Protocol

Title: InTSHA: Interactive Transition Support for HIV-infected Adolescents Using Social Media

NCT Number: NCT03624413

Protocol date: February 10, 2021

InTSHA: Interactive Transition Support for HIV-infected Adolescents Using Social Media - Detailed Protocol

I. Background and Significance

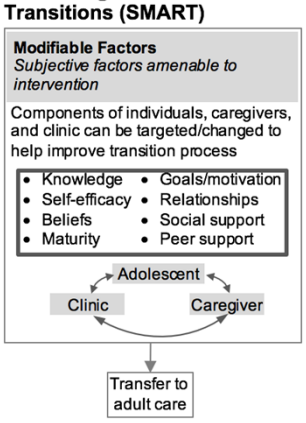
a. Historical background:

South Africa has the highest burden of adolescents living with HIV in the world and adolescents are poorly prepared for transition from pediatric to adult services. For a large majority of South Africans living with HIV, ART was not available until 2004.(1) This delay contributed to nearly 500,000 perinatal HIV infections in the late 1990s and early 2000s.(2) With large scale-up and improved access to ART in recent years, survivors of perinatally HIV-infection are now reaching adolescence and beyond.(3) As the wave of perinatally HIV-infected adolescents matures, an estimated 320,000 adolescents will transfer from pediatric- or adolescent-based clinics to adult services in the next 10 years in South Africa.(4-7) Currently, perinatally HIV-infected adolescents enter adult care at variable ages and developmental stages, without necessary preparation or support through the process.(8) My proposed research will develop and evaluate an innovative intervention designed to address this critical problem.

The transition from pediatric to adult services is a vulnerable time during which clinical outcomes commonly suffer. Despite an overall decrease in global HIV-related mortality, mortality among adolescents living with HIV increased 50% between 2005 and 2012.(9) In North America and Europe, adolescents living with HIV who transitioned from pediatric to adult care have been found to have high rates of mortality and virologic failure.(10-12) In South Africa, Davies et al. found that older adolescents (>15 years old) had lower viral suppression rates than younger adolescents at the time of transfer.(13) Effective interventions are clearly needed to improve clinical outcomes in this highly vulnerable population particularly in older adolescents transferring clinical care.

The Social-ecological Model of Adolescent and Young Adult Readiness to Transition (SMART) highlights modifiable targets of intervention that can be addressed through a social media behavioral intervention to improve transition care (Figure 1). The SMART model incorporates modifiable factors such as knowledge, skills/self-efficacy, relationships and social support that can be targets of interventions to improve transition care. Medical care during adolescence is typically complicated by increased risk-taking behavior, as well as decreased caregiver involvement, which occur during a time of rapid physical, emotional, and cognitive development.(14-17) When adolescents transition to adult care, they often do not receive the coordinated services that they received under pediatric care.(18) Qualitative studies with adolescents and clinicians from sub-Saharan Africa suggest that peer support, collaboration with health providers, and communication between adult and pediatric providers might assist in transition to adult services.(8, 19) The SMART model emphasizes eight modifiable factors, three key stakeholders (adolescents, caregivers, and clinicians) and their interconnected relationship in influencing successful transition to adult care.(20-22) The proposed social media intervention incorporates these stakeholders and addresses the modifiable factors in the SMART model to improve transition care for adolescents living with HIV.

Figure 1. Modified Social-ecological Model of Adolescent and Young Adult Readiness to Transitions (SMART)

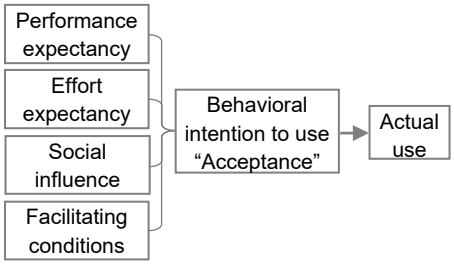


The use of social media has been shown to benefit several modifiable factors in the SMART model such as relationships, social support, and knowledge. Social media is defined as internet-based applications that allow the creation and exchange of user generated content; examples include *WhatsApp* and *Facebook*.(23) A recent meta-analysis found that social support was the most common reason for patients to use social media for health purposes.(24) Social media has also been used to improve the relationship between caregivers and patients when switching caregivers, a major barrier to transition for adolescents in South Africa.(8, 19, 24-26)

Although results vary in different settings, a recent meta-analysis has shown overall improved adherence and viral suppression among adults living with HIV using social media based health services technology.(27) Social media can address the modifiable variables in the SMART model such as knowledge, self-efficacy, goals, relationships, peer and social support, which could ultimately improve virologic suppression and retention in care during the transition to adult services.(28)

The success of social media interventions depends on the acceptance, ease of use, and perceived usefulness of the technology. If end users reject technology, misuse it, or do not incorporate it into their routine schedules, even effective and innovative health technology will fail.(29-31) The Unified Theory of Acceptance and Use of Technology (UTAUT) suggests that performance expectancy, effort expectancy, social influence and facilitating conditions influence behavioral intention to use health technology, which will lead to actual use by the end users (**Figure 2**).(32) This proposal will develop a social media-based intervention using easily available and accessible technology to optimize each of the domains in the UTAUT.

