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Impact of Unintended Pregnancy on HIV Viral Load Outcomes among Postpartum Women Living With HIV in Cape Town, South Africa: Clues from Postpartum Adherence Clubs for Antiretroviral Therapy Trial.

by

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To the memory of my departed beloved mother,

Phyllis Kaambwa Mwalye.

PREAMBLE

DECLARATION

I, Pumulo Justine Mwalye (MWLPUM002), 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.

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Date: 3rd February 2022

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DISSERTATION ABSTRACT

Introduction: Postpartum women living with HIV (WLWHIV) on antiretroviral therapy (ART) are at high risk of viraemia. We examined the association between unintended pregnancy and HIV viral load (VL) at 24 months postpartum in Cape Town, South Africa.

Methods: Data are from a randomised trial that compared different ART delivery modalities for postpartum women aged at least 18 years who had initiated ART during their most recent pregnancy, had a VL<400 copies/ml in the previous three months, and had no comorbidities necessitating regular clinical follow-up. Pregnancy intentions regarding the most recent pregnancy were self-reported at enrolment into the study. VL was measured at 24 months postpartum, with elevated VL defined as VL≥1000 copies/ml. Chi-squared tests and logistic regression were used to examine predictors of unintended pregnancy. The impact of unintended pregnancy on elevated VL was examined using Poisson regression models.

Results: Among 411 women included in the analysis (mean age: 28.7 years, 42% married/cohabiting, 75% with a parity≥2, and 86% with a VL<50 copies/ml), 57% reported that their most recent pregnancy was unintended. Compared to women aged 18-24 years, older women had a lower relative odds of unintended pregnancy [25-28 years, adjusted odds ratio (AOR): 0.34; 95% confidence interval (CI): 0.17-0.70; 29-34 years, AOR: 0.18; CI: 0.08-0.37; and ≥35 years, AOR: 0.35; CI: 0.14-0.89]. Additionally, unintended pregnancy was associated with being unmarried/not cohabiting (AOR: 4.44; CI: 2.78-7.09) and with higher parity (compared to parity=1: parity=2, AOR: 3.47; 95% CI: 1.86-6.50; and parity≥3, AOR: 6.38; 95% CI: 3.06-13.28). VL data at 24 months postpartum were available for 89% (366/411) of participants of whom 24% had elevated VL≥1000 copies/ml. Unintended pregnancy was associated with elevated VL in unadjusted analyses [risk ratio (RR): 1.54; CI: 1.03-2.28; p=0.032]. After adjustment for maternal factors and trial allocation, the association persisted despite not reaching statistical significance (adjusted risk ratio (aRR): 1.36; CI: 0.88-2.08; p=0.158).

Conclusion: Among postpartum WLWHIV in South Africa, unintended pregnancy is prevalent and could be a risk factor for elevated VL. Reproductive health counselling and support during routine care visits may reduce unintended pregnancies and its effects.

ORGANISATION OF DISSERTATION

The dissertation is divided into three parts: Part A, B and C.

Part A is the research protocol outlining the study's overview with a literature review, rationale, objectives of the study, methods, ethical consideration and limitations of the study.

Part B is the manuscript whose format follows submission guidelines of a selected peer-reviewed journal. It gives the introduction, methodological details, results, discussion of findings and ends with a conclusion.

Part C is the appendices section which includes supplementary tables, ethics documentation and selected journal submission guidelines.

The style of referencing for the whole dissertation is Vancouver.

LIST OF ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal care
AOR	Adjusted odds ratio
aRR	Adjusted risk ratio
ART	Antiretroviral Therapy
CHC	Community Health Centre
CI	Confidence interval
HIV	Human Immunodeficiency Virus
MOU	Midwife Obstetric Unit
MTCT	Mother-to-child transmission
OR	Odds ratio
PACART	Postpartum Adherence Clubs for Antiretroviral Therapy
PLHIV	People living with HIV
PMTCT	Prevention of mother-to-child transmission
RR	Risk ratio
SRH	Sexual and Reproductive Health
SSA	sub-Saharan Africa
UNAIDS	Joint United Nations Programme on HIV/AIDS
VL	Viral load
WHO	World Health Organisation
WLWHIV	Women living with HIV

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PART A: PROTOCOL

1. Introduction

1.1 Overview

Despite a period of progress in terms of HIV incidence declines in highly burdened eastern and southern African countries, estimates from the Joint United Nations Programme on HIV/AIDS (UNAIDS) show that HIV transmission has plateaued overall [1]. According to data, women are disproportionately affected by HIV, particularly in sub-Saharan Africa (SSA), where roughly 56 percent of people living with HIV (PLHIV) are women [1]. South Africa has one of the highest rates of PLHIV in the world, with a nationwide HIV prevalence of 14% in 2017 [2, 3]. In 2018, females constituted roughly 63 percent (4,700,000) of the total adult HIV population in South Africa [1]. The World Health Organisation (WHO) issued guidelines ("Option B+") in 2015, recommending that all pregnant and breastfeeding women living with HIV (WLWHIV) start lifelong antiretroviral therapy (ART) regardless of CD4 cell count or WHO clinical disease stage [4]. In 2016, WHO announced guidelines advising a "treat all" strategy, recommending that all people diagnosed with HIV start treatment immediately [5]. Consequently, the number of reproductive-aged women on ART, irrespective of their pregnancy status, has increased [5].

The fundamental purpose of ART is to lower HIV transmission risk and promote health through viral load (VL) suppression, but in many countries, achieving and sustaining viral suppression while pregnant, during childbirth, and after giving birth remains a challenge [6, 7]. The largest HIV treatment program worldwide is in South Africa [8], but despite the increase in ART coverage in the country resulting from WHO policy, not all pregnant and postpartum WLWHIV have sustained VL suppression. Suboptimal VL suppression may lead to higher mother-to-child transmission (MTCT) risk and maternal disease progression [6], and so, maintaining high ART adherence levels and viral suppression throughout breastfeeding, where the risk of transmission is ongoing, is critical [9]. Failure to retain women in care and adherent to ART at optimal levels during the postpartum period is a common problem undermining sustained viral suppression [10]. Compared to the general adult population, pregnant and postpartum WLWHIV may be more prone to having poor ART adherence and engagement in HIV care [10-12], likely because of added stressors related to this stage of life [13]. During the postpartum period, retention of women on ART becomes worse with time as well as compared to during pregnancy as demonstrated by studies from routine care settings across Africa [14, 15]. In SSA, only about 50% of WLWHIV maintain viral suppression until 12 months postpartum [16]. Among women who achieve initial viral suppression in South Africa, about a third experience viraemia within 12 months postpartum, with episodes of viraemia being experienced repeatedly over time [6].

WLWHIV are as likely to experience pregnancy as any other woman of reproductive age. Worldwide, over 1.5 million WLWHIV become pregnant and give birth yearly, most of whom receive ART during pregnancy and are expected to continue lifelong ART in the postpartum period [17]. Furthermore, WLWHIV and those at risk of acquiring HIV face additional sexual and reproductive health (SRH)

challenges, such as the possibility of an unintended pregnancy [18]. Not only does SSA have the highest HIV prevalence rate, but it also has the highest number of women with unmet contraceptive needs [19]. Unintended pregnancy is not only a family planning concern but also a public health concern globally, including in the field of HIV.

1.2 Literature Review

1.2.1 Prevalence of Unintended Pregnancy among WLWHIV

Unintended pregnancy is common among WLWHIV over the world, but the prevalence varies greatly by country. The 2014 global survey on SRH and Human Rights of WLWHIV, led by and conducted among WLWHIV, indicates that three out of every five women had at least one unplanned pregnancy during their lifetime, and less than 50% had ever accessed family planning services [20]. Data from Western countries has revealed that WLWHIV are now more likely to have children than they were earlier in the epidemic and that their unintended pregnancy rates are higher as opposed to those of HIV-negative women [21]. In the United States, for example, episodes of unintended pregnancy after HIV diagnosis are common with close to 80% being reported as unintended [22].

Studies done in SSA have also reported high prevalence of unintended pregnancies among WLWHIV. In a Malawian study assessing 220 pregnant WLWHIV who attended antenatal care (ANC) at a government hospital, 75% reported that they had unintended current pregnancies [23]. In a study conducted in Nigeria, 37% of 180 pregnant WLWHIV stated that their current pregnancy was unintended [24]. A study in Kenya looking at attitudes towards family planning among pregnant WLWHIV indicates that 59% had their current pregnancy unintentionally [25]. In Zimbabwe, a study looking at unmet need for family planning, contraceptive failure, and unintended pregnancy among WLWHIV and HIV-negative women found that out of 1059 postpartum WLWHIV, 45% had their most recent pregnancy unintended, while 34% of HIV-negative women reported having had an unintended pregnancy [26]. Similar studies in Uganda, Malawi, Swaziland, and Botswana showed prevalences of unintended pregnancy of 45%, 49%, 67%, and 44%, respectively [27-30]. In South Africa, fewer than 30% of pregnancies among WLWHIV are reported to have been planned [31, 32].

1.2.2 Predictors of Unintended Pregnancy among WLWHIV

Pregnancy intentions are shaped by a myriad of factors, including demographic, socio-economic, behavioural and health system-related factors. Age, marital status, and parity have been associated with unintended pregnancy [29, 30, 32-35]. Findings in a Tanzanian study indicate that there is an increasing risk of unplanned pregnancy with increasing age [36]. On the contrary, some studies in South Africa and Ghana have found an inverse relationship between age and unintended pregnancy [31, 37, 38]. In research conducted in South Africa by Brittain et al. and Haffejee et al., no association was found between age and pregnancy intendedness [39, 40]. These differences could be attributed to the different settings in which the studies were conducted. Being single is associated with unintended pregnancy,

according to findings from a Tanzanian study by Exavery and colleagues [41]. A study conducted by Haffejee et al. in South Africa indicates that women who are single and unemployed have higher chances of experiencing unintended pregnancies than those who are married and employed [40]. On the contrary, Nyarko found that married women in Ghana had higher risk of unintended pregnancy than those not married [38].

In research conducted by Warren et al. and Mayondi et al. in Swaziland and Botswana respectively, low education levels were linked to an increased risk of unintended pregnancy [29, 30]. In contrast, Ikamari and colleagues in their study in Kenya-Nairobi, found no association between formal education and pregnancy intention [42]. Some research findings in South Africa and developing countries show that income is associated with unintended pregnancy, with low-income women having a higher likelihood of experiencing an unintended pregnancy, as opposed to women with high income [34, 43, 44]. Findings from a study in South Africa show that women who consumed alcohol had a higher likelihood of reporting unintended pregnancy as opposed to non-consumers of alcohol [39]. On the other hand, Haffejee et al. found no significant association between alcohol intake and pregnancy intention in their study conducted in KwaZulu-Natal, South Africa [40].

At the health system level, SRH services play a vital role in preventing unintended pregnancies. Ensuring that WLWHIV have access to both ART and reproductive health services, preferably within the same health facility, is therefore key. Tweya and colleagues, in their study in Malawi attest that HIV care provision (including ART) together with family planning (including choice of contraceptive methods) may have helped avert unintended pregnancies among WLWHIV [45]. In many countries, however, SRH and HIV services remain isolated [46], contributing to high rates of unintended pregnancy among WLWHIV. The high unintended pregnancy levels in South Africa may be due to slow implementation of policies and guidelines to support and promote the integration of SRH-HIV services, and in practice, culminating in limited integration of SRH and HIV services [47]. In addition, health care providers do not often engage patients living with HIV in discussions relating to pregnancy intentions and/or contraceptive use, and even if they do, they do not go in depth [48].

1.2.3 Comparison of VL Outcomes in Women with Unintended Pregnancy versus Women with Intended Pregnancy

There is some evidence that an unintended pregnancy may lead to poorer ART outcomes, although this association has been insufficiently explored. Brittain and colleagues postulate that among women starting ART antenatally, unplanned pregnancy may commonly increase the chances of having elevated VL in the long-term [39]. A cohort study was conducted retrospectively in the United States among WLWHIV receiving ANC and giving birth at a single tertiary centre between 2007 and 2014. The results of this study show that women with unplanned pregnancy were less likely to have viral suppression at delivery than those with a planned pregnancy; this finding persisted even when potential confounders were accounted for [49]. In addition, following entry into ANC, the median duration until

stable viral suppression for women with an unintended pregnancy was longer as opposed to their counterparts and this persisted in multivariable analyses [49]. In a South African study looking at suboptimal adherence and elevated VL at a primary care clinic, unintended pregnancy was shown to be independently associated with elevated VL when entering ANC among women who were already on ART [50]. In a prospective study of 459 postpartum WLWHIV in Gugulethu, the percentage of women whose VL was elevated increased over time, with women reporting an unintended pregnancy having a higher likelihood of elevated VL than those reporting an intended pregnancy [39].

1.3 Rationale

Although earlier studies have looked at the prevalence and predictors of unintended pregnancy among WLWHIV in various contexts, the question of whether unintended pregnancy has an impact on HIV VL outcomes among postpartum WLWHIV has not been widely explored. Therefore, this study aims to address this research gap by examining the association between unintended pregnancy and HIV VL in a prospective cohort of postpartum WLWHIV in South Africa.

1.4 Purpose of study

To assess the impact of unintended pregnancy on HIV VL outcomes at 24 months postpartum in a South African cohort of postpartum WLWHIV who started ART during pregnancy using secondary data.

1.5 Specific Objectives

1. Examine the prevalence of unintended pregnancy among WLWHIV in the population of interest.
2. Identify the predictors of unintended pregnancy among WLWHIV in the population of interest.
3. Compare VL outcomes at 24 months in WLWHIV who had unintended pregnancies versus those who had intended pregnancies.

1.6 Conceptual Framework

Through a review of the literature, a conceptual framework has been developed and will serve as the basis for the overall study. Variables associated with unintended pregnancy include socio-economic and demographic factors like maternal age, parity, marital status (otherwise referred to as relationship status), education, employment status and type of housing, behavioural factors including alcohol consumption and/or drug use, and health system-related factors which include access to SRH/family planning and contraceptive use. These factors have the potential to confound/modify the relationship between pregnancy intention and HIV VL outcomes. Although access to SRH is a critical determinant of unintended pregnancy, it will not be looked at in this analysis because participants contributing data to this analysis were all recruited from the same clinic, thus it is assumed that all of the women had

equal access to SRH services. Alcohol use will also not be included in this analysis as we do not have data on alcohol use prior to pregnancy.

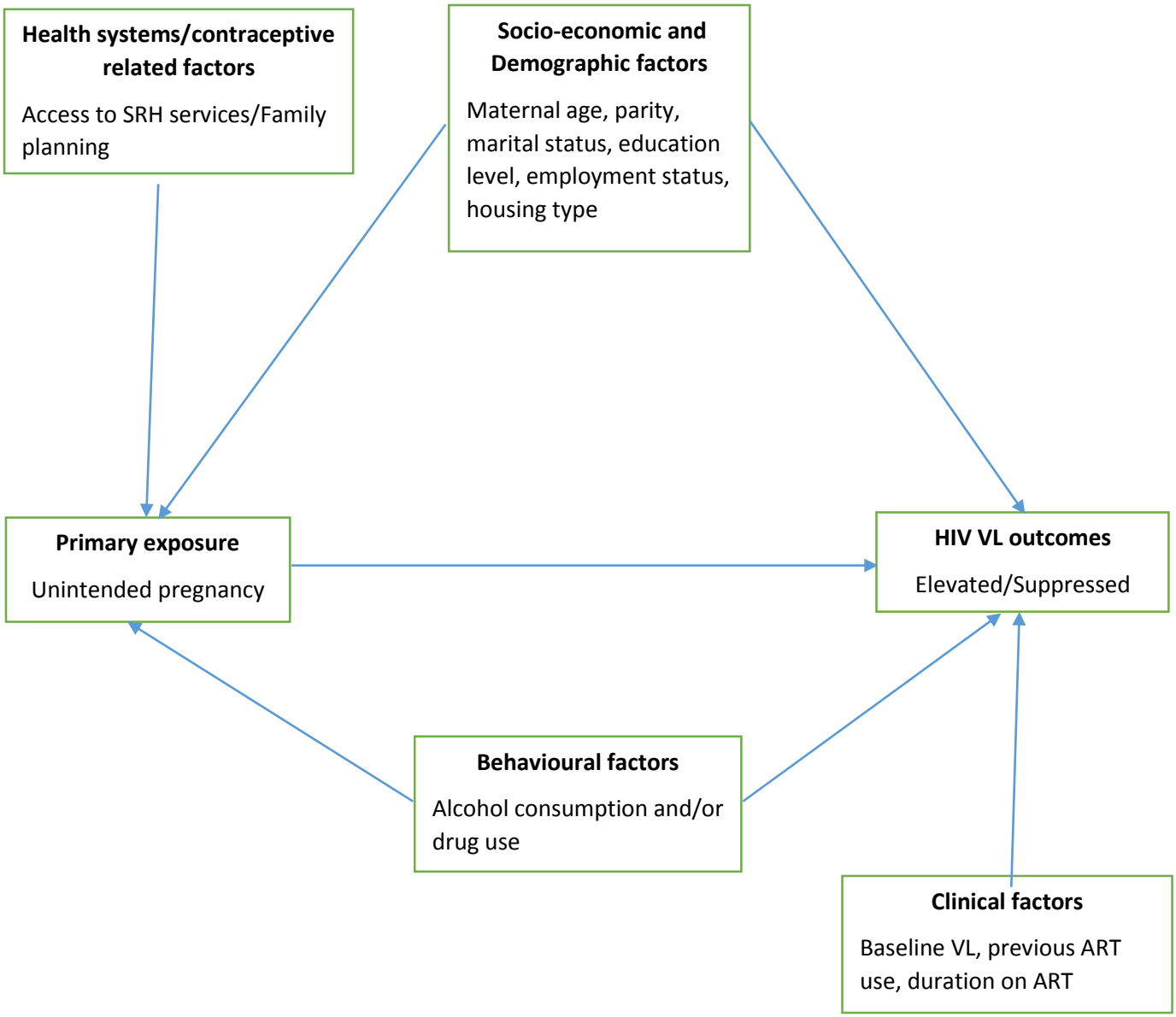

Figure 1: Conceptual framework

2. Methods

The proposed study will be an analysis of data that was collected during the PACART study. The PACART study's main characteristics are described in section 2.1. The proposed approach for the secondary analysis is given in section 2.2.

2.1. PACART Study

PACART is a pragmatic randomised controlled trial with longitudinal follow-up comparing maternal HIV viral suppression in women randomised to a differentiated ART service ("adherence club"; intervention) versus the standard of care (general adult ART clinic; control). The study's aim was to conduct an evaluation of two alternative approaches to HIV care and treatment provision for postpartum WLWHIV who had started ART antenatally [51]. The study was conducted at the Gugulethu Community Health Centre (CHC) in Cape Town, together with its related Midwife Obstetric Unit (MOU). The CHC is a primary care facility within the public sector, serving a low socioeconomic status population of around 350,000 people [52]. Incorporated within the CHC is an ART clinic that provides the general adult population with HIV care. Nurse-midwives run the MOU which provides ANC, obstetric services, postnatal care and PMTCT services to over 4000 women yearly [53].

2.1.1. Study Population

The study included WLWHIV who were at least 18 years old, were within 70 days postpartum, and had a live infant at the time of being screened. Other criteria for inclusion were having a suppressed VL (VL < 400 copies/ml) in the previous three months and no comorbidities necessitating regular clinical follow-up. Those with intentions of leaving Cape Town while the study was ongoing as well as those who had lost their infant/foetus were excluded from the study [51].

2.1.2 Sampling and Sample Size

Women were recruited at either postnatal clinic visits or at postpartum visits to the MOU ART clinic. Basic information about the study was provided to consecutive potentially eligible women who, if interested, were screened. Those eligible and potentially interested went through the informed consent process conducted by study counsellors. Women who consented underwent enrolment interviews and VL testing after which they were randomized to either the adherence club (intervention) or the general adult ART clinic (control). In total, 412 participants were enrolled into the study [51].

2.1.2.1 Description of Study Arms

For the intervention arm, referral of women from the MOU ART service to the adherence clubs was done postnatally. Every two months, a club visit was scheduled for an approximate one-hour session and these club visits were group-based with a community health worker attending all visits. A nurse conducted a clinical assessment and VL testing once a year. Referrals to the general adult clinic were made for participants with clinical complications.

For the control arm, the initial visit to the general adult ART clinic was usually within four weeks of being referred out from the MOU ART clinic. For the first four months, follow-up visits were scheduled at least once a month. Additional visits took place every two months for medication refills. Clinician review was scheduled six monthly. Routine laboratory investigations included VL testing, which was performed at four and twelve months after starting ART and yearly afterwards.

2.1.3. Data Collection

Participants in either arm were required to attend study measurement visits scheduled at 3, 6, 12, 18, and 24 months postpartum, in addition to the enrolment visit. These visits were conducted separately from the usual ART service sessions. Questionnaires were administered at every study visit for the purpose of collecting data on demographics, medical history, ART adherence and a range of other measures (see appendix A for maternal demographics questionnaire). There was a family planning and pregnancy intentions questionnaire which included such questions as: - "Which family planning methods did you use prior to your last pregnancy?", "In the 12 months before this last pregnancy, which family planning methods did you use?" and "Were you trying to have a baby when you found out you were pregnant (in your most recent pregnancy)?" (See appendix B for family planning and pregnancy intentions questionnaire) Collection of participants' blood samples was done at each study visit to measure VL; this was different from usual clinical monitoring, with the South African National Health Laboratory Services carrying out batch testing using the Abbott Realtime HIV-1 assay (Abbott Laboratories, Waltham, MA).

2.2 The Present Study

2.2.1 Study Design

The proposed study will be a secondary analysis of longitudinal data examining the association between unintended pregnancy and HIV VL outcomes at 24 months postpartum.

2.2.2 Study Population

All women enrolled in the PACART study will be included except those who withdrew. Subsequent analyses will not include those who had missing HIV VL at 24 months postpartum.

2.2.3 Sampling and Sample Size

Because this is a secondary analysis of data, no sample size calculation is required.

2.2.4 Variables

For the present analysis, there will be no additional measurements done. All data to be analysed will come from measurements taken in the PACART trial. Only a subset of indicators will be considered and some will be recoded where necessary. The primary dependent variable in this study is HIV VL at 24 months postpartum binarised as either elevated VL (defined as VL $\geq$ 1000 copies/ml) or suppressed VL (defined as VL < 1000 copies/ml). The choice of VL threshold was made on the basis of international and local policies for viraemia requiring clinical intervention [5, 54]. The primary exposure of interest is pregnancy intention dichotomized as unintended or intended. Other variables that may be of importance in this study are shown in table 1.

Table 1: Selected variables for inclusion in analysis

Variable	Operational Definition	Form/Scale	Possible values
Maternal age	Age of mother in completed years but categorized in age groups for analysis purposes	Categorical - ordinal	18 – 24 years, 25 – 28 years, 29 – 34 years, ≥35 years
Parity	Number of children woman has ever had	Numerical - discrete	1 2 ≥3
Maternal education	Whether woman has completed any high school or not	Categorical - binary	Completed any high school, not completed any high school
Relationship status	Woman's relationship status in terms of whether she is married/cohabiting or not.	Categorical - binary	Married or cohabiting, Unmarried and not cohabiting
Employment status	Whether woman is employed or not and categorized as employed and unemployed	Categorical - binary	Employed, Unemployed
Live in informal housing	Whether or not woman lives in an informal type of housing	Categorical - ordinal	No, Yes
Baseline viral load	Woman's viral load at enrolment	Categorical - binary	<50 copies/ml, ≥50 copies/ml
Previous ART use	Whether or not woman was on ART before index pregnancy	Categorical - binary	No, Yes
Duration on ART	Months on ART at the time of viral load assessment	Continuous	24+

2.2.5 Data Management and Analysis

Data management and ownership will remain with the investigators of the parent study. For this project, all programming scripts and workflows will be stored on a personal repository with back up on external drives. An up to date version of Stata or R software will be used to analyse the data. To begin with, exploratory statistics and data cleaning will be performed. To examine the overall prevalence of unintended pregnancy in the sample (Objective 1), simple descriptive analyses will be performed (see table 2).

