AIM 3 – RCT ASSENT/CONSENT

SRV Site Name
Assent/Consent to Participate in a Research Study
Participants age 15-24 years

UNC IRB Study # 16-3136

Assent/Consent Form Version Date: Version 1.3 dated 08-March-2021

Title of Study: ATN 138 - Connecting Youth and Young Adults to Optimize ART Adherence: Testing the Efficacy of the YouTHrive Intervention

Site Principal Investigator:
Site Principal Investigator Phone number:
Site Principal Investigator Email Address:

Sponsor: The University of North Carolina at Chapel Hill (UNC-CH)

Funding Source: National Institutes of Health (NIH)

Study Contact:
Study Contact telephone number:
Study Contact email:

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 assent/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 assent/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. By signing this form, you will not give up any of your legal rights.

What is the purpose of this study?
The purpose of this study is to understand ways in which technology can be used to support young people living with HIV. If you are eligible and agree to participate, you will receive access to online information, activities, and resources related to your health and well-being, as well as common problems that young people living with HIV face. You will have access to these online resources, either through the YouTHrive e-newsletter or through the YouTHrive website, for about 5 months.

How many people will take part in this study?
If you decide to participate, you will be one of approximately 300 people in this part of the study.

How long will your part in this study last?
You will be involved in the study for about five months. After your initial meeting today, you will return for in-person or online study visit in 5 months. Online visits will take place over a secure video chat platform. For online enrollment visits, you will meet with research study staff over secure video chat or the phone and they will guide you through the visit.

What will happen if you take part in the study?
If you choose to be in the study, you will be asked to sign this assent/consent form before you begin the study. This initial visit will last about 90 minutes.

Study staff will collect information from your medical record chart beginning from 60 days before the date you enroll in the study until the end of your study participation. We will also ask you to sign a medical records release form to collect information from any other clinics or providers in which you receive HIV care. The study staff will collect information such as the date of your HIV diagnosis, your viral load test dates and results in the past 12 months, your CD4 cell count test dates and results in the past 12 months, your HIV genotypic resistance test dates and results in the past 12 months, dates and attendance of your HIV care visits/appointments, and your antiretroviral therapy (ART) medications. This information will be protected in the same way the information from your medical record is protected. If you decide not to sign a medical records release form, you can still participate in this study.

As part of this study, we will collect a viral load measure from you at the time of enrollment, and the 5 month study visit. If you have had a viral load test within 60 days prior to each study visit, we will obtain the viral load test result from your medical record. You may also log into your online health portal and show us the viral load test results in person or over a secure video conferencing platform.

If you do not have a recent viral load test in your medical chart for us to record at the time of the enrollment, and the 5 month study visit, then we will collect a viral load measure through one of these ways: 1) conduct a blood draw during an in-person visit at our site; 2) we will mail you a self-collection kit to your home where you will collect blood by pricking your finger and mail the sample to a lab in a pre-paid mailer; or 3) you may go to an external lab to get a blood draw in person. The result of this viral load test from blood draw may be added to your medical record. In-person blood draw will take about 5-10 mL (about 1-2 teaspoons) of your blood to determine your current viral load.

After you have provided your assent/consent, you will give the study staff a list of ways to contact
you, such as your e-mail address and phone number, as well as the phone number of a relative or friend who knows how to get in contact with you. Study staff will not leave phone messages unless you give permission. The study staff will also not tell your relative or friend anything about this study, your participation in the study, or give any information about you unless you give permission. Your contact information will be used to remind you to come in for your study visits and to help you with transportation to your study visits, if needed. You also can choose not to give any information that you do not want to give. However, we ask that you give the study staff at least one form of communication to contact you.

The following is the schedule of study visits and what will be done at each visit:

Today: 1st study visit

1. You will meet with research study staff in person, over secure video chat, or over the phone and they will guide you through the visit. You will review and sign the consent or provide your consent.

