SUUBI4STIGMA: ADDRESSING HIV-ASSOCIATED STIGMA AMONG ADOLESCENTS

National Clinical Trial (NCT) Identified Number:
NCT04528732

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Sponsor:
Washington University in St. Louis

Grant Title:
Suubi4Stigma: Addressing HIV-Associated Stigma Among Adolescents

Grant Number:
R21MH121141

Funded by:
National Institute of Mental Health

Version Number: V.1.0
20201007

Approved:
October 7, 2020

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Funding: National Institute of Mental Health (NIMH)

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A. SIGNIFICANCE

A.1. HIV Prevalence. Globally,1.8 million children<15 years are living with HIV.[42] Sub-Saharan Africa (SSA), is heavily burdened by HIV, with 85% of new infections among adolescents happening in the region.[43] Within SSA, Uganda has an HIV prevalence of 7.2% among 15-49 year-olds, with higher prevalence in Masaka (12%) .[2,3] **Uganda** also reports unprecedented numbers of HIV-infected children, with close to 150,000 children (ages 0-14) living with HIV (CLWH).[44] While availability and access to free ART has decreased child mortality[45] it has increased the likelihood that more CLWH will transition into adulthood with HIV, a chronic, highly stigmatized illness.[47-49] Unfortunately, the stigma they experience results in a lower quality of life. Yet, stigma-reduction interventions targeting CLWH and their families in SSA are nonexistent.[34,35]

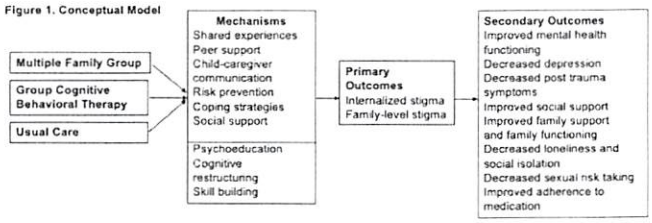
A.2. HIV-related Stigma and Associated Outcomes. Among people living with HIV (PLWH), stigma is a common experience associated with public blame and moral condemnation for contracting the infection.[9-11] Stigma is one of the greatest obstacles to slowing the spread of HIV, by perpetuating a culture of silence and fear, and preventing individuals from testing and seeking health care.[12] Stigma can be manifested internally based on perceived negative public attitude, encompassing feelings that the self is reprehensible, damaged and defective, associated with depression and PTSD,[15,16] feelings of loneliness and social isolation,[18-20] poor treatment and adherence,[16,21,22] HIV-related physical health,[23] HIV sexual risk behavior,[16] and increases in the risk of loss to follow up among PLWH,[50] including CLWH. Stigma can also be manifested externally through negative stereotypes (sexual risk taking behaviors), prejudice (fear, aversion, hatred), and discrimination, all of which create social barriers, including access to healthcare.[51] Moreover, many CLWH live with extended family members after losing their parents to HIV, where stigma is perpetuated through rejection, verbal insults, avoidance and ostracism due to unfounded fears of infection.[53-54] Family members are often condemned and stigmatized in similar ways, by virtue of their association with an HIV infected family member. [24-27] Stigma at the family-level may be manifested through gossip, name calling, rejection and social isolation, loss of social support, and harassment.[24-27] Family members are often held accountable for not preventing the perceived immoral behaviors of the HIV infected family member –leading to feelings of failure, anger, guilt and shame. [24] Such feelings negatively affect family caregiving roles, family functioning, and HIV health outcomes for PLWH, including CLWH. Due to this environment, CLWH may lose out on developing strong attachment bonds with family members and fail to develop a positive self-concept.Unsupportive social environments increase the risk for mental distress, including depression and trauma symptoms. It is critical, therefore, to develop HIV stigma-reduction interventions to improve life satisfaction, family functioning, and reduce the potential spread of HIV.

A.3. The Potential Role of Family Members in Addressing HIV/AIDS-associated Stigma among CLWH. The proposed study seeks to reduce HIV/AIDS-associated stigma (both internalized and family-level) and its negative impact on children and adolescents (10-14 years). Adolescence is a period of multiple vulnerabilities marked by the onset of physical and emotional maturation accompanied by the challenges of adapting to social, emotional, and cognitive changes.[38,56] Hence, a young person needs additional support, including emotional support and acceptance from family and community members. Yet, many CLWH cannot count on the "normal" transition to adolescence due to stigma where community and family members ostracize them for being HIV positive,[55 38, 58-62] and where family members suffer the same treatment due to their association with CLWH. Thus, understanding the role of family members, and involving them in the design and implementation of family-level HIV-related programs and interventions for CLWH is essential to their success.

