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

Statistical Analysis Plan v. 1.0
PHSC Study #930307

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# Contents

# Introduction

The Government of Nigeria (GoN) has prioritized programming for adolescents living with HIV (AHLIV) and is now focusing activities to better meet this population's needs. The USAID-funded SIDHAS project is supporting the GoN priorities through current and planned activities to better support retention in HIV care and adherence to antiretroviral therapy (ART) among ALHIV with the ultimate goal of ensuring that more ALHIV achieve viral suppression. 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 distribution of ART in community pharmacies as opposed to only in ART clinics. 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.

YouthPower Action will be implementing an m/e health intervention delivered via Facebook to promote adherence and retention for ALHIV through leveraging social networks and psycho-social support, with an emphasis on informational, emotional and network dimensions of social support. 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
- Moderated, closed group chats in a "secret" Facebook group where ALHIV can interact with their peers and with a trained health counselor
- Access to a trained counselor (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

# Evaluation Aim and Objectives

The principle aim of this evaluation 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.

# Study Design

This feasibility study will be a single-arm, pre-test/posttest study in which up to 50 ALHIV ages 15 to 19 will be enrolled to receive the m/eHealth intervention in five groups of 8 to 10 participants each.

Baseline data will be collected from all participants prior to intervention implementation. Endline data will be collected at the end of the intervention period. Data will also be collected on an ongoing basis throughout the delivery of the intervention to examine implementation processes and participant engagement.

## Sample Size and Sampling Design

The primary population of interest for this feasibility study is ALHIV, ages 15-19 years, receiving care from three facilities in Akwa Ibom State in Nigeria who have been enrolled in ART for 6 months or longer.

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 outcomes – improved retention in HIV care and ART adherence. 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 descriptively.

Eligible participants will be sequentially recruited from patients who attend clinic visits at the study facilities 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.

Additionally, at endline, we will recruit health facility and community-based organization (CBO) staff who took part in the intervention for data collection. All health facility and CBO staff involved in the intervention, directly or indirectly, will be interviewed.

## Data Collection and Instruments

Data will be collected through the following: (1) structured questionnaires administered during face-to-face interviews with ALHIV participants at baseline and endline, (2) clinical data for each participant will abstracted from electronic patient medical records, (3) participant engagement data on Facebook platform during intervention implementation, (4) communication log documenting messages sent from study participants to the group facilitator, (5) in-depth interviews administered to a subset of ALHIV intervention participants at endline, (6) in-depth interviews administered to health facility and CBO staff who took part in the intervention at endline, and (7) staff meeting notes.

### *1. ALHIV questionnaire*

Topics: Demographic information; HIV history, knowledge, stigma, and disclosure; social support; ART adherence, adherence self-efficacy, and barriers to adherence; retention in HIV services and barriers to retention; drug and alcohol use; depression; and cell phone/internet use. Added topics at endline on intervention acceptability, participation, and challenges.
Timing: Baseline and endline
Source: Structured questionnaire
Format: Face-to-face interview with data entered on a mobile tablet
Population: All ALHIV participants

### *2. Clinical data*

Topics: Age, sex, age at HIV diagnosis, date of ART enrollment, pre-ART WHO clinical stage, date of last clinic visit, number of clinic visits during study, date of last CD4 cell count and value, date of last viral load test and value
Timing: Endline
Source: Electronic medical record system at participating health clinics
Format: Electronic
Population: All ALHIV participants

### *3. Facebook engagement data*

Topics: Record of active members and activity in each group, including posts, comments, and reactions to posts.
Timing: Weekly, during the first 3 months of intervention implementation

Source: Grytics software linked to Facebook groups
Format: Automatically-collected engagement data
Population: Facilitators and participants in all Facebook intervention support groups

#### *4. Communication log*

Topics: Date, time, main reason for contact of ALHIV participants to intervention facilitators
Timing: Continuous during first three months of intervention implementation
Source: Structured form
Format: Paper form
Population: All intervention facilitators

#### *5. In-depth interviews for ALHIV*

Topics: For high-engagement ALHIV: Likes, dislikes, and suggestions for improvement for intervention platform, content, and implementation for each intervention component (informational messages, moderated group chats, unstructured access to peers and counselor). For low-engagement ALHIV: Reasons for non-participation and suggestions to enhance participation in the future.
Timing: Endline
Source: Semi-structured interview
Format: Face-to-face interview, audio recorded and transcribed, with note-taking
Population: 12-16 ALHIV intervention participants; 6-8 with high intervention engagement, 6-8 with low intervention engagement (see definitions of high and low engagement below)

