Informed Consent Forms

Adherence to HIV Treatment Postpartum: The Implications of Transitions Among Women Living with HIV in South Africa

ClinicalTrials.gov #: NCT04846569

Version 5.0

May 12, 2021

IRB Federalwide Assurance Numbers:

- FWA00004460 (Brown University)
- FWA00001637 (University of Cape Town)

Study Sponsor: National Institute of Mental Health (K01MH112443)

STUDY TITLE: Adherence to HIV Treatment Postpartum: The Implications of Transitions Among Women Living with HIV in South Africa

Consent Form for Participation in <u>Randomized Controlled Trial</u>

Version 5: 12 May 2021

Study Implementers: University of Cape Town School of Public Health and Family Medicine (South Africa) & Brown University School of Public Health (USA)
Study Sponsors: USA National Institute of Mental Health
Principal Investigator: Dr. Jennifer Pellowski
UCT Principal Investigator: Prof. Landon Myer

Introduction
You are invited to take part in a research study conducted with the University of Cape Town and Brown University School of Public Health (USA). This is a voluntary research study, which means that you do not have to take part if you do not wish to. This document is to help you decide if you would like to participate. This is a research study about pregnancy and motherhood, HIV medications and healthcare. The purpose of this study is to understand if a type of support for pregnant and postpartum women living with HIV can help women to take their medications and attend their clinic visits.

Research studies only include people who chose to take part. Please take your time to make a decision about taking part. If you have any questions, you may ask me now or at any point while we read over the consent form together. You are being asked to take part in this study because you are a pregnant woman, over the age of 18, are living with HIV, and on antiretroviral therapy (ART) to treat your HIV.

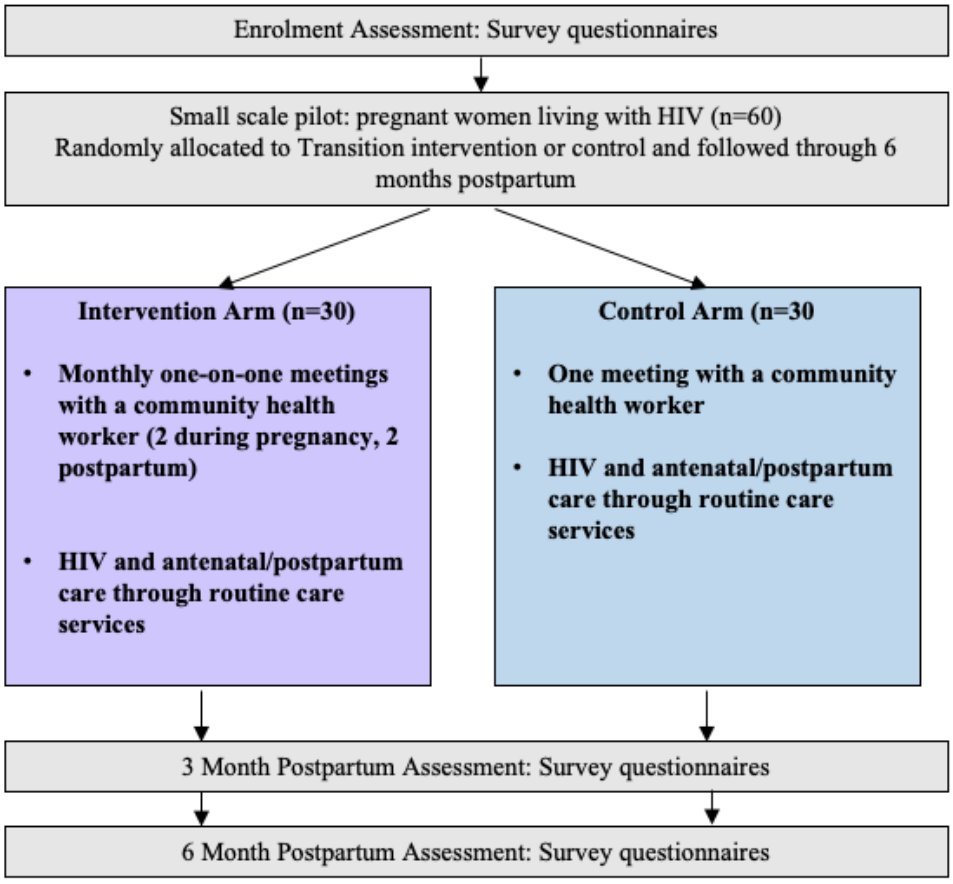
Why is this study being done?
We know that many women living with HIV experience challenges during pregnancy and postpartum. These include challenges with adjusting to life with their baby, partner and family challenges, or mental health issues. These challenges may make it difficult for women to take their HIV medications or attend their scheduled HIV clinic visits. We would like to understand if providing support for women helps women to take their medications and attend their clinic visits. The type of support that we are interested in is one-on-one meetings with a community health worker. This study is being funded by the National Institute of Mental Health in the United States. The information from this study will be useful to the researchers, who are thinking about conducting more studies on how to meet the healthcare needs of pregnant and postpartum women living with HIV.

