YouthPower Action- Feasibility study of an online support group intervention among adolescents living with HIV in Nigeria

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Study Summary

Title: YouthPower Action - Feasibility study of an online support group intervention among adolescents living with HIV in Nigeria

IRBNet #: 930307

Purpose: Study aim is to examine the feasibility and acceptability of an intervention designed to improve retention in HIV care services and improve anti-retroviral therapy (ART) adherence among adolescents ages 15-19 years living with HIV enrolled in ART services.

Design: A single group, pre/posttest design including structured questionnaires with adolescents living with HIV. Additionally, we will abstract clinical data from the medical record system. We will also conduct in-depth interviews with a subset of participants, as well as health care staff who are engaged in the intervention, at endline.

Study Population: Adolescents living with HIV (ALHIV), ages 15-19 years, who initiated ART at least 6 months prior to enrollment.

Study Site(s): Ikot Ekpene General Hospital, Uyo University Teaching Hospital, and Uyo Primary Health Center in Akwa Ibom State, Nigeria

Study Duration: Study duration is approximately 9 months from IRB approval to data analysis.

Objectives:

1. To examine the feasibility of implementing a mobile/electronic health (m/eHealth) intervention designed to improve retention in HIV care services and ART adherence among ALHIV ages 15-19 years through an online support group (using Facebook).
2. To assess acceptability of and engagement in the intervention by the target audience to inform improvements to the intervention.
3. To gather preliminary data on the psycho-social and health-related outcomes that the intervention is designed to affect to inform an outcome evaluation study that will be conducted following the conclusion of the feasibility study.
4. To collect information on recruitment, informed consent and data collection processes to inform the outcome evaluation study of the current intervention that will be conducted once findings from this feasibility study are incorporated into the intervention design.

Primary Endpoints/Outcomes:
The primary outcome of this study is to assess feasibility, as measured through participant acceptability and engagement in the intervention, and provider ability to implement. This information will be used to adjust the intervention prior to a subsequent outcome evaluation.

Acronyms and Abbreviations

AACTG	Adult AIDS Clinical Trials Group
ALHIV	Adolescents 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 24 years old account for 42% of all new non-pediatric HIV infections, the majority of whom live in sub-Saharan Africa.[1] The epidemic among adolescents living with HIV (ALHIV) differs substantially from that among adults, as mortality among ALHIV is increasing rather than decreasing over time. Between 2005 to 2012, the numbers of HIV-related deaths among ALHIV increased by 50%, while the number of deaths among all ages decreased by 30%.[2-4]

Adolescents 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 adolescents, largely due to reporting of program data for ages less than 15 and 15 years and older; however, available data show that even when adolescents 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 adolescents (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 adolescents. 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 adolescents 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 ALHIV in LMIC, there is preliminary evidence for the feasibility and potential impact on ART adherence on adolescents in high income countries.[21-24] Furthermore, two recent studies (in South Africa and the US) have integrated social networking into interventions for adolescents 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 adolescents in HIC to adolescents 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. (ADD GENERAL REF ABOUT SUPPORT GROUPS.) They

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

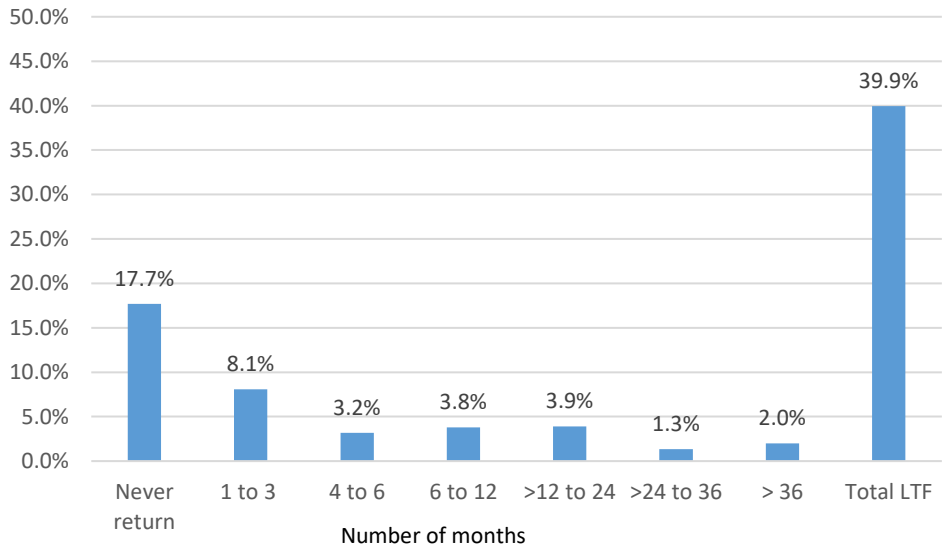
experiencing. Peer influences play a substantial role during the adolescent period. Older adolescents (age 15-19), in particular have increased autonomy and independence compared to younger adolescents, and frequently look towards peers during this time for experiences and relationships that often shape 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 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.[29]

