STUDY PROTOCOL
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Project Title: Integrating Safer Conception Counseling to Transform HIV Family Planning Services

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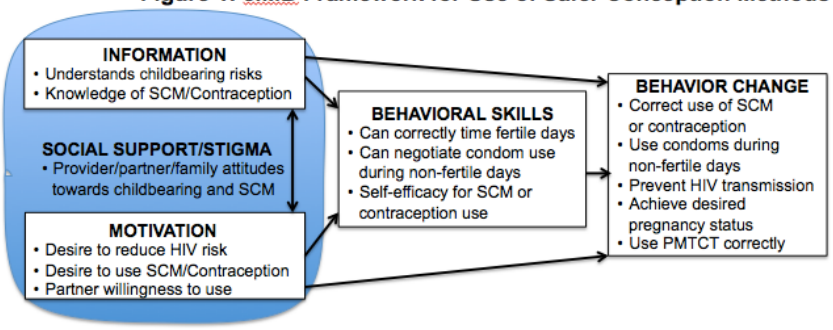
Overview. This 3-arm, cluster RCT will compare two models for implementing a comprehensive FP program that integrates SCC within current FP services in HIV clinics—an up to 6-session, multi-component, structured SCC intervention (SCC1), and a workshop to train FP providers on use of SCC guidelines (SCC2)—versus existing FP services (usual care). Both SCC1 and SCC2 will use routine screening for fertility desires and a workshop for training FP nurses to implement SCC, but SCC1 is differentiated by its use of a structured counseling SCC protocol and manual (as opposed to the clinical acumen of the trained FP nurses), and inclusion of client outreach and ongoing supervision support. Each arm will be implemented at 2 sites (6 sites in total) and each site will enroll 65 clients (total n=390) with serodiscordant partners who have childbearing desires at recruitment. Participants will be surveyed at baseline, months 6 and 12, and post-pregnancy for those who become pregnant prior to month 12. The primary outcome is correct use of SCM or contraception (depending on desired pregnancy status following SCC consult); secondary outcomes are pregnancy status, PMTCT use (if pregnant), partner seroconversion, and condom use. A cost-effectiveness analysis will also compare the 3 arms to inform policy and practice recommendations for settings of various resource levels.

Study Setting. The study will be conducted at 6 HIV clinics operated by The AIDS Support Organization (TASO), which are located in Masaka, Entebbe, Mbarara, Jinja, Mbale, and Rokangira. These sites are *highly comparable with regard to size of clientele, provider composition, and makeup of FP services, and are close enough to Kampala for facilitating effective coordination and oversight of the research*. TASO partnered with us to plan the proposed models for integrating SCC into its FP services, and to pilot SCC1 (see D.1). Each site resides within a hospital campus, provides HIV care to 6000-8000 index clients (65-75% female, 75-80% aged 15-49, ~70-80% on ART), with a staff of 15-20 medical providers (incl. 3-4 FP nurses), 12-15 counselors and 6-10 expert clients. Each provides reproductive health and FP services in-house, which focus on contraception and PMTCT; contraceptives provided onsite include oral pills, injectables, and condoms, while implants and tubal ligation require referral to nearby FP clinics. Other related services at TASO include assisted disclosure (including home-based couples HIV testing), and male circumcision.

Cluster RCT of two models for integrating SCC within existing FP programs vs. usual care
Each site will be randomly assigned (a blind drawing witnessed by the leadership of each clinic) to use one of the two models for integrating SCC into FP services (SCC1 or SCC2), or usual care (existing FP services).

Arm 1: Multi-component, structured intervention for integrating SCC into FP (SCC1)

Figure 1: eIMB Framework for Use of Safer Conception Methods



Drawing on an ecological adaptation of the Information, Motivation and Behavioral skills (eIMB) model of behavior change,[57] we developed a multi-component intervention that identifies and engages HIV clients (and partners) with fertility desires into SCC to facilitate an informed decision process regarding childbearing and corresponding use of contraception or SCM (and PMTCT once pregnant) based on their desired pregnancy decision. Applied to this context, IMB asserts that ***information*** about the transmission risks of childbearing and how SCM and PMTCT limit these risks is a prerequisite but insufficient to ensure use of SCM/PMTCT or contraception, and that motivation and behavioral skills to use these methods are critical. ***Motivation*** is fed by beliefs that SCM and PMTCT greatly reduce transmission risks and contraception prevents unplanned pregnancy, and confidence in being able to use these methods. ***Behavioral skills*** such as calculating the fertile days of a woman's ovulation cycle, using a syringe to manually inseminate the woman, and negotiate condom and contraception use with one's partner, are key to SCM and contraception use. The ***sociocultural context*** for childbearing in PLHA affects each of the IMB components: HIV+ peers, providers, partners, family and community are sources of information (or misconceptions), attitudes, beliefs, and support (or stigmatization) for childbearing and use of contraception, SCM and PMTCT, all of which affect knowledge, motivation, and self-efficacy for use of these methods. Stigmatization of childbearing by providers,[17,26,33] family and community[27] contributes to poor provider-patient communication about fertility needs and greatly impedes clients receiving needed SCC.