Table 2: Descriptive statistics of postpartum WLWHIV overall and stratified by pregnancy intendedness (dummy table)

Variable	Total, n (%)	Intended, n (%)	Unintended, n (%)
Number of women			
Mean age (SD)			
Maternal age (years)			
18 – 24			
25 – 28			
29 – 34			
≥35			
Parity			
1			
2			
≥3			
Relationship status			
Married or Cohabiting			
Unmarried/ not cohabiting			
Maternal Education			
Completed any high school			
Not completed high school			
Employment status			
Employed			
Unemployed			
Live in informal housing			
No			
Yes			
Baseline VL			
<50 copies/ml			
≥50 copies/ml			
Previous ART use			
No			
Yes			
Trial allocation			
Clinic			
Club			

n= frequency, SD=Standard deviation, VL= viral load, ART=antiretroviral therapy

Factors associated with unintended pregnancy (Objective 2) will be examined using Chi-squared tests and logistic regression. Baseline characteristics of women retained in the study and had VL data available at 24 months postpartum will be compared with those of women who were lost from the study using chi-squared tests. To compare HIV VL outcomes among women with intended pregnancy and those with unintended pregnancy (Objective 3), modified Poisson regression models with robust error variance will be built, taking into account potential confounders and diagnostic model checks performed. Demographic, socio-economic and biological variables will be adjusted for (model 1) and random allocation will also be adjusted for (model 2) to account for intervention effects. (See table 3 for unadjusted and adjusted analyses). Because of the potential for effect modification, stratified analyses (stratified by clinical factors-baseline VL, previous ART use and duration on ART) will be done. For all statistical tests a two-tailed significance level will be set at 5% ($p \leq 0.05$).

Table 3: Relationship between pregnancy intendedness and HIV VL of 1000 or more copies/ml at 24 months postpartum from adjusted and unadjusted models

Variables	Unadjusted models		Adjusted model 1*		Adjusted model 2**	
	RR(95% CI)	*P* value	aRR(95% CI)	*P* value	aRR(95% CI)	*P* value
Pregnancy intention (versus intended)						
Unintended						
Maternal age (versus 18 -24)						
25 – 28						
29 – 34						
≥35						
Parity (versus 1)						
2						
≥3						
Relationship status (versus Married or cohabiting)						
Unmarried/not cohabiting						
Maternal Education (versus Completed any high school)						
Not completed high school						
Employment status (versus Employed)						
Unemployed						
Live in informal housing (versus No)						
Yes						
Baseline VL (versus <50 copies/ml)						
≥50 copies/ml						
Previous ART use (versus No)						
Yes						
Months on ART at time of VL assessment						
Trial allocation						
Clinic						
Club						

*Model 1 adjusted for demographic, socio-economic and clinical variables, **Model 2 adjusted for all those in model 1 plus random allocation, VL=viral load, ART=antiretroviral therapy,
RR, Risk ratio; 95% CI, 95% Confidence interval,
aRR, adjusted risk ratio; VL, viral load

Sensitivity analysis will be done to determine whether any observed association is consistent at alternate VL outcome levels of ≥50 copies/ml and ≥400 copies/ml respectively.

3. Presentation and Dissemination of Study Findings

Study findings will be submitted in partial fulfilment of the requirements of the Master of Public Health degree, and will be made available to the University of Cape Town Bongani Mayosi Health Sciences library following examination. Results will also be submitted for publication in open source peer-reviewed journals specifically in the field of Epidemiology and Biostatistics, and presented to appropriate meetings should need arise.

4. Study Limitations

Since the study uses data from PACART, which is prospective in nature, there is a likelihood of bias arising from incomplete follow-up. Secondary data is limited to characteristics collected in the primary

trial; hence some potential confounding variables may be unavailable. Additionally, pregnancy intention is a complex construct to measure and in most cases, as in PACART, it is self-reported hence data on pregnancy intentions may not be accurate. Also, the study focus is only on one area (Gugulethu) which may make it difficult to generalize study findings and conclusions. Further, the study is not intended to include other maternal health care issues (e.g abortions and maternal depression resulting from unintended pregnancy) which are significant for maternal and child health.

5. Ethical Consideration

The parent study was approved by the Human Subjects Research Ethics Committee at the University of Cape Town (REF 194/2015) (see appendices C to F) and also by the local government and the facility manager. Prior to recruitment and randomization, the informed consent process was conducted in isiXhosa language (see appendix G for details on informed consent). Sufficient information was provided by counsellors and women were allowed to ask questions to allow them to make informed decisions and provide informed consent. The informed consent process was conducted in a private room. Unique participant identifiers were used for the purposes of anonymity. The present study will receive unidentified data as identifiers are not needed for this analysis. All data provided by the study team will be password protected, minimizing the risk of confidentiality issues. Approval to conduct this study will be sought from the Human Research Ethics Committee at the University of Cape Town.

6. Risks and Benefits

Despite this being secondary data analysis, there is potential risk of participants being identified and sensitive information being disclosed. In order to de-identify participants, data anonymisation using unique participant identifiers and data confidentiality through password use will be enforced. While there are no direct benefits to participants, there may be future, indirect benefits for participants and the general population through the knowledge to be generated by this research. The knowledge gained could inform policy makers and health service providers of areas needing intervention such as improving access to SRH services or providing enhanced support to women reporting that their pregnancy was unintended. This could result in improved maternal and child health.

7. Timeline

Table 4: Proposed timeline for the study

ACTIVITY	2021			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Literature review and ethics approval				
Data cleaning and analysis				
First dissertation draft				
Second draft				
Final draft and submission				

8. Budget

Minimal financial resources will be required because the study involves secondary data only. The dataset will be made available at no cost for research purposes. The University of Cape Town offers provision for supervision and support as part of the Master of Public Health programme for which the dissertation is a constituent element.

9. References

1. UNAIDS. HIV and AIDS Estimates UNAIDS; 2018 [updated 2018. Available from: https://www.unaids.org/en/regionscountries/countries/southafrica.
2. Simbayi L, Zuma K, Zungu N, Moyo S, Marinda E, Jooste S, et al. South African national HIV prevalence, incidence, behaviour and communication survey, 2017 Cape Town: Human Sciences Research Council; 2019.
3. South Africa Demographic and Health Survey 2016. [Internet]. NDoH, Stats SA, SAMRC and ICF. 2019 [cited 3rd December, 2020].
4. World Health Organisation. Guideline on When to Start Antiretroviral Therapy and on Pre-Exposure Prophylaxis for HIV Geveva, Switzerland: WHO; 2015 [Available from: http://ezproxy.uct.ac.za/login?url=https://search.ebscohost.com/login.aspx?direct=true&db=cmedm&AN=26598776&site=ehost-live.
5. World Health Organisation. Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach. Geneva: World Health Organization; 2016.
6. Myer L, Dunning L, Lesosky M, Hsiao N-Y, Phillips T, Petro G, et al. Frequency of Viremic Episodes in HIV-Infected Women Initiating Antiretroviral Therapy During Pregnancy: A Cohort Study. Clin Infect Dis. 2017;64(4):422-7.
7. Chetty T, Newell M-L, Thorne C, Coutsoudis A. Viraemia before, during and after pregnancy in HIV-infected women on antiretroviral therapy in rural KwaZulu-Natal, South Africa, 2010–2015. Trop Med Int Health 2018;23(1):79-91.
8. UNAIDS. Global information and education on HIV and AIDS: UNAIDS; 2020 [Available from: https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/south-africa.
9. Myer L, Essajee S, Broyles LN, Watts DH, Lesosky M, El-Sadr WM, et al. Pregnant and breastfeeding women: A priority population for HIV viral load monitoring. PLOS med. 2017;14(8):e1002375.
10. Tenthani L, Haas AD, Tweya H, Jahn A, van Oosterhout JJ, Chimbwandira F, et al. Retention in care under universal antiretroviral therapy for HIV-infected pregnant and breastfeeding women ('Option B+') in Malawi. Aids. 2014;28(4):589-98.
11. Nachega JB, Uthman OA, Anderson J, Peltzer K, Wampold S, Cotton MF, et al. Adherence to antiretroviral therapy during and after pregnancy in low-income, middle-income, and high-income countries: A systematic review and meta-analysis. AIDS. 2012;26(16):2039-52.
12. Cichowitz C, Mazuguni F, Minja L, Njau P, Antelman G, Ngocho J, et al. Vulnerable at Each Step in the PMTCT Care Cascade: High Loss to Follow Up During Pregnancy and the Postpartum Period in Tanzania. AIDS and Behavior. 2019;23(7):1824-32.
13. Knettel BA, Cichowitz C, Ngocho JS, Knippler ET, Chumba LN, Mmbaga BT, et al. Retention in HIV Care during Pregnancy and the Postpartum Period in the Option B+ Era: Systematic Review and Meta-Analysis of Studies in Africa. J Acquir Immune Defic Syndr. 2018;77(5):427-38.
14. Phillips T, Thebus E, Bekker L-G, McIntyre J, Abrams EJ, Myer L. Disengagement of HIV-positive pregnant and postpartum women from antiretroviral therapy services: a cohort study. J Int AIDS Soc. 2014;17(1):19242.
15. Haas AD, Tenthani L, Msukwa MT, Tal K, Jahn A, Gadabu OJ, et al. Retention in care during the first 3 years of antiretroviral therapy for women in Malawi's option B+ programme: an observational cohort study. Lancet HIV. 2016;3(4):e175-e82.
16. Abuogi LL, Humphrey JM, Mpody C, Yotebieng M, Murnane PM, Clouse K, et al. Achieving UNAIDS 90-90-90 targets for pregnant and postpartum women in sub-Saharan Africa: progress, gaps and research needs. J Virus Erad. 2018;4(Suppl 2):33-9.
17. Prevention of mother-to-child transmission (PMTCT): situation and trends. Global Health Observatory (GHO) Data. [Internet]. WHO. 2018 [cited 28 February, 2020.]. Available from: http://www.who.int/gho/hiv/epidemic_response/PMTCT_text/en/.

18. Loutfy M, Khosla R, Narasimhan M. Advancing the sexual and reproductive health and human rights of women living with HIV. J Int AIDS Soc. 2015;18(Suppl 5):20760.
19. United Nations Fund for Population Activities. Universal Access to Reproductive Healthcare: Progress and Challenges New York: UNFPA; 2016 [Available from: https://www.unfpa.org/publications/universal-access-reproductive-health-progress-and-challenges.
20. Narasimhan M, Orza L, Welbourn A, Bewley S, Crone T, Vazquez M. Sexual and reproductive health and human rights of women living with HIV: a global community survey. Bull World Health Organ. 2016;94(4):243-9.
21. Salters K, Loutfy M, De Pokomandy A, Money D, Pick N, Wang L, et al. Pregnancy incidence and intention after HIV diagnosis among women living with HIV in Canada. PLoS One. 2017;12(7).
22. Sutton MY, Zhou W, Frazier EL. Unplanned pregnancies and contraceptive use among HIV-positive women in care. PLoS One. 2018;13(5):e0197216.
23. O'Shea MS, Rosenberg NE, Tang JH, Mukuzunga C, Kaliti S, Mwale M, et al. Reproductive intentions and family planning practices of pregnant HIV-infected Malawian women on antiretroviral therapy. AIDS Care. 2016;28(8):1027-34.
24. Ezugwu EC, Iyoke CA, Nkwo PO, Ezegwui HU, Akabueze JC, Agu PU. Unintended pregnancy among HIV-positive pregnant women in Enugu, southeast Nigeria. Int J Gynaecol Obstet. 2016;132(1):60-3.
25. Akelo V, Girde S, Borkowf CB, Angira F, Achola K, Lando R, et al. Attitudes toward Family Planning among HIV-Positive Pregnant Women Enrolled in a Prevention of Mother-To-Child Transmission Study in Kisumu, Kenya. PLoS One. 2013;8(8):1-9.
26. McCoy SI, Buzdugan R, Ralph LJ, Mushavi A, Mahomva A, Hakobyan A, et al. Unmet Need for Family Planning, Contraceptive Failure, and Unintended Pregnancy among HIV-Infected and HIV-Uninfected Women in Zimbabwe. PLoS ONE. 2014;9(8):1-8.
27. Gutin SA, Namusoke F, Shade SB, Mirembe F. Fertility Desires and Intentions among HIV-Positive Women during the Post-natal period in Uganda. Afr J Reprod Health. 2014;18(3):67-77.
28. O'Shea MS, Rosenberg NE, Hosseinipour MC, Stuart GS, Miller WC, Kaliti SM, et al. Effect of HIV status on fertility desire and knowledge of long-acting reversible contraception of postpartum Malawian women. AIDS Care. 2015;27(4):489-98.
29. Warren CE, Abuya T, Askew I. Family planning practices and pregnancy intentions among HIV-positive and HIV-negative postpartum women in Swaziland: a cross sectional survey. BMC Pregnancy & Childbirth. 2013;13(1):1-10.
30. Mayondi GK, Wirth K, Morroni C, Moyo S, Ajibola G, Diseko M, et al. Unintended pregnancy, contraceptive use, and childbearing desires among HIV-infected and HIV-uninfected women in Botswana: across-sectional study. BMC Public Health. 2016;16:44.
31. Adeniyi OV, Ajayi AI, Moyaki MG, Goon DT, Avramovic G, Lambert J. High rate of unplanned pregnancy in the context of integrated family planning and HIV care services in South Africa. BMC Health Serv Res. 2018;18(1).
32. Iyun V, Brittain K, Phillips TK, Le Roux S, McIntyre JA, Zerbe A, et al. Prevalence and determinants of unplanned pregnancy in HIV-positive and HIV-negative pregnant women in Cape Town, South Africa: A cross-sectional study. BMJ Open. 2018;8(4).
33. Eliason S, Baiden F, Yankey BA, Awusabo-Asare K. Determinants of unintended pregnancies in rural Ghana. BMC Pregnancy & Childbirth. 2014;14(1):1-9.
34. Ali SA, Ali SA, Khuwaja NS. Determinants of Unintended Pregnancy among Women of Reproductive Age in Developing Countries: A Narrative Review. Journal of Midwifery & Reproductive Health. 2016;4(1):513-21.
35. Mohammed F, Musa A, Amano A. Prevalence and determinants of unintended pregnancy among pregnant woman attending ANC at Gelemso General Hospital, Oromiya Region, East Ethiopia: a facility based cross-sectional study. BMC women's health. 2016;16(1):56.

36. Calvert C, Baisley K, Doyle AM, Maganja K, Changalucha J, Watson-Jones D, et al. Risk factors for unplanned pregnancy among young women in Tanzania. J Fam Plann Reprod Health Care. 2013;39(4):e2.
37. Ameyaw EK. Prevalence and correlates of unintended pregnancy in Ghana: Analysis of 2014 Ghana Demographic and Health Survey. Maternal health, neonatology and perinatology. 2018;4:17.
38. Nyarko SH. Unintended Pregnancy among Pregnant Women in Ghana: Prevalence and Predictors. J Pregnancy. 2019:1-8.
39. Brittain KK, Phillips JT, Zerbe JA, Abrams JE, Myer JL. Long-term effects of unintended pregnancy on antiretroviral therapy outcomes among South African women living with HIV. AIDS. 2019;33(5):885-93.
40. Haffejee F, O'Connor L, Govender N, Reddy P, Sibiya MN, Ghuman S, et al. Factors associated with unintended pregnancy among women attending a public health facility in KwaZulu-Natal, South Africa. South African Family Practice. 2018;60(3):79-83.
41. Exavery A, Kanté AM, Njozi M, Tani K, Doctor HV, Hingora A, et al. Predictors of mistimed, and unwanted pregnancies among women of childbearing age in Rufiji, Kilombero, and Ulanga districts of Tanzania. Reprod Health. 2014;11:63.
42. Ikamari L, Izugbara C, Ochako R. Prevalence and determinants of unintended pregnancy among women in Nairobi, Kenya. BMC Pregnancy & Childbirth. 2013;13(1):1-9.
43. Ports KA, Haffejee F, Mosavel M, Rameshbabu A. Integrating cervical cancer prevention initiatives with HIV care in resource-constrained settings: A formative study in Durban, South Africa. Global public health. 2015;10(10):1238-51.
44. Haffejee F, Ports KA, Mosavel M. Knowledge and attitudes about HIV infection and prevention of mother to child transmission of HIV in an urban, low income community in Durban, South Africa: Perspectives of residents and health care volunteers. 2016. p. 171-8.
45. Tweya H, Feldacker C, Gugsa S, Phiri S. Contraceptive use and pregnancy rates among women receiving antiretroviral therapy in Malawi: a retrospective cohort study. Reprod Health. 2018;15(1):25.
46. Kendall T, Bärnighausen T, Fawzi WW, Langer A. Towards comprehensive women's healthcare in sub-saharan Africa: Addressing intersections between HIV, reproductive and maternal health. J Acquir Immune Defic Syndr. 2014;67:S169-S72.
47. Cooper D, Mantell JE, Moodley J, Mall S. The HIV epidemic and sexual and reproductive health policy integration: Views of South African policymakers Health policies, systems and management. BMC Public Health. 2015;15(1).
48. West N, Schwartz S, Phofa R, Yende N, Bassett J, Sanne I, et al. “I don't know if this is right … but this is what I'm offering”: healthcare provider knowledge, practice, and attitudes towards safer conception for HIV-affected couples in the context of Southern African guidelines. AIDS Care. 2016;28(3):390-6.
49. Dude AM, Miller ES, Garcia PM, Yee LM. Unintended pregnancy and viral suppression in pregnant women living with HIV. Am J Obstet Gynecol MFM. 2018;219(6):651-.
50. Brittain K, Remien RH, Mellins CA, Phillips TK, Zerbe A, Abrams EJ, et al. Determinants of suboptimal adherence and elevated HIV viral load in pregnant women already on antiretroviral therapy when entering antenatal care in Cape Town, South Africa. AIDS Care. 2018;30(12):1517-23.
51. Odayar J, Malaba TR, Allerton J, Lesosky M, Myer L. Delivery of antiretroviral therapy to HIV-infected women during the postpartum period: The Postpartum Adherence Clubs for Antiretroviral Therapy (PACART) trial. Contemp Clin Trials Commun. 2019;16:100442.
52. Myer L, Phillips T, Manuelli V, McIntyre J, Bekker LG, Abrams EJ. Evolution of antiretroviral therapy services for HIV-infected pregnant women in Cape Town, South Africa. J Acquir Immune Defic Syndr. 2015;69(2):e57-e65.
53. Myer L, Phillips TK, Zerbe A, Ronan A, Hsiao NY, Mellins CA, et al. Optimizing Antiretroviral Therapy (ART) for Maternal and Child Health (MCH): Rationale and Design of the MCH-ART Study. J Acquir Immune Defic Syndr. 2016;72 Suppl 2:S189-96.

54. World Health Organisation. Technical and operational considerations for implementing HIV viral load testing: interim technical update. Geneva: World Health Organisation; 2014.

PART B: JOURNAL MANUSCRIPT

Title: Impact of unintended pregnancy on HIV viral load outcomes among postpartum women living with HIV in Cape Town, South Africa: clues from Postpartum Adherence Clubs for Antiretroviral Therapy trial.

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Abstract

Introduction: Postpartum women living with HIV (WLWHIV) have high levels of viraemia. Some evidence suggests that an unintended pregnancy may be associated with viraemia, but additional research is needed. We examined the association between unintended pregnancy and HIV viral load (VL) outcomes at 24 months postpartum in Cape Town, South Africa.

Methods: We used data from a randomised trial comparing models of ART provision for postpartum women aged ≥18 years who had initiated ART during their recent pregnancy. Additional enrolment criteria included having VL<400 copies/ml in the previous three months, and no comorbidities requiring regular clinical follow-up. Pregnancy intentions were self-reported at enrolment into the study. VL was measured at 24 months postpartum, with elevated VL defined as VL≥1000 copies/ml. Predictors of unintended pregnancy were examined using chi-squared tests and logistic regression. The impact of unintended pregnancy on elevated VL was examined using Poisson regression models.

Results: A total of 411 women (mean age: 28.7 years) were analysed. Overall, 42% were married/cohabiting; 75% had parity≥2; and 86% had VL<50 copies/ml. At enrolment, 57% reported that their pregnancy was unintended. Compared to women aged 18-24 years, older women had a lower odds of unintended pregnancy [25-28 years, adjusted odds ratio (AOR): 0.34; 95% confidence interval (CI): 0.17-0.70; 29-34 years, AOR: 0.18; CI: 0.08-0.37; and ≥35 years, AOR: 0.35; CI: 0.14-0.89]. Additionally, unintended pregnancy was associated with being unmarried/not cohabiting (AOR: 4.44; CI: 2.78-7.09) and with higher parity (compared to parity=1: parity=2, AOR: 3.47; 95% CI: 1.86-6.50; and parity≥3, AOR: 6.38; 95% CI: 3.06-13.28). VL data at 24 months postpartum was available for 89% (366/411) of participants of whom 24% had elevated VL≥1000 copies/ml. Unintended pregnancy was associated with elevated VL in unadjusted analyses [risk ratio (RR): 1.54; CI: 1.03-2.28; p=0.032]. After adjustment for maternal factors and trial allocation, the association persisted despite not reaching statistical significance (adjusted risk ratio (aRR): 1.36; CI: 0.88-2.08; p=0.158).

Conclusion: Among postpartum WLWHIV in South Africa, unintended pregnancy is common and may be a risk factor for elevated VL. Reproductive health counselling and support during routine care visits may reduce unintended pregnancies and its effects.

1. Introduction

Despite the widespread adoption of contraception as a modern health technology, unintended pregnancies continue to be a health burden for women globally. During the period 2015-2019, an estimated 121 million unintended pregnancies among women aged 15-49 years were recorded worldwide (uncertainty interval: 112.8-131.5), with sub-Saharan Africa (SSA) having the highest rates [1]. Various factors have been found to be associated with unintended pregnancy among women of reproductive age in different countries. Among them are low income [1-4], higher parity [2, 5], complications during first pregnancy [6], older age [2, 7, 8], being unmarried [2, 5, 7, 9], living in rural areas [2], being unemployed [2, 9, 10], alcohol use and intimate partner violence [11], and low education levels [2, 12]. On the contrary, some studies have found that younger age is a predictor for unintended pregnancy [5, 10, 13]. Co-existing with unintended pregnancy is the burden of HIV, both of which are closely linked with unprotected sex.

South Africa has achieved significant success in expanding access to HIV services and currently has the world's largest HIV treatment programme [14]. The number of pregnant and postpartum women living with HIV (WLWHIV) on antiretroviral therapy (ART) has substantially increased with about 95% receiving ART in 2019 [15]. Suppression of viral load (VL) is the primary goal of ART to reduce HIV transmission risk and promote health. Yet, not all pregnant and postpartum WLWHIV receiving ART have sustained VL suppression over time [16-18]. Suboptimal VL suppression may lead to a higher risk of mother-to-child transmission (MTCT), horizontal transmission and maternal disease progression [19], thus maintaining high ART adherence levels and viral suppression while pregnant is important. In addition, sustained ART adherence and viral suppression are critical throughout the breastfeeding period, when the risk of MTCT is ongoing [20]. In sub-Saharan Africa (SSA), only about 50% of women maintain viral suppression through one year after giving birth [21]. Among women who achieve initial viral suppression in South Africa, about a third experience viraemia within 12 months postpartum with episodes of viraemia being experienced repeatedly over time [19].

