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# Standardized Patient Encounters to Improve Quality of Counseling for Pre-Exposure Prophylaxis (PrEP) in Adolescent Girls and Young Women (AGYW) in Kenya: Study Protocol of a Randomized Controlled Trial



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# Standardized Patient Encounters to Improve Quality of Counseling for Pre-Exposure Prophylaxis (PrEP) in Adolescent Girls and Young Women (AGYW) in Kenya: Study Protocol of a Randomized Controlled Trial

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**ABSTRACT (300 words, 300 limit)**

**Introduction** Adolescent girls and young women (AGYW) in sub-Saharan Africa are at high risk of HIV acquisition. Pre-exposure prophylaxis (PrEP) demonstration projects observe that AGYW uptake and adherence to PrEP during risk periods is sub-optimal. Judgmental interactions with health care workers (HCW) and inadequate counseling can be barriers to PrEP use among AGYW. Improving HCW competency and communication to support PrEP delivery to AGYW requires new strategies.

**Methods and analysis** PrIYA-SP is a cluster-randomized trial of a standardized patient actor (SP) training intervention designed to improve HCW communication skills and adherence to PrEP guidelines. We purposively selected 24 clinics offering PrEP services under fully programmatic conditions in Kisumu County, Kenya. At baseline, unannounced SP "mystery shoppers" present to clinics portraying AGYW in common PrEP scenarios for a cross-sectional assessment of PrEP delivery. Twelve facilities will be randomized to receive a two-day training intervention, consisting of lectures, role-playing with SPs, and a group debriefing. Unannounced SPs will repeat the assessment in all 24 sites following the intervention. The primary outcome is quality of PrEP counseling, including communication skills and adherence to national guidelines, scored on a checklist by SPs blinded to intervention assignment. An intention-to-treat (ITT) analysis will evaluate whether the intervention resulted in higher scores within intervention compared to control facilities, adjusted for baseline SP scores. We hypothesize that the intervention will improve quality of PrEP counseling compared to standard of care. Results from this study will inform guidelines for PrEP delivery to AGYW in low-resource settings and offer a potentially scalable strategy to improve service delivery for this high-risk group.

**Ethics and dissemination:** The protocol was approved by the institutional review boards at Kenyatta National Hospital and the University of Washington. An external advisory committee monitors social harms. Results will be disseminated through peer-reviewed journals and presentations.

**Strengths and limitations of this study:**

- The cluster randomized controlled trial design offers rigorous assessment of a clinical training intervention using standardized patient actors (SPs) to improve pre-exposure prophylaxis for HIV (PrEP) delivery to adolescent girls and young women in Western Kenya
- The study uses SPs, a validated method for evaluating health provider performance, to assess communication skills and compliance with Kenyan national PrEP guidelines
- The use of SPs to support provider training is a novel approach to improving clinical counseling in low-resource settings
- The pragmatic trial design offers the potential for application within the health system

- Study activities are subject to delays from public holidays, provider strikes, PrEP stock-outs, and staff turnover; these challenges depict realities within the health system thus contributing to study applicability

**Trial registration number** NCT03875950, Registered: March 15, 2019

**Keywords:** Adolescent girls and young women, PrEP, standardized patients, cluster-randomized trial, clinical training, HIV

## INTRODUCTION

Adolescent girls and young women (AGYW) in high HIV-burden settings in sub-Saharan Africa (SSA) have an eight-fold higher risk of HIV acquisition than males of the same age group[1], and in 2019, an estimated 320,000 new HIV infections occurred in AGYW globally[2]. Pre-exposure prophylaxis (PrEP) has been shown to be highly effective to prevent HIV transmission among adults, when adherence is high[3-8], and is a promising HIV prevention tool for groups at high risk of HIV acquisition, including AGYW.

Kenya is among the first countries in Africa to offer guidelines to support delivery of PrEP to AGYW[9] and conduct large PrEP delivery demonstration projects in public sector maternal and child health (MCH) and family planning (FP) clinics. PrEP initiation and continuation among AGYW is higher in real-world setting demonstration projects than RCTs among African women, yet important barriers remain preventing optimal PrEP use among this group[10, 11]. One of the major health system-level barriers to adolescent engagement in sexual and reproductive health services, including PrEP, is poor interactions with healthcare workers (HCW), specifically fear of judgement and lack of confidentiality[12-18]. Similarly, HCWs report lacking knowledge and skills in working effectively with this population, especially concerning HIV prevention[12-21]. Improving the quality of PrEP counseling tailored to AGYW is critical to support optimal use of PrEP.

Standardized patients (SPs) are an evidence-based training method for improving provider competency and quality of care[22-24]. SPs have been used to train providers in a variety of clinical skills[25] leading to improved patient outcomes[26, 27]. Increasingly, SPs are used as “mystery shoppers” posing as real patients to assess provider compliance with clinical guidelines. SPs have assessed provider competencies in tuberculosis care[28], sexual health assessment[23], and HIV care[24], with emerging evidence from low- and middle-income countries (LMICs) including South Africa and Kenya. SPs are especially effective at improving and assessing HCW skills in patient-centered communication, a key component of quality of care[29], including empathy, and adherence to clinical guidelines[24].

In a context of rapid roll-out of PrEP services to AGYW, it is important to evaluate practical strategies to ensure quality service delivery. A clinical training intervention using SPs may improve quality of PrEP delivery for AGYW, and ultimately scale-up and uptake of this effective prevention tool. This cluster randomized controlled trial (cRCT) will evaluate impact of a SP training intervention on the quality of PrEP counseling, including communication skills and adherence to national guidelines[30], among HCWs delivering PrEP to AGYW. Results from this study could demonstrate an evidence-based, scalable intervention to support optimization of PrEP as an attractive HIV prevention option for AGYW in Africa, with the ultimate goal of reducing HIV acquisition among this priority population.

## METHODS AND ANALYSIS

### Study design

The Simulated Patients to Improve PrEP Counseling for Adolescent Girls and Young Women in Kenya, "PrIYA-SP" study aims to evaluate the effectiveness of a clinical training program using SPs to improve PrEP counseling to AGYW. This cluster-RCT compares HCW adherence to national guidelines and communication skills between the intervention and comparison facilities. Comparison facilities do not receive the clinical training.

The present study extends the work of the PrEP Implementation for Young Women and Adolescents Program (PrIYA). This was a two-year implementation project to reach AGYW at high risk for HIV acquisition through integrated delivery of PrEP within routine maternal child health (MCH) and FP systems (18,19). PrIYA was implemented from June 2017 to December 2018 in 16 facilities (11 public, 4 faith-based, 1 private) in Kisumu County, Kenya. PrIYA was followed by a PrEP mentorship program in 21 additional sites (20–22). We then initiated the present follow-on study in 24 former PrIYA and PrIYA mentorship sites.

### Study sites and population

*Standardized patient actor selection and training*

Professional Kenyan actors are hired through an agreement with a Kenyan casting agency and selected to be representative of AGYW in Western Kenya. Actors are trained in the SP methodology during a 5-day training facilitated by a simulation expert. Training includes didactic demonstrations, role-play, paired practice, and small group discussions focused on preparing SPs to portray the patient cases realistically and accurately. Practice interactions between SPs and HCWs are video-taped and discussed. Consultation during the training informs refinement of case portrayal, use of measurement tools, as well as revisions to the case scripts to ensure accuracy, feasibility, and believability in field implementation.

*Eligibility criteria*

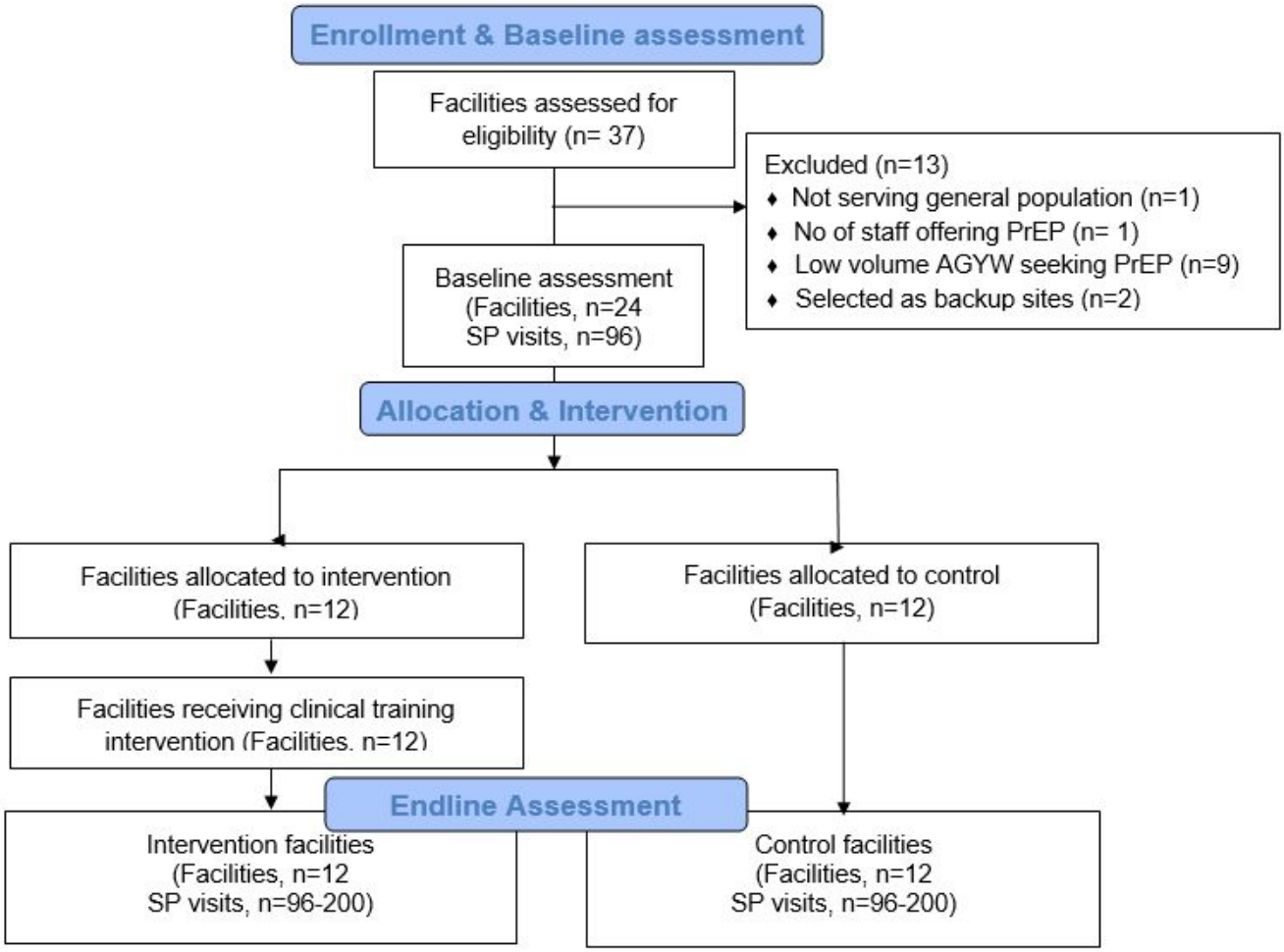
The study is being conducted at 24 large public health facilities, including former PrIYA Program and PrIYA mentorship sites, that provide PrEP care and counseling services to AGYW in Kisumu County, Kenya (Figure 1). Thirty-seven facilities were evaluated for inclusion, of which 24 were purposively selected based on expected patient volume of at least two AGYW seeking PrEP per week and willingness

of facility leadership to host research. Facilities with ongoing PrEP interventions involving PrEP delivery by research personnel were excluded. Sampling aimed for an even distribution across facility levels (county, sub-county, health center), settings (urban, peri-urban, rural), and types (public, private/faith-based).

