

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

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## Introduction

From June 2017 to January 2018, YP Action conducted a feasibility study of an online support group intervention designed to improve ART adherence and health service retention among YLHIV (FHI 360 PHSC study number 930307). The feasibility study included a pilot test of 5 structured sessions delivered by trained facilitators through Facebook groups to groups of 6-8 YLHIV. A total of 41 participants completed a baseline questionnaire; 38 of 41 enrolled and participated in the online groups. Overall, results from the feasibility study demonstrate that the intervention was feasible and acceptable to both participants and facilitators; additionally, some challenges were identified during the study.

For this study, we will be implementing the full version of the online support group intervention piloted in the feasibility study and conduct a randomized controlled trial to evaluate its impact on retention in HIV care services. The intervention components include:

- Informational messages that reflect the content of the structured group counseling curriculum, Positive Connections, and are posted to the group wall on a regular basis several times a week, for approximately 4 to 4.5 months
- Moderated, closed group chats in a “secret” Facebook group where YLHIV can interact with their peers and with a trained health counselor
- Access to a trained counselor via Facebook Messenger or phone 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

## I. Study Aim and Objectives

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

The objectives of the study are:

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

The study’s primary outcome is retention in HIV services at 6-9 months after enrollment. The study’s secondary outcomes are:

1. ART adherence
2. Social support

### 3. HIV knowledge and treatment literacy

## II. Study Design

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

The hypothesis being tested with this study is:

YLHIV who participate in SMART Connections will be more likely to be retained in HIV care at 6-9 months after enrollment than YLHIV in the control group.

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

Among YLHIV enrolled in ART services, those in the treatment group who are exposed to SMART Connections will have greater social support and, in turn, will be more likely to be retained in HIV care services at 6-9 months compared to those in the control group.

## III. Sample Size and Sampling Design

### Sample size

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

### Sampling and recruitment procedures

Eligible participants will be sequentially recruited from patients who attend clinic visits at the study facility until the total sample size has been achieved. Potential participants will be assessed for eligibility and written informed consent will be obtained from each participant prior to enrollment in the study.

### Randomization procedures

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

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

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

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

## IV. General Analytic Considerations

All primary analyses will be conducted under the intent-to-treat (ITT) principle, whereby participant data will be analyzed in the group each participant is randomized to regardless of randomization errors or other protocol violations. A per protocol analysis will be conducted if more than 5% of the population is affected by protocol violations such as randomization errors.

### A. Data Sources

#### 1. *Structured questionnaires*

Topics: Demographic information; HIV-related information; social support measures; depression/anxiety, alcohol and other substance use, and perceived and experienced stigma; and access to and use of mobile telephones and social media applications. Six-month and endline questionnaires will include additional questions pertaining to intervention participation.

Timing: Baseline, endline

Source: Structured interview

Format: Face-to-face interview with data entered on a mobile tablet

Population: Intervention participants

#### 2. *Clinical data abstraction*

Topics: Date and results of CD4 cell counts and viral load tests; date of HIV diagnosis; date of ART initiation; WHO clinical stage at ART initiation; regimen substitutions and switches; treatment discontinuation and interruptions; dates of ART refills; dates of ART clinic visits.

Timing: Periodically, through 12 months after enrollment.

Source: Electronic medical record system at participating health clinics

Format: Electronic form captured on mobile tablet

Population: Intervention participants

#### 3. *Participation data and push messages*

Topics: Timing and completeness of scheduled intervention activities, posts and comments related to each session

Timing: Ongoing during intervention

Source: Grytics software linked to Facebook groups

Format: Automatically-collected engagement data

Population: Facilitators and participants in all Facebook intervention support groups

#### 4. *In-depth interviews*

Topics: Experiences related to intervention implementation, challenges, if any, encountered and suggestions for improving the intervention to achieve greater participation.

Timing: endline

Source: Semi-structured interview

Format: For YLHIV: Up to 45 study participants (minimum 12 moderate/high participation in intervention, 12 low/no participation in intervention, and 12 with poor retention in ART care) at endline.

### 5. *Cost data*

Topics: Costs for intervention training, materials, supplies, and implementation; facilitator stipends, SBO supervisors to facilitators, monthly meetings for facilitators; costs of implementing in-person support groups by SIDHAS project

Timing: Post-intervention

Source: Data extraction from study financial records and from SIDHAS financial records

Format: Excel spreadsheet

Population: NA

### 6. *Documentation of personal messages*

Topics: Number and reason for personal messages to group facilitator (i.e. question about side effects, question about appointments, etc.).

Timing: During intervention implementation

Source: Communication log

Format: Paper form to be filled out by facilitator

Population: All intervention facilitators

## B. *Data Management*

Data collected during administration of structured questionnaires and clinical data abstraction will be recorded on tablets using Open Data Kit and will be uploaded to a secure, FHI-hosted server. The primary quantitative analyst will download data from the server and conduct regular checks for completeness and accuracy of collected data.

### *Missing data*

All primary analyses will be conducted using complete case analysis, meaning that we will analyze those observations for which complete data exist for the variables included in each analysis. Missingness (missing or refused) of each variable will be assessed using `mdesc` in Stata. If variables for a model have 5% or greater missingness, we will conduct multiple imputation. See details following each proposed model in sections VI and VII.

## C. *Created Variables*

### *Retention at endline*

This main outcome is defined as retention in clinical HIV services and on treatment, defined as having attended a scheduled HIV clinic visit within 4 weeks of the visit date. To be considered retained in HIV services at endline, an individual must, at endline, have picked up his/her medication for his/her most recently scheduled clinical follow-up visit within 4 weeks (28 days) of the date when it was scheduled to take place. "Endline" will be considered the date of the participant's endline interview, or, for those that did not participate in an endline interview, an approximate date based on the median length of time between baseline and endline for other participants enrolled in the same month. 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, defaulted, or has been recorded as lost to follow-up.

Cases that can be confirmed to have died or transferred to a facility outside the study facilities and retention data cannot be obtained reliably will be considered censored.

Nigeria's definition of retention in HIV services changed during the course of the study, to be more stringent (4 weeks vs. 12 weeks). We will therefore secondarily assess retention using the older, less stringent, definition.

