NEW YORK STATE PSYCHIATRIC INSTITUTE

INSTITUTIONAL REVIEW BOARD

MEMORANDUM

April 05, 2022

TO: Susie Hoffman, DPH

FROM: Dr. Edward Nunes, Co-Chair, IRB

Dr. Agnes Whitaker, Co-Chair, IRB

SUBJECT: EXPEDITED APPROVAL OF PROTOCOL AMENDMENT

The amendment to your protocol #7682 entitled: DEVELOPING A GENDER-ENHANCED PREP INFORMATION-MOTIVATION WORKSHOP FOR YOUNG SOUTH AFRICAN WOMEN **(To add Sofie Momin, a student at the Mailman School of Public Health, to work on coding and analyzing the 3-month telephone interview de-identified data, as per the 4/5/2022 memorandum)** has been approved by the Psychiatric Institute - Columbia University Department of Psychiatry Institutional Review Board.

Please note that this does not change the IRB's cycle of review. A progress report and an application for continuing review will still be required.

Signed copy on file at IRB.
EN/AW/sc2432

Protocol Title:
Developing a Gender-Enhanced PrEP Information-Motivation Workshop for Young South African Women

Version Date:
04/05/2022

Protocol Number:
7682

First Approval:
02/25/2019

Expiration Date:
No Expiration

Contact Principal Investigator:
Susie Hoffman, DPH
Email: sh51@columbia.edu
Telephone: 646 774 6938

Co-Investigator(s):
Curtis Dolezal
Theresa Exner

Research Chief:
Anke Ehrhardt, PHD

Cover Sheet

Choose ONE option from the following that is applicable to your study
If you are creating a new protocol, select "I am submitting a new protocol." As 5 Year Renewals are no longer required, this option remains for historical purposes.
I am proposing an amendment only to an existing protocol

Department & Unaffiliated Personnel

Department

What Department does the PI belong to?
Gender, Sexuality, and Health
Within the department, what Center or group are you affiliated with, if any?
HIV Center

Unaffiliated Personnel

List investigators, if any, who will be participating in this protocol but are not affiliated with New York

State Psychiatric Institute or Columbia University. Provide: Full Name, Degrees and Affiliation.

Abigail Harrison, PhD, Brown University School of Public Health (co-investigator)
Jill Hanass-Hancock, PhD, South African Medical Research Council, Office of the Executive Scientist-Research Strategy (Dual Principal Investigator)

Amendment

Describe the change(s) being made
I wish to add Sofie Momin to this protocol. Ms. Momin is a student at the Mailman School of Public Health. She will be working on coding and analyzing the 3-month telephone interview data along with other members of the team. This is de-identified data.
Provide the rationale for the change(s)
For her practicum project, Ms. Momin will be working on coding and analyzing the 3-month telephone interview data along with other members of the team. This is de-identified data. Ms. Momin has completed all required CITI training and her certificates are uploaded with this amendment request.
Comment on the extent to which the proposed change(s) alter or affect risks/benefits to subjects
This change will not alter or affect the risks/benefits to study participants
Comment on if the proposed change(s) require a modification to the Consent Form (CF)
The proposed change does not require a modification to the CF.

Procedures

To create the protocol summary form, first indicate if this research will include any of the following procedures
✓ Audio or Videotaping
✓ Internet-based Data Collection or Transmission

Population

Indicate which of the following populations will be included in this research
✓ Adults
✓ Non-English Speaking Participants

Research Support/Funding

Will an existing internal account be used to support the project?
No
Is the project externally funded or is external funding planned?
Yes
Select the number of external sources of funding that will be applicable to this study
3

Funding Source #1

Is the PI of the grant/contract the same as the PI of the IRB protocol?
Yes
Select one of the following
The grant/contract is currently funded
Source of Funding
Federal
Institute/Agency
NIMH
Grant Name
Developing a Gender-Enhanced PrEP Information-Motivation Workshop for Young South African Women
Grant Number
1R34MH115781
Select one of the following
Multicenter(NYSPI is the lead site)
Business Office
RFMH
Does the grant/contract involve a subcontract?
Yes
Subcontracted?
To
Name institution(s)

South African Medical Research Council, HIV Prevention Research Unit
Brown University School of Public Health

Funding Source #2

Is the PI of the grant/contract the same as the PI of the IRB protocol?
No
Who is the PI of the grant/contract?
Virginia Russel
Select one of the following
The grant/contract is currently funded
Source of Funding

Other
Sponsor
South African Medical Research Council, Internal funding
Select one of the following
Multicenter (NYSPI is a participating site)
Business Office
Other
Name
SA MRC
Does the grant/contract involve a subcontract?
No

Funding Source #3

Is the PI of the grant/contract the same as the PI of the IRB protocol?
No
Who is the PI of the grant/contract?
Jill Hanass-Hancock
Select one of the following
The grant/contract is currently funded
Source of Funding
Other
Sponsor
South African Medical Research Council
Select one of the following
Single Site
Business Office
Other
Name
South African Medical Research Council
Does the grant/contract involve a subcontract?
No

Study Location

Indicate if the research is/will be conducted at any of the following
This protocol describes research conducted by the PI at other facilities/locations
Yes
✓ International Sites

International Sites

Type in location(s)

South African Medical Research Council Ridge Road (Durban) Research Office
Addington Hospital, including mobile van, Durban

Uploaded Protocol Summary Form

Upload Document

Select file to upload.
PRISM PSF 7 January 2022.pdf

Lay Summary of Proposed Research

Lay Summary of Proposed Research

South African adolescent girls and young women (AGYW) remain at extraordinarily high risk of HIV infection. Oral pre-exposure prophylaxis (PrEP) has the potential to alter the epidemic in this vulnerable population, given that it is has been shown that if it is adhered to, oral PrEP can protect women from HIV infection. Yet, a critical question is whether AGYW will adopt and adhere to oral PrEP. Creating demand—generating interest among at-risk AGYW, who may know little about PrEP and be wary of using it—is critical. There were several barriers that drove non-adherence to PrEP in the VOICE clinical trial. These included low perceived risk, stigma around taking ARVs, mistrust of biomedical products, worries about potential adverse effects, and concerns about partner reactions. These factors may also dampen AGYW's uptake of oral PrEP, but limited attention has focused on creating demand and motivating uptake, a gap we aim to address. We propose that two innovations can reach young, at-risk AGYW, inform them about PrEP and motivate them to use it: (1) introducing PrEP through a gender lens in a one-session group workshop; and (2) peer-driven recruitment—recruiting women to attend the workshop by those who have already attended it. To inform intervention development, we will conduct eight focus groups with at-risk AGYW (aged 18-25), 10 qualitative interviews with focus group participants**,** and 20 qualitative interviews with men (10 HIV-positive, 10 HIV-negative or of unknown status) partnered with women in this age range that will explore knowledge of, beliefs about, motivators for, and concerns about using PrEP in the context of gendered relationship dynamics and PrEP-related stigma. Guided by gender theory and the Information Motivation Behavior (IMB) model, and in collaboration with a Working Group of AGYW, we will develop a virtual on-line (using the WhatsApp platform) group-based Gender-Enhanced (GE) Workshop to provide PrEP information and address AGYW's barriers to using it. In a pilot, we will compare AGYW (N=~~98~~ **100**) randomized to the virtual group-based GE workshop (with components that are conducted by participants on their own time as well as a "real-time" "live" interactive session) or to an Individual Access (IA) condition in which women are given access to a PrEP video and to websites that provide information on PrEP and on contraception options. The primary outcome is having an individual conversation with the study nurse about the possibility of taking up PrEP; secondary outcomes are undergoing HIV-testing and counseling and, if

PrEP-eligible, uptake of PrEP; and, for all women, hypothesized mediators (risk perception, gender barriers, peer norms, self-efficacy, outcome expectancies, PrEP-stigma, attitudes, information) post-intervention and at 3-months. For Peer-driven recruitment (PDR) AGYW randomized to either condition will be invited to become Peer Health Advocates (PHAs), who are paid to talk to social network members and refer up to three to the workshop type the PHA attended. We will evaluate acceptability and feasibility of PDR by assessing whether the method can be self-sustaining (i.e., on average >50% attendees become PHAs and >2 recruitees/PHA attend a workshop); and whether it reaches high-risk women, and women who would not be captured by other methods of recruitment (percent who score high on a new HIV risk tool; percent who never tested or attended family planning). If promising, these approaches will be further tested in a larger study.

Additionally, women who participated in Phase 1 FGs (N = 46) of this study will be invited to participate in a sub-study entitled Sexual and Reproductive Health and Rights of Young Women under the COVID-19 Epidemic (COVID and SRHR). The goal of the sub-study is to understand how the Coronavirus epidemic and related lock-down regulations are affecting young women's sexual and reproductive health and rights (SRHR) needs and ability to access sexual and reproductive health commodities and services over time (before, during different levels of and after lock-down). Participating women will complete three to four telephone interviews (depending on how long the lock-down lasts) over a one-year period. The interviews will employ mixed methods (quantitative, qualitative and photo-voice). Data collected as part of the sub-study will be combined with the quantitative descriptive data on demographic and sexual and reproductive health characteristics obtained from participating women just prior to the beginning of each FG.

Description of Subject Population

Sample #1

Specify subject population
Women focus group participants
Number of completers required to accomplish study aims
42
Projected number of subjects who will be enrolled to obtain required number of completers
72
Age range of subject population
18-25

Sample #2

Specify subject population
Men for semi-structured interviews
Number of completers required to accomplish study aims
20
Projected number of subjects who will be enrolled to obtain required number of completers
20

Age range of subject population
> = 18

Sample #3

Specify subject population
Initial pilot study participant peer health advocates "seeds"
Number of completers required to accomplish study aims
16
Projected number of subjects who will be enrolled to obtain required number of completers
18
Age range of subject population
18-25

Sample #4

Specify subject population
Pilot study participants recruited by peer health advocates
Number of completers required to accomplish study aims
100
Projected number of subjects who will be enrolled to obtain required number of completers
120
Age range of subject population
18-25

Sample #5

Specify subject population
FG women who participate in an Individual Qualitative Interview
Number of completers required to accomplish study aims
10
Projected number of subjects who will be enrolled to obtain required number of completers
10
Age range of subject population
18-25

Sample #6

Specify subject population
Women who participated in focus groups
Number of completers required to accomplish study aims
46
Projected number of subjects who will be enrolled to obtain required number of completers
46
Age range of subject population

18-25

Gender, Racial and Ethnic Breakdown

Participants for samples 1,3, 4, 5 and 6 will be self-identified women.
Participants for sample 2 will be self-identified men.

There are no race/ethnicity recruitment targets; however, we anticipate that most, if not all, will be Black African.

Description of subject population

Sample 1: Women aged 18-25 recruited from community sites and family planning clinics who are sexually active and interested in participating in a focus group discussion around women's HIV, STI, and pregnancy risk.

Sample 2: Men, aged 18 or older recruited from community sites and STD clinics, who have a female partner aged 18-25, and who are interested in participating in a semi-structured interview around men's views of HIV/STI and pregnancy protection.

Sample 3 - Women aged 18-25 recruited from community sites and family planning clinics who are sexually active, willing to participate in an educational workshop **or online activity**, and willing to recruit members of their social networks to subsequent workshops.

Sample 4 - Women aged 18-25 recruited by other women who attended a workshop **or online activity**, and who are sexually active and willing to participate in **the same activity**.

