HIV risk perception, actual HIV risk, sexual risk behaviours, and oral PrEP continuation at the 1-month follow-up in pregnant women not living with HIV in Cape Town, South Africa: A mediation analysis

by

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PREAMBLE

Declaration

I, Kgotlaganyo Moeletsi (MLTKGO011), hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

I empower the university to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

Signature: Signed by candidate

Date: November 2024

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To the God of my ancestors, to You be all the glory!

Abstract

Adolescent girls and young women (AGYW) of reproductive age in South Africa are heavily burdened with HIV. If taken effectively, oral preexposure prophylaxis (PrEP) prevents HIV acquisition in pregnant women without HIV. We investigated factors associated with oral PrEP continuation at the 1-month follow-up and the role of HIV risk perception and actual HIV risk in motivating oral PrEP continuation in pregnant women. Data from a cohort of pregnant and postpartum women without HIV in Cape Town, South Africa (PrEP-PP), were analysed using logistic regression models and mediation analysis to assess factors associated with oral PrEP continuation at 1-month and the extent to which HIV risk perception and actual HIV risk explain the relationship between sexual risk behaviours and oral PrEP continuation. Of the 1349 pregnant women enrolled, 84% initiated PrEP at the first antenatal care (ANC) visit. Unemployment (aOR=1.33; 95% CI=1.03-1.73), inconsistent condom use during sex (aOR=0.49; 95%CI=0.22-1.00), having a partner living with HIV/unknown HIV status partner (aOR=1.33; 95% CI=1.00-1.77), being at a medium-to-high risk of acquiring HIV (aOR=1.34; 95% CI=1.00-1.78), STI diagnosis at baseline (aOR=1.30; 95% CI=0.98-1.72), and having no current sex partner (aOR=1.63; 95% CI=0.95-2.89) were associated with oral PrEP continuation at 1-month follow-up. Using condoms sometimes during sex (aOR=0.53; 95% CI=0.23-1.12) and being unmarried/not cohabiting (aOR=1.25; 95% CI=0.95-1.66) were marginally associated with oral PrEP continuation. Two-thirds of women misclassified their perceived HIV risk as being at low-risk despite reporting condomless sex or having a partner living with HIV/unknown HIV status partner, highlighting the discordance between actual and perceived HIV risk. The actual HIV risk partially explained the relationship between sexual risk behaviours and oral PrEP continuation at 1-month. Future research is needed on improving accurate assessments of HIV risk to improve PrEP continuation in pregnancy and postpartum.

List of abbreviations

AGYW – Adolescent girls and young women

AIDS – Acquired Immunodeficiency Syndrome

ANC – Antenatal care

AOR – adjusted odds ratio

ART – Antiretroviral therapy

AYP – adolescents and young people

CCR5 – CC Chemokine Receptor 5

CFA – Confirmatory factor analysis

CFI – Comparative Fit Index

CI – Confidence interval

DWLS – Diagonally weighted least squares

FN – False negative

HBM – Health Belief Model

HBsAg – Hepatitis B Surface Antigen

HIV – Human immunodeficiency Virus

HREC – Human Research Ethics Committee

IPV – Intimate partner violence

IQR – Interquartile range

MOU – Maternal Obstetrics Unit

MSM – Men who have sex with men

MTCT – Mother-to-child transmission

OR – odds ratio

PBFW – Pregnant and Breastfeeding Women

PI – Principal investigator

PrEP – Preexposure prophylaxis

PREP-PP - Preexposure prophylaxis in pregnancy and postpartum period

RMSEA – Root mean square error of approximation

SEM – Structural equation modelling

SRMR – Standardised root mean square residual

STI – Sexually Transmitted Infection

TB – Tuberculosis

TLI – Tucker–Lewis Index

UCT – University of Cape Town

UNAIDS – Joint United Nations Programme on HIV/AIDS

US FDA – United States Food and Drug Administration

WLSMV – weighted least squares mean and variance adjusted

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A.PROTOCOL

1. Synopsis

Among AGYW, South Africa has the highest prevalence of human immunodeficiency (HIV) worldwide. Pregnant women not living with HIV are at a three-to fourfold greater risk of acquiring HIV and mother-to-child transmission (MTCT) due to several biological and behavioural changes. The initiation and continuation of oral preexposure prophylaxis (PrEP) can contribute to the minimisation and possible elimination of maternal HIV acquisition and, therefore, MTCT (vertical transmission). HIV risk perception has been suggested to be an intermediate factor, where it has been suggested that HIV risk perception in individuals may influence their decisions to continue the use of oral PrEP.

The main aim of the study was to evaluate whether sexual risk behaviours are mediated through, or correlated with, HIV risk perception and actual HIV risk and associated with oral PrEP continuation at the 1-month follow-up in pregnant South African women not living with HIV. The proposed study also aimed to 1) evaluate factors which affect oral PrEP continuation at 1 month follow-up in the pregnant women not living with HIV; 2) evaluate the relationship between actual sexual HIV risk and perceived HIV risk; and 3) To explore the odds of oral PrEP continuation among pregnant women not living with HIV, who had a medium-to-high HIV risk perception, at the 1-month follow-up on oral PrEP compared to those with no-to-low HIV risk perception and actual HIV risk.

The current study is a secondary analysis of the Pre-Exposure Prophylaxis in Pregnancy and Postpartum Period (PrEP-PP) study, Human Research Ethics (HREC) 297/2018, that will assess how HIV risk perception and actual HIV risk mediates the relationship between sexual risk behaviours and oral PrEP continuation at 1 month follow-up in pregnant women not living with HIV. The study design for this research was a retrospective cohort study. The inclusion and exclusion criteria of this study reflects those of the parent study, highlighted within the protocol. In the PrEP-PP study, the participants were recruited directly from a public health facility in Cape Town, South Africa with the help of a trained recruiter. Women who expressed interest in study participation underwent a rigorous screening process which was in line with the inclusion and exclusion criteria, to determine study participation eligibility. Before official enrollment into the study, the women were informed of the potential risks and benefits associated with study participation, which were outlined in the informed consent form delivered in the participant's home language (isiXhosa or Afrikaans). A prerecorded digital version of the consent form was given to the participants who had difficulties reading, so they could listen to the recording.

The data collected from the participants offer a range of advantages for both individual participants and for research. As emphasised in the PrEP-PP study, enrolled women experienced individual benefits, receiving the best possible HIV prevention including ongoing counselling, hepatitis B screening, testing and treatment of sexually transmitted infections (STIs), and receiving oral PrEP if they chose to initiate use. Additionally, there is minimal risk associated with this secondary study as no additional data

collection will be required. The parent study ensured the protection of the privacy and confidentiality of the women involved in the study by only making use of the participants' names on the informed consent forms, which were kept in locked cabinets. Deidentified participant numbers were used on all study documents. All digital information was stored in files protected by passwords. The study data was communicated through encrypted files that were also password protected, encrypted files.

The findings of this study will provide a better understanding of the current landscape regarding HIV risk perception, actual HIV risk, sexual risk behaviours, and oral PrEP continuation at the 1-month follow-up in pregnant women. The study will also provide insight on factors associated with or that influence oral PrEP continuation at the 1-month follow-up. The insights gathered from this research regarding oral PrEP continuation and sexual risk behaviours may have great transformative impact on various fronts, uncovering patterns associated with oral PrEP implementation and usage, allowing for the development of targeted strategies. Moreover, exploring the potential associations and potential mediating relationships of HIV risk perception and actual HIV risk between sexual risk behaviours and oral PrEP continuation is crucial. This can help us understand whether HIV risk perception is an appropriate target for HIV prevention programmes and interventions or if actual HIV risk is a better alternative, especially for HIV prevention programmes focusing on oral PrEP interest and adherence in pregnant and postpartum women not living with HIV. In essence, this dissertation has the potential to inform and shape more effective targets for HIV prevention programmes in this specific demographic.

2. Introduction

Sub-Saharan Africa has the highest HIV burden globally, with approximately 69% of people in this region living with HIV/AIDS, and approximately 3100 out of 4000 global HIV infections in AGYW aged 15-24 years old occurring in sub-Saharan Africa [1]. In South Africa, the epicentre of the HIV/AIDS epidemic, it is estimated that 7.9 million people were living with HIV in 2022 [2], with adolescent girls and women of reproductive age being at greatest risk of HIV infection. This high prevalence among these women is due to several complex biological, behavioural, and socio-economic factors [3–5].

South African pregnant and breastfeeding women (PBFW) not living with HIV are at a three- to fourfold increased risk of acquiring HIV per condomless sex act [6]. This is attributable, but not limited to, various behavioural and biological factors. Behavioural factors include frequent unprotected vaginal and anal sex and having multiple sexual partners [7]. Biological factors include inflammation in the female genital tract epithelium, having a large genital mucosa surface area, that is prone to trauma, and exposure to infectious fluids and pathogens [8,9]. As an implication of these factors, there is an increased risk of maternal HIV acquisition during the later stages of the pregnancy and during breastfeeding, significantly increasing the risk of vertical transmission in those who are pregnant and the burden of paediatric HIV.

Considering the numerous risk factors which contribute to the high HIV incidence during pregnancy (and after birth), Truvada was first approved by the United States Food and Drug Administration (US FDA) as an oral preexposure prophylaxis (PrEP) and HIV prevention medication that is meant to be used before and continued throughout periods of potential exposure to HIV-1 [10]. Oral PrEP is a safe and effective preventative intervention aimed at reducing the risk of HIV acquisition in high-risk populations. In pregnant women not living with HIV, the aim is to reduce their risk of acquiring HIV during pregnancy and postpartum and thus of MTCT. Therefore, during such periods, women could use oral PrEP discretely. However, several barriers currently exist to such oral PrEP use [11,12].

Although oral PrEP has great potential, not much is known about oral PrEP continuation in pregnant women not living with HIV, or about the factors affecting continued oral PrEP use. For oral PrEP to be effective, it must be used continuously during periods where the risk of acquiring HIV is high, both during pregnancy and the postpartum period. Mathematical modelling revealed that PrEP provision could reduce vertical HIV infection by 41% if 80% of all PBFW not living with HIV received oral PrEP [13].

Despite the increasing use and adoption of oral PrEP, some populations find it challenging to continue on oral PrEP. As countries approve the use and roll-out of oral PrEP for HIV prevention, systematic monitoring of continued follow-up and continuation is imperative for estimating the potential impact

oral PrEP has an intervention and measuring the success of programmes implementing the use of oral PrEP [14]. Additionally, continuation data will provide insight into whether there are any differences in oral PrEP continuation at follow-up among the different groups. In doing so, strategies for promoting oral PrEP continuation can be tailored to meet the needs of those specific groups of people.

HIV mediation analyses provide a valuable framework through which we can evaluate the impact of prevention programmes [15,16]. As a result, the effectiveness of prevention interventions can also be developed based on the identification of key intermediary factors. Perceived susceptibility/risk is one of the several central constructs in many studies on health behaviour changes, such as in the Health Belief Model (HBM). In many mediation analyses, perceived HIV risk, or the chances of acquiring HIV in the next year, while not taking oral PrEP, is included as an intermediary factor (or a mediator) [17], indicating that the perceived risk of HIV acquisition may be a key factor in individuals at high risk for acquiring HIV considering the use of oral PrEP or other HIV prevention methods. However, there is insufficient evidence to support this assumption. The ability to detect whether HIV risk perception mediates the relationship between certain exposures and outcomes in pregnant women not living with HIV will help determine whether HIV risk perception is an appropriate target for HIV prevention programmes. Furthermore, this study will provide information on whether actual HIV risk, defined as the lifetime risk of acquiring HIV through exposure to the HI-virus, is a decent alternative and target for HIV/AIDS infection prevention methods and interventions. This information will help inform future iterations of HIV prevention frameworks and cascades.

We hypothesise that pregnant women who perceive themselves to be at a high risk of HIV acquisition due to risky sexual behaviours are more likely to continue using oral PrEP at the 1-month follow-up than are those who perceive themselves to be at a lower risk of HIV acquisition.

3. Study aims and objectives

3.1 Aim

To evaluate whether the relationship between sexual risk behaviours and oral PrEP continuation at the 1-month follow-up is mediated through, or correlated with, HIV risk perception and actual HIV risk in pregnant South African women not living with HIV.

3.2 Objectives

1. To evaluate factors affecting oral PrEP continuation at the 1-month follow-up in pregnant women not living with HIV.

2. To evaluate whether pregnant women not living with HIV who are at an actual medium-to-high HIV risk (with a risk score of ≥ 2 sexual risk behaviours) for HIV are associated with how they perceive themselves as such, using the same risk score.
3. To evaluate whether pregnant women with risky sexual behaviours aligned with medium-to-high-risk perceptions will have greater odds of oral PrEP continuation (more likely to continue using oral PrEP during pregnancy) compared to those with lower-risk and/or lower risk perceptions.
4. To evaluate the mediational relationship of HIV risk perception and actual HIV risk between sexual risk behaviours and oral PrEP continuation at the 1-month follow-up in pregnant South African women not living with HIV.

4. Methodology

4.1 Study design

This study will involve the secondary analysis of data from participants who were recruited as part of the Preexposure Prophylaxis in Pregnant and Postpartum Period (PrEP-PP) study, an observational prospective cohort study of pregnant women who were recruited at their first antenatal care visit (ANC). The study design details have previously been described [7]. Additional approval was obtained for the secondary analysis (HREC 845/2023).

4.2 Study population

The PrEP-PP study enrolled consenting pregnant adolescent girls (≥ 16 years) and women not living with HIV at their first ANC visit from one public health clinic in Cape Town, Western Cape, South Africa (N = 1195), who were followed-up for 12 months postdelivery or until censorship for a mean of 18 months. Adolescent girls younger than 18 years old provided unassisted consent for study participation.

Inclusion criteria:

1. 16 years old and older.
2. Confirmed to be HIV-negative using 4th generation antigen HIV test.
3. Intend to give birth in the chosen MOU facility.
4. Confirmed to be pregnant.
5. Women with no psychiatric or medical reasons that prevent the use of oral PrEP.

Exclusion criteria

Individuals who do not fulfil the abovementioned inclusion criteria or who satisfy any of the following criteria will be excluded:

1. Simultaneous enrollment in another HIV-1 vaccine or prevention trial.
2. Hospitalisation within the past year, for non-obstetric health issues (e.g., caesarean section, miscarriage, preeclampsia).
3. Currently or previously receiving Tuberculosis (TB) treatment within the past 30 days.
4. A history of kidney-related disease.
5. Current hypertension diagnosis.
6. Showing signs of psychosis (including hallucinations, suicidal or homicidal ideations, or violent behaviour).
7. Current or historic use of anti-psychotic medication (e.g., treatment for bipolar disorders, schizophrenia, or postpartum psychosis following a past pregnancy).
8. A positive hepatitis B surface antigen (HBsAg) test upon screening.
9. A history of bone fractures that are not trauma-related.
10. Any other clinical, psychiatric, or social condition that, according to the judgement of the investigators would influence a participant's ability to provide consent or partake in the study.

4.3 Recruitment and enrollment

A sample of pregnant and postpartum women not living with HIV who participated in the PrEP-PP study will be included in this proposed secondary analysis. Trained health care providers at the study site coordinated group counselling sessions for women at their first ANC visit. Following testing and disclosure of the mother's HIV status, potentially eligible women were informed about the benefits and risks of using oral PrEP. After agreeing to participate, the women were directed to study recruiters, where the counsellors reviewed the screening consent form to evaluate the women's eligibility. Following the review of the screening consent form, all the participants who were eligible for and agreed to study participation followed the study consent form process, followed in their native language of either isiXhosa or Afrikaans **(see the informed consent form in Appendix A).**

4.4 Research procedures and data collection methods

In the parent study, there were four different sources of data, namely, survey methods, including those related to oral PrEP. The data for this secondary analysis will be obtained from the parent (PrEP-PP) study, where the relevant data will be requested through a data request form.

4.5 Data analysis and study variables

The baseline sociodemographic and sexual behaviour characteristics of the participants will be examined using the median and interquartile ranges (IQRs) for the continuous variables and proportions and percentages for the categorical variables.

Overall aim:

To perform univariable and multivariable logistic regression analyses to model the relationship between sexual risk behaviours and oral PrEP continuation at the 1-month follow-up and determine the log crude odds ratio (OR) and adjusted OR (aOR), adjusting *a priori* for maternal age, highest level maternal of education, and gestational age. The confounders are variables that are 1) associated with the exposure (sexual risk behaviours); 2) associated with the outcome (oral PrEP continuation at the 1-month follow-up); and 3) are not in the causal pathway between sexual risk behaviours and oral PrEP continuation at the 1-month follow-up. *A priori* adjustment of the confounders is based on prior knowledge of the association of the confounders with both the exposure and the outcome. The analysis for the overall aim will include a mediation analysis within a structural equation modelling framework for the suspected mediation process and the relationship between sexual risk behaviours and oral PrEP continuation at the 1-month follow-up in pregnant women not living with HIV, with HIV risk perception and actual HIV risk as potential mediators in the exposure–outcome relationship. We will estimate the direct and indirect effects and determine statistical mediation by analysing the significance of the indirect effects.

Study variables:

In the parent study, HIV risk perception data was gathered from women who were not on oral PrEP, where they were asked about their changes of acquiring HIV, within the next year, while not taking oral PrEP. Possible responses included “no chance at all”, “small chances”, “moderate chance”, “great chance”, and “I don’t know”. For our study, these responses were dichotomised into “no-to-low HIV risk perception” and “medium-to-high HIV risk perception (Table 1). In our study, actual HIV risk was a risk score composed of the sum of five risk factors, namely 1) STI diagnosis at baseline; 2) the number of sexual partners in the preceding three months; 3) condom use during sex in the preceding three months; 4) partner serostatus; and 5) marital status. Women with exposure to 1 or none of these risk factors were classified as being “no-to-low” actual HIV risk whereas those with exposure to 2 or more of these risk factors were considered to be at a “medium-to-high” actual HIV risk.

Table 1. Table of variables including exposure, outcome, potential mediators, and potential confounders

Variable		**Measurement**
Exposure (Sexual risk behaviours)	Number of sexual partners	Number of different people the woman had sex with in the preceding 3 months. Exposed: > 1 sexual partner in the preceding 3 months Unexposed (reference): 1 or no sexual partner in the preceding 3 months
	Partner serostatus	Partner serostatus defined as being a partner living with HIV (HIV positive), a partner not living with HIV (HIV negative), or unknown partner status. Exposed: partner living with HIV or unknown partner status Unexposed (reference): a partner not living with HIV
	Marital status	How the women described their main, current relationship. Defined as 'married or cohabiting', 'unmarried or not cohabiting', or 'no current sex partner'. Exposed: unmarried or not cohabiting Unexposed (reference): married or cohabiting and not having a current sexual partner
	STI diagnosis	Positive diagnosis of chlamydia, gonorrhoea, and/or trichomonas vaginalis at baseline. Exposed: positive diagnosis of any of the STIs Unexposed (reference): negative diagnosis for all the STIs
	Condom use	Reported use of male or female condoms during any sex in the preceding 3 months. Defined as 'always', 'almost always', 'sometimes', 'rarely', and 'never'. Exposed: Using a condom rarely, sometimes, or never. Unexposed (reference): Always or almost always using a condom

Potential mediators	HIV risk perception	How women would describe their chances of acquiring HIV in the next year, if they were not taking oral PrEP. Defined as 'no chance at all', 'small chance', 'moderate chance', and 'great chance'. 'No chance at all' and 'small chance' and 'moderate chance' and 'great chance' were combined and dichotomised into 'no-to-low risk' and 'medium-to-high risk' respectively. Being 'medium-to-high' risk is based on an individual's HIV risk perception based on the described sexual risk behaviours. Exposed: being at medium-to-high risk Unexposed (reference): being at no-to-low risk
	Actual HIV risk	The lifetime risk of acquiring HIV through exposure to the virus. Defined by having a risk score of 0 or 1 (no-to-low risk) and ≥ 2 (medium-to-high risk). The calculated risk score is based on marital status, number of sexual partners in the preceding 3 months, partner serostatus, STI diagnosis at baseline, and condom use in the preceding 3 months.
Outcome	Oral PrEP continuation	Binary outcome (continued/discontinued oral PrEP use). Described as continuation of oral PrEP use at the 1-month follow-up during pregnancy.
Potential confounders	Maternal age	Maternal age in years
	Gestational age	Gestational age at baseline in weeks
	Education	Highest level of maternal education (categorical)

The Proposed Mediation Model

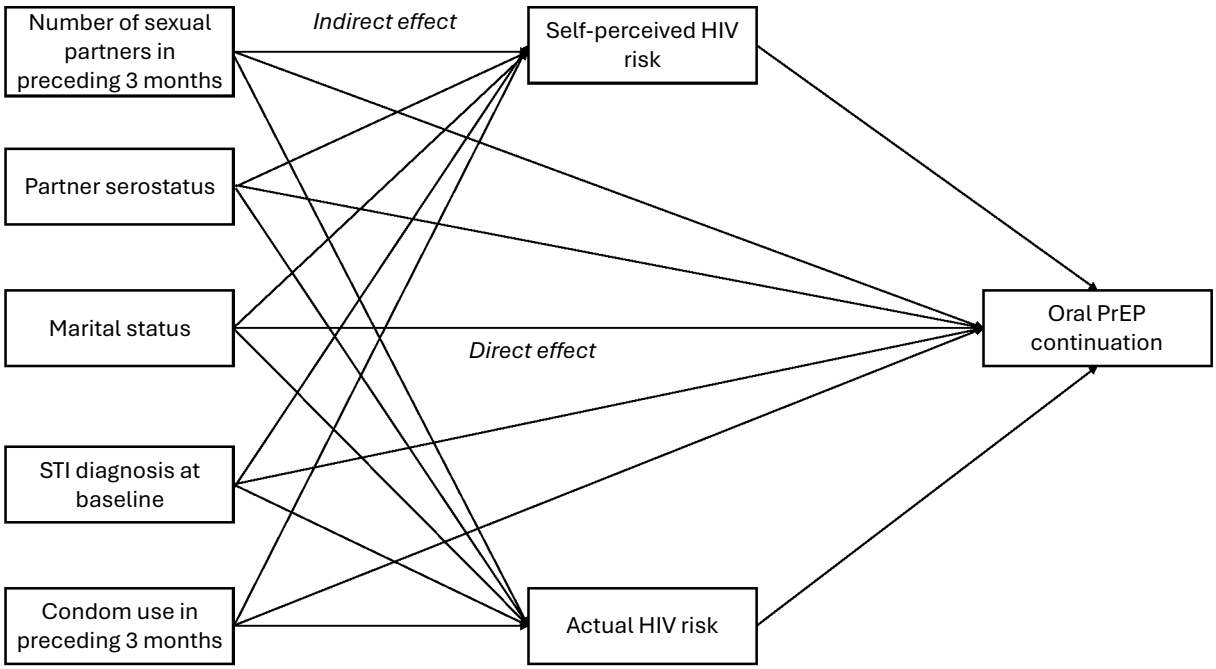

Fig. 1 A detailed mediation analysis within a structural equation modelling framework of the associations between exposure, outcome, and potential mediating factors

The model shown in figure 1 above is a mediation process. Mediation, specifically for the purpose of structural equation models (SEMs), refers to a third, intermediate variable (called the mediator) that helps explain how and why an exposure (also referred to as an exogenous variable) influences an outcome (sometimes referred to as the endogenous variable). In mediation analyses, there is a *direct effect* which is the pathway directly from the exposure variable through to the outcome variable while controlling for the mediator. The *indirect effect* is the pathway from the exposure variable to through to the outcome variable via the mediator. The above model suggests that there is a *direct effect* between the number of sexual partners in the preceding 3 months, partner serostatus, marital status, STI diagnosis at baseline, and condom use during sex in the preceding 3 months and oral PrEP use continuation at the 1-month follow-up. At the same time, there is an *indirect effect* from the exogenous variables to the endogenous variables via HIV risk perception. The model also suggests that there is an *indirect effect* from the exposure variable to the outcome variable via actual HIV risk.

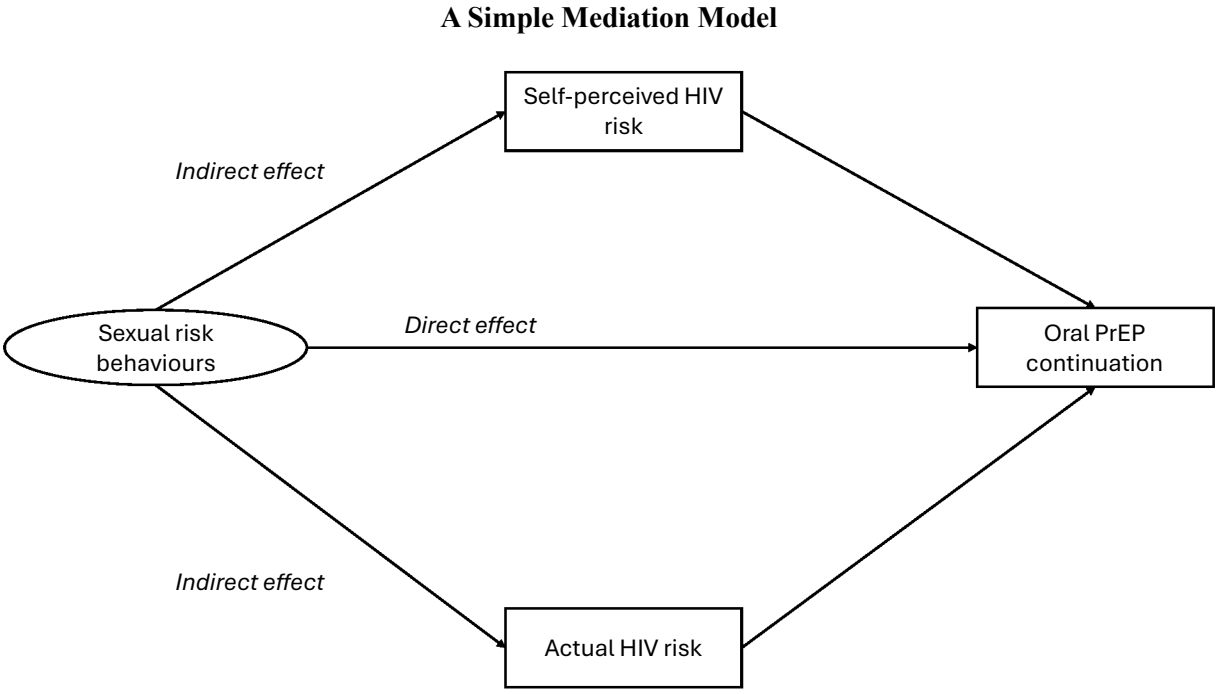

Fig. 2 A simplified mediation analysis pathway, within a structural equation modelling framework, of the associations between the exposure, outcome, and potential mediators**.** In this model, the latent variable 'sexual risk behaviours', is represented by an ellipse, and the observed variables are represented by rectangles

Objective 1:

To construct univariable and multivariable logistic regression models containing all factors to explore the crude and adjusted effects of the covariates on the outcome of oral PrEP continuation at the 1-month follow-up.

Objective 2:

To construct a confusion matrix to determine the proportion of individuals who correctly classified themselves as medium-to-high risk of actual HIV, given their perceptions of HIV risk.

Objective 3:

To explore the odds of oral PrEP continuation among pregnant women not living with HIV, who had a medium-to-high HIV risk perception, at the 1-month follow-up on oral PrEP compared to those with no-to-low HIV risk perception and actual HIV risk.

Objective 4:

To explore the relationship between sexual risk behaviours and oral PrEP continuation at 1 month following HIV risk perception and actual HIV risk within the structural equation modelling framework, using mediation analysis

4.6 Data management

The data obtained from the PrEP-PP study will continue to be managed according to the safety procedures used in the study. PrEP-PP data were collected on paper-based forms and participant information was captured in the customised study-specific RedCap database. The information was stored in a firewall protected University of Cape Town (UCT) server that was backed-up nightly.

In the PrEP-PP study, the study was integrated into the MOUs and women were recruited directly from their first ANC visit by trained recruiters, who are existing counsellors, nurses, and midwives who were trained, by the study team, in oral PrEP treatment. Women who were interested and eligible following the screening process were taken to the study place (Hanover Park) or the study trailer (Green Clinic Gugulethu) for informed consent and study enrollment procedures. Enrolled, consented women were invited to return every 3 months for study visits that corresponded with their next ANC visit.

4.7 Ethical considerations

Risks and benefits

Risks:

Potential risks associated with study participation included the following:

1. Risk arising from self-reported behavioural and psychosocial data related to psychosocial distress according to questionnaire items involving social support, mental health, and HIV status disclosure.
2. Potential risks linked to a loss of confidentiality owing to study procedures, such as during the data collection process.
3. Potential risks linked to participants disclosing their status, including the possibility of intimate partner violence because of disclosing their status.

Potential risks to participants who use oral PrEP include:

1. Side effects (headaches, gastrointestinal) for women on oral PrEP.
2. Adverse events for women on oral PrEP.
3. Potential risks arising from the collection of dried blood spots.

Benefits:

Direct benefits

The greatest benefits of pregnant women participating in the parent study included receiving the best possible HIV prevention, including ongoing counselling, screening for hepatitis B, testing and treatment

of STIs, and use of oral PrEP for women who decided to initiate oral PrEP treatment. Oral PrEP initiation and use can help prevent HIV infection in mothers during pregnancy and the postpartum period. Women who did not initiate oral PrEP treatment or who did initiate but did not adhere to their oral PrEP use received ongoing counselling and STI testing.

Indirect benefits

Through the identification of the optimal strategy for the delivery of PrEP to pregnant and postpartum women, the PrEP-PP study has the potential to improve HIV prevention methods and intervention implementation to protect against HIV infection and vertical transmission in women without HIV and their infants in Cape Town, the Western Cape Province, and across the country.

Informed consent

For this type of secondary analysis, informed consent was not needed. The survey protocol for the original study was approved by the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee (HREC).

The original study had two informed consent forms :

1. The first was for screening and testing of participants and included consenting to the screening survey (inclusion criteria questionnaire) and consenting to an HIV test and hepatitis B surface antigen testing. Informed consent was obtained from the enrolled participants.
2. The second is the main study informed consent form, which, together with the questionnaire, depicted those used in previous studies and was presented in the participants' native language (isiXhosa or Afrikaans) by trained interviewers. The study informed consent form provided comprehensive information on the purpose of the study, the study procedures, and the risks and benefits that mothers who participated were likely to encounter at the additional study visit.

   Staff emphasised the following to participants:

   - Study participant is voluntary, and whether mothers chose to participate would not influence the quality of their standard medical care for either mothers or their infants.
   - Mothers may leave the study at any point in the study, for whatever reason without compromising the quality of their standard medical health care.

Compensation/reimbursement

During the parent (PrEP-PP) study, the women were compensated for their participation and time. The women were compensated with a R250 grocery voucher at each study measurement visit as well as additional funds to cover transport costs. Additionally, all the participants were served refreshments on the day of their study visit.

Privacy and confidentiality

During the PrEP-PP study, the following steps were taken to ensure study confidentiality.

1. All the staff involved in data collection and management were trained on confidentiality and other patient protection issues.
2. All paper-based participant- and study-related information was locked away in cabinets at study office sites or at UCT, accessible only to the local principal investigator (PI) and the project manager.
3. Unique participant identification numbers were used on all study documentation for deidentification purposes.
4. All the electronic data were kept in password-protected files at UCT within a firewall-protected server.

This proposed secondary analysis will adhere to privacy and confidentiality measures similar to those of the PrEP-PP study.

Data dissemination

This secondary analysis and its findings will be completed in partial fulfilment of the requirements for the Master of Science (Epidemiology and Biostatistics) degree. The results obtained are expected to be presented and published in discussion with the investigators of the PrEP-PP study.

Conflicts of interest

No conflicts of interest have been declared by the researchers.

Resources

All necessary resources needed for the completion of this minor-dissertation have been accounted for. Moreover, the student/researcher has significant support from their supervisor (Dr Dvora Joseph Davey).

Authorship

The authorship will include myself, Kgotlaganyo Moeletsi (the MSc student), the principal investigator (Dr Dvora Joseph Davey), and the main investigators involved in the parent study (Professor Landon Myer, Professor Thomas Coates, Professor Linda-Gail Bekker, Professor Leigh Johnson,) and the data manager (Kalisha Bheemraj).

5. Study timeline

Table 2. Proposed schedule for minor-dissertation

	June 2023	July 2023	August 2023	September 2023	October 2023	November 2023	December 2023	January 2023	February 2023
HREC approval									
Literature review									
Data preprocessing/ management									
Data analysis									
Methodology write-up									
Discussion									
Minor-dissertation write-up									
Submission of minor-dissertation									

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B. STRUCTURED LITERATURE REVIEW

1. Introduction

Globally, HIV/AIDS is the greatest cause of death in women of reproductive age, aged between 15 and 49 years [1], with Sub-Saharan African AGYW aged 15 – 24 years being the most affected by this epidemic accounting for over 77% of new HIV infections in 2022 [2]. AGYW who come from this region are disproportionately affected by HIV infection; not only do they have higher rates of HIV infection than their male peers, but they also contract HIV five to seven years before their male peers do [3].

With over 7.9 million individuals infected and living with HIV [4], South Africa remains the epicentre of the HIV/AIDS epidemic. Additionally, the country also has the highest prevalence rate of HIV among AGYW, with AGYW being three times more likely to contract HIV than their male peers [5]. This disproportionality in HIV incidence between males and females is due to several complex "biological, social, behavioural, cultural, economic, and structural" factors [6]. Pregnant and breastfeeding (PBFW) South African women not living with HIV are at a three- to fourfold increased risk of HIV acquisition and seroconversion per condomless sex [7] due to factors such as changes in the female genital tract mucosa, such as upregulation of HIV-1 coreceptors, specifically CC Chemokine Receptor 5 (CCR5), in high progesterone states [8] and sexual behavioural changes that include having multiple sexual partners, male partners increasing sexual activity outside of their relationship with other sexual partners or a decreased frequency of condom use during pregnancy and postpartum [9-11]. Because of the increased risk of seroconversion during the later stages of pregnancy and breastfeeding, the risk of paediatric HIV increases significantly [12]. To address this issue, the South African Department of Health first approved the use of oral preexposure prophylaxis (PrEP) in pregnant women not living with HIV in 2018.

