

A savings intervention to reduce men's engagement in HIV risk behaviors

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GLOSSARY

ART	Antiretroviral therapy
CT	Chlamydia trachomatis
DHHS	Department of Health and Human Services
DSMB	Data and Safety Monitoring Board
HIV	Human immunodeficiency virus
HSV-2	Herpes simplex virus type 2
IDI	In-depth interviews
IRB	Institutional review board
IRDO	Impact Research & Development Organization
ml	Milliliter
NG	Neisseria gonorrhea
NIH	National Institutes of Health
ODK	Open Data Kit
PI	Principal Investigator
PMACS	Penn Medicine Academic Computing Services
PreP	Pre-exposure prophylaxis
RPR	Rapid plasma reagin
REDCap	Research Electronic Data Capture
SAE	Serious adverse event
SSA	Sub-Saharan Africa
STI	Sexually transmitted infection
UNIM	Universities of Nairobi, Illinois and Manitoba

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1. Abstract

This project will evaluate an innovative, theoretically-motivated economic intervention to reduce men's engagement in transactional sex and other risky behaviors. Leveraging innovations in mobile financial services and research on savings behavior in low-income countries, we propose to test an intervention that seeks to motivate high-risk, income-earning men in western Kenya to reduce their spending on risky behaviors and instead save their disposable income in local bank accounts. These bank accounts will include additional incentives to save in the form of lottery-based rewards linked to amounts saved. The intervention will also encourage participants to develop savings goals and strategies, and provide periodic reminders about saving regularly. Through a direct economic mechanism (incentives to shift expenditures from the present to the future) and a psychological mechanism (increasing future orientation), we hypothesize that the intervention will result in increased savings, reduced spending on transactional sex and alcohol, less risky sexual behavior, and reduced risk of HIV and sexually transmitted infections (STIs).

We will conduct a randomized controlled trial among men who are at high risk of HIV and STI infection and determine the effects of a savings intervention on health and economic outcomes. Specific aims of the project are as follows. Aim 1: Determine the impact of the intervention on incidence of HIV/STIs. Aim 2: Quantitatively and qualitatively assess mechanisms of behavior change among participants and a sample of their female partners. By testing an intervention to promote forward-looking behavior and reduce the risk of acquiring HIV and other STIs in a high HIV/STI burden setting, this project has great potential for scientific and public health impact.

2. Background

Transactional sex – the exchange of money, material support or goods in sexual relationships – is a leading driver of HIV transmission in SSA. Studies conducted in SSA show a high prevalence of transactional sex [1-3]. Although most studies have been conducted among women, several have reported on men. In Kenya's Nyanza region, one study found 65% of men reporting engagement in transactional sex [2]. In our recent pilot study in Kenya, 47% of men reported paying for sex in the past 3 months (we included relationships that involved transactional sex and sex with female sex workers) [4]. Because it is strongly associated with age-disparate sex, having multiple partners, alcohol use, and condom-less sex, transactional sex contributes to the high incidence of HIV and STIs in SSA [5, 6].

Efforts to reduce transactional sex and HIV/STI risk have been more heavily focused on women, with the goal of either reducing risks associated with transactional sex (through provision of health services) or reducing their reliance on transactional sex altogether (e.g. through cash transfers). For example, UNAIDS recommendations include PrEP, education subsidies, and cash transfers for economic empowerment [7-10]. However, the effectiveness of these interventions has been hindered by the relative lack of programs that target *men's* behavior. By testing an intervention to reduce men's engagement in transactional sex and other HIV risk behaviors, this project addresses a missing element of HIV/STI prevention efforts in SSA.

Heavy alcohol consumption is another important risk factor for HIV. Men in SSA have a 21-60% prevalence of heavy alcohol use (based on varying definitions), with the highest prevalence

among those aged 18-39 years [11, 12]. Heavy alcohol use is associated with 50-70% higher HIV risk, for reasons including the disinhibiting effect of alcohol on sexual behavior and alcohol outlets drawing other individuals with risk-seeking preferences [13, 14]. These data underscore the need for HIV/STI prevention interventions to also address heavy alcohol use. In addition to reducing men's engagement in transactional sex, our proposed intervention is also designed to reduce their spending on alcohol *and* to appeal to men with "risk-seeking" preferences.

This project will test an innovative economic intervention to reduce men's engagement in transactional sex and other risky behaviors. Our approach is motivated by empirical studies documenting that compared to women, men are more risk-seeking [15, 16] and less future-oriented [16, 17] – two attributes that influence health behaviors [18-20]. It is also inspired by evidence from SSA that access to savings products can increase savings and investment and build future orientation (i.e. reduce discounting of the future) [21, 22]. As mobile banking services become widely available in SSA, savings interventions have significant untapped potential to motivate men to reduce their spending on risky behaviors and save more of their income for the future. Savings interventions can influence men's behavior through a direct economic mechanism (incentives to decrease expenditures on transactional sex and alcohol while increasing savings for the future) and a psychological mechanism (increasing future orientation). Conceived in this way, savings interventions have a strong theoretical premise and are ideally suited to reducing income-earning men's engagement in HIV risk behaviors. They can complement biomedical and behavioral approaches that focus on women (e.g. PrEP, conditional cash transfers, etc.) in order to reduce the risks associated with transactional sex.

In partnership with a Kenyan bank, we will evaluate a savings intervention that is designed to appeal to men. Among savings interventions, "prize-linked savings" accounts that offer lottery-based incentives to save are particularly promising as a way to promote savings. Prize-linked savings accounts make saving for the future more compelling and engaging by giving individuals the chance to win prizes as a result of saving (in addition to offering standard interest).[23] They leverage the popularity of lotteries (without the harm associated with gambling) and are highly effective in increasing savings [24-26]. Such savings accounts are also most appealing to risk-seeking individuals, thereby enhancing their applicability for HIV prevention among high-risk men. Our savings intervention will provide men (a) lottery-based incentives to save, (b) opportunities to develop savings goals and strategies, and (c) periodic reminders about the savings incentives and goals. Building on our promising pilot study of this savings intervention in Kenya,[4] our interdisciplinary team proposes a randomized trial that includes long-term follow-up to assess intervention durability and qualitative methods to explore mechanisms of action.