How many people will take part in this study?
We plan to ask about 60 pregnant women living with HIV to take part in this study.

What will happen if I take part in this research study?
If you agree to take part, you will be randomised (like the flip of a coin) to one of two different options:

1. Transitions group: women assigned to this group will complete monthly one-on-one sessions with a community health worker for 4 months. If you are randomized to the Transitions group you will receive reimbursement for travel expenses for each one-on-one session (R20 for each visit).
2. Enhanced standard of care group: women assigned to this group will complete one session with a community health worker. If you are randomized to the enhanced standard of care group you will receive reimbursement for travel expenses for the one session with the community health worker.

"Randomised" means that you have a 50% chance of being in the group that will be invited to the Transitions group. You will also have a 50% chance of being in the group that receives one session with a community health worker. Neither the study staff nor you can choose which group you will be assigned to. The decisions are made by a computer and put into an envelope. The study staff do not know which group is in each envelope. After you are randomised, the staff member will provide you with more information about the group you are in.



If you agree to take part in this study, you will be asked to complete several activities.

First (today) your appointment will be about 1 hour:

1. You will be asked to provide contact information so that we may get in touch with you during the study. Study staff will talk with you about the best way to contact you.

If you miss one of your scheduled study visits, a staff member will contact you to find another day and time to complete your visit. If you repeatedly miss study visits or the study staff are unable to contact you using the information that you provide, it may be necessary to visit you at home to reschedule the missed study visit

2. You will be scheduled for your enrolment study measurement visit. This may be completed in person or over the phone. You will be asked to answer questions about your health, challenges that you might be having, taking your HIV medications, and attending scheduled clinic visits. These survey questions are in-depth and personal in nature. This visit will take between 1-2 hours.

Second, after you complete your enrolment study measurement visit, a community health worker will conduct a one-on-one session with you. If you have been randomised to the Transitions group, the community health worker will tell you about the rest of the counseling sessions that you will receive. You will receive reimbursement for travel expenses for each one-on-one session (R20 for each visit). All counseling sessions will be audio recorded.

Third, we will schedule your 2 study measurement visits, one at 3 months postpartum and one at 6 months postpartum. This may be completed in person or over the phone. Each visit will take between 1-2 hours. During each visit we will ask you about your health and your baby's health, challenges that you might be facing, and taking your HIV medication. These questions are in-depth and personal in nature.

Fourth, as part of this study, we will also be looking at and taking information from your routine medical records, and the records of your baby. This will include information about your use of health services as well as ART clinic, laboratory and pharmacy records. We would like your permission to access electronic databases that include all of these records. The Department of Health stores all of this information centrally at the Provincial Health Data Centre. We will use your and your baby's provincial folder number (or name and date of birth) to ask for this information directly from the Department of Health. This health record data will be linked to the other information you provide at study visits, however, your name and your baby's name will not be recorded with these records. All data that we review will be kept confidential.

Fifth, you will also be asked to provide a dried blood spot (DBS) sample at the 6 months postpartum visit. This involves a prick on the tip of your finger with a sterile lancet, and the drops of blood are used to fill a maximum of five spots on a filter paper. The DBS sample will be stored and used to check on your HIV viral load at a later time. Results from these tests are purely for research and will not be available to you, the clinic, or the study staff. If the health care providers at the clinic need to check your blood, they will take a separate blood sample. When it is stored, your blood and test results will not have your name or any other way of identifying you attached to it.

