Protocol

"Retention through mHealth for adolescents and young adults with HIV in care (REMAIN study) "

Version 1.0

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Background/ rationale:

AYWH aged 15-24 are the fastest growing population living with HIV globally. In 2019, AYWH accounted for 25–30% of new infections in sub-Saharan Africa[1]. This large group is comprised of children born with HIV surviving to older ages and a high number of incident infections[1–3], especially among girls and young women. Despite successful rollout of antiretroviral therapy (ART) and coordinated care, AYWH experience worse outcomes along the HIV care continuum, and AIDS-related mortality is the leading cause of death in AYWH[4]. In 2020, AYWH registered a 50% increase in mortality while mortality in other age groups decreased[1]. AYWH experience large gaps in HIV testing, delays in treatment initiation, and poor retention in care[5]. Improving these metrics for AYWH is critical to achieving the UNAIDS 95-95-95 goal of ending HIV by 2030[6].

AYWH experience poor retention in care. For every 10 AYWH enrolled in HIV care only 5 – 6 will be engaged in care 12 months later[7–9]. Neurodevelopmental factors play an important role in the poor retention in care of AYWH[10,11]. The developmental transition from childhood to adulthood is a period of intense physical, emotional, and social change. This neurodevelopmental process is associated with increased risk taking including sexual exploration and experimentation, and prioritization of short-term rewards over long-term health priorities, leading to establishment of negative lifelong health behaviour. **Thus, neurobiological differences in AYWH drive poor retention in care and require solutions targeted to their developmental stage.** Also, perinatally- and non-perinatally infected AYWH have differences in HIV knowledge, attitudes and treatment expectations[12]. For example, non-perinatally infected AYWH are more likely to be newly engaging in care and therefore may lack HIV knowledge, whereas perinatally-infected AYWH may come in and out of care and may be fatigued with health care engagement[12]. **Differentiating the needs of perinatally and non-perinatally infected AYWH is necessary for the optimized design of interventions that are effective for AYWH[12].**

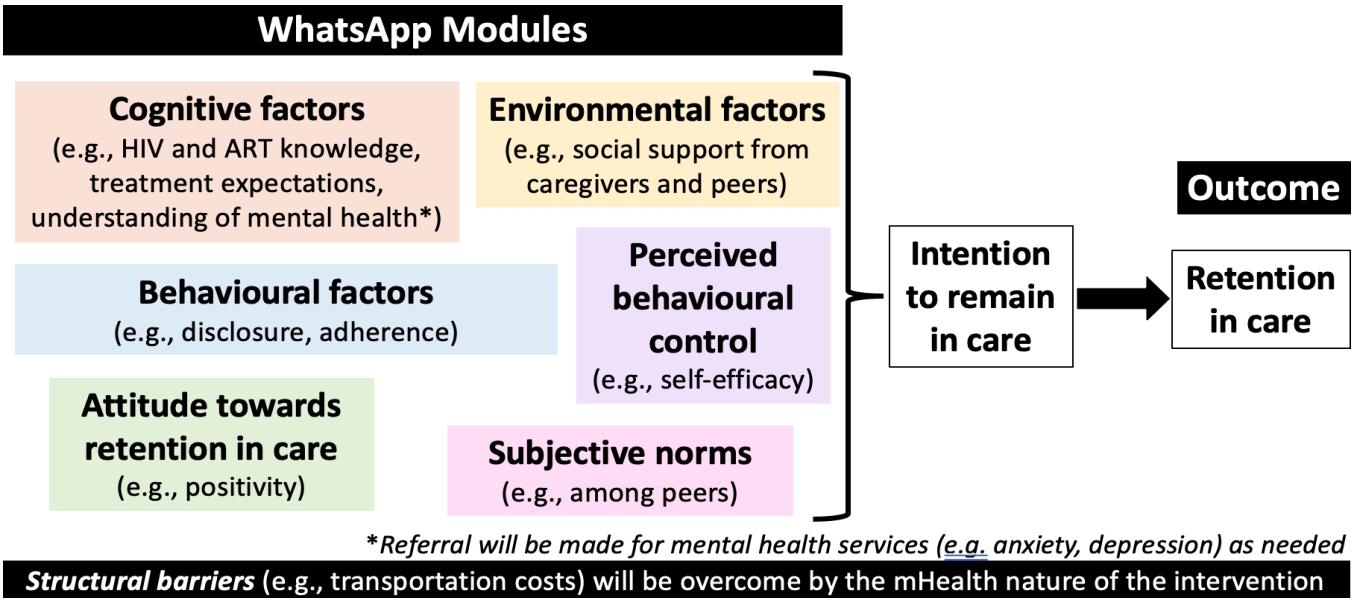
AYWH who are not retained in care continue to drive HIV transmission. Poor retention in care is associated with suboptimal ART adherence and virologic non-suppression, a major driver of the HIV epidemic[13]. In 2020, female AYWH contributed to 49% of all new HIV infections[1]. Adolescents explore sexuality, gender, and sexual relationships, and AYWH may engage in both risky generational and cross-generational sexual relationships, leading to new HIV infections and further fuelling the HIV epidemic. AYWH also experience stigma, disclosure issues, and are less likely to negotiate safe sex[14]. AYWH face social and environmental disadvantages, including poverty and gender identity questions, and are often engaged in health lacking safe spaces to discuss AYWH-specific issues[15,16]. These complexities, coupled with poor retention in care and virologic non-suppression, drive behavioural and vertical HIV transmission through AYWH pregnancy[13]. **Thus, keeping AYWH engaged in care will decrease HIV transmission and achieve milestones towards ending the HIV epidemic**.

