Using Social Media to improve ART Retention and Treatment outcomes among youth living with HIV in Nigeria - The Youth SMART study

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Funded by:	USAID – YouthPower Action
Study Sponsor:	FHI 360
FHI 360 Project Leader:	Lisa Dulli, FHI 360
Study Sites:	Akwa Ibom and Cross Rivers States, Nigeria

Principal Investigator
Dr. Lisa Dulli, FHI 360

Co-Investigators:
Dr. Donna McCarraher, FHI 360
Dr. Mario Chen, FHI 360
Ms. Kate Plourde, FHI 360
Ms. Kathleen Ridgeway, FHI 360
Ms. Catherine Packer, FHI 360
Dr. Tosin Idaboh, FHI 360
Ms. Kate Murray, FHI 360

SIDHAS Technical Advisors
Dr. Hadiza Khamofu, FHI 360
Dr. Oluwasanmi Adedokun, FHI 360

Site Study Coordinator
TBD

Nigeria Investigators
Professor Oladosu Akanbi Ojengbede, Center for Population and Reproductive Health (CPRH)
Dr. Adesola O. Olumide, CPRH
Ms. Tolulope Mumuni, CPRH

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Study Summary

Title: Using **S**ocial **M**edia to improve **A**RT **R**etention and **T**reatment outcomes among youth living with HIV in Nigeria - The Youth SMART study.

IRBNet #: 1151489

Purpose: Study aim is to examine the effect of an online structured support group intervention (SMART Connections) designed to improve retention in HIV care services among youth ages 15-24 years living with HIV enrolled in ART services.

Design: A randomized controlled trial in which youth living with HIV (YLHIV) will be allocated to standard of care (control) or standard of care plus an online support group and followed for 12 months. Structured questionnaires will be administered to participants at baseline, 6 and 12 months. Clinical data will also be extracted on participants. In-depth interviews with a subset of participants and intervention implementers will be completed at the end of the intervention period.

Study Population: YLHIV, ages 15 to 24 years, who are currently taking ART for up to 12 months, including newly initiating patients.

Study Site(s): SIDHAS-supported ART clinics located in Cross River and Akwa Ibom States in Nigeria.

Study Duration: Study duration is approximately 18 months from enrollment to endline data collection.

Objectives:

1. To test the effectiveness of a structured online support group (SMART Connections) to increase retention in HIV services among YLHIV.
2. To examine the effect of SMART Connections on secondary outcomes of social support, HIV knowledge and treatment literacy, and ART adherence among YLHIV.
3. To test the potential mediating effect of social support on the relationship between the intervention and primary outcome.
4. To document the costs of the intervention and calculate the unit cost per YLHIV retained. Intervention costs will also be descriptively compared to the costs of adolescent-focused, in-person support groups in the region.
5. To document participant engagement and perspectives regarding the content and delivery of the intervention to inform scalability and sustainability.
6. To document implementation and health care provider and support group facilitator perspectives regarding intervention content and delivery to inform scalability and sustainability.

Primary Endpoints/Outcomes:
The primary outcome of this study is retention in ART services. Secondary outcomes include social support, ART adherence, and HIV knowledge and treatment literacy.

Acronyms and Abbreviations

AACTG	Adult AIDS Clinical Trials Group
YLHIV	Youth living with HIV
ART	Anti-retroviral Treatment
AUDIT/AUDIT-C	Alcohol Use Disorders Identification Test
CBO	Community-based organization
EC	Ethics Committee
FHI 360	Family Health International
GoN	Government of Nigeria
IRB	Institutional review board
IDI	In-depth interview
IT	Information Technology
LGA	Local Government Area
LMIC	Low and middle income countries
LTF	Loss to follow-up
m/eHealth	Mobile/electronic health
MOS-SSS	Medical Outcomes Study – Social Support Survey
ODK	Open Data Kit
OIRE	FHI 360's Office of International Research and Ethics
PHQ-8	Patient Health Questionnaire Depression Scale - 8
PHSC	FHI 360's Protection of Human Subjects Committee
PI	Principal Investigator
PLHIV	People living with HIV
RMNCH	Reproductive, Mother, Newborn and Child Health
SHERO	Supporting Health and Redemption Organization
SIDHAS	Strengthening Integrated Delivery of HIV/AIDS Services
SMS	Short messaging service
USAID	United States Agency for International Development
YP Action	YouthPower Action project

Background

Globally, young people 15 to 25 years old account for more than 30% of all new HIV infections, the majority of whom live in sub-Saharan Africa.[1] The epidemic among youth living with HIV (YLHIV) differs substantially from that among adults, as mortality among YLHIV is increasing rather than decreasing over time. Between 2005 to 2012, the numbers of HIV-related deaths among YLHIV increased by 50%, while the number of deaths among all ages decreased by 30%.[2-4]

Youth face many challenges with adherence to antiretroviral therapy (ART) and retention in HIV care, including fear of stigma or disclosure to others, lack of social support, and limited knowledge about the disease itself.[5-8] There is a lack of age-disaggregated data on ART coverage for youth, largely due to reporting of program data for ages less than 15 and 15 years and older; however, available data show that even when youth are enrolled in care, they experience higher loss to follow up (LTF) and suboptimal adherence compared to younger children or adults.[7,9]

YouthPower Action (YPA) conducted a review of the peer-reviewed and grey literatures to identify interventions implemented in low and middle -income countries (LMIC) that have been shown to improve retention and adherence among youth (ages 10-19), as well as interventions that were successful among youth and adults (≥ 20 years of age) and had potential to be adapted for youth. Most interventions were conducted among adults and aimed to improve ART adherence, while fewer interventions targeted long-term retention in care. We identified that group counseling interventions show some evidence for effectiveness both on adherence and retention in care among adults, and have been implemented to a lesser degree with youth in LMIC.[10-14]

Our review also showed that mobile phones are an acceptable platform for delivering interventions to adult PLHIV in LMIC settings. mHealth interventions such as mobile reminders and interactive voice or SMS response also have some evidence of effectiveness in improving adherence in people living with HIV (PLHIV) in LMIC settings.[15-20] Although there is no published evidence for these interventions' effectiveness on YLHIV in LMIC, there is preliminary evidence for the feasibility and potential impact on ART adherence on youth in high income countries.[21-24] Furthermore, two recent studies (in South Africa and the US) have integrated social networking into interventions for youth and youth living with HIV in order to improve social support and found them to be acceptable and feasible.[25,26] Increasing availability of internet, feature and smart phones in LMIC makes these interventions possible. Therefore, mHealth interventions present an innovative opportunity to apply successful adherence and retention strategies from adults in LMIC and youth in high-income countries to youth in LMIC.

There is a small body of evidence supporting the effectiveness of support groups to improve health outcomes among PLHIV. In a quasi-experimental study in Kenya conducted among adult PLHIV, researchers found statistically significant decrease in LTF among intervention participants who participated in support groups compared to the comparison group.[11] Munoz and colleagues conducted a quasi-experimental study of a multi-faceted intervention that included support groups and found that, at 2 years, a significantly higher proportion of intervention group participants had >95% ART adherence compared to the comparison group (79.3% versus 44.1%), and a greater odds of viral load suppression (OR=2.46, 95%CI(1.03, 6.09)).[27] In a second study conducted in Kenya, Achieng and colleagues found that adherence was statistically significantly higher among those who participated in > 3 support group meetings (90% vs. 83%, $p < 0.05$), and who had pill counts performed by their clinician (90% vs. 76%, $p = 0.001$).[28] The role of social support has been extensively studied for a number of health outcomes and is correlated with many beneficial health effects. For PLHIV, social support can be limited because of the stigmatized nature of the disease. Support groups hold potential for increasing retention and adherence. One systematic review conducted in 2015 found that support groups were associated with an overall increase in retention in care.[29]

Support groups provide PLHIV an opportunity to extend their social network and to increase the social support available to them from others who are experiencing many of the same health and social issues that

they are experiencing. Peer influences play a substantial role during the youth period. Older youth (age 15-21), in particular, have increased autonomy and independence compared to younger youth, and frequently look towards peers during this time for experiences and relationships that often shape and define their early young adult perspectives and identities. However, despite the potential benefits of support groups, in-person support groups also present specific challenges to long-term sustainability such as costs associated with travel to meeting groups which are often beyond the means of participants and must be supported by the group organizers. Support groups can also encounter difficulties organizing meetings at times and places convenient to all members. Additionally, not all people are interested in or comfortable in in-person group settings.