Please initial below to indicate whether or not you give permission for us to take DBS sample from you. You may still remain in the study, even if you choose not to give a sample.

_____ (initial) I <u>agree</u> to have DBS sample as part of this research.

_____ (initial) I <u>do **NOT** agree</u> to have a DBS sample as part of this research.

How long will I be in the study?
This study will last approximately 8 months, or until you are 6 months postpartum.

Can I stop being in the study?
Yes. You can decide to stop at any time. Just tell the study researcher right away 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 she thinks that this is best for you, or if the study is stopped for some reason.

What are the risks of the study?
You will be asked to answer questions about sensitive topics, including your experiences with motherhood, your health and your medications.

- ✓ Completing the surveys can be long and you may get tired and you may need to take breaks.
- ✓ Some of these questions may make you uncomfortable or cause you to become upset. You do not have to answer any question that you do not want to and you can stop participating at any time. If you become distressed, we will have someone for you to talk with.
- ✓ By coming to the Project office it is possible others could find out that you are living with HIV/AIDS.
- ✓ Having to come to the Project office to complete the surveys may be inconvenient and may require you to get transportation and other forms of assistance, such as childcare, to participate.
- ✓ The total time to complete the study will be 14-18 hours across 8 months.

Are there benefits to taking part in the study?
There may be no direct benefits to you. It is hoped that the information that you provide in this study will give us better knowledge ways to make it easier for other women living with HIV to take their HIV medications and attend their HIV visits.

What other choices do I have if I do not participate in this study?
You are free to choose not to participate in the study. If you decide not to take part in this study, it will in no way impact the care that you receive here at the clinic and no one will be cross with you for deciding not to participate.

Will information about me be kept private?
Only the researchers will have access to the information you provide.

We cannot protect your confidentiality if…

- ✓ we discover that you plan to cause serious harm to yourself or others
- ✓ you tell us that you have a plan to have high-risk sex with a named person who does not know you are HIV positive. We may be legally required to protect that person.

Your name will not be put on any of your surveys. You will be given a secret code number. The list linking your secret code to any of your information will be kept separate. The list will be destroyed within 6- months of completion of the study. Any surveys completed will be kept on a computer that is protected by password and only the researchers directly involved in

this study will be able to see this. Voice recordings that collected during this project during the counseling sessions will be uploaded to a computer and protected in the same way as the surveys.

Your name will not appear in any publication. Your name will not be given to anyone else without your written consent.

Your contact details will be kept separate from all other information provided by you. If a Project staff member calls a number that you have provided, a message will only be left on an answering machine or with the person who answers if you have given permission for messages to be left at that number.

You should also know that the University of Cape Town and/or Brown Institutional Review Board (IRB) and the Office of Research Compliance may inspect study records as part of its auditing program, but these reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What are the costs of taking part in this study?

Apart from travel and your time costs, which we will reimburse you for, it will not cost you to participate in this study.

Will I be paid for taking part in this study?

For your time commitment, you will be compensated for each time you complete a study activity. Including today, there are three study visits to attend if you take part in the study. At the end of each study visit, you will be given R20 in cash for transport costs, and an R80 grocery voucher. Refreshments will be provided at all study visits. You will also receive a small gift for your baby, up to the value of R100, at the final study visit.

What are my rights if I take part in this study?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you can drop out at any time. There are no penalties or consequences if you decide that you do not want to participate.

You will be notified of all significant new findings during the course of the study that may impact your willingness to continue.

What happens if I get hurt taking part in this study?

There are no experimental medicines being used in this study and risk of injury due to study participation is very low. However, this research study is covered by an insurance policy taken out by the University of Cape Town if you suffer a bodily injury because you are taking part in the study.

The insurer will pay for all reasonable medical costs required to treat your bodily injury, according to the SA Good Clinical Practice Guidelines 2006. The insurer will pay without you

having to prove that the research was responsible for your bodily injury. You may ask the study doctor for a copy of these guidelines.

The insurer will *not* pay for harm if, during the study, you:

- Do not follow the study nurses' instructions
- Do not take reasonable care of yourself

If you are harmed and the insurer pays for the necessary medical costs, usually you will be asked to accept that insurance payment as full settlement of the claim for medical costs. However, accepting this offer of insurance cover does not mean you give up your right to make a separate claim for other losses based on negligence, in a South African court.