2. You will be asked to answer questions on a computer or a tablet by yourself in an assessment room (if completing today's visit in person) or on an internet-capable device that you have access to if you are answering the questions in a private area of your choice. The survey will take about 35-45 minutes and we will ask you questions about living with HIV, ART medications, how you are feeling (for example, mood and level of social support), substance use, internet use, and general information about yourself (race, ethnicity, income, education).
3. If you are randomly assigned to use the YouTHrive (YT) website (meaning you have a 50/50 chance like flipping a coin of being in this group), a study staff member will give you a unique username and password for the YT website, and take you on a brief tour of the website. You will have the opportunity to ask questions about YT. Please use as many of the website features as possible. You may use the website on a computer, smart phone, or both.
4. If you are randomly assigned to the YouTHrive e-newsletter (meaning you have a 50/50 chance like flipping a coin of being in this group), you will receive the newsletter in the form of an email or text once a week. The email or text will contain a link that you can click on. During today's visit, you will be shown examples and be asked whether you would prefer to receive links to the newsletters by email or text message.
5. We will collect a viral load measure from your medical chart (if you have a viral load in your medical record in the past 60 days), or through one of the other ways discussed above.
6. For in-person visits, we will collect a urine sample from you to determine recent drug use to determine whether study results are different or not by drug use. The results of this test are for research purposes only and will not be entered into your medical record. For online visits, we will not collect a urine sample for drug testing.

About five months from today: 2nd study visit

1. You will meet with research study staff in person, over secure video chat, or over the phone and they will guide you through the visit.
2. You will be asked to answer questions on a computer or a tablet by yourself in an assessment room (if completing this visit in person) or on an internet-capable device that you have access to if you are answering the questions in a private area of your choice. The survey will take about 35-45 minutes and we will ask you questions about living with HIV, ART medications, how you are feeling (for example, mood and level of social support), substance use, internet use, and general information about yourself (race, ethnicity, income, education).
3. We will collect a viral load measure from your medical chart (if you have a viral load in your medical record in the past 60 days), or through one of the other ways discussed above.
4. For in-person visits, we will collect a urine sample from you to determine recent drug use to determine whether study results are different or not by drug use. The results of this test are for research purposes only and will not be entered into your medical record. For online visits, we will not collect a urine sample for drug testing.
5. You may be offered the opportunity to participate in a short optional interview with clinic study staff about your experience for additional compensation.

What are the possible benefits from being in this study?

You will not receive any direct benefit from being in the study. The information learned from this study will assist us in learning about how programs, like YT, may be most helpful to young people like you.

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

You may feel uncomfortable or embarrassed by providing information about your HIV status, drug use, or other information while answering surveys or speaking with research staff. You are free to provide as little or as much information as you like during the survey. If any of the topics on the survey make you uncomfortable or if you find something upsetting, you can stop at any time, and we can refer you to a counselor who may be able to help you.

You may also be given the option to refer members of your social network to participate in the study. This may cause some embarrassment or discomfort. To avoid this, we will train you on how to present the coupons to your friends and acquaintances in a way that does not require disclosing any private information about yourself.

Drawing blood or pricking your finger may cause mild discomfort, bruising, or bleeding. Rarely people faint as a result of blood draws.

Potential risks of loss of confidentiality. There is some potential risk of disclosure of your HIV status or other personal behaviors if someone sees the website or newsletters on your phone, tablet, or computer. You will have a unique password-protected login to access the website and the connection will time out after a period of inactivity. The default text message is a generic text message that will serve as a weekly reminder, but will not contain any text about "medications," "dose," or "HIV." We will never collect information from you via SMS.

If you are assigned to use the YouTHrive website and you choose to upload a photo of yourself as your profile picture, there is the risk that others could recognize you, learn your HIV status, and learn that you are participating in the YouTHrive study. There is also the risk that other users could screenshot your photo. If you do not want to have your picture as your profile picture, you may choose one of many different avatars as your profile picture.

There is a chance that some users could engage in hostile communication in posts or comments. We will post general rules for using the website from the home page. Participants will be able to flag content that they feel is hostile or inappropriate from other users. The YT website will be monitored daily by research staff. Posts that are considered hostile may be removed by study staff. Additionally, if participants continue to engage in hostile communication, they may be removed from the study.