Sample 5 - Women aged 18-25, who have attended a focus group and who are willing to participate in an individual interview covering similar topics.

Sample 6 - Women aged 18-25, who attended a focus group and who are willing to participate in up to four telephone interviews as part of the Covid-19 substudy.

Recruitment Procedures

Describe settings where recruitment will occur

Population 1 - women for focus groups (FGs). Women will be recruited in community locations where young adults meet and in local public sector family planning (FP) clinics.

Population 2 - men for semi-structured interviews. Men will be recruited via referral from women participating in the FGs or will be recruited directly from clinic or community settings.

Population 3 - Initial pilot study participant peer health advocates ("seeds"). Women will be recruited in community locations where young adults meet and in local public sector family planning clinics.

Population 4 - Pilot study participants. Women will be recruited from among the social networks of other women who attended a workshop **or online activity**.

Population 5 - Women for individual interviews. At the completion of each Focus Group, women will be invited to indicate if they would be interested in participating in the individual interview.

Population 6 - Women for Covid-19 sub-study. Women who participated in FGs will be invited through telephone contact.

How and by whom will subjects be approached and/or recruited?

Population 1-3 - Fliers will be distributed by study staff in the above settings, and staff will invite interested women or men to be screened for eligibility.

Population 4 - Pilot study participants. Women will be recruited by other women who attended the workshop and who opted to become a Peer Health Advocate (PHA). **For the brief telephone interview with a subsample of pilot study participants (populations 3 and 4), text at the end of the structured 3-month follow-up will ask participants if they are willing to be included in the brief telephone interview. From among those who reply in the affirmative we will sample about 50%, in order to realize a sample of 40 telephone interviews.**

Population 5 - Staff will select randomly from among those willing to participate, and will then contact selected women to arrange the interview.

Population 6 - Participants for the sub-study will be contacted by the facilitator of their previous FG, who is a research assistant for the sub-study. The research assistant will send the participant a 'ward off letter' to their mobile phone asking for permission to contact them and tell them more about the COVID-19 study. The ward of letter can be sent as a SurveyMonkey (with reply option) and as a pdf attachment via WhatsApp (all participants have smartphones and WhatsApp). The research assistant will telephone participants who agree to be contacted and will explain the COVID 19 study to them.

How will the study be advertised/publicized?

The study will be advertised through fliers. Drafts of these are available for study populations #1 #2, and #3. Study population #4 fliers are being submitted with this application.
Advertisements are not needed for Study population #5, as they will comprise women who attend the Focus Groups.

The sub-study will not be advertised.

Do you have ads/recruitment material requiring review at this time?

Yes
Does this study involve a clinical trial?
No

Concurrent Research Studies

Will subjects in this study participate in or be recruited from other studies?
Yes
Describe concurrent research involvement
As described in this amendment, participants in the Covid-19 sub-study will be recruited from among participants in Phase 1 of the parent study.

Waiver of Consent/Authorization

Indicate if you are requesting any of the following consent waivers
Waiver of consent for use of records that include protected health information (a HIPAA waiver of Authorization)
No
Waiver or alteration of consent
Yes
Waiver of documentation of consent
Yes
Waiver of parental consent
No

Consent Procedures

Is eligibility screening for this study conducted under a different IRB protocol?
No
Describe procedures used to obtain consent during the screening process

Participants will be read a script requesting verbal consent for eligibility screening. An example is as follows:
Hello. I'm _____. I'm working with the South African Medical Research Council. Would you be willing to do a brief survey to see if you might qualify for a study that will create a new program to help young women protect themselves against HIV, other sexually transmitted infections and unintended pregnancy? The survey will only take 2 or 3 minutes. It's anonymous, so we don't take down your name. The survey asks for some background information and there are a few questions about your relationships, sexual behavior and HIV. If you don't want to participate, that's fine—it won't have any effect on (you/the services you receive here).

A. Would you be willing to participate?

• 1. Yes
• 0. No [THANK THE PARTICIPANT FOR THEIR TIME AND END INTERVIEW.]

Describe Study Consent Procedures

Informed consent will be obtained at the time the potential participant presents for the study activity (e.g., FG). In a private location**,** a trained study staff member will review the content of the consent form with the participant; will give the form to the potential participant to read or will read it outloud if the individual prefers; will ask if the potential participant has any questions; and will ask if s/he wants to participate and if so, will request that the consent form be signed. The staff member obtaining consent will affirm that the person freely gave consent. A copy of the consent form will be given to the participant.

For the pilot study (Phase 3) portion of the study, the consenting procedure for seeds will be in-person or via telephone. For participants subsequent to the seeds, the consenting procedure will be via telephone. The participant will be told that the consenting telephone call will be audio-recorded for documentation. A copy of the study Informed Consent form will be sent to the participant prior to the telephone call. During the consenting telephone call potential participants will be told about all study components and have the opportunity to ask questions and obtain clarification. The participant will provide IC verbally, and the entire consenting process will be audio-recorded for documentation. **For the subsample of pilot study participants invited to the brief telephone interview following the structured 3-month survey, a consent script will be read and audio-recorded for documentation prior to beginning the interview.**

For the COVID-19 sub-study, the research assistant will only follow-up with participants who reply to the ward-off letter and agree to be contacted for the sub-study. The RA will send study information and the informed consent (IC) documents (as pdf attachment via WhatsApp or email) to the participant and will identify a convenient time to conduct the telephone consent process. Participants will be informed that if they wish to have a witness present during the consenting process they may do so, but that this is not a requirement. During the consent telephone call, the research assistant will inform the potential participant about the opportunity to participate in the COVID-19 sub-study, share information about the content and procedures of the study and the risks and benefits. Participants who agree to enroll in the COVID-19 study will provide IC verbally, and the consenting process will be audio-recorded for documentation. The team will obtain delayed written IC after most COVID-19 lock down regulations have been lifted.

Indicate which of the following are employed as a part of screening or main study consent procedures
✓ Consent Form
✓ Consent Script

Justification for Waiver or Alteration of Consent

Waiver of consent is requested for the following

We request a waiver of consent for eligibility screening for the focus group (women), in-depth interviews (men) and pilot PHA workshop (women, "seeds" for the pilot). Verbal consent will be obtained via a script, but all the elements of informed consent will not be included.

We request a waiver of written documentation of consent for the Phase 3 pilot study because recruitment and consent for this portion of the study will be conducted via telephone.

We request a waiver of written documentation of consent for the COVID-19 sub-study because recruitment and consent for this study will be conducted via telephone as described earlier.

Explain why your research can not be practicably carried out without the waiver or alteration

This request for waiver of screening consent is made in order to preserve confidentiality of screened women and men. Many of the eligibility screens will be taking place in private spaces in public venues, when potential participants may be at a premium for time. The screens themselves contain a maximum of 7 brief questions, are de-identified, and will take less time to administer than a written consent procedure.

The request for waiver of written documentation of consent is made because at the present time in South Africa due to the COVID-19 restrictions, we have redesigned the intervention so it can be conducted virtually rather than in-person. Except for the initial "seed" participants, who may be recruited by staff in person, recruitment and screening will be done digitally or by telephone. It is not feasible to conduct in-person consenting at this time.

The request for waiver of written documentation of consent is made because at the present time in South Africa due to the COVID-19 lockdown, it is not feasible to conduct in-person recruitment, consenting, or interviews.

Describe whether and how subjects will be provided with additional pertinent information after participation
We will be conducting community feedback sessions following completion of the study, to which study participants, our community advisory board, and key collaborative agencies will be invited to attend.

Waiver of Documentation of Consent

Would the consent form signature be the only link between the subject's identity and the research data?
No
Is breach of confidentiality the main study risk?
Yes
Describe the study component(s) for which waiver of documentation is requested.

We request waiver of written documentation of consent for the Phase 3 pilot study. We will follow the procedures described above to obtain verbal consent for participation in the pilot study. The waiver is being requested because it is not feasible at this time to obtain in-person consent. All consenting conversations will be documented by audio-recording and the study staff member will sign the consent form affirming that the participant understood the study and consented to participate.

We request waiver of written documentation of consent for the COVID-19 sub-study. The reason is that because of the "lockdown" due to COVID-19 in South Africa it is not feasible to ask women to attend the study site to sign informed consent and undergo interviews. Instead, women will be sent the consent form via email or WhatsApp and a consenting telephone interview will be scheduled, during which study staff will review the consent form with the potential participant and ask if she has any questions. The participant will have the option of having a witness present during the consenting telephone interview. Participants will provide oral consent and this will be audio-recorded by the study staff for documentation. We will obtain written consent from study participants as soon as this is possible attendant upon the lifting of South African restrictions on transport and movement.

Persons designated to discuss and document consent

Select the names of persons designated to obtain consent/assent
Type in the name(s) not found in the above list

Virginia Russell, South African Medical Research Council, Office of the Executive Scientist (OES)
Nonkuleleko Tesfay, Project Director, South African Medical Research Council, OES
Silindile Khumalo, Project Director, South African MRC, OES
Research Assistants, South African Medical Research Council, OES:
Cebo Duma,
Themba Tshabalala,
Sizakele Sukazi,
Nonshonipho Bhengu
Ayanda Nzuza
Sue Wilson, MRC GHRU nurse

Methods to Protect Confidentiality

Will the study be conducted under a certificate of confidentiality?
Yes, we have already received a Certificate of Confidentiality

Compensation and/or Reimbursement

Will compensation or reimbursement for expenses be offered to subjects?
Yes
Please describe and indicate total amount and schedule of payment(s).
Include justification for compensation amounts and indicate if there are bonus payments.

Screening for eligibility (**Phase 1 and 2**) = R50 ($3.85). Since screening interviews entail only a few questions and do not require the participant to travel, a small reimbursement is deemed appropriate.
Focus group attendance = R150 (~$10.71) for time and travel expenses.
Semi-structured interview reimbursement (men and women) = R150 (~$10) for time and travel expenses.
Phase 3 pilot study
Attendance at pilot study workshop and completion of pre- and post-workshop assessments = R**250** (~$1**7**,00) for time and **internet access**.
Three-month follow-up interview = R**100** (~$7.70) for time and internet access.
Successful recruitment of an eligible women who attends the workshop = R100 (~$7.70). This is an incentive for women to recruit other women to attend the intervention.
In-depth follow up interview - R100

Covid-19 sub-study: participants will be compensated R150 (~$10) for participating in each study interview.

Uploads

Upload copy(ies) of unbolded Consent Form(s)
Upload copy(ies) of bolded Consent Form(s)
Upload copy(ies) of unbolded Consent Script(s)
Upload copy(ies) of bolded Consent Script(s)
Upload copy(ies) of recruitment materials/ads to be reviewed
Upload a copy of Certificate of Confidentiality
Upload copy(ies) of the HIPAA form
Upload any additional documents that may be related to this study
citiCompletionCertificate_11077253_48182388.pdf
citiCompletionCertificate_11077253_48182389.pdf
citiCompletionCertificate_11077253_48182390.pdf

Cover Page

Protocol Number:7682 Version Date:1/7/22

Protocol Title: Developing a Gender-Enhanced PrEP Information-Motivation Workshop for Young South African Women

Principal Investigator:Susie Hoffman

Email:sh51@cumc.columbia.edu

Telephone: 646-774-6938

Office: Mailman Building, Rm 350 Cell Phone:718-744-7686

Lay Summary

This section is intended to provide a basic overview of the study including a description of its purpose, methods, and subject population. The summary should provide a concise overview of the study for non-scientific and scientific members of the IRB. Please avoid medical or technical terminology. In general, the abstract of a grant does not provide a suitable lay summary.

