Informed Consent Form *(Adolescent/Young Adult Consent)*

Piloting a Smartphone App to Improve Treatment Adherence Among South African Adolescents Living With HIV

ClinicalTrials.gov ID NCT04661878
Sponsor Duke University

Document Version Date: 12 October 2022
(IRB Reference Date 21 November 2022)

ADOLESCENT/YOUNG ADULT Consent Form
(for those above Age 18)
for *MASI* Pilot RCT

Version 1.1 – 12 October 2022

Study Title: Developing a Smartphone App to Improve Treatment Adherence among South African Adolescents Living with HIV

Study Implementers: University of Cape Town (South Africa), Duke University School of Nursing (USA), University of North Carolina (USA), and Florida State University (FSU)
Study Sponsors: U.S. National Institute of Mental Health
Principal Investigators: Prof. Jacqueline Hoare & Dr. Marta Mulawa
Co-Investigators: Dr. Lisa Hightow-Weidman & Dr. Kathryn Muessig
ClinicalTrials.gov Identifier: NCT04661878

Introduction
We would like to ask for your permission to take part in a study. This form will tell you why we want to do this study. The goal of this study is to test a smartphone app called *MASI* to support adolescents and young adults living with HIV who are on HIV treatment. *MASI* stands for the isiXhosa phrase "**MA**sakhane **S**iphucule **I**mpilo Yethu".

Before you decide about taking part, you should know about the possible risks and benefits. This process is called informed consent. This informed consent form will give you an idea of what will take place during the study. Please ask us questions about anything that you do not understand or if you would like more information. We are happy to explain this to you more than once. Please take as much time as you need to talk about the study with your doctor or nurse, the study staff, or your family and friends.

Why is this study being done?
People living with HIV can take medication to treat HIV. Young people living with HIV may face difficulties in taking medication as prescribed by their doctor. *MASI* was made to help young people living with HIV get support and information about relationships, health, and wellness, including taking medication to treat HIV. There are different features of *MASI* that we would like to test out. Some versions of *MASI* include an anonymous social network where participants have usernames and avatars, but no identifying and/or personal information is needed. Other features help users to learn new information. The purpose of this research is to see if young people will use and like *MASI*. It will also help us learn if *MASI* has an effect on how young people take medication to treat HIV.

Your participation is voluntary.
Your decision to provide consent is voluntary, meaning it is your choice. If you provide consent, your decision to participate in each activity is voluntary. You can stop participating at any time with no penalty. You can refuse to answer any question. This does not affect care or benefits you receive from clinics or social services.

How many people will take part in the study?
If you decide to take part in this study, you will be one of about 50 participants in this study. Participants will be young people between the ages of 15-21 years who are living with HIV, live in Cape Town, and have been prescribed medication to treat HIV.

Are there any reasons you should not be in the study?
You should not be in this study if:

- You are younger than 15 years old or are older than 21 years old
- You are not living with HIV
- You have not been prescribed medication to treat HIV
- You attend a school for learners with special needs (e.g., School of Skills)
- You have repeated a grade/s in school more than once
- You do not feel comfortable using an app with content in English
- You plan to move outside of Cape Town in the next six months
- You do not have a smartphone that can download apps
- You are not able to successfully install the *MASI* app on your smartphone
- You have previously participated in the *MASI* app testing phase of our study

How long will your part in this study last?
If you agree to be in this study, your participation will be about 6 months.

What will happen if you take part in the study?
It is not clear if young people will use *MASI* or if the different features of *MASI* will improve the way they take their medication to treat HIV. For this reason, you will be assigned to receive one of two versions of *MASI* using a method called randomization. Randomization means that the group you are in is assigned by chance, like when you toss a coin. You have an equal chance of receiving either version of *MASI*.

If you choose to participate, you will do the following:

a. First, we will download and install *MASI* to your phone. This will allow us to make sure your phone is able to install *MASI*. If your phone is unable to download or install *MASI*, you will be reimbursed for your participation today. However, you will not be able to participate in the rest of the activities or future study visits.

b. You will be asked to complete a survey by answering questions that our research assistant will ask you in a private space. The survey will take about one hour. You'll be asked questions about your background, HIV-related knowledge, social support, loneliness, resilience, anxiety, depression, stigma, disclosure concerns, disclosure intentions, treatment adherence, and sexual activity.

c. After you have completed the survey, you will find out which version of the *MASI* app you will use. We will decide this randomly, like when you toss a coin. You cannot choose which version you will get. After you register and create a private username and password, we will teach you how to use the app.