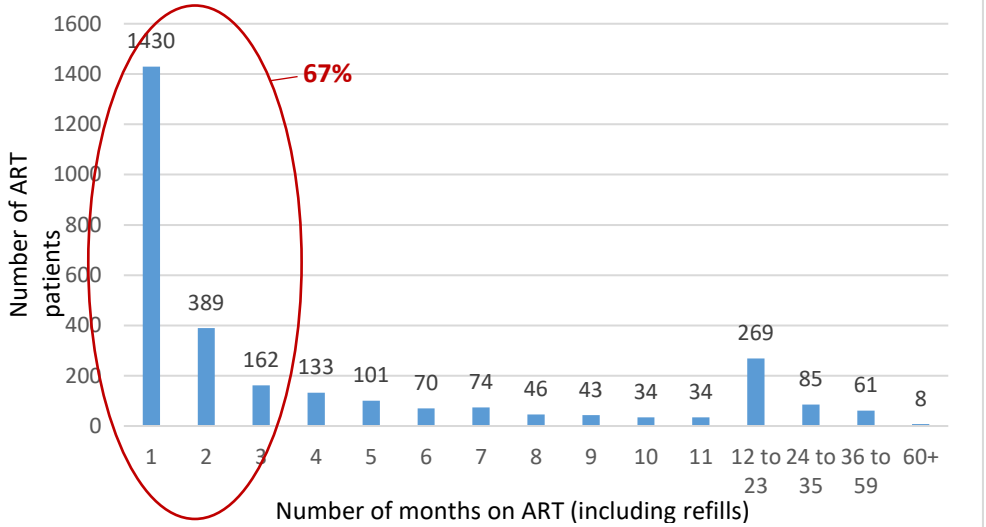
Nigeria

Nigeria is experiencing a generalized HIV epidemic. Although the overall prevalence of HIV in Nigeria is small compared to many countries in Eastern and Southern Africa, because of the size of its population, the country has the second largest burden of the disease in the world with an estimated 3,438,442 people currently living with HIV.[30]

Consistent with other countries in the region, youth (15-21) living with HIV in Nigeria experience high LTF from HIV treatment services, with the greatest losses occurring early in treatment. The USAID-funded Strengthening Integrated Delivery of HIV/AIDS Services (SIDHAS) project supports health facilities in PEPFAR designated priority, local government areas (LGA) throughout Nigeria. An analysis of data from SIDHAS in Rivers, Cross River, Lagos and Akwa Ibom States found that LTF is greatest in the first year after ART initiation and drops off considerably after 1 year (Figure 1)[1]. Among 6648 YLHIV ages 15-21 years who enrolled in ART between 2009 and 2016, 2939 were listed as LTF as of March 2017. Figure 1 below demonstrates the timing to LTF, with nearly half, 1430 or 49%, of those LTF never returning after their initial ART visit. A full two-thirds of those LTF fall out in the first three months after initiation.

[1] Figure 1 represents the number of months of ART received by a patient. At the initial visit, the patient is given 1 month (30 days) of ART, so the first column represents those who were initiated on ART, given 1 month of medication and never returned. Patients are typically given monthly refills for at least the first year, so the number of months of ART corresponds to the number of ART clinic visits.

Figure 1. Number of months on ART among YLHIV ages 15-21 initiating ART who were LTF in Lagos, Rivers, Akwa Ibom and Cross River States, Nigeria, 2009-2016 (n=2939 (44%) LTF of 6648 ever enrolled).



[2]

Table 1. Current status (as of March 2017) of a 12-month cohort of ART patients ages 15-21 who enrolled in ART between April 2015 and March 2016 in Akwa Ibom and Cross River states (n=2,043).

Status	n	%
Active on treatment	602	29.5%
Active, transferred in to ART	9	0.4%
Transferred out of service	63	3.1%
Dead	22	1.1%
Stopped ART	15	0.7%
Lost to follow	1332	65.2%

Anecdotal evidence collected during an information gathering trip in October 2016 for this study revealed that in-school youth, in particular, have a difficult time traveling to health facilities. Many SIDHAS staff and health facility personnel stated that many students in Nigeria attend boarding schools, and they often find it difficult to leave school to attend health care appointments. Students may not disclose their HIV status to teachers or other students, so leaving school for anything to do with their HIV infection can be challenging. Even among those YLHIV who live at home, going to health facilities and to meetings can raise questions for those to whom the YLHIV have not disclosed their HIV status. Therefore, SIDHAS is keen to work with YP ACTION to develop and test alternatives to existing strategies to identify additional tools to support better health outcomes among YLHIV.

Given the increasing access to and use of mobile phone technology in Nigeria, mHealth strategies have potential to meet the informational and social support needs of YLHIV who might not be able to participate or interested in in-person support groups. According to a survey conducted in 2014 by the Pew Research Center, 89 percent of Nigerians ages 18 and older own a cell phone, and phone ownership has been increasing at a dramatic rate over the past decade.[31] A 2012 study conducted in Nigeria found that, at the time, more than half of females ages 12-30 years owned a phone and almost all of the girls and women who

did not own a phone had access to one supporting the feasibility of using mobile phones as a medium for health interventions.[32]

Feasibility Study Results

From June 2017 to January 2018, YP Action conducted a feasibility study of an online support group intervention designed to improve ART adherence and health service retention among YLHIV (FHI 360 PHSC study number 930307). The feasibility study included a pilot test of 5 structured sessions delivered by trained facilitators through Facebook groups to groups of 8 YLHIV. A total of 41 participants completed a baseline questionnaire; 38 of 41 enrolled and participated in the online groups. For those who did not participate, one was excluded because her literacy was determined to be too low to effectively participate after recruitment, one person fell ill and was unable to participate in the initial group meeting so was excluded, and a third person dropped out because she said there was no cellular network coverage near her home. Thirty-five of 38 participants completed the endline interview.

All 35 respondents reported at endline that they: enjoyed being a member of the online group; received useful information from the group; better understood their HIV infection after participating in the group; and felt comfortable interacting with both the other members and the facilitators. All 35 respondents also agreed that they would like to continue to be part of the group, that Facebook groups are a good way for young people with HIV to interact and that such groups are a good way to get information to people living with HIV.

Among the 35 participants who completed the endline interview, 34 reported participating in at least one online session, with the 35th person reporting connectivity issues. About half (n=16) participated in all five sessions and 26 participated in three or more sessions. In terms of posting frequency, which was daily, five people stated they felt the facilitator postings were too frequent, and 27 reported the frequency was about right. Thirty-one out of 35 reported that they made new friends through the group.

We also identified a number of challenges during the feasibility study. In terms of enrollment, we learned that the original data on which we estimated numbers of eligible participants did not have updated ages. This led to a situation where, when our data collectors went to the selected study sites, there were far fewer eligible patients than anticipated, which caused delays in recruitment. As a result, we have changed the way the data from the SIDHAS project are extracted to provide a more accurate reflection of currently eligible patients; we have also expanded the age range to include up to 24 years olds. A second, important finding, was that many YLHIV under 18 who were still in their parent's/guardian's care did not know, according to the parent/guardian, that the disease for which they were being treated was HIV. This caused the parent/guardian to refuse participation on behalf of the YLHIV to prevent disclosure. For this outcome study, this is less likely to be an issue. The feasibility study included ART patients who had been on ART for a minimum of 6 months, and included many who were perinatally infected. This current study will recruit newly initiating ART patients who will be more likely to know their HIV status because most will have just been diagnosed.

Study Aim and Objectives

The principle aim of this research is to gather evidence on an intervention designed to improve retention in HIV care services among youth living with HIV, ages 15-24 years, enrolled in ART services.

Specific objectives include:

1. To test the effectiveness of a structured online support group (SMART Connections) to increase retention in HIV services among YLHIV.
2. To examine the effect of the SMART Connections on secondary outcomes of social support, HIV knowledge and treatment literacy, and ART adherence among YLHIV.