3. Study Rationale

Savings interventions can promote healthy behaviors among men through *multiple* mechanisms. Highly gendered labor markets in SSA place men at an economic advantage relative to women, with men being more likely to engage in skilled labor and to earn regular income. While this contributes to a power imbalance and transactional sex, it also reveals why savings interventions may be especially appropriate for men in this context. Specifically, savings interventions can incentivize men to reduce their spending on transactional sex and alcohol while concurrently saving it for the future (just as cash transfers may help women reduce their reliance on transactional sex). Indeed, research by leading scholars of economic development shows that giving households access to savings accounts boosts savings and desirable investment in human and physical capital [21, 27-29]. Research also suggests that due to differences in decision-

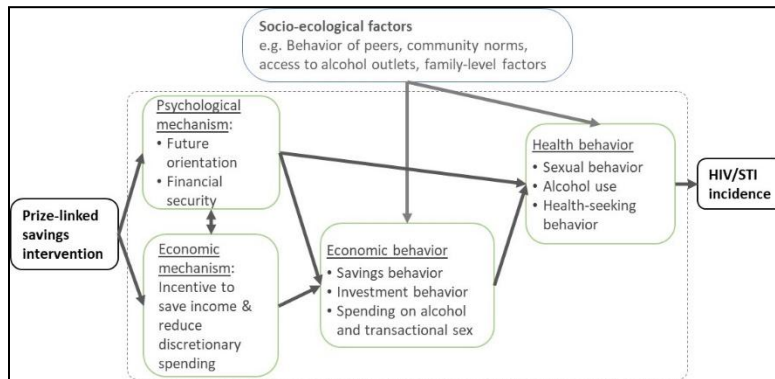


FIGURE 1. CONCEPTUAL FRAMEWORK TO ILLUSTRATE HOW SAVINGS INTERVENTIONS INFLUENCE HIV/STI RISK AMONG MEN

making factors between men and women (men are more risk-seeking and less future-oriented than women) [16, 17], savings interventions with strong incentives to save may be most effective for increasing men's propensity to save and reducing their engagement in deleterious health behaviors [18-20].

A large social science literature has examined the multiple motivations for men's and women's engagement in

transactional sex, from economic factors to status indicators to material expressions of love [3, 7]. Our conceptual framework (Figure 1) illustrates that while various socio-ecological factors undoubtedly influence men's behavior, savings interventions can work at the individual level, independently reducing men's engagement in risky health behaviors through two theoretical mechanisms. First, they incentivize men to reduce their spending on risky behaviors and save money for the future instead (a direct economic mechanism). Second, savings interventions trigger an increase in future orientation, making men more attentive to long-term goals (a psychological mechanism) and thereby generating changes in economic and health behaviors. Greater financial security and lower stress resulting from savings interventions further reduce immediately-gratifying, short-sighted behavior [30].

4. Study Design and Objectives

In Kenyan communities with high HIV/STI prevalence, men will be randomized to two groups: a *control group* that receives basic health education or a *savings intervention group* that receives a mobile banking account with incentives to save. The savings intervention will provide men (a) lottery-based incentives to save, (b) opportunities to develop savings goals, and (c) periodic reminders about the savings incentives and goals. Over a period of about 24 months, we will

evaluate the intervention's impacts on participants' economic and health outcomes. We will also carry out qualitative research with a subset of participants and their female partners.

The primary objective of the study **is** to determine the effect of the savings intervention on the following outcome:

- Composite incidence of HIV and other STIs over 24 months

Secondary objectives of the study are to determine the intervention's effect on the following health and economic outcomes. We also seek to evaluate various mechanisms by which the intervention may affect these outcomes.

- The total amount of savings and investment
- Total formal savings, and total household assets
- Investment behavior such as housing improvements, and schooling expenditures
- Expenditures on food and household needs
- Expenditures on alcohol and transactional sex
- Expenditures on gambling
- Self-reported sexual behavior, including number of transactional sex partners, total number of sexual partners and condom use.
- Alcohol use
- Survey-based measures of future orientation
- Survey-based measures of stress

We will qualitatively explore mechanisms through which the intervention influences outcomes as well as women's perceptions of the intervention. Longitudinal in-depth interviews with participants will explore impacts future orientation and decision-making. In parallel, longitudinal in-depth interviews with participants' female partners will explore their perceptions of the intervention and its impact on their partners' decision-making and on their own health and economic outcomes.

5. Study procedures

5.1 Study setting

This study will take place in Siaya County, Kenya, with a population of ~1 million. HIV prevalence in Siaya County is the 3rd highest in Kenya, at 15.3%, and other STI incidence is also high [31-33]. Although there is high poverty in the region, many men earn steady income through fishing, transport sector work, and informal labor. Studies have also documented high prevalence of heavy alcohol use and transactional sex [2, 12, 34].

5.2 Recruitment

In communities within Siaya County, study staff will meet with local leaders (village elders and beach management units) and provide general information on the study. Subsequently, we will **list relevant** venues such as beach landing sites and transportation stages that are ideally suited for recruiting high-risk men who earn steady income (i.e. those engaged in fishing activities, those engaged in the transport industry, those engaged in trading activities). We will select men who are potentially eligible for the study from these venues. Study staff will provide general

information on the study to men and refer them to nearby study offices where research assistants will screen them for eligibility.

5.3 Eligibility criteria

The study will include men who self-report alcohol or other substance use, and transactional sex. We will also interview a sub-sample of female partners of men who participate in the study, to collect data on their perceptions of the changes in men's behavior and household resources following the intervention.

The eligibility criteria for the randomized trial will be as follows:

- Male
- Age 18-39 years
- Resides in study community and plans to remain for the next 2 years
- Used alcohol or other substances in the past month
- Engaged in transactional sex (defined as payment of money, goods, or services in exchange for sex) in the past 3 months
- Has a steady cash income source that results in earnings every week
- Owns mobile phone
- Has national identification card (required for opening bank account)
- Has Kenya Revenue Authority PIN or is willing to create one (required for opening bank account)
- Has or is willing to open a bank account with partner financial institution

Importantly, HIV/STI status is not an eligibility criterion. Men who are seropositive for HIV at baseline will be eligible if they meet all other criteria as the intervention is intended to be HIV status-neutral. Including these men is important for reducing their risk of acquiring other STIs and for interrupting secondary HIV/STI transmission.

For the qualitative study, we will recruit female partners of male study participants.

5.4 Enrollment and randomization

Eligible individuals who initially agree to participate will provide written informed consent before enrollment in the trial. This will be followed by a questionnaire and HIV/STI testing. Participants will be stratified on baseline HIV status and within each stratum, they will be randomized (1:1) to an intervention or control group using a computer-generated sequence with blocks of sizes, 6, 10 or 12.