To address each eIMB construct, the multi-component intervention consists of: 1) training expert clients and village health team workers (VHTs) to engage in **client and community outreach and education** about the

childbearing needs of PLHA and availability of comprehensive FP services including SCC to promote SCM use and reduce childbearing stigma; 2) **provider training and supervision** to sensitize providers to childbearing needs of PLHA, reduce provider stigma of childbearing, and develop and sustain their skills and self-efficacy for providing SCC; 3) **routine screening of childbearing desires** to facilitate timely identification of clients in need of SCC or contraceptives; and 4) **structured, manualized SCC sessions** administered by FP nurses to promote informed childbearing decisions and use of SCM, PMTCT and contraception. *The intervention will be incorporated into the clinic's model of care and applied to all clients, not only research participants*.

(1) Client and community education and outreach: To increase support for SCC and use of SCM among HIV clients, partners, family and community, we will train 4 "expert clients" and 4 VHTs (who are clients of the clinic and already employed to serve the clinic's catchment area) to engage in enhanced outreach and education activities in the clinic and community. Expert clients are experienced clients of the clinic who are exemplary in their HIV disease management and assist in the clinic for a small incentive; 6-10 expert clients work at each site. VHTs are community members trained to provide education, referral and linkage services to other members when in need. *Expert clients and VHTs are present in most public and NGO HIV clinics across Uganda; they are trusted, respected and are often turned to for advice and guidance.* Training peers and popular opinion leaders to engage in outreach efforts as change agents within their communities has been successful in promoting behavior and attitude change,[58] including in HIV prevention.[59] We will select and train expert clients and VHTs who express interest in promoting safer conception (who are often those who recently had a child or who want to). *Expert clients will be trained to conduct brief education talks to clients in the waiting room and in informal one-on-one discussions, while the VHTs will be trained to include information about SCM during their health education talks and one-on-one consultations in the community.* These outreach efforts will focus on spreading the word about the availability of SCM, PMTCT and SCC in addition to FP and contraception at TASO, importance of PLHA communicating fertility desires to providers and partners, the genuine desire of HIV providers to support childbearing needs, and the importance of partner involvement in SCC. SCM education will emphasize how the methods reduce HIV risk while enabling conception.

African healthcare workers, including expert clients and VHTs, are prone to use a more directive style when interacting with clients, rather than the autonomy supportive style of Motivational Interviewing (MI) that proved useful in our pilot. Research with lay HIV counselors in South Africa[60] demonstrates that they can be trained in MI skills and we have developed a training program that focuses on three core MI skills: open questions, reflective listening, and pulling for change talk. While not fully compliant MI counseling, use of these communication strategies may greatly enhance their success in encouraging clients to consider using SCM, and male partners to participate in FP. MI strategies may be particularly useful in enhancing clients' motivation and reducing levels of internal and external stigma thereby increasing the likelihood of clients: initiating childbearing discussions with providers, engaging partners in SCC, and being open to using SCM. Our intervention will incorporate routine screening for childbearing desires and train providers to ask clients about fertility intentions, but it is equally important to empower clients to assert their need for childbearing support. *Half the trained expert clients and VHTs will be male to facilitate successful outreach to men. Clients who benefit from SCC and successfully use SCM to conceive will be asked to give brief waiting room testimonials about how SCM worked for them and how talking with their providers and accessing SCC helped. We will intentionally seek out men to participate in testimonials, to encourage other men to seek SCC*.

(2) Provider training, fidelity monitoring and supervision: Fig. 2 shows our plan for provider training and supervision. The first 4 hours of training uses experiential learning methods to sensitize providers to: their own attitudes and beliefs that stigmatize childbearing and impede rapport building; the risks and benefits of SCM; and the need for all providers to discuss fertility needs with clients. *All providers (doctors, nurses, counselors, expert clients) are included in this portion of the training to increase their knowledge and understanding of their role in supporting clients' use of SCM and contraception, and*