A.4. Multiple Family Groups (MFG) within Communities. Families' protective roles in influencing children's behavior and mental health have been well documented.[63-65] Studies have documented that quality of family relationships predicts child mental health functioning and overall adjustment, and that when families are consistently involved in children's lives, they experience a more positive transition through adolescence.[66,67] Parental skills have been associated with young people's psychological adjustment, less risky sexual behavior, and less susceptibility to peer pressure.[68-70] Moreover, parent-child communication and involvement may be adversely affected by stigma. Yet, children with more frequent and open communication with parents have been shown to have better psychological adjustment.[71-75] Therefore, family support strategies, including MFGs, may strengthen the functioning of families, hence addressing individual and family-level stigma.

A.5. Existing HIV Stigma Interventions Primarily Target Non-Infected Populations (NIP). The negative impact of HIV/AIDS-associated stigma has been well-documented. Yet recent reviews found that stigma

reduction interventions for CLWH in SSA are almost non-existent.[34,35] Existing interventions focus on reducing fear of HIV infection among NIP,[35] as they interact with PLWH. For example, of 48 stigma reduction interventions, only three aimed to reduce stigma among PLWH in SSA.[76,77] None targeted CLWH, nor assessed the impact of stigma reduction on HIV-related outcomes.[25] This study offers an opportunity to develop a culturally acceptable and effective family-level intervention to address HIV/AIDS-associated stigma and its impact on CLWH's wellbeing in SSA.



A.6. Theoretical Framework. The HIV Stigma Framework[36] suggests that HIV stigma impacts PLWH via distinct HIV stigma mechanisms of internalized, anticipated, and enacted HIV stigma. Anticipated and enacted HIV stigma involve experiences with others.[26, 37] Internalized stigma –the focus of this study, involves endorsing negative feelings and beliefs associated with HIV and applying them to the self. Family members of PLWH are also subjected to and experience stigma via similar mechanisms. Within this framework, MFG provides opportunities for parents and children to communicate in a safe setting. It focuses on addressing internalized and family-level stigma by normalizing shared experiences with other families,[78] foster peer support and family communication, facilitate optimism and morale, and enhance interpersonal and coping skills.[78] On the other hand, G-CBT for stigma, addresses internalized stigma through the core components of psychoeducation, cognitive restructuring, and skill-building to increase adaptive coping mechanisms.[79] These mechanisms may impact a range of psychological, behavioral, and health outcomes for CLWH and their families (Fig. 1).

B. INNOVATION

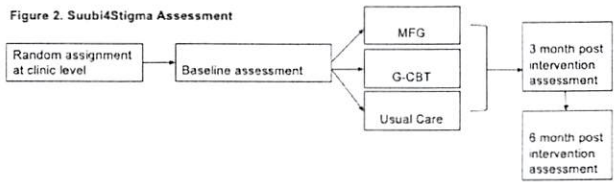
This study innovates in five complementary ways: 1) HIV/AIDS stigma-reduction interventions targeting CLWH in SSA are almost non-existent.[34, 35] This study will generate data driven knowledge to address HIV/AIDS-associated stigma among CLWH and within their families. 2) The study will apply and compare two innovative theoretically guided interventions G-CBT vs MFG,[41,80-82] to address HIV-associated stigma. 3) The MFG approach is culturally consistent with SSA's collective approach of families raising children "together," which strengthens its appeal to communities and its likelihood of success in addressing both individual and family-level stigma. 4) Delivery of G-CBT, which will be facilitated by trained para-counselors, is an approach that has not been tested in this context and with this specific population. In Uganda, para-counselors are trained to assist with the psychological needs of individuals, including those related to HIV/AIDS and mental health.[83, 84] 5) Partnering with local institutions, including health clinics and community organizations, grounds the project with a practical understanding of the needs of CLWH in Masaka, a region hardest hit by the HIV/AIDS (prevalence of 12% vs. 7.3 national average).[3] *Suubi4Stigma* makes use of existing community institutions to deliver its intervention, to building capacity and ensure eventual scale-up and sustainability.