Created variables will be defined as follows:

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**ltfu\_el** - care status at EL

0=in care at EL

Latest visit (i.e. **v5q036**) +/- 28 days from **today\_el/today\_el\_approx**  
actual visit (i.e. **v5q036**) more than 28 days before  
**today\_el/today\_el\_approx** AND follow-up visit (i.e. **v3q044**) on or after  
**today\_el/today\_el\_approx**

1=LTFU at EL

actual visit < **today\_el/today\_el\_approx** + 28 days AND latest MRE on or  
after **today\_el/today\_el\_approx**

8=Transfer

**transfer**==1 AND **q027** is before **today\_el/today\_el\_approx** AND **q027** is AFTER  
the latest visit (i.e. **v3q036**)

9=Death

**death**==1

.=Missing

Insufficient data to assess care status at endline. **latest\_mre** is before  
**today\_el/today\_el\_approx** AND latest follow-up date (i.e. **v1q044**) before  
**today\_el/today\_el\_approx**

### *Retention for survival analysis*

For the survival analysis, we will create two sets of variables indicating retention using a 28 day cutoff and using a 90 day cutoff to reflect the fact that the national guidelines for retention in HIV services changed from 12 weeks (i.e. 90 days) to 4 weeks (i.e. 28 days). For each recorded visit, we will also assess whether the participant is within their scheduled window and the number of days between the scheduled visit date and the date the visit was actually attended (**v1** denotes the first attended visit after study enrollment; **v2**, **v3**, **v4**, etc. will be calculated for all visits between study enrollment and date of EL questionnaire (or date EL questionnaire should have been conducted, based on enrollment date, for those LTFU in the study at endline):

For each visit, starting at visit 2 (i.e. **v2**):

- **v2\_days\_aftersched** = [visit date (**v2q036**)] - [date of prior scheduled visit (**v1q044**)]; missing if either date is . or jan 1 1990
- **v2\_ltfu\_28** = 1 if **v1\_days\_aftersched** >28; = 0 if **v1\_days\_aftersched** ≤28; missing if next scheduled visit date (**v1q044**) is missing (. or jan 1 1990).
- **v2\_ltfu\_90** = 1 if **v1\_days\_aftersched** >90; = 0 if **v1\_days\_aftersched** ≤90; missing if next scheduled visit date is missing (. Or jan 1 1990).

**ltfu\_28** LTFU status for survival analysis using 28 day cutoff

- **ltfu\_28**=1; lost to follow-up
  - **v2\_ltfu\_28**==1 OR **v3\_ltfu\_28**==1 OR **v4\_ltfu\_28**==1, etc.
  - Appears retained for all recorded visits, but earliest value of **today\_el**, **today\_el\_approx**, **latest\_mre** falls MORE than 28 days after latest instance of **vnq044**
- **ltfu\_28**=0; retained



- o `v2_ltfu_28==0 AND v3_ltfu_28==0 AND v4_ltfu_28==0`, etc. AND the earliest value of `today_el`, `today_el_approx`, `latest_mre` falls within 28 days of latest instance of `vnq044`
- `ltfu_28=8`; transferred out
  - o Retained up to the date of transfer (`transfer==1` and `q027`, transfer date, must be non-missing)
- `ltfu_28=9`; died
  - o Retained up to the date of death (`death==1` and `q028`, death date, must be non-missing)

`ltfu_90` LTFU status for survival analysis using 90 day cutoff

- `ltfu_90=1`; lost to follow-up
  - o `v2_ltfu_90==1 OR v3_ltfu_90==1 OR v4_ltfu_90==1`, etc.
  - o Appears retained for all recorded visits, but earliest value of `today_el`, `today_el_approx`, `latest_mre` falls MORE than 90 days after latest instance of `vnq044`
- `ltfu_90=0`; retained
  - o `v2_ltfu_90==0 AND v3_ltfu_90==0 AND v4_ltfu_90==0`, etc. AND the earliest value of `today_el`, `today_el_approx`, `latest_mre` falls within 90 days of latest instance of `vnq044`
- `ltfu_90=8`; transferred out
  - o Retained up to the date of transfer (`transfer==1` and `q027`, transfer date, must be non-missing)
- `ltfu_90=9`; died
  - o Retained up to the date of death (`death==1` and `q028`, death date, must be non-missing)

`ret_time_28` Time in days retained until LTFU, transfer, death, or censor

- If `ltfu_28=0`
  - o `ret_time_28=[latest follow-up date i.e. v8q044] - [BL survey date, today_b1]` IF `v8q044<today_el/today_el_approx`
  - o `ret_time_28=[latest visit date i.e. v7q036]+28-today_b1` IF retained for all visits recorded and latest available follow-up date is missing
  - o `ret_time_28=[today_el/today_el_approx]-today_b1` IF latest follow-up date `>today_el/today_el_approx` OR latest visit date +28 `>today_el/today_el_approx`
- If `ltfu_28=1`
  - o `ret_time_28=[latest follow-up date prior to LTFU, i.e. v6q044] - [today_b1]`
  - o `ret_time_28=latest visit date prior to LTFU, i.e. v5q036 + 28 - today_b1` IF latest follow-up date prior to LTFU is missing
- if `ltfu_28=8`
  - o `ret_time_28=latest follow-up date prior to or after transfer-today_b1` IF `q027>today_b1` AND `q027≤latest follow-up date prior to transfer`
  - o `ret_time_28=latest visit date prior to transfer + 28 -today_b1` IF `q027>today_b1` AND latest follow-up date prior to transfer is missing
- if `ltfu_28=9`
  - o `ret_time_28=q028-today_b1`

`ret_time_90` Time in days retained until LTFU, transfer, death, or censor

- If `ltfu_90=0`
  - `ret_time_90=[latest follow-up date i.e. v8q044] - [BL survey date, today_b1]` IF `v8q044<today_el/today_el_approx`
  - `ret_time_90=[latest visit date i.e. v7q036]+28-today_b1` IF retained for all visits recorded and latest available follow-up date is missing
  - `ret_time_90=[today_el/today_el_approx]-today_b1` IF latest follow-up date `>today_el/today_el_approx` OR latest visit date +28 `>today_el/today_el_approx`
- If `ltfu_90=1`
  - `ret_time_90=[latest follow-up date prior to LTFU, i.e. v6q044] - [today_b1]`
  - `ret_time_90=latest visit date prior to LTFU, i.e. v5q036 + 28 - today_b1` IF latest follow-up date prior to LTFU is missing
- if `ltfu_90=8`
  - `ret_time_90=latest follow-up date prior to or after transfer-today_b1` IF `q027>today_b1` AND `q027≤latest follow-up date prior to transfer`
  - `ret_time_90=latest visit date prior to transfer + 28 -today_b1` IF `q027>today_b1` AND latest follow-up date prior to transfer is missing
- if `ltfu_90=9`
  - `ret_time_90=q028-today_b1`

