iTransition: Developing a Multilevel Technology-Based Intervention to Support Youth Living with HIV from Adolescent to Adult Care

NCT04383223

Date: August 11, 2019

Title Page

Study Title
iTransition: Developing a Multilevel Technology-Based Intervention to Support Youth Living with HIV from Adolescent to Adult Care

Short Study Title
iTransition Development

Principal Investigator:
Sophia Hussen MD, MPH
Assistant Professor
Hubert Department of Global Health & Department of Epidemiology
Rollins School of Public Health
Emory University
[redacted]

Co-Principal Investigators:
Andrés Camacho-González
Associate Professor
Department of Pediatrics
Emory University School of Medicine
[redacted]

Research Study Coordinator:
Shamia Moore, MPH
Hubert Department of Global Health & Department of Epidemiology
Rollins School of Public Health
Emory University
[redacted]

Sponsoring Agency
NIH/NIMH

Date
August 11, 2019

Emory University

iTransition: Developing a Multilevel Technology-Based Intervention to Support Youth Living with HIV from Adolescent to Adult Care

1. STUDY AIMS, BACKGROUND, AND DESIGN

a. Purpose

The goal of this study is to develop a technology-based intervention to help providers and patients navigate the transition from pediatric to adult-oriented HIV care.

b. Relevant Literature

Healthcare transition (HCT) from pediatric/adolescent to adult-oriented care is a crucial yet often-neglected disruption to the Care Continuum for youth living with HIV (YLH). YLH fare worse at each Care Continuum stage than older adults. About 49% of YLH know their status; of these, 41% are linked to care, 31% are retained in care, and only 27% are virally suppressed. Optimizing engagement in care at each stage of the continuum is critically important to reduce morbidity/mortality and decrease transmission at the community level.

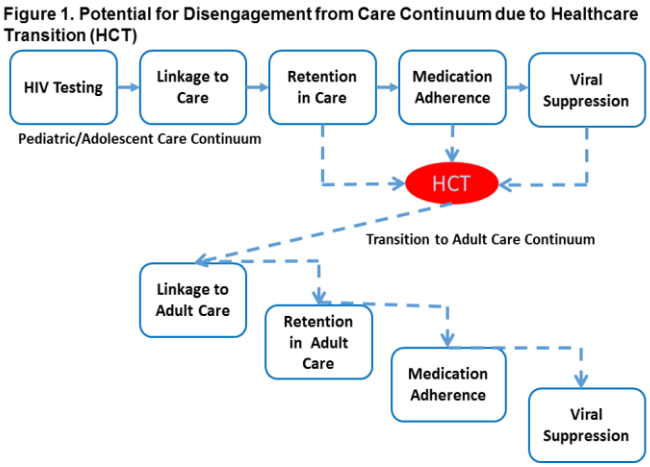

Figure 1. Potential for Disengagement from Care Continuum due to Healthcare Transition (HCT)

HCT from pediatric/adolescent to adult HIV care is a particularly high-risk period for disengagement from the Care Continuum (**Figure 1**). In Dr. Tanner's (MPI) recently completed multi-site study, only 37% of 135 HCT-eligible youth attended one adult clinic visit in a 9-month follow-up period. Dr. Hussen's (MPI) work in Atlanta documented two-year retention rates < 60% among those initially linked to adult care. Addressing barriers to continuous engagement through HCT and beyond is a critical step in meeting the NIH Office of AIDS Research priorities.

There are no evidence-based interventions to support HCT for YLH. The few existing HCT programs are single-center protocols, and none have been rigorously tested to document post-HCT clinical outcomes. These protocols are written exclusively from the pediatric/adolescent clinic perspective, and are characterized by a narrow focus on patient preparation; they do not address other YLH barriers, and adult provider's perspectives are largely neglected. No published work examines collaboration and co-planning between pediatric/adolescent and adult clinics. Given the individual, clinical and structural barriers to HCT, integrated, multi-level interventions that consider YLH, pediatric/adolescent providers, and adult providers are needed to ensure that YLH successfully transition to, and remain engaged in, adult care.

