PAAM PROTOCOL – WP3 Qualitative study

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 2.1; 18 December 2020

RESEARCH REFERENCE NUMBERS

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KEY STUDY CONTACTS

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Sponsor	East London NHS Foundation Trust
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)
Study Design	Qualitative study design
Methodology	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.
Research Sites	Lead Research Sites Perinatal Mental Health Services, East London NHS Foundation Trust, Birmingham Solihull NHS Foundation Trust We will also recruit participants (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	Explore attitudes, expectations and experiences of women from South Asian and Black ethnic minority groups who experienced perinatal mental health problems, experience of Perinatal Mental Health Services and of their partners/family members/carers and of different health professionals
Number of Participants/Patients	Total N=96: South Asian/Black (n=50) and White British (n=6) women with personal experience of perinatal mental health problems, partners/carers (n=15) and health professionals (n=25).
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 interviewed women

	Health professionals: midwives, health visitors, obstetricians, social workers, specialist perinatal and general mental health professionals
Analysis	Thematic analysis
Proposed Start Date	1 February 2020
Proposed End Date	31 December 2021
Study Duration	23 months Final dates dependent on REC approval and funding
Funder ref	NIHR HS&DR - Project: 17/105/14

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.

KEY WORDS:	Perinatal mental health service, ethnic minority, acceptability of mental health service, accessibility of mental health service
ACRONYMS	PMI - Perinatal Mental Illness PMHS - Perinatal Mental Health Service

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PATIENT AND PUBLIC INVOLVEMENT

In developing the application, we presented the ideas to the representatives of SUGAR (Service User and Carer Group Advising on Research) at City University of London. All service users were supportive and believed that this research is both very important and timely. They stated that there are significant issues affecting the use of perinatal mental health services by women from ethnic minorities that should be addressed.

To ensure we maximise the benefit of public and patient involvement throughout, we will set up a Lived Experience Advisory Panel (LEAP), consisting of 6-8 members. This panel will have representatives from different ethnic minority groups. LEAP will include service users with lived experience of mental illness and who have used mental health services in the perinatal period. We will also seek to involve women who did not engage with perinatal services as well as their partners and other carers. The LEAP members will meet 2-3 times per year throughout the project. They will provide advice on all aspects of the research process: i.e developing the topic guides for the qualitative study, interpretation of the findings from the analysis of NHS Digital databases and RIO reports, interpretation of findings from qualitative interviews and dissemination activities. LEAP members will play a key role in developing the guidelines for organising perinatal mental health services. They will also participate in dissemination workshops and develop plain summaries in English and other relevant languages so the results are accessible to all service users and the wider community. Co-applicant Syeda Tahir, has lived experience and has been involved in other research studies, will chair the LEAP meetings and have a leading role in coordinating PPI activities throughout the study. She will also attend regular meetings of the project team and will be involved in dissemination workshops. Tahir and other LEAP members will receive all relevant research training from the ELFT researchers. They will also have an opportunity to get involved directly in qualitative analysis.

STUDY PROTOCOL

Full Study Title: 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. The expected knowledge gain will significantly help to improve the design and delivery of perinatal mental health services for women from ethnic minorities.

To do this, we will 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. We will disseminate the findings to a range of stakeholders. The research will be supported by a Lived Experience Advisory Panel (LEAP). Additionally one member of our research team has lived experience of perinatal mental illness. We will carry out in-depth 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.

A draft interview topic guide will be developed in collaboration with LEAP but may be later revised following the results of other work packages from the study (WP1 &WP2). Finally, 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(S)

Are Perinatal Mental Health Services accessible and acceptable to South Asian and Black women who experience perinatal mental illness?

