Patterns of mobility, and the effect of mobility on viral suppression and retention among postpartum women living with HIV in South Africa

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Declaration

I, Robyn Mazriel, Student No. MZRROB001, 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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Dissertation Abstract

Introduction: In South Africa postpartum women have been shown to be at high risk of disengagement from HIV care and postpartum mobility may be related to disruptions in care. This study aimed to describe patterns of mobility, and explore associations with viral suppression and retention in the postpartum period.

Methods: This study used data from a prospective cohort study that enrolled women who initiated life-long antiretroviral therapy (ART) during their pregnancy in Gugulethu, Cape Town (March 2013 - June 2014), and an additional follow-up study at approximately 4 years postpartum. Patterns of self-reported mobility between delivery and the 4 year measurement visit were examined. Log-binomial models were used to explore the association between mobility (moving in the 3, 6 or 12 months prior to the study visit) and i) viral suppression (viral load (VL) ≤50 and ≤1000 copies/mL measured at the 12 month and 4 year measurement visit) and ii) retention in care (based on routine medical record data at approximately 12 months and 4 years postpartum).

Results: Among the 353 women in this analysis, 98 (28%) reported having ever moved between delivery and 4 years postpartum. Mobility was more likely to occur soon after delivery with 50% of the moves occurring within the first year following delivery; the most common reason for moving being to live with and receive support from family (44%). Moving within 3 months of the viral load measurement at 12 months postpartum was associated with having a VL≤50 copies/mL (aRR=1.61, 95% CI: 1.17-2.21). Moving in any window prior to the 12 month or 4 year postpartum viral load was not associated with viral suppression. Retention in care at both 12 months and 4 years postpartum was not associated with mobility.

Conclusions: These results demonstrate that movement following delivery is a common occurrence among postpartum women, but this movement did not seem to disrupt engagement in HIV care. There is a need for further research to understand the impact of this movement on postpartum women's viral suppression and retention in care, as well as on ways to support continued engagement in HIV care after delivery.

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Table of Contents

List of Tables

Protocol

Manuscript

Appendices

PART A: PROTOCOL

Protocol Synopsis

Background: Consistent retention in HIV care, specifically in the postpartum period, is a significant challenge in South Africa [1,2]. Postpartum women living with HIV have been consistently shown to be at high risk of disengagement from HIV care, particularly right after delivery [2,3]. One reason that postpartum women have a high risk of disengagement from care could be due to mobility. In South Africa, postpartum women often move after delivery to seek help with the baby from their family, as well as to return to work [1,4]. This type of mobility may introduce challenges to continued engagement with HIV care and optimal antiretroviral therapy (ART) adherence. However, research on the topic of postpartum mobility and its impact on HIV care engagement and treatment outcomes.

Methods: This proposed research will be a secondary data analysis of data drawn from a prospective cohort study, the Maternal and Child Health Antiretroviral Therapy study (MCH-ART, HREC REF 451/2012) and a follow-up cross-sectional study in the same cohort, the Long-term Adherence and Care Engagement study (LACE, HREC REF 866/2016) conducted at a primary healthcare facility in Gugulethu, Cape Town, South Africa.

The main objectives of this research are to (i) describe postpartum movement patterns, reasons for this movement among women in the MCH-ART and LACE studies, and to (ii) investigate the impact postpartum mobility has on viral suppression and retention in care, respectively.

Ethical Considerations: The MCH-ART and LACE studies received ethical approval from the University of Cape Town Human Research Ethics Committee and the Columbia University Institutional Review Board. As this study is secondary data analysis, there will be no direct contact with the participants of the primary studies. An anonymised dataset will be provided for analysis.

Outcomes: The evidence gained from this proposed research will contribute to the limited literature on postpartum women's mobility and how their mobility effects HIV treatment engagement and outcomes.

Introduction

Background

Population mobility has been identified as a key driver in the spread of HIV in sub-Saharan Africa [5]. Mobility may be associated with HIV acquisition, with reports showing higher HIV prevalence among mobile populations [6–9]. In South Africa population mobility is a frequent occurrence, with most mobility being classified as internal migration characterized by movement within South Africa between rural and urban areas [8]. More recently, there has been growing concern surrounding the impact of frequent mobility and movement on engagement in HIV care [1].

Access to antiretroviral therapy (ART) in South Africa has increased significantly over the past decade, with the country housing the world's largest ART program [10]. Specifically, the increased uptake of ART during pregnancy for women living with HIV has helped reduce mother-to-child transmission (MTCT) and improve maternal health outcomes [11]. These potential benefits of ART use during pregnancy and the postpartum period can be undermined by poor adherence and disengagement from HIV care, which could result in the increased risk of drug resistance, treatment failure, failure to achieve viral suppression, and subsequently, MTCT, maternal morbidity and mortality [12,13]. Despite the importance of remaining adherent to ART and engagement with HIV care, many women living with HIV are not retained in care or adherent to ART.

In South Africa, consistent retention in HIV care, specifically in the postpartum period, is a significant challenge [1,2]. Postpartum women living with HIV have been consistently shown to be at high risk of disengagement from HIV care, particularly right after delivery [2,3]. One reason that postpartum women have a high risk of disengagement from care could be due to mobility following delivery. In South Africa, postpartum women are highly likely to move after delivery to seek care and help with the baby from their family, as well as to return to work [1,4]. This type of mobility may introduce many challenges to continued engagement with HIV care and optimal ART adherence.

These findings emphasize the need for a better understanding of postpartum mobility and its impact on the gains of continuous ART adherence and engagement in care. However, research on

the topic of postpartum mobility and its impact on retention in care and ART adherence is scarce despite it being a significant cause for concern.

Background for proposed dissertation

The proposed dissertation will be a secondary analysis of data collected from the Maternal and Child Health Antiretroviral Therapy (MCH-ART) study, a prospective cohort study conducted at a primary healthcare facility in Gugulethu, Cape Town, that took place between March 2013 and June 2014. The study focussed on evaluating two strategies for delivering HIV care to postpartum women living with HIV and their HIV exposed infants [14]. A follow-up to the MCH-ART study, the Long-term Adherence and Care Engagement (LACE) study, examined long-term adherence and engagement in care among the MCH-ART study participants approximately 4 years postpartum. This proposed dissertation will focus on the aspect of mobility and movement in the postpartum period and the associations that exist between mobility and viral suppression and retention in HIV care.

Study Rationale

Postpartum retention in care in South Africa is a significant challenge, with numerous studies reporting that disengagement from HIV care occurs more frequently during the postpartum period in comparison to antenatal care (ANC) [2,15]. Mobility has been identified as a possible risk factor for care disengagement in postpartum women living with HIV [1]. In South Africa, postpartum women often move after delivery to receive support and care from their family members or caregivers [1,2]. Postpartum mobility therefore presents a challenge to continued HIV care access with potential impacts on viral suppression and retention in care.