Figure 2. Unified Theory of Acceptance and Use of Technology (UTAUT)



Summary of Significance and Scientific Premise of the proposal: This significance of this application is based on epidemiologic data showing the hundreds of thousands of adolescents are approaching the transition from pediatric to adult care, and that the majority of adolescents suffer poor outcomes during this transition. The premise of this proposal is based on data demonstrating that a lack of social support from both peers and clinicians is a primary determinant of these poor outcomes, and that social media has effectively improved retention in care and viral suppression through enhanced peer support in other settings. Using the UTAUT, this proposal will expand the potential of social media to address these and other modifiable factors in the SMART model.

II. Specific Aims

Objective: To develop and evaluate a social media behavioral intervention based on the Social-ecological Model of Adolescent and Young Adult Readiness to Transition (SMART) to improve transition care for adolescents living with HIV in South Africa.

Aim 1: Using qualitative methods, determine how social media can optimally overcome barriers and enhance facilitators to transition care for adolescents living with HIV in South Africa. I will use in-depth qualitative interviews purposively sampling adolescents before transition (n=10), after transition (n=10), those not engaged in care (n=10), caregivers (n=10) and healthcare providers (n=10) to determine how social media can address the modifiable factors in the SMART model, such as promoting peer support among adolescents living with HIV. For this aim, I will learn qualitative research methods for behavioral interventions including data collection, coding, analysis, and interpretation of qualitative data.

Aim 2: Iteratively develop a behavioral intervention to improve transition to adult care using existing social media. I will use an existing social media platform such as *WhatsApp* (or similar free messaging app) to deliver a behavioral intervention that addresses the modifiable SMART factors. I will then theater test the social media intervention and obtain feedback using focus groups with adolescents living with HIV (n=20), their caregivers (n=10), and healthcare providers (n=10) to provide verification of concept, receive input on design, and spark participatory redesign. In my training for this aim, I will learn social media's use in health interventions, technology acceptance models, and behavioral change theory.

Aim 3: Determine the acceptability and feasibility of the social media intervention among adolescents living with HIV who are transitioning to adult care in South Africa. I will perform a pilot randomized controlled trial with 40 adolescents receiving the social media intervention and 40 adolescents receiving standard of care. I will use in-depth interviews and quantitative surveys with adolescents living with HIV and to assess the acceptability and feasibility of the intervention as primary outcomes. I will also assess the secondary outcomes of peer support, connection to clinical staff, retention in care, and viral suppression at baseline and 6 months after randomization. To prepare for this aim, I will gain skills in clinical trial design, randomization, analysis, and interpretation.

Aim 4: Determine how stigma affects engagement in care for perinatally-acquired youth living with HIV during transition from pediatric to adult care. I will use in-depth qualitative interviews purposively sampling adolescents both engaged and not engaged in care before transition (n=10) and after transition (n=10) to examine the different mechanisms of stigma experienced by youth living with HIV and how it pertains to their engagement in HIV care during healthcare transition.

Aim 5: Iteratively develop a behavioral intervention using principles of motivational interviewing to reduce stigma among youth living with HIV for use in an existing social media intervention to improve engagement in care during healthcare transition. We will use data from the qualitative interviews in Aims 1 & 4 and comprehensive review of the literature to iteratively develop a technology-based intervention using intervention mapping to decrease stigma using principles of motivational interviewing. The intervention will be incorporated into the existing intervention developed in Aim 2 of this study using an existing social media platform, *WhatsApp*. We will test the social media intervention and obtain feedback using 2 focus groups with adolescents living with HIV (n=8-10) to provide verification of concept, receive input on design, and participatory redesign. Through conduct of this Aim, we will use intervention mapping to create a technology-based behavioral intervention using the principals of motivational interviewing.

Aim 6: Determine how InTSHA impacts knowledge and attitudes towards sexual and reproductive health among youth living with HIV. We will use a pre- and post- intervention questionnaire, using questions adapted from the World Health Organization's Framework for discussing sexual and reproductive health behaviors with young people. We analyze patterns of change, both between adolescents and as an aggregate, in adolescents' confidence in their SRH decision making. We will assess how the intervention changes their attitudes related to giving and receiving consent, understanding the importance of contraception and family planning, and rejecting pressures and stigmas related to sexuality.

Aim 7: Qualitatively assess individuals' experiences with sexual and reproductive health. We will conduct in-depth interviews with a convenience sample of up to 20 intervention participants (until saturation is met) using an in-depth interview guide based on the Theory of Planned Behavior. The 60 minute interviews will cover individuals' sources of knowledge about sex and sexuality, perceptions of social norms, personal relationship experiences, communication about sex with others, and thoughts and critiques of the INTSHA sexual and reproductive health module. The interviews will be recorded, transcribed, translated, and thematically analyzed using Dedoose. Combined with Aim 6, these results will inform the efficacy of mHealth in changing attitudes about sexual and reproductive health in adolescents living with HIV.

Aim 8: Evaluate the impact of the InTSHA intervention 12 months after randomization in the clinical trial.

Aim 9: Determine the long-term impact of InTSHA on ART adherence and HIV drug resistance among adolescents transitioning to adult care.

III. **Subject Selection**

a. Inclusion/exclusion criteria

Inclusion Criteria:

Adolescent participants (Aims 1-7) will meet the following criteria: 1. Aged 15 to 19 years; 2. Perinatally HIV-infected; 3. Receiving ART for at least 6 months; 4. Fully aware of their HIV status.
Caregiver participants (Aim 1) will be the self-defined primary caregivers of the adolescents transitioning to adult-based self-care.
Healthcare providers (Aims 1 & 2) will be South African adult and pediatric physicians, counselors, nurses, and psychologists who care for adolescents living with HIV before or after transition to adult care.
Exclusion Criteria (all participants): Inability to read and/or speak English or Zulu or severe mental or physical illness preventing informed consent.