WLWHIV or those at risk of acquiring HIV face additional sexual and reproductive health (SRH) challenges such as risk of unintended pregnancy [22]. According to the 2014 global survey on SRH and Human Rights, close to 60% of WLWHIV had at least one unplanned pregnancy during their life course and less than 50% had ever accessed family planning services [23]. The prevalence of unintended pregnancies among WLWHIV in the United States ranges from 23% to 78% [24-26] and in Canada approximately 60% of pregnancies among WLWHIV are unintended [27]. High levels of unintended pregnancies among WLWHIV have also been reported in other countries: 67% in Swaziland [28]; 45% in Uganda [29, 30]; 59% in Kenya [31]; 49% and 75% in Malawi [32, 33]; 44% in Botswana[34]; and 37% in Nigeria [35]. In South Africa, up to 71% of pregnancies among WLWHIV have been reported as unintended [11, 13, 36]. Results from prior research have shown that younger age, single relationship status, low education levels, being unemployed, lack of reproductive health counselling, higher parity

and alcohol use are associated with unintended pregnancy among WLWHIV [11, 13, 26, 34, 37, 38]. Unintended pregnancy is not only a family planning concern but also a public health concern, including in the field of HIV. Reducing unintended pregnancy is one of the components of the World Health Organization's (WHO) strategy for the prevention of mother-to-child transmission (PMTCT) [39]. Women living with HIV (WLWHIV) who experience unintended pregnancy may have HIV viral load (VL) outcomes determined by a host of different factors. Risk factors for elevated VL include alcohol use, intimate partner violence, younger age, being unmarried, low education levels, unknown HIV status before getting pregnant, not being on antiretroviral therapy (ART) prior to entry into antenatal care (ANC), sub-optimal adherence to ART, male partner involvement in PMTCT programs, HIV disease stage, the type of antiretroviral regimen women received and drug resistance, co-infection with other STIs, and CD4+ cell count [11, 26, 37, 40-46].

There is some evidence that an unintended pregnancy may lead to poorer ART outcomes, although the association between unintended pregnancy and elevated VL has been insufficiently explored. A cohort study of pregnant WLWHIV conducted retrospectively in the United States showed an association between unintended pregnancy and elevated VL at the time of delivery [26]. In South Africa, one cross-sectional study and one longitudinal study by Brittain and colleagues also found that unplanned pregnancy is a risk factor for elevated VL at the time of entry into antenatal care (ANC) and through 36-60 months postpartum, respectively [11, 37]. While the former study included women who were already on ART before they entered ANC, the latter included pregnant women who initiated ART during pregnancy. Some scholars have found that unintended pregnancy is associated with elevated VL in the last three months of the pregnancy [46] and MTCT [41, 43]. Additional analyses to explore the association between unintended pregnancy and HIV VL are needed to ascertain the existence and magnitude of this relationship in different populations. This is necessary to inform policy makers of areas needing interventions to help prevent unintended pregnancies and improve postpartum outcomes. This study therefore aimed to investigate the prevalence and predictors of unintended pregnancy and examine the relationship between unintended pregnancy and HIV VL outcomes at 24 months postpartum among WLWHIV who initiated ART antenatally in Cape Town, South Africa.

2. Methods

2.1 Study Design and Data Sources

Data used in this study are from the Postpartum Adherence Clubs for Antiretroviral Therapy (PACART) study. PACART is a pragmatic randomised controlled trial comparing two models of ART care provision for women in the postpartum period. Recruitment of women was done at the Gugulethu Community Health Centre (CHC), a government facility offering primary care to a population of around 350,000 people, majority of whom are of low socio-economic status [47]. Incorporated within the CHC is an ART clinic that provides the general adult population with HIV care. There is also a Midwife Obstetric Unit (MOU) associated with the CHC. Nurse-midwives run the MOU which provides ANC,

obstetric services, postnatal care and PMTCT services to over 4000 women yearly [48]. Women in this setting receive ART within the MOU during pregnancy and delivery as part of routine care, but are referred to general adult ART clinics during the early postpartum period. Postnatal services are delivered separately from these ART clinics and focus only on baby wellness.

For the primary trial, women were recruited at either early postpartum visits to the MOU ART clinic or postnatal visits to the baby wellness clinic. Basic information about the study was provided to consecutive potentially eligible women who, if interested, were screened. Eligible women were those who initiated ART during pregnancy, were aged at least 18 years, were within 70 days postpartum, had a live infant at the time of being screened, had a VL of <400 copies/ml in the previous three months and no comorbidities necessitating regular clinical follow-up. Those with intentions of relocating out of Cape Town while the study was ongoing were excluded from the study [49]. Those eligible went through the informed consent process conducted by study staff. Women who consented underwent enrolment interviews and VL testing after which they were randomised to attend either the adherence club (intervention) or the general adult ART clinic (control; standard of care) [49] for ongoing HIV care.

Adherence clubs are well established in Cape Town but have not been extensively tested among postpartum women. Women who were randomised to the adherence clubs were referred out from the MOU ART service to the adherence clubs postnatally. Club visits were scheduled every two months for an approximate duration of 1 hour and were group-based and run by community health workers. A clinical assessment and VL testing were conducted once a year by a nurse. Women randomised to the control arm were referred out to the general adult ART clinic where visits were scheduled at least once a month for the first four months, and then once every two months for the purpose of medication refill. Clinician review was scheduled six monthly. As part of routine laboratory investigations, VL testing was performed at four and twelve months after starting ART, and yearly after that [49].

2.2 Measures

In addition to the enrolment visit, women attended study measurement visits conducted at 3, 6, 12, 18 and 24 months postpartum; these were separate from routine ART service appointments. Questionnaires were administered at every study visit for the purpose of collecting data on demographics, medical history, ART adherence and a range of other measures. Questionnaires were translated into the predominant local language known as isiXhosa and then back-translated into English in order to guarantee accuracy. At each study visit, blood samples were collected from participants to measure VL; this was done separately from routine clinical monitoring. The South African National Health Laboratory Services did batch testing using the Abbott Realtime HIV-1 assay (Abbott Laboratories, Waltham, MA) [49].

The dependant variable of interest for this study was HIV VL at 24 months postpartum which was dichotomized as elevated (defined as VL ≥1000 copies/ml) or suppressed (defined as VL <1000 copies/ml) [50] for the purpose of modified Poisson regression. This VL threshold was selected on the basis of international and local guidelines [50-52]. The primary independent variable was unintended pregnancy which was self-reported at enrolment into the study: Women were asked "Were you trying to have a baby when you found out you were pregnant (in your most recent pregnancy)?" The resulting variable was a dichotomous variable. Based on existing knowledge from previous studies and on availability in the dataset, a number of baseline demographic and socio-economic characteristics (maternal age, parity, relationship status, education, employment status, type of housing) of the women were considered to be potential confounders in the relationship between unintended pregnancy and HIV VL outcomes. Baseline HIV VL, previous ART use and duration on ART were considered as possible effect modifiers of the same relationship. By design, all participants had a baseline VL <400 copies/ml.

2.3 Data Analysis

Data were analysed using STATA version 14.0 (StataCorp, College Station, Texas, USA) with $p \leq 0.05$ set as the level of statistical significance. Using standard descriptive statistics, baseline demographic, socio-economic and clinical data were described overall and by pregnancy intention status. Unintended pregnancy prevalence in the sample was estimated and predictors of unintended pregnancy were examined using chi-squared tests or Fisher's exact tests and logistic regression. Baseline characteristics of women who were retained in the study and had VL data available at 24 months postpartum were compared with those of women who were lost from the study using chi-squared tests or Fisher's exact tests. The impact of unintended pregnancy on HIV VL outcomes at 24 months postpartum was examined using unadjusted and adjusted modified Poisson regression models with robust error variance. Two adjusted models were built. The first model was adjusted for demographic, socio-economic and clinical variables to account for potential confounders. To account for intervention effects, the second model had an additional adjustment for random allocation in the PACART trial. Sensitivity analyses were performed using VL ≥400 copies/ml and ≥50 copies/ml as the outcome. These viral load thresholds were selected based on local thresholds for viral load monitoring [52, 53]. Because of the possibility of effect modification in the association between unintended pregnancy and HIV VL, additional models were stratified by baseline HIV VL, previous ART use, and duration on ART. A flow chart of the data analysis process is shown in figure 2 of Appendix K. Results are presented using odds ratios (OR) and risk ratios (RR) with 95% confidence intervals (CI).

Approval to conduct both the primary trial and the present study was granted by the University of Cape Town's Faculty of Health Sciences Human Research Ethics Committee (REF: 194/2015 and REF: 190/2021, respectively).

3. Results

3.1 Baseline characteristics

A total of 412 women were enrolled into the PACART trial. Excluding one woman who withdrew from the primary study, 411 women were included in analysis. Baseline characteristics of these women are described in Table 1. The mean age was 28.7 [standard deviation (SD) = 5.2] years, overall. The majority (67%, n=275) of the women were aged between 25 and 34 years; 75% (n=308) had a parity of at least two. Forty-two percent (n=173) were married/cohabiting and almost all the women (99%, n=405) reported having completed some high school/tertiary education. Sixty-eight percent (n=279) were unemployed and 53% (n=219) lived in informal housing. A considerable proportion (86%, n=355) of the women had baseline HIV VL <50 copies/ml and only 12% (n=50) were previously on ART. As stated above, all participants had a VL <400 copies/mL at enrolment into the study, by design.

3.2 Prevalence and Predictors of Unintended Pregnancy

More than half the women (57%, n=235) had an unintended index pregnancy (Table 1). Being unmarried or not cohabiting was significantly associated with unintended pregnancy. In adjusted analysis, the odds of having an unintended pregnancy among women who were not married/cohabiting were more than four times the odds among those who were married/cohabiting [adjusted odds ratio (AOR): 4.44; 95% CI: 2.78–7.09; Table 2]. Young age (18-24 years) was also a predictor of unintended pregnancy. Compared to women aged 18-24 years, those aged 25-28 years (AOR: 0.34, 95% CI: 0.17-0.70), 29-34 years (AOR: 0.18, 95% CI: 0.08-0.37) and ≥35 years (AOR: 0.35, 95% CI: 0.14-0.89) had a lower relative odds of unintended pregnancy. In addition, higher parity was a significant predictor of unintended pregnancy. Compared to a parity of one, those with a parity of 2 (AOR: 3.47; 95% CI: 1.86-6.50) and parity of 3 or more (AOR: 6.38; 95% CI: 3.06-13.28) had increased odds of unintended pregnancy (Table 2). There were no significant differences in maternal education, employment status and type of housing in those with intended and unintended pregnancies.

Table 1: Baseline characteristics of postpartum WLWHIV by pregnancy intendedness

Variable	Total, n (%)	Intended, n (%)	Unintended, n (%)	X^2	*P* value
Number of women	411	176	235		
Mean (SD) age (years)	28.7(5.2)	29.1(4.9)	28.4(5.4)		
Age category (years)					
18 – 24	84(20)	24(14)	60(26)	15.11	0.002*
25 – 28	122(30)	51(29)	71(30)		
29 – 34	153(37)	82(46)	71(30)		
.≥35	52(12)	19(11)	33(14)		
Parity					
1	103(25)	53(30)	50(21)	4.79	0.091
2	182(44)	76(43)	106(45)		
≥3	126(31)	47(27)	79(34)		
Relationship status					
Married or Cohabiting	173(42)	105(60)	68(29)	38.97	0.000*
Unmarried and not cohabiting	238(58)	71(40)	167(71)		
Maternal education					
Completed any high school/tertiary education	405(99)	174(99)	231(98)	0.70	**0.486**
Not completed any high school	6(1)	2(1)	4(2)		
Employment status					
Employed	132(32)	54(31)	78(33)	0.29	0.590
Unemployed	279(68)	122(69)	157(67)		
Live in informal housing					
No	192(47)	80(45)	112(48)		
Yes	219(53)	96(55)	123(52)	0.20	0.658
Baseline HIV VL					
<50 copies/ml	355(86)	160(91)	195(83)	5.38	0.025*
≥50 copies/ml	56(14)	16(9)	40(17)		
Previous ART use					
No	351(85)	158(90)	193(82)	4.02	0.045*
Yes	50(12)	15(8)	35(15)		
Missing	10(3)	3(2)	7(3)		
Trial allocation					
Clinic	205(50)	81(46)	124(53)	1.83	0.176
Club	206(50)	95(54)	111(47)		

X^2 = Chi-square statistic; n= frequency; VL= viral load; ART = antiretroviral therapy; SD = standard deviation; *statistically significant; p-value in bold obtained from Fisher's exact test

Table 2: Unadjusted and adjusted logistic regression models for the association between unintended pregnancy and selected predictor variables

Variable	UOR[a]	95%CI	P-value	AOR[b]	95%CI	P-value
Maternal age (years)						
18 – 24	1.00			1.00		
25 – 28	0.56	0.31-1.01	0.054	0.34	0.17-0.70	0.003*
29 – 34	0.35	0.19-0.61	0.000*	0.18	0.08-0.37	0.000*
≥35	0.67	0.33-1.45	0.333	0.35	0.14-0.89	0.027*
Parity						
1	1.00			1.00		
2	1.48	0.91-2.40	0.115	3.47	1.86-6.50	0.000*
≥3	1.78	1.05-3.02	0.032*	6.38	3.06-13.28	0.000*
Relationship status						
Married or Cohabiting	1.00			1.00		
Unmarried and not cohabiting	3.63	2.40-5.49	0.000*	4.44	2.78-7.09	0.000*
Maternal education						
Completed any high school/ tertiary education	1.00			1.00		
Not completed any high school	1.51	0.27-8.31	0.638	1.63	0.26-10.34	0.602
Employment status						
Employed	1.00					
Unemployed	0.89	0.59-1.36	0.59	1.02	0.64-1.63	0.937
Live in informal housing						
No	1.00			1.00		
Yes	0.92	0.64-1.35	0.658	1.06	0.68-1.66	0.792

***statistically significant p-values; [a]UOR, Unadjusted odds ratios; [b]AOR, Adjusted odds ratios (adjusted for all demographic and socio-economic variables shown); 95% CI, 95% confidence interval**

3.3 Comparison of HIV VL outcomes at 24 months postpartum

Out of the 411 women, 45(11%) had missing HIV VL data at 24 months postpartum and were excluded from subsequent analyses. Of the 45 women excluded, 39 were lost to follow up while six died. Women who were lost from the study were more likely to be married/cohabiting (58% vs 40%; p=0.024) and were more likely to be living in informal housing (71% vs 51%; p=0.011) than those who were retained (Table 3). Overall, the median duration on ART at time of VL assessment was 29.2 [interquartile range (IQR) = 2.5] months. The proportion of women who had elevated VL of ≥1000 copies/ml was 24% (89/366). Twenty nine percent (60/210) and 19% (29/156) of women with unintended and intended pregnancies respectively had VL of ≥1000 copies/ml at 24 months postpartum.

Table 3: Baseline characteristics of postpartum WLWHIV by whether or not they were retained at 24 months postpartum

Variable	Total, n (%)	Deaths and LTFU, n (%)	Retained, n (%)	X^2	*P* value
Number of women	411	45	366		
Mean (SD) age (years)	28.7(5.2)	27.3(4.7)	28.8(5.4)		
Age category (years)					
18 – 24	84(20)	14(31)	70(19)	4.78	0.188
25 – 28	122(30)	14(31)	108(30)		
29 – 34	153(37)	14(31)	139(38)		
.≥35	52(13)	3(7)	49(13)		
Parity					
1	103(25)	13(29)	90(25)	0.39	0.821
2	182(44)	19(42)	163(44)		
≥3	126(31)	13(29)	113(31)		
Relationship status					
Married or Cohabiting	173(42)	26(58)	147(40)	5.10	0.024*
Unmarried and not cohabiting	238(58)	19(42)	219(60)		
Maternal education					
Completed any high school/tertiary education	405(99)	44(98)	361(99)	**0.50**	**0.504**
Not completed any high school	6(1)	1(2)	5(1)		
Employment status					
Employed	132(32)	15(33)	117(32)	0.03	0.853
Unemployed	279(68)	30(67)	249(68)		
Live in informal housing					
No	192(47)	13(29)	179(49)		
Yes	219(53)	32(71)	187(51)	6.45	0.011*
Baseline HIV VL					
<50 copies/ml	355(86)	36(78)	319(87)	1.74	0.187
≥50 copies/ml	56(14)	9(22)	47(13)		
Previous ART use					
No	351(86)	36(80)	315(86)	1.47	0.224
Yes	50(12)	8(18)	42(12)		
Missing	10(2)	1(2)	9(2)		
Trial allocation					
Clinic	205(50)	24(53)	181(49)	0.24	0.623
Club	206(50)	21(47)	185(51)		

X^2 = Chi-square statistic; n= frequency; LTFU = lost to follow-up; VL= viral load; ART = antiretroviral therapy; *statistically significant, p-value in bold obtained from Fisher's exact test

In bivariate analysis, unintended pregnancy was associated with higher risk of elevated VL at 24 months postpartum (Table 4). The risk of having elevated VL among women with unintended pregnancy was approximately 50% higher than the risk among women reporting intended pregnancies (RR: 1.54; CI: 1.03-2.28; p-value: 0.032). It was also observed that elevated VL was more frequent among women whose HIV VL was ≥50 copies/ml at baseline and among women who were previously on ART. In adjusted analyses (adjusted model 1-adjusted for demographic, socio-economic and clinical variables and adjusted model 2-additional adjustment for trial allocation), the risk of elevated VL remained higher in those with unintended pregnancy versus intended pregnancy albeit not reaching statistical significance [aRR: 1.36; CI: 0.88-2.09; p=0.155 and aRR: 1.36; CI: 0.88-2.08; p=0.158 respectively].

Table 4: Unadjusted and adjusted Modified Poisson regression models for the association between Pregnancy intendedness and HIV VL ≥1000 copies/ml at 24 months postpartum

Variables	Unadjusted models		Adjusted model 1		Adjusted model 2	
	RR [95%CI]	*P* value	aRR [95%CI]	*P* value	aRR [95%CI]	*P* value
Pregnancy intention						
Intended	1.00		1.00		1.00	
Unintended	1.54 [1.03-2.28]	0.032*	1.36 [0.88-2.09]	0.155	1.36[0.88-2.08]	0.158
Maternal age (years)						
18 – 24	1.00		1.00		1.00	
25 – 28	0.95 [0.60-1.52]	0.853	0.95 [0.55-1.63]	0.861	0.96[0.56-1.64]	0.883
29 – 34	0.69 [0.42-1.13]	0.141	0.73 [0.41-1.32]	0.307	0.74[0.41-1.32]	0.309
≥35	0.54 [0.26-1.13]	0.102	0.50 [0.22-1.12]	0.094	0.50[0.22-1.11]	0.091
Parity						
1	1.00		1.00		1.00	
2	1.03 [0.64-1.63]	0.916	1.10 [0.66-1.85]	0.704	1.09[0.65-1.82]	0.734
≥3	1.10 [0.67-1.79]	0.703	1.28 [0.71-2.29]	0.409	1.28[0.71-2.30]	0.396
Relationship status						
Married or Cohabiting	1.00		1.00		1.00	
Unmarried and not cohabiting	1.32 [0.89-1.94]	0.160	1.15 [0.75-1.74]	0.507	1.14[0.75-1.73]	0.534
Employment status						
Employed	1.00		1.00		1.00	
Unemployed	1.14 [0.76-1.70]	0.526	1.10 [0.74-1.64]	0.614	1.11[0.74-1.65]	0.605
Live in informal housing						
No	1.00		1.00		1.00	
Yes	0.89 [0.62-1.29]	0.547	0.88 [0.61-1.27]	0.507	0.88[0.61-1.26]	0.486
Baseline HIV VL						
<50 copies/ml	1.00		1.00		1.00	
≥50 copies/ml	1.72 [1.13-2.61]	0.011*	1.47 [0.94-2.29]	0.085	1.47[0.94-2.30]	0.089
Previous ART use						
No	1.00		1.00		1.00	
Yes	2.06 [1.39-3.06]	0.000*	1.81 [1.15-2.85]	0.010*	1.87[1.18-2.96]	0.007*
Months on ART at time of VL assessment	1.00 [0.95-1.03]	0.741	1.00 [0.97-1.03]	0.931	1.00[0.97-1.03]	0.825
Trial allocation						
Clinic	1.00				1.00	
Club	0.83 [0.58-1.20]	0.333			0.79[0.55-1.14]	0.209

***statistically significant p-values; VL=Viral load; ART=antiretroviral therapy; RR=Unadjusted risk ratios; 95% CI=95% Confidence interval; aRR=adjusted risk ratios; Model 1 adjusted for demographic, socio-economic and clinical variables; Model 2 adjusted for all those in model 1 plus random allocation**

In sensitivity analysis (elevated VL defined as ≥400 copies/ml and ≥50 copies/ml), similar results were obtained (Table H.1 and Table H.2). In stratified analysis, the role of clinical variables namely: previous ART use, baseline HIV VL and duration on ART were investigated (Table H.3). No evidence of effect modification was found in the association between unintended pregnancy and HIV VL outcomes.

4. Discussion

This study explored the impact of unintended pregnancy on HIV VL outcomes at 24 months postpartum among WLWHIV in Cape Town. More than half (57%) of the women had an unintended index pregnancy. Predictors for unintended pregnancy in our study were higher parity, being unmarried or not cohabiting, and younger age. Twenty nine percent of those with an unintended pregnancy and 19% of those with an intended pregnancy had an elevated VL at 24 months postpartum. There was increased risk of an elevated VL at 24 months postpartum among women with unintended pregnancy, albeit the association did not reach statistical significance after adjustment for other factors.

As in our study, other studies conducted in South Africa, Ethiopia and elsewhere have similarly reported high levels of unintended pregnancy [11, 13, 25-27, 36, 38, 54]. The high levels of unintended pregnancy found in our study could be because health care providers do not often engage patients living with HIV in discussions relating to pregnancy intentions and/or contraceptive use, and even if they do, they do not go in depth [55]. This argument though, applies only to women who were already in HIV services before the pregnancy. Among sexually active women in South Africa, the prevalence of modern contraceptive use was 60% in 2016 [56], and access to these contraceptive services is free at all levels of the health service [57]. However problems such as poor service delivery, inequitable access, and incorrect and inconsistent contraceptive use among certain subgroups of women, particularly those in younger ages and those from rural areas, remain [57, 58]. This, including contraceptive failure and non-use of contraceptives may be plausible reasons for the high prevalence of unintended pregnancy found in our study.

Higher parity was associated with increased odds of having an unintended pregnancy. This could be because women with more children become satisfied with the number of children they already have such that they no longer desire more[59]. Some women may decide to avoid further pregnancies for fear that they may not afford to take care of additional children due to economic constraints/hardships [59, 60]. Our finding that higher parity is associated with unintended pregnancy aligns with findings from South Africa [13, 36], Botswana [34] and Uganda [54, 61]. On the contrary, a United States study revealed that nulliparous women were more likely than higher parity women to have unintended pregnancy [26].

Our study results also show that unmarried or non-cohabiting women have higher odds of experiencing an unintended pregnancy than their married or cohabiting counterparts. This finding is in line with previous studies [11, 13, 22, 26]. One possible reason for this finding in our study could be fear of

having to raise the child alone should the man not take responsibility [62]. Younger age in our study was also associated with unintended pregnancy, although this finding contrasts with a finding by Brittain et al. in which there was no association between age and pregnancy intention [11]. Consistent with our finding, however, are findings from another South African study [36] and a United States study [26]. If the goal of reducing the number of unintended pregnancies is to be realized, knowing the predictors of unintended pregnancy is helpful. Understanding unintended pregnancy demographic disparities may help in determining where policy and programmatic interventions should be focused.