It is important to follow the study nurses' instructions and to report straightaway if you suspect study related bodily harm.

Who can answer my questions about the study? Who do I contact?
Take as long as you would like before you decide. We will answer any questions that you have now about this study, including if anything was unclear or if you need further information.
If you have questions later, you may call the Principal Investigator, Dr. Jennifer Pellowski (Telephone: +1 860 908 2406, Email: Jennifer_pellowski@brown.edu) or the local investigator Prof. Landon Myer (Telephone: 021 406 6661, Email: landon.myer@uct.ac.za). If you fall ill, suffer side effects, or if you are injured during study activities, please immediately contact Dr. Jennifer Pellowski or Prof. Landon Myer. The ongoing ethical conduct of the study remains the responsibility of the principal investigators.

If you have any complaints about participation in this study, or would like more information about the rules for research studies, or the rights and welfare of people who take part in this study, you may contact the University of Cape Town's Faculty of Health Sciences Human Research Ethics Committee (Telephone: 021 406 6338) or Brown University Research Protections Office (Telephone: +1 401-863-3050 or toll-free at: +1 866-309-2095).

Documentation of Consent
If you accept to participate, please read the statements below and circle the appropriate responses below. If you need assistance, we will help you. Then, write your name, sign and date this form. You will receive a copy of this document for your future reference and so that you will have the contact information in case you have any questions or concerns.

I have read and understand this consent form.	YES	NO
All my questions have been answered to my satisfaction.	YES	NO
I agree to take part in the study.	YES	NO
I give permission to be contacted for follow-up for this study.	YES	NO
I can be contacted for future follow-up studies. (OPTIONAL)	YES	NO

Name and Surname of Participant

Today's Date (day/month/year)

Signature

For the researcher to complete:

I have discussed the proposed research with this participant and provided ample time for questions and answered all questions. In my opinion, this participant understands the risks, benefits and alternatives (including non-participation) and is capable of freely consenting to participate in this research.

Name and Surname of Person Obtaining Consent

Signature of Person Obtaining Consent

Today's Date (day/month/year)

STUDY TITLE: Adherence to HIV Treatment Postpartum: The Implications of Transitions Among Women Living with HIV in South Africa

Consent Form for Participation in <u>In-Depth Interview</u>

Version 5: 12 May 2021

Study Implementers: University of Cape Town School of Public Health and Family Medicine (South Africa) & Brown University School of Public Health (USA)
Study Sponsors: USA National Institute of Mental Health
Principal Investigator: Dr. Jennifer Pellowski
UCT Principal Investigator: Prof. Landon Myer

Introduction
You are invited to take part in a research study conducted with the University of Cape Town and Brown University School of Public Health (USA). This is a voluntary research study, which means that you do not have to take part if you do not wish to. This document is to help you decide if you would like to participate. This is a research study about pregnancy and motherhood, HIV medications and healthcare. The purpose of this study is to understand what you thought of the Transitions intervention and what are some ways that we can improve it.

Research studies only include people who chose to take part. Please take your time to make a decision about taking part. If you have any questions, you may ask me now or at any point while we read over the consent form together. You are being asked to take part in this study because you were randomized to receive the Transitions intervention.

Why is this study being done?
We know that many women living with HIV experience challenges during pregnancy and postpartum. These include challenges with adjusting to life with their baby, partner and family challenges, or mental health issues. These challenges may make it difficult for women to take their HIV medications or attend their scheduled HIV clinic visits. We would like to understand what you thought of providing support for women and your suggestions for how to improve this study. This study is being funded by the National Institute of Mental Health in the United States. The information gathered from this study will be useful to the researchers, who are thinking about conducting more studies on how to meet the healthcare needs of pregnant and postpartum women living with HIV.

How many people will take part in this study?
We plan to ask about 30 pregnant women living with HIV to take part in this study.

What will happen if I take part in this research study?
If you agree to take part in this study, we will conduct an in-depth interview with you that will last 45 minutes to 1 hour. We will ask you questions about your experiences within the

Transitions intervention, what you liked, what you would have changed, and any other suggestions you have for us.

How long will I be in the study?
Your participation in this study will only be today.

