COVER PAGE

Official Study Title: Feasibility of Positive Links for Youth Care Engagement Intervention

NCT number: NCT05689515

IRB Approval Date: 05.04.2023

Unique Protocol ID: HSC20220752H

Concise Summary

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with us.

1. What problem is this study trying to solve?
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future**.**

We are studying whether use of a mobile smartphone application (an App) helps 18 to 29-year-olds living with HIV achieve success in with their HIV care and feel supported by their clinic community.

For more information, please see the *Why is this Study being Done* section below.

2. What will happen to me during the study and how is this different from continuing with usual care? What are all my options for treatment, including the pros and cons?

Should you agree to participate in the study, you will be assigned to either the App group or a regular care group. If you are in the regular care group, you'll continue to see your health care providers and meet with a member of the study team three times over a year. If you are assigned to the App group, you'll continue to see your health care providers, receive access to an application (App) to use on your smartphone, and meet with a member of the study team three times over a year. You will be taught how to use this App, which contains appointment reminders, a secure group chat function with other participants, as well as your medical lab results, among other features.

Participation in the study will not change your care in the clinic or medications. Those will continue to be guided by your provider.

For more information, please see the ***What will be done if you decide to be in the research*** section below.

3. How much time will I spend on the study?

You will meet with us for 5 visits while in the study, 1 baseline visit (initial), 2 follow-up visits at 6 months and 12 months and 2 check-in visits at 3 months and 9 months. For the baseline and follow-up visits, you will be asked to answer questions and to complete some questionnaires; further details are provided in the procedures section. These visits should each take about one hour. For the check-in visits, the App group, will complete the visits through messaging in the App. The Control group, will complete the visits by via phone call to check in. At your initial and 12-month visits, if you have not had a viral load checked within the last 2 months, we will complete a research blood draw (blood volume of 2 mL, approximately half a teaspoon). For participants in the App group, you will be asked to use the App to engage with providers and with the virtual support group. The amount of time you spend on the App is up to you. Your participation in the study will last for approximately 12 months.

4. **Could taking part in the study help me and are there risks?**

Participants assigned to the App group may receive support from the App community, but there is no guarantee that you will receive any benefit from being in this study. There is a risk of loss of confidential information gathered as part of the study. We take several measures to ensure this will not occur, including password encryption of the files and providing access only to study team members.

For more information, please *see **How could you or others benefit from your taking part in this study*** section below. For details and a list of risks you should know about, please see the ***What are the risks of participation in the research*** section below.

5. What else should I consider before I make my decision?

If you do not have a smartphone, one can be provided for you during the 12 months of the study. It will need to be returned upon completion or discontinuance of the study.

There is compensation for study participants; please see the payments section for more details.

Please review the rest of this document for additional details about these topics and other information you should know before making a decision about participating in this research.

Consent to be part of a Research Study
To be conducted at
FFACTS Clinic
University of Texas Health Science Center at San Antonio (UT Health San Antonio)
and University Health

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety, and welfare as a participant in the research. The PI for this study is Dr. Barbara Taylor, MD, MS, affiliated with UT Health San Antonio, Texas.

Funding
The National Institute of Mental Health of the National Institutes of Health, a federal agency that promotes scientific research, is funding this study. This organization is providing money to UT Health San Antonio so that the researchers can conduct the study.

Purpose of this study – "Why is this study being done?"

A greater proportion of youth living with HIV face challenges when it comes to keeping up with their clinic visits, taking medications, etc. We are testing a smartphone app that can provide support with appointment and medication reminders, resources, communication with providers, and an anonymous virtual group chat for support. You are asked to participate in this research study of the smartphone app for youth living with HIV.

The researchers hope to learn whether usage of the smartphone app will be helpful in supporting 18–29-year-olds in their care. This study will compare the effects, good and/or bad, this smartphone app has on people who use it, and on HIV care outcomes, in comparison to those that do not use the app.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you are an individual 18–29 years of age with HIV who has either been recently diagnosed or has had trouble engaging with HIV care in the past.

How many people are expected to take part in this study?
This study will enroll approximately 60 study participants. Forty participants will be in the App group, and twenty will receive regular care and come in for three visits.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to attend approximately five research study visits with the researchers or study staff. Each visit will last approximately one hour, or add an hour to a routine visit.

It may be necessary for you to return to the hospital/clinic every 6 months. We will attempt to make the study visits in conjunction with the routine standard of care visits you have with your provider.

When it is determined that you are eligible for the research study, you will be assigned by chance (like flipping a coin) to one of two study groups.

- The first group will continue with their routine care with their provider and attend 5 study visits.
- The second group will be given access to the app, in addition to their routine care and 5 study visits. Information on the smartphone app and how to use it will also be provided. This group will continue using the app throughout the study period.