RESEARCH OBJECTIVE(S)

The overarching aim of this study is to contribute to improving the care provided to women from ethnic minority backgrounds that experience mental health problems in the perinatal period. This will be achieved by:

1. *Exploring South Asian and Black women's understanding and experiences of living with perinatal mental illness.*

2. *Exploring South Asian and Black women's experiences of Perinatal Mental Health Services and accessing Perinatal Mental Health Services*

3. *Exploring experiences of partners/family members/carers of ethnic minority women with perinatal mental illness*

4. *Exploring the experiences of healthcare professionals working with women with perinatal mental health problems*

5. *Comparing White British women's understanding and experiences of living with perinatal mental illness with experiences of South Asian and Black women*

STUDY DESIGN AND METHODS OF DATA COLLECTION AND DATA ANALYSIS

Types of Data

Participant demographic variables (full name, age (birth date), religion, immigrant generation, ethnicity, marital status, employment status, level of education, children (No. and ages), preferred language, household members, will be collected after the interview. For women who accessed Perinatal Mental Health Services (PMHS) we will also include questions on diagnosis (if known) and previous contact with mental health services. For women who did not access PMHS we will include question on type of perinatal mental illness (if diagnosed by primary care) and previous contact with mental health services.

For women who experienced perinatal mental health problems the interview guide will explore their experience of living with their illness, how their illness impacted on their relationships and support from family/friends. For those that accessed PMHS the topic guide will also explore pathways to care, any barriers in accessing PMHS, facilitators in accessing PMHS, ways to improve PMHS, their experience of the PMHS and whether they found it acceptable, importance of social networks, use of non-NHS services and relationships with healthcare providers.

For women who did not access PMHS, in addition to their experiences of Perinatal Mental Illness (PMI) the topic guide will also explore barriers in accessing PMHS, perception of PMHS, use of non NHS services, importance of social networks, how to increase accessibility to PMHS and how they managed their illness without treatment.

For partners/family members/carers the topic guide will explore their understanding of the woman's PMI, how her illness has impacted them/their family, barriers and facilitators in her accessing treatment/PMHS, and their experience of the treatment from the PMHS.

For healthcare professionals the topic guide will explore their experience of caring for women with PMI, in particular caring for ethnic minority women with PMI, their referral pathway for women with PMI, barriers and facilitators in South Asian/Black women accessing PMHS and ways to improve engagement with PMHS.

Data Collection Methods

Data will be collected using qualitative one-on-one, in depth, face to face interviews. The duration of the interview will aim to last between approximately 60 to 90 minutes. Interviews will be conducted by research assistants (including bilingual researcher/s in an Asian language (Hindi/Punjabi/Urdu/Bengali) and by a peer researcher. If an interpreter is required for any of the interviews this will be arranged in advance. 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 (11). Interviews will be conducted at a date, time and location convenient to the participant. Participants will have the preference of conducting the interview at home or another preferred location such as a children centre. We will routinely offer to participants a possibility of having a spouse/partner/friend present during interviews. Topic guides will be devised based on the reviewed literature, findings from other work packages of this study (1 and 2) and based on input from the LEAP panel. With participants' consent, interviews will be recorded on a digital voice recorder and supplemented by additional field notes.

COVID-19 Contingency Plan:

In light of COVID-19, contingencies of fieldwork are required for data collection to continue and reduce the risk of potential exposure to COVID-19 by participants and researchers. As an alternative and suitable qualitative method for face-to-face interviews, we will be implementing remote interviews such as phone calls and video calls. This has been recommended by the HRA in the COVID-19: Guidance for sponsors, sites and researchers (see section 3.1.2. https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/covid-19-guidance-sponsors-sites-and-researchers/).

In our study, participants will be offered the option of either a phone call or a video call. If participants choose the option of a video call, this will be done using the software that has been approved by their local NHS Trust. For example, the preferred video conference software recommended by ELFT is Zoom.

For phone call interviews, participants will provide their contact number on which to be contacted by the researcher for the purpose of the interview. For video call interviews, the researcher will send a link to the participant via email to join the video (instructions will be included). Prior to the interview taking place, both the researcher and participant will undertake pre-interview software checks to ensure that a smooth remote interview is possible.

With participants' permission, interviews whether via phone call or video call will be audio-recorded with Trust-approved encrypted audio-recorders. If an interpreter is required for the interview, remote interpreting will be adapted to include an interpreter in another location. It is anticipated that all three parties will be at separate sites, which leads to a three-way phone call or video call. We will recruit interpreters from the Newham Language Shop who currently hold a contractual relationship with ELFT. All interpreters recruited from the Newham Language Shop are DBS certified and Community Interpreting Level 3 qualified.