Missingness will be handled in the following way:

- If a follow-up date (i.e. `v7q044`) is missing (. or Jan 1 1990) and retained up to that point, retention must be assessed using the clinic visit date at which the follow-up date is missing. Consider retention time to be the visit date + 28 days as a conservative estimate of the follow-up time. Consider censored if retained up to that point.
- If a participant has died [`died==1`] but is missing date of death [`q028`] and appears to be retained throughout the entire study period, retention time is assessed based on the latest attended visit (i.e. `v2q036`), given that we do not know if participant died prior to the scheduled follow-up date.
- If a participant has transferred [`transfer==1`] but is missing date of transfer [`q027`] and appears to be retained throughout the entire study period, participant is categorized as transferred (`ltfu_28/ltfu_60/ltfu_90==8`) and retention time is assessed based on the latest available follow-up date (i.e. `v7q044`)
- If medical record data are incomplete towards the end of the study period (i.e. `latest_mre` falls before `today_el/today_el_approx`), then retention is assessed using `latest_mre` as the pseudo-endline date. Retention cannot be assessed into the future.
- If no visit data for participant during the study period or all visit dates for participant are missing during the study period (. or Jan 1 1990), then retention time is missing and LTFU status is missing.
- We will generate a variable, `conservative`, to indicate whether participants have complete medical record data (`conservative=1`) or have a gap during the beginning of the study period (`conservative=.`).

`conservative=1 if (v1q036-today_b1)<=56 & v1q036!=.`

`conservative=.` otherwise

#### *Other variables for descriptive analysis of retention data*

Other variables will be created to describe retention and clinic visits during the study period:

`n_visits`=number of clinic visits attended during the study period

- Code: `gen n_visits=.`

```

forvalues i=11(-1)1 {
  replace n_visits=`i' if v`i'q036!=. & n_visits==. & ((v`i'q036<=today_el &
  today_el!=.) | (v`i'q036<today_el_approx & today_el_approx!=.))
}
replace n_visits=0 if v1q036==. | ( v1q036<today_b1 & v2q036==.)

```

**n\_missed\_28**=Number of clinic visits missed by more than 28 days during the study period

- Code: `egen n_missed_28=rowtotal(v21tfu_28 v31tfu_28 v41tfu_28 v51tfu_28 v61tfu_28 v71tfu_28 v81tfu_28 v91tfu_28 v101tfu_28 v111tfu_28)`

**mean\_followup\_mo**=Mean months of follow-up time during the study period

- Code: 

```

forvalues i=1/11{
  gen v`i'fu=v`i'followup if ((v`i'q036<=today_el & today_el!=.) |
  (v`i'q036<=today_el_approx & today_el_approx!=.))
}

egen followup_total=rowtotal(v1fu v2fu v3fu v4fu v5fu v6fu v7fu v8fu v9fu
v10fu v11fu)

gen mean_followup=followup_total/n_visits

gen mean_followup_mo=floor(mean_followup/30.44)

replace mean_followup_mo=1 if mean_followup_mo==0

```

#### *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 to evaluate the extent to which each group was implemented as planned. The difference between the scheduled date and the actual date 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*

Facilitators will be asked to identify the highest- and lowest-engaged participants in their Facebook groups. High and low engagement participants will be recruited at endline to participate in IDIs.

#### *Social Support [MOS-SSS]<sup>1</sup>*

People sometimes look to others for companionship, assistance, or other types of support. How often is each of the following kinds of support available to you if you need it?		
Factor	Item no.	Item
Emotional/ Informational support	1	Someone you can count on to listen to you when you need to talk
	2	Someone to give you information to help you understand a situation
	3	Someone to give you good advice about a crisis
	4	Someone to confide in or talk to about yourself or your problems
	5	Someone whose advice you really want

<sup>1</sup> Information on MOS-SSS scoring is available from: [http://www.rand.org/health/surveys\\_tools/mos/social-support/scoring.html](http://www.rand.org/health/surveys_tools/mos/social-support/scoring.html)

	6	Someone to share your most private worries and fears with
	7	Someone to turn to for suggestions about how to deal with a personal problem
	8	Someone who understands your problems
Tangible support	9	Someone to help you if you were confined to bed
	10	Someone to take you to the doctor if you needed it
	11	Someone to prepare you meals if you were unable to do it yourself
	12	Someone to help with daily chores if you were sick
Affectionate support	13	Someone who shows you love and affection
	14	Someone to love and make you feel wanted
	15	Someone who hugs you
Positive social interaction	16	Someone to have a good time with
	17	Someone to get together with for relaxation
	18	Someone to do something enjoyable with
Additional item	19	Someone to do things with to help you get your mind off things

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

- **Tangible Support Subscale (TAN)**
  - `ss_tan_raw_bl`, `ss_tan_raw_el`: Sum items 9-12
  - `ss_tan_avg_bl`, `ss_tan_avg_el`: Average items 9-12
- **Emotional/Informational Support Subscale (EMI)**
  - `ss_emi_raw_bl`, `ss_emi_raw_el`: Sum items 1-8
  - `ss_emi_avg_bl`, `ss_emi_avg_el`: Average items 1-8
- **Affectionate Support Subscale (AFF)**
  - `ss_aff_raw_bl`, `ss_aff_raw_el`: Sum items 13-15
  - `ss_aff_avg_bl`, `ss_aff_avg_el`: Average items 13-15
- **Positive Social Interaction Subscale (POS)**
  - `ss_pos_raw_bl`, `ss_pos_raw_el`: Sum items 16-18
  - `ss_pos_avg_bl`, `ss_pos_avg_el`: Average items 16-18
- **Total Score**
  - `ss_tot_raw_bl`, `ss_tot_raw_el`: Sum items 1-19
  - `ss_tot_raw_chng`:  $\Delta$  BL to EL: total raw score, EL – total raw score, BL
  - `ss_avg_bl`, `ss_avg_el`: **Weighted average:**  $(ss\_tan\_avg + ss\_emi\_avg + ss\_aff\_avg + ss\_pos\_avg + item\ 19) / 5$
  - `ss_avg_chng`:  $\Delta$  BL to EL, `ss_avg_el` – `ss_avg_bl`

The confirmatory factor analysis will inform which approach to score generation we present and use in the final analyses.

