University of Cape Town

Psychosocial predictors of HIV treatment outcomes among young pregnant and postpartum women living with HIV

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NHLSAN001

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in the

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Preamble

1. Declaration

I, Sandiswe Noholoza (NHLSAN001), hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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

Signature: Signed by candidate

Date: ……14 March 2021……

2. Acknowledgements

To my supervisor, Dr Kirsty Brittain, you are every student's dream supervisor. Thank you for your endless support, encouragement, guidance, and advice throughout this process. From the beginning up until this point, you have gone above and beyond for my academic career and overall career aspirations. For that I will forever be grateful. You have inspired me to believe in myself and my capabilities and observing how hardworking, compassionate and supportive you are always inspires me to be that kind of leader in every space I am in. Thank you!

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Finally, a big thank you to the Almighty God.

3. Abstract

Introduction: Young pregnant and postpartum women's suboptimum antiretroviral therapy (ART) adherence and engagement in HIV care remains a global concern despite improvements in prevention of mother-to-child transmission (PMTCT) and general ART services. Various psychosocial risk factors have been individually shown to be associated with HIV infection. However, longitudinal, and quantitative research on the impact of these psychosocial risk factors on HIV treatment outcomes is limited, particularly among young pregnant and postpartum women living with HIV (WLHIV) in low-income countries like South Africa. Furthermore, knowledge on the cumulative impact of these often-co-occurring psychosocial risk factors on HIV treatment outcomes is limited. This analysis examined the prevalence and co-occurrence of four key psychosocial risk factors [unintended pregnancy, depression, hazardous alcohol use and intimate partner violence (IPV)]. Furthermore, the analysis quantitatively examined the cumulative impact (defined as psychosocial burden) of these psychosocial risk factors on HIV treatment outcomes among young pregnant and postpartum WLHIV.

Methods: This was a secondary data analysis of a pilot study ("Masibambisane Girls") that designed and evaluated the role of a peer support intervention to mitigate the negative impact of stigma among young (16 – 24 years old) pregnant and postpartum WLHIV attending antenatal care (ANC) at the Gugulethu midwife obstetric unit (MOU), in Cape Town, South Africa. Participants were followed up to 6 months post enrolment. This analysis includes data collected from 114 of these pregnant (n=55) and postpartum (n=59) women. Psychosocial burden (primary exposure variable) was calculated as a sum score of the four key psychosocial risk factors. Each psychosocial risk factor threshold met scored the participant one point on psychosocial burden such that the minimum score was zero and the maximum was four. The prevalence of each exposure variable was analyzed using descriptive statistics and associations between them and with the outcome variables (engagement in care and HIV viral load <50 copies/mL) were examined using Chi^2 tests and Fischer exact tests for sparse data. Poisson regression models were built to examine the association between psychosocial burden and HIV treatment outcomes before and after adjusting for sociodemographic and clinical confounding variables.

Results: Overall, data from 114 women who were followed up for 6 months was analyzed (median age: 23 years, median gestation 25 weeks, median days postpartum: 6 days). There was an 88%, 14%, 19% and 32% prevalence of unintended pregnancy, probable depression, hazardous alcohol use and IPV respectively. Furthermore, probable depression and hazardous alcohol use were more prevalent among pregnant versus postpartum women. No statistically significant associations were found among these psychosocial risk factors. However, there was some indication of an association between depression and unintended pregnancy (P=0.095), depression and IPV (p=0.087) and hazardous alcohol use and IPV (p=0.119). The risk factors that most commonly co-occurred were unintended pregnancy and IPV (in 16% of women). Overall, pregnant women had significantly higher psychosocial burden scores than postpartum women. Analysis of HIV treatment outcomes revealed that 60% of women were engaged in care and among the 58 women who had an available viral load result within the window of follow up, 78% were virally suppressed. There was some indication of depression being a potential predictor of engagement in care (p=0.151). However, no statistically significant associations were found between any of the other psychosocial risk factors nor psychosocial burden scores and either HIV treatment outcome, before and after adjusting for potential confounders.

Conclusions: This analysis mostly supports the existing body of literature on the prevalence of psychosocial risk factors and HIV treatment outcomes. However, more extensive research is needed to confirm associations among psychosocial risk factors and rigorously assess the cumulative impact of psychosocial risk factors (psychosocial burden) on HIV treatment outcomes.

4. List of Abbreviations:

AIDS	Acquired immunodeficiency virus
ANC	Antenatal care
ART	Antiretroviral therapy
AUDIT	Alcohol Use Disorders Identification Test
CI	Confidence Interval
CRF	Case report form
EPDS	Edinburgh Postnatal Depression Scale
HIV	Human immunodeficiency virus
IPV	Intimate partner violence
IQR	Interquartile range
MCH	Maternal and Child health
MOU	Midwife Obstetric Unit
MTCT	Mother-to-child transmission
NHLS	National Health Laboratory Service
PMTCT	Prevention of mother-to-child transmission
PTSD	Post Traumatic Stress Disorder
WLHIV	Women living with HIV

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A. Protocol

1. Protocol Synopsis

Background

Under Option B+ guidelines, all pregnant women in South Africa are eligible to initiate lifelong ART upon HIV diagnosis, regardless of CD4 cell count or clinical disease stage. However, despite these and other remarkable advances in the uptake and availability of ART within PMTCT programmes, pregnant and postpartum women's adherence to ART and retention in HIV care remains a global concern. Pregnant and postpartum women tend to have elevated viral load due to poor engagement in HIV care and thus poor ART adherence and viral suppression.

Furthermore, in South Africa, young women (16-24 years old) are at a greater risk of HIV infection and poorer HIV treatment outcomes compared to older women. Research has shown that young women have a higher risk of both MTCT and maternal mortality compared to older women. Given the high burden of HIV and incidence of pregnancy in this group, young pregnant and postpartum women represent an important population for research and interventions to improve both maternal and child health.

Poor HIV treatment outcomes in this group are concerning for both maternal health and child health outcomes because a third of infant HIV infections are due to poor uptake of PMTCT services including timely HIV testing and maternal and infant ART uptake. Alongside the devastating dangers of poor ART adherence for child health, the leading cause of maternal deaths in many developing countries is HIV/AIDS; most of which occur postpartum.

Poor HIV treatment outcomes and subsequent elevated viral load among pregnant and postpartum women living with HIV (WLHIV) is function of various health system and individual-level risk factors. Individual-level risk factors encompass psychological and social ('psychosocial') challenges faced by the individual; such as early or unintended pregnancy, anticipated and experienced stigma, lack of social support, alcohol and substance abuse, intimate partner violence (IPV) and mental health challenges such as depression and anxiety. While health system level risk factors are well studied, there remains a gap in the understanding of the impact of each of these risk factors on the HIV treatment outcomes of young pregnant and postpartum WLHIV, and most importantly there is a gap in the understanding of how psychosocial risk factors co-occur and what their cumulative impact is on HIV treatment outcomes in this group. The proposed study has the potential to provide a quantitative understanding of psychosocial burden; this knowledge has the potential to guide how we prioritize and optimize intervention strategies for HIV related maternal and child health outcomes.

Aim & objectives

Study aim:

The aim of this study is to quantitatively examine the prevalence and co-occurrence of psychosocial risk factors and examine the cumulative impact of key psychosocial risk factors (psychosocial burden) on HIV treatment outcomes among young pregnant and postpartum WLHIV.

Objectives:

I. To describe the prevalence and co-occurrence of key psychosocial risk factors experienced by young pregnant and postpartum WLHIV and examine the associations among these risk factors.

II. To examine the impact of individual psychosocial risk factors on HIV treatment outcomes among young pregnant and postpartum WLHIV, where these risk factors include:
    a. Unintended pregnancy
    b. Depression
    c. IPV
    d. Hazardous alcohol use
III. To explore the cumulative impact of these psychosocial risk factors (psychosocial burden) on HIV treatment outcomes among young pregnant and postpartum WLHIV.

Study design

The data used in this study will be provided by a pilot study ("Masibambisane Girls") that was conducted in Gugulethu outside Cape Town and has previously been approved by the University of Cape Town's Faculty of Health Sciences Human Research Ethics Committee (UCT-HREC; REF: 267/2019). Masibambisane Girls was part of a multi-phase study that designed and evaluated the role of a peer support intervention to mitigate the negative impact of stigma among young pregnant and postpartum WLHIV. Young pregnant (n=60) and postpartum (n=59) WLHIV were approached at the Gugulethu Midwife Obstetric Unit (MOU). Following an informed consent process, they completed a questionnaire-based enrolment study visit after which they were randomized to two study arms; (I) Peer support intervention arm (invited to attend peer support groups of ~8 pregnant and postpartum women every 4 weeks for 6 months) or (II) Control arm (received the local standard of care i.e. no attendance of peer support group). Lastly enrolled women attended study visits at the third- and sixth-month post enrolment.

This secondary analysis will only make use of baseline data collected prior to randomization in the Masibambisane Girls study. Women whose data will be included in this analysis will need to meet the following inclusion and exclusion criteria:

Inclusion criteria

- Be enrolled in the Masibambisane Girls study, having met criteria below:
    - Aged 16-24 years
    - Confirmed HIV+
    - Confirmed pregnant (with confirmation via urine pregnancy testing per local standard of care), or recently postpartum
    - Accessing antenatal or immediate postpartum PMTCT services at Gugulethu MOU
    - Planning on remaining a resident of Cape Town for at least 6 months after enrolment
    - Able to provide informed consent for research, including ability to speak isiXhosa or English

Exclusion criteria

- Withdrawal from the Masibambisane Girls study

Ethical considerations

Informed consent and enrolment of minors:

Ethical approval for the Masibambane Girls Study was obtained from the University of Cape Town's Faculty of Health Sciences Human Research Ethics Committee (UCT-HREC). Informed consent was

obtained from participants aged ≥18 years old. Informed minor assent was obtained for participant's aged ≥16years old but <18 years old. The Masibambisane Girls Study obtained a waiver from UCT-HREC which permitted participants who were minors to decide whether or not they would like parental consent to join the study. It was necessary to include minors (<18 years old) in this research because this an at-risk population for HIV infection and poor HIV treatment outcomes in South Africa. Furthermore, young women are most impacted by psychosocial challenges such as unintended pregnancy, alcohol or other substance use, and mental health challenges. As a result, young women are at highest risk of disengagement from HIV care and thus at highest risk of experiencing poor HIV treatment outcomes. Hence it is important to focus on this group in research. This is a secondary analysis and thus no additional data on any of the participants enrolled in the primary study will be collected.

Risks and benefits:

This is a secondary data analysis and thus there will be no direct contact with participants and no additional data will be collected from participants. Furthermore, all the data that will be used has been anonymised via PIDs that were assigned at enrolment. As such, this analysis presents very minimal risk to the participant. All the data used in this analysis will have already been collected and abstracted for the purposes of the primary study and as such only anonymised data will be used for this analysis. In the event that I need access to original participant files or medical records, I will do so with the supervision of my supervisor.

Given that this is a secondary analysis, there will be no direct benefits to the participant. However, this analysis aims to provide an in-depth and quantifiable understanding of the role of psychosocial burden on HIV treatment outcomes among young WLHIV. The knowledge obtained from this analysis may potentially guide the prioritization and optimization of intervention strategies for HIV related maternal and child health outcomes. This is the potential indirect benefit to participants.

2. Introduction

2.1. Background

Sub-Saharan Africa has the highest burden of HIV globally [1]. According to UNAIDS statistics, South Africa alone had 7.7 million people living with HIV in 2018 and 240 000 of those were new infections [2]. Women are disproportionally affected by HIV. In South Africa, 62.67% of adults living with HIV in 2018 were women [2]. Furthermore, young women (15 – 24 years old) are twice as likely to be living with HIV than their male peers [3,4]. It has been reported that almost 2000 adolescent and young women are infected with HIV every week in South Africa, with young women of child-bearing age accounting for the highest burden of HIV [2,4]. Antenatal care (ANC) attendance is an important entry point for HIV testing and the overall HIV cascade for many young women [5,6]. This places a heavy burden on prevention of mother to child transmission (PMTCT) programmes across the country because young women also account for a third of all pregnancies in South Africa, and many first test HIV positive and/or initiate antiretroviral therapy (ART) during the antenatal period [5,7,8].

2.2. HIV treatment outcomes among pregnant/postpartum women

In South Africa, under Option B+ guidelines, all pregnant women are eligible to initiate lifelong ART upon HIV diagnosis, regardless of CD4 cell count or clinical disease stage. In order to optimize maternal and child health outcomes, women need to be tested for HIV, initiated on ART and reach viral suppression before or early in pregnancy [9,10]. ART adherence during this time is crucial to achieve and maintain viral suppression, as elevated HIV viral load at delivery accounts for the greatest risk of mother-to-child transmission (MTCT) of HIV [11]. Retention in HIV care is necessary for ART adherence, which in turn is necessary for viral suppression [12,13]. However, despite remarkable advances in the uptake and availability of ART within PMTCT programmes, pregnant and postpartum women's adherence to ART and retention in HIV care remains a global concern, especially during the postpartum period [6,8]. It has been shown that pregnant and postpartum women tend to have elevated viral load due to poor engagement in HIV care and thus poor ART adherence and viral suppression [8]. This is concerning for both maternal health and child health outcomes. Sub-Saharan Africa is home to 90% of the world's HIV infected children [15]. A third of infant HIV infections are due to poor uptake of PMTCT services including timely HIV testing and maternal and infant ART uptake [8]. Alongside the devastating dangers of poor ART adherence for child health, the leading cause of maternal deaths in many developing countries is HIV/AIDS; most of which occur postpartum [7].

2.3. Young women as an at-risk population

Compared to older women, adolescent and young women have even poorer PMTCT outcomes. For example, this group has poorer uptake of PMTCT services, and is more likely to delay ART initiation and have poorer ART adherence [5,6,8,16]. Elevated viral load resulting from suboptimal ART adherence in this group poses a threat not only to the successes of ART programmes but also those of PMTCT programmes. Research has shown that in South Africa, younger women have a higher risk of both MTCT and maternal mortality compared to older women [5,16]. Given the high burden of HIV and incidence of pregnancy in this group, young pregnant and postpartum women represent an important population for research and interventions to improve both maternal and child health. In order to address elevated viral load among pregnant and postpartum women, it is imperative to understand and address the risk factors that contribute to sub-optimal HIV treatment outcomes in this group, in a context specific and targeted manner.

2.4. Risk factors for poor HIV treatment outcomes

Poor HIV treatment outcomes and subsequent elevated viral load is a function of various health system and individual-level factors. Health system factors are well documented in the literature. They encompass issues of health facility accessibility (geographic and financial) and a lack of resources in health facilities; including shortages in health personnel, equipment and medication [17]. Other health system factors that impact HIV treatment outcomes include long queues, health worker attitudes and stigmatisation, especially towards young women [18]. While health system factors are well studied and there are continuous attempts to address them, individual-level risk factors are often not well understood and are rarely appropriately addressed, especially among young women.

Individual-level risk factors for poor HIV treatment outcomes encompass psychological and social ('psychosocial') challenges faced by the individual; such as early or unintended pregnancy, fears and experiences of stigma, trauma and posttraumatic stress disorder (PTSD), lack of social support, alcohol and substance abuse, non-disclosure to family members, intimate partner violence (IPV), lack of partner support and mental health challenges such as depression and anxiety [5,18-22]. Young women are more susceptible to one or more of these risk factors and as a result are more likely to miss one or more steps along the PMTCT cascade, resulting in sub-optimal maternal and child outcomes [6,8]. Every risk factor contributes to the individual's psychosocial burden and may cumulatively place the individual at greater risk of poor HIV treatment outcomes and thus elevated viral load.

2.4.1. Unintended pregnancy

Unintended pregnancy is a common risk factor among young pregnant and postpartum women. Many young women discover that they are HIV positive during this already stressful period of their lives. In South Africa, many are often unmarried and had not intended on becoming pregnant [7-8]. As a result, young women struggle with not only having to accept and obtain support for their pregnancy, but also for their HIV status [7]. Many young women experience the dual anticipated or enacted stigma of early or unintended pregnancy and that of living with HIV. As a result, they may become reluctant or ashamed to seek HIV care or to take ART [5,7,14,15]. Furthermore, these women often experience high levels of stress, depression and anxiety and a lack of social support, all of which are associated with poor engagement in HIV care [19-20].

2.4.2. Psychological challenges

Psychological challenges are another important risk factor and may be driven by other individual-level risk factors. It has been shown that high levels of depressive symptoms among pregnant women living with HIV (WLHIV) are associated with poor treatment adherence [14]. Lowenthal et al. states that the emotional effects of living with HIV can be very severe for younger women, particularly as HIV infection tends to occur alongside other developmental and socio-economic challenges in low-income countries, such as poverty and lack of schooling and employment opportunities, and traumatic life events. [22,23]. Consequently, an HIV diagnosis tends to further exacerbate existing mental health challenges, therefore placing this group at further risk of poor HIV treatment outcomes and subsequent elevated viral load [23].

For example, lifetime and recent traumatic events such as physical and sexual assault, criminal victimization, IPV and loss may have devastating long-lasting psychological effects, leading to mental health challenges such as depression and PTSD [24, 25]. People living with HIV (especially women) have a higher exposure to and burden of traumatic life events compared to people not living with HIV [26]. Furthermore, a strong association has been shown between recent and lifetime

trauma/PTSD and poor HIV treatment outcomes [22,27-29]. Alongside substance use and biological mechanisms, the mechanism through which trauma leads to poor HIV treatment outcomes includes mental health challenges, which often go unidentified and untreated. This is especially true in low-income/low-resource settings [24, 25]. 2.4.3. Intimate partner violence (IPV).