At enrollment, study staff will record participants' locator information and collect and verify primary and 1-2 alternate phone numbers. This information will be confirmed at each study visit.

5.5 Interventions

To support the long-term health promotion goals of the study, we will provide basic education on HIV and STIs, including post-test counseling, to participants in both study groups

5.5.1 Control group

Participants will receive basic information on the importance of saving for the future.

5.5.2 Intervention group

We will develop a partnership with a local bank with branches in the study communities. Participants will receive assistance from bank staff and research assistants in opening and using a savings account. They will also receive an education session that emphasizes the importance of saving for the future, provides a tutorial on how to earn interest on savings, and addresses common barriers to saving (lack of trust, lack of information, etc.). We will use educational materials developed in our pilot study [4], with modifications based on participant feedback. In addition, participants will receive 500 Shillings from the study team as an initial deposit into their accounts.

At the time of enrollment, research assistants will discuss with participants their reasons for saving, their savings goals, and the challenges to saving money each month. The research assistants will encourage participants to develop a savings goal amount and to define a purpose(s) for saving (e.g. future investment related to farming or businesses, household expenses on durable goods, children's education, etc.) and concrete strategies to save, including developing a timeframe and amount needed to save to achieve investment goals. This activity is based on prior research demonstrating that setting savings goals and implementation plans can increase the motivation to save [21, 28].

Participants will be told about lottery-based incentives for saving money in their account. Specifically, they will have a chance of winning monetary prizes each month based on the amount by which their account balance goes up during the month. For example, as in our pilot study, for every 100 Kenyan Shillings (~US\$1) of new savings each month, participants will receive 1 ticket for the monthly lottery. Each month's lottery will have several prizes, including a limited number of larger value prizes of approximately 5,000-10,000 Shillings and many smaller prizes of approximately 500-2,000 Shillings. Prizes will be deposited directly into bank accounts and winning participants will be informed by text message. In addition, participants may receive text messages each month reminding them of savings goals and strategies, as well as the lottery-based incentives for saving. This approach builds on promising findings in the savings literature [28]. Participants who do not win any prize in a given month may receive text messages encouraging them to save and reminding them of the goal they set.

5.6 Follow-up

Participants will be followed for a period of about 24 months. Participants will complete follow-up visits at about 6, 12, 18, and 24 months. Extensive effort will be put in place to ensure that enrolled participants are retained in the study. We may also contact participants at about 3, 9, 15, 21 months for a brief survey, which will be useful for promoting retention in the study.

Within one week prior to each 6-monthly follow-up visit, study staff will call participants to determine the optimal location, date, and time for the visit. If study staff are not able to reach a participant on the phone, staff will (1) call other phone numbers obtained at baseline; (2) attempt a home visit using the locator information obtained at baseline; and/or (3) contact local leaders to ask if they know the participant's whereabouts while maintaining confidentiality (i.e. no health or economic information about the participant will be discussed). If participants have moved to another community temporarily or permanently, we will attempt to visit them in the new location (it is important to note here that participants in the intervention group will be able to benefit from

the savings intervention regardless of where they live since banking can be done via mobile phones and does not require going to a physical bank branch). To maximize retention of participants we will utilize the tracking techniques developed in our recently completed randomized trial of an HIV self-testing intervention in Kenya (*Jikingo* study), which followed ~2,000 participants for 24 months with an 87.6 % retention rate. These tracking techniques consisted of a locator form from participants at enrollment that included any phone numbers that could be used to contact them as well as detailed directions to their home and workplace. We also arranged to meet participants at alternate locations if they have moved away from their initial residence. In past studies involving long-term follow-up, we have been able to achieve retention rates of 85-95% per year using such a combination of retention strategies.

5.7 Measurement of HIV and other STIs

We will evaluate the presence of HIV, neisseria gonorrhoeae (NG), and chlamydia trachomatis (CT) at baseline, 12 months, and 24 months. Participants will be notified that they can come in between scheduled visits if they have active STI symptoms and would like to be tested for NG and CT. We will also test for herpes simplex virus type 2 (HSV-2) at baseline and 24 months. These STIs are known to be biological markers of sexual risk behaviors and most have high prevalence and incidence in Kenya [35-37] and other parts of SSA [38-41].

HIV testing. HIV testing will be performed by trained research assistants with counseling certificates and in accordance with HIV antibody testing algorithms recommended by Kenya's Ministry of Health [42]. Those who test HIV-positive will be referred to the nearest health facility, where free treatment with ART is available. Testing will not be repeated for those who test HIV-positive at enrollment or at 12-months.

HSV-2 testing. At baseline and 24 months, a blood sample will be collected from participants and transported at the end of the day to the IRDO laboratory in Kisumu or an IRDO reference lab.

For HSV-2 testing, a minimum of 6 mls of whole blood will be collected in SSTs or red top vacutainer tubes. The samples will be placed on a rack inside a cooler box and transported at ambient temperature or cold pack. Shipment will be monitored by use of thermometers or data loggers placed inside the cooler boxes. Samples will be tested for HSV-2 antibody (Kalon HSV-2 IgG ELISA, which has higher sensitivity than other HSV-2 enzyme immunoassays [43, 44] according to manufacturer instructions and recommended cut-off for HSV-2 positivity).

Those who test positive for HSV-2 will be informed of their results and given health information, counseling and referral to a local health facility. Like HIV testing, HSV-2 testing will not be repeated at future study visits for those who test positive.

CT and NG testing. At baseline, 12 and 24 months, the male participants will be asked to provide 10-20 milliliter (ml) of first void or "first catch" urine into a screw capped urine container free of any preservatives. It is recommended that the participants provide the urine sample at least after 1 hour since the last urination. The male participants will be advised not to cleanse the tip of the penis area prior to collecting the urine sample.

