Demonstration Site Summary

Positively Connected for Health (PC4H)

Children's Hospital of Philadelphia, Philadelphia FIGHT

Philadelphia, PA

In the Ryan White HIV/AIDS Program (RWHAP), Part F: Special Projects of National Significance (SPNS) Initiative

Use of Social Media to Improve Engagement, Retention, and Health Outcomes along the HIV Care Continuum

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ABBREVIATIONS AND DEFINITIONS

Acronym/Abbreviation	Definition
ACASI	Audio Computer Assisted Self Interview Instrument
AEM	AIDS Education Month
AI	Adolescent Initiative (CHOP's Adolescent HIV clinic)
App	Application (mobile)
ART	Antiretroviral Therapy; HIV Treatment Medication
AYA	Adolescents and Young Adults
C2P	Connect to Protect
CAB	Community Advisory Board
CBO	Community Based Organizations
CCI	College of Computing Informatics (Drexel University)
CHOP	Children's Hospital of Philadelphia
CoC	Certificate of Confidentiality
DBHi	CHOP's Department of Biomedical Health Informatics
DCC	Data Coordinating Center
EMA/I	Ecological Momentary Assessment/Intervention
EBI	Evidence-based Interventions
EMR/EHR	Electronic Medical Record/Electronic Health Record
FAQs	Frequently Asked Questions
FQHC	Federally Qualified Health Center
ETAC	Evaluation and Technical Assistance Center
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
HIV+	HIV-positive
IRB	Institutional Review Board
mHealth	Mobile health
MI	Motivational Interviewing
MSE	Multisite Evaluation
QDS	Questionnaire Development System; questionnaire and survey development software used for MSE data collection measures
PC4H	Positively Connected for Health; Intervention Title
PrEP	Pre-Exposure Prophylaxis
REDCap	Research Electronic Data Capture
SI	CHOP's Special Immunology Clinic
SMS	Short Messaging System
STI	Sexually Transmitted Infection
TYS	*TreatYourSelf*: medication adherence and engagement in care mobile app created by CHOP
UCLA	University of California, Los Angeles
VL	Viral Load; Amount of HIV virus copies per ml/blood
YAB	Youth Advisory Board
YCAB	Youth Community Advisory Board
Y-HEP	Youth Health Empowerment Project: Philadelphia FIGHT's youth health center
YLH	Youth Living with HIV
YMSM	Young Men who have Sex with Men
YTW	Young Transgender Women

EXECUTIVE SUMMARY

This demonstration project is a mobile application (app) and digital literacy workshop intervention--**Positively Connected for Health (PC4H)**--focused on improving health outcomes of young people living with Human Immunodeficiency Virus (HIV), ages 14-34, through engagement and retention in care, and medication adherence.

Youth and young adults make up less than a third of our total population, yet they account for over 40% of new infections in the U.S., of which, young men who have sex with men (YMSM), young transgender women (YTW), and youth of color are disproportionately affected. Recent data suggest that only half of young people who are prescribed antiretroviral therapy (ART) achieve viral load (VL) suppression compared to more than 75% of HIV-positive (HIV+) adults. Medication adherence is required for optimal health outcomes; however, many young people are simultaneously experiencing depression, stigma, substance abuse, and housing instability—factors associated with poor adherence. Further, youth often report that needing to take medications at the same time every day, medication side effects, and simply forgetting also increases the likelihood of non-adherence.

There are few interventions that have been developed and tested to improve medication adherence and engagement and retention in care specifically for HIV+ youth. Two small studies of YMSM of color have shown intensive case management to be a promising intervention to improve retention in care and increase the initiation of ART, but from a public health perspective, these services require abundant time and resources. Additionally, these services are not available outside routine clinic hours further limiting the capacity and ability of these interventions to reach young people in real time.

Mobile health interventions, however, are well suited to fill this gap. Mobile phones, particularly text messaging, are a common mode of communication for young people, including youth that are economically disadvantaged, and can serve as a useful tool in engagement in care. As such, leveraging the connectedness of mobile technology and health outcomes, this initiative developed an app, *TreatYourSelf* (TYS)*,* and digital literacy workshop, *APPlify Your Health*. *TreatYourSelf* was designed to provide young people living with HIV with the opportunity to document adherence, receive incentives for their adherence, and create a support network of other young people living with HIV all within an app. Key functions of *TreatYourSelf* include: reminders for medication, refill, and appointments, calendar features to track adherence, discussion forums, a "heart" contact to store and easily reach out to trusted contacts, and a Leaderboard that allows participants to collect points for adherence and compare how they are doing visually with their peers. The *APPlify Your Health* workshop was designed to teach young people about the various functions of the app and improve health literacy through a youth-centric curriculum that provides information on other digital health tools and skills on how to critically review health information. With this intervention, this initiative aims to increase engagement and retention in care, and improve medication adherence for young people living with HIV.

INTRODUCTION

Philadelphia Neighborhoods

1. Brewerytown
2. Cedar Park
3. Cedarbrook
4. Fairmount
5. Haddington
6. Harrowgate
7. Hartranft
8. North Central
9. Point Breeze
10. Schuylkill
11. South Philadelphia
12. West Kensington
13. Wharton
14. Wissahickon Park

Source: Philadelphia NIS neighborhoodBase

Scope of Problem

Young people age 13-29 represent only 21% of the population in the United States, but account for 39% of new HIV infections nationally.[1] In Philadelphia, adolescents and young adults aged 13-24 accounted for 24% of all newly diagnosed HIV infections in 2016.[2] Fewer than half of youth who are prescribed antiretroviral therapy (ART) achieve viral suppression.[3] Social media and mobile technology, which are used frequently by youth, have the potential to be a platform to deliver interventions that provide support and feedback in real time as youth go about their daily lives, and can be mobilized to improve health outcomes.

Youth living with HIV (YLH) experience physical, cognitive, and social/emotional developmental changes that may impact ART prescription and adherence.[4] Behaviorally-infected youth face multiple unique challenges in terms of adherence from the time of diagnosis. Some factors associated with non-adherence are common across age ranges and include housing instability, not understanding the need for medicine, mental health and substance use problems, side effects, forgetting or not having their medications with them, and complications in daily routines.[5,6] Factors associated with longitudinal failure to adhere to ART in this vulnerable population include younger age, disease progression, depression, and fear of disclosure of diagnosis. The consequences of sub-optimal adherence to medications can be severe, including the development of resistance and lack of viral suppression, rendering infected individuals more likely to transmit the virus to someone else through unprotected sex or intravenous drug use.[7] [8] *TreatYourSelf* and *APPlify Your Health* aim to address these factors by improving digital health literacy, medication adherence, engagement in care through social networking and support with peers and support networks (care providers, family, etc), and accessibility to resources in real time.

Rationale and Evidence for Intervention Approach

With over 400 million cell phones and tablets in use and 142 billion text messages sent every month in the United States as reported in 2018,[9] mobile phones have become a common mode of communication among youth, including those who are economically disadvantaged.[10] This low-cost, convenient technology has been beneficial in a variety of health care settings and has been shown to be an effective tool for behavior change.[11,12] Evidence suggests that digital or mobile health (mHealth) interventions, such as text-messaging, smartphone apps, and using an ecological momentary assessment and intervention (EMA/I) approach, may increase medication adherence among children and adolescents living with other chronic diseases such as asthma and diabetes.[13,14]

Text-messaging was the first mobile health delivery platform to demonstrate effectiveness for interventions. Several studies have used both daily and weekly unidirectional, standardized SMS medication reminders for HIV+ individuals in low-resource settings, and our previous work shows promise of daily, personalized, interactive SMS medication reminders to improve medication adherence among YLH in the US.[15-18] This intervention called TX TXT is now one of few CDC evidence-based interventions (EBI) recommended for YLH.[18] Additionally, reviews of the literature on text messaging interventions for health behavior change have identified key characteristics for success, including interactivity and tailoring of messages, which were associated with higher retention rates.[19]

More recently, the advent of smartphones, which are owned by 65% of U.S. consumers[20] (with an even higher proportion among youth) creates new opportunity for mHealth interventions using mobile websites, social networking, gaming, and applications (apps). EMA/I theory suggests that real-time interventions, deployed within a person's real world environment, may be more likely to change behavior by intervening as people go about their daily lives. Currently, over 50 mobile apps are available related to HIV prevention and treatment.[21] Only a handful, however, exist specifically for individuals living with HIV to address adherence (iStayHealthy and PozTracker) and get support or find community (HIV Connect) through app stores on iPhone or Android phones. There were no theory driven apps specifically designed for YLH that were proven effective as of July 2016.

Previous studies of HIV+ youth and similar substance abusing populations have shown that mobile phone-based (text messaging or app) time and location-based reminders for medication adherence and relapse prevention are feasible and acceptable and show some promise for behavior change.[22] Qualitative data suggest some of these features would be most appealing to individuals living with and at-risk for HIV, but few available apps have been studied or evaluated and few are based in health behavior theory.[23] Given the failure of many traditional HIV primary and secondary prevention interventions to demonstrate effectiveness in implementation and the promise of mHealth for adolescents and young adults who are difficult to reach, but frequent users of mobile technologies, there is an urgent need to evaluate and develop new theory-based interventions that are both feasible and represent the best options for significant impacts.

Unfortunately, few interventions have been developed or tested that target linkage, retention, and ART adherence among emerging adults living with HIV. Several studies of a brief motivational interviewing (MI) intervention for YLH show a short-term decrease in viral load and unprotected sex acts when compared to controls, but adherence was not measured and

these differences were not sustained over time.[24] Additional protective factors associated with adherence include higher levels of self-efficacy, motivational readiness, and increased social support.[7]

Additionally, while young people under 30 are the most likely to look up health information on the Internet, they are the least likely to seek follow up support from a doctor, indicating another way is needed to link young people with technology access directly to their providers.[10] The barriers for young people living with HIV also include struggling with health literacy.[25] Youth and young adults living with HIV need to understand how to make appointments and come to them on time, understand the importance of taking ART at exactly the same time each day to avoid development of resistance, know how to refill their medications and how much time is needed to do this, know when to call ahead for urgent visits, understand what applications are needed for health insurance or income assistance, know when to seek medical care for emergencies, be able to identify symptoms and tell them to a provider, and understand the process for referrals to specialists. In today's health care environment, much of this is done online through patient portals, electronic medical record (EMR) systems, health apps, and online applications. Smart phones, in particular, are driving changes to how young people access not only health information, but also their health care. Of note, minorities, those with no college exposure, and those with lower income are increasingly using their phone as their primary source of Internet access[26] and are the least likely to be engaged in HIV care. In Dr. Dowshen's previous study using SMS reminders for HIV+ youth, she showed that despite service interruptions, youth made maintaining a mobile phone plan a priority and quickly contacted the project coordinator to rejoin the intervention when service was restored.[16] Clinical staff at Children's Hospital of Philadelphia (CHOP) often communicate with patients via text message and both clinical organizations have located patients who have dropped out of care through Facebook.

Using mobile technology as a delivery tool grounded in health behavior theory allows for an ecological momentary intervention; that is, providing youth individually tailored messages in real time and at optimal times and locations when they are needed in order to address key health behaviors.

Addressing the Gaps

The Positively Connected for Health (PC4H) intervention offers a mobile app, *TreatYourSelf,* that focuses on improving engagement and retention in care and adherence to ART with a digital literacy educational workshop, **APPlify Your Health**, to demonstrate and support app usage (see Figure 1) for adolescents and young adults.

***TreatYourSelf* (TYS)**. A new mobile app designed for and with input from YLH with the goal of increasing adherence to ART. With an interdisciplinary team of game/app designers, research team, adolescent medicine physician, and a "patient expert", the app is grounded in health behavior theory, including the integrated model of behavior prediction, supportive accountability, and uses an ecological momentary approach.

The *TreatYourSelf* app allows users to document medication adherence and receive immediate feedback and incentives for adherence over time. TYS provides users the options to program standalone time-based medication reminders as well as mixed time and location-based medication reminders. Additionally, this app provides a network of social support via 1-1 chats and group forums, which may overcome some of the isolation and multiple layers of stigma often experienced by YLH. The participants will also have the ability to provide encouragement or "kudos" to other users for accomplishing goals. This initiative prioritizes privacy; any sharing of information between participants is anonymous through avatars, an approach which has shown promise for behavior change in other health games without compromising social connectedness.[27]

APPlify Your Health. This 20-60 minute digital health workshop was designed to ensure that patients had the digital health literacy skills needed in today's environment to support their health and wellbeing. *APPlify Your Health* is designed to engage YLH through real-time, youth-centric 1:1 tutoring sessions or small group instruction using sample mobile devices to allow them to become familiar with the various functions of the TYS app, personally tailor the use of the app for their needs, and address major issues that arise when using technology for health care including confidentiality and security, disclosure and adherence. *APPlify* was modified for TYS from Philadelphia FIGHT's original workshops that focused on apps and other tech tools to support health behaviors and goals. As a 1-on-1 session, APPlify takes, on average, about 20

minutes to deliver. In a group setting, the workshop runs about 1 hour, as the conversations may become more robust with more participants in the group. The workshop covers how to use the TYS app as well as other key information related to managing healthcare online, such as privacy and confidentiality, adherence or managing their medication reminders, disclosure of personal information and appropriate behavior in an online environment, and discussion of who will be part of a participant's care team. Using mobile device labs, introductory lessons on the app features help youth customize the app for their preferences, and discuss key concepts of digital health literacy that will benefit them as they seek medical care. By including *APPlify Your Health* into this integrated PC4H intervention, this initiative will increase the likelihood of success in achieving our expected outcomes for YLH across the continuum of care as they engage with the TYS app. Both group and individual sessions are offered pending youth preferences. See appendix for entire curriculum.

Target Audience

The target population(s) for this intervention are adolescents and young adults living with HIV, who know their HIV status, are already linked to care or have been out of care, but are not virally suppressed, and in need of additional support for retention in care and medication adherence.