Please also paste of a copy of the Lay Summary into the PRISM PSF Form.

South African adolescent girls and young women (AGYW) remain at extraordinarily high risk of HIV infection. Oral pre-exposure prophylaxis (PrEP) has the potential to alter the epidemic in this vulnerable population, given that it is has been shown that if it is adhered to, oral PrEP can protect women from HIV infection. Yet, a critical question is whether AGYW will adopt and adhere to oral PrEP. C*reating demand*—generating interest among at-risk AGYW, who may know little about PrEP and be wary of using it—is critical. There were several barriers that drove non-adherence to PrEP in the VOICE clinical trial. These included low perceived risk, stigma around taking ARVs, mistrust of biomedical products, worries about potential adverse effects, and concerns about partner reactions. These factors may also dampen AGYW's *uptake* of oral PrEP, but limited attention has focused on *creating demand and motivating uptake***,** a gap we aim to address. We propose that two innovations can *reach* young, at-risk AGYW, *inform* them about PrEP and *motivate* them to use it: (1) introducing PrEP through a gender lens in a one-session group workshop; and (2) peer-driven recruitment—recruiting women to attend the workshop by those who have already attended it. To inform intervention development, we will conduct six focus groups with at-risk AGYW (aged 18-25), 10 qualitative interviews with focus group participants, and 20 qualitative interviews with men (10 HIV-positive, 10 HIV-negative or of unknown status) partnered with women in this age range that will explore knowledge of, beliefs about, motivators for, and concerns about using PrEP in the context of gendered relationship dynamics and PrEP-related stigma. Guided by *gender theory* and the *Information Motivation Behavior (IMB)* model, and in collaboration with a Working Group of AGYW, we will develop a virtual (online) group-based Gender-Enhanced (GE) Workshop (using the WhatsApp® platform**)** to provide PrEP information and address AGYW's barriers to using it. In a pilot, we will compare AGYW (N=~~98~~**100**) randomized to the virtual group-based (GE) workshop (with components that are conducted by participants on

their own time as well as a "real-time" "live" interactive session) or to an Individual Access (IA) condition in which women are given access to a PrEP video and to websites that provide information on PrEP and on contraception options. The primary outcome is having an individual conversation with the study nurse about the possibility of taking up PrEP; secondary outcomes are undergoing HIV-testing and counseling and, if PrEP-eligible, taking up PrEP; and, for all women, *hypothesized mediators* (risk perception, gender barriers, peer norms, self-efficacy, outcome expectancies, PrEP-stigma, attitudes, information) post-intervention and at 3-months. For *Peer-driven recruitment (PDR)* AGYW randomized to either condition will be invited to become *Peer Health Advocates (PHAs),* who are incentivized to talk to social network members and refer up to three to the workshop type the PHA attended. We will evaluate acceptability and feasibility of PDR by assessing whether the method can be self-sustaining (i.e., on average >50% attendees become PHAs and >2 recruitees/PHA attend a workshop); and whether it reaches high-risk women, and women who would not be captured by other methods of recruitment (percent who score high on a new HIV risk tool; percent who never tested or attended family planning). If promising, these approaches will be further tested in a larger study.

Additionally, women who participated in Phase 1 FGs (N = 46) of this study will be invited to participate in a sub-study entitled Sexual and Reproductive Health and Rights of Young Women under the COVID-19 Epidemic (COVID and SRHR). The goal of the sub-study is to understand how the Coronavirus epidemic and related lock-down regulations are affecting young women's sexual and reproductive health and rights (SRHR) needs and ability to access sexual and reproductive health commodities and services over time (before, during different levels of and after lock-down). Participating women will complete three to four telephone interviews (depending on how long the lock-down lasts) over a one-year period. The interviews will employ mixed methods (quantitative, qualitative and photo-voice). Data collected as part of the sub-study will be combined with the quantitative descriptive data on demographic and sexual and reproductive health characteristics obtained from participating women just prior to the beginning of each FG.

Background, Significance, and Rationale

In this section, provide a brief summary of the status quo of the relevant work field, and how the proposed study will advance knowledge. Specifically, identify the gaps in knowledge that your project is intended to fill. If no gaps exist that are obviously and directly related to your project, explain how your proposed research will contribute to the overall understanding of your field. Describe potential impacts of your project within your field of study and in a broader context. Provide a critical evaluation of existing knowledge. The literature review does not have to be exhaustive.

Despite challenges, biomedical prevention tools have the potential to reduce the extraordinarily high HIV infection risk of young African women; identifying approaches to support effective implementation of oral PrEP to AGYW is therefore a time-sensitive priority. In South Africa (SA), prevalence among women is 5.6% at ages 15-19 years, increasing to 17.4% at ages 20-24, and 28.4% at ages 25-29 (1). By contrast, prevalence in men is 0.7%, 5.1, and 17.3% in the respective age groups. Trials of ARV-based prevention among women have had mixed results, with some showing a protective effect (2,3) and others not finding such an effect (4-6), especially among younger women (7,8).

Still, oral PrEP may be the best currently available option for realizing a population-level impact in this vulnerable group (9). ***First***, although PrEP may have lower bio-activity in the vagina than in the rectum (10), secondary analyses of trial data suggest that when adhered to, oral PrEP is efficacious in women (11,12). ***Second***, adherence to (and therefore effectiveness of) PrEP may be higher in open-label than in placebo-controlled trials, as was true in the open-label PROUD study among MSM compared to the placebo-controlled iPrEx trial [86% vs. 44% reduction in risk (13,14)] and HPTN 067, ADAPT-women, an open-label study in SA, where adherence

was 76% in the daily-dosing arm (15). ***Finally,*** longer-acting methods, which are potentially more effective than those requiring daily dosing, are not yet available. Oral PrEP is a core component of DREAMS (16), and the *SA National Strategic Plan 2017-2022* (17) *prioritizes its roll-out to AGYW.* **Thus, *identifying ways to support effective roll-out is a time-sensitive research priority*.**

Yet in implementation and demonstration studies currently underway, considerable attention has been given to identifying effective approaches to ensure high adherence to oral PrEP, but *much less attention to understanding how to present PrEP to AGYW in way that is appealing and will enable them to make informed decisions about **whether** to use it*. This is a significant gap, as adherence interventions are less appropriate and effective for women who are unsure if PrEP is the right option for them. Without substantial uptake among AGYW at high risk, PrEP's potential to slow incidence among them will be severely limited.

Even with a known efficacious product, the barriers that drove non-adherence to PrEP in the VOICE trial may dampen AGYW's *uptake* of oral PrEP. The qualitative studies of VOICE trial participants, their partners, and community members (VOICE-C; (18,19) revealed that non-adherence (which in some instances was really non-uptake) was driven by ***low perception of HIV risk and concerns about partners' reactions,*** along with concern about side effects, mistrust of an unproven investigational product, and stigma associated with taking ARV pills. Limited data are available from open-label PrEP studies to evaluate if these are barriers pertain in the context of a known safe and efficacious product. However, women who declined PrEP in CAPRISA 082 (20) cited reasons such as not being ready/willing to take it, concerns about forgetting pills and side effects, not feeling at risk, and belief that family would object; and qualitative data from HPTN 067/ADAPT (21) identified mistrust and stigma as factors influencing persistence with oral PrEP support tools could address some of these barriers, and others might be mitigated by longer-acting PrEP formulations; *but still others—not feeling at risk, stigma concerns, and belief that important persons would not approve—require targeted efforts to change knowledge and underlying beliefs*.

Gender-related norms for relationships and sexual behavior influence women's use of sexual health promotion methods. Longstanding research in women's HIV prevention (and contraception) shows the importance to women of their partners' acceptance of their sexual health promotion methods —even those that can be used covertly (22-26) —and this is likely to apply to oral PrEP as well (27,28). Men's views influenced women's participation in the VOICE placebo-controlled trial, as well as their use of study products (29). Relationship dynamics also influenced women's adherence (30) and disclosure (31) to partners in an open-label study of a vaginal gel. Understanding this gendered context is key to engaging women in PrEP use.

Gender theory serves as the overarching conceptual framework for identifying critical features that affect women's risk, risk perception, and agency. The above findings around women's concern with male partners' responses are in accord with the Theory of Gender and Power (Gender Theory). Developed by Connell (32), it informs understanding of how gender inequalities in the context of poverty drive the heterosexual HIV epidemics in the US and South Africa, creating vulnerability for men and women (33-36). Whereas men's greater power and norms of *masculinity* shape their behaviors and relations with women (multiple partners, rejection of condom use, acceptance of violence to enforce their prerogatives), women's lesser power and norms of *femininity* shape their response to male power in ways that further enhance their vulnerability (low perceived risk for HIV from stable partners, reluctance to use female condoms or insist on male condoms, and inability to negotiate the terms of sexual relationships, especially if violence is a threat). These relations remain largely intact, despite secular changes in SA granting some women greater economic power, and despite emerging "alternate" masculinities and femininities (34).

Intimate partner violence (IPV), in particular, is strongly associated with young women's increased

vulnerability to HIV acquisition (37, 38, & 39). This is due in part to women's limited agency in relationships characterized by IPV, and to their fear that suggesting condom use or other protective measures will promote abuse. Although oral PrEP may hold promises for women in violent relationships, as it is a method that can potentially be used covertly, use of oral PrEP also holds risks for women. Indeed, data from one PrEP trial have shown that women who experienced any form of partner abuse in the previous three months had lower adherence to PrEP, which they accounted for by stress, distraction, and even partners throwing away pills (40).

This framework gives insight into both the need for oral PrEP—a potentially covert method—in the context of women's lives, and *the potential sources of women's reluctance to use it*. It, thus, helps identify what ideas need to be *brought into consciousness* and challenged in order to create the possibility for women to adopt this critically important HIV prevention method. We propose a gender-enhanced workshop to foster women's understanding that norms for relationships and sexual behavior create risk for women (e.g., that they may be reluctant to use prevention tools that would benefit them if they think their partner may object), and that even if they believe they are acting safely, their loving, single partner can be HIV-infected). Thus, we aim to increase women's *risk perception* in line with community HIV rates and their actual rather than perceived prevention needs. Gender theory ensures that the potential for partner violence is acknowledged, and that women are given tools for avoiding it. Also, by projecting an alternative framework of gender-equality, gender theory can be used to elicit positive motivations for change. Similarly, evidence from contraceptive promotion indicates that giving women choice and a range of options increases overall use, as different products meet the needs of different women (41). Therefore, oral PrEP needs to be offered as one of the options women can use for protection.

The Information, Motivation, and Behavior (IMB) model directs attention to important proximal factors that underlie behavior change. The IMB model (42) posits that information, motivational factors, and behavioral skills influence the adoption of a new behavior. Accurate *Information* about PrEP includes its safety and efficacy; knowledge that efficacy is dependent on high adherence; that side effects, if they occur, are short term; and knowledge about why young women are at such high risk of infection. *Motivational Factors* include *positive outcome expectancies*; *negative outcome expectancies* are undesirable consequences. Motivational factors also include *perceived risk*, perceptions of *peer norms,* and *barriers and facilitators.* Based on the findings from VOICE-C, as well as studies of PrEP among men who have sex with men (MSM), *PrEP-related stigma* (~~50~~ 43) is likely to be among the most important negative outcome expectancies and to be reflected in the norms of social referents. The IMB model also highlights the importance of increasing *Behavioral Skills* and a sense of self-efficacy to adopt PrEP and persist with use despite barriers.