Data on the impact of unintended pregnancy on HIV VL outcomes among postpartum WLWHIV are scarce. The finding that unintended pregnancy may increase the chances of having elevated VL at 24 months postpartum is notable, given that elevated VL may lead to disease progression and an increased risk of both vertical and horizontal HIV transmission [26]. Some scholars posit that unintended pregnancy may lead to delayed entry into antenatal care [37, 63, 64] and consequently delayed ART initiation [11]. Unintended pregnancy may also lead to sub-optimal adherence to ART which in turn leads to unsuppressed HIV VL [37]. Therefore, reinforcing education regarding SRH (including family planning) and the potential negative effects of unintended pregnancy to WLWHIV, may contribute to the prevention and reduction of these unintended pregnancies in the medium and long term. Offering more follow-up services that include counselling in the postnatal period to all WLWHIV who experience an unintended pregnancy may also help avert the adverse effects such as elevated viral load that may result from unintended pregnancy. There are other risk factors that contribute to both unintended pregnancy and elevated VL that were not adequately accounted for in the multivariable analyses in our study, such as alcohol use and intimate partner violence before conception[11]. This is a possible reason for the lack of statistical significance in the adjusted models. Future research should consider including these factors in assessing the relationship between unintended pregnancy and elevated VL.

Limitations: Our study used secondary data which is limited to characteristics collected in the primary trial; hence some potential confounding variables such as alcohol use and intimate partner violence prior to pregnancy were unavailable and could not be adjusted for. Secondly, pregnancy intention was self-reported hence data on pregnancy intentions may not be accurate. Also, women's intentions involve complex factors which are not well represented by binary categorical measures of pregnancy intentions [65]. The multidimensional nature of pregnancy intentions therefore requires better pregnancy intention measures. Another limitation is that pregnancy intention was measured after delivery during which period the desirability of the pregnancy may have changed [54]. Women who had pregnancy losses were never enrolled into the study, so the prevalence of unintended pregnancy may be underreported as women who terminated their pregnancy would not have been enrolled.

Additionally, loss to follow-up/deaths may have biased our study results due to an imbalance in some of the baseline characteristics between those retained in the study and those lost from the study. More

women who were living in formal housing and more of those unmarried or not cohabiting remained in the risk set during follow- up, hence, the resulting odds ratios may be overestimated. To be eligible to participate in the trial, women had to have a VL<400 copies/ml, which may have resulted in the exclusion of certain high-risk population subgroups, limiting generalizability. Further, the study focus was only on one area which makes generalizability of study findings and conclusions to the wider population difficult. It is worthy of mention that all relationships presented in this study are associative only and not causative.

5. Conclusion

In this South African cohort of postpartum WLWHIV who initiated ART antenatally, the prevalence of unintended pregnancies was high. Younger age, higher parity and being unmarried or not cohabiting are factors found to have been associated with unintended pregnancy in our study. Our study has also highlighted that in this peri-urban setting where HIV rates are very high, unintended pregnancy may increase the chances of having elevated VL in the long term. Given that our findings cannot be generalized with certainty to other settings within the general population, more research regarding this topic is needed and should focus on WLWHIV in different settings and perhaps include different sets of variables. Addressing unintended pregnancy among WLWHIV may need a broad approach in order to avert its consequences such as delayed entry into ANC, late ART initiation, unsuppressed VL, and mother-to-child transmission. Comprehensive HIV care and support is needed, including psychosocial support, access to antiretroviral drugs as well as monitoring and management of these medications, monitoring and supporting retention in care, and VL monitoring so as to prevent vertical transmission during pregnancy, delivery and postpartum. In the long run, this may optimize both maternal and child health and also improve the prospective future for all children being born. Reproductive health counselling and support should be implemented and made a priority for women during routine care visits. More focus should be placed on addressing unintended pregnancies among higher parity women, unmarried women and younger WLWHIV. The importance of having HIV and SRH (including effective family planning and contraceptive use) services integrated in one place cannot be overemphasized.

6. References

1. Bearak J, Popinchalk A, Ganatra B, Moller AB, Tunçalp Ö, Beavin C, et al. Unintended pregnancy and abortion by income, region, and the legal status of abortion: estimates from a comprehensive model for 1990-2019. The Lancet Global health. 2020;8(9):e1152-e61.
2. Ameyaw EK, Budu E, Sambah F, Baatiema L, Appiah F, Seidu AA, et al. Prevalence and determinants of unintended pregnancy in sub-Saharan Africa: A multi-country analysis of demographic and health surveys. PLoS One. 2019;14(8):e0220970.
3. Wellings K, Jones KG, Mercer CH, Tanton C, Clifton S, Datta J, et al. The prevalence of unplanned pregnancy and associated factors in Britain: findings from the third National Survey of Sexual Attitudes and Lifestyles (Natsal-3). The Lancet. 2013;382(9907):1807-16.
4. Ameyaw EK. Prevalence and correlates of unintended pregnancy in Ghana: Analysis of 2014 Ghana Demographic and Health Survey. Matern Health Neonatol Perinatol. 2018;4:17.
5. Nyarko SH. Unintended Pregnancy among Pregnant Women in Ghana: Prevalence and Predictors. J Pregnancy. 2019:1-8.
6. Molla W, Hailemariam S, Mengistu N, Madoro D, Bayisa Y, Tilahun R, et al. Unintended pregnancy and associated factors during COVID-19 pandemic in Ethiopia: Community-based cross-sectional study. Women's health (London, England). 2022;18:17455057221118170.
7. Barrow A, Jobe A, Barrow S, Touray E, Ekholuenetale M. Prevalence and factors associated with unplanned pregnancy in The Gambia: findings from 2018 population-based survey. BMC Pregnancy and Childbirth. 2022;22(1):17.
8. Calvert C, Baisley K, Doyle AM, Maganja K, Changalucha J, Watson-Jones D, et al. Risk factors for unplanned pregnancy among young women in Tanzania. J Fam Plann Reprod Health Care. 2013;39(4):e2.
9. Haffejee F, O'Connor L, Govender N, Reddy P, Sibiya MN, Ghuman S, et al. Factors associated with unintended pregnancy among women attending a public health facility in KwaZulu-Natal, South Africa. South African Family Practice. 2018;60(3):79-83.
10. Ameyaw EK. Prevalence and correlates of unintended pregnancy in Ghana: Analysis of 2014 Ghana Demographic and Health Survey. Maternal health, neonatology and perinatology. 2018;4:17.
11. Brittain KK, Phillips JT, Zerbe JA, Abrams JE, Myer JL. Long-term effects of unintended pregnancy on antiretroviral therapy outcomes among South African women living with HIV. AIDS. 2019;33(5):885-93.
12. Finer LB, Zolna MR. Declines in Unintended Pregnancy in the United States, 2008-2011. N Engl J Med. 2016;374(9):843-52.
13. Adeniyi OV, Ajayi AI, Moyaki MG, Goon DT, Avramovic G, Lambert J. High rate of unplanned pregnancy in the context of integrated family planning and HIV care services in South Africa. BMC Health Serv Res. 2018;18(1).
14. UNAIDS. Global information and education on HIV and AIDS: UNAIDS; 2020 [Available from: https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/south-africa.
15. le Roux SM, Abrams EJ, Donald KA, Brittain K, Phillips TK, Zerbe A, et al. Infectious morbidity of breastfed, HIV-exposed uninfected infants under conditions of universal antiretroviral therapy in South Africa: a prospective cohort study. Lancet Child Adolesc Health. 2020;4(3):220-31.
16. Woldesenbet SA, Kufa-Chakezha T, Lombard C, Manda S, Cheyip M, Ayalew K, et al. Coverage of maternal viral load monitoring during pregnancy in South Africa: Results from the 2019 national Antenatal HIV Sentinel Survey. HIV Med. 2021;22(9):805-15.
17. Redd AD, Mukonda E, Hu N-C, Philips TK, Zerbe A, Lesosky M, et al. ART Adherence, Resistance, and Long-term HIV Viral Suppression in Postpartum Women. Open Forum Infect Dis. 2020;7(10).
18. Myer L, Redd AD, Mukonda E, Lynch BA, Phillips TK, Eisenberg A, et al. Antiretroviral Adherence, Elevated Viral Load, and Drug Resistance Mutations in Human Immunodeficiency Virus–infected Women Initiating Treatment in Pregnancy: A Nested Case-control Study. Clin Infect Dis. 2020;70(3):501-8.

19. Myer L, Dunning L, Lesosky M, Hsiao N-Y, Phillips T, Petro G, et al. Frequency of Viremic Episodes in HIV-Infected Women Initiating Antiretroviral Therapy During Pregnancy: A Cohort Study. Clin Infect Dis. 2017;64(4):422-7.
20. Myer L, Essajee S, Broyles LN, Watts DH, Lesosky M, El-Sadr WM, et al. Pregnant and breastfeeding women: A priority population for HIV viral load monitoring. PLOS med. 2017;14(8):e1002375.
21. Abuogi LL, Humphrey JM, Mpody C, Yotebieng M, Murnane PM, Clouse K, et al. Achieving UNAIDS 90-90-90 targets for pregnant and postpartum women in sub-Saharan Africa: progress, gaps and research needs. J Virus Erad. 2018;4(Suppl 2):33-9.
22. Loutfy M, Khosla R, Narasimhan M. Advancing the sexual and reproductive health and human rights of women living with HIV. J Int AIDS Soc. 2015;18(Suppl 5):20760.
23. Narasimhan M, Orza L, Welbourn A, Bewley S, Crone T, Vazquez M. Sexual and reproductive health and human rights of women living with HIV: a global community survey. Bull World Health Organ. 2016;94(4):243-9.
24. Rahangdale L, Stewart A, Stewart RD, Badell M, Levison J, Ellis P, et al. Pregnancy intentions among women living with HIV in the United States. J Acquir Immune Defic Syndr. 2014;65(3):306-11.
25. Sutton MY, Zhou W, Frazier EL. Unplanned pregnancies and contraceptive use among HIV-positive women in care. PLoS One. 2018;13(5):e0197216.
26. Dude AM, Miller ES, Garcia PM, Yee LM. Unintended pregnancy and viral suppression in pregnant women living with HIV. Am J Obstet Gynecol MFM. 2021;3(2):100300.
27. Salters K, Loutfy M, De Pokomandy A, Money D, Pick N, Wang L, et al. Pregnancy incidence and intention after HIV diagnosis among women living with HIV in Canada. PLoS One. 2017;12(7).
28. Warren CE, Abuya T, Askew I. Family planning practices and pregnancy intentions among HIV-positive and HIV-negative postpartum women in Swaziland: a cross sectional survey. BMC Pregnancy & Childbirth. 2013;13(1):1-10.
29. Gutin SA, Namusoke F, Shade SB, Mirembe F. Fertility Desires and Intentions among HIV-Positive Women during the Post-natal period in Uganda. Afr J Reprod Health. 2014;18(3):67-77.
30. Jarolimova J, Kabakyenga J, Bennett K, Muyindike W, Kembabazi A, Martin JN, et al. Contraceptive use following unintended pregnancy among Ugandan women living with HIV. PLoS One. 2018;13(10):e0206325.
31. Akelo V, Girde S, Borkowf CB, Angira F, Achola K, Lando R, et al. Attitudes toward Family Planning among HIV-Positive Pregnant Women Enrolled in a Prevention of Mother-To-Child Transmission Study in Kisumu, Kenya. PLoS One. 2013;8(8):1-9.
32. O'Shea MS, Rosenberg NE, Hosseinipour MC, Stuart GS, Miller WC, Kaliti SM, et al. Effect of HIV status on fertility desire and knowledge of long-acting reversible contraception of postpartum Malawian women. AIDS Care. 2015;27(4):489-98.
33. O'Shea MS, Rosenberg NE, Tang JH, Mukuzunga C, Kaliti S, Mwale M, et al. Reproductive intentions and family planning practices of pregnant HIV-infected Malawian women on antiretroviral therapy. AIDS Care. 2016;28(8):1027-34.
34. Mayondi GK, Wirth K, Morroni C, Moyo S, Ajibola G, Diseko M, et al. Unintended pregnancy, contraceptive use, and childbearing desires among HIV-infected and HIV-uninfected women in Botswana: across-sectional study. BMC Public Health. 2016;16:44.
35. Ezugwu EC, Iyoke CA, Nkwo PO, Ezegwui HU, Akabueze JC, Agu PU. Unintended pregnancy among HIV-positive pregnant women in Enugu, southeast Nigeria. Int J Gynaecol Obstet. 2016;132(1):60-3.
36. Iyun V, Brittain K, Phillips TK, Le Roux S, McIntyre JA, Zerbe A, et al. Prevalence and determinants of unplanned pregnancy in HIV-positive and HIV-negative pregnant women in Cape Town, South Africa: A cross-sectional study. BMJ Open. 2018;8(4).
37. Brittain K, Remien RH, Mellins CA, Phillips TK, Zerbe A, Abrams EJ, et al. Determinants of suboptimal adherence and elevated HIV viral load in pregnant women already on antiretroviral therapy when entering antenatal care in Cape Town, South Africa. AIDS Care. 2018;30(12):1517-23.

38. Teklu T, Belina S, Chemir F, Tessema M, Yismaw W. Unintended Pregnancy and Associated Factors Among HIV Positive Women in Ilu Aba Bora zone, South Western Ethiopia: A Facility-Based Cross-Sectional Study. HIV/AIDS (Auckland, NZ). 2021;13:197-203.
39. World Health O. PMTCT strategic vision 2010 - 2015: preventing mother-to-child transmission of HIV to reach the UNGASS and millennium development goals. Geneva: WHO; 2010. Report No.: 978-92-4-159903-0
40. Woldesenbet SA, Kufa T, Barron P, Chirombo BC, Cheyip M, Ayalew K, et al. Viral suppression and factors associated with failure to achieve viral suppression among pregnant women in South Africa. Aids. 2020;34(4):589-97.
41. Beyene GA, Dadi LS, Mogas SB. Determinants of HIV infection among children born to mothers on prevention of mother to child transmission program of HIV in Addis Ababa, Ethiopia: a case control study. BMC Infectious Diseases. 2018;18(1):327.
42. Huntington S, Thorne C, Newell M-L, Anderson J, Taylor GP, Pillay D, et al. The risk of viral rebound in the year after delivery in women remaining on antiretroviral therapy. AIDS. 2015;29(17).
43. Mnyani CN, Simango A, Murphy J, Chersich M, McIntyre JA. Patient factors to target for elimination of mother-to-child transmission of HIV. Globalization and Health. 2014;10(1).
44. Moyo F, Mazanderani AH, Murray T, Sherman GG, Kufa T. Achieving maternal viral load suppression for elimination of mother-to-child transmission of HIV in South Africa. AIDS. 2021;35(2).
45. Ngandu NK, Lombard CJ, Mbira TE, Puren A, Waitt C, Prendergast AJ, et al. HIV viral load non-suppression and associated factors among pregnant and postpartum women in rural northeastern South Africa: a cross-sectional survey. BMJ Open. 2022;12(3):e058347.
46. Woldesenbet S, Kufa T, Manda S, Ayalew K, Lombard C, Cheyip M, et al. Association between viral suppression during the third trimester of pregnancy and unintended pregnancy among women on antiretroviral therapy: Results from the 2019 antenatal HIV Sentinel Survey, South Africa. PLOS ONE. 2022;17(3):e0265124.
47. Myer L, Phillips T, Manuelli V, McIntyre J, Bekker LG, Abrams EJ. Evolution of antiretroviral therapy services for HIV-infected pregnant women in Cape Town, South Africa. J Acquir Immune Defic Syndr. 2015;69(2):e57-e65.
48. Myer L, Phillips TK, Zerbe A, Ronan A, Hsiao NY, Mellins CA, et al. Optimizing Antiretroviral Therapy (ART) for Maternal and Child Health (MCH): Rationale and Design of the MCH-ART Study. J Acquir Immune Defic Syndr. 2016;72 Suppl 2:S189-96.
49. Odayar J, Malaba TR, Allerton J, Lesosky M, Myer L. Delivery of antiretroviral therapy to HIV-infected women during the postpartum period: The Postpartum Adherence Clubs for Antiretroviral Therapy (PACART) trial. Contemp Clin Trials Commun. 2019;16:100442.
50. World Health Organisation. Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach. Geneva: World Health Organization; 2016.
51. World Health Organisation. Technical and operational considerations for implementing HIV viral load testing: interim technical update. Geneva: World Health Organisation; 2014.
52. Department of Health. The Western Cape Consolidated Guidelines for HIV Treatment: Prevention of Mother-to- Child Transmission of HIV (PMTCT), Children, Adolescents and Adults 2020 [Available from: https://www.westerncape.gov.za/assets/departments/health/hiv_guidelines_16012020.pdf.
53. Republic of South Africa National Department of Health. 2019 ART Clinical Guidelines for the Management of HIV in Adults, Pregnancy, Adolescents, Children, Infants and Neonates 2020 [updated March, 2020. Available from: https://www.health.gov.za/wp-content/uploads/2020/11/2019-art-guideline.pdf.
54. Napyo A, Nankabirwa V, Mukunya D, Tumuhamye J, Ndeezi G, Arach AAO, et al. Prevalence and predictors for unintended pregnancy among HIV-infected pregnant women in Lira, Northern Uganda: a cross-sectional study. Scientific reports. 2020;10(1):16319.

55. West N, Schwartz S, Phofa R, Yende N, Bassett J, Sanne I, et al. “I don't know if this is right … but this is what I'm offering”: healthcare provider knowledge, practice, and attitudes towards safer conception for HIV-affected couples in the context of Southern African guidelines. AIDS Care. 2016;28(3):390-6.
56. South Africa Demographic and Health Survey 2016. [Internet]. NDoH, Stats SA, SAMRC and ICF. 2019 [cited 3rd December, 2020].
57. Lince-Deroche N, Pleaner M, Morroni C, Mullick S, Firnhaber C, Harries J, et al. Achieving universal access to sexual and reproductive health services : the potential and pitfalls for contraceptive services in South Africa. S Afr Health Rev. 2016;2016(1):95-108.
58. Cooper D, Harries J, Moodley J, Constant D, Hodes R, Mathews C, et al. Coming of age? Women’s sexual and reproductive health after twentyone years of democracy in South Africa. Reprod Health Matters. 2016;24(48):79-89.
59. Ayieko J, Ti A, Hagey J, Akama E, Bukusi EA, Cohen CR, et al. HIV status and treatment influence on fertility desires among women newly becoming eligible for antiretroviral therapy in western Kenya: insights from a qualitative study. Reprod Health. 2017;14(1):93.
60. Mayhew SH, Colombini M, Kimani JK, Tomlin K, Warren CE, Mutemwa R, et al. Fertility intentions and contraceptive practices among clinic-users living with HIV in Kenya: a mixed methods study. BMC Public Health. 2017;17(1):626.
61. Atukunda EC, Mugyenyi GR, Atuhumuza EB, Kaida A, Boatin A, Agaba AG, et al. Factors Associated with Pregnancy Intentions Amongst Postpartum Women Living with HIV in Rural Southwestern Uganda. AIDS & Behavior. 2019;23(6):1552-60.
62. Alvarez-del Arco D, Rodríguez S, Pérez-Elías MJ, Blanco JR, Cuellar S, del Romero J, et al. Role of HIV in the desire of procreation and motherhood in women living with HIV in Spain: a qualitative approach. BMC Women's Health. 2018;18(1):24.
63. Lindberg L, Maddow-Zimet I, Kost K, Lincoln A. Pregnancy Intentions and Maternal and Child Health: An Analysis of Longitudinal Data in Oklahoma. Matern Child Health J. 2015;19(5):1087-96.
64. Dibaba Y, Fantahun M, Hindin MJ. The effects of pregnancy intention on the use of antenatal care services: systematic review and meta-analysis. Reprod Health. 2013;10(1):50-8.
65. Santelli JS, Lindberg LD, Orr MG, Finer LB, Speizer I. Toward a multidimensional measure of pregnancy intentions: evidence from the United States. Stud Fam Plann. 2009;40(2):87-100.