Research focusing on postpartum mobility and its effects on viral suppression and engagement with HIV care in South Africa is scarce. Majority of mobility related research focusses on mobility as a risk factor for HIV acquisition and its influence on access to HIV care [7]. There is a need to understand the patterns of mobility among postpartum women living with HIV and the associations that exist between mobility and engagement in HIV care. However, these data have not previously been described in our setting.

Literature Review

Introduction

Increased access to and uptake of ART during pregnancy for women living with HIV in recent years has helped reduce MTCT and improve maternal health outcomes [16]. Despite this accomplishment and the importance of remaining adherent to ART, postpartum women have been shown to be at high risk of disengagement from HIV care [2,17]. A factor that influences this disengagement that has been identified in research is mobility that commonly takes place following delivery of the baby [1,17]. This type of mobility may introduce many challenges to continued engagement with HIV care and optimal ART adherence. Based on these findings, this dissertation aims to investigate the impact of mobility during the postpartum period on viral suppression and retention in HIV care among postpartum women living with HIV. To inform this research, this literature review aims to evaluate existing literature on the influence of mobility on ART adherence and engagement with care.

Methods

Search Strategy

The literature search was done electronically to identify relevant literature focussed on mobility or mobile populations living with HIV, their experiences regarding mobility and their engagement with HIV care and ART adherence. The search was conducted on PubMed and Google Scholar. The search strategy included combinations of the search terms and their synonyms that are presented in Box 1. Studies were only included in the review if population mobility or some aspect of mobility such as clinic transfers or movement between clinics was evaluated, and the outcome of interest was a measure used to assess HIV care engagement or ART adherence.

Box 1: Literature review search strategy terms	
HIV:	Human immunodeficiency virus
Mobility:	Migrant, migration, migrate, relocate, relocation, travel
Engagement:	Disengagement, lost to follow-up, retention, retained, non-retention
Adherence:	Adherence, non-adherence, compliance, non-compliance, viral load, viral suppression
Postpartum:	Maternal, perinatal, postnatal

Results

The impact of mobility on HIV care cascade outcomes

Delays in HIV diagnosis and accessing or seeking care

In South Africa mobility is a frequent occurrence with movement between rural and urban areas or between provinces being the most common type of mobility in the country [18]. Individuals living with HIV's interaction with HIV care is likely to reflect their timing and patterns of movement [7,19]. A review on literature that focussed on migrants and their interaction with HIV care showed that migrants and mobile populations were more likely to enter into the healthcare system and HIV care later than non-migrants [7]. Research has shown that regular movement disrupts opportunities for HIV care access [17]. Mobile populations are therefore likely to experience delays in HIV diagnosis and treatment initiation, which could have negative effects on HIV treatment as prevention outcomes.

Mobility's effect on engagement with and retention in HIV care

Once they have been linked to HIV care, mobile populations also face many barriers to being retained in care. Regular travel makes it difficult for mobile individuals to remain enrolled in HIV care at a specific clinic, and also impacts their ability to access medication [7,17]. Mobile individuals are therefore more likely to be lost to follow-up (LTFU) than non-mobile individuals. A study on adult patients initiating ART in Lesotho reported that one year following ART initiation, migrant patients had a 6.69-fold increased rate of being LTFU in comparison to non-migrant patients [20].

Reengagement with HIV care following LTFU due to mobility or clinic transfer has also been shown to be suboptimal in current literature, with Hickey and colleagues [21] reporting that for patients who transferred out or were LTFU, the cumulative incidence of reengagement with care was 14% at 3 months following LTFU and 60% at 6 months following LTFU. These findings suggest that mobility plays a role in disrupting HIV care engagement, as well as hampers reengagement with care.

Mobility is also associated with and facilitates many of the barriers that hinder or delay engagement with HIV care. These barriers included fear of HIV-related stigma from the public at

the new location and clinic, unfamiliarity with the new environment and structural factors such as the long distance to the clinic and the cost of transportation [6,7,17]. While mobility can influence many barriers to care, some studies have also made evident that an interplay between mobility and barriers to HIV care engagement exists, with some barriers also prompting mobility. It has been shown that traveling for care and transfer to different clinics was sometimes influenced by the desire to avoid stigma in one's hometown as well as to seek anonymity in terms of receiving HIV care [6,16,22].

Furthermore, mobile populations also have different health-seeking behaviours with some studies reporting that mobile individuals are more likely to seek care only once they experienced symptoms or felt unwell [7]. More research on mobile populations and how they interact with HIV care is therefore necessary in order to better understand their behaviour in terms of HIV care engagement.

Effect of mobility on ART adherence

Disruptions to ART and treatment adherence were also common among individuals who would regularly travel. Numerous studies found that individuals that were mobile would report poor medication adherence behaviours when travelling [20,23–25]. This suboptimal treatment adherence can result in poor treatment outcomes [26]. A study conducted in East Africa looking at treatment outcomes between permanent residents and non-residents found that non-residents were less likely to be virally suppressed in comparison to residents (64% versus 84% virally suppressed) [24]. Similarly, a study conducted among isiZulu speaking adults living with HIV in South Africa reported that 19% of in-migrants and 26% of out-migrants were virally suppressed on the date at which they migrated into or out of the community in comparison to approximately 50% of non-migrants being virally suppressed [23].

The main barriers to complete ART adherence expressed by individuals were fear of medication side-effects while travelling, delaying taking of medication until they had reached their destination, and stigma-related fear of disclosure of HIV status when taking medication in public and around family members [6,7,19,27]. Taylor and colleagues [6] also identified interruptions in adherence due to a limited medication supply as a dominant barrier to adherence, especially during longer

journeys. This research suggests that barriers created by mobility and travel could negatively impact ART adherence, which could lead to poor treatment outcomes. This emphasizes the need for HIV care to consider mobile populations in order to address issues of ART adherence and HIV care engagement.

Mobility and its impact on HIV care cascade outcomes for postpartum women

Many studies that have evaluated possible reasons for the high risk of disengagement from HIV care in postpartum women have shown that an important factor that impacts engagement with care is mobility [28–30]. However, studies that focussed specifically on postpartum women's mobility were scarce, with only three studies being identified, one of which focussed on motivations for postpartum mobility while the other two focussed on movement between clinics in terms of linkage to care and LTFU.

Motivations for postpartum mobility and engagement with HIV care

Clouse and colleagues [1] sought to explore South African peripartum women's mobility in an effort to understand timing and motivations of travel. In line with the results of earlier studies evaluating postpartum engagement in care, they found that nearly all of their participants planned to travel after delivery of the baby [1]. The main motivations for this travel was to visit family to seek care and help with the baby, or to return to work in Johannesburg if they were employed [1]. The majority of participants also expressed their intention to continue HIV care following delivery, however care for the infant was often emphasized over care for the mother [1]. Of those participants who travelled, few had planned to seek care at the new location they would be travelling to [1]. This is a cause for concern as continuous engagement in HIV care and optimal treatment adherence is necessary to decrease the risk of HIV transmission and MTCT through breastfeeding, treatment failure and subsequent poor health outcomes.