All HCWs who are current employees at the study sites, provide PrEP services to AGYW, are 18 years or older, and are able to provide informed consent are approached for enrollment. Any HCWs who are working as research staff on another AGYW trial or intervention are excluded. We anticipate 10 HCWs or fewer per site will be eligible, totaling up to 240 HCWs.

This study was designed without public involvement. Members of the public were not invited to comment on the study design, were not consulted to develop patient-relevant outcomes, and were not involved in designing a dissemination plan.

**Figure 1. Adapted CONSORT Diagram for PrIYA-SP**



## Randomization

Facility cluster randomization is conducted using a stratified approach based on facility level (county/sub-county facility [high-level] vs. health center [low-level]) and facility patient volume (≥5 PrEP-seeking female clients per week [high volume] vs. <5 PrEP-seeking female clients per week [low volume]) to ensure balance by arm. Each facility is categorized by facility level and patient volume prior to randomization and assigned to four groups. The randomization assignment is generated by a biostatistician, resulting in 12 facilities allocated to the clinical training intervention arm and 12 facilities allocated to standard of care (Table 1).

**Table 1. Facility characteristics for PrIYA-SP restricted randomization**

| Facility level | Patient volume* | No. of facilities |
|---|---|---|
| Hospital | High volume | 8 |
| Hospital | Low volume | 3 |
| Health Centre | High volume | 6 |
| Health Centre | Low volume | 7 |

*High volume of PrEP-seeking female patients per week: ≥5=High volume, <5=Low volume

## Blinding

Given the study design as a cluster RCT of facilities with staff that will be aware of receiving training or not, it is impossible to blind all study team members and participants to randomization assignments. However, we are implementing procedures to minimize the number of individuals who are unblinded to study assignment and outcomes. Unannounced SPs are blinded to facility allocation. Data monitoring does not include information about study endpoints disaggregated by facility or study arm. Only the biostatistician, data manager, and designated field staff have access to data on study outcomes by study arm or facility. These reports are viewed exclusively during closed External Advisory Committee sessions, which do not include study team members. One month before the trial, the biostatistician will provide a list of the intervention facilities to study team members leading field implementation.

## Study procedures

*Case script development*

Standardized case scripts for both unannounced assessments and training encounters are developed by an SP expert, Kenyan and US clinicians, and adolescent and young adult researchers to represent common experiences and challenges faced by AGYW seeking PrEP in Western Kenya and our prior

studies[23, 24]. Each case follows a standard format, including a case summary, background highlighting chief complaint, medical and social history, and actor prompts. Development of the cases was informed by multiple sources through an iterative process. Themes and insights were incorporated from qualitative themes emerging from previously conducted in-depth interviews, focus group discussions among AGYW, feedback from PrIYA nurses with two years of experience delivering PrEP to AGYW in Kisumu, focus group discussions among a community advisory board, perspectives from PrEP-experienced study staff, key informant experiences, and national guidelines[30, 31]. Four unannounced and six classroom training case scripts were developed, representing unique PrEP use circumstances, including but not limited to sexual activity among young adolescents, transactional sex, multiple concurrent partners, and having an HIV-positive partner.

*Recruitment and enrollment*

The study team obtained permission from the National AIDS & STI Control Programme (NASCOP) and local county and district officials to enroll selected study facilities in the PrIYA-SP study. Leadership personnel at each of the study facilities are offered information about the study and invited to provide written informed consent (Additional File 1a) to participate in a health facility survey. We consult facility managers to identify HCWs delivering PrEP to AGYW and to negotiate release from work to participate in survey data collection, and if randomized, the training intervention. Identified HCWs are invited by a study interviewer to learn more about the study and, if interested, provide written informed consent (Additional file 1b). We track HCWs over time to monitor staff turnover and provide ongoing opportunities for informed consent by incoming HCWs delivering PrEP to AGYW.

*Baseline surveys and unannounced patient actor encounters*

At enrollment, surveys are administered to consenting facility managers by study staff to obtain baseline site-level characteristics describing staffing, presence of national and AGYW-specific guidelines, and PrEP service availability (Table 2). Study staff also administer surveys to HCWs to ascertain demographics, training history, beliefs about HIV[32], AGYW, and PrEP[20]; self-reported competency in PrEP delivery to AGYW; and self-reported knowledge of PrEP services. Unannounced SP actors, or “mystery shoppers”, present to the 24 study sites at baseline posing as AGYW seeking PrEP. Each facility receives four SP encounters at baseline (one visit per case script). During the clinic encounter, SPs perform their assigned scripted scenario with enrolled HCWs, as if they were a real patient. After the encounter, the SP fills out a post-consultation checklist to assess HCW adherence to national guidelines and communication skills, which is reviewed for completeness by a study team member. Study staff

coordinate with the health facility to remove any false “patient” information provided during the SP encounter from clinic forms and registers.

**Table 2. Adapted SPIRIT Diagram for PrIYA-SP trial**

| | Enrollment | Baseline | Trial implementation | | | |
|---|---|---|---|---|---|---|
| **TIMEPOINT**** | ***Month 0*** | ***Months 0-6*** | ***Months 6 – 9*** | ***Months 9 – 12*** | ***Months 12 – 15*** | ***Months 15 – 18*** |
| **ENROLLMENT:** | | | | | | |
| **Eligibility screen** | X | | | | | |
| **Informed consent** | X | | | | | |
| **Allocation** | | | X | | | |
| **INTERVENTION:** | | | | | | |
| **Clinical Training Intervention** ***(intervention arm only)*** | | | X | X | | |
| **ASSESSMENTS:** | | | | | | |
| **Facility Manager Survey**<br>*Respondent characteristics*<br>*HIV prevention training*<br>*HIV prevention/care guidelines*<br>*PrEP for adolescents and young adults*<br>*PrEP registry data collection* | | X | | | | |
| **Health Care Worker Survey**<br>*Demographics and training history*<br>*Beliefs about AGYW and PrEP*<br>*Beliefs about HIV*<br>*Self-rated competency in PrEP delivery to AGYW*<br>*Knowledge of PrEP services* | | X | | | X | X |
| **SP unannounced visit checklist**<br>*PrEP guidelines adherence*<br>*Communication skills* | | X | | | X | X |
| **SP training encounter checklist**<br>*PrEP guidelines adherence*<br>*Communication skills*<br>*Interpersonal skills* | | | X | X | | |

*Intervention approach using standardized patients*

Training materials for the intervention are informed by widely-used frameworks for clinical communication skills and high quality patient-provider interactions[22, 29, 33-40], the current Kenyan national guidelines for PrEP delivery[41], and qualitative interviews with AGYWs regarding PrEP seeking experiences conducted by study team members. The clinical training intervention is adapted from the training intervention implemented in the SPEED trial[24]. Enrolled HCWs from the 12 study sites randomized to receive the clinical training intervention are invited to attend two-day training events among groups of 5-10 HCWs. These events involve a combination of didactic lectures providing background information about the PrIYA-SP trial, adolescent health and development, Kenyan national guidelines for HIV prevention and PrEP delivery among AGYW, and structuring a high-quality patient-provider encounter.

Interactive group activities include a values clarification exercise and patient-centered communication activity, allowing HCW to practice reducing the influence of their personal beliefs within patient care and engaging patients in their own health decision-making processes.

HCW role-play with SPs to enact six case scripts depicting common experiences of AGYW seeking PrEP counseling. Each encounter is video-recorded and timed. Case scripts from the baseline unannounced visits are adapted for appropriate application in the training intervention. Following each role-play encounter, SPs complete a training checklist evaluating HCW PrEP competency, communication skills, and interpersonal skills. Trainings conclude with review of filmed SP role-play sessions with facilitated group debriefing to synthesize feedback and take-away messages.

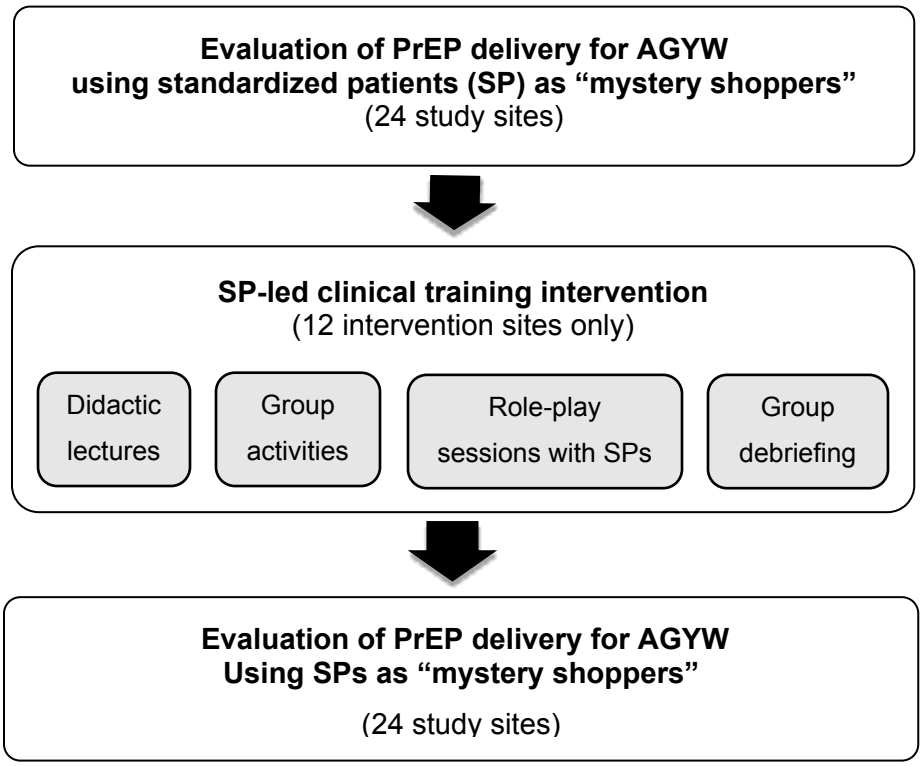
*Monitoring intervention fidelity*

We monitor intervention fidelity throughout the trial by evaluating SP actor fidelity to assigned PrEP case scripts. Study staff review a random sample of 10% of video-taped encounters at regular intervals throughout training intervention implementation, measuring actor fidelity by completing a standardized checklist adapted for this study. Fidelity checklists and scores inform refresher trainings for SPs throughout implementation of the training intervention. Individual training for actors requiring further support are facilitated as needed. Standard operating procedures and standardized training materials are consistently used for each training session. We track HCW completion of the training intervention and retention in study facilities over time.

*Intervention evaluation*

Once the training intervention is complete for all sites in the intervention arm, study staff re-administer the HCW surveys at all 24 facilities (Figure 2). Subsequently, SPs repeat the unannounced assessments conducted during the baseline evaluation at all 24 intervention and control sites. Case scripts are updated from those used at baseline and in the training intervention to minimize risk of SP discovery. Post-intervention scores used to measure quality of PrEP counseling are the same as in the baseline evaluation.

