Participant Enrolment Informed Consent Form for Intervention Participants.

Study title: Understanding the role of food insecurity and depression in non-adherence to Option B+ among perinatal Kenyan women living with HIV: A syndemics approach ("Healthy Mothers").

NCT05219552

Investigator	Role	Institution	Contact
Dr. Elizabeth Bukusi	Site Principal Investigator	Kenya Medical Research Institute (CMR)/ RCTP	254-20-2712537
Dr. Emily Tuthill	Principal Investigator	University of California, San Francisco	000-1-207-841-1983 (USA)

Participant literacy: ☐ literate ☐ illiterate

Researchers' Statement: This is a study being conducted by researchers from the Kenya Medical Research Institute (KEMRI) and the University of California, San Francisco (UCSF).

The purpose of this consent form is to give you the information you will need to help you decide whether or not you want to participate in our study. You may ask any questions about the purpose of the research, what happens if you participate, the possible risks and benefits, your rights as a voluntary participant, and anything else about the research or this form that is not clear. When we have answered all of your questions, you can decide whether you want to be in the study. This process is called 'informed consent.'

You are being asked to participate in this study because you are enrolled in HIV care (living with HIV) and pregnant.

Why is this study being done?
The purpose of the study is to learn how food insecurity and depression impact women during pregnancy and postpartum and how this impacts HIV treatment and breastfeeding. We want to understand the relationship between food insecurity and depression and how it impacts being able to take HIV medications. When multiple challenges create barriers for individuals that negatively impact their health this may be referred to as a syndemic.
In this phase of our study, we will explore the impact of an intervention we developed to support pregnant and postpartum women to overcome challenges related to adherence to HIV treatment and the prevention of mother to child transmission of HIV guidelines.

Who pays for this study?
This study is being funded by the U.S. National Institutes of Health.

How many people are taking part in this study?
40 pregnant women living with HIV will be asked to participate in this phase of our study.

What will happen if I take part in this study?
Here is what will happen if you agree to take part in the study:

In the first phase of our study, we found some women needed more information and support about breastfeeding and infant feeding options. We also found that most women struggled with financial insecurity. Therefore, the two main components of our intervention are: 1. Personalized support for optimal infant feeding, and 2. Monthly unconditional cash transfers to meet basic needs.

- **Infant feeding support:** As a study participant, you will meet with a lactation specialist 6 times- once during your pregnancy and 5 times postpartum. Whenever possible these meetings will also be coordinated with your regularly scheduled clinic appointments. The lactation specialist will assess you and your baby and provide information about optimal infant feeding including exclusive breastfeeding and weaning practices. The lactation specialist may also recommend specific treatments she may perform during the session such as using a warm compress or a breast pump

to express milk. You are under no obligation to receive any treatment you do not wish to receive. You may continue to participate in our study and receive support from the lactation specialist even if you choose not to receive a recommended therapy. The lactation specialist will not prescribe you any medications, but in some cases (for example if she identifies a breast infection) she may recommend prescribing a medication to your healthcare provider. You will be able to share your experiences with the lactation specialist and also ask her questions or express any concerns you may have about breastfeeding and / weaning your baby. Each session will last between 30-90 minutes depending on your needs.

- **Unconditional cash transfer:** Starting at approximately 30 weeks pregnancy, you will receive a monthly cash transfer of approximately 10,000KES sent to your mobile phone via MPESA. You will receive this amount monthly for approximately 10-months. If you do not have your own mobile phone, a simple phone will be provided to you for use during this study. The purpose of the cash transfer is to support you and your family to meet your basic needs. However, the money will be given to you without any conditions. This means the money is yours to spend, save or share with others (for example your family members) as you see fit. You will not be expected to repay any of the money you are given, nor will you be under any obligation to continue to participate in our study after receiving one or more monthly payments.
- **Surveys:** You will be asked to complete a series of surveys with the assistance of a staff member from our study. Our staff member will assist you to complete the surveys at this clinic in a private room. We will ask you about your housing, education, food and financial situation, physical and mental health, breastfeeding experiences (milk supply), relationship with your partner, social support, and HIV care. We will ask you to complete this survey just after you enroll in the study as well as at 6-weeks and 6-months after you have your baby. 2-weeks, 4-weeks and 3-months after you have your baby, we will ask you to complete a short survey focused on questions about how you are feeding your baby. Whenever possible, we will coordinate these surveys with your regular clinic appointments.
- **Measurement of infant weight:** After delivery, your baby's weight will be measured and recorded by a member of our study team at the clinic when you complete the surveys at 2-weeks, 4-weeks, 6-weeks, 3-months and 6-months.
- **Collecting information from medical records:** In addition to talking to you and measuring your infant's weight, the research staff will collect some information from your medical records. We will note the medications you take, the period you have been on HIV care and your hemoglobin levels and viral load when available. Information we collect will only be available to members of research team and health care providers involved in your health care.
- **Exit interview:** At the end of the intervention period, we will invite you to participate a brief interview where we will ask you some questions about your experiences including what you thought was most helpful or least helpful and what you liked or did not like about the intervention.