Mobility in the form of transfer of care or lost to follow up

Another reason for high postpartum mobility is the clinic transfer process that occurs after delivery of the baby. In South Africa, women living with HIV who have not started ART are placed on treatment during their pregnancy in integrated clinics that provide both HIV care and ANC [13]. However, following delivery women are required to transfer their HIV care and link to general

ART clinics [3]. This transfer process presents challenges to retaining women in HIV care and results in women being LTFU. Two studies in South Africa have shown that linkage to care for postpartum women in South Africa during this transfer process is poor, with a significant proportion of women not linking to care at all, or those that do link not being retained long-term [3,16].

Challenges of measuring retention and adherence in mobile populations

Mobility also presents a challenge for measuring patient retention in care and adherence. Movement between clinics is difficult to track in South Africa as health facilities are often not linked through electronic medical records [16]. Therefore, it is a challenge to determine whether a patient has completely disengaged from care or has sought care at a different clinic [31]. A study on mobility and clinic switching among postpartum women conducted in South Africa showed evidence of 38% of women thought to be LTFU continuing HIV care at other clinics either within the same province as the original clinic or in other provinces in South Africa [16]. Therefore, estimates of LTFU may not represent true disengagement from care, and instead represents patient drop-out from a specific clinic.

It is therefore important to account for patient mobility and movement between clinics as failure to do so could result in the under- or over-estimation of retention in care estimates. Fox and colleagues [22], comparing retention in care from the clinic perspective (what most studies report) to retention from the national perspective (which accounts for movement between clinics) in South Africa, found that retention was considerably higher when evaluated from a national perspective in comparison to a clinic perspective. This research suggests that retention and LTFU estimates taken from the perspective of a clinic, and which fails to account for patient movement between clinics, underestimates retention in care.

Conclusion and Gaps in Research

Based on the studies discussed in this literature review, mobility may lead to delays in seeking care and HIV diagnosis which increases the risk of HIV transmission and poor health outcomes. Studies have also shown that mobility negatively impacts engagement with and retention in HIV care, as well as interferes with optimal adherence to ART. Despite these findings, research on the

impact of mobility on HIV care engagement and ART adherence is scarce and few studies were identified that focussed on postpartum mobility and its effects of postpartum engagement with care. This is a cause for concern as consistent retention in HIV care is a significant challenge in South Africa and postpartum women are at high risk of disengaging from care [1,2]. This literature review's findings emphasize the need for more research on postpartum mobility and its impact on postpartum treatment adherence and engagement in care.

Given the findings in this review, this proposed research aims to evaluate postpartum women's patterns of mobility and investigate the associations that may exist between mobility and viral suppression and retention in care. The evidence gained from this research will contribute to the literature on postpartum women's mobility and how their mobility effects HIV treatment engagement and outcomes.

Study aims and objectives

Study aim

The aim of this research is to describe postpartum movement patterns and to investigate whether mobility is associated with viral suppression and retention in HIV care among postpartum women in the LACE study.

Objectives

1. To describe the movement patterns of postpartum women in the LACE study from delivery to approximately 4 years postpartum.
2. To investigate the association between mobility and viral load (VL) at two different follow-up points in the LACE study, at 12 months and approximately 4 years postpartum.
3. To investigate the association between mobility and retention in care using routine data from the LACE study, at 12 months and approximately 4 years postpartum.

Methodology

Study Design

This study will be a secondary data analysis of data from a prospective cohort study (the MCH-ART study HREC REF 451/2012) and a follow-up cross-sectional study in the same cohort (The LACE study HREC REF 866/2016) conducted at a primary healthcare facility in Gugulethu, Cape Town, South Africa. Data for this thesis will be drawn only from the MCH-ART study and the LACE study and no additional data will be collected.

The MCH-ART study

The Maternal and Child Health Antiretroviral Therapy (MCH-ART) study was a multi-phase prospective cohort study situated at the Gugulethu Midwife Obstetric Unit (MOU) in Cape Town, South Africa [14]. The study enrolled participants from March 2013 to June 2014 and followed up these participants for 18 months [14]. This study aimed to evaluate two strategies for delivering HIV care and treatment services to postpartum women living with HIV who initiated ART during pregnancy, and their HIV exposed infants [14].

The LACE study

The Long-term Adherence and Care Engagement (LACE) study was an additional cross-sectional study conducted following the completion of the MCH-ART study. The study aimed to examine the long-term adherence and care engagement among MCH-ART study participants [32]. Participants who were enrolled in the postpartum cohort of the MCH-ART study were requested to return for one additional study visit that would take place between 36 and 60 months postpartum [32].

Study Population

The analysis will be restricted to postpartum women living with HIV who initiated lifelong ART during their pregnancy and were enrolled in both the MCH-ART and LACE studies.

Research Setting

The primary studies collected data from a cohort of women based at a large antenatal clinic in Gugulethu, Cape Town, South Africa. Gugulethu is an area characterized by high levels of poverty,

unemployment and HIV [33]. ART and health services are provided free of charge in local public-sector health care facilities [33]. All pregnant women living with HIV have been eligible to be on lifelong ART irrespective of their clinical stage or CD4 count since 2013 [34]. ANC coverage in this setting is high at 95% [33]. Women living with HIV who are pregnant are provided with integrated ANC and ART services and are then required to transfer to general ART clinics for postpartum care.

Data Collection

This secondary analysis will be using data collected during the study measurement visits carried out in the MCH-ART and LACE studies. These measurement visits consisted of VL testing and the administration of questionnaires (Appendix A) to collect demographic information [14]. In the LACE study, maternal movement tables (Appendix B) were used to collect data on participants' mobility patterns and reasons for this mobility [32]. Specifically, the maternal relocation table which described movement after the delivery of the baby will be used in this secondary analysis. Additional data was also drawn from routine medical records obtained from the Western Cape Department of Health's Provincial Health Data Centre (PHDC). Using the provincial unique patient identifier, the PHDC is able to link participants healthcare access across all public facilities in the Western Cape [35]. These records will provide data on ART initiation and follow up in routine care for all women who were enrolled in the MCH-ART study [14].

Measurements

Mobility

Population mobility has been identified as a key risk factor for HIV infection [8]. Mobility is also increasingly being recognized as a potential barrier to HIV care [19]. There is great variation in the definitions for mobility in current HIV literature. This is due to mobility being a broad term encompassing many aspects of population movement [19]. Definitions include permanent migration, temporary mobility, frequent and repetitive migration, cross-border migration and internal migration [19,36]. This variation in definitions of mobility in literature has led to inconsistent findings about mobility as a risk factor for HIV [8,19].