To address the complexities of HIV infection among pregnant AGYW and other women of reproductive age not living with HIV, we need to understand the relationships or potential associations between sexual risk behaviours, HIV risk perception, actual HIV risk, and continuation of oral PrEP use following initiation. Sexual risk behaviours play an important role in determining one's risk of acquiring HIV, whereas HIV risk perception and knowing one's actual HIV risk may influence an individual's health-seeking behaviours, particularly in how they choose to interact with potential preventative measures and/or interventions. Therefore, this literature review sets out to understand how an individual's sexual risk behaviours influence their continuation of oral PrEP use, to prevent HIV acquisition and essentially, vertical transmission, and how their perceived susceptibility to HIV acquisition and the actual HIV risk may influence (and potentially mediate) the association/relationship between their sexual risk behaviours and oral PrEP continuation at the 1-month follow-up. These findings will allow us to investigate the factors affecting sexual risk behaviours, HIV risk perception, actual HIV risk, and continuation of oral PrEP use, as well as the opportunities, challenges, and gaps that need to be addressed

in the battle against HIV in pregnant, AGYW and other women of reproductive age who are not living with HIV.

2. HIV risk perception

HIV risk perception, defined as "one's belief about one's susceptibility to HIV infection" [13], is an important part in the HIV prevention cascade. Understanding one's risk for acquiring HIV is a crucial first step to sustained PrEP adherence and continuation and effective use of other HIV prevention methods, including condoms. These strategies rely on accurate perceptions by individuals about their susceptibility to HIV acquisition. This makes understanding the concept of HIV risk perception among pregnant women not living with HIV and other at-risk populations very important. A woman's perceived HIV risk is shaped by structural risk factors such as intimate partner violence (IPV) and behavioural risk factors including not having a stable partner and having multiple sexual partners [14-16]. Understanding such factors that influence HIV risk perception, particularly in pregnant women not living with HIV, is important for achieving successful and effective delivery and use of oral PrEP.

Many HIV/AIDS information campaigns are based on behaviourist and behavioural theories/models including, but not limited to, the Health Belief Model (HBM). This theory was one of the first theoretical models developed to help explain how health behaviour changes, and the premise of this theory, as well as other behaviourist and behavioural theories, is that an individual will act based on their intentions and behaviours [17]. It focuses mainly on threat perception and behavioural evaluation, "the two aspects of an individual's representation of health and health behaviours" [18]. According to the HBM, individuals will act to prevent sickness should they suspect that their personal health is threatened (perceived susceptibility), if they suspect that the illness would have serious outcomes (perceived severity), if they perceive that certain health-promoting actions will reduce their susceptibility to or severity of or lead to positive outcomes (perceived benefits), and if they believe that this health promoting action has few negative consequences (perceived barriers) [19,20]. When used properly, this theory can "provide organised assessment data" about individuals' "abilities and motivation to change their health status" [17]. However, several factors may influence an individual's HIV risk perception, such as having a partner living with HIV or a partner with an unknown serostatus, level of education, and sexual orientation [15,21,22], indirectly influencing their health-related behaviours. There is usually a discordance between HIV risk perception and actual HIV risk, which may mean people underestimate their chances of acquiring HIV.

3. Sexual risk behaviours

Sexual risk behaviours, which are any sexual behaviours that put an individual at risk of an adverse health outcome [23], including contracting STIs and HIV, play an important role in HIV transmission. These risky sexual behaviours increase the risk of acquiring HIV among at-risk populations including having condomless/unprotected sex, transactional sex, multiple sexual partners, and having sex while under the influence [24-27]. It is well established that engaging in these types of sexual risk behaviours can lead to HIV infection, especially considering that the main mode of HIV transmission is through sexual contact with a person living with HIV. Understanding these sexual risk behaviours and the factors that influence them, especially in pregnant AGYW and other women of reproductive age who are not living with HIV, is very important in the fight against seroconversion and HIV infection in both pregnant and non-pregnant AGYW not living with HIV and other populations, such as those testing positive for STIs, that are at high risk of infection.

There are several factors which contribute to engagement in risky sexual behaviours. Peer pressure, especially among AGYW, plays a significant role in engaging in such behaviour [25], where participating in sexual activities is normalised when trying to fit in with one's peers. Socioeconomic status and poverty are other driving forces for partaking in risky sexual behaviours, as it has been shown that low socioeconomic status is associated with a greater chance of engaging in transactional sex [28]. Age disparate relationships, often defined as "partnerships with an age-gap between partners of 5 years or more"[29], often play a role in the increased HIV risk amongst AGYW due to changes in their sexual behaviours [29-32] and economic and gender inequalities [33]. Changes in sexual behaviours include decreased condom use, where women in age-disparate relationships feel they cannot negotiate the use of condoms during sex [34]. Economic drivers include economic inequalities between men and women, where women enter into age-disparate relationships with men for financial and material gain, creating power imbalances within the relationship where men have more control over decisions pertaining to sex [35], such as condom use during sex. Other gender and cultural norms include men being viewed as providers for women in relationships and women having to "return the favour" by means of sex [36]. It is, therefore, apparent that there is a complex interplay between individual, social, and economic factors that influence one's sexual behaviours, and these complex factors need to be appropriately addressed for successful HIV prevention interventions.

4. Oral PrEP use and continuation

Truvada, an oral combination tenofovir and emtricitabine, was first approved by the US FDA in July 2012 as a highly effective preexposure prophylaxis (PrEP) in conjunction with other safe sexual behaviours to reduce infection with HIV-1 in adults at risk of HIV-1 infection [37,38]. In South Africa,

the roll-out of PrEP was first approved in 2016 for sex-worker sites and later rolled out in primary health-care facilities in 2019 [39]. The roll-out was expanded to other key populations, including serodiscordant couples, men who have sex with men (MSM), and AGYW.

Oral PrEP is a medication taken daily or on-demand by individuals not living with HIV before potential exposure to HIV to reduce their risk of acquiring the disease. When taken correctly, this medication reduces the risk of HIV infection through sex by 99% [40]. However, to ensure maximum efficacy, it is important that individuals adhere to and comply with the medication. Adherence to PrEP refers to the extent to which a patient takes their PrEP as prescribed by their healthcare professional [41]. In the context of PrEP for HIV prevention, especially in our population of interest, it is important to understand the factors affecting achievement of high levels of PrEP adherence and compliance as many individuals who initiate oral PrEP discontinue their PrEP use rapidly following initiation, and those who continue taking the medication struggle with adherence (initiation and continuation of use) and compliance.

Oral PrEP continuation is affected by many complex factors. First, individuals struggle with the stigma associated with taking PrEP, leading to concealment of their PrEP use and fears about disclosing the reasons behind their use of PrEP. Other fears and barriers include being perceived as living with HIV and receiving anti-retroviral therapy (ART) [42,43], forgetting to take the medication, and the fear and anticipation of experiencing side effects. Despite these challenges, many opportunities for ensuring successful adherence, i.e., continuation, exist. Approaches include innovative healthcare approaches such as community-based service delivery, the combination of family planning, antenatal, and postnatal services with PrEP services, especially for pregnant AGYW and other women of reproductive age not living with HIV; text messaging services to remind women to maintain retention and adherence; and long-term injectable PrEP formulations, notably injectable cabotegravir, which can mitigate issues of daily pill taking and improve adherence [44-46]. These approaches provide ways to improve adherence to and compliance with oral PrEP and reduce the risk of HIV acquisition among at-risk populations, specifically pregnant AGYW and other women of reproductive age not living with HIV.

5. Interactions between the factors

There exists a very complex relationship between HIV risk perception, actual HIV risk, sexual risk behaviours, and continued use of oral PrEP [47], and understanding this complex relationship is important in preventing HIV infection. An individual's perceived susceptibility to HIV infection based on their sexual risk behaviours influences how individuals choose to use PrEP. Engaging in risky sexual behaviours, such as having frequent unprotected sex or having a partner who is living with HIV partner or a partner whose HIV status is unknown, can influence how a person perceives their likelihood of acquiring HIV and therefore, how effectively they choose to use oral PrEP. A study by Joseph-Davey at al. [48], revealed that mothers expressed interest in taking oral PrEP because of the "lack of control

over their risky sexual behaviours", as they desired to reduce their chances of perinatal HIV transmission. Hill et al. [49] also showed that AGYW who perceived themselves to be at greater risk for HIV acquisition were interested in initiating oral PrEP in a bid to prevent HIV infection. Another study by Corneli et al. [50] revealed that having some type of HIV risk perception was associated with good adherence to prescribed oral PrEP. It is, therefore, crucial that we understand the interplay between these factors, as these factors may change over time, where an individual's risky sexual behaviours change, and, in turn, so could their HIV risk perception, actual HIV risk, and willingness to initiate and continue the use of oral PrEP.

Such a study is important especially in the South African context due to the increased risk of HIV acquisition during pregnancy and in the postpartum period [6] and vertical transmission. A study by Thompson et al., suggested that the chances of acquiring HIV was 3 to 4 times higher during late pregnancy and postpartum period per condomless sex act [6], as compared to the non-pregnant period. This contributes considerably to vertical transmission. It is suggested that the rate of vertical transmission of HIV ranges from 15% to 45% during pregnancy, labour, delivery, and breastfeeding in the absence of the use of a preventative intervention [51]. Therefore, it is crucial to prevent HIV acquisition during pregnancy and postpartum and decrease vertical transmission.

6. Methods

6.1 Mediation analysis within structural equation modelling

One such way to understand the relationship among sexual risk behaviour, oral PrEP use continuation, HIV risk perception, and actual HIV risk is through mediation analysis and structural equation modelling (SEM). Mediation analyses often offer insight into how an intervention does or does not work by investigating the degree to which the mediator (or the intermediate variable) explains the effect of an intervention [52]. On the other hand, SEMs are multivariate quantitative techniques that help explain and/or describe the relationships between variables by allowing researchers to test complicated mediation models in one step, which allows easy interpretations while simultaneously modelling and estimating associations between multiple dependent and independent variables [53,54].

7. Gaps in the literature and conclusions

Although there is increasing evidence on the relationship among sexual risk behaviours, HIV risk perception, actual HIV risk, and continued oral PrEP use, there are still some gaps that remain. The biggest gap is the lack of evidence on the associations between HIV risk perception and actual HIV risk through mediation analysis and SEMs to understand how these potential mediators may influence sexual risk behaviours and our intervention of interest, namely, oral PrEP continuation. Understanding the role

these two potential mediators may be useful in understanding whether actual HIV risk and HIV risk perception are appropriate factors to target when implementing HIV prevention interventions, which are aimed at HIV prevention in AGYW and other women of reproductive age not living with HIV.

Therefore, the literature review highlights the importance of understanding how sexual risk behaviours influence one's decision to initiate and continue the use of oral PrEP, specifically in women of reproductive age not living with HIV who may or may not be pregnant, and how this relationship may be influenced by one's perception of their susceptibility to HIV as opposed to their actual risk of acquiring this infection. This study also highlights the intricate nature of the relationship between sexual risk behaviour, HIV risk perception, actual HIV risk, and oral PrEP continuation and mediation analysis using SEM in shedding light on the relationships that exist between these variables.

8. Literature search strategy

For this literature review, a broad and non-systematic search strategy was used. Published and peer-reviewed English articles from the past 20 years were prioritised, with older resources cited for definitions. In addition, credible data was obtained from online health organisation reports and government statistics. The purpose of this approach was to gain a thorough and comprehensive understanding of the topic while not adhering to a rigid search strategy.

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C.MANUSCRIPT

HIV risk perception, actual HIV risk, sexual risk behaviours, and oral PrEP continuation at the 1-month follow-up in pregnant women not living with HIV in Cape Town, South Africa: A mediation analysis

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Abstract

Adolescent girls and young women (AGYW) of reproductive age in South Africa are heavily burdened with HIV. If taken effectively, oral preexposure prophylaxis (PrEP) prevents HIV acquisition in pregnant women without HIV. We investigated factors associated with oral PrEP continuation at the 1-month follow-up and the role of HIV risk perception and actual HIV risk in motivating oral PrEP continuation in pregnant women. Data from a cohort of pregnant and postpartum women without HIV in Cape Town, South Africa (PrEP-PP), were analysed using logistic regression models and mediation analysis to assess factors associated with oral PrEP continuation at 1-month and the extent to which HIV risk perception and actual HIV risk explain the relationship between sexual risk behaviours and oral PrEP continuation. Of the 1349 pregnant women enrolled, 84% initiated PrEP at the first antenatal care (ANC) visit. Unemployment (aOR=1.33; 95% CI=1.03-1.73), inconsistent condom use during sex (aOR=0.49; 95% CI=0.22-1.00), having a partner living with HIV/unknown HIV status partner (aOR=1.33; 95% CI=1.00-1.77), being at a medium-to-high risk of acquiring HIV (aOR=1.34; 95% CI=1.00-1.78), STI diagnosis at baseline (aOR=1.30; 95% CI=0.98-1.72), and having no current sex partner (aOR=1.63; 95% CI=0.95-2.89) were associated with oral PrEP continuation at 1-month follow-up. Using condoms sometimes during sex (aOR=0.53; 95% CI=0.23-1.12) and being unmarried/not cohabiting (aOR=1.25; 95% CI=0.95-1.66) were marginally associated with oral PrEP continuation. Two-thirds of women misclassified their perceived HIV risk as being at low-risk despite reporting condomless sex or having a partner living with HIV/unknown HIV status partner, highlighting the discordance between actual and perceived HIV risk. The actual HIV risk partially explained the relationship between sexual risk behaviours and oral PrEP continuation at 1-month. Future research is needed on improving accurate assessments of HIV risk to improve PrEP continuation in pregnancy and postpartum.

Keywords women not living with HIV · oral PrEP · HIV risk perception · actual HIV risk · mediation analysis · South Africa

1. Introduction

HIV remains a global public health threat. Currently, there are approximately 39.9 million people living with HIV/AIDS, with 1.3 million new HIV infections and 630000 HIV/AIDS-related deaths in 2023 [1]. Sub-Saharan Africans, specifically adolescent girls and young women (AGYW) as well as other women of reproductive age, are greatly affected by the HIV/AIDS epidemic. In 2022, AGYW aged 15-24 years accounted for over 77% of new infections in this region, making them three times more likely to acquire HIV than males [1].

In South Africa, the epicentre of the HIV/AIDS epidemic and where heterosexual sex is the most main mode of HIV transmission, there are over 7 million adults living with HIV, with women accounting for over 60% of new infections [2]. The disproportionality in HIV incidence has been attributed to several biological, socioeconomic, structural, cultural, and socio-behavioural factors. Biological drivers include genital inflammation due to the presence of inflammatory cytokines, immature genito-cervical mucosa in younger women, and a larger surface area of genital mucosa exposed to infectious pathogens and fluids for extended periods of time during sex [3-5]. Socio-behavioural drivers include intergenerational (age-disparate) relationships between older men and young women [6-8].This puts these young women at risk of HIV acquisition, as "HIV is a life-long infection with increased prevalence in older individuals" [4]. Other factors include gender inequalities and hierarchical gender roles, intimate partner violence (IPV), and poverty [9-11]. These factors put women, specifically those who are pregnant and postpartum, at risk of acquiring HIV thus, putting their offspring at risk of mother-to-child transmission (MTCT) of HIV.

Oral preexposure prophylaxis (PrEP) is one of the strategies that can be used to address this issue. It is a highly effective preexposure prophylaxis which can reduce the risk of HIV acquisition when used in conjunction with other safe sexual behaviours in adults at risk of HIV infection [12]. It can be taken daily or on-demand during times of increased risk by individuals not living with HIV before potential exposure to the HI-virus to reduce the risk of contracting the disease. Currently, on-demand PrEP is exclusively recommended for males only, who take "two pills 2-24 hours before sex, 1 pill 24 hours following the first dose, and 1 other pill 24 hours after the second dose" [13]. This approach is known as the 2-1-1 schedule. When taken correctly, this prophylactic can reduce the risk of HIV acquisition through sex by 99% [14]. Additionally, oral PrEP is safe to use during pregnancy and the postpartum period and is not associated with any adverse outcomes during these periods [15-17].

Oral PrEP roll-out in South Africa was first approved in 2016 at primary health care sites and was exclusively for sex workers [18]; however, roll-out was later expanded to other at-risk populations, including men who have sex with men (MSM), serodiscordant couples, pregnant women, and AGYW. However, despite the massive roll-out of oral PrEP by South Africa and other countries, it has been

difficult to achieve adherence (initiation and continuation) [19]. Monitoring oral PrEP continuation is imperative in providing estimates of the potential impact of oral PrEP as an HIV prevention method and in measuring the success of projects implementing oral PrEP use [20]. Although it holds promise, not much is known about oral PrEP use and continuation in pregnant women not living with HIV or about factors affecting oral PrEP continuation.

To understand the complexities of HIV infection in pregnant women not living with HIV, we need to understand the relationship between sexual risk behaviours, HIV risk perception, actual HIV risk, and oral PrEP continuation. Mediation analysis, which involves the presence of a mediator or intermediate variable, helps explain how or why an exposure variable influences the outcome variable. In the context of treatment studies, studying the mediational process helps us evaluate how the treatment/intervention achieves the study outcome of interest [21]. Moreover, it can also help us identify alternative, more efficient intervention strategies. Perceived susceptibility/risk is one of the key constructs when looking at health behaviour changes, and many HIV/AIDS interventions and prevention campaigns are guided mostly by behaviourist and behavioural models. One such model is the health belief model (HBM), which suggests that individuals will act based on their intentions and behaviour [22]. This model focuses mainly on threat perception and behavioural evaluation [23]. In many HIV mediation analyses, within the structural equation modelling network, risk perception is included as a mediator, suggesting that this variable may play a key role in influencing the outcome, which is oral PrEP continuation at the 1-month follow-up in the context of our study. Determining whether HIV risk perception mediates the relationship between certain exposures and outcomes in pregnant women not living with HIV will help determine if HIV risk perception is an appropriate target for HIV prevention programmes. Furthermore, determining actual HIV risk's role in mediating the relationship between the exposure and outcome might provide an alternative, more efficient target for evaluating the success of an intervention.

To address this gap, we used data from a cohort of pregnant and postpartum women not living HIV in Cape Town, South Africa. The goal of this secondary analysis was to assess factors affecting oral PrEP continuation at the 1-month follow-up in this cohort of women, as well as to investigate the mediating potential of HIV risk perception and actual HIV risk for the relationship between sexual risk behaviours and oral PrEP continuation at the 1-month follow-up.

2. Methods

2.1 Study participants

This study is a secondary analysis of the Pre-Exposure Prophylaxis in Pregnancy and Postpartum Period (PrEP-PP) study, where study recruitment began in August 2019 and ended in October 2021. For this secondary analysis, we included a sample of 1349 pregnant women not living with HIV. It utilised data collected on sociodemographic factors and attitudes and behaviours towards HIV acquisition. Eligible, consenting adolescents and women (≥ 16 years) were followed-up for 12 months post-partum. Details of the study design and data collection methods for the PrEP-PP study have been previously published [24].

2.2 Measures

Sexual risk behaviours

This was the exposure of interest, measured using a component indicator that was composed of five variables as indicated:

- Sexually transmitted infection (STI) diagnosis at baseline
- Number of sexual partners in the preceding three months
- Condom use during sex in the preceding three months
- Partner serostatus
- Marital status

The sexual risk behaviours component measure measures adolescent girls and women who had no sexual partners, one partner, or more than one partner and the frequency of condom use during sex in the preceding three months with those partners.

Each of the risk factors making up this component measure that was not already dichotomised, was dichotomised to allow for mediation analysis using structural equation modelling to investigate associations between sexual risk behaviours, HIV risk perception, actual HIV risk, and PrEP continuation at the 1-month follow-up.

Oral PrEP continuation at the 1-month follow-up

This outcome of interest was measured as the desire to want to continue with a PrEP prescription at the 1-month follow-up following PrEP initiation at baseline. This variable was dichotomised into those who

continued with their oral PrEP prescription and those who discontinued their oral PrEP prescription. Participants with no entries/missing data for this variable were considered to have discontinued their PrEP prescription.

Mediation

HIV risk perception was obtained from participants who were not taking oral PrEP. Participants were asked about their chances of acquiring HIV in the next year, with possible responses: “no chance at all”, “small chance”, “moderate chance”, “great chance”, and “I don’t know”. The variable was dichotomised into no-to-low HIV risk perception and medium-to-high HIV risk perception.

The actual HIV risk was calculated using a risk score, composed of five risk factors:

- STI diagnosis at baseline
- Number of sexual partners in the preceding three months
- Condom use during sex in the preceding three months
- Partner serostatus
- Marital status

Having no-to-low actual HIV risk included having 0 or 1 risk factor, and medium-to-high actual HIV risk included having ≥ 2 of the abovementioned risk factors. Any risk factor with no entry or a missing value was considered to be 0 to calculate the risk score.

2.3 Data analysis

The descriptive statistics were used to describe the data distribution. Medians and interquartile ranges (IQRs) were used for continuous variables and proportions and percentages were used for categorical variables, stratified by maternal age group. We assessed whether women who were at medium-to-high actual HIV risk had perceived themselves as such at baseline using a confusion matrix as the classification model. We fit univariable and multivariable models of each of the sociodemographic and sexual behaviour risk factors to examine which factors were associated with oral PrEP continuation at the 1-month follow-up to estimate the crude oods ratios (Ors), adjusted odds ratios (aORs), and 95% confidence intervals (CIs). Multivariable models were adjusted for continuous maternal age at baseline, gestational age at baseline, and level of education (categorical). Mediation analysis was performed within the structural equation modelling (SEM) framework using the *lavaan* package in R [25]. The model was based on categorical variables; therefore, we used Diagonally Weighted Least Squares (DWLS) to estimate the model parameters and Weighted Least Squares Mean and Variance adjusted (WLSMV) for the test statistics. Model fit statistics, namely, the comparative fit index (CFI), Tucker–Lewis index (TLI), root mean square of approximation (RMSEA), and standardised root mean square residuals (SRMR) were used to assess the adequacy of the structural equation model. A good model fit

is indicated by a CFI > 0.95, TLI > 0.95, RMSEA < 0.06, and SRMR < 0.08 [26]. All the statistical analyses were performed in R version 4.3.1 [25].

3. Results

3.1 Participant characteristics

We collected and analysed data from 1341 pregnant women not living with HIV, with participants being stratified into two age groups, those who are 16–24 years old and > 24 years old (Table 2). The median age at enrollment across the whole sample was 26 years (IQR = 22–31 years). The median gravidity was 2 (IQR = 1 – 3), with most of the women having a baseline gestational age ≥ 20 weeks (58.4%), a secondary level of education (90.1%), and were either unemployed or not studying (53.4%). Among those 16–24 years old, 68.9% of them were not married/not cohabiting whereas 42.6% were in the > 24 years old age group. A slightly higher proportion (31%) of women aged 16–24 years had a partner who was either living with HIV or had an unknown HIV status. Furthermore, 41% of women aged 16 – 24 years tested positive for an STI, while only 24% of those age > 24 years tested positive. Ninety-four percent of women across both age groups reported having only one sexual partner in the past three months. Similar proportions of women in both age groups reported having had vaginal sex at baseline (97% for 16–24 year-olds and 98% for those > 24 years), with more women aged > 24 years engaging in sex 5 or more times per month (45%), and rarely/never using condoms during sex (79%). A small proportion of women > 24 years of age perceived that they had a great chance of HIV acquisition (4%) compared to only 2% in women aged 16 – 24 years at baseline. A total of 58.5% of women in the 16 – 24 years old age group and 52% of those older than 24 years old perceived themselves to have no chance at all, of acquiring HIV.

3.2 Prediction of HIV risk perception versus actual HIV risk

Table 1. Confusion matrix results for the classification of the risk of HIV acquisition based on sexual risk behaviours among pregnant women not living HIV.

	HIV risk perception	
Actual HIV risk	Medium-to-high risk (≥ 2 risk factors)	No-to-low risk (0 or 1 risk factors)
Medium-to-high risk (≥ 2 risk factors)	107 (8.1%)	854 (64.7%)
No-to-low risk (0 or 1 risk factors)	41 (3.1)	317 (24.0%)

The confusion matrix (Table 1) included a total of 1319 classifications based on HIV risk perception and actual HIV risk. Actual HIV risk is defined as having a risk score of 0 or 1 (no-to-low risk) or a risk score of ≥ 2 (medium-to-high risk) and is the sum of five different risk factors, namely, marital status, number of sexual partners in the preceding three months, partner serostatus, STI diagnosis at baseline, and condom use during sex in the preceding three months. The risk score was calculated based on being positive for the exposure for the above variables. Being exposed would score 1 point whereas being unexposed would score 0 points, and these scores were tallied together for each exposure/non-exposure to make up the risk score. Overall, 72% of women who were at a medium-to-high risk (risk score ≥ 2) actual HIV risk accurately perceived themselves as being at such a risk. However, the matrix also shows that many of the women misclassified their risk of HIV acquisition. The false negative (FN) results revealed that 854 of the women misclassified their risk of HIV acquisition as being at no-to-low risk, whereas they are at medium-to-high actual HIV risk based on their sexual risk behaviours. This suggests a discordance between HIV risk perception and actual HIV risk. The specificity (27.1%) of the model, which refers to the number of true negative classes that the model/classifier was able to identify, demonstrates how poorly the model identifies the negative class (no-to-low risk). To show agreement between the two measures, we calculated Cohen's kappa coefficient, which was calculated to be κ=-0.00186 (p-value = 0.87), indicating poor agreement between HIV risk perception and actual HIV risk.

3.3 Factors affecting oral PrEP continuation at the 1-month follow-up

Oral PrEP continuation at the 1-month follow-up among pregnant women not living with HIV was regressed against sociodemographic characteristics, HIV risk perception, actual HIV risk, and sexual behaviours. Table 3 shows the ORs and aORs for both the univariable and multivariable models for factors affecting oral PrEP continuation at the 1-month follow-up. The multivariable model was adjusted for potential confounding variables of maternal age at baseline, gestational age at baseline, and highest level of maternal education.

The adjusted odds of continuing oral PrEP at the 1-month follow-up were associated with unemployment (aOR = 1.33, 95% CI: 1.03 – 1.73, p = 0.027). Furthermore, the odds of continuing oral PrEP use were 33% greater among those with partners who were living with HIV or with an unknown HIV status (aOR = 1.33, 95% CI: 1.00 – 1.77, p = 0.048) than among those whose partners were not living with HIV. Rarely or never using condoms during sex in the preceding 3 months was also associated with oral PrEP continuation at the 1-month follow-up (aOR = 0.49, 95% CI: 0.22 – 1.00, p = 0.064). Other sociodemographic and sexual factors associated with oral PrEP continuation at the 1-month follow-up included having at a medium-to-high actual HIV risk (aOR = 1.34, 95% CI: 1.00 – 1.78, p = 0.049) and having a positive STI diagnosis at baseline (aOR = 1.30, 95 CI: 0.98 – 1.72, p = 0.067). The odds of continuing oral PrEP use at the 1-month follow-up were 63% greater for women who reported having no current sex partners than for women who were either unmarried or not cohabiting (aOR = 1.63, 95% CI: 0.95 – 2.89, p = 0.082). Not being married/not cohabiting (aOR = 1.25, 95% CI: 0.95 – 1.66, p = 0.110) and sometimes using condoms during sex (aOR = 0.53, 95% CI: 0.23 – 1.12, p = 0.110) were marginally associated with oral PrEP continuation at the 1-month follow-up.

Table 2. Baseline characteristics of pregnant women not living with HIV in the PrEP-PP study in Cape Town, South Africa *(n = 1341).*

	Overall (n =1341)	**16 – 24 years (n = 560)**	**> 24 years (n = 781)**
Sociodemographic characteristics			
Gravidity			
Median (IQR)[a]	2 (1 – 3)	1 (- 2)	3 (2 – 3)
Gestational age (weeks) n (%)[b]			
< 20 weeks at baseline	548 (41.6)	190 (34.3)	358 (46.9)
≥ 20 weeks at baseline	770 (58.4)	364 (65.7)	406 (53.1)
Level of education n (%)[c]			
Primary or no education	21 (1.6)	9 (1.6)	12 (1.6)
Secondary	1189 (90.1)	502 (90.5)	687 (89.8)
Tertiary	110 (8.3)	44 (7.9)	66 (8.6)
Marital status n(%)			
Married/cohabiting	502 (37.2)	110 (19.6)	392 (50.2)
Unmarried/not cohabiting	719 (53.3)	386 (68.9)	333 (42.6)
No current sex partner	120 (9.5)	64 (11.4)	56 (7.2)
Employment status n (%)[d]			
Full-time employment	341 (25.8)	90 (16.2)	251 (32.8)
Part-time employment	119 (9.0)	28 (5.0)	91 (11.9)
Informal employment	8 (0.6)	2 (0.4)	6 (0.8)
Attending school/university	147 (11.3)	125 (22.5)	22 (2.9)
Unemployed/not studying	705 (53.4)	310 (55.9)	395 (51.6)
STI diagnosis at baseline n (%)[e]			
Positive	441 (31.1)	225 (40.6)	186 (24.3)
Negative	903 (68.4)	326 (58.7)	577 (75.4)
Not tested	6 (0.5)	4 (0.7)	2 (0.3)
Partner serostatus n (%)[f]			
Partner not living with HIV	936 (70.9)	383 (69.0)	553 (72.3)
Partner living with HIV or unknown status	384 (29.1)	172 (31.0)	212 (27.7)
HIV risk perception at enrollment n (%)[g]			
No chance at all	723 (54.8)	324 (58.5)	399 (52.2)
Small/moderate chance	554 (42.0)	218 (39.4)	336 (43.9)
Great chance	42 (3.2)	12 (2.2)	30 (3.9)

Table 2. (Continued)

PrEP initiation at baseline n (%)[h]			
Yes	1126 (85.3)	449 (83.8)	677 (86.4)
No	194 (14.7)	87 (16.2)	107 (13.6)
Sexual behaviours			
Vaginal sex at baseline n (%)[i]			
Yes	1285 (97.4)	537 (96.9)	748 (97.8)
No	34 (2.6)	17 (3.1)	17 (2.2)
Sexual activity in the preceding 3 months n (%)[j]			
< 5 times or no sex	762 (59.3)	348 (64.8)	414 (55.3)
≥ 5 times	523 (40.7)	189 (35.2)	334 (44.7)
Number of sexual partners in the preceding 3 months n (%)[k]			
No sexual partners	34 (2.6)	17 (3.1)	17 (2.2)
1 partner	1240 (94.0)	513 (92.6)	727 (95.0)
≥ 2 partners	45 (3.4)	24 (4.3)	21 (2.8)
Condom use during sex, in those sexually active n (%)[l]			
Always/almost always	52 (4.0)	21 (3.9)	31 (4.1)
Sometimes	274 (21.3)	148 (27.6)	126 (16.9)
Rarely/never	958 (74.6)	368 (68.5)	590 (79.0)

Note: Data available only for those who reported having vaginal sex or having sexual partners.

[a, c, d, e, f] Data available for only 1320 participants, 555 16 – 24 year olds and 765 > 24 year olds.

[b] Data available for only 1318 participants, 548 16 - 24 year olds and 770 > 24 year olds.

[g, i, k] Data available for only 1319 participants, 554 16 – 24 year olds and 765 > 24 year olds.

[h] Data available for only 1320 participants, 536 16 - 24 year olds and 784 > 24 year olds.

[j] Data available for only 1285 participants, 537 16 - 24 year olds and 748 > 24 year olds. 64 missing entries.

[l] Data available for only 1284 participants, 537 16 - 24 year olds and 747 > 24 year olds.