**Figure 2. PrIYA-SP trial schematic**




**Outcome measures**

The primary outcome of interest for this study is quality of PrEP counseling provided by HCWs delivering PrEP to adolescent girls and young women for HIV prevention in Kenya (Table 3). We define quality as the total score from the SP unannounced checklist, which includes sub-scores for domains of adherence to national PrEP guidelines and communication skills. The checklist contains 12 questions assessing adherence to PrEP guidelines using binary "done/not done" response options to indicate whether the PrEP counseling message was delivered by the provider during the SP unannounced visit (sub-score range: 0-12) according to the Kenyan National AIDS & STI Control Programme guidelines[41]. Seven questions assess communication quality with four scaled response options (strongly agree, agree, disagree, strongly disagree) (sub-score range: 0-21). Because there are few standard tools to assess patient-provider communication about HIV prevention with young people, questions to assess communication quality were informed by guidelines and tools used in other populations [22, 33-40] and adapted for this population. Higher total scores represent higher competency (overall score range: 0-33) and are rescaled to a percentage.

The secondary outcome for this study is quality of PrEP counseling by HCWs during the classroom simulated encounters in interpersonal skills, communication skills, and adherence to the national

guidelines for PrEP delivery comparing mean score percent from the first and last SP encounter. The interpersonal skills measure includes four dimensions (interviewing and collecting information, counseling and delivering information, rapport, and personal manner). The checklist assesses interpersonal skills with 4 scaled response options (1 – 4 with higher value indicating higher quality interpersonal skills) developed from the Van Zanten interpersonal skills assessment tool[40] (sub-score range: 4 - 16). We compute mean score percent for training intervention scores stratified by case script and from first to last case as a secondary outcome.

**Table 3. Primary and secondary outcomes and data sources for PrIYA-SP trial**

| Outcome measure | Data source* | Facilities assessed | Comparison | Timing of assessment |
|---|---|---|---|---|
| **Primary outcome:** HCW quality of PrEP counseling mean score percent from unannounced SP visit | SP unannounced visit checklist from endline assessment* | All intervention and control sites | Intervention vs. control sites | Post-intervention evaluation |
| **Secondary outcome:** **C**hange in interpersonal skills mean score percent among intervention participants between the first and last session | SP training checklist* | Intervention arm sites only | Initial training SP encounter to final training SP encounter | Intervention |
| **Other outcome:** Self-rated HCW PrEP competency, attitudes toward AGYW | Health care worker survey | All intervention and control sites | Intervention vs. control sites | Post-intervention evaluation |

*SP unannounced visit checklist and SP training checklist are available as Additional file 3 and Additional file 4, respectively

### Sample size calculation

Given the fixed number of clusters (24 facilities) included in this study, we used an *à priori* established expected baseline PrEP competency to estimate sample sizes to detect a 10-percentage point difference between the intervention and control arm with 80% power assuming a type 1 error rate of 0.05 and a two-sided test. Under these assumptions, if PrEP competency is 60% in the control arm, with standard deviation of 17.7%, and assumed coefficient of variation of 0.15, we would need an estimated 120 total SP encounters overall (6 SP encounters per site).

### Statistical methods and analysis

The primary analyses will use intention-to-treat (ITT) to evaluate whether the clinical training intervention using SPs results in higher quality of PrEP counseling scores at intervention facilities compared to control facilities. The ITT analysis assumes that HCWs in facilities randomized to receive the clinical training intervention are “exposed” to the training, and that HCWs in facilities randomized to not receive the

training intervention are “unexposed” to the training. We use a CONSORT diagram (Figure 1) to indicate the number of facilities and HCWs enrolled by study arm during the trial, numbers excluded, and reasons for exclusion. Descriptive statistics describing baseline characteristics of facilities by study arm will be presented to assess whether balance of these factors was achieved through randomization.

Generalized linear mixed models (GLMMs) will be used to compare post-intervention quality of PrEP counseling score percent between the intervention facilities and comparison facilities. (i.e., control arm). We will estimate the effect of the training intervention on the individual-level, using a GLMM with a Gaussian distribution and identity link, accounting for facility cluster and SP as random effects. These models will be adjusted for baseline quality of PrEP counseling score items that differ between study arms (p-value <0.05) ascertained using checklists completed by SP actors based on their assessment of care received by HCWs during unannounced SP encounters. This analytical approach allows individual-level outcomes to be modeled while accounting for correlation by cluster and SP. Regression coefficients and 95% confidence intervals will be estimated with a two-sided alpha of 5%. In sensitivity analyses, we will evaluate the intervention effect on individual components of PrEP competency and communication quality in separate GLMMs as well as differences in overall mean percent scores between cases, where case is included as a fixed effect.

### Ethics and dissemination

The PrIYA-SP study is registered at clinicaltrials.gov. Changes to the protocol are reviewed by both the University of Washington Institutional Review Board (IRB) and Kenyatta National Hospital Ethics and Research Committe (ERC) prior to implementation. Any changes to the protocol are communicated to coinvestigators and study staff through change memos, and the protocol at clinicaltrials.gov is updated. Results from this study will be disseminated through peer-reviewed journals, presentations at local and international conferences to national and global policymakers, community members and participants.

## DISCUSSION

There is high global commitment to reducing HIV incidence among AGYW and a mounting evidence-base that more research on PrEP delivery is needed to maximize the real-world effectiveness of this powerful HIV prevention tool. However, there are few interventions to improve the current quality of PrEP services for AGYW in high HIV-burden settings which may influence uptake and adherence. It is therefore important to evaluate novel and potentially scalable strategies to improve communication skills and adherence to national PrEP guidelines among HCW delivering PrEP to this population. The PrIYA-SP study fills a gap in evidence of HCW training programs in resource-limited settings to improve HIV

prevention services for AGYW[42, 43]. Our use of SPs to assess quality of PrEP delivery and as part of a clinical training intervention is novel. We use a randomized trial to evaluate the outcome of quality of PrEP services while adapting to schedules and services of the facilities. This study is responsive to the global motivation to reduce HIV acquisition among AGYW [44] by reducing barriers to PrEP uptake, as well as the Kenyan Ministry of Health request for novel interventions to inform the implementation of new adolescent-friendly HIV service guidelines[45]. If the SP-led clinical training intervention is effective at improving quality of PrEP counseling for AGYW, SP-led training interventions could be adopted as a recommended approach by Ministries of Health and PrEP scale-up initiatives within similar settings to expand improvements in quality PrEP delivery for AGYW.

*Limitations*

This study has limitations. As a pragmatic trial taking place within the Kenyan health system, study activities are subject to delays due to public holidays, health provider strikes, PrEP stock-outs and other reasons for staff shortages within facilities. Staff turnover is likely within this context, which could result in turnover of PrIYA-SP-trained HCWs and potentially diluted intervention effectiveness. We monitor staff shortages and turnover through operational tracking processes and will account for these changes in the analysis. Finally, our primary outcome depends on the quality of SP recall after the unannounced visits when completing the checklist with study staff. To minimize the potential for error in recall, the consultant-led SP training includes tactics for remembering details of interactions and study staff administer checklists to SPs immediately following unannounced visits.

## CONCLUSION

This training intervention for HCWs involving standardized patients has the potential to promote high-quality, patient-centered HIV prevention services for AGYW by providing HCWs with improved competency in Kenyan guidelines for PrEP delivery and enhanced communication skills. This study fills a need cited by HCW for expanded skillsets[14] and a desire cited by AGYW for respectful[16, 18, 46], and informative care[17]. This increase in quality of care delivery may, in turn, improve PrEP uptake and continuation to prevent HIV acquisition among this high-risk population.

## Trial status/registration

At the time of submission, trial implementation had not yet begun. The trial is registered at ClinicalTrials.gov NCT03875950).

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**Competing interests statement:** No authors declare a conflict of interest.

**Author contributions:** PK and GJS are the principal investigators and supervised the trial protocol development and implementation. PK, GJS, KW, BR, JP participated in designing the study. TO helped to develop intervention materials and trained the standardized patient actors. BR, KW, PK are responsible for the statistical design of the trial. FA and HL oversee field implementation of the trial. AL and KW wrote the initial draft of the paper. All authors critically revised, read, and approved the final manuscript.

**Data sharing statement:** The final trial dataset without identifiers will be made available to outside investigators with permission from Principal Investigators and University of Nairobi/Kenyatta National Hospital.

**Additional Files**

1. Additional file 1a: Example facility manager informed consent form
2. Additional file 1b: Example heath care worker informed consent form

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**Standardized Patient Encounters to Improve Counseling for Pre-Exposure Prophylaxis (PrEP) for HIV Prevention to Adolescent Girls and Young Women (AGYW) in Kenya**

**Consent for Facility Managers**

**Study Investigators**

| NAME | POSITION | DEPARTMENT | TELEPHONE NUMBERS |
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| Pamela Kohler | Co-Principal Investigator | Global Health, UW | +1-206-616-7962 |
| John Kinuthia | Site Principal Investigator | Kenyatta National Hospital | +254-0722-799-052 |
| Felix Abuna | Study Coordinator | Kenyatta National Hospital | +254 721 230652 |
| Harison Lagat | Study Coordinator | Kenyatta National Hospital | +254 716 977248 |
| Jillian Pintye | Co-Investigator | Global Health, UW | +1-206-437-9983 |
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**Emergency telephone number:** Dr. Felix Abuna, Telephone +254 721 230652
**Ethics and Research Committee Chairperson:** Professor AN Guantai, Telephone 020-272-6300 Extension 44102
**University of Washington Human Subjects Division**: Telephone +1-206-543-0098.

## A. Researchers' statement

### 1. Introduction

We are asking for your consent to volunteer for a research study. The study is being conducted by the Kenyatta National Hospital (KNH) and the University of Washington. The purpose of this consent process is to give you the information you will need to help you decide whether or not you want to participate. You may ask questions about the purpose of the study, what we would ask you to do, possible risks and benefits, your rights as a volunteer, and anything else about the study or this form that is not clear. When we have answered all of your questions, you can decide if you want to be in the study. This process is called "informed consent." We will give you a copy of this form for your records.

### 2. Purpose

We are asking you to participate in this study because you work in one of 24 clinics in Western Kenya selected for participation in a clinical trial. The trial will assess the current quality of PrEP counseling services for HIV prevention and evaluate whether a training course using standardized patient actors (SPs) improves PrEP service delivery to adolescent girls and young women (AGYW) in Kenya.

### 3. Procedures

If you agree to take part in the study, we will ask you to in participate in a survey at the beginning of the study. A study team member will administer the survey to you using an electronic tablet. The survey will ask about services and characteristic at this facility related to HIV prevention and treatment. Please provide the most current and accurate information that you can about this

facility. Your name will not be documented in this study. All information related to you will be kept confidential.

In addition, this facility may be selected to participate in a two-day didactic and role-playing training that would occur during normal working hours. In that case, we will speak with you and your staff in advance about those activities. There will be separate consent forms for those activities. At the end of the trial, we will ask that you complete another survey about this facility. Each survey will take 10-15 minutes to complete. One you have finished the surveys, your role in this study will end.

Today, if you agree to participate, you will sign this consent form and will be given a copy of this form for your records.

**4. Risks, Stress, and Discomfort**

Questions on this survey may be may make you feel uncomfortable, because they address HIV prevention and care services available for AGYW. You can stop the survey at any time if you do not feel comfortable. You can skip any question that you do not want to answer. You can withdraw from participation in the training or the study at any time. We will not share any information about you with your employer.

**5. Benefits**

You may directly benefit from this study as you gain understanding about how to improve health care relationships with AGYW in clinical settings, including improved practices, counseling, and support strategies that may help to improve the way PrEP is provided to this population.

**6. Other information**

***Your Participation is Voluntary***

This consent form gives information about the study. We will discuss the study with you and answer any questions you may have. If you agree to take part, we will ask you to sign your name on this form. We will offer you a copy to keep.