C. APPROACH

C.1. Preliminary Studies. This study is informed by findings and lessons learned from the investigative team. **Dr. Nabunya (MPI)** is a new investigator with extensive training and experience conducting research in Uganda among children and adolescents affected by HIV/AIDS. **Drs. Nabunya and Ssewamala (MPI)** have collaborated on several NIH-funded studies (Suubi-R21MH076475; Suubi-Maka R34MH081763; Bridges-R01HD070727). **Dr. Ssewamala (MPI),** served as the PI on four randomized control trials focused on children affected by HIV/AIDS in Masaka (Suubi-R21MH076475; Suubi-Maka-R34MH081763; Bridges- R01HD070727; Suubi+Adherence R01HD074949). These studies applied principles of MFGs as the delivery platform for the interventions. Study findings indicate improved social, economic, health and mental health outcomes for children and adolescents affected by HIV/AIDS and their caregivers.[57-62, 85-91] **Dr. Sensoy Bahar (Co-I)** has extensive expertise in qualitative research methodologies, including design, data collection, and analysis skills. **Dr. Mugisha (In-country PI)** has extensive expertise in mental health (including CBT intervention) and implementation of community based mental health programs. **Drs. Ssewamala and Sensoy Bahar** are currently implementing a NIMH-funded study (U19MH110001) that examines the implementation, effectiveness and sustainability of an MFG intervention for child behavioral challenges in Uganda, Ghana, and Kenya. **Dr.**

Trani (Co-I) has expertise in social exclusion, stigma, and mental health [92] (see team structure). **Dr. Neilands** is a biostastician and consultant on the proposed study who has worked with Dr. Ssewamala for over 10 years.

C.2. Study Overview. *Suubi4Stigma*, a mixed-methods sequential explanatory study,[93] will address the urgent need for theoretically and empirically informed interventions that seek to reduce HIV/AIDS-associated stigma and its negative impact on child health and psychosocial well-being. We will test the feasibility, acceptability and preliminary effects of the G-CBT versus MFG intervention, two evidence-based interventions that have, to date, been extensively used to address mental health functioning among children and adolescents. Specifically, clinics will be randomized to one of three study arms (see C.3). The conceptual model (Fig 1) specifies the expected relationship between the intervention arms, mechanisms and potential outcomes.



C.3. Research Design. We propose a three-arm pilot RCT evaluating the feasibility, acceptability, and preliminary impact of the G-CBT versus MFG interventions among 90 CLWH and their caregivers. Recruitment will utilize Dr. Ssewamala's existing relationships with medical clinics in Masaka. Nine clinics will be randomized to one of three study arms: 1) care as usual (n=3 clinics; 30 child-caregiver dyads); 2) G-CBT intervention + usual care (n=3 clinics; 30 child-caregiver dyads); and 3) MFG intervention + usual care (n=3 clinics; 30 child-caregiver dyads). Both treatment and control arms will be delivered over a 3-month period. Data will be collected at baseline (pre-intervention), 3-months and 6-months post-intervention initiation. Children in the same clinic will be assigned to the same study condition to avoid contamination (Fig.2).

C.3.1 Study Inclusion/Exclusion Criteria: *Inclusion criteria for children*: The target population for this study is CLWH enrolled in care at a health clinic that has partnered with ICHAD (Ssewamala et al.; Suubi+Adherence study). Child inclusion criteria are: 1) HIV+ status- defined as a child tested with confirmation by medical report and has been disclosed to; 2) prescribed ART; 3) living within a family (defined broadly - not necessarily with biological parents); and 4) ages 10 to 14. All eligible CLWH from a particular household will be enrolled in the study and will be assigned to the same study condition. *Inclusion criteria for parents/caregiving families*. Caregivers of CLWH who agree to participate in the study. *Exclusion criteria* includes a significant cognitive impairment of the child or parent that interferes with understanding the informed consent process. *Inclusion criteria for clinics*. Clinics registered and supported by the government to provide ART to CLWH in Masaka.

C.3.2. Research Setting: The child-caregiver dyads will be selected from 9 health clinics in the Masaka region where Reach the Youth-Uganda (RTY), our collaborating institution, collaborates with over 40 health clinics (see letters of support). Nine clinics will be randomly selected based on size (total number of CLWH served) and location (rural, semi-urban, urban).