The premise of the proposed study is that an *information/motivation workshop framed through a gender perspective* (Women's Sexual Health Options, a Gender-Enhanced Workshop) can increase SA AGYW's interest in PrEP and reduce barriers to considering it. Theory and experience suggest that framing PrEP as empowering and health enhancing; contextualizing HIV prevention through sexual rights and goals for the future; increasing women's understanding of how gendered relationship dynamics place them at risk; and fostering self-efficacy through practicing how to handle difficult situations can increase willingness to consider oral PrEP and reduce reluctance to adopt it. Based on materials already in use in the SA public sector, the standard of care for PrEP promotion when it is rolled out to AGYW is likely to emphasize information. We thus propose to test if a gender-enhanced PrEP information/motivation workshop can do better than one that only provides information.

Peer-driven recruitment may be effective in reaching high-risk AGYW to attend the workshops. In addition to altering social norms, demand-generation requires reaching large numbers of potentially eligible AGYW. *Peer-driven recruitment* (PDR) may be an effective approach for recruiting AGYW to learn about PrEP; we propose to evaluate its feasibility, acceptability, and ability to reach high-risk women, especially those who may not be captured by direct recruitment. AGYW participate in either the Gender-Enhanced WhatsApp group workshop or

individually-accessed weblink information-Only condition can themselves become *Peer Health Advocates (PHAs)* who are paid to talk to social network members, give them recruitment materials, and refer them to that workshop type.

The rationale for using chain referral to recruit women draws from sociological theories of group-mediated social control (44), whereby the power of peer influence is harnessed to affect group norms and behaviors (45). This network-based recruitment approach is ideally suited for engaging populations that are not well connected to care (46, 47), which typically is the case for AGYW, many of whom do not attend a family planning clinic until they become pregnant (48). Besides being effective and efficient (49), chain referral may alter group social norms around the target behavior—here, undergoing PrEP clinical assessment. Following on the experience of Bauman (50), PHAs will reach out to their network members and encourage them to attend a sexual health workshop that will be conducted by trained, professional staff. PHAs will be given recruitment materials that include information about PrEP, but will not explicitly invite network members to undergo PrEP clinical assessment, our primary outcome.

Rationale for the Covid-19 sub-study. Young women in KwaZulu-Natal are extremely vulnerable to negative sexual and reproductive health and rights (SRHR) outcomes and need to have access to SRHR services and commodities. The recent coronavirus epidemic and its socio-economic responses in the form of a country wide lock-down are likely to affect young women's sexual and reproductive health and rights, exposure to violence and ability to access SRHR services and commodities. In order to better understand the impact of the coronavirus epidemic on young women's SRHR needs and ability to access SRH commodities and SRHR services, this longitudinal sub-study will follow a cohort of young women over time

Specific Aims and Hypotheses

Concisely state the objectives of the study and the hypothesis or primary research question(s) being examined. There should be one hypothesis for every major study procedure or intervention. For pilot studies, it is important not to overstate the study's objectives. If there are no study hypotheses, describe broad study goals/aims.

The specific aims of this study are

1. **Formative Work**: To inform intervention development through
   a. Focus groups (**six** ~~eight~~) with at-risk AGYW aged 18-25, grouped by age and recruitment venue (community, family planning clinic) to explore knowledge of, beliefs about, motivators for, and concerns about PrEP in the context of gendered relationship dynamics and PrEP-related stigma;
   b. Qualitative interviews with 10 Focus Group participants to obtain more in-depth and individually-focused understanding of topics discussed in the Focus Groups.
   c. Qualitative interviews with men (10 HIV-positive and 10 HIV-negative or unknown status) who have female partners aged 18-25 to understand men's views of PrEP and of their partners' use of PrEP.
2. **Intervention development (revised)**: To develop—in collaboration with a working group of at-risk AGYW—develop a virtual group-based Gender-Enhanced PrEP Information-Motivational workshop, drawing on our formative data and strategies from our prior HIV prevention interventions; and to choose a PrEP video and a PrEP informational website for the individual digital access control condition.
3. **Pilot (revised)**: To evaluate acceptability, feasibility, and outcomes of the intervention components:
   a. Workshops: Compare participants (N=~~98~~ **100**) randomized to the virtual group interactive workshop with those randomized to individually-accessed links to a PrEP promotional video and PrEP information on the *primary outcome* of having an individual discussion with the study nurse about the possibility of taking up PrEP; undergoing HIV self-testing guided by the study nurse (either in-person at the GHRU office or via telehealth visit) (secondary outcome); if eligible for PrEP, initiating PrEP (secondary outcome and *hypothesized mediators* (risk perception, gender barriers, self-efficacy, outcome expectancies, PrEP-stigma,

peer norms, information) post-intervention and at 3-months;
b. Peer-driven recruitment: (1) Assess acceptability and feasibility of this recruitment method using criteria related to whether the approach could be self-sustaining (i.e., on average ≥50% attendees become PHAs and ≥2 recruitees/PHA attend a workshop); and (2) Evaluate whether PDR is able to reach women at high-risk (using a new HIV risk tool (10)) and not likely to be captured by other recruitment methods (i.e., percent who never tested or attended family planning).

COVID-19 sub-study objectives

Objective 1: To identify the SRHR needs and services accessed before the Coronavirus lock-down level 5 (Jan-March 2020)

Objective 2: To describe how the SRHR needs and access to SRHR services have changed under the different stages of Coronavirus lock-down (levels 1-5)

Objective 3: To describe how experiences of violence have changed over time (before and during different stages of Coronavirus lock-down)

Inclusion/Exclusion Criteria

This section details your study sample(s) and addresses the requirement for risk minimization.
You may choose to divide your sample by population (healthy controls vs. subjects) or by procedure (subjects who will have an MRI) and then define different sets of criteria for each.

For each sample, create or insert a table to describe detailed criteria for study inclusion and exclusion and the method you will use to ascertain each criterion. The method of ascertainment may describe tests, scales and instruments. When relevant, indicate the level of training of the person who will make the assessment (e.g. clinical interview by a psychiatrist).

Inclusion/Exclusion Criteria needs to be numbered and listed in outline form (see Table template below).

Focus Groups with women	
CRITERION	METHOD OF ASCERTAINMENT
Inclusion:	
1. Aged 18-25 2. self-reported HIV-negative or unknown status; ~~3.~~ heterosexual vaginal or anal intercourse reported in the past 6 months if aged 18-25 4. conversant in *isi*Zulu or English 5. willing to be audio-recorded as a FG participant	Completion on a computer "tablet" of screening questions or via pencil and paper if desired or via interview by trained bi-lingual staff if needed (illiterate). Proof of age will be required at FG attendance
CRITERION	METHOD OF ASCERTAINMENT
Exclusion:	

1. Obvious signs of cognitive Impairment	Trained bi-lingual staff will assess based on participant presentation
Qualitative semi-structured interviews with women	
Inclusion:	
1. Participant in the Focus Group willing to undergo an in-depth interview. Note that these are not newly recruited participants.	Will be randomly selected from volunteers who participated in a Focus Group.
Qualitative semi-structured interviews with men	
Inclusion:	
1. ≥18 years 2. Vaginal or anal sex with a female partner aged 18 to 25 yrs. ≥ 1x in the 3 months prior to screening 3. Willingness to self-report HIV status 4. Willing to be audio-recorded 5. Conversant in English or *isi*Zulu	Completion on a computer "tablet" of screening questions or via pencil and paper if desired or via interview by trained bi-lingual staff if needed (illiterate). Proof of age will be required.
Exclusion:	
1. Obvious signs of cognitive impairment	Trained bi-lingual staff will assess based on participant presentation
Initial Pilot Study participants, who agree to be Peer Health Advocates (PHAs) ("seeds")	
CRITERION	METHOD OF ASCERTAINMENT
Inclusion:	
1. The first **16** 'seed' PHAs will not have been Focus Group participants and will be required to agree to be PHAs before participating in the pilot study. This involves being willing to speak with others in their networks about HIV prevention and invite them to participate in the virtual interactive group-workshop or the individually-accessed weblink materials. (All other attendees will not be required to agree to this before participating, and it will be optional for them to decide on whether	Completion ~~on a computer "tablet"~~ of screening questions ~~or~~ via pencil and paper if desired or via interview by trained bi-lingual staff ~~if needed (illiterate~~). Proof of age will be required at workshop attendance.

or not to become a PHA.) Other eligibility criteria are identical to those for the Pilot Study: 1. Aged 18-25 2. self-reported HIV-negative or unknown status 3. heterosexual vaginal or anal intercourse reported in the past 6 months ~~if aged 18-25~~ 4. presently residing in eThekweni-metropolitan Durban; 5. has private internet access **6. Is not currently taking PrEP or planning to begin** 7. Conversant in *isi*Zulu or English 8. Willing to be audiotaped as a Pilot study participant	
Exclusion:	
1. Obvious signs of cognitive impairment 2. Was a FG participant	1.Trained bi-lingual staff will assess based on participant presentation. 2. Study records
Pilot Study participants, recruited by PHAs to the virtual interactive-group Gender-enhanced (GE) or Individually-Accessed weblink ~~Information~~-only (IA~~O~~) Activities ~~Workshop~~ for women	
Criteria:	
1. Aged 18-25 2. self-reported HIV-negative or unknown status 3. heterosexual vaginal or anal intercourse reported in the past 6 months 4. presently residing in eThekweni-metropolitan Durban; 5. has private internet access 6. **Is not currently taking PrEP or planning to begin** 7. Conversant in *isi*Zulu or English 8. Willing to be audiotaped as a Pilot study participant 9. Recruited by a peer health advocate (PHA) (someone she knew prior to being recruited)	Completion ~~on a computer "tablet"~~ of screening questions ~~or via pencil and paper if desired or~~ via **telephone** interview by trained bi-lingual staff ~~if needed (illiterate~~). Proof of age will be required.
Exclusion:	

1. Obvious signs of cognitive impairment	Trained bi-lingual staff will assess based on participant presentation.
COVID-19 sub-study	
Inclusion criteria Participated in the Phase 1 Focus Groups as part of the parent study	**Study records**
Exclusion criteria None	

Study Procedures

Provide a clear, concise narrative of study procedures with special attention to the subjects' involvement. Detail the overall study timeline and location of study procedures, list all interventions, assessments and interviews, estimate the duration of each procedure, provide dosing schedules, identify study personnel involved in each procedure, and provide credentials for relevant personnel. For complicated study designs, we strongly encourage attaching tables, flow-charts, and study algorithms.