Data Analysis Methods

Qualitative data will be analysed using thematic analysis following the guidance of Braun & Clarke (10) using NVivo qualitative analysis software. Specifically, interviews will be audio recorded and transcribed verbatim by an NHS-approved transcription agency which conforms to regulatory requirements.

A deductive approach will look in detail at certain aspects of participant's experience. Two members of the research team will first familiarise themselves with the transcripts by reading and re-reading them. Open coding will be used (making notes and headings in the text to describe the content). Similar codes will then be grouped under themes, and the identified themes and sub-themes will then checked and refined. To optimise validity, we will conduct respondent validation by checking the analytic interpretation with patients/professionals. Members of the LEAP panel will receive training in qualitative research methodologies and will assist with the thematic analysis. The LEAP members will be supported by the study co-ordinator, the CI and a co-applicant on the grant who has expertise in qualitative research.

Study setting

This study will be multi-centre including NHS organisations in England. The study participants will be recruited from Perinatal Mental Health services including two areas with the largest ethnic minority population, East London NHS Foundation Trust (ELFT) and Birmingham and Solihull Mental Health NHS Foundation Trust (BSMHFT). Women who have been referred to specialist perinatal mental health services (both inpatient and community) and who are suffering from psychiatric illnesses in the perinatal period (pregnancy and up to 1 year postpartum) are provided with care and treatment at these specialist services.

Participants will also be recruited from the community, such as children centres, health visitor baby clinics and community organisations, located in England. Participants will have the option for the interview to take place at their home or a preferred quiet location or alternatively NHS participating research sites. As the interview will be discussing sensitive topics, having the interview at home may be preferable for some women. As there may be potential risk for the researcher, they will adhere to the policies of NHS participating research sites with regards to Safe Working Practices (see below for more details).

SAMPLE AND RECRUITMENT

Inclusion Criteria

<u>Women with lived experience of perinatal mental illness</u>

1. Participant is willing and has capacity to give informed consent for participation in the study
2. Black(Black African/ Black Caribbean/ Black Other) or South Asian (Indian/Bangladeshi/Pakistani) ethnic minority and White British for a comparative subsample
3. Over the age of 16
4. Female
5. Have experienced mental health problems in the perinatal period (pregnancy and first postnatal year) 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) within the last two years

6. Are actively involved in the care of their baby
7. If currently under the care of perinatal mental health service, inclusion criteria is that a Consultant psychiatrist (for inpatients) or a Consultant Psychiatrist/Psychiatric nurse (for outpatients) are of an opinion that a patient's mental health is stable enough to participate in the interview.

Partners/Family members/Carers

1. Participant is willing and has capacity to give informed consent for participation in the study
2. Is related to or cares for a Black or South Asian woman with perinatal mental health problems (woman must consent for their partner/family member/carer to take part in the study).
3. Aged 16 or above

Health professionals

1. Participant is willing and has capacity to give informed consent for participation in the study
2. Have experience of working with women who experience mental health problems in the perinatal period
3. Aged 18 or above

Exclusion Criteria

1. There is no specific exclusion criteria if participants meet the inclusion criteria

Sampling

Size of Sample

It has been recommended that a minimum sample size of 13-30 participants has been recommended for adequate data saturation for thematic analysis (8, 9) thus having a sample size of 50 patients, 15 carers and 25 professionals is likely to provide a sufficient

representation of the views from all groups. This number is considered adequate for publications in journals because it may allow for thorough examination of the characteristics that address the research questions and to distinguish conceptual categories of interest, maximizes the possibility that enough data have been collected to clarify relationships between conceptual categories and identify variation in processes, and maximizes the chances that negative cases and hypothetical negative cases have been explored in the data (8, 9).

We will therefore aim to conduct qualitative interviews with approximately 50 South Asian/Black women with perinatal mental health problems (or less if saturation is achieved), both those who have accessed and not accessed PMHS. We also aim to stratify this sample by migration generation (first vs/second or third), in order to ensure a more representative sample. In addition, we aim to recruit a small cohort of 6 British white women who have experienced PMI in order to compare experiences between ethnicities. We will also recruit 15 (or less if saturation is achieved) partners/carers/family members of South Asian /Black women who have lived experience of PMI. Finally, we will recruit 25 (or less if saturation is achieved) healthcare professionals working with women with PMI and this cohort will be stratified by professional background (such as GPs, midwives, health visitors, obstetricians, social workers, psychiatrists and psychiatric nurses).

