

COVER PAGE

Title: Happy Homes, Healthy Families: A Relationship Strengthening Intervention for Pregnant Couples Affected by HIV in Zambia

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Study Title: Happy Homes, Healthy Families: A randomized trial to improve maternal and child health in Zambia

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about how to improve the health of Zambian families during and after pregnancy by helping couples communicate and live in harmony.

You are being asked to be in this research study because you are currently pregnant.

Up to 480 people (240 pregnant women and their male partners) will participate in the study.

What happens if I join this study?

If you join the study, you will be invited to attend two group educational events with your husband/male partner - one during pregnancy and one after the birth of the baby. During these events, there will be an education lesson on pregnancy and postpartum health topics, which will be delivered by a community health worker, followed by a "baby shower" event. During the first event, men and women will be together, but during the second event, men and women will meet in separate groups.

Half of the couples in this study will also be randomly assigned to have three additional meetings with a community health worker in their home (or another preferred location of your choosing) to talk about their family's health and their relationship with each other. If you are not assigned to this part of the study, you will be invited to have one condensed meeting as a couple with a community health worker in your home (or other preferred location) to receive educational material on your family's health and happiness at the end of the study.

The two group education sessions will take place on the weekend at a community venue and last three hours each. The individual couple sessions will last one hour 30 minutes each.

If you decide to participate, you will also be asked to complete a face-to-face questionnaire interview about your health, use of medical care, and relationship with your husband. We will interview you during pregnancy, 6 weeks postpartum, and 24 weeks postpartum. A trained interviewer will interview you one-on-one in a private location and record your responses into a tablet computer. We will also interview your husband/male partner in a private location and none of the information you share with us will be shared with him. We will not share the information he tells us with you.

We would also like permission to review your medical records.

If you are living with HIV, we would also ask you to have your blood drawn for viral load testing three times (once during pregnancy and twice postpartum) in order to see how well your body is responding to HIV treatment. Blood will be collected by trained, experienced health care providers with sterile equipment at the UTH laboratory.

How long will I be in the study?

If you decide to join this study, participation will last up to 15 months with some activities during pregnancy and up to 6 months after the birth.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include emotional discomfort, such as embarrassment or sadness when asked sensitive questions during the survey interview.

Blood draws may cause some physical discomfort but there is an extremely low risk of infection or any other physical consequence from the blood draws as these are routinely done for people living with HIV at the UTH laboratory.

Another possible risk could be social risk (e.g. risk to reputation) if information revealed during the course of the study were to be disclosed outside of the research team. We will do our best to make sure that the personal information gathered for this study is kept private by strict adherence to confidentiality but it cannot be guaranteed.

Who will see my research information?

The institutions involved in this study include:

- The University of Colorado, USA
- University of North Carolina, USA
- University Teaching Hospital

Researchers and officials at the institutions where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research will have access to the research data. All identifying data will be destroyed at the conclusion of the study. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Some things we cannot keep private. If you give us any information about child abuse we have to report that to legal authorities.

What are the possible benefits of the study?

By participating in this study, you will gain additional knowledge on how to have a healthy pregnancy and keep yourself and your infant healthy after birth. You will be able to ask any questions you have about health issues and we will provide relevant referrals and help you get care if needed. You may also learn new skills to help your marriage be more harmonious and happier. We hope that this will also make you happier and better able to

deal with stress in your life. The study may also lead to you and your husband/male partner being better able to promote your family's health.

Who is paying for this study?

This research is being paid for by the National Institute of Mental Health of the National Institutes of Health in the United States of America.

Will I be paid for being in the study?

You will be paid a small cash reimbursement (\$13) for each of the study activities that you participate in (group education events, couple education events, survey interviews, blood draws).

During each of the educational sessions (one during pregnancy and one postpartum) each couple will also be given a small baby gift and some refreshments.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not experience any problems with your medical treatment and you will still be able to receive the full spectrum of health services offered at the health facility.

Who do I call if I have questions?

You may ask me any questions you have now. If you have questions later, you may call xxx-xxx-xxx. If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UNZAREC Ethics Review Committee, by phone 0977807860; or email unzarec@unza.zm. You may also contact the University of Colorado Multiple Institutional Review Board (IRB) by email COMIRB@ucdenver.edu or phone 000-1-303-724-1055. These committees are concerned with the protection of volunteers in research projects.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature: _____

Date: _____

Print Name: _____

Consent form explained by: _____

Date: _____

Print Name: _____

Signature of witness _____

Date _____

Print Name: _____

Witness of Signature (check)

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Witness of consent process (check)

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