The research assistants will be required after receiving the urine in the screw capped container to swirl the urine cap to mix well. Using a disposable transfer pipette provided in the urine specimen collection kit, the research assistants will transfer approximately 7 ml of the urine from

the urine Cap into the Xpert CT/NG urine transport tube. The transport tube may not be under or overfilled as this may affect assay performance. The Xpert CT/NG urine transport tube will be tightened securely to avoid any leakages. The transport tube will be inverted 3-4 times to ensure the urine specimen and the transport tube reagent are well mixed. The urine cap will be recapped securely. The transport tube will be labelled with the participant's details including date/ time of collection and the collector's initials or signature. The collector will take care not to obscure the fill line on the transport tube. The Xpert CT/NG urine transport tube will be placed on the rack in a cool box and transport to the IRDO laboratory in Kisumu at ambient temperature or cold pack. The shipment temperature will be monitored from the field to the laboratory by use of thermometers or data loggers placed inside the cooler box. Testing will be performed with the Cepheid GeneXpert rapid PCR test for the detection of CT and NG. This test has 97.5% sensitivity and >99.4% specificity [45].

Treatment of CT, and NG: Treating curable STIs at baseline, 12-months, and participant initiated visits for STI symptoms will allow us to measure STI incidence at subsequent study visits. Those who test positive for CT or NG will be contacted by research assistants and informed of their results. Participants testing positive at scheduled study visits (baseline, 12 months, and 24 months) will receive compensation for transportation costs to visit nearby study offices to receive treatment according to Kenyan guidelines. A home visit will be conducted if the participant cannot be reached by phone. If a participant is unable/unwilling to come to study offices, staff will arrange to meet him at a convenient time and location where treatment will be provided. If participants contact study staff between scheduled study visits because they have active STI symptoms, they will be provided with syndromic treatment for CT or NG (based on Kenya's national guidelines) in addition to being testing for these two STIs.

5.8 Follow-up survey questionnaires

At each 6-monthly follow-up visit, research assistants will administer a questionnaire to obtain information on participants' employment, income, assets, formal and informal savings, expenditures on food items and non-food items (including alcohol, transactional sex, gambling), self-reported sexual behavior, alcohol use, **and** HIV and STI risk perceptions. The questionnaire will also measure various decision-making characteristics (e.g., future orientation) that are relevant study mediators.

5.9 Participant compensation

Participants will be offered compensation for time and transportation costs associated with study enrollment and follow-up visits at 6, 12, 18, and 24 months. Participants will not receive compensation for time and transportation costs associated with visits for STI testing and treatment that take place in between the scheduled 6-monthly follow-up visits. Participants randomized to the intervention will receive an initial deposit in their savings account and the potential to receive additional money through the lottery-based incentives. They will receive this initial deposit once they have finished their financial education and completed the procedures to open a bank account with the study's partner bank (which is where the deposit will be paid into).

6. Statistical Analyses

6.1 Primary outcome

The primary outcome is HIV/STI incidence, defined as the composite incidence of at least one of HIV or other STIs (herpes simplex virus type 2 (HSV-2), Neisseria Gonorrhoea (NG), and Chlamydia trachomatis (CT)) over 24 months. The combination of all STIs (including HIV) into a composite variable is justified as the risk factors for these STI's are similar. Compared to a strategy of considering the individual infection as separate variables, using the composite variable (any HIV/STI infection) should increase the number of events and hence our ability to detect an effect of the intervention. For participants who are HIV-positive at baseline (~20%) or HSV-2-positive (~40%), the outcome will be defined over all STIs other than HIV and/or HSV-2.

6.2 Secondary outcomes

Economic outcomes include the following:

- Savings and investment. Participants' total savings and investment at 24 months, defined as the money value of formal and informal savings as well as investments in physical and human capital. This outcome will be based on best practice survey questions used in our pilot study [4]. At each study visit, participants will be asked about savings and investment. We will aggregate these measures to calculate savings and investment at 24 months.
- Total formal savings, which will be the sum of savings balances in all formal bank accounts.
- Other measures of savings behavior, including total household assets (value of all assets), human capital investments (e.g., spending on children's education), and housing improvements. We will also look specifically at productive assets (e.g., spending on agricultural equipment).
- Expenditures on transactional sex and alcohol, an important outcome for learning whether any observed increases in savings are accompanied by reductions in spending on risky behaviors. Similarly, we will examine expenditures on food items and household needs (e.g., utilities) to confirm that these expenses are not being diverted in order to increase savings.
- Expenditures on gambling, to assess whether the intervention reduces this form of spending.

Health behaviors that we will examine include the following:

- Several measures of sexual behavior including: Number of transactional sex partners in the past 3 months (defined broadly to include financial and non-financial transfers to commercial and non-commercial sexual partners), engagement in any transactional sex in the past 3 months, number of sexual partners in the past 3 months, and condom use at last sex and in the past 3 months, number of transactional sex encounters in the past month.
- Alcohol use. The AUDIT-C scale is comprised of ranges for typical numbers of drinks (rather than precise number, which can be difficult to quantify for traditional and home-brewed alcohol) and the frequency of heavy drinking (≥ 6 drinks on one occasion).

Additional health outcomes

- Other health outcomes will include HIV, CT, and NG incidence between 0-12 months and 12-24 months in order to determine if there are temporal patterns in the intervention's effectiveness. For example, it may take time for reductions in risky sexual behavior to reduce HIV/STI risk, or alternatively, effects may be large initially but decrease over time if participants do not continue to save more and re-start engaging in risky sexual behavior – for example, unprotected sex.
- We will conduct exploratory analyses by examining whether the intervention increases self-reported engagement in care among participants who are HIV-positive, a likely possibility if there is higher saving, economic security, and future orientation.

Mediators

- We will consider variables measured in follow-up surveys that may mediate the intervention's effect on savings behavior, risky behaviors, and HIV/STI incidence. Future orientation will be assessed by a commonly-used scale that asks participants to make hypothetical choices between money received at two different times (e.g., 1,000 Shillings in 1 month vs. 1,100 Shillings in 2 months), the Cantril scale which measures participant's well-being [46], and a question that assesses participant's expectations about their longevity. We will examine participants' stress level[47] and their financial security [48], both of which will be measured with survey-based scales previously used in Kenya or SSA.

6.3 Power and sample size

Sample size and follow-up duration were selected in order to have adequate statistical power to detect reductions in composite HIV/STI incidence over 24 months (i.e. ≥ 1 STI, including HIV, over 24 months).