Figure 2: FP nurse training, supervision and fidelity monitoring by SCC arm

	Skills	Training Strategy	Hrs	Fidelity
Arm 1 (**SCC1**): **Multi-Component Structured Intervention**	Building rapport Exploring readiness Using Open questions Using Reflective listening Encouraging change talk Assessing health factors Assisting w/ disclosure family planning decision Confidence providing SCC Teaching SCM & use of tools Problem solving strategies Using text message system	Exploration of counselors beliefs and attitudes Didactic review of manual Videos / live demos Role plays Communication skills Intervention sessions Teaching use of tools Personalized feedback on MI skills Identification of implementation barriers and solutions SMS text training	16	Supervision weekly individual monthly group Sessions recorded, all reviewed until criteria met then 1 of 4 coded Session checklist: FP nurse completes; supervisor provides tailored feedback on coverage of content and MI skills 95% of text messages sent on time
Arm 2 (**SCC2**): **Training Workshop Intervention**	Building rapport Knowledge of SCM Confidence providing SCC Familiar w/ manual & tools	Lecture on benefit of SCC and history of stigma Review of manual w/ tools Live demos Role play of 1st session	8	Supervision on request from clinic doctors/FP clinic Sessions recorded, w/ random tapes coded Session checklists by nurses Yearly training update

ensure proper referral to FP nurses for SCC. FP nurses will conduct the SCC sessions because of their familiarity with conception and contraception methods. *FP nurses will complete an additional 12 hours of training for administering the SCC sessions*. We do not intend for the FP nurses to use all MI counseling skills, but will train them to use 3 core skills: open questions, reflective listening and pulling for change talk. Training will be led by Goggin and Beyeza-Kasheysa. Beyeza-Kasheysa and Amongin (Project Director) will monitor fidelity (see appendix for supervision checklist; and Fig. 2). *With this being a proof of concept trial, we need to ensure implementation of the intervention is adequate. TASO will not ask its staff to take on the added burden of SCC without proof of efficacy, but it's staff needs to be among the trained interventionists (for external validity and sustainability*); to offset the added burden, the study pays for one added FP nurse per intervention site (including SCC2 sites), but all FP nurses at these sites will be trained and expected to implement SCC.

Tools will be developed to facilitate SCC [session checklists, posters for the waiting and clinician rooms, pregnancy planning calendar, client SCM kits (needleless syringe, plastic cup, non-spermicidal condoms, lubricant), client pictorial instruction brochures (see appendix) and video demonstrations]. *Guided by our consultant, Shannon Weber, who has been using brief, simple SCM instructional videos created for use on Youtube by videotaping counseling role plays and testimonials of successful couples, we will create video clips for use in training FP nurses as well as to be used by the nurses to train clients, and for clients to refer to at home or where they can access the internet*. These low cost videos can be made quickly and will be made using nurse role plays at first, but we will engage actual clients (with consent) who use the services over time. *We will be particularly keen to engage male clients/partners in videos, as a way to foster male involvement*.

(3) Routine screening of childbearing desires: *To ensure clients receive either SCC or contraception as needed, a single question, "Are you thinking about trying to conceive a child within the next 12 months?" will be asked by expert clients* at the triage station (which is where clients go after checking in for their visit) *for all reproductive aged men (age 18-60) and women (age 18-45)*. The screening item is liberally worded so that it is inclusive of clients who are considering childbearing but may not be certain about their own desire or that of their partner, which will enable more clients to receive support from SCC to make an informed decision. Clients who report childbearing desires will be seen by a trained FP nurse for a SCC consult during the same clinic visit or scheduled for a future visit if the client is willing and able to bring their partner in for the consult. If the client is interested in participating in the study, the partner will need to come in for HIV testing prior to receiving the first SCC consult. Clients with no childbearing desires will be seen by the FP nurse for contraception.

(4) Structured (up to 6) monthly SCC sessions: *Sessions will follow a structured protocol and the manual used in the pilots (see appendix),* which we will adapt to include linkage to the clinic's contraception services for a more comprehensive FP program. The first consult focuses on: the client's relationship context; the client's health, review of risks and benefits related to childbearing and need for any medical treatments prior to conception; and fertility desires of both the client and partner and the need for a joint agreement to be reached. This will help the couple make an informed decision about childbearing, and determine whether SCC or contraception services are needed; contraception will be recommended until a joint agreement on childbearing is reached. This joint decision process can be aided by SCC even in the absence of the partner, as shown in the pilot where many clients decided against childbearing after discussing with their partner after the consult.