PART C: APPENDICES

Appendix A: Maternal Demographics

PACART

MATERNAL PID: ☐☐☐☐☐-☐☐ Date: ☐☐/☐☐☐/☐☐☐☐

4. MATERNAL DEMOGRAPHICS Visit 1, Version 3

Singathanda ukubuza imibuzo ngendawo apho usuka khona, inkcukacha ngemfundo yakho, impangelo yakho kwaye nangendlu ohlaya kuyo

We would like to ask some questions about where you are from, your schooling, employment and your household

1. Wawuzalelwe apha eMzantsi Afrika? *Were you born in South Africa?* ..... ☐ Ewe/*Yes* ☐ Hayi/*No*

IF YES, PLEASE SKIP TO QUESTION 3

2. Uzalelwe kweliphi ilizwe? *In which country were you born?* _____

SKIP TO QUESTION 4

3. Uzalelwe apha eKapa? *Were you born in Cape Town?*..... ☐ Ewe/*Yes* ☐ Hayi/*No*

IF YES, PLEASE SKIP TO QUESTION 6

4. Uzalelwe kweyiphi na idolophu? *In which town/city were you born?* _____

5. Uzalelwe kweliphi na iphondo? *In which province were you born?*

☐ Western Cape	☐ Eastern Cape	☐ Free State
☐ Gauteng	☐ Kwazulu-Natal	☐ Limpopo
☐ North-West	☐ Northern Cape	☐ Mpumalanga
☐ Omnye, cacisa *Other, **specify**:*_____		☐ Don't know

6. Uthetha oluphi ulwimi ekhaya? Khetha ulwimi olunye kuphela. *What language do you speak at home? Choose one.*

☐ isiXhosa *Xhosa*	☐ isizulu *Zulu*	☐ Isibhulu *(Afrikaans)*
☐ isiNgesi *English*	☐ Omnye, cacisa *Other, **specify**:*_____	

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7. Lelephi elona banga liphezulu oliphumeleleyo? *What is the highest level of education that you have **completed**?*

- ☐ Awufundanga *No schooling*
- ☐ Isikolo samabanga aphantsi, bhala ibanga ophelele kulo *Primary school, **specify grade*** _____
- ☐ Isikolo samabanga aphezulu, bhala ibanga ophelele kulo *High school, **specify grade*** _____
- ☐ Idiploma okanye isatifiketi *Post-secondary diploma or certificate*
- ☐ Isidanga esiphantsi saseDyunivesithi *Bachelor's degree*
- ☐ Isidanga esiphezulu saseDyunivesithi *Honour's, master's or doctoral degrees*

8. Uyasebenza ngoku okanye uyafunda? *Are you currently working and /or studying?...* ☐ Ewe/*Yes* ☐ Hayi/*No*

IF NO, PLEASE SKIP TO QUESTION 10

9. Ukuba nguEwe, yeyephi kwezi zilandelayo echaza, bhetele ukuba wenza ntoni? Khetha ibenye. *Which of one the following best describes what you do? Choose one only.*

- ☐ Ndiphangela isigxina *Employed full-time*
- ☐ Ndiphangela ngalomaxesha *Employed part-time*
- ☐ Ndiphangela izingxungxo/ndingumatheng 'ethengisa *Informal job/hawker*
- ☐ Ndihamba isikolo/ Ndingumfundi *Attending school/learner*
- ☐ Uhamba isikolo semfundo enomsila *Attending tertiary education facility*
- ☐ Omnye, cacisa *Other, specify:*_____

10. Uhlala kwikhaya elinjani? Ketha impendulo enye kuphela. *What kind of home do you live in? Choose one.*

- ☐ Indlu yesitena *Formal house*
- ☐ Ehostele *Hostel*
- ☐ Ityotyombe elisemva kwendlu yomnye umntu *Shack/informal dwelling in backyard*
- ☐ Ityotyombe /Ematyotyombeni *Shack/informal dwelling in informal settlement*
- ☐ Eflethini *Flat/apartment*
- ☐ Omnye, cacisa *Other, specify:*_____

11. Ingaba indlu yakho inazo ezi zinto zilandelayo: Funda kwaye uphendule yonke imibuzo. *Does your house have the following: Read and answer for all.*

a. Indlu yangasese *A toilet inside* ..... ☐ Ewe/*Yes* ☐ Hayi/*No*

b. Amanzi abalekayo empompeni *Running water inside* ..... ☐ Ewe/*Yes* ☐ Hayi/*No*

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c. Umbane *Electricity inside* ..... ☐ Ewe/*Yes* ☐ Hayi/*No*

d. Isikhenkcisi *A refrigerator* ..... ☐ Ewe/*Yes* ☐ Hayi/*No*

e. Umnxeba *A home telephone* ..... ☐ Ewe/*Yes* ☐ Hayi/*No*

f. Umabona kude *A television* ..... ☐ Ewe/*Yes* ☐ Hayi/*No*

12. Ngowuphi owona mthombo wemali kwikhaya lakho? Khetha impendulo enye. *What is the MAJOR source of income for your household? Choose one.*

☐ Awukho *None*

☐ Umsebenzi osisigxina *Full-time employment*

☐ Umsebenzi oza ngalomaxesha *Part- time employment*

☐ Umsebenzi wezingxungxo/ Umthengisi *Informal employment*

☐ Umhlala phantsi *Pension*

☐ Imali yesibonelelo kaRhulumente *Social grant*

☐ Imali yesibonelelo sokukhubazeka kaRhulumente *Disability grant*

☐ Enye imali yesibonelelo, chaza *Other grant, specify type:*_____

☐ Omnye, cacisa Other, specify:_____

☐ Andazi *Don't know*

13. Ngokulinganisela, uthini umvuzo wendlu yakho ngenyanga? Khetha impendulo enye. *On average, what is your household's monthly income? Choose one.*

☐ ≤ R500

☐ R501 – R1000

☐ R1000 – R5000

☐ R5000 – R10000

☐ R10000 – R15000

☐ R15000 – R25000

☐ ≤ R 25000

☐ Andazi / *Don't know*

14. Bangaphi abantu abahlala kule ndlu bedibene nawe(abadalanabancinci)? *Including yourself, how many people (adults and children) live in your house?* ..... ☐☐

15. Bangaphi abantu abadala (iminyakaeyi-16 nangaphezulu) bedibene nawe abahlala kule ndlu? *How many adults (aged 16 or older), including you, live in your house?* ..... ☐☐

16. Bangaphi abantwana (iminyaka eyi-15 nangaphantsi) abahlala nawe? *How many children (aged 15 and under) live in your house?* ..... ☐☐

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Singathanda ngoku ukubuza imibuzo edibene nesimo okuso sothandano
We would now like to ask some questions about your relationships

17. Ukhona umntu othandana naye ngoku? *Are you currently in a relationship?*..... ☐ Ewe/*Yes* ☐ Hayi/*No*

IF NO, PLEASE SKIP TO QUESTION 23

18. Ungaluchaza njani uthando lwakho? *How would you describe your current relationship?*

☐ Nditshatile, sihlala kunye *Married, living together*
☐ Anditshatanga ,ndiyahlalisana *Not married, living together*
☐ Nditshatile, asihlali kunye *Married, not living together*
☐ Anditshatanga, asihlali kunye *Not married, not living together*
☐ Omnye, cacisa *Other, specify:*_____

19. Lixesha elingakanani uthandana naye lomntu? *How long have you been in a relationship with this person?*

☐ Iintsuku *Days,* ***specify number:*** _____ ☐ Iiveki *Weeks,* ***specify number:*** _____
☐ Iinyanga *Months,* ***specify number:*** _____ ☐ Iminyaka *Years,* ***specify number:*** _____

20. Ingaba eli qabane lakho ngutata womnye wabantwana bakho (kunye nalo ukhulelwe nguye)? *Is your current partner the parent of any of your children? (including most recent pregnancy)?*..... ☐ Ewe/*Yes* ☐ Hayi/*No*

21. Kulonyaka udlulileyo, ingaba ukhe wabelena ngesondo nomnye umntu ngaphandle kwakhe lomntu uthandana naye ngoku? *In the last 12 months have you had any sexual relationships/sexual partners other than your current partner?*..... ☐ Ewe/*Yes* ☐ Hayi/*No*

IF NO, PLEASE SKIP TO QUESTION 24

22. Bunjani ubudlelwane bakho namanye amaqabane ngaphandle kweqabane lakho eli uthandana nalo? Rhangqa konke okungqamene nawe. *What is/was the nature of these other relationship(s)?*

a. Umlingane/nditshatile *Spouse/ married*..... ☐ Ewe/*Yes* ☐ Hayi/*No*
b. Iqabane lam *Boyfriend*..... ☐ Ewe/*Yes* ☐ Hayi/*No*
c. Iqabane lethutyana *Casual Partner/One Night Stands*..... ☐ Ewe/*Yes* ☐ Hayi/*No*

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d. Omnye *Other*:..... ☐ Ewe/*Yes* ☐ Hayi/*No*

Uti ewe, cacisa ***If yes, specify:*** _____

SKIP TO QUESTION 24

23. Ingaba luhlobo oluphi lobudlwelwane okanye lothandano okhe wanalo kwezinyanga ziyi-12 zidlulileyo?
What relationship(s) have you had in the past 12 months?

a. Umlingane/nditshatile *Spouse/ married*..... ☐ Ewe/*Yes* ☐ Hayi/*No*

b. Iqabane lam *Boyfriend*..... ☐ Ewe/*Yes* ☐ Hayi/*No*

c. Iqabane lethutyana *Casual Partner/One Night Stands*..... ☐ Ewe/*Yes* ☐ Hayi/*No*

d. Omnye *Other*:..... ☐ Ewe/*Yes* ☐ Hayi/*No*

Uti ewe, cacisa ***If yes, specify:*** _____

Singathanda ngoku ukubuza imibuzo edibene nokukhelwa kwakho kwaye nabantwana bakho
We would now like to ask some questions about your pregnancies and children

24. Wakhe wakhulelwa phambi koku ukukhulelwa? *Have you ever been pregnant before this most recent pregnancy?*..... ☐ Ewe/*Yes* ☐ Hayi/*No*

IF NO, PLEASE SKIP TO QUESTION 28

25. Ukhulelwe kangaphi ngaphambili (oku kuquka esi isisu)? *How many times have you been pregnant in total (including most recent pregnancy)?*..... ☐☐

26. Ngelixesha ubukhulelwe ngaphambili phambi kokuba ukhulelwe ngoku, ingaba ukhe wanikwa amayeza akhusela usana ukuze lungasulelwa yiNtsholongwane kaGawulayo (apha sithetha ngeepilisi ezikhusela umntwana hayi amachiza okuthomalalisa iNtsholongwane kaGawulayo atyiwa ubomi bakho bonke).
When you were pregnant before this last pregnancy have you ever been given medication at the clinic to keep your baby from getting HIV infected? (prophylaxis NOT lifelong ART)..... ☐ Ewe/*Yes* ☐ Hayi/*No*

IF NO, PLEASE SKIP TO QUESTION 28

27. Ukuba nguEwe, zingaphi izisu ufumane la machiza ngesisizathu? *If yes, during how many pregnancies have you received medication for this purpose?*..... ☐☐

28. Bangaphi abantwana obazeleyo? *How many children have you given birth to?*..... ☐☐

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29. Bangaphi kwaba bantwana abaphilayo? *How many of these children are living?* ..... ☐☐

30. Bangaphi kwaba bantwana abahlala nawe ngoku? *How many of these children currently live with you?* .. ☐☐

31. Bangaphi kwaba bantwana bakho ekufumaniseke ukuba baphila neNtsholongwane kaGawulayo? *How many of your children have been diagnosed with HIV?* ..... ☐☐

IF NO CHILDREN HAVE TESTED HIV POSITIVE, SKIP TO QUESTION 33

32. Kwaba bantwana baphila Nentsholongwane kaGawulayo bangaphi abasaphilayo? *How many of these children who have tested HIV- positive are currently living?* ..... ☐☐

NGOKU SIFUNA UKUKUBUZA MALUNGA NOHAMBO
WE NOW WANT TO ASK YOU ABOUT TRAVEL

33. Ingaba uneenjongo zokuhamba apha eKapa kwinyanga ezayo? *Are you planning on travelling out of Cape Town in the next month?* ..... ☐ Ewe/*Yes* ☐ Hayi/*No*

IF NO, END OF QUESTIONNAIRE

34. Ingaba uzohamba ixesha elingakanani? *Approximately how long will you be away?*

☐ Iintsuku *Days, specify number:* _____ ☐ Iiveki *Weeks, specify number:* _____

☐ Iinyanga *Months, specify number:* _____ ☐ Andazi *Don't know*

☐ Okunye, cacisa *Other, **specify**:* _____

35. Uneenjongo zokuya kweyiphi idolophu? *To which town/city are you travelling?* _____

36. Uneenjongo zokuya kweliphi iphondo? *To which province are you travelling?*

☐ Western Cape	☐ Eastern Cape	☐ Free State
☐ Gauteng	☐ Kwazulu-Natal	☐ Limpopo
☐ North-West	☐ Northern Cape	☐ Mpumalanga
☐ Omnye, cacisa *Other, **specify**:* _____		☐ Don't know

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37. Sesiphi na esona isizathu sokuba ubenohambo? *What is the main reason that you are travelling?*

- ☐ Uyondwendwela usapho *Visit family*
- ☐ Kukho ilungu losapho eligulayo *Family illness*
- ☐ Kukho umphanga ekhaya *Family death*
- ☐ Yokwenza izinto zamasiko *Traditional ceremony*
- ☐ Esinye, cacisa *Other, **specify**:*_____

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Appendix B: Family Planning and Pregnancy Intentions

PACART

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8. FAMILY PLANNING & PREGNANCY INTENTIONS Visit 1, Vers 1

Sicela uphendule lemibuzo edibene nezocwangciso kwaye neenjongo onazo zokukhulelwa kwakho kwixesha elizayo
We would like to ask you some questions about family planning and your future pregnancy intentions

1. Kwezi zi sikhuselo zocwangciso zeziphi owakhe wasisebenzisa ngahambi kokuba ukhululwe? (Phendula yonke) *Which family planning methods did you ever use prior to your last pregnancy? (Answer all)*

a.	Ipilisi eziselwayo *Oral contraceptive pill*	☐ Ewe/*Yes* ☐ Hayi/*No*
b.	Isitofu se-2('noristerat NET-en') *2-month injectable ('noristerat NET-en')*	☐ Ewe/*Yes* ☐ Hayi/*No*
c.	Isitofu se-3 ('depo,petogen') *3-month injectable ('depo, petogen')*	☐ Ewe/*Yes* ☐ Hayi/*No*
d.	Isivalo –mlomo lwesibeleko (IUD) *Intra-uterine device*	☐ Ewe/*Yes* ☐ Hayi/*No*
e.	Isivalo nzala sabantu basetyhini *Female sterilization*	☐ Ewe/*Yes* ☐ Hayi/*No*
f.	Isivalo nzala sabantu besikhomo *Male sterilization*	☐ Ewe/*Yes* ☐ Hayi/*No*
g.	Idyasi kamkhwenyana *Male condom*	☐ Ewe/*Yes* ☐ Hayi/*No*
h.	Idyasi kamkhwenyana (yabantu basetyhini) *Female condom*	☐ Ewe/*Yes* ☐ Hayi/*No*
i.	Isivalo nzala esifakwa phakathi kweenyama zakho *Implant*	☐ Ewe/*Yes* ☐ Hayi/*No*
j.	Olunye uhlobo *Other method:*	☐ Ewe/*Yes* ☐ Hayi/*No*

Uti ewe, cacisa *If yes, specify:* _____

2. Kwezinyanga zilishumi elinesibini phambi kokuba ukhulelwe loluphi uhlobo locwangciso ntsapho ubulisebenzisa? (Phendula yonke imibuzo) *In the 12 months before this last pregnancy, which family planning methods did you use? (Answer all)*

a.	Ipilisi eziselwayo *Oral contraceptive pill*	☐ Ewe/*Yes* ☐ Hayi/*No*
b.	Isitofu se-2('noristerat NET-en') *2-month injectable ('noristerat NET-en')*	☐ Ewe/*Yes* ☐ Hayi/*No*
c.	Isitofu se-3 ('depo,petogen') *3-month injectable ('depo, petogen')*	☐ Ewe/*Yes* ☐ Hayi/*No*
d.	Isivalo –mlomo lwesibeleko (IUD) *Intra-uterine device*	☐ Ewe/*Yes* ☐ Hayi/*No*

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e. Isivalo nzala sabantu basetyhini *Female sterilization* ☐ Ewe/*Yes* ☐ Hayi/*No*

f. Isivalo nzala sabantu besikhomo *Male sterilization* ☐ Ewe/*Yes* ☐ Hayi/*No*

g. Idyasi kamkhwenyana *Male condom* ☐ Ewe/*Yes* ☐ Hayi/*No*

h. Idyasi kamkhwenyana (yabantu basetyhini) *Female condom* ☐ Ewe/*Yes* ☐ Hayi/*No*

i. Isivalo nzala esifakwa phakathi kweenyama zakho *Implant Implant* ☐ Ewe/*Yes* ☐ Hayi/*No*

j. Olunye uhlobo *Other method*: ☐ Ewe/*Yes* ☐ Hayi/*No*

Uthi ewe, cacisa *If yes, specify:* _____

3. Ingaba ubuzama ukuba nosana ngelixesha ufumanisa ukuba ukhulelwe (Kwesi isisu)? *Were you trying to have a baby when you found out you were pregnant (in this most recent pregnancy)?* ☐ Ewe/*Yes* ☐ Hayi/*No*

4. Emva kokuba mntwana wakho ezelwe ukhe wasebenzisa ucwangciso ntsapho? *Since the birth of your baby, have you used any family planning?* ☐ Ewe/*Yes* ☐ Hayi/*No*

IF NO, → SKIP TO QUESTION 7

5. Ukube ngoEwe, usebenzisa oluphi uhlobo? *If yes, what method are you using? (Answer all)*

a. Ipilisi eziselwayo *Oral contraceptive pill* ☐ Ewe/*Yes* ☐ Hayi/*No*

b. Isitofu se-2('noristerat NET-en') *2-month injectable ('noristerat NET-en')* ☐ Ewe/*Yes* ☐ Hayi/*No*

c. Isitofu se-3 ('depo,petogen') *3-month injectable ('depo, petogen')* ☐ Ewe/*Yes* ☐ Hayi/*No*

d. Isivalo –mlomo lwesibeleko (IUD) *Intra-uterine device* ☐ Ewe/*Yes* ☐ Hayi/*No*

e. Isivalo nzala sabantu basetyhini *Female sterilization* ☐ Ewe/*Yes* ☐ Hayi/*No*

f. Isivalo nzala sabantu besikhomo *Male sterilization* ☐ Ewe/*Yes* ☐ Hayi/*No*

g. Idyasi kamkhwenyana *Male condom* ☐ Ewe/*Yes* ☐ Hayi/*No*

h. Idyasi kamkhwenyana (yabantu basetyhini) *Female condom* ☐ Ewe/*Yes* ☐ Hayi/*No*

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MATERNAL PID: ☐☐☐☐☐-☐☐ Date: ☐☐/☐☐☐/☐☐☐☐

i. Isivalo nzala esifakwa phakathi kweenyama zakho *Implant*..... ☐ Ewe/*Yes* ☐ Hayi/*No*

j. Olunye uhlobo *Other method*:..... ☐ Ewe/*Yes* ☐ Hayi/*No*

Uti ewe, cacisa ***If yes, specify***: _____

6. Ulufumene phi ucwangciso ntsapho emva kokuba umntwana wakho ezelwe? *Where did you get your family planning after the birth of your baby?* _____

SKIP TO QUESTION 8

7. Kutheni ungasebenzisi naluphi na uhlobo locwangciso? *Why are you not using any method of family planning since the birth of your baby?*

_____
_____

8. Kwezinyanga zilishumi elinesibini ukhe wancokola nomlingane wakho ngocwangciso ntsapho? *In the last 12 months, have you discussed family planning or pregnancy with your partner?*..... ☐ Ewe/*Yes* ☐ Hayi/*No*

9. Cinga ngohlobo oziva ngalo ngoku. Khetha ukuba ngowuphi umbono ongqinelana nawo ochaza iinjongo onazo zokuba nomntwana kwilixa 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? Choose one.*

☐ Ndigqibe ukuba andifuni ukuba nomntwana kwixesha elizayo *I have decided that I do not want to have a child in the future*

☐ Ndingafuna ukuba nomntwana kwithuba lenyanga eziyi-12 ezizayo *I may want to have a child in the next 12 months*

☐ Ndingafuna ukuba nomntwana ngelinye ixesha ingezizo inyanga eziyi-12 ezizayo *I may want to have a child sometime in the future but not in the next 12 months*

☐ Andiqinisekanga ukuba ndiyamfuna okanye andimfuni umntwana kwixesha elizayo *I am unsure about whether or not I want to have a child in the future*

☐ Okunye,cacisa *Other,* ***specify***:_____

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CRF COMPLETED BY: ☐☐☐

Appendix C: PACART ethical approval

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

Room ES2-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

17 April 2015

HREC REF: 194/2015

Prof L Myer
Epidemiology & Biostatistics
Public Health & Family Medicine
Falmouth Building

Dear Prof Myer

PROJECT TITLE: POSTPARTUM ADHERENCE CLUBS FOR ANTIRETROVIRAL THERAPY (PACART)

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

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

Approval is granted for one year until the 30th April 2016.

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.

Yours sincerely

pp T Burgess

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
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 Convention on Harmonisation 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 guidelines.

HREC 194/2015

Appendix D: Form FHS006 Protocol Amendment

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Form FHS006: Protocol Amendment

HREC office use only (FWA00001637; IRB00001938)

☑ Approved | ☐ Type of review: Expedited | ☐ Full committee

This serves as notification that all changes and documentation described below are approved.

Signature Chairperson of the HREC | Date 14/4/2020

Note: All major amendments must include a local PI Synopsis justifying the changes for the amendment. Please note that incomplete amendment submissions will not be reviewed.

Comments from the HREC to the Principal Investigator:

Note: The approval of this protocol amendment does not grant annual approval. Please complete the FHS016 / FHS017 form for annual approval at least one month before study expiration.

Principal Investigator to complete the following:

1. Protocol Information

Date (when submitting this form)	01 March 2020
HREC REF Number	194/2015
Protocol title	Postpartum Adherence Clubs for Antiretroviral Therapy
Protocol number (if applicable)	Protocol version 4, 1st August 2019
Principal Investigator	Professor Landon Myer
Department / Office Internal Mail Address	5th Floor Falmouth Building, Division of Epidemiology and Biostatistics, School of Public Health & Family Medicine

1.1 Is this a major or a minor amendment? (see FHS008hlp) Major (tick box) Minor (tick box)	☐ Major	☒ Minor
1.2 Does this protocol receive US Federal funding?	☐ Yes	☒ No
1.3 If the amendment is a major amendment and receives US Federal Funding, does the amendment require full committee approval? **Note:** Any protocol amendments for **Full Committee** review MUST be submitted on the monthly HREC submission dates. (Please email an electronic copy to hrec-enquiries@uct.ac.za)	☐ Yes	☐ No

2. List of Proposed Amendments with Revised Version Numbers and Dates

Please itemise on the page below, all amendments with revised version numbers and dates, which need approval.
This page will be detached, signed and returned to the PI as notification of approval. Please add extra pages if necessary.

PACART Protocol Version 5.0, 1st March 2020

3. Protocol status (tick ✓)

☐	Open to enrolment
☐	No participants have been enrolled
☐	Closed to enrolment (tick ✓)
☐	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
☒	Research-related activities are complete, data analysis only

4. Proposed changes will affect: (tick ✓ all the categories that apply)

	Protocol
☐	Study objectives, design (including investigator's brochure, clinical activities, study length)
☐	Study instruments, questionnaires, interview schedules
☐	Sample size
☐	Recruitment methods
☐	Eligibility criteria (inclusion and exclusion criteria)
☐	Drug/device (composition, amount, schedule, route of administration, combination with other drugs/devices, safety information)
☒	Data collection/ analysis
☐	Principal Investigator. (Please attach revised conflict of interest and PI declaration statements. Refer: sections 7 and 8.4 in the New Protocol Application Form FHS013)
☐	Consent form and information sheet
☐	Recruitment materials (e.g. advertisements)
☐	Administrative (e.g. change in sponsor's name, change in contact information)
☐	Other. Please specify:

4.1 In your opinion, will there be any **increase** in risk, discomfort or inconvenience to participants?	☐ Yes	☒ No
If yes, please provide a detailed justification/explanation:		

4.2 What follow-up action do you propose for participants who are already enrolled in the study?	
☐	Inform current participants as soon as possible
☐	Re-consent current participants with revised consent/assent forms (append)
☒	No action required
☐	Other. Please describe:

5. Detailed description of the change(s)

Please attach, for each amendment, a summary of all changes which clearly indicates:

i. Old wording (e.g. ~~strikethrough~~ text, CHANGED FROM and CHANGED TO)

ii. New wording (e.g. *italicized*, **bold**, tracked)

iii. Detailed rationale/ justification/ explanation for each change

6. Ethics Review Levy – cost including vat

Cost for Major Amendments - R3 691.20

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

For invoicing purposes, please provide:	
Sponsor's name	
Contact person	
Address	
Telephone number	
Email Address	

7. Signature

My signature certifies that I will maintain the anonymity and/ or confidentiality of information collected in this research. If at any time I want to share or re-use the information for purposes other than those disclosed in the original approval, I will seek further approval from the HREC.

Signature of PI		Date	2019/10

Appendix E: FHS016 Annual Progress Report/Renewal

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30.10.2020
☐ Not approved	See attached comments		
Signature Chairperson of the HREC		Date Signed	4/10/2019

Comments to PI from the HREC
Thank you for the deviation document

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	02 September 2019		
HREC REF Number	194/2015	Current Ethics Approval was granted until	30 April 2019
Protocol title	Postpartum Adherence Clubs for Antiretroviral Therapy		
Protocol number (if applicable)	Protocol Version 4.0		
Are there any sub-studies linked to this study?	☒ Yes ☐ No		
If yes, could you please provide the HREC Ref's for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.	764/2016		
Principal Investigator	Professor Landon Myer		
Department / Office Internal Mail Address	School of Public Health & Family Medicine, 5th Floor, Falmouth Building		

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

1.1 Does this protocol receive US Federal funding?	☐ Yes	☒ No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval? **Note:** Any annual approvals for **Full Committee** review MUST be submitted on the monthly HREC submission dates. (Please send electronic copy for full committee review to hrec-enquiries@uct.ac.za)	☐ Yes	☐ No
If yes in 1.2 please complete section 1.3 below for invoicing purposes		
1.3 Annual Approval for **full committee** review	- R 3450 (inclusive of vat)	

For invoicing purposes, please provide:	
Sponsor's name	
Contact person	
Address	
Telephone number	
Email Address	

2. List of documentation for approval

- Protocol, Version 4 (01 August 2019)
- Study deviation form, FHS011
- DSMB report

3. Protocol status (tick ✓)

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

4. Enrolment

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

Number of participants enrolled to date	412
Number of participants enrolled, since last HREC Progress report (continuing review)	0
Additional number of participants still required	0

5. Refusals

Total number of refusals (participants invited to join the study, but refused to take part)	51

6. Cumulative summary of participants

Total number of participants who provided consent	412
Number of participants determined to be ineligible (i.e. after screening)	1385
Number of participants currently active on the study	41
Number of participants completed study (without events leading to withdrawal)	347
Number of participants withdrawn at participants' request (i.e. changed their mind)	2
Number of participants withdrawn by PI due to toxicity or adverse events	0
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	0
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	16
We are unable to contact these participants.	
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	
6 participants have died. One was stabbed and 5 died of medical causes.	