d. Once your visit is complete, you will be asked to spend at least 5 minutes a day on the app for 6 months. We will be able to monitor where you go within the app, what features/articles you use, and the length of time you spend on the app. You may get push notifications, in-app notifications, or text messages about new content and features in the app. You may turn off push notifications and text messaging in the study app. Any contact you receive from us will not include sensitive or private information. You will be given 1GB of smartphone data each month to support your use of the app during this period.

e. After about three months, you will be asked to complete another survey. The survey will take about one hour. We may ask you to come in person to do the survey, or we may call you to do the survey over the phone. That survey will ask similar questions to the initial survey and will also ask about their experiences using *MASI* and being in the study.

f. About six months from today, you will be asked to do a third and final survey. This survey will take about one hour to complete. We may ask you to come in person to do the survey, or we may call you to do the survey over the phone. That survey will ask similar questions to the 3-month survey.

g. Your survey responses from the three surveys will be entered into a secure database on a password-protected computer and stored on a secure server.

h. At either the three-month or six-month visit, you may be invited to do an additional one-on-one interview.

   - If you choose to do this one-on-one interview, you will be asked about your experiences with *MASI* and about your experiences with HIV treatment and living with HIV. This interview will be recorded, and we will use the voice recording to write down our conversation.

i. All study-related documents, including the recordings for those invited to the one-on-one interview, will be kept private. Documents will be kept in a locked project office and in password protected files on password protected computers and secure servers. Any documents containing your name and personal information will be kept separate from other study records, and will be stored securely. These files will be seen only by study staff and will be kept for 5 years following the close of the study.

Will you receive anything for being in the study?
You will be given R250 at each visit for time and travel. We will also give you refreshments, including a snack and a drink. There are no other costs for you to be in the study. If you do a survey over the phone, we will give you the R250 reimbursement via a Shoprite money transfer voucher. We will send you a voucher number and pin via SMS or WhatsApp after completing the survey. If you are asked to complete an in-depth interview at one of the visits, you will receive an additional R250 for your participation in this activity.

What are the COVID-19 risks and plans?
The virus that causes COVID-19 is mainly spread between people who are in close contact (especially closer than 2m) with each other. The virus can spread from an infected person's mouth or nose in small particles when they cough, sneeze, speak, or breathe, even if the infected person does not feel sick. Another person can then contract the virus when they breathe in infectious particles, or if particles come in contact with the eyes, nose, or mouth.

To reduce the spread of COVID-19, and to limit your exposure, we will follow all up-to-date UCT-approved guidelines and recommendations. Our goal is to provide quality research visits while keeping you, your family, and our research team safe and healthy.

What are the risks of being in the study?

During the surveys, we may talk about sensitive things like HIV, relationships, medication, and sex. You may find these topics uncomfortable.

Also, you may be uncomfortable using *MASI* or having others see you using *MASI*. You should login to *MASI* from a place where you feel safe and comfortable. If someone sees you using *MASI*, they may know that you are in a health and wellness study. This could be a loss of confidentiality for you and others who are using the app. You should protect your phone with a password or PIN. You should also delete messages sent from our study team after you have read them. This will lower the chances of someone finding out about your participation in this study.

Some users may have a version of *MASI* that allows them to make a post or view posts made by others. If you post in *MASI*, your post will only be seen by our study team and other study participants. You should not share things in the app that could allow other participants to know who you are. If you post information about yourself in *MASI*, there may be a loss of privacy. You should only post information that you are comfortable sharing. There may be times when our study team contacts you based on something you shared to make sure you are okay. We may call you or send you a message via SMS, WhatsApp, or *MASI*. If you share information about being hurt by someone, or if we are worried that you may harm yourself or others, we are required to report this information and will work with you to make sure you get help. We will only contact your caregiver with your permission.

We will try our best to create a safe and comfortable space in *MASI* for everyone. However, it is possible that you may become uncomfortable or upset due to posts other participants share. *MASI* will be checked on business days by our study team; however, we do not review or approve posts made by participants before they appear in *MASI*.

You may get messages from study staff. The messages will mostly be reminders to log onto *MASI*. They will also tell you about new activities in *MASI*. To make sure no one else reads your text messages, you should protect your phone with a password or PIN and change your text message settings so the content of the messages does not appear on the main screen when you receive a message.

How will we minimize these risks?

We will collect data in a private area so that you can speak without being overheard. The surveys will have a study ID number instead of names. Any data linking your name to your study ID number will be kept in a locked project office and/or in password protected files on password protected computers and secure servers. Any electronic data that are collected from you will be kept on secure and confidential servers at the University of Cape Town, Duke University, the University of North Carolina, and Florida State University.