Research Study Procedures – as a participant, you will undergo the following procedures:

Time commitment per visit is as follows:

	Visit 1 (baseline)	**Visit 2** (3-month check-in)	**Visit 3** (6-month follow-up)	**Visit 4** (9-month check-in)	**Visit 5** (12-month follow-up)
Informed Consent	10 min	-	-	-	-
Demographics Questionnaire	5 min	-	-	-	-
Randomization	5 min	-	-	-	-
App Training	0-10 min (only for those randomized to app)	-	-	-	-
Patient Health Questionnaire-9 (PHQ-9)	5-10 min	-	5-10 min	-	5-10 min
Self-Efficacy (SEMCD) Questionnaire	5 min	-	5-10 min	-	5-10 min
PYD Sustainability Scale Questionnaire	10 min	-	10 min	-	10 min
Substance Abuse/Mental Illness Screener Questionnaire	5-10 min	-	5-10 min	-	5-10 min

HIV-Associated Stigma Screener Questionnaire	5-10 min	-	5-10 min	-	5-10 min
System Usability Survey	-	-	5-10 min	-	5-10 min
Check-In Questionnaire	-	5-10 min	-	5-10 min	-
TOTAL TIME COMMITMENT	~75 min	5-10 min	30-60 min	5-10 min	30-60 min

In addition to the in-person visits listed above, there will also be a "check-in" visit conducted at 3 months and 9 months. For the Control group, this will consist of a telephone call to ask how you're doing, if you're still engaged in care, how you're doing with your medication, and if you need any resources from us. This should last about 10 minutes. For the Intervention group, this will consist of a message in the App.

Conditional Procedure:

Laboratory Testing: HIV Viral Load testing

- This test will only be done if previous results from standard of care treatment are not already available within 60 days of Visit 2 (6-month follow-up) and/or Visit 3 (12-month follow-up).
- The blood volume obtained for research will be 2 mL, or about half a teaspoon.
- 5-minute time commitment

Future Use of Your Information or Biospecimens Collected as Part of Your Participation

Identifiers may be removed and the de-identified information could be used for future research studies or distributed to another investigator for future research studies, without additional informed consent from you or your legally authorized representative.

Return of Research Test Results for Genetic Tests to Subjects

It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. If you request, we will provide your viral load information to your HIV care team.

Pregnant person Follow-up
If you become pregnant during your participation in this research study, you will be asked to sign a separate consent form for continued participation.

Texting - The research team would like to communicate with you regarding your participation via text message. These messages may include information related to your participation in the study and payment information, if applicable. In order to do this, we will share your name and phone number with Tinger Connect within UT Health San Antonio RedCap. Standard text messaging rates will apply if you do choose to receive the text messages.

Ending Participation Early

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- You do not follow instructions from the researchers.
- The study is stopped.

The researchers will discuss your options for medical care when your participation in this study ends.

Risks – "What are the risks of participation in the research?"

The frequency that people experience a certain side effect can range from rarely to very likely, and risks may be classified as not serious to very serious. The possible risks for this study, along with their severity and likelihood, are outlined below.

Risks and Discomforts

Risks associated with drawing blood
Blood will be drawn by inserting a needle into one of your veins.
Likely (20-30 subjects out of 100) and Not Serious:
- Temporary mild pain/tenderness or discomfort
- Bruising at the site of the blood draw

Less Likely (5-10 subjects out of 100) and Not Serious:
- May feel faint, dizzy, or lightheaded
- Infection may occur

Risks associated with questionnaires
Less likely (less than 5-20 subjects out of 100) and Not Serious:
You will be asked to complete questionnaires concerning mental health, self-efficacy, social support, and general demographic information. As a result, you may be asked questions that are uncomfortable to answer. You do not have to answer these questions if you choose not to.

Risks associated with data breaches
Rare (less than 5 subjects out of 100) and Serious:
Confidential information will be gathered as part of the study. There is a risk of loss of confidential information. We take several measures to ensure this will not occur, including password encryption of the files and providing access only to study team members.

Are there Risks related to withdrawing from the study?
If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. This visit includes questionnaires. There is no risk to you if you do not complete the final withdrawal procedures, and you can choose not to participate in them.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems, even though the researchers are careful to avoid them. In the event of a research-related adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

The possible benefit of participating in this study is support through the App, for those participants randomized to the App group. There is no guarantee or promise that you will receive any benefit from this study.

We hope the information learned from this study will benefit other people with similar conditions in the future.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

Taking part in this study is voluntary. Instead of being in this study, you have the alternative option to not enroll in the study, and to continue receiving the standard treatment provided as part of your usual care.