If the client has not disclosed to their partner and the client wants to seek conception, they will be linked to TASO's assisted disclosure program (including the option of home-based joint couples testing), as disclosure is key to acquiring partner cooperation with TUI/MSI. *If the HIV status of the partner is negative or unknown, the client will be strongly encouraged to have their partner come in for HIV testing (though this is not required, unless the client is being screened for study participation*), as the partner's HIV status informs the selection of the best SCM. *The nurse will stress the importance of the partner attending SCC sessions and clients will be given a formal invitation letter to give to their partner* to inform them of the value of SCC, how SCM reduces risk of transmission, and the importance of being HIV tested and participating in SCC. Invitation letters have been used successfully by TASO and others to engage male partners in PMTCT.[61] *Furthermore, home-based counseling will be offered if the partner cannot attend in person or over the phone*, and the client reports difficulties with properly using SCM; this is a feasible and sustainable strategy at TASO, which has long offered home-based services as an option to the few clients who are unable to make it to the clinic. However, *despite our recognition of the important role that both male and female partners play in childbearing decisions and the ability to use SCM, partners will not be required to attend SCC in order for clients to receive SCC. Our pilot showed that women have an especially hard time getting their uninfected partners to attend, and neither we nor TASO or the MoH are comfortable withholding SCC from these women who need the service.* We do not know how effective SCC can be without both partners attending, even though *several couples in the pilot were*

able to successfully use SCM when the partner did not attend. The proposed study will provide data to answer this important question. In our pilot, most female partners attended SCC, but if not, she will be given a referral (via the male client) to come to TASO or the hospital FP clinic for contraception if they decide against childbearing; or if seeking childbearing the male will be asked to report on the timing of his partner's fertile period with information from his partner, or the nurse will phone the partner for this information with consent from the male. After conception, the FP nurse will provide PMTCT services; if clients have a miscarriage, the cause will be addressed if possible, than contraception or further SCC offered, as desired.

SCC Introductory Consultation (45-60 minutes): * Build rapport and supportive environment; encourage client/couple to express needs and expectations. * Discuss context related to readiness for childbearing (partner HIV status; HIV disclosure; partner's fertility desire; # of existing children; health of relationship; available resources/supports; work patterns separating the couple). * Review HIV and health risks of childbearing for mother, infant, & partner, & factors that contribute to or protect from risk (SCM; ART; CD4; PMTCT; STIs; alcohol use; nutrition). Encourage delaying pregnancy if medical condition not optimal (not on ART > 6 mos.; CD4<200; active STI) and provide treatment (for STIs, acute OIs, or ART) as needed. * Encourage client/couple to consider this information and take time to decide whether or not they want to have a child, and return the next week for either SCC or contraception counseling and services accordingly.
SCC Session 1 (20-30 minutes): * Review client/couple's decision: if no longer desire a child, provide contraception; otherwise continue with SCC. * Teach client to time the woman's ovulation period and fertile window using pregnancy calendar. * Client/couple receives instruction on selected SCM (TUI, or MSI if female HIV+ and male HIV-). Brochures and tool kit specific to the chosen method (e.g., condoms, lube, syringe, plastic cup) are given to client to take home; instructional video will be shown; SMS texts will be used to remind client of start of fertile period if they have a phone. * Discuss other risk reduction options: circumcision (if negative male; available at TASO); sperm washing (available for ~$1000) and PrEP (available for ~$120 monthly) are available by referral, but are cost prohibitive for nearly all. * Review with client/couple their action plan for the coming month prior to 2nd session.
Follow-up sessions (up to 5 sessions; scheduled after female's menstrual period each month til pregnancy; 20 min): * Ascertain how well the client/couple identified the timing of woman's ovulation and used selected SCM. * Assess whether calendar, SMS texts and tool kit were helpful; identify strategies to overcome barriers. * Assess infected partner's ART adherence and refer for adherence counseling if needed. * Use tracking form (see manual) to record success and challenges related to use of SCM. * If partner did not attend, and SCM was not used successfully, discuss with client strategies for engaging partner. * Pregnancy test if woman's period is skipped; if pregnant, HIV test the partner and start HIV+ mothers on PMTCT. * Partner HIV test is done at completion of intervention and again 3 months later to confirm. If after 6 mos. of correct SCM use pregnancy has not been achieved, SCC is discontinued and the couple referred to fertility clinic for infertility tests. Guidelines call for waiting 12 mos., but they do not account for use of SCM to target the fertile period. Infertility tests ($70) will be paid for by the study for research participants, so that we can collect data on infertility rates, which are unknown in this population; otherwise, clients will need to pay for these tests.

Arm 2: Training workshop for integration of SCC into FP (SCC2)
This model for integrating SCC into existing FP services mimics the approach used by the MoH for infusing new services. Like SCC1, SCC2 will also use screening of childbearing desires and clients who report such desires will be encouraged to discuss this with their providers, and the triage station will record the information in the client's chart so that providers can refer the client to the FP nurses for SCC or contraception. Training of FP nurses (see Fig. 2) will be mostly educational and use role plays, but will not train on use of MI style communication with clients. A simplified manual and some (SCM instructional brochures, fertility calendar) but not all tools (instructional videos; SCM kits) produced for SCC1 will be used in SCC2. Supervision will not be provided by the study supervisors; rather, FP nurses may consult with clinic physicians and the FP clinic on the hospital campus when needed, which is the typical approach for new services. Like SCC1, SCC2 sessions will be recorded and a random selection coded for fidelity by the Project Director, but feedback will not be given to the nurses, as this is not the norm when new services are added. *SCC2 is designed to reflect how new treatment advances are integrated into routine care by the MoH, and to represent a viable, less intensive alternative to the structured, multi-component SCC1, the comparison of which provides critical data to guide the MoH and other policy makers on how to best incorporate SCC into FP services.* SCC sessions attended by participants will be logged and research participant surveys will assess SCC and FP services received.