Sampling technique

We will use a non-probabilistic, purposive sampling strategy to sample women with experience of perinatal mental health problems and use the following sampling criteria:

- Ethnicity: South Asian or Black (and White British for comparison).
- Engagement with perinatal mental health services: accessed or not accessed. For the purpose of this study “access” is defined as having attended at least one appointment with the PMHS.
- Migration generation: First vs /second or /third.
- In addition, we will make every attempt to maximise the variability in terms of deprivation by targeting women from areas with different deprivation indices (living environment, income, employment, education, deprivation, etc). This will be closely monitored during recruitment.

A snowball sampling strategy is the most appropriate method to recruit partners/carers/family members of women with lived experience of PMI. To do this, we will ask women with experience of PMI for contact details of partners/cares/family members and then contact them and ask if they would agree to speak to a researcher about taking part in the study. If they provide more than one person's contact details, we will ask them to rank them in accordance with how important that person`s support has been in the period of perinatal mental illness. If the person who is ranked first does not wish to take part in the study, we will contact the person who is ranked second, but we will interview maximum one partner/carer/family member per participant. If we are unable to recruit the required sample of partners/carers/family members in this way, we will expand recruitment by asking women who have not been approached to take part in the study but fulfil the inclusion criteria to provide their partners/cares/family members so that the research team can contact them and ask if they would take part in the study.

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

RECRUITMENT

Participants that received help from the PMHS will be recruited from PMHS. Participants that did not receive help from the PMHS will be recruited from Participant Identification Sites (PIC) such as GP practices, health visitor clinics, midwife appointments and community organisations. Recruitment from community organisations will not utilise any NHS/HSC sites or staff aside from the study research teams in ELFT and BSMHFT. Participants will also be recruited through snowballing methods in the community (via adverts in the media, WhatsApp groups etc).

<u>South Asian and Black women with experience of PMI and access to PMHS</u>

South Asian/Black women with experience of PMI and who have accessed PMHS will primarily be identified and recruited from PMHS. The multi-disciplinary clinical care team will identify potential participants and initially approach them. A clinician will obtain consent to contact details and the research team will contact the participant to discuss participation in the study.

Potential participants who have accessed the PMHS will be identified through the following routes:

1. Inpatients that fit eligibility criteria on the Mother and Baby unit will be invited to participate on discharge and provided an information sheet before consent is taken.
2. Outpatients who fit eligibility will be approached by the clinical care team and provided an information sheet before consent is taken.
3. Patients who have recently been discharged (within last 6 months) and who fit eligibility will be invited to participate and will be contacted via phone, letter, and email or in person by clinical care team and sent an information sheet in the post or via email.

South Asian and Black women with experience of PMI and have not accessed PMHS

Potential participants who have not accessed the PMHS will be identified through the following routes:

1. Women who were referred but did not attend their appointments in PMHS will be contacted by a member of clinical care team who will obtain consent to contact after providing them with an information sheet and answering all questions. Alternatively, they will be sent an information sheet in the post and asked to contact the research team if they wish to consider taking part in the study (this will be done only if an appointment letter for appointment with PMHS was also sent in the post to the same address).
2. Women where a referral to the PMHS was recommended by a health professionals but who declined to be referred or did not attend their appointments with the PMHS will be contacted by a health professional from a Participant Identification Site (GP practices, health visitor clinics, community and specialist midwives) who recommended a referral to PMHS. Women who did not wish to be referred to the PMHS, or did not attend their appointments with the PMHS, will be identified by a health professional (other non-perinatal mental health practitioners, GPs, midwives, health visitors) who wanted to refer them to the PMHS. Women will be contacted by health professionals from the PIC sites and offered to take part in the study. If the

participant is happy to take part the health professional will obtain their consent to contact and refer them to the research team.

