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ClinicalTrials.gov#: NCT04566861

IRB Approved Consent Documents: Initial Screening Consent

Title: Happy Mother-Healthy Baby: An Anxiety-focused Early Prenatal Intervention

Document Date: October 1, 2018

HAPPY MOTHER, HEALTHY BABY STUDY

Screening Consent for Participation in the Study Eligibility Screening

(This consent statement must be read (prior to Eligibility Screening) to those women who are pregnant and are interested in being screened for eligibility to participate in the trial)

Introduction: *As-salaam-u-alaikum.* My name is [XXXX], we are part of Rawalpindi Medical University and with the Obstetric Department at the Holy Family Hospital. Since 2004, we have been working in different parts of Pakistan to help improve maternal and child health. This research is funded by the National Institute of Health in the USA. In the past we have also partnered include the Lady Health Worker (LHW) Program, the Health Services Academy in Islamabad, and international organizations. We are doing research to learn if a new program that we developed for pregnant women, "Happy Mother, Health Baby" (HMHB), can reduce distress in pregnancy.

The purpose of the Happy Mother Healthy Baby Research Project: Many mothers feel stressed, nervous, or anxious during pregnancy. This can effect mother's health and can cause problems for her growing baby. The purpose of the research is to learn if our HMHB program can reduce this anxiety and improved their wellbeing.

Why are we requesting your participation in this screening?: We want to include about 1200 pregnant mothers like you from Rawalpindi who are over 18 years old and have some signs of being anxious. We will only include in our study pregnant women who have certain stress related problems. Therefore, to see if you can be in our study, we would like your permission to ask you some questions and collect information.

What data will we collect?: If you agree, I will ask your age and education, and about how you are feeling today. I would also look at your medical records, including your antenatal card, to see if you have had any health conditions that would make it not possible to take part.

Do I have to take part?: No, you do not have to take part in this screening, participation is voluntary. You have a right to withdraw at any time without giving any reason, without penalty or loss of benefits to which you are otherwise entitled. Refusing to take part will not result in any penalty or loss of benefits.

What are the possible benefits of taking part?: By participating in this screening, we will determine if you are eligible to take part in the HMHB study. The purpose of the HMHB study is to help mothers \ to lower their level of anxiety. The HMHB program will also help mothers notice feeling nervous and deal with it so that it is less likely to harm her or her infant.

What are the possible disadvantages and risks of taking part?: We will be asking you questions that may take about 5 to 15 minutes of your time, and answering may make you tired. Also, talking about your feelings can sometimes be difficult and might make you upset. If you feel stressed, you will be offered to speak to a counselor. You can refuse to answer any questions that you are not comfortable answering. You also have the right to stop the interview at any time if you feel unhappy.

Payment for participation: You will not receive any payment for participation in this screening.

Will my information be kept confidential?: All information that we collect from you will be kept confidential and safe. This includes the information you tell us and any information about you or your baby that we copy from your medical records. Although the information from the screening is confidential, if you are at risk of hurting yourself or your child, it is the legal and ethical responsibility of the research team to share that information with others. If we learn that you are very stressed or

unwell, we will ask your permission before letting a health care provider know so that you can get care. We will also make arrangements, with your consent, for you to be seen as early as possible.

Who approved this study?: The Ethical Review Board of Rawalpindi Medical University and the Ethical Review Board of Johns Hopkins University have approved this study. This research is funded by the National Institutes of Mental Health in the United States. This study is protected by a Certificate of Confidentiality that helps keep your information private when stored in the US.

Who I can contact in case of complaints?: To learn more about this screening, you can call the phone numbers provided at the end of this information sheet at any time Monday to Friday, from 9AM to 5 PM.

Gynaecology and Obstetrician Department
Phone number: xxxxxxx

What do I do to participate?

If you agree to take part in this screening, you will be asked to sign or put a thumb impression on the consent form.

Name of person taking consent: …….