This intervention is primarily designed to support clinical work in community health care settings, public health clinics, and other health care settings serving similar populations who might have limited access to other kinds of supports. Individuals who would use these intervention tools may include:

- Director of medical clinics
- Physicians
- Nurse Practitioners
- Social Workers
- Case Managers
- Community Health Workers

Intervention Description
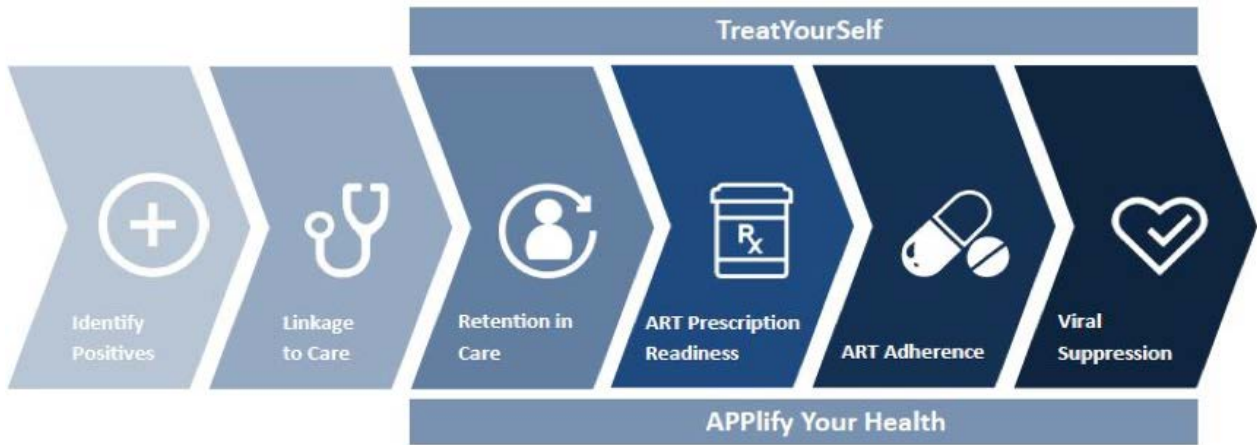
Figure 1. TYS and *APPlify Your Health* across the HIV Care Continuum

Intervention Approach & Theoretical Framework

TYS is guided by three theoretical frameworks: (1) **Fishbein's integrated model of behavioral prediction** (2) **ecologic momentary interventions** (EMI) **approach** and (3) **supportive accountability model. The integrated model of behavioral prediction** posits that people act on their intentions when they have the necessary skills, and environmental constraints do not impede performing a behavior,[28] and this theory has been successfully applied to the development of HIV primary prevention interventions. This theory may be particularly useful in identifying targets and approaches for linkage, retention, and adherence interventions. Particularly, TYS is designed to improve self-efficacy and in turn intention to

improve medication adherence**. EMI** emphasizes that interventions should provide support and feedback in real time as youth and young adults go about their daily lives.[29] The **Supportive Accountability Model** argues that human support increases adherence through accountability to a coach who is seen as trustworthy, benevolent, and having expertise.[30]

APPlify is guided by two methodological approaches: 1) **Harm reduction**, and 2) **Popular and participatory education models.** The harm reduction philosophy reinforces meeting all our patient-participants "where they are" by emphasizing non-judgmental interactions. The app and this workshop are designed to support youth, even when youth disclose engaging behaviors that may not be in their best interest. These behaviors can include pressing the ignore button or snoozing too many times with medication reminders or discussing risky sex behavior during the workshop. It's not the job of the *APPlify* instructor(s) to chastise participants when these topics arise. Rather, instructors should guide participants to specific app features or online resources that may help further support youth as they navigate choices related to their well-being. **Popular and participatory education models** emphasize the autonomy and expertise of young people, acknowledge and validate their emotional realities, and allow for feedback contributing to continual improvement. A conscious effort was made to design the workshop to be highly participatory; rather than a direct instruction model, where participants are merely receiving information, the workshop is designed to be guided by the youth who are present so that they may take ownership of the app. Below, an intervention Typology summarizes key elements of the intervention, including the intervention functions and technology-based delivery platforms described in detail following the table.
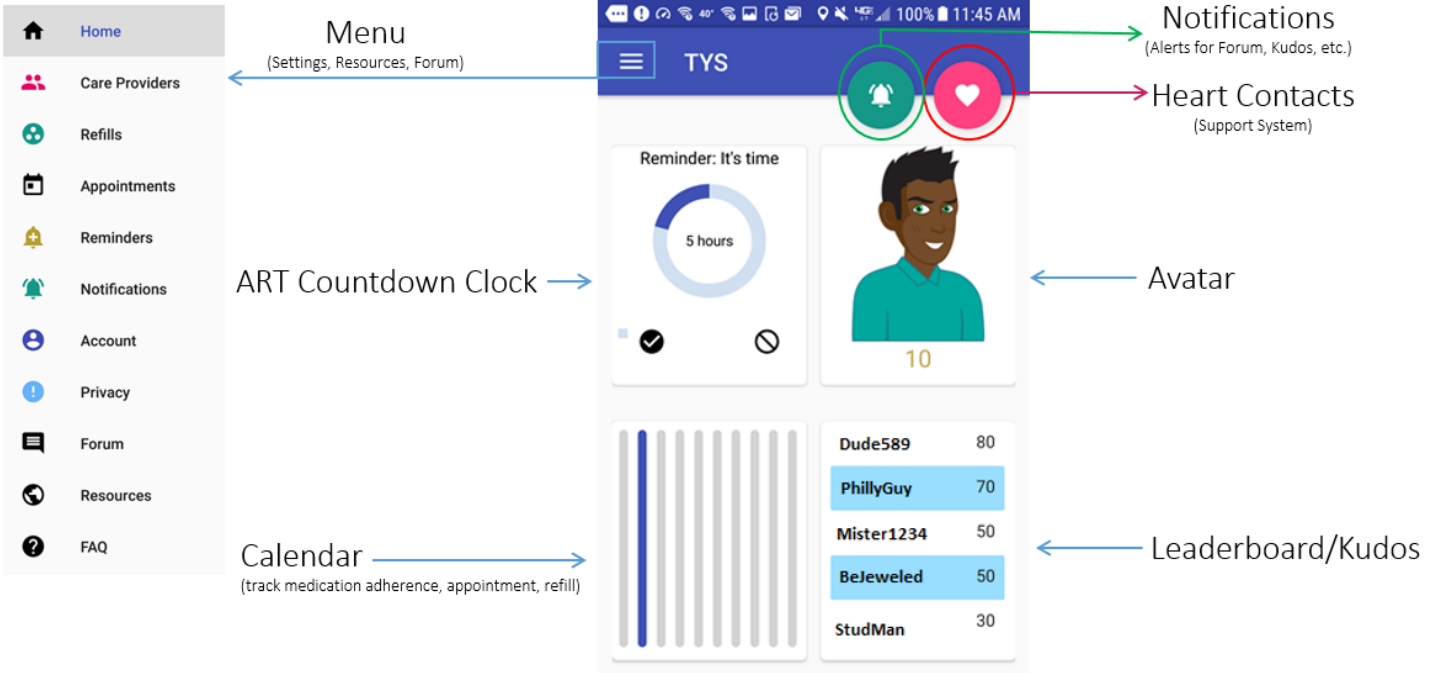
Intervention Typology

Positively Connected for Health (PC4H), Philadelphia FIGHT/CHOP (Philadelphia, PA)

Program Summary	Social Media Intervention Overview	Evaluation Summary

Study Population
 	
Age: 14-34
Gender: All
Race/Ethnicity: All (primarily AA)
Sexual Orientation: All
Sample Size: 48 HIV+
Language: English
Setting: Clinic, community setting
 	
Inclusion Criteria
Unaware of HIV status: Yes
Newly Diagnosed: Yes
Not linked/engaged in care: Yes
Not retained in care/Out of care: Yes
Not adherent to HIV medication: Yes
Not virally suppressed: Yes
Must own or being willing to use a study provided Android phone: Yes
	Intervention type
	Adapted from prior intervention
	Adjunct to existing services
	
	Technology Platforms Used
	Mobile App: Yes (new)
	Text Messaging: Yes, live
	
	Functions
	Communication: Yes
	Education: Yes, APPlify Your Health (workshops, digital health literacy program)
	Gaming: Yes, leaderboard, avatar stock images customizable, point accumulation notification
	Information: Yes, resources page
	Reminders:
	  General: Yes, Rx refills
	  Medical appointments: Yes, automated + personalized
	  Medication adherence: Yes, automated + personalized
	Self-monitoring/tracking: Yes, medication adherence and care continuum measures via calendar
	Skills building: Yes, to navigate healthcare and provide support for Rx adherence
	Social support/networking: Yes (on App)
		Evaluation Comparison Group: Yes, historical comparison to Adolescents and Young Adults (AYA) not enrolled using CAREWare data
		
		HIV Health Outcome Measures
		Increase HIV testing/positivity rate/ HIV awareness: Yes
		Improve linkage/engagement in care: Yes
		Improve retention in care: Yes
		Improve medication adherence: Yes
		Improve viral suppression: Yes
		Improve utilization of support services: No
		Improve health literacy: Yes
		
		Other Ryan White Part Funding
		Parts A, B, C, D:
		  FIGHT (A, B, C, D, F)
		  CHOP (A and D)

Intervention Description

TreatYourSelf Mobile App

Menu (Settings, Resources, Forum)

ART Countdown Clock

Calendar (track medication adherence, appointment, refill)

Notifications (Alerts for Forum, Kudos, etc.)

Heart Contacts (Support System)

Avatar

Leaderboard/Kudos

TreatYourSelf is designed to be used on any device that runs on an Android operating system and is available to participants through an invitation-only download link. Designed with input from YLH and a larger youth community advisory board, and grounded in health behavior theories, <u>key features of the app include medication reminders and adherence tracking, refill and appointment reminders, leaderboard and adherence points, internal community supports through discussion forums, peer-to-peer kudos, and listing of community-based resources</u>.

Reminders:

Time-based reminder

Location Reminder (Optional)

Location Reminder Set
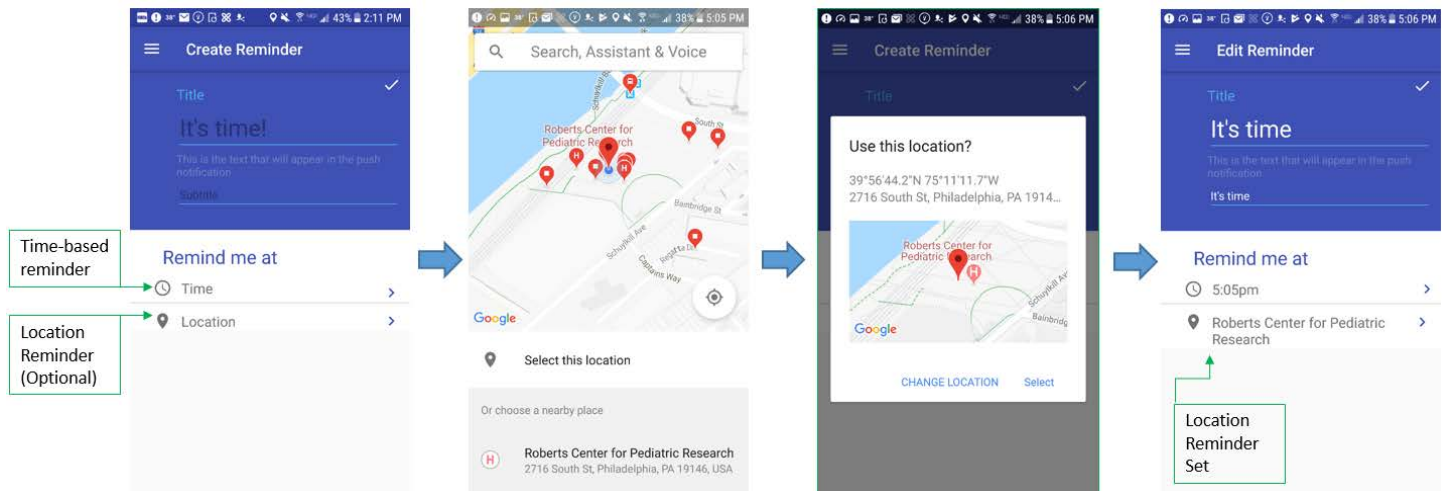
Push notifications. Participants receive pop up reminders at times they programmed in the app to help them remember to take their ART medication, prescription refills, and appointment reminders. Participants are able to customize the messaging content of the pop up reminder themselves or use the default option for both the main title and subtitles.

- **Medication reminder** push notifications prompt the user to answer if they did or did not take their medications or "Snooze" (to get reminded later with another push notification) with the option of using smart reminders (location-based reminders that go off within a geofence of a specified location once the user enters the area).

- **Refill reminders** are programmed to remind the user 30 days from the last day they picked up their medication. For example, if a user enters in the date they picked up their medication from a pharmacy in the application, the app will remind the user 30 day from that day to pick up their next refill.

- **Appointment reminders** can be programmed in the app's calendar section or side menu as soon as they set a date/time for their next visit.

Additionally, users may review their most recent past notifications by clicking on the green notifications button.
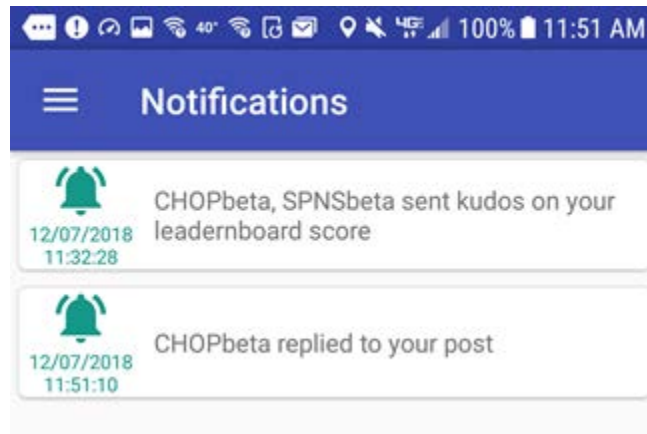
Medication Reminder Countdown. Additionally, there is a countdown clock on the home screen that shows the time left until the next medication reminder. This clock gives participants a visual cue in advance of their next reminder.
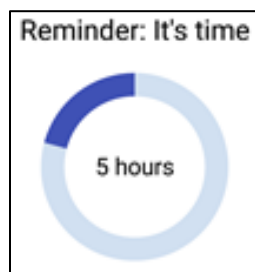
Medication Adherence Self-Monitoring & Tracking:

Self-monitoring. The push notification reminders (pictured above) also prompt the user to answer if they did or did not take their medications. Responses are recorded in the app and used for calculating points in the leaderboard screen and the calendar.

Calendars. The home screen of the application depicts a calendar that shows the recorded medication adherence information. Participants can choose from different views: week or month.
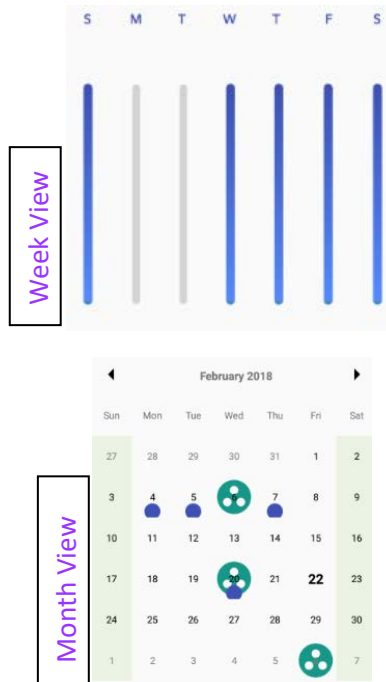
When the calendar is open, there are 3 different colored dots underneath each day to indicate medication adherence:

- Purple = recorded meds taken
- Grey = recorded meds not taken

Additionally, users are able to save and view their medical appointments in the calendar (square calendar icon) as well as their refills (green circle icon with three white dots). Dark blue circle on top of the date indicates today's date for the user.
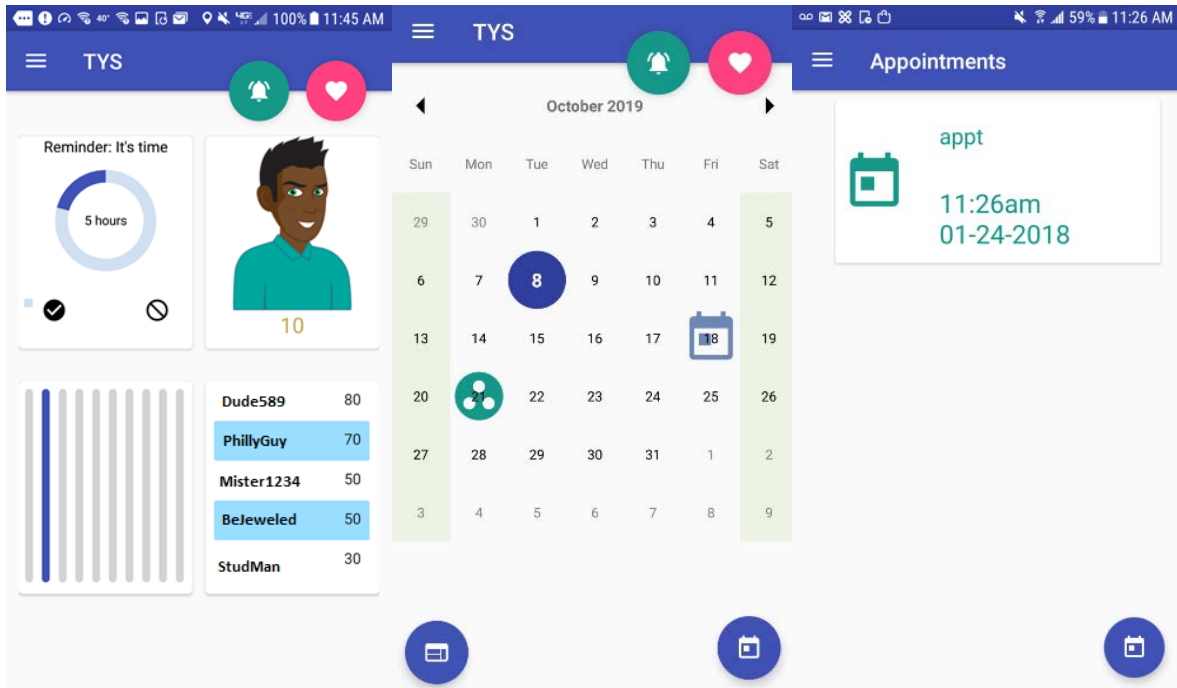
Gaming:

The TYS app uses a system of immediate feedback and incentives based on gamification, which operates on theoretical principles of aligning with users' intrinsic motivation and providing carefully selected extrinsic rewards to achieve behavior change.