Arm 3: Existing FP services (usual care control) Each study site currently provides FP services that focus on providing contraception and PMTCT care, but there's no SCC. *The usual care sites will continue to provide FP services as is, with no use of routine screening of childbearing desires or SCC*. Routine HIV and FP care in Uganda is unlikely to incorporate SCC during the course of this study, as SCC guidelines have been available

for years, yet SCC has remained scarce in Uganda and SSA. Also, TASO has indicated it has no plans to integrate SCC into usual care until the study ends and it sees efficacy and cost-effectiveness data.

Process evaluation and clinic capacity/fidelity: To assess clinic level FP capacity, fidelity to FP guidelines and inform data interpretation and sustainability, we will 1) interview clinic administrators and FP nurses at all sites at baseline, 12 and 24 months, 2) analyze routinely collected clinic FP data, and 3) use FP services data from participant surveys to triangulate with the nurse/administrator interview data. Also, at SCC1 sites we will explore what aspects of the intervention are working better than others via (a) interviews of FP nurses and expert clients conducting outreach, and 10 client participants (5 seeking and 5 not seeking children) at months 12 and 24, and (b) activity logs of FP nurses and expert clients.
Interview Content: Clinic administrators interviews will focus on successes and challenges in providing FP/SCC services and the influence of structural barriers. FP nurses interviews will focus on successes and challenges in engaging clients and their partners in: FP/SCC, making fertility decisions, and understanding and using SCM; client follow-up; male engagement; and the influence of cultural and structural barriers. For the SCC1 arm, the client interviews will explore experiences with FP/SCC services received, partner engagement in SCC and using SCM/contraception, and how to improve services. To assess the quality and reach of the client/community education and outreach activities, interviews with trained expert clients and VHTs will focus on the content of their messaging regarding availability of SCM and SCC, potential for reducing risk, and the importance of communicating with providers and partners; this description will be compared across the interview administrations over time to assess for change in quality with ongoing training and supervision, and use of MI style communication skills. We will also ask about client and community responses to their outreach, observed resistance, and how they responded to resistance. *See the appendix for drafts of the interview guides.* The expert clients and VHTs will be asked to keep a log of their outreach activities, including group talks in the clinic waiting room, or in the village, and one-on-one discussions, both in terms of when an activity occurred and number of people present. These data will be complemented by session checklists completed by FP nurses (see Fig. 2 in D.2.3.1). The site coordinators will interview the clients and expert clients/VHTs, and the senior investigators will interview the FP nurses and administrators. Clients and providers will receive 20,000 Ush (~$6) for the interview. ***Analysis***: Interviews will be audio-recorded, transcribed and translated into English. Wagner and Goggin will lead the data analysis. Data will be entered in *Atlas-ti*, organized thematically with a codebook, and coded by two team members using a grounded theory approach; inter-coder reliability will be assessed and consensus reached where there's disagreement.[62,63] Topical codes will be used to index interviews. Results will be aggregated to identify common themes and patterns across participants.[64,65]

Routinely collected clinic data will be used to analyze FP services in the overall clinic population to examine clinic capacity and fidelity to the intervention. The triage book and childbearing screening item (in SCC1/SCC2 sites) will be used to determine: (a) # who do not want children and % receiving contraception services, and (b) # reporting childbearing desires. FP registries will indicate # new clients receiving FP services (not seen by FP in past year), and % of FP recipients using dual contraception. These will be tracked longitudinally to assess intervention effects on clinic level FP services. % of clients receiving FP referrals after triage will be compared across all 3 arms using research cohort data, since childbearing screening is not used at the usual care site.

Research Participants. The assigned FP programs at each study site will be implemented clinic-wide for all clinic clients, but the 66 study clients enrolled at each site will meet the following ***eligibility criteria***:
1. *Adults of reproductive age* (men age 18-60; women age 18-45).
2. *Considering childbearing with their spouse/partner*. This will be determined via the triage screening item.
3. *Reports having disclosed HIV status to partner*. TASO counselors provide clients with assisted disclosure services to help them disclose to partners. Therefore, interested clients who have not yet disclosed their HIV status to their partner will be assisted to do so if they wish, after which they can be considered for enrollment.
4. *Partner is HIV-negative*. All couples can benefit from SCC and FP, but we focus on discordant couples due to the heightened value of SCC for reducing horizontal HIV transmission. We will use a rapid HIV test to confirm partner's status, and offer the option of a home-based test (a service offered by TASO) if necessary. Confirming the partner's status enables us to accurately assess intervention effects on seroconversion.