Assumptions. We anticipate composite HIV/STI incidence to be 15-20% per year, with contributions from each STI as follows. HSV-2: Data from Kenyan men show annual HSV-2 incidence among all men (adjusting for ~40% HSV-2 prevalence at baseline) of 6-10% [37]. Incidence has been even higher among young men and higher-risk men (e.g., recent data for 18-35 year old men from the Afya Jozi Afya Jamii study). CT/NG: Composite CT/NG annual incidence was 7-8% in studies among Kenyan men [36], though some studies have reported higher incidence[40]. HIV: Annual incidence of <1% is assumed from recent studies, and our anticipated incidence adjusts for baseline prevalence [49]. Accounting for co-infection with multiple STIs and baseline prevalence of HIV and HSV-2 (20% and 40%), our anticipated composite HIV/STI incidence is conservative.

Power for HIV/STI incidence. Table 1 shows relative reductions in composite HIV/STI incidence detectable with 80% power (two-sided, $\alpha=0.05$) for a total of 1,500 participants (~750 per group). Table 1 assumes annual incidence in the control group of 15%, 17% or 20% annually. Under these assumptions a relative reduction of 21-25% is detectable. We included a conservative assumption of 20% attrition over 24 months (expected to be lower given our prior studies). Calculations are based on a two-group Chi-squared test of proportions. Based on our pilot study, we anticipate it will be possible to enroll the target number of participants in ~6 months.

Table 1. Detectable reduction in composite HIV/STI incidence over 24 months (N=1,500, 80% power, 20% attrition, two-sided $\alpha=.05$)

	Scenario		
Composite HIV/STI incidence rate in control group (per 12 months)	15%	17%	20%
Composite HIV/STI incidence rate in control group (per 24 months)	(28%)	(31%)	(36%)
Detectable relative reduction in composite incidence (relative to control) ¹	0.25	0.23	0.21

¹ $1 - (\text{Rate in the intervention group}) / (\text{Rate in control group})$

6.4 Primary analyses

The primary analysis will use an intention-to-treat approach. Using a logistic regression model, and controlling for baseline HIV and HSV-2 status, we will estimate the odds ratio for treatment versus control of at least one STI/HIV infection at 24 months. A two-sided Type I error rate of 0.05 will be used for hypothesis testing of the treatment effect.

6.5 Secondary analyses

Secondary analyses of economic outcomes and health behaviors will use generalized estimating equations to estimate the effect of the intervention at each 6-month follow-up interval and any intervention by time effects. The secondary analysis of HIV, CT, and NG incidence between 0-12 and 12-24 months will also use generalized estimating equations.

Associations between savings and expenditures. Secondary analyses using linear models will explore the association between total savings and (1) expenditures on risky behavior including transactional sex, alcohol and gambling and (2) investment related expenditures (e.g. housing, schooling).

Sub-group analyses. We will repeat the primary analyses using an interaction term between the intervention and each of 5 subgroup categories: (1) individuals who show baseline levels of more vs. less risk-seeking preferences (above/below median value), (2) different ages (above/below median age), (3) socioeconomic status based on median baseline household assets, (4) marital status (married/living as married vs. not), and (5) seropositivity (HIV) at baseline. For each of these five ‘interaction’ models we will first test the null hypotheses that the treatment effect

including the interaction term explains no variation in outcome. The Type I error rate will be 0.05. This analysis will help identify an effect of the intervention if it unexpectedly has a negative effect on one of the subgroups and a positive effect on its complement. Next we will describe the subgroup combinations showing the maximum benefit from the intervention using frequentist multiplicity-adjusted benefiting subgroup identification methods [50].

Baseline characteristics of individuals with missing outcome data will be described overall and by study group. Longitudinal patterns of dropout will be described by study group. Multiple imputation will be used to impute both the predictor and outcome variables at 24 months, and models created using the imputed variables combined using standard methods.

Mechanisms. As exploratory analyses of mechanisms through which the intervention may affect health and economic outcomes, we will examine the effect of the intervention on survey-based measures of future orientation, stress, and financial security. We will also undertake causal mediation analyses to further explore mechanisms.

7. Qualitative study procedures

We will conduct longitudinal in-depth interviews (IDIs) at 12 and 24 months, in a sub-sample of men and their primary female partners. These IDIs will provide a better understanding of changes in men's behavior and their future orientation and female partners' perceptions about changes in men's behavior. The emphasis will be to collect detailed narratives from participants in order to understand mechanisms by which the intervention influences health and economic outcomes and to assess potential 'spillover effects' of the intervention (benefits or harms) across multiple domains and populations. IDIs with women will also assess feasibility and interest in the savings intervention, which can inform a future study that examines whether effects on HIV/STI incidence are larger when the intervention is offered to both men and women. The interview procedures for the IDIs will be informed by survey data collected during the first few rounds of the quantitative survey (at baseline and 6 months) and by the research teams' field observations during the first year of the intervention.

7.1 Qualitative study sampling and recruitment

We will use purposive and theoretical sampling approaches to compose a cohort of approximately 25 men from the Aim 1 study population. First, for 12-month qualitative data collection, a sample of $n=20$ participants will be selected from the study sample, with over-sampling from the intervention group given that the main objective of understanding how the intervention influences behavior (with control group participants included to gain further insight on socio-ecological factors as well as health and economic decision-making), and with additional purposive sampling to ensure balance across savings behaviors. Specifically, 6 month study data will be used to produce a randomly selected list of $n=20$ men from the intervention arm, of whom $n=10$ had high savings ($>$ median) and $n=10$ had low savings ($<$ median) at 6 months after study start, as well as $n=5$ men from the control arm. Study team members will review study data on sexual behavior for the initial list of $n=25$ men, and replace as needed to attain a balanced sample with heterogeneity across levels of sexual risk behavior at 12 months. Study team members will contact these individuals (either by phone or in person during one of the 6-monthly follow-ups) to tell them about the qualitative study interviews and ask if they are interested in participating in the qualitative study. If they are interested, team members will arrange an

appointment with them for the interviews. Prior to the interviews starting, the study team will remind the individual they provided informed consent to take part in the qualitative study during enrollment of the main study and confirm they are still interested. Should the initial n=25 men not all agree to participate, additional individuals will be purposively selected for contact following the procedures described above to attain heterogeneity across savings and sexual behavior and oversampling for intervention participants.

For 24 months interviews, 12-month outcome data will be used to, select additional men as needed (no more than 10) from the intervention group to ensure the sample includes men who had high savings (>median) and low savings (<median) at 18 months, thus capturing diverse experiences with the intervention, as well as to account for any attrition. In addition, at this stage we will employ theoretical sampling as needed on the basis of emergent qualitative data at 12 months to ensure theoretical saturation of the data. I.e., any salient categories of participants identified through analysis of 12 month qualitative data, which require further exploration at 24 months, will be identified and used to further inform strata for sampling of the additional individuals.