Traditional interventions to improve AYWH retention in care are inadequately tailored to AYWH[17,18] and to their route of infection. Current interventions targeting the AYWH population specifically include facility-based and community-based interventions, including differentiated HIV care, task shifting and down referral, patient tracking, and peer interventions[17–19]. Facility- and community-based interventions may not to be effective in improving retention in care for AYWH[20], especially those living in low-resourced settings. **These interventions are limited by structural barriers like physical space and transportation costs, and often not effective** due to lack of time flexibility and little privacy[18] – all important factors for effective retention of AYWH in care. Moreover, they may be affected by the ever evolving global challenges like the COVID-19 lockdown[17] restrictions, and currently in Uganda, the Ebola Virus disease outbreak[21]. Importantly, they are largely extrapolated from adult HIV care[18] with minimal regard for route of infection. In 2016, the Ministry of Health Uganda rolled out nation-wide clinic-based adolescent friendly services to improve retention in care and adherence which included adolescent safe spaces, holding specific clinic days for AYWH and flexible clinic hours; however, in a post hoc mixed evaluation, the impact of these interventions on retention in care were disappointing. Only 53% of AYWH were active in care at 24 months, while only 56% received a viral load test and of these only 77% were suppressed at 12 months[22] All these interventions require physical presence of AYWH and the health care team, as well as physical infrastructure. These ventures are costly for many health facilities where human resources are an ever-present challenge. Notably, only 30% of health facilities evaluated were able to establish adolescent safe spaces[23]. Although community-based interventions may offer some advantages over those in facilities, they are still more restrictive. Thus, more flexible approaches tailored to adolescent needs should be developed.

mHealth interventions for AYWH could supplement and augment in-person HIV care visits and improve retention in care. In sub-Saharan Africa, >70% of AYWH aged 15-24 have access to mobile phones and about 60% have daily access to the internet[24,25]. Many AYWH use the internet to access social media sites for entertainment and health information[26,27] Therefore, social media-based interventions are promising, and they enable additional interactive features attractive to AYWH, including memes, visual images, and videos, and allow flexible timing of use. The two published studies evaluating social-media based interventions used Facebook- and Mxit-based peer groups. They reported that AYWH found the interventions acceptable, increased their knowledge about HIV, and improved HIV self-efficacy[25,28]. However, these interventions used less popular (Facebook) or no longer used (Mxit) social media applications, and they did not offer individual-level interaction with AYWH. Given AYWH demonstrated high acceptability of social-media based mHealth interventions in these studies, further research is needed to examine the effect of social-media based interventions to improve retention in care. Studies are needed on how interventions can be tailored to the neurodevelopmental needs of AYWH and consider unique needs of perinatally and non-perinatally infected AYWH. **The key knowledge gaps include:** 1) the impact of adolescent-tailored social media-based mHealth interventions on retention in care of AYWH who are new to or newly re-engaging in care; and 2) optimization of the design of social-media based mHealth interventions to improve retention in care of AYWH for both perinatally- and non-perinatally infected AYWH while also catering for the neurodevelopmental needs of AYWH.