3. Community organisations and charities that work with ethnic minority women with PMI or in the perinatal period will also support with recruitment. We will work collaboratively with community organisations in England in order to advertise the study to their members. Staff from community organisations will obtain consent to contact from potential participants that fulfil the inclusion criteria. Potential participants will be contacted by the study team and will be given detailed information about the study and sent an information sheet in the post or via email.
4. We will also approach leaders from community groups and faith leaders in England to promote the study and approach potential participants (obtain consent to contact) and refer them to the study team. In addition, potential participants will be recruited through leaflets/adverts in local children's centres, GP practices, maternity services, health visiting services, local cafes, community organisations, places of worship and local printed and social media and these potential participants will be able to contact study team directly on a phone number or email provided in the advert if they wish to take part. Some participants may also be recruited through snowballing i.e. they may learn about the study from existing participants (or someone else who had seen the advert) who will pass them the advert/researcher contact details and they will contact the study team if they are interested in taking part. We will recruit women who did not seek help for their illness but perceive that they experienced significant mental health problems through methods 3,4 and 5.
5. Women interested in taking part in the study will be offered an interview slot at a date, time and location that is convenient for them.

<u>White British women with experience of PMI</u>

White British women who have experienced a PMI will be identified and recruited using the same methods detailed for South Asian/Black women.

<u>Partners, Carers and Family members of South Asian/Black women with a PMI</u>

1. Women that have consented to take part in the study will be asked for contact details of their partners/carers/family members so that we can contact them and ask if they wanted to take part in a qualitative interview. Women will be provided with an information sheet to give to their partners/carers/family members. Those interested in taking part will be offered an interview slot at a date, time and location that is convenient for them. Women and partners/carers/family members will be interviewed at separate times and locations to reinforce confidentiality.
2. Women that have not been recruited into the study but have experience of a PMI will be asked for contact details of their partners/carers/family members so that we can contact them and ask if they wanted to take part in a qualitative interview. Those interested in taking part will be offered an interview slot at a date, time and location that is convenient for them.

<u>Healthcare professionals working with women with PMI</u>

We aim to recruit a stratified sample of healthcare professionals (such as GPs, midwives, health visitors, obstetricians, social workers, psychiatrists and psychiatric nurses). Health professionals will be approached through study collaborators from specialised perinatal mental health teams and asked if they wish to participate in the study after being provided an information sheet. Professionals will also be contacted via email, phone and post and will be offered to take part in the study. We will also advertise the study to professionals via social media. Those interested in taking part will be offered an interview slot at a date, time and location that is convenient for them.

COVID-19 Contingency Plan:

- ***Potential participants will be made aware that due to the COVID-19 outbreak, all interviews will be held remotely via phone calls or video calls***
- ***The appointment will be arranged at a time convenient to the participant***
- ***Participants will be instructed to ensure that they are in a private, quiet space for the duration of the interview for confidentiality purposes .***

Consent

All eligible participants that have PMI (South Asian/Black/White) will be contacted by a member of their clinical care team, a healthcare professional involved in their care (GP/midwife/health visitor), or a member of a community organization who will obtain consent to contact after providing them with an information sheet and answering all questions. Consent to contact will be taken in person or over the phone. Consent to contact sheets will then be picked up by a member of the research team, who will then contact the participant, meet them at a location/date/time that is convenient for them and provide them with another information sheet before obtaining their informed consent. Participants will be given the option to go away and discuss the information sheet with family and friends and provide consent another day if they wish, or sign consent immediately if they have read and understood the information sheet and are happy to proceed.

Partners/carers/family members will be contacted by a member of the research team over the phone (provided that consent to contact has been given by the woman) and be invited to attend the interview at at a location/date/time that is convenient for them. They will be offered an opportunity to receive an information sheet prior to the interview. At the time of interview they will be provided with another information sheet before obtaining their informed consent. Participants will be given the option to go away and discuss the information sheet with family and friends and provide consent another day if they wish, or sign consent immediately if they have read and understood the information sheet and are happy to proceed.