IV. Subject Enrollment

AIM 1: After obtaining institutional and all relevant IRB approvals, we will offer enrollment to adolescents living with HIV (ages 15 to 19 years) accessing antiretroviral therapy at Mahatma Gandhi Hospital who remain in pediatric care, those that have transitioned to adult care, and those who were lost to care during the transition process as determined by prior research study. Participants will be referred to study staff by HIV clinicians. We will also offer enrollment to caregivers of adolescents living with HIV after the adolescent as given assent or consent to participate. In addition, we will offer enrollment to healthcare providers caring for HIV-infected adolescents prior to or after transition to adult care.

Participants will participate in an in-depth interviews focusing on topics:

Optimal platforms WhatsApp, Facebook, Snapchat, MIXIT to determine acceptability, usability, flexibility, data requirements
Social media issues Social media use, privacy of cellular phone and online data, cyber bullying
Modifiable factors from SMART model Knowledge, self-efficacy, beliefs, maturity, goals/motivation, relationships with clinical staff, peer and social support, experience with HIV disclosure and stigma

AIM 2: We will offer enrollment to 20 HIV-infected adolescents (ages 15 to 19 years) accessing antiretroviral therapy at Mahatma Gandhi Hospital into two separate focus groups. In addition, we offer enrollment two separate focus groups of healthcare providers (10) and a focus group with caregivers (10). Informed consent and assent will be obtained as below.
We will review the importance of confidentiality within the focus group and that information discussed in the focus group should not be discussed outside of the focus group. These adolescents will have had prior interactions with each other based on their adolescent support group attendance on each clinic day and on interactions in the waiting room of the clinic. For this reason, there is no increased risk of disclosure of HIV status based on participation in the focus group.

In each focus group we will demonstrate the behavioral intervention using social media and encourage active participation in the use of social media intervention. We will then use obtain feedback on the intervention based on the Unified Theory of Acceptance and Use of Technology (UTAUT) technology acceptance model.

AIM 3: After the development of the behavioral intervention delivered through social media in Aim 2, we will offer enrollment to all adolescents living with HIV at Mahatma Gandhi Hospital and KwaMashu Poly Clinic after their physician determines that they are ready to transfer to adult care. Informed consent and assent will be obtained as in the above procedure. The consent/assent procedure will obtain consent for medical records review.

Adoelscents will be randomized (1:1) to receive the behavioral intervention delivered via social media vs. standard of care. All participants will be shown how to password protect their mobile phones. Participants will complete a questionnaire at baseline and after six months to evaluate peer support, connection to clinic, depression, self-esteem and transition readiness. We will conduct in-depth interviews with adolescents in the intervention arm to assess acceptability. We will perform a medical records review and evaluate clinic attendance and viral load before and 6 months after the enrollment.

AIM 4: We will offer enrollment to adolescents living with HIV (ages 15-19 years old) accessing antiretroviral therapy at Mahatma Gandhi Hospital and KwaMashu Poly Clinic, those that have transitioned to adult care, and those who were lost to care as determined by a prior research study. Participants will be referred to study staff by HIV clinicians. We will also offer enrollment to adolescents who participated in in depth interviews for AIM 1 of this study. Participants will complete in-depth interviews exploring the different mechanisms of stigma using the HIV Stigma Framework, including enacted, anticipated, and internalized stigma, and its impact on their engagement in HIV care during healthcare transition.

Aim 5: We will offer enrollment to 20 adolescents living with HIV (ages 15 to 19 years old) accessing antiretroviral therapy at Mahatma Gandhi Hospital and KwaMashu Poly Clinic into two separate focus groups and who were enrolled in the randomized control trial in Aim 3 of this study to pilot testing the mobile health intervention. Informed consent and assent will be obtained as outlined below. We will review the importance of confidentiality within the focus group and that all information discussed during the focus group should not be discussed outside of the group. As in Aim 2, these adolescents will have had prior interactions with each other based on their adolescent support group attendance on clinic days and during interactions in the waiting room of the clinic, thus there is no increased risk of disclosure of HIV status based on participation in the focus group. We will obtain feedback on the intervention using the UTAUT acceptance model.

Aim 6: We will provide the pre- and post-intervention questionnaire about sexual and reproductive health to adolescents living with HIV (ages 15 to 19 years old) accessing antiretroviral therapy at Mahatma Gandhi Hospital and KwaMashu Poly Clinic who were enrolled in the randomized control trial in Aim 3 of this study pilot testing the mobile health intervention. We anticipate enrolling all future participants after approval of the amended protocol with an n of approximately 60. Informed consent and assent will be obtained as outlined below. The questionnaire will be delivered on paper after the last session, with research staff available to help answer any questions.

Aim 7: We will offer enrollment to up to 20 conveniently sampled adolescents living with HIV (ages 15 to 19 years old) accessing antiretroviral therapy at Mahatma Gandhi Hospital and KwaMashu Poly Clinic into two separate focus groups and who were enrolled in the randomized control trial in Aim 3 of this study to participate in a 60-minute semi-structured, in-depth interview. Informed consent and assent will be obtained as outlined below. We will review the importance of confidentiality and anonymity with the participants before beginning the interviews, and ensure that they can refuse to answer any questions and stop the interview at any point.

