Assessing the Feasibility of Economic Approaches to Prevent Substance Abuse Among Adolescents

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Study Protocol

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SPECIFIC AIMS

Adolescent alcohol and drug use (ADU) is a growing public health concern globally, especially in low resource settings such as Sub-Saharan Africa (SSA), where the epidemics of ADU and HIV/AIDS are co-occurring. ADU plays a significant role in the epidemiology of HIV among adolescents and young adults in SSA, who accounted for over 40% of new infections globally in 2019.[1] ADU is associated with higher rates of HIV risk behaviors such as condomless sex,[2] and lower rates of HIV testing.[3-5] Among adolescents and youth living with HIV (AYLHIV), ADU is a significant barrier to achieving positive HIV treatment outcomes including enrollment and retention in HIV care,[6] adherence to antiretroviral therapy,[7-9] and achieving viral suppression.[8,10] Among HIV-infected adults, it has been shown that alcohol and drug misuse increase AIDS mortality, even among virally suppressed and medication adherent persons.[11-13] Uganda, one of the poorest countries in SSA, has high rates of HIV/AIDS (6.2%)[14] and alcohol use,[15] and illicit drug use is on the increase.[16] Previous studies have reported high rates of alcohol consumption among adults living with HIV.[17-19] Fishing communities – a key vulnerable population in Uganda[20] - have high levels of ADU including among adolescents and youth,[16,21-23] which lead to poor HIV prevention and care outcomes.

ADU typically onsets in adolescence as an experimental behavior that may escalate into problematic use and disorders.[24,25] In addition to mental health problems,[26] poverty,[27-29] poor parental supervision,[30] community norms related to drug use,[31,32] and developmental risk factors such as risk-taking, social roles and social transitions influence risk for ADU.[33-35] AYLHIV in particular experience numerous stressors (e.g. bereavement, HIV stigma and discrimination, death, worry, and chronic pain)[36-38] and mental health problems (e.g. depression and hopelessness),[39-42] which increase their risk for ADU. Consistent with motivational theories of alcohol and drug use,[43-47] AYLHIV may use alcohol and drugs as a mechanism for coping with stress and mental health problems such as depression,[45,48,49] which are common among AYLHIV. Household poverty, which is rampant in AIDS-affected households,[50] is associated with an increased risk for ADU[51] and potentiates other risk factors such as stress and mental health problems to heighten the risk for ADU. Despite our knowledge of the higher risk for ADU among AYLHIV,[52-55] there is lack of evidence-based interventions targeting ADU risk among AYLHIV.

Efforts to prevent ADU are rooted predominantly in the substance use risk reduction/protection enhancement model[56] and require understanding of the risk and resilience factors for ADU. Only 10 ADU interventions have been evaluated in SSA: most have been ineffective in preventing or reducing ADU and none of these interventions has targeted AYLHIV. The majority of these interventions, which are largely school-based, focus on individual and intra-personal risk factors for ADU, without attention to structural risk/resilience factors for ADU. The few existing studies on ADU among AYLHIV have been conducted in high-income countries. These studies focus on younger adolescents yet ADU typically emerges and escalates in middle-late adolescence. Further, these studies rely on self-reports of ADU which can be undermined by under-reporting of ADU. To address these challenges, we propose a study titled *Assessing the Feasibility of Economic Approaches to Prevention of Substance Abuse among Adolescents.* The study will investigate the epidemiology, underlying risk and resilience factors for ADU among AYLHIV and evaluate the effects of a economic empowerment intervention on ADU among AYLHIV. We propose to utilize biological measures of ADU to overcome challenges associated with self-reported ADU.

Study objectives

The proposed study will investigate the following specific aims:

Aim 1a. Examine the prevalence and consequences of ADU in a cohort of 200 AYLHIV (ages 18-24) seen at six (6) HIV clinics in southwestern Uganda. We will utilize adolescent self-reports and biological measures of alcohol and drug use (urine).

Aim 1b. Using a mixed methods approach, identify the multi-level (individual, interpersonal, community and structural) factors associated with ADU among AYLHIV

Aim 2: Using a subset of the sample, explore the feasibility and short-term effects of a economic empowerment intervention on ADU among AYLHIV.