Theory-driven psychosocial-based interventions for AYWH, including mHealth interventions to improve retention in care, are promising but need further development. Existing psychosocial interventions have a small-to-moderate effect on AYWH behaviour and modestly improve outcomes like adherence[17,19,29]. However, their effect on retention in care for new, and newly re-engaging, AYWH is not yet fully explored[17,19]. In a meta-analysis of 36 interventions to keep AYWH engaged in care, 60% were conducted in high income countries[17,19] and 80% of the studies were grounded in theory; however, only one utilised social media for intervention delivery. Thus, there is a lack of research on social media-based interventions to improve AYWH retention in care, especially in low-resourced settings. We propose to begin addressing these gaps by leveraging Social Cognitive Theory (SCT)[30,31] and Theory of Planned Behaviour (TPB)[32]. SCT accounts for the interrelation among relevant cognitive and environmental factors with behaviour, while the TBP integrates the attitudes, subjective norms, and perceptions of behavioural control over intention and behaviour. Using qualitative and mixed methods. We propose to develop and pilot test an adolescent-tailored social media-based mHealth intervention accounting for these domains to improve retention in care for AYWH. The ultimate aim of the intervention is to improve viral suppression and other HIV treatment outcomes, thus reducing AYWH morbidity, mortality, and onward transmission.
Intervention development will be informed by a conceptual framework (Figure 1) derived from two theories relevant to health behaviour change: the SCT[30,31] and the TPB[32]

Figure 1: Intervention conceptual framework



In this study, we propose to adapt a novel WhatsApp-based intervention called U-SMART (Uganda-SMART). Compared to other social media instant messaging applications, WhatsApp has superior privacy,

accessibility, and interactivity and is used widely in SSA; up to 60% of AYWH have access to a smartphone with access continually growing[33]. We also propose to examine the preliminary impact of the intervention on six-month clinic retention with the aims below:

SPECIFIC AIMS

Aim 1: Define the cognitive, environmental, and behavioural challenges and their impact on behavioural intention for AYWH who are new or newly re-engaging in HIV care. We will use in-depth interview (IDIs) with 30 AYWH to achieve this aim.

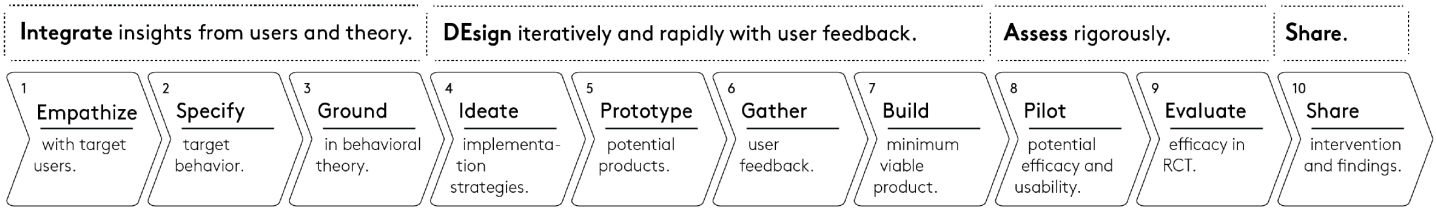
Aim 2: Iteratively develop a social media-based adolescent-tailored mHealth intervention to improve retention in care for AYWH who are new or newly re-engaging in care. We will use data from Aim 1 above to develop the intervention. We will conduct two separate series of IDIs to gather feedback from AYWH (*n* = 15) and ISS clinic counselors (*n* = 10) to achieve this aim.

Aim 3: Test the acceptability, feasibility, and preliminary impact of the developed adolescent-tailored mHealth intervention for retention in care of AYWH who are new to or newly re-engaging in care. Here we will randomize 50 AYWH to either receive the intervention immediately or to the deferred intervention arm.

