Cover Page

Participant Consent Form

Study Title: AllyQuest Adherence App Intervention for HIV-positive Men Who Have Sex With Men and Transgender Women: Pilot Trial (AQ2)

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University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
Participants age 15 – 29 years (Aim 2)

IRB Study # 18-2061

Consent Form Version Date: 23 June 2021

Title of Study: Piloting a Sequential Multiple-Assignment Randomization Trial to evaluate AllyQuest: an mHealth intervention for HIV-positive young MSM and TWSM to optimize HIV medication adherence and care outcomes

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CONCISE SUMMARY

This purpose of this research study is to understand how an app can improve medication adherence for young men and transgender women living with HIV.

If you enroll in this phase of the study you will first take a survey, and download the app onto your phone. A viral load measure will be collected by one of the following methods: 1) from your medical chart, 2) an in-person blood draw, 3) a self-collection kit mailed to your home, or 4) if you have the results from a recent viral load test (for example, paper copy or in your online health portal), you can show us those results or take a screenshot and upload it to a HIPAA-compliant website. After enrollment, you will use the app for ~5 minutes every day.

Three and six months after your initial study visit, you will have follow-up visits which can take place in-person or remotely. At these visits you will take a survey and a viral load measure will be collected by one of the following methods: 1) from your medical chart, 2) an in-person blood draw, 3)a self-collection kit mailed to your home, or 4) if you have the results from a recent viral load test (for example, paper copy or in your online health portal), you can show us those results or take a screenshot and upload it to a HIPAA-compliant website.

At least one time during the study, you will be asked to prick your finger and collect your blood onto a paper card which you will mail to the study staff. You may also be asked to take part in an interview to tell us your thoughts about the app.

Participating in this study may bring up emotions, as you'll be asked to talk about things that may be difficult or sensitive to you. You are free to share as much or as little as you are comfortable with. There is a minor physical risk of pain, discomfort or injury from up to three blood draws or three finger pricks that are part of this study. The blood draw procedures are the same as your standard clinical care. The finger prick will feel similar to touching the top of a pin or sewing needle.

If you are interested in learning more about this study, please continue reading below.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study at any time, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You can ask the researchers named above, or study staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

Rates of HIV are high among young men and transgender women, and we want to address this by helping to provide tools one would need to engage in care and find social support. The purpose of this study is to test a smartphone app for young men and transgender women living with HIV to improve their adherence to antiretroviral therapy (ARTs), the medication(s) used to treat HIV. This phase of the study is to test if an app can improve adherence, and how support from an adherence counselor impacts adherence.

How many people will take part in this study?

If you decide to participate, you will be one of approximately 75 people in this phase of the study. You may also be one of up to 25 people selected to participate in an interview after six months of using the app.

How long will your part in this study last?

Participation in the study lasts six months. Participating in the study involves an initial meeting (about 3 hours) with study staff to enroll in the study. This can be done remotely or in person. You will take a survey, download the app on your phone, get a tour of the app, and a viral load measure will be obtained.

Then you will use the app on your phone for six months. The app is meant to be used every day, for about 5-10 minutes. Some participants will have access to a coach, who they can talk to through the app. After three months, you will do an online or in person follow-up visit (about 1 hour) where you will take another survey and a viral load measure will be collected again. Another in person or online follow-up visit (about 1 hour) will be done after another three months (six months from the first visit) where you will take a survey and a viral load measure will be collected.

Your follow-up study visits can be done remotely or in person, depending on your preference and whether or not you have a recent VL in your medical record. You may also be selected to participate in an interview after your six-month study visit (~1 hour).

What will happen if you take part in the study?

If you agree to take part in this study, you will meet with a member of the study team either in person or remotely via a videoconferencing platform such as Zoom to conduct a 3 hour in-person session with you. You will take a survey and they will help you to download the app and introduce you to the app features. There will be two versions of the app. Both versions of the app will allow you to log your medications and learn more about staying healthy, but one version also has a coach that you can text with about your medication adherence or for other support. You will be randomly assigned to one version of the app or another. If you have had a viral load test (VL) within the last year, a VL measure will be collected from your medical chart. If you have access to your online health portal or a paper copy of your test results, you may also show us a VL test result from within the last year in person or over a video call, or take a screenshot of the VL results and upload it to a secure website. If you have not had a VL test in the last year, we will collect an in-person blood draw from you at our site or an external lab to test your VL or send you a self-collection kit mailed to your home where you will collect blood by pricking your finger to measure your VL.