#### *6. In-depth interviews for health facility and CBO staff*

Topics: Experiences related to intervention implementation, challenges encountered, suggestions for improving the intervention to achieve greater participation.
Timing: Endline
Source: Semi-structured interview
Format: Face-to-face interview, audio recorded, with note-taking
Population: All health facility and CBO staff engaged in the intervention

#### *7. Staff meeting notes*

Topics: Study staff and facilitator feedback on intervention during implementation
Timing: Monthly during intervention implementation
Source: Written notes
Format: Notes taken during monthly meetings
Population: All study staff and facilitators attending monthly meetings

## Created Variables

### *Timeliness of scheduled intervention activities*

Timeliness of each scheduled intervention activity, including scheduled postings and group chats, will be calculated using Facebook group data from Grytics as a way to evaluate the feasibility of the intervention. The difference between the scheduled time and the actual time will be calculated for each intervention activity; timeliness will be dichotomized with activities coded as timely if they occurred within one week of the scheduled time, and untimely if they occurred outside of this one-week window. The proportion of missing data will be reported.

### *High and low intervention engagement*

Engagement in the intervention will be evaluated for each participant and will be calculated for each week of intervention implementation as well as overall engagement with the intervention during the period of implementation. The Grytics platform will collect data on when and how participants engage with the Facebook group; from this, weekly engagement scores will be created indicating the sum of the number of

times a participant "likes," comments on a post, or creates their own post on the group. Weekly engagement scores will also be summed for an overall intervention engagement score. Engagement will then be coded as an ordinal variable with codes for high, medium, and low participation; participants will be categorized as high engagement if they fall within the top 25% of all participants on the intervention (i.e. their overall intervention engagement score is in the highest quartile), and low engagement if they fall within the bottom 25% of all participants (i.e. overall intervention engagement score in lowest quartile). High and low engagement participants will be recruited at endline to participate in IDIs.

### *MOS-SSS social support sub-scale scores*[1]

Scores for each subscale (emotional/informational, tangible, affectionate, positive social interaction) of the MOS-SSS as well as the total score will be calculated be as follows:

- Tangible Support Subscale (TAN)
  - Raw score: Sum Items 9-12
  - Transformed score: [(Raw score-4)/16]*100
- Emotional/Informational Support Subscale (EMI)
  - Raw score: Sum Items 1-8
  - Transformed score: [(Raw score-8)/32]*100
- Affectionate Support Subscale (AFF)
  - Raw score: Sum Items 13-15
  - Transformed score: [(Raw score-3)/12]*100
- Positive Social Interaction Subscale (POS)
  - Raw score: Sum Items 16-18
  - Transformed score: [(Raw score-3)/12]*100
- Total Score
  - Raw score: Sum items 1-19
  - Transformed score: [(Raw score-19)/76]*100

We will do list-wise deletion of cases with missing data for scale items, and will also report the proportion of missing data to inform questionnaire modification for the outcome study.

### *Depression*[2]

Depression will be evaluated through the adolescent survey through the items of the PHQ-8. 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 as follows:

- Total score: Sum q605-612

The total score has a possible range of 0 to 24. Depression will be represented via an ordinal variable scored as follows:

- Not depressed (variable=0) if total score <10
- Major depression (variable=1) if total score 10-19
- Severe major depression (variable=2) if total score ≥20

We will do list-wise deletion of cases with missing data for scale items, and will also report the proportion of missing data to inform questionnaire modification for the outcome study.

### *Retention in care*

Retention in HIV services will be measured using data abstracted from the medical record system on date of visits between enrollment and the endline of this study. To be considered retained in HIV services, an

[1] Information on MOS-SSS scoring is available from: http://www.rand.org/health/surveys_tools/mos/social-support/scoring.html
[2] Information on PHQ-8 scoring is available from: http://patienteducation.stanford.edu/research/phq.pdf

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. Appointments are scheduled monthly. Missing data will be considered not retained in care.