Broadly, in this study mobility will be based on women's self-report of movement to new locations following delivery. Mobility as an exposure will be analysed as a binary variable, as either having moved within 3, 6 or 12 months of the measurement visit or having not moved during this time period. Among women who move, movement will also be characterised as movement into or out of the home area (Gugulethu), as well as movement within and out of the Western Cape.

Adherence and viral load

There are many methods that exist in the literature for measuring and defining treatment adherence, however there is currently no gold standard measure of adherence [37]. VL is often used as a proxy measure for treatment adherence and is considered a standard measure for treatment success [37]. While VL is commonly used as a proxy measure for adherence, it can be influenced by multiple factors other than adherence such as treatment resistance [38]. Nonetheless treatment success is often determined by a patient's VL [38]. In this analysis VL will be used as a proxy measure for adherence. The outcome of viral suppression will be defined as VL thresholds of ≤50 copies/mL and ≤1000 copies/mL based on routine guidelines [13].

Retention in care

As with adherence there are various methods that can be used to measure retention in care. Timely linkage to and retention in care is imperative for the success of HIV treatment, as it allows for access to ART [39]. Adequate access to ART and HIV care is essential to attain a high level of adherence to achieve and sustain viral suppression [39]. Despite the recognized importance of retention in care for treatment success in the literature, no gold standard measure currently exists [39].

For this study, a cross-sectional definition of retention in care will be used. Retention will be defined as at least one contact with routine HIV care during a specific window of time [40]. In this secondary analysis, retention in care at 12 months postpartum was measured using routinely collected medical records and defined as evidence of an HIV-related clinical contact for the period 9-18 months postpartum. We will also measure retention at the LACE visit, approximately 4 years postpartum.

Data Management and Analysis Plan

Data Management

As per the MCH-ART and LACE study protocols, data that was collected was entered into a password-protected Microsoft Access database. Database files stored on the University of Cape Town (UCT) firewall protected network drive. Anonymous participant identification numbers were used, except for provincial data, with no participant names or identifiers being attached to participant data. For provincial data, identifiers had to be collected in order to link the routine data. Once linked the identifiers were removed and the data is now identified using only the unique participant identifier. Anonymised data for analysis will be shared as an encrypted file using the UCT file sender or on a password protected external hard drive.

Descriptive Analysis

All statistical analyses will be done in Stata 15 (Stata Corporation, College Station, Texas). Initial exploration of all variables will be done to identify missing data and any patterns related to missing data. Descriptive statistics will be used to describe the demographic and clinical characteristics of the study participants. This analysis will include means and standard deviations, frequencies and proportions or medians with interquartile ranges with chi-squared tests, Fisher's exact tests, rank sum tests or t-tests, as will be appropriate for the variables of interest.

Patterns of Mobility

Data collected on the maternal movement of the postpartum women in the study will be analysed to detect any patterns of movement for our first objective. To describe the patterns of mobility in the study, descriptive statistics summarising different aspects of participant mobility will be used. This will include: number of times moved, the area of movement, timing of movement, and reasons for moving. Movement into and out of the host clinic's area (Gugulethu), as well as movement within and out of the province (Western Cape) will also be considered.

The Effect of Mobility on Viral Suppression and Retention in Care

For the second objective, the primary outcome of interest is viral suppression which will be defined as viral thresholds of ≤50 copies/mL and ≤1000 copies/mL. Log-binomial regression models will be used to identify predictors of viral suppression for both thresholds, with variables being

included as predictors if they are considered to be associated with viral suppression based on previous literature within the limits of the data that has been collected, as well as the bivariate analysis. Log-binomial regression models will be run to identify predictors at each time point, 12 months and 4 years postpartum, to assess the associations that exist for each time point separately. In particular, the association between mobility in the past 3, 6 and 12 months before the measurement visit and VL will be explored.

The third objective's primary outcome of interest is retention in care, which is defined as at least one contact with routine HIV care at approximately 12 months postpartum, as well as retention at the LACE visit approximately 4 years postpartum. The included participants in this analysis will be restricted to a subset of women who did not report leaving the province (Western Cape). The reason for this is that the routine data used to measure retention is only available from facilities in the Western Cape. Variables will be included as predictors in the model based on previous literature within the limits of the data that has been collected, and the bivariate analysis. In particular, the association between mobility in the past 3, 6 and 12 months before the measurement visit and retention will be explored.

For these analyses, risk ratios and adjusted risk ratios with 95% Confidence Intervals (CI) will be reported. Statistical significance for these exploratory analyses will be set at an α-level of 0.10 to be suggestive of a significant effect that warrants further study.

Ethical considerations

The MCH-ART and LACE studies received ethical approval from the University of Cape Town Human Research Ethics Committee and the Columbia University Institutional Review Board (Appendix C and D). As this study is secondary data analysis, there will be no direct contact with the participants of the primary studies.

Consent

All women enrolled in the primary studies completed written informed consent which included consent to review their routine medical records and consent to be contacted for future research

(Appendix F). No further informed consent will be required for this research as it is secondary analysis.

Risks

As this is secondary analysis, there are no direct risks for this study as there is no direct contact with the primary study's participants. Nonetheless, a possible risk in this research is a breach of confidentiality, however many measures will be taken to ensure that study participants will remain anonymous during the study period.

Benefits

As this research is secondary analysis, there are no direct benefits to the primary study's participants. However, this study aims to contribute to the limited research on mobility and postpartum women's engagement with HIV care. This study aims to further understanding and knowledge of patterns of mobility among postpartum women living with HIV and the influence of mobility on postpartum engagement in HIV care.

Confidentiality

For this secondary analysis there will be no contact with the primary study's participants, however efforts will be made to protect participant confidentiality at all times during the study process. No participant identification information will be attached to participant data, and anonymous participant identification numbers will be used for the analysis.

Timeframe

Table 1: Timeframe for study activities

	Feb 2020	Mar 2020	Apr 2020	May 2020	June 2020
Protocol submission					
Data Analysis					
Manuscript Write-up					
Dissertation submission					

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PART B: MANUSCRIPT

Patterns of mobility, and the effect of mobility on viral suppression and retention among postpartum women living with HIV in South Africa

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The article meets the requirements set out in the Instructions for Authors for the Journal of the International AIDS Society (JIAS). As per the MPH dissertation guidelines, co-authors and their contributions are noted in the acknowledgments section of this dissertation. The JIAS Instructions for Authors are included in Appendix I of the dissertation.

Abstract

Introduction: In South Africa postpartum women have been shown to be at high risk of disengagement from HIV care and postpartum mobility may be related to disruptions in care. This study aimed to describe patterns of mobility, and explore associations with viral suppression and retention in the postpartum period.

