

Informed Consent Form

Title: Efficacy Trial for a Smartphone Game to Prevent HIV among Young Africans

NCT Number: NCT04437667

IRB Approval Date: 4/26/2021

EMORY UNIVERSITY / KENYA MEDICAL RESEARCH INSTITUTE

Parental Consent for Child to be a Research Subject

Title: Efficacy Trial for a Smartphone Game to Prevent HIV among Young Africans

Emory IRB #: IRB00108404, **KEMRI SERU #:** CGHR/11/3812, **License #:** NACOSTI/P/20/4542

Principal Investigator:

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Funding Source: U.S. National Institute of Mental Health

Introduction

Your child is being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to allow your child to be in the study or not to be in the study. **It is entirely your choice. If you decide to allow your child to take part, you can change your mind later on and withdraw your child from the research study. Your child can also skip any questions that he/she does not wish to answer on the questionnaires.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like your child to participate. By signing this form you will not give up any legal rights.

Study Overview

The purpose of this study is to test a new way for adolescents to learn how to protect themselves from unwanted pregnancy and HIV and reach their future goals using a game on a smartphone. We plan to recruit a total of 1,000 adolescents and 52 parents for this study. The study will last 4 years and all the activities will take place when your child is not in school.

Procedures

If both you and your child agree for your child to take part in the study, here is what will happen:

Survey: Your child will sit in front of a tablet wearing headphones. He/she will hear questions through the headphones and will enter his/her answers on the tablet (this is called a survey). Your child will complete the survey thirteen times over the period of 4 years (**when he/she is not in school**).

Each survey will take about 60 minutes. These questions will be about your child, his/her health, and his/her goals. The survey will include questions about sexual behavior and alcohol and drug use. If your child feels uncomfortable with these questions, he/she can refuse to answer any question. He/she can also stop taking part in the survey at any time.

If your child is chosen to play the study game, he/she will also answer a short survey about the game. This survey will take about 30 minutes. The questions will be about his/her feelings about the game and about who he/she shared the game with.

HIV and HSV-2 test: Your child will receive an HIV test and a test for HSV-2, which is a different virus that is also transmitted through sex. This test will happen at the beginning and at the end of the study. For the HIV test, a nurse will prick your child's finger and the test results will be ready in 15 minutes. For the HSV-2 test, a nurse will draw a little of your child's blood from his/her arm and the test results will be ready at a local clinic in about 2 weeks.

Before the test a trained counselor will explain the test, what will happen and why it is important, and the possible results. A counselor will also give you and/or your child your child's HIV test results and answer any questions you have. If your child's HIV test is positive, the counselor will give more information on how to discuss his/her status with him/her and what you and he/she should do next (like who to talk to and how to tell others about his/her HIV status) and how to get care (a list of places to get care and documents to give to the center where he/she chooses to get care). The study team will check that your child is connected to a center for treatment. Antiretroviral treatment for HIV is free. To get your child's HSV-2 test results, you will go to a local clinic where a nurse will give you and/or your child his/her results. If the HSV-2 test is positive, you will also receive counseling about how to talk to your child about his/her diagnosis and about the signs of the virus and care. If he/she has signs of HSV-2 on his/her body, your child will be referred to a clinic so he/she can get some medicine for free.

While your child is younger than 15, you or another adult will need to be present during the testing and counseling and you will receive his/her test results. Once your child is 15 or older, he/she may choose not to have an adult there for this part of the study. We will still encourage him/her to invite you or another adult to be there, or to talk to you or another adult about the results if they are positive.

Game: Your child may be selected to play one of two games. We will lend your child a smartphone which will have the game on it. The only thing your child will be able to do on the phone is play the game: all other functions of the phone will be turned off. He/she will not be able to use the phone to make phone calls, send SMS, or use the internet, even if he/she puts in a SIM card and adds airtime. Your child will only have the phone during the November-December **game play period** each year of the study. At the end of each **play period**, we will collect the phone from him/her. We will ask your child to play the game for at least 10 hours during each **of these time periods**. We will be able to see from the phone how your child played the game but we will not share this information with you.

Interviews and Focus Group Discussions #1: Your child may be chosen as part of a small group of adolescents who will participate in individual interviews once a year. The interviews will be about his/her experiences with the game, including how he/she is playing, and who he/she is talking about the game with. After the end of the study, the adolescents in this group will be invited to a group discussion to talk about their experiences with the study and the game. Each interview and discussion will last up to 90 minutes and will be audio-recorded. It will take place either in person or via phone.