It is important that you know the following:

- You do not have to be in this study if you do not want to,
- You may decide not to join the study, or to stop the study at any time

***Costs to You***

There is no cost to you for participation.

***Reimbursement***

Staff from this facility who participate in the training will receive light refreshments and reimbursement for transport.

**7. Source of funding**

The study team and/or the University of Washington are receiving financial support from the National Institutes of Health in the United States.

**8. Confidentiality of Research Information**

The information you provide during the interview will be kept secret by the study staff. This information is about this facility and not you personally. We will not publish or discuss in public anything that could identify you. All paper forms will be stored in a room under lock and key. Electronic data will be stored on a password protected server. Only authorized study team members will have access to study data. Study results will have no identifiable data that can be traced back to you.

This trial will be registered at ClinicialTrials.gov and available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. This website will only include a summary of the results. You can search the website at any time.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

The records of this discussion may be reviewed by assessment staff and representatives of:

- University of Washington, including the Institutional Review Board
- Kenyatta National Hospital and University of Nairobi Ethics and Research Committee

There are some limits to this protection. We will voluntarily provide the information to:

- A member of the US federal government who needs it in order to review or monitor the research;
- People at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly

**9. Research-Related Injury**

It is unlikely that you will be injured as a result of participating in this discussion. There is no program for monetary compensation or other forms of compensation for injuries. You do not give up any legal rights by signing this consent form.

**10. Concerns or Questions**

If you ever have any questions about the study you should contact Dr. Felix Abuna, Telephone +254 721 230652. If you have questions about your rights as a research participant, or feel you have been harmed by the study, you should contact Professor Guantai, the Chair of the KNH/UoN ERC, at 2726300-Extension 44102. You can also contact the UW HSD at +1-206-543-0098.

**B. Study Participant's Statement**

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have more questions later, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the KNH/UoN Ethics and Research Committee at 2726300-Extension 44102. I will receive a copy of the consent form.

_____ _____

Participant's Name Date

_____

Signature

Copies to: Researcher
Participant

**Standardized Patient Encounters to Improve Counseling for Pre-Exposure Prophylaxis (PrEP) for HIV Prevention to Adolescent Girls and Young Women (AGYW) in Kenya**

**Consent for Health Care Worker Patient Encounter and Training**

**Study Investigators**

| NAME | POSITION | DEPARTMENT | TELEPHONE NUMBERS |
|---|---|---|---|
| Grace John-Stewart | Co-Principal Investigator | Global Health, UW | +1-206-543-4278 |
| Pamela Kohler | Co-Principal Investigator | Global Health, UW | +1-206-616-7962 |
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## A. Researchers' statement

### 1. Introduction

We are asking for your consent to volunteer for a research study. The study is being conducted by the Kenyatta National Hospital (KNH) and the University of Washington. The purpose of this consent process is to give you the information you will need to help you decide whether or not you want to participate. You may ask questions about the purpose of the study, what we would ask you to do, possible risks and benefits, your rights as a volunteer, and anything else about the study or this form that is not clear. When we have answered all of your questions, you can decide if you want to be in the study. This process is called "informed consent." We will give you a copy of this form for your records.

### 2. Purpose

We are asking you to participate in this study because you work in one of 24 clinics in Western Kenya selected for participation in a clinical trial. The trial will assess the current quality of PrEP counseling services for HIV prevention and evaluate whether a training course using standardized patient actors (SPs) improves PrEP service delivery to adolescent girls and young women (AGYW) in Kenya.

### 3. Procedures

If you agree to take part in the study, we will ask you to in participate in a quality of care assessment, and you may be selected to attend a training. If you consent to take part, you are agreeing to be evaluated by an unannounced standardized patient actor (SP). Unannounced SPs are trained actors who will portray an adolescent girl or young woman who is seeking PrEP

services at your clinic. SPs will come to your clinic, at any time, for the duration of the study period lasting 3 years. Even if you consent to participate, you personally may not have a visit with a SP since only a few SPs will visit each clinic. We ask that you do not inquire whether a patient is an SP. Instead, it is important that you treat the SP like any other patient. There is a high likelihood that you will not know that this patient is an SP. The SPs will not provide any feedback to you about care that they receive. After the visit, the SP will complete a brief checklist to evaluate the visit with a study team member. Your name will not be documented in this checklist.

At the beginning of the study, you will be asked to complete short surveys about your background, knowledge of PrEP guidelines, and your clinical and communication skills. You may be asked to take this survey again at the end of the study. Each survey will take 10-15 minutes to complete.

Your clinic may be selected to participate in a 2-day provider training. If selected, you would be invited to take part in this training. The training will consist of lecture, group discussion, and role-playing sessions, and will occur during normal working hours. Content will include review of national PrEP guidelines, counseling female adolescents and young adults about PrEP and communication skills.

The role-playing will include several encounters with trained SPs. In each encounter, the SP will play the role of a female adolescent or young adult using a pre-scripted scenarios. The sessions will be video-taped and may be shared with your training group, the SP, and the study trainer as part of a debriefing process. The SP actors will provide verbal and written feedback on the scenario.

If you agree to participate, you will sign this consent form and will be given a copy of this form for your records. We will ask you for your written permission to release your videos for future trainings and education.

**4. Risks, Stress, and Discomfort**

The encounters with the SPs may make you feel uncomfortable. You may not know when a patient is an SP. If you participate in the training, you will receive feedback on your performance from colleagues, the actor, and the trainers, which may make you uncomfortable . You may also feel uncomfortable if the actor presents concerns about sensitive or difficult topics like HIV risk behaviors, violence, or mental health issues. You can stop any role-playing session if you do want to participate any further. You can stop the debriefing session at any time if you do not feel comfortable. In addition, you can withdraw from participation in the training or the study at any time, including being recorded. We will not share any information about you or your performance with your supervisor.

**5. Benefits**

You may directly benefit from this training as you gain understanding about how to improve health care relationships with AGYW in clinical settings, including improved practices, counseling, and support strategies. What we learn from you may help to improve the way that PrEP care and counseling services are provided to AGYW in Kenya.

**6. Other information**

***Your Participation is Voluntary***

This consent form gives information about the study. We will discuss the study with you and answer any questions you may have. If you agree to take part, we will ask you to sign your name on this form. We will offer you a copy to keep.

It is important that you know the following:

- You do not have to be in this study if you do not want to
- You may decide not to join the study, or to stop the study at any time

***Costs to You***

There is no cost to you for participation.

***Reimbursement***

If you participate in the training, you will receive light refreshments and reimbursement for transport.

**7. Source of funding**

The study is funded by National Institutes of Health in the United States.

**8. Confidentiality of Research Information**

The information you provide during the interview will be kept secret by the study staff. We will not publish or discuss in public anything that could identify you. The video recordings of the role-playing sessions in the training will not be directly linked to your name or contact information. Video recordings from the sessions will be stored in a password protected file on a password protected computer. All paper forms will be stored in a room under lock and key. Electronic data will be stored on a password protected server. Only authorized study team members will have access to study data. You have the option sign a separate form that will authorized us to use video recordings for educational purposes. Study results will have no identifiable data that can be traced back to you.

This trial will be registered at ClinicialTrials.gov and available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. This website will only include a summary of the results. You can search the website at any time.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

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**10. Concerns or Questions**

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_____ _____

Participant's Name Date

_____

Signature

Copies to: Researcher
Participant

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# Standardized Patient Encounters to Improve Quality of Counseling for Pre-Exposure Prophylaxis (PrEP) in Adolescent Girls and Young Women (AGYW) in Kenya: Study Protocol of a Cluster Randomized Controlled Trial



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# Standardized Patient Encounters to Improve Quality of Counseling for Pre-Exposure Prophylaxis (PrEP) in Adolescent Girls and Young Women (AGYW) in Kenya: Study Protocol of a Cluster Randomized Controlled Trial

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**ABSTRACT (300 words, 300 limit)**

**Introduction** Adolescent girls and young women (AGYW) in sub-Saharan Africa are at high risk of HIV acquisition. Pre-exposure prophylaxis (PrEP) demonstration projects observe that AGYW uptake and adherence to PrEP during risk periods is sub-optimal. Judgmental interactions with health care workers (HCW) and inadequate counseling can be barriers to PrEP use among AGYW. Improving HCW competency and communication to support PrEP delivery to AGYW requires new strategies.

**Methods and analysis** PrIYA-SP is a cluster-randomized trial of a standardized patient actor (SP) training intervention designed to improve HCW adherence to PrEP guidelines and communication skills. We purposively selected 24 clinics offering PrEP services under fully programmatic conditions in Kisumu County, Kenya. At baseline, unannounced SP "mystery shoppers" present to clinics portraying AGYW in common PrEP scenarios for a cross-sectional assessment of PrEP delivery. Twelve facilities will be randomized to receive a two-day training intervention, consisting of lectures, role-playing with SPs, and group debriefing. Unannounced SPs will repeat the assessment in all 24 sites following the intervention. The primary outcome is quality of PrEP counseling, including adherence to national guidelines and communication skills, scored on a checklist by SPs blinded to intervention assignment. An intention-to-treat (ITT) analysis will evaluate whether the intervention resulted in higher scores within intervention compared to control facilities, adjusted for baseline SP scores and accounting for clustering by facility. We hypothesize that the intervention will improve quality of PrEP counseling compared to standard-of-care. Results from this study will inform guidelines for PrEP delivery to AGYW in low-resource settings and offer a potentially scalable strategy to improve service delivery for this high-risk group.

**Ethics and dissemination:** The protocol was approved by institutional review boards at Kenyatta National Hospital and University of Washington. An external advisory committee monitors social harms. Results will be disseminated through peer-reviewed journals and presentations.

**Strengths and limitations of this study:**

- The cluster randomized controlled trial design offers rigorous assessment of a clinical training intervention using standardized patient actors (SPs) to improve pre-exposure prophylaxis for HIV (PrEP) delivery to adolescent girls and young women in Western Kenya
- The study uses SPs, a validated method for evaluating health provider performance, to assess communication skills and compliance with Kenyan national PrEP guidelines
- The use of SPs to support provider training is a novel approach to improving clinical counseling in low-resource settings
- The pragmatic trial design offers the potential for application within the health system

- Study activities are subject to delays from public holidays, provider strikes, PrEP stock-outs, and staff turnover; thus intervention fidelity may be limited by real-world circumstances

**Trial registration number** NCT03875950, Registered: March 15, 2019

**Keywords:** Adolescent girls and young women, PrEP, standardized patients, cluster-randomized trial, clinical training, HIV

## INTRODUCTION

Adolescent girls and young women (AGYW) age 15 to 24 years old in high HIV-burden settings in sub-Saharan Africa (SSA) have an eight-fold higher risk of HIV acquisition than males of the same age group [1], and in 2019, an estimated 320,000 new HIV infections occurred in AGYW globally[2]. Pre-exposure prophylaxis (PrEP) has been shown to be highly efficacious to prevent HIV transmission among adults, when adherence is high[3-8], and is a promising HIV prevention tool for groups at high risk of HIV acquisition, including AGYW.

Kenya is among the first countries in Africa to offer guidelines to support delivery of PrEP to AGYW[9] and conduct large PrEP delivery demonstration projects in public sector maternal and child health (MCH) and family planning (FP) clinics. PrEP initiation and continuation among AGYW is higher in real-world setting demonstration projects than randomized controlled trials (RCTs) among African women, yet important barriers remain preventing optimal PrEP use among this group[10, 11]. One of the major health system-level barriers to adolescent engagement in sexual and reproductive health services, including PrEP, is poor interactions with healthcare workers (HCW), specifically fear of judgement and lack of confidentiality[12-18]. Similarly, HCWs report lacking knowledge and skills in working effectively with this population, especially concerning HIV prevention[12-21]. Improving the quality of PrEP counseling tailored to AGYW is critical to support optimal use of PrEP.