Our long-term goal is to better understand the epidemiology and consequences of ADU among AYLHIV in high-risk environments and evaluate a culturally tailored intervention that could prevent harmful ADU and improve the overall and long-term health and well-being of AYLHIV. The proposed study will be conducted in fishing communities located in three districts of the greater Masaka region of southwestern Uganda - a region heavily affected by HIV (12% prevalence vs national average of 6.2%) and high rates of household poverty and

alcohol/drug use. The findings from this proposed study will contribute to our understanding of the epidemiology, risk and resilience factors and consequences of alcohol and drug use among AYLHIV, in order to inform the development of effective ADU prevention intervention. If warranted, these findings will inform the design of an R01 grant to examine the long-term effects of a family-based economic empowerment intervention on ADU among AYLHIV.

RESEARCH STRATEGY

A.1. SIGNIFICANCE.

Adolescent alcohol and drug use (ADU) is a significant public health challenge in SSA. About 41.6% of adolescents in SSA have used at least one psychoactive agent.[57] Alcohol is the most commonly used drug;[57] one third of adolescents have used alcohol in their lifetime[57,58], 22.5 million are current drinkers, and over 50% engage in heavy episodic drinking.[58] Alcohol use nearly doubles during the transition to adulthood, from 21.4% of adolescents aged 16-19 to 34.1% of young adults aged 20-24 years.[58] Uganda, one of the poorest countries in SSA, has the second highest rate of per capita alcohol consumption in SSA (15.1 liters of pure alcohol vs regional average of 6.2 liters of pure alcohol).[15] Over 30% of Ugandan adolescents and youth have used alcohol[59,60] and about 20% misuse alcohol.[16] These estimates reach even greater magnitudes in the country's fishing villages – a key HIV vulnerable population- where ADU is normative.[61-64] A few studies have assessed ADU among AYLHIV. A study conducted in Rwanda found that 61% of AYLHIV receiving medication from a clinic had drunk alcohol within 6 hours prior to having sex.[54] In South Africa, a prior study found that 53.8% of the male AYLHIV and 5% of female AYLHIV had ever used drugs.[65,66] In Uganda, a recent cross-sectional study of 479 adolescents aged 12 – 17 years found that 5.9% reported use of at least one psychoactive substance, including alcohol (4.3%), marijuana (2.1%) and other drugs (2.1%) such as cocaine, glue and heroine.[67] ADU is a key driver of new HIV infections and poor HIV care outcomes in SSA. It is associated with HIV risk behaviors such as increased sexual risk-taking,[33,34,68] unprotected sex,[2] early sexual debut,[69-71] an increased number of sexual partners,[2,69,70] resulting in transmission of HIV.[9,68,72,73] ADU is also associated with sub-optimal mental health e.g. depression[74-76] and suicidal ideation.[77] Among AYLHIV, ADU impedes adherence to anti-retroviral therapy (ART),[7-9] retention in care,[6] and viral suppression.[8,10] Among HIV-infected adults, ADU have been shown to increase susceptibility to AIDS mortality, even among HIV virally suppressed and medication adherent persons.[11-13]

AYLHIV are more vulnerable to ADU, which may affect their HIV care outcomes. Adolescence is a period characterized by exploration of new roles, identities, and behaviors including experimentation with ADU.[78] A multitude of factors influence ADU and these include individual factors (e.g. sensation seeking, impulsivity, mental health),[79-84] interpersonal factors (e.g. peer pressure, parental drug use, poor parental monitoring)[85-95] and structural factors (e.g. availability of alcohol and drugs, exposure to ADU marketing, community drug use attitudes, laws and policies).[85,90] AYLHIV, also experiment with ADU, which may escalate into problematic ADU. AYLHIV face numerous HIV-related psychosocial challenges including HIV stigma, bereavement, chronic pain, relationship stress and poverty, which heighten their risk for ADU.[96-98] Indeed, research reports indicate a higher burden of mental health problems among AYLHIV,[97,99-102] which may lead to ADU. The co-occurrence of mental health problems and ADU is common, including among AYLHIV.[103-110] Both ADU and mental health difficulties are associated with non-adherence to ART[100,111-113] and risky sexual behaviors among AYLHIV,[112,114-116] which could lead to secondary transmission of HIV and ART resistance due to non-adherence.[117-119] Poor mental health and poverty, which are rampant in poor countries, are significant risk factors for ADU. Poor mental health[106,120,121] and poverty[27-29] are rampant among HIV-affected households, and both are significant risks factor for acquiring HIV[122] and for poor HIV treatment outcomes.[123,124] AYLHIV living in poverty-stricken households face greater challenges in accessing and sustaining HIV treatment due to economic factors such as lack of transport to clinics[125,126] and inadequate meals to support medication adherence,[127-129] which could lead to psychological distress and consequently, ADU.[130] Poverty adversely affects the quality of family relationships including parent-child communication, involvement[131-133] and parenting skills,[134,135] which increases susceptibility to emotional and behavioral challenges and increased risk for ADU.[93,95,132,136-140]