Aims 8/9: We will offer enrollment to the 80 participants already enrolled in the InTSHA study. Participants will attend one additional research visit at least 12 months after completion of the intervention in the intervention group and 12 months after randomization for the control group. During the visit, participants will complete a follow-up questionnaire and have a blood draw. All participants will have a viral load assessment.

V. Procedures for obtaining informed consent (including timing of consent process)

Aims 1-2 and 4-7: Since adolescents in South Africa do not require parental/caregiver consent for clinical care, many of them attend clinical appointments without an adult caregiver present. We will offer enrollment to unaccompanied minors ages 15 to 18 if they are interested. With their assent, we will contact their caregiver via telephone to obtain telephone consent with the assistance of the attached telephone consent script. If the adolescent is accompanied by an adult caregiver, a trained research assistant fluent in English and Zulu will obtain written consent from guardians in Zulu or English for adolescents aged less than 18 years old and assent from the adolescent participants. Written assent will be obtained from all participants under the age of 18 years. Informed consent from caregivers will be obtained for the prospective implementation of all proposed study protocols for adolescents less than 18 years old that have given assent to participation either in person or via telephone. Adolescents under the age of 18 years who do not assent to participate in the research will not be able to participate. Adolescents 18 years old or older will provide their own consent.

Aim 3,8,9: Since this is an intervention study, we will require written assent from all participants under the age of 18 years. Informed consent from caregivers will be obtained for the prospective implementation of all proposed study protocols for adolescents less than 18 years old that have given assent to participation either in person or via telephone. Adolescents under the age of 18 years who do not assent to participate in the research will not be able to participate. Adolescents 18 years old or older will provide their own consent. For aims 8 and 9 participants will be asked to re-consent to be in the extended study.

The consenting process will take place in a private room. The consent form and telephone script will comprehensively provide the following information: (a) introduction to the consent process, explaining the consent 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 and leave the study at any time; and (j) rights and complaints. After each major section, research staff obtaining consent 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.

VI. Study Procedures

Study visits and parameters to be measured (lab tests, X-ray and other tests)

Aim 1: We will recruit participants from Mahatma Gandhi Hospital's Pediatric and Adult HIV Clinics. Adolescent participants will be identified and referred by the hospital clinicians after clinic visits. We will purposefully sample three groups of 10 adolescents each based on transition status. The first group will consist of adolescents retained in care who have not yet transitioned to adult care (pediatric clinic) and the second group of adolescents retained in care will have already transitioned to adult care (adult clinic). The third group will consist of up to 10 adolescents not retained in care and who were lost during the transition process. I will identify this third group by a tracking protocol that I successfully used previously to characterize the clinical status of all adolescents at Mahatma

Gandhi Hospital (4KL2TR001100-04; “Retention in Care for HIV-infected Adolescents Transitioning to Adult Care”); potential participants will be referred for enrollment by clinic contact tracers as they attempt to re-engage adolescents in care or by clinicians after their return to clinical care. In addition, we will interview approximately 10 caregivers and 5 adult and 5 pediatric healthcare providers (counselors, nurses, and physicians). We will attempt to enroll equal number of male and female participants in each group. Interviews will be conducted in Zulu or English and last about 1 hour.
Measures: The in-depth interviews will evaluate the current use of social media and its impact on modifiable factors in the SMART model. We will aim for thematic saturation in each group.

Aim 2: The initial version of the InTSHA social media intervention will be based on data in Aim 1 and existing adolescent-friendly curriculum.(33, 34) We will then theatre test the intervention by demonstrating the InTSHA intervention with participants and allowing them to interact on the social media platform. We will also demonstrate the use of educational content delivery, facilitated group discussions, message boards, and meet-ups via social media. We will then use an iterative process with 2 separate focus groups of 8 - 10 adolescents each, 2 focus groups of 8–10 healthcare providers each, and one focus group of 8 - 10 caregivers who have used the InTSHA intervention. Focus groups will be conducted separately for English and Zulu and will last approximately 90 minutes. Analysis: We will analyze the intervention development using the plan, engage, execute, reflect and evaluate process.(35, 36) We will then conduct the focus group based on the UTAUT model of technology acceptance to reflect on usefulness and acceptability the intervention.(37) The focus group discussions will evaluate the usability, challenges, and expectations of the intervention. The discussions will be recorded, transcribed, and translated into English. Transcriptions will be uploaded, organized, and coded using Dedoose software (version 7.0.23, LA, California).(38) We will then use an iterative process after each round of focus group session (adolescents, healthcare providers, and caregivers) to evaluate feedback for each version of the intervention based on coded themes identified during focus group feedback sessions. The intervention will subsequently be revised based on focus group feedback prior to demonstration with the next round of focus group participants. The final intervention will be based on the iterative process from all focus groups as well as input from our collaborative research team. To ensure fidelity of the intervention, we will use an intervention manual for content with training of the research team and healthcare providers. Only one team will monitor and facilitate the sessions.

Aim 3: Recruitment will take place over 15 months. We anticipate enrolling groups of 5 - 10 subjects based on preferences defined in Aim 1. During visit one, we will collect baseline demographic data, baseline questionnaires, and have viral load assessments on all participants. The second research visit will take place 6 months after randomization. This research visit will evaluate acceptability and feasibility and perform in-depth interviews exploring the UTAUT model of technology acceptance with all participants in the experimental arm.(37) In addition, all subjects will complete follow-up questionnaires and have viral load assessment.