Points System. Every time participants record that they took their medication in response to push notification prompts, points are recorded. The amount of points depends on adherence streaks (taking medications for multiple days in a row). Each user gets 10 points per day with an additional 5 points for every 5 day streak (see below for accrual system). The accrued points for users resets to zero at the end of each month so that new users can join and participate in a level playing field and current users who may have struggled previously have an opportunity to improve, keeping all users engaged and competitive.

Number of Days (streak) User Recorded They Took Their ART

Day 01-05: 10 points per day
Day 06 -10: 15 points per day
Day 11- 15: 20 points per day
Day 16-20: 25 points per day
Day 20-25: 30 points per day
Day 26-30: 35 points per day

Leaderboard. As each user earns points for daily adherence, these points are displayed under the user's avatar on a leaderboard, with the person with the most points for that month listed first. This way users have a visual of how they are doing compared with their peers and able to support those peers who are doing well and those who may be struggling.
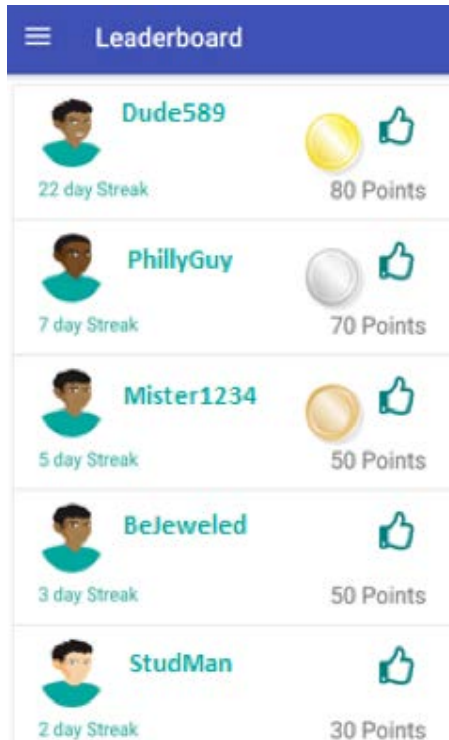
Avatar. TYS also has an Avatar feature that allows users to select one of 60 avatar character images to use as their personal avatar that is displayed on the **home screen**, in the **Discussion Forum,** and on the **Leaderboard**. Using an avatar instead of a picture helps protects users' privacy and maintain anonymity in the Discussion Forum and Leaderboard as well as allow users to be creative in choosing an avatar they feel best represents them in the app.

Social Support/Networking:

Creating a network of social support through group-based gaming and interaction is also an integral part of the *TreatYourSelf* app. Creation of social networks of individuals with similar health problems has been shown to be effective in improving adoption of new health behaviors. The app provides opportunities for social support, including, the **Discussion Forum**, the **Heart Contacts**, and the **Leaderboard**, all described above, that may overcome some of the isolation and multiple layers of stigma often experienced by YLH.

Communication:

Leveraging the supportive accountability model of mHealth interventions, the TYS application has two main communication features: Heart Contacts and Discussion Forums.

Heart Contacts. TYS has a heart icon that functions as a contact button that participants can update with contact information for anyone in their support network. This button, which is accessible from the TYS homepage as a heart icon, opens a pink heart contacts page which allows participants to directly text (via SMS) or call their providers or other support persons when they need help. See below for sample image:
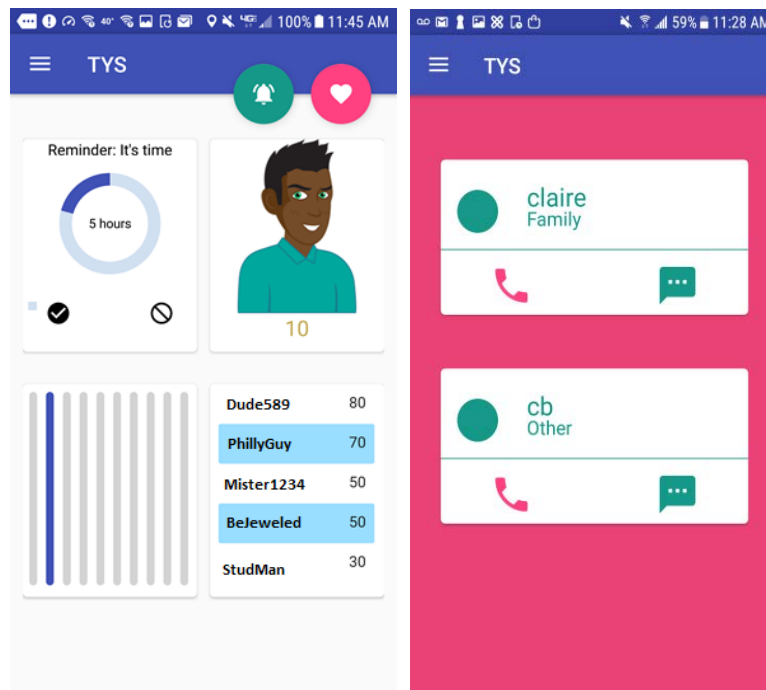
Discussion Forums. TYS also has a private discussion forum feature that allows for communication between participants in a group format. The forums are pre-populated with topics such as disclosing to a partner or pre-exposure prophalaxis (PrEP), and an option for app users to generate their own topics. In this capacity, users are able to anonymously talk about topics of interest to them in a supportive community with moderation by a clinic staff member. Again, within an ecologic momentary approach, adding human contact and support in the real times and places where needed may provide distinct advantage over traditional methods where adherence or other concerns may not be addressed by patient and provider for months between clinical visits.
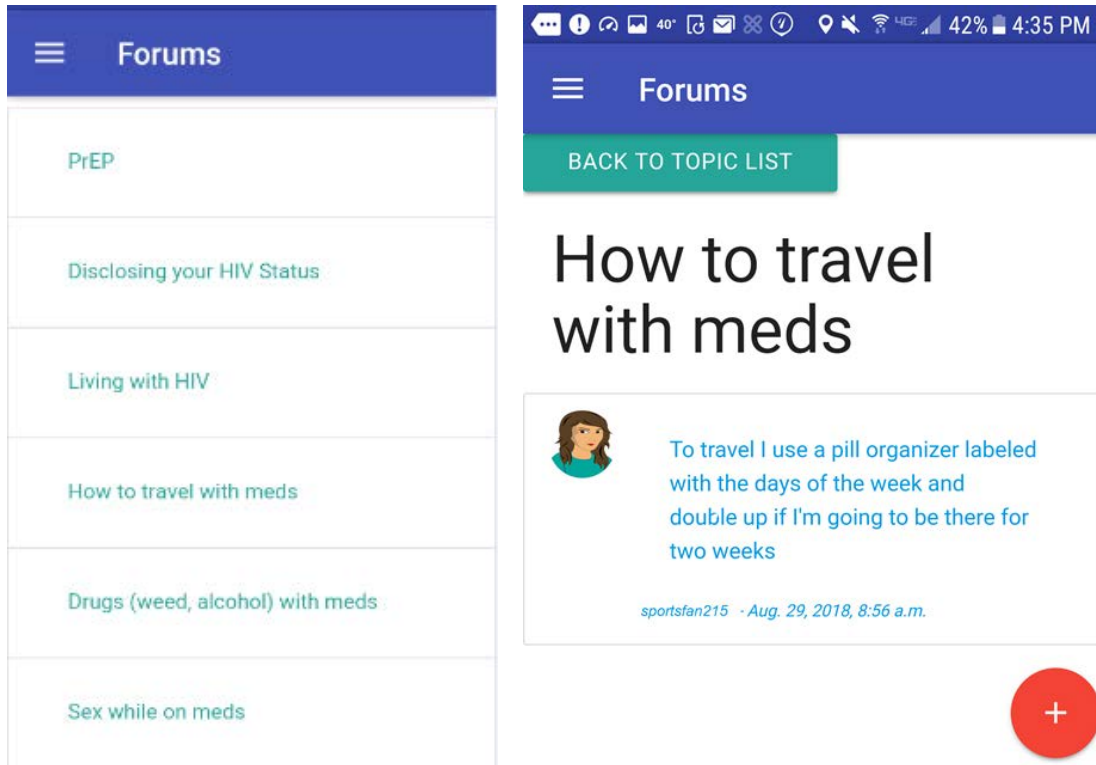
Information Resources:

Resources. The TYS app has a Resource section that provides a curated list of other mobile-friendly sites that provide additional information. The current list includes:

- iknowUshould2
- Take Control Philly
- The Body
- AIDS InfoNet
- AIDSinfo
- The AIDS Library
- InSpot
- National HIV Infoline
- HIV Hotlines – PA, NJ, & DE
- Project Safe
- Project Inform

- POZ Magazine
- PWN (Positive Women's Network)
- AIDS Library Resource Guide
- 211 SEPA
- PrEP Facts – San Francisco AIDS Foundation
- AVERT
- ASK the HIV Doc YouTube Playlist
- Greater Than AIDS
- PrEP Philadelphia FIGHT
- Project TEACH - Adherence

Frequently Asked Questions (FAQs). The FAQs page in the TYS app provides help regarding different features of the app (points system, changing their avatar, creating reminders, etc.), resetting their password, and how to get in touch with the project team.
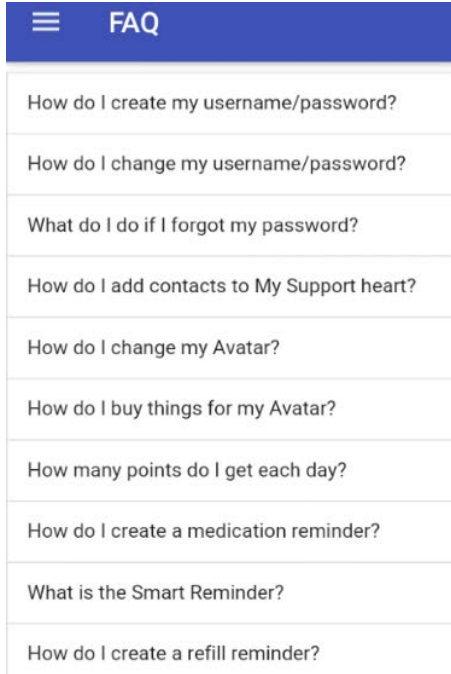
APPlify Your Health

Education:

In addition to the *TreatYourSelf* app, the intervention also includes the *APPlify Youth Health* workshop for youth which was adapted for the TYS application from a 2-hour digital health literacy workshop created by Philadelphia FIGHT's Education team. This 20-60-minute workshop engages young people individually or in small groups and allows them to become familiar with the various functions of the TYS app.

APPlify your Health is designed to prepare youth to be community members when it comes to the "social" parts of TYS and encourage them to embrace the app as a tool that they will want to engage with in managing their care. To achieve this, this *APPlify* curriculum was designed carefully with a guiding pedagogical philosophy that 1) believes that young people are the experts of their own experience and 2) integrates a harm-reduction approach.

The workshop has four specific learning goals. Participants will:

- Be proficient with all features of the *TreatYourSelf* app
- Identify strategies for navigating the social and emotional challenges that the app may address
- Identify and apply best practices for behavior in online spaces in order to support health goals
- Learn additional mobile-technology resources (apps & mobile sites) to support health goals and manage HIV care

Skill Building:

This workshop is designed to strengthen digital literacy skills through a series of activities while also improving health literacy. Some of these skills include:

- Practice using core features of the operating system
  - Through actions that the app requires such as setting dates and times or typing with the keyboard, participants who may not have much experience using their phone might gain practice in how to use features in other contexts on their phone. As one example, the user interface that is presented for participants to set the time of their medication reminders is the same interface used to set times for other "stock" Android apps, such as an alarm clock. By practicing this skill in the workshop, users may feel more confident interacting with other parts of their device that they hadn't previously explored. This is especially true for users who receive a project-provided phone.
- Using apps as tools to help manage health
  - The workshop asks the participant to discuss how they currently use digital tools to manage their care. This question gets the participant accustomed to the idea that a smartphone can help manage their care if they haven't thought this way already.
  - The workshop uses questions to engage young people with every feature about how they might use that feature and why that feature might be helpful to them. For example, a discussion around how and when one might use reminder features gets at core concepts of both adherence and privacy in healthcare. The workshop is intended to help health care professionals talk with youth about the challenges they face and how the app can support these challenges.
  - The workshop teaches young people about how to find and analyze reliable online health information and why this is critical for managing their own healthcare.

Technology Platforms/Channels

Mobile App

TreatYourSelf is a smartphone/tablet application designed to be used on any device that runs an Android operating system. The app is currently only available through an invitation-only download link as a way to ensure that all users meet intervention inclusion criteria. Designed to be used daily, the app provides: medication reminders, medication logging and tracking, internal community supports via discussion forums, and prompts to reach out to external supports via the heart contacts button.

Text Messaging/Voice Calls

Within the TYS app, users are able to program people in their support system within the heart contacts button with whom they will be able to text message (SMS) or voice call directly.

Intervention Core Elements/Components

The TYS app is the core component of this intervention. Input was also sought from a larger youth community advisory aboard. The key features of the app are:

- Medication reminders and adherence tracking
- Refill and appointment reminders/scheduling
- Real-time support from other users: forum discussion and 1-1 chats
- Gaming features: leaderboard and adherence points
- Avatar characters

Further, we found that it is beneficial to incorporate an educational component (*APPlify Your Health* workshop) with the app. This creates the space for participants to ask questions, learn in a guided hands-on environment, and connects them to a staff member who can provide additional support throughout the intervention. Core components of *APPlify* should include:

1) Its core pedagogical philosophy, rooted in a non-judgmental, harm reduction approach to behavior change with youth and using guiding questions to allow youth to be the experts of their own lives rather than a direct instruction model that simply explains how the app works.

2) Focus on the following key concepts around digital health literacy: 1) confidentiality, privacy, and disclosure in health care and in social media, 2) the management of health care in digital spaces such as adherence, appointments, and refills as part of the practice of maintaining good health, and 3) finding and assessing quality online health resources.

In the end, the participants should be able to discuss the topics and concerns that they have. Further, since instructors are working with youth, the tone and approach of the workshop is youth focused.

Adaptable Key Characteristics/Components

The TYS app is a core component to the PC4H intervention and there are various features that can be adapted to meet specific needs of various AYA populations.

Avatar Characteristics. While this is critical to the app, the actual character images could be modified to meet the needs of different populations.

Discussion Forum Topics. Different pre-populated topics could be added and current topics could be removed. This is definitely an area where different programs or practices may want to customize to their specific needs of their patients/clients.

Resources. This section could be customized for specific geographic regions or populations and can include not only informational or national resource websites, but also local social service resources and health care partners. For example, the app could include links to the organization or clinics providing the intervention, community partners, or other local support services.

APPlify Your Health's curriculum is also readily adaptable for different populations and to different apps. While the pedagogical approach and key digital health lessons should remain the same (see above), the specific content can vary widely particularly if adapted to another app. In fact, the curriculum is designed in such a way that allows for each session to be different from the one before. The accompanying PowerPoint (if used) is minimalistic enough to allow instructors to use their preferred methods and expertise to engage with youth (See appendix for full curriculum).

IMPLEMENTATION

Pre-Implementation Activities

Suggested pre-implementation activities for replication of PC4H can be found below:

Time frame	Activity	Description
Month 1	Regulatory or Organizational Approvals	• If running PC4H as a study or program evaluation, check with your organization's institutional review board (IRB) or program oversight committee to complete proper regulatory paperwork and obtain approvals before commencing.
Month 1	Poll	• Ask future participants about their current mobile phone use, data plans, and type of mobile device owned. TYS is only available on Android smartphone devices, requires a data plan or consistent access to WiFi internet, and is accessible on the latest Android operating systems.
Month 1-2	Mobile App and Digital Health Literacy Workshop Adaptation and Development	• Adapt customizable features of the TYS app for intended audience • Update the APPlify Your Health workshop to reflect the adaptations made in the TYS app as well as include any updated digital health information and how to operate new technology instructional information (new versions of Android phones or operating systems). • Design supplementary paper copy and/or digital materials on any health topic to be distributed during APPlify Your Health workshop.