Consistent with other countries in the region, adolescents (15-19) 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). The largest loss occurs at initiation with 17.7% of all patients never returning after initiating ART. Monthly LTF remains substantial through the first 3 to 6 months then reduces to 3.8% from 6 to 12 months and continues to drop from there.

Figure 1. Number of months between ART initation and last clinic visit for those lost to follow-up among all youth (15-19 years) ever initiated on ART (n=5,197), SIDHAS data, Scale-up LGAs in 4 States.



Similar to young people in other LMIC in the region, ALHIV in Nigeria have not been specifically targeted with interventions to improve health outcomes, beyond the broader orphans and vulnerable children activities which are not specific to ALHIV. The Government of Nigeria (GoN) has prioritized this sub-population and is now focusing activities to better meet its needs. The USAID-funded SIDHAS project is supporting the GoN priorities by implementing or planning to implement activities to support better retention in health services and adherence to ART among ALHIV. In the SIDHAS FY2017 work plan, ALHIV will be targeted with adolescent-

specific support groups, in addition to broader activities designed to reach all ART clients, including intensive case management for new ART patients, reduced frequency of ART follow-up visits for stable patients (from monthly to quarterly), and permitting the distribution of ART in community pharmacies as opposed to only in ART clinics. As part of its plans for the adolescent support groups, SIDHAS has voiced interest in working with YP ACTION to structure the support groups using the USAID-funded Positive Connections curriculum for adolescent support groups.[30]

Anecdotal evidence collected during an information gathering trip for this study revealed that in-school adolescents 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, support groups, or other reasons related to their HIV infection. 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 ALHIV who live at home, going to health facilities and to meetings can raise questions for those to whom the ALHIV 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 ALHIV.

Given the increasing access to and use of mobile phone technology in Nigeria, m/eHealth strategies have potential to meet the informational and social support needs of ALHIV 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]

Study Aim and Objectives

The principle aim of this research is to examine the feasibility and acceptability of an intervention designed to improve retention in HIV care services and improve anti-retroviral therapy (ART) adherence among adolescents ages 15-19 years living with HIV enrolled in ART services.

Specific feasibility study objectives include:

1. To examine the feasibility of implementing an online, mobile/electronic health (m/eHealth) intervention designed to improve retention in HIV care services and ART adherence among ALHIV ages 15-19 years using an online support group (using Facebook).
2. To assess acceptability of, demand for and engagement in the intervention by the target audience to inform improvements to the intervention.
3. To gather preliminary data on the social and health-related outcomes that the intervention is designed to affect to inform a follow-on outcome evaluation study.
4. To collect information on recruitment, informed consent and data collection processes to inform the design of the intervention for the follow-on outcome evaluation study.

Methods

Design

This feasibility study will be a single-arm, pre-test/posttest study in which ALHIV ages 15 to 19 will be enrolled to receive six of the fourteen sessions from the Positive Connections curriculum through the m/eHealth intervention that will use Facebook to conduct online structured support groups. Up to 50 participants will be enrolled to form five groups of 8 to 10 participants. Baseline data will be collected from all participants, then

participants will participate in the 6 sessions of the 14-session structured educational and group counseling curriculum through the online platform. Upon completion of the six sessions, endline data will be collected, approximately three to four months after baseline. Data will also be collected on an ongoing basis throughout the delivery of the intervention session to examine implementation processes.