Standardized patients (SPs) are an evidence-based training method for improving provider competency and quality of care[22-26]. SPs have been used to train providers in a variety of clinical skills[27] leading to improved patient outcomes[28, 29]. Increasingly, SPs are used as “mystery shoppers” posing as real patients to assess provider compliance with clinical guidelines. SPs have assessed provider competencies in tuberculosis care[30], sexual health assessment[23], and HIV care[24], with emerging evidence from low- and middle-income countries (LMICs) including South Africa and Kenya. SPs are especially effective at improving and assessing HCW skills in patient-centered communication, a key component of quality of care[31], and adherence to clinical guidelines[24].

In a context of rapid roll-out of PrEP services to AGYW, it is important to evaluate practical strategies to ensure quality service delivery. A clinical training intervention using SPs may improve quality of PrEP delivery for AGYW, and ultimately scale-up and uptake of this effective prevention tool. This cluster randomized controlled trial (cRCT) will evaluate impact of a SP training intervention on the quality of PrEP counseling at the visit-level, including adherence to national guidelines[32] and communication skills, provided by HCWs delivering PrEP to AGYW. Results from this study could demonstrate an evidence-based, scalable intervention to improve delivery of PrEP as an attractive HIV prevention option for AGYW in Africa, with the ultimate goal of reducing HIV acquisition among this priority population.

## METHODS AND ANALYSIS

### Study design

The Simulated Patients to Improve PrEP Counseling for Adolescent Girls and Young Women in Kenya, "PrIYA-SP" study aims to evaluate the effectiveness of a clinical training program using SPs to improve PrEP counseling to AGYW. This cluster-RCT compares HCW adherence to national PrEP delivery guidelines and communication skills between the intervention and comparison facilities assessed post SP-led training intervention. PrEP delivery by HCW is evaluated via standardized checklists prepared by SPs acting as "mystery shoppers" during unannounced PrEP-seeking encounters. PrEP delivery scores are measured at the SP encounter level and compared between intervention and control sites, clustering by facility. Comparison facilities do not receive the clinical training.

The present study extends the work of the PrEP Implementation for Young Women and Adolescents Program (PrIYA). This was a two-year implementation project to reach AGYW at high risk for HIV acquisition through integrated delivery of PrEP within routine maternal child health (MCH) and FP systems[19, 33]. PrIYA was implemented from June 2017 to December 2018 in 16 facilities (11 public, 4 faith-based, 1 private) in Kisumu County, Kenya. PrIYA was followed by a PrEP mentorship program in 21 additional sites involving in-clinic guidance from former PrIYA nurses to HCW in non-PrIYA sites about best practices for delivering PrEP to AGYW. Following conclusion of the PrEP mentorship program, we initiated the present follow-on study in 24 former PrIYA and PrEP mentorship sites.

### Study sites and population

*Eligibility criteria for facilities and healthcare workers*

The study is being conducted at 24 large public health facilities, including former PrIYA Program and former PrIYA mentorship sites, that provide PrEP care and counseling services to AGYW in Kisumu County, Kenya (Figure 1). Thirty-seven facilities were evaluated for inclusion, of which 24 were purposively selected based on expected patient volume of at least two AGYW seeking PrEP per week.All facility managers approached for inclusion agreed to participate in the study. Facilities with ongoing PrEP interventions involving PrEP delivery by research personnel were excluded. Sampling aimed for an even distribution across facility levels (county, sub-county, health center), settings (urban, peri-urban, rural), and types (public, private/faith-based) to ensure generalizability of results.

All HCWs who provide PrEP delivery services to AGYW, are current employees at the study sites, are 18 years or older, and are able to provide informed consent are approached for enrollment. Within Kenyan FP and MCH settings, nurses, clinical officers, and doctors predominantly comprise the HCW cadres trained to deliver PrEP, with other cadres such as HIV Testing Services counsellors less frequently involved. Any HCWs who are working as research staff on another AGYW trial or intervention are excluded. We anticipate 10 HCWs or fewer per site will be eligible, totaling up to 240 HCWs.

*Patient and Public Involvement*

This study was designed without public involvement. Members of the public were not invited to comment on the study design, were not consulted to develop patient-relevant outcomes, and were not involved in designing a dissemination plan. Results of the study will be disseminated through peer-reviewed journals, presentations at local and international conferences to national and global policymakers, community members, and participants.

**Randomization**

Facility cluster randomization is conducted using a stratified approach based on facility level (county/sub-county hospital vs. health center) and facility patient volume of PrEP clients (≥5 female PrEP clients per week [high volume] vs. <5 female PrEP clients per week [low volume]) to ensure balance by arm. Stratification groups were selected to further reduce potential imbalance between intervention and control facilities. We do not expect that facility level and volume of AGYW seeking PrEP would be meaningfully correlated because facility-level patient volume of PrEP clients is not determined by facility level within the health system in Western Kenya. Each facility is categorized by facility level and patient volume of PrEP clients prior to randomization and assigned to four groups. The randomization assignment is generated by a biostatistician, resulting in 12 facilities allocated to the clinical training intervention arm and 12 facilities allocated to standard of care (Table 1). We do not expect contamination between intervention and control sites, as selected facilities are geographically located with sufficient distance from each other to limit HCW interaction between facilities. Further, the intervention takes place over a short time period (6 months) to minimize staff turnover.

**Table 1. Facility characteristics for PrIYA-SP restricted randomization**

| Facility level | Patient volume* | No. of facilities |
|---|---|---|
| Hospital | High volume | 8 |
| Hospital | Low volume | 3 |
| Health Centre | High volume | 6 |
| Health Centre | Low volume | 7 |

*High volume of female PrEP clients per week: ≥5=High volume, <5=Low volume

## Blinding

Given the study design as a cRCT of facilities with staff that will be aware of receiving training or not, it is impossible to blind all study team members and participants to randomization assignments. However, we are implementing procedures to minimize the number of individuals who are unblinded to study assignment and outcomes. Unannounced SPs are blinded to facility allocation. Data monitoring does not include information about study endpoints disaggregated by facility or study arm. Only the biostatistician, data manager, and designated field staff have access to data on study outcomes by study arm or facility. These reports are viewed exclusively during closed External Advisory Committee sessions, which do not include study team members. One month before the trial, the biostatistician will provide a list of the intervention facilities to study team members leading field implementation. In their roles as "mystery shoppers", unannounced SPs are trained to be indistinguishable by HCW from real AGYW seeking services within study sites, thus HCW are in essence "blinded" to SPs. During the classroom role-play encounters within the clinical training intervention, SPs are known to the HCW as actresses. To reduce discovery of unannounced SPs in the post-intervention evaluation, different actresses from those participating in the baseline assessment and training intervention are employed as "mystery shoppers".

## Study procedures

*Standardized patient actor selection and training*

Professional Kenyan actors are hired through an agreement with a Kenyan casting agency and selected to be representative of AGYW in Western Kenya. Actors are trained in the SP methodology during a 5-day training facilitated by a simulation expert. Training includes didactic demonstrations, role-play, paired practice, and small group discussions focused on preparing SPs to portray the patient cases realistically and accurately. Practice interactions between SPs and HCWs are video-taped and discussed. Consultation during the training informs refinement of case portrayal, use of measurement tools, as well as revisions to the case scripts to ensure accuracy, feasibility, and believability in field implementation. Two SPs are assigned to each case script for a total of eight SPs who consistently perform cases at all health facilities throughout the baseline assessment and clinical training intervention. After the intervention period, a new group of SPs are hired and trained to perform unannounced case scripts in the same manner for the post-intervention evaluation to reduce chance of SP discovery by HCWs.

*Case script development*

Standardized case scripts for both unannounced assessments and training encounters are developed by an SP expert, Kenyan and US clinicians, and adolescent and young adult researchers to represent common experiences and challenges faced by AGYW seeking PrEP in Western Kenya and our prior studies[23, 24]. Each case follows a standard format, including a case summary, background highlighting chief complaint, medical and social history, and actor prompts. Development of the cases was informed by multiple sources through an iterative process. Themes and insights were incorporated from qualitative themes emerging from previously conducted in-depth interviews, focus group discussions among AGYW, feedback from PrIYA nurses with two years of experience delivering PrEP to AGYW in Kisumu, focus group discussions among a community advisory board, perspectives from PrEP-experienced study staff, key informant experiences, and national guidelines[32, 33]. Four unannounced and six classroom training case scripts were developed, representing unique PrEP use circumstances, including but not limited to sexual activity among young adolescents, transactional sex, multiple concurrent partners, and having an HIV-positive partner.

*Recruitment and enrollment*

The study team obtained permission from the National AIDS & STI Control Programme (NASCOP) and local county and district officials to enroll selected study facilities in the PrIYA-SP study. Leadership personnel at each of the study facilities are offered information about the study and invited to provide written informed consent (Supplementary file 1) to participate in a health facility survey. We consult facility managers to identify HCWs delivering PrEP to AGYW and to negotiate release from work to participate in survey data collection, and if randomized, the training intervention. Identified HCWs are invited by a study interviewer to learn more about the study and, if interested, provide written informed consent (Supplementary file 1). We track HCWs over time to monitor staff turnover and provide ongoing opportunities for informed consent by incoming HCWs delivering PrEP to AGYW.

*Baseline data collection through surveys and unannounced patient actor encounters*

At enrollment, surveys are administered to consenting facility managers by study staff to obtain baseline site-level characteristics describing staffing, presence of national and AGYW-specific guidelines, and PrEP service availability (Table 2). Study staff also administer surveys to HCWs to ascertain demographics, training history, beliefs about HIV[34], AGYW, and PrEP[20]; self-reported competency in PrEP delivery to AGYW; and self-reported knowledge of PrEP services. Unannounced SP actors, or "mystery shoppers", present to the 24 study sites at baseline posing as AGYW seeking PrEP. Each facility receives four SP encounters at baseline (one visit per case script). During the clinic encounter, SPs

perform their assigned scripted scenario with enrolled HCWs, as if they were a real patient. After the encounter, the SP fills out a post-consultation checklist to assess HCW adherence to national guidelines and communication skills using standardized questions with binary ("done"/"not done") or four-point Likert scale response options. The checklist includes a section eliciting open-ended responses from SPs about each encounter. SPs are trained in how to fill out the checklist using a rubric and checklists are reviewed by a study team member after each encounter to ensure completeness and consistency across SPs. Study staff coordinate with the health facility to remove any false "patient" information provided during the SP encounter from clinic forms and registers.