7. Progress of study

Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:
We have enrolled 412 participants. We have completed 3, 6, 12, and 18-month visits. 347 participants have completed their 24-month visit and have completed their study participation. There are 41 participants who have yet to complete their 24-month visits.

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

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

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

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

9. Amendments (tick ✓ all that apply)

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

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

10. Adverse events

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

10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?		
☒ Yes	☐ No	☐ Not applicable
If yes, please describe:		
Yes. Women who have stopped antiretrovirals are counselled by the study counsellor and referred to the ARV clinic for assessment and recommencement of treatment. Women and/or their children who have signs or symptoms of illness are referred to the appropriate health facility for further management.		

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

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

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

11.3 If yes, please identify the agency and attach a summary of the findings.					
Agency Name		Report attached	☐ Yes	☐ No	☐ Not applicable
		DSMB report attached	☒ Yes	☐ No	☐ Not applicable

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

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

12. Level of risk (tick ✓)

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

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

13. Statement of conflict of interest

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

14. Signature

My signature certifies that the above is complete and correct.			
Signature of PI		Date	02 September 2019

Appendix F: Form FHS010 Study Closure Report

UNIVERSITY OF CAPE TOWN | FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

HUMAN RESEARCH ETHICS COMMITTEE
27 JAN 2021
HEALTH SCIENCES FACULTY

Form FHS010: Study Closure Report

HREC office use only (FWA00001637; IRB00001938)			
Noted and filed. This serves as acknowledgement that this study is closed.			
☑ Approved	Study closure report		
☐ Not Approved	Study closure report		
Chairperson of the HREC signature/Designee		Date	30/1/24

Note: Please note that incomplete submissions will not be reviewed.
Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za.

Please clarify your plan for research-related activities during COVID-19 lockdown

1. Principal Investigator to complete the following:

Date (when submitting this form)	21 Jan 2020
HREC REF Number	194/2015
Protocol Title	Postpartum Adherence Clubs for Antiretroviral Therapy
Protocol number (if applicable)	Protocol version 5, 01 March 2020
Principal Investigator	Professor Landon Myer
Department / Office Internal Mail Address	5th Floor Falmouth Building, Division of Epidemiology and Biostatistics, School of Public Health & Family Medicine

2. Please confirm (tick ✓)

This study is closed to enrollment	✓ Yes	☐ No
Participants have completed all research-related interventions	✓ Yes	☐ No
Participants have completed all research-related follow-up	✓ Yes	☐ No
Data analysis is complete	✓ Yes	☐ No
Your sponsored protocol is closed	✓ Yes	☐ No

If you answered 'no' to any of the above questions, you must keep your study open until all research activity is completed.

3. What is the reason for closing the study? (tick ✓)

Research completed	✓	No time	
Terminated due to toxicity/adverse event		PI left UCT or affiliated sites	
Slow accrual		Insufficient funding	
Loss of interest		Research never began	
Other. Please specify:			

4. For clinical trials, please describe the arrangements for provision of care after research, including (where applicable) post-trial access to the investigational product.

Not applicable

5. Please explain how the research findings have been disseminated to participants, communities, and/or stakeholders.

Results were presented at the Conference for Retroviruses and Opportunistic Infections 2020. A manuscript of the primary finding has been drafted and is being finalized for submission to a medical journal. Results will be presented at the next Western Cape Provincial Research Day and at the next Gugulethu community health centre health promotion event.

6. Please confirm (tick ✓)

Have you submitted a final report to the Provincial Health Research Committee?	☐ Yes	☐ No	✓ N/A
Please note: Researchers must submit final reports to the relevant research co-ordinator/research directorate at City Health Department, GSH, RXH, TBH, PGWC (for non-tertiary hospitals) within six months of completion of the study and may be required to report the findings of the study to other relevant authorities including the PHRC.			

7. Please indicate how, and for how long, the data will be stored and protected.

Research data will be stored for 5 years post-study closure. Participant files and other study documentation will be archived and stored by Metrofile with potential access restricted to the PI.

8. Please list or attach any papers, abstracts, presentations or other outputs generated from this study.

Odayar J, Malaba TR, Allerton J, Lesosky M, Myer L. Delivery of Antiretroviral Therapy to HIV-Infected Women During the Postpartum Period: The Postpartum Adherence Clubs for Adherence Clubs for Antiretroviral Therapy (PACART) Trial. *Contemporary Clinical Trials Communications*.

Odayar J, Lesosky M, Malaba TR, Kabanda S et al. Differentiated Care for Postpartum ART in South African Women Living with HIV: An RCT. In: Conference on Retroviruses and Opportunistic Infections, Boston, USA; 2020.

9. Signatures

Signature of PI		Date	25 January 2021

Appendix G: Informed Consent Form Version 3

Isihloko Soluphando: Amaqumrhu asekuhlaleni zokutyiwa kwamachiza okuthomalalisa intsholongwane ngendlela eyiyo emva kokubeleka

Title of Research: Postpartum Adherence Clubs for Antiretroviral Therapy (PACART)

YINTONI INJONGO YOLUVAVANYO?
WHAT IS THE PURPOSE OF THE STUDY?

Sisuka kwiDyunivesithi yaseKapa. Senza uvavanyo ukuthelekisa iindlela ezimbini ezahlukileyo zokunikezela unyango lweNtsholongwane kaGawulayo kubafazi abaphila nale Ntsholongwane kaGawulayo emva kokuba bebelekile. Uyacelwa ukuba uthathe inxaxheba kolu vavanyo, olwenziwa kwiCandelo lokuBelekisa lase Gugulethu. (MOU)

We are from the University of Cape Town. We are doing a research study to compare two different ways of providing HIV treatment to HIV-positive women after they deliver a baby. You are being asked to take part in this study, which is being done at the Gugulethu Midwife Obstetric Unit (MOU).

Siyazi ukuba kubalulekile ukuba abafazi abaphila neNtshlongwane kaGawulayo nabantwana babo bafumane ukhathalelo lwe Ntsholongwane kaGawulayo emva kokubeleka. Kolu vavanyo sithelekisa indlela ezimbini zokunikezela ngolunyango. Ulwazi esilufumana koluvavanyo luyakunceda ukuphucula amaziko onyango luka Gawulayo kubafazi abasanda kubeleka, ukwenzela ukuba bahlale bekukhathalelo nonyanzeleko lonyango.

We know that it is essential for HIV-positive women and their babies to receive HIV care and treatment after delivery. In this study we are comparing two different ways of providing this treatment. Information learned in this study will help us to improve HIV services for women who have recently delivered a baby, so that they can remain in care and adherent to treatment.

Uyacelwa uthathe inxaxheba koluvavanyo ngoba ungumama onesimo esaziwayo solosuleleko lweNtsholongwane kaGawulayo, oqale ukuthatha amachiza okuthomalalisa kolukhulelo lakho lokugqibela, nonyamezeleyo kuzo. Injongo yale fomu yesivumelwano kukunika iinkcukacha ezizakunceda ukuba uthathe isigqibo sokuba uyafuna na ukuthatha inxaxheba koluphando okanye hayi.

You are being asked to take part in this study because you are a woman with known HIV-infection who started taking HIV drugs during your last pregnancy, and who is adherent to them. The purpose of this consent form is to give you information to help you decide if you want to take part in this study or not.

KWENZEKA NTONI UKUBA NDIYAVUMA UKUTHATHA INXAXHEBA?
WHAT HAPPENS IF I AGREE TO TAKE PART?

Ungenelelo no kungacetywa
Enrolment and randomization

Ukuba uyavuma ukuthabatha inxaxheba uyakwenza oku kulandelayo:

- Phendula imibuzo edibene nezihloko eziquka oku kulandelayo: indlu yakho, inombolo zakho zomnxeba, ukukhulelwa kwakho kwaye neenkcukacha zakho zempilo, ukusebenzisa kwakho amachiza eNtsholongwane kaGawulayo, nokondliwa kosana.

- Kuzakutsalwa igazi elingange 5ml (itispuni enye) engalweni yakho
- Uzakukhethwa ngokungacetywanga (oku kokuguqulwa kwengqekembe) kwenye yalamaqela mabini, ayakunikwa unyango ngendlela ezahlukeneyo.
    1. **Amaqumrhu asekuhlaleni okutya amachiza ngendlela eyiyo:** Abafazi abakhethelwe kweli qela bayakufumana ukhathalelo lweNtsholongwana kaGawulayo namachiza kumaqela asekuhlaleni, (iklabhu) ahlanganela kwiziko lasekuhlaleni, kumgama onganga 600m ukususka kwiziko lempilo laseGuguletu. Abantwana babo bayakuthunyelwa kumaziko amancinci empilo akufutshane ukwenzela unyango lwesiqhelo luqhubekeke.
    2. **Ikliniki kawonke-wonke yonyango lweNtsholongwane kaGawulayo:** Abafazi abakhethelwe kweli iqela bayakuthunyelwa kwiziko labatya amachiza eNtsholongawe kaGawulayo e Guguletu Day Hospital bafumane ukhathalelo nonyango lweNtsholongwane kaGawulayo. Abantwana babo bayakuthunyelwa kwiziko elincinci lokhathalelo lwesiqhelo lwabantwana. Oku luqhubekeko lwesiqhelo lwabafazi abaphila neNtsholongwane kaGawulayo nabantwana babo abahamba kwiziko lokubelekisa.

If you agree to take part you will do the following today:

- *Answer questions about a number of topics including: your household, your contact details, your pregnancy and medical history, your HIV testing history, your use of HIV medications and infant feeding.*
- *Have 5mls (1 teaspoon) of blood taken from your arm.*
- *You will then be randomized (like a flip of a coin) to one of two groups, who will each receive their HIV treatment in different ways:*
    1. ***Community-based adherence club:** Women assigned to this group will receive HIV care and medicines at the adherence clubs, which meet at the community centre about 600m from the Gugulethu Community Health Centre (CHC). Their babies will be referred to their nearest primary health care clinic for routine baby care.*
    2. ***General antiretroviral therapy (ART) clinic:** Women assigned to this group will be referred to the ART clinic at the Gugulethu CHC for HIV care and treatment. Their babies will be referred to their nearest primary health care clinic for routine baby care. This is currently the standard of care for all HIV-positive women and their babies attending the MOU.*

"Ukhetho olungacetywanga" kuthetha ukuba uyakuba ne 50 yepesenti yokuba seqeleni oluyakufumana ukhathalelo kwiklabhu yasekuhlaleni/ Uyakuba ne50 yepesenti yokuba kwiqela elizakuthunyelwa kwikliniki yokuxilonga iNtsholongwane kaGawulayo. Lilonke amathuba okuyo kweliphi na iziko lempilo ayalingana. Abaphangeli bophando nabathathi nxaxheba abayi kukhetha ukuba uzakuya kweliphi iziko lempilo. . Izigqibo zenziwa yi kompyutha zifakwe emvulophini. Abasebenzi bophando abazi ukuba leliphi iqela elisemvulophini.

***"Randomized"** means that you will have a 50% chance of being in the group that will receive care at the adherence club. You will also have a 50% chance of being in the group that gets referred to an ART clinic. 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 staff does not know which group is in each envelope.*

Amatyelelo ophando lomlinganiselo

Study measurements visits

Emva kokuba wena nomntwana wakho nikhethwe ngokungacetywanga,uyakucelwa ukuba utyelele amaxesha amayi 5 omlinganiselo emva inyanga eziyi 3, inyanga eziyi 6, nenyanga eziyi 12, nenyanga eziyi 18, nenyanga eziyi 24 emva kokubeleka. Lamatyelelo ovavanyo ohlukile kumatyelelo esiqhelo

akho emva kokubeleka nokhathalelo lwakho lweNtsholongwane kaGawulayo. Utyelelo ngalunye luyakuthatha kangange mizuzu engamashumi amathathu ukuya kwiyure.

After you and your baby are randomized, you be asked to attend a further 5 study measurement visits at approximately 3 months, 6 months, 12 months, 18 months and 24 months after delivery. These study visits are separate from the usual clinic visits that you will have for your postpartum and HIV care. Each visit will take about 30-60 minutes.

Kula matyelelo uyakwenza oku kulandelayo:

- Ukuphendula uluhlu olwahlukeneyo lwemibuzo kutyelelo ngalunye. Imibuzo ingaquka ezi zihloko zilandelayo:
    - Ulwazi ngempilo yakho yakamva nje, amachiza akho eHIV, ukwaziwa kwesimo sakho seHIV, ubandlululo, isimo sengqondo (kuquka nokusetyenziswa iziyobisi notywala) ukusetyenziswa kocwangciso-ntsapho, impilo yomntwana, nokhathalelo lwempilo nokuba wena uziva njani ngokhathalelo lwe Ntsholongwane kaGawulayo olufumeneyo.
- Utsalo gazi olunganga 5mls (itispuni enye) kwingalo yakho kuwo onke amatyelelo akho

At these visits, you will do the following:

- *Answer different sets of questions at each visit. Questions may include the following topics: your recent medical history, your HIV medications, HIV disclosure, stigma, mental health (including drug and alcohol use), family planning use, infant feeding, infant health and health care and how you feel about the HIV care that you have received.*
- *Have 5mLs (1 teaspoon) of blood will be drawn from your arm at every visit.*

Utyelelo lwakho lokugqibela lomlinganiselo luyakuba kwinyanga eziyi 24 emva kokubeleka. Emva koku akuyi kulindeleka ukuba utyelele uvavanyo, kodwa uyakuqhubeka ngokhathalelo lwesiqhelo lweNtsholongwane kaGawulayokwiqela lasekuhlaleni eklabhini okanye kwi kliniki yamachiza eHIV ngokufanelekileyo.

Your last study measurement visit will be at 24 months after delivery. After this you will no longer be required to attend study visits, but will continue with routine HIV care either at the adherence club or at the ART clinic as appropriate.

QAPHELA: Igazi elitsalwe kutyelelo ngalunye luya kugcinwa kuphononongwe ubungakanani beNtsholongwane ka Gawulayo egazini lakho kwixa elizayo. Iziphumo zeli gazi aziyi kwaziswa kuwe, kwi kliniki okanye kubasebenzi bovavanyo. Igazi lakho eligciniweyonazo naziphina iziphumo zovavanyo azisayi kuba nagama lakho nalo naluphina uhlobo lokuba unakanwe. Xa abasebenzi bezempilo abajongene notyelelo lwakho lolandelelwano ekliniki okanye eklabhini yokuthatha amachiza ngokufanelekileyo befuna ukujonga ubungakanani beNtsholongwane kaGawulayo bayakuthatha I spesimeni segazi esahlukileyo.

***NOTE:** The blood that is drawn at each visit will be stored and used to check your viral load (this is the amount of HIV in your blood) at a later time. Results from these tests will not be available to you, the clinic, or the study staff. Your stored blood and any study test results will not have your name or any other means of identifying you on it. When the health care workers who do your routine follow-ups at the clinic or the adherence club need to check your viral load, they will take a separate blood specimen.*

UKUPHONONONGWA KWE REKHODI ZONYANGO
REVIEW OF MEDICAL RECORDS

Ngokuyinxenye yolu vavanyo siyakujonga sithathe ulwazi lohlukuhlo, zecala lobelekiso, zekliniki ekhupha amachiza okuthomalalisa iNtsholongwane neze klabhu yokutya amachiza

ngokufanelekileyo, ezase lebhu nerekhodi zase khemesti, nencwadana yendlela eya empilweni yomntwana. Kwezi rekhodi sinomdla kuhlukuhlo nokhathalelo kwiziko lobelekiso notyelelo lolwandelelwano lwakho nomntwana emva kokubeleka.

Lonke ulwazi esithe saluphononongа salutsala luyimfihlelo kwaye akukho gama lamthathi-nxaxheba eliyakubhalwa kwimiqulu yovavanyo.

As part of this study we will also be looking at and taking information from your antenatal, obstetric, ART clinic or adherence club, laboratory and pharmacy records as well as your baby's road to health booklet. From these records we are interested in your antenatal and obstetric care and the follow-up care that you and your baby receive postnatally.

All the data that we review and abstract is confidential and no participant names are recorded on study documents.

UTYELELO LOLANDELELWANO OLUPHOSAKELEYO
FOLLOW-UP OF MISSED VISITS

Uyakucelwa ukhuphe iinkcukatcha zakho zoqhagamshelwano ukuze sikwazi ukukuthinta ngeli xesha lovavanyo. Abasebenzi bovavanyo bayakuthetha nawe ngeyona ndlela iyiyo yoqhagamshelwano nawe. Ukuba uphose elinye lamaxesha amisiweyo ovavanyo, ilungu labasebenzi bovavanyo liyakukuthinta ukuze kufumaneke olunye usuku nexesha lotyelelo. Ukuba usoloko uphosa amaxesha otyelelo okanye umsebenzi wovavanyo akakufumani, esebenzisa iinkukacha ebezikhutshwe nguwe, kuya kubayimfuneko ukuba sikundwendwele ekhaya ukuze siphinde simise olunye utyelelo lovavanyo.

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

UQHAGAMSHELWANO KWIXA ELIZAYO LOVAVANYO
CONTACT FOR FUTURE STUDY

Emva kotyelelo lwakho lokugqibela emva kwenyanga eziyi 24 emva kokubeleka, singaphinde siqhagamshelane nawe kwixa elizayo ukuze uthathe inxaxheba kolunye uphando lovavanyo. Ngelo xeshauyakucelwa uphinde ujonge utyikitye olunye uxwebhu lwesivumelwano. Ungakhetha ukungathathi nxaxheba nakoluphi uvavanyo kwixesha elizayo ukuba uyacelwa. Uyakucelwa ukuba unikeze ngenkcukacha zakho zoqhagamshelwano ukuze sikwazi ukukuthinta ngophando lovavanyo olongezelelweyo. Abasebenzi bovavanyo baya kuthetha nawe ngeyona ndlela ingcono yokuqhagamshelana nawe.

After the completion of your last visit at 24 months postpartum, we might contact you again in the future to take part in other research studies. At that time, you would be asked to review and sign another consent form. You can choose not to take part in any future studies if you are asked. You will be asked to provide contact information so that we can get in touch with you regarding additional research studies. Study staff will talk with you about the best way to contact you.

YINTONI IMINGCIPHEKO ELINDELEKILEYO EKUTHATHENI INXAXHEBA KOLUPHANDO?
WHAT ARE THE POTENTIAL RISKS OF TAKING PART IN THE STUDY?

Ungaziva ungonwabanga ngeminye imibuzo emayela nawe oyakuthi uyibuzwe. Ungavumi ukuphendula nawuphina umbuzo ongafuni kuwuphendula.

Ukhona umngcipheko ekwabelaneni ngenkcukacha zakho nezonyango. Siya kulumka ekugcineni iinkcukacha zakho ziyimfihlo kangangoko esinokwenza ngako. Utsalo-gazi lwenziwa ngokwesiqhelo kukhathalelo lonyanga lwaye lunemingciphekwana engephi yokuziva ungonwabanga. Abasebenzi abanamava bayakutsala eligazi phantsi kwemeko zococeko ukuze ukhuseleke kulemingcipheko.

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.

There is some risk in sharing personal and medical information. We will be careful to keep all your information as private as possible.

Drawing blood is normally done as part of routine medical care and presents a slight risk of discomfort. Experienced staff will draw blood under sterile conditions in order to protect you against these risks.

YINTONI INZUZO ELINDELEKILEYO EKUTHATHENI INXAXHEBA KOLU VAVANYO
WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

Akukho nzuzo engqamene nawe ekuthatheni inxaxheba kolu vavanyo, kodwa ukuba sibona ingxaki yokhathalelo lwempilo kuwe nakumntwana wakho ngeli xesha ukolu phando, siyakuqinisekisa ukuba uthunyelwa kwiziko lempilo elililo. Ulwazi olufunyenwe kolu vavanyo lunganceda ukuphucula iinkonzo ezinikeza amachiza okuthomalalisa iNtsholongwane ka Gawulayo kubafazi abaphila naleNtsholongwane eKapa, kwiPhondo leNtshona-Koloni, nakuMzantsi Afrika jikelele.

There is no direct benefit to you if you take part in this study, but if we identify any health care problem for you or your baby during the course of the study, we will make sure that you are referred to the appropriate health care services. In addition, the information gained in this study may help to improve ART services for HIV-infected pregnant women in Cape Town, the Western Cape Province, and across South Africa.

ZIINTONI EZINYE IINDLELA ZOKUTHABATHA INXAXHEBA?
WHAT ARE THE ALTERNATIVES TO TAKING PART?

Ezinye iindlela ekuthabatheni inxaxheba koluvavanyo kukuqhubeka ngokhathalelo lwakho lomlinganiselo lwabo bonke abafazi abaphila neHIV abakunyango lwamachiza entsholongwane emva kokubeleka, lo nto ithetha ukuba uyakuthunyelwa ukusuka kwicandelo lobelekiso ukuya kwikliniki yakho yonikezo machiza okuthomalalisa intshongwane eGuguletu CHC. Umntwana wakho uyakuthunyelwa ngokukhawuleza kwikliniki encinci ekufutshane kuwe azuze nolawulo olungaphezulu.

The alternative to taking part in this study is to continue with the standard of care for all HIV-positive women on ART postpartum, which means that you will be referred from the MOU to your nearest general ART clinic, which is the ART clinic at the Gugulethu CHC. Your baby will be referred as soon as possible to your nearest primary health care facility for further management.

KUTHIWANI NGEMFIHLELO
WHAT ABOUT CONFIDENTIALITY?

Ukuba uyavuma ukuthabatha inxaxheba, lonke ulwazi oluqokelelwe ngexesha lophando luyakugcinwa luyimfihlelo. Igama lakho aliyi kubhalwa kuma xwebhu ovavanyo lingasayi kusetyenziswa naluphina ulwazi okanye ispesimeni zaselebhu eziqokelelwe ngokuyinxenye yovavanyo.

Zonke izixhobo zophando ziya kugcinwa kwi khabhati etshixwayo. Ngabasebenzi bophando kuphela nabaphononongi boqhubeko abaya kuba nendlela yokufikelela kwezizixhobo. Bonke abasebenzi abaqokelela iinkcukacha nabolawulo bayakufumana uqeqesho lwemfihlelo.

Ngeli xesha kusenzwa le nkxamleko yokugcina iimfihlelo, ukuba abasebenzi bophando bafumanisa ukuba ungasemngciphekweni wokuzenzakalisa, okanye omnye umntu, okanye umntwana okwimpatho-mbi yabantwana okanye/nokungahoywa, abasebenzi bophando bayakwazisa abasemthethweni.

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 it will not be used in connection with any information or lab specimens that are collected as part of the study.

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

While these efforts will be made to maintain confidentiality, if the study staff learns 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.

KUTHIWANI NGE INSHORENSI?
WHAT ABOUT INSURANCE?