Mobile health (mHealth) interventions are accessible and practical for youth, including YLH. Youth have high levels of technology access and usage; nationally, nearly 100% of youth aged 18-29 own a mobile phone, and 92% own a smartphone. A recent survey by Dr. Camacho-González (co-I) found that 97% of YLH at Atlanta's Grady Infectious Disease Program (IDP) clinic owned a smartphone and had a monthly plan with unlimited data or minutes (unpublished data). Youth commonly use the Internet to access health information and are open to mHealth interventions. Other advantages of mHealth interventions for youth include versatility, flexibility, and the ability to deliver content that is "targeted, tailored, and personalized," while also being

standardized to ensure fidelity. Notably, mHealth interventions can also provide *real-time intervention engagement metrics*, or ***paradata,*** to researchers.

Healthcare providers use web- and mobile phone-based resources continually in their daily workflow for communication, documentation, education, and clinical decision-making. Web-based tools can enhance providers' communication with patients and with each other. An example of *patient-provider communication* is the *OncoLink* website, in which patients create a tailored cancer survivorship plan (for follow-up after acute cancer treatment) to be discussed with their providers. To improve *provider-provider communication* about patient care, web-based platforms have also been developed for: **(1)** dissemination of standardized tools to ensure that important data are always included in communications, and **(2)** increased legibility, accessibility (including remote accessibility), and avoidance of transcription errors. The application of technology to *documentation* has led most U.S. clinics to use an electronic medical record (EMR) system for patient charting, writing orders, and interfacing with laboratories. Finally, providers frequently access mobile apps for *education* and assistance with *clinical decision-making* (e.g., UpToDate™, Epocrates™). *An mHealth intervention has a high likelihood of uptake and appeal to both YLH and healthcare providers, as both groups are avid utilizers of mobile apps for improving their health (YLH) and clinical practice (providers), respectively.*

To address the dearth of evidence-based interventions to improve HCT for YLH, we propose to develop and pilot test *iTransition,* a multilevel mHealth intervention designed to support YLH and their (pediatric/adolescent and adult) care providers.

c. Brief Overview of Research

This protocol is for Phase I, which comprises the development of the iTransition mobile intervention in conjunction with patients (youth living with HIV) and providers (physicians, nurses, and other staff caring for YLH either before or after HCT. Of note, this development work (and the subsequent pilot testing which will be outlined in separate IRB protocols) will occur at two sites: (1) here in Atlanta at Emory and the Grady IDP clinic, and (2) the Children's Hospital of Philadelphia (CHOP).

Aim: To develop *iTransition,* an mHealth intervention designed to improve care engagement through HCT by targeting YLH, pediatric/adolescent and adult providers' needs.

d. Anticipated Significance

We will pilot test this intervention in subsequent phases of this study. It is our hope that ultimately, iTransition will be an effective intervention that can be disseminated in clinics across the country to help YLH stay engaged in care through the HCT period and beyond.

2. PARTICIPANT POPULATION

a. Participants

There are three different types of participants in this study, all of whom will provide input to study investigators as they develop the iTransition web app. **(1)** The youth advisory board (YAB) will be made up of YLH either just before or just after the transition from pediatric to adult care. **(2)** Healthcare providers in the Grady IDP and CHOP clinics will be recruited to serve as "Transition Champions" in the clinics, and to give provider perspectives on the app being developed. **(3)** Usability testing participants: these youth will do a one-time testing session of preliminary version(s) of the app and give feedback on ease of use and content. YAB members may participate, but these can also be different youth.

b. Inclusion Criteria

Youth Advisory Board (YAB): 18+ years old, living with HIV (YLH), going through a healthcare transition from pediatric/adolescent HIV care to adult HIV care in the next 12 months OR have recently

(within the last 24 months) switched from pediatric/adolescent HIV care to adult HIV care. Recruited from CHOP/Grady health systems HIV clinics.
Providers aka "Champions": Care providers (physicians, nurses, social workers) who care for adolescents and adults living with HIV in Philadelphia, PA or Atlanta, GA area. (Providers who are adults 18+)
Usability Testing: 18+ years old, living with HIV (YLH), going through a healthcare transition from pediatric/adolescent HIV care to adult HIV care in the next 12 months OR have recently (within the last 24 months) switched from pediatric/adolescent HIV care to adult HIV care. Recruited from CHOP/Grady health systems HIV clinics.