3. To test the potential mediating effect of social support on the relationship between the intervention and primary outcome.
4. To document the costs of the intervention and calculate the unit cost per YLHIV retained. Intervention costs will also be descriptively compared to the costs of adolescent-focused, in-person support groups in the region.
5. To document participant engagement and perspectives regarding the content and delivery of the intervention to inform scalability and sustainability.
6. To document implementation and health care provider and support group facilitator perspectives regarding intervention content and delivery to inform scalability and sustainability.

Methods

Design

This study will be a randomized controlled trial (RCT) of the SMART Connections, a socio-behavioral intervention using an online social media either platform (Facebook) designed to improve retention in HIV care services. Participants will be randomized to the online intervention group or control group.

The hypothesis being tested with this study is:

> YLHIV who participate in SMART Connections will be more likely to be retained in HIV care at 12 months after enrollment than YLHIV in the control group.

Secondarily, we will also test the role of social support as a potential mediator of the intervention effects on retention in care:

> Among YLHIV enrolled in ART services, those in the treatment group who are exposed to SMART Connections will have greater social support and, in turn, will be more likely to be retained in HIV care services at 12 months compared to those in the control group.

Structured questionnaires will be completed through face-to-face interviews with YLHIV participants at baseline, at six months, and at endline, which will occur after 12 months of participation. Clinical data on ART diagnosis, visits and biological tests (CD4 and viral load) will be abstracted from electronic patient medical records. At six months and endline, we will repeat the structured questionnaires from baseline, adding questions on participation and perspectives on the intervention. Additionally, in-depth interviews (IDI) with a subset of participants will be conducted at the completion of the intervention.

We will use a software program, Grytics, which is specifically designed to collect and analyze Facebook group data. We will collect data on the number of active members, the number of posts, the number of comments, and the number of reactions to posts by type (“wow,” “love,” “like,” “angry,” “haha,” and “sad”), per session. We will also document the number and reason for personal messages to the group facilitator, such as question about side effects, question about appointment, etc. Monitoring the push messages from the group facilitator will also permit analysis of the degree of fidelity to the messages and delivery schedule that is implemented.

Intervention Description

The intervention to be tested is based on our current understanding of existing evidence gathered through a systematic literature review identifying intervention strategies that have been shown to increase ART adherence or retention in HIV care among adults or youth in LMIC settings. The systematic review was supplemented with a review of effective interventions among youth in high-income countries that had the potential to be adapted to a LMIC setting. From these reviews, two intervention strategies stood out: structured group counseling and using mobile technologies to improve reach and uptake of health information and services. Experiences from the SIDHAS staff in Nigeria indicate that face-to-face group counseling or support groups have proven a challenge to implement in this setting. Difficulties finding times

when youth are available to meet, coupled with the expenses associated with travel and meeting venues, limit the sustainability of this approach at this time. Therefore, the focus of this experimental intervention will be to deliver components of the structured group counseling through a mobile/electronic technology platform (m/eHealth). A limitation of this intervention is that, although it addresses psycho-social barriers to adherence and retention, it does not directly address other types of barriers such as difficulties accessing HIV care facilities. The current intervention has been revised based on findings from the feasibility study.

The overall aim of the intervention is to promote retention in HIV care services through leveraging social networks and psycho-social support, with an emphasis on informational, emotional and network dimensions of social support. The platform selected for this intervention is Facebook. To inform this decision, workshops were conducted with YLHIV in Akwa Ibom State prior to the feasibility study to gather input into intervention design. Text messaging through SMS platform and Facebook were the top two platforms suggested by participants. Facebook has been used in a similar manner for other health promotion interventions.[25,33-39] More information on Facebook groups and Facebook's data use policy are attached to this protocol in Appendices 2 through 5.

The intervention components include:

- Informational messages that reflect the content of the structured group counseling curriculum, Positive Connections, and are posted to the group wall on a regular basis several times a week, for approximately 4 to 4.5 months
- Moderated, closed group chats in a "secret" Facebook group where YLHIV can interact with their peers and with a trained health counselor
- Access to a trained counselor via Facebook Messenger for the duration of the intervention who will be able to provide information or basic counseling on ART/HIV care related issues, with referral to health care services as needed

FHI 360 will work with the SIDHAS local implementing partners that are responsible for community-based interventions to carry out SMART Connections. These partners include the Women Community Livelihood Foundation (WOCLIF) based in Uyo and the Positive Development Foundation (PDF) in Calabar Municipal and Calabar South LGAs. We will recruit support group facilitators from these organizations to train to deliver the online support group intervention. These facilitators have been extensively trained to facilitate in-person support groups for other HIV-related support groups. They will receive intervention training and an implementation guide that outlines the key informational messages that will be shared, group discussion prompts, and a delivery schedule. The informational messages have been developed from key messages identified in each of the Positive Connections curriculum sessions. Positive Connections is a 14-session curriculum, developed by members of the Interagency Youth Working Group with funding through the USAID Prevention Technologies Agreement.[40] Positive Connections curriculum provides guidance to professionals trained in HIV counseling to create support groups for YLHIV.

Figure 2: Positive Connections topics:

- Understanding HIV
- Disclosure and Developing Trust in Relationships
- Treatment and Adherence
- Nutrition and Health
- Growing and Changing
- Sex and Relationships
- Pregnancy: Planning and Prevention
- Sexual Health and Positive Prevention
- Violence and HIV
- Communication and Problem-Solving Skills
- Exploring Your Feelings
- Knowing Your Rights: Handling Stigma and Discrimination
- Making Decisions and Planning for the Future
- Your Support Network and Next Steps.

Each SMART Connections group will consist of approximately 15 to 20 YLHIV, and approximately 15 groups in total will be formed. Once a sufficient number of YLHIV have been recruited and randomized to form a group, the group will begin with an initial, in-person group meeting with the group facilitator. Online groups will be formed by local government area to ensure participants are able to travel to this initial meeting.

During this meeting, the participants will have an opportunity to meet one another, possibly for the first time, and the facilitators face-to-face. The intent and design of the intervention will be described and ground rules for participation will be set. Ground rules will be discussed and accepted by the group members, but at a minimum, group members will be advised not to talk about what is discussed in the online group with people outside of the group. A brief activity that highlights confidentiality and the consequences of breaking confidentiality will be implemented. During this meeting, the participants will also receive their study phones and the facilitator will record their contact information (telephone numbers, email addresses and Facebook ID). Those who prefer can use their existing sim card (in the study phone), phone or Facebook ID to participate in the project, as long as they are willing to provide the information to the facilitator to enable them to be enrolled in the group. The facilitator will enroll each participant into the virtual group, and then a demonstration of how to open, log-in, post comments and log-out of the group will be made. Each participant should demonstrate the ability to log in and out to the facilitator. The facilitator will also set conditions and expectations for responding to posts and messages by the facilitator, such as limiting his/her responses to group members to business hours and perhaps certain times of the day. Also, the facilitator will instruct the participants if they need to contact the facilitator individually, to send a message to call back when it is safe to do so without risk of breaking confidentiality and the facilitator will call the person.

For those participants who are randomized to the control arm, they will receive their study phone when they return for their next clinic visit.

Standard of care services

All study participants, in both study arms, will receive standard services currently available to YLHIV in these SIDHAS-supported facilities and communities. The services currently include: routine clinical care for HIV treatment including laboratory testing (CD4, viral load tests); active case management by community volunteers with intensive adherence support during the first 4 weeks of ART; adherence support through phone calls and SMS reminders; and enhanced adherence counseling for patients with unsuppressed viral loads.

Additionally, ALHIV 15 to 19 years have the option of attending in-person support groups based on the Positive Connections curriculum in five of the eight study LGAs. ALHIV support groups are capped at 20 participants each. Groups meet once a month and pay transportation reimbursements and provide refreshments to those who attend. These groups are open to all and participants join and leave at any point, without regard to the Positive Connections curriculum. Groups are also provided educational materials for participant use. Youth 20 and 21 years old can attend similar, monthly, in-person support groups for adults living with HIV, following a Positive Health, Dignity, and Prevention curriculum used by the Ministry of Health, but no transportation payments are made.