Focus Groups with women

Recruitment and Screening. Women will be recruited for Screening by the Medical Research Council team which has extensive experience in direct outreach recruitment. Screening will take place in community venues through direct outreach in the community and youth-based CBOs, and among women accessing services at the Addington Hospital family planning clinics. The Addington Hospital has a mobile van that visits various community venues to offer services, and the MRC team will be able to conduct recruitment at these sites. Women will be approached through the use of a recruitment flier and will be invited to be screened in person for participation in the FG, respectively, using a scripted offer of screening. Verbal consent for screening will be obtained and documented and will not include any identifying information. Screening will be anonymous and will be conducted by trained staff. Following verbal consent, which should take only a few minutes, women will be invited to complete the screening process themselves, using a computer tablet. Those who have difficulty with the computer program will be given a paper form to complete, or if they have difficulty with reading or do not wish to complete the assessment themselves, they will be taken to a private location where the screening can be verbally administered and later entered into the program. Those screened will receive a small incentive (R50, ~$3.85 USD). To fill the cells shown in the Table 1, we anticipate screening 432 women (1 of 6 will be eligible). Eligible women will be invited to a FG; if interested, contact information will be obtained. We will aim to recruit 12 women per FG, with the criterion that 7 attend for the FG to be run. Therefore, the number of participants completing FGs will range from a minimum of 42 to a maximum of 72. Women will sign informed consent for the focus groups when they arrive to attend.

Focus group procedures. Brief assessments of risk characteristics will be self-administered. FGs will last approximately two and one-half hours and will be digitally audio-recorded. FGs will employ a topic guide. Women will be reimbursed R150 (~$10.71) for time and transport, and refreshments will be provided. FGs will be conducted by the MRC study coordinator or social science research assistant (RA) in isiZulu, the language of this region. The facilitator will have prior relevant experience and be trained by co-investigators from the MRC (Russell and Morar), who will also monitor FGs. A second staff member will serve as observer and make notes on topics discussed and observations of group members' level of engagement, embarrassment, or suspicion. The facilitator and observer will write a summary, including salient topics and group participation/ dynamics not captured on the audio-recording, and will debrief with Morar and Russell. We expect all focus groups to be completed within a 4-month time frame.

Qualitative semi-structured interviews (SSIs) with women

Recruitment and Screening. We will conduct semi-structured interviews with 10 AGYW who attended FGs. Participants will be invited to attend an interview on the same topics as FG at the end of the group. Those who are interested will be asked to provide contact information for follow-up. After each (of 6) focus groups, study staff will randomly select and schedule interviews with one to two women, for a total of 10 women, five each from each of the two age groups.

Procedures. A written informed consent is obtained from each woman before the interview. The interview will last approximately 60 minutes, be conducted in English or isiZulu by an experienced female social science research assistant in a private setting, and be audio recorded. Women will be reimbursed R150 (~$10.71 USD) for time and transport. Interviewers will write summaries of each interview at its completion to highlight key themes and issues raised.

Qualitative semi-structured interviews (SSIs) with men

Recruitment and Screening. We will screen 180 men to obtain a sample of 10 HIV+ (100 men screened; 10% eligible) and 10 HIV- or unknown status men (80 men screened; 12.5% eligible) for qualitative interviews. Men will be referred by women in the FGs or recruited directly by study staff in STD clinics and community settings. Men will be given a recruitment flier and will be invited to be screened by trained study staff immediately for participation in the interview, using a scripted offer of screening. Those referred by women will contact trained study staff and will be given a scripted screening offer. Verbal consent for screening will be obtained and documented, and will not include any identifying information. Screened men will receive a small incentive (R50, ~$3.85 USD). Eligible men will be invited to the interview, to be conducted immediately if desired (for those recruited in clinic settings) or scheduled to accommodate participant availability. Contact information will be obtained from those interested in participating at a subsequent time so they can be reminded of the interview time. The screening process should take about 5 minutes, including verbal consent.

Procedures. Prior to participating in the interview, men will be told about study procedures and written informed consent will be obtained, which will take 5-10 minutes. Those recruited from CBO or clinic settings will be informed that participation is voluntary and a decision not to participate will have no effect on their access to services. After written informed consent is obtained, a brief assessment of risk characteristics will be self-administered (approximately 10 minutes). SSIs will last approximately 60 minutes, be conducted in isiZulu by an experienced male social science research assistant in a private setting and be audio-recorded. Men will be reimbursed R150 (~$10.71 USD) for time and transport, and refreshments will be served. SSIs will employ a topic guide. We expect all qualitative interviews to be completed over a 4-month period.

Pilot Study: Gender-enhanced (GE) virtual interactive group vs Individually-Accessed (IA~~O~~) activities ~~Workshop~~ for women

Recruitment and screening. Recruitment of initial workshop Peer Health Advocates (PHAs). Trained Staff will directly recruit an initial group of **16** women ("seeds") with the help of Addington Gateway clinic staff and IDWG participants, who will provide study information to potential participants through flyers. Interested women will contact study staff to be screened for eligibility or be screened on the spot. We anticipate screening 30 women to identify 16 seeds. Seeds will be randomized to attend either the virtual group-based Gender-Enhanced (GE) workshop or the individually-accessed (IA) weblink only material**.** Women eligible at this step will meet the same eligibility criteria described above, and, additionally, will *be willing to speak with others in their networks about HIV prevention and invite them to attend the workshop (i.e., to become Peer Health Advocates [PHAs]).* They will not have been FG members. We will ensure that women from the two age groups are included and will stratify by age before randomizing them to participate in the GE workshop or IA material. This group (the seeds) comprises both Wave 1 attendees and Wave 1 PHAs.

Subsequent recruitment. Subsequent PHAs (Waves 2-4) will be drawn from workshop attendees (who do not have to agree to be PHAs), and their numbers will be supplemented if needed using Wave 1 recruitment procedures. At the end of a workshop (or, for IA participants, after viewing the online materials), study staff will invite all participants to become PHAs and to reach out to their network members to help them prevent HIV infection. PHAs will invite network members to participate in the activity (GE or IA) they, themselves, participated in (and will inform them that brief assessments are included). We will repeat this process three more times, for a total of four recruitment "waves" (see Table below). We expect that the initial PHAs (n=**16**, *Wave 1*) will refer 28 workshop attendees. Of these 28, we expect at least 50% will agree to be PHAs (*Wave 2)*. These 14 will average two referrals (n=28) who are eligible and participate. We expect half of participants to agree to be PHAs (*Wave 3)*, through a total of four waves. If we fail to enroll 14 new PHAs from the pool of attendees, we will add new recruits, as for the initial seeds. We expect each wave will take approximately two months. To attain a target ~~98~~ **100** participants attending and completing Waves 2 through 4, we anticipate that we may need to enroll up to 120 women.

Peer-driven recruitment waves and follow-up N = ~~100~~ ~~98~~ **100**	Wave 1 (seeds)	Wave 2	Wave 3	Wave 4 **(if needed)**	
Study Months					
Wave 1: Seeds randomized (1:1) to attend GE or **IA condition** ~~O Workshop (WS)~~	1**6**				
Wave 2: Recruitees who **participate** ~~attend WSs~~ ~~WS~~ Attendees who become PHAs		28 14			
Wave 3: Recruitees who **participate** ~~attend WSs~~ ~~WS a~~**A**ttendees who become PHAs			28 14		
Wave 4: Recruitees who **participate** ~~attend WSs~~ ~~WS~~ **A**ttendees who become PHAs				28	
Total Attendees/wave (N= ~~98~~**100**)	1**6**	28	28	~~28~~**30**	
Follow-up interviews		16	28	28	28

In total, we expect that ~~98~~ **100** women will attend and complete the intervention and assessment activities. To balance recruitment chain size, PHAs will be allowed up to 3 recruitees. PHAs *will not* assess eligibility for workshop attendance, but they will be able to inform potential recruitees of age eligibility, that interactive groups will be audio-recorded, and that the intervention activities are for women *who have had sex*. PHAs will receive R100 (approximately

$7.69) for each recruitee who is eligible and participates in the activities; they will be told that they will not be paid unless their recruitee is eligible for and completes the activities. To reduce the possibility of coaching, PHAs will be told that staff will confirm criteria; proof of age will be required, and the assessment will ask several questions about sexual activity that may reveal inconsistencies if the recruit was never sexually active. To reduce the possibility of coercion, in the eligibility screener we will ask recruitees how long they have known the PHA who recruited them and if they felt coerced in any way to attend. Any PHA found to be engaging in such behavior will be informed that she may no longer recruit and that she will not get paid for any recruitees who report her as their recruiter.

Procedures for Eligibility screening, informed consent, and study enrollment. Procedures are shown in the flowcharts (Figure 1 & 2) for seeds and subsequent participants, respectively. Following wave 1 (seeds) (who will be recruited directly by study staff), potential participants will contact study staff by telephone. Women will send their recruitment coupon and official identification to verify age on an online platform, WhatsApp®. Eligibility criteria will be assessed telephonically, using a scripted eligibility screener preceded by verbal consent for eligibility screening. A copy of the study Informed Consent form will be sent to the participant and reviewed with her. The consenting procedure will be conducted telephonically and will be audio-recorded to document the participant's verbal consent. Potential participants will be told that the study includes (1) a pre- and post-intervention questionnaire; (2) GE: online activities prior to and after the group session and 1 online interactive-group workshop of 90 minutes; IA: being sent links to PrEP and contraceptive information and to a PrEP video; and (3) a 3-month follow-up **survey, with some participants selected for an** interview. After consenting, participants will complete a self-administered questionnaire.

Figure 1. Study flow – Seeds

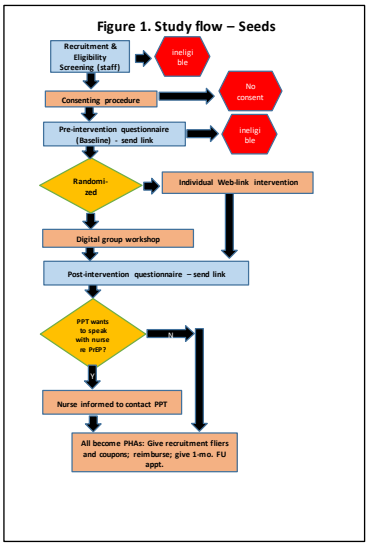
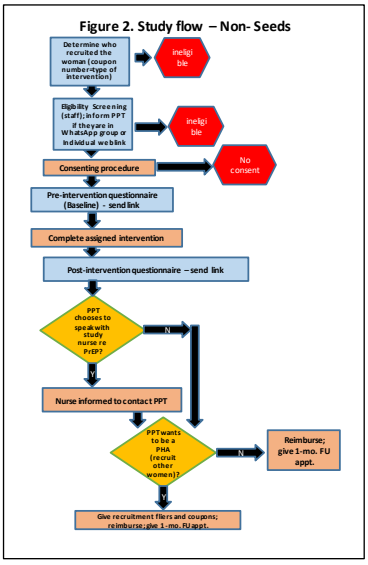


Figure 2. Study flow – Non- Seeds



Conduct of workshops. Both the GE and IA interventions will be conducted via WhatsApp, in English (and Zulu) by bi-lingual study staff. The GE workshop will begin with several assignments that are conducted asynchronously (i.e., participants are sent materials for an activity that they conduct on their own), followed by a 90-minute synchronous (i.e., in real time) interactive group session To avoid contamination, PHAs will recruit only for the online condition they attended. In the GE condition a maximum of six attendees/workshop group is ideal; the minimum number of women needed to run a workshop will be four. Therefore, based on a sample of ~100, with ~50 in the GE condition, we expect to conduct 8-12 online GE workshop groups. In the IA condition, women will be sent the links for the online intervention materials as soon as they have completed the pre-intervention assessment. They can access and review these materials whenever they want. Women in both conditions will receive ~~R200~~ R250 (~$17.00) for completing the intervention and assessments. R50 will be given immediately upon enrolling, so that women will be able to pay for mobile phone airtime to access the materials; the remainder will be given upon completion of the post-intervention assessment.