We will ask men in the qualitative cohort if they are willing to name a female partner whom the study could invite to participate in IDIs at 12 months and 24 months. Men will not be required to name partners. Communications to both men and their named partners will stress that data collected from all participants (male and female) will be strictly confidential and will not be shared with their partner. The up to n~25 female partners will be contacted to ascertain their interest in learning about the qualitative study, and appointments made to conduct in person informed consent procedures. All female partners enrolled for interviews will be interviewed independently of the male participants, at separate times and locations to further reinforce protections for confidentiality.

7.2 Qualitative interviews

Qualitative interviews will be conducted at study offices or another private location convenient for participants. Informed consent procedures include consent for audio recording of the interviews, which will be completed during the enrollment of the main study. Research assistants trained in qualitative methods will use in-depth semi-structured interview (IDI) guides with specific topic areas, questions, and suggested probes. The IDI guide for men will elicit their beliefs, experiences, and decision-making processes regarding saving for the future, sexual behavior, and alcohol use. Topics will include perceived risk and severity of HIV/STIs and alcohol use, perceived consequences for self and for partners, norms for sexual behavior and alcohol use, attributions and motivations for risk behaviors, and perceptions of ways in which the intervention does or does not influence decision-making (intervention group only). We will ask men to narrate their considerations when saving or spending money, the perceived tradeoffs they face, and any changes in financial stress or future plans over time.

The IDI guide for female partners will explore female partners' perceived risks and severity of HIV/STIs, their own risk behavior, and perceptions of partners' risk behavior, including on primary partnership (domains including trust, communication, and interpersonal violence). We will explore women's perceptions of the intervention's effect on partners' behaviors and the

consequences (mental and emotional, health, and economic) for the women themselves. Interviews will be audiotaped, transcribed and translated by the interviewers for analysis.

We will submit IDI guides in an ethics submission modification prior to the 24 month interviews.

7.3 Qualitative analyses

Audio recordings of interviews will be transcribed and translated to English for analysis using a qualitative software program (Dedoose.) We will use an interpretivist [51] qualitative analysis approach in the domain of theory-generative research. This approach involves using both ‘abductive’ and ‘inductive’ analysis methods to produce new empirical findings examined in light of multiple existing sociological and behavioral theories. The method is akin to constructivist grounded theory [52], in that it involves iterative rounds of coding of textual data and memo creation, but does not foreground or privilege a pre-existing heuristic or model; rather it requires in-depth familiarity with a broad range of theories and allows for observational surprises in order to foster theory construction and generate new explanatory hypotheses.

The process, led by the qualitative lead investigator and involving the researchers engaged in data collection, is as follows:

- 1) Developing a coding framework. After initial data review and discussion, we will construct a theoretically-informed coding framework, with conceptual categories following the domains of inquiry, along with additional theoretical categories emergent in the data. Team members will apply codes to textual data in a qualitative analysis software program, discussing ‘difficult to code’ segments and resolving interpretive differences through discussion and consensus-building to ensure inter-coder reliability.
- 2) Theoretical refinement. During defined phases of data collection and analysis, the team will revise the coding framework in light of new additional findings, and apply new codes and sub-codes to the accumulated empirical data; at a final phase, we will assess whether additional sampling is needed to achieve theoretical saturation.
- 3) Interpretation. Code queries and data extraction will be conducted to review coded data segments in light of research questions and theoretical sampling categories for comparison, with emergent themes, counter-evidence, and deviant cases documented in memos. The memos will be used to construct narratives of the core meanings emergent in the data, and to identify whether findings either confirm or point to a need to modify and extend existing theories in novel ways.

Findings will be described and displayed in matrices and diagrams, to communicate our understanding of the role of the savings intervention in participants’ spending decisions as well as in any changes in participants’ health behaviors, financial security, and planning for the future, exploring also its effects on the lives of female partners across multiple domains. The analysis will yield an understanding of any unanticipated or anticipated positive and negative consequences of the intervention, and elucidate any observed pathways through which the intervention influences outcomes.

8. Ethical considerations and approval

Approvals will be obtained from institutional review boards (IRBs) in Kenya and the US before commencement of study activities involving human subjects. We will seek approval from the University of Pennsylvania IRB and the Maseno University Ethics Review Committee (MUERC) (telephone: +254-721543976; e-mail: muerc-secretariate@maseno.ac.ke). All study documents and data collection tools will be submitted to the IRBs, as will modifications to the study protocol.

All study staff will be required to undergo training in human subjects research and good clinical practice.

8.1 Informed consent

Verbal informed consent will be obtained prior to written informed consent in order to screen men for eligibility for the study. This will be captured in REDCap. The verbal consent process will be offered in English, Kiswahili, or Dholuo (as per the participant's preferences). We will emphasize this verbal consent is just to obtain permission to allow us to screen participants for eligibility and if they are found eligible, we will continue with the enrollment process (i.e., obtaining written informed consent).

Written informed consent will be obtained from all participants in the main study and qualitative interviews by trained research assistants. The research assistants will find a private place and provide the potential participant with a paper consent form. The research assistants will carefully explain the nature and purpose of the study to each potential participant, potential risks and benefits, compensation for participation, and will describe the two study groups to which participants will be randomized. The consent process will be offered in English, Kiswahili, or Dholuo (as per the participant's preferences). Our study team has prior experience in obtaining informed consent for research and clinical trials within the cultural context in Kenya. The informed consent procedure has been designed to maximize understanding of potential risks. Participants will be told that they may decline to participate at any point.

Men and women invited to take part in qualitative sub-study (aim 2) will also be given a detailed description about the qualitative study procedures, potential risks and benefits, and compensation for participation. The research assistants will emphasize that data collected from all participants (male and female) will be strictly confidential and will not be shared with their partner. While the qualitative interviews will be conducted later in the study (12 and 24 months after the start of the intervention), we will inform participants about these future study procedures at the time of recruitment in to the study sample. We will emphasize that initial consent to participate in the IDIs does not obligate men to participate in them at later dates. Separate informed consent forms for the IDIs will be administered when these interviews are conducted. We will create and submit these in an ethics modification prior to when we conduct the IDIs.

The study team will obtain consent for interim STI testing and treatment from all participants who seek testing and treatment in between scheduled study visits because they have active STI symptoms.

