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Adherence Connection for Counseling, Education, and Support (ACCESS)-II
NYU Principal Investigator (PI) - Ann-Margaret Navarra
Protection of Human Subjects
January 31, 2024

The primary objective of the proposed clinical trial, ***Adherence Connection for Counseling, Education, and Support (ACCESS)-II,*** is to test the efficacy of ACCESS-II on antiretroviral treatment (ART) adherence and HIV-viral load in Black and Hispanic HIV-infected (HIV+) adolescents and young adults (AYA), **ages 18-29 years** (N=120) using a longitudinal (12 and 24 week outcomes), two-group, randomized controlled trial (RCT). Participants in the intervention condition will use videoconferencing to connect synchronously with trained HIV+ peer health coaches who will deliver eight weekly, 60-minute cognitive behavioral/motivational sessions for improved ART adherence. Participants in the control will connect asynchronously to a web-based HIV ART adherence education condition.

In accordance with policy from the National Institutes of Health (NIH) on the use of single institutional review board (IRBs) for multi-site research, Principal Investigator (PI)/NYU will be utilizing a single IRB for this multi-site research project. **NYU will be the IRBs of record for the ACCESS II RCT.**

ACCESS II RCT study team. The study lead PI is Ann-Margaret Dunn Navarra, PhD, CPNP-PC, FAAN, a NINR-funded nurse scientist and K23 scholar at Stony Brook University School of Nursing with over two decades of clinical and research experience with Black and Hispanic HIV+AYA. Dr. Dunn Navarra is highly qualified to lead the ACCESS II RCT and will be joined by a multi-disciplinary team of internationally recognized scientists with complementary expertise to meet stated study aims. Allison Vorderstrasse, PhD, Dean and Professor of Elaine Marieb College of Nursing - UMass Amherst will provide expertise for implementation of the web-based HIV ART adherence education control condition. Lloyd Goldsamt, PhD is a Senior Research Scientist at NYU Meyers and a licensed clinical psychologist. His expertise includes HIV and substance use prevention among high-risk AYA and stigmatized populations and program evaluation. He will be the contact PI at NYU Meyersproviding guidance for intervention content on substance use and stigma and evaluation of ACCESS II. Michael Rosenberg, MD, PhD is an Associate Professor of Pediatrics at Albert Einstein College of Medicine and an infectious disease specialist at Jacobi Hospital with 30 years of experience in the medical management of Black and Hispanic HIV+AYA. He will serve as a collaborator and HIV medical content expert. Susanne Burger, MD is an infectious disease specialist at Jacobi Hospital/North Central Bronx. She will serve as a physician collaborator for participant recruitment from North Central Bronx. Murli Purswani, MD is a pediatric infectious disease specialist at BronxCare Health System with 40 years of experience in the medical management of Black and Hispanic HIV+AYA. He will serve as a collaborator for participant recruitment. Jason Fletcher, PhD is a senior biostatistician at NYU Meyers with over 15 years of experience in public and community health research. He will provide methodologic guidance for quantitative data analysis and randomization.

Eva Liang, MA is the project manager on this study at NYU Meyers. The Project Manager will work closely with the study PI (AM Navarra) to coordinate study activities and oversee achievement of study milestones. This entails supervision of peer health coaches, assistance with supervision of research staff (including student researchers), leading the implementation phase and other efforts to ensure that project goals and objectives are met within the prescribed time frame and funding parameters. Brandon Paulk is an assistant research scientist and senior peer health coach. Brandon Paulk will synchronously deliver eight weekly, 60-minute cognitive behavioral/motivational sessions for improved ART adherence using videoconferencing to

participants randomized in the intervention group. Damian Ruff is an assistant research scientist and senior peer health coach. Damian Ruff with also, synchronously deliver eight weekly, 60 minute cognitive behavioral/motivational sessions for improved ART adherence using videoconferencing to participants randomized in the intervention group. Collectively this research team is well-poised to successfully carry out the proposed study.

Risks to Human Subjects

Human Subjects Involvement, Characteristics, and Design

Overview of aims, research design and number of participants to be enrolled:

AIM 1. Evaluate the effect of ACCESS-II on the primary outcomes of self-reported ART adherence and HIV viral load and secondary outcomes of self-efficacy, HIV knowledge, HIV stigma, psychological distress (depression, anxiety, posttraumatic stress), social support, and substance use.

Primary hypothesis. Black and Hispanic HIV+AYA participants in the ACCESS II RCT intervention condition will have greater ART adherence and HIV viral load reduction, when compared to the asynchronous web-based HIV ART adherence education control.

AIM 2. Identify which socioecological factors (self-efficacy, HIV knowledge, HIV stigma, psychological distress (depression, anxiety, posttraumatic stress), social support, and substance use) are associated with ART adherence and HIV viral load outcomes.

The goal is to characterize adherence phenotypes among Black and Hispanic HIV+AYA participants of ACCESS II.

Research Design and Intervention – Overview. To achieve these aims, a longitudinal (12 and 24- week study outcomes), two-group, randomized controlled trial (RCT) is proposed in a sample population of 120 perinatally and behaviorally, HIV+ AYA (ages 18-29 years). Participants in the intervention condition will use videoconferencing to connect synchronously with trained HIV+ peer health coaches who will deliver eight weekly, 60-minute cognitive behavioral[1–4] motivational[5] sessions for improved ART adherence. Participants in the control will connect asynchronously to a web-based HIV ART adherence education condition.

Study participants will access the intervention and control conditions outside of the clinical setting using study funded smartphones. Self-reported adherence and viral load (extracted from the medical records) of study participants will be measured, and uploaded to REDCap. Knowledge about ART, adherence self-efficacy, HIV stigma, social support, psychological distress (depression, anxiety, posttraumatic stress) and substance use will be measured using survey measures. Statistical analyses will be computed to assess the potential impact of ACCESS on adherence and HIV viral suppression, and will also be computed to assess changes in knowledge about ART, adherence self-efficacy, HIV stigma, social support, psychological distress (depression, anxiety, posttraumatic stress), and substance use among participants in both the intervention and control conditions.

Characteristics of the Human Subjects. Characteristics of the target study population include ethnic minority, Black and Hispanic HIV+AYA; both males and females are eligible for participation. The specific criteria for participation in the study are listed below.

Inclusion criteria for participation in this study are:

- HIV seropositive status (perinatally and behaviorally infected youth)
- Ages 18-29 years

- English speaking
- Currently being prescribed an oral antiretroviral treatment regimen
- Evidence of difficulty with virologic suppression (*detectable quantitative HIV serum viral load ≥20 copies/ml)*
- No neuro-cognitive deficits which would impede participation in videoconferencing sessions or completion of study measures

Expected Number of Human Subjects. We determined the study sample size (N=120) based on our prior K23 research and the best available peer-reviewed evidence. Pilot findings from our K23 showed that the average change over one year was a 0.28 $\log^{10}$ reduction (47.5%) in viral load; thus, the average change was in the desired direction. The interval estimate was consistent with small increases in VL, no change, and larger reductions (CI=95% -0.12, 0.66), which is why a larger study which includes phenotyping is needed. We compared a 0.28 $\log^{10}$ viral load reduction to other US-based mHealth adherence interventions with HIV+AYA including our published state of the science integrative review on technology-enabled adherence interventions conducted in the US with HIV+AYA.[6] Many studies are small pilots and do not include virologic outcomes[7–10] or the intervention had no significant effect on viral load.[11,12] Among included RCTs, findings from one study using text-messaging reminders (N=105) showed no post intervention effect on HIV viral load.[13] Results of a multisite RCT testing a two-session computer-delivered motivation intervention (N=76) showed a small post-intervention decrease in viral load (Cohen's d= 0.19 at 6 months).[14] Another smaller RCT (N=37) testing cell phone support demonstrated a statistically significant reduction in viral load at 24-weeks (p=0.002) and 48 weeks (p=0.04).[15] A recent RCT study protocol testing an mHealth adherence intervention (texting and videoconferencing) with HIV+ youth was powered at 85% to detect a 25% difference in virologic suppression at 12 weeks.[16]

Therefore, our projected sample size (n = 120, 60 per treatment condition) will achieve 80% power to detect medium to large effects (d = .44 to .57) for $\log^{10}$ viral load reduction associated with treatment (assuming within-individual correlations ρ = .3 to .6). We will have 80% power to detect differences of 23% to 25% in viral load suppression between treatment groups (assuming viral load suppression in the control group of 20% to 50%) and small correlations between primary outcomes and individual and interpersonal influences on ART adherence (Pearson's r = .25, Spearman's ρ = .27). Based on pilot findings showing a 32.1% increase in adherence (large effect d = 1.12), the current study would have more than 90% power to detect a comparable effect (assuming within subject correlations of ρ = .3 to .6).

Rationale for Involvement of a Vulnerable Population. The ACCESS adherence intervention was designed to address the serious and lifelong challenge of antiretroviral adherence in HIV+ AYA. **The target population of ACCESS II RCT is ethnic minority AYA ages 18 to 29 years**, as the incidence of HIV-infection in this cohort is alarming. Among the 100,000 HIV+ AYA, 70% are represented by Blacks and Hispanics.[17] Nearly 23,000 new cases of HIV were reported among Black and Hispanic AYA in 2017,[17] despite availability of effective antiretroviral therapy (ART) for decades.[18] Treatment recommendations for infected individuals include lifelong treatment with antiretroviral medications. Suboptimal ART adherence (<90%) is described among 39% of this cohort,[19] and only half are virologically suppressed (viral load <200 copies/ml),[20] leading to high risk for sexual transmission.[17,21–25] Innovative and robust ART adherence strategies are critical to reducing these ethnic/racial minority health disparities.[26,27] To date, adherence interventions among HIV+AYA have been of limited in number and efficacy.