Methods: This study used data from a prospective cohort study that enrolled women who initiated life-long antiretroviral therapy (ART) during their pregnancy in Gugulethu, Cape Town (March 2013 - June 2014), and an additional follow-up study at approximately 4 years postpartum. Patterns of self-reported mobility between delivery and the 4 year measurement visit were examined. Log-binomial models were used to explore the association between mobility (moving in the 3, 6 or 12 months prior to the study visit) and i) viral suppression (viral load (VL) ≤50 and ≤1000 copies/mL measured at the 12 month and 4 year measurement visit) and ii) retention in care (based on routine medical record data at approximately 12 months and 4 years postpartum).

Results: Among the 353 women in this analysis, 98 (28%) reported having ever moved between delivery and 4 years postpartum. Mobility was more likely to occur soon after delivery with 50% of the moves occurring within the first year following delivery; the most common reason for moving being to live with and receive support from family (44%). At 12 months postpartum, women who moved within 3, 6 or 12 months of the viral load measurement were more likely to be virally suppressed. Moving in any window prior to the 4 year postpartum viral load was not associated with viral suppression. Retention in care at both 12 months and 4 years postpartum was not associated with mobility.

Conclusions: These results demonstrate that movement following delivery is a common occurrence among postpartum women, but this movement did not seem to disrupt engagement in HIV care. There is a need for further research to understand the impact of this movement on postpartum women's viral suppression and retention in care, as well as on ways to support continued engagement in HIV care after delivery.

Introduction

Population mobility has been identified as a key driver in the spread of HIV in sub-Saharan Africa and studies have shown higher HIV prevalence among mobile populations [1–5]. More recently, there has been growing concern surrounding the impact of movement on engagement in HIV care [6–8]. In South Africa population mobility is a common occurrence, with most mobility being classified as internal migration characterized by movement between rural and urban areas within South Africa [5].

Increased access to and uptake of antiretroviral therapy (ART) during pregnancy for women living with HIV in recent years has helped reduce mother-to-child transmission and improve maternal health outcomes [8]. Despite this accomplishment and the importance of remaining adherent to ART, postpartum women are at high risk of disengagement from care, specifically following delivery [6,9–11]. Mobility could be one reason for postpartum women's disengagement from care following delivery. In South Africa, women often move after delivery to seek care and help with the baby from their family, as well as to return to work [2,6,12,13]. Additionally, women are required to transfer their HIV care and link to a general ART clinic after delivery and this has been shown to present a significant challenge to retaining women in care [6,10]. These types of mobility may introduce many challenges to continued engagement with care and optimal ART adherence. Despite these findings, research focusing on postpartum mobility and its effects on viral suppression and retention in care is scarce. Most mobility related research focusses on movement as a risk factor for HIV acquisition and its influence on access to HIV care, with little focus on postpartum women's experiences of mobility and HIV care.

To address this gap in the literature, we examined patterns of movement and engagement with HIV care up to 4 years postpartum. The objectives were (i) to describe movement patterns of postpartum women from delivery to approximately 4 years postpartum and (ii) to explore whether movement was associated with viral suppression and retention in care at approximately 12 months and 4 years postpartum.

Methods

Study design and setting

This is a secondary data analysis of women living with HIV who initiated lifelong ART during their pregnancy and were enrolled in both the Maternal and Child Health Antiretroviral Therapy (MCH-ART) and the follow-up Long-term Adherence and Care Engagement (LACE) studies [14,15]. The MCH-ART study aimed to evaluate two strategies for delivering HIV care and treatment services to postpartum women and their HIV-exposed infants [14]. The LACE study was an additional follow-up visit which aimed to examine long-term adherence and care engagement among MCH-ART study participants [15].

These studies were conducted at a primary healthcare facility in Gugulethu, Cape Town, South Africa. Gugulethu is an area characterized by high levels of poverty, unemployment and HIV [16]. Antenatal care (ANC) coverage in this setting is high at 95% [16]. ART and health services are provided free of charge in local public-sector care facilities. Since 2013, all pregnant women living with HIV are eligible to be on lifelong ART irrespective of their clinical stage or CD4 count [17]. Pregnant women living with HIV are provided with integrated ANC and ART services and are then required to transfer to general ART clinics after delivery for postpartum care.

Data sources

This analysis used data collected during the study measurement visits conducted throughout the MCH-ART and LACE studies. The MCH-ART study enrolled pregnant women who presented for ANC at the integrated clinic from March 2013 to June 2014 and followed-up these women for 18 months. For the LACE study, participants who were enrolled in the postpartum cohort of the MCH-ART study were requested to return for one additional study visit that would take place between 36 and 60 months postpartum. The sample at baseline for the MCH-ART study was 471 women. The proportion of the baseline sample was 87% at 12 months postpartum (n=411) and 75% at approximately 4 years postpartum (n=353).

The measurement visits were conducted separate from routine care and consisted of viral load (VL) testing and the administration of questionnaires to collect demographic information.

Additionally, in the LACE study maternal movement tables were used to collect self-report of participants' mobility following delivery.

Additional data was drawn from routine medical records obtained from the Western Cape Department of Health's Provincial Health Data Centre [18]. These records provided data on ART initiation and follow-up in routine care for all women enrolled in the MCH-ART study. The provincial unique patient identifier makes it possible to link participants' healthcare access across all public facilities in the Western Cape.

Measurements

The main constructs that this analysis sought to measure were mobility, viral suppression, and retention in HIV care. Mobility was based on women's self-report of movement to a new location following delivery. All movement after delivery was described. The primary exposure was analyzed as a binary variable, defined as either having moved or not in windows of 3, 6 or 12 months prior to the outcome measurement.

Outcome measures:

Outcomes were assessed at approximately 12 months postpartum (the primary MCH-ART timepoint) and approximately 4 years postpartum (at the LACE visit). VL and retention in HIV care were assessed. Viral suppression was defined as VL thresholds of ≤50 and ≤1000 copies/mL based on routine guidelines [19]. Retention in care at 12 months postpartum was defined as evidence of an HIV-related clinical contact for the period 9-18 months postpartum. Retention in care was also measured at the LACE visit at approximately 4 years postpartum.

Data analysis

All data analyses were done in Stata 15 (Stata Corporation, College Station, Texas). Descriptive statistics were used to describe the demographic and clinical characteristics of study participants. This analysis used means and standard deviations (SD), frequencies and proportions or medians and interquartile ranges (IQR), with chi-squared tests, Fisher's exact tests, t-tests or rank sum tests where appropriate for the variables of interest.

Patterns of postpartum movement were described using descriptive statistics summarizing different aspects of participant mobility, including frequency and timing of movement, reasons for movement, and area of movement.