Evidence-based culturally tailored interventions to prevent ADU in AYLHIV are lacking. Several studies have examined the risk and resilience factors for ADU[56] but few interventions targeting ADU have been tested in SSA. Only 10 ADU interventions have been evaluated in SSA[79,141-149] and only a few have been successful.[79,142,143,146,148,149] The majority have been implemented in school settings,[79,145-149] which may exclude adolescents in fishing communities that have high rates of school dropout. These interventions largely target

individual and interpersonal risk factors for ADU, with a focus on providing participants with information on ADU and its consequences, or building life skills. Only one intervention targeted the family[144] – an important developmental context for adolescents- with a focus on enhancing parenting skills. None of these interventions has targeted risk factors such as poverty and mental health that may undermine AYLHIV's coping skills and resources. Family-based economic empowerment (FEE) interventions have the potential to prevent ADU among AYLHIV by reducing poverty and its associated mental impacts, and also bolster AYLHIV and their families' resources to overcome the challenges associated with HIV. In our previous studies, we have utilized FEE strategies to reduce poverty, improve mental health and HIV care outcomes (e.g. medication adherence) among AYLHIV and other AIDS-affected adolescents in Uganda.[123,132,150-153] In this application, we propose to build on this growing evidence by examining the feasibility of utilizing FEE to address ADU among AYLHIV.

A.2. THEORETICAL FRAMEWORK. Our conceptual approach is informed by the socio-ecological model (SEM),[154] social causation and drift theories,[155] and asset theory.[156,157] We have applied the SEM as a basis for investigating the contextually relevant risk and resilience factors for ADU. SEM posits that environmental factors fall into four broad domains: micro-, meso-, exo-, and macro systems and interactions within and between these domains determine behavior. This model has demonstrated effectiveness in identifying risk and resilience factors for prevention planning and intervention for ADU.[158-162] Social causation and social drift theories suggests that problem alcohol drinking may be both a response to and driver of poverty.[163] Acute and chronic stress associated with living in a poverty-impacted environment increases the likelihood of ADU, which causes further material/economic deprivation, hence fueling the cycle of alcohol misuse, and contributing to downward social mobility. Research in Uganda has reported a higher burden of alcohol and drug abuse among poor populations,[164] and many poverty-impacted Ugandan households engage in informal alcohol production for income-generating purposes.[165] Impoverished youths are burdened with hopelessness due to lack of opportunities for improvement in their economic wellbeing.[166,167] As a result, for impoverished AYLHIV, they may be inclined to spend on instant pleasures such as alcohol and drugs as a coping mechanism since they are less likely to believe they can afford the costs associated with accessing and maintaining long-term care for HIV. Our proposed FEE intervention is based on Asset theory[168] and is intended to improve economic wellbeing and relieve poverty and its related consequences such as poor mental health,[169,170] and create a more hopeful/optimistic outlook for the future, thus reducing AYLHIV's engagement in risk-taking behaviors including alcohol and drug use. The proposed FEE will be one of the first studies to primarily examine the impact of FEE interventions on reducing ADU among AYLHIV in poverty-impacted communities.

