Data protection and patient confidentiality

All investigators and study site staff must comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act’s core principles.

- Coded, depersonalised data will be created where the participant’s identifying information is replaced by an unrelated sequence of characters.
- Data will be securely maintained and the linking code will be kept in separate locations using encrypted digital files within password protected folders and storage media.
- Access will be limited to the minimum number of individuals necessary for quality control, audit, and analysis.
- Confidentiality of data will be preserved when the data are transmitted to sponsors and co-investigators

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