The current SIDHAS project ends in September 2018, with field activities closing out in June 2018; therefore, it is currently unknown which support services will continue beyond these dates. A follow-on project is planned and details will be recorded once USAID Nigeria releases this information. In any case, we will include questions to assess exposure to other support groups and other community-based support activities.

Study Setting

This study will take place in six local government areas (LGA) in Akwa Ibom and two LGAs in Cross River states. Akwa Ibom and Cross River lie adjacent to one another and share many socio-cultural similarities. The two states also represent the highest HIV prevalence in Nigeria. All of the study facilities lie within approximately two hours travel by car from the FHI 360 Akwa Ibom state office in Uyo, including the two LGAs in Cross River. The SIDHAS program currently supports a total of 85 health facilities in these eight LGAs service approximately 1,500 YLHIV ages 15-24 who are currently on ART.

Study Population

The primary population of interest for this study is YLHIV, ages 15-24 years in Akwa Ibom and Cross River, Nigeria. Eligibility criteria to participate in the study include:

- HIV positive and know their status
- Actively on ART for up to 12 months including newly initiating patients
- Age 15 to 24 years
- Can demonstrate basic literacy necessary to participate in online chats[3]

Exclusion criteria include:

- Unable to attend the initial intervention group meeting for treatment participants
- Currently enrolled in another research study related to HIV service retention or ART adherence
- Critically or severely ill requiring hospitalization or such that the individual is unable to provide informed consent at the time of study recruitment

Sample Size and Sampling Design

Sample size

Our primary outcome is retention in HIV care. We will need to recruit 250 experimental participants and 250 control participants to be able to detect a 0.125 difference in the cumulative probability of retention at 12-months (0.45 in the control group and 0.575 in the intervention group), corresponding to a hazard ratio of 0.69, with 80% power and 5% significance level for a two-sided comparison using the log-rank test. These calculations also assumed exponential times to event and a 10% loss to follow-up.

Sampling procedure and recruitment: Eligible participants will be sequentially recruited from patients who attend clinic visits at the study facility until the total sample size has been achieved. Patients currently attend ART clinic visits monthly. If recruitment extends beyond 8 weeks, alternately, we will ask the health ART clinic point person to identify potentially eligible patients based on eligibility criteria from their facility records and to contact the person by telephone to tell them about the study and, if interested, to invite them to come to the facility if they may be interested in participating in a research study.

The health care providers who provide ART services to patients within the study facilities will be oriented on the study and asked to refer YLHIV ages 15-24 as they present to services to the study staff member who will be stationed in the facility during the recruitment period. ART services are set within the general outpatient clinic where the reason for the patient's visit cannot be known by others waiting with them. Study staff will be stationed in a separate location within the facility so that they do not know with whom the health staff have discussed the study. YLHIV who approach the study staff will be informed about the research study.

Potential participants will be assessed for eligibility and written informed consent will be obtained from each participant prior to enrollment in the study. The study staff will communicate verbally that the study is for youth living with HIV and the groups will be made up of youth living with HIV. The study staff will verbally confirm that the potential participant believes he/she meets the study eligibility criteria. Parental consent will also be obtained for non-emancipated potential participants who are ages 15-17 years.

[3] The design of the intervention will require basic (e.g. at least some primary school) literacy to read and respond to text messages and online chats. We want to ensure those who are enrolled in the study have the potential to benefit from the intervention. Therefore, during recruitment, the data collector will screen potential participants by providing 3 short messages that will be part of the intervention and ask the participant to read them aloud. Only those who can read the messages will be eligible to enroll in the study. Data collectors will record the number of potential participants who are deemed ineligible and the reason for ineligibility, including inability to read the screening messages. During the feasibility phase, only one person was deemed initially eligible, but then determined to be unable to read adequately to participate.

The total number of participants will be recruited sequentially and will likely be proportionate to the total eligible patient volume across participating facilities as illustrated in (Table 2). These numbers are just illustrative and not set recruitment targets.

Table 1. Participating health facilities, estimated number of eligible patients and sampling plan for facilities.

State	LGA	Facility	Est. # of eligible patients per facility	Total per LGA	% of sample	Distribution of sample by study arm	
						Control Arm (n=250)	Treatment arm (n=250)
Akwa Ibom	Ikot Ekpene	Ikot Ekpene Primary Health Centre	70	130	17.69 %	44	44
		Ikot Ekpene General Hospital	60				
	Mbo	Enwang Primary Health Centre	20	87	10.88 %	27	27
	Okobo	Okobo General Hospital	12	52	7.07%	18	18
		Okopedi Primary Health Centre	40				
	Oron	Oron General Hospital (Iquita)	65	146	19.86 %	50	50
		Oron Operational Base PHC	81				
	Uruan	Idu-Uruan Primary Health Centre	34	111	15.10 %	38	38
		Ituk Mbang Methodist General Hospital	77				
	Uyo	Uyo Base Primary Health Centre	88	1177	15.92 %	40	40
		University of Uyo Teaching Hospital	29				
Cross River	Calabar Municipal	Calabar General Hospital	39	39 60	13.47 %	34	34
	Calabar South	Dr Lawrence Henshaw Memorial Hospital	20				
		Ekpo Abasi Primary Health Center	40				
Totals				735	100%	250	250

Randomization procedures

A randomization manager from FHI 360, who is not otherwise involved in the study, will prepare a computerized randomization list using permuted blocks before the start of the study. These envelopes will be given to study staff in charge of the enrollment process. These staff will open the randomization envelopes and inform the participant which group s/he has been assigned to. Participants will be randomized in a 1:1 ratio to proceed with the study procedures. The master randomization list will be maintained at FHI 360 and will not be available to study staff.

Randomization groups will be concealed in sequentially numbered, sealed opaque envelopes (SNOSE). We will instruct study staff never to open an envelope until the participant has given consent to participate in the study, is found to be eligible for the study, and is available to start intervention and control study procedures. The opened randomization envelopes will be retained as source documents and will be kept under secure and restricted access to protect the confidentiality of the participants.

This is an open-label study – neither study staff nor participants will be blinded to study treatment arms after the point of randomization. Nonetheless, strict policies will be in place to preserve randomization integrity. Randomization documentation will be stored in a secure location. Data recording, assessment of

the primary and secondary study outcomes, and other assessments will be blinded to treatment arm where possible.

In-depth Interviews

Participants

IDIs will be conducted at the conclusion of the intervention sessions with a sub-set up to 36 purposely selected YLHIV participants (who are 18 years of age and older) assigned to the intervention group from in the original sample at the conclusion of the SMART Connection sessions. The sample will include up to 12 individuals per group who are classified as:

- Having moderate/high participation in the group
- Having low participation in the group
- Having opted not to join the group to which they were assigned

Participants in the on-line support groups will be categorized as having moderate/high participation or low participation, based on the assessment of the online support group facilitators based on participants' frequency of posts, likes, comments on posts, and private messages to the facilitator. Those who are categorized as moderate/high participation will be asked questions to explore their perspective (likes, dislikes and suggestions for improvement) on the intervention platform, intervention content, and the implementation of the three components (push informational messages, moderated group chats and unstructured access to peers and their counselor through the Facebook site). For those with low participation, we will explore reasons for non-participation and suggestions for changes, if any that could serve to enhance participation. We will also conduct IDIs with participants who were randomized to the intervention arm but did not join an online support group to explore reasons for non-participation and experiences with the study outcomes independently from the intervention. Within each of these three participant groups, we will purposely sample participants who have good retention in care and those who have not been retained in care or who have missed some clinic appointments.

Data collection

Responses to structured questionnaires will be recorded in electronic files on computer tablets. Contact information, including name, phone number, address, date of birth, sex, medical record number, and name and relationship for a second contact person, if available, will be recorded. All identifying information/ contact information will be recorded in a separate, password-protected file and only a unique study identification number will be recorded with all data collection instruments (structured questionnaire, clinical data abstraction form, in-depth interview responses). All interviews will be conducted in a private setting either onsite at the facility or offsite at a nearby location, per the participant's preference. All interviews (structured or IDIs) will be conducted by trained data collectors. Informed consent forms and questionnaires will be translated into Oro, Ibibio and Efik, and available to be administered in English as well, per the participant's preference.