How long will I be in the study?
Participation in the study will involve 7-8 study visits, with the first one being during your last trimester/pregnancy, then at 2-weeks, 4-weeks, 6-weeks, 3-months and 6-months postpartum. Each visit will last between 30-90 minutes.

Can I stop being in the study?
Yes. You can decide to stop participating in the study at any time. You can simply tell us if you wish to stop being in the study and at which point all participation will end, including receipt of lactation support and the cash transfer. Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, you are not eligible to participate, if you do not follow the study rules, or if the study is stopped.

What risks can I expect from being in the study?
Social Risks. One potential risk of study participation includes social risks (e.g., risks to reputation) if your personal information provided during the surveys or final interview were to be disclosed outside of the research team. We have procedures in place to ensure that your personal information revealed during the interview is kept private and not disclosed to anyone outside of our research team. There may also be social risks associated with receiving the unconditional cash transfers including pressure family or friends to share money or things you purchase with the money. No one outside of the research team, including those involved in your regular care, family or friends will be given any information about the cash transfers.

Risk of discomfort. Some of the questions in the surveys, interviews or posed by the lactation specialist may cover sensitive topics and may make you uncomfortable or upset. You are free to refuse to answer any questions you do not wish to answer or stop the surveys/ interview/ meeting at any time.

Potential loss of privacy or confidentiality. One potential risk of study involvement is loss of privacy. Your information will be handled with as much privacy as possible. In order to protect your name, we will use a unique identification number that is only linked to you. Information identifying you will be kept in a secure location. All identifying information will be omitted from any data distributed to others, or any publications to result from this study.

Are there benefits to taking part in this study?
We expect you to benefit from the unconditional cash transfer as well as personalized support from a lactation specialist. How and to what extent you may benefit is not yet known. This study will help researchers learn how and to what extent an intervention involving breastfeeding support and cash transfers would benefit pregnant and postpartum women living with HIV and improve infant and maternal health outcomes so we can develop and promote such programs on a larger scale to support mothers living with HIV in the future.

What other choices do I have if I do not take part in this study?
You are free to decide whether or not to participate in this study. There are absolutely no consequences for not participating and your care at the clinic will not be affected in anyway.

Will my personal information be kept private?
We will not attempt to collect information that is very personal. However, should you disclose personal details throughout the survey or interview, we will do our best to ensure that your personal information is kept private. Though, we cannot guarantee total privacy. Information identifying you will be kept in a secure location. If study information is published or presented at scientific meetings, your name and other personal information will not be used. Organizations that may look at and/or copy your research records for study purposes include: KEMRI, representatives from the University of California, and representatives from the NIH. Only our study team, including our financial administrator will have access to your name, phone number and information about the cash transfer. This information will also be kept private and secured and will be securely disposed of once the intervention is complete.

What are the costs of taking part in this study?
There will be no costs to you as a result of taking part in this study.

Will I be paid for taking part in this study?
In addition to receiving the monthly cash transfer, you will receive 800KES for your time and travel expenses to the clinic after participating in each research encounter you have with study staff.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose whether or not to take part in this study. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits including the usual healthcare services you receive at the clinic.