Study Approach

Study overview: We will engage AYWH aged 15-24 who are new to or newly re-engaging in care at the Mbarara University of Science and Technology (MUST)/Mbarara Regional Referral Hospital's Immune Suppression Syndrome (ISS) clinic. In Aim 1, using IDIs, We will identify their HIV knowledge gaps (cognitive factors in Figure 1), environmental and social challenges (environmental factors in Figure 1) and behavioural factors. We will then apply Aim 1 findings to develop a social media based mHealth adolescent-tailored intervention using the WhatsApp platform to improve retention in care (Aim 2). The intervention development approach will follow the Integrate DEsign Assess and Share (IDEAS) framework for developing digital health behaviour change interventions (Figure 2). Based on this framework, we will initiate intervention design using theory and participant insight (Aim 1), which allows for rapid and iterative designs with feedback from AYWH (Aim 2). We will conclude with rigorous assessment of the intervention through a pilot randomized clinical trial (Aim 3). We will assess the primary outcomes of intervention acceptability and feasibility and an exploratory outcome of preliminary impact on 6-month retention in care.

Figure 2: IDEAS framework for developing digital health interventions



Study population and research setting: The study setting for Aims 1, 2 and 3 will be the MUST/MRRH ISS clinic. The ISS clinic offers comprehensive HIV care services, including an adolescent-specific clinic. The clinical care is managed by two separate clinical teams offering specialized paediatric and adult HIV care according to the Uganda Ministry of Health guidelines[34], adapted from World Health Organization (WHO) guidelines. To date, the ISS clinic has cared for over 3,000 children and adolescents with HIV, with 1,500 active in care. The ISS clinic is an outpatient HIV testing facility and the initial interface for all patients who are new to care. The clinic enrolls about 18 new patients per month, half of them aged 15-24.

Eligibility/enrolment:
AYWH

- Inclusion criteria for all study aims
  - AYWH (age 15-24 years) who are new to care or re-engaging in care; we will enroll emancipated minors per Ugandan laws (e.g.; children who head households) or 15-17 year-olds with parental consent.
  - Ability to understand (verbal and /or written) English and/or Runyankole.
  - Additionally in study aim 3, access to a smart phone
- Exclusion criteria- inability to provide informed consent (e.g., intoxication, mental disability).

Adherence counselors (Aim 2)

- Inclusion criteria
  - Have provided ART adherence counseling at the ISS clinic for a period of ≥ 1 one year
  - Able to understand (verbal and/or written) English and/or Runyankole
- Exclusion criteria
  - Inability to provide informed consent i.e due to critical illness or current mind-altering substance use

For all study aims, we will enrol AYWH aged 15-24 who are either new to HIV care or newly re-engaging in care (defined as previously lost to follow-up [LTFU] based on missing appointments for 6 months or more) and are fluent in English or the local language, Runyankole. As part of routine care, AYWH who are LTFU are tracked down by clinic-based trackers in order to re-engage them in care. A study screener will generate a list of all eligible participants from the HIV testing register and ISS clinic database, this will be done bi-weekly, any participant who meets study criteria will be approached for screening and recruitment. AYWH who would have been newly enrolled or re-engaging into care in the preceding two weeks to the generation of the list will be considered for screening and enrolment. All participants aged ≥18 years and those who are <18 years but are considered emancipated minors as per Ugandan lwas will provide informed consent; AYWH who are minors will provide assent and parental permission and consent will be obtained. Emancipated minors by Ugandan laws (e.g., children who head families) will also provide informed consent.
The consenting/assenting process will take place in a private room and will comprehensively include the following information: (a) introduction to the consent/assent process, explaining the consent/assent form and compliance with institution policy and country laws; (b) emphasis that participation is voluntary; (c) nature and purpose of the study; (d) explanation of study procedures; (e) potential discomforts and risks, as well as plans to protect participants from these risks; (f) potential benefits; (g) alternatives to participation in the study; (h) confidentiality, including how data will be used and how it will be kept private; (i) refusal/withdrawal, including right to withdraw consent/assent and leave the study at any time; and (j) rights and complaints. After each major section, research staff obtaining consent/assent will pause and check for understanding- for example, by asking the potential participant to repeat, in their own words, what "the right to refuse" means.

Aim 1: Define the cognitive, environmental, and behavioural challenges and their impact on behavioural intention for AYWH who are new or newly re-engaging in HIV care**.** In Aim 1, We will complete the intervention conceptual framework (steps 1-3 of the IDEAS framework, Figure 2).

