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**Multi-Centre Trial of a Group Psychological Intervention for Maternal Low mood in British mothers of South Asian Origin**

 **Participant information leaflet**

We would like to invite you to take part in a new research trial exploring the effectiveness of a culturally adapted Positive Health Programme to help British South Asian mothers who may experience postnatal low mood. Before you decide whether to take part you need to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss with others if you wish. Do ask if there is anything unclear or if you would like further information, and take your time to decide whether you would like to take part.

**What is the Positive Health Programme?** The Positive Health Programme is an educational life skills programme that has been culturally adapted specifically for BritishSouth Asian mothers. Sessions will include activities that focus on improving confidence, building self-esteem and promoting a healthier lifestyle. These will take place once a week (for the first two months) and then fortnightly (up to two months). There will be 12 sessions in total. All sessions will take place in a familiar and comfortable location at a local Children’s Centre or a similar venue. These group sessions will be for 60-90 minutes each and you will have the opportunity to meet other women in similar circumstances. Some of the group sessions may be audio recorded for quality checks. You will be reimbursed for any travel costs made to and from the Children’s Centre and we will provide refreshments and crèche services at each session.

**Why is the study being done?** Many organisations offer emotional support to women after childbirth, understanding that motherhood can bring its own unique challenges. Despite good family support, many British South Asian mothers still experience loneliness and low mood and stress. Postnatal low mood is not only difficult for the mother the mother, but can also have adverse effects on the child and the family.In order to understand how to best help women, we will be comparing women who have routine treatments at the G.P and other health practices to women who are included in the Positive Health Programme (alongside their usual treatment).

**Aim and objectives of the study** The aim of this proposed study is to evaluate the clinical and cost effectiveness of a culturally adapted group psychological intervention (Positive Health Programme, PHP) in primary care for British South Asian (BSA) women with postnatal low mood compared with treatment as usual(TAU).

**Inclusion Criteria** Self-ascribed British women of South Asian origin, over the age of 16 years and living with their infants up to the age of 12 months (1Year). For the purpose of this study the South Asian groups being included are mothers who identify as Indian, Pakistani or Bangladeshi.

**Why have I been invited?** You have been approached because you are of a British South Asian background with a child up to the 12 months of age or you have recently given birth.

**Can I talk to other people about this?** Yes, it’s fine to talk to other people and to show them the leaflet. Other people can be with you when the researcher comes to visit you, as long as you want them to be there.

**Do I have to take part?** No, giving consent to participate in the study and engaging in the study is completely voluntary. You are free to leave the study at any time and without giving any reason. This will not affect the care you receive now or at any time in the future.

**What do I have to do?** If you agree to take part, we will complete a consent from and the Patient Health Questionnaire to check you are eligible to take part in the study. You will then be asked to arrange a convenient time for a researcher to visit you at a location of your choosing to complete assessments which will take about 60-90 minutes. You will then be randomly allocated by computer to receive either the Positive Health Programme (plus treatment as usual) **OR Treatment as usual (TAU)**.

You will be contacted again at 4 months and then 12 months for follow up assessments. It is important that you try to complete all follow-up assessments, whichever group you are allocated to. This ensures we have all the information we need to properly determine the effectiveness of the programme in improving outcomes.

**What are the possible advantages of taking part in this study?** We hope that you will find the programme helpful and will find participation interesting and feel that you have made an important contribution to research aimed at improving support for British South Asian mothers experiencing low mood and stress following childbirth.

**Are there any potential risks to taking part?**

**We do not think that the study involves any physical risks or harm. However sometimes, talking about your experiences and feeling may be difficult and can cause emotional upset. The following steps will be taken if you will experience any discomfort or emotional distress: If you do not feel comfortable answering any question you have a right to refuse to answer that question or to stop the interview at any stage. If you get distressed you can stop the interview without giving any reason or if you wish you can express your concerns to the researcher. You can take a break at any time and the assessments can be stopped and completed at another time if needed.**

 **Qualitative Interviews** Regardless of which group you are in, we will contact some of you again towards the end of the study and will ask you to take part in an interview. The aim of the interview is to discuss your experiences of being part of the study or if you chose not to take part then to explore the barriers that may have hindered participation. Interviews will take approximately 45-60 minutes, and will be held at a time and place convenient for you. If you are invited to take part in an interview the researcher will explain the aim of the interview and give you an opportunity to ask questions. The interviews will be audio-recorded and transcribed. We may wish to use anonymized direct quotations from the interviews in research presentations and publications. You will have time to consider if you wish to take part in one of these interviews. You are not obliged to take part in the interview and you will have the opportunity to opt out at any stage. Any expenses incurred in taking part in these interviews will be reimbursed.

 **Confidentiality** All information that is collected about you during the research will be kept strictly confidential in accordance to the Data Protection Act of 1998 with respect to data collection, storage and destruction.If you consent to take part in this project, your medical records may be inspected by the researchers for purposes of analyzing the results. Your name, however, will not be disclosed anywhere. All information which is collected about you during the course of the research will be kept strictly confidential. For quality purposes MAHSC-CTU Monitors will at some point will look at the information collected during the course of the research Any information about you in our records will be given a separate ID number and we will have your name and address removed so that your data remains confidential. If you tell us information which suggests risk or serious danger to yourself or others we will inform the staff involved in your care. In case of any criminal activity revealed by you during the course of the trial the concerned services will be informed about it, in case it has not been done previously by the medical practitioner. Dissemination of results will not show your identification anywhere.

**What will happen to the results of the research study?** The findings of the study will be presented at appropriate academic and mental health conferences and events and will be published in mental health journal and other publications with the aim of reaching a wide audience of mental health professionals and service users.

**Who is organising and funding the research?** This study is funded by National Institute for Health Research, HTA programme and the study sponsor site is Lancashire Care NHS Foundation Trust.

**How do I withdraw if I wish to do so?** The research will be most valuable if few people do withdraw from it, so we would encourage you to discuss any concerns you have with the project team before agreeing to participate.

You can withdraw from the study at any time. If you wish to withdraw from the study, please contact a member of the study team to confirm your wishes regarding the use of the data collected to date, and regarding further contact.

**Who has reviewed the study?**  All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed by an independent reviewer for the NIHR. A favourable opinion from the research ethics committee does not guarantee that you will not come to any harm if you take part, but it means that the committee is satisfied that your rights have been respected, any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information on which to base a decision.

If you decide to participate in this study you will be given a copy of the information sheet and the signed consent form to keep.

**What do I do if I wish to make a complaint?** If you have a concern about any aspect of this trial, you should ask to speak to the researchers who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the trial, you can contact the trial manager….. **[add details]**

 *We would like to thank you for reading this information sheet.*

**For more information please contact the following researchers:**

**[LOCAL STUDY TEAM DETAILS]**