Ideally, one of the most critical sources of support for pregnant and postpartum women ought to be their partners, however IPV is often a barrier to that. Intimate partner support is important for ART adherence among pregnant and postpartum WLHIV. As reviewed by Hodgson et al, many studies find that women feel they need their partner's emotional and financial support and sometimes even their permission to initiate and remain engaged in HIV care [18]. Alongside financial and physical support, emotional support has been shown to improve ART uptake in the PMTCT cascade [15].

However, many women often fear disclosing their HIV status to their partners in fear of experiencing or exacerbating IPV, let alone relying on their partners for ART adherence support. Studies have shown an association between HIV infection and IPV and furthermore increased experiences of IPV as a result of disclosure [30-32]. WLHIV have also been reported to be at a higher risk of all forms of IPV including sexual, physical and emotional abuse [33]. It is therefore no surprise that experienced and anticipated IPV has been reported to be a barrier for ART adherence [18]. The experience of IPV is highest among women of low socio-economic status and with lower levels of education, and this vulnerable population has a high burden of HIV [30]. As highlighted by Matseke et al., very few studies report on the combination of HIV, pregnancy and IPV, particularly in low-income settings [30]. However, it is known that IPV among pregnant women has serious negative implications for both maternal and infant health [34].

Women are generally at increased risk of experiencing IPV due to community, society and cultural level norms such as gender inequality, patriarchy as well as socio-structural inequities [35]. However, young women are at a higher risk of experiencing IPV due to their higher risk of being impacted by these contributing factors. Furthermore, age-disparity, shorter relationship duration and relationship instability has been associated with an increased risk of IPV among young women [35,36]. Therefore, in order to address HIV treatment outcomes among young WLHIV, it is imperative to understand the prevalence and impact of IPV in this group.

2.4.4. Hazardous alcohol use

Alcohol abuse is a major public health concern among men and women in South Africa [37]. In addition, hazardous alcohol and substance use among young pregnant and postpartum women has been identified as a common risk factor for poor HIV treatment outcomes [18,21]. WLHIV who use alcohol at hazardous levels are more likely to miss PMTCT and HIV care appointments and are more likely to miss ART doses [21]. Hazardous alcohol use in this group may be a manner of coping with underlying psychological challenges such as depression and anxiety that may be driven or exacerbated by the challenges that come with being young, pregnant, and living with HIV as well as a coping mechanism for recent and lifetime traumatic events [25].

2.5. Co-occurrence of psychosocial risk factors

These psychosocial risk factors are often associated with each other and together may cumulatively increase young women's risk of suboptimal HIV treatment outcomes. For example, IPV (a traumatic event) is associated with increased levels of depression, anxiety, PTSD, alcohol and substance abuse, all of which individually are associated with poor maternal and child health outcomes [30, 35]. In turn, there is also an association between hazardous alcohol use and increased levels of IPV, unintended pregnancy and depression [30, 37]. Any hazardous alcohol use among people living with

HIV is extremely concerning because hazardous alcohol use is typically accompanied by a group of psychosocial risk factors that lead to sub-optimal HIV outcomes. There is also an association between all the above discussed risk factors and depression/anxiety [23, 30]. It is therefore important to understand the cumulative impact of psychosocial risk factors (psychosocial burden) because they often are not experienced in isolation; rather, they co-exist and may have a cumulative and synergic impact on HIV treatment outcomes in this group. If not well addressed, individual-level psychosocial factors among young pregnant and postpartum women threaten to undermine the advancements made at the health-system level.

Study Rationale:

To address the issue of elevated viral load among young pregnant and postpartum women, it is important to not only understand health system-level risk factors but to also understand psychosocial risk factors. ART and PMTCT services may be accessible and well operated but, if not adequately addressed, psychosocial risk factors may continue to drive poor ART adherence and elevated viral load, both of which fuel MTCT and poor maternal health outcomes. Although limited, some interventions to minimize the impact of psychosocial risk factors have been tested, however targeted interventions for young/adolescent WLHIV in particular remain very limited [38,39]. There is a gap in the understanding of the impact of each of these risk factors on the HIV treatment outcomes of young pregnant and postpartum WLHIV, and most importantly there is a gap in the understanding of how psychosocial risk factors co-occur and what their cumulative impact is on HIV treatment outcomes among pregnant and postpartum women.

A review investigating the risk factors for low access, initiation and adherence to ART by mothers in sub-Saharan Africa found that qualitative studies give better insight as far as describing psychosocial risk factors but very few have been able to quantify their impact and rank them according to importance [15]. Quantitative studies on ART adherence often neglect to investigate important psychosocial risk factors such as IPV because they are difficult to measure; while placing more emphasis on socio-demographic factors, which are easier to measure [15]. As mentioned before, psychosocial risk factors are complex and dynamic. Many studies do not quantitatively measure psychosocial risk factors and furthermore do not examine how they co-occur and what the cumulative impact of psychosocial risk factors on HIV treatment outcomes is.

This study thus aims to describe the prevalence and co-occurrence of key psychosocial risk factors and quantitatively examine their cumulative impact, i.e. psychosocial burden, on HIV treatment outcomes among young pregnant and postpartum WLHIV in South Africa. A quantitative understanding of psychosocial burden has the potential to guide how we prioritize and optimize intervention strategies for HIV related maternal and child health outcomes.

3. Study aim and objectives

3.1. Study aim

The aim of this study is to quantitatively examine the prevalence and co-occurrence of psychosocial risk factors and examine the cumulative impact of key psychosocial risk factors (psychosocial burden) on HIV treatment outcomes among young pregnant and postpartum WLHIV.

For the purposes of the broader study (described below) and this secondary analysis, the primary outcome variable will be a composite measure of engagement in HIV care and viral suppression, measured within a window around the 6 months study visit. Engagement in care will be defined as any evidence of engagement in HIV services, based on laboratory tests which will include HIV viral load and CD4 cell count tests. Viral suppression will be defined as viral load <50 copies/mL, and <1000 copies/mL in sensitivity analyses.

3.2. Objectives

I. To describe the prevalence and co-occurrence of key psychosocial risk factors experienced by young pregnant and postpartum WLHIV and examine the associations among these risk factors.

II. To examine the impact of individual psychosocial risk factors on HIV treatment outcomes among young pregnant and postpartum WLHIV. Where HIV treatment outcomes are a composite measure of engagement in HIV care and viral suppression within a window around the 6 months study visit and psychosocial risk factors include:
   a. Unintended pregnancy
   b. Depression
   c. IPV
   d. Hazardous alcohol use

III. To explore the cumulative impact of these psychosocial risk factors (psychosocial burden) on HIV treatment outcomes among young pregnant and postpartum WLHIV.

4. Methodology

4.1. Study design

The data for this secondary analysis will be obtained from a pilot study ("Masibambisane Girls") that was conducted in Gugulethu outside Cape Town, South Africa (the primary study). Masibambisane Girls was part of a multi-phase study that designed and evaluated the role of a peer support intervention to mitigate the negative impact of stigma among young pregnant and postpartum WLHIV.

Phase 1 was the formative research, using in-depth-interviews to investigate how stigma manifests in the lives of young pregnant and postpartum WLHIV and exploring the features of peer support interventions that may be useful in mitigating the effects of this stigma.

Phase 2 was the designing and development of a peer support intervention, using the information learned in phase 1 and adapting existing materials specifically to mitigate the effects of stigma among young pregnant and postpartum WLHIV.

Phase 3 ("Masibambisane Girls") - was the primary study which provided data for this secondary analysis, a pilot study assessing the implementation and potential impact of the intervention (face-to-face peer support groups) to mitigate the negative impact of stigma on HIV treatment outcomes among young pregnant and postpartum WLHIV.

In the primary study, young pregnant (n=60) and postpartum (n=59) WLHIV were approached at the Gugulethu Midwife Obstetric Unit (MOU). Following an informed consent process, they completed a questionnaire-based enrolment study visit after which they were randomized to two study arms:

- Arm A (peer support intervention): Women randomized to this arm were invited to attend peer support groups of ~8 pregnant and postpartum women. Each group was to meet every 4 weeks for 6 months after randomization.
- Arm B (control): Women randomized to this arm received the local standard of care; which is integrated HIV and antenatal care at the MOU during pregnancy and referral to general adult HIV clinics within seven days postpartum.

In both arms, participation had no interreference on any aspects of the women's routine antenatal and postpartum care, nor their HIV care. The only difference between women in Arm B and those in arm A was that they were not randomized to attend the peer support groups.

Women randomized to each arm attended two additional study visits after 3 and 6 months of follow-up. The primary outcome measured was retention in routine HIV care and HIV viral load suppression after 6 months of follow-up.

This secondary analysis will be a cross-sectional analysis of only the baseline data collected prior to randomization from the above described Masibambisane Girls pilot study. The sample size calculation for the parent study is detailed in the primary study protocol. This secondary analysis will include data from all participants that were enrolled in the parent study, excluding women who withdrew and those who did not complete all measures in the parent study.

4.2. Study setting

The primary study ("Masibambisane Girls") study was conducted at the Gugulethu MOU, based at the Gugulethu Community Health Centre ~18km from Cape town, South Africa. Like many townships in South Africa, Gugulethu has a high burden of various socio-economic challenges such as poverty, unemployment and crime. Although relatively lower than other areas of the country, Gugulethu has a high prevalence of HIV infection. The local antenatal HIV prevalence is ~28% [40]. The Gugulethu MOU offers primary ANC services and has been successfully offering PMTCT services since 2003. Masibambisane Girls recruited young pregnant and postpartum WLHIV who were receiving ANC and immediate postpartum care at the MOU.

4.3. Study population

Women in this secondary analysis will need to meet the following inclusion and exclusion criteria:

Inclusion criteria

- Be enrolled in the primary study, having met criteria below:
    - Aged 16-24 years
    - Confirmed HIV+

- Confirmed pregnant (with confirmation via urine pregnancy testing per local standard of care), or recently postpartum
- Accessing antenatal or immediate postpartum PMTCT services at Gugulethu MOU
- Planning on remaining a resident of Cape Town for at least 6 months after enrolment
- Able to provide informed consent for research, including ability to speak isiXhosa or English

[Note: No restrictions were made based on gestation (among pregnant women), timing of HIV diagnosis, or prior exposure to ART or PMTCT]

Exclusion criteria

- Withdrawal from the primary study

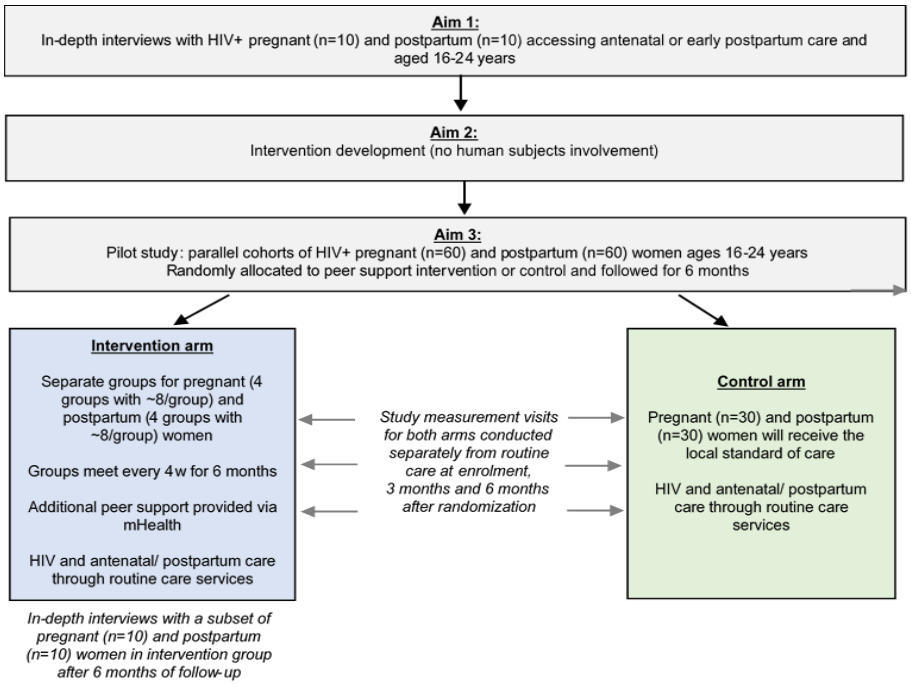

Figure A: Primary study ("Masibambisane Girsl") schema.

4.4. Data collection

This research is a secondary data analysis of data collected from the Masibambisane Girls study. At study visits, questionnaire-based measures were administered by trained study staff in either English or IsiXhosa, depending on the participant's preference. The measures were administered in a private room at the study site to ensure confidentiality. Furthermore, participant folders were labelled using assigned participant ID numbers and kept in cabinets in a secured room at the study site. The data was collected on hard copy case report forms (CRFs), quality control checked and captured into a study specific secured ACCESS database.

4.5. Study Measurements

4.5.1. Exposure variables

During the enrolment study visit of the primary study, consenting participants were administered questionnaire-based measurements by a trained interviewer to assess the Masibambisane Girls study objectives. The questionnaires assessed sociodemographic characteristics, maternal and child health and various psychosocial factors including unintended pregnancy, psychological distress and depression, alcohol and substance use and IPV. Most of these measurements had been administered in this setting before and were all translated into isiXhosa, which is the predominant language in the community, and then back-translated into English to ensure accuracy by study personnel who are native isiXhosa speakers.

In this analysis, data from four of these enrolment measurements will be used to assess psychosocial burden, based on four common psychological and social challenges faced by young pregnant and postpartum WLHIV in this setting: unintended pregnancy, depression, hazardous alcohol use and IPV. We will use the scoring methods in these standardized questionnaires to calculate psychosocial burden as the sum of psychosocial risk factors reported. We focus on the following risk factors and relevant self-report questionnaires:

- Unintended pregnancy (London Measure of Unplanned Pregnancy: score <10) – This questionnaire uses the 6 item London Measure of Unplanned Pregnancy tool [41]. The questionnaire measures unintended pregnancy. Respondents are asked about their intent to be pregnant, desire for motherhood, contraceptive use, pre-conceptual preparations, personal circumstances/timing of the pregnancy and their partner's influence. Each question is scored between zero and two and the maximum overall score is 12. The scores are categorised into unintended (0-3), ambivalent (4-9), and intended (10-12). For this analysis we will combine unintended and ambivalent. Thus, a score of <10 will be considered as "unintended" and a score of ≥10 will be considered as "intended" pregnancy. This measure has been used by our team before [42].

- Depression (Edinburgh Postnatal Depression Scale (EPDS): score ≥13) – This is a ten-item questionnaire that measures probable depression, based on the respondent's emotional state and associated behaviour in the past week [43]. Each question is scored between zero and three and the scoring method includes reverse scoring for certain questions. An overall score of 13 or higher indicates probable depression. This measure has been used by our team before [44, 45].

- Hazardous alcohol use (Alcohol Use Disorders Identification Test-Consumption (AUDIT-C): score ≥3) – This is a three-item questionnaire that measures risky drinking in the past year, based on the amount and frequency of alcohol consumption, including the frequency of binge drinking [46]. Each question is scored between zero and four and the maximum score is 12. A total score of 3 or higher indicates probable hazardous alcohol use. This measure has been used by our team before [44].

- Intimate partner violence (World Health Organization Violence Against Women) – This is a thirteen-item questionnaire that was developed by the World Health Organization to assess the prevalence of IPV [47]. The respondent is asked about psychological, physical and sexual violence that they may be experiencing or have experienced from a partner in the past 12

months and all responses are either ‘yes’ or ‘no’. There is no scoring on this questionnaire but for the purposes of this analysis, a ‘yes’ response to any of the questions will be considered as experiencing IPV. This measure has also been used by our team before [44].

As described above, each of these questionnaires, with the exception of the IPV questionnaire, uses a scoring method whereby scoring above a certain threshold signifies that the respondent may be experiencing that risk factor. For example, a score of 13 and above on the EPDS questionnaire signifies that the participant is experiencing probable depression. In the primary study, that would then prompt the interviewer to refer the participant for psychological help. It is important to note that the IPV questionnaire has no scoring system. As stated above, we will consider **any** report of IPV on the questionnaire as meeting the threshold for the IPV risk factor.

In this analysis, meeting the threshold for a risk factor gives a participant a score of 1 on the psychosocial burden variable. Therefore, the highest a participant can score for psychosocial burden is 4 (meaning the participant met the threshold for all four risk factors) and the lowest is zero (meaning the participant did not meet the threshold for any of the risk factors). Psychosocial burden will thus be a quantifiable variable, with of range of 0 – 4.

4.5.2. Outcome variables

The primary study did not draw bloods for any study procedures during any of the study visits. However, as part of informed consent, participants were asked to consent to study personnel accessing their medical records under strictly confidential conditions and for the purposes of the study only. As part of the primary study, the research team accessed participants’ electronic medical records from the National Health Laboratory Service (NHLS) database which includes data for all lab tests conducted nationally. This means that we had access to participants’ medical records from any other public health centers, which is especially important for participants who will have given birth by six months of follow up because all postpartum women are referred to general adult clinics for HIV care immediately postpartum.