Anything that you share in *MASI* will only be shown with your username. You should pick a username that does not include your real name, email address, or your social media account. If you choose to share information in the app, that post will only be seen by other participants in this study and study staff. You should not share information that could reveal your identity. If you choose to share private information about yourself in *MASI*, it may result in the loss of your privacy to other participants. Our study team may remove posts that go against our app's rules.

Any study messages that are sent to you will not show that you are in a research study. Messages will not have identifying and personal information.

Our research team has skills in keeping data safe. Also, all staff will get extra training on keeping information safe. Staff will receive training about privacy, respect and keeping you safe.

What about confidentiality?
We will do our best to keep your personal information private. We will not publish any identifiable information from this study such as your name, address or phone number. We will not share information that you tell the research team unless we are worried that you may harm yourself or others. Then we legally must report it per the South Africa's Children's Act. The research team must report deliberate neglect or physical, sexual or emotional abuse of a child. We will report this information to child welfare or the police. Your records may be reviewed by the sponsor of the study (U.S. National Institutes of Health) and their representatives, Duke University, University of North Carolina, Florida State University, or University of Cape Town institutional ethical committees, and study staff.

What are the benefits of being in the study?
There may not be direct benefits from being in this study. Young people may benefit from this study later. The information learned in this study may help to improve *MASI* so that it can better support young people living with HIV who are on HIV treatment.

What happens if you do not want to take part?
You can stop taking part in the study at any time. There will be no penalty if you choose not to participate or withdraw from the study. If the researcher feels it is in participant's best interest, they may end study participation at any time.

Persons to contact for problems or questions
If you have questions on the study, you can talk to anyone on our research team including the Principal Investigators: Prof. Jacqueline Hoare +27 (0) 21 404 2165 or Dr. Marta Mulawa marta.mulawa@duke.edu +1 919 689 9555. It is the principal investigators job to make sure this study is always ethical. If you have any complaints about your participation in this study, or would like more information about the rules for research studies, or the rights of people who take part in those studies, you may contact the Duke University Health System Institutional Review Board (IRB) Office at +1 919 668 5111 or by visiting irb.duhs.duke.edu/contact-us. Similarly, the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee can be contacted on +27 (0) 21 406 6338 to answer questions about rights and welfare of research subjects.

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.

I AGREE TO PARTICIPATE IN THIS STUDY:

☐ Yes ☐ No

_____ _____

Signature Date

IF PARTICIPANT CANNOT SIGN THEIR NAME, A WITNESS WILL VERIFY THE DOCUMENTATION WITH A WRITTEN "MARK."

_____ _____

Signature of witness Date

I CERTIFY THAT I HAVE EXPLAINED THE NATURE AND PURPOSE, PROCEDURES AND THE POSSIBLE RISK AND POTENTIAL BENEFITS OF THIS RESEARCH STUDY.

_____ _____

Signature of researcher Date

Can we contact you to follow-up for this study and future studies?

☐ Yes ☐ No

Informed Consent Form *(Adult Consent – Permission for Adolescent Participation)*

Piloting a Smartphone App to Improve Treatment Adherence Among South African Adolescents Living With HIV

ClinicalTrials.gov ID NCT04661878
Sponsor Duke University

Document Version Date: 12 October 2022
(IRB Reference Date 21 November 2022)

ADULT Consent Form
Giving PERMISSION for Adolescents to Choose Participation
for *MASI* Pilot RCT

Version 1.1 – 12 October 2022

Study Title: Developing a Smartphone App to Improve Treatment Adherence among South African Adolescents Living with HIV

Study Implementers: University of Cape Town (South Africa), Duke University School of Nursing (USA), University of North Carolina (USA), and Florida State University (USA)
Study Sponsors: U.S. National Institute of Mental Health
Principal Investigators: Prof. Jacqueline Hoare & Dr. Marta Mulawa
Co-Investigators: Dr. Lisa Hightow-Weidman & Dr. Kathryn Muessig
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Introduction
We would like you to allow your child to take part in a study. This form will tell you why we want to do this study. The goal of this study is to test a smartphone app called *MASI* to support adolescents and young adults living with HIV who are on HIV treatment. *MASI* stands for the isiXhosa phrase "**MA**sakhane **S**iphucule **I**mpilo Yethu".

Before you decide if we can invite your child into the study, you should know about the possible risks and benefits. This process is called informed consent. This informed consent form will give you an idea of what will take place during the study. Please ask us questions about anything that you do not understand or if you would like more information. We are happy to explain this to you more than once. Please take as much time as you need to talk about the study with your child, their doctor or nurse, the study staff, or your family and friends.