Who can answer my questions about the study?
You can talk to the researchers about any questions, concerns, or complaints you have about this study. Contact the study staff at 0724 428 216. You may also contact the secretary of the Ethics Review Committee, SERU at KEMRI P.O. Box 54840-00200, Nairobi. Phone contacts 020-272-2541 or 020-272-678, 073340003 or email seru@kemri.org or the Institutional Review Board at the University of California, San Francisco at 000-1-415-476-1814. Or you may write to: Committee on Human Research, Box 0962, University of California, San Francisco (UCSF), San Francisco, CA 94143. These committees are concerned with the protection of volunteers in research projects.

Consent: You have been given a copy of this consent form.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You can decide not to participate or to withdraw from the study at any point in time without penalty or loss of benefits to which you are entitled. If you decide not to take part in this study, there will be no penalty to you and you will not lose your regular medical care. **If you wish to participate in this study, you should sign below.**

Do you provide consent to have the interview recorded? Yes___ No ___ DATE _____

Name of Participant (printed)

Signature or Fingerprint* of Participant Date

Name of Study Staff Administering Consent (printed) Position/Title

Signature of Study Staff Administering Consent Date

*If the participant is unable to read and/or write, an impartial witness must be present during the consent discussion. After the written informed consent form is read and explained to the participant, and after he or she has orally consented to participate in this study, and has either signed the consent form or provided his or her fingerprint, the witness must sign and personally date the assent form. By signing the assent form, the witness attests that the information in the assent form and any other written information was accurately explained to, and apparently understood by, the participant, and that assent was freely given.

Name of Person Witnessing Consent (printed)

Signature of Person Witnessing Consent Date

Participant Enrolment Informed Consent Form for Study Participants.

Study title: Understanding the role of food insecurity and depression in non-adherence to Option B+ among perinatal Kenyan women living with HIV: A syndemics approach ("Healthy Mothers").

Investigator	Role	Institution	Contact
Dr. Elizabeth Bukusi	Site Principal Investigator	Kenya Medical Research Institute (CMR)/ RCTP	254-20-2712537
Dr. Emily Tuthill	Principal Investigator	University of California, San Francisco	000-1-207-841-1983 (USA)

Participant literacy: ☐ literate ☐ illiterate

Researchers' Statement: This is a study being conducted by researchers from the Kenya Medical Research Institute (KEMRI) and the University of California, San Francisco (UCSF).

The purpose of this consent form is to give you the information you will need to help you decide whether or not you want to participate in our study. You may ask any questions about the purpose of the research, what happens if you participate, the possible risks and benefits, your rights as a voluntary participant, and anything else about the research or this form that is not clear. When we have answered all of your questions, you can decide whether you want to be in the study. This process is called 'informed consent.'

You are being asked to participate in this study because you are enrolled in HIV care (living with HIV) and pregnant.

Why is this study being done?
The purpose of the study is to learn how food insecurity and depression impact women during pregnancy and postpartum and how this impacts HIV treatment and breastfeeding. We want to understand the relationship between food insecurity and depression and how it impacts being able to take HIV medications. When multiple challenges create barriers for individuals that negatively impact their health this may be referred to as a syndemic.
In this phase of our study, we will explore the experiences of pregnant and postpartum women engaged in HIV care and their adherence to the prevention of mother to child transmission of HIV guidelines

Who pays for this study?
This study is being funded by the U.S. National Institutes of Health.

How many people are taking part in this study?
40 pregnant women living with HIV will be asked to participate in this phase of our study.

What will happen if I take part in this study?
Here is what will happen if you agree to take part in the study:

- **Surveys:** You will be asked to complete a series of surveys with the assistance of a staff member from our study. Our staff member will assist you to complete the surveys at this clinic in a private room. We will ask you about your housing, education, food and financial situation, physical and mental health, breastfeeding experiences (milk supply), relationship with your partner, social support, and HIV care. We will ask you to complete this survey just after you enroll in the study as well as at 6-weeks 6-months after you have your baby. 2-weeks and 4-weeks and 3-months after you have your baby, we will ask you to complete a much shorter survey focused on questions about how you are feeding your baby. Whenever possible, we will coordinate these surveys with your regular clinic appointments.

- **Measurement of infant weight:** After delivery, your baby's weight will be measured and recorded by our Research Associate at the clinic when you complete the surveys at 2-weeks, 4-weeks, 6-weeks, 3-months and 6-months.
- **Collecting information from medical records:** In addition to talking to you and measuring your infant's weight, the research staff will collect some information from your medical records. We will note the medications you take, the period you have been on HIV care and your hemoglobin levels and viral load when available. Information we collect will only be available to members of research team and health care providers involved in your healthcare.