At six months and endline, the participant will be contacted during his/her regularly scheduled clinic appointment to complete the relevant questionnaire. If the participant misses the scheduled appointment by more than one week, the study staff may attempt to contact the participant and/or his/her parent using the contact information provided by the participant/participant's parent up to three times over two weeks to reschedule the final interview and ask if the participant wishes to continue to take part in the research. The person who calls or visits the participant will not identify himself/herself as part of the study to avoid inadvertent breach of confidentiality. For the mid-course and endline interviews, interviews may be conducted by telephone if the participant is unable to return to the facility within 4 weeks of the scheduled interview.

After completion of the intervention sessions, in-depth interviews, using a semi-structured interview guide, will be conducted with up to 36 participants. We will conduct an additional round of IDIs with a sub-set of 8-12 intervention arm participants at 12 months to explore sustainability.

Structured questionnaires

Participants will be asked to respond to structured questionnaires through face-to-face interviews conducted by trained interviewers using computer tablets prior to the launch of the intervention, after completing the intervention sessions and at the end of the study period. Data to be collected include: basic demographic information (e.g. sex, age, education level, relationship status (e.g. married, partnered, single), living arrangements (whether they live with a parent or guardian, how many people are in their household, and relationship to those people), as well as contact information (phone number, place of residence); HIV-related information including how long since diagnosis, current ART regimen, last CD4 and viral load test date and results, disclosure status, self-reported adherence; social support measures covering emotional, instrumental, informational and network social support dimensions; factors associated with poor retention and adherence, including depression/anxiety, alcohol and other substance use, and perceived and experienced stigma; and access to and use of mobile telephones and social media applications. Forms will be administered at baseline and again at six months and endline, which will be 6 and 12 months after the intervention is initiated, respectively. Six-month and endline questionnaires will include additional, closed- and open-ended questions pertaining to intervention participation. Telephone interviews may be conducted in place of face-to-face interviews for participants who, after at least 2 attempts to schedule in-person interviews, are unable or unwilling to return to the clinic for interviews after the intervention and at the end of the study period.

Clinical data

A data abstraction sheet will be developed to abstract relevant clinical data for each study participant. Trained data collectors will abstract data periodically (approximately quarterly) through 15 months after enrollment. As noted, the form will only record the participant's unique study ID for identification purposes. Data to be abstracted will include: date and results of CD4 cell counts and viral load tests; date of HIV diagnosis; date of ART initiation; WHO clinical stage at ART initiation; dates of ART refills; dates of ART clinic visits.

Participation data

Data from the group participation will be collected and analyzed using a social media analytics tool called Grytics (https://grytics.com/). We will collect data on a weekly basis per group on the number of active members, the number of posts, the number of comments, the number of reactions to posts by type ("wow," "love," "like," "angry," "haha," and "sad"). We will also document the number and reason for personal messages to the group facilitator, such as question about side effects, question about appointment, etc. For messages, we will ask the facilitator to keep a log of messages indicating the date, time and main reason for contact.

In-depth interviews

IDIs will be conducted by trained interviewers, experienced in IDI administration, after obtaining informed consent. Once eligible participants are identified, the interviewer will contact the participant to request their participation in the interview and arrange a time to meet the participant at the health facility or another private location acceptable to the participant for the interview. The interviewer will audio-record the interview, in addition to taking notes during the interaction. The digital audio recording will then be translated and transcribed into a Microsoft Word file, which will be password protected and uploaded to the study SharePoint site for data analysis. A separate folder will be created on SharePoint with access limited to study staff within FHI 360.

A second round of IDIs will be conducted with a subset of 8-12 intervention arm participants at 12 months to explore sustainability of intervention participation.

IDIs will also be carried out with all health facility and community-based organization (CBO) staff involved in intervention coordination or implementation at the conclusion of the intervention sessions. The aim of these interviews will be to explore experiences related to intervention implementation, challenges, if any, encountered and suggestions for improving the intervention to achieve greater participation.

Cost data

Data on costs for intervention training, materials, supplies and implementation will be extracted from study financial records by study staff and entered into an Excel spreadsheet. These costs will also include facilitator stipends, CBO supervisors to facilitators and monthly meetings for facilitators. To describe relative costs of in-person support groups, data will be extracted from SIDHAS financial records.

Measures

We will collect basic demographic information on participants (sex, age, marital/relationship status, education, occupation, religion) as well as background information on the participant's HIV infection: when diagnosed, when started ART, disclosure of HIV status to others, viral load and CD4 testing. Additionally, we will collect data on psycho-social factors associated with poor retention and adherence, including depression/anxiety, alcohol and other substance use, and perceived and experienced stigma.

The measures for which data will be collected are outlined below, by study objective. A summary of the measures and source of data, by objective, is found below in Table 1.

Objective 1: To test the effectiveness of a structured online support group (SMART Connections) to retention in HIV services among YLHIV.

Retention: This main outcome is defined as retention in clinical HIV services and on treatment. We will abstract data from the clinic electronic medical record system on date of all visits, which are typically monthly, to ART services between enrollment and the endline of this study.

Retention is defined as having attended a scheduled HIV clinic visit within three months of the visit date. For our primary analysis, using a survival analysis approach, we will record the dates for all scheduled clinic visits for each participant, then follow the data up to three months from the date of the last visit attended. If a participant fails to return after a scheduled visit for more than three months, the date of the missed visit will be the date of loss to follow-up recorded, unless a death or transfer of service is documented.

We will also report on the proportion of participants, by study arm, who are retained at 12 months after enrollment. To be considered retained in HIV services, an individual must, at 12 months after enrollment, have picked up his/her medication for his/her most recently scheduled clinical follow-up visit within 3 months of the date when it was scheduled to take place. We will record, from the medical record, if a participant has knowingly enrolled in services elsewhere (transferred), in which case attempts to contact the participant will be made, if feasible; we will also record if the participant has died or has been recorded as lost to follow-up.

In addition to clinic records, at the end of the study, personal contact information, including phone number and home address, gathered during study enrollment will be used to trace participants who do not return for endline interviews to determine if the person has transferred care elsewhere. If the person has transferred care, we will request the SIDHAS staff, who have access to clinic records in SIDHAS-supported facilities, to verify the patient has attended his/her 12-month appointment within the 3 -month timeframe.

Objectives 2 and 3:

2. To examine the effect of the online support group on social support, HIV knowledge and treatment literacy, and ART adherence among YLHIV.
3. To test the potential mediating effect of social support on the relationship between the intervention and primary outcome.

Social support: To measure social support, we will use the Medical Outcomes Study – Social Support Survey (MOS-SSS).[41] This scale, developed in the early 1990's, has been used extensively in a number of different countries and with a variety of health outcomes, including HIV in China, Ireland, the US and in Ghana.[42-50] The MOS-SSS is a 19-item scale that covers the dimensions of emotional, information, affectionate and tangible social support in addition to positive social interaction.

Adherence to anti-retroviral treatment: Adherence to ART will be measured through self-reported measures in the structured questionnaire of treatment adherence and challenges with taking medication as prescribed. In the study, we will measure self-reported adherence using the AIDS Clinical Trials Group adherence measure (AACTG baseline: http://caps.ucsf.edu/uploads/tools/surveys/pdf/2098.4186.pdf).[51] This validated measure has been widely used to measure adherence for research purposes. We will also extract viral load and CD4 cell count data from patient medical records.

HIV Knowledge and Treatment Literacy: A set of 15 knowledge-based questions covering HIV transmission, diagnosis, treatment, and treatment monitoring have been developed based on topics covered in the Positive Connections curriculum. Each item is scored 1 if answered correctly and 0 if answered incorrectly. A total knowledge score is calculated based on the sum of the items with a possible range of 0 to 10.