We will make every effort to protect your confidentiality, but there is a small possibility that your name or HIV status could become known to others.

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

You will be informed if the study staff learns of any new risks.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions, have undermined the right or privacy of another participant, or because the entire study has been stopped.

How will your privacy be protected?

Your participation in this study will be kept confidential and private as permitted by law. This includes information you provide on the survey, the audio and video recording of the interview, and anything you enter on the YT website.

Every effort will be taken to protect your identity as a participant in this study. 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. Any data linking your name to your study ID number will be kept in a locked cabinet in a locked room at the study site, but separate from where your study records are stored. Staff members involved in this study are required to sign a form stating that they will protect and keep private all information on every person in the study.

Some personal information, such as your name or birthdate, may be shared with the lab processing your blood sample.

No subjects will be identified in any report or publication about this 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, SRV site name 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 SRV site name, the University of North Carolina at Chapel Hill (UNC-CH), research sponsors, or government agencies for purposes such as quality control or safety.

At the end of the study, all of your information from the study will be coded and stored at Emory University in Atlanta, Georgia.

A description of this study will be available on http://clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can access this website at any time.

To help further protect your privacy, the Adolescent Trials Network (ATN) has obtained a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). It adds special protection for research information that identifies you. It says that we do not have to identify you, even under a court order or subpoena. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

Still, we may report medical information (if you need medical help), probable harm to yourself or others, or probable child abuse or neglect, and the government may see your information if it audits us. This Certificate does not mean the government approves or disapproves of our project. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written assent/consent to receive research information, then the researchers may not use the Certificate to withhold that information.

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.

In addition, your records may be reviewed by certain agencies or people who make sure that the study staff are doing what they are supposed to and everyone in the study is being protected. Under the guidelines of the Federal Privacy Act, the sponsoring agency at the National Institutes of Health (NIH) and the UNC-CH IRB may look at your records. If your study records are reviewed, your identity could become known to them. However, these persons are expected to maintain your individual confidentiality. This means that they will not tell others information about you or that you are in the study. By signing this form, you are allowing such access.

[Insert SRV site-specific HIPAA language unless SRV uses stand-alone HIPAA authorization form]

Will you receive anything for being in this study?
You will be compensated the following for each study activity to help cover the cost of your time:

- Enrollment visit: $75
- 5-month visit: $75

If you complete all of the study activities listed above, you will receive a total of $150.

If you are asked to participate in an online interview during the 5-month visit and choose to do so, you will receive an additional $50 incentive.

You may be asked to complete a blood self-collection kit at some of the study visit time points (enrollment and 5 months), particularly for online study visits. You will receive $25 each time you return the kit (up to 2 times). This would be in addition to the study visit compensation amounts listed above.

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.

Are there any costs to you for taking part in this study?
You will not be charged for anything that is done for this study. This includes study visits and use of the study intervention (YT) site. You or your health insurance company will have to pay for any medical care that is not part of this study, as you would usually do.

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 SRV site name to help conduct this study. The researchers do not, however, have a direct financial interest with the sponsor or funding source or in the final results of the study.

What if you are an employee at SRV site name?
Taking part in this research is not a part of your job duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

[If applicable to SRV] What if you are a student at SRV site name?

You may choose not to be in the study or stop being in the study before it is over at any time. This will not affect your class standing or grades at SRV site name. You will not be offered or receive any special consideration if you take part in this research.

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 any questions, please 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 University of North Carolina at Chapel Hill (UNC-CH) Institutional Review Board (IRB) at 919-966-3113 or by email to IRB_subjects@unc.edu.

UNC IRB Study # 16-3136

Title of Study: ATN 138 - Connecting Youth and Young Adults to Optimize ART Adherence: Testing the Efficacy of the YouTHrive Intervention

Site Principal Investigator:

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

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 Research Team Member Obtaining Assent/Consent Date

_____
Printed Name of Research Team Member Obtaining Assent/Consent