Healthcare professionals interested in taking part in the interview will be contacted over the phone and be invited to attend the interview at at a location/date/time that is convenient for them. They will be offered an opportunity to receive an information sheet prior to the interview. At the time of interview they will be provided with another information sheet before obtaining their informed consent. Participants will be given the option to go away and discuss the information sheet with family and friends and provide consent another day if they wish, or sign consent immediately if they have read and understood the information sheet and are happy to proceed

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. Participants will be informed about the

following: the purpose of the study, the types of data and methods of data collection, confidentiality and anonymity conditions associated with the data, time commitment expected from participants, the right to decline information, the opportunity to withdraw at any time, details of any risks, any plans for debriefing, how the data will be used, benefits of the research and how the results of research can be made available to participants. 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. If participant is under the care of perinatal mental health team, 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. Participants will be given the option to go away and discuss the information sheet with family and friends and provide consent another day if they wish, or sign consent immediately if they have read and understood the information sheet and are happy to proceed.

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.

COVID-19 Contingency Plan:

In light of COVID-19 and keeping participants and researcher safe, we have modified face-to-face interviews to remote interviews. We will obtain informed consent verbally from all participants taking part in the research. All participants will receive a copy of the consent form when they are sent the participant information sheet. Once they feel they have had enough time to review the study information, a mutually agreed time will be agreed to conduct the interview. At the beginning of the interview, the researcher will check if the participant has any questions about the study. Then, they will read out each statement in the consent form to the participant. The researcher will check that the

participant agrees with each statement, and will tick a box on the consent form next to each statement to confirm this. If the participant verbally agrees with all statements, the researcher will accept this as verbal consent for their participation in the research study. A copy of the informed consent document will be emailed or posted to the participant for their personal records.

ETHICAL AND REGULATORY CONSIDERATIONS

Deception

The participants will not be deceived in any way about the purpose of the study. All information regarding the study will be given verbally and in writing prior to the interview.

Participant withdrawal

Participants' right to withdrawal from the research at any time will be made clear at the onset of the study. The participant will have the right to withdraw retrospectively. Participants data will be retained even if they withdraw from the study.

Debriefing

When the research data gathering is complete, any further information will be provided to the participants to complete their understanding of the nature of the research study. If the researcher feels the interviewee needs further help and support after the interview, they will be given contact details of the support services in their area.

Benefits to participants

Women with PMI

Inviting women from ethnic minority communities to discuss their illness, experience of living with a PMI and experience of perinatal mental health services gives them a voice and the opportunity to discuss their experiences without judgement. Talking about their illness may also provide a sense of self-awareness for the participants. Participants are able to explore and gain an insight into their illness and may also gain a new perspective. This sense of self-awareness and self-exploration may be empowering for the participant. Furthermore, they will be assisting in research aimed to improve the quality of care of PMHS and access to PMHS for ethnic minority women with PMI, which may also offer a sense of purpose. Participants will be compensated with £30 for the time they took to attend the interview.

Partners/carers/family members

Participants may look forward to contributing towards research that will improve the quality of care received by ethnic minority women with PMI, a subject that has impacted their lives so personally. Participants will be compensated with £30 for the time they took to attend the interview.

Healthcare professionals

Healthcare professionals may look forward to contributing towards research that aims to improve PMHS. They may feel a sense of value by sharing their experiences of dealing with and caring for ethnic minority women with PMI and sharing their views on how to improve the quality of care for these patients.

COVID-19 Contingency Plan:

Due to having to pay participants remotely, participants will be reimbursed £30 in cash or shopping vouchers, depending on the local Trust policy. The options available to the participants will be confirmed by the researcher prior to the participant confirming their decision whether to partake in the interview.

Risks to participants

Recalling a difficult event/s, may cause some distress for the participant during the interview. If at any point during the interview the participant feels too distressed or upset to continue, they can either pause or withdraw from the study. Reassurance will be provided as the interview proceeds in an attempt to reduce the interviewees' discomfort. If the interviewee cries during their interview, a few moments will be provided for the emotional release that crying offers. If the crying continues, they will be asked if they wish to discontinue or proceed with the interview. Tissues will be offered. Participants will be provided with a list of support sources for follow-up care, that may be helpful, should the above occur as a result of their participation. The researcher who will be conducting the interviews is not a professional psychologist or psychotherapist by background, therefore will not offer therapeutic support. Support sources will be liaised with the clinical team at the participating NHS Trust(s). Participants recruited from community organisations will be provided with an information sheet about support services available nationally. The researcher will also identify local community organisations and pass on the details to the participant where this might be necessary. All of the above information will be provided on the Participant Information Sheet prior to their informed consent in the research study

SAFE-WORKING PRACTICES

The research team will comply with the lone working policy stated by their Trust. Researchers will inform a colleague that they have arrived at the location of the interview and upon leaving. Contact details of the interviewee and location of the interview will be shared with a colleague in advance. Risk may identify the requirement for a home visit to be undertaken in pairs. Clear lines of reporting will be produced within the team so that someone has clear responsibility for monitoring the whereabouts of staff and taking action when necessary.

