TITLE OF RESEARCH STUDY: Increasing early infant male circumcision uptake in Zambia: Like Father Like Son (NCT04119414)

INVESTIGATORS: Dr. Stephen M Weiss

PURPOSE: This research study is designed to develop the most effective ways to offer the Like Father Like Son + Spear & Shield program as a foundation for a clinical trial.

PROCEDURE: This study will recruit 300 pregnant couples (600 men and women) from 4 Community Health Centers in Lusaka, Zambia; 75 couples from each clinic. To participate in this study, your partner must enroll with you, and you will participate in the study from when you enroll until 6 months following delivery. If you agree to participate, you will be asked to attend four men or women's groups and two couple sessions that will all be audio recorded. The total time for each visit will not be more than 2 hours.

STUDY VISIT: If you agree to participate in the study, you will be asked to do the following at the clinic site where you enroll in a private room**:**

1) Questionnaires:
    a. You will each respond to a questionnaire at the time you enroll in the study and respond to a questionnaire 6 months following delivery. The first questionnaire will be conducted with headphones on a computer laptop in a private office. The second questionnaire will be conducted on the telephone.
2) Group sessions (4 men's or women's groups):
    a. Group sessions will be about adult and child voluntary medical male circumcision the acceptability of medical male circumcision, and the potential to undergo medical male circumcision at the clinic. The groups will meet once every week for about two hours for the first month of your participation in the study. The sessions will be about the risks and advantages of male circumcision and how to protect you and your partner from sexually transmitted infections, including HIV.
3) Couple sessions (2):
    a. The couple sessions will be prior to delivery and one week following delivery, and will be on early male infant circumcision, and circumcision for fathers and sons. Each session will include a brief paper and pencil questionnaire on your attitudes about circumcision. The session will be about the risks and advantages of infant male circumcision. If you wish, you may ask a family member who is part of the process of decision making about circumcision to attend the couple sessions.

TIME: We expect that you will be in this research study for nine visits for a maximum of 2 hours for each group session and one hour for the couple session and the first questionnaire; the telephone questionnaire is estimated to take 3-5 minutes.

RISKS: The questionnaires and groups include questions and discussions about your opinions about adult, child, and early male infant circumcision. There is a possibility you might feel anxiety,

embarrassment and fatigue while answering these questions. There is also a potential risk of negative consequences that could be suffered if confidentiality of information obtained in the study were breached.

A number of steps will be taken to protect the confidentiality of your data and identity. Our study staff have been trained in ethical conduct, confidentiality protection, and other topics related to your protection. To reduce any risk to the confidentiality of your participation in this project, all communication and correspondence will be kept strictly confidential. The assessments are confidential and will be conducted in a private office area inside each clinic. All information collected regarding your participation will be identified by code and all information with your name and contact details will be kept separately in a locked cabinet in the investigator's offices in Lusaka. Only your unique code will be listed on measures, data records, and computer files.

When you attend the group sessions, there is the potential risk of a group member divulging information that is shared during the group session. To protect your confidentiality, study staff leading the group will emphasize the importance of keeping information shared during the group within the group. All group members will be asked to pledge to maintain the confidentiality of the group information.

It is also possible that during your participation in the study we may become aware of problems that require intervention. You should be aware that there are certain ethical limits to confidentiality. Should you tell a study staff member that you are having suicidal thoughts, you will be immediately referred to a physician, psychologist or qualified mental health professional for evaluation, and actions may be taken to protect you. If you indicate that you have plans to in any way physically or sexually harm another person, we are required to take steps to intervene. If you indicate that you believe that you are at risk of being physically or sexually harmed, steps will be taken to protect you.

BENEFITS: You may not experience any direct benefit from participation in this study. However, you may experience some benefit from discussion of information and experiences that may be helpful; you may also benefit from discussing your experiences with a trained interviewer.

The major benefit resulting from your cooperation in this research is to help us find the most effective ways to offer early male infant circumcision in Zambia.

ALTERNATIVE TREATMENTS: You have the alternative not to participate in this study. If you do not choose to participate in this study you will still be able to receive standard medical treatment at the clinic and your decision will in no way affect the quality of your care or your employment.

COMPENSATION: You will be paid Zambia Kwacha K100 each for each visit (9) to compensate you for your time and effort.

COMPENSATION FOR INJURY: Although risks are unlikely, if injury should occur, treatment will in most cases be available. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not routinely available.

CONFIDENTIALITY: Your consent to participate in this study includes consent for the investigators and their assistants to review the results of the interviews and groups for the purposes of this study. Audio recordings will be kept confidential to the extent permitted by law, and response to the questions will be identified by code number only. The code will be kept in a locked file in the

office of the study investigators. Information that you provide will be destroyed in three years, when the study is complete. Your records and results will not be identified as pertaining to you in any report published in any scientific journal. The US Department of Health and Human Services (DHHS) and/or the US Food and Drug Administration (FDA) may request to review the study records.

Your records may also be reviewed for audit purposes by authorized University employees or other agents who will be bound by the same provisions of confidentiality. In an effort to protect your privacy and the privacy of other participants, you agree to keep confidential any and all information regarding other study participants you may meet at the Like Father Like Son Project (e.g., names, etc.). Violation of this agreement could result in being terminated from the study.

WITHDRAWAL FROM THE STUDY: Participation in this study is voluntary. If you choose not to participate, you will not be denied any benefit to which you would be otherwise entitled and your employment will not be affected. You are free to withdraw from the study at any time, and if you do so, you will not suffer any penalty. If you decide to leave the study, contact the investigator or the study contact so that you will have no further contact. The investigators also reserve the right to remove you from the study without your consent at such time that they feel that it is in the best interest for you medically or for administrative reasons. Information that has been collected during your participation in the study prior to your withdrawal will be retained by the investigator.

QUESTIONS: The staff of the research program will be available to discuss with you any questions you may have about the study. At the completion of the study a staff member will be available to discuss with you the results of the study. This research is being funded by the National Institutes of Health. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research. You will be provided with a copy of your signed consent form. If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to the Like Father Like Son study team or contact the study investigators.

Dr. Robert Zulu
phone: 260 966 825 230

This research has been reviewed and approved by an Institutional Review Board ("IRB"). If you have any questions about your rights as a research subject, you may contact the IRB Representative at the University of Miami at (305) 243-3195 or by email, acoltes@umiami.edu or the University of Zambia Biomedical Research Ethics Committee Representative at 260-1-256067 if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	IRB Approval Date