Who should provide consent?
These adults can give consent: (1) the *parent* (including adoptive parents); (2) if no parent, the *guardian* (either court-appointed OR as indicated by the parent in a Will); (3) if no guardian, a *foster parent*; (4) if no foster parent, a *caregiver* (any person other than a parent or guardian, who cares for a child); (5) and if the child is from a child-headed household with no supervisory adult, a *trusted adult chosen by the minor*.

In addition to your consent, your child will also need to provide assent to participate in the study.

Why is this study being done?
People living with HIV can take medication to treat HIV. Young people living with HIV may face difficulties in taking medication as prescribed by their doctor. *MASI* was made to help young people living with HIV get support and information about relationships, health, and wellness, including taking medication to treat HIV. There are different features of *MASI* that we would like to test out. Some versions of *MASI* include an anonymous social network where participants have usernames and avatars, but no identifying and/or personal information is needed. Other features help users to learn new information. The purpose of this research is to see if young people will use and like *MASI*. It will also help us learn if *MASI* has an effect on how young people take medication to treat HIV.

Your participation is voluntary. Your child's participation is voluntary.
Your decision to give consent is voluntary. If you give consent, your child's decision to participate is also voluntary. Your child can stop participating at any time with no penalty. Your child can refuse to answer any question. This does not affect benefits from clinics or social services.

How many people will take part in the study?
If your child decides to take part in this study, they will be one of about 50 participants in this study. Participants will be young people between the ages of 15-21 years who are living with HIV, live in Cape Town, and have been prescribed medication to treat HIV.

Are there any reasons your child should not be in the study?
Your child should not be in this study if:

- They are younger than 15 years old or are older than 21 years old
- They are not living with HIV
- They have not been prescribed medication to treat HIV
- They attend a school for learners with special needs (e.g., School of Skills)
- They have repeated a grade/s in school more than once
- They do not feel comfortable using an app with content in English
- They plan to move outside of Cape Town in the next six months
- They do not have a smartphone that can download apps
- They are not able to successfully install the *MASI* app on their smartphone
- They have previously participated in the *MASI* app testing phase of our study

How long will your child's part in this study last?
If your child agrees to be in this study, their participation will be about 6 months.

What will happen if your child takes part in the study?
It is not clear if young people will use *MASI* or if the different features of *MASI* will improve the way they take their medication to treat HIV. For this reason, your child will be assigned to receive one of two versions of *MASI* using a method called randomization. Randomization means that the group your child will be in is assigned by chance, like when you toss a coin. Your child will have an equal chance of receiving either version of *MASI*.

With your permission, your child will be asked to participate in our study. If your child chooses to participate, they will do the following:

a. First, we will review what it means to participate in this study with your child and ask if they want to be a part of the study. If they decide to be a part of the study, they will sign an assent form. This is a form that says they agree to participate.

b. Next, we will download and install *MASI* to your child's phone. This will allow us to make sure your child's phone is able to install *MASI*. If their phone is unable to download or install *MASI*, your child will be reimbursed for their participation today. However, they will not be able to participate in the rest of the activities or future study visits.

c. Your child will be asked to complete a survey by answering questions that our research assistant will ask them in a private space. The survey will take about one hour. Your child will be asked questions about their background, HIV-related knowledge, social

support, loneliness, resilience, anxiety, depression, stigma, disclosure concerns, disclosure intentions, treatment adherence, and sexual activity.

d. After your child completes the survey, they will find out which version of the *MASI* app they will use. We will decide this randomly, like when you toss a coin. You or your child cannot choose which version they will get. After your child registers and creates a private username and password, we will teach them how to use the app.

e. Once your child's visit is complete, they will be asked to spend at least 5 minutes a day on the app for 6 months. We will be able to monitor where your child goes within the app, what features/articles they use, and the length of time they spend on the app. Your child may get push notifications, in-app notifications, or text messages about new content and features in the app. Your child may turn off push notifications and text messaging in the study app. Any contact you or your child receive from us will not include sensitive or private information. Your child will be given 1GB of smartphone data each month to support their use of the app during this period.

f. After about three months, your child will be asked to complete another survey. The survey will take about one hour. We may ask your child to come in person to do the survey, or we may call them to do the survey over the phone. That survey will ask similar questions to the initial survey and will also ask about their experiences using *MASI* and being in the study.

g. About six months from today, your child will be asked to do a third and final survey. This survey will take about one hour to complete. We may ask your child to come in person to do the survey, or we may call them to do the survey over the phone. That survey will ask similar questions to the 3-month survey.

h. Your child's survey responses from the three surveys will be entered into a secure database on a password-protected computer and stored on a secure server.

i. At either the three-month or six-month visit, your child may be invited to do an additional one-on-one interview.