Structured questionnaires will be completed through face-to-face interviews with ALHIV participants at both baseline and endline. Clinical data on ART diagnosis, visits and biological tests (CD4 and viral load) will be abstracted from electronic patient medical records. At endline, we will repeat the structured questionnaires from baseline, adding questions on participation and perspectives on the intervention. Additionally, in-depth interviews with a subset of participants will be conducted, stratified by participation in group counseling (high participation and low/no participation). We will also conduct IDIs with health facility and CBO staff who take part in the intervention.

We will use a software specifically designed to collect and analyze Facebook group use data. 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. 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 adolescents in LMIC settings. The systematic review was supplemented with a review of effective interventions among adolescents 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 adolescents 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 to HIV care facilities.

The overall aim of the intervention is to promote adherence and retention 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 ALHIV in Akwa Ibom State 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] The advantages to using a Facebook platform are as follows:

- Facebook was well-known among adolescents who participated in the workshops. Nigeria has the largest number of Facebook users on the African continent and among the highest cell phone penetration rate (89% in 2015) in Africa[31]
- Facebook groups can be constructed with a limited number of people, and the membership can be controlled through an administrator[40]

- Facebook groups' privacy can be set to "secret" mode, which makes it impossible for non-members to find the groups through searching either within Facebook or through other search engines such as Google[40]
- The Facebook platform requires users to log-in from their device, so participants can also log-out, preventing other users of their phone to view anything on the Facebook application
- Using an online social media platform permits the users to create user names that can disguise their real identities, if they choose, which can even further reduce their exposure to unintentional disclosure
- The use of social media platforms to deliver health information is more cost effective than SMS programs and are as a result more likely to be sustainable beyond the project period

More information on Facebook groups and Facebook's data use policy are attached to this protocol in appendices.

The m/eHealth 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 for approximately 6 months [data collection for the feasibility study will last 3 months, though the intervention will continue for the full 6 months for participants]
- Moderated, closed group chats in a "secret" Facebook group where ALHIV can interact with their peers and with a trained health counselor on a biweekly basis
- Access to a trained counselor via Facebook Messenger (during normal business hours) 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 partner, SHERO (Supporting Health and Redemption Organization), responsible for community-based interventions to carry out the m/eHealth interventions. FHI 360 YP ACTION study staff will work with SHERO and the Akwa Ibom State FHI 360 SIDHAS staff to train and support the m/eHealth support group facilitator. Facilitators, who are community volunteers with SHERO, have been extensively trained to facilitate support groups for other HIV-related support groups, 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 will be 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.[30] The Positive Connections curriculum provides guidance to professionals trained in HIV counseling to create support groups for ALHIV between 15 and 19 years of age. It also provides 14 sessions to be covered during support group meetings, covering the following topics:1) Understanding HIV; 2) Disclosure and Developing Trust in Relationships; 3) Treatment and Adherence; 4) Nutrition and Health; 5) Growing and Changing; 6) Sex and Relationships; 7) Pregnancy: Planning and Prevention; 8) Sexual Health and Positive Prevention; 9) Violence and HIV; 10) Communication and Problem-Solving Skills; 11) Exploring Your Feelings; 12) Knowing Your Rights: Handling Stigma and Discrimination; 13) Making Decisions and Planning for the Future; and 14) Your Support Network and Next Steps.

Each virtual support groups will consist of 8 to 10 ALHIV between the ages of 15 to 19 years. Once a sufficient number of ALHIV have been recruited to form a group, the group will begin with an initial, in-person group meeting with the group facilitator and co-facilitator. 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 generic SMS to call back when it is safe to do so without risk of breaking confidentiality and the facilitator will call the person.

Study Setting

This feasibility study will take place in Ikot Ekpene and Uyo, a local government areas (LGA) with a population of approximately 428,000 (as of 2006) that lies in the State of Akwa Ibom.[41] Ikot Ekpene is a commerce center in the region for palm oil and other agricultural products. The USAID-funded SIDHAS project currently supports four ART treatment centers in the LGA, one of which, the Ikot Ekpene General Hospital, will serve as a study site for the feasibility study. In Ikot Ekpene General Hospital there are currently 3 physicians, 18 nurses, 3 laboratory staff and 2 pharmacists who support HIV services. As of March 2016, the four SIDHAS-supported health facilities in the LGA were serving a total of 4,773 PLHIV actively on treatment, including 69 ALHIV ages 15-19. From March 2015 to April 2016, 52 new ALHIV enrolled in ART services in these two facilities.