### *Internalized stigma*

We will use the 3-item Internalized Stigma factor (q213-q215) since this factor has been confirmed through a previous factor analysis with the larger sample size in a study with ALHIV in Zambia. We will evaluate the internal consistency of this factor at both baseline and endline and present the Cronbach's alpha for baseline and endline separately. If the Cronbach's alpha is approximately 0.6, we will run the analysis on the 3 items in Factor #1. If the Cronbach's alphas are low or there is a large change in reliability, we will use the items individually and not present them as a factor. The factor will be scored according to the team's previous work with these measures by creating factor-based composite scores by averaging across the standardized variables. Given the interest in measuring changes over time, standardization will be done using the means and standard deviations of each item at baseline. To be scored, subjects must have valid observations from at least 2 of the 3 items. Otherwise, the score will be missing.

### *External stigma*

External stigma will be measured in the adolescent survey (q216-q219) and scored by creating factor-based composite scores by averaging across the standardized variables retained in the analysis. We will evaluate the internal consistency of this factor at both baseline and endline and present the Cronbach's alpha for baseline and endline separately. Given the interest in measuring changes over time, standardization will be done using the means and standard deviations of each item at baseline. To be scored, subjects must have valid observations from at least 3 of the 4 items. Otherwise, the score will be missing.

### *Alcohol use risk*

Risky alcohol use will be measured by administering the AUDIT-C[3] in the adolescent survey (q601-q603) and will be scored and categorized following AUDIT-C scoring guidelines:

- Total score=q601+q602+q603

Risky alcohol use will be denoted as an ordinal created variable following AUDIT-C guidelines:

- Males, age 29 and younger
    - Total score 8-12: Severe risk (variable=3)
    - Total score 6-7: High risk (variable=2)
    - Total score 4-5: Moderate risk (variable=1)
    - Total score 0-3: Low risk (variable=0)
- Females, age 29 and younger
    - Total score 8-12: Severe risk (variable=3)
    - Total score 6-7: High risk (variable=2)
    - Total score 3-5: Moderate risk (variable=1)
    - Total score 0-2: Low risk (variable=0)

To be scored, subjects must have valid observations from at least 2 of the 3 items. Otherwise, the score will be missing.

[3] https://www.hepatitis.va.gov/provider/tools/audit-c.asp

## Measures

| Concept/variable | Measure | Source of data | Timing of data collection | Type of data analysis |
|---|---|---|---|---|
| **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 | Logistic challenges (internet connection, electricity, airtime) | Staff meeting notes | During implementation | Qualitative |
| | Logistic challenges (internet connection, electricity, airtime) | ALHIV questionnaire<br>• Added endline questions | Endline | Qualitative |
| | ALHIV cell phone/ internet use | ALHIV questionnaire<br>• 701-711 | Baseline and endline | Quant, descriptive |
| | Perspectives on feasibility, challenges and strategies to improve the delivery and uptake of the intervention | Staff IDI | Endline | Qual |
| Fidelity of implementation | Ability to push out correct messages, hold regularly scheduled group chats as directed in intervention guide | Facebook engagement data<br>• For each activity: Timeliness of scheduled postings and group chats | During implementation | Timeliness: Quant, descriptive |
| **Objective 2:** To assess acceptability of, demand for and engagement in the intervention by the target audience to inform improvements to the intervention. | | | | |
| Acceptability | Open-ended questions on perspectives regarding intervention components and how to improve the intervention | ALHIV IDI | Endline | Qualitative |
| | Closed-ended questions on perspectives regarding intervention components | ALHIV questionnaire<br>• Endline questions | Endline | Quant, descriptive |
| 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 of high and low engagement participants) | Facebook engagement data<br>• For each group: # active members, posts, comments, reactions/week<br>• For each member: # engagements by type/week | During implementation | Quant, descriptive |
| | Number, type, reason for and outcome of personal communications between facilitator and members | Communication log | During implementation | Quant, descriptive |
| **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: Emotional/Information support subscale | ALHIV questionnaire<br>• 301-308 | Baseline and endline | Quant, scoring |