ART use is not an eligibility criterion, but SCC will be used to advise and support clients to start and adhere to ART before trying to conceive with SCM. TASO provides ART to all clients in serodiscordant relationships.

Note that only the HIV+ client will enroll in the study and participate in the survey research, not their partners.

Recruitment. *We will enroll 3-4 clients per month over 18 months at each site, which is feasible as >20 clients met this eligibility criteria in each recruitment month in our pilots*. Recruitment will be stratified by sex to ensure a 50/50 gender balance, which will better enable us to examine intervention effects on partner seroconversion

and to gain the perspective of both male and female clients regarding fertility. We could enroll the sample more quickly, but the long enrollment period ensures we can recruit the target number of men, and enables us to have our 3 site coordinators manage three sites each (min. 1 day per week at each clinic) to limit personnel costs. *Clients at the SCC1 and SCC2 sites who report at triage that they desire to have a child with a negative or unknown HIV status partner will be referred by triage to the site coordinator for screening.* Screening (incl. partner HIV testing) and baseline survey will be completed prior to the initial SCC consultation. *At the usual care site, the childbearing screening item will be included at triage only during the days of recruitment, which will be used to identify potential participants* who will than be referred to the site coordinator for the same screening conducted at the intervention sites; the data from the screening item will not be placed in the client's chart or given to the FP nurse, as this screening is not part of usual care. Clients who decline to bring their partner in for HIV testing (but are otherwise eligible) and thus do not participate, will be asked to provide basic sociodemographic and partner characteristics in order to assess how they differ from the enrolled clients.

Data Collection

Assessment schedule: The baseline assessment will be done by the site coordinator once eligibility is confirmed, followed by assessments at months 6, 12, and post-pregnancy (if pregnancy occurs prior to month 12). To minimize attrition we will collect contact info (phone numbers and maps of homes), including contact information for family or friends who have frequent contact with the client. Clinic staff will also be able to help us track clients that we have difficulty reaching. In our current study we achieved 94% retention at Month 12.
Participant Compensation: Participants will receive 20,000 Ush (~$6 USD) at each assessment.

Measures. Assessments will include measures of the primary and secondary outcomes and variables that map to our eIMB conceptual framework for understanding use of SCM and contraception, as listed below. Survey measures have been translated into Luganda in our prior research. The survey will be interviewer-administered using computer-assisted software, and administration time is 45-60 minutes.

Primary outcome: *Correct use of contraception or SCM over the past 6 months, depending on pregnancy intentions*; a single binary indicator will be created for use as the primary outcome, while continuous and categorical measures of frequency and duration of use will be used in secondary analyses. Correct use of contraception is defined as always using both condoms and another modern contraceptive (e.g., oral pills, DEPO injection, IUD implant) (i.e., dual contraception) over the past 6 months (since last survey), and will be ascertained via self-report and chart review (provision of non-condom contraceptive). Male participants will be asked to consent (it won't be required) to the coordinator calling their partner on the phone to assess use of non-condom contraceptives; these data will be kept confidential from the male. This definition is consistent with FP policy and practice in Uganda,[66] as condoms are important for HIV prevention, but used too inconsistently to prevent pregnancy, hence the need for an added contraceptive. If a participant becomes single or abstinent during the course of the study, avoiding pregnancy and use of contraception will be considered the desired behavior. The primary outcome will define whether SCM or contraception use was consistent (and changed to correspond with changes in pregnancy intentions) with pregnancy intentions over the entire study period.

To assess correct SCM use, respondents will be asked if they used TUI, MSI, or sperm washing in the past 6 months and how often. Given the cost of sperm washing, TUI (applicable for all couples) and MSI (applicable for couples in which the male is HIV negative) are the two feasible methods for most clients. Clients will be asked in an open-ended format to describe exactly how they implemented the method. For each method, the interviewer will be looking for 3-5 pre-established pieces of information (e.g., identifying the timing of woman's fertile period; # of days in the fertile period; using condoms outside of the fertile period; collection of semen and insertion using syringe) from the participant's response, which will be used to rate the response as indicating "fully accurate" use of the method, "partially accurate" or no use. Only fully accurate use will be considered correct SCM use for the primary analysis, but the 3-level variable will be examined in secondary analysis. Social desirability may influence responses, but clients are not likely to be able to describe the method in such detail unless they are actually following the procedures. This assessment will occur prior to administering the SCM knowledge part of the survey (which uses a less detailed description of the method) to avoid biasing the measure of SCM use. We will ask about partner use of PrEP and male circumcision, but these methods will not be considered when rating proper SCM use since they are not specific to the context of conception.