Time frame	Activity	Description
Month 2	Promotional Materials and Partner Engagement for Future Recruitment	• Create promotional materials to engage interested participants to inquire on how they can become involved in PC4H and use the TYS app. If enrolling entire clinic or organization's clients, create promotional materials letting everyone know changes or updates to the center/program are forthcoming. • Reach out to community partners and stakeholders to work with them in future implementation planning. • Consider recruitment strategies, including engaging with clinical team, recruitment events (e.g., pizza parties), increased incentives (food, monetary, prize), and reaching out directly to eligible participants or partner organizations
Month 2	Usability Testing	• Conduct usability testing (test features in demo app) to ensure adapted features are functional and operating as desired. Note changes and ask app developer on timeline to implement changes. If no changes, proceed to staff training.
Month 2-3	Clinical or Program Staff Training	• Train staff who will be implementing PC4H intervention to your target population on how to conduct APPlify Your Health workshop as well as how to use the TYS app.

Youth and Community Advisory Board

Youth Advisory Boards (YAB) or Community Advisory Boards (CAB) are groups of youth or community leaders/members who can share their knowledge, perspectives, and experiences. YABs and CABs can provide invaluable input in how to design or implement an adapted feature, project, or program and serve as champions or ambassadors for uptake with the intended audience. Organizations may create their own YAB/CAB or opt to utilize an existing YAB/CAB in a partner organization such as was done in this PC4H project with Adolescent Initiative's (AI) Youth Community Advisory Board (YCAB).

The Adolescent Initiative, an integrated system of clinical care, research, training and prevention for adolescents at-risk or living with HIV, at CHOP has their own YCAB comprising 17 members ages 13-18 years old. All members are African American and all are students, either in high school or college. They are both HIV-positive and HIV-negative. The YCAB meets on the 1st and 3rd Thursdays of every month and the facilitator for this group is an AI staff member. The YCAB provides feedback on training and prevention efforts, research studies and activities, the iknowUshould2 campaign, Hip Hop for Philly, and other community-focused events to help AI improve the health of adolescents in the Philadelphia Metropolitan area. New members are generally recruited via referrals from current members who are aging out or who have limited time to meet as well as through a public application process.

For this project, this initiative consulted the YCAB on the PC4H flyers as well as features of the app and mobile preferences. These youth voted on the app name, icon and provided feedback on the app features that were tested through the focus groups. They also provided feedback on the image and language of the flyers so that this initiative was best able to reach youth. Any ongoing implementation of PC4H would benefit from a YCAB to provide ongoing feedback about *TreatYourSelf* and *APPlify* for consistent quality improvement.

Marketing / Social Marketing

Marketing and social media marketing may help with general interest and uptake of the PC4H intervention. For example, our primary marketing tools during the demonstration project were the PC4H Flyers as this initiative was specifically recruiting within the FIGHT and CHOP clinics. If this intervention was to be adopted widely or used across multiple clinics, a broader marketing strategy using social media to promote the intervention through use of images or digital flyers would be appropriate.

For the demonstration project, flyers were posted in the health clinics' consult rooms and waiting areas where this initiative recruited participants, in the case management waiting area and in case management offices, and in educational spaces within the organization where young people living with HIV might see them, such as FIGHT digital literacy center, the Critical Path Learning Center. Additionally, PC4H was promoted widely in the community at numerous public events, conferences, and on social media:

(1) **FIGHT's AIDS Education Month (AEM) Events.** AEM is a month-long series of conferences and events organized by Philadelphia FIGHT with over 100 planning partners every June. The goal is to reach a broad segment of Philadelphia around HIV education, promote HIV testing, and reduce stigma widely. The largest event of the month is the annual END AIDS: HIV Prevention and Outreach Summit, a day-long Summit held at the convention center that hosts over 1400 attendees. FIGHT and CHOP had a table at the HIV Prevention and Outreach Summit staffed by a PC4H team member with flyers and other project materials for any youth who attend and were interested. Additionally, a project team member also distributed flyers at the Beyond the Walls: Prison Healthcare and Re-entry Summit Philadelphia FIGHT's other large conference during AIDS Education Month focused on the intersection of HIV and criminal justice. Lastly, Philadelphia FIGHT and CHOP co-sponsor Hip Hop for Philly during AIDS Education Month, a free hip hop concert for young people to attend if they get tested for HIV or engage in HIV education. Through mini-events leading up to Hip Hop for Philly, FIGHT and CHOP promoted the project materials in order to reach young people.

(2) **iknowUshould2 campaign.** This CHOP web-based social media campaign (website, Twitter, Facebook, Instagram, YouTube) encourages improving HIV and sexually transmitted infections (STI) knowledge, awareness, and testing, helps link newly diagnosed HIV+ youth to care and the PC4H project. Additionally, this campaign promotes and partners with various health promotion and awareness events each year, such as Hip Hop for Philly—where youth are able to receive rapid HIV testing, urine gonorrhea and chlamydia testing, and learn about ART or PrEP. Youth receive health counseling from health educators and clinical providers, and newly diagnosed youth are linked to care for follow-up services. At each of these events, project team members were also present to answer questions about the PC4H project and distribute flyers.

(3) **Conferences and Community Events**. Project team members also attended distributed flyers at the Philly Trans Health Conference. Additionally, all marketing materials were shared with Philadelphia Connect to Protect (C2P) project partners and at their events so they could also make flyers available to youth who visit their organizations.

Outreach and Recruitment

Outreach and recruitment considerations for each organization are critical prior to implementing PC4H. The strategies can vary if the organization is a Community-Based Organization (CBO), Federally Qualified Health Center (FQHC) or a hospital clinic setting. Following below are some examples of how the two organizations in this demonstration project utilized similar, yet distinct, outreach and recruitment methods:

Clinics

Clinical in-reach is key to recruitment of participants who will use *TreatYourSelf*. All outreach and recruitment for this intervention was conducted at three Philadelphia FIGHT health centers: Youth Health Empowerment Project (Y-HEP) Health Center, Jonathan Lax Treatment Center, and John Bell Health Center; and two CHOP clinics: AI and SI. This was primarily due to our project protocols that limited recruitment and enrollment to those who were patients of these 5 clinics. Depending on the clinical structure, recruitment may look different for sites wishing to adopt the intervention. Some of the practices used at Philadelphia FIGHT and CHOP are outlined below.

Philadelphia FIGHT

Flyers. Flyers are posted in all waiting room areas and throughout the administrative and drop-in spaces.

Collaboration with Providers and Provider Referral. Presenting information about the PC4H intervention during weekly case conference meetings with medical providers and during staff meetings with the medical case managers was a critical method for getting providers to learn about the intervention and understand how it might be useful for

some of their patients. Providers and staff learned about the project and met the PC4H team. Following these presentations, the project staff met individually with each provider and most case managers to go through potential patients that would be eligible or who providers believed would benefit from the intervention. Many providers had different preferences for recruitment (e.g., daily emails, email list of all provider patients, instant messaging by the project team during clinic visit, etc.), so it was important that the project team cultivate a relationship with each provider and then devise an individualized plan to maximize recruitment. Because we had a target number of participants to reach for recruitment into the evaluation, the PC4H team was very proactive in monitoring when participants checked in to their appointments, and for providers that were comfortable, the recruiter would instant message the provider in their exam room to remind them that they were seeing someone who might be eligible. This gentle reminder helped guide the providers to letting patients know there was a project that they might be eligible for and alerting our recruiter to come to the waiting area if the patient was interested in meeting with them. However, this level of monitoring patients may not be necessary if clinics aren't actively recruiting patients for a project, but offering the intervention as an option for any young person who is interested.

Medical Chart Review. For the project evaluation, staff digitally flagged medical charts of eligible patients within the EHR so that providers would be prompted during their clinic visit to ask patients if they were interested. If the patient wished to learn more about the intervention, the provider would give the patient a flyer and refer the patient to a project team member for follow up. Flagging medical charts for patients who might need extra support is a great way to help remind providers that *TreatYourSelf* could be a great tool for some youth struggling with their appointments or adherence.

Cold calls. Directly reaching out to patients who had been out of care to introduce the intervention and link them back into care was one of the most successful methods used. To date, this has been an effective recruitment strategy for some youth to not only introduce them to the intervention but to incentivize them to come back into the clinic and reconnect them to care.

Children's Hospital of Philadelphia

Flyers. Flyers were posted in clinic consult rooms and waiting room areas. Social workers also provided flyers to patients who were a good fit; these patients then reached out to the project team to learn more about the project and were able to enroll.

Collaboration with Providers and Provider Referral. In the AI clinic, for youth with behaviorally-acquired HIV, each week, there is a case review meeting where all physicians, nurse practitioners, social workers, and research staff discuss the past week's patients and upcoming week's schedule of patients. Here, project staff and clinic staff are able to identify patients who may need the intervention. Providers then refer the project team to appropriate patients and the project team is able to approach patients to recruit after their medical or social work appointments.

In addition to the AI clinic providers, this initiative also recruited at the co-located SI Clinic which serves many perinatally-infected YLH. Each week, one of the SI social workers from the clinic would reach out to the project team with a list of potential participants and their appointment times. The project team would then recruit the patients after their clinical visit.

Medical Chart Review. Project team members reviewed the medical charts of patients to identify potential patients and then discussed these patients with medical providers or social workers to deem appropriateness for participation in the intervention.

Intervention Procedures & Protocols

Enrollment (*APPlify* & Baseline)

If during a medical or case management visit, the participant is interested in the intervention, they would meet with a Project team member to have a 1:1 *APPlify* workshop and download the *TreatYourSelf* app. If they are unable to stay to

complete the *APPlify* workshop and baseline visit, the project team member can schedule a time to meet with the participant or offer a group workshop. During enrollment, the project team member should secure a private room (i.e., either consult or meeting room) to run *APPlify* and download the app. The total amount of time needed to run *APPlify Your Health* (15-20 min), download the app and make sure it is set up and working for the patient (10 min), and allow time to answer any questions (5-10 min), is between 30-40 minutes (see *APPlify* curriculum in appendix). The participant received a $20 Amazon or Wawa gift card and 2 SEPTA tokens for their time and effort in completing *APPlify*, as part of the project protocols, but it is recommended that some incentive be provided for anyone running the intervention.

Project Phone Distribution

Since this app was only able available for Android, this initiative decided to provide participants who owned iPhones or did not have a phone, with an Android phone if they were otherwise eligible. These phones are distributed at the enrollment project visit, or at a subsequent visit should a participant lose access to an android phone after enrollment. Each participant who needs a phone is provided an Android phone, a charger, a phone case, and a screen protector. Please see project phone distribution checklist in the appendices.

Project Partners

For this project to run successfully a number of key partners will need to be involved including clinical and non-clinical staff, community partners, and other internal resources. Below are examples of how we successfully engaged these partners in our demonstration project:

Clinic and Case Management Partners. At CHOP, project team members collaborated with all the staff at the [Adolescent Initiative](#) Clinic (physicians, nurse practitioners, registered nurses, social workers, and other research staff). In addition, this initiative also collaborated with the [Special Immunology](#) clinic, specifically working closing with the social work team. At FIGHT, the project team worked closely with three of their clinics: [Y-HEP Health Center](#), [Jonathan Lax Treatment Center](#), FIGHT's HIV specialty clinic, and the [John Bell Health Center, FIGHT's primary care adult clinic](#). This collaboration meant developing and maintaining relationships with the physicians, case management, and social service staff at each clinic as well as the front desk staff.

Community Partners. Both CHOP and FIGHT collaborated with the [iknowUshould2](#) campaign and the Hip Hop for Philly committee, a collaborative HIV testing effort that included over 12 different youth-serving agencies in Philadelphia. In addition, this initiative worked with our C2P partner sites.

Technology Partners. As the major component of this intervention is a mobile app, having a technology partner was critical to the success of this project. Dr. Dowshen and her team developed a relationship with Drexel University's College of Computing and Informatics (CCI). This initiative worked closely with Drexel University's Empathic Research Group and CCI developers in the design of TYS and led the development of the app. Drexel's CCI team continued to support the app throughout the project, providing critical updates, fixing bugs, and maintaining the app on the server.

In-House Partners. Both CHOP and FIGHT are organizations with different departments that were integral to the implementation of the intervention. At CHOP, there was also collaboration with the Department of Biomedical Health Informatics (DBHi) to host the app. Without this collaboration, this initiative would be unable to host the app or the server features of the app which would be too large to store in the app locally on individual phones. Without hosting, this initiative would be unable to have app usage information sync with the server to obtain any information about app usage, including medication adherence. At FIGHT, there was also collaboration with their AEM planning committee to get tables at major events during AIDS Education Month in June reserved for the promotion of our project and to allow us to distribute project materials.

TIPS FOR FUTURE IMPLEMENTATION OR REPLICATION

Staffing for Replication

Sites wishing to replicate and implement the PC4H intervention would need to 1) offer and support youth to download the *TreatYourSelf* app, 2) facilitate the *APPlify Your Health* workshop as part of the process of introducing the app in order to increase the likelihood of its usage, 3) be able to monitor and troubleshoot app issues over time.

Staff who could implement this intervention includes anyone who is working one-on-one or directly with youth (14-34) living with HIV including: physicians, medical case managers, adherence specialists, therapists or mental health professionals, community health workers, and treatment education staff who work directly with YLH. The intervention is intended to be implemented during a routine medical or case management visit although more time would be needed to ensure fidelity to the intervention than the typical time allotted for a medical visit. The total amount of time needed to run *APPlify Your Health* (15-20 min), download the app and make sure it is set up and working for the patient (10 min), and allow time to answer any questions (5-10 min) is between 30-40 minutes. Additionally, staff time may be needed over the course of 6-12 months to help troubleshoot any technical issues with the app. It is estimated that about 5-10 minutes is needed for typical troubleshooting and can be done over the phone, during a routine visit, or scheduled as a separate visit. It is recommended that, at minimum, staff ask patients about their use of the app during any routine visits as a check in to ensure there aren't any issues that have prevented the patient from using the app effectively.

Staff implementing PC4H should have the following skills:

1) Excellent communication and interpersonal skills to interact with staff, youth, and community partners
2) The ability to handle multiple, time dependent tasks in a fast paced environment
3) Excellent organizational skills and ability to pay strict attention to detail
4) Familiarity of HIV prevention and the HIV care continuum
5) Comfortability using and manipulating technology, and mobile apps in particular
6) Comfort in discussing issues around adherence, confidentiality online, and stigma and privacy as it relates to using technology for one's health care.

To implement at sites, at least one staff member would need to be an administrator in the google play store console to be able to give permissions to specific users to download the app as it is not public for the protections of YLH. Those staff members should also understand TYS app functions and familiarize themselves with the *APPlify Your Health* curriculum prior to delivering the intervention.

For implementation using a separate team to do a project evaluation in combination with the intervention, in addition to clinical providers, staffing would require the following roles which may be combined, requiring fewer staffing, pending availability of time:

Key Staff Roles

***Investigator/Evaluator**, (if evaluation at replication is desired)*

- Designs and develops PC4H protocols
- Assures intervention is implemented according to protocol and data is collected in timely and accurate manner
- Collaborates with app development team to design and develop new features for the mobile app

Project Manager/Director

- Supervises intervention staff
- Develops site-specific intervention protocol
- Monitors project's budget and finances

Project Manager (>.05FTE)

- Oversees the replication and quality of *APPlify Your Health*
- Understands and oversees the strategy to promote usage of TYS within the clinical site or community-based organization and day-to-day coordination/management of PC4H implementation activities
- Ideally this person should be intimately part of a clinical team. They could be a social worker, clinician, adherence specialist, or research director.

Research Assistant/Recruiter

- Conducts outreach and recruitment of participants
- Conducts screening, consent, *APPlify* workshop, and TYS visits
- Supports smartphone and TYS app technical assistance to participants and collaborates with app development team regarding bugs/issues experienced by participants

Data Manager/Biostatistician

- Collaborates with PC4H team to develop analysis plans, sample sizes, and apply appropriate methodologies
- Cleans and manages collected data (app usage, *APPlify* satisfaction, digital health literacy, etc)
- Prepares accurate and meaningful reports of analyses including summary tables, charts, plots, and graphs, and interpretation of results

Because the intervention itself is a short workshop and an app, replication should not require resources that are unavailable to most HIV settings. The goal is to use this intervention as an additional tool to support adherence and retention in care. For implementation of the intervention without any evaluation or minimal evaluation components, we recommend the following staffing be assigned or designated to ensure fidelity to the intervention:

TreatYourSelf and APPlify Instructor (Approx. .10-.25FTE depending on how many patients are enrolled in the intervention)

- Runs *APPlify* group or 1:1 workshops with patients
- Helps patients download the app and set it up
- An effective communicator who can discuss complex issues around confidentiality, adherence, and digital health literacy with young people
- This person can be a social worker, clinician, case manager, adherence specialist, sexual health educator, community health worker who is the "go-to person" for the intervention.
- Ideally this person is embedded in a clinical setting or team.