Table 3. Associations between maternal sociodemographic characteristics and sexual behaviours and factors affecting oral PrEP continuation, defined as continuing PrEP prescription at the 1-month follow-up post PrEP initiation in pregnant women not living with HIV *(n = 1127).*

	Continue at 1 month (n = 762, 67.6)	**Discontinue at 1 month (n = 365, 32.4)**	**Crude OR (95% CI)**	**p value**	**Adjusted OR** (95% CI)**	**p value**
Maternal age in years Median (IQR)	26 (22 – 31)	26 (22 – 30)	1.01 (0.99 – 1.03)	0.400	1.01 (0.98 – 1.03)	0.500
Gestational age in weeks Median (IQR)	22 (15 – 30)	22 (15 – 32)	0.99 (0.98 – 1.01)	0.300	0.99 (0.98 – 1.01)	0.400
Gravidity n (%)						
1 pregnancy	240 (21.3)	127 (11.3)	-		-	
>1 pregnancies	522 (46.3)	238 (21.1)	1.16 (0.89 – 1.51)	0.300	1.08 (0.78 – 1.50)	0.600
Level of education n (%)						
Primary or no education	13 (1.2)	4 (0.4)	-		-	
Secondary	690 (61.2)	330 (29.3)	0.64 (0.18 – 1.83)	0.400	0.67 (0.19 – 1.90)	0.500
Tertiary	59 (5.2)	31 (5.2)	0.59 (0.15 – 1.82)	0.400	0.59 (0.16 – 1.85)	0.400
Marital status n (%)						
Married/cohabiting	281 (26.8)	149 (14.2)	-		-	
Unmarried/not cohabiting	423 (40.4)	195 (18.6)	1.15 (0.89– 1.49)	0.300	1.25 (0.95 – 1.66)	0.110
No current sex partner	58 (5.1)	21 (1.9)	1.46 (0.87 – 2.55)	0.200	1.63 (0.95 – 2.89)	**0.082***
Employment status n (%)						
Employed	337 (29.9)	186 (16.5)	-		-	
Unemployed/not studying	425 (37.7)	179 (15.9)	1.31 (1.02 – 1.68)	**0.034***	1.33 (1.03 – 1.73)	**0.027***

Table 3. (Continued)

STI diagnosis at baseline n (%)						
Negative	506 (44.9)	260 (23.1)	-		-	
Not tested	2 (0.2)	2 (0.2)	0.51 (0.06– 4.30)	0.500	0.50 (0.06 – 4.17)	0.500
Positive	254 (22.5)	103 (9.1)	1.27 (0.97– 1.67)	**0.090***	1.30 (0.98 – 1.72)	**0.067***
Partner's serostatus n (%)						
Partner not living with HIV	525 (46.6)	271 (24.0)	-		-	
Partner living with HIV or unknown status	237 (21.0)	94 (8.3)	1.30 (0.99 – 1.73)	**0.065***	1.33 (1.00 – 1.77)	**0.048***
HIV risk perception at enrollment n (%)						
No-to-low risk	668 (59.3)	330 (29.3)	-		-	
Medium-to-high risk	94 (8.3)	35 (3.1)	1.33 (0.89 – 2.02)	0.200	1.31 (0.88 – 2.00)	0.200
Actual HIV risk n (%)						
No-to-low risk	191 (16.9)	109 (9.7)	-		-	
Medium-to-high risk	571 (50.7)	256 (22.7)	1.27 (0.96 – 1.68)	**0.089***	1.34 (1.00– 1.78)	**0.049***
Sexual behaviours						
Vaginal sex n (%)						
No	20 (1.8)	8 (0.7)	-		-	
Yes	742 (65.8)	357 (31.7)	0.83 (0.34 – 1.84)	0.700	0.81 (0.33 – 1.79)	0.600
Number of sexual partners in the past 3 months n (%)						
No sexual partners	20 (0.7)	8 (1.8)	-		-	
1 partner	713 (63.3)	346 (30.7)	0.82 (0.34 – 1.82)	0.600	0.80 (0.33 – 1.77)	0.600
≥ 2 partners	29 (2.6)	11 (1.0)	1.05 (0.35 – 3.08)	> 0.900	1.14 (0.37 – 3.41)	0.800

Table 3. (Continued)

Sexual activity in the past 3 months n (%)						
< 5 times or no sex	439 (39.9)	303 (19.5)	-		-	
≥ 5 times	214 (27.6)	143 (13.0)	1.03 (0.80 – 1.34)	0.800	1.02 (0.79 – 1.32)	0.900
Condom use during sex, in those sexually active n (%)						
Always/almost always	35 (3.2)	9 (0.8)	-		-	
Sometimes	161 (14.6)	76 (6.9)	0.54 (0.24 – 1.15)	0.130	0.53 (0.23 – 1.12)	0.110
Rarely/never	546 (49.7)	272 (24.7)	0.52 (0.23 – 1.04)	**0.083***	0.49 (0.22 – 1.00)	**0.064***

* significant at p-value < 0.10.

** adjusted for maternal age at baseline, highest level of maternal education, and gestational age.

3.4 Mediation analysis

Measurement model

Our confirmatory factor analysis (CFA) yielded CFI = 0.67, TLI = 0.34, RMSEA = 0.06, and SRMR = 0.11. Collectively, these model fit statistics do not suggest a good model fit where the variables that make up our latent construct of sexual risk behaviours (comprising of variables condom use in the preceding three months, the number of sexual partners in the preceding 3 months, STI diagnosis at baseline, partner serostatus, and marital status) accurately capture the latent variable.

Structural model

To test this hypothesis, we performed a mediation analysis within a structural equation modelling framework. We first tested the mediating roles of both HIV risk perception and actual HIV risk on the relationship between sexual risk behaviours and oral PrEP continuation at the 1-month follow-up, without adjusting for other covariates. The standardised estimates for this structural equation model are presented in Figure 1, and the results were examined.

The direct effect of sexual risk behaviours on oral PrEP continuation at the 1-month follow-up was not statistically significant ($\beta = 0.001$, $p = 0.964$, 95% CI = -0.133 – 0.103). The results further indicated that sexual risk behaviours had a positive, nonsignificant association with HIV risk perception ($\beta = 0.010$, $p = 0.765$, 95% CI = -0.144 – 0.21). HIV risk perception also had a positive, nonsignificant association with oral PrEP continuation ($\beta = 0.098$, $p = 0.105$, 95% CI = -0.020 – 0.237). The indirect effect of sexual risk behaviours on oral PrEP continuation at the 1-month follow-up through HIV risk perception, which was estimated using the product of the two coefficients was not significant ($\beta = 0.001$, $p = 0.820$, 95% CI = -0.022 – 0.036), suggesting that HIV risk perception is not a significant mediator between sexual risk behaviours and oral PrEP continuation.

Sexual risk behaviours had a significant, negative association with actual HIV risk ($\beta = -2.25$, $p < 0.001$, 95% CI = 4.212 – 8.839). Similarly, the results also showed a significant, negative association between actual HIV risk and continuation of oral PrEP at the 1-month follow-up ($\beta = -0.09$, $p < 0.015$, 95% CI = 0.020 – 0.171), implying that women who are at medium-to-high actual HIV risk are less likely to continue to use oral PrEP at the 1-month follow-up. The indirect effects of sexual risk behaviours on oral PrEP continuation via the mediator actual HIV risk were significant ($\beta = 0.195$, $p = 0.007$, 95% CI = 0.113 – 0.921), suggesting that actual HIV risk is a partial mediator of the relationship between sexual risk behaviours and oral PrEP continuation at the 1-month follow-up.

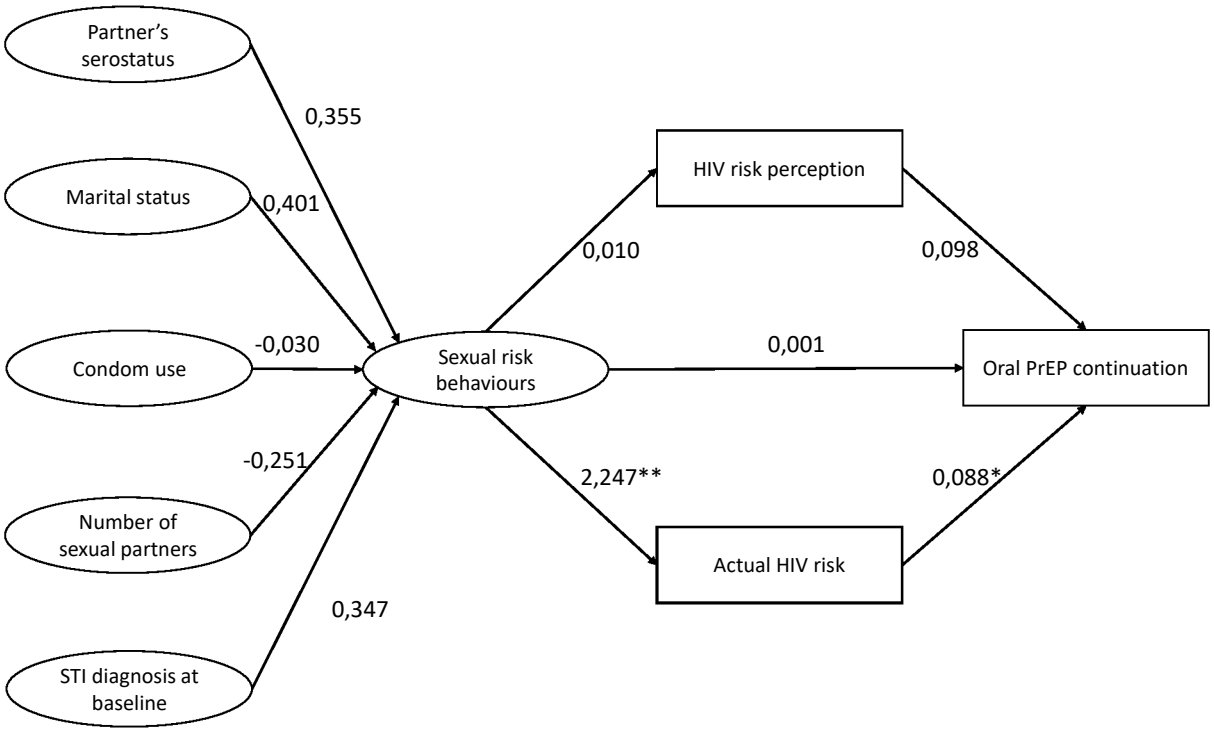
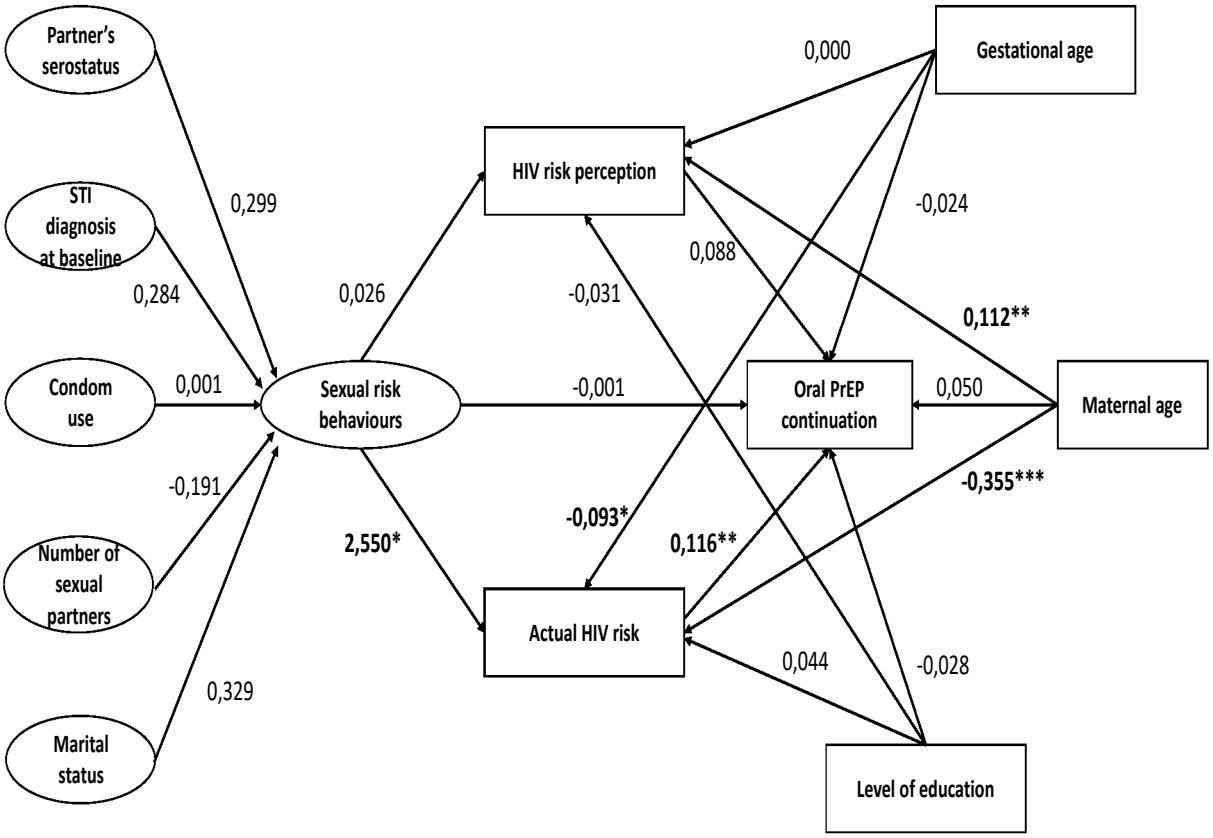


Fig. 1 The results for the unadjusted mediation analysis within the structural equation modelling framework

We further explored the model by adjusting for covariates that were potential confounders for the relationship between sexual risk behaviours and oral PrEP continuation at the 1-month follow-up, namely, maternal age, gestational age, and highest level of maternal education. The results from the adjusted model (Figure 2) indicated that the direct relationship between sexual risk behaviours and oral PrEP continuation at the 1-month follow-up was not significant (β = -0.001, p = 0.945, 95% CI = -0.129 – 0.095). Sexual risk behaviours were not associated with the perception of a medium-to-high risk of HIV acquisition (β = 0.03, p = 0.383, 95% CI = -0.076 – 0.289). Furthermore, HIV risk perception was not associated with oral PrEP continuation (β = 0.09, p = 0.130, 95% CI = 0.003 – 0.211). The indirect pathway was not statistically significant, suggesting that HIV risk perception is not a significant mediator in the relationship between sexual risk behaviours and oral PrEP continuation at the 1-month follow-up (β = 0.002, p = 0.615, 95% CI = -0.014 – 0.061). Among the covariates included in the second model (Figure 2), maternal age was associated with medium-to-high HIV risk perception (β = 0.11, p = 0.017, 95% CI = 0.003 – 0.036). This indicates that with increasing maternal age, there is also an increase in the perception of risk of HIV acquisition. Maternal age was also negatively statistically associated with actual HIV risk (β = -0.35, p < 0.001, 95% CI = -0.075, -0.057), with the direction of the association suggesting that an increase in maternal age is associated with decreased actual HIV risk

(no-to-low risk actual HIV risk). Gestational age was negatively associated with actual HIV risk (β = -0.09, p = 0.014, 95% CI = -0.018, -0.001), suggesting that those who are further along in their pregnancy (increased gestational age) are likely to be at no-to-low risk of actually acquiring HIV (decreased actual HIV).

The indirect effects of sexual risk behaviours on oral PrEP continuation through HIV risk perception were not significant (β = 0.002, p = 0.615, 95% CI = -0.014 – 0.061), suggesting that HIV risk perception is not a significant mediator between sexual risk behaviours and oral PrEP continuation. The indirect effects of sexual risk behaviours on oral PrEP continuation at the 1-month follow-up, through actual HIV risk, were statistically significant (β = 0.296, p = 0.013, 95% CI = -0.347 – 1.658). This indicates that actual HIV risk is a significant partial mediator in the relationship between sexual risk behaviours and oral PrEP continuation at the 1-month follow-up. Furthermore, the model fit statistics for our unadjusted and adjusted mediation models yielded CFI = 0.992, TLI = 0.987, RMSEA = 0.041, SRMR = 0.099, CFI = 0.755, TLI = 0.792, RMSEA = 0.148, and SRMR = 0.11. This suggests that the unadjusted model has a better model fit.



* p < 0.05 ** p < 0.01 *** p < 0.001

Fig. 2 Results for the adjusted mediation model using structural equation modelling

4. Discussion

In this study of pregnant women not living with HIV, in Cape Town, South Africa, we sought to explore the risk factors associated with oral PrEP continuation at the 1-month follow-up and the mediation potential of HIV risk perception and actual HIV risk in the relationship between sexual risk behaviours and oral PrEP continuation at the 1-month follow-up. Oral PrEP was offered to the pregnant women at study baseline, with about 85% of women initiating oral PrEP. Of those who returned at the 1-month follow-up, 67.7% of the women continued using oral PrEP at the 1-month follow-up.

Oral PrEP continuation

In our analysis, we found that having a partner living with HIV or an unknown HIV status, having no current sex partner, being at a medium-to-high actual HIV risk, having an STI diagnosis at baseline, never or rarely using condoms during sex in the-preceding three months, and being unemployed were associated with oral PrEP continuation at the 1-month follow-up in pregnant women not living with HIV. Consistent with previous findings in persons from Kenya and South Africa [27,28], continuing oral PrEP use while having a partner living with HIV or an unknown HIV status, suggests that individuals continue oral PrEP use moderately well when they are unaware of their partner's HIV status or if they are aware that their partners are living with HIV. This makes it vital that there is education for people in who are in diverse (serodiscordant) relationships regarding protecting oneself, and their partner, from becoming infected with HIV. Women with no current sexual partners may have continued using oral PrEP because relationship statuses change overtime. Continued use would guarantee them protection against HIV infection should they get into relationships as time progresses. Our findings also contradict other study findings [29], where it was found that there was decreased condom use following oral PrEP adherence. Both these findings in our study underscore oral PrEP's perceived value in reducing the risk of HIV infection. Our evidence also highlights that the study participants may understand their risk of HIV infection given their frequent participation in condomless sex. This knowledge may be attributed to the ongoing HIV counselling for the women where HIV education and support is offered to women enrolled in the study. A recent study in pregnant women not living with HIV in Cape Town, South Africa [30], also found that women with an STI diagnosis at baseline continued oral PrEP use at study follow-up, consistent with our findings. This implies that women with historic STI diagnoses may be away of their predisposition to HIV infection. Other factors marginally associated with oral PrEP continuation included sometimes using condoms during sex in the preceding three months and not being married/not cohabiting.

Our results did not support the hypothesis that women with a medium-to-high HIV risk perception would continue oral PrEP use at the 1-month follow-up. Inconsistent with our study, other studies in pregnant women in Kenya and Malawi demonstrated that having a high perceived risk of HIV infection is associated with oral PrEP interest and/or continuation [27, 31-33]. Our findings somewhat align with the HBM, which suggests that individuals will act and take on preventative measures should they feel they are at risk of acquiring an illness or that their personal health is threatened [34]. Although a small proportion, more women who perceived themselves to be at a medium-to-high risk of HIV acquisition continued with oral PrEP at 1-month follow-up on PrEP. This was also noted for the actual HIV risk variable.

HIV risk score, HIV risk perception, and actual HIV risk

Women at a medium-to-high actual HIV risk misclassified themselves as being at no-to-low risk of HIV acquisition. This classification was based on an adapted risk score that we used to fit our data and reflect our sexual risk behaviours. The misclassification is representative of South African young women's tendency to misclassify their risk of acquiring HIV and may indicate a lack of knowledge or acknowledgement of sexual risk behaviours that may contribute to HIV acquisition. One other reason there could be for this misclassification between HIV risk perception and actual risk is there is no consensus for a perfect actual HIV risk score, with various studies making use of different variables and methods to calculate this risk score [32,35]. This discordance between HIV risk perception and actual HIV risk can put pregnant women not living with HIV at risk of acquiring HIV during periods of sexual activity. A reason for this misperception may be that participants were certain as to how they would assess their risk of HIV acquisition or may have limited knowledge regarding disease transmission [36]. This is concerning as this means pregnant women undermine their risk and could potentially partake or continue to partake in behaviours that would increase their risk of acquiring HIV and vertical transmission to their offspring. Another reason would be that these women may believe their partners are also not living with HIV and, therefore, assume their risk of HIV acquisition is low. This necessitates more partner HIV testing so women can have more accurate perceptions of their risk of HIV acquisition. This also highlights the need for access to oral PrEP regardless of self-perceived HIV risk, especially in high prevalence settings.

Our findings could be useful for raising awareness by highlighting the tendency of AGYW and other women of reproductive age to misclassify their risk of acquiring HIV. This could create a demand for oral PrEP, as women will have a clearer idea of their chances of becoming infected due to their sexual behaviours. Because our recommendation is access to oral PrEP for all, regardless of risk, we also further suggest that screening for oral PrEP recommendation not to be put at the forefront, as this is the current guideline. These screenings are prone to desirability bias, where respondents give answers that

they perceive to be more socially desirable/acceptable. Access to PrEP for all may also combat stigma, where oral PrEP use becomes "normalised" versus it being used exclusively by those viewed to be at risk of acquiring HIV.

Mediation by HIV risk perception and actual HIV risk

To understand the mediation potential of HIV risk perception and actual HIV risk, we performed a mediation analysis through the structural equation modelling framework to investigate this relationship. The hypothesised role of HIV risk perception as a potential mediator was not supported, and the hypothesised mediation role of actual HIV risk was supported. Contrary to available literature [32], our study found that HIV risk perception did not mediate the relationship between sexual risk behaviours and oral PrEP continuation. Our finding could be impacted by our inability to accurately capture the latent variable (our exposure) of sexual risk behaviours by failing to incorporate all aspects/variables that make up this variable. The mediation results indicate that actual HIV risk partially mediated the relationship between sexual risk behaviours and oral PrEP continuation at the 1-month follow-up, therefore it is fair to assume that actual HIV risk is a plausible mechanism for oral PrEP continuation at the 1-month follow-up in pregnant women not living with HIV. However, it is important to note that both sexual risk behaviours and actual HIV risks are made up of the same variables, resulting in these two variables being highly correlated.

Our findings have relevance for both research and clinical practise with regards to pregnant women not living with HIV. Firstly, these findings demonstrate the importance of understanding factors which influence oral PrEP continuation amongst women not living with HIV and any other mechanisms which might drive or influence oral PrEP continuation. We also assert that future research thoroughly investigates the role that actual HIV risk plays, as significant findings underscore the importance of accurately assessing and determining women's risk of HIV acquisition in PrEP studies. However, these PrEP studies should not only focus on addressing and changing sexual risk behaviours but should also focus on improving the accurate perception of one's risk amongst individuals. Lastly, our non-significant findings for the indirect path via HIV risk perception suggests that future interventions and/or other studies should not solely focus on HIV risk perception as a relevant intermediate variable for oral PrEP continuation. Other studies could focus on longitudinal studies to investigate the mediation potential of HIV risk perception on the relationship between sexual risk behaviours and oral PrEP continuation by assessing risk perception at multiple time points.

Stigmatisation and oral PrEP use

Stigma surrounding the use of oral PrEP is newly emerging as a barrier to oral PrEP interest, initiation, and [37,38]. More effort is needed to dismantle stigma associated with the use of oral PrEP, especially in PBFW. The first step is publicising oral PrEP as an intervention that is effective in reducing the chances of acquiring HIV, when taken correctly, amongst those not living with HIV as opposed to an intervention targeted for those who are at "significant risk" of HIV acquisition. Furthermore, campaigns promoting oral PrEP use should also focus on promoting positive images of oral PrEP users as the use of oral PrEP has been associated with a negative image [39]. One way to achieve this is through a change in the language used. Oral PrEP needs to be spoken of as an intervention for "sexual wellbeing" and not for those practising risky sexual behaviours [40]. Campaigns should also emphasize the positives of taking oral PrEP [39], especially for PBFW, such as non-negotiation during sex unlike when using condoms. Addressing and ultimately reducing stigmas will allow us to maximise the HIV prevention benefit of oral PrEP.

Limitations

Our results have some limitations. Firstly, the participant's data was collected from only one clinic located in an urban area, which may affect the generalisability of the study findings to other pregnant women not living with HIV. A suggestion would be to conduct more research of this nature in a different setting, such as a rural area, and across more than one clinic. Secondly, reporting on HIV risk perception based on sexual risk behaviours may have been susceptible to issues of social desirability. Women may have provided answers on their sexual behaviours which they deemed more socially desirable versus providing more accurate information pertaining to their sexual behaviours. Alternative interviewing techniques, that allow anonymity in the collection of sensitive information regarding sexual risk behaviours, could be used. One alternative technique would be Audio-Computer Assisted Self-Interview (ACASI) where interviewees listen to pre-recorded questions regarding sensitive topics and answer through other gadgets. Thirdly, there were model fit issues, specifically for the CFA for capturing the latent/exposure variable (sexual risk behaviours). Variables used to capture the latent variable did not accurately capture the latent variable, which could possibly undermine the validity of any of the subsequent analysis related to mediation analysis within a structural equation modelling framework and how it influences PrEP continuation. Therefore, there should be a reassessment of the measurement model or the use of different or alternative analytic approaches.

5. Conclusions

Our results highlight the relationship between sexual risk behaviours, HIV risk perception, actual HIV risk, and oral PrEP continuation at the 1-month follow-up. A better understanding of the relationship between actual HIV risk and HIV risk perception is required to possibly encourage health-seeking behaviours among at-risk populations. We established that actual HIV risk, defined as the lifetime risk of acquiring HIV through exposure to the HI-virus, is a plausible mechanism in understanding PrEP continuation in pregnant women not living with HIV based on their sexual risk behaviours. However, we could not establish the overall mediation relationship of HIV risk perception between sexual risk behaviours and oral PrEP continuation at 1 month follow-up. Based on the findings of the relationship between sexual risk behaviours and oral PrEP continuation at the 1-month follow-up, it is recommended that women be categorised based on their actual/real risk of HIV acquisition, based on their sexual behaviours, instead of categorisation by their perceived risk.

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D.APPENDICES

Appendix A: Informed consent forms

TITLE OF RESEARCH: Evaluation of pre-exposure prophylaxis (PrEP) initiation, retention and adherence in pregnant and breastfeeding women

INTRODUCTION

Good Morning/Afternoon. My name is_____. I work for the University of Cape Town. We would like to ask you to participate in a research study. The purpose of the study is to evaluate the use of pre-exposure propylaxis, also known as PrEP, which is an antiretroviral drug, to prevent HIV acquisition in pregnant and breastfeeding women. This study is being run by public health researchers from the University of Cape Town, South Africa in collaboration with researchers from the University of California, Los Angeles. We have selected (*select one:)* Gugulethu Midwife Obstetric Unit (OR Hanover Park) Midwife Obstetric Unit to recruitstudy participants.

Before you decide if you want to take part, I will tell you more about the risks and benefits are to you and your unborn baby, and what would be expected of you. This information is described in theconsent form, which I will give to you now. You will follow a video of the consent form being read, and a counselor is here to answer any questions. If you agree to participate, I will ask you to sign theform or make your thumb print mark confirming your willingness to participate. I will give you a copy of the signed consent form to keep.

Why is this study being done?

During pregnancy and breastfeeding, the risk of HIV infection is high. The purpose of the study is to evaluate if pregnant and breastfeeding women like you are interested in taking pre-exposure prophylaxis (called PrEP) to prevent HIV. If women do take it, we will evaluate how long they take itfor and how they feel when they take it. Even though previous research has shown that antiretroviral therapy does not increase risk of maternal or infant health problems, we will keep track of any side effects to the mother or infant during the study. At this time, PrEP is not used in South Africa in pregnant and breastfeeding women.

By taking part in this study you will help us collect data that will help determine how to best providePrEP for pregnant women, and reduce the number of pregnant women and babies infected with HIV.

Why are you being asked to take part?

Because you are pregnant and are HIV-negative, and you are coming to a community health centerfor your care. This study will help prevent you and your baby from getting HIV.

How many people will take part in the study?

1200 HIV-negative pregnant women.

How long will the study last?

The study lasts until 12 months after you give birth. There is one study visit every 3 months.

What do we do to decide if you are eligible to take part?

For you to participate in this study you must be:

1) 16 years old or older,
2) attending your first antenatal care visit for this pregnancy,
3) be HIV-negative at your first antental care visit,
4) not have any psychological or health problems that could prohibit the use of PrEP
5) planning to give birth in Cape Town,
6) willing to participate in the study.

What will happen if you decide to take part in the study? You will then have certain tests and procedures. These include:

- Recording your personal information, like your age and education level
- As part of the study you will be offered PrEP, which is the oral pill containing antiretroviralsthat prevents HIV
- If you take PrEP, we will take your blood every 6 months to see if you are taking the PrEP.You will not be told the results of these tests.
- If you do not want to take PrEP, you will still be in the study. You will complete the otherparts of the study as normal
- We will offer you HIV counseling and male/female condoms, to prevent HIV

- We will also test your blood at the first visit, and every 3 months to see if your kidney healthchanges. If the kidney health changes you may have to stop taking PrEP until your kidney health improves.
- At every visit, you will receive an HIV test to confirm your status. We will invite your partner(s) to come in for testing as well (though this is not required).
    - If you become HIV-infected, we will help you start treatment immediately and give you counseling to prevent mother to child transmission of HIV.
    - We will follow you up for 6 months to make sure your treatment is working and referyou for additional specialized treatment if any problems are found.
- We will collect samples using a vaginal swab to test you for common sexually transmitted infections (STIs)
    - If you test positive we will give you treatment and we will give you a letter from the clinic that you can give to your partner(s) so they can come get treatment
- We will have access to your medical files to evaluate your or your baby's other health care, laboratory results or health, or hospitalizations during the study (antenatal, postpartum andinfant medical files).
- You will receive the phone number of the study nurse to call or SMS if you have any questionsor concerns, or any side effects you want to report. You can call any time even in between visits.
- In order to follow you up through post-birth, we need to collect contact information from you. This will include phone number(s), email addresses, and home addresses, for you, family members, friends, or others that may help us find you if we lose touch.
- Your participation in each visit may take up to 1.5-2 hours. This will include collecting samples from you, and the time it takes to complete the survey.

What are the risks and discomforts of this study?

Short term side effects of PrEP include nausea, vomiting, dizziness, headache, and fatigue. Theyusually go away the first week or two of PrEP.

Longer term side effects of PrEP include changes in your kidneys, which may mean the kidneys aren'tworking as well as they should. We will follow kindney health and stop PrEP if we find any changes.

Kidney changes usually go away after you stop taking PrEP. The other rare side effect is decreased bone density, which means your bones may fracture more easily, but this will go away after you stop taking PrEP.

Infant side-effects include that the baby may have PrEP in breast milk but there wer no infant side effects. We will record any health problems in the infant during the first year.

Psychological effects: Telling your partner and/or family you are taking PrEP to prevent HIV may cause some stress for you and your partner(s). If you are diagnosed with HIV, telling your partner and/or family may cause some stress for you and your partner(s). If you think your partner(s) will abuse you as a result of finding out that you are taking PrEP or if you are diagnosed with HIV, pleasediscuss this with a member of the study team.

Are there any benefits to you for being in the study?

If you decide to take PrEP during pregnancy and breastfeeding, your risk of getting HIV is very low, up to 99% lower if you don't take PrEP if you take the pills everyday. Your baby will also be protectedfrom HIV if you take PrEP. If you do not decide to take PrEP, you will receive counseling on HIV prevention and testing at each visit to help you protect yourself and your infant from HIV.

What other choices do you have?

Taking part in this study is voluntary. If you choose not to participate, your care at this clinic will NOT be affected today or in the future. If after you join the study, you decide that you no longer want to be involved, you can speak with one of the nurses or study staff, and we will take you off our list and you will not be contacted about the study again.

What will happen when the study is over?

When the study is over, you will no longer be able to get PrEP through the study. We will counsel you about other methods to reduce the risk of getting HIV, including condoms, and tell you how youcan get free condoms from the clinic. Once PrEP is provided in the clinic, we will refer you to other sources of PrEP if you decide to continue taking it.

Will your test results be shared with you?

We will share test results collected during your visits with you and the study nurse will explain what they mean. This includes regular HIV tests, STI tests, and kidney function tests. However, youwill not receive tests that we will evaluate for adherence to PrEP.

Will the results of the research be shared with you?

Once all participants have finished the study, we will write a summary of the results and have it atthe MOU. If you want a copy, we will let you know when it is ready and can provide it to you.

Will any of your blood, tissue or other samples be stored and used for research in the future?

No.

Will you receive any reward for taking part in this study?

At the end of each visit, you will be given a R100 grocery voucher, R20 for transport, and food anddrink while you are at the visit. There is no payment for participation.

Who will see the information which is collected about you during the study?

All information that will be collected from your will be kept confidential. No one but the researcherswill be able to see it. We will not tell anyone about your participation. Your name will not be linkedto your information. Only the special study number we give you will be able to identify you, and only the researchers will know what your number is. We will lock this information up with a lock and key.

What happens if I get hurt taking part in this study?

This research study is covered by an insurance with the University of Cape Town if you suffer a bodily injury because you are taking part in the study. The insurer will pay for all reasonable medical costs required to treat your bodily injury. The insurer will pay without you having to provethat the research was responsible for your injury. You may ask the study doctor for a copy of theseguidelines. The insurer will *not* pay for harm if, during the study, you:

- Use medicines or other substances that are not allowed

- Do not follow the study doctor or nurses's instructions
- Do not tell the study doctor or nurse that you have a bad side effect from the study medicine
- Do not take reasonable care of yourself and your study medicine

It is important to follow the study nurse or doctor's instructions and to report straight away if youhave a side effect from the study medication.

Who do I speak to if I have any questions about the study?

If there is anything that is unclear or if you need further information, please ask us and we will provide it.

FOR ADDITIONAL INFORMATION:

The UCT's Faculty of Health Sciences Human Research Ethics Committee can be contacted on 021 406 6338 in case you have any ethical concerns or questions about your rights or welfare as a participant on this research study.

If you have any questions or have any problems while taking part in this research study, youshould contact:

Professor Landon Myer
School of Public Health and Family Medicine Faculty of
Health Sciences, University of Cape TownTel: 021 406
6661
Email: Landon.Myer@uct.ac.za

If you have questions about this trial, you should first discuss them with your doctor or the Ethics Committee. After you have consulted your doctor or the Ethics Committee and if they have not provided you with answers to your satisfaction, you should write to the South African Medicines Control Council (MCC) at:

The Registrar

Medicines Control Council

Department of Health

Private Bag X828 PRETORIA

001

CONSENT FOR STUDY PARTICIPATION

CONSENT STATEMENT:

I have read this form, or someone has read it to me. I have been offered a copy of this consent form. I was encouraged and given time to ask questions. I agree to participate in the PrEP study,including regular data collection. If I decide to take PrEP, I agree to provide lab specimens as explained in the consent form. I know that I may withdraw my consent at any time. My participation is voluntary. I understand that whether or not I take part will not affect my health care services received today, or at any time in the future.

Please indicate your consent with your signature.

Volunteer's name _____

_____

Signature of Volunteer Date (DD/MM/YYYY)

Staff member's name_____

_____

Signature of study staff Date (DD/MM/YYYY)

If the volunteer is unable to read or write the entire counselling process must be observed by an independent witness who can then confirm the procedure once the she has given consent.