After three months, you will have a follow-up appointment which can be in-person or remote. You will take a survey and we will collect a VL measure from your medical chart if you have had a VL test within the two months before your visit. If you have access to your online health portal or a paper copy of your test results, you may also show us a VL test result from within the two months before your visit in person or over a video call, or take a screenshot of the VL results and upload it to a secure website. If you do not have a VL in your medical chart from the past two months, we will collect an in-

person blood draw from you at our site or an external lab to test your VL or send you a self-collection kit mailed to your home where you will collect blood by pricking your finger to measure your VL. If you have not done a mail in blood collection kit yet, you will be mailed one after your 3 month visit.Around your 3 month visit, you may be re-assigned to receive the other version of the app (with or without the counselor), or you may continue with the version that you have been using. You will be notified of this change by a pop-up message in the app. In either case, you will still be able to see the medications you have logged so far and continue tracking your medications.

After six months, you will have another follow-up appointment in person or remotely to complete another survey and we will collect a VL measure from your medical chart if you have had a VL test within the two months before your visit. If you have access to your online health portal or a paper copy of your test results, you may also show us a VL test result from within the two months before your visit in person or over a video call, or take a screenshot of the VL results and upload it to a secure website. If you do not have a VL in your medical chart from the past two months, we will collect an in-person blood draw from you at our site or an external lab to test your VL or send you a self-collection kit mailed to your home where you will collect blood by pricking your finger to measure your VL. You may also be asked to participate in an interview with study staff to understand your experiences using the app. Interviews will be audio recorded and members of the study team will transcribe and analyze the tapes from the recorded interview sessions.

What are the possible benefits from being in this study?

Personal benefits may or may not include helping you remember to take your medication and go to clinic visits, and improved well-being. Research is designed to benefit society by gaining new knowledge. You may not benefit personally from being in this research study. However, your participation may increase the type of resources other young men and transwomen have access to that may better help them protect their health and the health of others like them.

What are the possible risks or discomforts involved from being in this study?

You will be using the app today and over the next six months. Other participants in the study will also be using the app during this time. On the social wall of the app you will be able to see what other participants post and they will be able to see what you post. Study staff monitor posts to the social wall every day to make sure that all posts follow the app's terms of use which prohibit hostile or abusive language. Posts that do not follow these rules will be removed. However, it is possible that you will read a post that you disagree with or that offends or upsets you. You are not required to post to the social wall and you may alert the study staff if you see a post that you think does not follow the app's terms of use.

During the study, you will be asked questions about yourself and your thoughts on the app. Some of these questions may be sensitive and you may not want to answer them. You can choose to answer the questions you feel comfortable answering.

You may also be given the option to refer members of your social network to participate in the study. This is voluntary. If you choose to do so, it may cause some embarrassment or discomfort. To avoid this, we will explain to you on how to present the referral coupons to your friends and acquaintances in a way that minimizes disclosing private information about yourself.

You may potentially experience pain, discomfort or injury from the blood draw and finger stick testing in this study. The blood draws will follow the same procedures as your standard clinical care. The finger prick for self-collected blood draw may hurt for a few seconds right after sticking your finger. The feeling may be similar to touching a pin or sewing needle.

We make every effort to ensure mailed home blood collection kits are packaged discreetly. However, there is the risk that someone in your home could see the kit.

If you are asked to participate in an interview after six months of using the app, your voice will be recorded. Participating in an interview is voluntary. Your name will not be recorded and the recording will only be used by research team members. The recording is kept in a locked, secure computer server and is only available to select study staff. After the study is over, the recording will be destroyed. You may choose to have your interview not recorded.

We will make every effort to protect your confidentiality by keeping the data or personal information you provide in locked files or secure computer servers and the app is password protected. However, there is a small possibility that your HIV status or other personal behaviors could become known to others, for example, if someone sees the app on your phone. For this reason we recommend turning on a password or lock feature to your main phone while you are in this study. You will have a unique password-protected login to access the app, and you will use the app with a username that does not identify you.

How will your privacy be protected?