Design: We will purposively enrol 30 AYWH to conduct IDIs. Purposive sampling will ensure that the sample reflects a diversity of age (15-18 vs 19-24), and HIV care status (new to care vs newly re-engaging in care).
Interview guide: We will design the interview guide to elicit discussions that will explore and define participants' HIV knowledge gaps, social, environmental, and behavioural barriers to HIV care. Other concepts from the SCT and TPB will be included in the interview guide will include attitudes, subjective norms, and perceived behavioural control. We will iteratively refine the interview guide through thorough literature review utilizing the SCT and TPB theoretical frameworks. After translation to Runyankole and back-translation to English, the interview guide will be piloted with five AYWH participants and revised prior to formal study enrollment. Any new domains will prompt regulatory review.
IDIs will be conducted face-to-face and one-on-one by trained research assistants and will be guided by open-ended questions in the interview guide, we will begin each interview with basic demographic data collection. We will digitally record participant interviews in their preferred language (English or Runyankole). Interviews will be conducted in a private space and last up to 90 minutes. All audio recordings will be transcribed and translated into English, the study PI will verify all transcripts and any discrepancies will be

addressed within 24 hours of the interview. ,Qualitative research methods will be guided by Consolidated criteria for REporting Qualitative research (COREQ) guidelines[35].

Analysis: We will analyze IDIs using content analysis[36], in an iterative, multi-step process. Here we will review transcripts for key concepts to develop a codebook and use the codebook to code the data using software (Dedoose). We will use these codes to develop thematic categories that are both deductive (guided by the SCT and TPB) and inductive (guided by new concepts discovered from data). We will double-code at least 25% of the interviews to ensure reliability and provide ongoing feedback as we iteratively refine and review major and minor themes and resolve data interpretation discrepancies to inform the mHealth adolescent-tailored intervention development.

Sample size consideration: Sample size for IDIs is based on thematic saturation. We will enroll up to 30 AYWH for IDIs, as prior studies have demonstrated that this number is sufficient to reach saturation[37,38].

Aim 2: Iteratively develop a social media-based adolescent-tailored mHealth intervention to improve retention in care for AYWH who are new or newly re-engaging in care**.** In Aim 2, we will design the intervention iteratively with user feedback (steps 4-7 of the IDEAS framework, Figure 2).

Intervention development: We will develop and iteratively refine an mHealth-based adolescent-tailored intervention as per the IDEAS model in the design phase (Figure 1, Figure 2)[39]. The intervention will emphasize dealing with antecedent factors that affect retention in care and we will utilize themes from Aim 1 interviews relevant to a potential intervention to improve retention in care to design and refine the intervention. We will develop the intervention using constructs from the SCT and TPB. Constructs utilised from the SCT will include cognitive factors (e.g., HIV & ART knowledge, treatment expectations, and understanding of mental health) and environmental factors (e.g., social support, Figure 1). Constructs utilised from the TPB include behavioural factors (e.g., disclosure, adherence). changing attitudes towards retention in care, subjective norms and behaviour control (Figure 1). These are all important antecedent and ongoing factors for retention in care. Structural barriers (transportation costs, physical clinic space availability) will be overcome by the mHealth nature of the intervention. We anticipate the intervention will encompass 12 modules, with each module delivered bi-weekly over 6 months. The intervention aims to modify participants' antecedent factors and barriers to retention in care by providing skills and knowledge that can modify these antecedent factors. After developing an initial intervention manual, we will conduct two separate series of IDIs to gather feedback from AYWH (*n* = 15) and ISS clinic counselors (*n* = 10) who meet eligibility criteria (as described above). We will use these IDIs to refine the intervention iteratively, consult the study mentorship team and hold discussions before reaching a consensus; after which we will build a minimum intervention package for use in Aim 3.

Analysis: The IDIs will be analysed using content analysis as in Aim 1 above.

Aim 3: Test the acceptability, feasibility, and preliminary impact of the developed adolescent-tailored mHealth intervention for retention in care of AYWH who are new to or newly re-engaging in care**.** In Aim 3, I will "Assess rigorously and Share" (steps 8-10 of the IDEAS framework, Figure 2).