B. INNOVATION.

The proposed study innovates in the following ways: **(1) We focus on older adolescents and young adults in a high-risk environment to elucidate the contextually relevant risk and resilience factors for ADU.** Late adolescence and early adulthood are also when depression and other common mental health problems first emerge[24,25] yet majority of prior studies typically focus on younger adolescents. Most of the prior studies are constrained by the small samples of AYLHIV who report ADU. In this proposal, we focus on AYLHIV in fishing communities – vulnerable communities that have high rates of HIV and drug use. Together, this approach will ensure that we have a large sample size of AYLHIV reporting ADU, to explore the risk and resilience factors and their potential interactions. Such knowledge is necessary to develop effective interventions to prevent/reduce ADU among AYLHIV. **(2) Our intervention targets the most commonly occurring risk factors for ADU (i.e. poverty and mental health problems).** Only a few ADU interventions evaluated in SSA have targeted the family context.[144] No study has targeted poverty and its attendant impacts (e.g. mental health) as a risk factor for ADU. In this proposal, we will examine the feasibility, acceptability and short-term effects of a family-based economic empowerment intervention to reduce/prevent risky and hazardous alcohol drinking and drug use. The proposed FEE intervention is based on Asset theory[168] and is intended to improve economic wellbeing and create a more hopeful/optimistic outlook for the future, and thus reduce AYLHIV's engagement in risk-taking behaviors including alcohol and drug use. This will be one of the first studies to examine the impact of FEE interventions on reducing alcohol/drug use among AYLHIV in poverty-impacted communities. **(3) We utilize biological measures to address limitations of self-reported drug use.** Self-reported measures are frequently used to assess ADU yet, due to a number of factors including the legal drinking age, gender, religious practices, social/cultural acceptability around alcohol use, recall and social desirability bias, these measures result in significant under-reporting of ADU.[171,172] In addition, in SSA including Uganda, a substantial proportion of all alcohol consumed (~40% in LMICs and ~89% in Uganda[173]) is homemade,[58] which makes it difficult to determine the quantity of alcohol consumed. Hence, the inclusion of biological measures for ADU (urine test) can overcome

the measurement limitations encountered from the reliance on self-reported data to provide more accurate data on the prevalence of ADU.

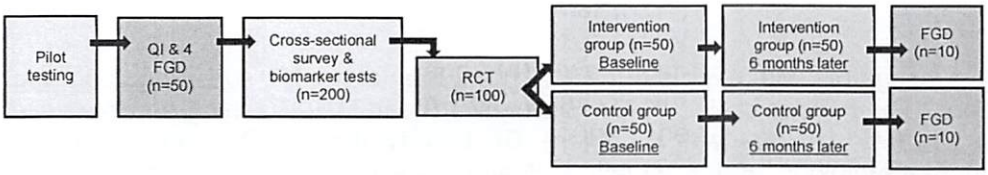
C. APPROACH.

C.1. Study Team.

We are a multidisciplinary team of investigators with expertise on AYLHIV's mental health, substance use and economic empowerment interventions. The team is co-led by Dr. Brathwaite (Lead MPI-Washington University in St. Louis-WUSTL) and Dr. Mutumba (MPI-University of Michigan). **Dr. Brathwaite** is a Research Assistant Professor WUSTL with training in Epidemiology and Population Health. She has research experience in substance use disorders and mental health among vulnerable/marginalized populations. She has published research focused on developing tools designed to predict future depression among adolescents in low and middle income countries,[174,175] and to predict depression and hopelessness among AYLHIV in Uganda.[176] She has experience working with vulnerable populations who use substances and has conducted research on substance use including persons who inject drugs in the UK,[177-180] smoking among migrants from SSA and ethnic minority groups in Europe,[181-183] and research on the burden of alcohol use among households in Trinidad and Tobago.[184,185] More recently she has been involved in intervention research[186] and analysis focused on the effects of schools-based mental health interventions and the impact of family-based economic empowerment interventions on adherence, economic and educational outcomes among AYLHIV in low resource communities in Uganda. **Dr. Mutumba** is an Assistant Professor at the University of Michigan with extensive experience conducting research among AYLHIV in Uganda. She has worked on several HIV clinical trials (UARTO[187] and ARROW[188]), managed complex national studies in SSA,[189,190] and has extensive clinical and research experience working on adolescent substance use and mental health among AYLHIV across a range of settings.[36,191-196] Currently, she is collaborating with Dr. Ssewamala (Co-I) to test a multi-level school and family-based stigma reduction intervention that includes a family-based economic empowerment component for AYLHIV. Drs. Brathwaite and Mutumba have an established working relationship through their joint mentor and Co-I, Dr. Ssewamala who is also executive director of the International Center for Child Health and Development (ICHAD). Drs. Mutumba and Brathwaite will co-lead and oversee all aspects of the study including recruiting and training research assistants, developing of quantitative and qualitative data collection tools and study protocols, designing intervention materials, analyzing data, and disseminating findings. Dr. Brathwaite will be responsible to communicating with NIH. **Dr. Filiatreau (Co-I)** is a Postdoctoral Research Associate at WUSTL with training in Epidemiology and Public Health, and has research experience with AYLHIV in SSA. Her research centers on characterizing the psychosocial well-being of people living with HIV in resource-constrained settings and estimating the effects of mental health and ADU on HIV treatment and care in these populations.[197-202] More recently she has been involved in work using novel epidemiologic methods to estimate longitudinal HIV care continuum outcomes among people entering HIV care and quantify the effects of a range of both hypothetical and implemented interventions on these outcomes.[203] Dr. Filiatreau will assist Dr. Brathwaite in developing the quantitative survey instrument and support analysis of quantitative data. **Dr. Ssewamala (Co-I),** a Professor at WUSTL, is an accomplished expert in designing and implementing economic empowerment interventions and conducting research among AYLWHIV in Uganda. He has led multiple NIH-funded studies conducted in Uganda for the last 15+ years (Suubi, R21MH076475; Suubi-Maka, R34MH081763, Bridges, R01HD070727; Suubi+Adherence, R01HD074949).[131,151,204-211] These studies, all conducted in Uganda, have been highly acceptable and feasible, yielding positive health and development outcomes, and have had high adherence to study protocols. Dr. Ssewamala directs the International Center for Child Health and Development (ICHAD), which has an office with >50 full-time staff in the study region (see Resources). The proposed study will leverage the community connections established through these NIH-funded studies. Dr. Ssewamala is the mentor of Drs. Mutumba, Brathwaite and Filiatreau and will contribute to the designing and implementation of the economic empowerment intervention component of the study. **Dr. Mugisha, Consultant** is a clinical psychologist and Senior Lecturer of Mental Health at Kyambogo University in Uganda. He has worked extensively on mental health among varied populations including AYLHIV in Uganda. A skilled qualitative methodologist, he will contribute to developing qualitative interview guides, analysis and interpretation of study findings, and support Dr. Mwebembezi with study implementation. **Dr. Mwebembezi (In-country PI)** is the executive director of Reach-the-Youth (RTY), our local implementing partner in Uganda. His responsibilities will include: 1) recruiting, hiring and training research assistants to conduct cross-sectional and qualitative interviews; 2) ensuring staff have the necessary precertification including CITI Human Subjects Protection Training; 3) ensure all research activities are conducted per the approved research protocol.