*Technical Support (*approximately .05FTE)

- Ensures that the app is working properly on patient phones
- Troubleshoots any issues that arise
- Pushes out updates if necessary and alerts users
- This position could be the same person as the *TreatYourSelf* and *APPlify* Instructor or it could be an IT person within an organization.
- This person should have a high comfort level with technology and/or experience with help desk support.

Key Attributes of Staff Roles

The specific attributes for each role are the following:

Role	Qualifications	Skills/Attributes
Project Manager/Director	▪ Master's degree in Education, Public Health, Public Administration, Social Work or related field ▪ Minimum 5+ years in HIV/AIDS prevention and outreach ▪ Leadership and project management experience	▪ Extensive organizational leadership, financial, and project management experience ▪ Ability to anticipate, quickly address and make correct decisions ▪ Diplomacy, outstanding representation of organization including public presentations ▪ Experience in working with Electronic Health Records
Research Assistant/Recruiter	▪ Bachelor's degree ▪ Experience working with youth and young adults ▪ Prior research experience a plus	▪ Ability to work with a variety of professional gatekeepers including medical providers, case management staff, and front desk staff. ▪ Excellent written and oral communication ▪ High attention to detail ▪ Experience using smartphone devices
Data Manager/Biostatistician	▪ Master's, preferably PhD is Biostatistics ▪ Minimum of 3+ years of relevant experience	▪ Proficient with statistical analysis and common statistical packages (e.g., SPSS, STATA) ▪ Minimum of 3+ years of relevant experience ▪ Knowledgeable about database utilization in statistical analysis ▪ Familiar with UNIX and windows OS
TreatYourSelf and APPlify Instructor; Technical Support	▪ Bachelor's/Master's degree in Education, Public Health, Social Work, or other related field ▪ Minimum 2 years of experience in social media, technology, and education	▪ Ability to use, instruct on, and help others troubleshoot issues with smartphone devices, mobile opertating systems, app features, and digital health materials and resources. ▪ Able to build and execute communication and social media strategy

Training Activities

Before the intervention could be implemented, key staff from both sites needed to be trained on *APPlify Your Health*, the *TreatYourSelf* app, and on administering android phones.

APPlify **Workshop**. Since the workshop was developed by FIGHT, CHOP staff members were trained on how to conduct the workshop during a 1-hour training session. After the session, staff were able to provide feedback and practice administering the workshop. Of note, the training had to be modified from its original plan as the final app was not released when the project started so there were multiple iterations of the workshop as updates to the app were released. See workshop manual in appendix.

TreatYourSelf **app.** For the intervention, project team members met regularly with the app developers to keep up with app changes and monitor any bugs or app features that were not working correctly. Project staff had to become experts on all the TYS app functionality to be able to effectively communicate about the features during *APPlify* as well as keep abreast of any technical issues that patients may bring to them in order to best troubleshoot the problem.

Project Phones. For this intervention this initiative purchased Android phones for participants who did not own an Android phone since the TYS app was only available for Android phones on Lollipop or later operating systems. Each site (CHOP and FIGHT) had different requirements for purchasing and distributing phones so each site trained their staff on ordering phones, setting up phones, tracking, distributing, and at the end of the project period recollecting phones. The trainings were conducted by the Project Manager at CHOP and the Digital Health Educator at FIGHT.

App Development and Usage

Developing an app is a challenging endeavor that generally ends up being quite time and resource intensive. Below are some considerations for future implementation:

- <u>Consider using an existing app platform that is open source</u>: While developing a unique and innovative app is exciting, it can (and will likely) take multiple years and tens to hundreds of thousands of dollars to create a

functional product. If possible, it might be more cost and time effective to use an already developed platform with customization to meet your needs if possible.

- Hire developers that best fit the goals of your project: If you do decide to create your own app, finding the right app developer partner is crucial to its success. There are different strategies for partnering with app developers— one strategy is to use an academic partner. These partnerships are generally more affordable and you may be able to be more creative with app features because they are willing to experiment with new ideas. Conversely, many academic app developers may use less experienced students to give them opportunities for learning and this may take longer than originally planned. If going with the academic partner, it is crucial to have experienced app developers at the lead on the project who will use a tangible project management system to communicate progress to all parties. It is also recommended that the app developers clearly communicate with the team about which desired app features may be more difficult, more timely, and more expensive to complete and why before deciding on final features. This will save both parties a good deal of time and money down the road. The other strategy is to use a commercial app development company, which may mean that the developers are more experienced, have a larger team two work on the app, and be able to complete the app on a faster timeline. However, these developers will likely be much more expensive with every added feature or modification costing more money. Commercial developers will often use a common platform which may not permit desired tailoring or customization and they may be more motivated by profit as compared to academic developers.
- Consider versions for different phone types: To reach more participants, it is critical that the app is available on more than one operating system. Having only one operating system limits the number of participants who will be able to benefit from its features. Ensure that there is enough money in the budget to have both IOS and Android versions available.
- Create hard deadlines for app development & back up plans for when deadlines are not met: One of the biggest app development issues were delays in development. App delays will happen, but in order to keep moving the project forward, develop a timeline with very clear deadlines for each feature as well as procedures to follow if those deadlines are not going to be met. This timeline should also account for time to test each feature and fix any bugs. In addition to the timeline, the app developers should use an online project management tool that everyone is able to view so you can get updates about app develop frequently. It is also recommended that weekly meetings to discuss app development are held so that the developers can communicate any issues or changes that need to be made to the original design. This process will hold all partners accountable. Further, it is necessary to have a budget for each and every feature so that if changes need to be made, all partners have all the information they need and everyone is clear about budget expectations.
- Outline procedure for hosting backend data: One issue this initiative had regarding the backend data, which was critical for this project, would be which organization would host and manage the backend data. Originally, our academic developers were supposed to manage the backend data but due to some HIPPA related issues, it was decided that CHOP should host the backend data. It is recommended any future initiatives ensure that this discussion happens prior to the start of the project and that it is actually written into the contract.
- Develop and update digital Health literacy workshop & app guide: Although young people are usually very tech savvy, this initiative found it was very important to have a digital literacy workshop and/or one-on-one discussion and app guide prior to using the app. The youth all enjoyed learning how to use the app before they were sent off to use it; most of them reported this experience as being beneficial.

Engagement with Clinical Team or Clinic Flow

Engagement of clinical staff and consideration of integrating into current workflow is important:

- Conduct focus groups with clinical team to get feedback & buy-in on program: Since this initiative was reaching participants at their healthcare provider, and relied heavily on the clinical team to connect us with participants it is critically important to have clinical team buy-in. Additionally, since this app is aimed at helping patients improve adherence and stay engaged in care, it would be important to receive feedback from healthcare providers about what they would find useful in an app. Do they also want to see the backend app data? Would this information help inform their interactions with their patients?

- Clinical workflow: In our project, the research team provided the app and provided technical assistance on any app related issues. This initiative would suggest engaging the clinical team in this process and potentially have the clinical team (e.g., social workers, case managers, etc.) provide the app to the participant and talk about how this could be useful for the participant. This engagement may improve participation and it would increase the communication between health care provider and patient regarding app use and medication adherence.

Enrollment in PC4H

Some considerations and suggestions to enroll into PC4H:

- Increase number of staff who recruit & conduct PC4H visits: PC4H only had one recruiter at each organization, which proved to be challenging particularly at FIGHT where there are multiple clinics at multiple locations. It is recommended to have at least 2 full-time recruiters and enrollers; however, if you engage the clinical team as suggested above, that may address this issue. There were also multiple staff transitions in the recruiter/enroller roles each year during the 4 years of the intervention. Having more than one recruiter/enroller at each organization would allow for an uninterrupted and smoother transition as one person leaves and another one enters into the role.
- Consider a two tier model of recruitment (1-2 recruiters & 1-2 folks to complete PC4H visits): Instead of one person recruiting and enrolling the all participants, it might be helpful to have one person (or a member of the clinical team) recruit participants and then another (potentially also a member of the clinical team) enroll the participant in the project. This would afford the recruiters more time to talk to multiple participants in one day and give the person completing the enrollment more time to work individually with participants.
- Shorten enrollment visit or lengthen the time of the clinical visit so that enrollment is built into the visit: If integrated into clinical care, it would be beneficial to build in the enrollment into the clinical visit. One of our main recruitment challenges was the length of time to enroll, which caused a lot of participants to delay enrollment. If enrollment was shorter and built into the clinical visit time, it is likely that more patients would have participated.

Additional Resources Needed for Implementation

Although not required for implementation, for patients without phones or without Android phones, we recommend setting aside funds to provide smartphones and 1-year unlimited data plans as a digital health equity strategy. This would support patients particularly at-risk of being lost to care or struggling with adherence who do not have Android phones.

Sustainability

It is important to consider the long-term sustainability of any intervention:

- Collaborate with fellow colleagues in similar fields or initiatives and think about future joint funding opportunities: It is important to think about technology and program sustainability as well as researching if the technology/program is effective and warrants further study and evaluation. The initiative can be opened up to and may be used for other populations of adolescents and young adults with other chronic diseases that require high levels of engagement in care and adherence (ie liver transplant patients) or youth on HIV PrEP. CHOP/FIGHT began collaborating with fellow SPNS initiative grantees from Penn State whom also created a native app. The plan is to take the most effective strategies from both initiatives and work on expanding access to these programs to people living with HIV in Pennsylvania and the surrounding tri-state area. Efforts to secure funding through federal, state, local health departments, and private companies such as pharmaceutical organizations should be explored by preparing preliminary budgets, letters of intent, project summaries, and identifying and securing meetings with key stakeholders. We have also partnered with other researchers and program developers to incorporate and sustain particular features of the app on different platforms (one currently funded large NIH trial using some of the app features together with an motivational interviewing case management intervention for youth on ART and PrEP).

LESSONS FROM THE FIELD

Successes

Final development of *TreatYourSelf* App

Our biggest accomplishment for this Demostration Project was having a final, fully functional app. The app version 1.9 was completed on November 30, 2018.

Android TreatYourSelf (TYS) Layout
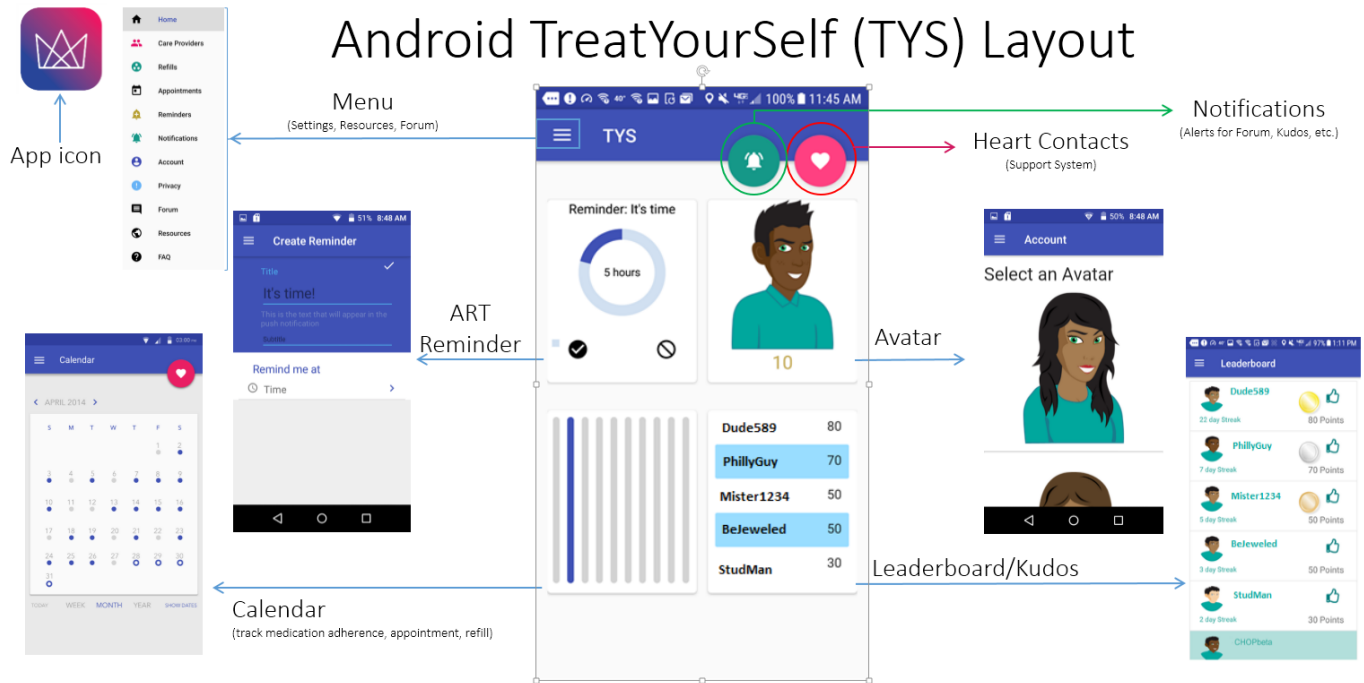
Satisfaction with *APPlify Your Health* Workshop

An integral part of PC4H is the *APPlify Your Health* Workshop, which is conducted by the Recruiter at CHOP and by the Digital Health Educator/Recruiter at FIGHT. After the workshop, participants complete a brief satisfaction survey (see appendix) to determine what participants found the most helpful.

Quotes from open ended questions.

PROMPT: What were the most useful parts of the course of information for you?

"The step-by-step guide on how to use the app."

"The most useful parts of the course information for me would be being able to remind myself to take my meds as well as set reminders for upcoming appointments and future refills."

PROMPT: What did you like about the way the instructor taught the course?

"She made sure I understood everything, and answered all of my questions."

"I like the way the instructor made me feel comfortable in using the apps as well as going over each step and how to use the app."

"The step-by-step verbal instructions; As well as, visual instructions provided."

PROMPT: Is there anything else you would like the instructor to know about your experience?

"that im very grateful that I was chosen to be a party of this study. it will really help me and my health."

Overall, participants felt that workshop was useful and they felt more able to use the TYS app effectively (Table 1). Further, instructors of the workshop were highly rated; the majority of participants (85-90%) felt that the instructor was organized, knew the subject well, and was understandable. Participants also liked receiving additional hard-copy materials on app features to take home.

Table 1. Survey Summary: Number of participants who agreed or strongly agreed (N=48)

Question	Agree N (%)	Strongly Agree N (%)
I will use TYS more now because of the workshop	15 (31.3)	29 (60.4)
I found what I learned important and relevant	14 (29.2)	33 (68.8)
I feel proficient using the avatar	20 (41.7)	25 (52.1)
I feel proficient using the medication reminder	14 (29.2)	33 (68.8)
I feel proficient using the calendar	16 (33.3)	32 (66.7)
I feel proficient using the leaderboard/forum	14 (29.2)	25 (52.1)
The instructor knows the subject well	8 (16.7)	40 (83.3)
The instructor was clear and understandable	4 (8.3)	43 (89.6)
The instructor was organized	5 (10.4)	43 (89.6)
The instructor answered all my questions	4 (8.3)	43 (89.6)
The instructor provided feedback during exercises	6 (12.5)	42 (87.5)
I found the handouts useful	18 (40.0)	27 (60.0)

Satisfaction with *TreatYourSelf* App

After 3 months of enrollment, this initiative asked returning participants to complete a survey to determine what features of the app participants found most helpful, how much they feel the app helps them with adherence to medication, refills, and appointments, whether they want to continue to use the app, whether they would recommend it to a friend, and what improvements they would suggest.

PROMPT: What features of the app did you find the most helpful?

"My favorite feature about the app was that it really did remind me at the time I need to take my meds."

"The 10-day calendar that showed me how well I was taking my meds."