Log-binomial regression models were used to examine the association between mobility which occurred in the past 3, 6 or 12 months and each outcome, viral suppression and retention in care, respectively. Inclusion of covariates in the models followed a stepwise model building approach and was based on findings in previous literature (within the limits of the data that has been collected) and if they reached $p<0.10$ in the bivariate analysis. Covariates that were included in models based on previous literature included age, education level, timing of HIV diagnosis and baseline CD4 count [3,9,20,21]. Models were run to identify predictors at approximately 12 months and 4 years postpartum, to assess the associations that exist for each time point separately. The retention outcome was limited to women who did not report leaving the province (Western Cape) due to the routine data only being available for facilities in the Western Cape. Design effect was included in the models to control for any influence the MCH-ART study could have on the outcomes of interest. Design effect was defined as a binary variable where women were allocated to either the MCH-ART intervention arm or the control arm. For these analyses, unadjusted and adjusted risk ratios with 95% Confidence Intervals (CI) are presented. Associations below an α-level of 0.10 were also considered in this exploratory analysis to be indicative of an effect that warrants further study.

Ethics

The MCH-ART and LACE studies received ethical approval from the University of Cape Town Human Research Ethics Committee and the Columbia University Institutional Review Board. Ethical approval for this secondary analysis was obtained from the University of Cape Town Human Research Ethics Committee. All women included in this analysis completed written informed consent for study participation which included consent to review and link their routine medical records.

Results

Overall, 353 women were eligible and included in the analysis (Table 1). Their mean age was 32.57 years at LACE enrolment (approximately 4 years postpartum). At both MCH-ART (ANC) and LACE enrolment, approximately 24% of women completed secondary school and 37% were married or cohabiting. Over 95% of women had disclosed their HIV status to at least one person, therefore it was not included in the analysis.

Patterns of mobility

There were 98 women (28%) who reported having ever moved between delivery and the LACE study visit, with a total number of 125 moves occurring (Table 2). The median number of moves was 1 (IQR: 1-2), with 50% of the moves occurring within the first year following delivery. The most common reasons for moving were to live with and receive support from family (44%) or live with their partner (19%).

Women who moved at least once were more likely to have had lower socioeconomic status (SES) (33% versus 24%) and to be living in informal housing (61% versus 48%) when they enrolled in the MCH-ART study, compared to women who did not move (Table 1). Women who ever moved were slightly younger in age than those who did not move. At LACE enrolment (approximately 4 years postpartum), women who had ever moved were less likely to be employed (36% versus 49%) and were more likely to be living in formal housing (60% versus 49%) compared to women who did not move.

Table 1. Description of 353 postpartum women living with HIV at approximately 4 years postpartum. All women initiated lifelong ART during pregnancy. The table is grouped by whether women reported moving during the postpartum period or not.

	Ever Moved	Not Moved	Total	p-value
Number of participants	98 (28)	255 (72)	353 (100)	
Baseline Characteristics (at MCH-ART enrolment)				
Mean Age (in years)	27.88 (4.59)	28.94 (5.71)	28.64 (5.50)	0.103
Education				0.177
Completed secondary school	19 (19)	67 (26)	86 (24)	
Less than secondary school	79 (81)	188 (74)	267 (76)	
Employment Status				0.315
Employed	35 (36)	106 (42)	141 (40)	
Not employed	63 (64)	149 (58)	212 (60)	
Socioeconomic Status				0.019
Lowest	32 (33)	62 (24)	94 (27)	
Moderate	40 (41)	84 (33)	124 (35)	
Highest	26 (27)	109 (43)	135 (38)	
Relationship				0.359
Married/cohabiting	34 (35)	102 (40)	136 (39)	
Not married/cohabiting	64 (65)	153 (60)	217 (62)	
Housing				0.020
Formal	38 (39)	134 (53)	172 (49)	
Informal	60 (61)	121 (48)	181 (51)	
Gravidity (Median (IQR))	1 (1-2)	1 (1-2)	1 (1-2)	0.137
Diagnosed with HIV in this pregnancy	58 (59)	136 (53)	194 (55)	0.322
Postpartum Characteristics (at LACE enrolment)				
Mean Age (in years)	31.84 (4.68)	32.85 (5.77)	32.57 (5.50)	0.120
Education				0.591
Completed secondary school	22 (23)	64 (25.)	86 (24)	
Less than secondary school	76 (78)	190 (75)	266 (76)	
Employment Status				0.021
Employed	35 (36)	126 (49)	161 (46)	
Not employed	63 (64)	129 (51)	192 (54)	
Socioeconomic Status				0.195
Lowest	38 (39)	77 (30)	115 (33)	
Moderate	31 (32)	79 (31)	110 (31)	
Highest	29 (30)	99 (39)	128 (36)	
Relationship				0.304
Married/cohabiting	33 (34)	101 (40)	134 (38)	
Not married/cohabiting	65 (66)	154 (60)	219 (62)	
Housing				0.069
Formal	59 (60)	126 (49)	185 (52)	
Informal	39 (40)	129 (51)	168 (48)	
Gravidity (Median (IQR))	2 (2-3)	3 (2-3)	2 (2-3)	0.478
Currently pregnant	7 (7)	12 (5)	19 (5)	0.473

Table 2. Descriptive statistics of the mobility patterns of 98 postpartum women living with HIV who initiated ART during pregnancy who had reported moving at least once after delivery.

Variable	Ever Moved
Number of women who ever moved	98 (78)
Total number of moves	125 (100)
Number of times moved (median and IQR)	1 (1-2)
Number of times moved	
1	76 (61)
2	18 (14)
3	3 (2)
4	1 (1)
Area of movement	
Moved into Gugulethu	11 (9)
Moved out of Gugulethu	19 (15)
Moved within the Western Cape	55 (44)
Moved out of the Western Cape	40 (32)
Time of movement	
1 year postpartum	62 (50)
2 years postpartum	31 (25)
3 years postpartum	24 (19)
4 years postpartum	8 (6)
Relocation Reason	
Family	55 (44)
Employment	4 (3)
Partner	24 (19)
Moved to own house	7 (6)
Transferred HIV care	1 (1)
Unclear	34 (27)

Mobility and viral suppression

VL measures were available for 349 women (98%) out of the 353 women in the study at both approximately 12 months and 4 years postpartum. Of these women, 66% were virally suppressed at 12 months postpartum, and 56% were virally suppressed at 4 years postpartum. The association between mobility in the 3, 6 and 12 months prior to the VL measurement, and viral suppression was assessed (Table 3 and 4). Bivariate associations are reported in Supplementary Table 2 and 3. The MCH-ART trial arm did not alter any of the associations for the VL outcomes.

