Title: A Smartphone Game to Increase Engagement in Care among African Adolescents Living with HIV

NCT#: NCT06913660

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Your Child is Being Asked to Be in a Research Study

Concise presentation of key concepts

Your child is being asked to be in a research study. A research study is designed to answer a scientific question. If you agree for your child to be in the study he/she will be one of 120 adolescents who taking part in the study at KEMRI.

Why is this study being done?
This study is being done to answer the question: does a certain game help adolescents living with HIV to stay healthy, take their medication, and remain in care? Your child is being asked to be in this research study because he/she is between the ages of 15 and 21 and living with HIV.

Does your child have to be in the study?
It is your decision to allow your child to be part of this research study. You do not have to allow your child to be in it. Your choice will not affect your child's access to medical care for his/her condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to allow my child to participate in this study?
If your child is eligible and you want him/her to be part of the study, your child will participate in 5 survey study visits, 3 blood tests and, if selected, an interview or a group discussion, over a 10-month period. All of these procedures will be paid for by the study.

How is this study going to help your child?
If your child is in the study, he/she will be helping the researchers answer the study question. Your child's HIV viral load will also be tested, which can help him/her and his/her care provider know more about his/her health and care. If selected to play the study game, we will also lend your child a study phone on which he/she will have a game to play.

What are the risks or discomforts I should know about before making a decision?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include being uncomfortable with the questions asked, being uncomfortable with the content of the game, the possibility that having a phone with an HIV game on it could indicate to others that he/she is living with HIV, loss of privacy, and breach of confidentiality. A full list of expected risks and

how likely they are is in the “What are the possible risks and discomforts?” section of this document.

Alternatives to Joining This Study

Since this is not a treatment study, the alternative is not to allow your child to participate.

Costs

You and your child WILL NOT have to pay for any of the study procedures.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.). Take time to consider this, and talk about it with your family and friends.

Emory University/ Kenya Medical Research Institute
'MyGoals' Study
Consent to be a Research Subject

Title: A Smartphone Game to Increase Engagement in Care among African Adolescents Living with HIV **IRB**

#:00002974

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Sponsor: U.S. National Institute of Mental Health

Introduction

Your child is being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to allow your child to be a part of 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.** The decision to join or not join the research study will not cause you or your child to lose any medical benefits. If you decide not to allow your child to take part in this study, your child's doctor will continue to treat him/her.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study staff explain the study 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 to allow your child to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify your child. At most the Web site will include a summary of the results. You can search this Web site at any time.

What is the purpose of this study?

The purpose of this study is to test a game for smartphones to help adolescents living with HIV to take their antiretroviral therapy as directed, to cope with HIV stigma, to improve their emotional health, and to better develop healthy relationships.

What will I be asked to do?

If you agree to allow 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. Your child will hear questions through the headphones and will enter his/her answers on the tablet (this is called a survey). He/she will complete the survey five times over nine months. Each survey will take about 60 minutes. Some questions will be about your child, how he/she feels, and his/her goals. Other questions will be about taking his/her antiretroviral medicine, if he/she has felt stigmatized because of his/her HIV, and his/her past sexual behavior and alcohol use. If your child feels uncomfortable with any of the questions, he/she may refuse to answer them. He/she can also stop taking part in the survey at any time.

If your child is part of the group that plays the game, he/she will also be asked to answer a short survey about the game. This survey will take about 30 minutes. The questions will be about your child's feelings about the game and about who he/she shared the game with.

Viral load test: Your child will have his/her viral load tested as part of this study. Viral load measures how much HIV is in the blood and if your child's antiretroviral therapy is working well. It is the same test that your child takes as part of his/her usual medical care. This test will happen at the beginning, in the middle, and at the end of the study. A nurse will draw blood from your child's arm and the blood sample will be sent to a laboratory for testing. 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 your child his/her viral load test results and answer any questions your child has.

Game: Your child may or may not be selected to complete this part of the study. Selection will happen randomly- this is like flipping a coin to decide which group your child will be part of. If your child is selected, we will lend him/her a mobile phone with the game on it. There will not be a SIM card in it or airtime. We will ask your child to play the game for at least 30 minutes a day for six weeks, then to play as much as he/she wants for the rest of the study period. He/she will have the phone available for the nine months of the study. At the end of this time, we will collect the phone. We will be able to see from the phone how your child played the game and what information he/she logged about his/her medication and appointments but we will not share this information with you, or your child's healthcare provider.