Data to be collected and when the data is to be collected
Demographic data will be collected on all adolescents during a chart review and will include age, sex, age at diagnosis, history of opportunistic infections, length of time on ART, ART regimen, last viral load, last clinic visit, and last pharmacy refill. Data will be collected from a combination of electronic records (Tier.net and NHLS) and paper charts. Additional data on vital status and location of care services will be obtained through the tracker program. Only de-identified data will be entered into the database. Viral load will be measured at enrollment and 6 months after randomization. Pharmacy refill and clinic appointment data will be collected during enrollment in the study.

Aim 4: We will recruit participants from adolescents who participated in AIM 1 interviews, and from Mahatma Gandhi Hospital's and KwaMashu Poly Clinic's Pediatric and Adult HIV Clinics. Adolescent participants will be identified and referred by the hospital clinicians after clinic visits. We will purposefully sample two groups of 10 adolescents each based on transition status. The first group will consist of adolescents who have not yet transitioned to adult care (pediatric clinic) and the second group of adolescents will have already transitioned to adult care (adult clinic). Within each group of 10 adolescents, we will purposefully sample up to 5 adolescents not retained in care. I will identify adolescents not retained in care by a tracking protocol that I successfully used previously to characterize the clinical status of all adolescents at Mahatma Gandhi Hospital (4KL2TR001100-04; "Retention in Care for HIV-infected Adolescents Transitioning to Adult Care"); potential participants will be referred for enrollment by clinic contact tracers as they attempt to re-engage adolescents in care or by clinicians after their return to clinical care. We will attempt to enroll equal number of male and female participants in each group. Interviews will be conducted in Zulu or English and last about 1 hour.
Measures: The in-depth interviews will evaluate the different mechanisms of stigma based on the HIV Stigma Framework and its impact on engagement in HIV care during transition from pediatric to adult care. We will aim for thematic saturation in each group.

Aim 5: The intervention will be a social media-based interactive motivational interviewing intervention for youth living with HIV during healthcare transition. Content will incorporate findings from existing data from in-depth interviews in Aim 1 & 4, intervention mapping and interactive strategies using principals of motivational interviewing, in addition to an informational component. The informational component will address misconceptions about HIV and healthcare transition, aiming to reduce fears about transition through education, graphics, and videos. To promote attitude and behavior change, motivational interviewing will be used including open-ended questions, affirmations, reflective listening, and exploration of reasons for stigma. Participants enrolled in the randomized control trial in Aim 3 of this study will pilot test the stigma intervention module for InTSHA. We will use an iterative process with 2 separate focus groups of 8 - 10 adolescents each who have used the stigma intervention module for InTSHA. Focus groups will be conducted separately for English and Zulu and will last approximately 90 minutes. The focus groups will be conducted based on the UTAUT model of technology acceptance to reflect on usefulness and acceptability of the intervention.(37) The focus group discussions will evaluate the usability, challenges, and expectations of the intervention. The discussions will be recorded, transcribed, and translated into English. Transcriptions will be uploaded, organized, and coded using Dedoose software (version 7.0.23, LA, California).(38) We will identify coded themes during the first focus group session and use an iterative process to evaluate feedback for each version of the intervention. The intervention will subsequently be revised based on focus group feedback prior to demonstration with the next round of focus group participants. The final intervention will be based on the iterative process from both focus groups as well as input from our collaborative research team. To ensure fidelity of the intervention, we will use an intervention manual for content with training of the research team. Only one team will monitor and facilitate the sessions.

Aim 6: The same subjects enrolled in Aim 3 will be provided with a pre- and post- intervention questionnaire. During visit one, we will collect data on an additional 9 questions about consent, contraception, family planning, social pressures, and communication related to SRH. The second research visit will take place 6 months after randomization, after the intervention has been completed, to assess changes in beliefs and attitudes towards SRH over time.

Data to be collected and when the data is to be collected

An additional 9 questions about attitudes and beliefs on SRH will be collected by adding to the existing pre and post questionnaire.

Aim 7: We will recruit participants from adolescents who participated in the clinical trial in Aim 3 from Mahatma Gandhi Hospital's and KwaMashu Poly Clinic's Pediatric and Adult HIV Clinics. Adolescent participants will be identified and referred by the hospital clinicians after clinic visits. We will conveniently sample up to 20 adolescents (based on saturation of major themes) who completed the intervention. We will attempt to enroll equal number of male and female participants of varying ages. Interviews will be conducted in isiZulu or English and last about 1 hour. Measures: The in-depth interviews will evaluate personal experiences with sexual and reproductive health as adolescents living with HIV based on the Theory of Planned Behavior and how our mobile health intervention affected attitudes and beliefs of sexual and reproductive health. We will aim for thematic saturation in each group.

Aims 8: We will recruit only patient previously enrolled in the InTSHA study. Participants will complete the same follow-up questionnaire that was completed at the end of the study. Participants will have a single blood draw to evaluate long term viral suppression.

Aim 9: All participants will have a single additional research visit as in Aim 8. Participants will have a single blood draw (same as aim 8) to evaluate tenofovir levels and for HIV genotyping to evaluate for drug resistance in those individuals with viremia. Samples from individuals with a detectable viral load >500 copies/ml will be sent for genotype analysis. We will attempt to perform HIV-1 genotype analysis for those with low level viremia with viral loads between 200 and 500 copies/ml; however, amplification of the HIV genome may not be possible with low level viremia. For participants with undetectable viral loads, development of HIV drug resistance is not a concern.