C.3.3. Recruitment of Participants: Screening and Recruitment. Procedures tested in our previous studies (see C.1.) will be used. Participants will be identified and recruited from the healthcare clinics associated with RTY and ICHAD. A list of all eligible families will be created from medical records. Providers will present the project to adult caregivers of eligible children during appointments. If caregivers are interested, verbal consent to be contacted by research staff (on-site during clinics) will be requested (see human subjects sections). Informed Consent. During the face-to-face meeting, the child's primary caregiver will read and sign a standard consent form. In doing so, the caregiver will be consenting to participation for themselves and their child. Children will sign an assent form that will be read aloud verbatim. If either the child or the caregiver refuses to participate, they will not be enrolled. (see human subjects section). Enrollment. Dyads will be enrolled in one of the three study arms. Only children and their caregivers who meet inclusion criteria will be selected (See C.3.1.). For each of the 9 clinics, a list of "eligible participants" will be generated and used to randomly select 10 children (and their caregivers), constituting the "actual" participants for that clinic. For the qualitative component, dyads with the highest, medium, and lowest levels of attendance in two treatment arms (6 clinics) will be identified post intervention. Two families within each of these groups in the 6 treatment clinics will be invited to participate in qualitative interviews (2x3x6=36 dyads). This sampling method will ensure that participants with varying experiences are represented. This will allow us to identify common patterns and

variations in participants' experiences. The sample size will be sufficient for theoretical saturation,[93-96] and will allow for identification of common patterns and/or variations across participant experiences.

C.3.4. Study Arms: Control Arm: Participants in this arm will receive the traditional clinic intervention that focuses on testing services (National HIV & AIDS Strategic Plan 2016-2020). Currently, patients coming to the clinic receive testing and ART treatment as well as information about the disease management. Both children and caregivers receive this information.

Treatment Arm 1 (G-CBT): In addition to usual care, children in this arm will receive a 10-session G-CBT for HIV/AIDS-associated stigma. While G-CBT has not been tested in SSA to reduce HIV/AIDS-associated stigma, it has been found effective in reducing self-stigma among adults with mental illness both in the U.S. and other countries.[97-99] G-CBT has been widely used and found to be more effective than individual CBT on a range of mental disorders among children,[100-103] including a potential low-cost alternative to individual therapy in developing countries where access to psychotherapy is scarce due to its high cost.[104-105] G-CBT is likely to offer more opportunities for normalization, positive peer modeling, reinforcements, social support, exposure to social situations and feedback sources, given the context of shared experiences.[106-113] Within G-CBT, for stigma we will utilize core components of CBT (psychoeducation, cognitive restructuring, and skill-building to increase adaptive coping mechanisms):[79] 1) exploration of HIV's role and impact of stigma in CLWH's life; 2) use of cognitive restructuring to identify and address the negative stigma-associated beliefs, loss of self-worth, self-blame; and 3) skill-building around stress management and emotion-focused coping strategies to address negative feelings (e.g. assertiveness, relaxation skills and problem solving skills).[114] CBT typically has a cognitive component which involves helping the person develop the ability to identify and challenge unrealistic negative thoughts, and a behavioral component to promote helpful behavioral responses.[114] The research team will ensure: 1) 2) the developmental and cognitive adaptation of the content for children between 10-14 years, and 3) the cultural adaptation of the G-CBT to local context. Content will be tailored to match children's ability to comprehend and implement the therapeutic techniques, including age appropriate activities, child friendly materials, simplified language and visuals (e.g. cartoons),[115] less complex behavioral techniques and more support, structure and feedback.[116] In addition, the cultural adaptation is intended to enhance its treatment relevance, credibility, efficacy and effectiveness by aligning it to the socioeconomic situation, cultural beliefs, family, political and health systems in the region.[117-118] G-CBT's cultural adaptation will be ensured by intensive consultative meetings with experienced in-country mental health workers and community leaders, led by in-country PI Mugisha. G-CBT will be facilitated by trained para-counselors selected using an agreed upon criteria with the community. They will participate in a 5-day training and receive monthly group supervision. Each group will have 10 participants and will last approximately 1 hour. Caregivers will not participate in G-CBT. Sessions will be delivered twice a week, outside of school hours.