**Table 2. Adapted SPIRIT Diagram for PrIYA-SP trial**

| | Enrollment | Baseline | Trial implementation | | | |
|---|---|---|---|---|---|---|
| **TIMEPOINT**** | ***Month 0*** | ***Months 0-6*** | ***Month s 6 – 9*** | ***Month s 9 – 12*** | ***Month s 12 – 15*** | ***Months 15 – 18*** |
| **ENROLLMENT:** | | | | | | |
| **Eligibility screen** | X | | | | | |
| **Informed consent** | X | | | | | |
| **Allocation** | | | X | | | |
| **INTERVENTION:** | | | | | | |
| **Clinical Training Intervention** ***(intervention arm only)*** | | | X | X | | |
| **ASSESSMENTS:** | | | | | | |
| **Facility Manager Survey**<br>*Respondent characteristics*<br>*HIV prevention training*<br>*HIV prevention/care guidelines*<br>*PrEP for adolescents and young adults*<br>*PrEP registry data collection* | | X | | | | |
| **Health Care Worker Survey**<br>*Demographics and training history*<br>*Beliefs about AGYW and PrEP*<br>*Beliefs about HIV*<br>*Self-rated competency in PrEP delivery to AGYW*<br>*Knowledge of PrEP services* | | X | | | X | X |
| **SP unannounced visit checklist**<br>*PrEP guidelines adherence*<br>*Communication skills* | | X | | | X | X |
| **SP training encounter checklist**<br>*PrEP guidelines adherence*<br>*Communication skills*<br>*Interpersonal skills* | | | X | X | | |

## Intervention

Enrolled HCWs from the 12 study sites randomized to receive the clinical training intervention are invited to attend two-day training events among groups of 5-10 HCWs, totaling 20 repeated training events. All HCWs, regardless of cadre, will receive the same two-day training to ensure consistency of exposure to PrEP delivery guidelines and patient-provider communication content. During the trial period, HCW maintain normal daily functions aside from participation in the 2-day training event. These events involve a combination of didactic lectures providing background information about the PrIYA-SP trial, adolescent health and development, Kenyan national guidelines for HIV prevention and PrEP delivery among AGYW, and structuring a high-quality patient-provider encounter. Interactive group activities include a values clarification exercise and patient-centered communication activity which focuses on

understanding the patient's perspective, verbal and nonverbal communication, expressing empathy, and shared decision-making[31]. These activities allow HCW to practice reducing the influence of their personal beliefs within patient care and engaging patients in their own health decision-making processes.

Training materials for the intervention are informed by widely-used frameworks for clinical communication skills and high quality patient-provider interactions[22, 31, 35-42], the current Kenyan national guidelines for PrEP delivery[43], and qualitative interviews with AGYWs regarding PrEP seeking experiences conducted by study team members. The clinical training intervention is adapted from the training intervention implemented in the SPEED trial – a stepped-wedge RCT evaluating the effect of a SP-led training intervention on adolescent retention in HIV care in Kenya (details published previously)[24].

HCW role-play with SPs to enact six case scripts depicting common experiences of AGYW seeking PrEP counseling. Each encounter is video-recorded and timed. During the informed consent process, HCW agree to video recording during the training sessions; video equipment is readily visible in role-play spaces such that HCW are aware of the recording. HCW may opt to sign a video and photo release form premising use of the videos in educational or dissemination settings beyond the training event. Case scripts from the baseline unannounced visits are adapted for appropriate application in the training intervention. Following each role-play encounter, SPs complete a training checklist evaluating HCW adherence to PrEP guidelines, communication skills, and interpersonal skills. Trainings conclude with review of filmed SP role-play sessions with facilitated group debriefing to synthesize feedback and take-away messages.

Overall, the clinical training intervention is developed to accommodate a mixed skillset within diverse HCW cadres that could be applied and sustained across the health system by the Kenyan Ministry of Health.

*Monitoring intervention fidelity*

We monitor intervention fidelity throughout the trial by evaluating SP actor fidelity to assigned PrEP case scripts. Study staff review a random sample of 10% of video-taped encounters at regular intervals throughout training intervention implementation, measuring actor fidelity by completing a standardized checklist adapted for this study. Fidelity checklists and scores inform refresher trainings for SPs throughout implementation of the training intervention. Individual training for actors requiring further support are facilitated as needed. Standard operating procedures and standardized training materials are consistently used for each training session. We track HCW completion of the training intervention and retention in study facilities over time.

*Data collection for intervention evaluation*

Once the training intervention is complete for all sites in the intervention arm, study staff re-administer the HCW surveys at all 24 facilities (Figure 2). The new group of SPs are hired and trained to perform case scripts and, subsequently, SPs repeat the unannounced assessments conducted during the baseline evaluation at all 24 intervention and control sites. Case scripts are updated from those used at baseline and in the training intervention to minimize risk of SP discovery by HCWs. Post-intervention checklists and scores used to measure quality of PrEP counseling at each SP encounter are the same as in the baseline evaluation.

*Data management*

Data are collected by trained study staff into REDCap – an encrypted, web-based data management application -- using password-protected electronic tablets to protect participant confidentiality. The Kenya-based data manager oversees data entry, management, and monitoring throughout the study and a Seattle-based statistical team oversees data cleaning, reporting, and interim analyses. All data, including video recordings, are stored on a secure server at the University of Washington throughout the trial and for at least 3 years after trial completion. A Data Monitoring Committee is not needed as this trial is low-risk to study participants. An External Advisory Committee reviews trial progress and social harms.

## Outcome measures

The primary outcome of interest for this study is quality of PrEP counseling provided by HCWs delivering PrEP to adolescent girls and young women for HIV prevention in Kenya, measured at each unique SP encounter and compared between intervention and control sites (Table 3). We define quality as the total score from the SP unannounced checklist, which includes sub-scores for domains of adherence to national PrEP guidelines and communication skills. The checklist contains 12 questions assessing adherence to PrEP guidelines using binary "done/not done" response options to indicate whether the PrEP counseling message was delivered by the provider during the SP unannounced visit (sub-score range: 0-12) according to the Kenyan National AIDS & STI Control Programme guidelines[43]. Seven questions assess communication quality with four scaled response options (strongly agree, agree, disagree, strongly disagree) (sub-score range: 0-21). Because there are few standard tools to assess patient-provider communication about HIV prevention with young people, questions to assess communication quality were informed by guidelines and tools used in other populations [22, 35-42] and adapted for this population. Higher total scores represent higher quality of PrEP counseling (overall score range: 0-33) and are rescaled to a percentage. Quality of PrEP counseling was selected as the primary outcome for this study as it represents an important proximate outcome of the training intervention to improve PrEP services for AGYW that results from an intervention to improve HCW counseling. This may in turn improve AGYW adherence. PrEP uptake and adherence among AGYW, and these outcomes will be evaluated as other important outcomes of programmatic PrEP delivery in other related work

The secondary outcome for this study is quality of PrEP counseling by HCWs during the classroom simulated encounters in interpersonal skills, communication skills, and adherence to the national guidelines for PrEP delivery comparing mean score percent from the first and last SP encounter. The interpersonal skills measure includes four dimensions (interviewing and collecting information, counseling and delivering information, rapport, and personal manner). Empathy is assessed indirectly as a construct within the interpersonal skills assessment, measured as a combination of skills including active listening and validation. The checklist assesses interpersonal skills with 4 scaled response options (1 – 4 with higher value indicating higher quality interpersonal skills) developed from the Van Zanten interpersonal skills assessment tool[42] (sub-score range: 4 - 16). We compute mean score percent for training intervention scores stratified by case script and from first to last case as a secondary outcome.

**Table 3. Primary and secondary outcomes and data sources for PrIYA-SP trial**

| Outcome measure | Data source* | Facilities assessed | Comparison | Timing of assessment |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| **Primary outcome:** Quality of PrEP counseling mean score percent from unannounced SP visits | SP unannounced visit checklists from endline assessment* | All intervention and control sites | Intervention vs. control sites | Post-intervention evaluation |
| **Secondary outcome:** **C**hange in interpersonal skills mean score percent among intervention participants between the first and last session | SP training checklist* | Intervention arm sites only | Initial training SP encounter to final training SP encounter | Intervention |
| **Other outcome:** Self-rated HCW PrEP competency, attitudes toward AGYW | Health care worker survey | All intervention and control sites | Intervention vs. control sites | Post-intervention evaluation |

*SP unannounced visit checklist and SP training checklist are available as Additional file 3 and Additional file 4, respectively

### Sample size calculation

Given the study is conducted in 24 facilities comprising the total number of clusters, , we used an *à priori* established expected baseline quality of PrEP counseling to estimate sample sizes to detect a 10-percentage point difference between the intervention and control arm with 80% power assuming a type 1 error rate of 0.05 and a two-sided test. Under these assumptions, if quality of PrEP counseling is 60% in the control arm, with standard deviation of 17.7%, and assumed coefficient of variation between SP encounters of 0.15, we would need an estimated 120 total SP encounters overall (6 SP encounters per site).

### Statistical methods and analysis

The primary analyses will use intention-to-treat (ITT) to evaluate whether the clinical training intervention using SPs results in higher quality of PrEP counseling scores at SP encounters taking place in intervention facilities compared to control facilities. The ITT analysis assumes that HCWs in facilities randomized to receive the clinical training intervention are “exposed” to the training, and that HCWs in facilities randomized to not receive the training intervention are “unexposed” to the training. We use a CONSORT diagram (Figure 1) to indicate the number of facilities and HCWs enrolled by study arm during the trial, numbers excluded, and reasons for exclusion. Descriptive statistics describing baseline characteristics of facilities by study arm will be presented to assess whether balance of these factors was achieved through randomization.

Generalized linear mixed models (GLMMs) will be used to compare post-intervention quality of PrEP counseling score percent from SP encounters between the intervention facilities and comparison facilities. (i.e., control arm). We will estimate the effect of the training intervention on the individual SP

encounter level, using a GLMM with a Gaussian distribution and identity link, accounting for facility cluster and SP as random effects. These models will be adjusted for baseline quality of PrEP counseling score items that differ between study arms (p-value <0.05) ascertained using checklists completed by SP actors based on their assessment of care received by HCWs during unannounced SP encounters. This analytical approach allows individual-level outcomes per SP encounter to be modeled while accounting for correlation by facility-level cluster and SP. Regression coefficients and 95% confidence intervals will be estimated with a two-sided alpha of 5%. In sensitivity analyses, we will evaluate the intervention effect on individual components of PrEP guideline adherence and communication quality in separate GLMMs as well as differences in overall mean percent scores between cases, where case is included as a fixed effect.

**Ethics and dissemination**

The PrIYA-SP study is registered at clinicaltrials.gov. This study was approved by the University of Washington Institutional Review Board (IRB) and Kenyatta National Hospital Ethics and Research Committee (ERC). Changes to the protocol are reviewed by both institutions prior to implementation and appropriate updates are made to clinicaltrials.gov. Any changes to the protocol are communicated to coinvestigators and study staff through change memos.. Results from this study will be disseminated through peer-reviewed journals, presentations at local and international conferences to national and global policymakers, community members and participants.

## DISCUSSION

There is high global commitment to reducing HIV incidence among AGYW and a mounting evidence-base that more research on PrEP delivery is needed to maximize the real-world effectiveness of this powerful HIV prevention tool. However, there are few interventions to improve the current quality of PrEP services for AGYW in high HIV-burden settings which may influence uptake and adherence. It is therefore important to evaluate novel and potentially scalable strategies to improve adherence to national PrEP guidelines and communication skillsamong HCW delivering PrEP to this population. The PrIYA-SP study fills a gap in evidence of HCW training programs in resource-limited settings to improve HIV prevention services for AGYW[44, 45]. Our use of SPs to assess quality of PrEP delivery and as part of a clinical training intervention is novel. We use a randomized trial to evaluate the outcome of quality of PrEP services while adapting to schedules and services of the facilities. This study is responsive to the global motivation to reduce HIV acquisition among AGYW [46] by reducing barriers to PrEP uptake, as well as the Kenyan Ministry of Health request for novel interventions to inform the implementation of new

adolescent-friendly HIV service guidelines[47]. If the SP-led clinical training intervention is effective at improving quality of PrEP counseling for AGYW, SP-led training interventions could be adopted as a recommended approach by Ministries of Health and PrEP scale-up initiatives within similar settings to expand improvements in quality PrEP delivery for AGYW.