VII. Biostatistical Analysis

Study Endpoints:

Outcomes:

Aim 1: The in-depth interviews will evaluate the current use of social media and its impact on modifiable factors in the SMART model as indicated in **Table 5**. We will aim for thematic saturation in each group.

Table 5. Interview Domains

Optimal platforms • WhatsApp, Facebook, Snapchat, MIXIT to determine acceptability, usability, flexibility, data requirements
Social media issues • Social media use • Security • Privacy of cellular phone and online data • Cyber bullying

Modifiable factors from SMART model
- HIV knowledge
- Self-efficacy
- Beliefs
- Maturity
- Goals/Motivation
- Peer and social support
- Relationship with clinical staff
- Experience with HIV disclosure and stigma

Aim 2: I will then use an iterative process after each round of focus group session (adolescents, healthcare providers, and caregivers) to evaluate feedback for each version of the intervention based on coded themes identified during focus group feedback sessions. The intervention will subsequently be revised based on focus group feedback prior to demonstration with the next round of focus group participants. The final intervention will be based on the iterative process from all focus groups as well as input from our collaborative research team.
Aim 3: We will determine the primary outcomes of acceptability (quantitative assessment of acceptability based on the UTAUT developed by Dr. Holden)(29, 31) and feasibility (enrollment, participation and completion thresholds >80% for each). We will also measure secondary outcomes of retention in care (pharmacy refill and clinic attendance in last 6 months) and viral suppression (<400 copies/ml) comparing pre-transition with 6 months after randomization. In addition, we will explore other factors based on modifiable variables in the SMART model including: adolescent peer support (Child and Adolescent Social Support Scale),(39) self-esteem (Rosenberg scale),(40) depression (PHQ-9),(41) and stigma (Internalized AIDS stigma scale),(42) connection to clinic (Working Alliance Inventory),(43) and transition readiness (TRANSITION Q).(44)
Aim 4: In-depth interviews will examine the different mechanisms of stigma and its impact on engagement in HIV care, including retention in care, adherence to medications, and viral suppression. We will aim for thematic saturation in each group.
Aim 5: I will use an iterative process as described in Aim 2 after each focus group session with adolescents to evaluate feedback for each version of the stigma-based intervention based on coded themes identified during focus group feedback sessions. The stigma content will be revised based on focus group feedback prior to demonstration with the second focus group. The final stigma intervention content will be based on the iterative process from both focus groups, as well as input from our collaborative research team.
Aim 6: A targeted questionnaire assesses sexual and reproductive health behaviors and attitudes, adapted from the WHO Framework for asking about SRH with Adolescents.
Aim 7: In-depth interviews will examine the adolescent attitudes about sexual and reproductive health and its impact on engagement in HIV care, including sources of information about sex, access to sexual health resources, personal experiences with relationships, and communication about reproductive health. We will aim for thematic saturation in each group.
Aim 8: We will measure of retention in care (pharmacy refill and clinic attendance in last 6 months) and viral suppression (<200 copies/ml) comparing results from 6 months after randomization to 12 months after randomization. In addition, we will explore other factors based on modifiable variables in the SMART model including: adolescent peer support (Child and Adolescent Social Support Scale), (41) self-esteem (Rosenberg scale), (42) depression (PHQ-9), (43) and stigma (Internalized AIDS stigma scale), (44) connection to clinic (Working Alliance Inventory), (45) and transition readiness (HIV Adolescent Readiness for Transition). (46)
Aim 9: We will compare short term adherence (tenofovir levels) among adolescents in the InTSHA intervention group to the standard of care group. In addition, for viremic adolescents we will evaluate for the presence of HIV drug resistance searching specifically for Protease, Integrase, and Reverse Transcriptase mutations. We will use the Stanford database of HIV Drug resistance to determine significant HIV drug resistance mutations.

Statistical methods

Aim 1: We will use an inductive, content analytic approach to identify benefits and potential negative impacts of social media use during transition to adult care.(32, 51) Interviews will be translated from the local language (Zulu) into English and transcribed. Transcriptions will be uploaded, organized, and coded using Dedoose software (version 7.0.23, LA, California).(52) We will use open coding to inductively construct descriptive categories based on themes identified in the interviews. We will create a codebook based on themes identified in a subset of interviews. We will use an iterative process to construct categories based on the coded text. Broader themes will be created using linking and framing of coded text.

Aim 2: We will analyze the intervention development using the plan, engage, execute, reflect and evaluate process.(55, 56) We will then conduct the focus group based on the UTAUT model of technology acceptance to reflect on usefulness and acceptability the intervention.(57) The focus group discussions will evaluate the usability, challenges, and expectations of the intervention. The discussions will be recorded, transcribed, and translated into English. Transcriptions will be uploaded, organized, and coded using Dedoose software (version 7.0.23, LA, California).(52) We will then use an iterative process after each round of focus group session (adolescents, healthcare providers, and caregivers) to evaluate feedback for each version of the intervention based on coded themes identified during focus group feedback sessions. The intervention will subsequently be revised based on focus group feedback prior to demonstration with the next round of focus group participants. The final intervention will be based on the iterative process from all focus groups as well as input from our collaborative research team. To ensure fidelity of the intervention, we will use an intervention manual for content with training of the research team and healthcare providers. Only one team will monitor and facilitate the sessions.