c. Exclusion Criteria

i. Aged 17 or younger
ii. Unwillingness to participate in study activities

d. Recruitment Process

Participants will be recruited from CHOP/Grady Health HIV clinics or partner organizations.
In Atlanta: The principal investigator, a Grady IDP clinician with established access to this clinic, will perform participant selection in the Grady IDP clinic. The investigator will communicate with medical providers (colleagues) for their own participation and/or referral of potential participants. Passive recruitment using flyers in waiting rooms and other venues may be used. Verbal solicitation in waiting rooms or with permission to approach after/before medical visits from medical team will also be used. Study team will also review records (password-protected Excel/Redcap databases listing screened or enrolled participants and their contact information) collected in other studies where participants gave permission to contact for future studies, and contact these potential participants by phone, in-person, or email to notify them a new study they may be eligible to participate in. Due to the eligibility requirement of upcoming or recent HCT, colleague referral will likely be used first. CHOP will follow similar procedures using their research team on site in Philadelphia.

e. Recruitment Materials

Recruitment materials will include flyers to be placed in the clinic for self-referral of participants.

3. STUDY PROCEDURES

a. Procedures

YAB: YAB members will be asked to participate in 60-90-minute meetings/visits twice a month for 6-12 months (a total of 12-24 meetings) with other YAB members, the research study and web-app design team either in-person or by video conference (using Zoom or other secure video-conference technology) meetings to discuss healthcare transition experiences and health web-app preferences. Meetings may be site-specific (Philadelphia-only/Atlanta-only) or across sites pending availability of attendees. Video conference meetings will not be recorded.

Providers aka "Champions": Participate in approximately 60-minute meetings for 6-12 meetings over 1 year with other providers, the research study and web-app design team either in-person or by video conference (using Emory's secure video conferencing system or Zoom technology) meetings to discuss healthcare transition from provider-prospective and HCT web-app preferences.

Usability Testing: Participate in one 90-120-minute (1.5-2 hours) in-person study visit with up to 0-2 other participants, to discuss opinions on web-app features/activities and functionality, YLH- specific HCT content and resources, design layout (wireframe) and aesthetics (colors, font, etc) to help research, design, and expert panel

(consultants) further develop iTransition. Participants may be given opportunity to click-through the web-app during the session if a test/demonstration version is available during the study visit. Participants may have individual or group (3 participants maximum) usability testing study visit. Visit will be audio recorded, transcribed, password-protected, and stored on a secure/private drive accessible only to the research team. PHI will not be collected or recorded, and a study ID or pseudonym will be used in place of identifiers and established prior to recording. If participants disclose identifiers accidentally during a study visit that is audio-recorded, the study team will pause the recording and rewind to rerecord over the identifier before continuing the session. All audio recordings will be transcribed and password-protected at the earliest convenience of the study and after verification the audio recordings will be destroyed.

Information from YAB/Provider meetings will help develop/inform iTransition creation and then will be tested for usability. Feedback from usability will further help develop iTransition. Iterative process in design and feedback, redesign and feedback until iTransition is developed/completed.

4. RESEARCH RISKS

a. Risk and Lessening Risk

The potential risks to participants are detailed as follows:

- Some YAB participants may be uncomfortable answering questions about their past care engagement, particularly if it was suboptimal: all information used in enrollment and recruitment describing the research activities will include a detailed description of the content and expected participation of the respondent, such that the respondent is aware of the nature of the questions to be included. Providers may similarly experience discomfort when reflecting on their own practices that may not have been helpful to YLH going through HCT. However, it will be emphasized that their input does not require personal sharing of such experiences. Additionally, participants will have the option to refuse to answer or skip any questions on the surveys that they are uncomfortable answering.

- For participants who choose to provide their name and address or other personally identifying information to study personnel, there is a risk that these data could be unintentionally disclosed to someone not authorized to access the data, compromising the privacy of the participant. To reduce this risk, all contact information for the study participants will be kept in a password protected location, with access restricted to the retention officer and PI.

b. Adequacy of Protection against Risks

Protections against Risk

To minimize the risk of participants feeling uncomfortable, we will reassure them that they do not need to divulge personal stories/anecdotes. We will also ask YAB and Provider Champions to avoid discussing details of the app development sessions outside of the group.