Please initial all boxes

1.	I confirm that I have understood the information in the attached document. I have had the chance to carefully consider it and ask questions. I was provided with satisfactory replies for my questions.	
2.	I understand that my participation is entirely voluntary. I am free to withdraw at any time without giving any reason; my decision to withdraw from the screening will not impact any medical care that I receive or my legal rights.	
3.	I understand that the information collected will be kept confidential. I also give permission to the research team and other professionals associated with HMHB study to access my information, when needed.	
4	In case of serious concerns to my health, I agree to my health care provider being informed.	
5.	I agree to take part in the screening and be asked questions regarding my mood.	

Name of participant Date Signature

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If the participant is unable to provide a signature above:

Name of witness	Date	Signature
.....	.....	.....
Name of person taking consent	Date	Signature
.....	.....	.....

Cover Page:

ClinicalTrials.gov#: NCT03880032

IRB Approved Consent Document: Main Trial Participation Consent

Title: Happy Mother-Healthy Baby: An Anxiety-focused Early Prenatal Intervention

Document Date: April 20, 2022

HAPPY MOTHER, HEALTHY BABY STUDY

Main Consent to Participate in the Study

(This consent statement must be read (prior to Baseline Data Collection) to those women who screen eligible and are interested in participating in the study)

Introduction: *As-salaam-u-alaikum.* Thank you for your interest in our new program, "Happy Mother, Healthy Baby" (HMHB). We are conducting research to learn if HMHB can improve maternal well-being and child health at Holy Family Hospital. Before you decide to take part in this research, you need to know the purpose of this program and what it will involve.

The purpose of the Happy Mother Healthy Baby Research Project: Many mothers feel stressed, nervous, or anxious during pregnancy. The purpose of this research is to learn if our HMHB program can reduce this anxiety and improve their wellbeing. This could help the health of both the mother and her baby. If you participate, we will ask your permission to also collect information about your baby's health.

Why are we requesting your participation in this program?: We want to include about 1200 pregnant mothers like you from Rawalpindi who are over 18 years old and have some signs of being anxious. Mothers who agree to take part will be divided into two groups.

- If you are put in the Routine Care group, hospital staff will help you with issues related to your health or your baby's health, when you come for up to 8 antenatal care visits. They are trained to help you with any mental health concerns you might have, such as feeling anxious. You will also be reimbursed for your transportation to come to these antenatal visits and for the costs of ultrasounds indicated by your providers at Holy Family Hospital.

- If you are in the HMHB group, you will receive this same help from hospital staff, and also participate in the HMHB intervention. Our intervention includes six main sessions plus up to six additional sessions, if needed, that will focus on managing stress while you are pregnant. The number of the six additional sessions will depend on your stage of pregnancy when you enroll. Each session will be done here with our project staff, will last about 45 minutes, and will focus on specific goals for improving your health and your child's health. Your family will be invited to participate in three sessions to facilitate your getting their support. As in the Routine Care group, you will also be reimbursed for your transportation to come to these antenatal visits and for the costs of ultrasounds indicated by your providers at Holy Family Hospital.

Can I choose which group I want to be in?: No. We will use a computer program to put you in one of the groups, with an equal chance of being in either of the two groups, like tossing a coin. The researchers, who ask you questions and analyze the information, will not know which group you are in. Only the hospital staff and research team members at the hospital will know. This will help make sure that the findings are not affected by this information.

What data will we collect? Participation in the study depends on your allowing us access to your chart to record information about the pregnancy, the growth of your baby, and about medical conditions and medications. In addition to data we collect during your participation in routine antenatal care visits (group 1) or the HMHB sessions (group 2), we will also collect some information at four different times. I will describe these now, referring to them as "Start of Study Visit", "Late Pregnancy Visit", "Delivery/Birth Visit", and "End of Study Visit". Questions at some of the visits will refer to sensitive topics. Specifically

- At the ***Start of Study Visit*** we will ask you about some demographic information (like your age, years of education), about your mood, stress you are feeling, your relationships with others, any

health problems you have experienced recently, medication you may be taking, and/or any care you might have sought. This visit will take about 1 hour.