8.2 Vulnerable populations

Children, fetuses, neonates, or prisoners are not included in this research study. For the qualitative interviews with female partners, pregnant women are neither excluded if they meet the other eligibility criteria, nor removed from the study if they become pregnant during the study. However, there are no study procedures that should affect the condition of the pregnant woman or fetus.

8.3 Participant withdrawal

Participants may withdraw from the study at any time without impact to their care. They may also be discontinued from the study at the discretion of the Investigator for lack of adherence to intervention or study procedures or visit schedules, and due to adverse events. The Investigator or the Sponsor may also withdraw participants who violate the study plan, to protect the participant for reasons related to safety or for administrative reasons. It will be documented whether or not each participant completes the study.

Data Collection and follow-up for withdrawn participants. No additional data will be collected or follow-up attempted for participants who withdraw completely from the study.

Early termination visits. The 6-monthly follow-up survey will serve as the final data collection for participants who withdraw. No additional data will be collected or follow-up attempted for participants who terminate their involvement with the study.

Reporting of adverse events and unanticipated problems. In the unlikely event that a serious adverse event (SAE) is considered possibly, probably or definitely related to the study, or in the event of unexpected incidents or protocol violations, reporting to University of Pennsylvania IRB and MUERC will occur. Suspected events will be reviewed by study investigators prior to submission to the IRBs. The Investigator will promptly notify the Penn IRB and MUERC of all on-site unanticipated, adverse events that are related to the research activity within 24 hours from the time of site awareness, with further follow-up as needed as the investigation continues. Other unanticipated problems related to the research involving risk to participants or others will also be reported promptly.

8.4 Protecting privacy and confidentiality

Every effort will be made to ensure that privacy is maintained during study visits. Because enrollment and follow-up visits will occur at study offices (following venue-based referrals) rather than at participants' homes, we will be more likely to maintain privacy and avoid stigmatization. Study offices will be rented spaces in study communities and we will choose offices that have private rooms for screening and enrollment. Conducting enrollment at study offices rather than at participants' homes also reduces the concern that participants' household members may learn about their alcohol use or engagement in transactional sex.

Rapid HIV testing and sample collection for STI testing will take place in study offices. STI testing results will be shared with participants subsequently and those testing positive for curable STIs will be asked to come to an IRDO study site nearby for treatment. The reason for the visit will be unknown to non-study members, as the IRDO office will not be a health facility. Sample collection and provision of test results will be done in a manner that is highly confidential and in a setting where privacy is ensured. Test result information will be linked to participants only by a unique study identification number and not by their names. At all times possible, the samples and

test results will be kept secure under lock and key and only accessible by authorized research staff. Authorized research staff with International Air Transport Association (IATA, transportation of dangerous goods / training in biomedical safety procedures) will conduct the transfer of the urine and blood samples from the field site to the study (IRDO) laboratory in Kisumu.

Aggregate statistics on HIV tests will be reported to the government health facility serving the catchment area where testing is done, as per Kenyan guidelines. As a result, participants' identity will not be disclosed when aggregate HIV testing results are shared with Kenya's Ministry of Health.

STI tests will not be reportable to local government facilities since IRDO will not be using MOH test kits.

For STI tests, index clients who test positive will be counseled to avoid future infection, urged to inform the partner(s), and asked if they would like assistance with partner notification.

8.5 Potential study risks

Based on data from our pilot randomized trial and several other studies of savings interventions, we believe there are relatively few risks to study participants. Potential risks for participants may include distress from answering personal questions about sexual behavior, alcohol use, or savings balances. There is also a potential risk of loss of confidentiality. We believe these risks are minimal. In 2018, we successfully carried out a pilot study of prize-linked savings interventions with 300 adult men in the same setting where this study will take place. No adverse events were reported in the study.

An additional risk stems from HIV and other STI testing that will take place in the study at baseline, 12-, and 24-months. Participants may experience psychological distress associated with the testing and learning of test results. We believe these risks are minimal based on a number of studies we have conducted in the region that involve HIV and STI testing. Research assistants will be trained counselors who have experience performing HIV and STI testing and will be able to provide pre- and post-test counseling in addition to referral to appropriate health services.

There is also a risk that participants in the intervention groups who win monetary prizes as a result of saving money will spend that additional interest income on alcohol or transactional sex. Based on a large body of research on the effects of sizeable cash transfers on spending patterns in low-income settings,[29, 53] we believe this risk is minimal. Nearly all studies conducted in SSA show that large cash transfers do not get spent on alcohol, cigarettes, or transactional sex.

8.6 Potential study benefits

Participants in both study groups (intervention and control) will benefit from access to free HIV and other STI testing. Participants who receive a positive result will benefit from receiving free treatment of curable STIs and referral to care and treatment for HIV.

Participants in the intervention group will also benefit from the opportunity to receive a bank account and obtain lottery-based interest if they save money. Those who save more money may experience an increase in financial security and a decrease in financial stress.

Participants will contribute to a body of knowledge about effective interventions to increase savings and to reduce risky behaviors among men. This can indirectly benefit those who may be targeted by future interventions, including adolescent girls and young women who face high HIV/STI risks stemming from age-disparate relationships and transactional sex.

8.7 Risk/benefit assessment

The risks faced by participants in this study are far outweighed by the benefits to participants and the community, as well as the importance of the knowledge to be gained. Given that nearly 2 billion people globally lack access to formal financial services and remain “unbanked,” there is a vital need to identify strategies to promote uptake and use of savings accounts in low-income settings. Moreover, given the high morbidity and mortality due to HIV and other STIs in sub-Saharan Africa and the role of transactional sex and heavy alcohol use in driving STI and HIV infections, there is a vital need for approaches that can reduce men’s engagement in transactional sex. This study will advance the evidence base for interventions to promote savings, and to reduce transactional sex and other risky health behaviors. We will follow Kenyan National guidelines and treat syndromic participants prior to their test results returning. There is no risk in providing participants with treatment even if their results come back as negative for CT and/or NG based on local national guidelines.

8.8 Data and safety monitoring plan

Overall, the level of risk to study participants is low and no investigational drugs or devices are being provided or evaluated.

A DSMB will be convened to provide oversight of the trial. The role of the DSMB will be to review a) study enrollment, b) fidelity to the intervention, c) safety, and d) unexpected problems that might arise during the study. The study team will convene the DSMB consisting of 3-4 members whose expertise cover the following areas: 1) HIV/STI prevention, prevention of alcohol abuse, 2) econometrics and biostatistics, 3) medical ethics, and 4) randomized trials. Membership will consist of persons completely independent of the investigators who have no financial, scientific, or other conflict of interest with the trial. A written DSMB Charter containing these responsibilities will be drafted and signed by all DSMB members and the trial leadership (including the PIs).