Fingerprint of volunteer:

Witness:

I confirm that I am independent of the study and that I witnessed the entire informed consent counselling process in the home language of the volunteer

Name: _____

Signature: _____

Date (DD/MM/YYYY): _____

Thank you.

CONSENT FOR STUDY PARTICIPATION (INFANT—to be signed at first post-partum study visit)
CONSENT STATEMENT:

I have read this form, or someone has read it to me. I have been offered a copy of this consent form. I was encouraged and given time to ask questions. I permit my child to be in this study. Iknow that after choosing to be in this study, I may withdraw my child at any time. I am voluntarily allowing my child to participate in this study. I understand that whether or not my child takes part will not affect their health care services received today, or at any time in the future.

Please indicate your consent with your signature.

Child's name _____

Mother's name _____

_____

Signature of Mother Date (DD/MM/YYYY)

Staff member's name_____

_____

Signature of study staff Date (DD/MM/YYYY)

If the volunteer is unable to read or write the entire counselling process must be observed by an independent witness who can then confirm the procedure once the she has given consent. Fingerprint of volunteer:

Witness: I confirm that I am independent of the study and that I witnessed the entire informed consent counselling process in the home language of the volunteer

Name: _____

Signature: _____

Date (DD/MM/YYYY):

_____

Thank you.

Appendix B: Questionnaires

0. Participant ID

Participant ID

1. Maternal Physical Examination Form

Visit Date	_____
Visit Code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7
ANTHROPOMETRY	
Height	_____ (cm)
Weight	_____ (Kg)
MUAC	_____ (cm)
Reading - Time of measurement	_____
Blood pressure - Systolic	_____ (mmHg)
Blood pressure - Diastolic	_____ (mmHg)
Method of measurement	◯ Manual ◯ Automated
Location of measurement	◯ Left Arm ◯ Right Arm
Date of the last menstrual cycle	_____
Expected delivery date	_____

Nurse or Staff Member
Any other comments _____
Nurse/staff initials _____
Signature _____

2. Demographic History Questionaire

Enkosi ngokuvuma ukuthatha inxaxheba kolu phando! Olu phando lubalulekile kuba luzakusinceda ekuphuhliseni iikqubo ukuthintela ukusuleleka kwentsholongwane ye-HIV phakathi kwamabhinqa akhulelweyo nancancisayo kunye nabantwana babo. Ndizakukubuza imibuso ngawe, ngesinqandamathe sakho/ngeezinqandamathe zakho, kwakunye nokuziphatha kwakho ngesondo ngethuba ukhulelwe/ubukhulelwe. Zonke iimpendulo zakho zizakuhlala ziyimfihlo, kwaye andizukulibhala kule fomu igama lakho. Udliwano-ndlebe luzakuthatha into engangemizuzu engama-30 - 45. Ukuba unayo imibuzo okanye ufuna uncedo, nceda uvakalise kwilungu loluphando. Nceda uphendule zonke iimpendulo ngokunyanisekileyo.

Thank you for agreeing to participate in this study! This study is important as it will help us to better understand the uptake and adherence to pre-exposure prophylaxis (PrEP) to prevent HIV in pregnant and breastfeeding women. Today you will be asked questions about yourself, your partners, and about your sex behaviours during your pregnancy. All of your responses are confidential, and I will not attach your name to any of this information. This session will take about 30-45 minutes. Please answer all questions honestly. If you have questions or need assistance, please let a member of the study staff know. Do you have any questions before we begin?

Visit date _____

Sizokubuza imibuzo embalwa malunga nemvelaphi yakho, izizathu zokukhulelwa kwakunye nokuhlala kwakho. Ukuba uziva ungakhululekanga ngokuphendula umbuzo othile, ndixelele ukuze ndiwudlule lombuzo.

We are now going to ask you a few questions about your personal background, pregnancy intentions and living situation. If you feel uncomfortable answering any of the questions, please tell me to skip to the next question.

1. Uneminyaka emingaphi?

How old are you? _____ (Age in years)

2. Uthetha oluphi ulwimi ekhaya?

What language do you speak at home?

- ◯ isiXhosa
- ◯ isiZulu
- ◯ Afrikaans
- ◯ English
- ◯ Other, Specify

2.1 What language do you speak at home? Other, specify _____

3. Leliphi izinga lemfundo oligqibileyo? What is the last grade that you have completed?	◯ None ◯ Grade 1 / Standard A ◯ Grade 2 / Standard B ◯ Grade 3 / Standard 1 ◯ Grade 4 / Standard 2 ◯ Grade 5 / Standard 3 ◯ Grade 6 / Standard 4 ◯ Grade 7 / Standard 5 ◯ Grade 8 / Standard 6 ◯ Grade 9 / Standard 7 ◯ Grade 10 / Standard 8 ◯ Grade 11 / Standard 9 ◯ Grade 12 / Standard 10 ◯ Attended some tertiary education (University/College) ◯ Completed tertiary education (University/College)
4. Ingaba uyasebenza okanye uyafunda? Are you currently working and/or studying?	◯ Yes ◯ No
5. Yeyiphi kwezi zilandelayo ekuchaza ngcono? Which one of the following best describes what you do?	◯ Uphangela isigxina / Employed full-time ◯ Uphangela manqapha-nqapha / Employed part-time ◯ Isingxungxu okanye umsebenzi onje ngokuthengisa endlini okanye esitratweni / Informal job/hawker' ◯ Ungumfundi wesikolo / Attending school/learner ◯ Ungumfundi webanga eliphezulu / Attending tertiary education (University/College)
6. Ingaba ikhona ingeniso? Do you earn an income?	◯ Yes ◯ No
7. Ingayimalini ingeniso yakho oyifumana nyanga nenyanga? Approximately how much income do you earn per month?	◯ Yi 1000 nangaphantsi ngenyanga / Less than R1 000 per month ◯ R1001 - R5000 ngenyanga / R1 001 to R5 000 per month ◯ R5 001 - R10 000 ngenyanga / R5 001 to R10 000 per month ◯ R10 001 - R15 000 ngenyanga / R10 001 to R15 000 per month ◯ Ngaphezulu kwe R15 000 ngenyanga / More than R15 000 per month
8. Ingaba uyayifumana na imali yesibonelelo sikakurhulumente? Do you currently receive any social assistance in the form of government grants?	◯ Yes ◯ No
9. Uhlala kwikhaya elinjani? What kind of home do you live in?	◯ Ityotyombe/uhlaliso olungahlelwanga/ Shack/informal dwelling ◯ Indlu yesitena / Formal house ◯ Iflethi / Flat ◯ Indlu kamasipala / council home ◯ Enye, Cacisa / Other, Specify

What kind of home do you live in? Other, specify	_____

10. Ingaba indlu yakho inazo ezinto zilandelayo?

Does your household have any of the following?

10.1 Indlu yangasese engaphakathi / A toilet inside	◯ Yes ◯ No
10.2 Amanzi empompo ngaphakathi endlini / Running water inside	◯ Yes ◯ No
10.3 Umbane ngaphakathi endlini / Electricity inside	◯ Yes ◯ No
10.4 Isikhenkcezisi / ifriji / A refrigerator	◯ Yes ◯ No
10.5 Umnxeba wasendlini / A telephone	◯ Yes ◯ No
10.6 Umabonakude / A television	◯ Yes ◯ No
11. Bangaphi abantu, kuquka nawe, abahlala kwikhaya lakho (abantwana nabantu abadala)? Including yourself, how many people (adults and children) live in your house?	_____
12. Ingaba unawo na umakhal'ekhukhwini okanye ifowuni? Do you have access to a cell phone?	◯ Yes ◯ No
13. Ukuba unawo, ngubani umnikazi womnxeba? Who owns the cell phone you use?	◯ Ndim / I do ◯ Liqabane lam / My husband or boyfriend ◯ Ilungu losapho / A family member ◯ Umhlobo wam / A friend who is not my boyfriend or my family
14. Zingaphi inombolo zomnxeba obukhe wanazo kuleminyaka mibini idlulileyo? How many cell phone numbers have you had in the past 2 years?	_____
15. Ingaba uyamsebenzisa na u-Whatsapp kumakhal'ekhukhwini wakho? Do you use Whatsapp on your phone?	◯ Yes ◯ No

16. Ingaba unalo na ikhadi lebhanki? Do you have a bank account?	◯ Yes ◯ No
17. Ingaba wena unemoto okanye ukhona umntu apho ohlalakhona onemoto? Do you or someone in your household have access to a car?	◯ Yes ◯ No
18. Usebenzisa ntoni ixesha elininzi xa upheka? What do you mainly use to cook?	◯ Irhasi / Gas ◯ Iparafini / Paraffin ◯ Umbane /Electricity ◯ Inkuni /Wood ◯ Enye(cacisa) / Other (specify)
18.1 What do you mainly use to cook?	_____
19. Phambi kokuba azalwe umntwana, Ingaba uceba(uplana) ukuhamba uyokuhlala nosapho okanye abahlobo abahlala ngaphandle kwase Gugulethu (or Hanover Park) ? Before the baby is born, do you plan to travel to stay with family or friends who live outside of Gugulethu (or Hanover Park) ?	◯ Yes ◯ No
20. Emva kokuba ezelwe umntwana, Ingaba uceba(uplana) ukuhamba uyokuhlala nosapho okanye abahlobo abahlala ngaphandle kwase Gugulethu (or Hanover Park) ? After the baby is born, do you plan to travel to stay with family or friends who live outside of Gugulethu (or Hanover Park) ?	◯ Yes ◯ No
21. Ingaba uceba ukuyaphi? Where do you plan to go?	◯ Entshona koloni, kodwa hayi apha eGugulethu bhala igama lendawo / In Western Cape, but not Gugulethu ◯ eMzantsi Afrika kodwa hayi apha eEntshona koloni / In South Africa, but not Western Cape ◯ Ngaphandle kwaseMzantsi Afrika / Outside of South Africa
21.1 Where do you plan to go? specify [city, town, province or country]	_____
22. Uzohlala nabani phaya? [khetha zonke ezingqamane nawe] Who will you stay with there ? [tick all that apply]	☐ Iqabane / Partner ☐ Ilungu losapho/ Family member ☐ Umhlobo /A friend

23. Ingaba uceba ukuhlala ixesha elingakanani na?

How long do you plan to stay?

- ◯ Intsuku / days
- ◯ Uzohlala isigxina / Permanent move
- ◯ Andiyazi / Don't know

23.1 How long do you plan to stay? specify the number

_____
(Days)

Pregnancy and Fertility Intention questions

24. Uye wakhulelwa izihlandlo ezingaphambi (oku kuquka ukukhulelwa kwakho ngoku)?

How many times have you been pregnant (including this time)?

_____

25. Bangaphi abantwana obazeleyo?

How many children have you given birth to?

_____

26. Bangaphi abantwana bakho abaphilayo?

How many of these children are living

_____

27. Wakhe wayivavanyelwa i-HIV ngaphambili?

Did you first test for HIV before this pregnancy?

- ◯ Yes
- ◯ No

Ngezantsi kunemibuzo ebuza ngemeko kunye nezimvo zakho ngeli xesha ukhulelweyo. Nceda ucinge ngolukhulelo lwangoku xa uphendula lemibuzo ingezantsi.

Below are some questions that ask about your circumstances and feelings around the time you became pregnant. Please think of your current pregnancy when answering the questions below.

28. Ndizokufunda ezintetho zilandelayo malunga nenyanga okhulelwe ngayo.
Nceda ukhethe inthetha engqamelene nawe kakhulu:

I will read the following statements about the month that you became pregnant. Please select the one that best reflects your situation:

- ◯ Mna/thina besingalu sebenzisi ucwangciso./ I/we were not using contraception (a method to prevent pregnancy)
- ◯ Mna/thina besilusebenzisa ucwangciso, kodwa hayi lonke ixesha / I/we were using contraception, but not on every occasion
- ◯ Mna/besilusebenzisa rhoqo ucwangciso, kodwa sisazi ukuba ohlobo locwangciso alusebenzi . / I/we always used contraception, but knew that the method had failed at least once
- ◯ Mna/besilusebenzisa rhoqo ucwangciso. / I/we always used contraception

29. Ingaba olukhulelo lwenzeke ngexesha elilungileyo okanye ngexesha elingalunganga?

Do you feel that the pregnancy happened at the right time or wrong time?

- ◯ Lixesha elilungileyo / right time
- ◯ Lixesha elingalunganga / wrong time

30. Ndizokufunda ezintetha zilandelayo malunga nenjongo zakho zokukhulelwa. Khetha eyona engqamane nesimo sakho:

I will read the following statements about your intention to get pregnant. Please select the one that best reflects your situation:

- ◯ Bendizimisela ukukhulelwa / I intended to get pregnant
- ◯ Ingcinga zam bezintshintsha-tshintsha / my intentions kept changing
- ◯ Bendingazimisele ukukhulelwa / I did not intend to get pregnant

31. Ndizokufunda ezintetha zilandelayo malunga nemvakalelo zakho zokuba nosana. Khetha eyona engqamane nesimo sakho

I will read the following statements about your feelings about having a baby. Please select the one that best reflects your situation:

- ◯ Bendifuna ukuba nosana / I wanted to have a baby
- ◯ Imvakalelo zam bezibethabethana ngokuba nosana / I had mixed feelings about having a baby
- ◯ Bendingafuni ukuba nosana / I did not want to have a baby

32. Ndizokufunda ezintetha zilandelayo malunga nesigqibo seqabane lakho ngokuba nosana. Nceda ukhethe intetha engqamelene nawe kakhulu

I will read the following statements about your partner's decision to have a child. Please select the one that best reflects your situation:

- ◯ Iqabane lam, nam sivumelene ukuba ndikhulelwe / My partner and I had agreed that we would like me to be pregnant
- ◯ Iqabane lam, nam sixoxile ukuba sibenabantwana sobabini kodwa asavumelana ukuba mna ndikhulelwe / My partner and I had discussed having children together, but hadn't agreed for me to get pregnant
- ◯ Asikhange sixoxe ngokuba nabantwana sobabini / We never discussed having children together

33. Phambi kokuba ukhulelwe, ikho into oyenzileleyo ukuphucula impilo yakho ulungiselela ukukhulelwa?

Before you became pregnant, did you do anything to improve your health in preparation for pregnancy?

- ◯ Yes
- ◯ No

34. Phambi kokuba ukhulelwe, ikho into oyenzileleyo ukuphucula impilo yakho ulungiselela ukukhulelwa? (Nceda ukhethe zonke ezingqamelene nawe)

Before you became pregnant, did you do anything to improve your health in preparation for pregnancy? (Please tick sought medical/health advice all that apply)

34.1 Nditye iFolic Acid

I took folic acid

- ◯ No
- ◯ Yes
- ◯ N/A

34.2 Ndiyekile okanye ndibuyise unyawo ekutshayeni Opted or cut down smoking?	◯ No ◯ Yes ◯ N/A
34.3 Ndiyekile okanye ndibuyise unyawo ekuseleni I stopped or cut down drinking alcohol.	◯ No ◯ Yes ◯ N/A
34.4 Nditye ukutya okusempilweni I ate more healthy	◯ No ◯ Yes ◯ N/A
34.5 Ndiye ndafuna amacebiso empilo Sought medical/health advice	◯ No ◯ Yes ◯ N/A
34.6 Ndiye ndathatha amanye amanyathelo nceda uchaze. I did other things.	◯ No ◯ Yes ◯ N/A
I did other things (specify)	_____

Notes from the interviewer

Any other comments	_____
Interviewer code	_____
Interviewer's signature	_____

3. Partner questionnaire

Visit Date	_____ (date (dd-mm-yyyy))
Visit Code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7

Sizokubuza imibuzo ethile malunga nezimo zakho zobudlelwane ezidlulileyo nezangoku. Impendulo zakho zizohlala zikhuselekile ebantwini, kuquka neqabane lakho. Ukuba uziva ungakhululekanga ekuphenduleni eminye imibuzo, ungacela udlulwe lombuzo.

We are going to ask you some questions about your previous and current relationships. Your answers will remain confidential from everyone, including your partner. If you feel uncomfortable answering any of these questions, you can ask the interviewer to skip the question.

Partner and HIV testing

1. Ingaba ukhona umntu owabelana naye ngesondo? Is there someone that you are having sexual relations with?	◯ Hayi / No ◯ Ewe, notata walontwana ndikhulelwe yena / Yes, with the father of my unborn baby ◯ Ewe, nomnye umntu ongenguye utata walomntwana ndikhulelwe yena / Yes, with someone else
2. Ungachaza njani isimo sobudlelwane sakho? How would you describe your current, main relationship?	◯ Utshatile, nihlala kunye / Married, living together ◯ Utshatile, anihlali kunye / Married, not living together ◯ Anitshatanga, nihlala kunye / Not married, living together ◯ Anitshatanga, anihlali kunye / Not married, not living together ◯ Enye, Cacisa: / Other, Specify:
2.1 How would you describe your current, main relationship? Other, specify	_____
3. Nithandane ixesha elingakani neqabane lakho (bhala inyanga)? How long have you been in a relationship with this person? (please note months)	◯ Months ◯ Years (months)
3.1 How long have you been in a relationship with this person?	_____

3.2 How long have you been in a relationship with this person?	_____
4. Ingaba iqabane lakho ngoku ngutata womnye wabantwana bakho? (uquka nalo ukhulelwe yena) Is your current partner the parent of any of your children? (including current pregnancy)	◯ Yes ◯ No
5. Ingaba wabelana ngesondo nabanye abantu (nokuba ayiloqabane lakho)? Do you have relationships/sexual partners with any other people (even if you are not currently in a relationship)?	◯ Yes ◯ No
6. Ingaba iqabane lakho linawo amanye amaqabane? Does your other partner have other partners?	◯ No ◯ Yes ◯ I don't know
7. Ingaba elinye iqabane lakho liyakuxhasa ngemali okanye ngezinto ezithengwe ngemali? Does your other partner provide you with material or financial support?	◯ Yes ◯ No
8. Chaza intlobo yesimo sobudlelwane bakho namanye amaqabane? What is the nature of your other relationship(s)?	
8.1 Iqabane otshate nalo / Spouse/married	◯ Yes ◯ No
8.2 Iqabane Boyfriend/ girlfriend	◯ Yes ◯ No
8.3 Iqabane lamanqapha-nqapha / Casual partner/one night stands	◯ Yes ◯ No
8.4 Other	◯ Yes ◯ No
8.4.1 What is the nature of your other relationship(s)? other,specify	_____

9. Leliphi ibanga lemfundo iqabane lakho eligqibileyo? What is the highest level of education that your current main partner has completed?	◯ None ◯ Grade 1 / Standard A ◯ Grade 2 / Standard B ◯ Grade 3 / Standard 1 ◯ Grade 4 / Standard 2 ◯ Grade 5 / Standard 3 ◯ Grade 6 / Standard 4 ◯ Grade 7 / Standard 5 ◯ Grade 8 / Standard 6 ◯ Grade 9 / Standard 7 ◯ Grade 10 / Standard 8 ◯ Grade 11 / Standard 9 ◯ Grade 12 / Standard 10 ◯ Attended some tertiary education (University/College) ◯ Completed tertiary education (University/College)
10. Ingaba iqabane lakho liyafunda okanye liyaphangela? Is your current main partner employed and/or studying?	◯ Yes ◯ No
11. Yeyiphi kwezi zilandelayo echaza iqabane lakho ngcono? Which one of the following best describes what your current main partner does?	◯ Uphangela isigxina / Employed full-time ◯ Uphangela manqapha-nqapha / Employed part-time ◯ Isingxungxu okanye umsebenzi onje ngokuthengisa endlini okanye esitratweni / Informal job/hawker ◯ Ungumfundi wesikolo / Attending school/learner ◯ Ungumfundi webanga eliphezulu(idyunivesiti okanye ikholeji)/ Attending tertiary education (University/College)
12. Ingaba iqabane lakho langoku okanye amaqabane akho akhe avavanyelwa i-HIV? Has your current main partner(s) ever been tested for HIV?	◯ No ◯ Yes ◯ I don't know
13. Lwalunini uvavanyo lwakhe lwakutsha nje lweHIV? When was your current main partner's most recent HIV test done?	◯ 0-6 linyanga / months ◯ 6-12 linyanga / months ◯ >12 linyanga / months ◯ Andiyazi / I don't know
14. Uvavanyo lwakhe lalusenzelwa phi? Where was your current main partner's test done?	◯ Uluntu / Community ◯ Isibhedlele okanye iziko lezempilo / Hospital or health centre ◯ Okunye / Other
14.1 Where was your current main partner's test done? Other specify	_____

15. Zithini iziphumo zakhe zovavanyo lweHIV zakutsha nje? What was the result of your current main partner's most recent HIV test?	◯ Akanayo intsholongwane / HIV negative ◯ Uphila nentsholongwane / HIV positive ◯ Andazi / Don't know
16. Uzive kanjani iziphumo zovavanyo lweHIV zeqabane lakho? How did you find out about your current main partner's HIV status?	◯ Iqabane lam lindixelele ngokwalo / Partner told me directly on his own ◯ Iqabane lam lindixelele emva kokuba ndimbuzile / Partner told me after I asked ◯ Ndive komnye umntu / Heard from somebody else ◯ Ndihambe neqabane lam ngoku beliyofumana iziphumo / I went with my partner when he got his results ◯ Sihambe sobabini neqabane lam ukuya kuvavanyo lweHIV / We tested together as a couple ◯ ndiqikelele / I just guessed, assumed, figured it out ◯ Undinike intluva/ undinike umkhondo / My partner left clues ◯ Okunye/ Other (read out the options)
16.1 How did you find out about your current main partner's HIV status? Other specify	_____
17. Ingaba iqabane lakho lisebenzisa amachiza okuthomalalisa intsholongwane ngoku? Is your current main partner currently taking antiretroviral drugs?	◯ Hayi/No ◯ Ewe/Yes ◯ Andiyazi/ I don't know
18. Ingaba iqabane lakho liyazi ukuba ubukhe waya kuvavanyo lweHIV? Does your current main partner know that you have had an HIV test?	◯ Hayi/No ◯ Ewe/Yes ◯ Andiyazi/ I don't know
19. Iqabane lakho lifumanise njani ukuba ubukhe waya kuvavanyo lweHIV How did your current main partner find out that you had an HIV test?	◯ Iqabane lam liye kuvavanyo nam / Partner tested with me ◯ Iqabane lam ndilixelele ngokwam / I told my partner directly that I had an HIV test ◯ Iqabane lam ndilixelele emva kokuba lindibuzile / I told my partner after my partner asked ◯ Iqabane lam live ngomnye umntu / Partner heard from someone else ◯ Iqabane lam lizicingele, liziqikelelele / Partner guessed, assumed, or figured it out
20. Ungaziva ukhululekile ukucela iqabane lakho langoku liyokuvavanyela i-HIV? Would you feel comfortable asking your current main partner to test for HIV?	◯ Hayi/No ◯ Ewe/Yes ◯ Andazi/ I don't know

21. Wakhe wayo vavanyela i-HIV neqabane lakho langoku?

Have you ever attended couples HIV testing with your current main partner?

- ◯ Yes
- ◯ No

22. Ungaziva ukhululekile ukuhamba neqabane lakho langoku ukuya kuvavanyela i-HIV?

Would you feel comfortable going with your current main partner for couples HIV testing?

- ◯ Hayi/No
- ◯ Ewe/Yes
- ◯ Andazi/I don't know

23. Ukuba uvavanyo lwasekhaya/ izixhobo zokuzivavanya bezifumaneka, ucinga ukuba iqabane lakho langoku belinokuziva likhululekile ukuzivavanyela i-HIV ekhaya?

If HIV home/self-testing kits were available, would you feel comfortable taking a test to your current main partner so that he could test for HIV?

- ◯ Hayi/No
- ◯ Ewe/Yes
- ◯ Andazi/ I don't know

24. Mangakanani amathuba okuba iqabane lakho linawo na amanye amaqabane?

How likely do you think it is that your current main partner has other sex partners?

- ◯ Awekho amathuba / Not likely at all
- ◯ Mancinci / Somewhat likely
- ◯ Makhulu / Very likely

25. Ungaziva ukhululekile ukucela abanye abantu obukhe wabelana ngesondo nabo ukuba baye kuvavanya i-HIV?

Would you feel comfortable asking any of the other people that you have had sex with to test for HIV?

- ◯ Hayi/No
- ◯ Ewe/Yes
- ◯ Andazi/ don't know

Notes from the interviewer

Any other comments

_____

Interviewer's code

_____

Interviewers signature

_____

4. PrEP Knowledge and Attitudes

Visit date	_____ (date (dd-mm-yyyy))
Visit Code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7

Ndizokubuza imibuzo malunga nolwazi lwakho kwakunye nengcinga zakho nge-PrEP, ndizokubuza malunga nenxaso oyifimanayo ekhaya kwakunye naseluntwini. Ndiyakucela uzame ukuphendula lemibuzo ngokunyanisekileyo.

I am going to ask you about your previous knowledge and thoughts about PrEP. I will also ask about your social support system at home and in the community. Please do your best to answer these questions as honestly as possible.

1. Phambi kokuba uze apha, wakhe wava nge-PrEP? Before today's visit, had you heard about pre-exposure prophylaxis or PrEP?	◯ Yes ◯ No
2. Waqala ukuva nge-PrEP phi? Where did you first learn about PrEP?	◯ Ekliniki / Clinic ◯ Esikolweni / School ◯ Ngelungu losapho / Family member ◯ Ngetshomi / umhlobo / Friend ◯ Kunomathotholo okanye umabona kude / Radio/TV ◯ Okunye / Other
2.1 Where did you first learn about PrEP? Other, specify	_____

3. Phambi kokuba uze apha, yeyiphi kwezi echaza ngcono ulwazi lakho lwe-PrEP?

Before today's visit, which of the following best described your understanding of what PrEP was?

3.1 Ukusebenzisa i-condom ukuze uzikhusele kwi-HIV Using condoms to prevent HIV	◯ Yes ◯ No
3.2 Ukuthatha amayeza (okanye ARV) emva kokuba usethubeni lokusuleleka yi-HIV ukuze uzikhusele ekufumaneni i-HIV Taking medicine (or ARVs) after you are exposed to HIV to prevent getting HIV	◯ Yes ◯ No

3.3 Iyeza okanye ipilisi olithathayo xa ufuna ukuzikhusela kwi-HIV Medicine you take when you are HIV-negative to prevent you from getting HIV	◯ Yes ◯ No
3.4 Okunye Other	◯ Yes ◯ No
3.4.1 Before today's visit, which of the following best described your understanding of what PrEP was? (Other, specify)	_____

I-PrEP yindlela entsha yokukhusela umntu kwi-HIV, iquka ukuthatha ipilisi ngomlomo rhoqo ngokusuku. La mayeza (amachiza) asebenza ngokunqanda I-HIV ekusuleleni umntu, ungayisebenza naxana ukhulelwe okanye uncancisa usana, ikhuselekile.

PrEP is a new method for preventing HIV that involves taking a daily pill by mouth. This medication works to keep HIV from establishing infection, and is safe to use in pregnancy and breastfeeding.

4. Ingaba uyamazi omnye umntu othatha okanye osebenzisa i-PrEP? Do you know anyone taking PrEP?	◯ Hayi / No ◯ Ewe / Yes ◯ Andazi / Don't know
5. Ngubani omaziyo othatha okanye osebenzisa iPrEP? Who do you know that is taking PrEP?	
5.1 Iqabane lakho Spouse/partner	◯ Yes ◯ No
5.2 Ilungu losapho lwakho Family member	◯ Yes ◯ No
5.3 Itshomi/isihlobo Friend	◯ Yes ◯ No
5.4 Umntu osebenza naye Colleague	◯ Yes ◯ No
5.5 Umntu ofunda naye esikolweni Classmate	◯ Yes ◯ No

5.6 Okunye (Cacisa) Other (specify)	◯ Yes ◯ No
5.6.1 Who do you know that is taking PrEP? (Other, Specify)	_____
6. Ingaba unalo na uloyiko okanye ixhala malunga ne-PrEP ? Do you have fears or concerns about PrEP?	◯ Yes ◯ No
7. Ingaba ikhona into ekuxhalabisayo okanye ekoyikisayo ngokusebenzisa i-PrEP rhoqo ngosuku? Do you have concerns about taking PrEP every day?	◯ Yes ◯ No
7.0 Yintoni le ikoyikisayo okanye ikwenza ixhala ngokuthatha iPrEP rhoqo ngosuku? What fears or concerns do you have about taking PrEP every day?	
7.1 Ubungakanani okanye incasa yepilisi Size or taste of pills	◯ Yes ◯ No
7.2 Abantu akumelanga bathathe ipilisi ngaphandle kokuba bayagula People should not take drugs unless they are sick	◯ Yes ◯ No
7.3 Abantu bazocinga ndine-HIV People will think I have HIV	◯ Yes ◯ No
7.4 Iqabane lam lizokucaphuka My partner will be upset	◯ Yes ◯ No
7.5 Izakuchaphazela impilo yosana lwam Effect on my baby's health	◯ Yes ◯ No
7.6 Ndicinga ukuba ezipilisi azizokuyikhusela i-HIV I don't think the pills will prevent HIV	◯ Yes ◯ No
7.7 Izoba ngumthwalo ukuthatha ipilisi ngosuku Burdensome to take pill every day	◯ Yes ◯ No
7.8 Okunye / Other	◯ Yes ◯ No
7.8.1 What fears or concerns do you have about taking PrEP every day? Other, specify	_____

8. Ingaba unexhala ngemiphumela ebangwa yile-PrEP? How worried are you about side effects from PrEP?	◯ NdineXhala kakhulu / Very worried ◯ Ndinexhala kodwa alikho ngamandla / Somewhat worried ◯ Andinalo ixhala / Not worried
9. Ucinga ukuba iPrEP izosebenza kangakanani na ekukhuseleni iHIV ? How effective do you think PrEP will be at preventing HIV?	◯ Ayizosebenza tu /Not at all effective ◯ Izosebenza kodwa kancinci / Slightly effective ◯ Izosebenza kodwa hayi kangako /Moderately effective ◯ Izosebenza kakhulu / Very effective ◯ Andiqinisekanga / Unsure
10. Ingaba unawo na umdla wokuthatha iPrEP? Are you interested in taking PrEP?	◯ No ◯ Yes ◯ Unsure
11. Umdla wakho ungakaninani ekuthatheni iPrEP? How interested are you in taking PrEP?	◯ Ndinomdla kakhulu /Very interested ◯ Ndinomdla kancinci / A little interested ◯ Ndinomdla kodwa hayi kangako /Somewhat interested ◯ Andinamdla kakhulu /Very uninterested ◯ Andiqinisekanga /Unsure
12. Esona sizathu sakho sofuna ukuthatha i-PrEP sithini? What is the MAIN reason that you would like to take PrEP?	◯ Iqabane lam linetsholongwane kagawulayo / My partner is HIV positive ◯ Andizazi ziphumo ze-HIV zeqabane lam / I don't know my partner's status ◯ Ndinamaqabane angaphezulu kwesinye / I have more than one partner ◯ Iqabane lam linamanye amaqabane / My partner has other sex partners ◯ Ukukhusela umntwana wam ekufumaneni i-HIV / To protect my child from getting HIV ◯ Ndicinga ukuba ndinganayo i-HIV / I think I may have HIV ◯ Okunye / Other
12.1 What is the MAIN reason that you would like to take PrEP? Other	_____

Notes from the interviewer

Any other comments	_____
Interviewer's code	_____
Interviewer's signature	_____

5. PrEP Readiness Scale

Visit date	_____ (date (dd-mm-yyyy))
Visit Code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7

Ndizokubuza imibuzo malunga nolwazi lwakho kwakunye nengcinga zakho nge-PrEP. i-PrEP yindlela entsha yokukhusela umntu kwi-HIV, iquka ukusela ipilisi ngomlomo rhoqo ngosuku. La mayeza(amachiza) asebenza ngokunqanda I-HIV ekusuleleni umntu, kukhuselekile ukuyisebenzisa xa ukhulelwe naxana uncancisa. Ndizokubuza malunga nenxaso oyifimanayo ekhaya kwakunye naseluntwini. Ndiyakucela uzame ukuphendula lemibuzo ngenyaniso. Ukuba uziva ungakhakhulukekanga ekuphenduleni omnye walemibuzo, nceda uvakalise siwudlule lombuzo.

Lemibuzo llandelayo nceda uvakalise ukuba awuvimi ngamandla, awuvumi, uphakathi nendawo, uyavuma okanye uyavuma ngamandla

I am going to ask you about your previous knowledge and thoughts about PrEP. PrEP is a new method for preventing HIV that involves taking a daily pill by mouth. This medication works to keep HIV from establishing infection,and is safe to use in pregnancy and breastfeeding. I will also ask about your social support system at home and in the community. Please do your best to answer these questions as honestly as possible. If you feel uncomfortable answering any of these questions, you can skip the question

For the following questions please tell me if you strongly disagree, disagree, neither agree or disagree, agree or strongly agree

1. Ndikulungele ukuthatha i-PrEP ukuze ndizikhusele kwi-HIV. I am ready to start taking medication (PrEP) to protect against HIV.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
2. Ndiyakholwa ukuba ukuthatha i-PrEP kuzondikhusela kwi-HIV. I believe taking PrEP can keep me healthy.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Andiphikisi kwaye andivumi / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree

3. Ndiyakholwa ukuba ukuthatha i-PrEP kuzogcina usana lwam lusempilweni. I believe that taking PrEP can keep my baby healthy.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
4. Ndizokwazi ukuqhagamiselana nabasebenzi bophando ukuba ndinemibuzo okanye iingxaki malunga ne-PrEP? I would know how to contact the study staff if I had problems or questions about the PrEP medication.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
5. Ukuba andiziseli kakuhle ipilisi ze-PrEP ngalendlela ndixelelwe ngayo ndingafumana i-HIV. If I don't take my PrEP medication exactly as instructed, I might get infected with HIV.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
6. Ndiyakhathazeka ngempilo yomntwana wam ukuba ndisela-PrEP. I worry about my baby's health if I take PrEP (R)	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Andiphikisi kwaye andivumi / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
7. Ndiyakhathazeka ngokukhulelwa kwam ukuba ndisela i-PrEP. I worry about my pregnancy if I take PrEP (R)	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
8. Impilo yam okanye umntwana wam izoba xenge-xenge ukuba ndisela iPrEP. My or my baby's health will be worse if I take PrEP (R)	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
9. Ukusela ipilisi/amayeza e-PrEP akuzondinceda ncam. Taking PrEP medication would not really help me. (R)	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
10. Nokuba kunzima kangakanani, ndizokwazi ukuxelela abasebenzi bophando xana ndiphosile ukusela amayeza wam e-PrEP. Even when it may be difficult, I will be able to let the study staff know if I miss doses of my PrEP medication.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
11. Ukusela amayeza/ipilisi ze-PrEP ngendlela eyiyo kuzondikhusela ekufumaneni i-HIV. Taking my PrEP medication as prescribed would keep me from getting HIV.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree

12. Ndizosela amayeza/ipilisi zam ze-PrEP nokuba zizondigulisa kuqala kuba ndiyayazi ukuba imiphumela izakuphela.

I would take my PrEP medications even if they made me sick at first because the side effects would go away.