C.2. Research design and study sites.

We propose a mixed-methods study comprising 4 components: **(1)** focus group discussions (FGDs) with AYLHIV (n=20) and in-depth qualitative interviews (QI) with health providers (n=10). AYLHIV will be recruited from two randomly selected clinics; 10 participants per FGD; **(2)** a cross-sectional survey (CS) with 200 AYLHIV; **(3)** a randomized control trial (RCT) with a sub-group of AYLHIV (n=100); and **(4)** two post-intervention FGD with AYLHIV (n=10 per study group). The study will be conducted in six randomly selected HIV clinics located in fishing districts within the Greater Masaka region of Southwestern Uganda- a region heavily affected by HIV (12% prevalence vs. 6.2% national average)[212] with high rates of household poverty and alcohol use.[62,213] Urine tests for ADU will be conducted among all 200 AYLHIV who participate in the cross-sectional survey and among the 100 who participate in the RCT at the two time points. However, given the minimum and maximum detection times for different drugs of abuse in the urine, we will not exclude those with a positive self-report but negative urine test results from being included in the RCT. Additional analyses will explore the association between self-reported use and biomarkers.



C.3. Inclusion criteria.

The target populations for this study are: 1) AYLHIV, 2) healthcare providers at the selected HIV clinics. All study participants will be recruited from the selected HIV clinics. **Inclusion criteria for clinics: 1)** located in the - fishing districts with known HIV hotspots (i.e. 2 randomly selected clinics per district); **2)** accredited by the Uganda Ministry of Health as a provider of ART; **3)** currently have established services for AYLHIV. **Inclusion criteria for AYLHIV:** 1) male or female AYLHIV aged 18-24 years 2) medically diagnosed with HIV and aware of their HIV status; 3) enrolled in care at one of the selected HIV clinics. **Inclusion criteria for health providers:** health providers (1 - 2 per clinic) will be recruited from each of the selected clinics. **Inclusion criteria for participants of the RCT:** a sub-sample of AYLHIV (n=100) with a positive self-report for ADU will be randomly selected and randomly assigned at the clinic level (3 clinics per group) to either an intervention group (n=50) or a control group (n=50). AYLHIV from the control (n=10) and intervention groups (n=10) will participate in two FGDs at the end of the intervention.

Exclusion criteria for RCT and post-intervention FGD: any AYLHIV with negative self-report for ADU. **Exclusion criteria for all participants:** anyone with a significant cognitive impairment that interferes with their understanding of the informed consent process, or who is unable/unwilling to consent.