### *Social Isolation [PROMIS Social Isolation 4a]<sup>2</sup>*

For this abbreviated, 4-item instrument, raw scores will be created by summing all four items. Conversion tables will be used to convert the raw score to a T-score for each participant.

Item no.	Item	Never	Rarely	Sometimes	Usually	Always
1	I feel left out	1	2	3	4	5
2	I feel that people barely know me	1	2	3	4	5
3	I feel isolated from others	1	2	3	4	5
4	I feel that people are around me but not with me	1	2	3	4	5

### *Depression [PHQ-8]<sup>3</sup>*

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.<sup>4</sup>

Over the last 2 weeks, how often have you been bothered by any of the following problems?					
Item no.	Item	Not at all	A few days	More than half the days	Most all of the days
1	Little interest or pleasure in doing things	0	1	2	3
2	Feeling down, depressed, or hopeless	0	1	2	3
3	Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4	Feeling tired or having little energy	0	1	2	3
5	Poor appetite or overeating	0	1	2	3
6	Feeling bad about yourself, or that you are a failure, or have let yourself or your family down	0	1	2	3
7	Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8	Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or	0	1	2	3

<sup>2</sup> Information on scoring the PROMIS Social Isolation instrument is available from: [chrome-extension://oemmndcbldboiebfnladdacbfmadadm/http://www.healthmeasures.net/images/PROMIS/manuals/PROMIS\\_Social\\_Isolation\\_Scoring\\_Manual.pdf](chrome-extension://oemmndcbldboiebfnladdacbfmadadm/http://www.healthmeasures.net/images/PROMIS/manuals/PROMIS_Social_Isolation_Scoring_Manual.pdf)

<sup>3</sup> Information on PHQ-8 scoring is available from: <http://patienteducation.stanford.edu/research/phq.pdf> and [chrome-extension://oemmndcbldboiebfnladdacbfmadadm/https://www.selfmanagementresource.com/docs/pdfs/English\\_-\\_phq.pdf](chrome-extension://oemmndcbldboiebfnladdacbfmadadm/https://www.selfmanagementresource.com/docs/pdfs/English_-_phq.pdf)

<sup>4</sup> PERC S. Personal Health Questionnaire Depression Scale (PHQ-8). [Internet]. 2013; <http://patienteducation.stanford.edu/research/phq.pdf>.

	restless that you have been moving around a lot more than usual				
--	---	--	--	--	--

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
- Δ BL to EL: total raw score, EL – total raw score, BL

For pre-post comparison, we will present the mean and standard deviation of the scores at each time point. We will also descriptively present the percentage of participants who fall into each category below at each time point:

- 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

#### *HIV-related stigma [HIV Stigma Scale-12 items]<sup>5</sup>*

The abbreviated version of the HIV Stigma Scale has four sub-scales: Personalized stigma, disclosure concerns, concerns about public attitudes, negative self-image; each of these items is scored on a 4-point scale (1-4). A raw score will be generated for each sub-scale by summing the following items:

<i>Next I'd like to ask you some questions about how you feel about having HIV and sharing that information with other people.</i>		
Factor	Item no.	Item
Personalized stigma	1	214. Some people avoid touching me once they know I have HIV
	2	215. People I care about stopped calling after learning I have HIV
	3	216. I have lost friends by telling them I have HIV
Disclosure concerns	4	217. Telling someone I have HIV is risky
	5	218. I work hard to keep my HIV a secret
	6	219. I am very careful who I tell that I have HIV
Concerns about public attitudes	7	220. People with HIV are treated like outcasts
	8	221. Most people believe a person who has HIV is dirty
	9	222. Most people are uncomfortable around someone with HIV
Negative self-image	10	223. I feel guilty because I have HIV
	11	224. People's attitudes about HIV make me feel worse about myself
	12	225. I feel I'm not as good a person as others because I have HIV

<sup>5</sup> Scoring information available from:

[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5450123/pdf/12955\\_2017\\_Article\\_691.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5450123/pdf/12955_2017_Article_691.pdf)

Possible scores for each sub-scale range from 3 to 12. A greater score indicates a greater level of perceived HIV-related stigma. A total score will also be created by summing all 12 items. Changes in the total score from baseline to endline will also be calculated.

The confirmatory factor analysis will inform the approach to score generation we present and use in the final analyses.

#### *Alcohol use risk [AUDIT-C]*

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. 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.

Item no.	Item	Response options
Q601 [item 1]	How often do you have a drink containing alcohol?	0 =Never 1=Monthly or less 2=2 to 4 times a month 3=2 to 3 times a week 4=4 or more times a week
Q602 [item 2]	How many drinks containing alcohol do you have on a typical day when you are drinking?	0=1 or 2 1=3 or 4 2=5 or 6 3=7, 8, or 9 4=10 or more
Q603 [item 3]	How often do you have six or more drinks containing alcohol on one occasion?	0=Never 1=Less than monthly 2=Monthly 3=Weekly 4=Daily or almost daily

Risky alcohol use will be measured by administering the AUDIT-C<sup>6</sup> in the 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

<sup>6</sup> <https://www.hepatitis.va.gov/provider/tools/audit-c.asp>

- 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)

AUDIT-C scoring guidelines specify that participants missing one or more response to the three items should be excluded from calculation of a total score; however, participants who respond "never drank alcohol" to q601 will be included with a total score of 0.

### *Food insecurity [HHS]<sup>7</sup>*

Food insecurity will be measured using the FANTA project 3-item Household Hunger Scale. This tool was developed for use in LMIC settings that is capable of measuring food insecurity in a comparable way (i.e. cross-cultural equivalency). The abbreviated 3-item version of the scale asks if participants had experienced any of the following within the past 30 days, and if yes, how frequently:

- Was there ever no food to eat of any kind in your house because of lack of resources to get food
  - [if yes] How often did this happen? (Rarely [1-2 times], Sometimes [3-10 times], Often [more than 10 times])
- Did you or any household member go to sleep at night hungry because there was not enough food
  - [if yes] How often did this happen? (Rarely [1-2 times], Sometimes [3-10 times], Often [more than 10 times])
- Did you or any household member go a whole day and night without eating anything at all because there was not enough food
  - [if yes] How often did this happen? (Rarely [1-2 times], Sometimes [3-10 times], Often [more than 10 times])

Following scoring guidelines, a new variable will be created for each question with the following response options:

- Indicated that this type of food insecurity did not happen (variable=0)
- "Rarely" or "sometimes" (variable=1)
- "Often" (variable=2)

An aggregate score will be created by summing the three new variables. The aggregate score will have a minimum score of 0 and a maximum score of 6. Results at each time point will be represented as mean aggregate score at each time point. We will also present the proportion of participants in each of the following household hunger categories as per the HHS scoring guide:

- Aggregate score 0-1: Little to no hunger in household
- Aggregate score 2-3: Moderate hunger in household
- Aggregate score 4-6: Severe hunger in household

### *Adherence*

Adherence will be dichotomized at baseline and endline (*adh\_bl*, *adh\_el*) based on self-reporting having missed one more medication dose in the past 3 days (q422).