Workshop content. Workshop content will be developed as part of this study by a group of **10**~~20~~ women who will

be recruited from among participants in FGs, and who will constitute at Working Group (WG). FG participants who, in the judgment of the FG facilitator and observer, were active, knowledgeable, and insightful will be contacted individually to elicit their interest in being a WG member and, if interested, will be interviewed jointly by a study team member and a CAB member using guidelines that emphasize ability and commitment to attend all WG sessions. They will not be study participants, but will be reimbursed for their time spent developing the workshop content. WG members will attend six three-hour interactive sessions. They will be reimbursed for time and transport (R250/session), and refreshments will be provided. Meetings will be conducted by two bilingual staff members in English, allowing for translation in Zulu as needed. Sessions will follow a standard protocol. The goal of the WG is to create workshop material, including group-based exercises, slogans, and out-reach materials. Activities will include group developmental work; drafting and revising key workshop messages and activities and exercises to convey them; and developing or refining outreach materials. WG will be digitally recorded, and the RA will keep process notes.

Although workshop content will be developed along with this working group, we anticipate that it will include adaptations and tailoring of the following activities, drawn from our prior work:

- **What are my goals for the future? What are my priorities?** This exercise, using card-sorting, is designed to explore future goals in order to place HIV prevention in the context of helping women to achieve future life plans, including plans for conception and contraception.
- **Why are women at risk?** This exercise includes 1) a scripted role-play and discussion to explore why women do not consider themselves at risk, and 2) a personal vulnerability analysis using a Self-Test on STDs, pregnancy risk, and HIV to gauge knowledge.
- **What are my sexual rights?** This exercise includes 1) an exploration of women's sexual rights and how gender stereotypes present a barrier to asserting one's rights in a relationship; and 2) discussion in which women identify difficult partner reactions, including any form of IPV, to their use of prevention options, brainstorm ways of dealing with these reactions, and are acquainted with resources to support women in abusive relationships.
- **What are my options?** Drawing on a PowerPoint-based information-only didactic educational presentation developed by the US Women and PrEP Working Group, we will provide an overview of different protective methods. For each method, we will discuss 1) the degree of control a woman has over its use; 2) its effectiveness in preventing pregnancy, HIV and other STDs; and 3) a consideration of positive and negative attributes to help women to understand what method(s) may work best for them. The presentation also presents women's HIV/STI transmission risk and PrEP basics, including efficacy, side-effects, dosing and adherence. It will be modified by the WG to ensure relevance and colloquial content.
- **What would it mean to take PrEP?** In this decisional balance brainstorm activity, women will use sticky notes to identify and talk through the various outcomes of PrEP uptake, including those that are positive, negative, as well as ambivalent or a blend of positive and negative.
- Both the GE and I**A~~O~~ conditions ~~workshops~~** will have a component to sensitize women to the potential for partner abuse and instruct them how to assess signs of potential abuse and present strategies to minimize the risk. Women will be coached on safety approaches and given targeted referrals in the case of partner abuse.
- ***Brief instruction for women who want to be Peer Health Advocates (PHAs)*** on effective communication skills and how to approach and motivate up to three members of their networks to attend the workshop will be provided at the end of both the GE and IA conditions. Interested women in both conditions will be provided with outreach materials to assist in peer-outreach, with the enhanced materials developed by the WG. The Comparison Individually-Accessed (IA) Condtion. In the IA condition, women will be sent the links for the

online intervention materials as soon as they have completed the pre-intervention assessment. These include a link for the PrEP information/motivational video that also is part of the GE workshop, and links for a SA government-sponsored PrEP information website and a government-sponsored contraceptive information website. These materials constitute what would ordinarily be available to women receiving information about PrEP in a clinic or by themselves on the web. Women will be able to access and review these materials whenever they want. Additionally, participants will be sent the IPV component described above, and will be given instruction for women who want to be PHAs, as described above.

Quality Control. All GE intervention sessions will be audio-recorded, with the recording serving as the basis for weekly supervision. Facilitators' reports, completed following each session, will indicate problems, unusual circumstances and difficult issues.

Post intervention activities (both conditions). Brief post-assessments will be conducted. As part of the post-assessment, women will be asked if they want to speak with the study nurse about PrEP and/or about anything else. Notifications will be sent to staff when anyone responds "yes"; the study nurse will be notified to make a counseling appointment with the woman. After the post-assessment, women who wish to become PHAs will be given recruitment coupons and literature. Contact information will be confirmed and appointments for 3-month follow-up assessments made.

PrEP clinical assessment. After completing the online intervention (either condition), women will be invited to undergo individual counseling to help them determine if they want to take up PrEP. The counseling will be conducted by the MRC-GHRU staff nurse (who is a trained HIV C&T counselor), either remotely using WhatsApp or at the MRC- GHRU Ridge Road Site, in a private space. If the participant wishes to take up PrEP, the nurse will conduct HIV counseling and testing (HCT). Counselling and, if chosen, HIV-testing (optional) will be conducted using the MRC Gender and Health Research Unit PrEP counselling and HIV-testing SOP. This SOP follows standard DOH guidelines and uses publicly available and approved HIV-self testing kits (OraQuick). If women wish to self-administer the HIV test from home, the nurse will be available for guidance in conducting the test and for counseling regarding the results.

Eligibility for PrEP will be determined according to the DOH clinical guidelines for offering PrEP. Those who do not choose to speak with the nurse after the intervention activities may do so at a later time. Women who are PrEP-eligible (HIV-negative) and want to initiate PrEP will be referred to the Addington Hospital PrEP access program, and will be followed clinically according to procedures being used there. This study does not provide PrEP.

Health and social service referrals. Women who test HIV-positive will actively referred to HIV care and treatment services at Addington hospital. Attendees who require other services will be referred (escorted if necessary) to a community study partner.

3-month follow-up **survey**~~interview~~. All participants will be reminded of this **survey** ~~interview~~ by short text-message system (SMS) or mobile phone call. They will be reimbursed R100 (~$7.70). Additionally, we will ~~purposively~~ select **40** ~~10~~ women for **brief telephone** ~~in-depth~~ interviews, covering topics related to outcomes of the interventions, any behavior changes including PrEP uptake that were adopted, and their experiences in successfully recruiting (or not) other women to the intervention. These women will be compensated an additional R100. **To recruit these women, at the end of the 3-month follow-up survey all women will be asked if they would be willing to participate in a brief (15 minute) telephone interview. From among those who agree, we will select 50% (every other woman), or more if necessary. Verbal consent will be obtained prior to beginning the interview and will be audio-recorded. Consent text is included at the beginning of the interview.**

COVID-19 Sub-study procedures.

Recruitment and consenting procedures: Participants for this sub-study will be recruited from the PrEP study

phase one participants. This includes 46 women 18-25 years old, who participated in the PrEP study focus-group discussion (FGDs). The FGs discussed the sexual and reproductive health needs of young women, their knowledge about PrEP and potential barriers and enablers to use PrEP. The participating women were recruited from central Durban, were sexually active, and had to report being HIV- or of unknown status. All participants had access to mobile phones (although this was not by design). Information on their SRH and prevention methods usage is available from a quantitative assessment conducted just before the focus group. Potential participants for the sub-study will be sent a ward-off letter by the facilitator of their previous FG, who is the research assistant for the sub-study. The 'ward off letter' will be sent to their mobile phone asking for permission to contact them and tell them more about the COVID-19 study. The ward off letter can be sent as a SurveyMonkey (with reply option) and as a pdf attachment via WhatsApp (all participants have smartphones and WhatsApp). The research assistant will only follow-up with participants who reply to the ward-off letter and agree to be contacted for the sub-study. The RA will send study information and the informed consent (IC) documents (as pdf attachment via WhatsApp or email) to the participant and will identify a convenient time to conduct the telephone consent process. Participants will be informed that if they wish to have a witness present during the consenting process they may do so, but that this is not a requirement. During the IC call, the research assistant will inform the potential participant about the opportunity to participate in the COVID-19 sub-study, share information about the content and procedures of the study and obtain informed consent verbally. The consenting process will be audio-recorded for documentation. The team will obtain delayed written IC after most COVID-19 lock down regulations have been lifted

Data collection: Participants in the sub-study will participate in a baseline and two to three follow-up telephonic interviews (depending on the length of the lockdown) at approximately three months apart during different levels of the South African lock-down and its aftermath. Interviews will be administered by trained female study interviewers with previous experience interviewing young women. Baseline interviews will elicit experiences before and after initial COVID-19 lock down procedures in March-May 2020. Follow-up interviews will prompt only current/recent experiences. Participants will be asked if they are willing to give permission for the interviews to be audio-recorded, but this is not a study requirement (i.e., there is a separate check-off on the consent form).

The interview questions are guided by the UNFPA framework on sexual and reproductive health and rights. The questions will elicit information in four sections: 1) demographics and living arrangements, 2) COVID-19 impact 3) SRHR needs, commodities and service usage and 4) experience of violence and access to rights services and support. The question guide will include short questions that prompt SRHR issues and service use with dichotomous answers and Likert scale response options. Experiences of SRHR issues and coping strategies will be explored with open ended questions, the responses for which the interviewer will document by hand if the interview is not being audio-recorded. In addition, we will give our participants the option to send us a picture that expresses to them how they are managing the current COVID-19 epidemic. This picture will allow us to start the interview with a personal account from the participants as well as give the participant an opportunity to share information in a more creative way. Participants will be instructed to use photo techniques that do not breach confidentiality (e.g. close ups, pictures of objectives or facilities etc.).

The baseline interview will take approximately 45 minutes to complete; follow-up interviews will take approximately 30-45 minutes to complete. Participants will be reimbursed R150 (~$10) for completing each interview.

Service Providers Support: During the interview issues may arise that require further engagement through counselling or referrals. The team has a nurse and councilor on standby, who can provide telephonic support and counselling and assist with referrals where needed. The PrEP study is implemented in the catchment area

of the Addington Gateway Clinic in Durban. The Clinic, MatCH and LoveLife also form part of the PrEP-project's advisory group. Linkage to services can therefore be provided directly for those women who remained in Durban during lock-down. For those who have left the town during the lock-down, the team will also provide telephonic counselling and support and refer women to the appropriate local services. A list of services already exists for the IDWG participants and will be developed for other participants after they agree to be contacted for the informed consent phone conversation. Participants will also be provided with the nurse contact details and WhatsApp number in the informed consent form and following each interview. Hence participants will be able to request support even after the interviews.

Social Support in Real Time: Social support during lock-down will also be provided through a COVID-19 WhatsApp group for those participants who want to participate in such a group. The PrEP study participants all have access to a phone and are familiar with WhatsApp and know each other already from the FGs. Therefore, the team can set up an additional WhatsApp communication group for ongoing questions and support of participants. Participants will only be added to the group if they wish to do so and are informed about the potential risks. The sub-study project coordinator will monitor this group on a daily basis and ensure that group rules are clear and correct information and support is provided.

Data analysis: The analysis of these data will include descriptive statistics for the binominal or Likert scale questions of the study. We will assess trends over time and differences between different stages before and during the lock-down. The qualitative data (open ended questions) will be documented and typed up as a debrief report by the research assistant. We will analyze this data using guided content analysis. We will triangulate the quantitative, qualitative data from the COVID sub-study and the quantitative PrEP FG study data and develop case study reports for each participating woman.