Uyo is the State Capital and the University of Uyo Teaching Hospital is the leading academic health facility in the state.

Study Population

The primary population of interest for this feasibility study is ALHIV, ages 15-19 years in Akwa Ibom State in Nigeria. Eligibility criteria to participate in the study include:

- HIV positive and currently on ART for at least 6 months
- Age 15 to 19 years
- Can demonstrate basic literacy necessary to participate in online chats[1]

Exclusion criteria include:

- Not planning to remain in the study area (within Akwa Ibom State) for the duration of the study (approximately 6 months)
- Currently enrolled in an in-person support group
- 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

The primary target population for this intervention is ALHIV who initiate ART in the first 12 months following initiation. An outcome evaluation study is planned for this intervention after the feasibility study. Because the number of ALHIV newly enrolling in ART in the study sites is relatively small, to avoid depleting our potential

[1] 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. This information will also inform feasibility.

participant pool for the outcome study, we will restrict eligibility for this feasibility phase to ALHIV who have been enrolled in ART for 6 months or longer. This eligibility restriction may result in a biased sample for the feasibility study because these adolescents have already been retained in care for 6 months and may be different than those who are enrolled 0-6 months after enrollment in ART. However, this will permit overlap with the target population for the feasibility and outcome studies, but also preserve adequate numbers of ALHIV to be enrolled in the outcome study, which should begin approximately 6 months after the feasibility study is initiated.

Sample Size and Sampling Design

The intent of this feasibility study is to ascertain if each of the intervention components can be implemented in a way that could lead to the intended outcome. Given that the target group size for group counseling is between 8-10 individuals, we will enroll enough participants to form 5 m/eHealth support groups (40-50 individuals). This sample size was determined based on logistical considerations and to provide sufficient data for addressing the objectives in a descriptive manner. 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 4 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 come to the facility if they may be interested in participating in a research study.

At endline, in-depth interviews, using a semi-structured interview guide, will be conducted with 6 to 8 participants who have moderate to high participation in the intervention (the cut-off to be determined once participation data are available) and 6 to 8 interviews with participants who have low to no participation in the intervention.

Revised endline structured questionnaires with added questions on intervention acceptability, participation and challenges, and the in-depth interview guides will be submitted separately for ethics review near the end of the study. We will do this to ensure we include questions on any important issues that arise during implementation.

Data collection

The health care providers who provide ART services to patients within the two study facilities will be oriented on the study and asked to refer ALHIV ages 15-19 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. ALHIV 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 adolescents living with HIV and the groups will be made up of adolescents 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. 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 numbers 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.

At endline, the participant will be contacted during his/her regularly scheduled clinic appointment to complete the endline 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.

Structured questionnaires

Participants will be asked to respond to structured questionnaires through face-to-face interviews conducted by trained interviewers prior to the launch of the intervention and at the end of the project 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 endline, which will be 3 months after the intervention is initiated. Endline questionnaires will include additional, closed- and open-ended questions pertaining to intervention participation, perspectives on utility and acceptability of the intervention, any barriers to participation encountered and suggestions for improvement in the intervention.

Clinical data

A data abstraction sheet will be developed to abstract relevant clinical data for each study participant. 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 most recent CD4 cell count and viral load test; date of HIV diagnosis; date of ART initiation; WHO clinical stage at ART initiation; date of last ART prescription; date of last ART clinic visit.

Participation data

Data from the group participation will be abstracted 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 message indicating the date, time and main reason for contact.

In-depth interviews

IDIs will be conducted with a sub-set of ALHIV participants from the original sample. Participants in group on-line group counseling will be categorized as having moderate/high participation or low/no participation, the cut-off for which will be determined after participation data have been collected and examined. 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, the content of the intervention, 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/no participation, we will explore reasons for non-participation and suggestions for changes, if any that could serve to enhance participation.

IDIs will also be carried out with all health facility and community-based organization (CBO) staff involved in intervention coordination or implementation. 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.