Table 1. Confidence interval estimates for a sample size of *n* = 50

Rated intervention positively	90% CI	95% CI
0.6	0.47 – 0.72	0.45 – 0.74
0.7	0.58 – 0.81	0.55 – 0.82
0.8	0.68 – 0.89	0.66 – 0.90
0.9	0.80 – 0.96	0.78 – 0.97

Power considerations: For the Aim 3 primary outcomes of intervention 1) acceptability, 2) feasibility, and we hypothesize that 35/50 participants (70%) will rate the intervention positively on the Acceptability of intervention measure (AIM) and Feasibility of intervention measure (FIM) outcome domains. With the sample size of 50, our 95% confidence interval around the estimate of 70% positive response will range from 0.55 – 0.82. The confidence interval range will remain acceptable even if the intervention is rated lower (60% positive rating) or higher (80% or 90% positive rating, Table 1). This level of precision around for determining the primary outcomes is sufficient to determine the success of the pilot trial and rationale to progress to a larger trial.

Randomization and intervention implementation: We will allocate 25 AYWH per arm (total *N* = 50), either to receive the immediate intervention (at first HIV care visit) or to a wait list control group (to receive the intervention six months later). Participants will be randomized in a 1:1 ratio using permuted block randomization, using pre-filled sealed envelopes, randomization will be tracked in REDCap and reviewed after every 10 participants to ensure fidelity. Procedures in the intervention arm will be determined in Aim 2, but we anticipate up to 12 modules to cover all relevant theory-driven components; these modules will be delivered via WhatsApp every 2 weeks over 6 months (Table 2). The module content will be adjustable for level of adolescent developmental stage, prior HIV care exposure (new to care vs re-engaging in care) and by route of infection (perinatal vs non-perinatal infected).

Table 2: Aim 3 intervention procedures and relevant conceptual theory.

Visit / time point	Conceptual theory constructs	Session activity
Enrolment		Overview and phone set up, questionnaire administration
Sessions 1 – 12 Every 2 week for the immediate intervention group and wait list control groups (to start 6 months later)	Cognitive factors	01. Understanding HIV 02. ART regimens and common side effects 03. Treatment expectations 04. Dealing with stress and anxiety
	Environmental factors	05. Stigma and rights 06. Social support 07. Exploring your feelings
	Behavioural factors	08. Treatment adherence 09. Self-efficacy and ART adherence 10. Health and nutrition 11. Positive prevention 12. Reproductive health
At 6 months		Outcome assessment: IDIs and questionnaires for acceptability, feasibility, and usability. HIV viral load results extracted from clinical chart, questionnaire.
At 12 months		Repeat outcome assessment (immediate intervention arm only).

Study procedures: All prospective participants will be screened for eligibility and enrolment as described in the eligibility/enrolment sections above. If found eligible, they will undergo informed consent/assent to join the study. Participants will then be allocated to either receive the intervention immediately (at the time of enrolment) or the waitlist control group (six months after enrolment).

Participants in the immediate intervention group will then start to receive the intervention while those in the waitlist control group will receive the usual standard of care at the ISS clinic which includes baseline counseling and initial one-monthly review and subsequent three-monthly reviews.

Research assistant-administered questionnaires: Participant socio-demographics, clinical information such as mode of HIV acquisition, staging, ART regimen, socioeconomic status, mental health, social support, and self-efficacy will be collected as shown in the table 3 below.

Table 3. Summary of data collection by study aim.

Data collection	Source	Aim 1	Aim 2	Aim 3
Demographics	Structured questionnaire	X		X
Health care information	ART regimen, mode of HIV acquisition, HIV staging,	X		X
		X		X
Alcohol use	Alcohol Use Disorders Identification Test-Consumption (AUDIT-10) [40]	X		
Depression	Centers for Epidemiological Studies-Depression (CESD)^[41,42]	X		
Anxiety/psychosocial distress	25-Item Psychological Distress Scale[43]	X		
Perceived social support (family and friends)	A standardized social support scale[44]			
Mobile phone utilization	Structured questionnaire	X		
Anticipated acceptability for mHealth service delivery	Acceptability of intervention measure, Feasibility of intervention measure, systems usability scale, IDIs interview guide	X	X	X

At the end of follow-up we will conduct IDIs with 10 AYWH, five from each arm to assess feedback about the intervention. IDI interview guide will include domains like intervention appeal, likes/dislikes, barriers/facilitators to participation and concerns.