Timing of DSMB Meetings: The DSMB will meet as needed during the implementation period (with a virtual meeting taking place at least once every 12 months), and at end of the study for review of data and findings. At the annual meeting, the analyst for the study and the PI will present summaries of the trial progress: enrollment, intervention fidelity and any unexpected problems. Following its meetings, the DSMB will present its recommendations in writing to continue or modify the trial to the National Institutes of Health (NIH) and the study Principal Investigator (PI).

Responsibilities of DSMB will include:

- Reviewing the **project documents as needed** for data safety and monitoring;
- Evaluating the progress of the project, including periodic assessments of data quality and timeliness, recruitment, accrual and retention, participant risk versus benefit, and other factors that can affect study outcome;

- Reviewing study performance, make recommendations and assist in the resolution of problems reported by the PI;
- Making recommendations to protect the safety of the study participants;
- Making recommendations concerning continuation, termination or other modifications of the trial based on the observed beneficial or adverse effects of the treatment under study;
- Ensuring the confidentiality of the study data; and,
- Reviewing any problems with study conduct, enrollment, sample size, and/or data collection.

Data and safety monitoring reports: A report to the DSMB will be prepared every 6 months. Reports will describe enrollment, intervention fidelity, and unanticipated problems. We will specifically examine patterns in alcohol use and sexual risk behaviors in the two study arms in order to assess whether the intervention is increasing the likelihood of these behaviors.

DSMB membership and affiliation: We will constitute a DSMB for the study that includes specialists from Kenya and the US – including clinicians, scientists, and other relevant specialists who have research expertise in the interface between HIV/STI prevention and behavioral economics in SSA. The DSMB membership will be reviewed and approved by the funding agency. DSMB members will have no direct involvement with the study investigators or intervention.

Confidentiality and conflicts of interest: All materials, discussions and proceedings of the DSMB will be completely confidential. Members and other participants in DSMB meetings are expected to maintain confidentiality. Each DSMB member will sign a conflict of interest statement which includes reporting of any relationships that could be perceived as a conflict of interest related to the study and/or associated with commercial interests pertinent to study objectives.

9. Data management

We have developed standard operating procedures for data security and confidentiality procedures at collection, transfer, entry and storage levels, and will make these readily accessible to all staff members who have access to confidential study data. All study data will remain secure at the University of Pennsylvania for the duration of the study. All study tablets used for data collection will be password protected. Data may be collected using Research Electronic Data Capture (REDCap), SurveyCTO, or Open Data Kit (ODK), which are secure online tools for data collection and storage. To ensure the integrity of the data, regular quality checks may be run in REDCap or any statistical software (such as STATA or SAS) to assess for missing data and invalid field entries. Completed surveys will not live on the tablet, but rather as encrypted data on the password protected REDCap application. All electronic study data will be stored on a secure terminal server at the University of Pennsylvania on Penn Medicine Academic Computing Services (PMACS) secure servers with access limited only to authorized staff. All computers and servers will be encrypted and password-protected with limited access. Files on PMACS servers are encrypted both in motion and at rest. Backup of the data will be done by designated study staff onto a secure server at the University of Pennsylvania. All electronic information will be recorded using study identification numbers, rather than participant names.

Physical data collection forms will be stored at IRDO headquarters in Kisumu, which will be the operating headquarters of the study. No participants will have any identifier on the data forms;

names and signatures on consent forms, will be kept under lock and key by the Study Coordinator and after signing, will be accessible only to the PIs, Coordinator and IRDO's Internal Research Monitor and Research Manager. Any other identifiers (such as names, last five digits of the national identification card, month and year birth, etc. - collected to merge participant data across survey rounds and ensure accuracy in data reporting) will be stored in a separate database on REDCap. This database will be accessible to the PIs, Coordinator, IRDO's Coordinator/data manager, and IRDO staff. All sensitive information is stored separately from any identifying information to prevent breach of confidentiality.

Records Retention. At the end of the study, data will be kept for up to 5 years for electronic version on the University of Pennsylvania terminal server, and up to 2 years for paper forms, including consent forms at the IRDO facility in Kenya.

10. Team structure

The following table lists the research team members and their main responsibilities.

Role	Name	Responsibilities
PI	Dr. Harsha Thirumurthy	Dr. Thirumurthy will lead study design, execution, analysis, and presentation of study data.
Site PI	Dr. Mark Ayallo	Dr. Ayallo will contribute to study design, intervention implementation, and data analysis while also overseeing program-research coordination.
Co-Investigators	Dr. Carol Camlin	Dr. Camlin will assist the project team with the development of the qualitative protocol, IDI guides, and analysis and results dissemination.
	Dr. Connie Celum	Dr. Celum will provide research expertise on HIV prevention intervention design and implementation along with STI/HIV incidence measurement.
	Dr. Sue Napierala	Dr. Napierala will be involved in developing the study design, protocol, data collection instruments, and will assist with study implementation, quantitative and qualitative data analysis, and results dissemination.
	Dr. Mary Putt	Dr. Putt will collaborate in the design of the study and analysis of data.
	Redempter Odeny	Redempter Odeny will support the intervention implementation, and data analysis while also overseeing program-research coordination.

Role	Name	Responsibilities
	Teniola Egbe	Will serve in the study as the Project Manager from University of Pennsylvania (UPENN)
	Elizabeth Bair	Elizabeth Bair is the Senior Statistical Analyst from UPENN who will support data management and statistical analysis at UPENN

11. Dissemination

The results will be shared with the participants, study site staff and other stakeholders. Findings will also be presented at local and international meetings and conferences attended by those working on HIV prevention and treatment, and behavioral economics. In addition, we will publish study results in peer-reviewed journals to ensure wider dissemination. Study participants' identities will not be used in any reports or publications.

12. Timeline

The project period is anticipated to last five years, as per the timeline below.

	Year 1				Year 2				Year 3				Year 4				Year 5			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Study preparation, IRB submissions, stakeholder consultations																				
Enrollment of trial participants																				
Follow-up surveys																				
Longitudinal qualitative interviews																				
Quantitative and qualitative analysis																				
Manuscripts & dissemination																				

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