Treatment Arm 2 (MFG): In addition to usual care, children-caregiver dyads in treatment arm 2 will receive the MFG intervention. Rooted in family systems theory, structural family theory and social learning theory with elements of psychoeducation and social group work, MFG is a family-centered, group-delivered, evidence informed, strength-based 10-session (weekly) intervention for children whose families struggle with poverty and associated stressors,[78,85, 86, 89,119-123] and integrates components of existing evidence-based practices that successfully improve parental management, mental health promoting family processes, and family strengthening.[124-131] Specific MFG session content will draw on the current interventions implemented by ICHAD.[132,133] Sessions will focus on the core components of MFG, also known as 4Rs and 2S's (rules, responsibility, relationships, respectful communication, stress and social support). Sessions focused on HIV and stigma will be adapted from our Suubi curriculum and resources from the Ministry of Health. The protocols have been designed to provide opportunities during each session to directly apply content to the realities of family life, emergent cultural and values perspectives, as well as tailor messages to age of child.[80] These will include group activities, role plays, sharing experiences and family take home activities. Families (children and caregivers) will be combined into groups to promote communication and support within and among families. Each group will have no more than 10 families. Parent peers (n=6) and community health workers (n=6) already trained in MFG delivery focused on child behavioral health used for the SMART Africa-Uganda study (U19MH110001) and Suubi4Her study (R01MH113486) will be invited to participate and receive a refresher training focused on *Suubi4Stigma*'s new content. During MFG implementation, facilitators will receive 2 hours per month of group supervision across sites. Given the significant and protective role families play in children's

health and mental health (section A.4.), we expect that strengthening family functioning and dialogue by involving caregivers through MFG will lead to better child outcomes, including HIV/AIDS-associated stigma. MFG sessions will last approximately 1 hour and will be delivered twice a week, outside of school hours.

Table 1. Variables and Instruments

Variable	Measurement	Reliability	Time point
Demographics (Respondent: Adolescent)			
Gender, family composition/structure, income, caregiver education & employment	Socio-demographic questionnaire	n/a	B, 3, 6
Moderators			
Rural/urban/semi-urban; economic/household income; gender		n/a	B, 3, 6
Mechanisms of Change			
Shared experiences, peer and family support, family communication, interpersonal and coping skills	Semi-structured interviews	n/a	6
(Respondent: Adolescent)			
Mental Health Functioning	Youth Self-Report [139] Adapted Child Depression Inventory [135] Adapted Tennessee Self-Concept Scale (TSC-2)* *(tested in Suubi Studies)* [97,42,100,137,138] Beck Hopelessness Scale [139]	n/a 0.65 0.81 0.79	B, 3, 6
Post-Traumatic Stress Disorder	The Child PTSD Reaction Index [140]	0.88	B, 3, 6
Family Support	Social Support Behaviors Scale (SS-B) [141]	0.77	B, 3, 6
Social Support	Friendship Qualities Scale [142,143]	0.81-0.88	B, 3, 6
Stigma and Shame	The Shame Questionnaire [144,145] Stigma-by-association scale for children [146] HIV Stigma mechanism measure [17]	0.84; 0.89-0.90 0.87-0.89	B, 3, 6
Medication Adherence	Youth Self Report, [147] Viral loads Pill Counting, Pharmacy Records	n/a n/a	B, 3, 6 Ongoing
Loneliness and Social Isolation	UCLA Loneliness Scale Version 3 [148] The Lubben Social Network Scale (LSNS-18) [149]	0.89 -0.94	B, 3, 6
Sexual risk taking	Adapted Youth AIDS Prevention Project used in CHAMP [9, 10] Questions adapted from Auslander et al. [151] & Slonim-Nevo et al. [152]	n/a 0.72	
Intervention feedback	Semi-structured interviews	n/a	6
(Respondent: Caregiver)			
Stigma and Shame	AIDS-related stigma scale [153] HIV/AIDS Stigma and Discrimination [154]	0.75 0.72-0.85	B, 3, 6
Family Relations	Family Environment Scale/Family Assessment Measure [112,155,156]	0.54-0.87	B, 3, 6
Intervention feedback	Semi-structured interviews	n/a	6
COST			
Cost of staff time, supplies, overhead for mental health and economic interventions	Project records; Admin. review	n/a	ongoing

C.3.5. Assessments (Aim 1): Participants will be interviewed at baseline and post-test (3 & 6-months post-intervention initiation). Child and caregiver assessments (Table 1) will be conducted by a trained research assistant at each clinic (in a private location) and take approximately 60 minutes with a 10-minute break and will be administered in Luganda, local language of the region. Assessments will be translated and back translated into the local language from English by a certified translator. The research team, including the MPIs, are fluent in Luganda, which will be helpful in cross-checking the translated documents. Measures have been validated in SSA. Content and construct validity will be conducted for all measures to ensure cultural validity. Process measures will be used to monitor fidelity and intervention implementation.