Can I stop being in the study?
Yes. You can decide to stop at any time. Just tell the study researcher right away 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 she thinks that this is best for you, or if the study is stopped for some reason.

What are the risks of the study?
You will be asked to complete surveys and discussions that include sensitive topics about your experiences with motherhood, your health and your medications.

- ✓ Completing the interview can be long and you may get tired and you may need to take breaks.
- ✓ Some of these questions may make you uncomfortable or cause you to become upset. You do not have to answer any question that you do not want to and you can stop participating at any time. If you become distressed, we will have someone for you to talk with.
- ✓ By coming to the Project office it is possible others could find out that you are living with HIV/AIDS.
- ✓ Having to come to the Project office to complete the surveys may be inconvenient and may require you to get transportation and other forms of assistance, such as childcare, to participate.
- ✓ The total time to complete the study will be 45 minutes to 1 hour.

Are there benefits to taking part in the study?
There may be no direct benefits to you. It is hoped that the information that you provide in this study will give us better knowledge ways to make it easier for other women living with HIV to take their HIV medications and attend their HIV visits.

What other choices do I have if I do not participate in this study?
You are free to choose not to participate in the study. If you decide not to take part in this study, it will in no way impact the care that you receive here at the clinic and no one will be cross with you for deciding not to participate.

Will information about me be kept private?
Only the researchers will have access to the information you provide.

We cannot protect your confidentiality if…

- ✓ we discover that you plan to cause serious harm to yourself or others
- ✓ you tell us that you have a plan to have high-risk sex with a named person who does not know you are HIV positive. We may be legally required to protect that person.

Your name will not be put on any of your surveys. You will be given a secret code number. The list linking your secret code to any of your information will be kept separate. The list will be destroyed within 6- months of completion of the study. Any surveys completed will be kept on a computer that is protected by password and only the researchers directly involved in this study will be able to see this. Voice recordings that collected during this interview will be uploaded to a computer and protected in the same way as the surveys. When the interviews are transcribed to written form all names you mention will be de-identified.

Your name will not appear in any publication. Your name will not be given to anyone else without your written consent. Your contact details will be kept separate from all other information provided by you. If a Project staff member calls a number that you have provided, a message will only be left on an answering machine or with the person who answers if you have given permission for messages to be left at that number.

You should also know that the University of Cape Town and/or Brown Institutional Review Board (IRB) and the Office of Research Compliance may inspect study records as part of its auditing program, but these reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants

What are the costs of taking part in this study?
Apart from travel and your time costs, which we will reimburse you for, it will not cost you to participate in this study.

Will I be paid for taking part in this study?
For your time commitment to our project, you will be compensated for your time. At the end of this session, you will be given R20 in cash for transport costs, and an R80 grocery voucher. Refreshments will be provided at all study visits.

What are my rights if I take part in this study?
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Who can answer my questions about the study? Who do I contact?
Take as long as you would like before you decide. We will answer any questions that you have now about this study, including if anything was unclear or if you need further information.
If you have questions later, you may call the Principal Investigator, Dr. Jennifer Pellowski (Telephone: +1 860 908 2406, Email: Jennifer_pellowski@brown.edu) or the local investigator Prof. Landon Myer (Telephone: 021 406 6661, Email: landon.myer@uct.ac.za). If you fall ill, suffer side effects, or if you are injured during study activities, please immediately contact Dr. Jennifer Pellowski or Prof. Landon Myer. The ongoing ethical conduct of the study remains the responsibility of the principal investigators.

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Documentation of Consent

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I have read and understand this consent form.	YES	NO
All my questions have been answered to my satisfaction.	YES	NO
I agree to take part in the study.	YES	NO
I give permission to be contacted for follow-up for this study.	YES	NO
I can be contacted for future follow-up studies. (OPTIONAL)	YES	NO

____________________________________ ______________

Name and Surname of Participant — Today's Date (day/month/year)

____

Signature

- -

For the researcher to complete:

I have discussed the proposed research with this participant and provided ample time for questions and answered all questions. In my opinion, this participant understands the risks, benefits and alternatives (including non-participation) and is capable of freely consenting to participate in this research.

____

Name and Surname of Person Obtaining Consent

______________________________ ________________________

Signature of Person Obtaining Consent — Today's Date (day/month/year)