Study counselor training: Two qualified counselors based at the ISS clinic will receive training on the intervention protocol and will be dedicated to delivery of the intervention, one counselor per trial arm to avoid trial arm contamination. We will have a back up counselor in case any one of them is absent or off. We will create a training manual for the intervention content, including mechanisms to adjust for neurodevelopmental stage and route of infection. It will also include guidance on maintenance of participant privacy throughout the follow-up period and procedures for any necessary mental health referrals. We will also create a protocol adherence and fidelity checklist[45,46] to ensure all sessions are delivered as per protocol.

Primary outcomes of acceptability, feasibility, and usability of the adolescent-centered intervention:

Definitions and quantitative analysis:
1) **Acceptability:** The intervention will be considered acceptable if ≥70% (35/50) of intervention participants rate all 4 items on the Acceptability of Intervention Measure (a 5-point Likert scale) as "agree" or higher.
2) **Feasibility** will be defined by the Feasibility of Intervention Measure[47,48], and achieved if ≥70% (35/50) rated all 4 items on the Feasibility of Intervention Measure (a 5-point Likert scale) as "agree" or higher.
3) **Usability** will be defined by the Systems Usability Scale, and achieved if ≥70% (35/50) rated all 10 items on the Systems Usability Scale[49] (a 5-point Likert scale) as "agree" or higher. At the end of follow-up, we will conduct IDIs with 10 AYWH (five from each arm) to assess feedback about the intervention.
Hypothesis: *>70% of AYWH will find the intervention acceptable and >70% will rate the intervention as good or higher on the systems usability scale.*

Qualitative analysis: We will assess acceptability and feasibility through the content analysis approach outlined in Aim 1 to analyze the IDIs in Aim 3.

Secondary outcomes: preliminary impact on 6 and 12-month retention in care: We will compare the proportion of participants who are still actively engaged in care at the end of 6 months in the immediate intervention and wait list control arm. Being active in care will be defined as not missing more than one consecutive scheduled visit. The main exposure will be the group to which participants were randomized (immediate intervention vs wait list control group). All analyses will be adjusted for gender and age and route of infection, socioeconomic status, mental health and whether they are new or re-engaging in care, which may affect retention in care. We will also compare 6 and 12-month retention in the immediate intervention group only for sustainability of effect. Although the sample size will be small, we will perform regression analyses to explore mechanisms for retention in care through change in key variables (self-efficacy, mental health and route of infection).
Hypothesis: *6-month retention in care will be 20% higher in the intervention group compared to the wait list control arm*.

Participant retention and withdrawal
The study is designed to improve retention in care (and study follow-up); however, to ensure uniform retention in follow-up, we will employ the clinic standard of care methods for retention, including a locator map for the participants' primary residence which will be collected at enrolment, secondary phone numbers with pre-written participant-approved messages that should be used if we need to contact the participant through a secondary contact. This information will be stored separately from other participant information and will be keep securely in a locked cabinet. Participants will be able to withdraw from the study at any time and this will not in any way affect their care and treatment at the ISS clinic.
Potential problems and alternative strategies

Risk of contamination between study arms: To prevent this, the study will employ separate counsellors per trial arm and these counsellors will instructed to only exchange WhatsApp messages with participants when they are receiving the intervention. Bias related to counsellor skill will be mitigated through structured training and the use of a manual prior to recruitment, we will assess intervention delivery for fidelity every three months..

Participant recruitment: We will recruit participants from the ISS clinic; however, if I experience challenges with adequate enrollment, then I will expand to the Mbarara Municipal clinic, which is less than 1 km away and services a similar population of AYWH.

Source of materials, recruitment of subjects and informed consent
We will obtain Institutional Review Committee approval for this study through the Mbarara University of Science and Technology and the Mass General Brigham Institutional Review Board, as well as the Uganda National Council of Science and Technology. Approval will cover recruitment, written and informed consent, enrollment, data collection, retention, study procedures, protection from risk, data safety, monitoring, and analysis.

Potential risks and protection against risk
Study participants will face the following risks from the study procedures:

1. Risk: Risk of inadvertent exposure of protected health and personal information, including HIV status address and location information.
   This risk also includes a third party gaining access to a participant's phone and gains access to their *WhatsApp* communications.

   Protection: Inadvertent exposure of confidential information, including HIV status and medical and social history will be minimized by conducting interviews in private spaces,. Data will not be linked to participant name or date of birth except through a separately stored participant ID number. Data will only be accessed by the research assistants, and PI. The database containing abstracted chart data, interviews, and questionnaire results will be locked behind the MGH firewall and stored in a secure database. Tablets and computers containing patients' information will be password locked and kept in a lockable cabinet accessible only to the research assistants and study PI.