"It's definitely been helpful lately . . . sometimes I fall off, but it [the app] is helping me be consistent. It really forces you to take it [HIV medication]."

"When the app was working the medication reminder and the refill prescription reminders were amazing features also the fact that's u could call your care team straight from the app helped."

The majority of participants (32/35 = 91%) reported that they would prefer to use the app in addition to their regular medical care rather than regular care without the app and 94% reported that they would use the app after the project was over. Table 2a and 2b further summarize responses from the survey.

Table 2a.

Question	Always N (%)	Often N (%)	Sometimes N (%)	Never N (%)
How often did you read your messages?	18 (51.4)	7 (20.0)	5 (14.3)	5 (14.3)
Did you find the messages or app functions intrusive or bothersome?	3 (8.6)	2 (5.7)	8 (22.9)	22 (62.9)

Table 2b.

Question	Very Much N (%)	Somewhat N (%)	Not Much N (%)	Not At All N (%)	Refused to Answer
Did the messages respect your privacy?	28 (80.0)	4 (11.4)	0	3 (8.6)	0
Do you think the app helped you miss fewer doses of your meds?	16 (45.7)	7 (20.0)	3 (8.6)	8 (22.9)	1 (2.9)
Do you think the app will make you more likely to call your healthcare provider if you have questions?	18 (51.4)	9 (25.7)	4 (11.4)	4 (11.4)	0

Communication with Clinical Team

While this project was conducted by the PC4H project team, buy-in from the clinical team was important. One of the metrics of success this initiative was interested in was communication with the clinical teams. At CHOP, participants were enrolled from two clinics—Adolescent Initiative Clinic and Special Immunology Clinic. The recruiter at CHOP worked closely with the social workers in both clinics to identify patients that would be a good fit as well as assist with engaging patients back in care for those who had been lost. Here are some examples from the clinical team regarding how the intervention was helpful for them:

"Having a reliable phone has been significant not only for the app but to be able to reach [patients] by phone to improve treatment/adherence. Improved clinic visits- due to reminders and phone." – Deborah Calvert, MSW, LSW at Special Immunology Clinic

> *CHOP Case Study:*
> *Claire* is a 20 year old female living with HIV who is patient at CHOP. Prior to being enrolled in PC4H, Claire was out of care and had missed multiple HIV-related medical visits. Social workers also reported having difficulty reaching her for follow-up visits and HIV care. When Claire was finally reached for a visit, she referred to PC4H by her social worker and enrolled. Since being enrolled in this intervention, Claire has only missed one medical visit and has been actively engaged in care, especially meeting with her social workers.*

At FIGHT, participants were enrolled from three clinic sites---Y-HEP Health Center, Jonathan Lax Health Center, and John Bell Center. A streamlined process for communication amongst the education, research, and clinical staff was established to work efficiently and collaboratively across departments at Philadelphia FIGHT. The research team utilized EMR systems to pre-screen the charts of potentially eligible patients prior to their next scheduled appointment. Lists of eligible

participants were created by project staff and reviewed with each relevant medical provider. Providers were given the opportunity to reach out to potential participants themselves or authorize project staff to reach out on their behalf. If patients were interested, a project specific or tandem medical/research visit was scheduled for the patient. FIGHT research staff also worked closely with case managers dedicated to serving young adult clients with HIV and remained available for "walk-in" project visits in the instance that an eligible potential participant arrived to one of the three participating clinics without an appointment seeking services. A closed instant messaging service was utilized within the FIGHT offices/buildings to facilitate timely communication between research staff, case managers, clinical staff, and front line staff who are not specifically trained on project operations but are often the first staff to intercept participants. Research staff also used an email system with the EMR to communicate directly with medical providers who provided care to eligible participants when in-person meetings were not possible. EMR messaging provided a means to securely communicate PHI when necessary. While some of these processes were utilized in other projects/studies, PC4H helped establish a more standardized procedure for FIGHT staff across departments to use not only in this project, but across other initiatives.

Engagement and Retention in Care

One of the eligibility criteria for PC4H was being out of care for at least a 6-month period sometime in the last 24 months. Poor retention in care is a significant challenge for this population as many of our youth and young adults have other competing needs (e.g., mental health, housing instability, etc.) that take priority over or preclude patients from seeking care regularly as required for their chronic disease. This initiative has some participants who were enrolled in PC4H because they were considered out of care. Of these participants, all have attended at least one medical visit since they started the project. Additional success metrics are identified below:

Participants	# of Medical Visits Attended	# of Missed Medical Visits	# of Social Work Visits Attended	# of Missed Social Work Visits
Riley*	1	1	1	1
Kyle*	3	0	3	0
Bella*	3	3	3	2

*names changed for confidentiality

Challenges & Barriers

App development delays. The biggest challenge was the delay in app development for both the Android and iPhone apps. PC4H chose to go with an Academic developer rather than a private app company. The research team believed this partnership would be a more cost-effective means for developing the app and would create a mutually beneficial research partnership among faculty and students. The original contract for app development was with a lab that ended up dissolving when the Lead Investigator moved to a different university. While another lab absorbed this project, PC4H experienced significant difficulties obtaining a functioning app. The app developers promised a fully completed Android app in June 2016, with a complete iOS app to follow 6 weeks later; however, there were significant delays.

To address these delays in development, in January 2017, the PC4H team began extensive meetings that occurred over the course of the next 7 months (3/29, 4/3, 4/5, 4/13, 4/26, 7/13, 8/28) with Drexel and CHOP legal counsel, technology transfer teams, research teams, information systems teams, contract people, and Philadelphia FIGHT IT and Finance Directors to discuss the contract and expectations. Finally, on May 12th, nearly 11 months after the originally promised date, the developers delivered a very basic Android app or otherwise known as a minimum viable product. Due to the delays, it was decided to focus effort and resources on completing the Android app and to not develop the iPhone app. By August 2017, Drexel ultimately agreed to create a new timeline and put two developers on the project who were much more senior than the previous developer. Despite these efforts, without the iPhone app, the project team had to purchase Android phones and plans so that this initiative could still enroll participants who primarily used an iPhone.

Further, once there was a minimum viable product for the app and it was released to participants, there were many bugs that needed to be fixed. Our app developers continued to make updates and revisions to the app but the bugs were difficult for both the team and the participants.

In addition to the delays in development, the complexities of the app became more apparent as the senior developers reviewed the code. During our weekly development team meetings, the PC4H research team learned that there were some features that would be too time consuming or too costly to develop (e.g., avatar customization feature) based on our timeline and budget. Thus, the project team had to prioritize certain features and halt development of others. Throughout this process PC4H learned how critical frequent communication and flexibility was to the overall success of the project.

Management of Backend Data. An integral component of the app was the development of and access to backend data. PC4H wanted to have an administrative interface that allowed us to access participant app usage data in real-time. Originally, it was proposed that the university developing the app would host the backend data, meaning that the app data would be on their server. However, due to privacy concerns from the legal departments of both CHOP and the University developing the app, it was decided that CHOP would host the backend data. To host the backend data, CHOP's Department of Biomedical Health Informatics (DBHi) had to develop a mirror image of the server. This process of backend development and server transfer was delayed quite a few months due to programming issues as well as workload for both departments. Without the backend data server established, this initiative had to initially use a version of the app not connected to the server while one was developed for later use.

Recruitment. Since PC4H recruited participants at the time of their clinical visits, and the consenting, screening, and enrollment visit usually took up to 120 minutes, many participants were unable to stay for the enrollment visit. This meant that this initiative would consent a participant to the project, but have to schedule another visit for the participant to come back to clinic to complete enrollment. Often this led to long gaps of time between consent and enrollment, delaying the time participants were able to engage with the intervention. For future implementation we suggest trying to minimize time for any evaluation or other activities to increase uptake and focus on the applify workshop and the app itself.

During the demonstration project that may not be issues in future replication were due to eligibility criteria, app development delays, and regulatory oversight requirements. When this project was first initiated, this initiative had limited eligibility criteria that decreased the number of potentially eligible participants. This issue was further exacerbated with the app delays since recruitment and enrollment could not start until a minimum viable app was ready to roll out to participants. Ultimately, the PC4H team was able to expand the PC4H eligibility to increase the number of potential participants. In order to expand the eligibility criteria, this initiative had to submit multiple amendments across the CHOP and FIGHT IRBs and each of these amendments took several weeks to be reviewed.

EVALUATION RESULTS AND METHODS

In this demonstration project, the team conducted a local evaluation (in addition to the HRSA SPNS multisite evaluation (MSE) conducted with other city sites implementing a social media or app intervention) and these methods below may be replicated for those adapting and implementing PC4H in the future if evaluation is desired to assess intervention effectiveness. Evaluation may be limited to a single follow-up or multiple follow-ups over the course of one year similar to the local evaluation conducted for this demonstration project. For this demonstration project, evaluation was conducated at baseline and follow up visits.

Follow-up Visits. This initiative followed up with participants at 3 months, 6 months, 12 months, and 18 months (18-mo MSE only) as part of the project evaluation. At these PC4H visits, the team members check the app on the participant's phone to make sure it is working properly and answer any questions. PC4H team members typically spent about 5-10 minutes with participants for general troubleshooting and at times this was done over the phone, during a routine visit,

or scheduled as a separate visit. PC4H team members asked patients about their use of the app during any visits as a check in to ensure there weren't any issues preventing the patient from using the app to its full effect.

Aims for Local Evaluation

Aim 1. Determine acceptability, feasibility, and preliminary efficacy of the *TreatYourSelf* (TYS) medication adherence application with *APPlify Your Health* literacy workshop in improving engagement and retention in care, and viral suppression for HIV+ youth in Philadelphia.

Exploratory aim: Explore relationship between app usage patterns (low/high utilizers) and outcomes of interest.

Monitoring Progress

The table below describes progress indicators and timelines for internal evaluation:

Indicator	Description	Timeline
Intervention Reach	Number of participants actively engaged in the intervention	May 2017 – May 2018
TYS App Development	Final, functioning, fully developed app	September 2015 – November 2018

Participants for Local Evaluation

In Philadelphia, youth and young adults aged 13-29 accounted for 45% of all newly diagnosed HIV infections in 2016.

The AI and SI Clinics at CHOP, and the Philadelphia FIGHT clinics-- Jonathan Lax Treatment Center, John Bell Health Center, and Y-HEP Health Center—provide HIV services to youth and young adults in Philadelphia. In 2017, the AI clinic provided services to 115 young people; 95% were African American, 90% were male, 8% identified as transgender and 75% were uninsured or had Medicaid. At SI, there were 241 patients in total and of those 61% were African American, 51% were male, and 73% had Medicaid. While this intervention was piloted at CHOP and FIGHT, this initiative believes that this intervention could be used at all HIV-focused health centers in the Philadelphia region who serve youth and young adults.

Based on the population of these clinics and the fact that youth and young adults make up the largest proportion of newly diagnosed HIV infections, implementation for PC4H focuses on HIV+ adolescents and young adults who know their status, are aged 14-34, and are already linked to care.

Inclusion criteria for participation in this project stipulates that participants must be:

1) HIV positive
   AND
2) One or more of the following:
   a. Newly diagnosed who tested HIV positive for the first time within the last 12 months;
      AND/OR
   b. Patients who are aware of their HIV positive status but have never been engaged in HIV care (e.g., never had an HIV medical visit after being diagnosed with HIV);
      AND/OR
   c. have been out of care for at least 6 months in the last 24 months
      AND/OR OR
   d. Virally unsuppressed (viral load ≥200 copies/ml)
3) Own an Android smartphone or is willing to use a PC4H project-provided Android smartphone if they do not own one compatible with the project app
4) About to start, newly initiated, or have had trouble in the past adhering to ART medication

All participants in the MSE evaluation were also included in the local evaluation. The project also compared high-end and low-end users of the *TYS* app.

Evaluation Procedures in Demonstration Project

Recruitment, Consent, Screening. During recruitment until consent, PC4H team member could only have 1-way communication with the potential participant per the organization's recruitment guidelines so as not to collect identifiable or project data prior to consent and Health Insurance Portability and Accountability Act (HIPAA) authorization. The PC4H team member approached a patient before/after their medical appointment at either CHOP or FIGHT clinics. The PC4H team member introduced themselves and provided a brief introduction of PC4H and project materials (i.e., flyer). If the participant was interested in learning more about the project, the PC4H team member reviewed the informed consent form with the youth. If the youth was interested in the project and consented, then the PC4H team member moved onto screening. During screening, the PC4H team member was able to ask youth questions to determine eligibility and if eligible, obtained contact information from the participant. If the youth needed more time to decide, then the PC4H team member gave them more time to decide participation and provided them with the flyer and a copy of a blank consent form so the youth could review project information on their own time. All recruitment, consent, and screening procedures were conducted in a private room at the clinic sites. Please see appendices for more details on these procedures and materials.

Enrollment (*APPlify* & Baseline). If the participant was unable to stay to complete the *APPlify* workshop and baseline visit, the PC4H team member scheduled a different time to meet with the participant after completion of recruitment, consent, and screening. However, if the participant was able to stay, they completed the *APPlify* workshop and downloaded *TreatYourSelf*. During enrollment, the PC4H team member secured a private room (i.e., either consult or meeting room) to conduct the APPlify visit. Before the workshop, the participant completed the eHEALS survey in Research Electronic Data Capture (REDCap)[31], a secure web application for building and managing online surveys and databases. Once completed, the PC4H team member administered the workshop (see *APPlify* curriculum in appendix). After the workshop was completed, the project team member launched the workshop satisfaction survey in REDCap. The participant was given the option to either read and complete the survey individually, or have the PC4H team member administer the surveys to them orally. After the workshop, the participant completed local baseline REDCap surveys on ART regimen, past ART adherence, and mobile phone usage. Finally, the PC4H team member launched Evaluation and Technical Assistance Center's (ETAC) national multisite evaluation baseline Audio Computer Assisted Self Interview Instrument (ACASI) survey in Questionnaire Development System (QDS) software (see QDS and Baseline checklists in appendix for more details). Once the workshop and baseline visit procedures were completed, the participant received a $20 Amazon or Wawa gift card and 2 SEPTA tokens (public transportation) for their time and effort in completing *APPlify* and $25 Amazon or Wawa gift card (later adjusted to $50 towards the end of the enrollment deadline to boost enrollment) and 2 SEPTA tokens for their time and effort in completing baseline. To note, baseline procedures and *APPlify* can be completed on different days, if more convenient to participant, but were still completed within seven days following the APPlify workshop.

Project Phone Distribution. Since this app was only able available for Android, this initiative decided to provide participants who owned iPhones or did not own a smartphone, with an Android phone if they were otherwise eligible. These phones were distributed at the enrollment visit, or at a subsequent visit if a participant lost access to an android phone after enrolment. Each participant who needed a phone was provided an Android phone, a charger, a phone case, and a screen protector. Please see study phone distribution checklist in the appendices.

Follow-up Visits. This initiative followed up with participants at 3 months (local only), 6 months, 12 months, and 18 months (MSE only). At these project visits, the team members checked the app on the participant's phone to make sure it was working properly and answered any questions. Thereafter, the PC4H team member launched the surveys via REDCap (e.g., ART Regimen, etc.) and then the QDS ACASI survey. At each visit, the participant was compensated for their time (e.g., gift cards and SEPTA tokens). To note, the national MSE evaluation did not have a project visit at 3 months; this 3-month visit was part of the local evaluation only. The local evaluation concluded after the 12-month

visit and thus did not have an 18-month visit. Please see checklists for 3-month, 6-month, 12-month, and 18-month project visits.

In between PC4H visits. The PC4H team members reached out to participants once a month to check-in and also conducted medical chart reviews. Medical chart reviews were completed via REDCap for CHOP and FIGHT at specific project visit time points, and completed via Excel for University of California, Los Angeles (UCLA).

 ETAC's for 6-months prior to enrollment throughout their 18-month visit for all applicable project-related labs. The medical chart reviews completed for UCLA ETAC were uploaded to the UCLA ETAC web project portal. Please see medical chart review instructions and in between study visit checklist in the appendices.

Methods for Local Evaluation

This project is a pre-post design with comparison of outcomes of interest to historical controls. Specifically, the outcomes of interest are (1) app satisfaction, (2) viral suppression at 12 months, (3) incident STI infection, and (4) retention in care.