Assessment and management of risk

Assessment and management of risks will be reviewed. A risk management plan and Standard Operating Procedures for dealing with any potential risk/harm to the participant will be developed in conjunction with clinicians from the PMHS. This will include potential physical risk and psychological distress. If the participant discusses thoughts of suicide/harm during the

interview, this information will be reported to clinical staff. For participants who have not accessed PMHS, any identified risks will be reported to their GP.

RESEARCH ETHICS COMITTEE (REC) and OTHER REGULATORY REVIEW & REPORTS

Before the study will start, approvals will be obtained by the Health Research Authority, Research Ethics Committee, and approval from Research and Development. These independent stakeholders will review the study protocol and any supporting documents such as informed consent forms, participant information sheet, invitation letter to participants and interview schedule. Feedback and any potential amendments will be sent and modifications will be completed. All correspondence with the REC will be retained. The REC will be notified at study completion.

Peer review

The study protocol was presented to the multi-disciplinary research team at the Unit for Social and Community Psychiatry at East London NHS Foundation Trust and expert advice from clinicians who have experience in qualitative research was received and integrated in the final protocol. This protocol has also been independently reviewed by Professor of Clinical Communication at CITY University; Professor Rosemarie McCabe and Dr Qulsom Fazil a lecturer at the University of Birmingham. The feedback and comments they provided were incorporated in the final protocol.

Regulatory Review & Compliance

Before we enrol potential participants into the study, we will obtain sponsorship from East London NHS Foundation Trust, NHS Research Ethics Committee, Health Research Authority and Research and Development approvals.

Protocol compliance

If, in any case an accidental protocol deviation occurs during the research, this will be clearly documented on relevant forms and reported to the Chief Investigator and Sponsor immediately. Immediate action will be taken if deviations are frequent.

Data protection and patient confidentiality

Subject to the 2018 Data Protection Act, information obtained about the participant during the study will be kept confidential. Personal information collected will be kept secure and maintained. Data will be stored in password protected folders, in which the researchers will only have access. When analysing the data collected from the interviews, participant names will be replaced with data codes. This will be maintained throughout the data analysis process. This will allow other members of the research team to discuss themes, whilst maintaining confidentiality and anonymity of personal information. All data will be kept anonymised at dissemination including the use of direct quotes. For the duration of the study, the research team will have the responsibility to store and keep safe the data. Access will be limited to the minimum number of individuals necessary for quality control, audit, and analysis.

Indemnity and Insurance

This will be through the standard NHS indemnity scheme.

Amendments

If amendments need to be made to this protocol, the NHS R&D, HRA and REC will be notified. An amendment form will be created in IRAS. The changes will be summaries and brief explanations will be given on each case of amendment. The documents that have been amended will be attached, so changes can be identified.

Data Storage

Any personally-identifiable data will be treated in a confidential manner, with access limited to the research team. The NHS Code of Confidentiality, East London NHS Foundation Trusts Policies and Procedures, and Good Clinical Practice guidelines will be adhered to, as will the Data Protection Act 2018 and the General Data Protection Regulations.

All research staff involved in the study will be appropriately trained, supervised and supported with regards to the collection, storage, processing and disclosure of personal information. All data will only be used for purposes of the research set out in the participant information sheet and this protocol. To support confidential work with data, each participant will be assigned a unique identification code (where the participant's identifying information is replaced by an unrelated sequence of characters) that will be used on all research data and storage systems. The researcher will hold a coding log for the anonymization of study participants. The person's identifiable information will be stored separately from the anonymised research data and

appropriate secure systems will be used to store this; (locked filing cabinets at The Unit for Social and Community Psychiatry, password protected/encrypted documents on password protected secure computers). Any personal data will only be accessible to the minimum number of individuals (from the research team) necessary for data analysis or audit. Only anonymised data will be transmitted to co-investigators at other sites. Non-personal data will be stored for 10 years after completion of the research in accordance with terms of the Sponsors Policies' and procedures. The Programme Co-ordinator for PAAM will act as the data custodian for data generated by this research.