- ◯ Andivumi ngamandla / Strongly Disagree
- ◯ Andivumi / Disagree
- ◯ Ndiphakathi nendawo / Neither Agree nor Disagree
- ◯ Ndiyavuma / Agree
- ◯ Ndivuma ngamandla / Strongly Agree

13. Usapho lwam nabahlobo bam endizobaxelela ukuba ndikwi-PrEP, bazondikhumbuza ukusela amayeza wam.

My family and friends who I will tell I am on PrEP would help me remember to take my medication.

- ◯ Andivumi ngamandla / Strongly Disagree
- ◯ Andivumi / Disagree
- ◯ Ndiphakathi nendawo / Neither Agree nor Disagree
- ◯ Ndiyavuma / Agree
- ◯ Ndivuma ngamandla / Strongly Agree

14. Ndiyayazi ukuba ndizokwazi ukusela amayeza wam e-PrEP kakuhle.

I know that I will be able to take my PrEP medication correctly.

- ◯ Andivumi ngamandla / Strongly Disagree
- ◯ Andivumi / Disagree
- ◯ Ndiphakathi nendawo / Neither Agree nor Disagree
- ◯ Ndiyavuma / Agree
- ◯ Ndivuma ngamandla / Strongly Agree

15. Kuzokubaluleka ukuba ndithathe amayeza am e-PrEP kakuhle nangexhesa ngemini.

It would be important to me to take my PrEP medication correctly and on time every day.

- ◯ Andivumi ngamandla / Strongly Disagree
- ◯ Andivumi / Disagree
- ◯ Ndiphakathi nendawo / Neither Agree nor Disagree
- ◯ Ndiyavuma / Agree
- ◯ Ndivuma ngamandla / Strongly Agree

Lemibuzo ilandelayo ibuza ngokuxelela abanye abantu ukuba uzothatha inxaxheba koluphando.

These next items ask about you telling other people that you're taking part in this study.

16. Ingaba ukhona umntu oceba ukumchazela ngecebo lakho lokuthatha i-PrEP?

Do you plan to tell anyone about your plan to take PrEP?

- ◯ Hayi / No
- ◯ Ewe/ Yes
- ◯ Andifuni ukuthatha iPrEP / Don't plan on taking PrEP

Ukuba uceba ukuxelela umntu ukuba usela iPrEP , phendula u-ewe okanye u-hayi kumntu oceba ukumxelela koluluhlu lusezantsi.

If you plan to tell anyone about your plan to take PrEP, answer "yes" or "no" for each person(s) you plan to disclose to in the list below.

17.1 Umnyeni/ Iqabane lakho/ Umntu owabelana ngesondo naye?

Your husband/boyfriend/sex partner?

- ◯ Yes
- ◯ No

17.2 Umama okanye Utata wakho?

Your mother or your father?

- ◯ Yes
- ◯ No

17.3 Ubhuti okanye usisi wakho?

Your sister or your brother?

- ◯ Yes
- ◯ No

17.4 Amanye amalungu osapho lwakho?

Other family members?

- ◯ Yes
- ◯ No

17.5 Umhlobo/ itshomi? Friends?	◯ Yes ◯ No
17.6 Abamelwane? Neighbours?	◯ Yes ◯ No
17.7 UNesi okanye ugqirha abangaphandle koluphando? Nurse or doctor outside the study?	◯ Yes ◯ No
17.8 Abanye abantu(cacisa) Other persons	◯ Yes ◯ No
17.8.1 Abanye abantu(cacisa)/ Other persons? Please specify:	_____

Ucinga ukuba lomntu uzokuncedisa akukhumbuze kwaye akuxhase ekusel amayeza akho ePrEP?

Do you think his/her/their reaction will be supportive to remind you to take (or continue taking) PrEP?

18.1Umnyeni/ Iqabane lakho / Umntu owabelana ngesondo naye? Your husband/boyfriend/sex partner?	◯ No ◯ Yes ◯ N/A
18.2 Umama okanye Utata wakho? Your mother or your father?	◯ No ◯ Yes ◯ N/A
18.3 Ubhuti okanye usisi wakho? Your sister or your brother?	◯ No ◯ Yes ◯ N/A
18.4 Amanye amalungu osapho lwakho? Other family members?	◯ No ◯ Yes ◯ N/A
18.5 Umhlobo/ itshomi? Friends?	◯ No ◯ Yes ◯ N/A
18.6 Abamelwane? Neighbors?	◯ No ◯ Yes ◯ N/A
18.7 UNesi okanye ugqirha abangaphandle koluphando? Nurse or doctor outside the study?	◯ No ◯ Yes ◯ N/A

18.8 Abanye abantu(cacisa) Other persons?	◯ No ◯ Yes ◯ N/A
18.8.1 Abanye abantu(cacisa)/ other persons? (explain)	_____
Any other comments	_____
Interviwer's code	_____
Interviewers signature	_____

6. PrEP HIV Stigma

Visit date	_____ (date (dd-mm-yyyy))
Visit Code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7

Ndizokubuza ngengcinga kwakunye nemvakelelo zakho ngokusebenzisa I-PrEP kwakunye ne-HIV
Ukuba uziva ungakhululekanga ekuphenduleni omnye umbuzo apha, ungandixelela ndiwudlule lo mbuzo.

I am now going to ask you about your thoughts and feelings about using PrEP and about HIV. If you feel uncomfortable answering any of the questions, please tell me to skip to the next question.

1. Ndiziva ndinentloni ngokusebenzisa iPrEP I feel ashamed of using PrEP	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
2. Ndiziva ndihlazekile ukusebenzisa i-PrEP I feel embarrassed about using PrEP	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
3. Ndiziva ndisemandleni ukusebenzisa I-PrEP? I feel empowered to use PrEP	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
4. Ndicinga ukuba abantu bazokundinika ubunzima (ngokuthi bahlekise ngam okanye bandihlebe) ukuba ndiyabaxelela ukuba ndisela i-PrEP I think people will give me a hard time (such as make fun of me, or talk badly about me) if I tell them I am taking PrEP	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
5. Ndicinga ukuba abantu bazondigxeka ukuba ndithatha i-PrEP? I think people will judge me negatively if I take PrEP?	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree

6. Ndicinga ukuba ndikomkhulu umngcipheko wobudlobongela okanye ukudlwengulwa ukuba ndisela iPrEP I think I am at greater risk for physical violence or rape if I take PrEP.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
7. Abantu bazocinga ukuba ndiziphethe kakuhle ukuba ndisela i-PrEP. People will think I am behaving responsibly by taking PrEP	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
8. Ndoyika ukuba ndingafumana iHIV xa ndinodibana namathe omntu ophila neHIV I fear that I could contract HIV if I come into contact with the saliva of a person living with HIV	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
9. Andinofuna ukuhlala ecaleni komntu one-HIV, umzekelo emotweni , ecaweni okanye kwigumbi lokulinda. I would not like to sit close to someone living with HIV, for example on public transport, at church or in a waiting room	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
10. Ndinganetloni ukuba kungakho umntu one-HIV kusapho lwam. I would be ashamed if someone in my family had HIV	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
11. Ngamanye amaxhesa abantu bathetha kakubi ngabantu ababacingela ukuba baphila ne HIV kwabanye abantu. People sometimes talk badly about people thought to be living with HIV to others	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
12. Abantu abacingelwa ukuba baneHIV baphela bengahlonitshwa. People thought to be living with HIV lose respect and standing	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
13. Abantu abacingelwa ukuba baphila ne-HIV bayathukwa, baxhatshazwe futhi/ okanye bagrogriswe. People thought to be living with HIV are verbally insulted, harassed and/or threatened	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
14. Abantu abacingelwa ukuba baphila ne-HIV bayebabethwe ngamanye amaxhesha. People thought to be living with HIV are sometimes physically assaulted	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Andiphikisi kwaye andivumi / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree

15. Ngamanye amaxesha abantu bachaza abanye abantu ukuba bane-HIV ngaphandle kwemnvume yabo. People sometimes disclose that other people are HIV positive without their permission.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
16. Ngamanye amaxesha abasebenzi bezempilo bathetha kakubi ngabantu abaphila okanye abacingelwa ukuba baphila ne-HIV kwabanye abantu. Health workers sometimes talk badly about people living with or thought to be living with HIV to others	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
17.Ngamanye amaxesha abasebenzi bezempilo bachaza ukuba abantu baphila ne HIV ngaphandle kwemvume yabo. Health workers sometimes disclose that other people are HIV positive without their permission	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
Any other comments	_____
Interviewer's code	_____
Interviewer's signature	_____

7. Sexual Behaviour

Ngoku sizokubuza imibizo embalwa ngokwabelana ngesondo. Nakubani na ukwabelana ngesondo kohlukile kwaye akukho mphendulo elungileyo nengalunganga- sicela usixelele ngamava akho. Ngaphandle kokuba ndikhankanya olunye uhlobo lokwabelana ngesondo, xa ndisithi ukwabelana ngesondo koluphando, ndithetha indoda xa ifake ubudoda bayo kwisini sobufazi okanye ezimpundiwini. Ukuba uziva ungakhululekanga ekuphenduleni omnye walemibuzo, nceda uvakalise udlulwe lombuzo.

We are now going to ask you a few questions about your sex life. Everyone's sex life is different and there are no right or wrong answers - please just tell us about your own experience. Unless I mention another kind of sex in particular, when I say "sex" during this survey I mean when a man's penis is inserted into a woman's vagina or her butthole. If you feel uncomfortable answering any of these questions, you can skip the question.

Visit date

_____
(date (dd-mm-yyyy))

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A. General sexual behaviors
Ndizoqala nje ngeminye imbibuzo yokwabelana ngesondo

I am going to start with some general questions about your sex life.

1. Bangaphi abantu owakhe wabelana ngesondo nabo ebomini bakho?

How many sex partners have you had in your life?

_____
(No. of sex partners)

2. Wakhe wadlwengulwa okanye wanyanzelwa ngokwabelana ngesondo?

Have you ever been forced to have sex or raped in the past?

- ◯ Yes
- ◯ No

B. Sexual behaviours of the past 12 months before pregnancy

3. Kwezi nyanga ziyi-12 zidlulileyo phambi kokuba ukhulelwe, bangaphi abantu owabelane ngesondo nabo?

In the past 12 months before you became pregnant, how many different people did you have sex with?

_____ (No. of sex partners)

4. Kungaphi usabelana ngesondo kwinyanga ezi-12 phambi kokuba ukhulelwe?

How often did you have sex in the past 12 months before you became pregnant?

- ◯ Kanye ngenyanga okanye nganeno / Once a month or less often
- ◯ 2-4 ngenyanga / 2-4 times a month
- ◯ 5-20 ngenyanga / 5-20 times per month
- ◯ 20 nangaphezulu ngenyanga / more than 20 times per month
- ◯ Andazi / Don't know

5. Kukangaphi usebenzisa ikhondom ngethuba ubusabelana ngesondo kwezinyanga ezi-12 phambi kokuba ukhulelwe?

How often did you use a male or female condom when you had sex in the past 12 months before you became pregnant?

- ◯ Zange / Never (not at all)
- ◯ Nqabile / Rarely (not very often)
- ◯ Ngamanye amaxesha / Sometimes (about half the time I had sex)
- ◯ Phantse lonke ixesha / Almost always (almost every time I had sex)
- ◯ Rhoqo / Always (every time)
- ◯ Andiyazi / Don't know (not sure)

6. Ubukhe wabelana ngesondo ezimpundu (iqabane lakho lifaka isini salo sobudoda ezimpundwini zakho) kwezinyange zi-12 zidlulileyo?

Did you ever have anal sex (where he puts his penis in your butthole) in the past 12 months before you became pregnant?

- ◯ Yes
- ◯ No

7. Ubukhe wabelana ngesondo ngomlomo (Xana efaka umlomo wakho kwisini sakhe sobudoda) kwinyanga ezi-12 phambi kokuba ukhulelwe?

Did you ever have oral sex (when you put your mouth on his penis) in the past 12 months before you became pregnant?

- ◯ Yes
- ◯ No

8. Ubukhe wadlwengulwa okanye wanyanzelwa ngokwabelana ngensondo kwinyanga ezi-12 phambi kokuba ukhulelwe?

Have you been forced to have sex or raped in the 12 months before you got pregnant?

- ◯ Yes
- ◯ No

C.Past 3 months
Ngoku ndizokubuza malunga ngokwabelana ngesondo kwezinyanga zintathu zidlulileyo

I am now going to ask you questions about your sex life in the last 90 days (3 months).

9. Kwezi nyanga ziyi-3 zidlulileyo phambi kokuba ukhulelwe, Bangaphi abantu owabelane ngesondo nabo? How many different people did you have sex with in the past 3 months?	_____ (No. of sex partners)
10. Ingaba omnye wabantu nguyise walomntwana ukhulelwe yena? Were any of these people the father of the baby of the current pregnancy?	◯ Yes ◯ No
11. Kukangaphi usabelana ngesondo kwezinyanga zintathu zidlulileyo? How often did you have sex in the past 3 months?	◯ Kanye ngenyanga okanye nganeno / Once a month or less often ◯ 2-4 ngenyanga / 2-4 times a month ◯ 5-20 ngenyanga / 5- 20 times per month ◯ 20 nangaphezulu ngenyanga / More than 20 times per month
12. Kukangaphi usebenzisa ikhondom ngethuba ubusabelana ngesondo kwezinyanga ezi-3 phambi kokuba ukhulelwe? How often did you use a male or female condom when you had sex in the past 3 months?	◯ Zange / Never (not at all) ◯ Nqabile / Rarely (not very often) ◯ Ngamanye amaxesha / Sometimes (about half the time I had sex) ◯ Phantse lonke ixesha / Almost always (almost every time I had sex) ◯ Rhoqo / Always (every time)
13. Ubukhe wasebenzisa ikhondom ngexesha lokugqibela usabelana ngesondo? Did you use a condom the last time you had sex?	◯ Yes ◯ No
14. Ubukhe wabelana ngesondo ezimpundu (iqabane lakho lifaka isini salo sobudoda ezimpundwini zakho) kwezinyanga zi-3 zidlulileyo? Have you had anal sex in the past 3 months (where he puts his penis in your butt)?	◯ Yes ◯ No
15. Ubukhe wabelana ngesondo ngomlomo (Xana efaka umlomo wakho kwisini sakhe sobudoda) kwinyanga ezi-3 phambi kokuba ukhulelwe? Have you had oral sex in the past 3 months (when you put your mouth on his penis)?	◯ Yes ◯ No

16. Wakhe wanyanzelwa ngokwabelana ngesondo okanye wadlwengulwa kwezinyanga zintathu zidlulileyo? Have you been forced to have sex or raped in the past 3 months?	◯ Yes ◯ No
Any other comments	_____
Interviewer's code	_____
Interviwer's signature	_____

8. Risk perception & IPV

Visit date	_____ (date (dd-mm-yyyy))
Visit code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7

Ngoku sifuna ukubuza ngemizwa yakho malunga ne-HIV. Azikho impendulo ezilungileyo nezingalunganga. Sixelele ngemvakalelo yakho nangempilo yakho. Ukuba uziva ungakhululekanga ekuphenduleni omnye umbuzo apha, ungandixelela ndiwudlule lo mbuzo.

I will now ask about your feelings about HIV. Again, there are no right or wrong answers - please just tell us about your own feelings and experiences. If you feel uncomfortable answering any of these questions, you can skip the question by pressing "Next question."

1. Ungawachaza njani amathuba akho okufumana iHIV kulonyaka ulandelo? How would you describe your chances of getting HIV in the next year?	◯ Amathuba awekho / No chance at all ◯ Amathuba mancinci / Small chance ◯ Amathuba aphakathi /Moderate chance ◯ Amathuma makhulu /Great chance
2. Ungawachaza njani amathuba etshomi zakho ezingamantombazane okufumana iHIV kulonyaka ulandelayo? How would you describe your female friends' (your girlfriends) chances of getting HIV in the next year?	◯ Amathuba awekho / No chance at all ◯ Amathuba mancinci / Small chance ◯ Amathuba aphakathi / Moderate chance ◯ Amathuma makhulu / Great chance
3.Ungawachaza njani amathuba womntwana wakho lo umkhulelweyo wokufumana iHIV kulonyaka ulandelayo? How would you describe your infant's chances of getting HIV in the next year	◯ Amathuba awekho / No chance at all ◯ Amathuba mancinci / Small chance ◯ Amathuba aphakathi / Moderate chance ◯ Amathuma makhulu /Great chance
4. Uxhalabe kangakanani ngoku hlukunyezwa okanye ukudlwengulwa kwezinyanga zintathu zilandelayo? How concerned are you about sexual violence or rape in the next 3 months?	◯ Andixhalabanga tu / Not concerned at all ◯ Ndixhalabile kancinci / Somewhat concerned ◯ Ndixhabalile / Concerned ◯ Ndixhalabe kakhulu / Very concerned

5. Uxhalabe kangakanani ngokubethwa emzimbeni okanye ukuhlaselwa kwezinyanga zintathu zilandelayo? How concerned are you about being attacked physically in the next 3 months?	◯ Andixhalabanga tu / Not concerned at all ◯ Ndixhalabile kancinci / Somewhat concerned ◯ Ndixhabalile / Concerned ◯ Ndixhalabe kakhulu / Very concerned

Siza kubuza imibuzo embalwa malunga nobundlobongela bokudlakathiswa liqabane. Ukuba uziva ungakhululekanga ekuphenduleni omnye umbuzo ungachaza udlulwe lombuzo. Kwezi nyanga ziyi-12 zidlulileyo wakhe wazifumana ukwezinye zezimeko zilandelayo?

We are going to ask you a few questions relating to partner violence. If you feel uncomfortable answering any of these questions, you can skip the question. In the last 12 months, have you experienced any of the following?

UKUDLAKATHISWA NGOKWASENGQONDWENI / Psychological Violence

1. Iqabane lakho likhe lakuthuka okanye lakwenza uzive ungalunganga? Has your partner insulted you or made you feel bad about yourself?	◯ Yes ◯ No
2. Likhe lakwenza wazifumanisa ukuba usithobile isidima sakho phambi kwabanye abantu? Has your partner belittled or humiliated you in front of other people?	◯ Yes ◯ No
3. Likhe lakoyikisa lakuphatha kakubi ngabom? Has your partner done things to scare or intimidate you on purpose?	◯ Yes ◯ No
4. Likhe lakugrogrisa ngokonzakalisa wena okanye umntu omkhathaleleyo? Has your partner threatened to hurt you or someone you care about?	◯ Yes ◯ No
5. Likhe lakuqhwaba ngempama okanye lakugibisela ngento enokwenzakalisa? Has your partner slapped you or thrown something at you that could hurt you?	◯ Yes ◯ No
6. Likhe lakutyhala okanye lakunyola? Has your partner pushed or shoved you?	◯ Yes ◯ No
7. Likhe lakubetha ngenqindi okanye ngento enokonzakalisa? Has your partner hit you with a fist or with something else that could hurt you?	◯ Yes ◯ No

8. Likhe likukhabe,likurhuqe okanye likubethe?

Has your partner kicked you, dragged you or beaten you up?

◯ Yes
◯ No

9. Likhe likukrwitshe okanye likutshise ngabom?

Has your partner choked or burnt you on purpose?

◯ Yes
◯ No

10. Likhe likugrogrise okanye lisebenzise umpu, imela okanye nasiphi isixhobo kuwe?

Has your partner threatened to use or used a gun, knife or other weapon against you?

◯ Yes
◯ No

UKUDLAKATHISWA NGOKWESONDO / SEXUAL VIOLENCE

11. Likhe likunyanzele ngokwabelana ngesondo ngaphandle kwemvume yakho? / Has your partner physically forced you to have sexual intercourse when you didn't want to?

◯ Yes
◯ No

12. Wakhe wabelana ngesondo ungafuni, kuba unoloyiko lwento iqabane lakho elinokuthi liyenze?

Did you ever have sexual intercourse when you didn't want to because you were afraid of what your partner might do?

◯ Yes
◯ No

13 Likhe likunyanzele ngokwabelana ngesondo ngendlela ofumanisa ukuba ukuthathela phantsi okanye uyakwenyelisa?

Has your partner forced you to do something sexual that you found degrading or humiliating?

◯ Yes
◯ No

THIS IS FOR THE INTERVIEWER.

14. Nokuba ngomphi na umama ofunyanwe ukuba uyaxhatshazwa liqabane lakhe nangayiphi na indlela uzokudluliswelwa kunontlalontle okufuphi, Ilitha Labantu kwakunye neSouth African Police Services (silandela umthetho: Domestic Violence Act, No 116 of 1998). Umphathi wophando uzoqinisekisa ukuba umthathi nxaxeba ungxulumene nenkonzo zoncedo.

Any woman found to be experiencing domestic or partner violence in any form will be referred to a social worker at the local NGO, Ilitha Labantu and the South African Police Service (per the Domestic Violence Act, No. 116 of 1998). The study coordinator will follow up to ensure the participant has linked to assisting services.

◯ Yes
◯ No

Any other comments

Interviewer's code

_____

Interviewer's signature

_____

9. EPDS

Visit date	_____ (date (dd-mm-yyyy))
Visit code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7

EPDS: Singathanda ukwazi ukuba ubuziva njani kuleveki iphelileyo. Nceda ukhethe esondeleyo kwindlela obuziva ngayo kwiveki edluleyo, hayi nje indlela oziva ngayo namhlanje. Ukuba uziva ungakhulekanga ukuphendula le mibuzo, ungavakalisa siwudlule lombuzo.

We would like to know how you have been feeling in the past week. Please choose the answer that comes closest to how you have felt in the past week, not just how you feel today. Please read all the options for each statement. If you feel uncomfortable answering any of these questions, we can skip the question.

1. Ndibenako ukuhleka ndikwazi nokuphawula izinto ezihlekisayo I have been able to laugh and see the funny side of things	◯ Njengoko bendihleli ndisenza. / As much as I always could ◯ Hayi kangako okwangoku / Not quite so much now. ◯ Ngokucacileyo hayi kangako okwangoku. / Definitely not so much now. ◯ Hayi kwaphela. / Not at all.
2. Bendikuthakazelela ukonwabela izinto. I have looked forward to things with enjoyment.	◯ Njengoko ndandisenza. / As much as I ever did. ◯ Kancinci kunendlela endandisenza ngayo/ A little less than I used to. ◯ Ngaphantsi kunendlela endandisenza ngayo. / Much less than I used to. ◯ Kunqabile ukuba kubenjalo. / Hardly at all.
3. ndiye ndasola isiqu sam ngokungeyomfuneko xa izinto zazihamba kakubi. I have blamed myself unnecessarily when things went wrong	◯ Ewe, ixesha elininzi. / Yes, most of the time. ◯ Ewe, ngelinye ixesha. / Yes, some of the time. ◯ Hayi kangako. / Not very much. ◯ Hayi, zange. / No, never
4. Bendinexhala ngaphandle kwesizathu. I have been anxious or worried for no good reason	◯ Hayi, konke-konke. / No, not at all. ◯ Kunqabile ukuba kubenjalo. / Hardly ever. ◯ Ewe, ngamanye amaxesha. / Yes, sometimes. ◯ Ewe, kakhulu. / Yes, very much.
5. Ndiye ndaziva ndisoyika okanye ndiduduzela ngaphandle kwesizathu. I have felt scared or panicky for no very good reason	◯ Ewe, kaninzi. / Yes, quite a lot. ◯ Ewe, ngamanye amaxesha. / Yes, sometimes. ◯ Hayi kakhulu. / No,not much. ◯ Hayi konke konke. / No, not at all

6. Izinto zindongamele Things have been overwhelming me	◯ Ewe, amaxesha amaninzi bendingakwazi ukwenzanto kwaphela. / Yes, most of the times I haven't been managing at all. ◯ Ewe, ngamanye amaxesha bedingankwazi ukwenzanto njengesiqhelo. / Yes, sometimes I haven't been managing as well as usual. ◯ Hayi, ixesha elininzi bendikwazi ukwenza izinto kakuhle. / No, most of the time I have managed quite well. ◯ Hayi, bendikwazi ukwenza izinto kakuhle oko. / No, I have been managing as well as ever.
7. Bendingonwabanga kangangokuba bekubanzima nokulala. I have been so unhappy that I have had difficulty sleeping	◯ Ewe, ixesha elininzi. / Yes, most of the time. ◯ Ewe, ngamanye amaxesha. / Yes, sometimes. ◯ Hayi kakhulu. / Not very much. ◯ Hayi konke konke . / No, not at all.
8. Ndaye ndaziva ndilusizi okanye ndinxunguphele I have felt sad or miserable	◯ Ewe, ixesha elininzi. / Yes, most of the time. ◯ Ewe, kaninzi. / Yes, quite a lot. ◯ Hayi kakhulu. / Not very much. ◯ Hayi konke konke. / No, not at all
9. Bendingonwabanga kangangokuba bendikhala I have been so unhappy that I have been crying	◯ Ewe, ixesha elininzi. / Yes, most of the time. ◯ Ewe, kaninzi. / Yes, quite a lot. ◯ Ngamanye amaxhesa qha. / Only sometimes. ◯ Hayi Azange / No, never
10. Ingcinga yokuzenzakalisa ikhe yandifikela The thought of harming myself has occurred to me	◯ Ewe, kaninzi. / Yes, quite a lot ◯ Ngamanye amaxesha. / Sometimes ◯ Zange ifane yenzeke. / Hardly ever ◯ Azange / Never
Any other comments	_____
interviewer's code	_____
Interviewer's signature	_____

10. AUDIT-C

Visit date	_____
Visit code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7

Ngoku sizakubuza imibuzo ngokusebenzisa kwakho utywala. Nceda urhangqe impendulo engqamene nawe kumbuzo ngamnye:Ukuba uziva ungakhululekanga ekuphenguleni umbuzo othile, ungavakalisa siwudlule.

I am now going to ask you some questions about your use of alcohol. Please select the relevant answer for each question. If you feel uncomfortable answering any of these questions, you can ask to skip the question

1. Emva kokuba ufumanise ukuba ukhulelwe usisele kangakanani isiselo isinotywala ? Since you found out you were pregnant how often do you have a drink containing alcohol?	◯ Zange / Never ◯ Kanye ngenyanga nangaphantsi / Monthly or less ◯ Kabini ukuya kwisine enyangeni / 2-4 times a month ◯ Kabini ukuya kwisithathu enyangeni / 2-3 times a week ◯ Kane nangaphezulu evekini / 4 or more times a week
2. Emva kokuba ufumanise ukuba ukhulelwe zingaphi iiglasi zesiselo esinotywala oziselayo ngemini? Since you found out you were pregnant how many standard drinks containing alcohol do you have on a typical day when drinking?	◯ 1 okanye 2 / 1 or 2 ◯ 3 Okanye 4 / 3 or 4 ◯ 5 Okanye 6 / 5 or 6 ◯ 7 ukuya 9 / 7 to 9 ◯ 10 okanye ngaphezulu / 10 or more
3. Emva kokuba ufumanise ukuba ukhulelwe, kukangaphi usela iiglasi (zotywala) ezi-5 nangaphezulu ngexesha elinye? Since you found out you were pregnant how often do you have six or more drinks on one occasion?	◯ Zange/ Never ◯ Ngaphantsi kwenyanga / Less than monthly ◯ Ngenyanga / Monthly ◯ Ngeveki / Weekly ◯ Ngosuku okanye malunga nosuku / Daily or almost daily
4. Kunyaka ophelileyo kukangaphi, ufumanisa ukuba awukwazi ukuyeka ukusela xa sele uqalile? During the past year, how often have you found that you were not able to stop drinking once you had started?	◯ Zange/ Never ◯ Ngaphantsi kwenyanga/ Less than monthly ◯ Ngenyanga / Monthly ◯ Ngeveki / Weekly ◯ Ngosuku okanye malunga nosuku / Daily or almost daily

5. Emva kokuba ufumanise ukuba ukhulelwe kukangaphi ungakwazi ukwenza into ubumele ukuyenza ngenxa yokuba ubusela utywala? Since you found out you were pregnant how often have you failed to do what was normally expected of you because of drinking?	◯ Zange / Never ◯ Ngaphantsi kwenyanga / Less than monthly ◯ Ngenyanga / Monthly ◯ Ngeveki / Weekly ◯ Ngosuku okanye malunga nosuku / Daily or almost daily
6. Kulo nyaka uphelileyo kukangaphi ufuna ukusela utywala ekuseni kuba ufuna ukuqala usuku lwakho kakuhle emva kokuba ubusela kakhulu utywala ngezolo? During the past year, how often have you needed a drink in the morning to get yourself going after a heavy drinking session?	◯ Zange / Never ◯ Ngaphantsi kwenyanga / Less than monthly ◯ Ngenyanga / Monthly ◯ Ngeveki / Weekly ◯ Ngosuku okanye malunga nosuku / Daily or almost daily
7. Kulonyaka uphelileyo kukangaphi uzifumanise unesazela okanye uzisola emva kokuba usele? During the past year, how often have you had a feeling of guilt or remorse after drinking?	◯ Zange / Never ◯ Ngaphantsi kwenyanga / Less than monthly ◯ Ngenyanga / Monthly ◯ Ngeveki / Weekly ◯ Ngosuku okanye malunga nosuku / Daily or almost daily
8. Kulonyaka uphelileyo ukhe awakwazi ukukhumbula into eyenzeke kubusuku obudluleyo ngenxa yokuba ubusele? How often have you been unable to remember what happened the night before because you had been drinking?	◯ Zange / Never ◯ Ngaphantsi kwenyanga/ Less than monthly ◯ Ngenyanga / Monthly ◯ Ngeveki / Weekly ◯ Ngosuku okanye malunga nosuku / Daily or Almost daily
9. Ukhe wena okanye omnye umntu wonzakala ngenxa yokusela kwakho? Have you or someone else been injured as a result of your drinking?	◯ Hayi / No ◯ Ewe, kodwa hayi kunyaka ophelilieyo. / Yes, but not in the past year ◯ Ewe, kunyaka ophelilieyo. / Yes, during the past year
10. Emva kokuba uvile ukuba ukhulelwe ngubani osela ,naye kakhulu? Since you found out you were pregnant, who do you mostly drink with?	◯ Ndedwa / No one (alone) ◯ Iqabanwe lam langoku / My current partner ◯ Abahlobo bam / My friends ◯ Amanye okanye elinye qabane / Other sex partner(s) ◯ Abantu endisebenza nabo / People I work with ◯ Okunye / Other
10.1 Since you found out you were pregnant, who do you mostly drink with? Other (specify)	_____
11. Ukusukela kokuba uvile ukuba ukhulelwe, ubuselaphi utywala? Since you have been pregnant, where do you drink alcohol?	◯ Ekhaya / At home ◯ Eshibhini / At shebeen ◯ Endaweni ethengisa ukutya/ At bar or restaurant ◯ Emsebenzini / At Work ◯ Ekhayeni Letshomi / At friends home ◯ Okunye (cacisa) / Other (specify)
11.1 Since you have been pregnant, where do you drink alcohol? (Other)	_____

12. Sikhona isizalwana sakho, okanye isihlobo, unesi, okanye omnye umntu obekhathazekile ngendlela obusela ngayo utywala waze wakucebisa ukuba uthobe isantya? Has a relative or a friend, a doctor or a nurse, or anyone else, been worried about your drug use or said to you that you should stop using drugs?	◯ Hayi / No ◯ Ewe, kodwa hayi kunyaka ophelilieyo / Yes, but not in the past year ◯ Ewe, kunyaka ophelilieyo. / Yes, during the past year
Any other comments	_____
Interviewer's code	_____
Interviewer's signature	_____

11. DUDIT

Visit date	_____
Visit code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7

DUDIT: Sizakubuza imibuzo malunga nokusebenzisa iziyobisi. Nceda urhangqe impendulo eyiyo ngombuzo ngamnye kule ingezantsi. Ukuba uziva ungakhululekanga ukuphendula omnye walombuzo ungasixelela siwudlule lombuzo.

We are now going to ask you some questions about your use of drugs. Please circle the relevant answer for each question below:

If you feel uncomfortable answering any of these questions, you can skip the question by pressing "Next question."