    - If your child chooses to do this one-on-one interview, they will be asked about their experiences with *MASI* and about their experiences with HIV treatment and living with HIV. This interview will be recorded, and we will use the voice recording to write down our conversation.

j. All study-related documents, including the recordings for those invited to the one-on-one interview, will be kept private. Documents will be kept in a locked project office and in password protected files on password protected computers and secure servers. Any documents containing your child's name and personal information will be kept separate from other study records, and will be stored securely. These files will be seen only by study staff and will be kept for 5 years following the close of the study.

Will your child receive anything for being in the study?
Your child will be given R250 at each visit for time and travel. We will also give you and your child refreshments, including a snack and a drink. There are no other costs for your child to be in the study. If your child does a survey over the phone, we will give them the R250 reimbursement via a Shoprite money transfer voucher sent to an adult who is at least 18 years

old. We will ask your child to identify an adult who can receive the voucher, and then will send them a voucher number and pin via SMS or WhatsApp after your child completes the survey. If your child is asked to complete an in-depth interview at one of the visits, they will receive an additional R250 for their participation in this activity.

What are the COVID-19 risks and plans?
The virus that causes COVID-19 is mainly spread between people who are in close contact (especially closer than 2m) with each other. The virus can spread from an infected person's mouth or nose in small particles when they cough, sneeze, speak, or breathe, even if the infected person does not feel sick. Another person can then contract the virus when they breathe in infectious particles, or if particles come in contact with the eyes, nose, or mouth.

To reduce the spread of COVID-19, and to limit your exposure, we will follow all up-to-date UCT-approved guidelines and recommendations. Our goal is to provide quality research visits while keeping you, your family, and our research team safe and healthy.

What are the risks of being in the study?
During the surveys, we may talk with your child about sensitive things like HIV, relationships, medication, and sex. Your child may find these topics uncomfortable.

Also, your child may be uncomfortable using *MASI* or having others see them using *MASI*. We will tell your child to login from a place where they feel safe and comfortable. If another person sees your child using the app, they may know that your child is in a health and wellness study. This could be a loss of confidentiality for your child and others who are using the app. We will suggest that your child protect their phone with a password or PIN. We will also tell your child to delete messages sent from the study team after they have read them. This will lower the chances of someone finding out about their participation in this study.

Some users may have a version of *MASI* that allows them to make a post or view posts made by others. If your child posts in the app, their post will only be seen by our study team and other study participants. We will tell all participants that they should not share things in the app that could allow other participants to know who they are. If your child posts information about themselves in the app, there may be a loss of privacy. We will tell your child to only post information that they are comfortable sharing.

There may be times when our study team contacts your child based on something they shared to make sure they are okay. We may call them or send them a message via SMS, WhatsApp, or *MASI*. If your child shares information about being hurt by someone, or if we are worried that they may harm themselves or others, we are required to report this information and will work with your child to make sure they get help. We will only contact you with your child's permission.

We will try our best to create a safe and comfortable space in the app for everyone. However, it is possible that your child may become uncomfortable or upset due to posts other participants share. The app will be checked on business days by our study team; however, we do not review participant-posted content before it appears in the app.

Your child may get messages from study staff. These will be text messages or messages in the app's message center. The messages will mostly be reminders for your child to log onto the app. They will also tell them about new activities on the app. To make sure no one other than your child can read their text messages, we will tell your child to protect their phone with a

password or PIN and to change their text message settings so the content of the messages does not appear on the main screen when they receive a message.

How will we minimize these risks?

We will collect data in a private area so that your child can speak without being overheard. The surveys will have a study ID number instead of names. Any data linking your child's name to their study ID number will be kept in a locked project office and/or in password protected files on password protected computers and secure servers. Any electronic data that are collected from your child will be kept on secure and confidential servers at the University of Cape Town, Duke University, the University of North Carolina, and Florida State University.

Anything that your child chooses to share in *MASI* will only be shown with their username. We will tell your child to pick a username that is not their real name, email address, or their social media accounts. If your child chooses to share information in the app, that post will only be seen by other participants in this study and study staff. We will tell participants not to share information that could reveal their identity. If your child chooses to share private information about themselves in the app, it may result in the loss of their privacy to other participants. Our study team may remove posts that go against our app's rules.

Any study messages that are sent to your child will not show they are in a research study. Messages will not have identifying and personal information.

Our research team has skills in keeping data safe. Also, all staff will get extra training on keeping information safe. Staff will receive training about privacy, respect and keeping your child safe.