In accordance with the 2019 national guidelines, pregnant women who are initiating or re-initiating ART have their first viral load test three months after initiating treatment and again at delivery [48]. WLHIV who are already on treatment have a viral load test at the first ANC visit and again at delivery unless subsequent viral load failure is suspected. Those initiating ART at any time after 28 weeks gestation have a viral load test at delivery and again three months after delivery. Lastly, all WLHIV have a viral load test at delivery and six months postpartum.

For the purposes of this secondary analysis, the primary outcome variable will be a composite measure of engagement in HIV care and viral suppression, measured within a window around the 6 months study visit. Engagement in care will be defined as any evidence of engagement in HIV services, based on laboratory tests which will include HIV viral load and CD4 cell count tests. Viral suppression will be defined as viral load <50 copies/mL, and <1000 copies/mL in sensitivity analyses. A composite measure of the above HIV treatment outcomes will be created to fully capture the ultimate goal of ART use in PMTCT services, which as described by Myer et al, is to keep mothers engaged in HIV care and virally suppressed for the purpose of both treatment and prevention [49]. Additional sensitivity analyses will be conducted using assumptions about any missing outcome data.

5. Data management and analysis plan

The data that will be used in this analysis has already been collected and captured into a password-protected Microsoft Access database for the primary study. In this secondary analysis, all data analysis, including data cleaning and descriptive statistics analysis will be done using the statistical software package STATA 14.2 (Stata Corporation, College Station, Texas). For all analyses, statistical significance will be determined using a threshold p-value of 0.05 and 95% Confidence Intervals (CI).

5.1. Variable definitions

As stated above, the exposure variable for this analysis is psychosocial burden, with a range of 0-4. Psychosocial burden will be analyzed as discrete, non-negative integer variable i.e. a count variable. The outcome variable will be a composite measure of engagement in HIV care and viral suppression.

5.2. Descriptive analysis

Data will be explored to identify missing data, and any missing data will be resolved by reviewing participants' CRFs. The baseline characteristics of pregnant and postpartum women WLHIV will be described. Means and standard deviations will be used to describe normally distributed continuous variables, medians and inter-quartile ranges (IQR) will be used to describe non-normally distributed variables. For categorical variables, we will use frequency and proportions. We will also use proportions, graphs and summary statistics to conduct univariate analyses of the exposure and outcome variables.

5.3. Bivariate analysis

To explore the associations between psychosocial risk factors (objective I) and the associations between the outcome variable and (i) individual psychosocial risk factors and (ii) psychosocial burden (objectives II and III), we will conduct Wilcoxon rank-sum and Kruskal-wallis tests for continuous variables and Chi-squared and Fischer exact tests for categorical variables.

5.4. Regression analysis

We will conduct regression analyses to explore how (i) individual psychosocial risk factors and (ii) psychosocial burden at baseline (enrolment) predicts HIV treatment outcomes after 6 months of follow up. We will use Poisson regression models with robust error variance [50]. We will adjust for the following potential confounders: poverty score (calculated based on employment status, housing type and access to household resources), relationship status, educational attainment, timing of HIV diagnosis, and pregnancy status at baseline (pregnant vs. postpartum). Model diagnostics will be performed for all models and deviance or likelihood ratio chi-square statistics used to select the best models.

5.5. Sensitivity analyses

Sensitivity analyses will be conducted to explore the robustness of the findings under different assumptions i.e. determining the impact of different outcome definitions (using different thresholds), the impact of outliers or making assumptions about missing data.

6. Potential limitations

Psychosocial risk factor data was obtained through self-report and thus there is a potential for response bias and recall bias. There may be bias in the way participants recalled their alcohol consumption and associated behaviour in the past year or how they recalled their mental state in the past week when responding to the AUDIT and EPDS questionnaires respectively. In both instances, there is a potential for participants to recall and respond only as it relates their most recent experiences. For all self-report questionnaires (Pregnancy intentions, AUDIT, EPDS and IPV), there is potential for social desirability bias whereby participants may have only reported "socially desirable/socially correct" experiences in fear of being condemned, to avoid further discussion on the matter or to avoid being referred for help. For example, women may have under-reported experiences of IPV or EPDS to avoid being referred for counselling. Women may have also under-reported hazardous alcohol consumption in fear of being condemned considering the baby wellness advice they receive at the clinic. Considering that this is a young population, facing multiple stigmas as described above, social desirability bias may be more prevalent. These questionnaires have been used in this setting before and, in order to minimize bias, women are told during the informed consent process and reassured during the interview that there are no "correct" responses and that their responses will be kept strictly confidential.

7. Ethical considerations

7.1. Ethical approval and Consent

Ethical approval for the primary study was obtained from the University of Cape Town's Faculty of Health Sciences Human Research Ethics Committee (UCT-HREC). Informed consent was obtained from participants aged ≥18 years old and informed minor assent was obtained for participant's aged ≥16years old but <18 years old. The primary study also obtained a waiver from UCT-HREC which permitted participants who were minors to decide whether or not they would like parental consent to join the study.

7.2. Potential risks and confidentiality

This is a secondary data analysis and thus there will be no direct contact with participants. Furthermore, all the data that will be used has been anonymised via PIDs that were assigned at enrolment. As such, this analysis presents very minimal risk to the participant. I as the student conducting this research have worked on the primary study and had access to participant study files for which I underwent GCP and confidentiality training prior to beginning study activities. All of the data used in this analysis will have already been collected and abstracted for the purposes of the primary study and as such I will only use anonymised data for this analysis. In the event that I need access to original participant files or medical records, I will do so with the supervision of my supervisor.

7.3. Potential benefits

Given that this is a secondary analysis, there will be no direct benefits to the participant. However, this analysis aims to provide an in-depth and quantifiable understanding of the role of psychosocial burden on HIV treatment outcomes among young WLHIV. The knowledge obtained from this

analysis may potentially guide the prioritization and optimization of intervention strategies for HIV related maternal and child health outcomes. This may be the indirect benefit to participants.

8. Logistics

The analysis will take place over 3-4 months, including data management, data analysis and the write-up.

9. Budget

There is no budget for this secondary data analysis, as it is completed in partial fulfilment of the requirements of the Masters in Public Health Degree.

10. Dissemination

This analysis will be submitted as part of meeting the requirements for a Masters in Public Health degree at UCT. The findings of this study may be submitted to relevant peer-reviewed journals for publication and the abstract may be submitted to relevant academic platforms and conferences.

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B. Manuscript

1. Introduction

In many sub-Saharan African countries, HIV disproportionally affects young women (ages 15 – 24 years old), largely driven by underlying psychosocial, socio-economic and biological risk factors that may be unique to this group or more prevalent than in other groups [1-2]. In South Africa, young women account for the highest burden of new HIV infections and many are first diagnosed with HIV and/or initiate antiretroviral therapy (ART) during pregnancy [2-6]. However, young pregnant and postpartum women's suboptimum ART adherence and engagement in HIV care remains a global concern [7-8]. Furthermore, younger women living with HIV (WLHIV) have a higher risk of both mother-to-child transmission (MTCT) of HIV and maternal mortality compared to older women and thus represent a crucial population in HIV prevention and management research [5,9].

High HIV infection rates are driven by a number of psychosocial risk factors. Despite the global upscaling of HIV treatment programmes, including prevention of mother-to-child transmission (PMTCT) programmes, the same psychosocial risk factors often drive poor HIV treatment outcomes, including suboptimal engagement in HIV care and adherence to ART, and are a cause for concern for both maternal and child health outcomes. Psychosocial risk factors driving poor HIV treatment outcomes may include unintended pregnancy, alcohol and substance abuse, fears and experiences of stigma, lack of social support, intimate partner violence (IPV), trauma/PTSD, anxiety and depression [5,10-13]. These risk factors are individually dynamic and complex and may influence HIV treatment outcomes through various mechanisms. Among young pregnant women in particular, these psychosocial risk factors may be compounded by a new HIV diagnosis [14], particularly as HIV infection tends to co-occur alongside or further exacerbate other psychosocial and socio-economic challenges [14-16]. This is especially true in low-income settings [14].

Unintended pregnancy is common among young women in South Africa [17] and has been shown to be associated with various maternal behaviours such as late initiation of antenatal care (ANC) and poor ART adherence [17]. Young women may experience the dual stigma related to both early or unintended pregnancy and that of living with HIV, and the need to hide their HIV status may pose a challenge for them in remaining in HIV care and adhering to ART [5,18-20]. Furthermore, these women often experience psychological challenges like depression and anxiety. Perinatal depression is common in South Africa, and high levels of depression and anxiety among young pregnant and postpartum WLHIV are associated with poor HIV treatment outcomes, including engagement in care and ART adherence [11,12,19].

Hazardous alcohol use often co-occurs with both unintended pregnancy and depression, all of which are associated with sub-optimal HIV treatment outcomes [15]. Indeed, hazardous alcohol use in this group may be a coping mechanism for underlying psychosocial challenges. Notably, there has been a rise in the rate of alcohol use among young women in South Africa, particularly in disadvantaged communities [15], and hazardous alcohol use is a common risk factor for poor HIV treatment outcomes among young pregnant and postpartum women [10,13,15]. Finally, WLHIV are at a higher risk of all forms of IPV compared to HIV-negative women, including sexual, physical and emotional abuse, and IPV is associated with increased levels of depression, anxiety and hazardous alcohol use [21-23]. Although few studies report on the combination of HIV, pregnancy and IPV in low-income settings [21], it is known that IPV among pregnant women has serious negative implications for both maternal and infant health, including maternal HIV treatment outcomes [20,21,24]. The experience of IPV is highest among women of low socio-economic status and with lower levels of education, a group who are particularly vulnerable to poor HIV treatment outcomes [21].

Despite increasing evidence of the role of psychosocial risk factors in HIV treatment outcomes, there remains a gap in our understanding of how these psychosocial risk factors affect outcomes among young women in particular. Furthermore, these risk factors often co-occur and may have a cumulative synergistic impact on HIV treatment outcomes [25-27], but there is a gap in our understanding of how psychosocial risk factors co-occur and what their cumulative impact is on HIV treatment outcomes in this population. While there are qualitative studies that describe psychosocial risk factors and their co-occurrence and association with HIV treatment outcomes, there is a scarcity of quantitative research in this regard [20, 28, 29]. This information is needed to design interventions to improve ART outcomes in this vulnerable population.

The aim of this study is thus to quantitatively examine the prevalence and co-occurrence of psychosocial risk factors and examine the impact of psychosocial burden on HIV treatment outcomes among young pregnant and postpartum WLHIV, where we define psychosocial burden as the co-occurrence of multiple psychosocial risk factors.

2. Methods

2.1. Setting and Participants

This is a secondary data analysis of a pilot study (the "Masibambisane Girls" study) that evaluated the role of a peer support intervention to mitigate the negative impact of stigma among young pregnant and postpartum WLHIV (ClinicalTrials.gov NCT04036851). The study was based at the Gugulethu Midwife Obstetric Unit (MOU) at the Gugulethu Community Health Centre, which provides primary ANC and PMTCT services to the residents of Gugulethu and surrounding communities. Similar to many townships, Gugulethu is burdened with various socio-economic challenges such as poverty, unemployment, crime and other public health concerns. The pilot study enrolled young (16 – 24 years old) pregnant and postpartum WLHIV who were receiving ANC or immediate postpartum care at the MOU. Signed informed consent was obtained from all participants (Appendix F - H). The study obtained a waiver to give minors (<18 years old) the option to give assent and/or parental/guardian consent. Enrolled women completed a questionnaire-based enrolment study visit after which they were randomized to one of two study arms; (I) Peer support intervention arm, where groups of women were invited to attend monthly face-to-face peer support groups, or (II) Control arm, where they received the local standard of care i.e. no peer support groups. All enrolled participants attended two additional study visits after 3 and 6 months of follow-up. All study visits took place separately from the intervention and from any routine maternal or child health care. This is an analysis of only baseline data collected prior to randomization in the parent study. The study was reviewed and approved by the Human Research Ethics Committee of the University of Cape Town Faculty of Health Sciences (Appendix I).

2.2. Measures

In the parent study, consenting participants were administered questionnaire-based measures by a trained interviewer, most which had been administered in this setting before and had all been translated into isiXhosa, the predominant local language, and back-translated into English to ensure accuracy (Appendix A-E). The measures were administered in either English or IsiXhosa, depending on the participant's preference, in a private room at the study site to ensure confidentiality. The data was collected on hard copy case report forms (CRFs), quality control checked and captured into a study specific secured Microsoft ACCESS database. Baseline demographic information such as

relationship, education and employment status, gravidity and timing of HIV diagnosis was collected at the enrolment visit. A poverty score that categorized participants by least, moderately or most disadvantaged was also calculated, based on current employment status and a standardized composite asset index score based on housing type and basic household assets and facilities [30]. Among others, the following self-report psychosocial measures were also administered at the enrolment visit.

Unintended pregnancy

The 6 item London Measure of Unplanned Pregnancy tool was used to assess the intendedness of the index pregnancy [31]. Each question was scored between zero and two and the maximum overall score was 12. The scores are generally categorised into unintended (0-3), ambivalent (4-9), and intended (10-12) [31]. For this analysis we combine the unintended and ambivalent categories, such that a score of <10 was analysed as "unintended" and a score of ≥10 was analysed as "intended" pregnancy. This measure has been used in this setting before [32].

Depressive symptoms

The 10 item Edinburgh Postnatal Depression Scale (EPDS) was used to assess depressive symptoms in the past week [33]. Each question is scored between zero and three, for a maximum score of 30. An overall score of 13 or higher was used to indicate probable depression, based on the original development of the scale [33]. Although this scale was originally designed for use among postpartum women, the scale has been validated for use in pregnancy [34]. This measure has been validated for use in South Africa and used in this setting before [30,35-36].

Hazardous alcohol use

The 3 item Alcohol Use Disorders Identification Test-Consumption (AUDIT-C) scale was used to assess harmful alcohol use in the 12 months, based on the amount and frequency of alcohol consumption, including the frequency of binge drinking [37]. Each question is scored between zero and four and the maximum score is 12. A total score of 3 or higher was used to indicate hazardous alcohol use, based on the original development of the scale [37]. This measure has been used in this setting before [36].

Intimate partner violence

The 13-item Violence Against Women scale, developed by the World Health Organization, was used to assess IPV [38]. Women were asked to indicate whether or not they had experienced acts of psychological, physical and sexual violence at the hands of an intimate partner in the past 12 months. For the purposes of this analysis, a woman responding that she had experienced at least one act of violence was considered as having experienced IPV. This measure has also been used in this setting before [36].

Psychosocial burden

In this analysis, we calculated a psychosocial burden score based on data obtained from the four psychosocial measures listed above. Meeting the threshold for any of the risk factors scored a participant a score of 1 on the psychosocial burden variable. For each participant, the sum of psychosocial risk factor 'thresholds met' was summed such that the highest a participant could score for psychosocial burden was 4 (meaning the participant met the threshold for all four risk factors) and the lowest was zero (meaning the participant did not meet the threshold for any of the risk factors). The higher the score, the higher the psychosocial burden experienced. For descriptive

purposes, we term these categories ‘minimal’ (score=0), ‘low’ (score=1), ‘moderate’ (score=2), ‘high’ (score=3) and ‘extreme’ (score=4) burden.

HIV treatment outcomes

Engagement in care and HIV viral load around 6 months after enrolment into the study were the primary outcomes in this analysis. For these outcomes, a window of 3 months before and 6 months after the 6-month study visit was used. For women who did not attend the 6-month study visit, the median time of follow-up among those who did attend was used as a proxy date. Engagement in care was defined as any documented HIV-related laboratory test at any health facility in the country, including CD4 cell count, HIV viral load, or creatinine tests. Laboratory data were abstracted from the National Health Laboratory Service (NHLS) database. For the viral load outcome, participants were considered virally suppressed at a viral load threshold of ≤50 copies/mL. Given that not all participants had a viral load test within the outcome window, sensitivity analyses were performed to account for missing data by using best- and worst-case scenarios: participants with missing viral load results were assumed to be virally suppressed (<50 copies/mL), and then subsequently assumed to have elevated viral loads (≥50 copies/mL) [39].

2.3. Data analysis

Data were analyzed using STATA 14.2 (Stata Corporation, College Station, Texas). Descriptive statistics were used to describe the baseline characteristics of the study population and to describe the prevalence of the key psychosocial risk factors. Psychosocial burden (primary exposure variable) was calculated as a sum score of the four key psychosocial risk factors and analyzed as a count variable in further analyses. Psychosocial risk factors were analyzed as binary categorical variables throughout the analysis and their association with each other and with outcome variables was examined by way of bivariate analyses using Chi^2 tests and Fischer exact tests for sparse data. Both outcome variables were analysed as binary categorical variables. The association between psychosocial burden and engagement in care or viral load suppression was assessed using Poisson regression models with robust error variance [40]. Key confounding variables were adjusted for in the models if found to be associated with the outcome variable in literature or in bivariate analyses. These include age, pregnancy vs. postpartum status, poverty level and ART at entry into ANC. For all analyses, a threshold p-value of 0.05 and 95% confidence intervals (CI) were used to assert statistical significance.

3. Results

3.1. Baseline demographics

Between August 2019 and February 2020, 60 pregnant and 59 postpartum WLHIV were enrolled in the parent study. Women who withdrew (n=3) and those who did not complete all measures in the parent study (n=2) were excluded from this analysis, resulting in a sample of 114 women (55 enrolled during pregnancy and 59 enrolled postpartum). Table 1 shows the baseline sociodemographic and psychosocial characteristics of these women by pregnancy/postpartum status. The women were between the ages of 16 and 24 years old, with a median age of 23 years [Interquartile range (IQR): 21-23 years]. The median gestation was 25 weeks [IQR:16-30 weeks] among pregnant women and the median number of days postpartum was 6 days [IQR:3-13 days] among postpartum women. More than 96% of women were in a relationship at enrolment, and 35% were married or living with their partners. Most women had only completed primary school or some high school (61%) and were neither employed nor studying (59%). For a majority of women, this was their first pregnancy (54%). Most women were diagnosed HIV-positive prior to this pregnancy (60%) and were on ART at the time of enrolment into the study (92%). The median CD4 cell count at entry into ANC was 475 [IQR:315-632] cells/mm^3.

3.2. Prevalence of psychosocial risk factors

Overall, 88% of women reported that their current or recent pregnancy was unintended (Table 1). At enrolment, 14% of women scored above threshold for probable depression during the past week, with depression more common among women who were pregnant at enrolment (22% versus 7% among postpartum women, p=0.021). At enrolment, 19% of women scored above the threshold for hazardous alcohol use during the past 12 months, with hazardous alcohol use being more common among women who were pregnant at enrolment (27% versus 12% among postpartum women, p=0.037). Lastly, 32% of women overall reported having experienced at least one act of IPV in the past 12 months.

Table 1. Baseline sociodemographic and psychosocial characteristics of 114 pregnant and postpartum young women living with HIV.

Variable	Total sample – n (%)	Pregnant – n (%)	Postpartum – n (%)
Number of participants	114	55 (48.3)	59 (51.7)
Age in years – median [IQR]	23 [21-23]	23 [20-24]	22 [21-23]
Gestation in weeks - median [IQR]	-	25 [16-30]	-
Days postpartum – median [IQR]	-	-	6 [3-13]
Gestation at entry into ANC in weeks – median [IQR]	16 [10-23]	14 [9-21]	16 [11-23]
CD4 cell count (copies/mm^3) at entry into ANC – median [IQR]	475 [321-635]	467 [315-616]	483 [326-675]
Relationship status			
Single (Not in a relationship)	4 (3.5)	2 (3.6)	2 (3.4)
Married/Cohabiting	40 (35.1)	17 (30.9)	23 (39)
Unmarried/Not cohabiting	70 (61.4)	36 (65.5)	34 (57.6)
Educational attainment			
Primary/some secondary	70 (61.4)	36 (65.5)	34 (57.6)
Completed secondary/any tertiary education	44 (38.6)	19 (34.5)	25 (42.4)
Current employment/studies			
Unemployed/not studying	69 (60.5)	30 (54.5)	39 (66.1)
Employed/studying	45 (39.5)	25 (45.5)	20 (33.9)
Poverty level (Employment + Housing Type + Assets)			
Most disadvantaged	46 (40.4)	19 (34.5)	27 (45.8)
Moderately disadvantaged	29 (25.4)	17 (30.9)	12 (20.3)
Least disadvantaged	39 (34.2)	19 (34.6)	20 (33.9)
Primigravida	61 (53.5)	30 (54.5)	31 (52.5)
Time of HIV diagnosis			
Before this pregnancy	68 (59.7)	29 (52.7)	39 (66.1)
During this pregnancy	46 (40.3)	26 (47.3)	20 (33.9)
On ART at enrolment	105 (92.1)	46 (83.6)	59 (100)
Pregnancy intention			
Unintended	100 (87.7)	47 (85.5)	53 (89.8)
Intended	14 (12.3)	8 (14.5)	6 (10.2)
Depression during past week	16 (14)	12 (21.8)	4 (6.8)
Hazardous alcohol use during past 12 months	22 (19.3)	15 (27.3)	7 (11.9)
Any intimate partner violence during past 12 months	36 (31.6)	22 (40)	14 (23.7)
Number of risk factors reported (psychosocial burden)			
0 (Minimal)	8 (7)	3 (5.4)	5 (8.5)
1 (Low)	54 (47.4)	21 (38.2)	33 (55.9)
2 (Moderate)	38 (33.3)	20 (36.4)	18 (30.5)
3 (High)	12 (10.5)	9 (16.4)	3 (5.1)
4 (Extreme)	2 (1.8)	2 (3.6)	0

3.3. Co-occurrence and associations between psychosocial risk factors

The most common co-occurring risk factors were unintended pregnancy and IPV (reported by 16% of women), followed by 10% of women reporting both unintended pregnancy and alcohol use, and 7% of women reporting unintended pregnancy, alcohol use and IPV (Fig 1). The co-occurrence of all four key psychosocial risk factors was observed in only 2% of women. No statistically significant associations were observed between depression and alcohol use, alcohol use and unintended pregnancy, or unintended pregnancy and IPV. Although not statistically significant, depression was more common among women reporting IPV (22% of those who reported IPV scored above threshold for depression versus 10% of those who did not report IPV; p=0.087) and was less common among women reporting an unintended pregnancy (12% versus 29% among those reporting an intended pregnancy; p=0.095). Finally, hazardous alcohol use was somewhat more common among women reporting IPV, with 28% of those reporting IPV scoring above threshold for hazardous alcohol use compared to 15% among women reporting no IPV (p=0.119).

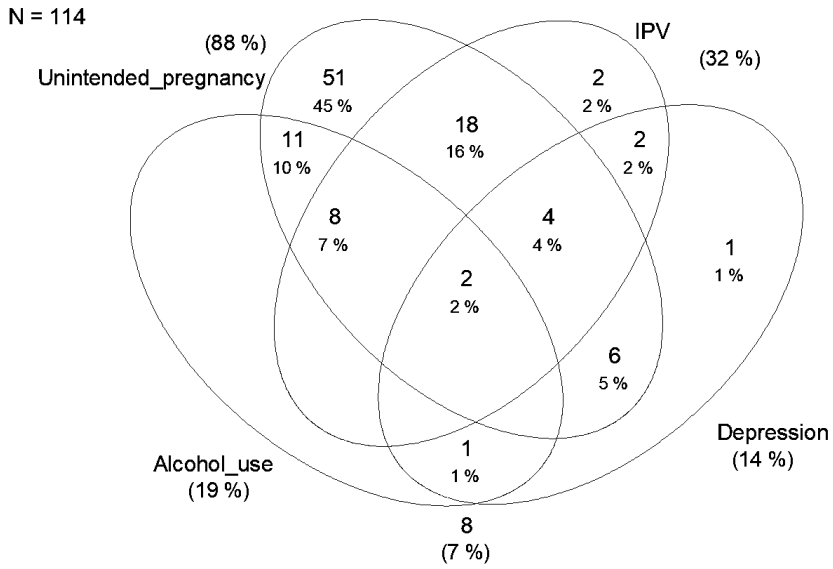

Fig 1. Venn diagram illustrating the co-occurrence of key psychosocial risk factors among pregnant and postpartum women living with HIV (Depression, hazardous alcohol use, intimate partner violence and unintended pregnancy).

3.4. Psychosocial burden

Overall, 93% of women had a psychosocial burden score of one or greater, meaning that they had met the threshold for at least one of the four key risk factors. Most women had a psychosocial burden of one i.e., 'low' psychosocial burden' (47% versus 33% and 11% of women who scored two and three, respectively) (Fig 2a). Overall, only 2% of women scored the maximum psychosocial burden score of four. Pregnant women had significantly higher psychosocial burden scores compared to postpartum women (mean score: 1.7 versus 1.3; p=0.012) and were thus more likely to report having experienced multiple psychosocial risk factors (Fig 2b).

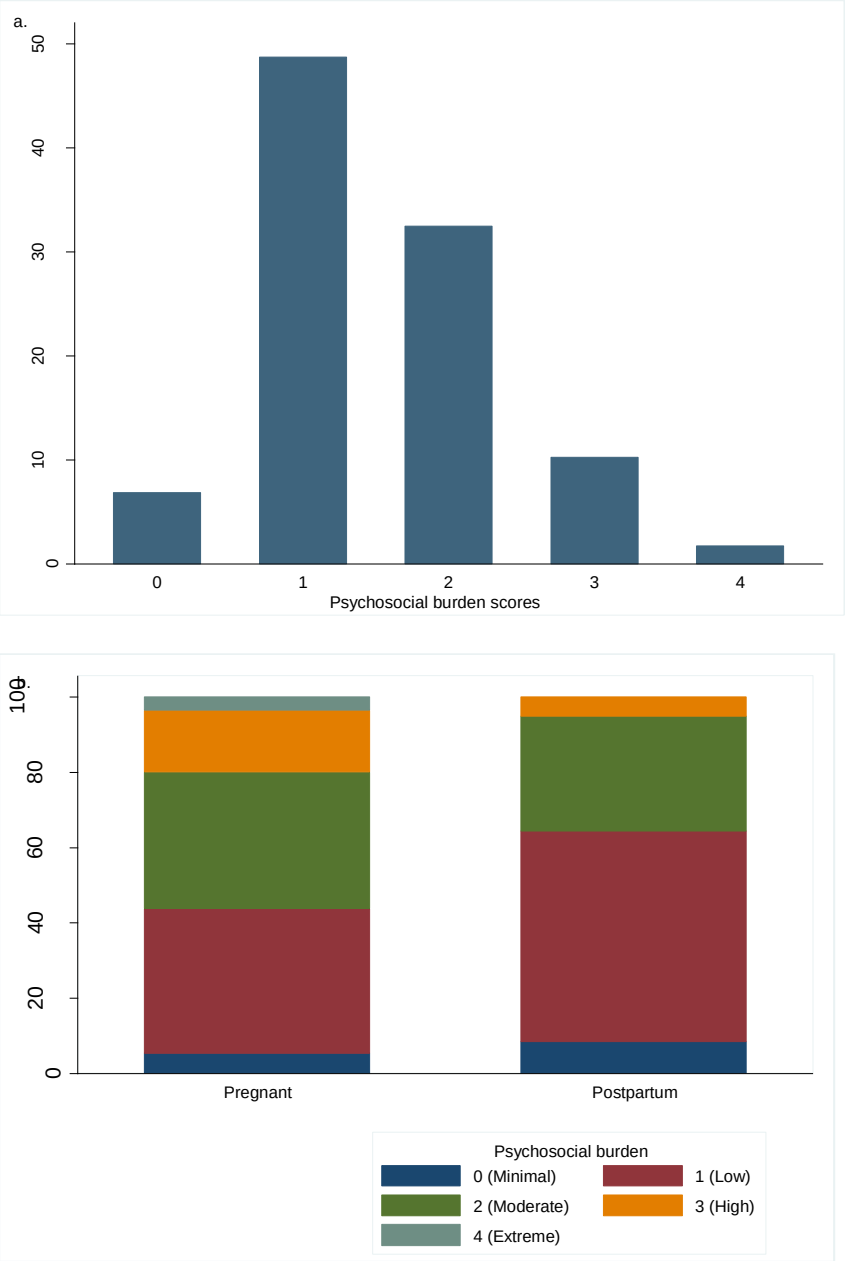

Fig 2. Psychosocial burden scores of 114 pregnant and postpartum women living with HIV; a) Overall psychosocial burden scores, b) Psychosocial burden score categories of pregnant versus postpartum women.

3.5. HIV treatment outcomes and psychosocial risk factors/ burden

3.5.1. Engagement in care

Overall, 60% of women had evidence of engagement in HIV care within the window around 6 months after enrolment, with similar levels of engagement among women enrolled during pregnancy versus postpartum (60% and 59% respectfully). No statistically significant associations were found between engagement in care and any of unintended pregnancy, hazardous alcohol use or IPV in unadjusted models or after adjusting for age, poverty level and pregnancy vs. postpartum status (Table 2.1). In an adjusted model, women who scored above threshold for depression were slightly less likely to be engaged in care compared to women scoring below threshold (RR=0.65 [CI:

0.37-1.17]; p=0.151), although this association was not statistically significant. No statistically significant association was found between psychosocial burden and engagement in care in either unadjusted or adjusted models.

3.5.2. Viral suppression (<50 copies/mL)

Out of 114 participants included in this analysis, only 58 (51%) had a viral load test within the window around 6 months after enrolment into the study. Among these 58 women, 78% were virally supressed (<50 copies/mL) with similar levels of viral suppression among women enrolled during pregnancy versus postpartum (74% and 81% respectfully). No statistically significant associations were found between viral load suppression and each individual psychosocial risk factor in either unadjusted models or after adjustment for pregnancy vs. postpartum status and ART use at entry into ANC (Table 2.2). These null findings were unchanged when assuming that women without viral load tests had (i) suppressed and (ii) elevated viral load, respectively (Appendix J). No statistically significant association was found between psychosocial burden and viral load suppression in either unadjusted or adjusted models (Table 2.2).

Table 2.1. Poisson regression analyses for the association between key psychosocial risk factors or psychosocial burden and engagement in HIV care during the window of follow up.

	Total sample – n (%)	Not engaged in care – n (%)	Engaged in care – n (%)	Unadjusted models		*Adjusted models	
				Risk ratio [95% CI]	P-value	Risk ratio [95% CI]	P-value
Pregnancy intentions							
Intended	14 (12.3)	5 (10.9)	9 (13.2)	Ref		Ref	
Unintended	100 (87.7)	41 (89.1)	59 (86.8)	0.92 [0.60, 1.40]	0.692	0.96 [0.63, 1.46]	0.850
Probable depression							
No	98 (14.0)	37 (80.4)	61 (89.7)	Ref		Ref	
Yes	16 (86.0)	9 (19.6)	7 (10.3)	0.70 [0.39, 1.25]	0.233	0.65 [0.36, 1.17]	0.151
Hazardous alcohol use							
No	92 (80.7)	37 (80.4)	55 (80.9)	Ref		Ref	
Yes	22 (19.3)	9 (19.6)	13 (19.1)	0.99 [0.67, 1.46]	0.953	1.01 [0.69, 1.49]	0.954
Intimate partner violence							
No	78 (68.4)	33 (71.7)	45 (66.2)	Ref		Ref	
Yes	36 (31.6)	13 (28.3)	23 (33.8)	1.12 [0.81, 1.51]	0.521	1.09 [0.79, 1.49]	0.605
Psychosocial burden score							
Mean (SD) score	1.5 (0.8)	1.6 (1.0)	1.5 (0.7)	0.96 [0.79, 1.17]	0.704	0.96 [0.79, 1.17]	0.686

*Adjusted for age, pregnancy vs. postpartum status and poverty level.

Table 2.2. Poisson regression analyses for the association between key psychosocial risk factors or psychosocial burden and viral load suppression at <50 copies/mL during the window of follow up.

	Total sample – n (%)	Not virally suppressed – n (%)	Virally supressed – n (%)	Unadjusted models		*Adjusted models	
				Risk ratio [95% CI]	P-value	Risk ratio [95% CI]	P-value
Pregnancy intentions							
Intended	8 (13.8)	1 (7.7)	7 (15.6)	Ref		Ref	
Unintended	50 (86.2)	12 (92.3)	38 (84.4)	0.87 [0.64, 1.18]	0.369	0.88 [0.65, 1.18]	0.385
Probable depression							
No	53 (91.4)	12 (92.3)	41 (91.1)	Ref		Ref	
Yes	5 (8.6)	1 (7.7)	4 (8.9)	1.03 [0.65, 1.65]	0.888	1.03 [0.59, 1.79]	0.913
Hazardous alcohol use							
No	47 (81)	11 (84.6)	36 (80)	Ref		Ref	
Yes	11 (19)	2 (15.4)	9 (20)	1.07 [0.77, 1.48]	0.689	1.11 [0.78, 1.59]	0.562
Intimate partner violence							
No	39 (67.2)	9 (69.2)	30 (66.7)	Ref		Ref	
Yes	19 (32.8)	4 (30.8)	15 (33.3)	1.03 [0.77, 1.37]	0.861	1.02 [0.76, 1.39]	0.881
Psychosocial burden score							
Mean (SD) score	1.47 (0.7)	1.5 (0.5)	1.5 (0.8)	1 [0.86, 1.67]	0.977	1.01 [0.85, 1.21]	0.872

*Adjusted for pregnancy vs. postpartum status and ART status at entry into antenatal care.

4. Discussion

This analysis examined the prevalence and co-occurrence of psychosocial risk factors among young pregnant and postpartum WLHIV and quantitatively examined the cumulative impact of psychosocial burden on HIV treatment outcomes. The majority of women in this study reported that their pregnancy was unintended; almost one in three women reported experiencing IPV; one in five reported hazardous alcohol use and 14% scored above threshold for probable depression. The co-occurrence of unintended pregnancy and each of IPV and alcohol use was observed among 16% and 10% of women, respectively. Although not statistically significant, depression appeared more common among women reporting IPV and less common among women reporting an unintended pregnancy; and hazardous alcohol use was more common among women reporting IPV. In this sample, engagement in HIV care was sub-optimum but among women with available viral load results within the follow-up period, most women were virally supressed. No statistically significant associations were found between any of the key psychosocial risk factors or psychosocial burden and each of engagement in care or viral suppression, however there was some evidence of an association between engagement in care and probable depression, with women scoring above threshold for probable depression being less likely to have evidence of engagement in care.

The high prevalence of unintended pregnancy observed here is consistent with findings from this region as well as other low-income settings [41-43]. Similarly, the prevalence of IPV in this sample is consistent with the estimated global prevalence of around 30% [44]. Probable depression and hazardous alcohol use were also relatively high as has been previously shown [45-47]. Interestingly, probable depression and hazardous alcohol use were significantly more common among pregnant women versus postpartum women in this analysis. Possible explanations are discussed further below.

Although not statistically significant, the associations between IPV and each of depression and hazardous alcohol use are supported by literature and possible pathways have been suggested. IPV and depression have been shown to be associated among pregnant and postpartum women in low-income settings in South Africa [48], with experiences of IPV possibly acting as a direct trigger for mental health issues such as anxiety and depression. Additionally, hazardous alcohol use has been shown to be associated with IPV in similar low-income settings in South Africa [15,21]. Although this analysis found no statistically significant evidence of an association, unintended pregnancy has been associated with IPV in low-income settings in South Africa, and it has been suggested that life disruptions linked to unintended pregnancy may heighten existing vulnerabilities which may lead to depression and IPV [49].

The co-occurrence of unintended pregnancy and IPV is of concern. It has also been suggested that the mechanism by which unintended pregnancy and IPV may co-occur is that IPV perpetuates gender-unequal norms (at the societal and individual level) that limit women's decision-making power in partnerships, including decisions about their reproductive health. One of the consequences of this is unintended pregnancy [50-52]. Surprisingly, our findings show that most women were experiencing only one psychosocial risk factor (low psychosocial burden) around the time of enrolment. Despite the low psychosocial burden observed overall, we found that on average, pregnant women experienced significantly higher psychosocial burden scores than postpartum women. An explanation for this may be that most pregnancies were unintended: it may take time to accept an unintended pregnancy and adapt to the associated psychosocial and socio-economic

challenges and, as such, women enrolled postpartum had already had the time to accept and adapt, hence the lower psychosocial burden in this group.

The finding of suboptimum levels of engagement in HIV care are consistent with relevant literature. In a systematic review of studies conducted in Africa (including South Africa) between 2012 and 2017, Knettel et al. found pooled estimates of 73% engagement in HIV care among pregnant and postpartum women at 6 months for studies reporting less than 12 months of follow up and 76% engagement in HIV care at 12 months for studies reporting 12 months or more of follow up [7]. Both estimates are slightly above what was found in this analysis, highlighting the high-risk nature of this group (young WLHIV). On the other hand, the finding that most of the key psychosocial risk factors were not associated with HIV treatment outcomes is contrary to related literature. Unintended pregnancy has been shown to be a predictor of poor ART adherence and elevated viral load among a sample of WLHIV in this setting [16,49].

Similarly, IPV has been shown to predict poor engagement in HIV care and viral failure [53-55]. It has been suggested that WLHIV avoid disclosing their HIV status to their partners in fear of IPV, and that non-disclosure hinders consistent engagement in HIV care at ART adherence [53]. It has also been suggested that the association between IPV and depression may be another pathway to poor engagement in care and poor ART adherence among WLHIV who experience IPV [56]. Depression on its own has been shown to predict poor engagement in care mainly through poor ART adherence, which subsequently leads to viral failure [57, 58]. Lastly, alcohol use has also been associated with poor ART adherence [47,59, 60]; the increased risk of missing HIV care appointments is suggested as a direct pathway [13,15]. The finding that psychosocial burden was not associated with HIV treatment outcomes in this analysis was unexpected but is consistent with our findings of no associations between most individual psychosocial risk factors and HIV treatment outcomes.

The differences between our findings and what has been observed in literature may be explained firstly by the fact that contrary to most of the existing literature, this analysis focused exclusively on younger women who may overall have different patterns of psychological risk factor burden. However, larger scaled studies would be best suited to draw robust conclusions. Secondly, a couple of limitations were identified in this analysis. Firstly, in the original study, participants were followed only up until 6 months post enrolment. This may not have been enough time to adequately examine the impact of individual risk factors or psychosocial burden on HIV treatment outcomes.

Additionally, many women did not have viral load results available within the window of follow up. National laboratory backlogs due to the Covid-19 pandemic may have further exacerbated existing delays in routine laboratory data processing, additionally routine ART appointments may have been delayed in order to reprioritise health services towards the pandemic. Sensitivity analyses were conducted to explore the impact of missing data, however the results were unchanged. Secondly, the sample size was small in the original study and further reduced in this analysis by the exclusion of participants who withdrew from the original study or did not complete all measures. Thus, the analysis may have been underpowered. Thirdly, another limitation of this analysis is that exposure variable data was obtained through self-report which runs the risk of self-report bias and may have led to lower psychosocial burden scores than expected. However, the observed prevalence statistics were similar to what has been previously observed, and the measurement tools were validated and had been used in this setting before. Lastly, all the participants in this analysis were recruited from the same ANC clinic which serves the surrounding community, thus also considering the small sample size, the generalizability of these findings may be limited.

Despite these limitations and although this analysis did no show associations between psychosocial risk factors or psychosocial burden and HIV treatment outcomes, this analysis exclusively focused on young WLHIV. Thus adding to the body of evidence that shows that the prevalence of these psychosocial risk factors in this group are high and need to be addressed; particularly given the known effects of psychosocial risk factors on other maternal and child health outcomes. Furthermore, the finding that pregnant women have higher psychosocial burden suggests a potential risk for not only poor maternal HIV treatment outcomes that may be contributing to HIV related maternal morbidity and mortality, but also suggests an increased risk of MTCT. It is known that young WLHIV are at greater risk of maternal mortality and MTCT, and to prevent this we need to appropriately study and roll-out targeted and evidence-based interventions that will address the sub-optimum HIV treatment outcomes among young WLHIV. To achieve that, larger-scale research studies with longer periods of follow up are necessary. This has the potential to enable us to rank psychosocial risk factors according to importance and that, coupled with an understanding their cumulative impact, has the potential to effectively inform how relevant HIV-related interventions are prioritized to address sub-optimum HIV treatment outcomes among young pregnant and postpartum WLHIV.

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C. Appendices

1. Questionnaires

Appendix A: Demographic Questionnaire

		Date: __ __/__ __ __/__ __ __ __
1	Mingaphi iminyaka yakho? *What is your age?*	_____ iminyaka *(years)*
2	Loluphi ulwimi oluthethayo ekhaya? *What language do you speak at home?*	isiXhosa = 1 isiZulu = 2 Afrikaans = 3 IsiNgesi *English* = 4 Olunye *Other* = 5, cacisa *specify*: _____
3	Ingaba uyaphangela ngoku kwaye/okanye uyafunda? *Are you currently working and/or studying?*	Hayi *No* = 0 → gqithela ku *SKIP to* Q5 Ewe *Yes* = 1
4	Ungayichaza njani impangelo yakho yangoku okanye izifundo zakho? *How would you describe your current work or studies?*	Ndiyaphangela ixesha elipheleleyo *Employed full-time* = 1 Ndiyaphangela ngamaxesha athile *Employed part-time* = 2 Ndikwisikolo samabanga aphakathi *In secondary school* = 3 Ndikwiziko lemfundo ephakamileyo *Tertiary study* = 4 Enye *Other* = 5, cacisa *specify*: _____
5	Leliphi elona nqanaba liphezulu lokufunda/lemfundo olugqibileyo? *What is the highest level of schooling/education that you have completed?*	i-Grade *Grade*: _____ okanye *or* i-Standard *Standard*: _____ okanye *or* ☐ Imfundo ephakamileyo *Postsecondary/tertiary*
6	Uhlala kwikhaya elinjani? *What kind of home do you live in?*	Ityotyombe/ityotyombe ezimbacwini *Shack/informal dwelling* = 1 Indlu yesitena *Formal house* = 2 Ifulethi/Indlu kamasipala *Flat/council home* = 3 Enye *Other* = 4, cacisa *specify*: _____
7	Ingaba indlu yakho inazo ezizinto zilandelayo: (Funda uze uphendule malunga ngazo zonke) *Does your house have the following: (Read and answer for all)*	

a	Indlu yangasese engaphakathi *A toilet inside*	Hayi *No* = 0 Ewe *Yes* = 1
b	Amanzi empompo ngaphakathi endlini *Running water inside*	Hayi *No* = 0 Ewe *Yes* = 1
c	Umbane ngaphakathi endlini *Electricity inside*	Hayi *No* = 0 Ewe *Yes* = 1
d	Isikhenkcezisi *A refrigerator*	Hayi *No* = 0 Ewe *Yes* = 1
e	Umnxeba *A telephone*	Hayi *No* = 0 Ewe *Yes* = 1
f	Umabonakude *A television*	Hayi *No* = 0 Ewe *Yes* = 1
8	Ingaba okukukhulelwa kokokuqala/ibikokokuqala ukukhulelwa kwakho? *Is/was this pregnancy your first pregnancy?*	Hayi *No* = 0 Ewe *Yes* = 1 → gqithela ku *SKIP to* Q11
9	Sewukhe wakhulewa amatyeli amangaphi ngaphambi kolukhulelo /kolukhulelo lwamvanje? *How many times have you been pregnant before this pregnancy/recent pregnancy?*	Inani lamatyeli okhe wakhulelwa ngawo *Number of previous pregnancies*: __
10	Bangaphi abantwana obabelekileyo ngaphambi kolukhulelo/kolukhulelo lwamvanje? *How many children have you given birth to before this pregnancy/recent pregnancy?*	Inani lwabantwana *Number of children*: __
11	Ingaba uzifumanise une HIV koku ukukhulelwa okanye ngaphambi koku ukukhulelwa? *Did you first test HIV positive in this pregnancy/recent pregnancy or before this pregnancy/recent pregnancy?*	Koku ukukhulelwa *In this pregnancy* = 1 Ngaphambi koku ukukhulelwa *Before this pregnancy* = 2
12	Wazifumanisa nini ukuba une-HIV? *When did you first test HIV-positive?*	Umhla *Date*:__ __ / __ __ / __ __ __ __
13	Lalusezelwani oluvavanyo lwe-HIV? *Why was this HIV test conducted?*	Ndavavanywa xeshikweni ndikhulelwe *Tested during pregnancy* = 1 Ndavavanywa ngokuzithandela/ngokuzivolontiya *VCT/Wanted to be tested* = 2 Ndaxelelwa ukuba ndine-TB *Diagnosed with TB* = 3

		Ndandilaliswe esibhedlele Admitted to the hospital = 4 Enye *Other* = 5, cacisa *specify*: _____
14	Ingaba unaso i-smartphone? *Do you have a smartphone?*	Hayi *No* = 0 → isiphelo *END* Ewe *Yes* = 1
15	Ingaba uyabelana nomnye umntu ngesmartphone sakho? *Do you share your smartphone with anyone else?*	Hayi *No* = 0 → gqithela ku *SKIP to* Q20 Ewe *Yes* = 1
16	Ukuba ewe, wabelana nabani ngesmartphone sakho? *If yes, with whom do you share your smartphone?*	
17	Lixesha elingakanani unayo lenombolo yemfonomfono? *How long have you had your current cell phone number?*	Iinyanga *Months*: _____ Iminyaka *Years*: _____
18	Zingaphi inombolo zemfonomfono okhe wanazo kwezinyanga zili-12 zigqithileyo? *How many cell phone numbers have you had in the past 12 months?*	Inani *Number*: _____
19	Ingaba usebenzisa i-*prepaid* okanye i-*contract*? *Do you use a prepaid or contract service?*	Ukuhlawula *Prepaid* = 1 Isivumelwano *Contract* = 2
20	Ingaba uyamsebenzisa u-WhatsApp kwimfonomfono yakho? *Do you use WhatsApp on your cell phone?*	Hayi *No* = 0 Ewe *Yes* = 1
21	Ingaba sewukhe walisebenzisa iqela lokuncokola lika WhatsApp ngaphambili? *Have you used a WhatsApp group chat before?*	Hayi *No* = 0 Ewe *Yes* = 1
22	Uyamsebenzisa uFacebook? *Do you use Facebook?*	Hayi *No* = 0 Ewe *Yes* = 1
23	Uyawasebenzisa amaqela akuFacebook? *Do you use Facebook groups?*	Hayi *No* = 0 Ewe *Yes* = 1

Date completed: __ __ / __ __ __ / __ __ __ __	Initials: _____
Date of QC: __ __ / __ __ __ / __ __ __ __	Initials: _____
Date captured: __ __ / __ __ __ / __ __ __ __	Initials: _____

Appendix B: Pregnancy Intentions Questionnaire

PREGNANCY INTENTIONS		Date: __ __/__ __ __/__ __ __ __
Lemibuzo ingezantsi imalunga neemeko neemvakalelo zakho ngethuba lokhulelo nelocwangciso kunye neemvakalelo zakho ngokuba nabanye abantwana kwixesha elizayo. *Below are some questions about your circumstances and feelings around the time you became pregnant, family planning use, and your feelings about having more children in the future.*		
1.	Ubuzama ukukhulelwa ngethuba ofumanise ngalo ukuba ukhulelwe (kolu ukhulelo/kukhulelo lwakutsha nje)? *Were you trying to have a baby when you found out you were pregnant (in this pregnancy / recent pregnancy)?*	Hayi *No* = 0 Ewe *Yes* = 1 Andazi *Don't know* = 9
2.	Kwinyanga eziyi-12 phambi kolukhulelo, ubusebenzisa oluphi uhlobo lokucwangciso-ntsapho? *In the 12 months before this pregnancy, what methods of family planning did you use?* Rhangqa konke okungqamene nawe. *Circle all that apply*.	a. Iipilisi eziselwayo *Oral contraceptive pill* b. Isitofu se-2('noristerat NET-en') *2-month injectable ('noristerat NET-en')* c. Isitofu se-3 ('depo,petogen') *3-month injectable ('depo, petogen')* d. Isivalo–mlomo wesibeleko (IUD) *Intra-uterine device* e. Isivalo nzala sabantu ababhinqileyo *Female sterilization* f. Isivalo nzala sabantu abangamadoda *Male sterilization* g. Idyasi kamkhwenyana *Male condom* h. Idyasi kamkhwenyana (yabantu ababhinqileyo) *Female condom* i. Olunye uhlobo,cacisa *Other method, specify* j. Bendingacwangcisi *None*
Nceda ucinge ngolu ukhulelo/ngolukhulelo lwakutsha nje xa uphedula lemibuzo ingezantsi: *Please think about your current / recent pregnancy when answering the questions below:*		

3.	Kwinyanga endikhulelwe ngayo… (Nceda utikishe intetha engqamene nawe kakhulu): *In the month that I became pregnant… (Please tick the statement which most applies to you):*	Mna/besingalusebenzisi ucwangciso *I/we were not using contraception* = 1 Mna/besilusebenzisa ucwangcisa, kodwa hayi lonke ixesha *I/we were using contraception, but not on every occasion* = 2 Mna/besilusebenzisa rhoqo ucwangciso, kodwa siyazile ukuba olahlobo locwangciso luye alasebenza (igqabhukile, ishenxile, iphumile, iphumele ngaphandle, ayisebenzanga) noba kuye kwakanye nje *I/we*

		always used contraception, but knew that the method had failed (i.e. broke, moved, came off, came out, not worked etc) at least once = 3 Mna/besilusebenzisa rhoqo ucwangciso *I/we always used contraception* = 4
4.	Kwindima yokuba ngumama (okokuqala, okanye ndiphinda) ndiziva ukuba ukhulelo lwenzeke… (Nceda utikishe intetha engqamene nawe kakhulu): *In terms of becoming a mother (first time or again), I feel that my pregnancy happened at the… (Please tick the statement which most applies to you):*	Ngexesha elilungileyo *Right time* = 1 Ok, kodwa ibingeloxesha elulingileyo ncam *Ok, but not quite right time* = 2 Ngexesha elingalunganga *Wrong time* = 3
5.	Nje phambi kokuba ndikhulelwe… (Nceda utikishe intetha engqamene nawe kakhulu): *Just before I became pregnant… (Please tick the statement which most applies to you):*	Bendizimisele ukukhulelwa *I intended to get pregnant* = 1 Iingcinga zam bezingangqamenanga *My intentions kept changing* = 2 Bendingazimiselanga ukukhulelwa *I did not intend to get pregnant* = 3
6.	Nje phambi kokuba ndikhulelwe… (Nceda utikishe intetha engqamene nawe kakhulu): *Just before I became pregnant… (Please tick the statement which most applies to you):*	Bendifuna ukuba nosana *I wanted to have a baby* = 1 Imizwa yam ibibethabethana ngokuba nosana *I had mixed feelings about having a baby* = 2 Bendingafuni ukuba nosana *I did not want to have a baby* = 3
7.	Phambi kokuba ndikhulelwe… (Nceda utikishe intetha engqamene nawe kakhulu): *Before I became pregnant… (Please tick the statement which most applies to you):*	Mna neqabane lam sivumelene ukuba ndikhulelwe *My partner and I had agreed that we would like me to be pregnant* = 1 Mna neqabane lam, sixoxile ngokuba sibenabantwana sobabini kodwa besingekavumelani ukuba mna ndikhulelwe *My partner and I had discussed having children together, but hadn't agreed for me to get pregnant* = 2 Asikhange sixoxe ngokuba nabantwana sobabini *We never discussed having children together* = 3
8.	Phambi kokuba ukhulelwe, ikhona into oyenzileleyo ukuphucula impilo yakho ulungiselela ukhulelo? (Nceda utikishe zonke engqamene nawe) *Before you became pregnant, did you do anything to improve your health in preparation for pregnancy? (Please tick all that apply)*	a. Nditye iFolic Acid *Took folic acid* b. Ndiyekile okanye ndibuyise unyawo ekutshayeni *Stopped or cut down smoking* c. Ndiyekile okanye ndibuyise unyawo ekuseleni *Stopped or cut down drinking alcohol* d. Nditye ukutya okusempilweni *Ate more healthily* e. Ndiye ndafuna iingcebiso zezeempilo *Sought medical/health advice*

		f. Ndiye ndathethe amanye amanyathelo nceda uchaze: *Took some other action, please describe:* _____ g. Akukho nenye endiyenzileyo kwezi zingentla ngaphambi kokuba ndikhulelwe *I did not do any of the above before my pregnancy*
9.	Ingaba umthathi nxaxheba ukhulelwe okanye usanda kubeleka? *Is the participant pregnant or postpartum?*	Ndikhulelwe *Pregnant* = 1 Ndisanda kubeleka *Postpartum* = 2 → gqithela ku *SKIP to* Q12
10.	Ingaba uceba ukusebenzisa ucwangciso-ntsapho emva kokubeleka? *Are you planning to use any form of family planning after delivery?*	Hayi *No* = 0 → Isiphelo *END* Ewe *Yes* = 1 Andiqinisekanga *Unsure* = 9 → Isiphelo *END*
11.	Ukuba ngu-Ewe loluphi uhlobo ocinga ukuba ungalusebenzisa? *If yes, what method do you think you might use?* Rhangqa konke okungqamene nawe *Circle all that apply*	a. Iipilisi eziselwayo *Oral contraceptive pill* b. Isitofu se-2('noristerat NET-en') *2-month injectable ('noristerat NET-en')* c. Isitofu se-3 ('depo,petogen') *3-month injectable ('depo, petogen')* d. Isivalo–mlomo sesibeleko (IUD) *Intra-uterine device* e. Isivalo nzala sabantu ababhinqileyo *Female sterilization* f. Isivalo nzala sabantu abangamadoda *Male sterilization* g. Idyasi kamkhwenyana *Male condom* h. Idyasi kamkhwenyana (yabantu ababhinqileyo) *Female condom* i. Olunye uhlobo,cacisa _____ *Other method, specify* → Isiphelo *END*
12.	Ingaba lukhona uhlobo locwangciso-ntsapho olusebenzisayo ngoku? *Are you currently using any form of family planning?*	Hayi *No* = 0 → Gqithela ku *SKIP to* Q14 Ewe *Yes* = 1

13.	Usebenzisa oluphi uhlobo? *What method are you using?* Rhangqa konke okungqamene nawe *Circle all that apply*	a. Iipilisi eziselwayo *Oral contraceptive pill* b. Isitofu se-2('noristerat NET-en') *2-month injectable ('noristerat NET-en')* c. Isitofu se-3 ('depo,petogen') *3-month injectable ('depo, petogen')* d. Isivalo–mlomo sesibeleko (IUD) *Intra-uterine device* e. Isivalo nzala sabantu ababhinqileyo *Female sterilization* f. Isivalo nzala sabantu abangamadoda *Male sterilization* g. Idyasi kamkhwenyana *Male condom* h. Idyasi kamkhwenyana (yabantu ababhinqileyo) *Female condom* i. Olunye uhlobo,cacisa _____ *Other method, specify*
14.	Cinga ngendlela oziva ngayo ngoku. Yeyephi kwezintetha zilandelayo echaza bhetele iingcinga zakho ngokuba nomntwana kwixesha elizayo? *Think about how you feel right now. Which of the following statements best describes your own thinking about having a child in the future?*	Ndingafuna ukuba nomntwana kwithuba leenyanga eziyi-12 ezizayo *I may want to have a child in the next 12 months* = 1 Ndingafuna ukuba nomntwana ngelinye ixesha elizayo kodwa hayi kwezinyanga ziyi-12 zizayo *I may want to have a child sometime in the future but not in the next 12 months* = 2 Ndigqibe ngelokuba andifuni ukuba nomntwana kwixesha elizayo *I have decided that I do not want to have a child in the future* = 3 Andiqinisekanga ukuba ndiyamfuna okanye andimfuni umntwana kwixesha elizayo *I am unsure about whether or not I want to have a child in the future* = 4 Okunye *Other* = 5, cacisa *specify*: _____

Date completed: __ __ / __ __ __ / __ __ __ __	Initials: _____
Date of QC: __ __ / __ __ __ / __ __ __ __	Initials: _____
Date captured: __ __ / __ __ __ / __ __ __ __	Initials: _____

Appendix C: AUDIT Questionnaire

AUDIT						Visit Date: __ __ / __ __ __ / __ __ __ __
Ngoku sizakubuza imibuzo ngokusebenzisa kwakho utywala kulonyaka udlulileyo. Nceda urhangqe impendulo engqamene nawe kumbuzo ngamnye: *We are now going to ask you some questions about your use of alcohol during <u>the past year</u>. Please circle the relevant answer for each question below:*						
		0	1	2	3	4
1.	Ubusela kangakanani utywala? *How often do you have a drink containing alcohol?*	Zange→ Isiphelo *Never → End*	Kanye ngenyanga nangaphantsi *Monthly or less*	Kabini ukuya kwisine enyangeni *2-4 times a month*	Kabini ukuya kwisithathu evekini *2-3 times a week*	Kane nangaphezulu evekini *4 or more times a week*
2.	Zidla ngobangaphi iiglasi zeziselo ezinotywala oziselayo ngemini xa usela? *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 Okanye 9 *7 to 9*	10 okanye ngaphezulu *10 or more*
3.	Kukangaphi usela iiglasi ezintandathu nangaphezulu ngexesha? *How often do you have six or more drinks on one occasion?*	Zange *Never*	Ngaphantsi kwenyanga *Less than monthly*	Ngenyanga *Monthly*	Ngeveki *Weekly*	Ngosuku okanye malunga nosuku *Daily or almost daily*
4.	Kunyaka ophelileyo, kukangaphi ufumanisa ukuba awukwazi ukuyeka ukusela xa sele uqalile? *During the past year, how often have you found that you were not able to stop drinking once you had started?*	Zange *Never*	Ngaphantsi kwenyanga *Less than monthly*	Ngenyanga *Monthly*	Ngeveki *Weekly*	Ngosuku okanye malunga nosuku *Daily or almost daily*

5.	Kulo nyaka uphelileyo kukangaphi ungakwazi ukwenza into ubumele ukuyenza ngenxa yokuba ubusela? *During the past year, 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*
		0	1	2	3	4
6.	Kulo nyaka uphelileyo kukangaphi ufuna ukusela utywala ekuseni kuba ufuna ukuqala usuku lwakho kakuhle emva kokuba ubusela ngezolo? *During the past year, how often have you needed a drink in the morning to get yourself going after a heavy drinking session?*	Zange *Never*	Ngaphantsi kwenyanga *Less than monthly*	Ngenyanga *Monthly*	Ngeveki *Weekly*	Ngosuku okanye malunga nosuku *Daily or almost daily*
7.	Kulonyaka uphelileyo kukangaphi uzifumanise unesazela okanye uzisola emva kokuba usele? *During the past year, how often have you had a feeling of guilt or remorse after drinking?*	Zange *Never*	Ngaphantsi kwenyanga *Less than monthly*	Ngenyanga *Monthly*	Ngeveki *Weekly*	Ngosuku okanye malunga nosuku *Daily or almost daily*
8.	Kulonyaka uphelileyo ukhe awakwazi ukukhumbula into eyenzeke kubusuku obudluleyo ngenxa yokuba ubusele? *During the past year, have you been unable to remember what happened the night before because you had been drinking?*	Zange *Never*	Ngaphantsi kwenyanga *Less than monthly*	Ngenyanga *Monthly*	Ngeveki *Weekly*	Ngosuku okanye malunga nosuku *Daily or almost daily*
9.	Ukhe wena okanye mntu wumbi 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*

		0	1	2	3	4
10.	Sikhona isizalwana sakho, okanye isihlobo, ugqirha okanye umntu osebenzela ezempilo obekhathazekile ngendlela osela ngayo waza wakucebisa ukuba uthobe isantya? *Has a relative or friend, doctor or other health worker been concerned about your drinking or suggested you cut down?*	Hayi *No*		Ewe, kodwa hayi kunyaka ophelilieyo *Yes, but not in the past year*		Ewe, kunyaka ophelilieyo *Yes, during the past year*
11.	Ngubani osela naye ixesha elininzi? Who do you mostly drink alcohol with?	Akekho (Ndodwa) *No one (alone)* = 0 Neqabane lam *Current partner* = 1 Namalungu osapho lwam *Family members* = 2 Nabahlobo bam *Friends* = 3 Nomnye umntu/abanye abantu endabelana nabo ngesondo *Other sex partner(s)* = 4 Nabantu endisebenza nabo *Work colleagues* = 5 Okunye *Other* = 6, cacisa *specify*: _____				
12.	Ubusela phi utywala ixesha elininzi? *Where do you mostly drink alcohol?*	Ekhayeni lam *At home* = 0 Esimokolweni/etywaleni *At shebeen* = 1 Ebhareni okanye kwivenkile yokutyela *At bar or restaurant* = 2 Ekhayeni lomhlobo wam *At friend's home* = 3 Emsebenzini *At work* = 4 Okunye *Other* = 6, cacisa *specify*: _____				
AUDIT score: _____ AUDIT-C score: _____	Referral required? *AUDIT score >6* *AUDIT-C score ≥3*	No Yes → inform project manager and refer to SOP for referrals				

Date completed: __ __ / __ __ __ / __ __ __ __	Initials: _____
Date of QC: __ __ / __ __ __ / __ __ __ __	Initials: _____
Date captured: __ __ / __ __ __ / __ __ __ __	Initials: _____

Appendix D: EPDS Questionnaire

EPDS					Visit Date: __ __ / __ __ __ / __ __ __ __ Visit (select): 1 / 2 / 3
Singathanda ukwazi ukuba ubuziva njani kuleveki iphelileyo. Nceda ukhethe impendulo esondeleyo kwindlela ubuziva ngayo kwiveki edlulileyo, hayi nje indlela oziva ngayo namhlanje. Nceda ufunde lonke uluhlu lwenkcaza nganye. *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.*					
		0	1	2	3
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 ngoku *Not quite so much now*	Ngokucacileyo hayi kangako ngoku *Definitely not so much now*	Hayi kwaphela *Not at all*
2.	Bendikuthakazelela ukonwabela izinto *I have looked forward with enjoyment to things*	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.	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, ngenyelinye 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.	Ndaziva ndisoyika okanye ndiphakuzela 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*

		0	1	2	3
6.	Izinto zindongamele *Things have been getting on top of me*	Ewe, amaxesha amaninzi bendingakwazi ukumelana nezinto kwaphela. *Yes, most of the times I haven't been managing at all*	Ewe, ngamanye amaxesha bedingakwazi ukumelana nezinto njengesiqhelo *Yes, sometimes I haven't been managing as well as usual*	Hayi, ixesha elininzi bendikwazi ukumelana nezinto kakuhle *No, most of the time I have managed quite well*	Hayi, bendikwazi ukumelana nezinto 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 ithe yandifikela *The thought of harming myself has occurred to me*	Ewe, kaninzi *Yes, quite a lot*	Ngamanye amaxesha *Sometimes*	Zange ifane indifikele *Hardly ever*	Azange *Never*

EPDS score: _____	Referral required? *EPDS score ≥13*	No Yes → inform project manager and refer to SOP for referrals
Date completed: __ __ / __ __ __ / __ __ __ __		Initials: _____
Date of QC: __ __ / __ __ __ / __ __ __ __		Initials: _____
Date captured: __ __ / __ __ __ / __ __ __ __		Initials: _____

Appendix E: WHO Violence Against Women Questionnaire

WHO VIOLENCE AGAINST WOMEN QUESTIONNAIRE		Visit Date: __ __ / __ __ __ / __ __ __ __	
Siza kubuza imibuzo embalwa malunga nobundlobongela bokudlakathiswa liqabane. Kwezi nyanga ziyi-12 zidlulileyo wakhe wazifumana ukwezinye zezimeko zilandelayo? *We are going to ask you a few questions relating to partner violence. In the last 12 months, have you experienced any of the following?*			
Ukudlakathiswa ngokwasengqondweni *Psychological violence*			
		Ewe *Yes*	Hayi *No*
1.	Iqabane lakho likhe lakuthuka okanye lakwenza uzive ungalunganga? *Has your partner insulted you or made you feel bad about yourself?*	1	0
2.	Likhe lakuthobela isidima okanye lakumenya phambi kwabanye abantu? *Has he belittled or humiliated you in front of other people?*	1	0
3.	Likhe lakoyikisa lakuphatha kakubi ngabom? *Has he done things to scare or intimidate you on purpose?*	1	0
4.	Likhe lakugrogrisa ngokonzakalisa wena okanye umntu omkhathaleleyo? *Has he threatened to hurt you or someone you care about?*	1	0
Ukudlakathiswa ngokwasemzimbeni *Physical violence*			
5.	Likhe lakuqhwaba ngempama okanye lakugibisela ngento enokwenzakalisa? *Has he slapped you or thrown something at you that could hurt you?*	1	0
6.	Likhe lakutyhala okanye lakunyola? *Has he pushed or shoved you?*	1	0
7.	Likhe lakubetha ngenqindi okanye ngento enokonzakalisa? *Has he hit you with a fist or with something else that could hurt you?*	1	0
8.	Likhe lakukhaba,lakurhuqa okanye lakubetha? *Has he kicked you, dragged you or beaten you up?*	1	0
9.	Likhe lakukrwitsha okanye lakutshisa ngabom? *Has he choked or burnt you on purpose?*	1	0
10.	Likhe lakugrogrisa okanye lasebenzisa umpu, imela okanye nasiphi isixhobo kuwe? *Has he threatened to use or actually used a gun, knife or other weapon against you?*	1	0

Ukudlakathiswa ngokwesondo *Sexual violence*			
		Ewe *Yes*	Hayi *No*
11.	Likhe lakunyanzela ngokwabelana ngesondo ngaphandle kwemvume yakho? *Has he physically forced you to have sexual intercourse when you didn't want to?*	1	0
12.	Wakhe wabelana nalo ngesondo ungafuni kuba unoloyiko lwento anokuthi ayenze? *Did you ever have sexual intercourse when you didn't want because you were afraid of what he might do?*	1	0
13.	Likhe lakunyanzela ngokwabelana ngesondo ngendlela ofumanisa ukuba ukuthathela phantsi okanye uyakwenyelisa? *Has he forced you to do something sexual that you found degrading or humiliating?*	1	0

Referral required?	No Yes → inform project manager and refer to SOP for referrals

Date completed: __ __ / __ __ __ / __ __ __ __	Initials: _____
Date of QC: __ __ / __ __ __ / __ __ __ __	Initials: _____
Date captured: __ __ / __ __ __ / __ __ __ __	Initials: _____

2. Ethics consent forms and approvals

Appendix F: Adult participant consent form

TITLE OF RESEARCH:	**Peer support for young HIV+ pregnant & postpartum women**

WHAT IS THE PURPOSE OF THIS STUDY?

We are researchers from the University of Cape Town. You are being invited to take part in a voluntary study that is being conducted at the Gugulethu Midwife Obstetric Unit (MOU). This document is to help you decide if you would like to participate. The purpose of this study is to compare two different options for support for young women who are living with HIV.

We know that many young women who are living with HIV experience challenges because of their HIV. Many women also experience challenges because of an unintended pregnancy, alcohol or other substance use, or mental health problems. This may make it difficult for women to attend their scheduled clinic visits and to take their medication. We would like to understand whether peer support groups for pregnant and postpartum women can help women to attend their clinic visits and take their medication.

You are being asked to take part in this study because you are aged 16-24 years, living with HIV and receiving your pregnancy or postpartum care at the Gugulethu MOU. The purpose of this consent form is to give you information to help you decide if you want to take part in this study.

WHAT DO I HAVE TO DO IF I AGREE TO TAKE PART?

If you agree to take part, you will be randomized (like the flip of a coin) to two different options:

1. Peer support group: Women assigned to this group will be invited to attend peer support groups and will be given the option of joining a WhatsApp group for peer support.
2. Comparison group: Women assigned to this group will continue to receive standard health care during pregnancy and postpartum, including routine HIV care, but will not attend any additional services.

“Randomized” means that you have a 50% chance of being in the group that will be invited to the peer support groups. You will also have a 50% chance of being in the group that receives standard health care during pregnancy and postpartum but does not receive any additional services. Neither the study staff nor you can choose which group you will be assigned to. The decisions are made by a computer and put into an envelope. The study staff do not know which group is in each envelope.

If you agree to take part in this study, you will be asked to complete a study measurement visit today. Randomization will occur at the end of the study visit. You will then be asked to attend two additional study measurement visits: one after 3 months, and one after 6 months. Each visit will take between 1 and 2 hours.

At each visit you will be asked to answer questions. These will include questions about:

- Your health and your baby's health
- Challenges that you might be facing
- Living with HIV
- Attending scheduled clinic visits and taking your medication

As part of this study, we will also be looking at and taking information from your routine medical records, and the records of your baby. This will include information about your use of health services as well as ART clinic, laboratory and pharmacy records. We would like your permission to access electronic databases that include all of these records. The Department of Health stores all of this information centrally at the Provincial Health Data Centre. We will use your and your baby's provincial folder number (or name and date of birth) to ask for this information directly from the Department of Health. All data that we review will be kept confidential. Your name and your baby's name will not be recorded with these records.

You will be asked to provide contact information so that we may get in touch with you during the study. Study staff will talk with you about the best way to contact you. If you miss one of your scheduled study visits, a staff member will contact you to find another day and time to complete your visit. If you repeatedly miss study visits or the study staff are unable to contact you using the information that you provide, it may be necessary to visit you at home to reschedule the missed study visit.

After the completion of your last visit after 6 months, it is possible that we will contact you again at your next clinic visit or at another time in the future to take part in additional research studies. At that time, you would be asked to review and sign another consent form. You can choose to not take part in any future studies if you are asked. You will be asked to provide contact information so that we may get in touch with you regarding additional research studies. Study staff will talk with you about the best way to contact you.

WHAT ARE THE POTENTIAL RISKS?

If you decide to take part, you may feel uncomfortable about some of the personal questions you are asked. You may refuse to answer any question that you do not want to answer. If any of the questions make you want to talk more with someone, we will refer you to counselling services either in the Gugulethu Community Health Centre or nearby organisations providing counselling and support services. There is some risk in sharing personal information. We will be careful to keep all your information as private as possible.

WHAT ARE THE POTENTIAL BENEFITS?

There may be no direct benefit to you if you take part in this study. However, the information learned in this study will help us to improve services for pregnant and postpartum women who are living with HIV in Cape Town and across South Africa.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

If you decide not to take part, you will continue your routine care as usual. Whether or not you decide to take part will not affect the standard health care services you receive, at this or at any other facility.

WHAT ABOUT CONFIDENTIALITY?

If you agree to take part, all information collected during the study will be kept strictly confidential. Your name will not be written on the study forms and will not be used in connection with any information that is collected as part of the study.

All study materials will be stored in locked filing cabinets. Only study staff will have access to these materials. All staff involved in data collection and management will get specific training in confidentiality.

Even with these procedures in place, if the study staff learn that you are a risk to yourself or someone else or of possible child abuse and/or neglect, study staff will tell the proper authorities.

WILL I BE GIVEN ANYTHING FOR TAKING PART?

Including today, there are three study visits to attend if you take part in the study. At the end of each study visit, you will be given R20 in cash for transport costs, and an R80 grocery voucher. Refreshments will be provided at all study visits. You will also receive a small gift for your baby, up to the value of R100, at the final study visit.

ARE THERE ANY COSTS?

There is no cost for being in this study.

CAN I LEAVE THE STUDY?

Participation in the study is fully voluntary. You have the right to decide whether or not to take part in the study, to refuse to answer any questions, or to withdraw from the study at any time without any penalty. It will have no effect on the care that you receive at the Gugulethu MOU or any other health facility.

DO YOU HAVE ANY QUESTIONS?

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

FOR ADDITIONAL INFORMATION:

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

Prof 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 any questions about your rights as a research participant, you may contact the following member of the Ethics committee:

Prof Marc Blockman

Chair, Human Research Ethics Committee

Faculty of Health Sciences, University of Cape Town

Tel: 021 406 6338

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 be in this study. I agree to allow the investigators to use my and my baby's provincial folder number (or name and date of birth) to request health information directly from the Department of Health. I know that after choosing to be in this study, I may withdraw at any time. My being in the study is voluntary. I understand that whether or not I participate 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

Staff member's name_____

_____

Signature of study staff Date

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 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 of witness_____

_____

Signature of witness Date

Thank you.

Appendix G: Parental Consent Form

TITLE OF RESEARCH:	**Peer support for young HIV+ pregnant & postpartum women**

WHAT IS THE PURPOSE OF THIS STUDY?
We are researchers from the University of Cape Town. Your daughter/this young woman is being invited to take part in a voluntary study that is being conducted at the Gugulethu Midwife Obstetric Unit (MOU). The purpose of this document is to give you information about the study. The purpose of this study is to compare two different options for support for young women who are living with HIV.

We know that many young women who are living with HIV experience challenges because of their HIV. Many women also experience challenges because of an unintended pregnancy, alcohol or other substance use, or mental health problems. This may make it difficult for women to attend their scheduled clinic visits and to take their medication. We would like to understand whether peer support groups for pregnant and postpartum women can help women to attend their clinic visits and take their medication.

Your daughter/this young woman is being asked to take part in this study because she is aged 16-24 years, living with HIV and receiving her pregnancy or postpartum care at the Gugulethu MOU.

WHAT DOES SHE HAVE TO DO IF SHE AGREES TO TAKE PART?
If she agrees to take part, she will be randomized (like the flip of a coin) to two different options:

3. Peer support group: Women assigned to this group will be invited to attend peer support groups and will be given the option of joining a WhatsApp group for peer support.
4. Comparison group: Women assigned to this group will continue to receive standard health care during pregnancy and postpartum, including routine HIV care, but will not attend any additional services.

"Randomized" means that she has a 50% chance of being in the group that will be invited to the peer support groups. She will also have a 50% chance of being in the group that receives standard health care during pregnancy and postpartum but does not receive any additional services. Neither the study staff nor your daughter/this young woman can choose which group she will be assigned to. The decisions are made by a computer and put into an envelope. The study staff do not know which group is in each envelope.

If she agrees to take part in this study, she will be asked to complete a study measurement visit today. Randomization will occur at the end of the study visit. She will then be asked to attend two additional study measurement visits: one after 3 months, and one after 6 months. Each visit will take between 1 and 2 hours.

At each visit she will be asked to answer questions. These will include questions about:

- Her health and her baby's health
- Challenges that she might be facing
- Living with HIV
- Attending scheduled clinic visits and taking her medication

As part of this study, we will also be looking at and taking information from her routine medical records, and the records of her baby. This will include information about her use of health services as well as ART clinic, laboratory and pharmacy records. We would like her permission to access

electronic databases that include all of these records. The Department of Health stores all of this information centrally at the Provincial Health Data Centre. We will use her and her baby's provincial folder number (or name and date of birth) to ask for this information directly from the Department of Health. All data that we review will be kept confidential. Her name and her baby's name will not be recorded with these records.

She will be asked to provide contact information so that we may get in touch with her during the study. Study staff will talk with her about the best way to contact her. If she misses one of her scheduled study visits, a staff member will contact her to find another day and time to complete her visit. If she repeatedly misses study visits or the study staff are unable to contact her using the information that she provides, it may be necessary to visit her at home to reschedule the missed study visit.

After the completion of her last visit after 6 months, it is possible that we will contact her again at her next clinic visit or at another time in the future to take part in additional research studies. At that time, she would be asked to review and sign another consent form. She can choose to not take part in any future studies if she is asked. She will be asked to provide contact information so that we may get in touch with her regarding additional research studies. Study staff will talk with her about the best way to contact her.

WHAT ARE THE POTENTIAL RISKS?
If she decides to take part, she may feel uncomfortable about some of the personal questions she is asked. She may refuse to answer any question that she does not want to answer. If any of the questions make her want to talk more with someone, we will refer her to counselling services either in the Gugulethu Community Health Centre or nearby organisations providing counselling and support services. There is some risk in sharing personal information. We will be careful to keep all her information as private as possible.

WHAT ARE THE POTENTIAL BENEFITS?
There may be no direct benefit to her if she takes part in this study. However, the information learned in this study will help us to improve services for pregnant and postpartum women who are living with HIV in Cape Town and across South Africa.

WHAT ARE THE ALTERNATIVES TO TAKING PART?
If she decides not to take part, she will continue her routine care as usual. Whether or not she decides to take part will not affect the standard health care services she receives, at this or at any other facility.

WHAT ABOUT CONFIDENTIALITY?
If she agrees to take part, all information collected during the study will be kept strictly confidential. Her name will not be written on the study forms and will not be used in connection with any information that is collected as part of the study.
All study materials will be stored in locked filing cabinets. Only study staff will have access to these materials. All staff involved in data collection and management will get specific training in confidentiality.

Even with these procedures in place, if the study staff learn that she is a risk to herself or someone else or of possible child abuse and/or neglect, study staff will tell the proper authorities.

WILL SHE BE GIVEN ANYTHING FOR TAKING PART?

Including today, there are three study visits to attend if she takes part in the study. At the end of each study visit, she will be given R20 in cash for transport costs, and an R80 grocery voucher. Refreshments will be provided at all study visits. She will also receive a small gift for her baby, up to the value of R100, at the final study visit.

ARE THERE ANY COSTS?
There is no cost for being in this study.

CAN SHE LEAVE THE STUDY?
Participation in the study is fully voluntary. She has the right to decide whether or not to take part in the study, to refuse to answer any questions, or to withdraw from the study at any time without any penalty. It will have no effect on the care that she receives at the Gugulethu MOU or any other health facility.

DO YOU HAVE ANY QUESTIONS?
If there is anything that is unclear or if you need further information, please ask us and we will provide it. Do you have any questions?

FOR ADDITIONAL INFORMATION:
If you have any questions or have any problems while your daughter/this young woman is taking part in this research study, you should contact:

Prof 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 any questions about her rights as a research participant, you may contact the following member of the Ethics committee:

Prof Marc Blockman
Chair, Human Research Ethics Committee
Faculty of Health Sciences, University of Cape Town
Tel: 021 406 6338

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 allow the participant to decide whether or not to be in this study.

Please indicate your consent with your signature.

Name _____

_____
Signature Date

Staff member's name_____

_____
Signature of study staff Date

If this adult 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 adult has given consent.

Fingerprint of adult:

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 this adult.

Name of witness_____

_____
Signature of witness Date

Thank you.

Appendix H: Minor Assent Form

TITLE OF RESEARCH:	**Peer support for young HIV+ pregnant & postpartum women**

WHAT IS THE PURPOSE OF THIS STUDY?
We are researchers from the University of Cape Town. You are being invited to take part in a voluntary study that is being conducted at the Gugulethu Midwife Obstetric Unit (MOU). This document is to help you decide if you would like to participate. The purpose of this study is to compare two different options for support for young women who are living with HIV.

We know that many young women who are living with HIV experience challenges because of their HIV. Many women also experience challenges because of an unintended pregnancy, alcohol or other substance use, or mental health problems. This may make it difficult for women to attend their scheduled clinic visits and to take their medication. We would like to understand whether peer support groups for pregnant and postpartum women can help women to attend their clinic visits and take their medication.

You are being asked to take part in this study because you are aged 16-24 years, living with HIV and receiving your pregnancy or postpartum care at the Gugulethu MOU. The purpose of this assent form is to give you information to help you decide if you want to take part in this study.

WHAT DO I HAVE TO DO IF I AGREE TO TAKE PART?
If you agree to take part, you will be randomized (like the flip of a coin) to two different options:

1. Peer support group: Women assigned to this group will be invited to attend peer support groups and will be given the option of joining a WhatsApp group for peer support.
2. Comparison group: Women assigned to this group will continue to receive standard health care during pregnancy and postpartum, including routine HIV care, but will not attend any additional services.

"Randomized" means that you have a 50% chance of being in the group that will be invited to the peer support groups. You will also have a 50% chance of being in the group that receives standard health care during pregnancy and postpartum but does not receive any additional services. Neither the study staff nor you can choose which group you will be assigned to. The decisions are made by a computer and put into an envelope. The study staff do not know which group is in each envelope.

If you agree to take part in this study, you will be asked to complete a study measurement visit today. Randomization will occur at the end of the study visit. You will then be asked to attend two additional study measurement visits: one after 3 months, and one after 6 months. Each visit will take between 1 and 2 hours.

At each visit you will be asked to answer questions. These will include questions about:

- Your health and your baby's health
- Challenges that you might be facing
- Living with HIV
- Attending scheduled clinic visits and taking your medication

As part of this study, we will also be looking at and taking information from your routine medical records, and the records of your baby. This will include information about your use of health services as well as ART clinic, laboratory and pharmacy records. We would like your permission to access electronic databases that include all of these records. The Department of Health stores all of this information centrally at the Provincial Health Data Centre. We will use your and your baby's

provincial folder number (or name and date of birth) to ask for this information directly from the Department of Health. All data that we review will be kept confidential. Your name and your baby's name will not be recorded with these records.

You will be asked to provide contact information so that we may get in touch with you during the study. Study staff will talk with you about the best way to contact you. If you miss one of your scheduled study visits, a staff member will contact you to find another day and time to complete your visit. If you repeatedly miss study visits or the study staff are unable to contact you using the information that you provide, it may be necessary to visit you at home to reschedule the missed study visit.

After the completion of your last visit after 6 months, it is possible that we will contact you again at your next clinic visit or at another time in the future to take part in additional research studies. At that time, you would be asked to review and sign another assent or consent form. You can choose to not take part in any future studies if you are asked. You will be asked to provide contact information so that we may get in touch with you regarding additional research studies. Study staff will talk with you about the best way to contact you.

WHAT ARE THE POTENTIAL RISKS?
If you decide to take part, you may feel uncomfortable about some of the personal questions you are asked. You may refuse to answer any question that you do not want to answer. If any of the questions make you want to talk more with someone, we will refer you to counselling services either in the Gugulethu Community Health Centre or nearby organizations providing counselling and support services. There is some risk in sharing personal information. We will be careful to keep all your information as private as possible.

WHAT ARE THE POTENTIAL BENEFITS?
There may be no direct benefit to you if you take part in this study. However, the information learned in this study will help us to improve services for pregnant and postpartum women who are living with HIV in Cape Town and across South Africa.

WHAT ARE THE ALTERNATIVES TO TAKING PART?
If you decide not to take part, you will continue your routine care as usual. Whether or not you decide to take part will not affect the standard health care services you receive, at this or at any other facility.

WHAT ABOUT CONFIDENTIALITY?
If you agree to take part, all information collected during the study will be kept strictly confidential. Your name will not be written on the study forms and will not be used in connection with any information that is collected as part of the study.
All study materials will be stored in locked filing cabinets. Only study staff will have access to these materials. All staff involved in data collection and management will get specific training in confidentiality.

Even with these procedures in place, if the study staff learn that you are a risk to yourself or someone else or of possible child abuse and/or neglect, study staff will tell the proper authorities.

WILL I BE GIVEN ANYTHING FOR TAKING PART?
Including today, there are three study visits to attend if you take part in the study. At the end of each study visit, you will be given R20 in cash for transport costs, and an R80 grocery voucher.

Refreshments will be provided at all study visits. You will also receive a small gift for your baby, up to the value of R100, at the final study visit.

ARE THERE ANY COSTS?
There is no cost for being in this study.

CAN I LEAVE THE STUDY?
Participation in the study is fully voluntary. You have the right to decide whether or not to take part in the study, to refuse to answer any questions, or to withdraw from the study at any time without any penalty. It will have no effect on the care that you receive at the Gugulethu MOU or any other health facility.

]DO YOU HAVE ANY QUESTIONS?
If there is anything that is unclear or if you need further information, please ask us and we will provide it. Do you have any questions?

FOR ADDITIONAL INFORMATION:
If you have any questions or have any problems while taking part in this research study, you should contact:

Prof 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 any questions about your rights as a research participant, you may contact the following member of the Ethics committee:

Prof Marc Blockman
Chair, Human Research Ethics Committee
Faculty of Health Sciences, University of Cape Town
Tel: 021 406 6338

ASSENT STATEMENT:
I have read this form, or someone has read it to me. I have been offered a copy of this assent form. I was encouraged and given time to ask questions. I agree to be in this study. I agree to allow the investigators to use my and my baby's provincial folder number (or name and date of birth) to request health information directly from the Department of Health. I know that after choosing to be in this study, I may withdraw at any time. My being in the study is voluntary. I understand that whether or not I participate will not affect my health care services received today, or at any time in the future.

Please indicate your assent with your signature.

Volunteer's name _____

_____

Signature of Volunteer Date

Staff member's name_____

_____
Signature of study staff Date

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 she has given assent.

Fingerprint of volunteer:

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

Name of witness_____

_____
Signature of witness Date

Thank you.

Appendix I: Unassisted Minor Assent Form

TITLE OF RESEARCH:	**Peer support for young HIV+ pregnant & postpartum women**

WHAT IS THE PURPOSE OF THIS STUDY?
We are researchers from the University of Cape Town. You are being invited to take part in a voluntary study that is being conducted at the Gugulethu Midwife Obstetric Unit (MOU). This document is to help you decide if you would like to participate. The purpose of this study is to compare two different options for support for young women who are living with HIV.

We know that many young women who are living with HIV experience challenges because of their HIV. Many women also experience challenges because of an unintended pregnancy, alcohol or other substance use, or mental health problems. This may make it difficult for women to attend their scheduled clinic visits and to take their medication. We would like to understand whether peer support groups for pregnant and postpartum women can help women to attend their clinic visits and take their medication.

You are being asked to take part in this study because you are aged 16-24 years, living with HIV and receiving your pregnancy or postpartum care at the Gugulethu MOU. The purpose of this assent form is to give you information to help you decide if you want to take part in this study.

WHAT DO I HAVE TO DO IF I AGREE TO TAKE PART?
If you agree to take part, you will be randomized (like the flip of a coin) to two different options:

3. Peer support group: Women assigned to this group will be invited to attend peer support groups and will be given the option of joining a WhatsApp group for peer support.
4. Comparison group: Women assigned to this group will continue to receive standard health care during pregnancy and postpartum, including routine HIV care, but will not attend any additional services.

"Randomized" means that you have a 50% chance of being in the group that will be invited to the peer support groups. You will also have a 50% chance of being in the group that receives standard health care during pregnancy and postpartum but does not receive any additional services. Neither the study staff nor you can choose which group you will be assigned to. The decisions are made by a computer and put into an envelope. The study staff do not know which group is in each envelope.

If you agree to take part in this study, you will be asked to complete a study measurement visit today. Randomization will occur at the end of the study visit. You will then be asked to attend two additional study measurement visits: one after 3 months, and one after 6 months. Each visit will take between 1 and 2 hours.