Payments – Will there be any payments for participation?

Participants will receive a few small gifts at study visits (less than $25 value total) and reimbursements of $25 at each study visit (up to $125). Participants in the smartphone application (App) arm of the study will receive compensation of $50/month to cover the data plan costs of using the App.

The researchers will provide you with a MasterCard®. Compensation will be automatically credited after completion of each study visit or data plan month. Your name, address, date of birth, and social security number will be shared with a third-party solely for the purposes of compensation processing. This information will only be used for the administration of the compensation (ClinCard) and will be kept strictly confidential.

In addition to the compensation on the card, you may also elect to receive study-related messages (text and/or email). These messages will contain information confirming that money has been loaded onto your card. You may also receive reminder messages with information about your next appointment with researchers or study staff.

Please indicate your willingness to receive messages related to compensation:

- □ **Yes,** I would like to participate (please select the best method(s) for communication)
  - o Cell Phone (text messages)
  - o Email
- □ **No,** I choose not to participate

Costs – Will taking part in this study cost anything?

You or your health insurance company will be responsible for the cost of treatments and procedures that would be done whether or not you took part in this study, such as HIV viral loads ordered by your provider. Ask the researchers if you have any questions about what it will cost you to take part in this study.

If you do not have a smartphone, the study team may provide one, free of charge during this study. At the end of your participation, you must return all equipment to the study team.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the Federal Government. With this Certificate, the researchers cannot be forced to disclose, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings or any other person not connected to the research, your (or your family member's) name or any of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, 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). 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 consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under certain circumstances. Circumstances that warrant the release of your information without your permission include: abuse and/or neglect, intention to harm yourself or others, or certain communicable diseases, or other scientific research that is in compliance with applicable Federal regulations governing the protection of human participants in research. Should you require medical treatment as it relates to the information, document, or biospecimen pertains, additional consent will be obtained.

Limits of Confidentiality
Even without your consent, suspected or known abuse or neglect of a child, disabled, or elder abuse, threatened violence to self or others or other local health reporting requirements will be reported to appropriate authorities.

Research policies require that private information about you be protected, and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include: your medical history and blood work, information that we get from your medical record, information contained in your underlying medical records related to your medical history and treatments prior to the study, information that is created or collected during your participation in the study including medical and

treatment history, information you give us during your participation in the study such as during interviews or from questionnaires, results of blood tests; sensitive information like your HIV status, demographic information like your age, marital status, the type of work you do and the years of education you have completed.

We will get this information by asking you and/or by looking at your chart at the FFACTS clinic, if you have one.

Please indicate your willingness to Positive Links For Youth by initialing below, however, if you choose not to allow us to collect data from you using this app, you will not be able to participate in this study.

___ Yes
___ No

We would like to reach out to your HIV care providers for information about your blood work, specifically your CD4 and viral load levels, and your upcoming medical visits. Please indicate your willingness to allow us to do this by initialing below. If you do not wish your us to contact your HIV care providers, you can still participate in this study,

___ Yes
___ No

How will your PHI be shared?
Because this is a research study, we will be unable keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study, including:

- The sponsor of the study (National Institute of Mental Health of the National Institutes of Health), UT Health San Antonio, and the entities that they use to monitor, administer, or conduct the research
- University of Virginia PositiveLinks IT group and collaborators
- TigerConnect, university approved texting platform
- The committee that checks the study data on an ongoing basis, to determine if the study should be stopped for any reason
- The members of the local research team
- The Institutional Review Board and the Compliance Office of UT Health San Antonio, and other groups that oversee how research studies are carried out
- The Research offices at UT Health San Antonio and University Health

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of FFACTS Clinic for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?

You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to Dr. Barbara Taylor, Department of Medicine, Division of Infectious Diseases, UT Health San Antonio, 7703 Floyd Curl Dr. MSC 7881, San Antonio, TX 78229. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

You will only have access to your PHI until the end of the study.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:

Primary contact:
Dr. Barbara Taylor, MD, MS, can be reached at (210) 567-4661.

If primary contact is not available:
The Infectious Diseases Research Coordinator can be reached at (210) 354-5255.

The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UT Health San Antonio, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.

Adult Signature Section

- You have voluntarily decided to take part in this research study.
- You authorize the collection, use and sharing of your protected health information as described in this form.

Printed Name of Subject	Signature of Subject	Date	Time AM PM

Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent and Authorization	Date	Time AM PM

☐Consent and authorization was obtained from this individual who is unable to read and/or write but can otherwise communicate and/or comprehend English. The method used for communication with the subject was: _____.
The specific means by which the subject communicated agreement to participate was:
_____