What about confidentiality?
We will do our best to keep your child's personal information private. We will not publish any identifiable information from this study such as your child's name, address or phone number. We will not share information that your child tells the research team unless we are worried about your child being hurt or your child harming themselves or others. Then we legally must report it per the South Africa's Children's Act. Our research team must report deliberate neglect or physical, sexual or emotional abuse of a child. We will report this information to child welfare or the police. Your child's records may be reviewed by the sponsor of the study (U.S. National Institutes of Health) and their representatives, Duke University, University of North Carolina, Florida State University, or University of Cape Town institutional ethical committees, and study staff.

What are the benefits of being in the study?
There may not be direct benefits from being in this study. Young people may benefit from this study later. The information learned in this study may help to improve *MASI* so that it can better support young people living with HIV who are on HIV treatment.

What happens if you do not want to take part?
You or your child can stop taking part in the study at any time. There will be no penalty if you or your child choose not to participate or withdraw from the study. If the researcher feels it is in participant's best interest, they may end study participation at any time.

Persons to contact for problems or questions
If you have questions on the study, you can talk to anyone on our research team including the Principal Investigators: Prof. Jacqueline Hoare +27 (0) 21 404 2165 or Dr. Marta Mulawa marta.mulawa@duke.edu +1 919 689 9555. It is the principal investigators job to make sure this study is always ethical. If you or your child have any complaints about their participation in this study, or would like more information about the rules for research studies, or the rights of people who take part in those studies, you may contact the Duke University Health System Institutional Review Board (IRB) Office at +1 919 668 5111 or by visiting irb.duhs.duke.edu/contact-us. Similarly, the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee can be contacted on +27 (0) 21 406 6338 to answer questions about rights and welfare of research subjects.

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 your child. At most, the website will include a summary of the results. You can search this website at any time.

I AGREE FOR MY CHILD TO CHOOSE WHETHER TO PARTICIPATE IN THIS STUDY:

☐ Yes ☐ No

_____ _____
Signature Date

IF PARTICIPANT CANNOT SIGN THEIR NAME, A WITNESS WILL VERIFY THE DOCUMENTATION WITH A WRITTEN "MARK."

_____ _____
Signature of witness Date

I CERTIFY THAT I HAVE EXPLAINED THE NATURE AND PURPOSE, PROCEDURES AND THE POSSIBLE RISK AND POTENTIAL BENEFITS OF THIS RESEARCH STUDY.

_____ _____
Signature of researcher Date

Can we contact you to follow-up for this study and future studies?

☐ Yes ☐ No

Informed Consent Form *(Adolescent Assent)*

Piloting a Smartphone App to Improve Treatment Adherence Among South African Adolescents Living With HIV

ClinicalTrials.gov ID NCT04661878
Sponsor Duke University

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ADOLESCENT Assent Form
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Study Implementers: University of Cape Town (South Africa), Duke University School of Nursing (USA), University of North Carolina (USA), and Florida State University (USA)
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ClinicalTrials.gov Identifier: NCT04661878

Introduction
We would like to ask for your permission to take part in a study. This form will tell you why we want to do this study. The goal of this study is to test a smartphone app called *MASI* to support adolescents and young adults living with HIV who are on HIV treatment. *MASI* stands for the isiXhosa phrase "**MA**sakhane **S**iphucule **I**mpilo Yethu".

Before you decide about taking part, you should know about the possible risks and benefits. This process is called informed consent. This informed consent form will give you an idea of what will take place during the study. Please ask us questions about anything that you do not understand or if you would like more information. We are happy to explain this to you more than once. Please take as much time as you need to talk about the study with your doctor or nurse, the study staff, or your family and friends.

Why is this study being done?
People living with HIV can take medication to treat HIV. Young people living with HIV may face difficulties in taking medication as prescribed by their doctor. *MASI* was made to help young people living with HIV get support and information about relationships, health, and wellness, including taking medication to treat HIV. There are different features of *MASI* that we would like to test out. Some versions of *MASI* include an anonymous social network where participants have usernames and avatars, but no identifying and/or personal information is needed. Other features help users to learn new information. The purpose of this research is to see if young people will use and like *MASI*. It will also help us learn if *MASI* has an effect on how young people take medication to treat HIV.

Your participation is voluntary.
Your decision to provide assent is voluntary, meaning it is your choice. If you provide assent, your decision to participate in each activity is voluntary. You can stop participating at any time with no penalty. You can refuse to answer any question. This does not affect care or benefits you receive from clinics or social services.

In order to participate, your parent or caregiver will also need to give consent.

How many people will take part in the study?
If you decide to take part in this study, you will be one of about 50 participants in this study. Participants will be young people between the ages of 15-21years who are living with HIV, live in Cape Town, and have been prescribed medication to treat HIV.