Every effort will be taken to protect your identity as a participant in this study. The information you share and any clinical data such as your VL results are confidential. You will not be identified by name in any report or publication of this study or its results. Instead, you will be known only through a study ID number to accurately interpret and analyze the data. You will also only be identified using a study ID number if you participate in the interview process. This will allow the researchers to prepare a transcript of the audio recorded interviews following the session. Your name will not appear on any transcripts; instead, we will only use your study ID number. Any data linking your name to your study ID number will be kept in a locked cabinet in our private office. After the audio recording has been transcribed, it will be kept in a locked server folder and will be destroyed at the close of the study.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be

reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

Every effort will be made to keep your participation in the study and any personal information about you private and confidential. However, absolute confidentiality cannot be guaranteed. For example, if a study staff member learns something that would immediately put you or others in danger, the study staff member is required by law to take steps to keep you and others safe. This means that study staff members have to report to the authorities (hospital, police, or social services) any information you say that suggests that you might be in danger, such as telling study staff that you plan to hurt or kill yourself, hurt or kill someone else, or if someone is abusing or neglecting you.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Will you receive anything for being in this study?

You can receive up to $420 for completing all required study activities. Some individuals may receive up to an additional $100 for participating in optional study activities. The amounts for all study activities are described below:

Required study activities:

Study visits: You will receive $75 after enrollment and taking your baseline survey in today's session, $50 after you do the follow-up survey at the 3-month visit, and $50 after you do the follow-up survey at the 6-month visit. If you complete all 3 study visits, you will receive an additional $50 bonus after you do the follow-up survey at the 6-month visit.

Self-collection blood sample: You will also have the opportunity to earn $25 for each (up to 3 times) self-collected blood sample.

Intervention App use: In this study you are asked to use the study app every day for approximately 5 – 10 minutes. As part of this study's testing how to support forming daily habits, you will have the possibility of earning between $0 and $120 based on how much you use the app. At your 3-month study visit, you will receive an amount between $0 and $60 that corresponds to how much you used the app during the first 3 months of the study. Each day that you do at least one activity in the app (for example, read an article, log your medications, post to the social wall) you will move closer to the maximum amount of $60. Each day that you do not do any activities in the app you will move closer to the minimum amount of $0. You will be able to track your daily progress toward this amount through your app's homescreen. Similarly, at your 6-month study visit, you will receive an amount between $0 and $60 that corresponds to how much you used the app during the second 3 months of the study (study months 4 to 6). If you use the app every day during your 6-month time in the study, you will receive the total amount of $120.

Optional study activities:
Exit interview: Up to 25 people will be selected to participate in an exit interview. If you are selected for an exit interview at your 6-month study visit, you will receive $50 for completing the interview.

Referral coupons: You may also be given the option to refer members of your social network to participate in the study. For each person you recruit who screens eligible and completes initial enrollment steps, you will receive an incentive of $10. You will receive this $10 incentive for up to 5 of these referrals for a maximum of $50.

Will it cost you anything to be in this study?
There will be no costs for being in the study.

Who is sponsoring this study?
This research is being sponsored by the University of North Carolina at Chapel Hill and funded by the National Institutes of Health (NIH). This means that the sponsor, the University of North Carolina at Chapel Hill (UNC-CH), is providing money from NIH to each site to help conduct this study. The intervention that is being tested in this study was developed through a collaboration between Ayogo Inc. (a private for-profit technology company) and UNC. Ayogo Inc. may have rights to parts of the intervention being used in this study. If this intervention is successful at some point in the future, Ayogo Inc. may receive financial benefits. However, there are no plans to compensate you for any future commercial use of this intervention.

A review of these arrangements was conducted at UNC. It was concluded that any direct possible benefit to the person(s) listed above is remote. Based on this information, your participation in this research study is not likely to affect either your safety or the scientific quality of the study. If you would like more information, please ask the researchers listed in the first page of this form.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research at any time before, during or after your participation. If you have questions, or concerns, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the UNC-CH Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

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IRB Study # 18-2061

Title of Study: Piloting a Sequential Multiple-Assignment Randomization Trial to evaluate AllyQuest: an mHealth intervention for HIV-positive young MSM and TWSM to optimize HIV medication adherence and care outcomes

Principal Investigator: Kate Muessig, PhD

Participant's Agreement (for online assent/consent)
If you select yes below to the first question, you are voluntarily agreeing to take part in this research study.

Do you agree to participate in the study?

- ○ Yes, I agree to participate in the study.
- ○ No, I do not agree to participate in the study.

OR

Participant's Agreement (for online assent/consent)

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

_____

Electronic Signature of Research Participant

OR

IRB Study # 18-2061

Title of Study: Piloting a Sequential Multiple-Assignment Randomization Trial to evaluate AllyQuest: an mHealth intervention for HIV-positive young MSM and TWSM to optimize HIV medication adherence and care outcomes

Principal Investigator: Kate Muessig, PhD

Participant's Agreement (for in-person assent/consent):

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent