EXAMINING PATTERNS OF INTIMATE PARTNER VIOLENCE AND DEPRESSION AMONGST A COHORT OF PREGNANT AND POSTPARTUM WOMEN IN CAPE TOWN, SOUTH AFRICA

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Dissertation submitted to the University of Cape Town in partial fulfilment of the requirements for the degree Master of Public Health (Epidemiology and Biostatistics)

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PREAMBLE

Declaration

I, Kayla Bagg, hereby declare that the work on which this dissertation 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 submitted for another degree in this or any other university. I further declare that this work was not public prior to my registration for the degree of Master of Public Health (Epidemiology and Biostatistics).

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Date: 11/02/2024

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Abstract

Depression and intimate partner violence (IPV) frequently co-occur among women in South Africa with elevated risk in the antenatal and postnatal period. In South Africa, IPV is ranked as the second highest burden of disease after HIV. The prevalence of maternal mental health problems during pregnancy and during postpartum is alarming, particularly among women in low- and middle-income countries (LMIC). IPV and depression negatively impact persistence and adherence to oral pre-exposure prophylaxis (PrEP). Pregnant women have been identified as a key population, vulnerable to sexual and reproductive health (SRH) risks such as the acquisition of human immunodeficiency virus (HIV). In this study, we described patterns in IPV and depression in a cohort of pregnant women.

Data was retrospectively analysed from a cohort of 1195 HIV-negative women on oral PrEP. Participants were recruited from two midwife obstetric units (MOU) in Gugulethu and Hanover Park. Data was collected between August 2019 and October 2021. Women were followed from enrolment (first antenatal care [ANC] visit) to 12 months post-partum with 3-monthly interviews. Data was analyzed from the baseline and first postpartum visit.

Of 1195 participants, 77 (6.4%) were aged 16–18 years and 409 (34.2%) were aged 19–24. 79.3% of women (n=948) fell into the category of either 'unplanned' or 'ambivalent' using the London Measure of Unplanned Pregnancy (LMUP). At baseline, 147 women (12.3%) reported experiencing IPV. Among women aged 16–18 years, 13.5% of them reported signs or symptoms that placed them above the Edinburgh Postnatal Depression Scale (EPDS) threshold of 11, compared to 5.9% who reported symptoms placing them below the EPDS threshold of 11. 25.8% of women who scored above 11 on the EPDS threshold reported experiencing IPV compared to 11.2% of women who reported experiencing IPV who scored below 11 on the EPDS threshold.

Results from the multivariable analysis indicate that women between the ages of 16–18 years are 3.15 (95% CI: 1.30, 7.07) times as likely to score above 11 on the EPDS compared to women > 25 years. Women who reported experiencing IPV at baseline had 2.77 (95% CI: 1.61, 4.61) times the odds of an EPDS score >11 compared to those who did not experience IPV at baseline, controlling for age, income, whether the woman was a social grant recipient, LMUP threshold, and current relationship status. Amongst women who reported experiencing IPV at baseline (n=147), at their first visit postpartum 8 (5.4%) women fell above the EPDS threshold of 11, while 82 (55.8%) women fell below the threshold of 11. Data was missing for the remaining 57 women.

These results indicate that women who experience IPV during their pregnancy are more likely to report being depressed at baseline. In SA, IPV prevalence is high among pregnant women and its association with emotional distress during pregnancy suggests the need for interventions addressing both IPV and depression. In conjunction with this, addressing issues of IPV and depression can positively impact adherence to oral PrEP which can also be closely monitored.

This mini dissertation is made up of three parts. Part A is the research protocol, Part B is the journal-ready manuscript, and Part C are the appendices.

Acronyms and abbreviations

AGYW	Adolescent girls and young women
ANC	Antenatal care
CI	Confidence interval
EPDS	Edinburgh Postnatal Depression Scale
HIC	High-income countries
HIV	Human immunodeficiency virus
IPV	Intimate partner violence
IQR	Interquartile range
LMIC	Low- or middle-income countries
LMUP	London Measure of Unplanned Pregnancy
LTFU	Loss to follow-up
MDG	Millennium Development Goals
MOU	Midwife obstetric unit
OR	Odds ratio
PrEP	Pre-exposure prophylaxis
PTSD	Post-traumatic stress disorder
SA	South Africa
SRH	Sexual and reproductive health
TB	Tuberculosis
UCT	University of Cape Town
WHO	World Health Organization

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PART A: RESEARCH PROTOCOL

Aims, objectives, background

Aims

The primary aim of this study is to describe patterns of intimate partner violence (IPV) and depression during pregnancy and one year postpartum among women enrolled in antenatal care in Cape Town, South Africa (SA).

The secondary aim of this study is to uncover whether there is a relationship between depression and IPV amongst women by different covariates. Of particular importance here are age, whether the women receive a social grant or not, relationship status, income level, and whether the pregnancy was unintended or intended.

Objectives

Women who are pregnant and postpartum are one of the most at-risk groups of experiencing both IPV and depression, yet so little research exists which seeks to examine how IPV and depression, separately and together, have the potential to negatively impact this vital period [1-3]. The study of both patterns during pregnancy and in the postpartum period, also known as the perinatal period, may shed light on the dangerous situation these women find themselves in [1-3]. In conjunction with this, research directly relating to how IPV develops and changes during this period, and how IPV and depression are related during this period, has been heavily under-researched in low- or middle-income countries (LMIC), particularly in SA where the prevalence of IPV and symptoms of depression are dangerously high [3-4].

All women enrolled in the study tested negative for human immunodeficiency virus (HIV), and at baseline, most of the women had initiated oral pre-exposure prophylaxis (PrEP), a drug given to individuals who are exposed to HIV to halt the acquisition of the virus. IPV and depression negatively impact PrEP adherence and persistence, which are particularly important given how vulnerable perinatal women are to HIV acquisition, making it an important component of this research [5-10].

Background

Both IPV and depression are life-changing events women all over the world experience. The World Health Organization (WHO) estimates that 15% to 71% of women in their lifetime, especially when they are pregnant, will experience some form of violence perpetrated by an intimate partner [11-12]. In conjunction with this, the prevalence of

depression amongst pregnant and post-partum women is prevalent, especially amongst women in LMIC [12].

As will be highlighted in the following paragraphs, instances of IPV and depression are highly related and unfortunately define the pregnancy experiences of many women all over the world, particularly in South Africa.

Patterns of intimate partner violence during pregnancy

One in three South African women will experience IPV (sexual, physical, or emotional) at least once in their lifetime, according to research examining the prevalence of IPV in women in South Africa [12]. Pregnant and postpartum women are often at greater risk of experiencing IPV, because of their vulnerable positions regarding pregnancy intentions and being dependent on a partner [1-2, 5]. Thus, instances of IPV amongst pregnant and postpartum women must be also focused on, given the myriad of adverse health outcomes that threaten not only the life of the mother but also the life of the child [11]. Women who experience any form of violence during their pregnancy, especially when committed by an intimate partner, are less likely to seek antenatal care or delay the process of seeking care during their pregnancy [13].

While this delay in healthcare-seeking behaviour can be attributed to many aspects of the lives of these women when delving into their socio-economic and cultural context, fear, and shame because of IPV is a huge motivating factor [13]. It is important to note that instances of IPV do not occur without the influence of other driving forces, where for this research project IPV alongside feelings of depression will be critically analyzed to gain an in-depth understanding of the experiences of pregnant and postpartum women living in Cape Town, SA.

Patterns of depression during pregnancy

Symptoms and instances of depression are at a global high amongst all members of different populations [1]. One integral population group that is often omitted from vital conversations around the prevalence of depression is pregnant and postpartum women. All over the world, but particularly in LMIC, depression has come to be a recognized feature of the experiences of these women, with the severity of the symptoms depending on their unique social context [1]. Recording of instances of depression amongst pregnant and postpartum women has mainly utilized the Edinburgh Postnatal Depression Scale (EPDS) to ascertain whether women have depression or not in much of the literature and will be utilized in this research project [1, 4, 11, 13]. Much like IPV, when a woman experiences severe symptoms

of depression during pregnancy, it can also lead to adverse birth outcomes, namely major consequences for infant growth and development [1]. While there is a wide range of sources documenting the development of depression in the postnatal period, from the review of the literature there seems to be little information regarding how symptoms of depression change while a woman is pregnant, an important gap that this research hopes to fill.

Although the primary aim of this study is to examine whether patterns of IPV and depression exist amongst women who are pregnant and postpartum, which the literature has shown to be a major problem hindering the quality of life of these women, the secondary aim of this research is to ascertain whether there is a relationship between IPV and depression.

The link between intimate partner violence and depression amongst pregnant women

The link between IPV and depression among perinatal women has been well documented and shown a significant link between instances of IPV and symptoms of depression, however, this data comes mainly from high-income countries using Western-centric scales to measure these phenomena that may not accurately represent the experience of women in LMIC [4].

Considering this gap, studies have been conducted which have provided statistically significant evidence to show that in pregnant and postpartum women living in SA, a positive relationship exists between IPV and depression [4]. This is further substantiated by evidence showing that depression and IPV frequently co-occur where the risk for both IPV and depression is significantly increased during the antenatal and postnatal period [1].

Impact of IPV and depression on PrEP adherence

As mentioned previously, almost all women enrolled in the study initiated oral PrEP at baseline. The link between both IPV and depression and adherence to PrEP has been well documented overseas, and in SA [5-10]. Women who struggle with their mental health, particularly depression, are less likely to access healthcare services and adhere to medicine regimes as prescribed by doctors [7]. Experiences of IPV amongst pregnant women present similar barriers to PrEP adherence. Here, not only the act of violence, but the fear of violence hinders PrEP adherence and persistence [8].

Acknowledging the importance of IPV and depression on PrEP adherence and persistence amongst pregnant and postpartum women cannot be underestimated, especially when looking at services offered to women in the health care settings and how addressing the two phenomena can have a positive impact on the health of these women, both directly and indirectly.

Significance

Women who are pregnant and postpartum are one of the most at-risk groups of experiencing both IPV and depression, yet so little research exists which seeks to examine how IPV and depression, separately and together, have the potential to negatively impact this vital period. It is potentially helpful to investigate how these occurrences develop during pregnancy and postpartum so that we can learn more about the dangerous situation in which these women are placed in. In conjunction with this, research directly relating to how IPV develops and changes during this period, and how IPV and depression are related during this period, has been heavily under-researched in LMIC, particularly in South Africa where the prevalence of IPV and symptoms of depression are dangerously high.

Study hypothesis ahead of methodology

Given the prevalence of both outcomes amongst women living in low-middle income settings, in the context of the primary aim the researcher hypothesizes that patterns do exist with regards to women who experience IPV are at higher risk of developing depression, particularly amongst women who did not intend to get pregnant at that time. With regards to the secondary aim, it is hypothesized that in the cohort of pregnant and postpartum women, depression and IPV have a positive relationship – meaning that as depression increases, IPV increases and vice versa, especially in the postpartum period. In the context of the covariates mentioned in the "aims" section, it is hypothesized that for women under the age of 20, who are receiving a social grant, who are not in a relationship, and where the pregnancy was unintended, this relationship will be stronger.

Methods

Scientific design

The design for this study will be a retrospective cohort study. This choice is justified by the nature of the parent study which is an observational cohort study. In conjunction with this, since this study aims to uncover patterns of IPV and depression amongst women in the cohort, a retrospective study was deemed the most appropriate to conduct longitudinal analyses of the data. According to previous studies, the sufficient sample size needed to detect a discernible pattern in both depression and IPV is over 1200 with 80% power [4, 11].

Study population

The total number of participants who were enrolled in the parent study is n = 1201. While 1201 participants were enrolled in the study, this study made use of the data for 1195 women – omitting 6 from the final analysis It is important to note that almost all participants were initiated on oral PrEP at baseline. These participants are roughly evenly distributed between the two main study sites, midwife obstetric units (MOU) in both Gugulethu and Hanover Park.

Inclusion and exclusion criteria

The inclusion and exclusion criteria for this study echo that of the parent study, which are as follows.

Inclusion criteria: (1) ≤ 16 years old, (2) confirmed HIV-negative, (3) intend on giving birth in the MOU facility, (4) confirmed to be pregnant, and (5) without psychiatric or medical contraindications to PrEP.

Exclusion criteria: (1) concurrent enrolment in another HIV vaccine or prevention trial, (2) medical hospitalization in the last year related to obstetric health, (3) active tuberculosis (TB) or received TB treatment in the last 30 days, (4) history of renal disease, (5) clinical diagnosis of hypertension, (6) exhibiting psychotic symptoms, (7) history of taking anti-psychotic medication, (8) positive Hepatitis B, (9) history of bone fracture not related to trauma, and (10) any other condition (medical, psychiatric, or social) which would hinder the ability of the participant to be enrolled in the study.

Recruitment and enrolment

In the parent study, participants were recruited directly from antenatal care (ANC) with the help of a trained recruiter. This study recruiter underwent a three day training programme to ensure they understand the aims and objectives of the study, in conjunction with what their roles as recruiters entail. Women who are interested in participating in the study will go through an in-depth screening process, guided by the inclusion and exclusion criteria, to see if they are eligible to participate in the study. Once these women make it past the screening process, they will be directed to the study sites at either location where the enrolment process begins.

Since this study made use of the data collected in the parent study, the recruitment and enrolment procedures of participants do not differ.

Research procedures

The parent study made use of a myriad of data collection methods, namely, survey measures, in-depth interviews, laboratory measures, and information abstracted from routine medical records. All this data was collected between August 2019 and October 2021. Women were followed from enrolment (ANC visit) to 12 months postpartum with interviews happening every three months. Given the nature of this study, where the primary aim is to see whether patterns of IPV and depression change over time in the cohort of women, the data needed for this study comes from the survey measures (Appendix B). This questionnaire was translated from English to isiXhosa and Afrikaans and back-translated to ensure the translations captured the appropriate phrasing of the questions.

In the parent study, these surveys were given to women who met the eligibility criteria to participate in the study. According to the researchers, it was noted that it would take participants approximately 30-45 minutes to complete the survey. Before the COVID-19 pandemic, women were interviewed by a study interviewer in a private setting allowing the women to feel comfortable with sharing personal information. During the COVID-19 pandemic, participants were interviewed telephonically by the study interviewer and a translator if necessary. These interviews were digitally recorded on two devices. To maintain the confidentiality of the participants each study participant received a unique participant identification number that allows researchers to identify which participants they are speaking to.

Since this research project is a secondary analysis of data obtained by the parent study, the procedure that will be followed in this case is requesting the data via the data manager of the parent study by highlighting certain variables needed for the study, following privacy and confidentiality procedures highlighted later in the protocol.

Risks and benefits

In the parent study, before the women were enrolled in the study, they were made aware of the potential risks that could arise by participating in the study. These were highlighted in the informed consent form given to the participants, available in both isiXhosa and Afrikaans. In conjunction with this, the researchers accounted for women who could not

read by creating a pre-recorded digital copy of the consent form the participants could listen to in their first language (Appendix A).

The benefits associated with using the data from these participants are two-fold. The first is regarding the individual, as highlighted by the parent study, where women enrolled in the study benefitted by receiving the best possible standards of care not only relating to pregnancy but also other diseases, such as hepatitis B, HIV, and sexually transmitted infections (STIs). In conjunction with the medical counselling these women received, they were also given a safe space to talk about their emotional states, which is often a space not available to these women.

On the broader level, this dissertation study has a myriad of benefits. The first is that this study can shed light on the current state of both IPV and depression during pregnancy and the postpartum period, and how changes in both phenomena occur amongst the women while they were enrolled in this study. Uncovering this link has the potential to inform health services about the standard of care they provide at antenatal care visits, indicating that more attention is needed regarding the problem of IPV and depression during pregnancy. In conjunction with this, shedding light on the patterns of IPV and depression and the association between these two outcomes has the potential to provide recommendations for healthcare policies, specifically focusing on ANC and standard of care relating to IPV and depression.

Process of obtaining informed consent

To ensure the informed consent process was thorough and highlighted all the potential risks and benefits associated with the study, two consent forms were developed for the parent study. The first consent form was for the participants to read through and sign before participating in the screening survey at their first ANC visit – allowing researchers to ascertain whether the women fit the criteria to be involved in the study or not. The second informed consent form was the main one dedicated to the actual study. Both consent forms are attached as Appendix A.

It is important to note that in the parent study, the study staff emphasized that volunteering in the study was entirely their choice and that if a woman chooses not to participate in the study or decides to withdraw at any point during the study it will not hinder their access to quality medical care.

These informed consent documents were translated, and back-translated, into isiXhosa and Afrikaans allowing women whose first language is not English to fully grasp the informed consent process. In conjunction with this, women were allowed to listen to or watch, a recording of the informed consent form should they have issues with reading. A combination of these methods guaranteed that women fully understood the study they were enrolling in.

Since this study is embedded in the parent study and will be using the data available without interviewing participants, the informed consent processes used in the parent study are sufficient.

Privacy and confidentiality

Integral to conducting research of the highest quality is the protection of the privacy and confidentiality of the women involved in the study. In the parent study, this was guaranteed by only using names on the informed consent documents, which were kept in the locked cabinet at one of the study offices only accessible by those involved in the study. Each woman was assigned a unique patient identification number that allowed researchers to differentiate between research participants. As highlighted earlier, in the subsection of data safety and monitoring under methodologies, any printed questionnaire or informed consent form is kept in a locked cabinet at the study sites only accessible by researchers in the study. When it comes to electronic data, these are kept at the University of Cape Town (UCT) within a firewall-protected server with nightly backups which are password protected.

Since this study will be making use of secondary data, privacy and confidentiality will be followed by not having access to any names of the information about the women. The data sent will be password protected and the researcher will ensure no colleagues will have access to the data to protect the integrity of the participants involved.

Data analysis and monitoring

Data analysis

For this study, the focus will be on the quantitative data collected through questionnaires given to women at ANC visits at specific points in time, which will be highlighted later in the paragraph. This data was collected by trained study investigators, who before their involvement in the study participated in a three day training course conducted by the principal investigators.

When it comes to data analysis for this study, it is vital to know that the data was kept in password-protected files stored at UCT within a firewall-protected server with nightly backups. To ensure the accuracy and reliability of the data collected, the existing Department of Health staff and study staff will be required to undergo training. This training involves an overview of the aims and objectives of the study, alongside the study protocol. Of particular importance for those involved in the study is information relating to conducting high-quality studies void of breaches of the study protocol. This study will take a different approach to the parent study, where patterns of intimate partner violence and depression will be analyzed amongst pregnant and postpartum women. Since the primary aim of the study is to uncover whether there are patterns in both intimate partner violence and depression in the cohort, data will be collected at different points in enrolment: at baseline and at the first postpartum visit the moms attended.

Data monitoring

All soft copies of data – signed informed consent forms, questionnaire responses, and any other relevant documents – were kept in a locked cabinet at the study sites in Gugulethu, Hanover Park, or UCT offices strictly accessible by researchers involved in the project. Hard copies of data were equally protected, where they were kept in password-protected files solely accessible by researchers in the study. This data will be stored at UCT within a firewall-protected server to ensure its safety. Data monitoring in the parent study was led by highly specialized trained individuals who throughout the study led weekly conference calls with all those involved in the study to ensure the safety of both the participants and the data was being upheld.

For this study, only the data the researcher requests will be sent through password-protected, encrypted files to ensure it is not accessible by others. In conjunction with this, the researcher will ensure data is not shared with any colleagues. Simultaneously, the researcher will ensure to make copies of the data, so the original dataset sent by the principal investigators of the parent study is not ruined.

Resources

The necessary resources needed to complete this minor dissertation have all been accounted for. The researcher has a working laptop and a safe working space where research can be conducted. In conjunction with this, the researcher has sufficient support from Dr Alex de Voux (the supervisor) and other colleagues should any help be needed.

Conflicts of interest

No conflicts of interest were declared by the researchers.

Authorship

Authorship will include myself, the MPH student, the principal investigator (Dr Alex de Voux), and the main investigators in the parent study (Professor Landon Myer, Professor Thomas Coates, Professor Linda-Gail Bekker, Assoc. Professor Maia Lesosky, Dr Leigh Johnson, Dr Dvora Joseph Davey, Dr Lisa Frigati, and Dr Greg Petro), the data managers (Lerato Hlatshwayo and Kalisha Bheemraj), and Hayli Geffen who assisted with the biostatistics aspect of the research.

Ethics and regulatory compliance

As seen under the 'risks and benefits' and 'privacy and confidentiality sections', stringent guidelines were in place to ensure the parent study complied with the Declaration of Helsinki (2013) and the Department of Health document that outlines principles and structures regarding ethics in human research (2014). Since this study is a secondary analysis of the data collected from the parent study, ethical and regulatory compliance will mimic the parent study. Of particular importance for this study is the confidentiality of the data received, where measures to keep this confidential have been highlighted.

Time schedule

	March	April	May	June	July	August	September	October	November	December	January	February
Ethical approval												
Data management												
Data analysis												
Results												
Discussion												
Final write-up of minor dissertation												
Submission of minor dissertation												

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PART B: MANUSCRIPT

Examining how patterns of intimate partner violence and depression change over time amongst pregnant and postpartum women in Cape Town, South Africa

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Abstract

Depression and intimate partner violence (IPV) frequently co-occur among women in South Africa (SA) with elevated risk in the antenatal and postnatal period. Both phenomena have also been shown to reduce uptake and adherence to human immunodeficiency virus (HIV) treatments. In this secondary analysis, we examined patterns of IPV exposure and depression in a cohort of pregnant HIV-negative women on oral pre-exposure prophylaxis (PrEP). Data from 1195 women at enrolment was retrospectively analyzed from an existing dataset. Participants were recruited from two midwife obstetric units in Cape Town and followed from enrolment to 12 months post-partum with 3-monthly interviews. Women between the ages of 16–18 years were 3.15 (95% CI: 1.30, 7.07) times as likely to score above 11 on the Edinburgh Postnatal Depression Scale (EPDS), indicating depression, compared to women >25 years. Women who self-reported experiencing IPV at baseline had 2.77 (95% CI: 1.61, 4.61) times the odds of an EPDS score ≥11 compared to those who did not report experiencing IPV at baseline. In conjunction with this, the London Measure of Unplanned Pregnancies (LMUP) was used to determine the pregnancy intentions of the mothers. The prevalence of maternal mental health problems during pregnancy and postpartum is alarming, particularly among women in low- and middle-income countries (LMIC). These include IPV and depression which could lead to poor adherence to oral pre-exposure prophylaxis (PrEP) and ultimately HIV infection. Screening for depression in the postpartum period may also have an impact on IPV victimization. Identifying pregnant women who are experiencing either IPV or depression and linking them with the necessary services, may improve PrEP outcomes.

Key words

Intimate partner violence · depression · pre-exposure prophylaxis · perinatal · patterns

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*As highlighted in the UCT MPH degree requirements, advisors are not to be listed as authors on the journal ready manuscript. Instead, their contribution to the finished work will be stated under acknowledgements. Once the final manuscript is submitted to the journal AIDS and Behaviour for publication, the advisors will be listed on the cover page.

Introduction

Rates of intimate partner violence (IPV) against women in societies all over the world have reached abhorrent rates, where global estimates of both lifetime and annual rates of IPV indicate that "one in three women have experienced some form of violence, physical or sexual, by a male partner" [1, 2].

Simultaneously, the experience of IPV has a profound impact on the health and well-being of these women, where the social consequences of experiencing IPV are reflected in many facets of their lives [3]. It has been highlighted that "increased levels of depression, post-traumatic stress disorder (PTSD), suicidal ideation, alcohol or drug abuse, unintended pregnancy and unsafe abortions, and feelings of powerlessness" are deeply connected to women's experiences of IPV [2].

IPV does not occur in a vacuum. The social determinants of health are constantly intersecting, adding to the pervasiveness of the issue. Examples of these social determinants include socio-economic inequality, adversity, and level of education [2,4-6]. Schneider et al. note that depression and IPV frequently co-occur among women [7]. Increased levels of both IPV and depression have been reported amongst pregnant women, where the risk for both phenomena is heightened in the perinatal[1] periods, thus leading to negative health outcomes for both the child and the mother [3,7].

In South Africa (SA) IPV has been ranked the second highest burden of disease after human immunodeficiency virus (HIV) [8]. The reported lifetime prevalence of IPV amongst pregnant women in SA ranges from 27-48%, making them a key population to focus on when implementing strategies to mitigate the impact of IPV [9]. Shamu et al. highlight how "being young or adolescent, single marital status, separated or divorced during pregnancy, belonging to ethnic minorities, and low educational status" are some risk factors that place pregnant women, or women whose pregnancies are unplanned, at greater risk of experiencing IPV [9, 10].

IPV forms part of an intricate interaction between personal, emotional, psychological, and social factors for pregnant women [11]. This nature of intersectionality, coupled with the consequences of mental health issues during the perinatal period, is devastating, especially among women in low- or middle-income countries (LMIC) [12,13]. The estimated rates of depression amongst pregnant women during the perinatal periods are between 15.8% and

[1] The period from when you become pregnant and up to a year after giving birth.

19.8% in LMIC [10]. Govender et al. highlight how "maternal age, socio-economic status, unplanned pregnancies, violence, social support, history of previous mental disorder" are significant risk factors experienced by pregnant women that make them especially vulnerable to experiencing depression [10]. Much like IPV, adverse outcomes are associated with experiencing depression during the perinatal periods. These have physical repercussions for both the mother and child but have greater consequences for the relationship between not only the mother and her child but also the mother and her partner [14].

Sexual and reproductive health (SRH) risks associated with mental health and IPV include increased HIV acquisition risk and poorer adoption and continuation of pre-exposure prophylaxis (PrEP)[2] [2,15]. It is well documented that both experiences of IPV and depression harm PrEP adherence and persistence [16-20]. Velloza et al. highlighted how healthcare engagement and medication adherence, particularly oral PrEP, are negatively impacted by mental health conditions, such as depression [17]. This is important given the high burden of depression amongst adolescent girls and young women (AGYW) across sub-Saharan Africa, two key populations vulnerable to HIV acquisition and depression [17]. IPV places a constraint on the "acceptability, uptake, and use of HIV prevention methods" including oral PrEP [18]. Not only do experiences of violence impact PrEP uptake, but the fear of violence is an important barrier to adherence and persistence [18].

It is vital to look at the joint effects of both IPV and depression on the lives of not only the mothers but also their children. Limited research has been conducted in SA to investigate the myriad of factors associated with the experience of emotional distress during the perinatal periods. Within the limited research that has been conducted, IPV has been a major risk factor for experiencing depression during pregnancy [8]. The relationship between the two phenomena should not be seen as uni-directional and deterministic. Rather, IPV and depression are complex experiences intricately intertwined and compounded by other contextual factors [13]. This suggests that experiencing mental health problems, such as depression, should not only be seen as a risk factor for IPV but also as a consequence of IPV. A study conducted in Khayelitsha, a peri-urban township in Cape Town, found that 39% of women who reported depressive symptoms were simultaneously experiencing IPV, lacked support from their partner, fell into the lower income bracket, and were younger [7].

There is a dearth of information regarding the link between IPV and depression among pregnant women during the perinatal periods in sub-Saharan Africa, where rates of IPV are

[2] A safe and effective intervention to reduce the risk of HIV acquisition if exposed.

amongst the highest in the world [22]. Given the importance of both IPV and depression amongst pregnant and postpartum women, and the severe implications it has on the mother and the child, this research project has identified an important gap in the literature and aims to fill it [13].

The primary aim of this research project is to describe patterns of IPV and depression amongst pregnant and postpartum women enrolled in antenatal care in Cape Town, SA. The secondary aim of this study is to uncover whether there is a relationship between depression and IPV amongst women by different covariates. Of particular importance here are age of the mother, receipt of a social grant, relationship status, income level, and whether the pregnancy was unintended or intended.

Methods

Parent study description

This study was a secondary analysis of the parent study entitled "PrEP-PP: Pre-exposure Prophylaxis in Pregnancy and Postpartum Period" [23]. The parent study had a myriad of aims, but the primary aims of the study was to determine the distribution of women across the PrEP cascade [23]. In the parent study 4 sources of data were used; (1) survey measures; (2) in-depth interview measures in 60 randomly selected women (n=30 who were on PrEP compared with 30 not on PrEP); (3) laboratory measures; and (4) information abstracted from routine care records, including related to PrEP [23].

Study design

The design for this study is a retrospective cohort study. This choice was justified by the nature of the parent study which was an observational cohort study. In conjunction with this, IPV and depression were measured at two time points—the baseline and the first postpartum visit.

Study setting

Participants were recruited from two midwife obstetric units (MOUs) in Gugulethu and Hanover Park [23]. Both MOUs were defined as primary care facilities embedded in the public health sector. Hanover Park and Gugulethu are identified as areas where IPV occurs at high rates, where a study conducted in Hanover Park found a 15% prevalence rate of IPV amongst women in Hanover Park, Cape Town [12].

Study participants

The inclusion and exclusion criteria for this analysis were outlined as follows:

Inclusion criteria: (1) ≥16 years old, (2) confirmed HIV-negative, (3) intend on giving birth in the MOU facility, (4) confirmed to be pregnant, and (5) without psychiatric or medical contraindications to PrEP [23].

Exclusion criteria: (1) concurrent enrolment in another HIV vaccine or prevention trial, (2) medical hospitalization in the last year related to obstetric health, (3) active tuberculosis (TB) or received TB treatment in the last 30 days, (4) history of renal disease, (5) clinical diagnosis of hypertension, (6) exhibiting psychotic symptoms, (7) history of taking anti-psychotic medication, (8) positive Hepatitis B, (9) history of bone fracture not related to trauma, and (10) any other condition (medical, psychiatric, or social) which would hinder the ability of the participant to be enrolled in the study [23].

While the total number of participants who were enrolled in the parent study was 1201, 6 participants were omitted from the final analysis leaving 1195 participants included in the analysis.

Study procedures and data collection

Data were collected between August 2019 and October 2021. Women were followed from enrolment, first ANC visit, to 12 months postpartum with interviews every three months [23]. This questionnaire was administered by a trained researcher translated from English to isiXhosa and Afrikaans and back-translated to ensure the translations captured the appropriate phrasing of the questions.

Measures

The exposure of interest in this research project was whether women experienced IPV or not in the last 12 months. This was a self-reported measure, indicated with a “yes” or “no”. This considers all forms of IPV, including physical, sexual, and emotional violence perpetrated by a current, or former, partner or spouse [1,8,22].

The outcome of interest was depression which was assessed using the Edinburgh Postnatal Depression Scale (EPDS), a screening tool which enquires about depressive symptoms within a 7-day recall period [21]. While EPDS is traditionally used to diagnose depression in postpartum mothers other studies have shown great success when using the tool

to identify depression in antenatal moms [10,14]. An EPDS score of above 11 (≥ 11) was chosen as the threshold for clinical depression as prior research has shown this threshold score to identify perinatal moms at risk for clinical depression with adequate sensitivity and specificity [21].

While EPDS was developed as a tool to diagnose depression in perinatal moms oversees, in their study Lawrie et al. validated the use of the EPDS in the SA context, with several other studies making use of the scale [24, 25].

As highlighted in the parent study, if any woman reports experiencing either IPV or depression, they were referred to organizations in their community that would be able to provide them with support (23).

Another measure of interest in this analysis is looking at pregnancy intentions, measured by the "London Measure of Unplanned Pregnancy" (LMUP). Much like the EPDS, the LMUP threshold was developed in the United Kingdom (UK). In their study, Ernstoff validated the LMUP in the Cape Town area of SA, where once again several studies have made use of the threshold [26,27].

Data analysis

Quantitative data were collected through questionnaires administered to women at all study visits [23]. The questionnaires were delivered by trained study staff [23]. Both the primary exposure and outcome were measured at baseline and the first postpartum visit. Data were also analysed from the first postpartum visit the moms attended where a change in whether women fell above or below the EPDS threshold was investigated amongst women who reported having experienced IPV at baseline.

In the univariable analysis, the Fisher's Exact Test was used to generate p-values for the categorical variables, and the Wilcoxon Signed-Rank Test was used to generate p-values for numeric variables.

Multivariable logistic regression was used to look at the relationships between the main exposure and outcome, alongside other chosen variables included in Table 3. We considered a p-value of ≤0.05 to indicate statistical significance for both the univariable and multivariable analyses.

For this analysis, three variables were changed from their original form: "age category", "LMUP threshold", and "living status".

The adjustment in the age categories was motivated by the literature indicating that women between the ages of 18–24 years are most impacted by IPV [28]. In South Africa, the prevalence of IPV amongst women in South Africa is greatest between the ages of 15–24 years [29]. Thus, the age category was modified to bin all ages above 25.

When looking at the LMUP threshold, the levels "unplanned" and "ambivalent" were combined into a single category "unplanned" [30,31].

The variable "living status" was adjusted to "current relationship status", where the options are either "relationship" or "no relationship". The level of "relationship" takes into consideration whether the woman had a non-cohabiting or cohabiting partner.

Results

Cohort characteristics

In the cohort of women, 77 (6.4%) reported being between the ages of 16–18 years and 409 (34.2%) women reported being between the ages of 19–24 (Table 1). The median gestational age of women at baseline was 21 weeks (interquartile range [IQR]=15–31 weeks) (Table 1). More than half of the women in the cohort (55.1%) reported not having an income. Table 1 shows that 15.8% of women (n=189) reported having 2 or more partners in the last 12 months. The majority of women (n=777, 65%) reported not using contraception in the last 12 months and 92.1% of women reported currently being in a relationship. 79.3% of women (n=948) fell into the category of either 'unplanned' or 'ambivalent' using the LMUP as seen in Table 1. 1071 women (89.6%) reported having completed secondary education. At baseline, 147 women (12.3%) reported experiencing IPV. Overall, 7% of women (n=89) scored above or equal to 11 (≥ 11) on the EPDS scale, suggestive of symptoms consistent with probably depression as seen in Table 2.

Factors associated with an Edinburgh Postnatal Depression Scale (EPDS) score greater than 11

Univariable regression results

Among women aged 16–18 years, 15.6% reported signs or symptoms indicative of probable depression, compared to 84.4 % who reported symptoms placing them below 11 (< 11) on the EPDS threshold (Table 3).

Table 1: Baseline characteristics of pregnant women accessing oral HIV pre-exposure prophylaxis, Cape Town, South Africa (n=1195)

	n	% of total
Gestational age (weeks)		
Median (IQR)	21	15-31
Age categories (years)		
16-18	77	(6.4)
19-24	409	(34.2)
25+	709	(59.3)
Education level		
Primary	21	(1.8)
Secondary	1071	(89.6)
Tertiary	103	(8.6)
Income category (ZAR)		
None	658	(55.1)
< R5000	447	(37.4)
+ R5000	90	(7.5)
Social grant recipient		
Yes	525	(43.9)
No	670	(56.1)
Contraception use in the last 12 months		
Always used contraception	64	(5.4)
Always used contraception, but knew the method had failed at least once	29	(2.4)
Not using contraception	777	(65.0)
Used contraception, but not on every occasion	325	(27.2)
London Measure of Unplanned Pregnancy threshold		
Planned	247	(20.7)
Unplanned / ambivalent	948	(79.3)
Current relationship status		
Relationship	1100	(92.1)
No relationship	95	(7.9)
IPV reported in the last 12 months		
Yes	147	(12.3)
No	1048	(87.7)

PrEP initiation at baseline		
Yes	1009	(84.4)
No	186	(15.6)
Primigravida		
First baby	405	(33.9)
Not her first baby	790	(66.1)
Condom use		
Yes	363	(30.4)
No	789	(66.8)
Missing	34	(2.8)
Partner number in the last 12 months		
1 partner	1006	(84.2)
2+ partners	189	(15.8)
Alcohol use since finding out they were pregnant		
Alcohol use	593	(49.6)
No alcohol	602	(50.4)
Drug use since finding out they were pregnant		
Drug use	10	(0.8)
No drugs	1185	(99.2)
STI result		
STI	373	(31.2)
No STI	817	(68.4)
Missing	5	(0.4)
Risk perception of HIV at baseline		
High chance	136	(11.4)
Low chance	409	(34.2)
No chance at all	650	(54.4)
SES category		
Lowest SES	381	(31.9)
Moderate / high SES	814	(68.1)

Table 2: Baseline characteristics stratified by EPDS threshold (n=1195)

	EPDS ≥ 11 N = 89		EPDS < 11 N = 1109		
	n	% of above threshold	n	% of below threshold	p-value
Gestational age (weeks)					
Median (IQR)	23	15-31	21	15-31	0.318
Age categories (years)					
16-18	12	(13.5)	65	(5.9)	**0.016**
19-24	33	(37.1)	376	(34.0)	
25+	44	(49.4)	665	(60.1)	
Education level					
Primary	2	(2.2)	19	(1.7)	0.689
Secondary	78	(87.6)	993	(89.8)	
Tertiary	9	(10.1)	94	(8.5)	
Income category (ZAR)					
None	56	(62.9)	602	(54.4)	0.073
< R5000	31	(34.8)	416	(37.6)	
+ R5000	2	(2.2)	88	(8.0)	
Social grant recipient					
Yes	37	(41.6)	488	(44.1)	0.658
No	52	(58.4)	618	(55.9)	
Contraception use in the last 12 months					
Always used contraception	6	(6.7)	58	(5.2)	**0.034**
Always used contraception, but knew the method had failed at least once	1	(1.1)	28	(2.5)	
Not using contraception	56	(62.9)	721	(65.2)	
Used contraception, but not on every occasion	26	(29.2)	299	(27.0)	
London Measure of Unplanned pregnancy threshold					0.056
Planned	11	(12.4)	236	(19.7)	
Unplanned / ambivalent	78	(87.6)	870	(72.8)	
Current relationship status					
Relationship	74	(83.1)	1026	(92.8)	**0.003**
No relationship	15	(16.9)	80	(7.2)	

IPV reported in the last 12 months					
Yes	23	(25.8)	124	(11.2)	**0.0002**
No	66	(74.2)	982	(88.8)	
PrEP initiation at baseline					
Yes	77	(86.5)	932	(84.3)	0.651
No	12	(13.5)	174	(15.7)	
Primigravida					
First baby	40	(44.9)	365	(33.0)	**0.026**
Not her first baby	49	(55.1)	741	(67.0)	
Condom use					0.138
Yes	32	(36.0)	331	(29.9)	
No	50	(56.2)	748	(67.6)	
Missing	7	(7.9)	27	(2.4)	
Partner number in the last 12 months					
1 partner	64	(71.9)	942	(85.2)	**0.002**
2+ partners	25	(28.1)	164	(14.8)	
Alcohol use since finding out they were pregnant					
Alcohol use	53	(59.6)	540	(48.8)	0.061
No alcohol	36	(40.4)	566	(51.2)	
Drug use since finding out they were pregnant					0.540
Drug use	1	(1.1)	9	(0.8)	
No drugs	88	(98.9)	1097	(92.6)	
STI result					0.339
STI	23	(25.8)	350	(31.6)	
No STI	65	(73.0)	752	(68.0)	
Missing	1	(1.1)	4	(0.4)	
Risk perception of HIV at baseline					
High chance	12	(13.5)	124	(11.2)	0.079
Low chance	21	(23.6)	388	(35.1)	
No chance at all	56	(66.3)	594	(53.7)	
SES category					
Lowest SES	31	(34.8)	350	(31.6)	0.555
Moderate / high SES	57	(65.2)	756	(68.4)	

Women who reported signs or symptoms indicating probable depression had a higher median gestational age (23 weeks; IQR=15–31), compared to women with an EPDS score <11 (median gestational age=21 weeks; IQR=15–31). Among women with probable depression, 62.9% reported having no income compared to 54.4% among women with an EPDS score <11..

A higher proportion of women with probable depression reported not currently being in a relationship (16.9%) compared to 7.2% of women <11 on the EPDS threshold. More women among those with probable depression said that this was their first baby, compared to those with an EPDS score <11, 45% and 33% respectively. Among women with probable depression, 28% reported having more than 2 partners in the last 12 months compared to 15% of women reporting more than 2 partners among women with an EPDS score <11. 59.6% of women with probable depression reported using alcohol at baseline compared to 48.8% of women <11 on the EPDS threshold. Table 2 shows that 26% of women with probable depression on the EPDS threshold reported experiencing IPV in the past 12 months compared to 11.2% of women with <11 on the EPDS threshold and reported experiencing IPV in the last 12 months as seen in Table 3.

Out of a total of 147 women who reported experiencing IPV at baseline, at their first postpartum visit, 8 mothers (5%) reported signs and symptoms consistent with probable depression, while 82 mothers (56%) fell < 11 on the EPDS threshold, while the remaining 57 women were lost-to-follow-up and did not attend their first postpartum study visit.

Multivariable regression results

Results from a univariable model indicate that women between the ages of 16–18 years were 3.15 (95% CI: 1.30, 7.07; p-value=0.007) times as likely to report probable depression than women above the age of 25 years, controlling for age, income, receipt of a social grant, LMUP category, and relationship status (Table 3). When looking at the association between IPV and EPDS shows that women who report experiencing IPV at baseline had 2.77 (95% CI: 1.61, 4.61) times the odds of experiencing probable depression compared to those who did not experience IPV at baseline, controlling for the aforementioned variables.

Table 2: Factors associated with signs and symptoms of depression using the Edinburgh Postnatal Depression Score among pregnant women in Gugulethu and Hanover Park, Cape Town, August 2019 to October 2021.

	Univariable analysis		Multivariable analysis	
	OR	95% confidence interval	OR	95% confidence interval
Age (years)				
16-18	4.13	1.76, 8.84	3.15	1.30, 7.07
19-24	1.28	0.79, 2.04	1.06	0.61, 1.84
25+	Ref	Ref	Ref	Ref
Income (ZAR)				
None	Ref	Ref	Ref	Ref
<R5000	0.26	0.04, 0.86	0.90	0.54, 1.47
R5000+	0.80	0.50, 1.26	0.29	0.05, 0.99
Social grant recipient				
Yes	0.90	0.58, 1.40	0.94	0.57, 1.55
No	Ref	Ref	Ref	Ref
London Measure of Unplanned Pregnancy (LMUP)				
Planned	0.52	0.26, 0.97	0.67	0.33, 1.25
Unplanned / ambivalent	Ref	Ref	Ref	Ref
Current relationship status				
Relationship	0.38	0.21, 0.72	0.41	0.22, 0.79
No relationships	Ref	Ref	Ref	Ref
Intimate partner violence (IPV) reported in the last 12 months				
Yes	2.77	1.63, 4.56	2.77	1.61, 4.61
No	Ref	Ref	Ref	Ref

Women who fell into the "planned" category of the LMUP threshold have a decreased odds of 0.67 (95% CI: 0.33, 1.25) of probable depression compared to those who fall into the LMUP category of "unplanned" or "ambivalent", controlling for age, income, receipt of a social grant, LMUP category, and relationship status. Women who reported earning more than R5000 are 0.29 (95% CI: 0.05, 0.99) times as likely to experience probable depression compared to women who report having no income controlling for the aforementioned variables in Table 3.

Discussion

The results of this study indicate that women who report experiencing IPV are more likely to be depressed compared to those women who do not report experiencing IPV. These results indicate a relationship between IPV and depression, confounded by other variables included in the analysis. It is important to situate these results with other studies conducted on the topic.

This study found that 12.3% of women reported experiencing IPV at baseline, while 7.4% of women reported signs of clinical depression, indicating probable depression. 25.8% of women who reported probable depression reported experiencing IPV compared to 11.2% of women who reported experiencing IPV who fell <11 EPDS threshold. In conjunction with this, in both the univariable and multivariable analyses, it was found that women who reported experiencing IPV in the last 12 months at baseline were nearly 3 times as likely to experience probable depression compared to women who did not report experiencing IPV. This is an important result and shows that women with probable depression (≥ 11 on the EPDS threshold) report more instances of IPV than those who fell below 11 on the EPDS threshold.

In this study, the pregnant women included in the analysis were all on oral PrEP. Central to the aims of the parent study is to examine PrEP adherence amongst pregnant and postpartum women [23]. This study explores factors that impact adherence to PrEP, thus addressing the main aims of the parent study.

Other PrEP trials conducted in SA, Kenya, and Uganda, indicated that women with depressive symptoms had 25–27% lower PrEP adherence compared to those who reported no depressive symptoms [16]. Similarly, Velloza et al. found that women with depression were less likely to adhere to oral PrEP regimens than women without depression (adjusted risk ratio 0.79, 95 CI 0.63, 0.99) [17]. Similar results were highlighted when looking at experiences of IPV amongst women, where it was demonstrated that IPV also has an impact on PrEP adherence [18].

A study conducted by Gibbs et al. reported that the prevalence of IPV within the last 12 months was 10.55% [3]. In their study, Shamu et al. found that IPV prevalence ranged from 2% to 57% during pregnancy [9]. This is a wider estimate compared to Malan et al. who reveal that the prevalence of pregnant women who experience IPV ranges from 27% to 48% [11]. In the study conducted by Groves et al., they reported that 25% of women experienced some form of IPV during their pregnancy, an estimate which is 2 times the prevalence of IPV among pregnant women in this study [8]. In SA, 9.8% of adults will experience a depressive episode at some point, with prevalence highest among young people aged 18-34 years and the likelihood highest amongst women (odds ratio (OR) 1.78, 95% CI 1.3-2.4) [15].

Mirroring these results, this study 25.8% of women who reported probable depression reported experiencing IPV compared to 11.2% of women who reported experiencing IPV who fell below 11 EPDS threshold. In conjunction with this, in both the univariable and multivariable analyses, it was found that women who reported experiencing IPV in the last 12 months at baseline were nearly 3 times as likely to experience probable depression compared to women who did not report experiencing IPV.

There are many reasons to explain the discrepancies in the results from these studies. Here it is important to look at where these studies were conducted. Another reason for the discrepancies could be how both IPV and depression were measured. Here, IPV was a self-reported measure where pregnant women either indicated “yes” or “no” to experiencing any form of violence at their baseline visit. There are numerous factors present in a woman’s life that impact whether one can openly report IPV. Some of these include the stigma and shame associated with experiencing IPV and the nature of the relationship the woman is in, where having a partner who is coercive impacts how overt one can be about experiences of violence at the hands of a partner [8,14,21,32,33]. Given the stigma and fear associated with reporting IPV, it is likely that IPV was underreported in the parent study. An additional consequence of IPV is the abuse of either drugs or alcohol [9,12,22,32,33]. Russel et al. note there is a higher risk of experiencing both emotional and physical IPV amongst girls who are heavy alcohol users [33]. The relationship between experiences of IPV and substance can also be seen in a different light – where women who are abused are more likely to turn to either alcohol or drugs as a coping mechanism [9].

Another important risk factor for experiencing IPV during pregnancy is the intention behind the pregnancy – whether it was planned or unplanned. In their study, Malan et al. indicated that 76.7% of women in their study reported that their pregnancy was unplanned [11]. Pregnancy intentions are an important variable to look at when investigating the relationship

between depression and IPV amongst pregnant women and shed light on the mental state of not only the mother but also their partner [2,9-12,22]. Pregnancy intentions have been highlighted as a significant risk factor for both maternal depression and experiences of IPV [10,12]. In conjunction with this, when a pregnancy is unplanned or unintended, it harms financial security in the household [2]. Unplanned pregnancies are usually blamed on the female partner, which Shamu et al. have noted to hurt the mental state of the pregnant mom [9].

In their unadjusted model, Govender et al. report that women who experienced physical violence during their pregnancies were 5 times more likely to have symptoms of depression [10. Similarly, Gibbs et al. reported that the odds of IPV were significantly increased among women reporting depressive symptoms (OR = 1.31 [1.15-1.50], $p<0.0001$) [3]. These results further contribute to the growing literature highlighting the association between IPV and poor mental health outcomes. The link between the two is commonly accepted in the field, but most of the evidence is based on data collected in high-income countries (HIC) [21]. Thus, these research findings fill the gap by adding evidence from LMIC that demonstrates this association. In conjunction with this, there remains a troubling dearth of research conducted looking at trends of violence throughout pregnancy [9]. This result suggests regardless of prior mental health history, IPV during pregnancy negatively impacts levels of emotional distress, an important finding giving insight into the experiences of pregnancy for many women [8].

Our results highlighting the association between IPV and depression suggest that more interventions can be designed and tailored to specifically fit the needs of pregnant women [14]. It is also important to note that these findings indicate more effort needs to be placed at the antenatal and postnatal visits, where questions surrounding IPV and symptoms of depression need to be asked. Pregnant women are especially vulnerable, and the implications of experiencing violence during their pregnancy, and mental ill-health impact not only the mother but also the child [3,9,10,12].

Age was found to be an important factor in pregnant women who scored ≥ 11 on the EPDS threshold in this study. In the multivariable analysis, it was found that women between the ages of 16-18 were 3 times more likely to score ≥ 11 on the EPDS threshold compared to women who were above the age of 25. Few studies noted the importance of age, which indicates an important gap that needs to be looked at in further depth in future research.

Almost all women at baseline reported initiating oral PrEP. Pregnant women have been identified as a high-risk group when it comes to HIV exposure [19,20]. Many factors inhibit

adherence to the PrEP regime, where both experiences of IPV and depression have been identified as factors that halt adherence amongst women in SA [19,20]. Partners may not be supportive of women taking PrEP, given the stigma associated with taking PrEP, thus making it a crucial factor that cannot be overlooked when examining adherence [19].

There are several limitations of this study. Firstly, while the design of the study was a retrospective cohort, only two study visits were analyzed – the baseline visit, and then the first visit postpartum. Future research can look at more than two study visits, allowing for a more in-depth analysis of how IPV and depression amongst pregnant and postpartum women change over time.

Another limitation is the self-reported nature of the variables. As highlighted earlier, experiences of both IPV and depression are fraught with stigma which impacts the ability of women to openly report adverse experiences, without fear of the potential repercussions of being ostracized or experiencing further violence because they disclose these experiences.

Conclusion

The findings from this study indicate that IPV and poor mental health, specifically symptoms relating to depression, are correlated among pregnant women. Income status, LMUP category, age category, and whether one receives social grants or not, are demonstrated to have a significant impact on this relationship. These results indicate that screening for both experiences of IPV and symptoms of depression at antenatal and postnatal visits to clinics can significantly improve the quality of life of pregnant women [8,13,14,22]. By identifying these issues at the start of the pregnancy, the trajectory of the pregnancy can be positive. Going beyond disclosing either IPV or depression, pregnant women can be linked with specialized services focusing on supporting women who are struggling during their pregnancy. As a result of this linkage, both PrEP adherence and persistence can be improved and monitored more closely amongst pregnant women who report IPV and depression given the negative impact both these experiences have on the lives of the women [16-22]. More research is needed to examine patterns of IPV and depression throughout the pregnancy, but this study highlights how at baseline, a relationship does exist between experiences of IPV and depression.

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Statements and declarations

Conflict of interest

No conflicts of interest declared by the authors.

Ethics approval

This study was performed in line with the principles of the 1964 Declaration of Helsinki. Ethics approval was granted by the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee, HREC REF: 337/2023.

Informed consent

Participants were given the informed consent form at their first ANC visits. These consent forms were translated, and back translated, into isiXhosa and Afrikaans. Study staff

emphasized that participation in the study was entirely voluntary and that if a woman chose not to participate in the study or decides to withdraw at any point during the study it would not hinder their access to quality medical care.

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PART C: APPENDICES

Appendix A: Parent study informed consent form

PrEP-PP consent for pregnant women
Updated 26 August 2020 FINAL

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 how best to prevent HIV 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 recruit study participants. Before you decide if you want to take part, I will tell you more about the study participation including the benefits and risks to you and your unborn baby, and what would be expected of you. This information is described in the consent 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 the form 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 how best to prevent HIV in pregnancy and breastfeeding women. We will provide you with HIV counseling and testing, testing for sexually transmited infections and risk reduction counseling. In addition, you will have the option of taking a medication that can help prevent HIV. By taking part in this study you will help us collect data that will help determine how to best to prevent HIV in 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 this MOU for 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
- 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 refer you for additional specialized treatment if any problems are found.
- We will offer you HIV counseling and male/female condoms, to prevent HIV
- We will collect samples using a vaginal swab to test you for common sexually transmitted infections (STIs). We will also test the swab for other things, like the normal bacteria or viruses that live in your vagina (all women have these).
    - 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 and infant medical files).
- You will receive the phone number of the study nurse to call or SMS if you have any questions or 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.
- As part of the study you have a choice of starting PrEP, which is the oral pill containing antiretrovirals that prevent HIV
- ***If you do not want to take PrEP, you can still participate in the study.***
    - ***You will complete the other parts of the study as normal***
- If you take PrEP, we will take your blood every 6 months to see if you are taking the PrEP. We will store this blood to test it at the end of the study. You will not be told the results of these tests.
- If you decide to take PrEP, we will test your blood at the first visit, and every 3 months to see if your kidney health changes. If the kidney health changes you may have to stop taking PrEP until your kidney health improves.

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

Yes!

1. You will receive counseling on HIV prevention and testing at each visit to help you protect yourself and your infant from HIV.
2. You will learn about your STI status and get treatment for any STIs.
3. You will get regular HIV testing and counseling for you and your partner if you choose.
4. We will be there to answer any HIV or STI related questions during your pregnancy.
5. And, if you decide to take PrEP your risk of getting HIV is very low. Your baby will also be protected from HIV if you take PrEP.

What are the risks and discomforts of this study?

HIV testing and counseling can be stressful, especially if you find out you have HIV. Being diagnosed with a STI can also be stressful.

Psychological effects: If you are diagnosed with HIV or a STI, 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 diagnosed with HIV or a STI, please discuss this with a member of the study team.

There are other side effects if you decide to take PrEP, most are short term and go away in 3-7 days including nausea, vomiting, dizziness, headache, and fatigue.
Longer term side effects of PrEP include changes in your kidneys, which may mean the kidneys aren't working 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.

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, we will counsel you about other methods to reduce the risk of getting HIV, including condoms, and tell you how you can 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, you will 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 at the 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 and drink 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 researchers will be able to see it. We will not tell anyone about your participation. Your name will not be linked to 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.

We will put the information about the kind of bacteria or viruses in your vagina in a database called the database for Genotypes and Phenotypes (dbGaP). The National Institutes of Health (NIH) of the U.S. controls this database. dbGaP allows researchers to collect and share information with each other, which may result in learning new important things more quickly. The information in this database will be stored permanently. Other researchers must get permission from a special committee to be able to use the data in the dbGaP database. Qualified researchers who get permission to use information from dbGaP may be from outside the University of Cape Town. Some may be from other universities or from companies. But we will not include your name, medical record number, or contact information in dbGaP. We will label all the information with a study code number.

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 prove that the research was responsible for your injury. You may ask the study doctor for a copy of these guidelines. 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 you have 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, you should contact:

Professor Landon Myer
School of Public Health and Family Medicine
Faculty of Health Sciences, University of Cape Town
Tel: 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 Health Products Regulatory Authority (SAHPRA) at:

South African Health Products Regulatory Authority

Private Bag X828

Pretoria

0001

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 HIV prevention study, including regular data collection. 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:

7

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. I know 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.

PATIENT CONSENT FORM (INFANT)- Participant Copy

1. I have read the consent form, or it has been read to me.
2. I understand the contents of the consent form
3. I agree to permit my child's participation in the PrEP study
4. I understand that I may withdraw my consent at any time.
5. I understand that my child will receive the usual standard of care offered by this clinic.

Child's name _____

Patient name: _____

Signature: _____

Date (DD/MM/YYYY): _____

Name of the person obtaining consent: _____

Designation: _____

Signature: _____

Date (DD/MM/YYYY): _____

Appendix B: Parent study questionnaire

1. Maternal Physical Examination Form

Participant ID	_____
Visit Date	_____
Visit Code	○ Baseline ○ 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)
Blood pressure - Method of measurement	○ Manual ○ Automated
Blood pressure - Location of measurement	○ Left Arm ○ Right Arm
Date of the last menstrual cycle	_____
Expected delivery date	_____

What is participant's gestational age at baseline?

_____ (in weeks)

Nurse or Staff Member

Blood pressure P is SBP >140 and/or SBP >80, participant is not eligible to take PrEP.

Any other comments

_____

Nurse/staff initials

_____

2. Demographic History Questionaire

Participant ID _____

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.

0. Participant's date of birth (DOB) _____

1. Uneminyaka emingaphi?

How old are you? _____ (Age in years)

2. Uthetha oluphi ulwimi ekhaya?

What language do you speak most often 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?	○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ >10
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?

- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10
- ○ >10

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 (okanye 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 Cape Town, 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 of days	_____ (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)?	○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ >10
25. Bangaphi abantwana obazeleyo? How many children have you given birth to?	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ >10

26. Bangaphi abantwana bakho abaphilayo? How many of these children are living?	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ >10
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
34.1 Ndityе iFolic Acid I took folic acid	○ Yes ○ No ○ N/A
34.2 Ndiyekile okanye ndibuyise unyawo ekutshayeni Stopped smoking?	○ Yes ○ No ○ N/A
34.3 Ndiyekile okanye ndibuyise unyawo ekuseleni I stopped or cut down drinking alcohol.	○ Yes ○ No ○ N/A
34.4 Ndityе ukutya okusempilweni I ate more healthy	○ Yes ○ No ○ N/A
34.5 Ndiye ndafuna amacebiso empilo Sought medical/health advice	○ Yes ○ No ○ N/A
34.6 Ndiye ndathatha amanye amanyathelo nceda uchaze. I did other things.	○ Yes ○ No ○ N/A
I did other things (specify)	_____

Notes from the interviewer
Any other comments _____
Interviewer Initials _____

3. Partner questionnaire

Participant ID	_____
Visit Date	_____ (date (dd-mm-yyyy))
Visit Code	○ Baseline

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 ○ Iqabane lamanqapha-nqapha / Casual partner/one night stand ○ Enye, Cacisa / Other, Specify
2.1 How would you describe your current, main relationship? Other, specify	_____
3. Nithandane ixesha elingakani neqabane lakho? How long have you been in a relationship with this person?	○ Months ○ Years
3.1 How long have you been in a relationship with this person? (Months)	_____

3.2 How long have you been in a relationship with this person? (Years)	_____
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?	○ Yes ○ No ○ 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) ○ Unsure
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?	○ Yes ○ No ○ I don't know ○ N/A
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 center ○ Don't know ○ 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 ○ N/A
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?	○ Yes ○ No ○ 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?	○ Yes ○ No ○ 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?	○ Yes ○ No ○ I don't know

21. Wakhe wayo vavanyela i-HIV neqabane lakho langoku? Have you ever attended couple's 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?	◯ Yes ◯ No ◯ I don't know
23. Ukuba uvavanyo lwasekhaya okanye izixhobo zokuzivavanya bezifumaneka, ucinga ukuba iqabane lakho langoku belinokuziva likhululekile ukuzivavanyela i-HIV ekhaya? If HIV home testing or self-testing kits were available, would you feel comfortable taking a test to your current main partner so that he could test for HIV?	◯ Yes ◯ No ◯ 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 ◯ Andiwazi / I don't know
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?	◯ Yes ◯ No ◯ I don't know

Notes from the interviewer	
Any other comments	_____
Interviewer's Initials	_____

4. PrEP Knowledge and Attitudes

Participant ID	_____
Visit date	_____ (date (dd-mm-yyyy))
Visit Code	○ Baseline

Ndizokubuza imibuzo malunga nolwazi lwakho kwakunye nengcinga zakho nge-PrEP. Ndiyakucela uzame ukuphendula lemibuzo ngokunyanisekileyo.

I am going to ask you about your previous knowledge and thoughts about PrEP. 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?	○ Yes ○ No ○ Unsure
5. Ngubani omaziyo othatha okanye osebenzisa iPrEP? Who do you know that is taking PrEP?	
5.1 Iqabane lakho Spouse/partner	○ Yes ○ No ○ Don't Know
5.2 Ilungu losapho lwakho Family member	○ Yes ○ No ○ Don't Know
5.3 Itshomi/isihlobo Friend	○ Yes ○ No ○ Don't Know
5.4 Umntu osebenza naye Colleague	○ Yes ○ No ○ Don't Know
5.5 Umntu ofunda naye esikolweni Classmate	○ Yes ○ No ○ Don't Know
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?	○ Yes ○ No ○ Unsure
Note to Interviewer: If the participant is interested 'yes", please refer for PrEP counseling following the CRFs.	
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 initials	_____

5. PrEP Readiness Scale

Participant ID	_____
Visit date	_____ (date (dd-mm-yyyy))
Visit Code	○ Baseline

Ndizokubuza imibuzo malunga nolwazi lwakho kwakunye nengcinga zakho nge-PrEP. Ndizokubuza malunga nenxaso oyifimanayo ekhaya kwakunye naseluntwini. Ndiyakucela uzame ukuphendula lemibuzo ngenyaniso.
Ukuba uziva ungakhakhulukekanga ekuphenduleni omnye walemibuzo, nceda uvakalise siwudlule lombuzo.

Lemibuzo ilandelayo 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. 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. Ndiikulungele 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.	○ 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	○ 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.	○ 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.	○ 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
- ○ 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?	○ Yes ○ No ○ N/A
18.2 Umama okanye Utata wakho? Your mother or your father?	○ Yes ○ No ○ N/A
18.3 Ubhuti okanye usisi wakho? Your sister or your brother?	○ Yes ○ No ○ N/A
18.4 Amanye amalungu osapho lwakho? Other family members?	○ Yes ○ No ○ N/A ○ I don't know
18.5 Umhlobo/ itshomi? Friends?	○ Yes ○ No ○ N/A
18.6 Abamelwane? Neighbors?	○ Yes ○ No ○ N/A
18.7 UNesi okanye ugqirha abangaphandle koluphando? Nurse or doctor outside the study?	○ Yes ○ No ○ N/A
18.8 Abanye abantu(cacisa) Other persons?	○ Yes ○ No ○ N/A
18.8.1 Abanye abantu(cacisa)/ other persons? (explain)	_____

19. Waneliseka kangakanani lulonwabo lwakho nesimo sakho sobudlelwane? In general, how would you rate your satisfaction with your social activities and relationships?	◯ Excellent ◯ Very Good ◯ Good ◯ Fair ◯ Poor
20. Ngaphandle kwabantwana bakho, zingaphi izizalwane oziva usondele kakhulu kuzo? Apart from your children, how many relatives do you have with whom you feel close?	◯ None ◯ 1-2 ◯ 3-5 ◯ 6-9 ◯ 10 or more
21. Zingaphi izihlobo okanye itshomi oziva usondele kakhulu kuzo? How many close friends do you have?	◯ None ◯ 1-2 ◯ 3-5 ◯ 6-9 ◯ 10 or more
Any other comments	_____
Interviewer's initials	_____

6. PrEP HIV Stigma

Participant ID	_____
Visit date	_____ (date (dd-mm-yyyy))
Visit Code	○ Baseline

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 initials	_____

7. Sexual Behaviour

Participant ID _____

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 ○ Baseline

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?	○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ >10 (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
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. Bangaphi abantu owabelane ngesondo nabo kwezinyanga zintathu zidlulileyo? How many different people did you have sex with in the past 3 months?	◯ 0 ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 ◯ >10 (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 initials	_____

8. Risk perception & IPV

Participant ID	_____
Visit date	_____ (date (dd-mm-yyyy))
Visit code	○ Baseline

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, please inform me so that I can skip the question."

1. Ungawachaza njani amathuba akho okufumana iHIV kulonyaka ulandelo, ukuba ubungathathi PrEP? If you weren't taking PrEP, 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 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 ○ Andiwazi / I don't know
3.Ungawachaza njani amathuba womntwana wakho lo umkhulelweyo wokufumana iHIV kulonyaka ulandelayo, ukuba ubungathathi PrEP? 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 purposе?	○ 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 uzokudluliselwa 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 initials	_____

9. EPDS

Participant ID	_____
Visit date	_____ (date (dd-mm-yyyy))
Visit code	○ Baseline

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

Interviewer

Nokuba ngomphi umama ofunyanwe ukuba usebungciphekweni okanye ebungozini uzokunikezelwa kuncedo olufanelekileyo. Umphathi wophando uzoqinisekisa ukuba umthathi nxaxeba ungxulumene nenkonzo zoncedo. Any woman that is found to be at risk will be referred to the appropriate services. Did you refer the participant? The study coordinator will follow up to ensure the participant has linked to assisting services.	○ Yes ○ No
Any other comments	_____
interviewer's initials	_____

10. AUDIT-C

Participant ID	_____
Visit date	_____
Visit code	○ Baseline
1. Kunyaka odlulileyo phambi kokuba ukhulelwe usisele kangakanani isiselo esinotywala ? In the year before 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.Kunyaka odlulileyo phambi kokuba ukhulelwe zingaphi iiglasi zesiselo esinotywala oziselayo ngemini? In the year before you were pregnant how many standard drinks containing alcohol did 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. Kunyaka odlulileyo phambi kokuba ukhulelwe, kukangaphi usela iiglasi (zotywala) ezi-5 nangaphezulu ngexesha elinye? In the year before you were pregnant, how often did you have 5 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. 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
5. 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
6. 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 5 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

7. 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
8. 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
9. 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
10. 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
11. 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
12. 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
13. 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
13.1 Since you found out you were pregnant, who do you mostly drink with? Other (specify)	_____

14. 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)
14.1 Since you have been pregnant, where do you drink alcohol? (Other)	_____
15. 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 alcohol usage or said to you that you should stop using alcohol?	○ Hayi / No ○ Ewe, kodwa hayi kunyaka ophelilieyo / Yes, but not in the past year ○ Ewe, kunyaka ophelilieyo. / Yes, during the past year

Interviewer

Nokuba ngomphi umama ofunyanwe ukuba usebungciphekweni okanye ebungozini uzokunikezelwa kuncedo olufanelekileyo. Umphathi wophando uzoqinisekisa ukuba umthathi nxaxeba ungxulumene nenkonzo zoncedo. Any woman that is found to be at risk will be referred to the appropriate services. Did you refer the participant? The study coordinator will follow up to ensure the participant has linked to assisting services.	○ Yes ○ No
Any other comments	_____
Interviewer's initials	_____

11. DUDIT

Participant ID	_____
Visit date	_____
Visit code	○ Baseline

DUDIT: Sizakubuza imibuzo malunga nokusebenzisa iziyobisi. Ukuba uziva ungakhululekanga ukuphendula omnye walombuzo ungasixelela siwudlule lombuzo.

We are now going to ask you some questions about your use of drugs. If you feel uncomfortable answering any of these questions, you can ask me to skip the question

1. Kunyaka odlulileyo phambi kokuba ukhulelwe ubukhe wasebenzisa iziyobisi ngapandle kotywala? In the year before you were pregnant, how often did 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. Kunyaka odlulileyo phambi kokuba ukhulelwe kukangakanani usebenzisa ngaphezu kohlobo olunye lweziyobisi ngexesha? In the year before you became pregnant how often did 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. kunyaka odlulileyo phambi kokuba ukhulelwe, mangaphi amaxesha osebenzisa iziyobisi ngosuku? In the year before you became pregnant, how many times did you take drugs on a typical day when you use drugs?	○ 0 ○ 1-2 ○ 3-4 ○ 5-6 ○ 7 or more

4. Kunyaka odlulileyo phambi kokuba ukhulelwe, zeziphi iziyobisi ubukhe wazisebenzisa?

In the year before you were pregnant, which drugs did you use?

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

6. Heroin	○	○
7. Nyaope	○	○
8. Other	○	○

4.8.1. Which drugs have you used during pregnancy? (Other specify) _____

5. 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

6. 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

7. 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

8. 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

9. 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

10. 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

11. Emva kokuba uvile ukuba ukhulelwe ubukhe awakwazi ukuyeka iziyobisi xa sele uziqalile ukuzithatha? 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
12. 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
13. 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
14. 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
15. 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

16. 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	○	○
8. Other	○	○

16.8.1 Which drugs have you used during pregnancy? (Other specify) _____

Interviewer

Nokuba ngomphi umama ofunyanwe ukuba usebungciphekweni okanye ebungozini uzokunikezelwa kuncedo olufanelekileyo.
Umphathi wophando uzoqinisekisa ukuba umthathi nxaxeba ungxulumene nenkonzo zoncedo.

Any woman that is found to be at risk will be referred to the appropriate services. Did you refer the participant?
The study coordinator will follow up to ensure the participant has linked to assisting services.

○ Yes
○ No

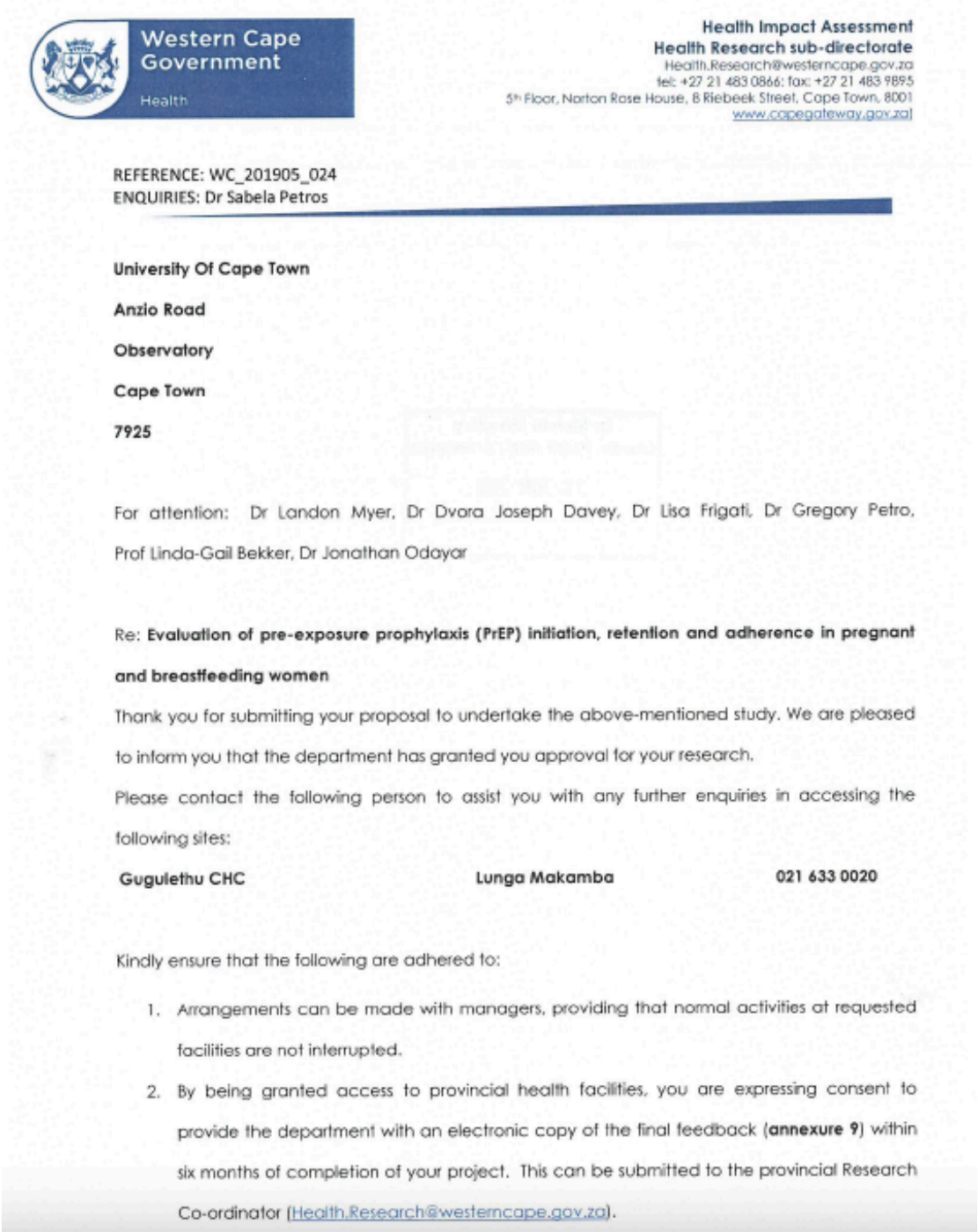
Any other comments

_____

Interviewer's initials

_____

Appendix C: Parent study Western Cape Department of Health approval



Western Cape Government
Health

Health Impact Assessment
Health Research sub-directorate
Health.Research@westerncape.gov.za
tel: +27 21 483 0866; fax: +27 21 483 9895
5th Floor, Norton Rose House, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za

REFERENCE: WC_201905_024
ENQUIRIES: Dr Sabela Petros

University Of Cape Town

Anzio Road

Observatory

Cape Town

7925

For attention: Dr Landon Myer, Dr Dvora Joseph Davey, Dr Lisa Frigati, Dr Gregory Petro, Prof Linda-Gail Bekker, Dr Jonathan Odayar

Re: **Evaluation of pre-exposure prophylaxis (PrEP) initiation, retention and adherence in pregnant and breastfeeding women**

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.

Please contact the following person to assist you with any further enquiries in accessing the following sites:

Gugulethu CHC	**Lunga Makamba**	**021 633 0020**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. By being granted access to provincial health facilities, you are expressing consent to provide the department with an electronic copy of the final feedback (**annexure 9**) within six months of completion of your project. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).

3. In the event where the research project goes beyond the estimated completion date which was submitted, researchers are expected to complete and submit a progress report (**Annexure 8**) to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).

4. The reference number above should be quoted in all future correspondence.

Yours sincerely

Dr Melvin Moodley
Director: Health Impact Assessment
26 JUN 2019
Signed by candidate

DR M MOODLEY

DIRECTOR: HEALTH IMPACT ASSESSMENT

Appendix D: Parent study HREC renewal

HUMAN RESEARCH ETHICS COMMITTEE
17 AUG 2022
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

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	Signed by candidate	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 (FHS010) if the study is completed within the approval period)

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-submission@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/ divisional/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:	

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

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

FSH016: 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:	75
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

Appendix E: Minor dissertation HREC approval

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room 45 E-52-E-Floor- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-submissions@uct.ac.za
Website: www.health.uct.ac.za/home/human-research-ethics

02 June 2023

HREC REF: 337/2023

Dr A de Voux
School of Public Health
Division of Epidemiology & Biostatistics
Falmouth Building
Email: alex.devoux@uct.ac.za
Student: BGGKAY002@myuct.ac.za

Dear Dr de Voux

PROJECT TITLE: EXAMINING HOW PATTERNS OF INTIMATE PARTNER VIOLENCE AND DEPRESSION CHANGE OVER TIME AMONGST PREGNANT AND POST-PARTUM WOMEN- SUB-STUDY LINKED 297/2018
(MASTER'S DEGREE-MS KAYLA BAGG)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 June 2024.

Please submit a progress form, using the standardised Annual Report Form (FHS016) if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: Ms Kayla Bagg will also be involved in this study.

Please quote the HREC REF 337/2023 in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

Signed by candidate

PROFESSOR M BLOCKMAN
CHAIRPERSON, FACULTY OF HEALTH SCIENCES HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637. Institutional Review Board (IRB) number: IRB00001938 NHREC-registration number: REC-210208-007
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2020), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

HREC/ref 337.2023

Appendix F: Target journal submission instructions – AIDS and Behaviour

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Competing Interests
Research involving human participants, their data or biological material
Informed consent
Editing Services
Open access publishing
Mistakes to avoid during manuscript preparation

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.

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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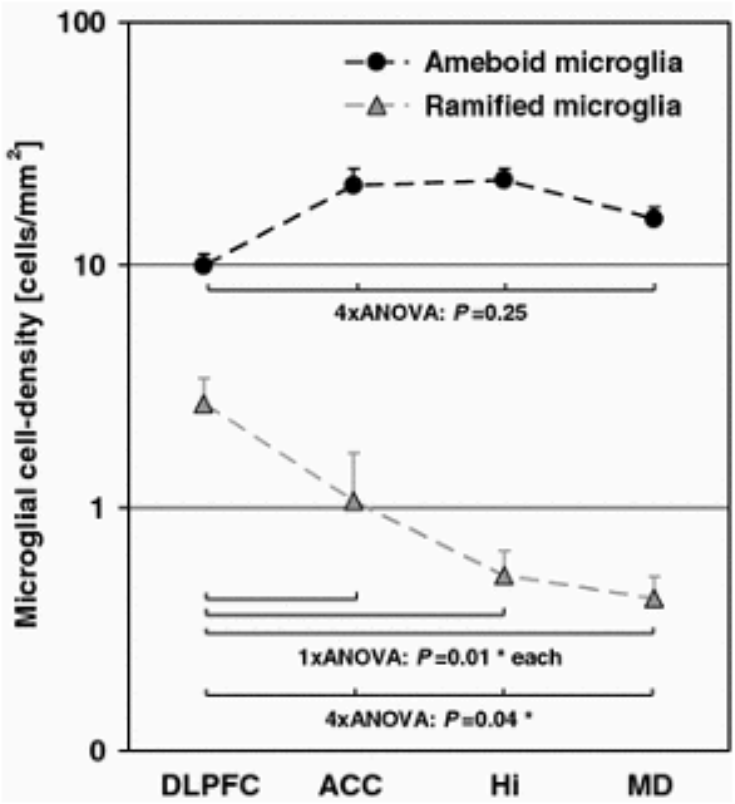
Artwork and Illustrations Guidelines

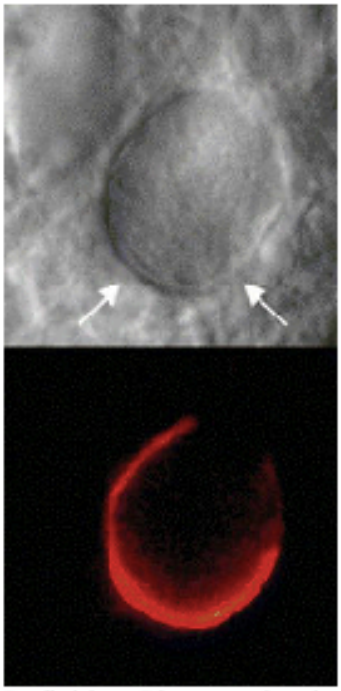
Electronic Figure Submission
Supply all figures electronically.
Indicate what graphics program was used to create the artwork.
For vector graphics, the preferred format is EPS; for halftones, please use TIFF format. MSOffice files are also acceptable.
Vector graphics containing fonts must have the fonts embedded in the files.
Name your figure files with "Fig" and the figure number, e.g., Fig1.eps.

Line Art



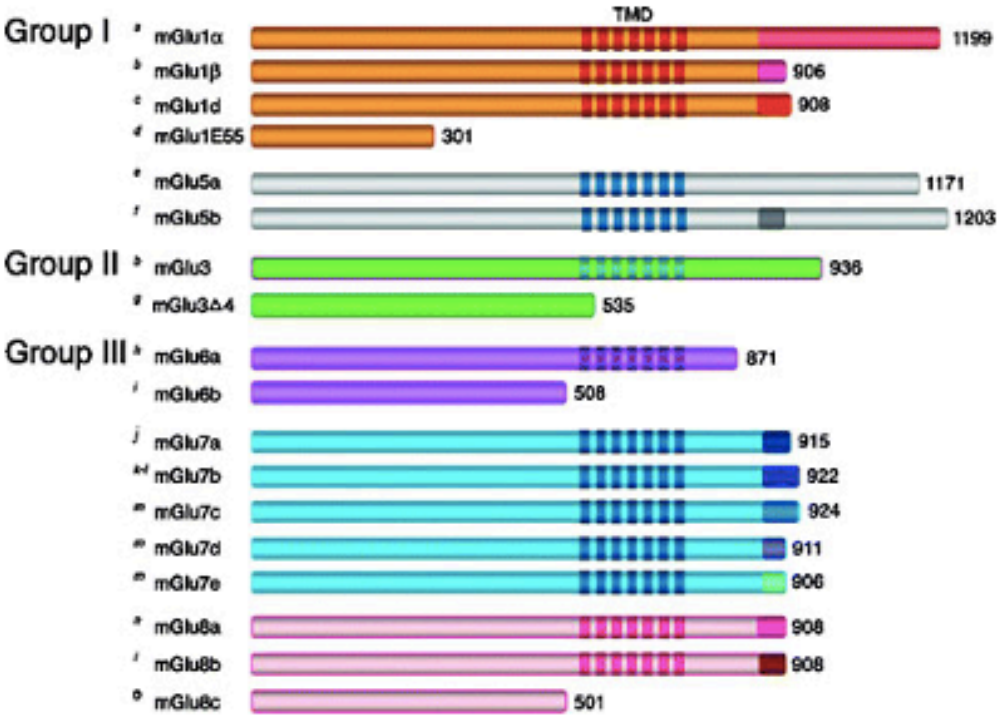
Definition: Black and white graphic with no shading.
Do not use faint lines and/or lettering and check that all lines and lettering within the figures are legible at final size.
All lines should be at least 0.1 mm (0.3 pt) wide.
Scanned line drawings and line drawings in bitmap format should have a minimum 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



Definition: a combination of halftone and line art, e.g., halftones containing line drawing, extensive lettering, color diagrams, etc.
Combination artwork should have a minimum resolution of 600 dpi.

Color Art

Color art is free of charge for online publication.
If black and white will be shown in the print version, make sure that the main information will still be visible. Many colors are not distinguishable from one another when converted to black and white. A simple way to check this is to make a xerographic copy to see if the necessary distinctions between the different colors are still apparent.
If the figures will be printed in black and white, do not refer to color in the captions.
Color illustrations should be submitted as RGB (8 bits per channel).

Figure Lettering

To add lettering, it is best to use Helvetica or Arial (sans serif fonts).
Keep lettering consistently sized throughout your final-sized artwork, usually about 2–3 mm (8–12 pt).
Variance of type size within an illustration should be minimal, e.g., do not use 8-pt type on an axis and 20-pt type for the axis label.
Avoid effects such as shading, outline letters, etc.
Do not include titles or captions within your illustrations.

Figure Numbering

All figures are to be numbered using Arabic numerals.
Figures should always be cited in text in consecutive numerical order.
Figure parts should be denoted by lowercase letters (a, b, c, etc.).
If an appendix appears in your article and it contains one or more figures, continue the consecutive numbering of the main text. Do not number the appendix figures,"A1, A2, A3, etc." Figures in online appendices [Supplementary Information (SI)] should, however, be numbered separately.

Figure Captions

Each figure should have a concise caption describing accurately what the figure depicts. Include the captions in the text file of the manuscript, not in the figure file.
Figure captions begin with the term Fig. in bold type, followed by the figure number, also in bold type.
No punctuation is to be included after the number, nor is any punctuation to be placed at the end of the caption.
Identify all elements found in the figure in the figure caption; and use boxes, circles, etc., as coordinate points in graphs.
Identify previously published material by giving the original source in the form of a reference citation at the end of the figure caption.

Figure Placement and Size

Figures should be submitted within the body of the text. Only if the file size of the manuscript causes problems in uploading it, the large figures should be submitted separately from the text.
When preparing your figures, size figures to fit in the column width.
For large-sized journals the figures should be 84 mm (for double-column text areas), or 174 mm (for single-column text areas) wide and not higher than 234 mm.
For small-sized journals, the figures should be 119 mm wide and not higher than 195 mm.

Permissions

If you include figures that have already been published elsewhere, you must obtain permission from the copyright owner(s) for both the print and online format. Please be aware that some publishers do not grant electronic rights for free and that Springer will not be able to refund any costs that may have occurred to receive these permissions. In such cases, material from other sources should be used.

Accessibility

In order to give people of all abilities and disabilities access to the content of your figures, please make sure that
All figures have descriptive captions (blind users could then use a text-to-speech software or a text-to-Braille hardware)
Patterns are used instead of or in addition to colors for conveying information (colorblind users would then be able to distinguish the visual elements)

Any figure lettering has a contrast ratio of at least 4.5:1

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Supplementary Information (SI)

Springer accepts electronic multimedia files (animations, movies, audio, etc.) and other supplementary files to be published online along with an article or a book chapter. This feature can add dimension to the author's article, as certain information cannot be printed or is more convenient in electronic form.
Before submitting research datasets as Supplementary Information, authors should read the journal's Research data policy. We encourage research data to be archived in data repositories wherever possible.

Submission
Supply all supplementary material in standard file formats.
Please include in each file the following information: article title, journal name, author names; affiliation and e-mail address of the corresponding author.
To accommodate user downloads, please keep in mind that larger-sized files may require very long download times and that some users may experience other problems during downloading.
High resolution (streamable quality) videos can be submitted up to a maximum of 25GB; low resolution videos should not be larger than 5GB.

Audio, Video, and Animations
Aspect ratio: 16:9 or 4:3
Maximum file size: 25 GB for high resolution files; 5 GB for low resolution files
Minimum video duration: 1 sec
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Informed consent

All individuals have individual rights that are not to be infringed. Individual participants in studies have, for example, the right to decide what happens to the (identifiable) personal data gathered, to what they have said during a study or an interview, as well as to any photograph that was taken. This is especially true concerning images of vulnerable people (e.g. minors, patients, refugees, etc) or the use of images in sensitive contexts. In many instances authors will need to secure written consent before including images.

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Summary of requirements

The above should be summarized in a statement and placed in a 'Declarations' section before the reference list under a heading of 'Consent to participate' and/or 'Consent to publish'. Other declarations include Funding, Competing interests, Ethics approval, Consent, Data and/or Code availability and Authors' contribution statements.

Please see the various examples of wording below and revise/customize the sample statements according to your own needs.

Sample statements for "Consent to participate":

Informed consent was obtained from all individual participants included in the study.

Informed consent was obtained from legal guardians.

Written informed consent was obtained from the parents.

Verbal informed consent was obtained prior to the interview.

Sample statements for "Consent to publish":

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The participant has consented to the submission of the case report to the journal.
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