12 months postpartum:

At 12 months postpartum, women who had moved within 3, 6 or 12 months of the VL measurement were more likely to be virally suppressed (VL≤50 and VL≤1000 copies/mL)

compared to women who had not moved. In bivariate analyses, those who were virally suppressed were slightly more likely to move within 3, 6 and 12 months of the VL measurement compared to those who were not virally suppressed (7% versus 4%, 8% versus 6%, 12% versus 9% respectively), however this difference was not statistically significant (Supplementary Table 2). Increasing age and having a higher CD4 cell count at MCH-ART study enrolment were both associated with having a VL≤50 and VL≤1000 copies/mL (Table 3). Being diagnosed with HIV in the current pregnancy was consistently associated with viral suppression. Having moderate SES increased the likelihood of having a VL≤50 (aRR=1.41, 95% CI: 1.13-1.78) and VL≤1000 copies/mL (aRR=1.20, 95% CI: 1.00-1.44) compared to low SES (Table 3).

4 years postpartum:

Mobility in any window prior to the 4 year postpartum VL was not associated with viral suppression in bivariate analyses (Supplementary Table 2 and 3) or multivariable models (Table 4). Those who were virally suppressed were less likely to have moved in the preceding 12 months compared to those who were not virally suppressed (6% versus 12%). However, this association did not persist in multivariable models and no association was observed between moving in the past 3 or 6 months and viral suppression. Women who were currently pregnant were more likely to have a VL≤50 (aRR= 1.40, 95% CI: 1.07-1.83) and VL≤1000 copies/mL (aRR=1.41, 95% CI: 1.09-1.81). Being employed increased the likelihood of having a VL≤50 (aRR=1.24, 95% CI: 1.03-1.48) and VL≤1000 copies/mL (aRR=1.17, 95% CI: 1.00-1.36). In the univariate model, increasing age increased the likelihood of having a VL≤50 copies/mL (RR=1.02, 95% CI: 1.00-1.03), however this association did not persist in the multivariable model.

Table 3. Log binomial regression model among 349 postpartum women living with HIV who initiated ART during pregnancy, predicting A) VL ≤50 copies/mL at approximately 12 months postpartum, and B) VL ≤1000 copies/mL at approximately 12 months postpartum. This table is grouped by whether movement occurred 3 months, 6 months or 12 months prior to the viral load visit. Unadjusted (RR) and adjusted (aRR) risk ratios are presented with 95% confidence intervals (CI).

	Moved within 3 months				Moved within 6 months				Moved within 12 months			
	Unadjusted		Adjusted		Unadjusted		Adjusted		Unadjusted		Adjusted	
	RR	95% CI	aRR	95% CI	RR	95% CI	aRR	95% CI	RR	95% CI	aRR	95% CI
(A) VL ≤50 copies/mL												
Moved	1.20	0.94 – 1.54	1.80	1.28 – 2.52	1.09	0.85 – 1.41	1.33	1.02 – 1.74	1.13	0.92 – 1.38	1.35	1.04 – 1.75
Age	1.03	1.01 – 1.04	1.02	1.01 – 1.04	1.03	1.01 – 1.04	1.03	1.01 – 1.04	1.03	1.01 – 1.04	1.03	1.01 – 1.04
Diagnosed with HIV in this pregnancy	1.14	0.98 – 1.34	1.14	1.00 – 1.29	1.14	0.98 – 1.34	1.14	0.99 – 1.30	1.14	0.98 – 1.34	1.16	1.02 – 1.33
Married/cohabiting	1.14	0.98 – 1.32	1.06	0.90 – 1.23	1.14	0.98 – 1.32	1.04	0.88 – 1.22	1.14	0.98 – 1.32	0.99	0.84 – 1.17
Socioeconomic Status (Low)	1	(ref)	1	(ref)	1	(ref)	1	(ref)	1	(ref)	1	(ref)
Moderate	1.43	1.14 – 1.79	1.48	1.15 – 1.90	1.43	1.14 – 1.79	1.41	1.13 – 1.78	1.43	1.14 – 1.79	1.43	1.13 – 1.80
High	1.32	1.05 – 1.67	1.31	1.02 – 1.69	1.32	1.05 – 1.67	1.25	0.99 – 1.58	1.32	1.05 – 1.67	1.26	0.99 – 1.59
CD4 count at baseline (<200)	1	(ref)	1	(ref)	1	(ref)	1	(ref)	1	(ref)	1	(ref)
200-350	1.13	0.88 – 1.45	1.10	0.88 – 1.38	1.13	0.88 – 1.45	1.16	0.90 – 1.49	1.13	0.88 – 1.45	1.26	0.95 – 1.66
350-500	1.01	0.76 – 1.33	1.02	0.80 – 1.29	1.01	0.76 – 1.33	1.07	0.82 – 1.39	1.01	0.76 – 1.33	1.16	0.87 – 1.53
>500	1.17	0.91 – 1.52	1.36	1.09 – 1.70	1.17	0.91 – 1.52	1.40	1.08 – 1.80	1.17	0.91 – 1.52	1.48	1.12 – 1.96
Design effect (intervention vs control arm)	1.28	1.10 – 1.50	1.27	1.09 – 1.48	1.28	1.10 – 1.50	1.26	1.08 – 1.48	1.28	1.10 – 1.50	1.28	1.08 – 1.50
(B) VL ≤1000 copies/mL												
Moved	1.22	1.03 – 1.44	1.74	1.32 – 2.29	1.14	0.95 – 1.37	1.32	1.07 – 1.62	1.15	0.99 – 1.34	1.37	1.10 – 1.71
Age	1.02	1.01 – 1.03	1.01	1.00 – 1.02	1.02	1.01 – 1.03	1.02	1.01 – 1.03	1.02	1.01 – 1.03	1.02	1.01 – 1.03
Diagnosed with HIV in this pregnancy	1.15	1.02 – 1.31	1.12	1.00 – 1.25	1.15	1.02 – 1.31	1.10	0.98 – 1.24	1.15	1.02 – 1.31	1.13	1.01 – 1.27
Married/cohabiting	1.13	1.00 – 1.28	0.99	0.88 – 1.13	1.13	1.00 – 1.28	1.03	0.91 – 1.17	1.13	1.00 – 1.28	1.00	0.88 – 1.14
Socioeconomic Status (Low)	1	(ref)	1	(ref)	1	(ref)	1	(ref)	1	(ref)	1	(ref)
Moderate	1.26	1.05 – 1.50	1.28	1.05 – 1.55	1.26	1.05 – 1.50	1.20	1.00 – 1.44	1.26	1.05 – 1.50	1.20	0.99 – 1.44
High	1.18	0.99 – 1.42	1.11	0.93 – 1.34	1.18	0.99 – 1.42	1.06	0.89 – 1.26	1.18	0.99 – 1.42	1.05	0.88 – 1.26
CD4 count at baseline (<200)	1	(ref)	1	(ref)	1	(ref)	1	(ref)	1	(ref)	1	(ref)
200-350	1.12	0.90 – 1.39	1.19	0.98 – 1.43	1.12	0.90 – 1.39	1.19	0.96 – 1.49	1.12	0.90 – 1.39	1.30	1.02 – 1.65
350-500	1.02	0.80 – 1.30	1.14	0.92 – 1.40	1.02	0.80 – 1.30	1.11	0.88 – 1.39	1.02	0.80 – 1.30	1.20	0.95 – 1.53
>500	1.24	1.01 – 1.53	1.45	1.17 – 1.79	1.24	1.01 – 1.53	1.45	1.14 – 1.85	1.24	1.01 – 1.53	1.56	1.19 – 2.04
Design effect (intervention vs control arm)	1.13	0.99 – 1.28	1.17	1.03 – 1.33	1.13	0.99 – 1.28	1.15	1.01 – 1.31	1.13	0.99 – 1.28	1.16	1.01 – 1.32