Criteria for Early Discontinuation

Define criteria that will be used to exit or drop subjects from the study. Indicate the time points when such criteria will be applied, and describe the rating instruments, parameters, and thresholds that will lead to a decision to terminate a subject's participation. In addition, explain procedures for managing subjects who are dropped from the protocol.

For treatment studies: To minimize risks to subjects, operationalized drop-out criteria should be defined so that subjects who worsen, or in some cases, fail to improve, are removed from the study and offered standard care. The threshold for drop-out should consider the level of risk associated with non-improvement for the specific disorder, the availability of alternatives, and the typical required duration of treatment. For example, emergence of suicidal intent, or psychosis, should prompt immediate clinical evaluation and withdrawal from the study.

There are no discontinuation criteria. A participant may withdraw from the study at any time.

COVID-19 sub-study: There are no discontinuation criteria. A participant may withdraw from the study at any time.

Blood and other Biological Samples

Describe how the sample will be used and indicate, when relevant, the amount of the sample. The IRB wants to know that the sample is sufficient for the purposes of the study, but that sampling is limited to what is minimally necessary.

If you've indicated that you intend to store a sample for future use, indicate where the sample will be stored, how long the sample will be stored, and to what purposes the sample will eventually be put. Check the IRB website at

http://irb.nyspi.org/irbdnn/Policies/GeneticResearch/tabid/96/Default.aspx for specific guidance and additional information about future use of DNA samples.

Women who participate in either intervention condition can decide to seek screening for PrEP eligibility, which includes HIV testing via the publicly available and approved HIV-self testing kits (OraQuick) using oral fluid. The GHRU nurse will conduct HIV counseling and testing (HCT) in person or, if women wish to self-administer the HIV test from home, the nurse will be available for guidance in conducting the test and for counseling regarding the results. Note that HIV testing is not a requirement of study participation; it will only be conducted if the participant chooses to be screened for PrEP eligibility.

COVID-19 sub-study: NA

Assessment Instruments

List all assessment instruments, indicate who will administer them, and provide an estimate the duration of each. The IRB wants to know that assessments instruments are appropriate measures for the purposes of the study and are no more burdensome than is necessary. The IRB will consider the burden of assessment instruments (in terms of time, sensitivity of material, etc.) in the risk/benefit analysis. Please attach copies or otherwise provide all non-standard instruments.

Pre-Focus Group and Semi-structured Interview self-assessment procedures. Participants in Focus Groups and Semi-structured interviews will complete a self-administered assessment on computer-assisted self-interviewing (CASI)-programmed laptops prior to the focus group or interview to obtain information on demographic characteristics and sexual risk behaviors.

Focus groups with women
FGs will be conducted by a trained female facilitator. FGs will employ a topic guide. Each FG will begin by exploring (a) Knowledge of PrEP, hearsay around PrEP from other women, men, others in the community; (b) (after basic PrEP information given): What questions do you have; what would lead you to consider PrEP for yourself; what would keep you from considering (or taking) PrEP; (c) Response to specific issues that have emerged among women: external and internal stigma around being at risk of HIV, around taking ARVs; concern about long- and short-term side effects, about daily pill-taking; (d) Discussion of risk perception and HIV and prevention tools (How do women like you view HIV in the community -- who is at risk; what places them at risk; do women such as you feel at risk for HIV; why or why not; how high a concern is HIV prevention relative to other life concerns and goals; (c) Knowledge/hearsay around PrEP from other women, men, others in the community), and finally, (e) Thinking about women such as you, what are goals and hopes for the future; worries and concerns; what does it mean to have/not have a partner; have/not have a baby; be/not be in school; have/not have a job; The focus group will last approximately two and 1/2 hours.

Qualitative semi-structured interviews with women from Focus Groups
AGYW will be asked to follow-up on topics from the FG, in particular, awareness about PrEP, as well as young women's lives, concerns, priorities and goals; HIV risk perception; relevance of HIV prevention for them; and prevention strategies they use/have used. The interview will explore what outstanding questions participants have about PrEP; what would lead them to consider/not consider PrEP and what outcomes they would expect to occur if they did take PrEP; and how partner and relationship factors, including the potential for new or exacerbated IPV, would play into their decisions.

Qualitative semi-structured interviews with men

The interviews will be conducted by a trained male interviewer. Interviews will employ a topic guide that will explore men's sexual relationships with young women, their risk reduction strategies, including familiarity with PrEP, their attitudes towards PrEP as a prevention strategy, how they would feel if they used PrEP, and how they would feel if their partners were to use PrEP with/without telling them. The interview will last approximately 45 minutes to one hour, depending on extent of partnerships and sexual behavior.

Pilot Study: Gender-enhanced (GE) virtual interactive-group workshop vs Individually-accessed condition for women.

Self-assessment procedures. Participants will complete self-administered assessments sent through a link to their phones prior to participating in the GE or IA online condition, prior to the workshop, immediately afterwards, and at 3-month follow-up. These self-administered questionnaires will be programmed using Qualtrics, an online survey platform that is housed in the New York State Psychiatric Institute**.**

HIV testing procedures. HIV infection status (for those who choose to undergo it) will be assessed using **a** ~~the~~ standard protocol being employed at the MRC GHRU (as described above) This is not a required part of study participation and will not involve retaining biological samples used for HIV testing.

Clinical records. The study nurse will retain her own private clinical records, following the standard HIV counseling and testing protocol. Only data relevant to the study outcomes will be included in study records

Study outcomes **–** Primary outcome. Undergoing an individual discussion with the study nurse about the possibility of taking up PrEP is the primary behavioral target of the study; undergoing HIV self-testing guided by the study nurse (either in-person at the GHRU office or via telehealth visit) is a secondary outcome, as is uptake of PrEP, if eligible. These outcomes ~~It~~ will be documented by the study nurse and at the 3-month **structured survey**~~interview~~. The 3-month **survey** ~~interview~~ also will assess other HIV- and pregnancy-prevention methods used. Other outcomes of interest include "stage of change" regarding PrEP uptake, use of contraception, HIV testing with a partner, changes in mediators, talking with partner and/or friends about HIV prevention or PrEP.

Sexual risk. High-risk will be defined as having unprotected vaginal or anal intercourse with a partner of unknown or HIV-positive status. Other risk factors considered will include number of partners (and number of HIV+ or unknown status) with whom one has unprotected sex, having a partner 10 or more years older or aged 35-44, experiencing IPV, social network members engage in transactional sex and/or experience IPV.

Hypothesized mediators and effect modifiers to be ascertained at each assessment include **PrEP information**--what PrEP is, common side effects, consequences of PrEP nonadherence (sample items: *most PrEP-related side effects are short-term; PrEP is highly effective in preventing HIV when taken every day).* **Perceived risk** will be assessed with the Perceived Risk of HIV scale (α = .91) (54) (sample item, *What is your gut feeling about how likely you are to get infected with HIV*?) (3), and modified to assess perceived risk for pregnancy. **Peer norms around PrEP** will be adapted from the 6-item social norm scale developed by Fernandez and colleagues (α = .82) (55) (sample items, *My partner/family would support my using PrEP;*); **Positive and negative outcome expectancies of using PrEP** will be developed based on FG findings (e.g. *If I use PrEP, I will avoid conflict with my partner; my partner will object; my partner will abuse me; I will be less worried about getting HIV)*, including items tapping **PrEP-related stigma** (e.g. *if I use PrEP, people will think I am promiscuous; people will think I am HIV-positive*); **PrEP attitudes,** developed from FG findings (*PrEP is a good option for me; I feel PrEP is safe to take; I feel PrEP will protect me from HIV)*. **Gendered HIV prevention barriers** based on our work in a prior intervention trial (e.g., *it is the man's prerogative to use HIV protection or not; if I use HIV prevention it means I don't trust my partner; my partner could punish me),* and **self-efficacy for PrEP** *(e.g., I would be able to take the PrEP tablets every day even if I sometimes didn't feel well; if I worried that someone would see the tablets, I was short on time, I went to my boyfriend's house).* We also will assess relationship factors, including baseline experience of IPV (56), acceptability of IPV and endorsement of traditional gender norms in relationships (57). These factors may alter (modify) the effectiveness of the GE intervention.

We also will ascertain women's use of PrEP and other prevention strategies through the follow-up interview (self-report).

Acceptability of the workshops will be assessed with items such as *the workshop was fun, boring, too long, too short; I didn't understand most of what was going on; I would recommend the workshop to a friend.* Feasibility of the workshops will be assessed using tracking data for (number attended, number who agreed to be PHAs) and facilitators' summary reports documenting any challenges.

Acceptability and feasibility of Peer Driven Recruitment. Data for indicators of acceptance and successful contacts will be obtained by tracking the number of women who agree to be PHAs and take referral coupons and, for each PHA, the number of recruitees who meet eligibility criteria and attend the workshop. ***Reach*** will be assessed by proportion of recruitees who (1) score *high* on the risk ~~tool and~~ (2) have never been tested and never attended a family planning clinic (an indicator of reach into networks unconnected to care). The pre- and post-workshop assessments are expected to take 15-20 minutes; the follow-up assessment is expected to take 20 to 40 minutes, depending on use of PrEP.

~~**In-depth**~~ **Brief telephone** interviews will cover topics related to outcomes of the interventions, any behavior changes including PrEP uptake that were adopted, and their experiences in successfully recruiting (or not) other women to the intervention**.**

COVID-19 sub-study

The table below describes the measured that will be included in the assesssments

Concept prompted	Measurement	Type of scale or question	No. of items	α
Demographics and living conditions				
Demographics	Gender, age, education/work status, SRH history already available from PrEP study pre-focus group assessment (see attachment 3)	n/a	3	n/a
Living conditions/ arrangements	STATSSA Census 2011 (Section H: Housing, Household Goods and Services and agricultural services) H02 Type of dwelling Available at http://www.statssa.gov.za/census/census_2011/CensusQuestionnaires/Census%202011_q_A.pdf Extra question - who lives with participants (before and during lockdown – important for violence question later) STATSSA Census 2011 Particulars of Household Tptal number of persons in the household	List choice List choice	3	n/a

	Available at http://www.statssa.gov.za/census/census_2011/CensusQuestionnaires/Census%202011_q_A.pdf Extra question of movement between lock-down stages			
Food security and hunger	Household Hunger Scale[22]	Index (using Likert like scales (Never, rarely, sometimes, often)	3	0.9
Experience with living conditions under COVID-19 (challenges and solutions)	Self-designed	Open ended	1	n/a
COVID 19				
COVID-19 symptoms experienced by participant or someone they live with	Self-designed based on DOH symptoms Fever, Cough, Difficulty breathing or Shortness of breath, CDC- Persistent pain or pressure in the chest	Binominal questions	5	
COVID-19 testing status	Self-designed	Binominal question	1	n/a
Reasons for not testing for COVID-19 (if showing symptoms)	Self-designed	Open ended	2	n/a
Concerns about the Covid-19 epidemic	Self-designed	Open ended	1	n/a
Mental health: CES-D 10	CES-D measuring symptoms of depression [23]	10 item screening scale (Likert style)	10	0.86