Focus Group Discussions #2: Your child may be chosen to participate in a focus group discussion or individual interview at the end of the study. This will include questions about his/her experience playing the game and using the information from the game in his/her life and his/her thoughts about how the game could be made available to others outside the study. Each interview and discussion will last up to 90 minutes and will be audio-recorded. It will take place either in person or via phone.

Risks and Discomforts

Parts of the game may embarrass your child or make him/her feel uncomfortable. Your child may be uncomfortable with the blood test for HSV-2 and HIV or concerned about his/her test results. You will know his/her HIV/HSV-2 results and this may make him/her uncomfortable. Some of the questions may embarrass your child or make him/her feel uncomfortable. If he/she feels uncomfortable with any questions in the discussions or on the survey, he/she may refuse to answer them. During focus group discussions, we cannot promise that other adolescents in the group will not share what he/she says with others. Your child should not say anything in the discussion group that he/she would not want others outside the group to hear; we will remind him/her about this before the discussion. He/she can stop being in the study at any time.

Benefits

Your child will have the chance to play a game on a smartphone during the November-December holiday every year. After the end of all the study activities, your child will receive a smartphone with the two games used in the study. When your child takes part in the study, he/she is helping us to find out if the game helps adolescent to learn how to protect themselves from unwanted pregnancy and HIV and reach their future goals. Your child will also be tested for HIV and HSV-2 and receive counseling about testing and protecting himself/herself.

Compensation

You and your child will not be offered payment for being in this study. However, for each study visit your child will be reimbursed Kshs 500 for his/her time and you will be reimbursed for airtime or transport costs. For any in-person activities there will be refreshments during study visits.

Confidentiality

The research team will keep any research records we create private to the extent we are required to do so by law. A study number rather than your child's name will be used on study records wherever possible. Your child's name and other facts that might point to him/her will not appear when we present this study or publish its results. Certain offices and people other

than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your child's study records. These offices include the Office for Human Research Protections, the funder, the Emory and KEMRI Institutional Review Board, the Emory Office of Compliance. Study funders may also look at your child's study records.

In the context of COVID-19, for procedures that require some physical proximity with study staff, the study staff will record body temperatures and ask about any COVID-19 symptoms. If the staff suspect or tentatively diagnose COVID-19 infection, we will be required to report to the local public health authorities as per the current Kenyan Ministry of Health guidelines.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the United States National Institutes of Health for this study. The Certificate of Confidentiality helps us to keep others from learning that your child participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies your child. For example, if Emory received a subpoena for study records, it would not give out information that identifies your child.

The Certificate of Confidentiality does not stop your child or someone else, like you, from giving out information about your child's participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your child's privacy.

The Certificate does not stop the research team from making the following disclosures about your child:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify your child) may be placed into public databases. Researchers will need to sign data use agreements before accessing the data in these databases. We will remove or code any personal information that could identify your child before his/her information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify your child from the information we share. Despite these measures, we cannot guarantee anonymity of your child's personal data.

Your child's data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your child's deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify him/her. If your child's data or specimens are labeled with his/her study ID, we will not allow the other investigators to link that ID to your child's identifiable information.

In general, aside from HIV and HSV-2 results as described above, we will not give you or your child any individual results from the study.

Withdrawal from the Study

You have the right to remove your child from the study at any time without penalty to yourself or to your child.

The researchers also have the right to stop your child's participation in this study without your or child's consent for any reason, especially if they believe it is in your child's best interest or if you or your child were to object to any future changes that may be made in the study plan.

Contact Information

Contact Dr. Victor Mudhune, Principal Investigator, KEMRI at [REDACTED]

- if you have any questions about this study or your child's part in it,
- if you have questions, or concerns about the research

Contact the KEMRI Scientific & Ethics Review Unit , ([REDACTED], Nairobi) at telephone [REDACTED]

- if you have questions about your child's rights as a research participant.
- if you have complaints about the research or an issue you rather discuss with someone outside the research team.

You may also contact Center Deputy Director, KEMRI, Center for Global Health Research at [REDACTED] or contact the Emory Institutional Review Board at [REDACTED].

You may also let the Emory IRB know about your child's experience as a research participant through our Research Participant Survey at <https://tinyurl.com/ycewgkke>.

TO BE FILLED OUT BY PARENT PROVIDING CONSENT FOR CHILD'S PARTICIPATION ONLY

Please **print** your name, **sign**, and **date** below if you agree to allow your child to be in this research study. By signing this consent and authorization form, you will not give up any of your or your child's legal rights. We will give you a copy of the signed form to keep.

Name of Subject

Signature of Subject (18 or older and able to provide consent)

Date **Time**

Name of Witness (where applicable)

Signature of Witness

Date **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion

Date **Time**