*Limitations*

This study has limitations. As a pragmatic trial taking place within the Kenyan health system, study activities are subject to delays due to public holidays, health provider strikes, PrEP stock-outs and other reasons for staff shortages within facilities. Staff turnover is likely within this context, which could result in turnover of PrIYA-SP-trained HCWs and potentially diluted intervention effectiveness. We monitor staff shortages and turnover through operational tracking processes and will account for these changes in the analysis. Finally, our primary outcome depends on the quality of SP recall after the unannounced visits when completing the checklist with study staff. To minimize the potential for error in recall, the consultant-led SP training includes tactics for remembering details of interactions and study staff administer checklists to SPs immediately following unannounced visits.

## CONCLUSION

This training intervention for HCWs involving standardized patients has the potential to promote high-quality, patient-centered HIV prevention services for AGYW by providing HCWs with improved competency in Kenyan guidelines for PrEP delivery and enhanced communication skills. This study fills a need cited by HCW for expanded skillsets[14] and a desire cited by AGYW for respectful[16, 18, 48], and informative care[17]. This increase in quality of care delivery may, in turn, improve PrEP uptake and continuation to prevent HIV acquisition among this high-risk population.

## Trial status/registration

At the time of submission, trial implementation had not yet begun. The trial is registered at ClinicalTrials.gov NCT03875950. All items from the World Health Organization Trial Registration Data Set are available for this study on ClinicalTrials.gov

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**Protocol version:** This article was developed from the study protocol version 1.3 (May 2019) which was the latest approved version by the University of Washington Institutional Review Board and Kenyatta National Hospital Ethics and Research Committee at the time of submission.

**Author contributions:** PK and GJS are the principal investigators and supervised the trial protocol development and implementation. JK is the site investigator and oversees Kenya-based implementation. PK, GJS, JK, KW, BR, JP participated in designing the study. TO helped to develop intervention materials and trained the standardized patient actors. BR, KW, PK are responsible for the statistical design of the trial. FA and HL oversee field implementation of the trial. AL and KW wrote the initial draft of the paper. All authors critically revised, read, and approved the final manuscript.

**Roles and responsibilities:** Principal investigators and co-investigators from University of Washington and Kenyatta National Hospital oversee study design, conduct, and ongoing study management. An External Advisory Committee monitors social harms. No other parties participate in protocol development, study design, conduct, or interpretation of results.

**Data sharing statement:** The final trial dataset without identifiers, full protocol, and/or statistical code will be made available to outside investigators with permission from Principal Investigators and University of Nairobi/Kenyatta National Hospital.

**Additional Files**

Supplementary file 1: Example facility manager and healthcare worker informed consent forms

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**Figure 1. Adapted CONSORT Diagram for PrIYA-SP**

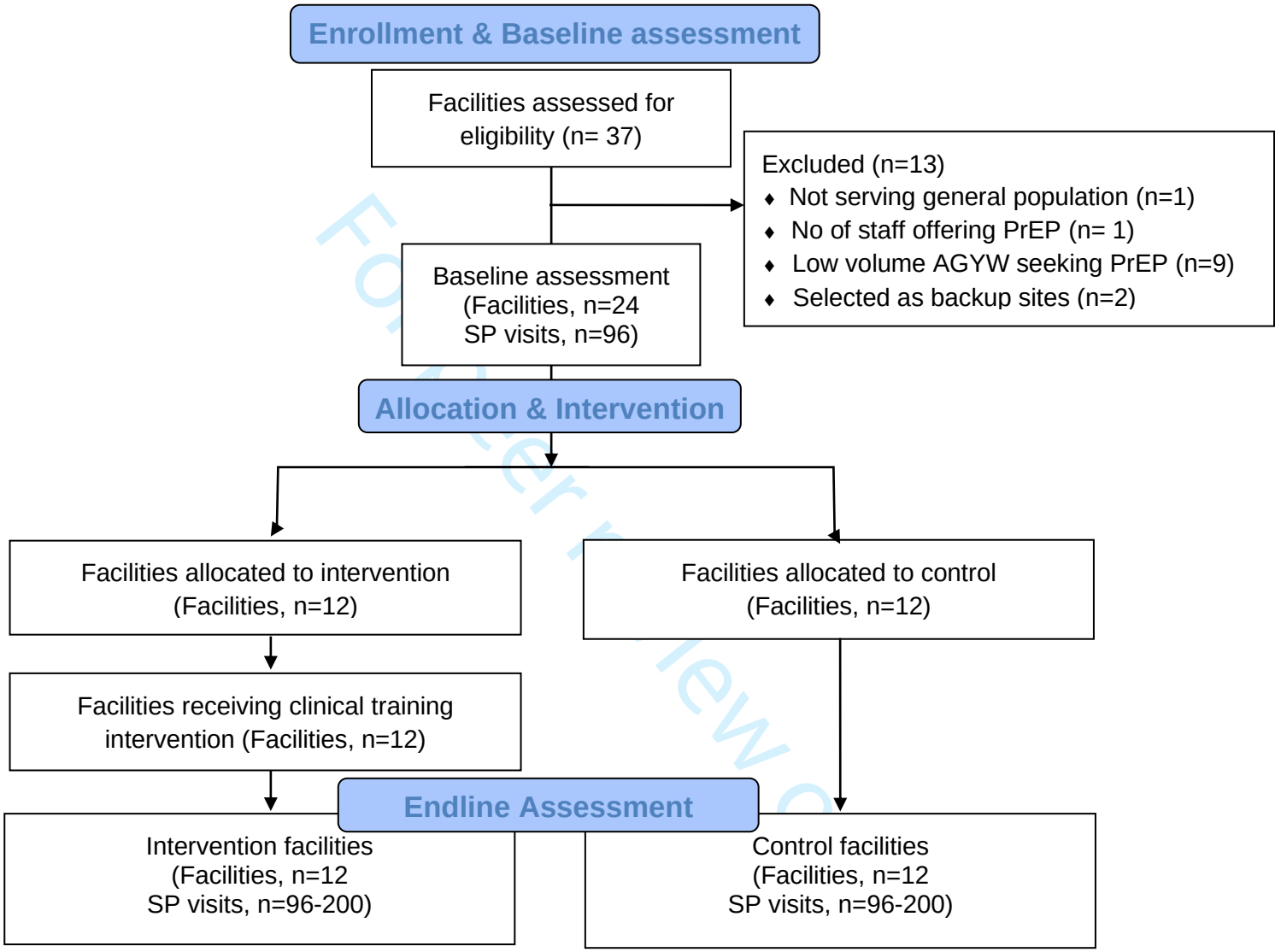
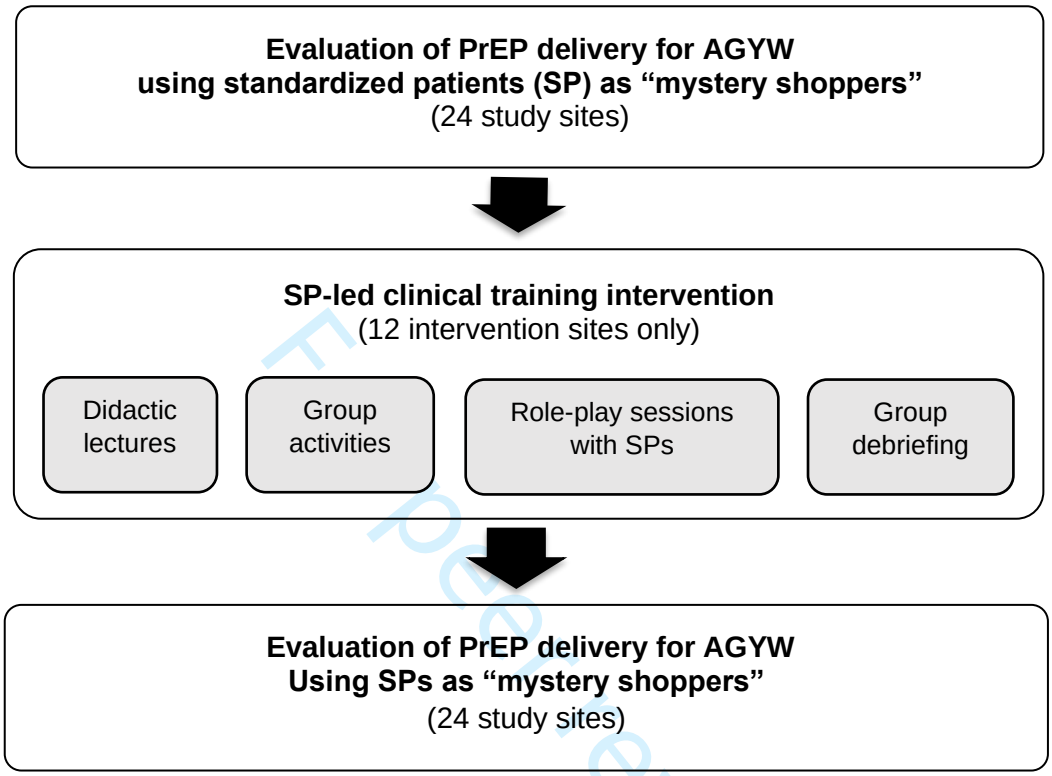


**Figure 2. PrIYA-SP trial schematic**



**Standardized Patient Encounters to Improve Counseling for Pre-Exposure Prophylaxis (PrEP) for HIV Prevention to Adolescent Girls and Young Women (AGYW) in Kenya**

**Consent for Facility Managers**

**Study Investigators**

| NAME | POSITION | DEPARTMENT | TELEPHONE NUMBERS |
|---|---|---|---|
| Grace John-Stewart | Co-Principal Investigator | Global Health, UW | +1-206-543-4278 |
| Pamela Kohler | Co-Principal Investigator | Global Health, UW | +1-206-616-7962 |
| John Kinuthia | Site Principal Investigator | Kenyatta National Hospital | +254-0722-799-052 |
| Felix Abuna | Study Coordinator | Kenyatta National Hospital | +254 721 230652 |
| Harison Lagat | Study Coordinator | Kenyatta National Hospital | +254 716 977248 |
| Jillian Pintye | Co-Investigator | Global Health, UW | +1-206-437-9983 |
| Kristin Beima-Sofie | Co-Investigator | Global Health, UW | +1-206-685-8332 |
| Kate Wilson | Co-Investigator | Global Health, UW | +1-206-685-0583 |

**Emergency telephone number:** Dr. Felix Abuna, Telephone +254 721 230652
**Ethics and Research Committee Chairperson:** Professor AN Guantai, Telephone 020-272-6300 Extension 44102
**University of Washington Human Subjects Division**: Telephone +1-206-543-0098.

## A. Researchers' statement

### 1. Introduction

We are asking for your consent to volunteer for a research study. The study is being conducted by the Kenyatta National Hospital (KNH) and the University of Washington. The purpose of this consent process is to give you the information you will need to help you decide whether or not you want to participate. You may ask questions about the purpose of the study, what we would ask you to do, possible risks and benefits, your rights as a volunteer, and anything else about the study or this form that is not clear. When we have answered all of your questions, you can decide if you want to be in the study. This process is called "informed consent." We will give you a copy of this form for your records.

### 2. Purpose

We are asking you to participate in this study because you work in one of 24 clinics in Western Kenya selected for participation in a clinical trial. The trial will assess the current quality of PrEP counseling services for HIV prevention and evaluate whether a training course using standardized patient actors (SPs) improves PrEP service delivery to adolescent girls and young women (AGYW) in Kenya.