Code:

gen adh\_el=.

---

<sup>7</sup> Information on scoring the HHS is available from: <https://www.fantaproject.org/sites/default/files/resources/HHS-Indicator-Guide-Aug2011.pdf>



```
replace adh_el=1 if q420==1 | q420==2 | q420==3 | q421==1 | q421==2 | q421==3 | q422==1 |  
q422==2 | q422==3 | q422==4 | q422==5; 0 otherwise
```

```
replace adh_el=0 if adh_el==. & (q420==4 | q420==5 | q420==6 | q421==0 | q422==0)
```

#### *VL suppression*

A dichotomous variable, `vl_sup`, will be created for each VL measurement instance to indicate virologic failure following the standard definition of virologic suppression being <1,000 cp/mL. The variable will be missing for any instances where VL measures were not available.

#### *HIV knowledge and treatment literacy*

HIV knowledge and treatment literacy will be assessed using a set of fifteen true/false questions [q226 – q240] administered at baseline, midpoint, and endline. For each knowledge question, a new variable will be created to more easily quantify correct responses and will be coded as 1 if a correct response was given, and 0 if an incorrect answer, "don't know" response, or refusal was given. For example:

```
q226_re=1 if q226=1, q226_re=0 if q226=0 | q226=8 | q226=99
```

At each timepoint, knowledge will be quantified as follows:

```
know=sum(q226_re-q240_re)/15*100
```

Changes in knowledge scores from baseline to endline will be quantified as follows:

```
know_chng=know_el - know_bl
```

Responsiveness to particular questions as well as changes from baseline to midpoint, and midpoint to endline, will also be assessed descriptively.

#### *Time on ART*

Time on ART at baseline, `art_time_bl`, will be created based off of medical record data reporting the date the participant started ART as well as the date the participant conducted their baseline questionnaire.

```
art_time_bl =q011(from MRE)-today_bl (from BL questionnaire)
```

## V. Analysis of participant characteristics

Data from the 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. A descriptive summary of participant characteristics will be presented by intervention and control groups at all time points. Participant characteristics will include age, marital/relationship status, education, religious affiliation, employment, and food insecurity/household hunger.

## VI. Analysis of Study Objectives

### **Objective 1.**

To test the effect of the intervention on the primary outcome, retention in care, we will report Kaplan-Meier cumulative retention probabilities with 95% confidence intervals and plots by study group. The retention probabilities between the groups will be compared with a logrank test stratified by site with a two-sided  $\alpha = 0.05$ .

The null hypothesis is:

YLHIV who participate in SMART Connections will have the same likelihood of being retained in HIV care at 270 days as YLHIV in the control group.

The alternative hypothesis is:

YLHIV who participate in SMART Connections will be more likely to be retained in HIV care at 270 days than YLHIV in the control group.

Data will be prepared using the `stset` command:

```
stset timevar, id(id_str) failure(ltfu_28=1) origin(time -0.01) exit(time 270)
```

Where:

timevar - time to failure in days, created variable **ret\_time\_28** defined above

idvar - participant ID **id\_str**

failvar - failure variable, created ordinal variable **ltfu\_28** defined above

The origin command includes participants with 0 survival time because these participants had the potential to be retained in care during the study period. The exit command specifies that 270 days is the latest timepoint at which we will assess retention.

Kaplan-Meier cumulative retention probabilities at endline with 95% confidence intervals, by study group:

```
sts list, by(group_itt) ci
```

Plots by study group:

```
sts graph, by(group_itt) ci
```

Log-rank test for difference in retention between groups, stratified by site:

```
sts test group, strata(facility) detail
```

Secondarily, we will also conduct the survival analysis described above using the 90 day cutoff variables (i.e. `ltfu_90`, `ret_time_90`).

We will also report on the proportion of participants, by study arm, who are retained at 12 months after enrollment. We will use additional regression models (For example, a multivariate Cox proportional hazards model) to explore factors associated with retention in further detail, such as time on ART at enrollment, age, and sex.

If the variables other than retention included in these models have  $\geq 5\%$  missingness, a multiple imputation model will be run as a secondary analysis. Multiple imputation creates multiple sets of plausible values for missing data that reflect the uncertainty about the missing data. The imputation model will include additional variables that are theoretically related to the variables being imputed (Chantala & Suchindra; Stuart, 2009; White, 2011): Age, sex, date of HIV test, date of ART initiation, depression, and social support. We will impute individual items (for example, individual items missing from the social support measure), rather than generated scores. Although there is some controversy as to whether to round categorical variables after imputation (Allison, 2005), we will round the values in each variable in order to facilitate interpretation of results and given expected very small proportion of missing data.

The multiple imputation procedure involves 3 phases (Rubin, 1996; Yuan, 2000):

1. The missing data are filled in  $m$  times to generate  $m$  complete data sets.
2. The  $m$  complete data sets are analyzed by using standard procedures.

3. The results from the m complete data sets are combined for inference.

Two main assumptions underlie the multiple imputation procedure. First, the data are assumed to be missing at random (MAR). According the SAS User Guide (2003a), for a variable to be MAR, “the probability that an observation is missing can depend on the observed variable values of the individual, but not on the missing variable values of the individual.” Although the MAR assumption cannot be verified, since independence from the missing values cannot be estimated, Schafer states that the assumption becomes more plausible as the number of variables included in the imputation model increases (Schafer, 1997). We will assess MAR and verify that there is no reason to think the missing-at-random assumption is violated using the `mi misstable patterns` command specified for the variables to be included in the multiple imputation. The second assumption is that of multivariate normality. However, according to Schafer (1997), inferences based on multiple imputation can be robust to departures from the assumption if the amount of missing data is not large.