Experience of mental health and psychosocial wellbeing (challenges and solutions)	Self-designed`	Open ended	1	n/a
SRHR , needs commodities and services				
SRHR services accessed	Set of questions developed from UNFPA rapid assessment tool for SRH and HIV linkages WHO. 2017. Sexual health and its linkages to reproductive health: an operational approach https://apps.who.int/iris/bitstream/handle/10665/258738/9789241512886-eng.pdf	Binominal set of questions	13	n/a
Experience of SRHR needs and access of services (challenges and solutions)	Self-designed	Open ended	1	n/a
Pregnancy prevention. contraceptives	South African Demographic Health Survey list of methods available in the public health sector at no cost to clients. UNDP/UNFPA/WHO/ World Bank Asking young people about sexual and reproductive behaviours: Illustrative Core Instruments John Cleland, Roger Ingham, Nicole Stone (John Cleland, 2005)	Binominal set of questions	11	n/a
Menstrual hygiene products	UNICEF Guide to menstrual hygiene materials (UNICEF, 2019) https://www.unicef.org/wash/files/UNICEF-Guide-menstrual-hygiene-materials-2019.pdf	Binominal set of questions	5	n/a

Experience with managing menstrual hygiene (challenges and solutions)	Self-designed	Open ended	1	n/a
Violence and Rights exposure				
Types of violence experienced by participant from anyone	SADHS 2016 Questionnaire	Binominal set of questions	2 with several options	n/a
In-depth experience of violence	Self-designed	Open ended	1	n/a
Intimate partner violence (IPV) experience only (applicable if participant has intimate partner)	WHO Domestic Violence Questionnaire v9 (World Health Organization, 2000) for - emotional - physical - sexual abuse	Adapted responses to Binominal set of question	4 5 2	n/a
In-depth experience of intimate partner violence	Self-designed	Open ended	1	n/a
Use of violence against women (VAW) support services	Self-designed	Open ended	1	n/a

Research Related Delay to Treatment

Research involving participants who are in need of treatment invariably involves delay to care, and this delay is associated with risk. Scheduling of procedures must be carefully organized to minimize delay. Other delay must involve only that minimally necessary to accomplish the aims of the research while respecting subject well- being and safety. Describe the delay, by virtue of research participation in this study, before a participant can receive treatment of known efficacy or standard care routinely offered in the community.

All study participants who opt for HIV testing and test HIV+ will be immediately referred for clinical services at Addington Hospital clinic. Women who opt to use PrEP also will be connected with PrEP services at Addington Hospital Gateway Clinic or another community-based program.

COVID-19 sub-study. These participants are not in need of treatment

Clinical Treatment Alternatives

Describe what other treatment or assessment options are available to subjects who do not participate in research.

None.

Risks/Discomforts/Inconveniences

"Risk" is a broad term used to convey the potential for harm, burden, and inconvenience related to research participation. Use this section to provide a comprehensive description of foreseeable physical, psychological, social, interpersonal, and economic risks introduced by the research. Include the source of the information. Consider both the probability and magnitude of harm and its impact. Describe the foreseeable harms associated with the research (untoward effects of a medication) and those related to delay to individualized treatment. Include data from the literature, and local data, if available, on risk rates and subject experiences with research procedures. Describe procedures in place to minimize risk. In general, please create a numbered list of risks/categories of risk, and in general put the list in the order of significance or level of risk, the most significant risks first followed by others.

Potential risks include the loss of confidentiality through the screening process, the FGs, interview scheduling or through the pilot study. As described above, participants will be screened for eligibility privately and anonymously. All study staff will sign confidentiality agreements. During the FGs and pilot study workshops, participants will be asked not to reveal outside of the groups anything related to an individual's personal information discussed during the group. Additionally, all women participating in the WhatsApp digital workshop condition will be asked to adopt nicknames that will serve as their WhatsApp name for the duration of the workshop. Participants will be asked to password protect their mobile phone or the WhatsApp program so that their own and other participants' "chats" cannot be accessed by anyone and to protect any personal information in case their phone is lost or misplaced. Before the synchronous portion of the workshop, participants will be encouraged to identify a private space where they participate without the group being overheard.
Women will be asked to respect the confidentiality and privacy of the other participants, including potential participants they may recruit if they choose to become Peer Health Advocates. This precaution applies to women in both conditions.

Another potential risk is that during the FG or workshop, women may recount or be reminded of unpleasant experiences with partners, especially concerning abuse. Some women also may experience discomfort when talking of sexual matters.

With respect to emotional distress on the part of study participants, the focus group and workshop facilitators and interviewers will be trained on techniques for dealing with participant distress and will have access to timely clinical back-up from the study nurse who is a trained counselor. Should the need arise the nurse will engage with the participant and conduct telephonic counseling and referrals. Additionally, all study participants will be given written information on where they can obtain community-based services in relation to intimate partner violence, access to contraception, and other social services.

COVID-19 sub-study: The major risks of participating in the sub-study are

1) Participants may be overheard by others during study interview telephone conversations, which could result in a negative impact -- including the possibility of physical, emotional or psychological harm from a person who lives currently with the participant -- if their sexual activities or experience of violence are unintentionally disclosed;

2) Participants may experience psychological distress as a consequence of discussing their experiences under

COVID-19 lockdown during the study interviews.

Regarding the risk of unintentional disclosure of confidential information in case the participant is overheard the study team will:

1) Agree with participant about time and place for the interview, highlighting to the participant that they need to indicate when they have access to a private space (ideally closed room).
2) Construct some of the confidential questions in such a way that they prompt short answers (e.g. yes or no) and therefore cannot disclose information to third parties.
3) The team will undergo an additional training on how to conduct telephonic interviews under the COVID-19 epidemic and lock-down stages. For this purpose, we will train the team on how to handle confidentiality during the interviews.
4) Participants will be telephoned from SAMRC phone lines; participants will be able to choose any place that is convenient and has reception.

To address the possibility that the interview may provoke or exacerbate psychological distress, the following will be undertaken:

1. Interviews will include a "check in" procedure which aims to determine the respondent's emotional state as the distressing topic is being discussed. Participants will be asked if they are okay, if they would like to take a short break, or if they need any support. Such "check in" procedures will decrease the likelihood that an interviewer will miss a nonverbal cue.
2. Interviewers will be trained on when and how to refer participants to services or the team counsellor.
3. In the event that participants may benefit from support or counselling the team includes a nurse on standby who is a trained counselor. Should the need arise the nurse will engage with the participant and conduct telephonic counseling and referrals. The nurse will connect to the established COVID-19 support structures (e.g. domestic violence, mental health, abortion etc.). We have prepared referral pathway options for the different locations in which the participants reside during COVID-19 lock-down conditions prior to the interviews

Methods to Protect Confidentiality

Describe the data management plan and the methods you will employ to protect subject privacy and the confidentiality of research data. The section should detail how information will be collected, recorded, coded, stored, transmitted, and as applicable, shared with other investigators so as to minimize risks related to breach of confidentiality. Confirm that identifiers are removed, to the extent possible, from research data, and explain if there are links between subject identity and research data, or if the data is anonymous. Also, indicate where the data is stored, who is responsible for its safekeeping, and who has access to subject identity and codes, if any, which cross-link research data and subject identity. Confirm that identifiable data is not collected, stored, or transmitted by mail, fax, on removable drives, laptops, or via the internet without proper protections, e.g. encryption.

All data, including data on paper forms, from computer tablets, and audio-recording of FGs will be handled by MRC-~~HPRU~~ staff, who are trained in GCP. Data will be returned to the MRC-~~HPRU~~ offices on a daily basis and stored in locked file cabinets or on password-protected, encrypted computer devices. Data from all screenings and brief assessments in Aim 1, and from eligibility screenings in the pilot will be entered directly into the pre-programmed tablets and backed up daily. A database system will be used to track recruitment-related activities, including coupons dispersed and returned. The pre-, post-, and 3-month follow-up assessments in the pilot will be programmed in a Qualtrics secure survey platform housed at the NYS Psychiatric Institute. Participants will access these surveys through a link sent to their phones. No individual identifiers will be collected in the surveys. No other individual identifiers (e.g., from consent forms) will be transmitted via any system, as they will be retained at the MRC GHRU. Data cleaning, variable creation, and data analysis will be conducted at the HIV

Center at the NYS Psychiatric Institute by Dolezal, with support from the HIV Center Methods Core. Audio-recordings from FGs and semi-structured interviews will be transcribed and translated by the MRC team. Any identifying information mentioned in these recordings (e.g., participant neighborhood) will be deleted from the transcripts. Transcripts will be identified by study ID number only. De-identified data will be shared with study collaborator, Dr. Abigail Harrison, of Brown University School of Public Health, who will lead the analysis of the qualitative data. Dr. Harrison will be assisted by Ms. Scarlett Bergam, a Master of Public Health student at Brown, in analyzing and managing the qualitative data. Ms. Bergam also will use these de-identified data for her Master's thesis at Brown University SPH under the supervision of Dr. Harrison. The Brown University IRB has reviewed and approved her involvement in analyzing these de-identified data.

Data sources will not include any identifiable information. Women in FGs and online workshops and men in SSIs will be encouraged to adopt nick names; we will not include identifying information on the audio recordings. Women who plan to attend the FG and men attending the interview will be asked to provide identifying information so they can be reminded of the day and time. This information will be destroyed after the scheduled FG or interview, regardless of whether or not the woman and men attended.

COVID-19 sub-study: All data will be kept strictly confidential. Data, audio-recordings and transcripts/debrief notes will only be available to the research team (fieldworker, transcribers, PI and Co-Is) and be kept at a password protected computer at the MRC. Written IC will be kept at a locked cabinet in the SRHR team data room. Staff handling this documentation will have to sign a confidentiality form and undergo project specific training.

Participant identifiers and not participant's name will be allocated to each questionnaire and transcript. We will use the existing identifiers from the PrEP study. Only the core research team (PIs, Co-I, excluding Dr. Hoffman) will have access to the individual participant names and their identifiers. This is kept on a password protected SAMRC computer Dr. Hoffman will only have access to de-identified data.

Potential publications from this study (e.g. peer reviewed articles, issue/policy briefs) may provide basic demographic information (gender and age) but not individual participant's information (names, address). Case studies will be anonymised and validated with participants. All materials will be stored in a locked box or filing cabinet at SAMRC. Electronic information will be stored on a USB key with password protection. In line with SAMRC standard practice and policy the data is to be stored on encrypted devices, either on an encrypted computer or an encrypted USB.

Direct Benefits to Subjects

Describe only benefits to individual subjects that are likely to accrue during the study itself. Do not include subject compensation or treatment to be provided at the end of the study, as these do not figure into the IRB's risk benefit considerations. Do not describe diagnostic and evaluation components unless subjects receive clinical feedback. Do not describe the anticipated scientific benefits of the research. Some studies offer no direct benefit to subjects.

There are no benefits to individual participants, other than the knowledge they may gain about options for protection against HIV, other STIs, and pregnancy, possible access to PrEP, and the potential for attitudinal change that will facilitate better safer-sex decision making. The information gained from this study will help design an intervention to promote uptake and sustained use of an efficacious HIV prevention tool, which could potentially help address the extraordinary vulnerability of young, South African women to HIV infection.

Therefore, we believe the risks are reasonable in relation to the anticipated benefits.

COVID-19 sub-study: There are no direct benefits to individual study participants and the study is not designed for their benefit. Participants may, however, benefit by gaining access to resources and services that they have difficulty obtaining were as a consequence of COVIC-19 lockdowns.

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