How long will I be in the study?
Participation in the study will involve 6 study visits, with the first one being during your last trimester/pregnancy, then at 2-weeks, 4-weeks, 6-weeks, 3-months and 6-months postpartum. Each visit will last between 30-90 minutes.

Can I stop being in the study?
Yes. You can decide to stop participating in the study at any time. You can simply tell us if you wish to stop being in the study. Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, you are not eligible to participate, if you do not follow the study rules, or if the study is stopped.

What risks can I expect from being in the study?
Social Risks. One potential risk of study participation includes social risks (e.g., risks to reputation) if your personal information provided during the surveys or final interview were to be disclosed outside of the research team. We have procedures in place to ensure that your personal information revealed during the interview is kept private and not disclosed to anyone outside of our research team.

Risk of discomfort. Some of the questions in the surveys, interviews may cover sensitive topics and may make you uncomfortable or upset. You are free to refuse to answer any questions you do not wish to answer or stop the survey at any time.

Potential loss of privacy or confidentiality. One potential risk of study involvement is loss of privacy. Your information will be handled with as much privacy as possible. In order to protect your name, we will use a unique identification number that is only linked to you. Information identifying you will be kept in a secure location. All identifying information will be omitted from any data distributed to others, or any publications to result from this study.

Are there benefits to taking part in this study?
There will be no direct benefit to you from participating in this study. This study will help researchers learn about the current experiences of pregnant and postpartum women living with HIV so we can develop and promote programs aimed to support mothers living with HIV in the future.

What other choices do I have if I do not take part in this study?
You are free to decide whether or not to participate in this study. There are absolutely no consequences for not participating and your care at the clinic will not be affected in anyway.

Will my personal information be kept private?
We will not attempt to collect information that is very personal. However, should you disclose personal details throughout the survey or interview, we will do our best to ensure that your personal information is kept private. Though, we cannot guarantee total privacy. Information identifying you will be kept in a secure location. If study information is published or presented at scientific meetings, your name and other personal information will not be used. Organizations that may look at and/or copy your research records for study purposes include: KEMRI, representatives from the University of California, and representatives from the NIH.

What are the costs of taking part in this study?
There will be no costs to you as a result of taking part in this study.

Will I be paid for taking part in this study?
In addition to receiving the monthly cash transfer, you will receive 800KES for your time and travel expenses to the clinic after participating in each research encounter you have with study staff.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose whether to take part in this study. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits including the usual healthcare services you receive at the clinic.

Who can answer my questions about the study?
You can talk to the researchers about any questions, concerns, or complaints you have about this study. Contact the study staff at 0724 428 216. You may also contact the secretary of the Ethics Review Committee, SERU at KEMRI P.O. Box 54840-00200, Nairobi. Phone contacts 020-272-2541 or 020-272-678, 073340003 or email seru@kemri.org or the Institutional Review Board at the University of California, San Francisco at 000-1-415-476-1814. Or you may write to: Committee on Human Research, Box 0962, University of California, San Francisco (UCSF), San Francisco, CA 94143. These committees are concerned with the protection of volunteers in research projects.

Consent: You have been given a copy of this consent form.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You can decide not to participate or to withdraw from the study at any point in time without penalty or loss of benefits to which you are entitled. If you decide not to take part in this study, there will be no penalty to you and you will not lose your regular medical care. **If you wish to participate in this study, you should sign below.**

Do you provide consent to have the interview recorded? Yes___ No ___ DATE _____

Name of Participant (printed)

Signature or Fingerprint* of Participant Date

Name of Study Staff Administering Consent (printed) Position/Title

Signature of Study Staff Administering Consent Date

*If the participant is unable to read and/or write, an impartial witness must be present during the consent discussion. After the written informed consent form is read and explained to the participant, and after he or she has orally consented to participate in this study, and has either signed the consent form or provided his or her fingerprint, the witness must sign and personally date the assent form. By signing the assent form, the witness attests that the information in the assent form and any other written information was accurately explained to, and apparently understood by, the participant, and that assent was freely given.

Name of Person Witnessing Consent (printed)

Signature of Person Witnessing Consent Date