Assignment to a Study Group. The proposed ACCESS II RCT uses a two group, parallel, longitudinal study design. Participants will be randomized to the ACCESS synchronous peer

intervention or the asynchronous web-based HIV ART adherence education control. Block randomization will be used; the randomization scheme will be developed by the biostatistician and implemented in Research Electronic Data Capture (REDCap) to ensure that assignment to treatment condition is evenly distributed within each site.[28,29] Study details will be reported using guidelines defined by the Consolidated Standards for Reporting Trials (CONSORT). This will include items defined in the checklist for parallel randomized trials and a flow chart detailing enrollment, allocation, follow-up, and analyses.[30,31]

Collaborating Sites. After approval from designated institutional review boards, HIV+ ethnic minority AYA will be recruited from the adult and pediatric HIV centers within Jacobi Medical Center, (North Central Bronx Network), and BronxCare Health System. BronxCare is only engaging in recruitment and not directly engaging in the consenting process. Dr. Michael Rosenberg will be designated site investigator at Jacobi Medical Center and North Central Bronx Network and Dr. Murli Purswani will be the designated site collaborator for recruitment at BronxCare Health System.

Jacobi Medical Center is part of the North Central Bronx Network, which includes a local affiliate, the HIV outpatient center of North Central Bronx (please see facilities and resources). The North Central Bronx HIV outpatient center treats 600 HIV+ adults and adolescents, offering an addition recruitment resource through their collaboration with Jacobi Medical Center.

BronxCare Health System is the largest voluntary, not-for-profit health and teaching hospital system serving the South and Central Bronx (please see facilities and resources).

IRB approved recruitment materials (i.e. pamphlets and fliers) will be posted in select Community-Based Organizations (CBOs) and Community Events serving HIV+ AYA throughout the City of New York. With assurances from the CBOs, these IRB approved recruitment materials may be posted in their physical space and posted electronically (social media pages, newsletters, website, etc.).

Compensation. Care was taken in the construction of the incentive schedule to prevent any coercion bias, yet participants will be compensated for their time. We will compensate participants with the support of ClinCard (https://www.clincard.com/). The schedule for compensation of completed study activities is as follows: $25 cash for completion of the consent process and basic demographics; $100 cash for the completion of baseline, 12 and 24-week data collection/testing; $25 cash for return of the study phone upon completion ($350 total possible compensation).

SOURCES OF MATERIALS

A trained project manager will collect and/or manage data for the primary study variables of adherence to antiretroviral treatment (3-day self-report), viral load, self-efficacy, knowledge about ART, HIV stigma, social support, psychological distress (depression, anxiety, posttraumatic stress), and substance use. Data collection timepoints are baseline, and 12 and 24 weeks. A description of study measures is provided below.

3-day self-report of ART adherence will be collected to describe subjective adherence behavior.

Serum HIV RNA quantitative viral load is a primary outcome biomarker and will be measured to eliminate the potential for social desirability bias associated with self-reported adherence.

Viral load data will be extracted from the medical records of participants by IRB approved designated representative at the clinical setting. Source documentation of serum HIV RNA quantitative viral load will be securely uploaded to REDCap by IRB approved staff at the clinical site (these staff members will have been approved for an NYU Kerberos ID).

Adherence self-efficacy or the sense of being able to adhere to prescribed HIV medications[32] is highly correlated with ART adherence among HIV+AYA,[33] and will be measured with the HIV-Medication Taking Self-Efficacy Scale (HIV MT SES).[34] The HIV MT SES is a 27-item survey measure including sub-scales for self-efficacy belief and outcome expectancy. It uses a 10-point Likert scale (0=*not confident*; 10=*completely confident*) to assess HIV-medication taking self-efficacy[34] with higher scores indicating higher levels of self-efficacy. HIV MT SES has robust construct validity (CFI=0.96, RMSEA=.046) and reliability (Cronbach's α =0.93) when tested with HIV+ adults.[34] It has been tested with HIV+AYA participating in a health technology-enabled adherence intervention.[35]

Knowledge about ART will be measured with the HIV Treatment Knowledge Scale,[36] a measure successfully implemented in our K23 pilot work.[37,38]

HIV stigma will be measured with the HIV Stigma Scale.[39] The HIV Stigma Scale has been tested to assess perceived stigma in HIV+AYA.[40,41]

Social support and isolation will be measured with the Adolescent Trials Network (ATN) iTech short measure[42] of the Patient-Reported Outcomes Measure Information System (PROMIS) Social Relationship scales.[43]

Psychological distress is operationalized as depression, anxiety and posttraumatic stress. Measurement of these variables is described below.

Depression will be measured with the Patient Health Questionnaire (PHQ-9).[44] The PHQ-9 includes 9 items from the DSM-IV criteria for depression with scores on a 4-point Likert scale (0=not at all, 3=nearly every day). Depression is scored as mild, moderate, moderately severe, and severe using composite scores of 5, 10, 15, and 20, respectively. Higher scores are associated with decreased functional status as measured by the SF-20 and scores ≥ 10 have a sensitivity and specificity of 88% for major depression.[44] The measure has been used among HIV+ AYA in the United States[45–47] with a Cronbach's α of 0.89.[45]

Question 9 on the PHQ-9 reads: "*Over the past 2 weeks, how often have you been bothered by any of the following problems?..Thoughts that you would be better off dead or of hurting yourself."* If a participant responds "*several days*", "*more than half the days*" or "*nearly every day*" to this PHQ-9 question at any of the scheduled visits (baseline, 12 or 24-weeks), the project manager will contact the lead PI (Dr. Navarra) and contact PI at NYU(Dr. Goldsamt) for guidance.

More specifically, if the participant is at imminent risk for suicide, law enforcement will be notified by Drs. Navarra or Goldsamt, who will call 911. Dr. Lloyd Goldsamt (contact PI and licensed clinical psychologist) and Dr. Navarra (board certified/licensed pediatric nurse practitioner) will also Zoom into the videoconferencing session for crisis management. Full details of managing adverse events are described on pages 15-20 in the Data and Safety Monitoring Plan.

Generalized anxiety disorder (GAD) will be measured with the Generalized Anxiety Disorder - 7 (GAD-7).[48] The measure has demonstrated validity and includes 7 items about symptoms in the past two weeks. Scores ≥ 10 indicate a probable case of GAD, with scores ≥ 15 considered to be severe.[48] Higher scores on the GAD-7 are associated with decreased functional status as

measured by the SF-20.[48] The GAD-7 has demonstrated validity and has been used among HIV+ AYA in the United States with a Cronbach's α of 0.86 to 0.87.[47,49,50]

Posttraumatic stress disorder (PTSD) will be measured with the Primary Care-PTSD Screen-5 (PC-PTSD).[51] The PC-PTSD is a brief measure using four-items to screen for symptoms of PTSD (re-experiencing, numbness, hyperarousal and avoidance behaviors) in primary care or ambulatory settings.[51] Total scores range from 0 to 4 with a score of 3 or greater indicating probable or positive screen for PTSD. The tool has been used among HIV+ AYA in the United States.[45,49,50]

Substance use will be assessed with a modified ATN designed for use in clinical settings.[42] The measure will assess use of tobacco, alcohol, marijuana and other drugs (i.e., cocaine or crack, amphetamine type stimulants, inhalants, sedatives, hallucinogens and opioids). The modified measure will assess substance use frequency, substance use related problems (i.e., health, social, financial), interference with functional status, concern from others regarding substance use, and failure to cut down on substance use.

Client Satisfaction and **Ease of Use** of the web-based platform (Rise) will be assessed by the participants enrolled into the control condition of the study during their eighth (last) session, using a modified Client Satisfaction Questionnaire and Perceived Ease of Use Scale. The measure will be used to assess the participant's satisfaction with the support and education received from the eight sessions in the web-based platform, along with the overall ease of use in operating and functioning the web-based platform over the eight sessions.

Study funded Smartphone questionnaire will assess smartphone ownership of participants and the feasibility of attending and completing the ACCESS II RCT study activities with the study funded smartphone. This 13-item questionnaire will assess how easy or difficult the study funded smartphone made it to communicate with the research team, to complete study activities and overall ease of participation in ACCESS II. This questionnaire will be used to determine participant's need for study funded smartphones.

Both viral load and self-reported adherence assessments of medication are assessed as a routine part of medical treatment, and therefore should pose no additional risk. Adherence self-efficacy is not routinely collected and may pose risk of embarrassment due to real or perceived low adherence self-efficacy. HIV Stigma will be measured with the HIV Stigma Scale and is also not routinely measured in clinical care and may also cause risk of discomfort. Mental health measures such as the PHQ-9 (depression), GAD-7 (anxiety), and PC-PTSD (trauma) are also not a routine component of clinical care. As such, there may be risk of discomfort and/or embarrassment. The project manager(s) will be made aware of this potential during training. We have delineated study procedures to manage any emotional discomfort in this protocol on pages 17-19. Social support and substance use are routinely assessed in clinical practice and therefore should not pose any risk of discomfort or embarrassment. However, we will implement training procedures for data collection to minimize all potential risk of discomfort. We have also selected study measures that are psychometrically valid, reliable and tested in HIV+ populations. Only ACCESS II RCT team members will have access to data collected and stored data will be protected as described in the confidentiality section.

Potential Risks to Subjects

To the best of our knowledge, there is no more than minimal risk of harm associated with participation in the intervention or control conditions, data collection and analysis. The main potential risk is loss of confidentiality related to data collection and participation in the intervention. Confidentiality will be ensured by safeguarding data collected, including

implementation of restrictions to the mobile platforms (study funded smartphones) by NYU Meyers information technology (IT) staff that will prevent study participants from audio or videotaping intervention sessions. Data collection using survey methodology will be conducted in a private setting using HIPAA compliant Zoom videoconferencing at baseline, and weeks 12 and 24. Data will be directly entered into REDCap at these timepoints.