Are there any reasons you should not be in the study?
You should not be in this study if:

- You are younger than 15 years old or are older than 21 years old
- You are not living with HIV
- You have not been prescribed medication to treat HIV
- You attend a school for learners with special needs (e.g., School of Skills)
- You have repeated a grade/s in school more than once
- You do not feel comfortable using an app with content in English
- You plan to move outside of Cape Town in the next six months
- You do not have a smartphone that can download apps
- You are not able to successfully install the *MASI* app on your smartphone
- You have previously participated in the *MASI* app testing phase of our study

How long will your part in this study last?
If you agree to be in this study, your participation will be about 6 months.

What will happen if you take part in the study?
It is not clear if young people will use *MASI* or if the different features of *MASI* will improve the way they take their medication to treat HIV. For this reason, you will be assigned to receive one of two versions of *MASI* using a method called randomization. Randomization means that the group you are in is assigned by chance, like when you toss a coin. You have an equal chance of receiving either version of *MASI*.

If you choose to participate, you will do the following:

a. First, we will download and install *MASI* to your phone. This will allow us to make sure your phone is able to install *MASI*. If your phone is unable to download or install *MASI*, you will be reimbursed for your participation today. However, you will not be able to participate in the rest of the activities or future study visits.

b. You will be asked to complete a survey by answering questions that our research assistant will ask you in a private space. The survey will take about one hour. You'll be asked questions about your background, HIV-related knowledge, social support, loneliness, resilience, anxiety, depression, stigma, disclosure concerns, disclosure intentions, treatment adherence, and sexual activity.

c. After you have completed the survey, you will find out which version of the *MASI* app you will use. We will decide this randomly, like when you toss a coin. You cannot choose which version you will get. After you register and create a private username and password, we will teach you how to use the app.

d. Once your visit is complete, you will be asked to spend at least 5 minutes a day on the app for 6 months. We will be able to monitor where you go within the app, what features/articles you use, and the length of time you spend on the app. You may get push notifications, in-app notifications, or text messages about new content and features in the app. You may turn off push notifications and text messaging in the study app. Any contact you receive from us will not include sensitive or private information. You will be given 1GB of smartphone data each month to support your use of the app during this period.

e. After about three months, you will be asked to complete another survey. The survey will take about one hour. We may ask you to come in person to do the survey, or we may call you to do the survey over the phone. That survey will ask similar questions to the initial survey and will also ask about their experiences using *MASI* and being in the study.

f. About six months from today, you will be asked to do a third and final survey. This survey will take about one hour to complete. We may ask you to come in person to do the survey, or we may call you to do the survey over the phone. That survey will ask similar questions to the 3-month survey.

g. Your survey responses from the three surveys will be entered into a secure database on a password-protected computer and stored on a secure server.

h. At either the three-month or six-month visit, you may be invited to do an additional one-on-one interview.

- If you choose to do this one-on-one interview, you will be asked about your experiences with *MASI* and about your experiences with HIV treatment and living with HIV. This interview will be recorded, and we will use the voice recording to write down our conversation.

i. All study-related documents, including the recordings for those invited to the one-on-one interview, will be kept private. Documents will be kept in a locked project office and in password protected files on password protected computers and secure servers. Any documents containing your name and personal information will be kept separate from other study records, and will be stored securely. These files will be seen only by study staff and will be kept for 5 years following the close of the study.

Will you receive anything for being in the study?
You will be given R250 at each visit for time and travel. We will also give you refreshments, including a snack and a drink. There are no other costs for you to be in the study. If you do a survey over the phone, we will give you the R250 reimbursement via a Shoprite money transfer voucher. We will ask you to identify an adult who is at least 18 years old who can receive the voucher, and then send them a voucher number and pin via SMS or WhatsApp after you complete the survey. If you are asked to complete an in-depth interview at one of the visits, you will receive an additional R250 for your participation in this activity.

What are the COVID-19 risks and plans?
The virus that causes COVID-19 is mainly spread between people who are in close contact (especially closer than 2m) with each other. The virus can spread from an infected person's mouth or nose in small particles when they cough, sneeze, speak, or breathe, even if the infected person does not feel sick. Another person can then contract the virus when they breathe in infectious particles, or if particles come in contact with the eyes, nose, or mouth.

To reduce the spread of COVID-19, and to limit your exposure, we will follow all up-to-date UCT-approved guidelines and recommendations. Our goal is to provide quality research visits while keeping you, your family, and our research team safe and healthy.

What are the risks of being in the study?
During the surveys, we may talk about sensitive things like HIV, relationships, medication, and sex. You may find these topics uncomfortable.

Also, you may be uncomfortable using *MASI* or having others see you using *MASI*. You should login to *MASI* from a place where you feel safe and comfortable. If someone sees you using *MASI*, they may know that you are in a health and wellness study. This could be a loss of confidentiality for you and others who are using the app. You should protect your phone with a password or PIN. You should also delete messages sent from our study team after you have read them. This will lower the chances of someone finding out about your participation in this study.