Table 1.

SOCIO-ECOLOGICAL FRAMEWORK		Time collected
Level	**Risk/protective factor**	
Individual	**Socio-demographic:** Gender; Age; orphanhood; education, income and unemployment; food insecurity[214]; experienced homelessness; refugee; day/boarding school; urban/rural residence. **Mental health:** Depression,[215] hopelessness,[216] Optimism[217]; Stress,[218] pain,[219] history of substance abuse[220]	CS, QI, FGD, RCT
Interpersonal/ Relationship	Loneliness[221]; number of close friends; bullying; interpersonal violence;[222,223] social support[224]; family cohesion[225,226]; childhood abuse/trauma;[227] family history of substance abuse,[220] sexual risk-taking[228]	
Community	Community norms; access to alcohol and illegal drugs	
Society	Educational campaigns; price and supply of alcohol, social stigma[229]	
Biomarkers	Urine alcohol and drug test	CS, RCT
Savings deposits	Savings	Monthly bank statements
Assessments	Self-reported alcohol and drug use[220]; Viral load from clinic records; Self-reported adherence[230]; depressive symptoms[215]; hopelessness[216]; physical health conditions; sexual risk-taking[228]	RCT

KEY: CS=cross-sectional survey; RCT=randomized control trial; QI= qualitative interview; FGD=focus group discussion

C.4. Recruitment of participants and informed consent.

Recruitment strategies will build on RTY (local implementing partner) and ICHAD's long-standing relationships (>15 years) with 39 health clinics in the greater Masaka region. We will capitalize on recruitment procedures tested in previous SUUBI studies that involve collaborating with health clinics in the region (namely Suubi+Adherence: 1R01HD074949-01, Suubi+Adherence-R2: R01HD074949-07, and Suubi4Stigma: R21MH121141). All participants will be recruited from the selected HIV clinics. For the cross-sectional survey, 200 AYLHIV will be recruited from across six clinics located in the greater Masaka region. . The designated study contact at each health clinic will present the project to all eligible AYLHIV 18-24 years during their clinic visits. If there is interest, they will provide verbal consent to be contacted by the research study team. The study coordinator will contact interested AYLHIV to inform them about , the required extent of participation, the risks and benefits of participating, and to ask any questions. Written informed consent will be obtained from AYLHIV 18-24 years and from healthcare providers >18 years to participate. The written consent documents will emphasize the following elements: 1) participation in the study is voluntary; 2) responses to study questions are confidential; 3) participants can terminate their participation at any time and their decision to withdraw from the study will not affect their access to services they are currently receiving in any way; 4) participants may be contacted to participate in the RCT if eligible. A screening tool will be developed to assess whether participants meet the study inclusion criteria. Participants' data will be protected by a Certificate of Confidentiality, which protects the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to individuals not involved in the research unless the participant consents.

C.5. Data collection and assessment.

After pilot testing of data collection interview tools, two separate **FGDs** will be conducted with AYLHIV (n=20) and in-depth **QIs** will be conducted with health providers (n=10). AYLHIV will be recruited from two randomly selected clinics; 10 participants per FGD. The FGDs and QIs will explore participants' perceptions on the multi-level risk and resilience factors associated with alcohol and drug use and recommendations for culturally appropriate ADU interventions for AYLHIV. Data from the qualitative phase will inform the questions to be asked in the cross-sectional survey. For the **cross-sectional survey**, 200 AYLHIV will complete an interviewer-administered survey comprising questions assessing their alcohol/drug consumption patterns and frequency as well as exposure to multi-level (individual, interpersonal, community and societal) factors that may be associated with risky and hazardous drinking and drug use among AYLHIV. To reduce social desirability bias, questions on ADU will be self-administered using audio computer assisted interviewing (ACASI). We refer to the social ecological framework[231] to guide data collection on the multiple levels of influence that are associated with harmful alcohol/drug use among AYLHIV (See Table 1 for socio-ecological framework and additional measures that will be collected at each time point). Questions assessing the presence of common mental disorders and the presence of other physical health conditions will be included.

Biological measures: A trained study research assistant will collect and test a urine specimen from each participant. The urine sample will be tested for up to 16 classes of the most commonly abused illicit drugs using the T-Cup 16 panel Compact Instant Drug Test Cup at the study site. The T-Cup can detect alcohol in the urine from as early as 8 hours to up to 80 hours after consumption. Minimum and maximum detection times for illicit drugs of abuse range from one hour to 40 days depending on the drug. AYLHIV will be tested during the cross-sectional survey and at baseline and 6-months follow-up during the RCT.