Intervention Delivery Fidelity. Independent observations using rating scales will be made with a random sample of 60% of intervention sessions for both G-CBT and MFG. These data will be used to assess: 1) the relationship between planned and actual implementation; 2) the integrity of implementation and; 3) how were altered to maximize effectiveness and acceptability.

Implementation/Evaluation. Having two facilitators per group will allow for detailed process notes on the implementation process and balancing "fidelity" and "fit" to local culture. Changes from the planned curriculum will be examined using process notes. Caregivers/children will report monthly on factors that affect their participation using an implementation checklist that assesses satisfaction and obstacles to program delivery: 1) factors interfering with youth or family participation (e.g. time, other priorities, stigma); 2) concrete obstacles (e.g. weather, transportation); and 3) site and staffing obstacles (e.g. time constraints).

C.3.6. Semi-structured Interviews (Aim 2). These interviews will: 1) Explore participants' intervention experiences and perceived impact of the intervention on change mechanisms (including shared experiences, peer and family support, family communication, interpersonal and coping skills); and 2) Identify multi-level facilitators and barriers to G-CBT and MFG intervention, implementation and participation. Participants in the two treatment arms will be asked for feedback on intervention acceptability and relevance via semi-structured interviews upon intervention completion. Semi-structured in-depth interviews will be conducted with caregivers and CLWH separately at post intervention for each treatment arm. The interviews will provide rich data on participants' processes and experiences with the program; processes behind key outcomes, mechanisms of change and mediating variables; and potential individual, family, contextual, programmatic, and structural factors affecting their experiences. At the end of the intervention, all facilitators will also be interviewed to gain a deeper understanding of implementation patterns and processes, including their views on sustainability. Interviews will be conducted in English or Luganda. Questions will be translated/back-translated by two team members fluent in both languages. Interviews will last about 1 hour and will be audio-taped.

C.3.6. Data Analysis

Aim 1: *Feasibility and Acceptability.* a) *Feasibility.* We will monitor recruitment rates and staff level of effort, number of screenings conducted, proportion eligible and agreed to enroll. Enrollment of 70% or higher will be

considered feasible.[159] We will also record the number of rescheduled, cancelled and missed sessions and assessments to inform estimation of staffing needs and retention protocols for a subsequent trial.
b) *Acceptability.* We will adapt satisfaction surveys, (e.g., the Client Satisfaction Questionnaire (CSQ-8)) to assess acceptability.[160] Items include: "How satisfied were you with the program?", "How helpful was the program in addressing HIV-associated stigma?" and "How likely are you to recommend this program to other families with CLHA?" Given the modest sample size, quantitative analyses of intervention data will be largely descriptive and concentrate on tabulating and summarizing satisfaction outcomes. In regards to hypotheses and methods for primary preliminary/exploratory analyses *to assess study feasibility*, we expect that: **H1**: Following intervention, relative to the control group, participants in both treatment arms (G-CBT and MFG) will have: **H1a**: lower mean count of children reporting HIV/AIDS-associated stigma; **H1b**: lower mean levels of reported HIV/AIDS-associated stigma and improved child psychosocial functioning; **H1c**: lower mean levels of reported child mental health challenges; **H1d**: higher mean levels of adherence. **H2**: Following intervention, relative to the CBT intervention arm, participants in the MFG intervention will have: **H2a**: lower mean count of children reporting HIV/AIDS-associated stigma; **H2b**: lower mean levels of reported HIV/AIDS-associated stigma and improved child psychosocial functioning; **H2c**: lower mean levels of reported child mental health challenges; **H2d**: higher mean levels of adherence. Children will be the unit of analysis for these primary preliminary analyses. We will plot means by group over time to describe overall patterns of change. We will use linear mixed models (LMMs) to evaluate the proposed hypotheses. We will fit LMMs to ensure that all requisite information is available to perform the types of analyses typically undertaken in a formal RCT of intervention efficacy and to obtain valuable effect size information. LMMs will include random intercepts for clinic membership and random intercepts and slopes for subjects (three-level models). Due to the modest sample size, significance testing will be de-emphasized. Similarly, although the modest sample size precludes formal investigation of moderation, we will use the same LMM approach described above to compare children across study arms over time on the moderators listed in Table 1. Additional analyses will consider the role of child gender as a moderator in line with NIH guidelines addressing the importance of sex and gender as critical moderators. These moderation analyses will be secondary exploratory analyses. Additional exploratory analyses will study parents and children jointly as the unit of analysis via dyadic analysis methods such as actor-partner and means-and-deviation models to quantify parent vs. child stigma effects and between- vs. within-dyad effects on mental health outcomes.[161,162]