Aim 3: Our primary focus is on estimating the acceptability and feasibility of the social media intervention for planning a larger clinical trial to measure efficacy. We will consider a feasibility / acceptability estimate of 80% or higher among the 40 participants as evidence that the social media program is acceptable to the population. Analysis. We will summarize the acceptability and feasibility data in the intervention group using standard summary statistics (e.g. counts/percentages; median and interquartile range of continuous measures). We will estimate the difference between the intervention group and the control for social support, connection to clinic, self-esteem, retention in care and virological suppression 6 months after randomization. The secondary outcomes will assist in planning a larger randomized clinical trial through a future R01 grant; the standard deviation for these differences is expected to be on the order of 8%. Depending on the number of individuals not retained in care or the number not virologically suppressed, we may use logistic regression to explore combinations of 2-3 variables potentially predictive of outcome. Assuming that the intervention is acceptable and feasible for participants, we would consider moving forward to an R01 if there was evidence of a benefit to participants, in terms of overall retention and virological suppression at 6 months, although we would not expect the difference to be statistically significant.

Power analysis (sample size, evaluable subjects, etc): With 40 participants in the experimental arm, if the true acceptability rate were 90% we would be able to rule out that acceptability was less than 70% with 90% power (alpha=0.05, one-sided) using an exact test.

Aim 4: We will use an inductive, content analytic approach to identify the different mechanisms of stigma and how they affect engagement in care during healthcare transition. Interviews will be recorded, transcribed, and translated into English. Transcriptions will be uploaded, organized, and coded using Dedoose software (version 7.0.23, LA, California).(52) We will use open coding to inductively construct descriptive categories based on themes identified in the interviews and then create a codebook based on themes identified in a subset of interviews. We will create categories based on the coded text using an iterative process and broader themes will be created using linking and framing of coded text.

Aim 5 and 7: We will analyze the stigma- and sexuality-focused interventions using the plan, engage, execute, reflect and evaluate process.(55, 56) We will then conduct the focus group based on the UTAUT model of technology acceptance to reflect on usefulness and acceptability of the

intervention.(57) The focus group discussions will evaluate the usability, challenges, and expectations of the intervention. The discussions will be recorded, transcribed, and translated into English. Transcriptions will be uploaded, organized, and coded using Dedoose software (version 7.0.23, LA, California).(52) I will use an iterative process as described in Aim 2 after each focus group session with adolescents to evaluate feedback for each version of the stigma- and sexuality-based interventions based on coded themes identified during focus group feedback sessions. The content will be revised based on focus group feedback prior to demonstration with the second focus group. The final intervention content will be based on the iterative process from both focus groups, as well as input from our collaborative research team. We will train the research team using an intervention manual for content to ensure consistency of the intervention. Only one team will monitor and facilitate the sessions.
Aim 6: We will summarize the sexual and reproductive health pre- and post- questionnaire data using standard summary statistics (e.g. counts/percentages; median and interquartile range of continuous measures). The questionnaire tests comfort with SRH topics in a uniformly negative (strongly disagree) to positive (strongly agree) 4 point Likert scale. We will estimate the difference in aggregate and question-specific score improvement between the intervention group and the control group in aggregate score on the questionnaire.
Aim 8: We will summarize viral suppression and retention in care in the intervention and control groups using standard summary statistics (e.g. counts/percentages; median and interquartile range of continuous measures). We will estimate the difference between the intervention group and the control for social support, connection to clinic, self-esteem, retention in care and virological suppression 12 months after randomization. The standard deviation for these differences is expected to be on the order of 8%. Depending on the number of individuals not retained in care or the number not virologically suppressed, we may use logistic regression to explore combinations of 2-3 variables potentially predictive of outcome.

Aim 9: We will summarize adherence (tenofovir levels) and significant HIV drug resistance in the intervention and control groups using standard summary statistics (e.g. counts/percentages; median and interquartile range of continuous measures). Although this study is not powered to detect a significant difference in the intervention and control arms for adherence or drug resistance, this will provide valuable explanatory detail for the primary results of this study.

VIII. Risks and Discomforts

Risk: Loss of privacy is a potential risk if information is compromised which could lead to unintended disclosure of personal medical information including HIV status.
Safeguard: The data from interviews and medical record review will be anonymous and identifiable information will not be recorded. All information will be stored on encrypted password-protected computers and loaded into a secure REDCap and Dedoose databases. Interviews will take place in a private setting. Participant names will not be recorded and personal identifiers will be limited to date of birth. Participants will be identified only by a unique study ID number. While the data is being collected, the list linking study ID numbers to patient file numbers (medical record numbers) will exist. This is necessary for cross-referencing the different data sources. Once all data has been collected, the list that links study ID numbers to medical record numbers will be permanently deleted. All steps in this de-identification process will occur on the password-protected, encrypted, study computer. Participants will be shown how to password protect their mobile phone. Only adolescents randomized to the intervention and study staff will have access to the social media site. Patient names or identifying information will not be used in online communications.

Risk: Loss of privacy including disclosure of HIV status during focus group discussions.

Safeguard: Adolescents will be enrolled from Mahatma Gandhi Clinic and KwaMashu Poly Clinic. Current procedures at the clinic include attendance in an adolescent support group on clinic days. Since adolescents will be recruited from this site, they will already have interacted with each other during these group meetings as well as in the waiting room of the clinic. This will minimize accidental disclosure of HIV status among focus group members. In addition, we will review the importance of confidentiality within the focus group and that information discussed in the focus group should not be discussed outside of the focus group.