C.6. Description of the RCT.

For the RCT, 100 AYLHIV with a positive self-report or urine ADU test (based on data from the cross-sectional survey) will be randomly recruited from the six clinics and randomly assigned at the clinic level (3 clinics per group) to either the control (n = 50) or intervention (n = 50) group. The intervention will be delivered over a period of six months, and with assessments at baseline, and 6 months (end intervention). Upon completion of the RCT, AYLHIV will be randomly selected to participate in two FGDs (n=10 from control group and n=10 from intervention group). AYLHIV in the intervention group will share how the intervention affected their alcohol/drug use as well as their recommendations on how to tailor/improve the intervention to be more culturally appropriate and effective in reducing ADU among AYLHIV in Uganda, while AYLHIV in the control group will share their experiences with ADU risk reduction sessions and how this influenced their ADU.

Description of the control condition: AYLHIV in the control condition will receive ADU risk reduction sessions tailored for AYLHIV. Working with Dr. Mugisha (Consultant), we plan to adapt, expand and tailor the Program for Appropriate Technology in Health (PATH) Life Planning Skills curriculum (Unit 11 on substance use),[232] to

include issues specific to AYLHIV. We will train research assistants, using an adapted facilitator's manual, to deliver the adapted curriculum. As part of the RCT, AYLHIV will complete a questionnaire (at baseline and end of the intervention) on their alcohol/drug use behaviors (self-report and biologically measured) and risk/resilience behaviors.

Description of the intervention group: In addition to the adapted ADU training module that the control group will receive, AYLHIV in the intervention arm will receive four (4) Financial Literacy (FL) training sessions and a Youth Development Savings account (YDA) for long-term savings. Although akin to conditional cash transfer interventions, which have become increasingly popular in the social development field by enabling individuals to meet basic needs while incentivizing pro-social behaviors,[132,169,233-235] EE interventions that apply matched savings accounts go beyond incentivizing behavior. They emphasize long-term investment and promote life-long financial inclusion by forming savings habits and establishing partnerships between the participants and local financial institutions and the actual intervention program. For the proposed study, the FEE intervention will be in the form of a YDA, where savings are housed at a local bank and deposits made by the adolescent are matched by the intervention to encourage savings. YDAs yield positive effects, including creating a greater sense of security, self-confidence, and future orientation for young people.[132,169,233-235] Each AYLHIV in the FEE intervention will receive a YDA held in their own name in a bank registered by the Central Bank (Bank of Uganda). We will form partnerships with national banks operating in the study area. . The account will then be matched with money from the program. The maximum Adolescent's contribution to be matched by the program will be an equivalent of US $20 per month per Adolescent or US $120 for the 6-month intervention period. Our prior studies indicate that the partner financial institutions have multiple and easily accessible deposit locations in the study area, and that participants can save these amounts.[132,169,233-235] Youth *who save the maximum amount will have a total of $240 at the end of the intervention ($120 in savings plus $120 from the match: a 1:1 match).* As in the studies that inform this application, each month, a bank account statement will be generated for every AYLHIV to note their accumulated savings. The statements are intended to act as "morale boosters" for the enrolled AYLHIV/ Unique to this study is our innovative spending model, which empowers participants to make informed financial decisions. During the intervention period, AYLHIV will have direct access to both their personal savings deposited in the accounts as well as the match provided by the study. This is different from our prior studies that required the participants' own savings and the match to be kept in separate accounts and to get approval by the research team to access the match.[132,169,233-235] This added unconditional component provides AYLHIV with a safety net to address short-term medical needs and financial and consumption emergencies if they arise. Participants will be provided with financial literacy sessions and mentorship tailored specifically to the needs of AYLHIV and ADU. We expect AYLHIV to be equipped with the knowledge to make well-informed consumption and expenditure decisions, but also feel supported in case of immediate medical needs. The research team will monitor, but not restrict, how participants spend their match. Additionally, the study team will have access to and review participants' bank statements to ascertain deposit and withdrawal frequency. Participants will be encouraged to utilize financial diaries to record their expenditures.

C.7.1 Quantitative Data analysis.