Some users may have a version of *MASI* that allows them to make a post or view posts made by others. If you post in *MASI*, your post will only be seen by our study team and other study participants. You should not share things in the app that could allow other participants to know who you are. If you post information about yourself in *MASI*, there may be a loss of privacy. You should only post information that you are comfortable sharing. There may be times when our study team contacts you based on something you shared to make sure you are okay. We may call you or send you a message via SMS, WhatsApp, or *MASI*. If you share information about being hurt by someone, or if we are worried that you may harm yourself or others, we are required to report this information and will work with you to make sure you get help. We will only contact your caregiver with your permission.

We will try our best to create a safe and comfortable space in *MASI* for everyone. However, it is possible that you may become uncomfortable or upset due to posts other participants share. *MASI* will be checked on business days by our study team; however, we do not review or approve posts made by participants before they appear in *MASI*.

You may get messages from study staff. The messages will mostly be reminders to log onto *MASI*. They will also tell you about new activities in *MASI*. To make sure no one else reads your text messages, you should protect your phone with a password or PIN and change your text message settings so the content of the messages does not appear on the main screen when you receive a message.

How will we minimize these risks?

We will collect data in a private area so that you can speak without being overheard. The surveys will have a study ID number instead of names. Any data linking your name to your study ID number will be kept in a locked project office and/or in password protected files on password protected computers and secure servers. Any electronic data that are collected from you will be kept on secure and confidential servers at the University of Cape Town, Duke University, the University of North Carolina, and Florida State University.

Anything that you share in *MASI* will only be shown with your username. You should pick a username that does not include your real name, email address, or your social media account. If you choose to share information in the app, that post will only be seen by other participants in this study and study staff. You should not share information that could reveal your identity. If you choose to share private information about yourself in *MASI*, it may result in the loss of your privacy to other participants. Our study team may remove posts that go against our app's rules.

Any study messages that are sent to you will not show that you are in a research study. Messages will not have identifying and personal information.

Our research team has skills in keeping data safe. Also, all staff will get extra training on keeping information safe. Staff will receive training about privacy, respect and keeping you safe.

What about confidentiality?
We will do our best to keep your personal information private. We will not publish any identifiable information from this study such as your name, address or phone number. We will not share information that you tell the research team unless we are worried that you may harm yourself or others. Then we legally must report it per the South Africa's Children's Act. The research team must report deliberate neglect or physical, sexual or emotional abuse of a child. We will report this information to child welfare or the police. Your records may be reviewed by the sponsor of the study (U.S. National Institutes of Health) and their representatives, Duke University, University of North Carolina, Florida State University, or University of Cape Town institutional ethical committees, and study staff.

What are the benefits of being in the study?
There may not be direct benefits from being in this study. Young people may benefit from this study later. The information learned in this study may help to improve *MASI* so that it can better support young people living with HIV who are on HIV treatment.

What happens if you do not want to take part?
You can stop taking part in the study at any time. There will be no penalty if you choose not to participate or withdraw from the study. If the researcher feels it is in participant's best interest, they may end study participation at any time.

Persons to contact for problems or questions
If you have questions on the study, you can talk to anyone on our research team including the Principal Investigators: Prof. Jacqueline Hoare +27 (0) 21 404 2165 or Dr. Marta Mulawa marta.mulawa@duke.edu +1 919 689 9555. It is the principal investigators job to make sure this study is always ethical. If you have any complaints about your participation in this study, or would like more information about the rules for research studies, or the rights of people who take part in those studies, you may contact the Duke University Health System Institutional Review Board (IRB) Office at +1 919 668 5111 or by visiting irb.duhs.duke.edu/contact-us. Similarly, the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee can be contacted on +27 (0) 21 406 6338 to answer questions about rights and welfare of research subjects.

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.

I AGREE TO PARTICIPATE IN THIS STUDY:

☐ Yes ☐ No

_____ _____

Signature Date

IF PARTICIPANT CANNOT SIGN THEIR NAME, A WITNESS WILL VERIFY THE DOCUMENTATION WITH A WRITTEN "MARK."

_____ _____

Signature of witness Date

I CERTIFY THAT I HAVE EXPLAINED THE NATURE AND PURPOSE, PROCEDURES AND THE POSSIBLE RISK AND POTENTIAL BENEFITS OF THIS RESEARCH STUDY.

_____ _____

Signature of researcher Date

Can we contact you to follow-up for this study and future studies?

☐ Yes ☐ No

Note to research staff: This signed assent form should be attached to the consent form.