The `mi` set of commands (`mi set`, `mi impute`, and `mi estimate`) will be used for the multiple imputation procedure. To allow results to be reproducible, a random-number seed will be set. M=10 imputed datasets will be created.

For participants that have complete medical record for the study period (i.e. `conservative=1`, `ltfu_28!=.` and `ret_time_28!=0`), we will also descriptively present the following by ITT intervention arm:

- `n_visits`=number of clinic visits attended during the study period
- `n_missed_28`=Number of clinic visits missed by more than 28 days during the study period
- `mean_followup_mo`=Mean months of follow-up time during the study period

## Objective 2.

To examine the association between treatment exposure and secondary outcomes of social support, HIV knowledge and treatment literacy, adherence and viral suppression, we will conduct significance testing using two-sided tests, with an alpha of 0.05. To examine the relationship between treatment exposure and social support, a continuous variable, we will conduct a t-test using treatment exposure (`group`) and change from baseline to endline in social support score (`ss_avg_chng`). We will similarly examine the relationship between treatment exposure and HIV knowledge by conducting a t-test using treatment exposure (`group`) and change from baseline to endline in total knowledge score (`know_chng`).

For adherence and viral suppression at endline, both of which will be dichotomized, we will conduct chi-square tests. We will also explore associations between treatment exposure and secondary outcomes using multiple linear regression models:

### 1. Social support

Model:	Multiple Linear Regression
Outcomes:	Change in social support score from baseline to endline ( <code>ss_avg_chng</code> , individual sub-scales)
Exposures:	Study group (intervention v. comparison)
Covariates:	Age, sex, education at baseline, depression score at baseline, social isolation score at baseline

### 2. HIV knowledge/treatment literacy

Model:	Multiple Linear Regression
--------	----------------------------

Outcomes: Change in knowledge score from baseline to endline (know\_chng)

Exposures: Study group (intervention v. comparison)

Covariates: Age, sex, education at baseline

### 3. Self-reported adherence

Model: Multiple Logistic Regression

Outcomes: Adherence at endline

Exposures: Study group (intervention v. comparison)

Covariates: Age, sex, education at baseline, household hunger score at baseline, time on ART at baseline, social support sub-scales, adherence at baseline

### 4. Viral load

Model: Multiple Linear Regression

Outcomes: Viral load at endline

Exposures: Study group (intervention v. comparison)

Covariates: Age, sex, education at baseline, household hunger score, adherence, time on ART at baseline, social support sub-scales

We will check that the following assumptions of multiple regression are met:

- Independence of observations (i.e. independence of residuals)
- Linear relationships between dependent variable and each independent variable, and between dependent variable and the independent variables collectively. Method: Scatterplots
- Homoscedasticity – variance does not change along line of best fit. Method: Plotting studentized residuals against unstandardized predicted values
- No multicollinearity. Method: Inspect correlation coefficients and VIF values
- No significant outliers, highly influential points, etc. Method: Exploratory data analysis
- Normal distribution of residuals. Method: Histogram with normal curve fitted, and normal p-plot of residuals

If any of the variables specified above have  $\geq 5\%$  missingness, a multiple imputation model will be run as a secondary analysis. The imputation model will include additional variables that are theoretically related to the variables being imputed (Chantala & Suchindra; Stuart, 2009; White, 2011):

Model 1: Age, sex, education at baseline, depression scores, social isolation scores

Model 2: Age, sex, education at baseline

Model 3: Age, sex, education at baseline, household hunger score at baseline, social support sub-scales

Model 4: Age, sex, education at baseline, household hunger score, adherence, social support sub-scales

Although there is some controversy as to whether to round categorical variables after imputation (Allison, 2005), we will round the values in each variable in order to facilitate interpretation of results and given expected very small proportion of missing data.

The multiple imputation procedure involves 3 phases (Rubin, 1996; Yuan, 2000):

1. The missing data are filled in  $m$  times to generate  $m$  complete data sets.
2. The  $m$  complete data sets are analyzed by using standard procedures.
3. The results from the  $m$  complete data sets are combined for inference.

The `mi` set of commands (`mi set`, `mi impute`, and `mi estimate`) will be used for the multiple imputation procedure. To allow results to be reproducible, a random-number seed will be set. M=10 imputed datasets will be created.

### Objective 3.

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

1. Establish a statistically significant relationship between the independent variable (intervention) and the dependent variable (retention in care)
2. Establish a statistically significant relationship between the mediator (social support) and the independent variable (intervention)
3. Establish a statistically significant relationship between the mediator (social support) and the dependent variable (retention in care)
4. Demonstrate that the relationship between the independent variable and the dependent variable is significantly reduced when the mediator is added to the model. The significance of the mediated effect can be assessed using a statistical procedure known as the Sobel test <sup>58</sup>.

The hypothesis is:

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

Analyses will proceed as follows:

Step 1. Multivariable logistic regression to establish relationship between intervention and retention in care

Model: Multivariable Logistic Regression Model

Outcomes: Retention at endline (`ret_el=0` | `ret_el=1`). Participants that died or transferred out will be excluded from analysis.

Exposures: Study group (intervention v. comparison)

Covariates: Age, sex, education.

Step 2. Multivariable linear regression to establish relationship between social support (`ss_tot_chng`) and intervention (`group`)

Model: Multivariable Linear Regression Model

Outcomes: Social support (change `bl` to `el`)

Exposures: Time (pre v. post), study group (intervention v. comparison), and `time*group`

Covariates: Age, sex, education.

Step 3. Multivariable logistic regression to establish relationship between social support (`ss_tot_chng`) and retention in care (`ret_el=0` | `ret_el=1`)

Model: Multivariable Linear Regression Model

Outcomes: Retention at endline (`ret_el=0` | `ret_el=1`). Participants that died or transferred out will be excluded from analysis.

Exposures: Time (pre v. post), social support, and `time*social support`

Covariates: Age, sex, education.

Step 4. Multivariable logistic regression to demonstrate strength of relationship between intervention (group) and retention in care (ret\_el=0| ret\_el=1) is diminished when social support (ss\_tot\_chng) is added to the model. To test the potential mediating effect of social support on the relationship between the intervention and primary outcome, we will estimate the mediation effects using the STATA `medeff` command, which is an update to the Sobel test and estimates the average causal mediation effect, direct effects, and total effect for a potential mediator.

Model: Multivariable Logisitic Regression Model

Outcomes: Retention at endline (ret\_el=0| ret\_el=1). Participants that died or transferred out will be excluded from analysis.