### 3. Procedures

If you agree to take part in the study, we will ask you to in participate in a survey at the beginning of the study. A study team member will administer the survey to you using an electronic tablet. The survey will ask about services and characteristic at this facility related to HIV prevention and treatment. Please provide the most current and accurate information that you can about this

facility. Your name will not be documented in this study. All information related to you will be kept confidential.

In addition, this facility may be selected to participate in a two-day didactic and role-playing training that would occur during normal working hours. In that case, we will speak with you and your staff in advance about those activities. There will be separate consent forms for those activities. At the end of the trial, we will ask that you complete another survey about this facility. Each survey will take 10-15 minutes to complete. One you have finished the surveys, your role in this study will end.

Today, if you agree to participate, you will sign this consent form and will be given a copy of this form for your records.

**4. Risks, Stress, and Discomfort**

Questions on this survey may be may make you feel uncomfortable, because they address HIV prevention and care services available for AGYW. You can stop the survey at any time if you do not feel comfortable. You can skip any question that you do not want to answer. You can withdraw from participation in the training or the study at any time. We will not share any information about you with your employer.

**5. Benefits**

You may directly benefit from this study as you gain understanding about how to improve health care relationships with AGYW in clinical settings, including improved practices, counseling, and support strategies that may help to improve the way PrEP is provided to this population.

**6. Other information**

***Your Participation is Voluntary***

This consent form gives information about the study. We will discuss the study with you and answer any questions you may have. If you agree to take part, we will ask you to sign your name on this form. We will offer you a copy to keep.

It is important that you know the following:

- You do not have to be in this study if you do not want to,
- You may decide not to join the study, or to stop the study at any time

***Costs to You***

There is no cost to you for participation.

***Reimbursement***

Staff from this facility who participate in the training will receive light refreshments and reimbursement for transport.

**7. Source of funding**

The study team and/or the University of Washington are receiving financial support from the National Institutes of Health in the United States.

**8. Confidentiality of Research Information**

The information you provide during the interview will be kept secret by the study staff. This information is about this facility and not you personally. We will not publish or discuss in public anything that could identify you. All paper forms will be stored in a room under lock and key. Electronic data will be stored on a password protected server. Only authorized study team members will have access to study data. Study results will have no identifiable data that can be traced back to you.

This trial will be registered at ClinicialTrials.gov and available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. This website will only include a summary of the results. You can search the website at any time.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

The records of this discussion may be reviewed by assessment staff and representatives of:

- University of Washington, including the Institutional Review Board
- Kenyatta National Hospital and University of Nairobi Ethics and Research Committee

There are some limits to this protection. We will voluntarily provide the information to:

- A member of the US federal government who needs it in order to review or monitor the research;
- People at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly

**9. Research-Related Injury**

It is unlikely that you will be injured as a result of participating in this discussion. There is no program for monetary compensation or other forms of compensation for injuries. You do not give up any legal rights by signing this consent form.

**10. Concerns or Questions**

If you ever have any questions about the study you should contact Dr. Felix Abuna, Telephone +254 721 230652. If you have questions about your rights as a research participant, or feel you have been harmed by the study, you should contact Professor Guantai, the Chair of the KNH/UoN ERC, at 2726300-Extension 44102. You can also contact the UW HSD at +1-206-543-0098.

**B. Study Participant's Statement**

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have more questions later, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the KNH/UoN Ethics and Research Committee at 2726300-Extension 44102. I will receive a copy of the consent form.

_____ _____

Participant's Name Date

_____

Signature

Copies to: Researcher
Participant

**Standardized Patient Encounters to Improve Counseling for Pre-Exposure Prophylaxis (PrEP) for HIV Prevention to Adolescent Girls and Young Women (AGYW) in Kenya**

**Consent for Health Care Worker Patient Encounter and Training**

**Study Investigators**

| NAME | POSITION | DEPARTMENT | TELEPHONE NUMBERS |
|---|---|---|---|
| Grace John-Stewart | Co-Principal Investigator | Global Health, UW | +1-206-543-4278 |
| Pamela Kohler | Co-Principal Investigator | Global Health, UW | +1-206-616-7962 |
| John Kinuthia | Site Principal Investigator | Kenyatta National Hospital | +254-0722-799-052 |
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**University of Washington Human Subjects Division**: Telephone +1-206-543-0098.

## A. Researchers' statement

### 1. Introduction

We are asking for your consent to volunteer for a research study. The study is being conducted by the Kenyatta National Hospital (KNH) and the University of Washington. The purpose of this consent process is to give you the information you will need to help you decide whether or not you want to participate. You may ask questions about the purpose of the study, what we would ask you to do, possible risks and benefits, your rights as a volunteer, and anything else about the study or this form that is not clear. When we have answered all of your questions, you can decide if you want to be in the study. This process is called "informed consent." We will give you a copy of this form for your records.

### 2. Purpose

We are asking you to participate in this study because you work in one of 24 clinics in Western Kenya selected for participation in a clinical trial. The trial will assess the current quality of PrEP counseling services for HIV prevention and evaluate whether a training course using standardized patient actors (SPs) improves PrEP service delivery to adolescent girls and young women (AGYW) in Kenya.

### 3. Procedures

If you agree to take part in the study, we will ask you to in participate in a quality of care assessment, and you may be selected to attend a training. If you consent to take part, you are agreeing to be evaluated by an unannounced standardized patient actor (SP). Unannounced SPs are trained actors who will portray an adolescent girl or young woman who is seeking PrEP

services at your clinic. SPs will come to your clinic, at any time, for the duration of the study period lasting 3 years. Even if you consent to participate, you personally may not have a visit with a SP since only a few SPs will visit each clinic. We ask that you do not inquire whether a patient is an SP. Instead, it is important that you treat the SP like any other patient. There is a high likelihood that you will not know that this patient is an SP. The SPs will not provide any feedback to you about care that they receive. After the visit, the SP will complete a brief checklist to evaluate the visit with a study team member. Your name will not be documented in this checklist.

At the beginning of the study, you will be asked to complete short surveys about your background, knowledge of PrEP guidelines, and your clinical and communication skills. You may be asked to take this survey again at the end of the study. Each survey will take 10-15 minutes to complete.

Your clinic may be selected to participate in a 2-day provider training. If selected, you would be invited to take part in this training. The training will consist of lecture, group discussion, and role-playing sessions, and will occur during normal working hours. Content will include review of national PrEP guidelines, counseling female adolescents and young adults about PrEP and communication skills.

The role-playing will include several encounters with trained SPs. In each encounter, the SP will play the role of a female adolescent or young adult using a pre-scripted scenarios. The sessions will be video-taped and may be shared with your training group, the SP, and the study trainer as part of a debriefing process. The SP actors will provide verbal and written feedback on the scenario.

If you agree to participate, you will sign this consent form and will be given a copy of this form for your records. We will ask you for your written permission to release your videos for future trainings and education.

**4. Risks, Stress, and Discomfort**

The encounters with the SPs may make you feel uncomfortable. You may not know when a patient is an SP. If you participate in the training, you will receive feedback on your performance from colleagues, the actor, and the trainers, which may make you uncomfortable . You may also feel uncomfortable if the actor presents concerns about sensitive or difficult topics like HIV risk behaviors, violence, or mental health issues. You can stop any role-playing session if you do want to participate any further. You can stop the debriefing session at any time if you do not feel comfortable. In addition, you can withdraw from participation in the training or the study at any time, including being recorded. We will not share any information about you or your performance with your supervisor.

**5. Benefits**

You may directly benefit from this training as you gain understanding about how to improve health care relationships with AGYW in clinical settings, including improved practices, counseling, and support strategies. What we learn from you may help to improve the way that PrEP care and counseling services are provided to AGYW in Kenya.

**6. Other information**

***Your Participation is Voluntary***

This consent form gives information about the study. We will discuss the study with you and answer any questions you may have. If you agree to take part, we will ask you to sign your name on this form. We will offer you a copy to keep.

It is important that you know the following:

- You do not have to be in this study if you do not want to
- You may decide not to join the study, or to stop the study at any time

***Costs to You***

There is no cost to you for participation.

***Reimbursement***

If you participate in the training, you will receive light refreshments and reimbursement for transport.

**7. Source of funding**

The study is funded by National Institutes of Health in the United States.

**8. Confidentiality of Research Information**

The information you provide during the interview will be kept secret by the study staff. We will not publish or discuss in public anything that could identify you. The video recordings of the role-playing sessions in the training will not be directly linked to your name or contact information. Video recordings from the sessions will be stored in a password protected file on a password protected computer. All paper forms will be stored in a room under lock and key. Electronic data will be stored on a password protected server. Only authorized study team members will have access to study data. You have the option sign a separate form that will authorized us to use video recordings for educational purposes. Study results will have no identifiable data that can be traced back to you.

This trial will be registered at ClinicialTrials.gov and available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. This website will only include a summary of the results. You can search the website at any time.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

The records of this discussion may be reviewed by assessment staff and representatives of:

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**9. Research-Related Injury**

It is unlikely that you will be injured as a result of participating in this discussion. There is no program for monetary compensation or other forms of compensation for injuries. You do not give up any legal rights by signing this consent form.

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_____ _____

Participant's Name Date

_____

Signature

Copies to: Researcher
Participant

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Page |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | p.1, lines 1-3 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | p.16, lines 27-29 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | p.16, lines 29-30 |
| Protocol version | 3 | Date and version identifier | p.17, lines 1-3 |
| Funding | 4 | Sources and types of financial, material, and other support | p. 16, lines 30-31 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | p.17, lines 9-11 |
| | 5b | Name and contact information for the trial sponsor | p.15, lines 1-5 |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | p.17, lines 11-12 |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | p.2, lines 22-23, p.7, lines 25-29, p.17 9-11 |
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | p.5, lines 1-32, p.6, lines 1-2 |

| | | | |
|---|---|---|---|
| | 6b | Explanation for choice of comparators | p.5, lines 9-15, p.7, lines 5-8 |
| Objectives | 7 | Specific objectives or hypotheses | p.5, lines 6-15 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | p.5, lines 6-15 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | p.5, lines 4-20 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | p.5, lines 4-20 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | p.10, lines 4-13 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | NA |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | p.11, lines 32-33, p.12, lines 1-6 |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | p.10, lines 8-9 |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | p.13, lines 1-30 |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | Table 2, Figure 2 |
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | p.14, lines 3-10 |

| | | | |
|---|---|---|---|
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | p.8, lines 30-32, p.9, lines 1-6 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | p.6, lines 28-31, p.7, lines 1-8 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | p.7, lines 21-29 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | p.7, lines 21-29 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | p.7, lines 21-29 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | p.7, lines 21-29 |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | p.9, lines 8-24, p.12, lines 8-15 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | p.9, lines 5-6 |
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | p.12, lines 16-22 |

| | | | |
|---|---|---|---|
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | p.14, lines 12-24, p.15, lines 1-10 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | p.15, lines 7-10 |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | p. 14, lines 13-17 |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | p.12, lines 22-23 |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | NA |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | p.2, line 22, p.12, lines 25-26, p.17, line 11-12 |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | p.2, line 22, p.12, lines 25-26, p.17, line 11-12 |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | p.2, lines 21-23, p.15, lines 13-21 |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | p. 15, lines 13-21 |
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | p. 8, lines 30-32, p.9, lines 1-6 |

| | | | |
|---|---|---|---|
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | NA |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | p.12, lines 16-24 |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | p.16, line 32 |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | p.17, lines 13-15 |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | NA |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | p.15, lines 12-21 |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | p.17, lines 4-8 |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | p.17, lines 13-15 |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | Supplementary file 1 |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | NA |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.