Risk: Loss of privacy including accidental disclosure of HIV status using social media.
Safeguard: Participants will be shown how to password protect their own mobile device. In addition, the majority of the content of the behavioral intervention will not involve HIV: self-efficacy, beliefs, maturity, goals/motivation, relationships, peer/social support. Any HIV-related content will not disclose individual's status. All activities involving HIV content will be scheduled; therefore, minimizing unexpected information arriving to mobile phones. Access to the social media discussion groups will be limited to study participants, their clinicians and research staff. Any breach of confidentiality or reported loss of protected health information will be reported to the clinical staff, Durban University of Technology and Partners IRB. Content will be suspended until an acceptable resolution has been determined by the IRB.

Risk: Guilt and Anxiety: One of the study components is an analysis of retention in care and viral suppression. The secondary outcome measures are retention in care and viral suppression, which can reflect default (loss to follow up) or virologic failure leading to feelings of guilt and anxiety.
Safeguard: Clinic staff will assist with contacting and finding those lost to follow up and adherence counseling will be available to those with virologic failure. These data will be de-identified following extraction. The interview component including information on retention and viral suppression for those identified as lost to follow up will be obtained prior informed consent.

Risk: A potential discomfort is anxiety, discomfort or fatigue during the interview. However, topics discussed are themes that are typically discussed in the clinical setting.
Safeguard: Trained adolescent counselors will be available after the interview session if required for any emotional distress. In addition, participants will be informed of their right to withdrawal from the study at any time.

Risk: Interviewing a vulnerable population that includes adolescents under the age of 18.
Safeguard: Minors under the age of 18 years (ages 15 to less than 18 years) will be offered assent to participate in the study. If they assent, then we will obtain informed consent from their caregivers. Adolescents under the age of 18 years who do not give assent to participate in the study will not be offered enrollment and their caregivers will not be contacted. Our research team has conducted more than 50 in depth interviews with adolescents less than 18 years old in similar settings.

Risk: Conflict between the adolescent and caregiver if both are enrolled, which may occur during the interview and consenting process.
Safeguard: Adolescents less than age 18 will provide assent to the study. Interviews will be conducted separately. Adolescents will be informed that their answers will not be shared with their caregivers. Caregivers will also be informed that their answers will not be shared with the adolescents.

Risk: Fear of impact on clinical care.
Safeguard: We will provide reassurance that responses or withdrawal from the study will not influence clinical care.

Risk: Misuse of electronic social media, cyberbullying, spreading of false information, or loss of disclosure.
Safeguard: The social media site will be a closed group where access will only be granted by invitation. Only adolescents randomized to the intervention will have access. The research team will monitor the site and any messages that are deemed inappropriate will be deleted.

Risk: Inducement to participate through provision of money for data (air time).
Safeguard: Participants will receive funds to cover the cost of their data to participate in the study. We will work with the local IRB, local clinical staff, caregivers and adolescents in Aim 1 to address concerns about coercion to participate in the research study by provision of money for data use.

Risk: Interference with clinical staff time
Safeguard: We will use research staff to monitor activity on the social media site. Clinical staff will participate at scheduled intervals. Currently the clinical staff spends two hours weekly involved in the adolescent support group; however, the activities are often poorly organized and lack focus. We will re-purpose, focus, and organize some of this time to include time involved in the social media intervention.

IX. Potential Benefits

Although, there is no direct benefit to the individual during the study, results of this research may assist in the development of methods to improve adolescent HIV care and transition to adult care. In addition, participants will be given 250 Rand (~$20 USD) to compensate them for their time spent doing the interviews, focus groups and completing the surveys.

Adolescents in Aim 3 will receive funds to compensate them for data use and air time for their cell phones. This will average approximately 20 USD per month. See protection against inducement above.

Adolescents in Aims 4, 5 and 7 will be given approximately 20 USD to compensate them for their time spent doing the stigma-related interviews and focus groups.

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

Potential benefits to society

Retention in care and viral suppression among HIV-infected adolescents transitioning to adult care are important for perinatally-HIV infected adolescents. Effective strategies to enhance retention in care and viral suppression among adolescents during transition to adult care are needed. Using social media to address the modifiable factors in the SMART model may improve retention and viral suppression rates among adolescents living with HIV as they transition to adult care. In addition, the knowledge gained in this study will assist with the development and evaluation of new interventions to address this vulnerable population.

X. Monitoring and Quality Assurance

Independent monitoring of source data

Data extracted from the clinic records will be reviewed by a second staff member for completeness and accuracy.
Transcriptions will be reviewed by two independent researchers for the development of themes.

Safety monitoring (DSMB)

Dr. Archary will be responsible for oversight of the research activities and data collected at Mahatma Gandhi Hospital and KwaMashu Poly Clinic. Dr. Zanoni and Haberer will communicate frequently with Drs. Archary and Moosa and Ms. Sibaya, as well as other study staff, by email and Skype (at least weekly). Dr. Zanoni will make study site visits at least twice annually, while Dr. Haberer will make a site visit annually. All serious adverse events will be reported to the Mahatma Gandhi Hospital and KwaMashu Poly Clinic clinical staff, University of KwaZulu-Natal Bioethics Review Committee and Partners Ethics Review Committee according to their requirements (generally 7-10 days). Data collection will be suspended until appropriate precautions have been taken to avoid repeat safety concerns.

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