Focus Group Discussion and/ or Interview: After we have collected the phones, we will ask your child to take part in a group discussion to tell us about his/her experiences playing the game. The group discussion will be recorded to make sure we do not miss anything that participants say. The group discussion will last about 90 minutes (1.5 hours) and may be conducted either in person or via phone or video call.
If your child is selected to play the game, he/she may also be asked to participate in a one-on-one interview with a researcher in the middle of the study period. This interview will be asking about how he/she is playing the game and his/her experience with the study. It will last about 1 hour and may be conducted either in person or via phone or video call.

Access to Medical Records: Someone from the study team or from the clinic where your child gets care will look at the information in his/her medical record. They will review medication information and your child's past viral load results, prescribed medications, and other information related to their HIV status and health. In addition, the staff will see how many appointments he/she has been attending. They will do this for the period of 12 months before the start of the study until the end of the study.

Who owns my child's study information and samples?

If your child joins this study, he/she will be donating blood samples and study information. Your child will not receive any compensation for these samples or information. If you decide to have your child leave the study, data and samples that were already collected may be still be used for this study. If you or your child would like the information he/she has already shared to be deleted, you and your child may let the study staff know at the time your child leaves the study.

What are the possible risks and discomforts?

There are unlikely to be side effects from the study game or procedures that are not known at this time. The most common risks and discomforts expected in this study are:

- Being uncomfortable with the questions that are asked in the survey or focus groups
- Being uncomfortable with the topics and stories in the game
- Being uncomfortable discussing living with HIV in a focus group
- Feeling a little pain during the blood draw for the viral load test

The less common risk in this study is that having a mobile phone with an app about HIV and which sends notifications about HIV medication and appointments could accidentally disclose your child's HIV status to others. It is possible that having the phone could draw attention to your child and risk someone trying to steal the phone.

Will my child benefit directly from the study?

Your child will have the chance to play a game on a smartphone for 9 months. When he/she takes part in the study, he/she is helping us to find out if the game helps adolescents like them to stay motivated and able to take their medication and build healthy relationships. Your child will also have his/her viral load tested twice and receive counseling about the meaning of his/her viral load and the importance of taking antiretroviral therapy. His/her HIV viral load may improve while he/she is in this study but it may not, and it may even get worse. This study is also designed to learn more about how the game can help adolescents control their viral load. The study results may be used to help others in the future.

Will my child be compensated for his/her time and effort?

Your child will get 500KSh for each completed study visit, to compensate him/her for his/her time and effort. If your child does not finish the study, we will compensate him/her for the visits completed. If he/she is selected to participate in all the study activities, he/she will be compensated 5000KSh total, if he/she completes all study visits. He/she will also be provided refreshments during any long study visit (for example, focus group discussion).

What are my and my child's other options?

If you decide not to allow your child to enter this study, your child will continue to receive his/her usual level of care for HIV and any other health conditions he/she may have.

How will you protect my child's private information that you collect in this study?

A study number, rather than your child's name, will be used on study records. Your child's name and other identifying information will not appear when we analyze, present, or publish the study results. 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 Institutional Review Board, the Emory Office of Research Compliance, KEMRI Scientific and Ethics Research Unit, and local research regulatory authorities. Study funders may also look at your child's study records. Emory and KEMRI will keep any research records we create private to the extent we are required to do so by law.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the 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 and the investigators 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 a member of your family, from giving out information about your child's participation in this study. For example, if you or your child let your insurance company know that your child is 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 own privacy.

The Certificate does not stop Emory and the investigators 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 your child 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. We will remove or code any personal information that could identify your child before your child's 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, KEMRI, or elsewhere. To help further science, we may provide your child's deidentified data to other researchers. If we do, we will not include any information that could identify your child. If your child's data 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 viral load results as described above, we will not give your child any individual results from the study.

Costs

There are no costs, research or standard of care related, associated with the study. There will be no costs to you or your child for participating in this study, other than basic expenses like transportation, for which your child is being reimbursed. Your child will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to have your child leave the study at any time without penalty. The researchers also have the right to stop your child's participation in this study without your or your 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. [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]
or [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 [redacted] or contact the Emory Institutional Review Board at [redacted]

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at [redacted]

TO BE FILLED OUT BY SUBJECT 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 legal rights. We will give you a copy of the signed form to keep.

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Name of Parent or Guardian

____ _______________

Signature of Parent or Guardian (18 or older and able to consent) **Date Time**

____ _______________

Name of Witness (if applicable) **Date Time**

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Signature of Witness

TO BE FILLED OUT BY STUDY TEAM ONLY

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Name of Person Conducting Informed Consent Discussion

____ ____________________
Signature of Person Conducting Informed Consent Discussion **Date** **Time**