Analysis of cross-sectional survey data: Frequency distributions and summary statistics for the outcome and all predictor variables will be derived. The prevalence of ADU from both biological tests and self-reports, assessed using the Smoking and Substance Involvement Screening Test (NIDA-Modified ASSIST)[220] among AYLHIV, will be calculated by dividing the number who tested positive for ADU by the total number of participants tested, and dividing the number screened to be of moderate or high risk in self-reported data by the total number of participants who completed the survey. To determine which multilevel factors are associated with substance misuse, we will fit logistic regression models comprising the outcome (ADU) and potential risk factors with standard errors adjusted for clustering by clinics.

Analysis of RCT data: Primary hypothesis. We hypothesize that participants in the intervention group will have a lower odds of ADU compared to participants in the control group. To test this hypothesis, we will fit three-level mixed-effects models. Each model will comprise the outcome, and fixed categorical effects for study group (intervention vs control), time (baseline, 6-months), and a group-by-time interaction term. Random intercepts will be fitted at the clinic and person level, with unstructured correlations among subjects' repeated measures. Robust Huber-White standard errors and test statistics will be computed for each model. We will assess the omnibus effects for study group, time, and their interaction. Post-estimation analyses will be conducted to assess time-within group simple effects and group within time simple effects. Secondary hypothesis. We hypothesize that AYLHIV in the intervention group will have better mental health outcomes including lower levels of

depressive symptoms, less hopelessness, improved adherence and achieve better viral suppression and improved economic outcomes than AYLHIV in the control group.

C.7.2. Qualitative data analysis

Interviews will be transcribed and uploaded to QSR NVivo12.[236] Analytic induction techniques[237] will be used for coding. Ten interview transcripts will be randomly selected, read multiple times and independently coded by the team using sensitizing concepts to identify emergent themes (open coding).[238] 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.[238,239] Codes and the inclusion/exclusion criteria for assigning codes will be discussed as a team to create the final codebook in NVivo. Each transcript will then be independently coded by two investigators using the codebook. Inter-coder reliability will be established. A level of agreement ranging from 66 to 97% based on level of coding indicates good reliability.[240] Disagreements will be resolved through team discussions. The secondary analysis will compare/contrast themes and categories within and across groups to identify similarities, differences, and relationships among findings. Member checking, peer debriefing, and audit trail will be used to ensure rigor.[241]

C.7.3. Data integration.

The qualitative and quantitative data analyses will be done separately. Findings will be integrated at the interpretation and discussion stages.[242] Conclusions and inferences will be synthesized for a more contextualized and thorough understanding of the multi-level factors associated with ADU among AYLHIV. The mixed methods design will serve two purposes: 1) Complementarity[243,244] and 2) Expansion.[243,244] Qualitative findings will be connected to quantitative findings where the former will provide explanations and context for findings produced by the latter. More specifically, the qualitative data will potentially provide further explanation and contextualization of the local factors that contribute to alcohol and drug abuse among AYLHIV in Uganda. The post-intervention FGDs with AYLHIV who participate in the RCT will explore participants' experiences with the intervention and share recommendations on how it can improve.

C.8. Potential challenges and alternative strategies.

We do not anticipate major threats to study implementation but we recognize potential concerns. We plan to utilize recruitment strategies that have been successful in ICHAD's NIH funded studies. Should recruitment or enrollment deviate from anticipated rates, we will schedule conference calls to enact solutions and adjust the analytic strategy if necessary.

C.9. Dissemination.

The research team will facilitate learning across stakeholders and maximize use of the evidence generated through dissemination meetings. Uganda's mental health policy recognizes the burden and impact of ADU on adolescents, their families and communities.[245] If findings warrant, we will leverage these policy guidelines to maximize dissemination of study findings.

D. TIMELINE.

First 4 months (April - July 2022) will be spent acquiring IRB, developing/pilot testing study guides and questionnaires, hiring and training project staff, recruiting clinics and selecting participants for the FGDs and QIs. In the next three months (August – October 2022), we will conduct the FGDs and QIs, analyze the transcripts, develop the survey questionnaire concurrently, and then conduct the survey from October and December 2022. Analysis of the quantitative survey will occur from December 2022 to January 2023. Concurrently (from January), we will work on refining the intervention manuals and start recruitment for the 100 participants of the intervention in February 2023. We will allow 8 months to implement the intervention (April– November 2023), giving enough time for follow-up 6 months later. We will conduct the post-intervention FGDs with AYLHIV in December 2023. The rest of the study period will be dedicated to data analysis, preparation of manuscripts, report writing and dissemination.

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