Additional psycho-social measures

We will also gather data on key psycho-social factors that have been demonstrated to be associated with adherence and retention in services elsewhere: alcohol and other drug use, depression, and stigma.[52] For alcohol use, we will use the AUDIT-C abbreviated, 3-item scale.[53] The AUDIT-C is an abbreviated version of the 10-item Alcohol Use Disorders Identification Test (AUDIT) tool developed by the World Health Organization to measure harmful and hazardous alcohol drinking behaviors.[54] For the AUDIT-C, each of the three items is scored on a 5-point scale (0-4), and the scores are totals across items for a final score that ranges from 0 to 12. A score of 3 or greater for women or a score of 4 or greater for men is indicative of harmful alcohol use.[53] We will measure other drug use through an item adapted from the AACTG adherence questionnaire.[51]

Depression will be measured using the 8 items from the Stanford Patient Education Research Center's Patient Health Questionnaire Depression Scale (PHQ-8).[55] The PHQ-8 asks respondents on how many days over the prior two weeks they experienced 8 possible symptoms, with response options of "not at all"=0, "a few days"= 1, "more than half the days"=2, and "most all of the days"=3. The score for each item is summed and a total score that ranges from 0 to 24 is assigned. Respondents who score 10-19 points are considered to have major depression and those who score 20 or more have severe depression.[55] Finally, for HIV-related stigma, we will use a 12-item scale that was adapted by Reinius and colleagues from the 40-item HIV Stigma Scale.[56] This shortened stigma scale covers four dimensions of stigma: personalized stigma, disclosure concerns, concerns about public attitudes, and negative self-image. Assessment of psychometric properties of the shortened scale revealed good validity and reliability as compared to the original scale.[56] Each item is scored on a 4-point Likert-type scale and the scores added within dimensions with possible scores ranging from 3 to 12.[56] A greater score indicates a greater level of perceived HIV-related stigma.

Objective 4: To document the costs of the intervention and calculate the unit cost per YLHIV retained. Intervention costs will be computed from the perspective of the program (as opposed to the perspective of the beneficiary.) They will be descriptively compared to the costs of adolescent-focused, in-person support groups in the region.

Cost data will include: costs associated with putting the intervention in place (training, materials, supplies, initial group meeting) and implementation (costs of cell phones, sim cards, airtime/data, facilitator stipend and staff time to purchase and distribute air time to participants).

Objective 5: To document participant engagement and perspectives regarding the content and delivery of the intervention.

Participation/engagement – For this we will record if youth participate in the components of the intervention; which components have the greatest uptake, which the least. As noted above, we will collect data on a weekly basis per group on the number of active members, the number of posts, the number of comments, the number of reactions to posts by type ("wow," "love," "like," "angry," "haha," and "sad"). We will also document the number and reason for personal messages to the group facilitator, such as question about side effects, question about appointment, etc. For messages, we will ask the facilitator to keep a log of message indicating the date, time and main reason for contact.

At the conclusion of the intervention, we will select a subset of participants for IDIs to explore their perspectives with regard to intervention content and delivery.

Objective 6: To document intervention content and fidelity by support group facilitators. At 6 months, once the intervention delivery is complete, we will analyze data from Grytics to evaluate whether facilitators were able to post push messages as outlined in the intervention guide. Timeliness and completion of each scheduled activity will be evaluated. Additionally, notes from facilitator meetings will be used to understand facilitators' experiences delivering the intervention.

Table 2. Summary of key study measures by objective.

Study objective	Concept/variable	Measures	Source of data
Objective 1; To test the effectiveness of a structured online support group to retention in HIV services among YLHIV.	Retention in HIV services	Dates of clinic visits during study Questions regarding clinic visits, missed visits, reasons for missing visits	Medical record data Structured questionnaires.
Objective 2: To examine the effect of the online support group on social support, HIV knowledge and treatment literacy, and ART adherence among YLHIV.	Social support	MOS-SSS items	Structured baseline and endline participant questionnaires
	ART Adherence	AACTG Adherence Assessment items Viral load	Structured baseline and endline participant questionnaires Medical record data
	HIV-related Stigma	12-item stigma scale	Structured baseline and endline participant questionnaires
	Substance use	AACTG Adherence Assessment items	Structured baseline and endline participant questionnaires
Objective 3: To test the potential mediating effect of social support on the relationship between the intervention and primary outcome.	Treatment exposure	Assignment to intervention or control	Based on study assignment
	Social support	MOS-SSS items	Structured baseline and endline participant questionnaires
	Retention in HIV services	Questions adapted from AACTG Adherence Assessment items Dates of clinic visits during study	Structured baseline and endline participant questionnaires Medical record data
Objective 4. To document the costs of the intervention and calculate the unit cost per YLHIV retained.	Cost to put the intervention in place	Training costs (travel, per diem, venue rental, materials)	Study financial records

Intervention costs will also be descriptively compared to the costs of adolescent-focused, in-person support groups in the region.	Implementation costs	Monthly facilitator meetings (transportation and refreshments) Facilitator stipend Equipment (phones) and supplies (airtime/data bundles)	SIDHAS and study financial records
	Estimated in-person support group costs	Facilitator stipend Venue costs Transportation costs for facilitator and participants Refreshments Equipment/supplies for meetings	SIDHAS financial records In-person support group reports (no individual-level data)
Objective 5: To document participant engagement and perspectives regarding the content and delivery of the intervention to inform scalability and sustainability.	Engagement	Number of sessions in which participants actively post comments or reply to comments. Number of comments per session.	Grytics software
	Perspectives on content and delivery	Perspectives on topic relevancy, clarity, usefulness. Perspectives on content structure (components of sessions).	Structured interviews and IDIs
	Perspectives on content and delivery	Perspectives on delivery frequency, facilitator engagement, medium of engagement.	Structured interviews and IDIs
Objective 6: To document implementation and fidelity	Fidelity of implementation	Ability to push out correct messages, hold regularly scheduled group chats as directed in intervention guide.	Grytics software linked to Facebook groups
	Intervention delivery	Perspectives on ease or difficulty delivering content as directed by manual. Perspectives on usefulness of facilitator manual to support implementation. Perspectives on frequency of delivery and time-burden required.	Facilitator meeting notes

Data Management and Analysis

Data management

Structured questionnaires

Structured questionnaires will be programmed into electronic format using Open Data Kit (ODK) software and data will be collected on password protected computer tablets, then uploaded to a secure FHI 360 server daily. Data on the tablets will be erased from the tablet once upload has been confirmed by the study analyst. The data will be stored in a password protected file on the secure server which is accessible only to study investigators. Data will be reviewed periodically during data collection for completeness and errors. Once data collection is complete, the final raw data set will be downloaded to FHI 360 study staff computers, which are also password protected, for final cleaning and analysis. Once the project is closed out, all data will be downloaded and stored in a FHI 360 SharePoint folder, and the server database will be deleted. A complete set of de-identified data will be made available and uploaded to a data-sharing site,

such as the USAID Development Data Library or similar open access database after completion and publication of study findings, no later than the end of the YouthPower Project contract.

Clinical data

A data abstraction form will be developed and programmed into computer tablets using ODK. These data will be entered into the tablets and uploaded to the secure server in the same manner as the structured questionnaires.

Participation data

Grytics permits users to collect use data from the Facebook groups for which they serve as administrators. For the purposes of this study, the group facilitator will be the primary administrator for the Facebook group. A study Facebook account will be registered to which only three study staff - the principal investigator, Lisa Dulli, the intervention design lead, Kate Plourde, and the lead quantitative data analyst, Kathleen Ridgeway - will have access. This study account will be listed as a co-administrator for each of the study Facebook groups. The study staff members will not engage in the groups; they will only run the weekly use analytics and download use data to a secure FHI 360 server. Grytics does not allow the members' usernames of the group to be displayed unless they opt-in. For this study, facilitators were asked to opt-in so we could differentiate between their activity and those of participants. All participant activity on the Facebook group is therefore anonymous. At the conclusion of the study, the Grytics account will be closed. No Facebook group data will remain on Grytics or on the study Facebook account; the only record will be the anonymous data on the FHI 360 server.

In-depth interviews

IDIs will be conducted by trained interviewers, with experience in IDI administration, after obtaining informed consent. The interviewer will audio-record the interview, in addition to taking notes during the interaction. The digital audio recording will then be translated and transcribed into a Microsoft Word file, which will be pass-word protected and uploaded to the study SharePoint site for data analysis. A separate folder will be created on SharePoint with access limited to study staff within FHI 360. Handwritten notes will be destroyed after being transcribed into electronic documents and verified by the contracted research organization. Audio-recordings will be destroyed once data analysis is complete.