Akukho mayeza okuhlola asetyenzisiweyo koluvavanyo. Ngoko, akukho inshorensi iyakufumaneka. Nangona, uyakukhuseleka ngokwemiqathango yeinshorensi yabasebenzi ekhusela abasebenzi beDyunivesiti okanye inshorensi ekhusela ngexesha lengozi okanye ukugula okubangelwe kukuba uthatha inxaxheba kolu vavanyo (iinkcukacha zokhuselo zolu vavanyo zincanyathiselwe kumqukumbelo ekupheleni kweli xwebhu)

There are no experimental medicines being used in this study. Therefore, no insurance has been obtained. However, you will be protected in terms of the study staffs' personal malpractice insurance or the university's insurance cover in the event of injury or illness that is caused by you taking part in this study (details of this insurance cover are attached in the appendix at the end of this document).

IKHONA INTO ENDIYAKUYINIKWA NGOKUTHATHA INXAXHEBA
WILL I BE GIVEN ANYTHING FOR TAKING PART?

Ekupheleni kotyelelo ngalunye, uyakunikwa iR20 ukubuyekeza imali yokukhwela ukuza kolulandelayo uvavanyo, neR120 eyi voucher yegrosara kwaye nesipho esincinci. Kuyakubakho into etyiwayo kutyelelo ngalunye.

At the end of each visit, you will be given R20 in cash to cover the transport cost to your next scheduled study visit, an R120 grocery voucher and a small gift. Refreshments will be provided at all visits.

KUKHO INTLAWULO EKUTHABATHENI INXAXHEBA?
ARE THERE ANY COSTS TO TAKING PART IN THE STUDY?

Akukho ntlawulo ngokuthatha inxaxhaeba koluphando.

There is no cost for being in this study.

NDINGALUSHIYA UPHANDO?
CAN I LEAVE THE STUDY?

Unelungelo lokugqiba ekubeni ungathathi nxaxheba kuvavanyo, ukwala ukuphendula nayiphi imibuzo, okanye ukurhoxa nangaliphi ixesha ngaphandle kwesohlwayo. Ayikuchaphazela ukhathalelo olufumanayo eGuguletu CHC okanye naliphi elinye iziko lempilo.

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

UNAYO IMIBUZO?
DO YOU HAVE ANY QUESTIONS?

Ukuba kukho into engacacanga okanye udinga ulwazi olungaphezu koku, nceda usibuze siyakukunika iimpendulo. Unayo imibuzo ngoku?

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 currently?

ULWAZI OLUTHE VETSHE:
FOR ADDITIONAL INFORMATION:

Ukuba unayo imibuzo okanye ubenengxaki ngeli xesha ubuthatha inxaxheba kolu vavanyo lophando, ungaqhagamshelana no:

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

Ukuba unayo nayiphina imibuzo malunga namalungelo akho nje ngomthathi-nxaxheba wophando, ungaqhagamshelana neli lungu lilandelayo lekomiti yophengululo:

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

INGXELO YESIVUMELWANO:
CONSENT STATEMENT:

Ndilifundile olu xwebhu, okanye ukhona umntu ondifundeleyo. Ndinikiwe ikopi yolu xwebhu. Ndomeleziwe ndanikwa ixesha lokubuza imibuzo. Ndiyavuma ukuthatha inxaxheba koluvavanyo. Ndiyayazi ukuba ukuba nangona ndikhethe ukuba koluvavanyo ndingarhoxa nangaliphi ixesha. Ukuthatha inxaxheba koluvavanyo kukuzikhethela ngokuzithandela kwam. Ndiyaqonda ukuba nokuba ndithatha inxaxheba okanye andiyithathi akuyi kuchaphazela iinkonzo zempilo endizifumane apha namhlanje, okanye nanini na kwixesha elizayo.

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 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.

NCEDA BONISA UKUVUMA NGEZANTSI NGOKUTYIKITYA:

PLEASE INDICATE YOUR CONSENT BELOW WITH YOUR SIGNATURE.

Ivolontiya / *Volunteer:*

Igama kunye Nefani / *Name and Surname* _____

Tyikitya / *Signature* _____ Umhla / *Date* _____

Umsebenzi wophando / *Staff member:*

Igama kunye Nefani / *Name and Surname* _____

Tyikitya / *Signature* _____ Umhla / *Date* _____

UKUBA IVOLONTIYA ALIKWAZI KUFUNDA OKANYE UKUBHALA, IVOLONTIYA LIYAKUBONAKALISA IMVUME NGOMNWE NAYO YONKE INKQUBO YODLIWANO-NDLEBE IYAKUQWALASELWA LINGQINA ELIZIMELEYO ELIYA KUNGQINA INKQUBO EMVA KOKUBA IMVUMELWANO YENZIWE

IF THE VOLUNTEER IS UNABLE TO READ OR WRITE, THE VOLUNTEER MUST INDICATE CONSENT WITH A FINGERPRINT AND THE ENTIRE COUNSELLING PROCESS MUST BE OBSERVED BY AN INDEPENDENT WITNESS WHO CAN CONFIRM THE PROCEDURE ONCE CONSENT HAS BEEN GIVEN.

Umnwe wevolontiya / *Fingerprint of volunteer:*

Ingqina / *Witness:*

Ndiyavuma ukuba ndizimele andikho kuphando kwaye ndiyayingqina yonke inkqubo yekhawunseling yoxwebhu lwesivumelwano ngolwimi lwasekhaya lwevolontiya.

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

Igama kunye Nefani / *Name and Surname* _____

Tyikitya / *Signature* _____ Umhla / *Date* _____

ENKOSI / *THANK YOU*

UMQUKUMBELEO: INGCACISO YEDYUNIVESITI YASE KAPA YEINSHORENSI ENGENASIPHENE
APPENDIX: EXPLANATION OF THE UNIVERSITY OF CAPE TOWN'S NO FAULT INSURANCE POLICY

KWENZEKA NTONI XA KUKHO INTO ENGAHAMBANGA KAKUHLE?
WHAT IF SOMETHING GOES WRONG?

Idyunivesiti yase Kapa ine inshorensi ekhusela kwixa lokwenzakala ngexesha uthatha inxaxheba kuvavanyo. Umntu welnshorensi uyakuhlawula zonke iindleko ezinxulumene nonyango ngokwe migaqo ye Good Clinical Practice Guidelines zaseMzantsi Afrika, ezisekwe phantsi kwe British Pharmaceutical Industry Guidelines (ABP) xa kukho umenzakalo okanye imiphumela eyenzeke ngokuthabatha inxaxheba ngqo kuvavanyo. Awuyikunyanzeleka ukuba ungqinisise ubutyala kwicala le Dyunivesiti.

Idyunivesiti ayiyi kuchaphazeleka kwilahleko, umenzakalo okanye/nengozi onokuthi uyifumane apho ilahleko iyakubangelwa koku kungezantsi:

- Kukusetyenziswa kwamachiza angagunyaziswanga
- Nawuphina umenzakalo ozizphumo zokungalandeli iimfuno zeprotokol okanye imiqathango obuyinikwe ngabasebenzi bophando
- Nawuphina umenzakalo obangelwe kukungakhathali kwakho.

The University of Cape Town (UCT) has insurance cover for the event that research-related injury or harm results from your participation in the study. The insurer will pay all reasonable medical expenses in accordance with the South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI) in the event of an injury or side effect resulting directly from taking part in the study. You will not be required to prove fault on the part of the University.

The University will not be liable for any loss, injuries and/or harm that you may sustain where the loss is caused by:

- *The use of unauthorised medicine or substances during the study;*
- *Any injury that results from you not following the protocol requirements or the instructions that the study staff may give you;*
- *An injury that results from negligence on your part*

[Researchers must bear in mind that it is unacceptable to impose a burden on participants who may not recognize symptoms or have the ready means to take action.]

By agreeing to take part in this study, you do not give up your right to claim compensation for injury where you can prove negligence, in separate litigation. In particular, your right to pursue such a claim in a South African court in terms of South African law must be ensured. Note, however, that you will usually be requested to accept that payment made by the University under the SA GCP guideline 4.11 is in full settlement of the claim relating to the medical expenses.

An injury is considered trial-related if, and to the extent that, it is caused by study activities. You must notify the study staff immediately of any side effects and/or injuries during the trial, whether they are research-related or other related complications.

UCT reserves the right not to provide compensation if, and to the extent that, your injury came about because you chose not to follow the instructions that you were given while you were taking part in the study. Your right in law to claim compensation for injury where you prove negligence is not affected. Copies of these guidelines are available on request.

Appendix H: Supplementary Tables

Table H.1: Unadjusted and adjusted Modified Poisson regression models for the association between Pregnancy intendedness and HIV VL of 400 or more copies/ml at 24 months postpartum

Variables	Unadjusted models		Adjusted model 1		Adjusted model 2	
	RR [95%CI]	*P* value	aRR [95%CI]	*P* value	aRR[95%CI]	*P* value
Pregnancy intention						
Intended	1.00		1.00		1.00	
Unintended	1.55[1.07-2.25]	0.018*	1.33[0.89-1.99]	0.151	1.33[0.90-1.97]	0.149
Maternal age (years)						
18 – 24	1.00		1.00		1.00	
25 – 28	1.00[0.64-1.56]	0.994	0.98[0.58-1.64]	0.948	1.00[0.60-1.65]	0.990
29 – 34	0.77[0.49-1.22]	0.279	0.71[0.45-1.36]	0.394	0.79[0.46-1.35]	0.398
≥35	0.58[0.29-1.16]	0.124	0.39[0.35-1.09]	0.082	0.52[0.25-1.08]	0.080
Parity						
1	1.00		1.00		1.00	
2	1.07[0.69-1.68]	0.737	1.15[0.70-1.88]	0.565	1.13[0.70-1.83]	0.575
≥3	1.23[0.77-1.95]	0.376	1.44[0.83-2.49]	0.184	1.46[0.85-2.51]	0.182
Relationship status						
Married or Cohabiting	1.00		1.00		1.00	
Unmarried and not cohabiting	1.47[1.01-2.13]	0.041*	1.29[0.87-1.92]	0.194	1.28[0.86-1.90]	0.213
Employment status						
Employed	1.00		1.00		1.00	
Unemployed	1.08[0.74-1.56]	0.680	1.06[0.74-1.51]	0.733	1.06[0.75-1.52]	0.709
Live in informal housing						
No	1.00		1.00		1.00	
Yes	0.79[0.56-1.12]	0.191	0.79[0.57-1.12]	0.189	0.79[0.56-1.10]	0.169
Baseline HIV VL						
<50 copies/ml	1.00		1.00		1.00	
≥50 copies/ml	1.61[1.08-2.40]	0.018*	1.37[0.91-2.09]	0.128	1.38[0.90-2.10]	0.130
Previous ART use						
No	1.00		1.00		1.00	
Yes	2.04[1.42-2.93]	0.000*	1.79[1.18-2.71]	0.006*	1.88[1.25-2.84]	0.003*
Months on ART at time of VL assessment	1.00[0.95-1.03]	0.681	1.00[0.97-1.03]	0.937	1.00[0.97-1.03]	0.779
Trial allocation						
Clinic	1.00				1.00	
Club	0.75[0.53-1.06]	0.10			0.70[0.50-0.99]	0.046*

***statistically significant p-values; VL=Viral load; ART= antiretroviral therapy; RR=Risk ratio; 95% CI=95% Confidence interval; aRR, adjusted odds ratios; Model 1 adjusted for demographic, socio-economic and clinical variables; Model 2 adjusted for all those in model 1 plus random allocation**

Table H.2: Unadjusted and adjusted Modified Poisson regression models for the association between Pregnancy intendedness and HIV VL of 50 or more copies/ml at 24 months postpartum

Variables	Unadjusted models		Adjusted model 1		Adjusted model 2	
	RR [95%CI]	*P* value	aRR [95%CI]	*P* value	aRR[95%CI]	*P* value
Pregnancy intention						
Intended	1.00		1.00		1.00	
Unintended	1.48 [1.07-2.05]	0.017*	1.21[0.85-1.72]	0.269	1.21 [0.86-1.71]	0.264
Maternal age (years)						
18 – 24	1.00		1.00		1.00	
25 – 28	0.88 [0.59-1.32]	0.556	0.83 [0.53-1.31]	0.425	0.85 [0.54-1.32]	0.473
29 – 34	0.80 [0.54-1.18]	0.263	0.78 [0.49-1.45]	0.310	0.79 [0.50-1.25]	0.315
≥35	0.52 [0.28-0.99]	0.047*	0.49 [0.25-0.96]	0.037*	0.50 [0.26-0.96]	0.037*
Parity						
1	1.00		1.00		1.00	
2	1.16 [0.79-1.72]	0.435	1.37 [0.89-2.11]	0.146	1.34 [0.88-2.05]	0.165
≥3	1.10 [0.72-1.68]	0.650	1.41 [0.86-2.31]	0.163	1.42 [0.87-2.32]	0.153
Relationship status						
Married or Cohabiting	1.00		1.00		1.00	
Unmarried and not cohabiting	1.63 [1.16-2.30]	0.004*	1.46 [1.02-2.11]	0.037*	1.44 [1.00-2.06]	0.046*
Employment status						
Employed	1.00		1.00		1.00	
Unemployed	1.05 [0.76-1.46]	0.738	1.02 [0.74-1.41]	0.877	1.03 [0.75-1.42]	0.843
Live in informal housing						
No	1.00		1.00		1.00	
Yes	0.82 [0.60-1.11]	0.197	0.86 [0.64-1.17]	0.354	0.85 [0.64-1.16]	0.316
Baseline HIV VL						
<50 copies/ml	1.00		1.00		1.00	
≥50 copies/ml	1.48 [1.03-2.13]	0.031*	1.32 [0.90-1.93]	0.142	1.31 [0.89-1.93]	0.158
Previous ART use						
No	1.00		1.00		1.00	
Yes	1.77 [1.26-2.48]	0.001*	1.63 [1.11-2.40]	0.012*	1.73 [1.18-2.55]	0.005*
Months on ART at time of VL assessment	1.00 [0.96-1.02]	0.611	1.00 [0.97-1.02]	0.805	1.00 [0.97-1.03]	0.981
Trial allocation						
Clinic	1.00				1.00	
Club	0.68 [0.50-0.92]	0.014*			0.67 [0.49-0.92]	0.011*

***statistically significant p-values; VL=Viral load; ART= antiretroviral therapy; RR= Risk ratio; 95% CI=95% Confidence interval; aRR= adjusted risk ratios; Model 1 adjusted for demographic, socio-economic and clinical variables; Model 2 adjusted for all those in model 1 plus random allocation**

Table H.3: Unadjusted and adjusted logistic regression models for the association between Pregnancy intendedness and HIV VL of 1000 or more copies/ml postpartum: stratified by Previous ART use, Baseline HIV VL and Duration on ART

Variables	Unadjusted models		Adjusted model 1		Adjusted model 2	
	RR [95%CI]	*P* value	aRR [95%CI]	*P* value	aRR[95%CI]	*P* value
Total sample						
Intended	1.00		1.00		1.00	
Unintended	1.54 [1.03-2.28]	0.032*	1.36 [0.88-2.09]	0.155	1.36[0.88-2.08]	0.158
Among women previously on ART						
Intended	1.00		1.00		1.00	
Unintended	0.85 [0.43-1.70]	0.659	0.89 [0.49-1.63]	0.724	0.90 [0.47-1.72]	0.753
Among women not previously on ART						
Intended	1.00		1.00		1.00	
Unintended	1.80 [1.13-2.87]	0.012*	1.58 [0.96-2.61]	0.067	1.57 [0.96-2.58]	0.069
Baseline HIV VL <50 copies/ml						
Intended	1.00		1.00		1.00	
Unintended	1.59 [1.02-2.47]	0.039*	1.41[0.87-2.28]	0.155	1.41[0.89-2.25]	0.141
Baseline HIV VL ≥50 copies/ml						
Intended	1.00		1.00		1.00	
Unintended	0.99 [0.43-2.25]	0.989	1.01[0.40-2.52]	0.974	1.10[0.50-2.45]	0.803
Months on ART< Median(29.24)						
Intended	1.00		1.00		1.00	
Unintended	1.44 [0.83-2.50]	0.184	1.17[0.67-2.04]	0.576	1.15[0.65-2.01]	0.618
Months on ART>Median(29.24)						
Intended	1.00		1.00		1.00	
Unintended	1.58 [0.90-2.80]	0.110	1.67[0.90-3.07]	0.098	1.67[0.91-3.06]	0.096

***statistically significant p-values; VL=Viral load; ART= antiretroviral therapy; RR=risk ratio; 95% CI=95% Confidence interval; aRR, adjusted risk ratios; Model 1 adjusted for demographic, socio-economic and clinical variables; Model 2 adjusted for all those in model 1 plus random allocation**

Appendix I: Ethics Approval for Study

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-submissions@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

23 April 2021

HREC REF: 190/2021

Dr J Odayar
Division of Epidemiology & Biostatistics
Falmouth Building-FHS
Email: Jasantha.odayar@uct.ac.za
Student: mwlpum002@myuct.ac.za
mwalyepj@gmail.com

Dear Dr Odayar

PROJECT TITLE: IMPACT OF UNINTENDED PREGNANCY ON HIV VIRAL LOAD OUTCOMES AMONG POSTPARTUM WOMEN LIVING WITH HIV IN CAPE TOWN, SOUTH AFRICA: CLUES FROM POSTPARTUM ADHERENCE CLUBS FOR ANTIRETROVIRAL THERAPY TRIAL (PACART)- MASTERS CANDIDATE-MS PUMULO J MWALYE

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 April 2022.

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: - Ms Pumulo Mwalye will also be involved in this study.

Please quote the HREC REF 190/2021 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.

HREC/REF 776/2020sa

Yours sincerely

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

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 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.

HREC/REF 776/2020M

Appendix J: Journal Submission Guidelines

JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY Open Access

Sections

1. SUBMISSION

Please carefully read through the Instructions for Authors and prepare your manuscript according to the guidelines, including structuring it manuscript based on the chosen article category. Manuscripts that do not follow the instructions may be returned to the authors for corrections.

Authors should kindly note that submission implies that the content has not been published or submitted for publication elsewhere except as a brief abstract in the proceedings of a scientific meeting or symposium.

Once the submission materials have been prepared in accordance with the Author Guidelines, manuscripts should be submitted online at https://mc.manuscriptcentral.com/jias. The submission system will prompt authors to use an ORCID iD (a unique author identifier) to help distinguish their work from that of other researchers. Click here to find out more.

You will be asked to suggest potential peer reviewers for your manuscript: they should be experts in the field and be able to provide an objective assessment of the manuscript. Any suggested peer reviewers should not have published with any of the authors of the manuscript within the past five years, should not be current collaborators, and should not be members of the same institution. Suggested reviewers will be considered alongside potential reviewers identified by the Editorial team.

Click here for more details on how to use ScholarOne.

2. AIMS AND SCOPE

The *JIAS* welcomes submissions on HIV-related topics from across all scientific disciplines, including but not limited to:

- Basic and biomedical sciences
- Behavioural sciences
- Epidemiology
- Clinical sciences
- Health economics and health policy
- Operations research and implementation sciences
- Social sciences and humanities, including political sciences and media

The *JIAS* prioritizes submissions from operational research and implementation science as publication of such material can provide valuable information on various algorithms for monitoring

and providing support for comprehensive, yet affordable and sustainable treatment, prevention and care programmes in different contexts.

Submission of HIV research carried out in low- and middle-income countries is strongly encouraged.

3. MANUSCRIPT CATEGORIES AND REQUIREMENTS

The *JIAS* accepts submissions in the following categories:

- Research
- Short report
- Review
- Debate
- Commentary
- Letter to the Editor
- Viewpoint

Research - full reports of data from original research studies

Abstract:
Headings: Introduction, Methods, Results, Conclusions
Word limit: 350 words

Main text:
Headings: Introduction, Methods, Results, Discussion, Conclusions
Word limit (quantitative): 3500 words; Tables do not contribute to the word count
Word limit (qualitative and mixed methods): 5000 words; tables with quotes contribute to the word count
Numbers of figures and tables: Unlimited
Additional files: Yes

Download the manuscript template

Short report - brief reports of data from original research, such as follow-up or confirmatory studies, case series and negative results

Abstract:
Headings: Introduction, Methods, Results and discussion, Conclusions
Word limit: 350 words

Main text:
Headings: Introduction, Methods, Results and discussion, Conclusions
Word limit: 2000 words
Numbers of figures and tables: 3
Additional files: No

Download the manuscript template

Review - comprehensive, authoritative descriptions and summaries of a specific subject area providing a systematic and substantial overview of the field

Abstract:
Headings: Introduction, Methods, Results and discussion (if applicable, otherwise Discussion only), Conclusions
Word limit: 350 words

Main text:
Headings: Introduction, Methods, Results and discussion (if applicable, otherwise Discussion only), Conclusions

Word limit: 5000 words
Numbers of figures and tables: Unlimited
Additional files: Yes

Download the manuscript template

Debate - presentation of an evidence-based argument

Abstract:
Headings: Introduction, Discussion, Conclusions
Word limit: 350 words

Main text:
Headings: Introduction, Discussion, Conclusions
Word limit: 3500 words
Numbers of figures and tables: 4
Additional files: No

Download the manuscript template

Commentary - focused and opinionated articles on important and timely issues, no original data

Abstract:
Headings: Introduction, Discussion, Conclusions
Word limit: 350 words

Main text:
Headings: Introduction, Discussion, Conclusions
Word limit: 2500 words
Numbers of figures and tables: 1
Additional files: No

Download the manuscript template

Letter to the Editor - comments on and responses to published articles

Abstract:
None

Main text:
Headings: None
Word limit: 500 words
Numbers of figures and tables: None
Additional files: No

Download the manuscript template

Viewpoint - constructive, stand-alone views on current topics

Abstract:
None

Main text:
Headings: None
Word limit: 1000 words
Numbers of figures and tables: 1
Maximum number of references: 15

Maximum number of authors: 5
Additional files: No

Download the manuscript template

4. PREPARING THE SUBMISSION

Cover letter
In the cover letter, please explain why your manuscript should be published in the journal. If necessary, address any issues relating to our editorial policies .and declare any competing interests (see Editorial Policies and Ethical Considerations)

Parts of the Manuscript
The manuscript should be submitted as a main text file including tables and figures. Appendices and supporting information should be submitted as separate files.

Main Text File
The text file should be presented in the following order:

1. Title page;
2. Keywords;
3. Abstract;
4. Main text;
5. Conflict of Interest Statement;
6. Authorship;
7. Acknowledgments;
8. References;
9. Tables;
10. Figures;

Title page
The title should not contain abbreviations, except commonly used abbreviations such as HIV or AIDS (see Wiley's best practice SEO tips).

On the title page, you should mention the title of the manuscript, list all authors' names in full, and list any study groups if applicable. Each authors' affiliation should be numbered in superscript consecutively and listed underneath, including department, institution, city and country.

The corresponding author should be marked with the symbol § in superscript and full contact details should be provided, including a telephone number with country code. Authors who have contributed equally to the work should be marked with the symbol * in superscript. Deceased authors should be marked with the symbol ^ in superscript. The email addresses of all authors should be listed by their initials.

Keywords
Pease provide six keywords. Keywords should be taken from those recommended by the US National Library of Medicine's Medical Subject Headings (MeSH) browser list at https://www.nlm.nih.gov/mesh/. Preferably alternate words to those found in the abstract in order to improve search hits for the article in repositories.

Abstract
The Abstract should not exceed 350 words and should be structured according to the headings of the selected article category (see above), excluding the heading "Discussion" for Research articles. Avoid using abbreviations and do not cite references in the Abstract. If you are reporting results from a controlled health care intervention, please include your trial registry, together with your unique identifying number at the end of the Abstract. For randomized controlled trials, follow the CONSORT extension for abstracts .