Secondary outcomes: (1) achievement of desired pregnancy status and pregnancy outcome [live birth or miscarriage (we will not be able to adequately assess induced abortions due to strong stigma and illegality of such abortions, making it very difficult to get accurate data] assessed via self-report and chart abstraction; (2) partner seroconversion, with HIV testing at month 12 in addition to testing as part of SCC); (3) PMTCT adherence (enrollment by 14 weeks gestation, ART use during pregnancy and post-delivery, infant ART

prophylaxis, and early infant diagnosis of HIV) for those who become pregnant, assessed via chart abstraction; (4) self-reported consistent condom use in past 6 months (generally for those not seeking childbearing, and all times outside of 3-day fertile period of each month for those seeking childbearing and using TUI/MSI).

Mediators/moderators of primary & secondary outcomes: All draw from our eIMB framework; knowledge, attitudes and beliefs measures were developed by our team and psychometric properties are established.[67]

Mediator/Moderator Variables	Instrument
Demographics: age, sex, education, work. **Reproductive history:** number of children, pregnancies, miscarriages/abortions **HIV/medical characteristics**: CD4; viral load; ART use & adherence; clinic attendance; STIs	- self-report developed in-house - self-report developed in-house - chart abstraction (viral load is consistently and routinely done for all patients annually at all sites); self-report; pharmacy refill data (which are highly predictive of viral load in resource constrained settings where all patients get their meds from clinic pharmacy)[68]
Partner/relationship-related variables: - Partner involvement in PMTCT/SCC/ANC visits - Childbearing desires/intentions - Power in relationship decision making	 - self-report developed in-house - self-report developed in-house - Relationship Control Scale;[69] alpha=.84
FP services used: Receipt of FP/SCC consults	- self-report developed in-house; chart abstraction
Information: Knowledge of SCM, effective contraception, and risks re. childbearing **Motivation:** to use SCM and contraception; - Partner willingness to use SCM/contraception **Behavioral skills:** - Self-Efficacy to use SCM and contraception - Communicate w/ provider re. childbearing needs **Ecological (socio-cultural):** - Internalized childbearing stigma - Perceived provider stigma of childbearing - Perceived community stigma of childbearing - Perceived cultural pressure for childbearing	- 20 true/false/don't know items developed in-house - 6 items; 10-pt scale; adapted Brief Motivation Scale;[70] alpha=.88[67] - 5 items; 5-pt scale; developed in-house; alpha=.85[67] - 5 items; 5-pt scale; adapted from Johnson et al.[71] alpha=.60[67] - 10 items; adapted from PCAS;[72] alpha= .71 - 2 items; 5-pt Likert scale; developed in-house; alpha =.72 - 1 item; 5-pt Likert scale; developed in-house - 3 items; 5-pt Likert scale; developed in-house; alpha =.94[67] - to be adapted from Pezeshki et al.[73]

Data Analysis Plan

Power analysis: 11% of PLHA in Uganda who want to prevent pregnancy use dual contraception[30] and our research shows 15% of PLHA trying to conceive use TUI or MSI.[37] Therefore, we expect the usual care arm will have a 15% rate of correct use of contraception/SCM (depending on pregnancy intentions), which is the primary outcome. Using an intra-class correlation (ICC) of 0.01 to control for clustering, based on other studies of reproductive health outcomes,[74] and 10% attrition at Month 12 (given the 6% in our current study), we will have > 80% power (2-tailed test) to detect a 4.5 percentage point difference (small effect size; d=.15) for our comparison of the usual care arm to the combined SCC1 & SCC2 arms on the use of contraception or SCM at month 12, and a 7-8 percentage point difference between the SCC1 and SCC2 intervention arms. In analysis of effects on contraception and SCM use separately, and with half the sample expected to decide to pursue pregnancy and half contraception based on our pilot data, our sample size will provide > 80% power to detect a 6.5 percentage point difference with regards to each of the outcomes when comparing usual care to SCC1 and SCC2 combined, and 8-9 percentage point difference between the SCC1 and SCC2 interventions.