Exposures: Time (pre v. post), study group (intervention v. comparison), social support, and time\*social support

Covariates: Age, education.

The following commands will be used:

```
medeff (regress M group x) (regress Y group M x), [sims(integer)  
seed(integer) vce(vcetype) Level(#) interact(varname) ] mediate(M)  
treat(T)
```

where:

M - potential mediator (ss\_tot\_chng)

x - pre-treatment variables

italicized components are optional:

sims - number of simulations for approximation of parameter uncertainty,  
default is 1000

seed - random number seed

vce - standard error specification - robust, cluster clustvar, bootstrap,  
or jackknife

level - confidence interval, default 95

The average causal mediation effect, direct effects, and total effect are stored in scalars.

We will then conduct a sensitivity analysis to quantify the degree of sequential ignorability violation as the correlation between the error terms of the mediator and outcome models, and then calculating the true values of the average causal mediation effect for given values of the sensitivity parameter rho. The original findings are deemed sensitive if the true effects are found to vary widely as function of rho.

```
medsens (regress M T x) (regress Y T M x), [sims(integer) seed(integer)  
Level(#) graph] mediate(M) treat(T)
```

If any of the variables specified above (including the variables used to create the social support scales) have ≥5% missingness, a multiple imputation model will be run as a secondary analysis. The imputation model will include all variables included in the model as well as those that are theoretically related to the variables being imputed (Chantala & Suchindra; Stuart, 2009; White, 2011): Social isolation, depression, household hunger.

The multiple imputation procedure involves 3 phases (Rubin, 1996; Yuan, 2000):

1. The missing data are filled in m times to generate m complete data sets.
2. The m complete data sets are analyzed by using standard procedures.

3. The results from the *m* complete data sets are combined for inference.

The *mi* set of commands (*mi set*, *mi impute*, and *mi estimate*) will be used for the multiple imputation procedure. To allow results to be reproducible, a random-number seed will be set. *M*=10 imputed datasets will be created.

We will additionally run a second multiple imputation model to impute the social support sub-scale average scores, rather than the individual items, to assess the extent to which imputation at the variable level and at the score level varies.

#### **Objective 4.**

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

- Facilitator training:
  - Travel
  - Per diem
  - Venue rental
  - Printed materials
  - Other training materials
  - Refreshments
- Other non-training related or pre-implementation costs

Costs of implementation are those associated with carrying out the activity including:

- Monthly facilitator meetings
  - Transportation reimbursement
  - Refreshments
- Facilitator stipend
- Equipment
  - Phones for facilitators
  - Airtime/data bundles for facilitators
  - Phones for participants
  - Airtime/data bundles for participants

We will also calculate the unit cost per participant, by dividing the total cost by the number of study participants who were assigned to a Facebook group, as well as the unit cost per participant retained, by dividing the total cost by the number of study participants who were assigned to a Facebook group and were retained in HIV care at endline.

#### **Objective 5.**

Participant engagement will be summarized descriptively by session and group using data collected by the Grytics software. We will summarize the number of participants' posts and comments, as well as "likes" and other reactions ("love," "haha," "sad," etc.) to scheduled posts, by intervention session, week, and group. Participant perspectives on intervention content and delivery from structured questionnaires conducted at endline will also be summarized using descriptive analyses including means and frequencies. Qualitative

analysis of in-depth interviews with participants at endline will provide further context and detail about participants' thoughts on the intervention and its usefulness.

#### Objective 6.

Intervention fidelity will be assessed descriptively by presenting the extent to which facilitators were able to post correct messages, hold scheduled group chats, and conduct other activities as directed in the intervention guide. Data on each facilitator's posts, comments, and other activity will be collected by the Grytics software and will be presented by facilitator, scheduled activity, intervention group, and session. Facilitators' perspectives on session topics and session-specific activities and the ease of delivering intervention content will be assessed through qualitative analysis of in-depth interviews with facilitators. Similarly, facilitator perspectives on the usefulness of the intervention guide and the time-burden required to deliver the intervention will be assessed through in-depth interviews with facilitators.

Concept/variable	Measures	Source of data	Type of data analysis
<b>Objective 1:</b> To test the effectiveness of a structured online support group to retention in HIV services among YLHIV.			
Retention in HIV services	Dates of clinic visits during study Questions regarding clinic visits, missed visits, reasons for missing visits	Medical record data  Structured questionnaires	Kaplan-Meier cumulative retention probabilities, log-rank test
<b>Objective 2:</b> To examine the effect of the online support group on social support, HIV knowledge and treatment literacy, and ART adherence among YLHIV.			
Social support	MOS-SSS items	Structured questionnaires	t-test
HIV knowledge and treatment literacy	HIV knowledge questions	Structured questionnaires	t-test
ART Adherence	AACTG Adherence Assessment items  Viral load	Structured questionnaires  Medical record data	Chi square test
HIV-related Stigma	12-item stigma scale	Structured questionnaires	t-test
Substance use	AACTG Adherence Assessment items	Structured questionnaires	Chi square test
<b>Objective 3:</b> To test the potential mediating effect of social support on the relationship between the intervention and primary outcome.			
Treatment exposure	Assignment to intervention or control	Based on study assignment	Causal mediation analysis
Social support	MOS-SSS items	Structured questionnaires	



Retention in HIV services	Questions adapted from AACTG Adherence Assessment items  Dates of clinic visits during study	Structured questionnaires  Medical record data	
<b>Objective 4.</b> To document the costs of the intervention and calculate the unit cost per YLHIV retained. Intervention costs will also be descriptively compared to the costs of adolescent-focused, in-person support groups in the region.			
Cost to put the intervention in place	Training costs (travel, per diem, venue rental, materials)	Study financial records	Descriptive: unit cost
Implementation costs	Monthly facilitator meetings (transportation and refreshments)  Facilitator stipend  Equipment (phones) and supplies (airtime/data bundles)	SIDHAS and study financial records	Descriptive
Estimated in-person support group costs	Facilitator stipend  Venue costs  Transportation costs for facilitator and participants  Refreshments  Equipment/supplies for meetings	SIDHAS financial records  In-person support group reports (no individual-level data)	Descriptive
<b>Objective 5:</b> To document participant engagement and perspectives regarding the content and delivery of the intervention to inform scalability and sustainability.			
Engagement	Number of sessions in which participants actively post comments or reply to comments.  Number of comments per session.	Grytics	Descriptive
Perspectives on content and delivery	Perspectives on topic relevancy, clarity, usefulness.  Perspectives on content structure (components of sessions)	Structured questionnaires  IDIs	Descriptive  Qualitative
Perspectives on content and delivery	Perspectives on delivery frequency, facilitator engagement, medium of engagement.	Structured questionnaires  IDIs	Descriptive  Qualitative
<b>Objective 6:</b> To document implementation and health care provider and support group facilitator perspectives regarding intervention content and delivery to inform scalability and sustainability.			
Fidelity of implementation	Ability to push out correct messages, hold regularly scheduled group chats as directed in intervention guide.	Grytics	Descriptive

## VII. Additional analyses

We will assess the construct validity of the MOS-SSS and HIV Stigma Scale-12 through confirmatory factor analysis. Both scales have been developed in high-income countries and have been found to have good psychometric properties in other settings.