Cost data

Information on costs will be collected using customized Excel spreadsheets. These spreadsheets are designed to appear similar to activity-based budgeting formats familiar to most program staff.

Analyses

A detailed analysis plan will be developed and subjected to technical review and approval by the FHI 360 Biostatistics department prior to analyses. As an overview, we describe the main analytical approaches here.

Primary Objective

The primary outcome for this study is retention HIV care. A participant will be considered to have been lost to HIV care if s/he has not picked up medication within 90 days of the last scheduled pick-up date. This 90-day grace period is given at each pick-up time period. Our data collection period will extend to 15 months to maximize completeness of the 12-month retention data and account for any participant who consistently picks-up medication through month 11 and then misses their pick up in months 12 and 13, but is still considered retained in care because they pick up in month 14. Cases that can be confirmed to have died or transferred to a facility outside the study facilities and retention data cannot be obtained reliably will be considered censored. Kaplan-Meier cumulative retention probabilities will be reported with 95% confidence intervals and plotted by study group. The retention probabilities between the groups will be compared with a logrank test stratified by site with a two-sided alpha = 0.05.

Secondarily, we will report on retention descriptively, examining lapses in care and return to treatment over the course of the 12-month follow-up.

Analysis plan for other objectives

To examine the association between treatment exposure and secondary outcomes of social support, adherence and viral suppression, we will conduct significance testing using two-sided tests, with an alpha of 0.05. To examine the relationship between treatment exposure and social support, a continuous variable, we will conduct a t-test. For adherence and viral suppression, both of which will be dichotomized, we will conduct chi-square tests.

For the third objective, to examine the potential mediating effect of social support on the relationship between the intervention and the primary outcome, retention in care, we will use the Barron and Kenney approach [57]. Kenney and colleagues describe a 4-step strategy for testing mediation, which includes:

1. Establish a statistically significant relationship between the independent variable (intervention) and the dependent variable (current modern contraceptive use)
2. Establish a statistically significant relationship between the mediator (HBM variable) and the independent variable (intervention)
3. Establish a statistically significant relationship between the mediator (HBM variable) and the dependent variable (current modern contraceptive use)
4. Demonstrate that the relationship between the independent variable and the dependent variable is significantly reduced when the mediator is added to the model. The significance of the mediated effect can be assessed using a statistical procedure known as the Sobel test [58].

To estimate the total costs for the intervention, we will use FHI 360's intervention costing approach to measure costs of intervention activities. FHI 360's approach classifies activities according to three distinct phases: design/development, preparation for implementation, and implementation. We will concentrate on the second and third phases, because costs of design and development activities are not repeated during scale-up. Costs associated with "preparing for implementation" include training of facilitators and other direct costs of implementation such as printing and field logistics. Costs of implementation are those associated with carrying out the activity.

In-depth interviews

As soon as possible after the IDIs are conducted, transcript text will be read carefully by the study investigators in order to: (1) ask any questions of the text that may be unclear; (2) point out areas in which interviewing and transcription techniques could be improved; and (3) identify recurrent themes and areas for future probing. Data-derived codes developed through inductive coding and retrieving will be used during analysis. A priori codes for retrieving text for key concepts related to the overall objectives also will be applied to the data. Investigators will determine a coding frame to be used based on the topic guides and the first few IDIs available for analysis. New codes will be added as necessary during transcript analysis. A qualitative data software program, such as QSR NVivo or a similar program, will be used to organize all qualitative data and prepare the data for analysis. Once all the transcripts have been coded, textual coding reports will be produced. Data reduction techniques will be used to examine codes in detail for sub-themes and patterns across the IDIs. Summary reports will be developed and recommendations for intervention adaptations will be made.

Study Management and Study Team Roles

Dr. Lisa Dulli, Scientist II, FHI 360 Health Services Research will serve as Principal Investigator (PI) for this research. She will be responsible for overall fiscal and administrative, issues as well as study development and implementation, and for overseeing analyses and reporting of study results. Catherine Packer, Research Associate II, FHI 360 will serve as study manager and support Dulli with logistical, budgeting, administrative issues. She will also provide quantitative and qualitative data analysis support to Kathleen Ridgeway, Research Associate I, FHI 360, who will serve as lead analyst for the study. Dr. Donna McCarraher, Director

Reproductive, Mother, Newborn and Child Health (RMNCH), FHI 360, will provide topical expertise for YLHIV to the study. Dr. Mario Chen will lead data analyses and oversee quantitative data analyses conducted by analysts. In Nigeria, a local study coordinator FHI 360, will be hired to support to both intervention and study implementation by serving as the primary point of contact for FHI 360 Nigeria and liaising with both the implementing organizations and data collection firm. Kate Plourde, Technical Officer, FHI 360 is leading development of the m/eHealth intervention, including adaptation of the Positive Connections support group curriculum for an online medium. Dr. Tosin Idaboh provides overall technical support to the study on behalf of the SIDHAS project. Study recruitment, enrollment and data collection activities have been contracted to the University of Ibadan's Center for Population and Reproductive Health (CPRH).

The CPRH study manager will be responsible for overseeing day-to-day data collection activities and for monitoring data quality and integrity. Both the CPRH study manager and the FHI 360 study coordinator will be responsible for alerting the FHI 360 PI to any protocol violations, adverse events or social harms. The PI and the FHI 360 study manager will ensure proper reporting of any protocol violations, adverse events or social harms to all respective ethics committees per standard policies and procedures.

Ethical Issues

This study aims to test the effectiveness of an mHealth intervention to increase retention in care and improve adherence to ART among youth, ages 15 to 24 years, living with HIV. Prior to study implementation, all study staff, including individuals who participate in data collection activities or intervention implementation, will have completed an approved research ethics training curriculum. The study will be submitted for ethical review and received approval from Research Ethics Committees in Calabar State, Akwa Ibom State, and FHI 360's Protection of Human Subjects Committee (PHSC) prior to collecting data.

Considerations for inclusion of minors

Minors between the ages of 15 to 17 years will be actively recruited into this study based on the need for effective interventions to improve retention in HIV treatment services and ART adherence among this age group.

Informed consent

All participants will be provided information on the intervention, on the scope and nature of the interviews to be conducted, the medical record data that will be recorded and the intervention data that will collected. We will obtain written informed consent to participate before any data collection is conducted, including data collection through Facebook groups, if they agree to participate. If the youth is less than 18 years of age and not emancipated, we will seek parental consent to participate and youth assent. If parental consent is required, the study staff will request that the potential participant's parent/guardian be contacted to provide informed consent. If the potential participant refuses, he/she will not be eligible to participate. If the potential participant accepts, the study staff will ask that the parent/guardian come to the health facility for the consent process. If the potential participant and parent/guardian prefer, the study staff can arrange to meet the parent at the patient's home. In cases where youth are younger than 18 years of age, if the youth is an emancipated minor through marriage or living independently from his/her parents/guardians, we will seek informed consent directly from the participant. It is important to note that the informed consent forms (including parental consent and youth assent) will not contain a reference to HIV for privacy purposes since a copy will be given to the participant/parent; however, both the provider who refers the youth to the study staff and the study staff who gains informed consent and interviews the participant will verbally tell the individual that the study is for youth living with HIV and the support group that is part of the intervention is to support YLHIV.

Participants who are invited for in-depth interviews will be at least 18 years old. The study staff will conduct an abbreviated oral consent form to obtain the participants' oral informed consent to participate in this

interview as well as to be audio-recorded. Participants who do not consent to audio-recording will not be interviewed.

Risks to Participation

We do not anticipate any serious physical, mental, or social risks due to participation in this research. The greatest risk of participation in the study is inadvertent breach of confidentiality. Measures will be taken to protect the confidentiality of the participants. For data collection – all interviews will be conducted in a private setting, data will be recorded on password protected devices, uploaded to a secure server and all data will be de-identified, with a separate file containing identifying information kept on a separate, password protected computer.

With regard to participation in the intervention under study, participants will be offered telephones to participate, but the participant can refuse the phone if he or she thinks it would cause concern among others. If a phone is lost, stolen or broken, it will not be replaced. Also, the phones will be one of the more typical entry-level smartphones sold to Nigerian consumers that meets our intervention needs so that those who have the phone won't be identified with the intervention or research.