At each visit you will be asked to answer questions. These will include questions about:

- Your health and your baby's health
- Challenges that you might be facing
- Living with HIV
- Attending scheduled clinic visits and taking your medication

As part of this study, we will also be looking at and taking information from your routine medical records, and the records of your baby. This will include information about your use of health services as well as ART clinic, laboratory and pharmacy records. We would like your permission to access electronic databases that include all of these records. The Department of Health stores all of this information centrally at the Provincial Health Data Centre. We will use your and your baby's

provincial folder number (or name and date of birth) to ask for this information directly from the Department of Health. All data that we review will be kept confidential. Your name and your baby's name will not be recorded with these records.

You will be asked to provide contact information so that we may get in touch with you during the study. Study staff will talk with you about the best way to contact you. If you miss one of your scheduled study visits, a staff member will contact you to find another day and time to complete your visit. If you repeatedly miss study visits or the study staff are unable to contact you using the information that you provide, it may be necessary to visit you at home to reschedule the missed study visit.

After the completion of your last visit after 6 months, it is possible that we will contact you again at your next clinic visit or at another time in the future to take part in additional research studies. At that time, you would be asked to review and sign another assent or consent form. You can choose to not take part in any future studies if you are asked. You will be asked to provide contact information so that we may get in touch with you regarding additional research studies. Study staff will talk with you about the best way to contact you.

WHAT ARE THE POTENTIAL RISKS?
If you decide to take part, you may feel uncomfortable about some of the personal questions you are asked. You may refuse to answer any question that you do not want to answer. If any of the questions make you want to talk more with someone, we will refer you to counselling services either in the Gugulethu Community Health Centre or nearby organisations providing counselling and support services. There is some risk in sharing personal information. We will be careful to keep all your information as private as possible.

WHAT ARE THE POTENTIAL BENEFITS?
There may be no direct benefit to you if you take part in this study. However, the information learned in this study will help us to improve services for pregnant and postpartum women who are living with HIV in Cape Town and across South Africa.

WHAT ARE THE ALTERNATIVES TO TAKING PART?
If you decide not to take part, you will continue your routine care as usual. Whether or not you decide to take part will not affect the standard health care services you receive, at this or at any other facility.

WHAT ABOUT CONFIDENTIALITY?
If you agree to take part, all information collected during the study will be kept strictly confidential. Your name will not be written on the study forms and will not be used in connection with any information that is collected as part of the study.
All study materials will be stored in locked filing cabinets. Only study staff will have access to these materials. All staff involved in data collection and management will get specific training in confidentiality.

Even with these procedures in place, if the study staff learn that you are a risk to yourself or someone else or of possible child abuse and/or neglect, study staff will tell the proper authorities.

WILL I BE GIVEN ANYTHING FOR TAKING PART?
Including today, there are three study visits to attend if you take part in the study. At the end of each study visit, you will be given R20 in cash for transport costs, and an R80 grocery voucher.

Refreshments will be provided at all study visits. You will also receive a small gift for your baby, up to the value of R100, at the final study visit.

ARE THERE ANY COSTS?
There is no cost for being in this study.

CAN I LEAVE THE STUDY?
Participation in the study is fully voluntary. You have the right to decide whether or not to take part in the study, to refuse to answer any questions, or to withdraw from the study at any time without any penalty. It will have no effect on the care that you receive at the Gugulethu MOU or any other health facility.

DO YOU HAVE ANY QUESTIONS?
If there is anything that is unclear or if you need further information, please ask us and we will provide it. Do you have any questions?

FOR ADDITIONAL INFORMATION:
If you have any questions or have any problems while taking part in this research study, you should contact:

Prof 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 any questions about your rights as a research participant, you may contact the following member of the Ethics committee:

Prof Marc Blockman
Chair, Human Research Ethics Committee
Faculty of Health Sciences, University of Cape Town
Tel: 021 406 6338

ASSENT STATEMENT:
I have read this form, or someone has read it to me. I have been offered a copy of this assent form. I was encouraged and given time to ask questions. I agree to be in this study. I agree to allow the investigators to use my and my baby's provincial folder number (or name and date of birth) to request health information directly from the Department of Health. I know that after choosing to be in this study, I may withdraw at any time. My being in the study is voluntary. I understand that whether or not I participate will not affect my health care services received today, or at any time in the future.

Please indicate your assent with your signature.

Volunteer's name _____

_____

Signature of Volunteer Date

Please confirm that you chose to provide assent without parental consent.

Volunteer's name _____

_____
Signature of Volunteer Date

Staff member's name_____

_____
Signature of study staff Date

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 she has given assent.

Fingerprint of volunteer:

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

Name of witness_____

_____
Signature of witness Date

Thank you.

Appendix J: Ethical approval for the parent study (Masibambisane Girls)

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

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

03 July 2019

HREC REF: 267/2019

Prof L Myer
School of Public Health & Family Medicine
Room 5.51, CIDER
5th Floor, OMB

Dear Prof Myer

PROJECT TITLE: PEER SUPPORT TO MITIGATE THE IMPACT OF STIGMA IN YOUNG HIV + PREGNANT & POSTPARTUM WOMEN: PILOT STUDY (SUB-STUDY LINKED TO 371/2018)

Thank you for your response letter dated 11 June 2019, addressing the issues raised by the Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study, including the following documentation: -

1. Synopsis
2. Protocol, v 1.0 dated 27 April 2019
3. Informed consent documents: -
    - Informed consent form, version 1.1 dated 11 June 2019
    - Minor Assent, version 1.1, dated 11 June 2019
    - Unassisted minor assent form, version 1.1 dated 11 June 2019
    - Parental consent form, version 1.1, dated 11 June 2019
    - Informed consent form for in-depth interview at study exit, version 1.0, dated 27 April 2019
    - Minor assent form for in-depth interview at study exit, version 1.0, dated 27 April 2019
    - Unassisted minor assent form for in-depth interview at study exit, version 1.0, dated 27 April 2019
    - Parental consent form for in-depth interview at study exit, version 1.0, dated 27 April 2019
4. Questionnaires: -
    - Demographics, Visit 1, version 1.0, dated 19 April 2019
    - Partner questionnaire, Visit 1, version 1.0, dated 19 April 2019
    - Partner questionnaire Visits 2 & 3, version 1.0 dated 19 April 2019
    - Pregnancy intentions, Visit 1, version 1.0, dated 19 April 2019
    - Pregnancy intentions Visits 2 & 3, version 1.0, dated 19 April 2019
    - Mental health Visits 2 & 3, version 1.0, dated 19 April 2019
    - Child Questionnaire, Visit 1, version 1.0, dated 19 April 2019
    - Child Questionnaire Visits 2 & 3, version 1.0, dated 19 April 2019
    - Adverse Childhood Experiences, Visit 1, Version 1.0, dated 19 April 2019
    - Violence Against Women, Visit 1, version 1.0, dated 19 April 2019
    - Violence Against Women, Visits 2 & 3, version 1.0, dated 19 April 2019
    - EPDS, Visits 1, 2 & 3, version 1.0, dated 19 April 2019

- AUDIT, Visit 1, version 1.0, dated 19 April 2019
- AUDIT Visit 2 & 3, version 1.0 dated 19 April 2019
- DUDIT, Visit 1, version 1.0, dated 19 April 2019
- DUDIT, Visit 2 & 3, version 1.0, dated 19 April 2019
- Perceived Availability of Social Support, Visits 1, 2 & 3, version 1.0, dated19 April 2019
- Adherence Self-Efficacy, Visits 1, 2 & 3, version 1.0, dated 19 April 2019
- Adherence, Visit 1, version 1.0 dated, 19 April 2019
- Adherence Visits 2 & 3, version 1.0, dated 19 April 2019
- Disclosure, Visit 1, version 1.0, dated 19 April 2019
- Disclosure Visits 2 & 3, version 1.0, dated 19 April 2019
- Living with HIV, Visit 1, version 1.0, dated 19 April 2019
- Living with HIV, Visits 2 & 3, version 1.0, dated 19 April 2019

5. Interview guide for in-depth interview at study exit, version 1.0, dated 27 April 2019
6. Form A for non-therapeutic research with minors

Approval is granted for one year until the 30 July 2020.

Please submit a progress form, using the standardised Annual Report Form 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)

Please quote the HREC REF 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

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS 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 2006), 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.

Appendix K: Ethical approval for this dissertation

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

Room G50- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-enquiries@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

23 November 2020

HREC REF: 792/2020

Dr K Brittain
School of Public Health & Family Medicine
Level 5, Office, 5347, Entrance 5
Falmouth Building
Email: kirsty.brittain@uct.ac.za
Student: nhlsan001@myucyt.ac.za

Dear Dr Brittain

PROJECT TITLE: PSYCHOSOCIAL PREDICTORS OF HIV TREATMENT OUTCOMES AMONG YOUNG PREGNANT AND POSTPARTUM WOMEN LIVING WITH HIV-MASTERS CANDIDATE-MISS SANDISIWE NOHOLOZA-SUB-STUDY LINKED TO 267/2019

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.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020 & 06 July 2020.

Approval is granted for one year until the 30 November 2021.

Please submit a progress form, using the standardised Annual Report Form 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: Miss Sandisiwe Noholoza will also be involved in this study.

Please quote the HREC REF 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

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS 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 2006), 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.

3. Selected tables and figures

Appendix L – Sensitivity analysis 1

Bivariate analysis of associations between individual psychosocial risk factors and HIV treatment outcomes; engagement in care and viral load suppression at <50 copies/mL during the window of follow up.						
	Viral load suppression (<50 copies/mL) (N=58)		*Viral load suppression (<50 copies/mL) (N=114)		**Viral load suppression (<50 copies/mL) (N=114)	
	n (%)	p-value	n (%)	p-value	n (%)	p-value
Unintended pregnancy						
No	7 (87.5)		13 (92.9)		7 (50)	
Yes	38 (76)	0.669	88 (88)	1.000	38 (38)	0.390
Probable depression						
No	41 (77.4)		86 (87.8)		41 (41.8)	
Yes	4 (80)	1.000	15 (93.8)	0.690	4 (25)	0.273
Hazardous alcohol use						
No	36 (76.6)		81 (88)		36 (39.1)	
Yes	9 (81.8)	1.000	20 (90.9)	1.000	9 (40.9)	0.878
Intimate partner violence						
No	30 (76.9)		69 (88.5)		30 (38.5)	
Yes	15 (79)	1.000	32 (88.9)	1.000	15 (41.7)	0.745

Sensitivity analysis - *Analysis B: Bivariate analysis assuming that participants with missing viral load values are virally supressed (<50 copies/mL). **Analysis C: Bivariate analysis assuming that participants with missing viral load values have elevated viral loads (>50 copies/mL).

4. Instructions for authors for the target journal

AIDS and Behaviour:

Instructions for Authors

Manuscript Submission

Sign up for alerts

Seth C. Kalichman, Ph.D.

Center for HIV Prevention & Intervention

2006 Hillside Road, Unit 1248

University of Connecticut

Storrs, CT 06269

Email: aidsandbehavior@yahoo.com

Submission is a representation that the manuscript has not been published previously and is not currently under consideration for publication elsewhere. A statement transferring copyright from the authors (or their employers, if they hold the copyright) to Springer will be required before the manuscript can be accepted for publication. The

Editor will supply the necessary forms for this transfer. Such a written transfer of copyright, which previously was assumed to be implicit in the act of submitting a manuscript, is necessary under the U.S. Copyright Law in order for the publisher to carry through the dissemination of research results and reviews as widely and effectively as possible.

AIDS and Behavior now offers the opportunity to publish abstracts for articles in English and Spanish. Although not required, I am hoping that you will take advantage of this chance to broaden access of your work. If you would like to include your Abstract in Spanish, please be sure that your Abstract is in the proper format and finalized. Be sure to remove all subheadings from the Abstract so that it reads as a continuous narrative of no more than 150 words in English. Then translate your final Abstract into Spanish. Upload the English version in the Editorial Manager System step for Abstracts and include both the English and Spanish versions in your Manuscript file that you upload into the system. The two abstracts should be placed together, first the English followed by the Spanish on a separate pages. Label the Spanish version "Resumen".

Manuscripts should be submitted to the Editor through Springer's Editorial Manager peer review system at:

http://aibe.edmgr.com

Manuscript Preparation

- Type double-spaced on one side of 8 ½ × 11-inch white paper using generous margins on all sides, (including copies of all illustrations and tables).

- A title page is to be provided and should include the title of the article, authors name (no degrees), authors affiliation, and suggested running head, and Declarations. The affiliation should comprise the department, institution (usually university or company), city, and state (or nation) and should be typed as a footnote to the authors name. The suggested running

  head should be less than 80 characters (including spaces) and should comprise the article title or an abbreviated version thereof. For office purposes, the title page should include the complete mailing address, telephone number, fax number, and email address of the one author designated to review proofs.

- Declarations
  All manuscripts must contain the following sections on the Title Page under the heading 'Declarations'.

  If any of the sections are not relevant to your manuscript, please include the heading and write 'Not applicable' for that section.

  • Funding (information that explains whether and by whom the research was supported)

  • Conflicts of interest/Competing interests (include appropriate disclosures)

  • Ethics approval (include appropriate approvals or waivers)

  • Consent to participate (include appropriate consent statements)

  • Consent for publication (consent statement regarding publishing an individual's data or image)

  • Availability of data and material (data transparency)

  • Code availability (software application or custom code)

  • Authors' contributions

  Please see the relevant sections in the submission guidelines for further information.

- With the exception of Brief Reports and Behavioral Surveillance Reports, initial submissions to AIDS and Behavior do not have word or page limits. Briefer and more succinct papers tend to review better and papers may be reduced in length as part of the review process. However, the length of the original submission is left to author discretion.

- An abstract is to be provided, preferably no longer than 150 words.

- A list of 4-5 key words is to be provided directly below the abstract. Key words should express the precise content of the manuscript, as they are used for indexing purposes.
- All sections should carry headings (such as INTRODUCTION, METHODS, RESULTS, DISCUSSION, CONCLUSIONS, etc.), typed flush left. All acknowledgments (including those for grant and financial support) should be typed in one paragraph (so–headed) on a separate page, that directly precedes the References section.
- Illustrations (photographs, drawings, diagrams, and charts) are to be numbered in one consecutive series of Arabic numerals. The captions for illustrations should be typed on a separate sheet of paper. All illustrations must be complete and final, i.e., camera-ready. Photographs should be large, glossy prints, showing high contrast. Drawings should be high quality laser prints or should be prepared with india ink. Either the original drawings or good–quality photographic prints are acceptable. Artwork for each figure should be provided on a separate sheet of paper. Identify figures on the back with authors name and number of the illustration. Electronic artwork submitted on disk should be in the TIFF or EPS format (1200 dpi

for line and 300 dpi for halftones and grayscale art). Color art should be in the CYMK color space. Artwork should be on a separate disk from the text, and hard copy must accompany the disk.

- Tables should be numbered (with Roman numerals) and referred to by number in the text. Each table should be typed on a separate sheet of paper. Center the title above the table, and type explanatory footnotes (indicated by superscript lowercase letters) below the table.
- AIDS and Behavior does not have a limit on number of authors. However, if deemed to be excessive the editor may request author justifications and reductions.

AIDS and Behavior uses Vancouver style as outlined in the American Medical Association Manual of style: A Guide for Authors and Editors, 10th Edition.

A reference number is allocated to a source in the order in which it is cited in the text. In text, identify references as Arabic numerals in brackets (1). If the source is referred to again, the same number is used. References are listed in numerical order in the Reference List at the end of the paper. Do not alphabetize. Use abbreviated names of journals according to the journal list in PubMed. List all authors and/or editors up to 6; if more than 6, list the first 3 followed by "et al." The following are examples.

1) McKirnan DJ, Vanable PA, Ostrow DG, Hope B. Expectancies of sexual "escape" and sexual risk among drug and alcohol-involved gay and bisexual men. J Subst Abuse. 2001;13(1-2):137-54.

2) van der Straten A, Cheng H, Moore, J et al. The use of the diaphragm instead of condoms in a phase III diaphragm trial. AIDS Behav. 2009; 13(3):564-72.

3) Eaton LA, Kalichman SC. Changes in transmission risk behaviors across stages of HIV disease among people living with HIV. J Assoc Nurses AIDS Care. 2009 Jan-Feb;20(1):39-49.

4) Bangsberg D, Hecht F, Charlebois E, Chesney M, Moss A. Comparing objectives measures of adherence to HIV antiretroviral therapy: electronic medication monitors and unannounced pill counts. AIDS Behav 2001, 5:275–281.

5) Richman D, Bozzette S, Morton S, et al. The prevalence of antiretroviral drug resistance in the US. Interscience Conference on Antimicrobial Agents and Chemotherapy. Chicago, 2001 [abstract LB-17].

6) Hirsch MS, D'Aquila RT, Kaplan JC. Antiretroviral therapy. In: DeVita VT, Hellman S, Rosenberg SA, eds. AIDS: Biology, Diagnosis, Treatment and Prevention. 4th ed. Philadelphia, PA: Lippincott-Raven; 1997.

7) Ray SC. Simplot for Windows, version 2.5. Available at: http.//www.med.jhu.edu/deptmed/sray/download/. Accessed November 7, 2001.

Verify that every instance of a number in text corresponds to the numbered reference.

Footnotes should be avoided. When their use is absolutely necessary, footnotes should be numbered consecutively using Arabic numerals and should be typed at the bottom of the page to which they refer. Place a line above the footnote, so that it is set off from the text. Use the appropriate superscript numeral for citation in the text.

Source: https://www.springer.com/journal/10461/submission-guidelines