- At the ***Late Pregnancy Visit*** we will ask you about any stress or nervousness you may be feeling in general or related to the pregnancy, the support you receive, the nature of your relationships, daily functioning, and use of medical services during your pregnancy. We will also access your chart and record information about pregnancy conditions, the growth of your baby (from ultrasound), and about medical conditions and medications. The interview done to collect this information will take about 1 hour and will be done during one of your already scheduled visits

- The ***Delivery/Birth Visit*** will be done as soon as possible after your delivery. We will only ask you a few questions about breastfeeding; these will take about 5 minutes. We will also access at your chart and record information about your labor and delivery, the care your received, and some information about your baby, like the weight and size.

- The ***End of Study Visit*** will be completed at your 6-week postpartum visit here at the hospital. At that time, we will do another interview, again asking you questions about stress, whether you feel anxious or down, the support you receive, the nature of your relationships, daily functioning, adverse events you may have experienced, breastfeeding of your infant, and use of medical services during your pregnancy. Other questions will include things like how confident you feel in taking care of your baby and of taking actions, and how close you feel to your baby. As with the other visits, we will also access your chart to record information about the pregnancy, the growth of your baby, and about medical conditions and medications. Finally, we will administer a scale to assess the development of your baby. If the results of the scale indicate that your baby is at risk of later developmental delays, we will re-contact you after completion of the study to give you this information and explain the test results. This visit will take up to two hours.

- Throughout the study we will access yours and your child's medical records when needed to get information about the health of you and your baby.

Do I have to take part?: No, you do not have to take part in this program, participation is voluntary. You have a right to withdraw at any time without giving any reason, without penalty or loss of benefits to which you are otherwise entitled. Refusing to take part will not result in any penalty or loss of benefits.

What are the possible benefits of taking part?: By participating in this program, mothers may be able to lower their level of anxiety. The program will also help mothers notice feeling nervous and deal with it so that it is less likely to harm her or her infant. The information you will provide taking part in the study will help us to improve maternal and child health services. Another benefit will be reimbursement for medically indicated ultrasounds during your prenatal care.

What are the possible disadvantages and risks of taking part?: We will be asking you questions at several points in time. This may take an hour of your time at each session and answering may make you tired. Also, talking about your feelings can sometimes be difficult and might make you upset. If you feel stressed, you will be offered to speak to a counselor. You can refuse to answer any questions that you are not comfortable answering. You also have the right to stop the interview at any time if you feel unhappy.

Payment for participation: You will not receive any payment. However, you will be reimbursed for transportation costs for the study visits and the costs of ultrasounds needed for your prenatal care, if you choose to take part. You will also receive a gift at the conclusion of the study in the form of gifts for the baby.

Will my information be kept confidential?: All information that we collect from you will be kept confidential and safe. This includes the information you tell us and any information about you or your baby that we copy from your medical records. Although the information from the surveys is confidential, if you are at risk of hurting yourself or your child– including infant neglect or abuse -- it is the legal and ethical responsibility of the research team to share that information with others. We will ask your permission before your information is shared with your health care providers.

Who approved this study?: The Ethical Review Board of Rawalpindi Medical University and the Ethical Review Board of Johns Hopkins University have approved this study. This research is funded by the National Institutes of Mental Health in the United States. This study is protected by a Certificate of Confidentiality that helps keep your information private when stored in the US.

Who I can contact in case of complaints?: To learn more about this study, you can call the phone numbers provided at the end of this information sheet at any time Monday to Friday, from 9AM to 5 PM.

Gynaecology and Obstetrician Department
Phone number: xxxxxxx

What do I do to participate?

If you agree to take part in this study, you will be asked to sign or put a thumb impression on the consent form. You must answer 'yes' and initial to all four questions in the boxes below in order to enroll in the study.

Name of person taking consent: …….

Please initial all boxes

1.	I confirm that I have understood the information in the attached document. I have had the chance to carefully consider it and ask questions. I was provided with satisfactory replies for my questions.	
2.	I understand that my participation is entirely voluntary. I am free to withdraw at any time without giving any reason; my decision to withdraw from the study will not impact any medical care that I receive or my legal rights.	
3.	I understand that the information collected will be kept confidential. I also give permission to the research team and other professionals associated with HMHB study to access my information and my baby's information from medical records, when needed.	
4.	I agree to take part in the study.	

Name of participant Date Signature

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If the participant is unable to provide a signature above.

Name of witness Date Signature

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Name of person taking consent Date Signature

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