Participants may feel perceived pressure to participate because the recruitment will occur at the subject's clinical setting. We will mitigate this potential risk during the process of informed consent by stressing the voluntary nature of study participation, and ability to withdraw at any time and without penalty.

Mobile Platform. There is no more than minimal risk of harm related to implementation of the mobile platform because HIPAA compliant Zoom videoconferencing will provide a safe and secure Health Insurance Portability and Accountability Act (HIPAA) compliant media platform for implementation of the remote videoconferencing sessions. The rationale for selection of HIPAA compliant Zoom videoconferencing was to safeguard confidentiality and privacy by using HIPAA compliant software. NYU Meyers IT administrative staff will be available for ongoing support throughout the study and will provide on-site availability for trouble shooting during delivery of the interventions. Restrictions will be added to the mobile platform by Meyers IT staff that will prevent study participants from audio or videotaping intervention sessions delivered by peer health coaches.

NYU HIPAA compliant Zoom videoconferencing services will be initiated and supported by the Director of NYU Meyers IT, David Resto with the support of his NYU Meyers IT team. Therefore, NYU Langone will not have access to this HIPAA compliant Zoom videoconferencing platform. Additionally, this HIPAA compliant Zoom videoconferencing platform will not be used for data storage; data storage of all videoconferencing metrics (i.e. Zoom session length) will be stored in REDCap. Audio/video recordings of ACCESS II RCT participant intervention sessions will be stored on a NYU Meyers secure server.

Study Funded Smartphones. Upon verbal consent at the clinical site, study participants will be provided with a study funded smartphone to allow for uniform access to the intervention and control conditions, and a means of facilitating contact with HIV+ AYA recruited for this study. The smartphone will also serve as a tool for obtaining electronic or e-consent via REDCap. Smartphones will be returned after completion of the intervention phase (expected at 24 weeks post enrollment), reset to factory settings by NYU Meyers IT staff, and reassigned to newly enrolled participants. The process of resetting smartphones by NYU IT will include a three-person reliability check. Phones will first be reset to factory setting by a designated NYU IT employee and then re-checked by a designated NYU IT Supervisor and the ACCESS II RCT project manager to confirm that the reset is complete.

Distribution and Activation of ClinCards. Upon verbal consent at the clinical site, study participants will be provided with a ClinCard with zero balance to allow for compensation upon completion of study activities. Participants will be instructed on the use of ClinCards by a trained member of the ACCESS II RCT research team, and receive support for use throughout the duration of study participation. Activation of the ClinCard will be done after e-consent is obtained by Eva Liang, NYU Project Manager. Given that ClinCard is a type of banking card, procedures for activation include providing the participant's name, address, and date of birth. Participants will be informed of these procedures during the informed consent process.

Protection for ClinCard use entail password protection which will be set by the study participant. Lost and/or stolen ClinCard will be replaced by NYU with no fee for participants.

Peer health coaches. There will be up to three paid, trained peer health coaches who will deliver the adherence intervention. Peer health coaches will share similar demographic characteristics of the study population (between the ages of 18-29 years of age, ethnic minority status, and English speaking). Peer health coaches employed for the ACCESS II RCT will also be high school graduates and with lived experience of ART medication self-management. The rationale for inclusion of peer health coaches is because of their unique skill set related to experience with self-management of HIV disease, and to help eliminate barriers of shame and/or stigma related to a HIV diagnosis and/or poorly controlled HIV disease.

There is no more than minimal risk of harm related to involvement of peer health coaches. A formal training protocol will be developed and will include a minimum of 40 hours of training on content related to HIV disease and medications, self-management of antiretroviral treatment, communication with study participants and use of HIPAA compliant Zoom videoconferencing communications. Role playing and practice sessions will be included to ensure competence. Peer coaches will also participate and complete all required components of HIPAA training. Additionally, the peer health coaches will be delivering the intervention from an NYU Meyers designated computer, located in a private office. The study project manager Eva Liang will be available to support the peer health coaches and for seamless delivery during the scheduled intervention sessions. Dr. Navarra (study lead PI at Stony Brook University) and Dr. Goldsamt (contact PI at NYU), and NYU Meyers IT staff will be available by phone, Zoom, and/or in-person to support the peer health coaches and for seamless delivery during the scheduled intervention sessions. As noted in an earlier section, restrictions will be added to the mobile platform by NYU Meyers IT that will prevent study participants from audio or videotaping intervention sessions delivered by peer health coaches.

It is not anticipated for the peer health coaches to become distressed during the intervention. However, in the event of distress (i.e. discomfort, depressive symptoms, anxiety and/or anger) during delivery of the intervention, the training procedure will be to conclude the remote video conferencing session but first to give the participant a five-minute warning. For example, during training peer health coaches would be instructed to say the following to the participant if experiencing distress while administering the intervention. "*This is a very interesting point that you are making and we will need to discuss this more. I am going to have to end this session in about five minutes and we will pick up on this last point during our next session. When is a good time to schedule the next session?*" After concluding the session, the peer health coach would immediately meet with the project manager, Eva Liang to discuss the component(s) of the conversation with the participant that caused distress for the peer health coach, and also for debriefing. If distress among any of the peer health coaches is present, Eva Liang would contact Drs. Navarra (study PI) and/or Goldsamt (co-investigator) immediately; these investigators would be available for discussion (in-person or via Zoom/phone), debriefing and/or problem solving.

Dr. Navarra will consult with Dr. Goldsamt (contact PI on site at NYU), and Dr. Rosenberg (physician collaborator at Jacobi), to determine if the distress is: 1) related to the need for additional training and/or whether it is a) minor and transitory, b) serious and transitory, or c) serious and recurrent or permanent. When distress is minor and transitory, Dr. Navarra will provide support until the peer health coach regains emotional equilibrium and feels ready to end the encounter. Distress that can be considered serious, that is, greater than would be

expectable in the course of delivering no more than minimal risk research, will warrant a referral to mental health care or counseling.

All such decisions will be made by Dr. Navarra with these study team members. Of note, Dr. Goldsamt is a clinically-trained psychologist licensed in the State of New York. Drs. Navarra and Rosenberg are trained and licensed clinicians and qualified to distinguish a minor and transitory event from a serious event.

ACCESS II RCT mHealth Intervention. There is no more than minimal risk of harm to participants while participating in the adherence intervention. Participants and peer health coaches will be trained on the use of HIPAA compliant Zoom videoconferencing applications by the members of the research team. Additionally, HIPAA compliant Zoom videoconferencing mobile applications will be downloaded by NYU Meyers IT staff to a 'study funded smartphone,' allocated to participants upon enrollment. Study participants will be instructed to log on to the remote videoconferencing sessions from their study funded smartphone **using a password protected, mobile application that will be securely downloaded by NYU Meyers IT.** Participants will also receive education on the importance of accessing the videoconferencing sessions from a private location.

ACCESS II RCT control condition - Web-based HIV ART adherence education.

Participants randomized to the web-based adherence platform will access a flat, secure, password-protected educational web-based platform using Rise software from an app on the home screen of a study funded smartphone. Session content and duration was informed by formative research, and directed to address multiple influences of adherence behavior (individual, interpersonal, health system, community, structural). Format of session content was narrative using a conversational style and supported by audio, video, and graphic illustrations. Validation of session content and usability was provided by respective content experts (HIV, nursing, medicine, psychology, informatics) during all phases of development and testing.

A total of eight developmentally and culturally tailored sessions were developed with session length ranging between 20 – 30 minutes. Each new session will be published weekly to the web-based platform and remain available to study participants for eight weeks. There is no more than minimal risk of harm to participants while participating in the control condition, as participants will be trained how to access these modules and protections will be in place to ensure privacy. We selected a control condition with evidence of feasibility among HIV+ participants in an RCT.[52] Participants randomized to the control condition will access the secure, password-protected RISE platform from their study funded smartphone, provided upon verbal consent at the clinical site. Study participants will be trained on use using the password-protected, mobile application.

The web-based platform will be available for each participant during the intervention period (8 weeks), and time and attention spent on the modules will be recorded. Given the potential for low literacy and findings from our earlier work and other evidence, educational content provided in these modules will be tailored to a sixth to seventh reading grade level.[53] Providing educational content in a traditional web-based platform format as a control condition will allow us to test the hypothesis that the delivery of the content and support by peer health coaches is the differentiating influence on ART adherence outcomes, and viral load.

Data Collection. There is no more than minimal risk of harm while collecting data using surveys, and during intervention or control conditions with participants by properly trained and supervised research staff. Additionally, in collaboration with the project manager, Dr. Navarra will provide regular supervision to the peer health coaches during all study phases to minimize

the potential for participant distress. However, it is possible that participants may experience a negative affect or distress as a result of interviews/assessments. Dr. Navarra and project staff including the trained peer health coaches will closely monitor potential distress.

Data collection of primary study variables will be conducted by a trained project manager using REDCap and HIPAA compliant Zoom videoconferencing and primarily includes surveys and self-report. In the event of participant distress, the participant will be debriefed and linked to a support staff member (i.e. social worker or psychologist) affiliated with their clinical agency. The project manager would also notify the Dr. Navarra immediately via phone.

This study is no more than minimal risk of harm, and distress and/or adverse events are not expected during the intervention. The plan for response by peer health coaches in the event of distress and/or adverse events is described in the Adverse Events and Reporting of Adverse Events sections (pp.17 - 20).

Alternate Treatments and Procedures. The main alternative treatment is to not participate in this study. If a subject chooses to not participate, standard medical care may be received including adherence education and support.