2. Risk: Emotional discomfort when being asked sensitive questions.
   AYWH will be interviewed using instruments to assess for symptoms of depression, anxiety, these are sensitive questions and may cause mild discomfort. Participants will be told they can refuse to respond to any questions that they do not feel comfortable responding to with no negative consequences.
   Protection: To ensure this discomfort is further minimized, the interviews will be conducted in private space by trained study research assistants. Participants will be able to skip any questions per their preference.

   Risk: As part of the interview, some of the AYWH may be screened for possible depression, anxiety, and having experienced SRH and abuse. The recommended instrument screening cutoff values will be used.
   Protection/action: AYWH will be referred to the MRRH's mental health unit for further evaluation and treatment. The details of the clinical care will not be prescribed or controlled by study staff.

Potential benefits and relation to risks
In the formative data collection, participants may benefit from sharing their experiences and their desired features of a social media counseling intervention. Participants in the pilot may benefit from additional support offered by the counselor and improved knowledge of HIV/AIDS. There may be indirect benefit in terms of improved care for AYWH and their peers as a result of dissemination of our research findings both within MUST and through scholarly publication of findings.

We feel the risks associated with the study are small. The benefits are consistent with cultural expectations and they follow the established standard with institutional review board approval in our other studies. We therefore believe the balance of benefit and risk is appropriate.

Importance of the knowledge to be gained
Innovative and acceptable interventions to improve retention of care for AYWH are still urgently needed. The knowledge generated will be a critical initial step in this direction and will help generate preliminary data to which interventions to improve retention in care of AYWH can be based, with the overarching goal of improving outcomes in this population.

Data and safety monitoring plan
We will work to ensure that high quality data is collected and the safety of study participants is upheld. Dr. Adong (study PI) will be responsible for oversight of the day-to-day activities at the ISS clinic of MRRH. Dr. Adong will conduct staff trainings, study monitoring, and result dissemination. Reports on study progress

will be generated at least monthly and shared among the investigators for discussion. The study PI will report any serious adverse events to the IRB within 7 days of the study being notified.

Study records

We will maintain, and store in a secure manner, complete, accurate and current study records throughout the study. Data will be entered as electronic records in REDCap installed on password locked study tablets, this will be done using encrypted devices protected by institutional firewalls, and will not contain any personal identifiers. Links between participant identifiers and study identification numbers will only be maintained in a separate, locked document. The investigator will retain all study records for at least five years after completion of the study. Study records include administrative documentation and regulatory documentation, as well as documentation related to each participant screened and/ or enrolled in the study, including consent forms, notations of all contacts with the participant, logs linking participant name to study identification number and other identifying information in study files, and all other source documents. After five years, these documents will be destroyed.

Participants' study information will not be released without their written permission, except as necessary for oversight by:

- Study investigators
- Study funders

Dissemination of results

Study results will be made available to the ISS clinic staff at the end of the study during one of their weekly meetings and AYWH will be given feedback of important study findings such as acceptability of the intevervention, effect of the intervention on retention in care and other treatment outcomes. This will be done during the AYWH scheduled bi-annual psychosocial meetings. The main study findings will be shared at academic conferences and published in peer-reviewed journals for international dissemination.

Investigator roles

Dr. Adong will be the overall PI for the study; she will be responsible for development of the study protocol, training and data collection materials, domestic regulatory approval, data management systems and quality control, data analysis, manuscript preparation, and result dissemination.

Dr. Kumbakumba will contribute to study protocol development and mentor Dr. Adong throughout the period of study implementation and result dissemination.

Dr. Haberer will be responsible for supporting protocol development, design of data collection tool, submission of international regulatory approval, quality control, data analysis and manuscript preparation. She will also provide overall mentorship for Dr. Adong throughout the period of the study.

Dr. Bebell will be responsible for supporting protocol development, design of data collection tool, quality control, data analysis and manuscript preparation. Dr. Bebell will also provide mentorship to Dr. Adong throughout the study period.

Drs. Psaros, Hedt-Gauthier and Bakeera-Kitaka will provide Dr. Adong with mentorship in mixed methods, advanced statistical methods and adolescent psychology respectively.

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