Power Analyses. Although the study purpose is to determine preliminary feasibility and acceptability, rather than conduct formal hypothesis tests, we conducted several power analyses using NCSS PASS to supply additional information. Our power analyses assume α=.05, power=.80, 81 participants retained at the final time point following 10% estimated attrition, and a clinic-based conservative unconditional ICC of 9.3% based on our previous SUUBI study of mental health in Uganda children.[163] For the target enrollment proportion of 70% to assess feasibility, the width to the limit of the confidence interval is 27.9% (standardized distance: .32). For continuous standard normal variables to assess acceptability (e.g., CSQ-8), the distance from the mean to the confidence limit is .30. These distances to confidence limits are between small (.20) and medium (.50) effect sizes. For preliminary efficacy exploratory analyses with two time points and paired comparisons of two out of the three groups at 81/3=27 participants per group (N=54 per comparison), minimum detectable standardized mean differences for continuous outcomes ranged from .79 to .97 for within-subjects correlations r ranging from .20 to .80. In sum, our study is powered to detect small-medium distances to confidence limits for descriptive statistics and large longitudinal analysis effects, though hypothesis testing is not the study focus.

Aim 2. Qualitative Data Analysis. All interviews will be audio-taped, transcribed and uploaded to QSR NVivo12 analytic software. Transcripts will be reviewed by the research team to develop a broad understanding of the content and identify topics of discussion and observation. Analytic induction techniques[164] will be used for coding. For initial coding, randomly selected ten transcripts will be read multiple times and independently coded by the team using a priori (from the interview guide) or emergent themes (open coding).[165] Broader themes will be broken down into smaller, more specific units until no further subcategory is necessary. Analytic memos will be written to further develop categories, themes, and subthemes, and to integrate the ideas that emerge from the data.[165, 166] The codes and the inclusion/exclusion criteria for assigning a specific code[167] will be discussed as a team to create the final codebook in NVivo. Each transcript will then be coded independently by two team members using the codebook to establish inter-coder reliability. A level of agreement between 66 to 97% indicates good reliability.[168] Disagreements will be resolved through

discussions in team meetings. The secondary analysis will compare themes within (including children versus caregivers) and across the two treatment groups to identify patterns, differences, and relationships among findings. Facilitators' data will be analyzed using the same procedures and will be compared and contrasted to participant data. To further ensure rigor, member check focus groups[169] to explore the opinions, beliefs and attitudes of participants, data audit trail, and analytic memos will be used.[96]

Data Integration and Triangulation: Although the qualitative and quantitative data analyses will be done separately, findings will be integrated at the interpretation and discussion stages. Conclusions and inferences will be synthesized for a more contextualized and thorough understanding of change mechanisms and the preliminary impact of each intervention arm. Qualitative and quantitative data will serve two purposes: 1) Complementarity; and 2) Expansion.[93,170, 171] Qualitative findings will be connected to quantitative findings where the former will provide explanations and context for findings produced by the latter. Moreover, the qualitative findings will complement our understanding of attendance and participant satisfaction for each treatment arm.

C.4. Study Timeline (Over 24 months): Study preparations, adaptation/refinement of interventions and instruments (months 1-3); Participant recruitment and baseline assessments (months 4-6); Intervention delivery (months 7-9); Post intervention assessments and follow-up (months 10-15); Data entry, analysis, report writing and dissemination of findings (months 4-24) (see study timeline).