DISSEMINATION STRATEGY

We will set up an Expert Reference Group (ERG) to develop draft guidelines 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 (e.g. Berrisford, Jankovic, Jovanovic, Crawley and Musters). 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. Guidelines will also be presented and feedback sought at the Executive Committee of Perinatal Section of Royal College of Psychiatrists and National Perinatal Mental Health Clinical Network. With this feedback the ERG will finalise the guidelines and disseminate 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.)

4. Presentations at national and international conferences

5. Scientific publications in high impact peer-reviewed journals to maximise dissemination and impact.

Dissemination, Outputs and anticipated Impact

Planned outputs of this research are:

1. Guidelines on the organisation of perinatal mental health services working with women from ethnic minority backgrounds - these will be coproduced with women and families with lived experience. These Guidelines will help make perinatal mental health services more accessible, enabling more women from ethnic backgrounds to access evidence based mental health care in a timely fashion during the perinatal period. This will be useful for areas across England but also for developing services internationally and will therefore influence national and international policy.

2. Workshops that will be designed for 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.

3. Scientific publications in high impact peer-reviewed and presentations at national and international conferences. In terms of informing patients, NHS professionals, and wider population about this research, our approach will allow us to engage with a wide range of relevant stakeholders throughout the study.

This approach will also facilitate successful communication of study results and implementation of guidelines for the organisation of perinatal mental health services for women from ethnic minority backgrounds. More specifically, active engagement of women

with lived experience will be an integral part of the proposed research study through LEAP involvement, service user co-applicant`s input, peer researcher and through their contribution at a PAAM stakeholder meeting. The study results will incorporate the views of women and their families but also of health professionals who will be actively engaged in the study through interviews and through a PAAM stakeholder meeting. Commissioners will be actively involved in designing guidelines through a stakeholder meeting in M24 and through workshops that will be designed on the basis of study results. Community organisations working with women from ethnic minority backgrounds and their families will also be involved in the stakeholder meeting. In addition, findings of the study will be disseminated through established professional networks (Royal College of Psychiatrists and Perinatal Mental Health Clinical Networks) , through relevant journals as well as through scientific conferences.

Future support following the completion of the study will be required as it is hoped that an international conference will be convened, focussing on the need of women from ethnic minorities in perinatal psychiatry and how this can impact uptake of these services by specific populations. It is hoped that this will be co-produced with experts with lived experience. This will add to the growing understanding of the importance of different presentations of mental illness in different cultures, with different parenting styles and traditions.

We envisage possible barriers for generating impact from our research, and these are 1) limited funding for perinatal mental health services and 2) reluctance of local commissioners to implement guidelines and recommendations stemming from our study.

In terms of funding, NHS England has made a commitment to perinatal mental health and all CCGs across the country will receive some money to develop specialised perinatal mental health services with the vast majority receiving enough to fund a complete team in line with Royal College of Psychiatrists Guidance (11). Regarding the risk of guidelines not being implemented by local commissioners, we are confident that with our comprehensive engagement and dissemination strategy this risk will be mitigated.

In terms of impact, our study results will significantly help to improve the design and delivery of perinatal mental health services for women from ethnic minorities and help to achieve NHS England's Five Year Forward View's objectives (10) to support additional women accessing evidence based specialist perinatal mental health treatment. Guidelines on

the organisation of perinatal mental health services for women from ethnic minority backgrounds that will be an output of this study will help to ensure that the services being developed are more culturally sensitive and in tune with the populations they serve, therefore improving the life chances of mothers and children from all backgrounds. This again will impact upon future policy for perinatal mental health services and maternity service development and thus will benefit patients and have a positive impact on public wellbeing. England is leading the way in perinatal mental health service development; it is important that we share our findings and our experiences globally to impact international policy development in this life changing area.

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