Main Text

Article sections

Introduction

The Introduction section should introduce the topic to readers without specialist knowledge in that area and must clearly outline the current state of knowledge in this field, the motivation and the aim of the study or the article.

Methods

The Methods section should include all information necessary to repeat the study, in particular, the study design, how data was collected and analyzed, clarifying the choice of methods that were made. If applicable, you should describe the setting of the study, the dates the study were conducted, and the sample or participants, as well as necessary power calculations and materials, including statistical packages, used. Interventions and programmes should be described in detail. Generic names for drugs or any molecules should be used.

All studies involving humans or animals require a statement on ethical approval, and for the former, the consent procedure that was followed. Please include the names of the ethics review board(s) that approved the study. If the research study was specific to one sex/gender, the reasons for this should be clearly stated.

Results

This section should include only data and findings from the authors' study. Presentation of statistical results should mention confidence intervals and levels of significance where appropriate. Quotes from qualitative study participants of less than three lines should be quoted in the text using quotation marks. For quotes longer than three lines, place the quote in a separate, indented paragraph and introduce it with a colon. No quotation marks are needed in this case. Details of the participant can be added in round brackets following the quote, but should not contain identifiable information to ensure confidentiality. Clarifications within the quotation should be placed in square brackets. In some cases, it may also be appropriate to organize quotes within a table. For details on the use of tables to display qualitative quotes, please see guidance below, under *Tables*.

Submitting authors should include data disaggregated by sex (and, whenever possible, by race or ethnicity) and provide a comprehensive analysis of gender and racial or ethnic differences. The authors should include the number and percentage of men, women and, if appropriate, transgender persons who participated in the research study. Anatomical and physiological differences between men and women (height, weight, body fat-to-muscle ratios, cell counts, hormonal cycles, etc.), as well as social and cultural variables (socio-economic, education, access to care, etc.), should be taken into consideration in the presentation of data and/or analysis of the results.

Discussion

In the Discussion section, you should discuss your main findings and place these within the context of the current body of knowledge in the field. Limitations of the study, for example, selection bias, can also be discussed, and should address how these influence the results and conclusions. If statistically significant differences were found between men and women or between different racial or cultural groups in the effects of the studied intervention, the implications, if any, for clinical and/or public health should be adequately discussed.

Conclusions

In your Conclusions section, state your key messages from the study and explain their importance and relevance, as well as implications. Future studies and recommendations can be included in this section. The conclusions drawn must be strictly based on the data provided.

Conflict of Interest Statement

Authors will be asked to provide a conflict of interest statement during the submission process. For details on what to include in this section, see the 'Conflict of Interest' section in the **Editorial Policies and Ethical Considerations** section below. Submitting authors should ensure they liaise with all co-authors to confirm agreement with the final statement.

Authorship

Please refer to the journal's Authorship policy in the **Editorial Policies and Ethical Considerations** section for details on author listing eligibility. The individual contributions of each author must be specified in the Authors' Contributions section. Please use authors' initials and state that all authors have read and approved the final manuscript. An example of a suitable statement is: "S.W., N.J., D.W. and S.S. performed the research. S.W., N.J., H.H. and T.L. designed the research study. H.H. and S.S. contributed essential reagents or tools. S.W., N.J. and D.W. analysed the data. S.W. and N.J. wrote the paper." Please see the 'Authorship' section in the Editorial Policies and Ethical Considerations section below for what constitutes authorship.

Acknowledgments

Contributions from anyone who does not meet the criteria for authorship should be listed, with permission from the contributor, in an Acknowledgments section. Financial and material support should also be mentioned. Thanks to anonymous reviewers are not appropriate.

References

All external sources of information should be referenced within the text, the tables and figures, using consecutive numbering in square brackets, e.g. [1], [3-5], [3,4]. The references should be up to date and adequately reflect the current state of knowledge in the field. Citation bias, for example, by country or point of view must be avoided. Numbers of references are unlimited for all article categories and should be formatted in standard Vancouver style; **see Sample references from ICMJE** . Unpublished observations, personal communications and manuscripts currently under consideration should be cited in the text in round brackets and not in the reference list.

Tables

They should be supplied as editable files, not pasted as images. Tables should be inserted into the text. They should have the header: "Table 1. Title of table". All tables should be cited in the text in consecutive order. The tables should not contain colour or shading, and no vertical, visible lines. If tables are copied or adapted from another source, permission must be sought by the authors prior to publication and these should be clearly cited as such. If a table spans more than one page, authors may want to consider uploading the table as an additional file instead. Tables should be self-contained and complement, not duplicate, information contained in the text. A legend can be provided underneath the title, listing any abbreviations or meanings of symbols used. If several tables are included, please ensure that symbols are used consistently. Legends should be concise but comprehensive – the table, legend, and footnotes must be understandable without reference to the text. All abbreviations must be defined in footnotes. Footnote symbols: †, ‡, §, ¶, should be used (in that order) and *, **, *** should be reserved for P-values. Statistical measures such as SD or SEM should be identified in the headings.

Guidance on the use of tables to display qualitative quotes:

Quotes placed in tables should be organized thoughtfully and strategically, to aid the clear presentation of results. Displaying quotes in tables may be particularly useful when comparing and contrasting subgroup variations in responses or showing temporal variation. Tables may also help visually organize themes when they correspond to the order or way in which findings are described in the text. Please note that tables that present quotes will contribute to the overall word count of the manuscript, with intention to avoid excessively long tables in which quotes are placed without sufficient context. Accordingly, the word limit for qualitative and mixed methods submissions is 5,000 words, inclusive of tables with quotes.

Figures
Figures should be cropped as closely as possible and have the header: "Figure 1. Title of figure". All figures need to be cited in the text in consecutive order.

Although authors are encouraged to send the highest-quality figures possible, for peer-review purposes, a wide variety of formats, sizes, and resolutions are accepted. **Click here** for the basic figure requirements for figures submitted with manuscripts for initial peer review, as well as the more detailed post-acceptance figure requirements.

Figure legends should be concise but comprehensive – the figure and its legend must be understandable without reference to the text. Include definitions of any symbols used and define/explain all abbreviations and units of measurement. If several figures are included, please ensure that symbols are used consistently.
Post-peer review, the manuscript should be submitted as a main text file including tables and figures. Tables and figures should also be submitted separately as high-resolution versions.

Additional Files

Appendices
Appendices will be published after the references. For submission, they should be supplied as separate files but referred to in the text.

Supporting Information
Supporting information is information that is not essential to the article, but provides greater depth and background. It is hosted online and appears without editing or typesetting. It may include tables, figures, videos, datasets, etc. **Click here** for Wiley's FAQs on supporting information.

Note : if data, scripts, or other artefacts used to generate the analyses presented in the paper are available via a publicly available data repository, authors should include a reference to the location of the material within their paper.

General Style Points
The following points provide general advice on formatting and style:

• **Abbreviations:** In general, terms should not be abbreviated unless they are used repeatedly and the abbreviation is helpful to the reader. Initially, use the word in full, followed by the abbreviation in parentheses. Thereafter use the abbreviation only.
• **Acronyms:** Acronyms should be used sparingly, and not in headings or in the Abstract. Only commonly known acronyms may be used, and they should be spelt out at first use followed by the abbreviation in brackets. SI units should be used, with litre and molar being permitted.
• **Units of measurement:** Measurements should be given in SI or SI-derived units. Visit the Bureau International des Poids et Mesures (BIPM) website **here** for more information about SI units.
• **Numbers:** Numbers under 10 are spelt out, except for: measurements with a unit (8mmol/l); age (6 weeks old), or lists with other numbers (11 dogs, 9 cats, 4 gerbils).
• **Trade Names:** Chemical substances should be referred to by the generic name only. Trade names should not be used. Drugs should be referred to by their generic names. If proprietary drugs have been used in the study, refer to these by their generic name, mentioning the proprietary name and the name and location of the manufacturer in parentheses.
• **Footnotes:** Footnotes are not allowed in the text, the information shall be included directly into the text, where it fits best, and if these are references, to include in the reference section at the end.
• **Language**: All submissions must be in UK English (International) and UN-accepted terminology should be followed. No capitalization should be used except for grammatically correct use, official names and titles, and abbreviations.
• **General recommendation:** Use line spacing of 1.5 and an easily readable font, for example, Times New Roman, size 12. Your manuscript should contain line numbers to facilitate editors' and reviewers' comments

Wiley Author Resources
Manuscript Preparation Tips: Wiley has a range of resources for authors preparing manuscripts

for submission available here . In particular, authors may benefit from referring to Wiley's best practice tips on Writing for Search Engine Optimization .

Editing, Translation, and Formatting Support: Wiley Editing Services can greatly improve the chances of a manuscript being accepted. Offering expert help in English language editing, translation, manuscript formatting, and figure preparation, Wiley Editing Services ensures that the manuscript is ready for submission.

5. EDITORIAL POLICIES AND ETHICAL CONSIDERATIONS

Editorial Review and Acceptance

The acceptance criteria for all papers are the quality and originality of the research and its significance to journal readership. Except where otherwise stated, manuscripts are single-blind peer reviewed, meaning that reviewers remain anonymous to the authors, although the authors' identity is known to the reviewers. Papers will only be sent to review if the Editors-in-Chief determine that the paper meets the appropriate quality and relevance requirements.

All manuscripts are reviewed by at least two independent experts with experience in the subject area and selected by the Editors. Dedicated statistical reviewers may be used if needed. Reviewers have to declare any competing interests to the Editors. Authors can suggest peer reviewers during the submission step. Suggested peer reviewers should not have co-authored publications with any of the authors during the past five years, should not be current collaborators, and should not be members of the same institution. Suggested reviewers will be considered alongside potential reviewers identified by the Editorial team. Authors may also request exclusion of individuals as potential reviewers: those who have clear competing interests, are close collaborators, or have given input into the manuscript previously.

The Editors assess revised manuscripts based on whether the authors have adequately addressed all comments. Re-reviews are only requested when revisions fall out of the technical expertise of the Editors. Further rounds of major revisions are usually not allowed, and manuscripts that have not been satisfactorily revised will be rejected. Minor revisions though may be requested as needed.

Wiley's policy on the confidentiality of the review process is available here.

Data Storage and Documentation

The *Journal of the International AIDS Society* expects that data supporting the results in the paper will be archived in an appropriate public repository. Whenever possible the scripts and other artefacts used to generate the analyses presented in the paper should also be publicly archived. Exceptions may be granted at the discretion of the editor for sensitive information such as human subject data or the location of endangered species. Authors are expected to provide a data accessibility statement, including a link to the repository they have used, to accompany their paper.

Protein and nucleotide sequences

For nucleic acid sequences, protein sequences or atomic coordinates, which are cited in the manuscript, and the accession number, together with the database where the information was deposited, should be cited in square brackets in the text, for example, [EMBL:AB026295, EMBL:AC137000, DDBJ:AE000812, GenBank:U49845, PDB:1BFM, Swiss-Prot:Q96KQ7, PIR:S66116]. Relevant databases are: EMBL Nucleotide Sequence Database (EMBL), DNA Data Bank of Japan (DDBJ), GenBank at the NCBI (GenBank), Protein Data Bank (PDB), Protein Information Resource (PIR) and the Swiss-Prot Protein Database (Swiss-Prot).

Mass spectrometry

Mass spectrometry data should be provided in the mzML format according to the HUPO Protein Standards Initiative Mass Spectrometry Standards Working Group guidelines. The data should also be deposited in the ProteomeExchange through the PRIDE website, and protein interaction data can be deposited through members of the IMEx consortium.

Structures
Protein structures can be submitted with one of the members of the Worldwide Protein Data Bank. Nucleic acid structures can be deposited with the Nucleic Acid Database at Rutgers. Crystal structures of organic compounds can be deposited with the Cambridge Crystallographic Data Centre.

Chemical structures and assays
Structures of chemical substances can be deposited with PubChem Substance. Bioactivity screens of chemical substances can be deposited with PubChem BioAssay.

Functional genomics data (such as microarray or CHIP-Seq data)
Please refer to standards proposed by the Functional Genomics Data Society and deposit your microarray data in MIAME-compliant format in one of the public repositories, for example, ArrayExpress or Gene Expression Omnibus (GEO). Deposition of high-throughput functional genomics sequencing data (such as RNA-Seq or ChIP-Seq data) with ArrayExpress or GEO in compliance with MINSEQE is also needed.

Computational modelling
Please prepare models of biochemical reaction networks using the Systems Biology Markup Language and submit your model to the BioModels database, as well as providing it as an additional file with your submission.

Plasmids
Please submit copies of your plasmids as DNA or bacterial stocks with Addgene, a non-profit repository, or PlasmID, the Plasmid Information Database at Harvard.

Ethical approval – Human and animal studies

Human Studies and Subjects
For manuscripts reporting medical studies that involve human participants, a statement identifying the ethics committee that approved the study and confirmation that the study conforms to recognized standards is required, for example: Declaration of Helsinki; US Federal Policy for the Protection of Human Subjects; or European Medicines Agency Guidelines for Good Clinical Practice.

A statement on the ethical aspects, including the consent procedure followed, must be included in the Methods section of the manuscript. The Editors may reject manuscripts where the research has not been carried out within an ethical framework. Images and information from individual participants will only be published where the authors have obtained the individual's free prior informed consent. Confidentiality of study participants must be ensured at all stages of research and reporting. Authors do not need to provide a copy of the consent form to the publisher; however, in signing the author license to publish, authors are required to confirm that consent has been obtained. Wiley has a standard patient consent form available for use.

Animal Studies
A statement indicating that the protocol and procedures employed were ethically reviewed and approved, as well as the name of the body giving approval, must be included in the Methods section of the manuscript. Authors are encouraged to adhere to animal research reporting standards, for example the The Gold Standard Publication Checklist from Hooijmans and colleagues or the ARRIVE reporting guidelines for reporting study design and statistical analysis; experimental procedures; experimental animals and housing and husbandry. Authors should also state whether experiments were performed in accordance with relevant institutional and national guidelines for the care and use of laboratory animals:

- US authors should cite compliance with the US National Research Council's Guide for the Care and Use of Laboratory Animals, the US Public Health Service's Policy on Humane Care and Use of Laboratory Animals, and Guide for the Care and Use of Laboratory Animals.
- UK authors should conform to UK legislation under the Animals (Scientific Procedures) Act 1986

Amendment Regulations (SI 2012/3039).
• European authors outside the UK should conform to Directive 2010/63/EU.

Clinical Trial Registration

The journal requires that clinical trials are prospectively registered in a publicly accessible database and clinical trial registration numbers should be included in all papers that report their results. Authors are asked to include the name of the trial register and the clinical trial registration number at the end of the abstract. If the trial is not registered, or was registered retrospectively, the reasons for this should be explained.

Research Reporting Guidelines

Standard of reporting

The *JIAS* endorses international standards of reporting. Please see the Uniform Requirements for Manuscripts Submitted to Biomedical Journals guidelines produced by ICMJE as a reference standard of reporting. Authors are also referred to the EQUATOR network website for further information on the available reporting guidelines for health research, and the MIBBI Portal for prescriptive checklists for reporting biological and biomedical research where applicable. A number of checklists are available for various study designs, including randomized controlled trials (CONSORT), interventional trials (SPIRIT), qualitative research (COREQ), systematic reviews (PRISMA), observational studies (STROBE), economic evaluations of health interventions (CHEERS), meta-analyses of observational studies (MOOSE) and diagnostic / prognostic studies (STARD and TRIPOD). For systematic reviews, an additional file should be provided by the authors listing all details concerning the search strategy. Please refer to the Cochrane Reviewers' Handbook for an example of how a search strategy should be presented.

Guidelines on mutation nomenclature are provided by the Human Genome Variation Society , and authors should use the recommended gene name by referring to the appropriate genetic nomenclature database, for example, HUGO for human genes, and the International Committee on Standardized Genetic Nomenclature for Mice. When describing human phenotypes, please use standardized terms, such as those proposed by the Elements of Morphology working group (see http://research.nhgri.nih.gov/morphology/index.cgi).

Contributions from pharmaceutical companies or other commercial organizations should follow the Good Publication Practice guidelinEs for pharmaceutical companies, which also apply to any companies or individuals that work on industry-sponsored publications, such as freelance writers, contract research organizations and communications companies.

The *JIAS* supports international standards of reporting of trials, in particular, prospective registering and numbering of clinical trials. Clinical trials are defined by the World Health Organization as all phase I to IV trials, which are research studies that prospectively assign human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Trials need to be registered prior to submission in a suitable, publicly available registry. Links to existing registries can be found through ICMJE here or through the primary registers that participate in the WHO International Clinical Trials Registry Platform. The trial registration number should be included as the last line of the manuscript Abstract.

Reporting by gender and race or ethnicity

Submitting authors should include data disaggregated by sex (and, whenever possible, by race) and provide an analysis of gender and racial differences. The authors should include the number and percentage of men, women and, if appropriate, transgender persons, who participated in the research study. Anatomical and physiological differences between men and women (height, weight, body fat-to-muscle ratios, cell counts, hormonal cycles, etc.), as well as social and cultural variables (socio-economic, education, access to care, etc.), should be taken into consideration in the presentation of data and/or analysis of the results. If statistically significant differences were found between men and women or between different racial or cultural groups in the effects of the studied

intervention, the implications, if any, for clinical and/or public health should be adequately discussed. If the research study was specific to one sex/gender, the reasons for this should be clearly stated. Please refer to the **SAGER guidelines** for more information

Species Names
Upon its first use in the title, abstract, and text, the common name of a species should be followed by the scientific name (genus, species, and authority) in parentheses. For well-known species, however, scientific names may be omitted from article titles. If no common name exists in English, only the scientific name should be used.

Genetic Nomenclature
Sequence variants should be described in the text and tables using both DNA and protein designations whenever appropriate. Sequence variant nomenclature must follow the current HGVS guidelines; see **varnomen.hgvs.org**, where examples of acceptable nomenclature are provided.

Conflict of Interest
Authors are required to submit a statement on competing interests, which exist when personal or financial relationships with persons or organizations may influence the interpretation of the data or how the author's work is presented. For details, see ICMJE's policy on competing interests **here**. In brief, all financial competing interests must be disclosed in this statement (reimbursements, fees, funding, salary payments from or ownership of any stocks or shares in an organization that may in any way gain or lose financially from the publication of the manuscript, either now or in the future, or applications for patents relating to the content of the manuscript), as well as non-financial competing interests (such as political, personal, religious, ideological, academic and/or intellectual interests) that are related to the work submitted. The competing interest statement should be included in the manuscript and will be published in the final article. If no competing interests exist, please state in this section, "The authors declare that they have (or The author declares that he/she has) no competing interests."

Copyright and libel
Legal responsibility to ensure that no material is published that infringes copyright or that includes libellous or defamatory content lies with the Journal of the International AIDS Society's publisher, the International AIDS Society. If a manuscript is judged by the journal Editors to include potentially libellous content, authors will be requested to adjust wording as necessary.

Commercial writers and editors
The involvement of scientific (medical) writers or anyone else who assisted with the preparation of the manuscript content should be acknowledged, along with their source of funding, as described in the European Medical Writers Association (EMWA) **guidelines** on the role of medical writers in developing peer-reviewed publications.

Funding
Authors should list all funding sources in the Acknowledgments section. Authors are responsible for the accuracy of their funder designation. If in doubt, please check the Open Funder Registry for the correct nomenclature: **https://www.crossref.org/services/funder-registry/**

Authorship
It is understood that all authors listed on submitted manuscripts have read and agreed to its content, and meet the authorship requirements as detailed by ICMJE **here**. The list of authors should accurately illustrate who contributed to the work and how. All those listed as authors should qualify for authorship according to the following criteria:

1. Have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
2. Have been involved in drafting the manuscript or revising it critically for important intellectual content;
3.Have given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content; and

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Appendix K: Flow Chart of Data Analysis Process

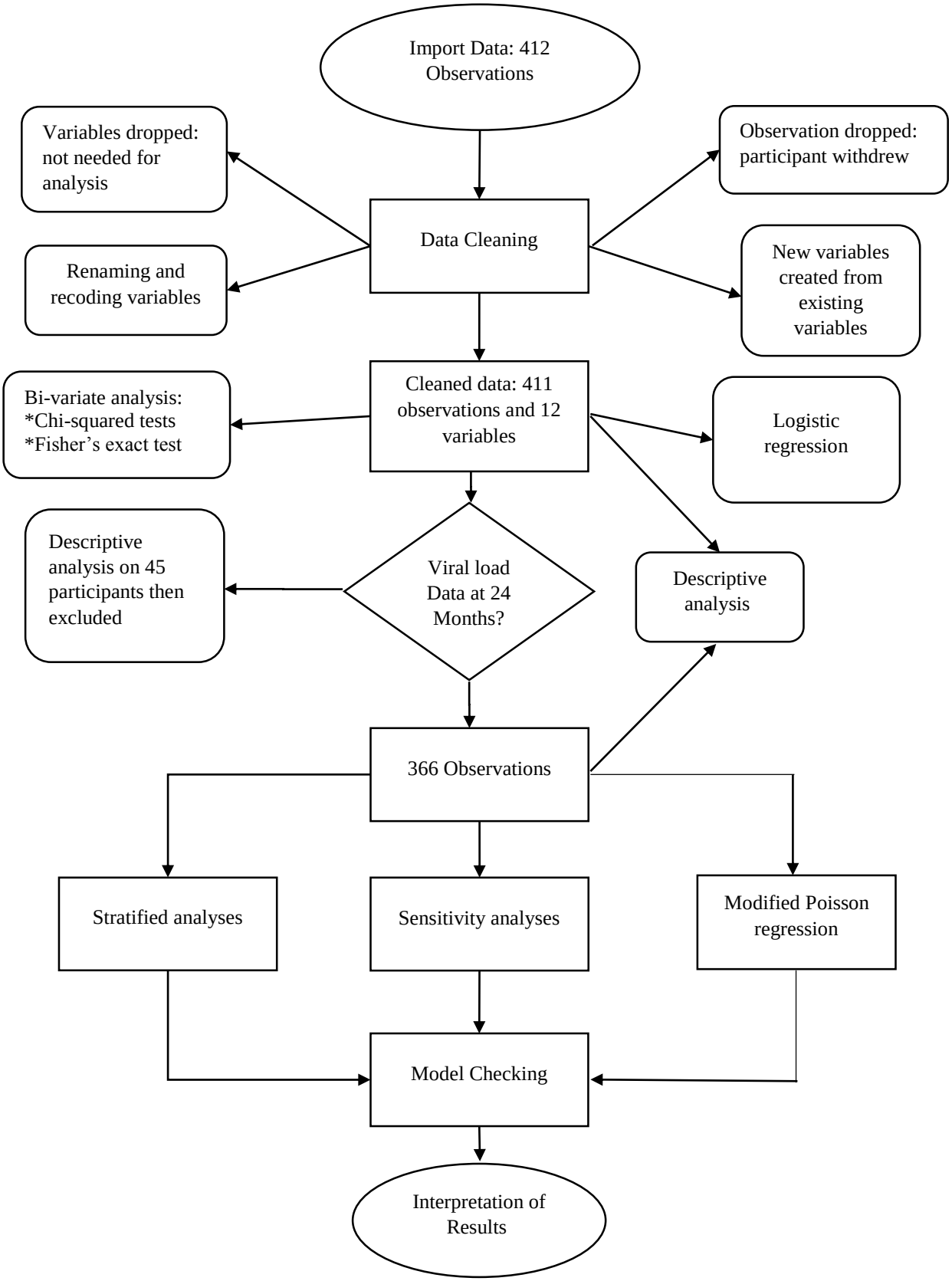

Figure 2: Flow chart of data analysis process