***Data analysis*:** Our primary analysis will be to compare the combined intervention arms (SCC1 & SCC2) against the usual care control to assess the effects of integrating SCC into FP services, and then compare the outcomes between the two intervention arms to determine whether the more intensive SCC1 shows a larger effect than the less intensive SCC2. The primary outcome-- correct use of contraception/SCM (depending on pregnancy intention)-- will be represented as a binary variable as defined in D.2.3.5, but we will also explore a categorical or continuous outcome derived from frequency of correct use throughout the study. Secondary outcomes to be investigated are pregnancy status, PMTCT use, consistent condom use, and seroconversion of partner. We will use an intent-to-treat approach in the primary analyses; secondary analyses will use only study completers. Participants remain in the study and analysis regardless if their relationship status changes during the study. Attrition weights will be used to account for dropouts, and analyses will incorporate design effects from this weighting in the calculation of standard errors and tests of significance. We will account for clustering, and with only 9 clusters/clinics we will conduct individual level analysis. *Regression methods can directly model correlations among units in a cluster (random effects or multilevel models) or more simply adjust standard errors for clustering (GEE, robust standard errors), but these approaches are not reliable with so few*

clusters,[75] so we'll use standard regression methods, but rather than attempt to estimate ICC directly, we will explore the sensitivity of significance levels using a range of plausible ICCs values for the outcomes.

Aim 1: Assess intervention effect on contraception/SCM use: *Hypothesis: Both SCC1 and SCC2 will be superior to usual care, and SCC1 will be superior to SCC2 regarding the primary outcomes*. We'll use logistic regression to compare rates of contraception or SCM use (depending on pregnancy intention) in the SCC1 and SCC2 interventions compared to the control condition, and investigate differences between SCC1 and SCC2 in a separate regression. The models will include covariates to adjust for baseline variables (e.g., childbearing stigma, age, sex) that may differ at baseline and to increase precision of the estimates.

Aim 2: Assess intervention effect on secondary outcomes (pregnancy status; PMTCT use, consistent condom use, partner seroconversion): We will use the same analytic strategy as described for Aim 1.

Aim 3: Examine eIMB moderators and mediators of intervention effects on SCM and contraception use. We will identify bivariate correlates of the primary outcome from among baseline variables using correlation coefficients, t-tests and chi square tests, followed by a stepwise regression approach to identify a parsimonious list of predictors. We will than use longitudinal analyses to investigate changes in the primary outcome relative to changes in dependent variables such as SCM knowledge, motivation and self-efficacy. Like the baseline cross-sectional analysis described above, we will start with bivariate analyses that will inform a subsequent stepwise regression approach. We will use clinic fixed effects, because with only 9 clinics, clustering standard errors to correct for correlation between patients in the same clinic would significantly reduce power. Robust estimation techniques can adjust for correlation in multiple observations of a given patient over time. We will use a similar analytic approach to examine determinants of the secondary outcomes. Lastly, we will investigate the paths through which the intervention works, and subgroups that benefit more from the intervention. E.g., male clients and their partners may use contraception/SCM more because of their greater control over decision making and ability to secure partner participation in SCC. We can test this hypothesis by adding an interaction term between gender and the intervention. Using methods described by MacKinnon[76] and others,[77,78] we will assess whether the intervention has a direct impact on contraception/SCM use or mostly though a mediating variable such as communication with provider about childbearing needs (which may result in clients being more apt to receive the information and encouragement needed to use SCM/contraception).[46,79]

Aim 4: Cost-effectiveness analysis. We will track all costs associated with implementing SCC1 and SCC2 beyond those of existing FP services (the costs of which we will also measure), such as labor costs associated with SCC sessions and consults with FP nurses, supervision of the FP nurses (in SCC1), contraceptives and SCM client kits, and cost of intervention materials (posters, SCM instructional videos). Labor costs are based on clinic-specific data, external sources, and our own documentation (e.g., # and length of SCC sessions, FP consults, supervision meetings). Fixed costs will be allocated to the intervention as the fraction of time the premises are used for the intervention (e.g., SCC sessions). Training materials and supplies will be costed at purchase prices. Development costs such as personnel costs for the SCC training workshop will be differentiated from ongoing operational costs, but will exclude research costs (e.g., surveys). We will also evaluate potential efficiencies in operational costs (SCC sessions and ongoing supervision) over time and differentiate between the fixed costs of the intervention and the marginal cost of adding an additional client to inform generalizability to other settings. The analysis will be performed from the clinic perspective as we cannot accurately incorporate costs incurred by the client (e.g., lost earnings on clinic visit days), but the coordinator will track the number and duration of SCC sessions, and the survey will assess transportation and other client costs. We will assess whether the intervention is cost-effective by assessing the cost-effectiveness ratio (CER), defined by the difference in per-capita cost of the two intervention models relative to the control. We will assess average overall and marginal cost per achieved pregnancy (without partner seroconversion) or prevented pregnancy (depending on the patient's desired pregnancy status) and compare those to published values such as Shade et al.[80] We will estimate confidence intervals for our CERs using bootstrap methods.[81]