ADEQUACY OF PROTECTION AGAINST RISKS

Recruitment and Informed Consent

Recruitment. Black and Hispanic HIV+AYA will be recruited from adult and adolescent HIV clinics at Jacobi Medical Center (North Central Bronx Network) and BronxCare Health System in New York City. Jacobi Medical Center is a part of the NYC Health and Hospital Corporation (HHC), the largest public healthcare system in the United States, and offers comprehensive HIV care services to 322 HIV+AYA, ages 18-29 years of age, most of whom are Black and Hispanic (please see letter of support). BronxCare Health System is a large voluntary, not-for-profit health and teaching hospital system serving the South and Central Bronx.

Each clinical site offers comprehensive treatment to Black and Hispanic HIV+AYA, ages 18-29 years. Between all HIV centers, there are daily clinic sessions available to patients and allowing sufficient time for recruitment by Dr. Navarra. Dr. Rosenberg (physician co-investigator), Dr. Burger (physician collaborator), and Dr. Murli Purswani (physician collaborator) will provide support for recruitment efforts at Jacobi Medical Center (North Central Bronx Network) and the BronxCare Health System. The project manager, under the direction of Dr. Navarra (PI), will coordinate all recruitment efforts as per approved IRB policies and procedures.
Our recruitment strategies will entail distributing IRB approved study flyers and materials, regular visits to clinic settings and communication with clinical staff, consultation with the NYU Langone Medical Center's recruitment and retention core (please see letter of support), and support from the ACCESS II RCT peer health coaches and/or peer recruiter. Peer recruiters will share similar characteristics of the target sample[54] (Black and Hispanic HIV+AYA, ages 18-29 years) and offer a virtual presence from NYU Meyers to potential participants at any one of the recruitment sites. Using HIPAA compliant Zoom videoconferencing, potential participants can speak with the ACCESS II RCT peer health coaches and/or peer recruiter, who will offer information, answer questions, and discuss concerns. They will also assist with triage of phone calls from interested participants. ACCESS II RCT peer health coaches and peer recruiters will not obtain signed written and/or verbal informed consent. Recruitment will be monitored by the PI in weekly research team meetings and daily check-ins with the study team.

The ACCESS II RCT will use EPIC to identify potential participants. A DataCore request will be placed by an ACCESS II RCT study team member (i.e. Principal Investigator, Project Manager) to identify potential participants based on study inclusion/exclusion criteria. The following data will be requested: Patient Name (first and last), Patient Date of Birth, Patient Contact Information, Language Spoken, Date of Last Clinic Visit, Medical Provider Contact Information, and HIV Viral Load (we will be requesting data for patients with a viral load greater than or equal to 20 copies/ml). Only IRB Approved Key Personnel from the ACCESS II RCT will have access to the DataCore/EPIC data. Any recruitment information sent by NYU Langone Email will utilize Send Safe email ("[SENDSAFE]").

Once potential participants have been identified, the ACCESS II RCT study team (i.e. Principal Investigator, Project Manager) will notify them as follows:

- Provide their treating physician (TP), Nurse Practitioner (NP), or their support staff (i.e. social workers, case coordinators a list of potential participants, recruitment fliers and pamphlets, and written and oral script to use when informing potential participants of the ACCESS II RCT.

OR

- Notify the TP, NP and/or their support staff that the ACCESS II RCT study team will directly contact potential participants, after their visit with the TP, NP and/or their support staff in the clinic/telemedicine setting. Participants will be contacted either in person at NYU provider visits, by phone and/or text, or SendSafe email. Potential participants will be notified by the TP, NP and/or their support staff that the ACCESS II RCT study team member will be contacting them.

OR

- Directly contacting the potential participant (via phone call, text, email) using the contact information provided by the DataCore list generated, to inform them of the ACCESS II RCT and gauge their interest. An oral or written script will be used by the ACCESS II RCT Research Team Member when contacting the potential participant.

Once contact is made with a potential participant, IRB approved recruitment language will be used to communicate the reason why they are being contacted.

Potential participants will be asked if they would like to participate in the ACCESS II RCT. Potential participants with whom the study is discussed in-person by the TP, NP and/or their support staff will be provided with an IRB approved study pamphlet and/or flier, and the contact information of the ACCESS II RCT Team.

Should the potential participant agree, the ACCESS II RCT Study Team will provide the potential participant with information regarding next steps for enrollment and participation.

With assurances from select Community-based Organizations (CBOs), IRB approved recruitment materials (i.e. pamphlets and fliers) will be posted in their clinic, community events, and communal spaces. With additional assurances from the CBOs, onsite verbal and written informed consent may be conducted by IRB Approved ACCESS II RCT Research Team Members, within a designated private location. Staff within the CBO will not be participating in the recruitment process, or participating in the research process.

With assurances from select pharmacies, IRB approved recruitment materials (i.e. pamphlets, flyers, palm cards) will be posted within their spaces. With additional assurances from the select

pharmacies, IRB approved recruitment materials (i.e. pamphlets, flyers palm cards) will be provided to patients receiving HIV medication (pick-up or drop-off) from the select pharmacies. Staff of the pharmacies will not be participating in the recruitment process, or participating in the research process.

With assurances from select community venues (i.e. bars, dance halls, night clubs, house balls) IRB approved recruitment materials (i.e. pamphlets, flyers, palm card) will be posted within their spaces. Staff of the community venues will not be participating in the recruitment process, or participating in the research process.

With assurances from select organizations, electronic and paper advertisement (i.e. newsletter, magazine, website, social media posts) of IRB approved recruitment materials (i.e. pamphlets and flyers) may be issued and distributed by these organizations to their select audience.

The ACCESS II research team members will conduct street-based recruitment using IRB approved recruitment materials (i.e. pamphlets, flyers, palm cards), including the distribution of materials at community events (i.e. Health Fairs, AIDS Walk) and at additional locations where the populations of interest may gather. At the time of distribution of IRB approved recruitment materials, the ACCESS II research team members may wear an IRB approved shirt.

CONSENTING PROCEDURES.

Eligibility Screening. Pre-screening for study eligibility will initiated locally in the clinical setting, as participants meeting study eligibility will be pre-identified by the medical team prior to their scheduled clinical visit. If the participant meets eligibility criteria and is interested in learning more about the ACCESS II RCT study, procedures to obtain verbal consent will be implemented locally in the clinical setting.

Verbal Consent. Patients expressing interest in learning more about the ACCESS II RCT study will be connected to an IRB approved member of the local research team (i.e. Jacobi Medical Center). The ACCESS II RCT research study will be reviewed with the patient using a verbal consent script (included as an attachment) and time allotted to answer questions. After all questions are answered, the participant will be given the opportunity to provide verbal consent and enroll in the study. The **Key Information** form and the site IRB approved ICF form will be provided to the participants to review before the participant initiates the e-consent process with the ACCESS II RCT research team. Members of the research team at clinic/recruitment sites are not responsible for obtaining informed consent for the ACCESS II study.

Participants providing verbal consent will be provided with a study funded smartphone to access the intervention. The phone will also serve as a tool for obtaining electronic or e-consent via REDCap. Participants providing verbal consent will also be given a zero balance ClinCard for compensation of their time and related to completion of the designated study activities. Source documentation of eligibility criteria and verbal consent will be securely uploaded to REDCap by IRB approved staff at the clinical site (these staff members will have been approved for an NYU Keberos ID).

If the patient elects to not provide verbal consent, they will be thanked for their time and given a study flyer with the ACCESS II RCT team contact information.

Any participant providing verbal consent will be referred to the ACCESS II RCT research team for the opportunity to provide informed written e-consent. In-person consent may be obtained locally by IRB approved the NYU ACCESS II RCT research team members as needed. Procedures to obtained informed written consent are described below.

Overview of Study Procedures for Informed Written Consent.
The ACCESS II RCT study protocol and related study measures will be approved by the NYU IRB. Informed written consent will be obtained by IRB approved designated investigators and study team members of the NYU ACCESS II RCT Research Team from HIV+ AYA ages ≥18 years. Options for consent include electronic or e-consent via REDCap link (text or email) to the study funded smartphone after the verbal consent has been obtained. Electronic IRB approved informed consent form (ICF) through REDCap will be used when the subject is being consented remotely.

At the discretion of physician collaborators, participants will be given the option to use the paper-based IRB approved ICF when consented in person at their clinical site. IRB approved members of the NYU ACCESS II RCT research team may obtain in-person informed consent at their clinical setting as needed. Clinical/Recruitment site team members will not be involved in obtaining informed consent. With assurances from select Community Based Organizations (CBOs), IRB approved ACCESS II RCT Research Team Members may collect in-person written or electronic informed consent from participants in private locations. CBO staff members will not be involved in obtaining informed consent.

All participants will be asked to give their signed written ICF to participate in ACCESS II RCT including data collection using surveys and medical record data extraction, and randomization to either the intervention or control condition. Only IRB Approved NYU ACCESS II RCT research team members will obtain (electronic or written) informed consent from ACCESS II RCT study participants.

All participants will also be asked to give their signed written ICF for audio video recordings, as participants randomized to the peer-led videoconferencing intervention condition will be recorded (audio video recordings). Procedures to obtain approved informed consent for audio video recordings will also include electronic consent via REDCap link (text or email) to the study funded smartphone.

Participants will again be given the option to use the paper-based audio video IRB approved consent form, if consented in-person at their clinical site. IRB approved members of the ACCESS II RCT Research Team may obtain signed written ICF for audio video recordings at their clinical setting, as needed.
Time will be allotted by the IRB approved designated investigator(s)/study team member to answer participant questions related to informed consent, audio video recordings and study procedures. We will emphasize that participation is voluntary, participants are free to stop participating at any time in the study and that they are free to refuse to answer any specific questions in the interviews. We will also stress that withdrawal from the study may occur at any time and this would not affect receipt of medical care and/or standing in the clinic.