1. Emva kokuba uvile ukuba ukhulelwe ubukhe wasebenzisa iziyobisi ngapandle kotywala Since you found out you were pregnant how often do you use drugs other than alcohol?	◯ Zange / Never ◯ Kanye ngenyanga okanye nganeno / once a month or less often ◯ 2-4 Ngenyanga/ 2-4 times a month ◯ 2-3 Ngeveki / 2-3 times a week ◯ 4 ngeveki okanye ngaphezulu / 4 times a week or more often
2. Emva kokuba uvile ba ukhulelwe kukangakanani usebenzisa ngaphezu kohlobo olunye lweziyobisi ngexesha? Since you found out you were pregnant how often do you use more than one type of drug on the same occasion?	◯ Zange / Never ◯ Kanye ngenyanga okanye nganeno / once a month or less often ◯ 2-4 Ngenyanga/ 2-4 times a month ◯ 2-3 Ngeveki / 2-3 times a week ◯ 4 ngeveki okanye ngaphezulu / 4 times a week or more often
3. Emva kokuba uvile ba ukhulelwe mangaphi amaxesha osebenzisa iziyobisi ngosuku? Since you found out you were pregnant how many times do you take drugs on a typical day when you use drugs?	◯ 0 ◯ 1-2 ◯ 3-4 ◯ 5-6 ◯ 7 or more
4. Kuxhaphake kangakanani ukuba uchaphazeleke kanobom ziziyobisi? Since you found out you were pregnant how often have you been influenced heavily by drugs?	◯ Zange / Never ◯ Ngeneno kunakanye ngenyanga / Less often than once a month ◯ Ngenyanga zonke / Every month ◯ Qho ngeveki / Every week ◯ Ngosuku okanye ngemini zonke / Daily or almost every day

5. Emva kokuba uvile ukuba ukhulelwe, wakhe waziva ukuba unqanqatheko lweziyobisi beluluqilima kangangokuba wahendeka? Since you found out you were pregnant have you felt that your longing for drugs was so strong that you could not resist it?	◯ Zange / Never ◯ Ngeneno kunakanye ngenyanga / Less often than once a month ◯ Ngenyanga zonke / Every month ◯ Qho ngeveki / Every week ◯ Ngosuku okanye ngemini zonke / Daily or almost every day
6. Emva kokuba uvile ukuba ukhulelwe kungangaphi usitya iziyobisi ungahoyi ukwenza into ubumele ukunyenza kuba uphantsi kwempembelelo zezi yobisi? Since you found out you were pregnant how often have you taken drugs and then neglected to do something you should have done?	◯ Zange / Never ◯ Ngeneno kunakanye ngenyanga / Less often than once a month ◯ Ngenyanga zonke / Everymonth ◯ Qho ngeveki / Every week ◯ Ngosuku okanye ngemini zonke / Daily or almost every day
7. Emva kokuba uvile ukuba ukhulelwe ubukhe awakwazi ukuyeka iziyobisi xa sele uziqalile ukuzithatha? Has it happened, Since you have been pregnant that you have not been able to stop taking drugs once you started	◯ Zange / Never ◯ Ngeneno kunakanye ngenyanga / Less often than once a month ◯ Ngenyanga zonke / Everymonth ◯ Qho ngeveki / Every week ◯ Ngosuku okanye ngemini zonke / Daily or almost every day
8. Emva kokuba uvile ukuba ukhulelwe ubukhe wafuna ukuthatha iziyobisi ekuseni kuba ngezolo ubuzithathe kakhulu? Since you found out you were pregnant how often have you needed to take a drug the morning after heavy drug use the day before?	◯ Zange / Never ◯ Ngeneno kunakanye ngenyanga / Less often than once a month ◯ Ngenyanga zonke / Everymonth ◯ Qho ngeveki / Every week ◯ Ngosuku okanye ngemini zonke / Daily or almost every day
9. Emva kokuba uvile ukuba ukhulelwe ubukhe wazisola okanye wanesazela kuba usebenzisa iziyobisi? Since you found out you were pregnant how often have you had guilt feelings or a bad conscience because you used drugs?	◯ Zange / Never ◯ Ngeneno kunakanye ngenyanga / Less often than once a month ◯ Ngenyanga zonke / Everymonth ◯ Qho ngeveki / Every week ◯ Ngosuku okanye ngemini zonke / Daily or almost every day
10. Wakhe wonzakala okanye kwenzakala omnye umntu (ngokwasengqondweni okanye ngokwasemzimbeni) ngenxa yokusebenzisa kwakho iziyobisi? Have you or anyone else been hurt (mentally or physically) because you used drugs?	◯ Hayi / No ◯ Ewe, kodwa hayi kunyaka ophelilieyo / Yes, but not in the past year ◯ Ewe, kunyaka ophelilieyo. / Yes, during the past year
11. Sikhona isizalwana sakho, okanye isihlobo, unesi, okanye omnye umntu obekhathazekile ngendlela osebenzisa ngayo iziyobisi ngayo waza wakucebisa ukuba uthobe isantya? Has a relative or a friend, a doctor or a nurse, or anyone else, been worried about your drug use or said to you that you should stop using drugs?	◯ Hayi / No ◯ Ewe, kodwa hayi kunyaka ophelilieyo / Yes, but not in the past year ◯ Ewe, kunyaka ophelilieyo. / Yes, during the past year

12. Zeziphi iziyobisi ubukhe wazisebenzisa ngoku ukhulelweyo?

Which drugs have you used during pregnancy?

	Yes	No
1.Dagga or marijuana	○	○
2.Tik	○	○
3.Cocaine or crack	○	○
4.Mandrax (button/ iqhosha)	○	○
5.Ecstasy (umgwinyo)	○	○
6.Heroin	○	○
7.Nyaope	○	○

12.7.1 Which drugs have you used during pregnancy? _____

Any other comments

_____

Interviewer's code

_____

Interviewer's signature

_____

1b. Infant Physical Examination Form

Infant PID	_____
Visit Date	_____
Visit code	◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7
Weight	_____ (g)
Length	_____ (cm)
Head Circumference 1	_____ (cm)
Head Circumference 2	_____ (cm)
MUAC 1	_____ (cm)
MUAC 2	_____ (cm)
Additional notes	_____
Assessor Initials	_____
Assessor's signature	_____

3b. Partner Questionnaire

Visit date	_____ (date (dd-mm-yyyy))
Visit Code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7

Sizokubuza imibuzo ethile malunga nezimo zakho zobudlelwane ukusuka emva kotyelelo lwakho lokugqibela. Impendulo zakho zizohlala zikhuselekile/zifihliwe ebantwini, kuquka neqabane lakho. Ukuba uziva ungakhululekanga ekuphenduli eminye imibuzo,ungacela siwudlule.

We are going to ask you some questions about your relationships since your last study visit. Your answers will remain confidential from everyone, including your partner. If you feel uncomfortable answering any of these questions, you can skip the question.

Partner and HIV testing

1. Ingaba ukhona umntu owabelana ngesondo naye? Since your last study visit is there someone that you are having regular sexual relations with?	◯ Hayi / No ◯ Ewe, notata walontwana ndikhulelwe yena / Yes, with the father of my unborn baby ◯ Ewe, nomnye umntu ongenguye utata walomntwana ndikhulelwe yena / Yes, with someone else
2. Ingaba liqabane elitsha na eli (obenalo emva kokuba uzosibona)? Is this partner a new partner (e.g. new since the last study visit)?	◯ Yes ◯ No
3. Ungachaza njani isimo sobudlelwane sakho? How would you describe your current, main relationship?	◯ Utshatile, nihlala kunye / Married, living together ◯ Utshatile, anihlali kunye / Married, not living together ◯ Anitshatanga, nihlala kunye / Not married, living together ◯ Anitshatanga, anihlali kunye / Not married, not living together ◯ Enye / Other
3.1 How would you describe your current, main relationship? Other	_____

4. Nithandane ixesha elingakani neqabane lakho (bhala iiveki okanye iinyanga)? How long have you been in a relationship with this person? (please note "weeks" or "months")	_____ (specify the time)
5. Ingaba wabelana ngesondo nabanye abantu (nokuba ayiloqabane lakho)? Do you have relationships/sexual partners with any other people (even if you are not currently in a relationship)?	◯ Yes ◯ No
6. Ingaba iqabane lakho linawo amanye amaqabane? Does your other partner have other partners?	◯ Andiyazi / I don't know ◯ Yes ◯ No
7. Ingaba elinye iqabane lakho liyakuxhasa ngezinto ezithengwayo okanye ngexhaso yemali? Does your other partner provide you with material or financial support?	◯ Yes ◯ No

8. Chaza intlobo yesimo sobudlelwane sakho namanye amaqabane? **What is the nature of your other relationship(s)?**	
8.1 Iqabane otshate nalo / Spouse/married	◯ Yes ◯ No
8.2 Iqabane / Boyfriend/ girlfriend	◯ Yes ◯ No
8.3 Iqabane lamanqapha-nqapha / Casual partner/one night stands	◯ Yes ◯ No
8.4 Okunye / Other	◯ Yes ◯ No
8.4.1 What is the nature of your other relationship(s)? other	_____

9. Leliphi ibanga lemfundo iqabane lakho eligqibileyo? What is the highest level of education that your current main partner has completed?	◯ None ◯ Grade 1 / Standard A ◯ Grade 2 / Standard B ◯ Grade 3 / Standard 1 ◯ Grade 4 / Standard 2 ◯ Grade 5 / Standard 3 ◯ Grade 6 / Standard 4 ◯ Grade 7 / Standard 5 ◯ Grade 8 / Standard 6 ◯ Grade 9 / Standard 7 ◯ Grade 10 / Standard 8 ◯ Grade 11 / Standard 9 ◯ Grade 12 / Standard 10 ◯ Uyile na kumabanga emfundo aphezulu kodwa awusigqibanga isfundo sakho / Attended some tertiary education (University/College) ◯ Uyile na kumabanga emfundo aphezulu kodwa wasigqibanga isfundo sakho / Completed tertiary education (University/College)
10. Ingaba iqabane lakho liyafunda okanye liyaphangela? Is your current main partner employed and/or studying?	◯ Yes ◯ No
11. Yeyiphi kwezi zilandelayo echaza iqabane lakho ngcono? Which one of the following best describes what your current main partner does?	◯ Uphangela isigxina / Employed full-time ◯ Uphangela manqapha-nqapha / Employed part-time ◯ Isingxungxu okanye umsebenzi onje ngokuthengisa endlini okanye esitratweni / Informal job/hawker ◯ Ungumfundi wesikolo / Attending school/learner ◯ Ungumfundi webanga eliphezulu(idyunivesiti okanye ikholeji) / Attending tertiary education (University/College)
12. Ingaba iqabane lakho ngoku lakhe layivavanyelwa i-HIV? Has your current main partner ever been tested for HIV?	◯ Andiyazi / I don't know ◯ Yes ◯ No
13. Lwalunini uvavanyo lwakhe lwakutsha nje lweHIV? When was your current main partner's most recent HIV test done?	◯ 0 - 6 months ◯ 6 - 12 months ◯ > 12 months ◯ I don't know
14. Uvavanyo lwakhe lalusenzelwa phi? Where was your current main partner's test done?	◯ Uluntu / Community ◯ Isibhedlele okanye iziko lezempilo / Hospital or health centre ◯ Okunye (cacisa) / Other (specify)
15. Zithini iziphumo zakhe zovavanyo lweHIV zakutsha nje? What was the result of your current main partner's most recent HIV test?	◯ Akanayo intsholongwane / HIV negative ◯ Uphila nentsholongwane / HIV positive ◯ Andazi / Don't know

16. Usifumanise njani isimo se-HIV seqabane lakho?

How did you find out about your current main partner's HIV status?

- ◯ Iqabane lam lindixelele ngokwalo / Partner told me directly on his own
- ◯ Iqabane lam lindixelele emva kokuba ndimbuzile / Partner told me after I asked
- ◯ Ndive komnye umntu / Heard from somebody else
- ◯ Ndihambe neqabane lam ngoku beliyofumana iziphumo / I went with my partner when he got his results
- ◯ Sihambe sobabini neqabane lam ukuya kuvavanyo lweHIV / We tested together as a couple
- ◯ Ndizicingele, ndiqikelele / I just guessed, assumed, figured it out
- ◯ Undinike intluva/ undinike umkhondo / My partner left clues
- ◯ Okunye / Other

17. Ingaba iqabane lakho lisebenzisa amachiza okuthomalalisa intsholongwane ngoku?

Is your current main partner currently taking antiretroviral drugs?

- ◯ Andiyazi / I don't know
- ◯ Yes
- ◯ No

18. Ingaba iqabane lakho liyayazi ukuba ubukhe wayokuvavanyela i-HIV??

Does your current main partner know that you have had an HIV test?

- ◯ Andiyazi / I don't know
- ◯ Yes
- ◯ No

19. Ingaba iqabane lakho lifumanise njani ukuba ubukhe waya kuvavanyo lweHIV?

How did your current main partner find out that you had an HIV test?

- ◯ Iqabane lam liye kuvavanyo nam / Partner tested with me
- ◯ Iqabane lam ndilixelele ngokwam / I told my partner directly that I had an HIV test
- ◯ Iqabane lam ndilixelele emva kokuba lindibuzile / I told my partner after my partner asked
- ◯ Iqabane lam live ngomnye umntu / Partner heard from someone else
- ◯ Iqabane lam lizicingele, liziqikelelele / Partner guessed, assumed, or figured it out

20. Ungaziva ukhululekile ukucela iqabane lakho langoku liyokuya kuvavanyela i-HIV?

Would you feel comfortable asking your current main partner to test for HIV?

- ◯ Andiyazi / I don't know
- ◯ Yes
- ◯ No

21. Wakhe wayo vavanyela i-HIV neqabane lakho langoku?

Since your last visit have you attended couples HIV testing with your current main partner?

- ◯ Yes
- ◯ No

22. Ungaziva ukhululekile ukuhamba neqabane lakho langoku ukuya kuvavanyela i-HIV?

Would you feel comfortable going with your current main partner for couples HIV testing?

- ◯ Andiyazi / I don't know
- ◯ Yes
- ◯ No

23. Ungaziva ukhululekile ukucela abanye abantu obukhe wabelana ngesondo nabo ukuba baye kuvavanya i-HIV? Would you feel comfortable asking any of the other people that you have had sex with to test for HIV?	◯ Andiyazi / I don't know ◯ Yes ◯ No
Interviewer's notes	_____
Interviewer's code	_____
Interviewer's signature	_____

4b. PrEP Knowledge and Attitudes

Visit date

_____
(date (dd-mm-yyyy))

Visit Code

- ◯ B
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6
- ◯ 7

Ndizokubuza imibuzo malunga nolwazi lwakho kwakunye nengcinga zakho nge-PrEP, ndizokubuza malunga nenxaso oyifimanayo ekhaya kwakunye naseluntwini. Ndiyakucela uzame ukuphendula lemibuzo ngokunyanisekileyo.

I am going to ask you about your previous knowledge and thoughts about PrEP. I will also ask about your social support system at home and in the community. Please do your best to answer these questions as honestly as possible.

0. Ingaba ubukhe wathatha iPrEP kwezintsuku ziyi-30 zidlulileyo?

Did you take PrEP in the last 30 days?

- ◯ Yes
- ◯ No

1. Phambi kokuba uze apha, wakhe wava nge-PrEP?

Before today's visit, had you heard about pre-exposure prophylaxis or PrEP?

- ◯ Yes
- ◯ No

2. Waqala ukuva nge-PrEP phi?

Where did you first learn about PrEP?

- ◯ Ekliniki / Clinic
- ◯ Esikolweni / School
- ◯ Ngelungu losapho / Family member
- ◯ Ngetshomi / umhlobo / Friend
- ◯ Kunomathotholo okanye umabona kude / Radio/TV
- ◯ Okunye / Other

2.1 Where did you first learn about PrEP? Other, specify

_____

3. Phambi kokuba uze apha, yeyiphi kwezi echaza ngcono ulwazi lakho lwe-PrEP?

Before today's visit, which of the following best described your understanding of what PrEP was?

3.1 Ukusebenzisa i-condom ukuze uzikhusele kwi-HIV

Using condoms to prevent HIV

- ◯ Yes
- ◯ No

3.2 Ukuthatha amayeza (okanye ARV) emva kokuba usethubeni lokusuleleka yi-HIV ukuze uzikhusele ekufumaneni i-HIV Taking medicine (or ARVs) after you are exposed to HIV to prevent getting HIV	◯ Yes ◯ No
3.3 Iyeza okanye ipilisi olithathayo xa ufuna ukuzikhusela kwi-HIV Medicine you take when you are HIV-negative to prevent you from getting HIV	◯ Yes ◯ No
3.4 Okunye Other	◯ Yes ◯ No
3.4.1 Before today's visit, which of the following best described your understanding of what PrEP was? Other, specify	_____

I-PrEP yindlela entsha yokukhusela umntu kwi-HIV, iquka ukuthatha ipilisi ngomlomo rhoqo ngokusuku. La mayeza (amachiza) asebenza ngokunqanda I-HIV ekusuleleni umntu, ungayisebenza naxana ukhulelwe okanye uncancisa usana, ikhuselekile.

PrEP is a new method for preventing HIV that involves taking a daily pill by mouth. This medication works to keep HIV from establishing infection, and is safe to use in pregnancy and breastfeeding.

4. Ingaba uyamazi omnye umntu othatha okanye osebenzisa i-PrEP? Do you know anyone taking PrEP?	◯ Hayi / No ◯ Ewe / Yes ◯ Andazi / Don't know
5. Ngubani omaziyo othatha okanye osebenzisa iPrEP? Who do you know that is taking PrEP?	
5.1 Iqabane lakho Spouse/partner	◯ Yes ◯ No
5.2 Ilungu losapho lwakho Family member	◯ Yes ◯ No
5.3 Itshomi/isihlobo Friend	◯ Yes ◯ No
5.4 Umntu osebenza naye Colleague	◯ Yes ◯ No

5.5 Umntu ofunda naye esikolweni Classmate	◯ Yes ◯ No
5.6 Okunye (Cacisa) Other (specify)	◯ Yes ◯ No
5.6.1 Who do you know that is taking PrEP? Other, Specify	_____
6. Ingaba unalo na uloyiko okanye ixhala malunga ne-PrEP ? Do you have fears or concerns about PrEP?	◯ Yes ◯ No
7. Ingaba ikhona into ekuxhalabisayo okanye ekoyikisayo ngokusebenzisa i-PrEP rhoqo ngosuku? Do you have concerns about taking PrEP every day?	◯ Yes ◯ No
7.0 Yintoni le ikoyikisayo okanye ikwenza ixhala ngokuthatha iPrEP rhoqo ngosuku? What fears or concerns do you have about taking PrEP every day?	
7.1 Ubungakanani okanye incasa yepilisi Size or taste of pills	◯ Yes ◯ No
7.2 Abantu akumelanga bathathe ipilisi ngaphandle kokuba bayagula People should not take drugs unless they are sick	◯ Yes ◯ No
7.3 Abantu bazocinga ndine-HIV People will think I have HIV	◯ Yes ◯ No
7.4 Iqabane lam lizokucaphuka My partner will be upset	◯ Yes ◯ No
7.5 Izakuchaphazela impilo yosana lwam Effect on my baby's health	◯ Yes ◯ No
7.6 Ndicinga ukuba ezipilisi azizokuyikhusela i-HIV I don't think the pills will prevent HIV	◯ Yes ◯ No
7.7 Izoba ngumthwalo ukuthatha ipilisi ngosuku Burdensome to take pill every day	◯ Yes ◯ No
7.8 Okunye / Other	◯ Yes ◯ No

7.8.1 What fears or concerns do you have about taking PrEP every day? Other, specify	_____
8. Ingaba unexhala ngemiphumela ebangwa yile-PrEP? How worried are you about side effects from PrEP?	◯ NdineXhala kakhulu / Very worried ◯ Ndinexhala kodwa alikho ngamandla / Somewhat worried ◯ Andinalo ixhala / Not worried
9. Ucinga ukuba iPrEP izosebenza kangakanani na ekukhuseleni iHIV ? How effective do you think PrEP will be at preventing HIV?	◯ Ayizosebenza tu /Not at all effective ◯ Izosebenza kodwa kancinci / Slightly effective ◯ Izosebenza kodwa hayi kangako /Moderately effective ◯ Izosebenza kakhulu / Very effective ◯ Andiqinisekanga / Unsure
10. Ingaba unawo na umdla wokuthatha iPrEP? Are you interested in taking PrEP?	◯ No ◯ Yes ◯ Unsure
11. Umdla wakho ungakaninani ekuthatheni iPrEP? How interested are you in taking PrEP?	◯ Ndinomdla kakhulu /Very interested ◯ Ndinomdla kancinci / A little interested ◯ Ndinomdla kodwa hayi kangako /Somewhat interested ◯ Andinamdla kakhulu /Very uninterested ◯ Andiqinisekanga /Unsure
12. Esona sizathu sakho sofuna ukuthatha i-PrEP sithini? What is the MAIN reason that you would like to take PrEP?	◯ Iqabane lam linetsholongwane kagawulayo / My partner is HIV positive ◯ Andizazi ziphumo ze-HIV zeqabane lam / I don't know my partner's status ◯ Ndinamaqabane angaphezulu kwesinye / I have more than one partner ◯ Iqabane lam linamanye amaqabane / My partner has other sex partners ◯ Ukukhusela umntwana wam ekufumaneni i-HIV / To protect my child from getting HIV ◯ Ndicinga ukuba ndinganayo i-HIV / I think I may have HIV ◯ Okunye / Other
12.1 What is the MAIN reason that you would like to take PrEP? Other	_____

Notes from the interviewer	
Any other comments	_____
Interviewer's code	_____
Interviewer's signature	_____

5b. PrEP Readiness Scale

Visit date	_____ (date (dd-mm-yyyy))
Visit Code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7

Ndizokubuza imibuzo malunga nolwazi lwakho kwakunye nengcinga zakho nge-PrEP. i-PrEP yindlela entsha yokukhusela umntu kwi-HIV, iquka ukusela ipilisi ngomlomo rhoqo ngosuku. La mayeza(amachiza) asebenza ngokunqanda I-HIV ekusuleleni umntu, kukhuselekile ukuyisebenzisa xa ukhulelwe naxana uncancisa. Ndizokubuza malunga nenxaso oyifimanayo ekhaya kwakunye naseluntwini. Ndiyakucela uzame ukuphendula lemibuzo ngenyaniso. Ukuba uziva ungakhakhulukekanga ekuphenduleni omnye walemibuzo, nceda uvakalise siwudlule lombuzo.

Lemibuzo llandelayo nceda uvakalise ukuba awuvimi ngamandla, awuvumi, uphakathi nendawo, uyavuma okanye uyavuma ngamandla

I am going to ask you about your previous knowledge and thoughts about PrEP. PrEP is a new method for preventing HIV that involves taking a daily pill by mouth. This medication works to keep HIV from establishing infection,and is safe to use in pregnancy and breastfeeding. I will also ask about your social support system at home and in the community. Please do your best to answer these questions as honestly as possible. If you feel uncomfortable answering any of these questions, you can skip the question

For the following questions please tell me if you strongly disagree, disagree, neither agree or disagree, agree or strongly agree

1. Ndikulungele ukuthatha i-PrEP ukuze ndizikhusele kwi-HIV. / I am ready to start taking medication (PrEP) to protect against HIV.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
2. Ndiyakholwa ukuba ukuthatha i-PrEP kuzondikhusela kwi-HIV. / I believe taking PrEP can keep me healthy.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Andiphikisi kwaye andivumi / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree

3. Ndiyakholwa ukuba ukuthatha i-PrEP kuzogcina usana lwam lusempilweni. / I believe that taking PrEP can keep my baby healthy.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
4. Ndizokwazi ukuqhagamiselana nabasebenzi bophando ukuba ndinemibuzo okanye iingxaki malunga ne-PrEP? / I would know how to contact the study staff if I had problems or questions about the PrEP medication.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
5. Ukuba andiziseli kakuhle ipilisi ze-PrEP ngalendlela ndixelelwe ngayo ndingafumana i-HIV. / If I don't take my PrEP medication exactly as instructed, I might get infected with HIV.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
6. Ndiyakhathazeka ngempilo yomntwana wam ukuba ndisela-PrEP. / I worry about my baby's health if I take PrEP (R)	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Andiphikisi kwaye andivumi / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
7. Ndiyakhathazeka ngokukhulelwa kwam ukuba ndisela i-PrEP. / I worry about my pregnancy if I take PrEP (R)	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
8. Impilo yam okanye umntwana wam izoba xenge-xenge ukuba ndisela iPrEP. / My or my baby's health will be worse if I take PrEP (R)	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
9. Ukusela ipilisi/amayeza e-PrEP akuzondinceda ncam Taking PrEP medication would not really help me. (R)	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
10. Nokuba kunzima kangakanani, ndizokwazi ukuxelela abasebenzi bophando xana ndiphosile ukusela amayeza wam e-PrEP. / Even when it may be difficult, I will be able to let the study staff know if I miss doses of my PrEP medication.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
11. Ukusela amayeza/ipilisi ze-PrEP ngendlela eyiyo kuzondikhusela ekufumaneni i-HIV. / Taking my PrEP medication as prescribed would keep me from getting HIV.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree

12. Ndizosela amayeza/ipilisi zam ze-PrEP nokuba zizondigulisa kuqala kuba ndiyayazi ukuba imiphumela izakuphela. / I would take my PrEP medications even if they made me sick at first because the side effects would go away.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
13. Usapho lwam nabahlobo bam endizobaxelela ukuba ndikwi-PrEP, bazondikhumbuza ukusela amayeza wam. / My family and friends who I will tell I am on PrEP would help me remember to take my medication.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
14. Ndiyayazi ukuba ndizokwazi ukusela amayeza wam e-PrEP kakuhle. / I know that I will be able to take my PrEP medication correctly.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
15. Kuzokubaluleka ukuba ndithathe amayeza am e-PrEP kakuhle nangexhesa ngemini. / It would be important to me to take my PrEP medication correctly and on time every day.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
Lemibuzo ilandelayo ibuza ngokuxelela abanye abantu ukuba uzothatha inxaxheba koluphando. **These next items ask about you telling other people that you're taking part in this study.**	
16. Ingaba ukhona umntu oceba ukumchazela ngecebo lakho lokuthatha i-PrEP? Do you plan to tell anyone about your plan to take PrEP?	◯ Hayi / No ◯ Ewe/ Yes ◯ Andifuni ukuthatha iPrEP / Don't plan on taking PrEP
Ukuba uceba ukuxelela umntu ukuba usela iPrEP , phendula u-ewe okanye u-hayi kumntu oceba ukumxelela koluluhlu lusezantsi. **If you plan to tell anyone about your plan to take PrEP, answer "yes" or "no" for each person(s) you plan to disclose to in the list below.**	
17.1 Umnyeni/ Iqabane lakho/ Umntu owabelana ngesondo naye? / Your husband/boyfriend/sex partner?	◯ Yes ◯ No
17.2 Umama okanye Utata wakho? / Your mother or your father?	◯ Yes ◯ No
17.3 Ubhuti okanye usisi wakho? / Your sister or your brother?	◯ Yes ◯ No
17.4 Amanye amalungu osapho lwakho? / Other family members?	◯ Yes ◯ No

17.5 Umhlobo/ itshomi? / Friends?	◯ Yes ◯ No
17.6 Abamelwane? / Neighbours?	◯ Yes ◯ No
17.7 UNesi okanye ugqirha abangaphandle koluphando? / Nurse or doctor outside the study?	◯ Yes ◯ No
17.8 Abanye abantu(cacisa)/ Other persons	◯ Yes ◯ No
17.8.1 Abanye abantu(cacisa)/ Other persons? Please specify:	_____

Ucinga ukuba lomntu uzokuncedisa akukhumbuze kwaye akuxhase ekusel amayeza akho ePrEP?

Do you think his/her/their reaction will be supportive to remind you to take (or continue taking) PrEP?

18.1Umnyeni/ Iqabane lakho / Umntu owabelana ngesondo naye? / Your husband/boyfriend/sex partner?	◯ No ◯ Yes ◯ N/A
18.2 Umama okanye Utata wakho? / Your mother or your father?	◯ No ◯ Yes ◯ N/A
18.3 Ubhuti okanye usisi wakho? / Your sister or your brother?	◯ No ◯ Yes ◯ N/A
18.4 Amanye amalungu osapho lwakho? Other family members?	◯ No ◯ Yes ◯ N/A
18.5 Umhlobo/ itshomi? Friends?	◯ No ◯ Yes ◯ N/A
18.6 Abamelwane? Neighbors?	◯ No ◯ Yes ◯ N/A
18.7 UNesi okanye ugqirha abangaphandle koluphando? Nurse or doctor outside the study?	◯ No ◯ Yes ◯ N/A
18.8 Abanye abantu(cacisa)/ Other persons?	◯ No ◯ Yes ◯ N/A
18.8.1 Abanye abantu(cacisa)/ other persons?	_____

Any other comments	
Interviwer's code	
Interviewers signature	

6b. PrEP HIV Stigma

Visit date	_____ (date (dd-mm-yyyy))
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Ndizokubuza ngengcinga kwakunye nemvakelelo zakho ngokusebenzisa I-PrEP kwakunye ne-HIV
Ukuba uziva ungakhululekanga ekuphenduleni omnye umbuzo apha, ungandixelela ndiwudlule lo mbuzo.

I am now going to ask you about your thoughts and feelings about using PrEP and about HIV. If you feel uncomfortable answering any of the questions, please tell me to skip to the next question.

1. Ndiziva ndinentloni ngokusebenzisa iPrEP / I feel ashamed of using PrEP	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
2. Ndiziva ndihlazekile ukusebenzisa i-PrEP / I feel embarrassed about using PrEP	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
3. Ndiziva ndisemandleni ukusebenzisa I-PrEP? / I feel empowered to use PrEP	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
4. Ndicinga ukuba abantu bazokundinika ubunzima (ngokuthi bahlekise ngam okanye bandihlebe) ukuba ndiyabaxelela ukuba ndisela i-PrEP / I think people will give me a hard time (such as make fun of me, or talk badly about me) if I tell them I am taking PrEP	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
5. Ndicinga ukuba abantu bazondigxeka ukuba ndithatha i-PrEP? / I think people will judge me negatively if I take PrEP?	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree

6. Ndicinga ukuba ndikomkhulu umngcipheko wobudlobongela okanye ukudlwengulwa ukuba ndisela iPrEP / I think I am at greater risk for physical violence or rape if I take PrEP.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
7. Abantu bazocinga ukuba ndiziphethe kakuhle ukuba ndisela i-PrEP People will think I am behaving responsibly by taking PrEP	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
8. Ndoyika ukuba ndingafumana iHIV xa ndinodibana namathe omntu ophila neHIV / I fear that I could contract HIV if I come into contact with the saliva of a person living with HIV	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
9. Andinofuna ukuhlala ecaleni komntu one-HIV, umzekelo emotweni , ecaweni okanye kwigumbi lokulinda. / I would not like to sit close to someone living with HIV, for example on public transport, at church or in a waiting room	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
10. Ndinganetloni ukuba kungakho umntu one-HIV kusapho lwam. / I would be ashamed if someone in my family had HIV	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
11. Ngamanye amaxhesa abantu bathetha kakubi ngabantu ababacingela ukuba baphila ne HIV kwabanye abantu. / People sometimes talk badly about people thought to be living with HIV to others	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
12. Abantu abacingelwa ukuba baneHIV baphela bengahlonitshwa. / People thought to be living with HIV lose respect and standing	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
13. Abantu abacingelwa ukuba baphila ne-HIV bayathukwa, baxhatshazwe futhi/ okanye bagrogriswe. / People thought to be living with HIV are verbally insulted, harassed and/or threatened	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
14. Abantu abacingelwa ukuba baphila ne-HIV bayebabethwe ngamanye amaxhesha. / People thought to be living with HIV are sometimes physically assaulted	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Andiphikisi kwaye andivumi / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree

15. Ngamanye amaxesha abantu bachaza abanye abantu ukuba bane-HIV ngaphandle kwemnvume yabo. / People sometimes disclose that other people are HIV positive without their permission.	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
16. Ngamanye amaxesha abasebenzi bezempilo bathetha kakubi ngabantu abaphila okanye abacingelwa ukuba baphila ne-HIV kwabanye abantu. / Health workers sometimes talk badly about people living with or thought to be living with HIV to others	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
17.Ngamanye amaxesha abasebenzi bezempilo bachaza ukuba abantu baphila ne HIV ngaphandle kwemvume yabo. / Health workers sometimes disclose that other people are HIV positive without their permission	◯ Andivumi ngamandla / Strongly Disagree ◯ Andivumi / Disagree ◯ Ndiphakathi nendawo / Neither Agree nor Disagree ◯ Ndiyavuma / Agree ◯ Ndivuma ngamandla / Strongly Agree
Any other comments	_____
Interviewer's code	_____
Interviewer's signature	_____

7b. Sexual Behaviour

Ngoku sizokubuza imibizo embalwa ngokwabelana ngesondo. Nakubani na ukwabelana ngesondo kohlukile kwaye akukho mphendulo elungileyo nengalunganga- sicela usixelele ngamava akho. Ngaphandle kokuba ndikhankanya olunye uhlobo lokwabelana ngesondo, xa ndisithi ukwabelana ngesondo koluphando, ndithetha indoda xa ifake ubudoda bayo kwisini sobufazi okanye ezimpundiwini. Ukuba uziva ungakhululekanga ekuphenduleni omnye walemibuzo, nceda uvakalise udlulwe lombuzo.

We are now going to ask you a few questions about your sex life. Everyone's sex life is different and there are no right or wrong answers - please just tell us about your own experience. Unless I mention another kind of sex in particular, when I say "sex" during this survey I mean when a man's penis is inserted into a woman's vagina or her butthole. If you feel uncomfortable answering any of these questions, you can skip the question.

Visit date

_____
(date (dd-mm-yyyy))

Visit Code

- ◯ B
- ◯ 2
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- ◯ 5
- ◯ 6
- ◯ 7

A. General sexual behaviors
Ndizoqala nje ngeminye imbibuzo yokwabelana ngesondo

I am going to start with some general questions about your sex life.