Note: IDI guides will be developed after the baseline data collection is conducted; these and their corresponding informed consent forms will be submitted for approval in a protocol amendment prior to the start of endline data collection.

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 examine the feasibility of implementing a mobile/electronic health (m/eHealth) intervention designed to improve retention in HIV care services and ART adherence among ALHIV ages 15-19 years,

Questions to be answered for this objective include: 1) Can the intervention be implemented as designed (factoring in constraints with human resources, IT, and/or infrastructure, policy and cultural context); 2) Which components pose the greatest challenges in terms of implementation and why; 3) What can be done to overcome those challenges; and 4) Do facilitators send out the correct informational messages at the correct frequency and engage with participants both during the structured moderated chat and at other times?

To meet this objective, we will document facilitator knowledge regarding the Positive Connections support group curriculum topics using a pretest and posttest during the weeklong training on the curriculum. We will document fidelity to implementation by monitoring the frequency and content of push messages sent to group members, as well as if the regularly scheduled structured group chat occurs following each session's messages. We will provide a log to facilitators to document additional correspondence between the facilitator and group members that will record date, time, reason for contact, action taken by the facilitator and medium of communication (Facebook post, SMS message, phone call or in-person meeting). We will also document any challenges encountered by the group members or facilitators in terms of enrolling members into the Facebook group, logging into or out of the group, telephone related challenges such as gaps in airtime credit or electricity charging problems. This information will be recorded in notes during monthly meetings with the facilitators. We will also explore such problems during the endline interviews.

During the baseline interviews with participants, we will include questions on cell phone ownership, use as well as barriers to use such as access to electricity, running out of credit, and experience using the internet and social media, including Facebook.

Objective 2: To assess acceptability of, demand for and engagement in the intervention by the target audience to inform improvements to the intervention.

The following will be measured to get at the concepts of accessibility, demand and participation.

Acceptability – To understand acceptability, at endline we will include a series of close-ended and open-ended questions on the structured questionnaire to explore the following: how do adolescents like or dislike the different components of the intervention? Are they acceptable – if so, what do they like best/least; if not, why not and how might they be changed to be better received? We will also explore whether adolescents are comfortable in mixed sex groups or if they prefer single sex groups. We will further explore these issues and

other, yet to be determined issues that may arise during implementation using a semi-structured in-depth interview approach.

Participation/engagement – For this we will explore if adolescents participate in the components of the intervention; which components have the greatest uptake, which the least. We will record how frequently a participant posted comments or questions. 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 endline, we will explore both through questions added to the structured questionnaire for ALHIV and through IDIs conducted with a subset of participants, why people participated or did not and how the intervention components might be changed to increase uptake.

Objective 3: To gather preliminary data on the social and health-related outcomes that the intervention is designed to affect to inform an outcome evaluation study that will be conducted following the conclusion of the feasibility study.

For the third objective, we will record measures of our intended health-related and psycho-social outcomes as specified below. Although the time period is too short and the sample size too small to attempt to assess the effect of the intervention on the measures of retention, adherence and social support, this feasibility study provides an opportunity to gather baseline information on all three measures to inform the outcome study, as well as to ensure our measures work with this group.

Retention: This main outcome is defined as retention in clinical HIV services and on treatment. In the feasibility study, retention will be assessed at 3 months after enrollment. We will abstract data from the clinic electronic medical record system on date of visits between enrollment and the endline of this study. To be considered retained in HIV services, an individual must, at 3 months after enrollment, have attended his/her most recently scheduled clinical follow-up visit within 1 month 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 recorded as lost to follow-up. 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.

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 feasibility 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).[42] This validated measure has been widely used to measure adherence for research purposes. We will also collect viral load and CD4 cell count data from patient medical records.

Social support: To measure social support, we will use the Medical Outcomes Study – Social Support Survey (MOS-SSS).[43] 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.[44-52] 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.

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.[53] For alcohol use, we will use the AUDIT-C abbreviated, 3-item scale.[54] 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.[55] 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.[54] We will measure other drug use through an item adapted from the AACTG adherence questionnaire.[42]

Depression will be measured using the 8 items from the Stanford Patient Education Research Center's Patient Health Questionnaire Depression Scale (PHQ-8).[56] 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.[56] Finally, for HIV-related stigma, we will use an adapted measure from the ongoing NIH-funded Pilot of family-based self-management for HIV-infected adolescents in two clinics in Ndola, Zambia.