| Concept/variable | Measure | Source of data | Timing of data collection | Type of data analysis |
|---|---|---|---|---|
| | MOS-SSS: Tangible support subscale | ALHIV questionnaire<br>• 309-312 | Baseline and endline | Quant, scoring |
| | MOS-SSS: Affectionate support subscale | ALHIV questionnaire<br>• 313-315 | Baseline and endline | Quant, scoring |
| | MOS-SSS: Positive social interaction subscale | ALHIV questionnaire<br>• 316-318 | Baseline and endline | Quant, scoring |
| | MOS-SSS: Total score | ALHIV questionnaire<br>• 301-319 | Baseline and endline | Quant, descriptive + scoring |
| Adherence to ART | AACTG Adherence self-efficacy | ALHIV questionnaire<br>• 401-403 | Baseline and endline | Quant, descriptive + scoring |
| | AACTG Frequency and reasons for missing medication in past month | ALHIV questionnaire<br>• 404-417 | Baseline and endline | Quant, descriptive |
| | AACTG last time missed taking medication | ALHIV questionnaire<br>• 419 | Baseline and endline | Quant, descriptive |
| | Other reasons for missing HIV medication | ALHIV questionnaire<br>• 418 | Baseline and endline | Qualitative |
| | 2+ day gaps in missed medications | ALHIV questionnaire<br>• 420 | Baseline and endline | Quant, descriptive |
| | Doses missed in past 3 days | ALHIV questionnaire<br>• 421 | Baseline and endline | Quant, descriptive + scoring |
| | Viral load | Clinical data | Endline | Quant, descriptive |
| Retention in HIV services | Retention self-efficacy (adapted from AACTG) | ALHIV questionnaire<br>• 501-502 | Baseline and endline | Quant, descriptive |
| | Retention (adapted from AACTG) | ALHIV questionnaire<br>• 503-505 | Baseline and endline | Quant, descriptive |
| | Dates of clinic visits during study | Clinical data | Endline | Quant, descriptive |
| HIV-related Stigma | Internalized stigma and external stigma<br>Adapted from: Kalichman, 2009; Wight, 2006; Boyes, 2013 | ALHIV questionnaire<br>• 209-219 | Baseline and endline | Quant, descriptive |
| | Internalized stigma | ALHIV questionnaire<br>• 213-215 | Baseline and endline | Quant, scoring |
| | External stigma | ALHIV questionnaire<br>• 216-219 | Baseline and endline | Quant, scoring |
| Alcohol use | AUDIT-C: Total score | ALHIV questionnaire<br>• 601-603 | Baseline and endline | Quant, descriptive |
| | AUDIT-C: Ordinal variable | ALHIV questionnaire<br>• 601-603 | Baseline and endline | Quant, descriptive + scoring |
| Substance use | Adapted from AACTG Adherence Assessment items | ALHIV questionnaire<br>• 604 | Baseline and endline | Quant, descriptive |
| Depression/anxiety | PHQ-8: Total score | ALHIV questionnaire<br>• 605-612 | Baseline and endline | Quant, descriptive |
| | PHQ-8: Ordinal variable | ALHIV questionnaire<br>• 605-612 | Baseline and endline | Quant, scoring |
| HIV knowledge | | ALHIV questionnaire<br>• 220-227 | Baseline and endline | Quant, descriptive |
| ALHIV disclosure of HIV status | | ALHIV questionnaire<br>• 207-208 | Baseline and endline | Quant, descriptive |

| Concept/variable | Measure | Source of data | Timing of data collection | Type of data analysis |
|---|---|---|---|---|
| Other ALHIV clinical data | Age of HIV Dx, date of ART enrollment, pre-ART WHO stage, CD4 count & date | Clinical data | Endline | Quant, descriptive |
| | ALHIV self-reported date of diagnosis and clinical measures | ALHIV questionnaire<br>• 201-206 | Baseline and endline | Quant, descriptive |
| **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 | During implementation | Qualitative |
| ALHIV recruitment data | | Screening questions for ALHIV questionnaire | Baseline | Quant, descriptive |
| ALHIV participant demographic information | | ALHIV questionnaire<br>• 101-120 | Baseline and endline | Quant, descriptive |

# Data Analysis

## Quantitative Analysis

Data from the ALHIV baseline questionnaire will be cleaned and analyzed descriptively prior to the second round of data collection. Descriptive statistics including means and frequencies will be generated for all quantitative variables collected at baseline in addition to aggregate scores for multiple items measuring potential outcomes such as ART adherence and self-efficacy, social support, retention in HIV services, HIV-related stigma, depression/anxiety, and substance use, for the ALHIV questionnaire; and adequate knowledge on content for each of the five intervention sessions, for the in-depth interviews for health facility and CBO staff.