Study Procedures for Informed Written E-Consent via HIPAA compliant Zoom Videoconferencing and REDCap

Participants will be sent an email or text to their study funded smartphone with the REDCap link to the IRB-approved ICF. This link will be sent by a member of the NYU ACCESS II RCT research team. Once the link is received, a date and time will be scheduled for an IRB approved ACCESS II RCT research team member to review the consent form with the participant. A trained member of the ACCESS II RCT research team will discuss the study and review information in the written ICF. Time will be allotted for the subject to ask any questions that they

may have about the study. Participants will be encouraged to ask questions that they have about the research prior to signing the ICF. Signed ICF will be obtained through REDCap displayed on the study funded smartphone. A copy of the signed ICF will be sent by text or email to the study funded smartphone, depending on the preference of the participant.

In-Person Paper-Based Consent

Only IRB Approved NYU ACCESS II RCT research team members will obtain (electronic or written) informed consent from ACCESS II RCT study participants. IRB Approved ACCESS II RCT Research team members may obtain in-person informed consent at Community-Based Organizations, with the assurance of the CBO. Participants requesting in-person paper based consent will be given the ICF to read and ask questions. Subjects will be required to read, sign and date each page of an IRB-approved ICF with study personnel and will be given a signed and dated copy. The original signed and dated ICF will be kept as source documentation. All study procedures will be explained in non-technical terms to enhance subject understanding of procedures. Subjects have the right to withdraw consent at any time.

Participants will be informed that their decision to participate or decline to enroll in the study will not affect any services they receive at their clinical site or any other organization.

Paper copies of consent forms will be kept in locked file cabinets at NYU Meyers. All research data will be kept on a computer that is password-protected in an encrypted file in the locked offices at NYU Meyers. Only the consent form, tracker (locator) form, and tracker computer will link the participant's name to the identification number. Members of the project team will receive intensive training about confidentiality.

We Will Not be Enrolling Mature or Emancipated Minor Status for Youth Ages 17 and Younger. The proposed study's research and the consent procedures are consistent with the guidelines for inclusion and protection of adolescents in epidemiological and clinical research. **For the purposes of informed consent, participants will fall into the category of legal adults (aged 18-29 years), who will sign their own consent forms.**

Planned Procedures to Protect Against Risk

Confidentiality of Data. Each study subject will be identified by a random number and not by name, address, social security number and/or medical record number. Data collected on study participants will not be shared with anyone outside of the research team. All data collected will be either entered into password protected computers and/or stored in locked file cabinets with access limited to study team members. After the study is completed, all links between patients and the study will be destroyed.

Email Correspondence: All email correspondence containing de-identified PHI will be conducted utilizing the send safe feature within the medical center email system and other approved site-specific secure networks.

Data Management. We are using REDCap[28,29] and built a secure and password-protected web-based database to manage recruitment, eligibility assessment, scheduling, ACCESS II RCT randomization and data collection. Recruitment and study data will be collected and managed using REDCap electronic data capture tools supported by the Health Sciences Library at NYU

Langone Health. Recruitment and response rates will be tracked in real time using REDCap reporting features. REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. REDCap is a robust, secure, HIPAA-compliant infrastructure with a consortium of more than 3,500 research partners worldwide.

All confidential information (demographic, survey and viral load data) will be stored electronically in REDCap with access limited to Dr. Navarra and IRB approved members of the study team. Numeric coding will be used to protect the identity of participants. Electronic files containing patient data and study materials will be backed up daily to protect against computer failure. Self-reported survey data and medically extracted viral load data will be directly inputted into REDCap. All computerized data will be kept on computers that are double password-protected. All study data collected in REDCap will be exported to EXCEL every three months and will be transferred to the NYU Meyers secure server for back-up, which is double password protected and available only to project staff. REDCap is backed up daily on NYU Langone Medical Center's REDCap Administrator to prevent loss of data. **HIPAA Training.** All research team members **including peer health coaches** will pass the protection of human subjects and research HIPAA exams and sign a protocol specific conflict of interest. Additional steps will be taken to protect the vulnerable population in this study. Team members will be trained on content related to New York State Department of Health (NYSDOH) HIV Confidentiality law, **http://www.health.ny.gov/publications/9192.pdf** and will also be expected to view the video entitled, 'Complex Issues with Research Involving Vulnerable Populations' available from the U.S. Department of Health and Human Services', http://www.hhs.gov/ohrp/education/training/ded_video.html#complex. Issues related to human subjects and confidentiality will also be re-reviewed in the training of peer health coaches . This will allow for questions and related discussion.

DATA AND SAFETY MONITORING PLAN

This study is no more than minimal risk but a data and safety plan is still important to ensure the well-being of the vulnerable population.

Safety and Monitoring Committee. In addition to the regular scheduled meetings with the ACCESS study team, a *Safety and Monitoring Committee* (SMC) will be formed. This SMC will be comprised of PI Navarra (leading the study), three independent experts as follows: (senior biostatistician/methods researcher; HIV bio-behavioral clinical trialist; health informatics researcher with specialty in mHealth). Dr. Navarra will provide oversight of the study and will be the senior researcher responsible for monitoring the trial. This committee will meet annually during the 4-year time period to review data adequacy, data analyses, results, and fidelity to the intervention. In collaboration with the other members of the mentorship team, this committee will create an action plan to address any concerns participants may have during the course of the study. In the event of any adverse events, reporting will follow the guidelines of the NYU IRB.

Protecting Confidentiality of Data. All participants will receive an identification number and this number will be used for all materials, and assessments. Only the consent forms will directly link the participant's name to participation in the ACCESS II RCT. Given that ClinCard is a type of banking card, procedures for activation include providing the participant name, address, and date of birth. Participants will be informed of these procedures during the informed consent

process.

Source documentation of eligibility criteria including viral load, and verbal consent will be securely uploaded to REDCap by IRB approved staff at the clinical site (these staff members will have been approved for an NYU Keberos ID).

***Exceptions to Confidentiality*.** The NYU - University Committee on Activities Involving Human Subjects (UCAIHS) has identified a number of circumstances in which confidentiality cannot be maintained. We cannot maintain the confidentiality of participants in four specific circumstances.

For participants who have reached the age of majority, that is, who are ages 18 years and older, confidentiality will not be maintained: (1) in the event the participant has perpetrated sexual abuse on a minor; (2) in the event the participant has perpetrated physical abuse on a minor; (3) if a participant reports current suicidality and is in imminent danger of suicide; and (4) if a participant reports current homicidality or a serious threat of physical harm to others. There are no other circumstances when confidentiality will be violated.

The following actions will be taken if any of these four circumstances is identified:

Child sexual or physical abuse. Child abuse will be reported to the local child protective services agency by Dr. Navarra who is a mandated reporter and complies with New York State Child abuse laws.

Suicidality. If participants are at imminent risk for suicide, law enforcement will be notified by Drs. Navarra or Goldsamt who will call 911. Dr. Lloyd Goldsamt (contact PI at NYU and licensed clinical psychologist) and Dr. Navarra (board certified/licensed pediatric nurse practitioner) will Zoom into the videoconferencing session for crisis management.

Homicidality or a serious threat of physical harm to others. When participants are at imminent risk for committing homicidal acts, law enforcement will be notified by Drs. Navarra or Goldsamt who will call 911. Dr. Lloyd Goldsamt (contact PI at NYU and licensed clinical psychologist) and Dr. Navarra (board certified/licensed pediatric nurse practitioner) will Zoom into the videoconferencing session for crisis management.

As part of the informed consent process, participants will also be informed that all information they provide in interviews and intervention sessions is confidential with these exceptions. The NYU IRB recommends the following language be used in the Confidentiality section of the consent form:

"*However, if you are in imminent danger of committing suicide or homicide the appropriate agency or authority will be contacted; and, if you are under 18 and currently being sexually or physically abused, or, if 18 or older, physically or sexually abusing someone else, a report will be made to the local child protective services organization or appropriate authority or organization."*

Compliance with IRB Requirements. Dr. Navarra will lead weekly hybrid team study meetings (in-person with optional Zoom call in procedures for team members off site) during years 1-4. One meeting per month will be directed to monitoring study safety, auditing selected cases for compliance with IRB requirements, conformance with informed consent requirements,

verification of source documents, and investigator compliance. Members of the study team will also participate in these monthly meetings.

Regulatory Issues

Reporting to NYU IRB

Adverse events, serious adverse events, participant complaints that cannot be handled by Dr. Goldsamt, and any research related injuries will be reported to the NYU IRB consistent with the NYU IRB guidelines. Dr. Goldsamt (contact PI at NYU), Dr. Navarra (lead PI at Stony Brook University) and co-investigators will determine which of the following best describes the event:

- **The event is serious, unexpected (in terms of its nature, frequency or severity) and related or possibly related to participation in the research.**

- **The event is not serious, but is unexpected (in terms of its nature, frequency or severity), related or possibly related to the research and suggests that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized.**

Dr. Goldsamt will report an adverse event or serious adverse event as described above (including death of a participant) within 24 hours of discovery of the event by the research team. In the event of a death, the NYU IRB (212) 263-4110 will be called immediately by telephone. All other events will be reported by email, telephone or fax. *NYU Event Requiring Prompt Reporting to the IRB* forms will be completed and submitted within 72 hours.

Reporting of Adverse Events and Serious Adverse Events to NINR

Adverse events will be reported to the NINR at least once per year as part of the annual progress report. This report will include a description and date of the event and the outcome/resolution. If there are no adverse events, a statement that no adverse events occurred will be included in the progress report.

Serious adverse events will be communicated to NINR within 72 hours and will include: date of the event, what occurred, actions taken by project staff, planned follow up, the time point in study (i.e. focus group or intervention) of the affected participant, whether the event appears to be related to the intervention, and whether the event affects future participation of the study participant.