Objective 4: To collect information on recruitment, informed consent and data collection processes to inform the outcome evaluation study of the current intervention that will be conducted once findings from this feasibility study are incorporated into the intervention design.

Reports from the local research partner, the Center for Population and Reproductive Health (CPRH), Ibadan, Nigeria, on recruitment, enrollment and the informed consent process will be used to understand challenges to study implementation and devise strategies to improve these processes for the outcome study to follow. After the baseline wave of data have been collected, we will hold a meeting with data collectors, study staff in Nigeria and health facility staff to document successes, keys for success as well as any challenges that they encountered and suggestions for improvement. The same meeting will be conducted after the endline wave of data collection. Meeting notes will be taken by a designated recorder and reviewed by study investigators.

Table 1. Summary of study measures by objective.

Study objective	Concept/variable	Measures	Source of data
Objective 1: To examine the feasibility of implementing a mobile/electronic health (m/eHealth) intervention designed to improve retention in HIV care services and ART adherence among ALHIV ages 15-19 years.	Feasibility of implementation	Provider topical knowledge on topics covered through Positive Connections	Training pre/posttest.
		Logistic challenges (internet connection, electricity, airtime)	Monthly facilitator/study staff meeting notes
			Baseline/endline structured participant questionnaires
		Perspectives on feasibility, challenges and strategies to improve the delivery and uptake of the intervention	Endline IDI with health facility staff and facilitators engaged in intervention implementation
	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
Objective 2: To assess acceptability of, demand for and engagement in the intervention by the target	Acceptability	Open-ended questions on perspectives regarding intervention components	Endline Structured participant questionnaire Endline IDIs with subset of participants

audience to inform improvements to the intervention.		and how to improve the intervention Closed-ended questions on perspective regarding intervention components.	 Endline Structured participant questionnaire
	Participation/engagement	Frequency of participation (number of active members, the number of posts, the number of comments, the number of reactions to posts by type) Number, type, reason for and outcome of personal communications between facilitator and members	Grytics software linked to Facebook groups Facilitator log of individual communications with group members
Objective 3: To gather preliminary data on the social and health-related outcomes that the intervention is designed to affect to inform an outcome evaluation study.	Social support	MOS-SSS items	Structured baseline and endline participant questionnaires
	Adherence to ART	AACTG Adherence Assessment items Viral load	Structured baseline and endline participant questionnaires Medical record data
	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
	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
	Depression/anxiety	PHQ-8	Structured baseline and endline participant questionnaires
Objective 4: To collect information on recruitment, informed consent and data collection processes to inform the outcome evaluation study of the current intervention that will be conducted once findings from this feasibility study are incorporated into the intervention design.	Challenges to recruitment, informed consent and data collection processes	Structured meetings with health facility and CBO staff engaged in intervention, as well as data collectors.	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 computer tablets, then uploaded to a secure FHI 360 server daily. The data will be stored in a password protected file on a 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 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 at FHI 360, and the server database will be deleted.

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, Katherine Ridgeway - will have access. This study account will be listed as a co-administrator for each of the study Facebook groups. The two study staff will not engage in the groups; they will only run the weekly use analytics and download use data to a secure FHI 360 server. Although Grytics does allow the members' usernames of the group to be displayed, when the data are downloaded, their usernames will be manually stripped by the PI or analyst and their participants' study identification numbers will replace the usernames in the dataset. 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 de-identified data on the FHI 360 server.

In-depth interviews

IDIs will be conducted by trained interviewers, 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.

Analyses

All analyses for this study will be descriptive in nature because of the small sample size for the feasibility study and the convenience sampling strategy. No statistical significance testing will be conducted. For quantitative data from structured questionnaires, medical data abstraction forms and Facebook groups, tables will be presented grouped by topics with measures of central tendency presented (mean, median, mode) or proportions as appropriate to the measure.

Structured questionnaires and clinical data

Descriptive analyses of pre- and posttest data will be presented. As appropriate for the different outcomes, data will be presented to describe changes from baseline to endline.