Data on intervention fidelity, ALHIV participation, and personal contact between participants and facilitators will be collected during implementation and cleaned and analyzed at intervention close. Descriptive statistics including means and frequencies will be generated for all quantitative variables, as well as for created variables evaluating timeliness of scheduled postings, accuracy of message content, and level of ALHIV engagement in the intervention.

Data from the endline ALHIV questionnaire, clinical data abstraction, and the communication log will be cleaned and analyzed after post-intervention data have been collected. Descriptive statistics including means and frequencies will be generated for all variables, as well as for created variables evaluating timeliness of scheduled posts and group chats, accuracy of message content, and adequate participant engagement.

Because the purpose of this study is to evaluate the feasibility and acceptability of the intervention, rather than evaluate any impact of the intervention on outcomes, no statistical testing will be conducted. The determination of intervention feasibility and acceptability and recommendation for continuation to a scaled-up intervention and full outcome analysis will be discussed in the following section. The proportion of missing data for all items will be evaluated to inform modification of the quantitative data collection tools.

## Qualitative analysis

All qualitative interviews will be audio-recorded and transcribed in English for analysis. For qualitative data from open-ended questions with ALHIV as well as qualitative data from IDIs with ALHIV and study staff, applied thematic analysis will be used (Guest, MacQueen, & Namey, 2012). Structural codes will first be applied to the data based on each open-ended question to group responses to the same question across all questionnaire responses. This allows for the generation of structural code reports which show participants' responses to a question. After that, data will be analyzed thematically in an iterative process, drawing on anticipated as well as emerging themes. Using codes derived from the data and from existing literature (if any), a codebook will be developed and used for coding and categorizing of data. Once all the responses 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 responses. Summary reports will be developed identifying the overall themes related to the study objectives. A qualitative data software program (QSR Nvivo) will be used to organize and prepare the data for analysis.

## Determination of Study Feasibility and Acceptability

The overall feasibility and acceptability of the intervention will be evaluated qualitatively through examining the following measures. Additionally, any additional information on the feasibility or acceptability of the intervention that may be emergent in the qualitative data with ALHIV and health facility and CBO staff will also be considered.

### *Feasibility*

Several criteria will be used to define feasibility:

| Construct | Measure | Evaluation Criteria |
|---|---|---|
| Study recruitment | Able to enroll the desired number of participants within the timeframe proposed (2 months) | Sample size of 40-50 ALHIV enrolled in the study in no more than 2 months<br>No more than 20% refusal rate among eligible ALHIV who are recruited to participate in the study |
| Study participation | The number of participants who enroll in the study who complete the endline data collection. | No more than 20% loss-to-follow-up at endline among those ALHIV who enroll in the study and complete the baseline interview |
| Fidelity to intervention design | Facilitators are able to deliver content to groups as planned | At least 80% of content is delivered within one week of scheduled delivery to all study support groups. |
| Participant participation | Participants report being able to access the online groups regularly. | At least 80% of participants can use the phones to access the groups, and log into the group for three out of the five sessions. |

### *Acceptability*

Acceptability of the intervention will be measured for both facilitators and participants.

| Construct | Measure | Evaluation criteria |
|---|---|---|

| | | |
|---|---|---|
| Facilitators find intervention acceptable | Facilitators report that intervention content is clear, easy to share and appropriate for their support group participants.<br><br>Facilitators report that the Facebook platform is an appropriate medium for interacting remotely with group participants.<br><br>Facilitators report being able to integrate the study intervention work into their other work without disruption. | No more than minor content-related revisions required.<br><br>Facilitators report that they have meaningful interaction with participants through the online forum.<br><br>Facilitators can implement activities during their normal working hours without considerable added efforts, compared to in-person support groups. |
| Participants find the intervention acceptable | Participants report having received new and relevant information through the intervention.<br><br>Participants report that they were comfortable interacting with the facilitator and their peers through the online medium.<br><br>Participants report they would recommend the intervention (online support group) to other ALHIV. | At least 50% of participants report having received information that is useful to them through the intervention.<br><br>At least 50% of participants actively engage in one or more interactions in the online group through posts, comments or reactions to comments.<br><br>At least 80% of those who actively engage report that they would recommend the online support group to other ALHIV. |

## Bibliography

Guest, G., MacQueen, K. M., & Namey, E. (2012). *Applied thematic analysis.*: Thousand Oaks: Sage.