Data Monitoring

Plans for Interim Analysis of Data

Procedures to Ensure the Validity and Integrity of the Data. All data files received during data collection will be verified weekly by a trained project manager. Data files will be reviewed monthly for quality by Drs. Navarra (PI) and Fletcher (biostatistician) with the assistance of trained project manager. We will examine individual survey data to determine whether some individuals may be having difficulty understanding items on the measures (i.e., refusing to answer more than 5% of survey). We will also review participant responses for possible systemic biases that may result when individuals are not truly responding to items but providing false or random answers. We propose to use STATA to identify possible non-random patterns of missing data. When items, data sources, or staff are associated with more than 5% missing data that are not due to planned interview skip patterns, we will determine the causes of

missing data and implement strategies to reduce it (e.g., retraining of staff). The time to complete different interviews will be summarized to identify participants who took much less or much more time than most others, which may indicate careless responding or difficulty understanding interview items. Also, on a weekly basis, the project manager will review due dates of scheduled intervention sessions and/or data collection visits for enrolled participants, and will inform Dr. Navarra and peer health coaches about past due interviews.

Data Safeguards. Access to NYU Meyers offices (433 First Avenue and 380 Second Ave) is restricted to research staff. The building is secure and monitored by security staff. File drawers containing participant information are kept locked when not in use. Only Dr. Goldsamt, and the project manager will have keys to these file cabinets. Paper copies of consent forms will be kept in a locked office in a locked cabinet at NYU Meyers.

Consent and other confidential paper forms will be scanned for electronic storage on project-specific folders on the NYU Meyers secure server. The folder is double password-protected and access to project-specific folders is restricted to members of the research team.

All computerized data, including REDCap, (survey measures, viral load, etc.) will be collected using computers that are double password-protected and are only labeled with participant identification numbers. All study data collected in REDCap will be exported to EXCEL on a every three months and transferred to the NYU Meyers secure server for back-up, which is also double password protected and available only to the research team. Peer health coaches will not be entering, cleaning, and/or analyzing data with the primary role of delivering the intervention. Peer health coaches will therefore not require and/or have access to the NYU Meyers shared drive or the REDCap platform. Peer health coaches will be meeting remotely with study participants via HIPAA compliant Zoom videoconferencing as part of the intervention and regularly attend study team meetings.

A master database that contains participant identifying information and participant identification (PID) numbers will be stored on REDCap. This data will be downloaded monthly into a project-specific folder on the NYU Meyers secure server. This folder is double password protected and can only be accessed by the study's staff members. NYU Meyers staff members who are not members of the research team for this study do not have access to this folder.

Adverse Events. Federal regulation (21 CFR Part 312) defines an "adverse event" (AE) as any untoward occurrence involving a study participant, or individual connected to the participant, occurring during the course of the study (including the study's follow-up period). Adverse events are categorized as either a Serious Adverse Event (SAE) or an Adverse Event (AE). **Adverse events are defined as negative experiences that do not involve imminent danger**. **Serious adverse events are negative experiences that involve imminent danger**.

Adverse events or serious adverse events are not expected during the course of this study. However, during the ACCESS-II study sessions 4 through 6, peer health coaches will explore participant's history and experiences with HIV stigma and disclosure concerns and related psychological distress and substance use. There is a potential for a participant to experience discomfort, depressive symptoms, anxiety and/or anger during this session and/or any of the ACCESS II RCT sessions. Peers health coaches will receive adequate training and supervision to minimize this potential.

Dr. Navarra is a highly trained, board certified pediatric nurse practitioner with 15 years of clinical experience in working with HIV+ AYA. Dr. Goldsamt (contact PI) is an experienced,

clinically-trained psychologist and will provide expertise in the development of the peer training protocol, allowing for peer health coaches to recognize and report any potential adverse events immediately (such as discomfort, depressive symptoms, anxiety and/or anger). The training protocol will also include content to facilitate recognition of serious adverse events including suicidal/homicidal ideation. As part of this training protocol, peer health coaches will be trained to not act as mental health counselors. Instead they will be instructed to notify Dr. Navarra immediately who will implement procedures for management of adverse events as described in reporting of adverse events below. In the event of an adverse event, the peer health coach will be delivering the intervention on site from an NYU Meyers designated computer. Additionally, Dr. Navarra (lead PI), Dr. Goldsamt (contact PI), Vorderstrasse (co-investigator), and Rosenberg (physician collaborator) will be available via cell phone 24 hours per day.

Other potential adverse events may also include participant discomfort with study procedures or inadvertent disclosure by peer health coaches of confidential research information to other persons and/or to staff at NYU Meyers. The potential for discomfort with study procedures will be minimized by training the members of the study team and peer health coaches to be sensitive to the needs of the participants (i.e. taking a 5-minute break, if needed). The potential for inadvertent disclosure by peer health coaches will be minimized by successful completion of the protection of human subjects and research HIPAA exams and by signing a protocol specific conflict of interest.

Reporting Adverse Events. This study is no more than minimal risk and adverse events are not expected. In the event of an adverse event during the intervention - remote videoconferencing sessions (i.e. discomfort, depressive symptoms, anxiety and/or anger), the peer health coach will verbally (phone or in person) notify the project manager, Eva Liang and Dr. Goldsamt immediately. If the participant is from Jacobi Medical Center, Dr. Rosenberg (clinician co-investigator at Jacobi) will be notified immediately to discuss whether or not mental health referral is needed. If the participant is recruited from North Central Bronx, Dr. Rosenberg may collaborate with Dr. Burger (physician collaborator) to discuss whether or not mental health referral is needed. If the participant is from BronxCare Health System, Dr. Purswani (physician collaborator at BronxCare Health System) will be contacted, if deemed necessary. If a participant is recruited from other methods of recruitment, the physician of that participant will be contacted, if deemed necessary. For participants recruited from other recruitment sites, Dr. Navarra with co-investigators will discuss if mental health referral is needed. All participants will be recruited from clinical sites staffed with psychosocial professionals (psychologists, social workers, and one psychiatrist) who would be available if referral to mental health services is needed.

In the event of a serious adverse event such as suicidal or homicidal ideation, the institutional emergency protocol of the clinical sites (Jacobi Medical Center (North Central Bronx Network, and BronxCare Health System), will be followed. This includes immediate referral to 24-hour psychiatric emergency services via the psychiatric emergency room. This protocol also includes referral to a 24-hour crisis number, 1-800-LIFENET with counselors available at all times. Additionally, the clinical site would be contacted immediately to notify clinical staff and if the SAE occurs after hours, an on-call physician may be reached 24 hours a day. In the event of an imminent life threatening emergency, 911 would be notified.

As noted in our consent form, we are obligated to break confidentiality of participants in the event of sexual and physical abuse, or if they report current suicidality or homicidality. If participants are at imminent risk for suicide during in-person interview (focus group or post intervention interview), they will be escorted to a hospital emergency room where appropriate,

or law enforcement will be notified. When participants are homicidal, law enforcement will be notified. All such decisions will be made by Drs. Navarra and Dr. Goldsamt in collaboration with co-investigators.

In the event that such adverse events are reported to Dr. Goldsamt, he will immediately communicate the event to the Vice Dean for Research at NYU Meyers, and this verbal report will be followed by a written report within 24 hours. The Vice Dean will immediately inform the Chairperson of the NYU Meyers IRB and jointly decide whether the reported event is a Serious Adverse Event (SAE). If the event is deemed to be a SAE, it will be reported to the NINR Project Officer within 72 hours of the event. The written report to NINR will be sent via email or fax. Dr. Goldsamt will also follow adverse event reporting procedures for the NYU IRB.

Dr. Goldsamt will determine if there is sufficient evidence of an adverse event to necessitate suspension of data collection, further IRB review, and/or modification of the protocol or other changes. If there is sufficient evidence, Dr. Goldsamt will immediately discuss the recommendation with the Chairperson of the IRB and reach a determination whether to suspend data collection or to stop the study from proceeding. Resumption shall be based on the concurrence of Drs. Goldsamt, Navarra, co-investigators, the Chairperson of the IRB and the Vice Dean. The Federal Agency (NINR) will receive a written report within 72 hours of any such suspension and/or resumption of data collection.

Dr. Goldsamt will provide an annual summary report of all adverse events to the IRB as part of the annual review. NYU Meyers will report all adverse events to the Federal Agency (NINR) as part of the Annual Progress Report. If no adverse events have occurred, the report will state, "*No adverse events affecting human subjects have occurred during this project year.*" As described above, SAEs will be reported to NINR within 72 hours of the event. Dr. Navarra is ultimately responsible for the Data and Safety Monitoring Plan as well as the NYU IRB.

Expertise of the Investigative Team. The lead PI (Dr. Navarra), contact PI (Dr. Goldsamt),co-investigator (Dr. Vorderstrasse), and physician collaborator (Dr. Rosenberg) have conducted many intervention studies, including those with populations of youth at risk. They are highly experienced in managing research issues with vulnerable youth during the course of an intervention, and with assessing sensitive topics while maintaining confidentiality and ethical standards. As a result, the ACCESS II RCT study team is well equipped to exercise excellent decision making and thoughtful consideration on all study related matters.

POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO HUMAN SUBJECTS AND OTHERS

Potential Benefits. Improving ART adherence and viral load suppression for Black and Hispanic HIV+AYA is an urgent public health matter. We developed ACCESS II RCT for Black and Hispanic HIV+AYA in response to critical methodological challenges with conventional approaches[6,55] and persistent minority health disparities leading to poor HIV virologic control.[60,56,57] Our approach is highly promising for HIV behavioral science, with potential broad effect on clinical treatment and prevention through the development of a scalable adherence intervention.[58] By reducing the structural barriers of travel and stigma, technology-enabled interventions can reduce minority health disparities.[59] Mobilizing peer health coaches using videoconferencing technology is a viable way to deliver a behavioral intervention targeting ART adherence[15,60] with a stigmatized and hard to reach population.[61] Our prior work demonstrated feasibility, acceptability, and improvement in HIV viral load and ART adherence. Furthermore,

there is a call for greater mobilization of peer health coaches to support HIV health outcomes, including adherence.[62] ACCESS II RCT will be complimentary to current national and public health peer initiatives targeting HIV+ and at-risk AYA.

Importance of the Knowledge to be Gained. One million US individuals are HIV+ including 100,000 AYA, ages 15-29 years.[17] Black and Hispanic AYA are disproportionately represented in the US HIV health crisis. Antiretroviral therapy (ART) effectively treats HIV infection and prevents HIV-related morbidity, mortality and sexual transmission,[21,63] but improved health outcomes are related to behavior[64]: benefits of ART are directly proportional to levels of adherence.[65] Optimal adherence is defined as 80 to 90% for protease-inhibitor-boosted regimens and greater than 90% for un-boosted regimens.[66] Black and Hispanic HIV+AYA have the lowest rates of ART adherence; nearly 40% reported suboptimal adherence (<90%) during the past week.[19] Virologic estimates show that only half of US AYA (ages 13-24 years) achieved suppression (HIV RNA level of <200 copies/ml).[20] Black and Hispanic HIV+ AYA are at high risk for virologic failure during their entire HIV treatment course, even after a period of virologic suppression.[67] Persistent HIV viremia due to suboptimal ART adherence is a primary contributor to the increasing number of HIV infections.[20,24] A shift in the current approach to ART adherence support is desperately needed.

Reasonableness of Subjects' Risks in Relation to Anticipated Benefits.
The human subjects' risks are related to loss of confidentiality, perceived pressure to participate, embarrassment related to suboptimal adherence, and/or difficulty using the mobile application for remote videoconferencing. Training procedures directed to peer health coaches and collaborative efforts with NYU Meyers IT will minimize these risks. Additionally, the Data and Safety Monitoring Plan is intended to address and monitor these risks and any potential threats to safety. Given the importance of the problem of suboptimal adherence in HIV+ AYA, the potential importance of the knowledge to be gained outweigh these potential risks to human subjects.

INCLUSION OF WOMEN AND MINORITIES

HIV-infection is primarily characterized as a disease mostly affecting non-whites and minorities. We expect our sample population to be largely comprised of Black and Hispanic AYA. Based on the current demographics of the clinic population across these three clinical settings, we expect less than 5.0% of the sample to be White, 60.0% - 70.0% of the population to be Black and 30.0% - 40.0% to be Hispanic. Given the current demographic characteristics of the population across the three clinical settings, we anticipate 40.0% - 45.0% of the sample to be female. These estimates are based on experience with recruitment for the completed K23 research study with HIV+ AYA.

References

1. Hansen DJ, Zamboanga BL, Sedlar G. Cognitive-behavior therapy for ethnic minority adolescents: broadening our perspectives. *Cogn Behav Pract*. 2000;7(1):54-60. doi:https://doi.org/10.1016/S1077-7229(00)80007-3

2. Kennard B, Brown L, Hawkins L, et al. Development and implementation of health and wellness CBT for individuals with depression and HIV. *Cogn Behav Pract*. 2014;21(2):237-246. doi:10.1016/j.cbpra.2013.07.003

3. Olem D, Sharp KM, Taylor JM, Johnson MO. Overcoming barriers to HIV treatment adherence: a brief cognitive behavioral intervention for HIV-positive adults on antiretroviral treatment. *Cogn Behav Pract*. 2014;21(2):206-223. doi:10.1016/j.cbpra.2013.09.003

4. Pantalone DW. Introduction: using evidence-based cognitive and behavioral principles to improve HIV-related psychosocial interventions. *Cogn Behav Pract*. 2014;21(2):145-148. doi:10.1016/j.cbpra.2013.12.006

5. Dinaj-Koci V, Wang B, Naar-King S, MacDonell KK, Adolescent Medicine Trials Network for HIVAI. A multi-site study of social cognitive factors related to adherence among youth living with HIV in the new era of antiretroviral medication. *J Pediatr Psychol*. 2019;44(1):98-109. doi:10.1093/jpepsy/jsy076

6. Navarra AM, Gwadz MV, Whittemore R, et al. Health technology-enabled interventions for adherence support and retention in care among US HIV-infected adolescents and young adults: an integrative review. *AIDS Behav*. 2017;21:3154-3171. doi:10.1007/s10461-017-1867-6

7. Dowshen N, Kuhns LM, Gray C, Lee S, Garofalo R. Feasibility of interactive text message response (ITR) as a novel, real-time measure of adherence to antiretroviral therapy for HIV+ youth. *AIDS Behav*. 2013;17(6):2237-2243. doi:10.1007/s10461-013-0464-6

8. Outlaw AY, Naar-King S, Tanney M, et al. The initial feasibility of a computer-based motivational intervention for adherence for youth newly recommended to start antiretroviral treatment. *AIDS Care*. 2014;26(1):130-135. doi:10.1080/09540121.2013.813624

9. La Grange R, Lewis M, Rockwern B. Using mobile technology to support adherence to medication: SMS text reminders and young people living with HIV. *J Adolesc Health*. 2012;50(2):S94. doi:10.1016/j.jadohealth.2011.10.247

10. Saberi P, Yuan P, John M, Sheon N, Johnson MO. A pilot study to engage and counsel HIV-positive African American youth via telehealth technology. *AIDS Patient Care STDs*. 2013;27(9):529-532. doi:10.1089/apc.2013.0185

11. Dowshen N, Kuhns LM, Johnson A, Holoyda BJ, Garofalo R. Improving adherence to antiretroviral therapy for youth living with HIV/AIDS: a pilot study using personalized, interactive, daily text message reminders. *J Med Internet Res*. 2012;14(2):e51. doi:10.2196/jmir.2015

12. Puccio JA, Belzer M, Olson J, et al. The use of cell phone reminder calls for assisting HIV-infected adolescents and young adults to adhere to highly active antiretroviral therapy: a pilot study. *AIDS Patient Care STDs*. 2006;20(6):438-444. doi:10.1089/apc.2006.20.438

13. Garofalo R, Kuhns LM, Hotton A, Johnson A, Muldoon A, Rice D. A randomized controlled trial of personalized text message reminders to promote medication adherence among HIV-positive adolescents and young adults. *AIDS Behav*. 2016;20(5):1049-1059. doi:10.1007/s10461-015-1192-x

14. Naar-King S, Outlaw AY, Sarr M, et al. Motivational Enhancement System for Adherence (MESA): pilot randomized trial of a brief computer-delivered prevention intervention for youth initiating antiretroviral treatment. *J Pediatr Psychol*. 2013;38(6):638-648. doi:10.1093/jpepsy/jss132

15. Belzer ME, Naar-King S, Olson J, et al. The use of cell phone support for non-adherent HIV-infected youth and young adults: an initial randomized and controlled intervention trial. *AIDS Behav*. 2014;18(4):686-696. doi:10.1007/s10461-013-0661-3

16. Amico KR, Dunlap A, Dallas R, et al. Triggered escalating real-time adherence intervention to promote rapid HIV viral suppression among youth living with HIV failing antiretroviral therapy: protocol for a triggered escalating real-time adherence intervention. *JMIR Res Protoc*. 2019;8(3):e11416. doi:10.2196/11416

17. Center for Disease Control and Prevention. *HIV Surveillance Report, 2017; Vol. 29*.; 2018. Accessed October 1, 2019. http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html.

18. Vella S, Schwartländer B, Sow SP, Eholie SP, Murphy RL. The history of antiretroviral therapy and of its implementation in resource-limited areas of the world. *AIDS*. 2012;26(10):1231-1241. doi:10.1097/QAD.0b013e32835521a3

19. MacDonell KK, Jacques-Tiura AJ, Naar S, Fernandez MI, ATN 086/106 Protocol Team. Predictors of self-reported adherence to antiretroviral medication in a multisite study of ethnic and racial minority HIV-positive youth. *J Pediatr Psychol*. 2016;41:419-428. doi:10.1093/jpepsy/jsv097

20. Center for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2017. Published 2019. Accessed September 12, 2019. http://www.cdc.gov/hiv/library/reports/ hiv-surveillance.html

21. Eisinger RW, Dieffenbach CW, Fauci AS. HIV viral load and transmissibility of HIV infection: undetectable equals untransmittable. *J Am Med Assoc*. 2019;321:451-452. doi:10.1001/jama.2018.21167

22. US Department of Health and Human Services. *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV.*; 2018. https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf

23. Prevention Access Campaign. *Risk of Sexual Transmission of HIV from a Person Living with HIV Who Has an Undetectable Viral Load: Messaging Primer & Consensus Statement*.; 2016. Accessed January 11, 2019. https://www.preventionaccess.org/consensus

24. Ellen JM, Kapogiannis B, Fortenberry JD, et al. HIV viral load levels and CD4+ cell counts of youth in 14 cities. *AIDS Lond Engl*. 2014;28(8):1213-1219. doi:10.1097/QAD.0000000000000183

25. Centers for Disease Control and Prevention. *Monitoring Selected National HIV Prevention and Care Objectives by Using HIV Surveillance Data—United States and 6 Dependent Areas, 2016*.; 2018. http://www.cdc.gov/hiv/library/reports/ hiv-surveillance.html.