1. Bangaphi abantu owakhe wabelana ngesondo nabo emva kotyelelo lwakho lokugqibela koluphando?

How many different people did you have sex with since your last study visit?

_____
(No. of sex partners)

2. Ingaba omnye wabantu nguyise walomntwana ukhulelwe yena?

Were any of these people the father of the baby of the current pregnancy?

- ◯ Yes
- ◯ No

3. Kukangaphi usabelana ngesondo emva kotyelelo lwakho lokuqgibela? How often did you have sex since your last study visit?	◯ Kanye ngenyanga okanye nganeno / Once a month or less often ◯ 2-4□ngenyanga / 2-4 times a month ◯ 5-20□genyanga / 5-20 times per month ◯ 20 nangaphezulu ngenyanga / More than 20 times per month (No. of sex partners)
4. Kukangaphi usebenzisa ikhondom eyotata okanye eyomama xa usabelana ngesondo emva kotyelelo lwakho lokuqgibela? How often did you use a male or female condom when you had sex since your last study visit?	◯ Zange / Never (not at all) ◯ Nqabile / Rarely (not very often) ◯ Ngamanye amaxesha / Sometimes (about half the time I had sex) ◯ Phantse lonke ixesha / Almost always (almost every time I had sex) ◯ Rhoqo / Always (every time)
5. Ubukhe wasebenzisa ikhondom ngexesha lokugqibela usabelana ngesondo? Did you use a condom the last time you had sex?	◯ Yes ◯ No
6. Ubukhe wabelana ngesondo ezimpundu (iqabane lakho lifaka isini salo sobudoda ezimpundwini zakho) emva kotyelelo lwakho lokuqgibela koluphando.? Have you had anal sex since your last study visit? (where he puts his penis in your butt)?	◯ Yes ◯ No
7. Ubukhe wabelana ngesondo ngomlomo (Xa efaka umlomo wakho kwisini sakhe sobudoda) emva kotyelelo lwakho lokuqgibela koluphando? Have you had oral sex since your last study visit? (when you put your mouth on his penis)?	◯ Yes ◯ No
8. Wakhe wanyanzelwa ngokwabelana ngesondo okanye wadlwengulwa emva kotyelelo lwakho lokugqibela koluphando? Have you been forced to have sex or raped since your last study visit?	◯ Yes ◯ No
Any other comments	_____
Interviewer's code	_____
Interviwer's signature	_____

8b. Risk perception & IPV

Visit date	_____ (date (dd-mm-yyyy))
Visit code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7

Ngoku sifuna ukubuza ngemizwa yakho malunga ne-HIV. Azikho impendulo ezilungileyo nezingalunganga. Sixelele ngemvakalelo yakho nangempilo yakho. Ukuba uziva ungakhululekanga ekuphenduleni omnye umbuzo apha, ungandixelela ndiwudlule lo mbuzo.

I will now ask about your feelings about HIV. Again, there are no right or wrong answers - please just tell us about your own feelings and experiences. If you feel uncomfortable answering any of these questions, you can skip the question by pressing "Next question."

1. Ungawachaza njani amathuba akho okufumana iHIV kulonyaka ulandelo? How would you describe your chances of getting HIV in the next year?	◯ Amathuba awekho / No chance at all ◯ Amathuba mancinci / Small chance ◯ Amathuba aphakathi /Moderate chance ◯ Amathuma makhulu /Great chance
2. Ungawachaza njani amathuba etshomi zakho ezingamantombazane okufumana iHIV kulonyaka ulandelayo? How would you describe your female friends' (your girlfriends) chances of getting HIV in the next year?	◯ Amathuba awekho / No chance at all ◯ Amathuba mancinci / Small chance ◯ Amathuba aphakathi / Moderate chance ◯ Amathuma makhulu / Great chance
3.Ungawachaza njani amathuba womntwana wakho lo umkhulelweyo wokufumana iHIV kulonyaka ulandelayo? How would you describe your infant's chances of getting HIV in the next year	◯ Amathuba awekho / No chance at all ◯ Amathuba mancinci / Small chance ◯ Amathuba aphakathi / Moderate chance ◯ Amathuma makhulu /Great chance
4. Uxhalabe kangakanani ngoku hlukunyezwa okanye ukudlwengulwa kwezinyanga zintathu zilandelayo? How concerned are you about sexual violence or rape in the next 3 months?	◯ Andixhalabanga tu / Not concerned at all ◯ Ndixhalabile kancinci / Somewhat concerned ◯ Ndixhabalile / Concerned ◯ Ndixhalabe kakhulu / Very concerned

5. Uxhalabe kangakanani ngokubethwa emzimbeni okanye ukuhlaselwa kwezinyanga zintathu zilandelayo? How concerned are you about being attacked physically in the next 3 months?	◯ Andixhalabanga tu / Not concerned at all ◯ Ndixhalabile kancinci / Somewhat concerned ◯ Ndixhabalile / Concerned ◯ Ndixhalabe kakhulu / Very concerned

Siza kubuza imibuzo embalwa malunga nobundlobongela bokudlakathiswa liqabane. Ukuba uziva ungakhululekanga ekuphenduleni omnye umbuzo ungachaza udlulwe lombuzo.

We are going to ask you a few questions relating to partner violence. If you feel uncomfortable answering any of these questions, you can skip the question.

UKUDLAKATHISWA NGOKWASENGQONDWENI / Psychological Violence

1. Iqabane lakho likhe lakuthuka okanye lakwenza uzive ungalunganga? Has your partner insulted you or made you feel bad about yourself?	◯ Yes ◯ No
2. Likhe lakwenza wazifumanisa ukuba usithobile isidima sakho phambi kwabanye abantu? Has your partner belittled or humiliated you in front of other people?	◯ Yes ◯ No
3. Likhe lakoyikisa lakuphatha kakubi ngabom? Has your partner done things to scare or intimidate you on purpose?	◯ Yes ◯ No
4. Likhe lakugrogrisa ngokonzakalisa wena okanye umntu omkhathaleleyo? Has your partner threatened to hurt you or someone you care about?	◯ Yes ◯ No
5. Likhe lakuqhwaba ngempama okanye lakugibisela ngento enokwenzakalisa? Has your partner slapped you or thrown something at you that could hurt you?	◯ Yes ◯ No
6. Likhe lakutyhala okanye lakunyola? Has your partner pushed or shoved you?	◯ Yes ◯ No
7. Likhe lakubetha ngenqindi okanye ngento enokonzakalisa? Has your partner hit you with a fist or with something else that could hurt you?	◯ Yes ◯ No

8. Likhe likukhabe,likurhuqe okanye likubethe?

Has your partner kicked you, dragged you or beaten you up?

◯ Yes
◯ No

9. Likhe likukrwitshe okanye likutshise ngabom?

Has your partner choked or burnt you on purpose?

◯ Yes
◯ No

10. Likhe likugrogrise okanye lisebenzise umpu, imela okanye nasiphi isixhobo kuwe?

Has your partner threatened to use or used a gun, knife or other weapon against you?

◯ Yes
◯ No

UKUDLAKATHISWA NGOKWESONDO / SEXUAL VIOLENCE

11. Likhe likunyanzele ngokwabelana ngesondo ngaphandle kwemvume yakho? / Has your partner physically forced you to have sexual intercourse when you didn't want to?

◯ Yes
◯ No

12. Wakhe wabelana ngesondo ungafuni, kuba unoloyiko lwento iqabane lakho elinokuthi liyenze?

Did you ever have sexual intercourse when you didn't want to because you were afraid of what your partner might do?

◯ Yes
◯ No

13 Likhe likunyanzele ngokwabelana ngesondo ngendlela ofumanisa ukuba ukuthathela phantsi okanye uyakwenyelisa?

Has your partner forced you to do something sexual that you found degrading or humiliating?

◯ Yes
◯ No

THIS IS FOR THE INTERVIEWER.

14. Nokuba ngomphi na umama ofunyanwe ukuba uyaxhatshazwa liqabane lakhe nangayiphi na indlela uzokudluliswelwa kunontlalontle okufuphi, Ilitha Labantu kwakunye neSouth African Police Services (silandela umthetho: Domestic Violence Act, No 116 of 1998). Umphathi wophando uzoqinisekisa ukuba umthathi nxaxeba ungxulumene nenkonzo zoncedo.

Any woman found to be experiencing domestic or partner violence in any form will be referred to a social worker at the local NGO, Ilitha Labantu and the South African Police Service (per the Domestic Violence Act, No. 116 of 1998). The study coordinator will follow up to ensure the participant has linked to assisting services.

◯ Yes
◯ No

Any other comments

Interviewer's code _____

Interviewer's signature _____

9b. EPDS

Visit date	_____ (date (dd-mm-yyyy))
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EPDS: Singathanda ukwazi ukuba ubuziva njani kuleveki iphelileyo. Nceda ukhethe esondeleyo kwindlela obuziva ngayo kwiveki edluleyo, hayi nje indlela oziva ngayo namhlanje. Ukuba uziva ungakhulekanga ukuphendula le mibuzo, ungavakalisa siwudlule lombuzo.

We would like to know how you have been feeling in the past week. Please choose the answer that comes closest to how you have felt in the past week, not just how you feel today. Please read all the options for each statement. If you feel uncomfortable answering any of these questions, we can skip the question.

1. Ndibenako ukuhleka ndikwazi nokuphawula izinto ezihlekisayo I have been able to laugh and see the funny side of things	◯ Njengoko bendihleli ndisenza. / As much as I always could ◯ Hayi kangako okwangoku / Not quite so much now. ◯ Ngokucacileyo hayi kangako okwangoku. / Definitely not so much now. ◯ Hayi kwaphela. / Not at all.
2. Bendikuthakazelela ukonwabela izinto. I have looked forward to things with enjoyment.	◯ Njengoko ndandisenza. / As much as I ever did. ◯ Kancinci kunendlela endandisenza ngayo/ A little less than I used to. ◯ Ngaphantsi kunendlela endandisenza ngayo. / Much less than I used to. ◯ Kunqabile ukuba kubenjalo. / Hardly at all.
3. ndiye ndasola isiqu sam ngokungeyomfuneko xa izinto zazihamba kakubi. I have blamed myself unnecessarily when things went wrong	◯ Ewe, ixesha elininzi. / Yes, most of the time. ◯ Ewe, ngelinye ixesha. / Yes, some of the time. ◯ Hayi kangako. / Not very much. ◯ Hayi, zange. / No, never
4. Bendinexhala ngaphandle kwesizathu. I have been anxious or worried for no good reason	◯ Hayi, konke-konke. / No, not at all. ◯ Kunqabile ukuba kubenjalo. / Hardly ever. ◯ Ewe, ngamanye amaxesha. / Yes, sometimes. ◯ Ewe, kakhulu. / Yes, very much.
5. Ndiye ndaziva ndisoyika okanye ndiduduzela ngaphandle kwesizathu. I have felt scared or panicky for no very good reason	◯ Ewe, kaninzi. / Yes, quite a lot. ◯ Ewe, ngamanye amaxesha. / Yes, sometimes. ◯ Hayi kakhulu. / No,not much. ◯ Hayi konke konke. / No, not at all

6. Izinto zindongamele Things have been overwhelming me	◯ Ewe, amaxesha amaninzi bendingakwazi ukwenzanto kwaphela. / Yes, most of the times I haven't been managing at all. ◯ Ewe, ngamanye amaxesha bedingankwazi ukwenzanto njengesiqhelo. / Yes, sometimes I haven't been managing as well as usual. ◯ Hayi, ixesha elininzi bendikwazi ukwenza izinto kakuhle. / No, most of the time I have managed quite well. ◯ Hayi, bendikwazi ukwenza izinto kakuhle oko. / No, I have been managing as well as ever.
7. Bendingonwabanga kangangokuba bekubanzima nokulala. I have been so unhappy that I have had difficulty sleeping	◯ Ewe, ixesha elininzi. / Yes, most of the time. ◯ Ewe, ngamanye amaxesha. / Yes, sometimes. ◯ Hayi kakhulu. / Not very much. ◯ Hayi konke konke . / No, not at all.
8. Ndaye ndaziva ndilusizi okanye ndinxunguphele I have felt sad or miserable	◯ Ewe, ixesha elininzi. / Yes, most of the time. ◯ Ewe, kaninzi. / Yes, quite a lot. ◯ Hayi kakhulu. / Not very much. ◯ Hayi konke konke. / No, not at all
9. Bendingonwabanga kangangokuba bendikhala I have been so unhappy that I have been crying	◯ Ewe, ixesha elininzi. / Yes, most of the time. ◯ Ewe, kaninzi. / Yes, quite a lot. ◯ Ngamanye amaxhesa qha. / Only sometimes. ◯ Hayi Azange / No, never
10. Ingcinga yokuzenzakalisa ikhe yandifikela The thought of harming myself has occurred to me	◯ Ewe, kaninzi. / Yes, quite a lot ◯ Ngamanye amaxesha. / Sometimes ◯ Zange ifane yenzeke. / Hardly ever ◯ Azange / Never
Any other comments	_____
interviewer's code	_____
Interviewer's signature	_____

10b. AUDIT -C

Visit date _____

Visit code
- ◯ B
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6
- ◯ 7

Ngoku sizakubuza imibuzo ngokusebenzisa kwakho utywala. Nceda ukhethe impendulo engqamene nawe kumbuzo ngamnye:Ukuba uziva ungakhululekanga ekuphenguleni umbuzo othile, ungavakalisa siwudlule.

I am now going to ask you some questions about your use of alcohol. Please select the relevant answer for each question. If you feel uncomfortable answering any of these questions, you can ask to skip the question

1. Emva kotyelelo lwakho lukugqibela koluphando, usisele kangakanani isiselo isinotywala ?

Since your last study visit how often do you have a drink containing alcohol?

- ◯ Zange / Never
- ◯ Kanye ngenyanga nangaphantsi / Monthly or less
- ◯ Kabini ukuya kwisine enyangeni / 2-4 times a month
- ◯ Kabini ukuya kwisithathu enyangeni / 2-3 times a week
- ◯ Kane nangaphezulu evekini / 4 or more times a week

2. Emva kotyelelo lwakho lokugqibela koluphando, zingaphi iiglasi zesiselo esinotywala oziselayo ngemini?

Since your last study visit how many standard drinks containing alcohol do you have on a typical day when drinking?

- ◯ 1 okanye 2 / 1 or 2
- ◯ 3 Okanye 4 / 3 or 4
- ◯ 5 Okanye 6 / 5 or 6
- ◯ 7 ukuya 9 / 7 to 9
- ◯ 10 okanye ngaphezulu / 10 or more

3. Emva kotyelelo lwakho lokugqibela koluphando kukangaphi usela iiglasi zotywala ezintandathu nangaphezulu ngexesha?

Since your last study visit how often do you have six or more drinks on one occasion?

- ◯ Zange/ Never
- ◯ Ngaphantsi kwenyanga / Less than monthly
- ◯ Ngenyanga / Monthly
- ◯ Ngeveki / Weekly
- ◯ Ngosuku okanye malunga nosuku / Daily or almost daily

4. Kunyaka ophelileyo kukangaphi ufumanisa ukuba awukwazi ukuyeka ukusela xa sele uqalile?

During the past year, how often have you found that you were not able to stop drinking once you had started?

- ◯ Zange/ Never
- ◯ Ngaphantsi kwenyanga/ Less than monthly
- ◯ Ngenyanga / Monthly
- ◯ Ngeveki / Weekly
- ◯ Ngosuku okanye malunga nosuku / Daily or almost daily

5. Emva kotyelelo lwakho lokugqibela koluphando, kukangaphi ungakwazi ukwenza into ubumele ukuyenza ngenxa yokuba ubusela utywala? Since your last study visit how often have you failed to do what was normally expected of you because of drinking?	◯ Zange / Never ◯ Ngaphantsi kwenyanga / Less than monthly ◯ Ngenyanga / Monthly ◯ Ngeveki / Weekly ◯ Ngosuku okanye malunga nosuku / Daily or almost daily
6. Kulo nyaka uphelileyo kukangaphi ufuna ukusela utywala ekuseni kuba ufuna ukuqala usuku lwakho kakuhle emva kokuba ubusela kakhulu utywala ngezolo? During the past year, how often have you needed a drink in the morning to get yourself going after a heavy drinking session?	◯ Zange / Never ◯ Ngaphantsi kwenyanga / Less than monthly ◯ Ngenyanga / Monthly ◯ Ngeveki / Weekly ◯ Ngosuku okanye malunga nosuku / Daily or almost daily
7. Kulonyaka uphelileyo kukangaphi uzifumanise unesazela okanye uzisola emva kokuba usele? During the past year, how often have you had a feeling of guilt or remorse after drinking?	◯ Zange / Never ◯ Ngaphantsi kwenyanga / Less than monthly ◯ Ngenyanga / Monthly ◯ Ngeveki / Weekly ◯ Ngosuku okanye malunga nosuku / Daily or almost daily
8. Kulonyaka uphelileyo ukhe awakwazi ukukhumbula into eyenzeke kubusuku obudluleyo ngenxa yokuba ubusele? How often have you been unable to remember what happened the night before because you had been drinking?	◯ Zange / Never ◯ Ngaphantsi kwenyanga/ Less than monthly ◯ Ngenyanga / Monthly ◯ Ngeveki / Weekly ◯ Ngosuku okanye malunga nosuku / Daily or Almost daily
9. Ukhe wena okanye omnye umntu wonzakala ngenxa yokusela kwakho? Have you or someone else been injured as a result of your drinking?	◯ Hayi / No ◯ Ewe, kodwa hayi kunyaka ophelilieyo. / Yes, but not in the past year ◯ Ewe, kunyaka ophelilieyo. / Yes, during the past year
10. Emva kotyelelo lwakho lukugqibela koluphando ngubani osela ,naye kakhulu? Since your last study visit , who do you mostly drink with?	◯ Ndedwa / No one (alone) ◯ Iqabanwe lam langoku / My current partner ◯ Abahlobo bam / My friends ◯ Amanye okanye elinye qabane / Other sex partner(s) ◯ Abantu endisebenza nabo / People I work with ◯ Okunye / Other
10.1 Since you found out you were pregnant, who do you mostly drink with? Other (specify)	_____
11. Emva kotyelelo lwakho lukugqibela koluphando, ubuselaphi utywala? Since your last study visit , where do you drink alcohol?	◯ Ekhaya / At home ◯ Eshibhini / At shebeen ◯ Endaweni ethengisa ukutya/ At bar or restaurant ◯ Emsebenzini / At Work ◯ Ekhayeni Letshomi / At friends home ◯ Okunye (cacisa) / Other (specify)

11.1 Since you have been pregnant, where do you drink alcohol? (Other)	
Any other comments	
Interviewer's code	
Interviewer's signature	

11b. DUDIT

Visit date	_____
Visit code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7

DUDIT: Sizakubuza imibuzo malunga nokusebenzisa iziyobisi. Nceda urhangqe impendulo eyiyo ngombuzo ngamnye kule ingezantsi. Ukuba uziva ungakhululekanga ukuphendula omnye walombuzo ungasixelela siwudlule lombuzo.

We are now going to ask you some questions about your use of drugs. Please circle the relevant answer for each question below:

If you feel uncomfortable answering any of these questions, you can skip the question by pressing "Next question."

1. Emva kotyelelo lwakho lokugqibela koluphando, ubukhe wasebenzisa iziyobisi ngaphandle kotywala Since your last study visit how often do you use drugs other than alcohol?	◯ Zange / Never ◯ Kanye ngenyanga okanye nganeno / once a month or less often ◯ 2-4 Ngenyanga/ 2-4 times a month ◯ 2-3 Ngeveki / 2-3 times a week ◯ 4 ngeveki okanye ngaphezulu / 4 times a week or more often
2. Emva kotyelelo lwakho lokugqibela koluphando usebenzisa ngaphezu kohlobo olunye lweziyobisi ngexesha? Since your last study visit how often do you use more than one type of drug on the same occasion?	◯ Zange / Never ◯ Kanye ngenyanga okanye nganeno / once a month or less often ◯ 2-4 Ngenyanga/ 2-4 times a month ◯ 2-3 Ngeveki / 2-3 times a week ◯ 4 ngeveki okanye ngaphezulu / 4 times a week or more often
3. Emva kotyelelo lwakho lokugqibela koluphando, mangaphi amaxesha osebenzisa iziyobisi ngosuku? Since your last study visit how many times do you take drugs on a typical day when you use drugs?	◯ 0 ◯ 1-2 ◯ 3-4 ◯ 5-6 ◯ 7 or more
4. Emva kotyelelo lwakho lokugqibela koluphando, kuxhaphake kangakanani ukuba uchaphazeleke kanobom ziziyobisi? Since your last study visit how often have you been influenced heavily by drugs?	◯ Zange / Never ◯ Ngeneno kunakanye ngenyanga / Less often than once a month ◯ Ngenyanga zonke / Every month ◯ Qho ngeveki / Every week ◯ Ngosuku okanye ngemini zonke / Daily or almost every day

5. Emva kotyelelo lwakho lokugqibela koluphando, wakhe waziva ukuba unqanqatheko lweziyobisi beluluqilima kangangokuba wahendeka?

Since your last study visit have you felt that your longing for drugs was so strong that you could not resist it?

- ◯ Zange / Never
- ◯ Ngeneno kunakanye ngenyanga / Less often than once a month
- ◯ Ngenyanga zonke / Every month
- ◯ Qho ngeveki / Every week
- ◯ Ngosuku okanye ngemini zonke / Daily or almost every day

6. Emva kotyelelo lwakho lokugqibela koluphando, kungangaphi usitya iziyobisi ungahoyi ukwenza into ubumele ukunyenza ?

Since your last study visit how often have you taken drugs and then neglected to do something you should have done?

- ◯ Zange / Never
- ◯ Ngeneno kunakanye ngenyanga / Less often than once a month
- ◯ Ngenyanga zonke / Everymonth
- ◯ Qho ngeveki / Every week
- ◯ Ngosuku okanye ngemini zonke / Daily or almost every day

7. Emva kotyelelo lwakho lokugqibela koluphando, ubukhe awakwazi ukuyeka iziyobisi xa sele uziqalile ukuzithatha?

Since your last study visit have you ever not been able to stop taking drugs once you started?

- ◯ Zange / Never
- ◯ Ngeneno kunakanye ngenyanga / Less often than once a month
- ◯ Ngenyanga zonke / Everymonth
- ◯ Qho ngeveki / Every week
- ◯ Ngosuku okanye ngemini zonke / Daily or almost every day

8. Emva kotyelelo lwakho lokugqibela koluphando, ubukhe wafuna ukuthatha iziyobisi ekuseni kuba ngezolo ubuzithathe kakhulu?

Since your last study visit how often have you needed to take a drug the morning after heavy drug use the day before?

- ◯ Zange / Never
- ◯ Ngeneno kunakanye ngenyanga / Less often than once a month
- ◯ Ngenyanga zonke / Everymonth
- ◯ Qho ngeveki / Every week
- ◯ Ngosuku okanye ngemini zonke / Daily or almost every day

9. Emva kotyelelo lwakho lokugqibela koluphando, ubukhe wazisola okanye wanesazela kuba usebenzisa iziyobisi?

Since your last study visit how often have you had guilt feelings or a bad conscience because you used drugs?

- ◯ Zange / Never
- ◯ Ngeneno kunakanye ngenyanga / Less often than once a month
- ◯ Ngenyanga zonke / Everymonth
- ◯ Qho ngeveki / Every week
- ◯ Ngosuku okanye ngemini zonke / Daily or almost every day

10. Emva kotyelelo lwakho lokugqibela koluphando, ubukhe wonzakala okanye konzakala omnye umntu (ngokwasengqondweni okanye ngokwasemzimbeni) Ngenxa yokusebenzisa kwakho iziyobisi?

Since your last study visit have you or anyone else been hurt (mentally or physically) because you used drugs?

- ◯ Hayi / No
- ◯ Ewe, kodwa hayi kunyaka ophelilieyo / Yes, but not in the past year
- ◯ Ewe, kunyaka ophelilieyo. / Yes, during the past year

11. Emva kotyelelo lwakho lokugqibela koluphando, sikhona isizalwana sakho, okanye isihlobo, unesi, okanye omnye umntu obekhathazekile ngendlela osela ngayo waza wakucebisa ukuba uthobe isantya?

Since your last study visit has a relative or a friend, a doctor or a nurse, or anyone else, been worried about your drug use or said to you that you should stop using drugs?

- ◯ Hayi / No
- ◯ Ewe, kodwa hayi kunyaka ophelilieyo / Yes, but not in the past year
- ◯ Ewe, kunyaka ophelilieyo. / Yes, during the past year

12. Zeziphi iziyobisi ubukhe wazisebenzisa emva kotyelelo lwakho lokugqibela koluphando?

Which drugs have you used since your last study visit?

	Yes	No
1.Dagga or marijuana	◯	◯
2.Tik	◯	◯
3.Cocaine or crack	◯	◯
4.Mandrax (button/ iqhosha)	◯	◯
5.Ecstasy (umgwinyo)	◯	◯
6.Heroin	◯	◯
7.Nyaope	◯	◯

12.7.1 Which drugs have you used during pregnancy? _____

Any other comments

_____

Interviewer's code

_____

Interviewer's signature

_____

HIV Testing

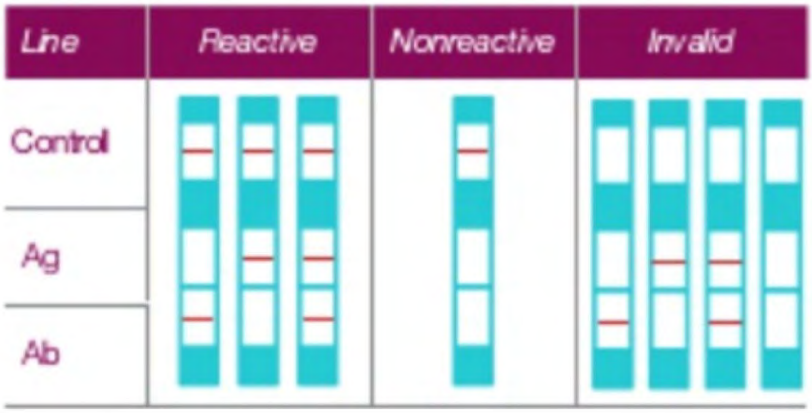
Visit date

_____

Visit code

- ◯ B
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6
- ◯ 7

HIV testing results



HIV testing results

- ◯ HIV negative (1 control line)
- ◯ HIV antigen and antibody positive (3 lines)
- ◯ HIV antibody negative/ antigen positive (2 lines)
- ◯ HIV antibody positive/ antigen negative (2 lines)
- ◯ Test invalid - no control line (repeat test)

Notes

_____

Interviewer's code

_____

Interviewer's signature

_____

Creatinine results

Visit date	_____
Visit code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7
Participant's date of birth	_____
Participant's weight	_____ (Kg)
Date of specimen collection	_____
Time of specimen collection	_____
Test Results	
Creatinine	_____ (umol/L)
Creatinine Clearance (eGFR)	_____ (ml/min)
Date of test	_____
Date test results given to participant	_____
Notes	_____
Nurse Initials	_____
Nurse signiture	_____

PrEP prescription

PrEP Medication Prescription	
Visit date	_____
Visit Code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7
Date of next visit	_____
Number of repeats	◯ Month 1 ◯ Month 2 ◯ Month 3
Name of Prescriber	_____
Registration Number	_____
Signature of Prescriber	_____

Creatinine results follow-up

Visit date	_____
Visit code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7
Participant's date of birth	_____
Participant's weight	_____ (Kg)
Date of specimen collection	_____
Time of specimen collection	_____
Test Results	
Creatinine	_____ (umol/L)
Creatinine Clearance (eGFR)	_____ (ml/min)
Date of test	_____
Date test results given to participant	_____
Notes	_____
Nurse Initials	_____
Nurse signiture	_____

PrEP prescription follow-up

PrEP Medication Prescription	
Visit date	_____
Visit Code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7
Date of next visit	_____
Number of repeats	◯ Month 1 ◯ Month 2 ◯ Month 3
Name of Prescriber	_____
Registration Number	_____
Signature of Prescriber	_____

PrEP-PP adherence and side effects

Visit date _____

Visit Code
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6
- ◯ 7

Lemibuzo izakubuza ngamava akho okusebenzisa I-PrEP. Ukuba awukhululekanga ngemibuzo, nceda undazise ndiwudlule lombuzo.

I will now ask you about your experience using PrEP. If you are not comfortable with any questions, please let me know to skip that question.

1. Kwentsuku ziyi-30 zidlulileyo, ukhe wayisela i-PrEP?

Have you taken PrEP in the last 30 days?
- ◯ Yes
- ◯ No

2. Ingaba ubukhe wanempawu okanye ukungaziva kamnandi xa usele i-PrEP?

Have you had any symptoms or bad feelings while taking PrEP?
- ◯ Yes
- ◯ No

3.1 Ukunyekelwa yintliziyo

Nausea
- ◯ Yes
- ◯ No

3.1 Ukunyekelwa yintliziyo

Nausea
- ◯ Ayindihluphi / It doesn't bother me
- ◯ Indihlupha kancinci / It bothers me a little
- ◯ Iyandihlupha / It bothers me
- ◯ Iyandihlupha kakhulu / It bothers me a lot

3.2 Ukugabha

Vomiting
- ◯ Yes
- ◯ No

3.2.1 Ukugabha

Vomiting
- ◯ Ayindihluphi / It doesn't bother me
- ◯ Indihlupha kancinci / It bothers me a little
- ◯ Iyandihlupha / It bothers me
- ◯ Iyandihlupha kakhulu / It bothers me a lot

3.3 Ukuhambisa kwesisu

Diarrhea
- ◯ Yes
- ◯ No

3.3.1 Ukuhambisa kwesisu Diarrhea	◯ Ayindihluphi / It doesn't bother me ◯ Indihlupha kancinci / It bothers me a little ◯ Iyandihlupha / It bothers me ◯ Iyandihlupha kakhulu / It bothers me a lot
3.4 Ukungabi namdla wokutya Appetite Change	◯ Yes ◯ No
3.4.1 Ukungabi namdla wokutya Appetite Change	◯ Ayindihluphi / It doesn't bother me ◯ Indihlupha kancinci / It bothers me a little ◯ Iyandihlupha / It bothers me ◯ Iyandihlupha kakhulu / It bothers me a lot
3.5 Intloko ebuhlungu Headache	◯ Yes ◯ No
3.5.1 Intloko ebuhlungu Headache	◯ Ayindihluphi / It doesn't bother me ◯ Indihlupha kancinci / It bothers me a little ◯ Iyandihlupha / It bothers me ◯ Iyandihlupha kakhulu / It bothers me a lot
3.6 Amaqhakuva amancinci Rash	◯ Yes ◯ No
3.6 Amaqhakuva amancinci Rash	◯ Ayindihluphi / It doesn't bother me ◯ Indihlupha kancinci / It bothers me a little ◯ Iyandihlupha / It bothers me ◯ Iyandihlupha kakhulu / It bothers me a lot
3.7 Ubushushu bomzimba (ifiva) Fevers	◯ Yes ◯ No
3.7.1 Ubushushu bomzimba (ifiva) Fevers	◯ Ayindihluphi / It doesn't bother me ◯ Indihlupha kancinci / It bothers me a little ◯ Iyandihlupha / It bothers me ◯ Iyandihlupha kakhulu / It bothers me a lot
3.8 Ezinye iintlungu Other Pain	◯ Yes ◯ No
3.8.1 Ezinye iintlungu Other Pain	◯ Ayindihluphi / It doesn't bother me ◯ Indihlupha kancinci / It bothers me a little ◯ Iyandihlupha / It bothers me ◯ Iyandihlupha kakhulu / It bothers me a lot

3.9 Ukubila Sweat	◯ Yes ◯ No
3.9.1 Ukubila Sweat	◯ Ayindihluphi / It doesn't bother me ◯ Indihlupha kancinci / It bothers me a little ◯ Iyandihlupha / It bothers me ◯ Iyandihlupha kakhulu / It bothers me a lot
3.10 Ukudinwa Fatigue	◯ Yes ◯ No
3.10.1 Ukudinwa Fatigue	◯ Ayindihluphi / It doesn't bother me ◯ Indihlupha kancinci / It bothers me a little ◯ Iyandihlupha / It bothers me ◯ Iyandihlupha kakhulu / It bothers me a lot
3.11 Ukujikelezelwa yintloko Dizziness	◯ Yes ◯ No
3.11.1 Ukujikelezelwa yintloko Dizziness	◯ Ayindihluphi / It doesn't bother me ◯ Indihlupha kancinci / It bothers me a little ◯ Iyandihlupha / It bothers me ◯ Iyandihlupha kakhulu / It bothers me a lot
3.12 Amaphupha angaqhelekanga Unusual Dreaming	◯ Yes ◯ No
3.12.1 Amaphupha angaqhelekanga Unusual Dreaming	◯ Ayindihluphi / It doesn't bother me ◯ Indihlupha kancinci / It bothers me a little ◯ Iyandihlupha / It bothers me ◯ Iyandihlupha kakhulu / It bothers me a lot
3.13 Ezinye/Other Cacisa/ specify:	◯ Yes ◯ No
3.13.1 Enye (cacisa) / Other (explain)	_____
4. Uzithatha kangaphi ngemini ipilisi zakho ze-PrEP? How many times a day do you take your PrEP pills?	_____ (Amaxesha/ No. of times)
5. Zingaphi ipilisi ozityayo ngexesha? How many pills do you take each time?	_____ (Inani le lepilisi/ No. of pills)