1) Viral suppression is defined as <200 copies/ml by the CDC
2) Incident STI infection is defined as new diagnosis of a STI, specifically Chlamydia and Gonorrhea.
3) Retention is care is defined as keeping AYA engaged in their HIV care. PC4H will measure retention in care by (1) number of missed vs completed appointments during the project period, (2) the number of completed visits over the number of scheduled visits, and (3) gaps in care of 6 months between completed clinic visits.

Enrollment

Due to varying cutoff dates for enrollment into the ETAC multisite evaluation (May 31, 2018) and with the local evaluation (August 31,2018), it was possible for participants to be enrolled in local evaluation only if they enrolled post May 2018.

Data Collection and Outcomes

Data Source	Description	Method of Collection	Time Points
Costing Data	• Cost of personnel hours • Cost of all intervention activities	• REDCap Form • Excel	• Monthly • Yearly
Intervention Exposure	Contact with PC4H team	REDCap Form	Daily
Backend-app Data	App usage data	Website	Daily
SURVEYS			
eHEALS	8-item measure of eHealth literacy designed to measure consumers combined knowledge, comfort, and perceived skills at finding, evaluating, and applying electronic health information to health problems.	Survey via REDCap	Baseline and 3 month visit
APPlify Your Health Workshop Satisfaction	Likert Scale and open-ended questions on the workshop content and instructor	REDCap Form	Baseline
ART Regimen	ART prescription and daily medication regimen: If they are currently taking their ART, what is their ART drug, how many pills per dose, and date they first started taking their current ART	REDCap Form	Baseline, 3-, 6-, 12-, 18-month visits
TYS App Satisfaction	Likert Scale, multiple choice, and open-ended questions	REDCap Form	Baseline and 3 months
Local Site Questions	include questions on mobile phone type, usage, and interruptions, ART adherence (using Visual Analogue Scale and questions from AIDS Clinical Trials Group), and information on sex (condom use,	REDCap Form	

Data Source	Description	Method of Collection	Time Points
	discussion with partner on use of PrEP).		
ACASI	QDS ACASI program collecting items on: SES, housing, incarceration, biomedical health, HIV care/Adherence encouragement, barriers to care, and technology uses and attitudes.	ACASI/QDS	Baseline, 6-, 12-, 18-month visits
MEDICAL CHART REVIEWS			
Pharmacy Refill	ART prescription information including medication(s), dose, frequency and date of initiation/Rx; refill dates	REDCap Form, EMR	Baseline, 3-, 6-, 12-, 18-month visits
Clinical Outcomes	CD2 count/percent; viral load, STI lab test (gonorrhea and chlamydia)	REDCap Form, EMR	Baseline, 3-, 6-, 12-, 18-month visits
MSE Medical chart review		Excel	Baseline, 6-, 12-, 18-month visits
Qualitative Data analyses	Satisfaction Surveys	REDCap form	Baseline, 3-, 12-month visits
Missed Medical Visits		REDCap form	Every missed visit is recorded
Phone Disruptions	Types of and length of disruptions	REDCap form	Every disruption is recorded

Primary outcome:

Participant's satisfaction with the workshop and the app through use of the surveys. This initiative calculates satisfaction using percentages for categorical variables (if participant found app to be helpful in remembering to take their medications or remember their medical appointments, etc.) and determining differences between the app satisfaction responses at 3- and 12-months in the project.

Secondary outcomes:

1) Viral load at 3-, 6-, 12, and 18-month visits;
2) Self-reported adherence[*], pharmacy refill[^], and app usage data at 3[*†], 6[†], and 12[*†], and 18 months.

Baseline Data Analysis

Baseline and demographic characteristics are summarized using standard descriptive statistics (e.g., means and standard deviations for continuous variables such as age and percentage for categorical variables).

Efficacy Analysis

Using a pre-post prospective design for TYS, this initiative collected and analyzed data at 4 time points: baseline, 3, 6, and 12 months post entry into the intervention. It is not a randomized clinical trial given that the aim of the project is to examine feasibility, uptake, and preliminary efficacy of the intervention overtime. A pre-post design limits our ability to determine causality, but our comprehensive data collection plan and rigorous analysis allows us to rule out alternative explanations if our intervention proves to be effective.

An outcome of interest will be an undetectable/suppressed viral load at 12 months. This initiative hypothesizes that (1) greater intervention uptake during the required 3 months of TYS app usage period will improve health outcomes at 12 months and (2) after controlling for baseline differences, participants who had higher uptake of intervention in the first 3 months will have a higher likelihood of undetectable/suppressed viral loads than those with lesser uptake. Logistic regression modeling will be use to predict undetectable/suppressed viral load at 12 months.

Training for Evaluation

Before this project could be implemented, clinical teams from both sites needed to be onboarded, trained, and receive human subjects, software, and organizational training.

Recruitment, Consent.   All project staff, particularly recruiters, were trained on recruitment and consent. For recruitment and consent, project staff were required to read organizational IRB guidelines, go through an initial training review with the project manager, practice recruiting and consenting other project team members. Once a staff member felt comfortable with the process, mock recruitment and consent visit was conducted with a third staff member observing. Staff were trained specifically on the important concepts (ethics, cultural competency) and language (no higher than a 6-8th grade reading level) to use when working with youth and young adults. These practice sessions and mock visits occurred as often as needed until all staff were fully competent in project procedures. See checklists in appendix.

Screening, Enrollment, & Follow-up Visits. Once project team members were able to successfully recruit and consent participants, they were trained on screening, project enrollment (beginning project), and conducting follow-up project visits. Screening, enrollment, and project visit data are all stored on REDCap. The REDCap instruments for PC4H data collection is managed by CHOP since they are the local DCC. Contact information, eligibility criteria, medical/pharmacy data, ART regimen, and surveys (eHEALS, local site surveys) are collected in REDCap. Project-specific REDCap and QDS training to staff was completed over 2 months. See checklists, QDS and REDCap guidelines, and REDCap codebook in appendix.

Surveys for National Evaluation at Project Visits (Baseline and follow-ups at 6, 12, and 18 months). For the national evaluation, participants had to complete the ETAC's Social Media ACASI Survey using QDS, which was designed by ETAC with input from all HRSA SPNS project city sites. Trainings for the surveys were conducted through webinars by the ETAC and further questions and clarifications were reviewed at all-site grantee meetings by ETAC team members as well as via email. At least 1-2 project team members from Philadelphia site attended these webinars and all-grantee meetings. Trainings for the ACASI survey were conducted for CHOP and FIGHT project team members by the data/project manager. Project team members were required to take the surveys individually a few times to familiarize themselves with the software and content, and then practiced administering this survey during a mock project visit with other team members. These practice sessions and mock visits occurred as often as needed until all staff were fully trained. See checklists and ACASI codebook in appendix.

APPlify **Workshop**. Since the workshop was developed by FIGHT, CHOP staff members were trained on how to conduct the workshop during a 1-hour training session. After the session, staff were able to provide feedback and practice administering the workshop. Of note, the training had to be modified from its original plan as the final app was not released when the project started so there were multiple iterations of the workshop as updates to the app were released. See workshop manual in appendix.

Medical Chart Review. All participant medical charts were reviewed for HIV-related labs, and ART medication prescriptions and refill data. Local evaluation medical chart data also included STI labs and were captured in REDCap (see REDCap codebook in appendix) and obtained by the electronic medical records at each site (CHOP: Epic, FIGHT: PrimeSuite) for baseline 3-, 6-, and 12-month project visit periods. Project Staff were trained on local evaluation medical chart reviews during the REDCap training. For the national evaluation, medical chart review was conducted in the ETAC's Excel template in ETAC specified waves (time periods) for baseline, 6-, 12-, and 18-month project visits by a project team member after project visits and uploaded to the UCLA ETAC web portal by each wave deadline.

Project-provided Phones. For this intervention this initiative purchased Android phones for participants who did not own an Android phone since the TYS app was only available for Android phones on Lollipop or later operating systems. Each site (CHOP and FIGHT) had different requirements for purchasing and distributing phones so each site trained their staff on ordering phones, setting up phones, tracking, distributing, and at the end of the project period recollecting phones. The trainings were conducted by the Project Manager at CHOP and the Digital Health Educator at FIGHT.

Results for Local Evaluation

Participant Enrollment & Retention

This intervention yielded fairly high retention rates from baseline throughout project visits for this hard-to-reach population.

Table 3a. Enrolled in MSE+Local

Site	# Enrolled*	# Completed 3-month visit	# Completed 6-month visit	# Completed 12-month visit	# Completed 18-month visit
CHOP	19	15	13	11	6
FIGHT	22	17	16	18	16
Total	41	32	29	29	22

*participants were considered enrolled when they completed the *APPlify* Workshop and baseline questionnaire

Table 3b. **Enrolled in Local-only** (7 additional youth were enrolled in local evaluations whom were not also in the MSE due to extended local enrollment deadlines)

Site	# Enrolled*	# Completed 3 month visit	# Completed 6-month visit	# Completed 12-month visit	# Completed 18-month visit**
CHOP	20	15	14	11	N/A
FIGHT	28	20	18	19	N/A
Total	48	35	32	30	N/A

*participants were considered enrolled when they completed the *APPlify* Workshop and baseline questionnaire
**Local assessment only went through 12-months

Table 3c. Retention Rates (Closed = # Completed / [# Completed + Missed Follow-Up Visit])

Assessment	MSE Retention Rate	Local Retention Rate (includes participants dually enrolled in MSE+local)
Baseline	41/41 = 100%	48/48 = 100%
3M (Local evaluation only)	32/40* = 80.0%	35/47* = 74.5%
6M	29/39*† = 74.4%	32/46*† = 69.6%
12M	29/40*† = 72.5%	30/45*† =66.7%
18M (MSE only)	22/33*† =66.7%	N/A

* Does not include participant(s) who withdrew
† Does not include participant(s) who are incarcerated
Note: Some participants never reached an 18 month visit for MSE due to late enrollment and project visit cutoff date.

Demographics

Participants (N = 48) at baseline were mean age 25.5 years (SD 4.6, range 17–34), and majority were male sex (75%), Black (68.75%), non-Hispanic/Latino (81.25%). See Table 4 for more information.

Table 4. Demographic Characteristics (7 participants in local-only did not participate in multisite evaluation)

Participant Characteristics	Enrolled in Multisite and Local Evaluation (N=41) n (%)	Enrolled in Local Evaluation Only (N=48) n (%)
Mean age (SD, Range)	25.46 (4.65, 17-34)	25.52 (4.64, 17-34)
Race		
Black or African American	30 (73.17)	33 (68.75)
White	3 (07.32)	4 (08.33)
Other or Multi racial	8 (19.51)	11 (22.92)
Ethnicity		
Hispanic/Latin	6 (14.63)	9 (18.75)
Non-Hispanic/Latin	35 (85.37)	39 (81.25)
Sex assigned at birth		
Male	30 (73.17)	36 (75.00)
Female	11 (26.83)	12 (25.00)
Reported Gender		
Cisgender Male	26 (63.41)	31 (64.58)
Cisgender Female	12 (29.27)	13 (27.08)
Trans Male	1 (02.44)	1 (02.08)
Trans Female	2 (04.88)	2 (04.17)
Other	0	1 (02.08)
Sexual Orientation		
Straight	15 (36.59)	16 (33.33)
Lesbian or Gay	17 (41.46)	21 (43.75)
Bisexual	7 (17.07)	9 (18.75)
Other/Don't know	2 (04.88)	2 (04.17)
HIV+ status	41 (100)	48 (100)
Risk^		
Unsuppressed VL (≥200 copies/ml)	33 (80.49)	32 (66.67)
Out of care for ≥6 months	17 (41.46)	22 (45.83)
Newly Diagnosed	6 (14.63)	8 (16.67)
Antiretroviral Therapy Status at Baseline		
On ART	40 (97.56)	42 (87.50)
Not on ART, but will start soon	1 (02.44)	6 (12.50)
Employment Status^		
Student	2 (04.88)	3 (06.25)
Full-time employed	9 (21.95)	13 (27.08)
Part-time employed	13 (31.71)	13 (27.08)
Disabled	6 (14.63)	6 (12.50)
Unemployed, but looking	9 (21.95)	11 (22.92)
Unemployed, not looking	3 (07.32)	3 (06.25)
Highest Level of Education Completed		
8th grade (junior high) or less	1 (02.44)	1 (2.08)
Some high school	6 (14.63)	7 (14.58)
Completed high school (Grade 12), HS diploma or GED	17 (41.46)	19 (39.58)
Some college, professional, vocational, or trade school	15 (36.59)	16 (33.33)
Associates degree or trade certificate	1 (02.44)	2 (04.17)
Bachelor's degree	1 (02.44)	3 (06.25)
Housing (Last 7 Days)		
A house, apartment or flat that you own or rent	16 (39.02)	20 (41.67)
Family member's house, apartment or flat	17 (41.46)	20 (41.67)
Lover or sexual partner's house, apartment or flat	3 (07.32)	3 (06.25)
Halfway house, drug treatment center, or independent living unit	1 (02.44)	1 (02.08)
Homeless shelter or mission	4 (09.76)	4 (08.33)

^Not mutually exclusive categories, totals will not = 100%

Majority of participants owned a smartphone prior to project enrollment (93.75%) and used their phones 11 hours a day on average and used WiFi for 9 hours on average (mostly whenever free WiFi was available). More than half had experienced at least one disruption in their phone plan service due to missed phone plan payment and/or their device lost, broken, stolen, or confiscated. Since the TYS app was only available on the Android platform, (54.17%) had to be provided project-loaned Android devices for 12-months.

Table 5. Smartphone Characteristics

Usage (Reported at Baseline)	n (%)
Phone Ownership*	
Android	23 (47.92)
iOS (iPhone)	22 (45.83)
No smartphone, basic only	3 (06.25)
Hourly Phone Use Daily	
Mean (SD, Range)	11.2 (7.00, 1-24)
Hourly WiFi Use Daily	
Mean (SD, Range)	9 (7.97, 1-24)
Phone Disruption in Past Year	
No disruption	21 (43.75)
1 time	12 (25.00)
≥2 times	15 (31.25)

*iOS and non-smartphone users were provided a project issued Android smartphone

Digital health literacy (knowledge, comfort, and perceived skills at finding, evaluating, and applying electronic health information to health problems) improved among participants from baseline to 3-month visit.

Table 6. eHEALS Digital Health Literacy

eHealth Literacy Scale Item	Pre=APPlify, N=48 Agree/Strongly Agree n (%)	3-Month, N=35 Agree/Strongly Agree n (%)
I know what health resources are available on the Internet	37 (77.1)	31 (88.6)
I know where to find helpful health resources on the Internet	37 (77.1)	32 (91.4)
I know how to find helpful health resources on the Internet	43 (89.6)	34 (97.1)
I know how to use the Internet to answer my questions about health	42 (87.5)	33 (94.3)
I know how to use the health information I find on the Internet to help me	35 (72.9)	34 (97.1)
I have the skills I need to evaluate the health resources I find on the Internet	39 (81.3)	30 (85.7)
I can tell high quality health resources from low quality health resources on the Internet	29 (60.4)	22 (62.9)
I feel confident in using information from the Internet to make health decisions	25 (52.1)	24 (68.6)

While there was high satisfaction with PC4H (app and workshop), good retention rates, improved digital health literacy, there was no significant differences in risk behaviors and self-reported adherence (See Tables 7 & 8a).