The virtual support groups, as with face-to-face groups commonly implemented, carry some risk that fellow group members or facilitators could disclose personal information to people outside of the group. Facilitators will be trained on issues of confidentiality, which is part of the curriculum being implemented. Group members will be brought together to set ground rules for participation which will include at a minimum the need to keep group discussions confidential. In terms of the platform to be used for communication among group members, we will use Facebook which provides secret groups that are not searchable or joinable by outsiders. Group membership will be strictly controlled by the main group administrator who is the facilitator. Group members will be instructed in logging into the application, logging out after use to prevent others with access to their phone from seeing the group and in locking their phones using its security features to avoid others gaining access to the phone without their permission. They will be instructed not to save passwords on their phone with a password manager, or to share their Facebook password with others. In the event that the facilitator or other group member(s) learn that a group member has intentionally permitted access to the Facebook group posts to a person outside the group, the facilitator will immediately remove the individual from the group until he/she can determine if the breach of confidentiality has actually taken place. If it is determined that the breach did in fact occur, then the person will not be invited back to be a member of the Facebook group and will be permanently blocked to protect the privacy of the other members. The facilitator and local study coordinator, would bring together all other members of the group, or those who may have been affected by the breach, in an in-person group to discuss the breach and how to handle the situation. Alternately, if the breach only affects one or a few members, the study staff and facilitator may contact the participants individually. If a participant prefers, the facilitator may meet with them individually instead of with the full group. Any such incident would be reported as soon as possible to both the local and FHI 360 ethics committees, per FHI 360 PHSC policy.

With regard to interview procedures, it is possible that some participants may be uncomfortable when asked about sensitive topics during the structured or in-depth interviews. To minimize the potential for any adverse events, study staff will conduct interviews in a private location. As part of the consent process, participants will be informed that they can refuse to answer any question and they can terminate an interview or their participation in the study at any time without penalty.

Additionally, in the case that a participant discloses a need for psychosocial support during an interview, referrals for additional psychosocial supportive services or other health services will be made as needed. A list of resources will be developed for the study sites. If these services are not available or accessible to the study participants, an alternative strategy will be developed to provide supportive services. In case of an emergency, such as disclosure of suicidal ideation or severe depression, the potential participant will be referred immediately to the health care provider on site. Additionally, monthly debriefings with facilitators

will be held throughout the study to enable staff to share experiences and support each other. They will also give feedback on how participants are receiving the intervention, any related questions, and share techniques for increasing rapport and gathering accurate information.

Anticipated benefits to participation

Participants in the study may directly benefit from participating in the mHealth intervention. The intervention is designed to lead to improvements in HIV treatment retention and adherence that could lead to improved health. Additionally, the intervention is designed to increase access to social support from other YLHIV, a problem for many YLHIV who fear disclosing their HIV status to others. Participants enrolled in the online support groups will be free to continue with those groups, if they choose, at the conclusion of the study. At the conclusion of the feasibility study, all Facebook groups continued by participants' choice.

Compensation

Although cell phone ownership is high in Nigeria (89% in 2015)[31], it is possible that youth who participate in this study may not have access to their own phones and may share them with others, such as a sibling or a parent. Because this study is an efficacy study to see if YLHIV who have access to the intervention experience better outcomes than those who do not access the intervention, the study will provide each YLHIV participant with a cellular phone for participation that he/she may keep at the end of the study. The phones that will be provided will be consistent with typical phones found in the community and will have no distinguishing characteristic that would identify the phone as part of a study or intervention. The value of the phones to be provided is estimated to be between 20,000 to 25,000 Nigerian Naira (approximately (US$55-$70). In addition to the telephone, participants will receive 1000 Naira (US$3) of data per month and a travel reimbursement of 1,500 Naira (US$4.5) for each trip to participate in each interview (baseline, mid-course and endline) and for the initial study group meeting. The travel reimbursement of 1,500 Naira is a standard rate set by the SIDHAS project. No additional compensation will be provided to parents for their permission for their child to participate.

Participant privacy and confidentiality

The collection of identifying information is required for this study. Personal identifiers (name, date of birth, telephone number, medical record number, address, phone number and phone number for a next of kin/additional contact) will be recorded in a separate, password-protected file with access only by study investigators and study staff. These will be associated with unique study identifiers, which will be the only identification recorded on data collection instruments. Once data collection, cleaning and data analysis are complete, the file containing the identifying information will be destroyed, leaving only a final, de-identified dataset. Handwritten notes taken during the in-depth interviews will be destroyed after being transcribed into electronic documents and verified by the contracted research organization. Audio-recordings will be destroyed once data analysis is complete, leaving a final de-identified interview transcript.

Anticipated Outputs and Results Dissemination

Findings from this research will be disseminated in a number of ways. Results will be shared with the SIDHAS project and USAID in Nigeria to allow for integration of findings into USAID-supported HIV care and treatment activities. Findings will also be shared with state and national stakeholders to inform future policy and practices related to HIV care and treatment services for YLHIV in Nigeria. A dissemination meeting is planned for all interested state, national and international stakeholders in Nigeria.

We will also disseminate results internationally by submitting abstracts on the work to international conferences and publishing one or more manuscripts in peer-reviewed journals.

Timeline:

	2018											2019												2020			
Activity	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**	**Apr**
USAID approval						X																					
FHI 360 Ethics Committee review	X																										
Akwa Ibom, Cross River and National EC reviews				X																							
Data collector training							X																				
Study enrollment and baseline data collection								X	X	X																	
Intervention implementation									X	X	X	X	X	X	X												
Mid-course data collection																X	X	X	X								
Endline data collection																							X[1]	X[1]	X[1]		
Data analysis																											
Results dissemination in-country																										X	
Manuscript for publication												X														X	

1. Three months will be allocated to gather data on retention from clinical records, because LTF is defined as having missed an appointment by 3 months.

Appendix 1: SIDHAS-support ART standard services for YLHIV

ART services targeting HIV-positive youth in Nigeria. (SIDHAS 2018)

*Steps in Service Delivery for the Pediatric and Youth Viral Load Suppression Tracking		
<1 – 9 years	**10 – 15 years**	**15 – 19 years[1]**
Each backstop/organizational focal person collates pediatric and youth clients' information in supported facilities		
Assign each youth and pediatric client to specific case managers for differentiated care.		
At arrival to the health facility, HCWs triage the pediatric and youth clients into three groups outlined above.		
Identify a primary committed parent/care giver and update their contact details.		
Provide Intensified Adherence Support during the first 4 weeks of treatment initiation.		
Where possible, see the **'family as one visitor'** and not make the family attend separate clinics even when appointments are given for the same day.	Younger youth' specific adherence challenges (e.g. taking medication at school; addressing why they alone are taking medication with siblings; rejecting medication due to bad taste; forgetting to take medication, etc.) and work with the caregivers to suggest how to address these issues.	Older youth' specific adherence challenges (e.g. taking medication at school/ away from home); Address transition to adulthood concerns.
Link the children and their caregivers to family adherence support groups		
Link families to community support services including enrolling in the SIDHAS OVC Care and Support program in scale-up and sustained-plus LGAs	Link families to community support services including enrolling in the SIDHAS OVC Care and Support program in scale-up and sustained-plus LGAs	**Link youth to facilitated youth-specific support groups using modules/sessions from the "Positive Connections Manual."**
Provide ongoing adherence support using: Adherence Support Calendar, phone calls, SMS reminders and home visits.		
Review viral load (VL) status for all pediatric and youth clients at EVERY facility visit.		
Enhanced adherence counselling for caregivers and youth with unsuppressed viral load		
Drug and Therapeutic Committee pays attention to treatment for pediatric and youth clients		
Conduct monthly data review of retention and VL status of the pediatric and youth clients		

1. All text highlighted in yellow are activities targeted to YLHIV enrolled in this study.

Appendix 2: Facebook data policy

Appendix 3: Safety at Facebook

Appendix 4: What are the privacy settings for groups?

Appendix 5: How do I remove or block someone from a group?

*Appendices in separate files.

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