COVER PAGE

Official Title: A Text-Based Adherence Game for Young People Living with HIV in Ghana

NCT #: 1227391

Document Date: May 3, 2021

Document: Consent Form

Komfo Anokye Teaching Hospital Institutional Review Board
Research & Development Unit
P.O. Box KS 1934, Kumasi, Ghana
Tel: +233 3220 00617. Email: kathirb@kathhsp.org or kathirb25@gmail.com

Participant Information Leaflet and Consent Form

Informed consent form (patient participants) in the randomised pilot trial

Title of Research: A text-based adherence game for young people

Name(s) and affiliation(s) of researcher(s): This study is being conducted by Drs. B. Norman and A. Enimil of the Komfo Anokye Teaching Hospital, Kumasi and Dr. N Tarantino of Rhode Island Hospital, Providence, RI, USA.

Background: You are being invited to take part in this research project because you are a patient at the *HIV Clinic* and between the ages 18 to 24. This study is about developing a text message game to help young people at the clinic with their treatment.

Purpose(s) of research: The purpose of this study is to determine what young people think of our text message game and whether it helps them with their treatment. We will use this information to make the game better.

Procedure of the research: You will be asked to complete a computerized questionnaire that asks about your background, treatment, and health three times during the next 12 months. This questionnaire takes 60 to 75 minutes to complete. Staff will also check your clinic record for relevant health information. If you do not have viral load test results on file from the past 3 months, clinic staff will request a test as part of your routine clinical care. Clinic staff may also request drug resistance testing, if clinically indicated. In addition, we will call you two other times during the study to ask similar questions. These calls will take 5-10 minutes. Finally, you will speak briefly with our research staff about ways to improve your treatment.

You may receive text messages as part of the study. These messages are part of the game we created. The game's purpose is to have fun, help you with your treatment, and connect you with people who support you (e.g., family, clinic staff, or peers). Other young people at the clinic with your health issue will be playing the game too. The researcher will tell you whether you were assigned to receive or not receive texts messages. This assignment is random, like flipping a coin.

If you are assigned to receive messages, researchers will enter your personal mobile phone number into a computer program. The program will then automatically send you text messages as part of the game. You may also receive text messages from research staff. The messages could be daily or less frequent. The messages will ask about your medicine or doctor's appointments. You may also be sent messages about health practices including sexual health. In addition, the messages will contain bits of a story to make the game more fun. You will choose a character name to represent you in the game. Answering questions will earn your character points. Researchers will text all players with updates on who is leading the game. You will also have the option of enrolling a treatment monitor. This can be a friend or family member who is aware of your health status and agrees to help you with your treatment. This person will be sent occasional text messages too. These messages may

include your mobile phone number so they can contact you. If you decide to participate, game rules will be explained in more detail. The game will run for six months.

Risk(s): The risks in this study are considered minimal, although there is the potential for a breach of confidentiality. You may also feel uncomfortable answering questions related to your treatment or health. You may refuse to answer any questions that make you uncomfortable.

Benefit(s): Although you may not directly benefit from participation in this study, the information we gain will be used to develop a text message game which may improve treatment for other young people with similar health issues.

Confidentiality: Every effort will be made to keep the information we learn about you private and confidential. To protect your information, you will be given a Personal Identification Number, or PIN. Only study staff will have access to your information. Demographic information will be stored on a password-protected computer. Your mobile phone number used in the game will be stored an encrypted and password-protected server. Only research staff will have access to this number. Other game participants will not have access to your information.

The text messages sent as part of the game will never contain direct information about your name, health issues, health clinic, or treatment. Code words will be used instead. For example, we might say "candy" instead of the name of your medication. You are encouraged to password protect your phone, if possible. This helps keep the game private. Please be aware that it is still possible that someone could see your phone and ask questions about what the game is about.

Study staff, the study sponsor (National Institute of Health), the United States Office for Human Research Protections (OHRP), and the Institutional Review Boards at Rhode Island Hospital, Kwame Nkrumah University of Science and Technology, and Komfo Anokye Teaching Hospital may review study records to provide ethical oversight.

The results of the study may be published in the future. However, all personal information will remain anonymous.

Voluntariness: Taking part in this study should be out of your own free will. It is up to you whether you want to be in the study. You are not required to participate.

Alternatives to participation: If you choose not to participate, this will not affect your treatment at the *HIV Clinic* in any way. This study is not a treatment study. If you choose not to participate in this project, there is no alternative therapy available. Information can be provided to you in a pamphlet, if requested, even if you decide not to be a part of this study.

Withdrawal from the research: You may choose to withdraw from the research at any time without having to explain yourself. You may also choose not to answer any question you find uncomfortable or private.

Consequence of Withdrawal: There will be no consequence, loss of benefit or care to you if you choose to withdraw from the study. Please note however, that some of the information that may have been obtained from you without identifiers (name etc), before you chose to withdraw, may have been modified or used in analysis reports and publications. These cannot be removed anymore. We do promise to make good faith effort to comply with your wishes as much as practicable.

Costs/Compensation: For your time, inconvenience, and transport to the hospital, we will compensate you with GH¢40.00 for each computerized assessment you complete to show our appreciation for your participation. You will also receive two phone credits worth GH¢80.00 each to pay for text messages and calls received as part of this study.

Contacts: If you have any question concerning this study, please do not hesitate to contact Dr. Norman on 207 064699.

Further, if you have any concern about the conduct of this study, your welfare or your rights as a research participant, you may contact:

The Office of the Chairman
Committee on Human Research and Publication Ethics
Kumasi
Tel: 03220 63248 or 020 5453785

CONSENT FORM

Statement of person obtaining informed consent:
I have fully explained this research to _____ and have given sufficient information about the study, including that on procedures, risks and benefits, to enable the prospective participant make an informed decision to or not to participate.

DATE: _____ NAME: _____

Statement of person giving consent:
I have read the information on this study/research or have had it translated into a language I understand. I have also talked it over with the interviewer to my satisfaction.

I understand that my participation is voluntary (not compulsory).

I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it.

I understand that I may freely stop being part of this study at any time without having to explain myself.

I have received a copy of this information leaflet and consent form to keep for myself.

NAME:_____

DATE: _____ SIGNATURE/THUMB PRINT: _____

Statement of person witnessing consent (Process for Non-Literate Participants):

I _____ (Name of Witness) certify that information given to

_____ (Name of Participant), in the local language, is a true reflection of what l have read from the study Participant Information Leaflet, attached.

WITNESS' SIGNATURE (maintain if participant is non-literate): _____

MOTHER'S SIGNATURE (maintain if participant is under 18 years): _____

MOTHER'S NAME: _____

FATHER'S SIGNATURE (maintain if participant is under 18 years): _____

FATHER'S NAME: _____