Participation data

Descriptive analyses of participation in structured moderated sessions, posts and comments/reactions by group and by sex will be presented.

In-depth interviews

Data analysis will begin during data collection by transcribing (and translating where needed) each audio-taped IDI. When necessary and possible, IDIs will be simultaneously transcribed and translated from the original language to English. All transcripts will be typed into a word processing program and password-protected; some transcripts may be handwritten first. Transcripts will be stored on password-protected computers. All data will be uploaded directly to a designated SharePoint folder. Data management logs may be created track and monitor data collection and transcription.

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. Procedures will be put into place to check for inter-coding discrepancies. 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.

Project 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. Kate Murray, 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 ALHIV to the study. Dr. Mario Chen will support data analyses as needed. In Nigeria, Dr. Ogha Okpokam, Technical Assistant for SIDHAS, FHI 360, will provide support to both intervention and study implementation by serving as the primary point of contact for FHI 360 Nigeria and liaising with both SHERO and the local organization contracted to collect data. 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. Study recruitment, enrollment and data collection activities have been contracted to CPRH.

Ethical Issues

This study aims to examine the feasibility and acceptability of an mHealth intervention to increase retention in care and improve adherence to ART among adolescents, ages 15 to 19 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 both the University of Uyo Institutional Health Research Ethics Committee (IHREC) 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 adolescent is less than 18 years of age and not emancipated, we will seek parental consent to participate and adolescent 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 adolescents are younger than 18 years of age, if the adolescent 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 adolescent 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 adolescent 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 adolescents living with HIV and the support group that is part of the intervention is to support ALHIV.

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. Also, the phones will be one of the more typical feature phone 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 will be held throughout the study to enable study 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 m/eHealth 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 ALHIV, a problem for many ALHIV who fear disclosing their HIV status to others. Although we are not powered to measure these outcomes for the feasibility phase, the intervention, if successful could lead to better health and psychosocial well-being.

Compensation

Although cell phone ownership is high in Nigeria (89% in 2015)[31], it is possible that adolescents 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 a feasibility study to see if ALHIV who can access the intervention do use it and what they think of it, the study will provide each ALHIV 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 feature 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 10,000 to 15,000 Nigerian Naira (approximately (US$30-45). In addition to the telephone, participants will receive 500 Naira (US$1.5) of airtime per month and a travel reimbursement of 1,500 Naira (US$4.5) for each trip for participating in each interview (baseline 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.

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.

Anticipated Outputs and Results Dissemination

Results from this study will inform the refinement of the study intervention. Necessary changes to improve feasibility and accessibility will be made prior to the next stage, an outcome evaluation study, to be implemented later this same calendar year. The outcome study will undergo a separate review process.

As part of the reporting for the feasibility study, the study investigators will work with USAID-Washington, USAID-Nigeria and SIDHAS staff to determine a set of criteria, prior to final data analysis, that would indicate the intervention is not feasible and the team will not move forward with the outcome study.

A report of feasibility study findings will be disseminated to stakeholders, including USAID, in the form of a document or presentation once data analysis is complete.

Timeline:

	2016					2017										
Activity	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**
USAID approval of study concept		X														
Identify and execute contract with local research partners						X										
Convene stakeholder meetings				X												
Develop/adapt intervention components			X	X	X	X										
Develop feasibility study protocol, DCIs, ICF			X	X	X											
Technical review of study documents					X											
Ethics review and approval of feasibility study (FHI 360) (submit by Jan 4)						X										
Ethics review and approval of feasibility study (IRB in Nigeria)						X	X									
Develop training materials for study implementation/SOPs/databases, etc.					X	X										
Train study personnel (e.g. data collectors)							X									
Train intervention staff and put all necessary intervention elements in place							X			X						
Feasibility study enrollment										X	X					
Baseline data collection										X	X					
Intervention implementation (3 months or 6 sessions)											X	X	X			
Endline Data collection													X	X		
Clean and analyze data													X	X		
Report feasibility findings and incorporate in to intervention for outcome evaluation															X	

Appendix 1: Facebook data policy

Appendix 2: Safety at Facebook

Appendix 3: What are the privacy settings for groups?

Appendix 4: How do I remove or block someone from a group?

*Appendices in separate files.

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