### Step 1. Correlation matrix

For each scale, we will first present a polychoric correlation matrix between all variables included in the scale, looking for medium to high correlations between items (see below), and ideally with few items having correlations smaller than  $\pm 0.1$ . We will then use the `matrix` command to store the correlation matrix.

STATA commands:

```
polychoric [var names]
matrix r=r(R)
```

### Step 2. Goodness-of-fit

MOS-SSS proposed factor structure:

- Tangible Support (latent construct=TAN)
  - [q309] Someone to help you if you were confined to bed
  - [q310] Someone to take you to the doctor if you needed it
  - [q311] Someone to prepare your meals if you were unable to do it yourself
  - [q312] Someone to help with daily chores if you were sick
- Emotional/Informational Support (latent construct=EMI)
  - [q301] Someone you can count on to listen to you when you need to talk
  - [q302] Someone to give you information to help you understand a situation
  - [q303] Someone to give you good advice about a crisis (serious problem)
  - [q304] Someone to confide in or talk to about yourself or your problems
  - [q305] Someone whose advice you really want
  - [q306] Someone to share your most private worries and fears with
  - [q307] Someone to turn to for suggestions about how to deal with a personal problem
  - [q308] Someone who understands your problems
- Affectionate Support Subscale (latent construct=AFF)
  - [q313] Someone who shows you love and affection
  - [q314] Someone to love and make you feel like you belong
  - [q315] Someone who hugs you
- Positive Social Interaction Subscale (latent construct=POS)
  - [q316] Someone to play with
  - [q317] Someone to get together with for relaxation
  - [q318] Someone to do something enjoyable with

HIV Stigma Scale-12 proposed factor structure:

- Personalized stigma (latent construct=PER)
  - [q214] Some people avoid touching me once they know I have HIV
  - [q215] People I care about stopped calling after learning I have HIV
  - [q216] I have lost friends by telling them I have HIV
- Disclosure concerns (latent construct=DIS)
  - [q217] Telling someone I have HIV is risky

- [q218] I work hard to keep my HIV a secret
- [q219] I am very careful who I tell that I have HIV
- Concerns about public attitudes (latent construct=PUB)
  - [q220] People with HIV are treated like outcasts
  - [q221] Most people believe a person who has HIV is dirty
  - [q222] Most people are uncomfortable around someone with HIV
- Negative self-image (latent construct=NEG)
  - [q223] I feel guilty because I have HIV
  - [q224] People's attitudes about HIV make me feel worse about myself
  - [q225] I feel I'm not as good a person as others because I have HIV

We will evaluate the goodness-of-fit of the proposed factor structures using CFI and/or RMSEA. We will report point estimates and confidence intervals and will accept the proposed factor structure if fit statistics are acceptable ( $CFI \geq 0.9$ ,  $RMSEA \leq .10$  or upper bound of RMSEA CI  $\leq .12$ )<sup>8</sup>.

STATA commands:

```
sem (proposed latent construct and factors here), from($r) stand
estat gof, stats(all)
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```

If the fit statistics are not acceptable, we will evaluate the model's modification indices to determine whether the factor structure can be revised slightly (for example, adding a path between terms if there is a theoretical or conceptual reason to support doing so). If this approach does not produce a model with acceptable fit statistics, we will conduct an exploratory factor analysis to evaluate alternative factor structures. Once arriving at a factor structure with acceptable fit statistics, we will assess convergent and discriminant validity by assessing whether the scales are correlated to items that should hold similarities (i.e. social isolation, depression) and not correlated to items that should not (i.e. HIV knowledge). We will assess this descriptively through scatter plots and test these

Secondarily, we will assess the relationship between the scale and the primary outcome. We hypothesize the following:

- MOS-SSS
  - Positive relationship between change in MOS-SSS score and retention
- HIV Stigma Scale-12
  - Negative relationship between change in HIV Stigma Scale-12 (higher scores indicate higher stigma) and retention

If any of the variables specified above have  $\geq 5\%$  missingness (missing or refused), a multiple imputation model will be run as a secondary analysis. The imputation model will include additional variables that are theoretically related to the variables being imputed (Chantala & Suchindra; Stuart, 2009; White, 2011): Age, sex, education at baseline, depression, social isolation, HIV knowledge/treatment literacy.

Although there is some controversy as to whether to round categorical variables after imputation (Allison, 2005), we will round the values in each variable in order to facilitate interpretation of results and given expected very small proportion of missing data.

The multiple imputation procedure involves 3 phases (Rubin, 1996; Yuan, 2000):

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<sup>8</sup> RMSEA is a measure of the average of the residual variance and covariance; good models have RMSEA values that are at or less than 0.08. CFI is an index that fall between 0 and 1, with values greater than 0.90 considered to be indicators of good fitting models (Hu et al., 1999.). For the purposes of this analysis we will use slightly less stringent cutoffs.

1. The missing data are filled in m times to generate m complete data sets.
2. The m complete data sets are analyzed by using standard procedures.
3. The results from the m complete data sets are combined for inference.

The `mi` set of commands (`mi set`, `mi impute`, and `mi estimate`) will be used for the multiple imputation procedure. To allow results to be reproducible, a random-number seed will be set. M=10 imputed datasets will be created.

## VIII. Qualitative analysis

All qualitative interviews will be audio-recorded and transcribed in English for analysis. For qualitative data from open-ended questions with YLHIV as well as qualitative data from IDIs with YLHIV, 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.

### Bibliography

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

Hu L, Bentler PM. Cutoff criteria for fit indices in covariance structure analysis: conventional criteria versus new alternatives. *Struct Equ Modeling*. 1999;6:1–55.)