Table 7. Risk Behaviors

Behavior (self-reported)	Baseline, N=48 n (%)	3-mo, N=35 n (%)	6-mo, N=32 n (%)	12-mo, N=30 n (%)
Traded sex for money, drugs, food, or a place to stay in the past 3 months	5 (10.42)	2 (5.71)	3 (9.38)	3 (10.0)
Condoms/latex protection usage during sex in last 3 months:				
Never	10 (20.83)	8 (22.86)	9 (28.13)	7 (23.33)
Some of the time	9 (18.75)	5 (14.29)	4 (12.50)	4 (13.33)
Half of the time	2 (04.17)	1 (02.86)	0 (0)	2 (6.67)
More than half of the time	4 (08.33)	2 (05.71)	4 (12.50)	3 (10.00)
Every time	11 (22.92)	11 (31.43)	6 (18.75)	7 (23.33)
N/A, no sex of any kind in the past 3 months	12 (25.00)	8 (22.86)	9 (28.13)	7 (23.33)
Talked to partner(s) about using PrEP	25 (52.08)	22 (62.86)	19 (59.38)	24 (80.00)

Table 8a. Self-reported ART adherence (ACTG)

ACTG Adherence Questionnaire	Baseline, N=48 n (%)	3-mo, N=35 n (%)	6-mo, N=32 n (%)	12-mo, N=30 n (%)
During the past 4 days, on how many days have you missed taking all your doses?				
None	30 (62.50)	21 (60.00)	17 (53.13)	19 (63.33)
1 day	5 (10.42)	8 (22.86)	4 (12.50)	4 (13.33)
2 days	6 (12.50)	3 (08.57)	4 (12.50)	3 (10.00)
3 days	2 (04.17)	0 (0)	3 (09.38)	2 (6.67)
4 days	4 (08.33)	3 (08.57)	4 (12.50)	1 (3.33)
Refused to Answer	1 (02.08)	0 (00.00)	0 (0)	1 (3.33)
When was the last time you missed any of your medications?				
Never skip medications	8 (16.67)	1 (02.86)	6 (18.75)	2 (6.67)
More than 3 months ago	1 (02.08)	6 (17.14)	2 (06.25)	5 (16.67)
1-3 months ago	7 (14.58)	8 (22.86)	5 (15.63)	3 (10.00)
2-4 weeks ago	3 (06.25)	3 (08.57)	2 (06.25)	3 (10.00)
1-2 weeks ago	8 (16.67)	4 (11.43)	13 (40.63)	6 (20.00)
Within the past week	15 (31.25)	11 (31.43)	1 (03.13)	6 (20.00)
Refused to Answer	6 (12.50)	2 (05.71)	3 (09.38)	5 (16.67)

Table 8b. Self-reported ART adherence (VAS)

Self-Report Visual Analog Scale (VAS) ART Adherence	Baseline N=42	3-month N=33	6-month N=32	12-month N=25	p-value (3-, 6-, 12-mo)
Mean VAS in the past 4 weeks, mean (SD)	76.2 (27.9)	88.2 (20.2)	81.2 (26.9)	85.2 (20.7)	*0.004*, 0.08, 0.05

While there were no significant differences in self-reported adherence (for VAS only) after 3-month follow up, there were significant improvements and maintenance in undetectable laboratory viral load test results from baseline through 12 months (p=0.01). Undetectable viral load is a key goal in HIV care and indicates participants are doing well with their ART medication adherence.

Table 9. VL: Baseline, 3-month, 6-month, and 12-month

	Baseline N=48	3-month N=31	6-month N=30	12-month N=31	p-value (3-, 6-, 12-mo)
Log viral load, n; mean (SD)	2.57 (0.17)	2.28 (1.15)	2.58 (1.48)	2.36 (1.38)	0.08, 0.90, 0.17
Undetectable viral load, n (%)	17 (35.4)	15 (48.4)	15 (50.00)	16 (51.6)	*0.03, 0.01, 0.01*

Note: Undetectable levels varied depending on the lab where the test was conducted in Philadelphia. The undetectable limit ranged from <15 to <40 copies/ml blood.

Routine screening of STIs is an important part of medical care for youth living with HIV since STIs can be treated to lessen HIV and STI secondary transmission to others. Below are tables displaying the number of participants who were screened for gonorrhea and chlamydia infection by anatomical site during or around the time of their medical appointments while they were participating in the project.

Table 10a. STI Testing at Baseline and Follow Up Visits

STI Testing	Baseline (N=48), n (%)	3-month (N=35), n (%)	6-month (N=32), n (%)	12-month (N=30), n (%)
Tested for GC/CT	38 (79.17)	23 (65.71)	18 (56.25)	19 (63.33)
Positive Result	10 (26.32)	7 (31.82)	3 (16.67)	2 (10.53)

Table 11a. STI Testing and Incidence by Anatomical Site: Baseline

Of 38 pts tested (At Baseline)	Site tested n	Positive result n
Chlamydia		
Urine	34	1
Oropharyngeal	22	0
Rectal	20	5
Vaginal	0	0
Cervical	3	0
Gonorrhea		
Urine	34	0
Oropharyngeal	22	3
Rectal	18	2
Vaginal	0	0
Cervical	3	0

Note: Positive anatomical site totals may not equal total number of people who tested positive because one person may have a positive result from multiple anatomical sites.

Table 11b. STI Testing and Incidence by Anatomical Site: 3-month

Of 23 pts tested (who returned for 3-mo visit)	Site tested n	Positive result n
Chlamydia		
Urine	23	4
Oropharyngeal	8	1
Rectal	8	1
Vaginal	0	0
Cervical	2	0
Gonorrhea		
Urine	23	2
Oropharyngeal	8	1
Rectal	8	2

Of 23 pts tested (who returned for 3-mo visit)	Site tested n	Positive result n
Vaginal	0	0
Cervical	2	1

Note: Positive anatomical site totals may not equal total number of people who tested positive because one person may have a positive result from multiple anatomical sites.

Table 11c. STI Testing and Incidence by Anatomical Site: 6-month

Of 18 pts tested (who returned for 6-mo visit)	Site tested n	Positive result n
Chlamydia		
Urine	14	1
Oropharyngeal	9	0
Rectal	9	2
Vaginal	2	0
Cervical	1	0
Gonorrhea		
Urine	14	1
Oropharyngeal	9	2
Rectal	9	2
Vaginal	2	0
Cervical	1	0

Note: Positive anatomical site totals may not equal total number of people who tested positive because one person may have a positive result from multiple anatomical sites.

Table 11d. STI Testing and Incidence by Anatomical Site: 12-month

Of 19 pts tested (who returned for 12-mo visit)	Site tested n	Positive result n
Chlamydia		
Urine	19	1
Oropharyngeal	12	0
Rectal	12	1
Vaginal	2	0
Cervical	3	0
Gonorrhea		
Urine	19	0
Oropharyngeal	12	1
Rectal	12	1
Vaginal	2	0
Cervical	3	0

Note: Positive anatomical site totals may not equal total number of people who tested positive because one person may have a positive result from multiple anatomical sites.

Multisite Evaluation Results for Philadelphia

Differences in mean changes in HIV care continuum outcomes were evaluated over time (from baseline to 18 months). The following outcomes were analyzed.

Table 12. HIV Care Continuum Outcomes and Data Source of MSE Analyses

Data Source	Outcome	Response levels
Medical Chart	Viral suppression	1 = < 200 copies/mL; 0 = otherwise
ACASI	HIV-related medical visit in past 6 months	1 = Yes; 0 = No
ACASI	Viral load test in past 6 months	1 = Yes; 0 = No
ACASI	Currently taking ART	1 = Yes; 0 = No
ACASI	Ability to take ART among participants currently taking ART	Continuous (range = 1-6)
ACASI	Virally suppressed	1 = Yes; 0 = No or Don't know

Presentation of the results begins with plots showing changes in mean outcome levels over time based on the observed data. Random-effects regressions are used to estimate outcome trajectories over time and draw statistical inference.

Statistical Methods Applied to Medical Chart Data

Viral load data points were not aligned across participants over the follow-up period. Therefore, it was not practical to calculate means at discrete time points. Plots show viral suppression outcome trajectories that are estimated at each follow-up time point using locally weighted least squares (loess) regression. Each plot shows three outcome trajectories for participants with a new HIV diagnosis (within a year of the baseline assessment), participants with a more established HIV infection, and all participants.

Random-effects logistic regressions were fit to model changes in the probability of viral suppression over time. Models included an intercept term, time as a continuous covariate, and random effects for each participant. Plots suggest curvilinear outcome trajectories, but we were unable to get curvilinear time trends to fit. Time was modeled as a linear trend. Odds ratios (OR) and 95% confidence intervals (CI) are presented for the odds of viral suppression for each additional 30 days in the project. Models were fit to two subgroups of participants (i.e., participants with a new diagnosis and participants with established infection) and the entire sample.

Statistical Methods Applied to ACASI Data

Plots show mean outcome levels at each time point, including baseline, 6, 12, and 18 months. Each plot shows three outcome trajectories for participants with a new HIV diagnosis (within a year of the baseline assessment), participants with a more established HIV infection, and all participants.

Outcomes were modeled using random-effects logistic regressions for the probability of the outcome occurring (e.g., an HIV-related medical visit), except the outcome for the ability to take ART. Ability to take ART was treated as a continuous measure and modeled using linear random-effects regression for mean changes in ability. Similar to medical chart analyses, models included an intercept term, time, and random effects for each participant. Time was modeled as a categorical covariate. OR are shown for binary outcomes and compare the odds of the outcome occurring for each follow-up time point versus the baseline timepoint. Estimated mean differences between each follow-up time point and the baseline assessment are shown for the continuous outcome (ability to take ART). Models were fit to the subgroup of participants with established infection and the entire sample. We had difficulty fitting models to the subgroup of newly-diagnosed participants due to the smaller sample size.
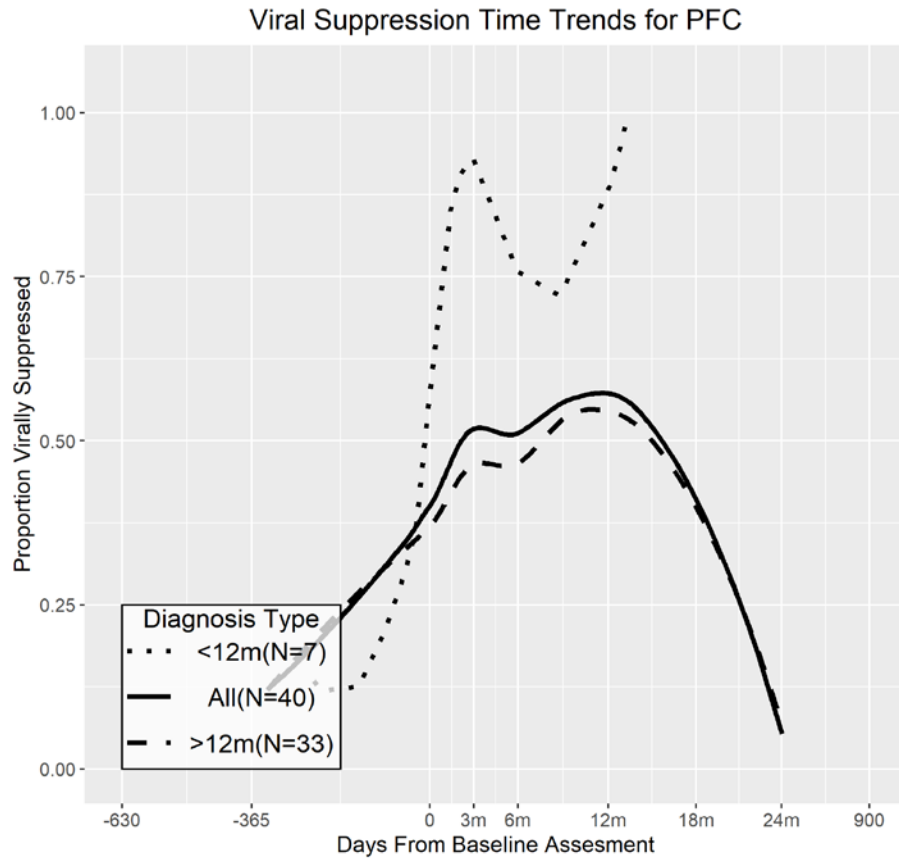
Medical Chart Data Results

Viral Suppression Time Trends for PFC

Viral Suppression Time Trends for PFC
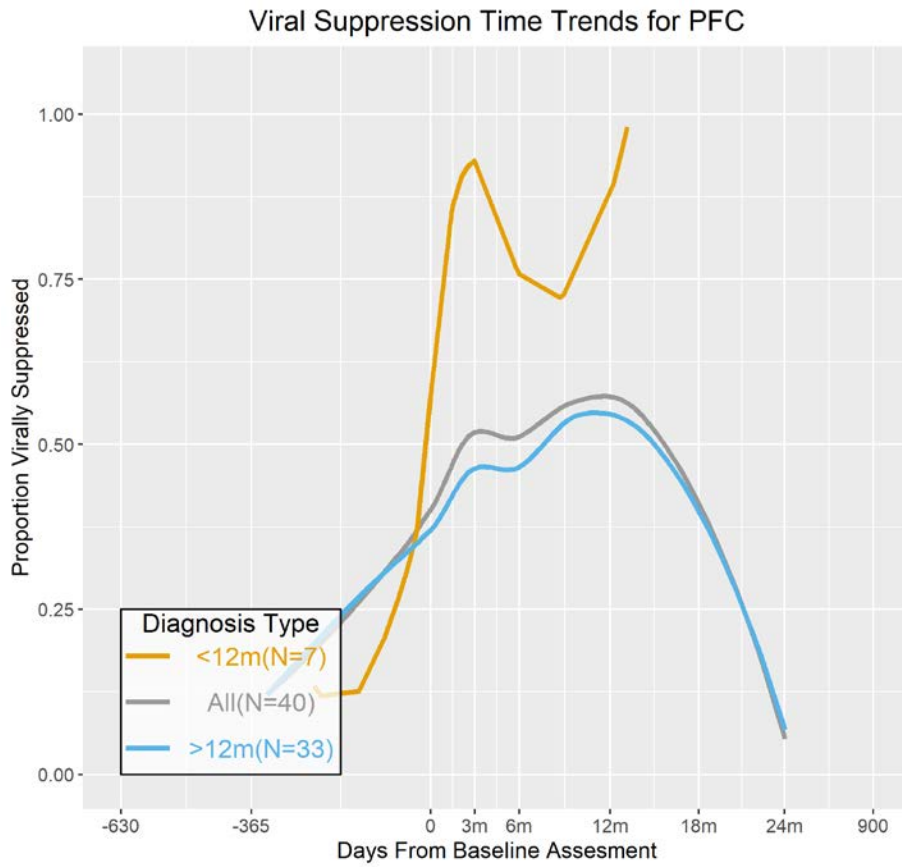
Table 13. Logistic Model: Viral Suppression

Model	Beta Estimate	OR	95% CI	P-value
Overall	0.07	1.07	(1.03, 1.12)	0.00
Established Cases (>12 Mo.)	0.06	1.06	(1.02, 1.11)	0.00
Recent Cases (<12 Mo.)	0.24	1.27	(1.04, 1.56)	0.03

Based on the plot, viral suppression rates increased over the initial follow-up period through the first year and then declined. The increase was faster over the initial 12-month follow-up period among newly-diagnosed participants; the sample size of 7 participants was too small to visualize any trends after 12 months. The logistic model showed a linear increase in the odds of viral suppression for each 30 day period in the project. Mirroring the plot, the increase in odds was most pronounced among newly-diagnosed participants [OR=1.27, 95% CI (1.04, 1.56)].

ACASI Data Results

Plots suggest initial increases in mean levels of self-efficacy for ART adherence (ability to take ART), and rates of viral suppression through the first six-months of follow-up; trends level off after six months. Changes in outcome levels over time are relatively small as evidenced by a lack of statistical significance in the regression models. One exception occurs for the self-efficacy for ART adherence (ability to take ART) among participants with established infection. Estimated mean differences in ability to take ART at 12 months [.85; 95% CI=.15-1.54] and 18 months [.71; 95% CI=-.03-1.45] compared to baseline were both relatively large in consideration of the possible range of values from 1 to 6.

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APPENDICES

1. PC4H Demonstration Project Pre-Implementation Activities Timeline
2. IRB Protocol (CHOP & FIGHT)
3. CHOP & FIGHT consent forms
4. Study Summary
5. Flyers (CHOP = Purple Banner, FIGHT = Green Banner)
6. Checklists (*APPlify*, Baseline, 3-, 6-, 12-, and 18-month visits; in-between visits; Android distribution; REDCap/QDS guide)
7. REDCap Data Collection Forms
8. Incentive Logs
9. *APPlify* Workshop Curriculum (Group and individual)
10. Participant Flowchart
11. Participant Timeline
12. TYS Quickstart
13. TYS Community Guidelines
14. Distributed Study Phone Usage Guidelines
15. TYS Privacy Policy
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17. Regulatory Timeline
18. Drexel/FIGHT Contracts (Years 1-4)
19. ETAC ACASI QDS Surveys (0-, 6-, 12-, and 18-month)
20. ETAC Qualitative Interview Consents and Interview Guide