To minimize risks to confidentiality, we will provide study data with all appropriate physical and operational security protections. Data will be stored in a physically secure environment, and all data files will have encryption and strong password protection. Access to data will be on a role-based standard; only those study staff who require access to identifying data to complete their study-related roles will be allowed access, as described above. All study staff will be trained in

security and confidentiality procedures, and will sign a confidentiality agreement before receiving access to any participant data.

We will also develop procedures to minimize indirect disclosure that a participant is participating in an HIV-related research study. For each mode of recontact information, we will ask specifically whether anyone else potentially has access to that mode of communication, and if it is acceptable to leave a non-specific message about participation in a health study. The contact information and permissions will be updated at each study visit. No study-related messages will ever mention HIV or the nature of the research study.

c. Certificate of Confidentiality

As this is NIH-funded research, this work will automatically be granted a Certificate of Confidentiality. This will help protect the participants' anonymity with regards to participation in our study.

5. CONFIDENTIALITY

a. Data Safety and Monitoring Plan

We have formed a Data Safety and Monitoring Plan including: Study investigators will dedicate one meeting (either in person or via teleconference call) each quarter to review study progress, recruitment, data quality, and participant safety. A report will be generated from each of these meetings and shared with the entire study team and NIH program officer.

The researchers and project staff will keep personal information (e.g., phone numbers, email addresses) confidential. Confidentiality and scientific ethics are of the utmost importance to study staff.

Although we will make every effort to protect participants' privacy, complete privacy cannot be absolutely guaranteed because participants will be participating in group discussions. We have taken steps to minimize the chance of a breach of confidentiality occurring. The consent forms emphasize that information about other participants should not be shared outside of the research site, and that participants should not reveal each other's HIV statuses to anyone outside of the study.

6. BENEFITS

a. Potential Benefits of the Proposed Research to Human Subjects and Others

Participants will have the opportunity to contribute to a novel intervention designed to improve HCT for YLH. Others will benefit because the study will result in an intervention (iTransition) that is ready to be tested.

b. Importance of the Knowledge to be gained

YLH have high rates of HIV infection and low rates of sustained engagement in care, especially during HCT. Developing a theory-based intervention has potential to significantly impact public health.

7. PAYMENT

YAB: $25 gift card per visit + roundtrip public transportation for in-person meetings.
Usability testing: $50 gift card + roundtrip public transportation
Providers: $50 gift card received quarterly (every three months) throughout 1 year Snacks/Beverages may be provided during in-person sessions.

8. COSTS

There will be no costs to the participants to join the study.

9. CONSENT/ASSENT PROCESS AND DOCUMENTATION OF CONSENT/ASSENT

a. Consent Process, Participant Access to Consent Form

Providers and youth in the YAB will complete written informed consent. Participants will meet with study team member in a private location to review the consent form and study procedures and will ask the participant if they understand the information reviewed and in the consent form and if they have any questions. The participant will be given time to decide to participate during this meeting or may opt to call a study team member at a later date when they have opted to participate, or they may deny participation. The participant will be given a paper copy of the consent form to keep and the study team will also retain a signed copy when consent has been given. For providers, only investigators/study staff who are not the employees' direct supervisors or close colleagues will obtain consent for research participation, and that subjects will be informed during the consent process that their decision to participate (or not participate) in the research will not affect their performance evaluation or employment and that their responses will not be shared with their supervisors. Similarly, for patients, investigators who provide care directly to a potential participant will not be involved in the consenting process.

Of note, youth who participate in the usability testing only (but not the YAB) will complete verbal consent; we are requesting a waiver of written consent for these participants. Since they will only have one interaction with our team, the consent form would potentially be the only piece of information linking their name to the study (and we would like to eliminate this).

10. MULTISITE COORDINATION

a. This is a multi-site study. Web app development activities will occur in both Atlanta (at Emory) and Philadelphia (at CHOP – the Children's Hospital of Philadelphia). Additional investigators at the University of North Carolina, Greensboro (UNCG) will also participate in iTransition development, but no participants will be enrolled at that site CHOP IRB has already granted exempt status for this portion of our project, and UNCG will be applying for the same. For the subsequent phases of the study (i.e. pilot testing, which will comprise separate IRB protocols), we are expecting to rely on the CHOP IRB although an official reliance agreement has not yet been signed.

11. FUNDING SOURCES

This study is being funded by the NIH/National Institute of Mental Health

•