6. Ukhona umntu okuncedisayo okukhumbuzayo ngokuthatha I-PrEP? Did anyone help you take PrEP?	◯ Yes ◯ No
7.Ngubani? Who helped you?	◯ Iqabane/ partner ◯ Itshomi/friend ◯ Usapho/ family ◯ Omnye(cacisa) /other (specify)
7.1 Other (specify)	_____
8. Bancede kanjani? How did they help?	◯ Ngokusa ezikweni lezempilo / brought me to clinic ◯ Bandikumbuzile ukuthatha amayeza / reminded me to take medicine ◯ Bandincede ngemiphumela / helped me with side effects ◯ okunye(cacisa)/other (specify)
9. Kwintsuku ezi-30 ezidlulileyo,zimini ezingaphi okhe walibala ukusela umlinganiselo wakho we-PrEP . In the last 30 days, on how many days did you miss at least one dose of any of your PrEP?	_____ (days)
10. Kwezi ntsuku zi-30 zidlulileyo, yeyiphi indlela encomekayo owatye kakuhle ngayo amachiza akho e-PrEP njengohlobo olufanelekikleyo? In the last 30 days, how good a job did you do at taking your PrEP in the way that you were supposed to?	◯ Kakubi kakhulu / Very poor ◯ Kakubi / Poor ◯ Ndiphakathi / Fair ◯ Kakuhle / Good ◯ Kakuhle kakhulu / Very good ◯ Kakuhle okugqithisileyo / Excellent
11. Kwezi ntsuku zi-30 zidlulileyo,kukangaphi usitya amachiza akho e-PrEP ngendlela omele ukuwatya ngayo? In the last 30 days how often did you take your PrEP in the way that you were supposed to?	◯ Zange / Never ◯ Akufane / Rarely ◯ Ngamanye amaxesha / Sometimes ◯ Ngesiqhelo / Usually
12. Kwintsuku ezi-7 ezidlulileyo,zimini ezingaphi okhe walibala ukusela umlinganiselo wakho we-PrEP? In the last 7 days, on how many days did you miss at least one dose of any of your PrEP?	_____
13. Kwezi ntsuku zi-7 zidlulileyo Yeyiphi indlela encomekayo owatye kakuhle ngayo amachiza akho e-PrEP njengohlobo olufanelekikleyo? In the last 7 days, how good a job did you do at taking your PrEP in the way that you were supposed to?	◯ Kakubi kakhulu / Very poor ◯ Kakubi / Poor ◯ Ndiphakathi / Fair ◯ Kakuhle / Good ◯ Kakuhle kakhulu / Very good ◯ Kakuhle okugqithisileyo / Excellent

14. Kwezi ntsuku zi-7 zidlulileyo,kukangaphi usitya amachiza akho e-PrEP ngendlela omele kuwatya ngayo? In the last 7 days how often did you take your PrEP in the way that you were supposed to?	◯ Zange / Never ◯ Akufane / Rarely ◯ Ngamanye amaxesha / Sometimes ◯ Ngesiqhelo / Usually ◯ Malunga lonke ixesha / Almost always
15. Kwintsuku ezi-30 ezidlulileyo, zeziphi izinto ezibangele ulibale, okanye ezenze kubenzima ukutya amachiza akho e-PrEP? Zifunde zonke.Urhangqe zonke ezikhe zakwehlela. In the past 30 days which of the following things made you miss a pill or made it hard for you to take your pills	◯ Yes ◯ No
15.1 Bendingekho ekhaya Was away from home	◯ Yes ◯ No
15.2 Zilahlekile Lost your pills	◯ Yes ◯ No
15.3 Bendixakekile ndisenza omnye umsebenzi Was busy with other things	◯ Yes ◯ No
15.4 Ndilibele Simply forgot	◯ Yes ◯ No
15.5 Bezininzi ipilisi ebekufuneka ndizityе Had too many pills to take	◯ Yes ◯ No
15.6 Bendifumana imiphumela Was getting side effects	◯ Yes ◯ No
15.7 Bendibaleka imiphumela okanye ndingaziva mnandi Wanted to avoid side effects or were feeling bad	◯ Yes ◯ No
15.8 Bendizinika ikhefu kwipilisi Wanted to take a break from the pill	◯ Yes ◯ No
15.9 Bendingafuni abanye bazi ukuba nditya ipilisi Did not want others to notice you taking PrEP	◯ Yes ◯ No

15.10 Kuye kwabakho utshintsho kwindlela endisebenza ngayo okanye kwizinto endizenzayo mihla nemihla Had a change in daily routine or work schedule	◯ Yes ◯ No
15.11 Bendicinga ukuba ipilisi ziyasebenza noba ezinye andizityanga Thought that the pills would still work even if a few were missed	◯ Yes ◯ No
15.12 Bendiba amachiza ayingozi/ayingozi kum Felt the drugs were toxic/ harmful to me	◯ Yes ◯ No
15.13 Bendiba amachiza ayingozi/ ayingozi kusana lwam Felt the drugs were toxic/ harmful to my baby	◯ Yes ◯ No
15.14 Ndizive ndingaphilanga Felt sick or ill	◯ Yes ◯ No
15.15 Ziye zandongamela Felt overwhelmed	◯ Yes ◯ No
15.16 Ndive ndiphantsi koxinizelelo Felt depressed	◯ Yes ◯ No
15.17 Esinye isizathu Other reason	◯ Yes ◯ No
15.17.1 Esinye isizathu / Other reason	_____
Any other comments	_____
Interviewer's code	_____
Interviewers signature	_____

Pregnancy and Infant outcomes

Infant PID	_____
Visit Date	_____
Visit Code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7
1. Number of fetuses	_____
2. Pregnancy outcome	◯ Live birth ◯ Miscarriage ◯ Still birth ◯ Ectopic ◯ Unknown
3. Date of pregnancy outcome	_____
4. Gestational Age at Outcome	◯ >= 37 weeks ◯ 13-36 weeks ◯ < =12 weeks ◯ Unknown
5. Infant death within 3 days of delivery?	◯ Yes ◯ No
6. Any congenital anomalies (Anything wrong with infant's health or appearance at birth or after birth)	◯ Yes ◯ No
6.1 Describe congenital anomaly	_____
7. Baby 1 gender	◯ Male ◯ Female
8. Baby 1 birthweight	_____ (Kg)
9. Baby 2 gender	◯ Male ◯ Female
10. Baby 2 birthweight	_____ (Kg)

11. Location of pregnancy outcome	◯ Clinic ◯ Hospital ◯ Home ◯ Other
12. Mode of delivery	◯ Vaginal ◯ Cesarean section
13. Did the participant have gestational diabetes during pregnancy?	◯ Yes ◯ No
14. When did participant first gestational diabetes?	◯ First Trimester ◯ Second Trimester ◯ Third Trimester
15. Did participant have gestational hypertension / pre-clampsia during pregnancy	◯ Yes ◯ No
16. When did participant first have gestational hypertension/ pre-eclampsia	◯ First Trimester ◯ Second Trimester ◯ Third Trimester ◯ Labour /delivery
17. Did participant have fever during pregnancy?	◯ Yes ◯ No
17.1 When did participant first have fever?	◯ First Trimester ◯ Second Trimester ◯ Third Trimester ◯ Labour / Delivery
18. Did participant have a rash during the pregnancy?	◯ Yes ◯ No
19. When did participant have rash?	◯ First Trimester ◯ Second Trimester ◯ Third Trimester
20. Did participant have any other complications during pregnancy?	◯ Yes ◯ No
21. Describe any other complications during the pregnancy?	_____
22. When did participant first have complication?	◯ First Trimester ◯ Second Trimester ◯ Third Trimester ◯ Labour /delivery

Baby information	
23. Baby date of birth	_____
24. Baby gestational age at birth	_____ (in weeks)
25. Baby current weight	_____ (Kg)
25.1 Repeated baby weight.	_____ (Kg)
26. Describe any acute illnesses identified?	_____
27. Any other comment	_____
Initials	_____
Signature	_____

Refusal questionnaire

Visit date	_____ (date (dd-mm-yyyy))
Why do you not want to participate in this study?	☐ I am not interested ☐ I am enrolled in another study ☐ I do not have time ☐ I am not comfortable divulging personal information about myself ☐ I am afraid of the results ☐ I am afraid of my partner's reaction if my results are positive ☐ I do not feel there are any benefits for me or my baby in testing for STIs ☐ I am not comfortable with collecting a vaginal swab specimen ☐ I am too stressed out ☐ You are conducting too many tests ☐ Other
If Other, please specify	_____
Any other comments	_____
Interviewer's code	_____
Interviewer's signature	_____

Missed Visit form

Visit Date	_____
Visit code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7
1.Reason for missing appointment	◯ Unable to contact participant ◯ Unable to schedule appointment within target window ◯ Participant refused visit ◯ Participant incarcerated ◯ Participant admitted to a healthcare facility ◯ Participant withdrew from the study ◯ Participant deceased ◯ Other
2. Other	_____
Interviewer's notes	_____
Interviewer's code	_____
Interviewer's signature	_____

Termination

Visit Date	_____
Visit code	◯ B ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7
Date of termination	_____
1.Reason for Termination	◯ End of study ◯ Death ◯ Participant refused further participation ◯ Participant unable to adhere to visit schedule ◯ Participant relocated, no follow-up planned ◯ Investigator decision ◯ Unable to contact participant ◯ Inappropriate enrollment ◯ Invalid ID due to duplicate screening/enrollment ◯ Early study closure
2. Other reasons	_____
Interviewer's notes	_____
Interviewer's code	_____
Interviewer's signature	_____

Appendix C: Ethics approval forms

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30-9-23
☐ Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee		Date Signed	18/8/2022

Note: Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za.
Please clarify your plan for research-related activities during COVID-19 lockdown.
Please use the latest form found on our website:
http://www.health.uct.ac.za/fhs/research/humanethics/forms

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	28 July 2022		
HREC REF Number	297/2018	Current Ethics Approval was granted until	30-09-2022
Protocol title	Evaluation of pre-exposure prophylaxis (PrEP) initiation, retention and adherence in pregnant and breastfeeding women		
Protocol number (if applicable)	Version 6.0		
Are there any sub-studies linked to this study?		✓ Yes	☐ No
If yes, could you please provide the HREC Reference number for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study			
Principal Investigator	Prof Landon Myer		

(Note: Please complete the Closure form (FHS017) if the study is completed within the approval period)

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Department / Office Internal Mail Address	Room 5.51, Level 5, Falmouth Building, Faculty of Health Sciences

1.1 Does this protocol receive US Federal funding?	✓ Yes	☐ No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval? Note: Any annual approvals for **Full Committee** review MUST be submitted on the monthly HREC submission dates. (Please send electronic copy for full committee review to hrec-submissions@uct.ac.za)	☐ Yes	✓ No

If yes in 1.2 please complete section 1.3 below for invoicing purposes

1.3 Ethics Renewal Fee

Please (tick ✓)appropriate box for billing purposes:

Submission Type	Description	New Fee (Vat Incl.)	tick ✓
Research funded solely from UCT departmental/ division/group budget	Annual evaluation of research progress report for re-certification	R0,00	☐
Non-sponsored student research for degree purposes at UCT/Other Universities & Colleges	Annual evaluation of research progress report for re-certification	R0,00	☐
Annual re-certification / Progress report (FHS016 Form)	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Full Committee Approval	R7000,00	✓
Annual re-certification / Progress report (FHS016 Form)	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Expedited review	R3 710.00	☐
Annual re-certification / Progress report (FHS016 Form)	National grant funded research - Annual evaluation of research progress report for re-certification for Full Committee Approval	R6000.00	☐
Annual re-certification / Progress report (FHS016 Form)	National Grant funded research for Annual evaluation of research progress report for re-certification for Expedited review	R1 500,00	☐

NB: Protocols funded by UCT (e.g. departmental funding / student research) and by certain grant funding organizations (e.g. MRC, NRF, CANSA,) are exempt from these charges.

Please provide details for invoicing, either complete section 1 or 2 :

1. Invoice billing – Directly to Sponsor

Sponsor's name	
Billing Address of Sponsor:	
Vat Number:	

Contact person	
Telephone number	
Email Address	
2. **Internal Journal Billing:**	
Fund Number:	472041
Cost Centre Number:	IDM1160
Account Holder Name:	Prof Landon Myer
Division of Account Holder:	Division of Epidemiology and Biostatistics

2. List of documentation for approval

FSH018: Annual report and renewal
Study Protocol version 6.0
SAHPRA 6-month report for clinical trials
DSMB quarterly report

3. Protocol status (tick ✓)

☐	Open Enrolment
✓	Closed to enrolment (tick ✓)
✓	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
☐	Research-related activities are complete, data analysis only
☐	Main study is complete but sub-study research-related activities are ongoing
☐	Study is closed → Please submit a Study Closure Form (FHS010)

4. Enrolment

Number of participants enrolled to date	1320
Number of participants enrolled, since last HREC Progress report (continuing review)	0
Additional number of participants still required	0

5. Refusals

Total number of refusals (participants invited to join the study, but refused to take part)	409

6. Cumulative summary of participants

Total number of participants who provided consent	2145
Number of participants determined to be ineligible (i.e. after screening)	825
Number of participants currently active on the study	275
Number of participants completed study (without events leading to withdrawal)	459
Number of participants withdrawn at participants' request (i.e. changed their mind)	119
Number of participants withdrawn by PI due to toxicity or adverse events	3
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	12
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up	377
1. Participants are considered lost to follow-up if they missed 2 consecutive study visits 2. Relocated outside the Cape Town region 3. No contact has been established with participant for more than 90 days	
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	78
Participants censored from the due to pregnancy loss and stillbirths	

7. Progress of study

Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:
Recruitment for the study ended October 2021. We are currently following up 275 women who are still active in the study and anticipant the last woman will exit the study 21st of February 2022. Our monthly retention has remained 50-55%. We are implementing all strategies available to us to improve retention including conducting interviews over the phone for those women who are unable to come in for their scheduled visits. In addition to conducting interviews, we have resumed home visits weekly to try and find women who are lost to follow-up and missed study visits. We list all SAEs in the attached spreadsheet. Most of these are related to pregnancy and infant outcomes.

8. Protocol violations and exceptions (tick ✓ all that apply)

☐	No prior violations or exceptions have occurred since the original approval

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

✓	Prior violations or exceptions have been reported since the last review and have already been acknowledged or approved
✓	Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review

9. Amendments (tick ✓ all that apply)

☐	No Prior amendments have been made since the original approval
✓	Prior amendments have been reported since the last review and have already been approved
☐	New protocol changes/ amendments are requested as part of this continuing review (See note below)

Note: If new protocol changes are being requested in this review, please complete an amendment form (FHS006).
Specific changes in the amended protocol and consent/assent forms must be **bolded**, italicised or tracked and all changes must include a rationale.

10. Adverse events

10.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established.
Please find attached all serious adverse events reported

10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?		
✓ Yes	☐ No	☐ Not applicable
If yes, please describe:		

11. Summary of Monitoring and Audit Activities (tick ✓)

11.1 Was this study monitored or audited by an external agency (e.g. SAHPRA, FDA)?		
✓ Yes	☐ No	☐ Not applicable

11.2 Did a Data and Safety Monitoring Board publish a report?		
✓ Yes	☐ No	☐ Not applicable

11.3 If yes, please identify the agency and attach a summary of the findings

Agency Name		Report attached	✓ Yes	☐ No	☐ Not applicable
		DSMB report attached	✓ Yes	☐ No	☐ Not applicable

11.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team?	
☐ Yes	✓ No
If yes, please explain:	

12. Level of risk (tick ✓)

12.1 In light of your experience of this research, please indicate whether the level of risk to participants has:	
☐	Increased
☐	Decreased
✓	Shown no change
If there has been a change, please explain:	

12.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the level of risk.
N/A

13. Insurance

Please confirm that valid no fault insurance is still in place? (tick ✓)			
✓ Yes	☐ No	☐ Not Applicable – N/A	
If yes, please complete the following			
Insurer's name:	Marsh Proprietary Limited		
Policy no:	BOWLT2200115	*Coverage Period:	01/03/2022 – 01/03/2023
For UCT sponsored studies please liaise the insurance office via fhs.sponsorship@uct.ac.za regarding the required documentation and information required obtain a renewed UCT No-fault Insurance Certificate			

14. Statement of conflict of interest

Has there been any change in the conflict of interest status of this protocol since the original approval? (tick ✓)	
☐ Yes	✓ No
If yes, please explain and if necessary: attach a revised conflict of interest statement (Section #7 in the New Protocol Application Form FHS013)	

15. Signature

My signature certifies that the above is complete and correct.			
Signature of PI	Signed by candidate	Date	16 Aug 22

UNIVERSITY OF CAPE TOWN — FACULTY OF HEALTH SCIENCES

Form FHS011: Study deviation

HREC office use only (FWA00001637; IRB00001938)			
This serves as acknowledgement of a protocol deviation as described below.			
Chairperson of the HREC signature	Signed by candidate	Date	14/12/22

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	
HREC REF Number	297/2016
Project Title	Evaluation of pre-exposure prophylaxis (PrEP) initiation, retention and adherence in pregnant and breastfeeding women
Protocol number (if applicable)	Version 6.0
Principal Investigator	Professor Landon Myer
Department / Office Internal Mail Address	Room 5.81, Level 5, Falmouth Building, Faculty of Health Sciences

2. Protocol deviation description

Please describe the deviation below, including the reason why the deviation occurred.

0029-39 yr old, 13 weeks gestation, inappropriately enrolled on the 15 July 2020. Hep B surface antigen tests was negative, NHLS results were positive. This was discovered on the 17/11/21. Participant was censored due to pregnancy loss has not returned for follow-up visits since enrolment.

0030-30 yr old, 17 weeks gestation, inappropriately enrolled on the 16/01/ 2021. Hep B surface antigen tests was negative, NHLS results were positive. This was discovered on the 17/11/21.

These participants were inappropriately enrolled as Hep B+ screening is an exclusion criterion for the study.

3. Follow-up actions

3.1 Please describe any follow-up action(s) taken or planned as a result of this deviation e.g. DSMB reporting, report to sponsor, informing participants.

The violation will be reported in the follow-up DSMB report. Both participants were referred for further assessments for liver function as they were prescribed Truvada.

3.2 Please describe what action(s) have or will be taken to prevent similar deviations in future.

Future actions are to flag discrepant rapid and lab tests, and retest when necessary.

4. Principal investigator's acknowledgement of responsibility

This signature indicates the PI has reviewed the deviation, taken appropriate follow-up action and implemented or plans to implement preventative steps where possible.

Signature of PI	Signed	Date	16 July 2022

Appendix D: Journal submission guidelines

AIDS and Behavior
Publishing model: Hybrid

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Submission guidelines

Contents

Instructions for Authors

Manuscript Submission

Manuscript Submission

Submission of a manuscript implies: that the work described has not been published before; that it is not under consideration for publication anywhere else; that its publication has been approved by all co-authors, if any, as well as by the responsible authorities – tacitly or explicitly – at the institute where the work has been carried out. The publisher will not be held legally responsible should there be any claims for compensation.

Permissions

Authors wishing to include figures, tables, or text passages that have already been published elsewhere are required to obtain permission from the copyright owner(s) for both the print and online format and to include evidence that such permission has been granted when submitting their papers. Any material received without such evidence will be assumed to originate from the authors.

Online Submission

Please follow the hyperlink "Submit manuscript" and upload all of your manuscript files following the instructions given on the screen.

Source Files

Please ensure you provide all relevant editable source files at every submission and revision. Failing to submit a complete set of editable source files will result in your article not being considered for review. For your manuscript text please always submit in common word processing formats such as .docx or LaTeX.

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Title Page

Please make sure your title page contains the following information.

Title

The title should be concise and informative.

Author information

The name(s) of the author(s)

The affiliation(s) of the author(s), i.e. institution, (department), city, (state), country

A clear indication and an active e-mail address of the corresponding author

If available, the 16-digit ORCID of the author(s)

If address information is provided with the affiliation(s) it will also be published.

For authors that are (temporarily) unaffiliated we will only capture their city and country of residence, not their e-mail address unless specifically requested.

Large Language Models (LLMs), such as ChatGPT, do not currently satisfy our authorship criteria. Notably an attribution of authorship carries with it accountability for the work, which cannot be effectively applied to LLMs. Use of an LLM should be properly documented in the Methods section (and if a Methods section is not available, in a suitable alternative part) of the manuscript.

Abstract

Please provide an abstract of 150 to 250 words. The abstract should not contain any undefined abbreviations or unspecified references.

Please note: For some articles (particularly, systematic reviews and original research articles), 250 words may not be sufficient to provide all necessary information in the abstract. Therefore, the abstract length can be increased from the 250-word limit (to up to 450 words) if the topic dictates, and to allow full compliance with the relevant reporting guidelines.

For life science journals only (when applicable)

Trial registration number and date of registration for prospectively registered trials

Trial registration number and date of registration, followed by "retrospectively registered", for retrospectively registered trials

Keywords

Please provide 4 to 6 keywords which can be used for indexing purposes.

Acknowledgements

An Acknowledgment section may be included to acknowledge, for example, people who have assisted with aspects of the work (but who do not qualify as authors), disclaimers, collaborations, etc.

Statements and Declarations

The following statements should be included under the heading "Statements and Declarations" for inclusion in the published paper. Please note that submissions that do not include relevant declarations will be returned as incomplete.

Competing Interests: Authors are required to disclose financial or non-financial interests that are directly or indirectly related to the work submitted for publication. Please refer to "Competing Interests and Funding" below for more information on how to complete this section.

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Text

Text Formatting

Manuscripts should be submitted in Word.

Use a normal, plain font (e.g., 10-point Times Roman) for text.

Use italics for emphasis.

Use the automatic page numbering function to number the pages.

Do not use field functions.

Use tab stops or other commands for indents, not the space bar.

Use the table function, not spreadsheets, to make tables.

Use the equation editor or MathType for equations.

Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

Headings

Please use no more than three levels of displayed headings.

Abbreviations

Abbreviations should be defined at first mention and used consistently thereafter.

Footnotes

Footnotes can be used to give additional information, which may include the citation of a reference included in the reference list. They should not consist solely of a reference citation, and they should never include the bibliographic details of a reference. They should also not contain any figures or tables.

Footnotes to the text are numbered consecutively; those to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data). Footnotes to the title or the authors of the article are not given reference symbols.

Always use footnotes instead of endnotes.

Acknowledgments

Acknowledgments of people, grants, funds, etc. should be placed in a separate section on the title page. The names of funding organizations should be written in full.

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References

Citation

Reference citations in the text should be identified by numbers in square brackets. Some examples:

1. Negotiation research spans many disciplines [3].

2. This result was later contradicted by Becker and Seligman [5].

3. This effect has been widely studied [1–3, 7].

Reference list

The list of references should only include works that are cited in the text and that have been published or accepted for publication. Personal communications and unpublished works should only be mentioned in the text.

The entries in the list should be numbered consecutively.

If available, please always include DOIs as full DOI links in your reference list (e.g. "https://doi.org/abc").

Journal article

Smith JJ. The world of science. Am J Sci. 1999;36:234–5.

Article by DOI

Slifka MK, Whitton JL. Clinical implications of dysregulated cytokine production. J Mol Med. 2000; https://doi.org/10.1007/s001090000086

Book

Blenkinsopp A, Paxton P. Symptoms in the pharmacy: a guide to the management of common illness. 3rd ed. Oxford: Blackwell Science; 1998.

Book chapter

Wyllie AH, Kerr JFR, Currie AR. Cell death: the significance of apoptosis. In: Bourne GH, Danielli JF, Jeon KW, editors. International review of cytology. London: Academic; 1980. pp. 251–306.

Online document

Doe J. Title of subordinate document. In: The dictionary of substances and their effects. Royal Society of Chemistry. 1999. http://www.rsc.org/dose/title of subordinate document. Accessed 15 Jan 1999.

Always use the standard abbreviation of a journal's name according to the ISSN List of Title Word Abbreviations, see

ISSN.org LTWA

If you are unsure, please use the full journal title.

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Tables

All tables are to be numbered using Arabic numerals.

Tables should always be cited in text in consecutive numerical order.

For each table, please supply a table caption (title) explaining the components of the table.

Identify any previously published material by giving the original source in the form of a reference at the end of the table caption.

Footnotes to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data) and included beneath the table body.

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Artwork and Illustrations Guidelines

Electronic Figure Submission

Supply all figures electronically.

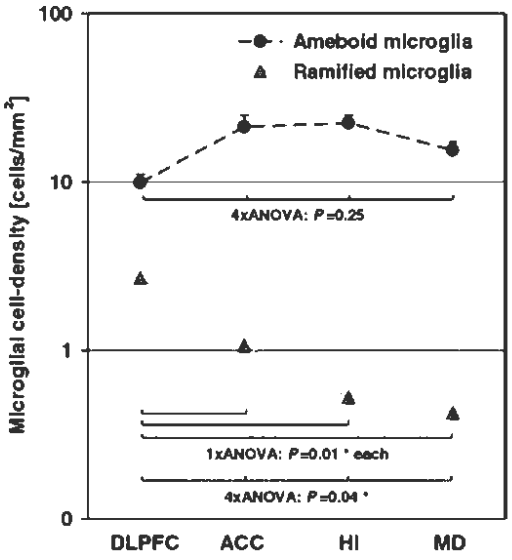
Indicate what graphics program was used to create the artwork.

For vector graphics, the preferred format is EPS; for halftones, please use TIFF format. MSOffice files are also acceptable.

Vector graphics containing fonts must have the fonts embedded in the files.

Name your figure files with "Fig" and the figure number, e.g., Fig1.eps.

Line Art



Definition: Black and white graphic with no shading.

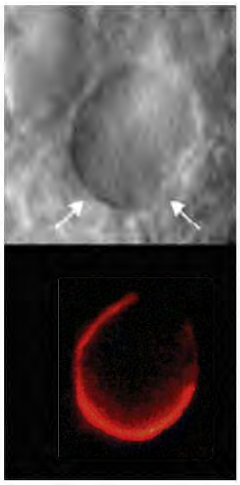
Do not use faint lines and/or lettering and check that all lines and lettering within the figures are legible at final size.

All lines should be at least 0.1 mm (0.3 pt) wide.

Scanned line drawings and line drawings in bitmap format should have a minimum resolution of 1200 dpi.

Vector graphics containing fonts must have the fonts embedded in the files.

Halftone Art

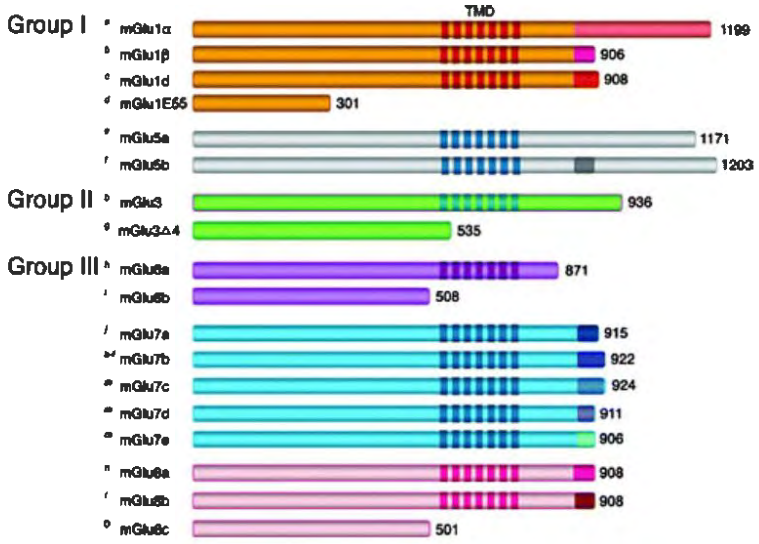


Definition: Photographs, drawings, or paintings with fine shading, etc.

If any magnification is used in the photographs, indicate this by using scale bars within the figures themselves.

Halftones should have a minimum resolution of 300 dpi.

Combination Art



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E. OPINION PIECE

1. Opinion Piece:

Mandating oral PrEP in pregnancy and postpartum: Protecting the Mother and Child

Over 40 years on, HIV/AIDS is still a global public health burden despite the widespread roll-out of anti-retroviral therapy (ART), with 29.8 million people living with HIV accessing ART in 2022 according to the latest UNAIDS report [1]. In Sub-Saharan Africa, adolescent girls and young women (AGYW) aged 15 – 24 years are most at risk of contracting HIV. In 2022 alone, 1.3 million people were newly infected with HIV, with AGYW from Sub-Saharan Africa accounting for 77% of these infections [1]. Pregnant women are highly vulnerable to HIV infection due to behavioural and biological factors, such as changes in the genital female tract mucosa and changes in the immune system and hormones. Oral preexposure prophylaxis (PrEP) is a United States Food and Drug Administration (FDA) approved preexposure prophylaxis. It is a combination of emtricitabine and tenofovir disoproxil fumarate that is 99% effective in preventing HIV acquisition, through sex, if taken effectively in those not living with HIV and are at risk of acquisition [2].

HIV risk perception versus actual HIV risk

HIV risk perception is defined as "one's belief about their susceptibility" [3] to HIV infection whereas actual HIV risk is the lifetime risk of acquiring HIV through exposure to the virus through certain behaviours and exposures. Risk perception is considered important in many health behaviour change models. The assumption of these models is that having a raised risk perception will lead to one engaging in more protective behaviours. However, risk perception is often found to be low even amongst individuals participating in risky sexual behaviours. Furthermore, individuals may continue to engage in sexual risk behaviours even when their perceived risk of being infected is high, highlighting a discordance between how people perceive their risk of HIV infection versus what their real risk of being infected is. This suggests that just looking at an individual's perceived HIV risk may not be a good enough approach for models and interventions concerned with health behaviour changes.

Current oral PrEP guidelines

In South Africa, oral PrEP use during pregnancy and postpartum is part of national guidelines, however, women are not obligated to initiate and use oral PrEP during these periods. The South African Department of Health's current guidelines advise on counselling and offering of HIV prevention methods in pregnant and breastfeeding women are at a considerable risk of HIV infection [4]. Screening for oral PrEP initiation mainly involves questions on sexual risk behaviours, namely reporting having had sex: without a condom, with more than one partner, with a partner with an unknown serostatus or a partner who is living with HIV and having a recent STI diagnosis or being in an age-gap relationship. However, most of these questions, which determine eligibility for being recommended oral PrEP, are

prone to respondents concealing the truth about their sexual behaviours especially during pregnancy and postpartum to make themselves look good. This leads to social desirability bias.

Benefits for mother and child

HIV infection is not only a concern for pregnant and non-pregnant mothers but for their infants as well. Should a mother acquire HIV during pregnancy and postpartum and not achieve viral suppression on ART, then they are at an increased risk of vertically transmitting HIV to their infants. A study by Joseph-Davey et al., [5] found that in an optimistic scenario where 80% of all pregnant women not living initiated oral PrEP then perinatal infection would decrease by 41%. Furthermore, oral PrEP use is safe during pregnancy and postpartum. There is no evidence of adverse birth outcomes when mothers are using oral PrEP during pregnancy and postpartum as opposed to untreated HIV infection in mothers which leads to adverse perinatal outcomes.

Guideline recommendations

Recommendations include making sure that every pregnant and postpartum woman not living with HIV is considered as being at a substantial actual risk of HIV infection (regardless of their perceived HIV risk), without undergoing oral PrEP eligibility screening and is subsequently initiated on oral PrEP. Emphasis should be placed on the effectiveness of oral PrEP, if taken correctly, in preventing HIV infection through sex. This will not only decrease the burden of HIV in women of reproductive age but also in neonates.

Potential concerns

Although the recommendations address issues of HIV prevention and vertical transmission, concerns remain. Barriers may still exist even with the implementation of the recommended policy, where every pregnant and postpartum woman is initiated on oral PrEP. First, there are issues of adherence. Pregnant and postpartum women may have a hard time adhering to oral PrEP due to side effects, perceived stigma, and their perceived HIV risk where although they were initiated on oral PrEP, they may still feel their risk is low. Second, oral PrEP does not prevent against STI infections and even during periods of oral PrEP use, oral PrEP use is not a substitute for a way to engage in irresponsible or high risk sex. A study in adolescents and young people (AYP) from East and Southern Africa [6] revealed that AYP perceived that the availability of oral PrEP could change their sexual behaviours influencing condom use, where they reported perceived reduced condom use and frequent condomless sex and sexual activities (increased number of partners and number of sexual encounters).

Additional insights

Another approach would be the implementation of PrEP counselling for pregnant and postpartum mothers not living with HIV. PrEP counselling is an approach that can help women understand their

risk of acquiring HIV based on their sexual risk behaviours and circumstances. It will allow the assessment of a woman's personal risk of being infected with HIV based on risk factors such as having multiple sexual partners, substance use/abuse, and relationship dynamics. It will also help adjust and correct the women's perception of their risk of acquiring HIV, aligning perceived HIV risk with actual HIV risk. Understanding their actual HIV risk may motivate the pregnant and postpartum women to initiate and continue (adhere) to oral PrEP. However, for PrEP counselling to work, healthcare providers need to be trained in providing good counselling to ensure oral PrEP continuation. This should involve rigorous training of counsellors in conveying HIV risk to pregnant and postpartum women in a non-judgemental way, encouraging sexual risk behaviour changes, providing support, and continued education and development of the counsellors, particularly regarding their counselling skills where understand and empathy are important.

Conclusions

Oral PrEP use in pregnancy and postpartum should be made a policy in South Africa, the country most affected by the HIV/AIDS epidemic. This will not be beneficial to mothers but to their infants as well, where the effective use of oral PrEP will prevent HIV acquisition in mothers and vertical transmission to their children. However, even through the implementation of the recommended policy, many challenges still exist in ensuring oral PrEP adherence. An approach to combating oral PrEP adherence issues is PrEP counselling, where women are made aware of their actual HIV risk through personal HIV risk assessments, ensuring that their perceived HIV risk aligns with their actual HIV risk. However, proper training of healthcare providers is needed to ensure the success of oral PrEP counselling.

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