26. Bradley H, Rosenberg ES, Holtgrave DR. Data-driven goals for curbing the U.S. HIV epidemic by 2030. *AIDS Behav*. 2019;23(3):557-563. doi:10.1007/s10461-019-02442-7

27. Fauci AS, Redfield RR, Sigounas G, Weahkee MD, Giroir BP. Ending the HIV epidemic: a plan for the United States. *JAMA*. 2019;321(9):844-845. doi:10.1001/jama.2019.1343

28. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009;42(2):377-381. doi:10.1016/j.jbi.2008.08.010

29. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: building an international community of software platform partners. *J Biomed Inform*. 2019;95:103208. doi:10.1016/j.jbi.2019.103208

30. Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010;340. doi:10.1136/bmj.c332

31. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010;340. doi:10.1136/bmj.c869

32. Rudy BJ, Murphy DA, Harris DR, Muenz L, Ellen J, Adolescent Trials Network for HIV/AIDS Interventions. Prevalence and interactions of patient-related risks for nonadherence to antiretroviral therapy among perinatally infected youth in the United States. *AIDS Patient Care STDs*. 2010;24(2):97-104. doi:10.1089/apc.2009.0198

33. Naar-King S, Templin T, Wright K, Frey M, Parsons JT, Lam P. Psychosocial factors and medication adherence in HIV-positive youth. *AIDS Patient Care STDs*. 2006;20(1):44-47. doi:10.1089/apc.2006.20.44

34. Erlen JA, Cha ES, Kim KH, Caruthers D, Sereika SM. The HIV medication taking self-efficacy scale: psychometric evaluation. *J Adv Nurs*. 2010;66(11):2560-2572. doi:10.1111/j.1365-2648.2010.05400.x

35. Mimiaga MJ, Bogart LM, Thurston IB, et al. Positive strategies to enhance problem-solving skills (STEPS): A pilot randomized, controlled trial of a multicomponent, technology-enhanced, customizable antiretroviral adherence intervention for HIV-Infected adolescents and young adults. *AIDS Patient Care STDs*. 2019;33(1):21-24. doi:10.1089/apc.2018.0138

36. Balfour L, Kowal J, Tasca GA, et al. Development and psychometric validation of the HIV Treatment Knowledge Scale. *AIDS Care*. 2007;19(9):1141-1148. doi:10.1080/09540120701352241

37. Dunn Navarra AM, Viorst Gwadz M, Bakken S, Whittemore R, Cleland CM, D'Eramo Melkus G. Adherence connection for counseling, education, and support: research protocol for a proof-of-concept study. *JMIR Res Protoc*. 2019;8:e12543. doi:10.2196/12543

38. Dunn Navarra A, Bakken S, Whittemore R, Gwadz M, Cleland C, D'Eramo Melkus G. Feasibility and acceptability of a peer-led mHealth adherence intervention for human immunodeficiency virus (HIV)-infected adolescents and young adults. *Nursing Research*. 2019;68(2):E95.

39. Berger BE, Ferrans CE, Lashley FR. Measuring stigma in people with HIV: psychometric assessment of the HIV stigma scale. *Res Nurs Health*. 2001;24(6):518-529.

40. Dowshen N, Binns HJ, Garofalo R. Experiences of HIV-related stigma among young men who have sex with men. *AIDS Patient Care STDs*. 2009;23(5):371-376. doi:10.1089/apc.2008.0256

41. Clum G, Chung SE, Ellen JM, Adolescent Medicine Trials Network for HIV/AIDS Interventions. Mediators of HIV-related stigma and risk behavior in HIV infected young women. *AIDS Care*. 2009;21(11):1455-1462. doi:10.1080/09540120902883069

42. McCumber M, Cain D, LeGrand S, et al. Adolescent medicine trials network for HIV/AIDS interventions data harmonization: rationale and development of guidelines. *JMIR Res Protoc*. 2018;7(12):e11207. doi:10.2196/11207

43. Cella D, Yount S, Rothrock N, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS): progress of an NIH Roadmap cooperative group during its first two years. *Med Care*. 2007;45(5 Suppl 1):S3-S11. doi:10.1097/01.mlr.0000258615.42478.55

44. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. *J Gen Intern Med*. 2001;16(9):606-613. doi:10.1046/j.1525-1497.2001.016009606.x

45. Chenneville T, Gabbidon K, Lynn C, Rodriguez C. Psychological factors related to resilience and vulnerability among youth with HIV in an integrated care setting. *AIDS Care*. 2018;30(sup4):5-11. doi:10.1080/09540121.2018.1488032

46. Edwards M, Quinlivan EB, Bess K, et al. Implementation of PHQ-9 depression screening for HIV-infected patients in a real-world setting. *J Assoc Nurses AIDS Care JANAC*. 2014;25(3):243-252. doi:10.1016/j.jana.2013.05.004

47. Shacham E, Estlund AL, Tanner AE, Presti R. Challenges to HIV management among youth engaged in HIV care. *AIDS Care*. 2017;29(2):189-196. doi:10.1080/09540121.2016.1204422

48. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A Brief Measure for Assessing Generalized Anxiety Disorder: The GAD-7. *Arch Intern Med*. 2006;166(10):1092. doi:10.1001/archinte.166.10.1092

49. Lynn C, Chenneville T, Bradley-Klug K, Walsh ASJ, Dedrick RF, Rodriguez CA. Depression, anxiety, and posttraumatic stress as predictors of immune functioning:

differences between youth with behaviorally and perinatally acquired HIV. *AIDS Care*. 2019;31(10):1261-1270. doi:10.1080/09540121.2019.1587354

50. Lynn C, Bradley-Klug K, Chenneville TA, Walsh AStJ, Dedrick R, Rodriguez C. Mental health screening in integrated care settings: Identifying rates of depression, anxiety, and posttraumatic stress among youth with HIV. *J HIVAIDS Soc Serv*. 2018;17(3):239-245. doi:10.1080/15381501.2018.1437585

51. Prins A, Ouimette P, Kimerling R, et al. The primary care PTSD screen (PC–PTSD): development and operating characteristics. *Prim Care Psychiatry*. 2004;9(1):9-14. doi:10.1185/135525703125002360

52. Hersch RK, Cook RF, Billings DW, et al. Test of a web-based program to improve adherence to HIV medications. *AIDS Behav*. 2013;17(9):2963-2976. doi:10.1007/s10461-013-0535-8

53. Navarra AM, Neu N, Toussi S, Nelson J, Larson EL. Health literacy and adherence to antiretroviral therapy among HIV-infected youth. *J Assoc Nurses AIDS Care JANAC*. 2014;25(3):203-213. doi:10.1016/j.jana.2012.11.003

54. White JJ, Dangerfield DT, Grieb SM. Methodological considerations for conducting focus groups in HIV prevention research among Black men who have sex with men. *Public Health Nurs*. 2019;36(3):439-445. doi:10.1111/phn.12592

55. Wu YP, Hommel KA. Using technology to assess and promote adherence to medical regimens in pediatric chronic illness. *J Pediatr*. 2014;164(4):922-927.

56. Lally MA, van den Berg JJ, Westfall AO, et al. HIV continuum of care for youth in the United States. *JAIDS J Acquir Immune Defic Syndr*. 2018;77(1):110-117. doi:10.1097/qai.0000000000001563

57. Wong K, Zucker J, Fernandes H, Cennimo D. Adolescent HIV viral load in an urban hospital in Newark, New Jersey. *Int J Pediatr Adolesc Med*. 2016;3(3):103-108. doi:https://doi.org/10.1016/j.ijpam.2016.04.001

58. Lenhart A. Teens, Social Media and Technology Overview. *Pew Internet Res Cent*. Published online 2015.

59. Mulawa MI, LeGrand S, Hightow-Weidman LB. eHealth to enhance treatment adherence among youth living with HIV. *Curr HIV/AIDS Rep*. 2018;15(4):336-349. doi:10.1007/s11904-018-0407-y

60. Pellowski JA, Kalichman SC. Recent advances (2011-2012) in technology-delivered interventions for people living with HIV. *Curr HIV/AIDS Rep*. 2012;9(4):326-334. doi:10.1007/s11904-012-0133-9

61. Kenya S, Jones J, Arheart K, et al. Using community health workers to improve clinical outcomes among people living with HIV: a randomized controlled trial. *AIDS Behav*. 2013;17(9):2927-2934. doi:10.1007/s10461-013-0440-1

62. Center for Disease Control and Prevention. Peer Support. Published 2019. Accessed October 12, 2019. https://effectiveinterventions.cdc.gov/en/care-medication-adherence/group-3/peer-support

63. Gross IM, Hosek S, Richards MH, Fernandez MI. Predictors and profiles of antiretroviral therapy adherence among African American adolescents and young adult males living with HIV. *AIDS Patient Care STDs*. 2016;30(7):324-338. doi:10.1089/apc.2015.0351

64. Coates TJ. An expanded behavioral paradigm for prevention and treatment of HIV-1 infection. *J Acquir Immune Defic Syndr*. 2013;63 Suppl 2(0 2):S179-S182. doi:10.1097/QAI.0b013e318299eff0

65. Boussari O, Subtil F, Genolini C, et al. Impact of variability in adherence to HIV antiretroviral therapy on the immunovirological response and mortality. *BMC Med Res Methodol*. 2015;15:10. doi:10.1186/1471-2288-15-10

66. Gordon LL, Gharibian D, Chong K, Chun H. Comparison of HIV virologic failure rates between patients with variable adherence to three antiretroviral regimen types. *AIDS Patient Care STDs*. 2015;29:384-388. doi:10.1089/apc.2014.0165

67. Wood SM, Lowenthal E, Lee S, Ratcliffe SJ, Dowshen N. Longitudinal viral suppression among a cohort of adolescents and young adults with behaviorally acquired Human Immunodeficiency Virus. *AIDS Patient Care STDs*. 2017;31:377-383. doi:10.1089/apc.2017.0078