Study Title: Adaptation of the Friendship Bench Intervention for HIV-infected Perinatal Women in Lilongwe

NCT Number: NCT04143009

Document Dated: 24 November 2020

This consent form should be signed only between 24 Nov 20 and 24 Sept 21
Approved by NHSRC, Malawi on 24 Nov 20

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Screening Consent

Consent Form Version Date: version 4.0 dated September 09, 2020
IRB Study #: 19-1689
NHSRC #: 19/08/2379
Title of Study: UNCPM 21910 - Phase 2 - Adaptation of the Friendship Bench mental health intervention for HIV-infected perinatal women in Lilongwe.

Principal Investigator: Brian Pence, PhD
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Principal Investigator Email Address: bpence@unc.edu
Funding Source and/or Sponsor: National Institute of Mental Health (NIMH)

Study Contact Telephone Number: Steve Mphonda; 0999 272 759
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CONCISE SUMMARY

The purpose of this research study is to understand how to support women who experience feelings of anxiety or sadness during pregnancy or after birth. Participants will include 92 HIV positive pregnant women and their 92 babies across 5 sites. The study will last about 18 months.

This portion of the study is a screening process which involves completion of a 20-item questionnaire and answering a few additional questions to determine whether you might be eligible for the full study.

During this screening process, we will ask some questions about your feelings in the past four weeks. Some of these questions may make you feel uncomfortable or embarrassed. You may choose not to answer any questions if you are uncomfortable with answering them. There is no other risk or benefit to you of participating in this screening process.

What are some general things you should know about research studies?

You are being asked to screen for this research study. To join the study is voluntary and you may refuse to join the study.

The research study will be discussed with you in detail. It is important that you understand that this is a screening consent. We would like your permission to ask you some questions to qualify you for this study. Signing the screening consent does **NOT** enter you in the study or obligate you to do so. You will be given a copy of this screening consent form. You can ask the

researchers named above, or your study coordinator, any questions you have about the study at any time.

What is the purpose of this study?
The purpose of this research study is to understand how to support women who experience feelings of anxiety or sadness during pregnancy or after birth. We estimate that approximately 92 women and 92 babies of these women will enroll in this study.

How long will your part in screening last.
The screening will be done at this time and will be followed immediately by the review of the main study. The entire visit which includes enrollment can last up to 1 hour.

What will happen if you take part in screening?
You will be asked to complete a 20-item questionnaire and to answer a few additional follow up questions about feelings of anxiety or sadness in the past four weeks. Should you qualify for study enrollment based off this screening session, we will discuss the study in greater detail, including the requirements of participation and the potential risks and benefits of study enrollment, before you are asked if you would like to enroll.

Are there any reasons you should not be in this study?
Your participation in this study is voluntary. This means that you do not have to participate in this study unless you want to.

What are the possible benefits of this screening?
There are no benefits for participation.

What are the possible risks or discomforts involved with screening?
There is a small chance that some of the questions may make you feel uncomfortable. You don't have to answer those questions if you don't want to. In fact, you don't have to answer any question that you choose not to answer. And that is fine. We will just skip that question and go on to the next one.

How will your privacy be protected?
All the information I receive from you during this screening process, including your name and any other identifying information, will be strictly confidential and will be kept under lock and key. We will not identify you or use any information that would make it possible for anyone to identify you in any presentation or written reports about this study. There will be no way to identify individual participants.

What if you want to complete the screening and then choose not to be part of the study?
You may choose to complete this screening and then after reviewing the complete main consent, choose not to be in the study. Your decision not to participate in the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at UNC.

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Who is sponsoring this study?
This study is being paid for by the National Institute of Mental health. Portions of Dr. Brian Pence's and his research team's salaries are being paid by this funding.

What if you have questions about this screening?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, you can contact Steve Mphonda, the Study Coordinator, at +265 999 272 759, or Dr. Brian Pence, the Principal Investigator, at +1 919 966 7446.

What if you have questions about your rights as a research participant?
I am happy to answer those for you now, or All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research participant, or if you would like to obtain information or offer input, you may contact the Chairman, Dr. Matias Joshua at +265 999 39 79 13OR the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

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Participant's Agreement:
If you have read this informed consent, or have had it read and explained to you, and understand the information, and you voluntarily agree to participate in this research study, **please sign your name, make your mark or place your thumbprint** in the signature area at the bottom of this page.

PART A: LITERATE PARTICIPANT

Participant is literate: ☐

_____	_____	_____
Participant Name (print)	Participant Signature	Date
_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

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PART B : ILLITERATE PARTICIPANT

Participant is illiterate: ☐

The study staff must complete this section, ONLY if an impartial witness is available.

The **study staff must write participant's name and date of consent** below.

Mark or Thumbprint of participant if unable to sign

Participant Mark or Thumbprint

Participant Name (print) _____ Date _____

Participant Name and Date Written By.....on.....

Study Staff Conducting Consent Discussion (print) _____ Study Staff Signature _____ Date _____

Impartial Witness Name (print) _____ Impartial Witness Signature _____ Date _____