Table 4. Log binomial regression model among 349 postpartum women living with HIV who initiated ART during pregnancy, predicting A) VL ≤50 copies/mL at approximately 4 years postpartum, and B) VL ≤1000 copies/mL at approximately 4 years postpartum. This table is grouped by whether movement occurred 3 months, 6 months or 12 months prior to the viral load visit. Unadjusted (RR) and adjusted (aRR) risk ratios are presented with 95% confidence intervals (CI).

	Moved within 3 months				**Moved within 6 months**				**Moved within 12 months**			
	Unadjusted		**Adjusted**		**Unadjusted**		**Adjusted**		**Unadjusted**		**Adjusted**	
	RR	**95% CI**	**aRR**	**95% CI**	**RR**	**95% CI**	**aRR**	**95% CI**	**RR**	**95% CI**	**aRR**	**95% CI**
(A) VL ≤50 copies/mL												
Moved	0.83	0.43 – 1.59	0.89	0.45 – 1.74	0.97	0.60 – 1.58	1.09	0.67 – 1.77	0.67	0.42 – 1.05	0.72	0.45 – 1.14
Age	1.02	1.00 – 1.03	1.01	0.99 – 1.03	1.02	1.00 – 1.03	1.01	0.99 – 1.03	1.02	1.00 – 1.03	1.01	0.99 – 1.03
Married/cohabiting	1.28	1.07 – 1.53	1.20	0.99 – 1.45	1.28	1.07 – 1.53	1.20	0.99 – 1.45	1.28	1.07 – 1.53	1.21	1.00 – 1.46
Employed	1.21	1.01 – 1.45	1.24	1.03 – 1.48	1.21	1.01 – 1.45	1.24	1.03 – 1.48	1.21	1.01 – 1.45	1.23	1.03 – 1.47
Currently pregnant	1.40	1.07 – 1.83	1.39	1.06 – 1.82	1.40	1.07 – 1.83	1.40	1.07 – 1.83	1.40	1.07 – 1.83	1.34	1.01 – 1.79
Design effect (intervention vs control arm)	0.91	0.76 – 1.09	0.90	0.76 – 1.08	0.91	0.76 – 1.09	0.90	0.75 – 1.07	0.91	0.76 – 1.09	0.93	0.78 – 1.11
(B) VL ≤1000 copies/mL												
Moved	1.14	0.79 – 1.64	1.26	0.85 – 1.87	1.15	0.84 – 1.57	1.29	0.93 – 1.80	0.87	0.63 – 1.19	0.94	0.68 – 1.29
Age	1.01	0.99 – 1.02	1.01	0.99 – 1.02	1.01	0.99 – 1.02	1.01	0.99 – 1.02	1.01	0.99 – 1.02	1.01	0.99 – 1.02
Married/cohabiting	1.24	1.07 – 1.43	1.15	0.97 – 1.36	1.24	1.07 – 1.43	1.16	0.98 – 1.37	1.24	1.07 – 1.43	1.15	0.97 – 1.35
Employed	1.15	0.99 – 1.33	1.17	0.99 – 1.36	1.15	0.99 – 1.33	1.17	1.00 – 1.36	1.15	0.99 – 1.33	1.17	1.00 – 1.37
Currently pregnant	1.35	1.10 – 1.65	1.41	1.09 – 1.81	1.35	1.10 – 1.65	1.41	1.09 – 1.81	1.35	1.10 – 1.65	1.38	1.08 – 1.78
Design effect (intervention vs control arm)	0.93	0.80 – 1.09	0.97	0.83 – 1.12	0.93	0.80 – 1.09	0.96	0.83 – 1.12	0.93	0.80 – 1.09	0.96	0.83 – 1.11

Mobility and retention in HIV care

The retention analysis was restricted to 315 women who did not report leaving the Western Cape. Of these women, 79% and 68% were retained in care at 12 months and 4 years postpartum, respectively. Retention in care at both 12 months and 4 years postpartum was not associated with having moved within 3, 6 or 12 months of the measurement visit (Table 5). The MCH-ART trial arm did not alter any of the associations for the retention in care outcome. Moderate SES was associated with increased likelihood of being retained in care in comparison to low SES for the 12 months (aRR=1.23, 95% CI: 1.04-1.45) and 4 years (aRR=1.25, 95% CI: 1.02-1.52) postpartum models, while the association with high SES (aRR=1.38, 95% CI: 1.13-1.67) was only statistically significant at 4 years postpartum. Age (aRR=1.01, 95% CI: 1.00-1.02) was associated with being retained in care at 12 months postpartum, while being married (aRR=1.20, 95% CI: 1.08-1.32) increased the likelihood of being retained in care at 12 months postpartum. Being currently pregnant (aRR=1.52, 95% CI: 1.18-1.97) increased the likelihood of being retained in care at 4 years postpartum. Having a higher CD4 count at baseline decreased the likelihood of being retained at 4 years postpartum in comparison to a CD4 count of <200, however this association was only statistically significant for a CD4 count of >500 (aRR=0.79, 95% CI: 0.64-0.99).

Table 5. Log binomial regression model among 315 postpartum women living with HIV who initiated ART during pregnancy, predicting A) retention in care at approximately 12 months postpartum, and B) retention in care at approximately 4 years postpartum (Restricted to women who did not report moving out of the Western Cape). This table is grouped by whether movement occurred 3 months, 6 months or 12 months prior to the viral load visit. Unadjusted (RR) and adjusted (aRR) risk ratios are presented with 95% confidence intervals (CI).

	Moved within 3 months				**Moved within 6 months**				**Moved within 12 months**			
	Unadjusted		**Adjusted**		**Unadjusted**		**Adjusted**		**Unadjusted**		**Adjusted**	
	RR	**95% CI**	**aRR**	**95% CI**	**RR**	**95% CI**	**aRR**	**95% CI**	**RR**	**95% CI**	**aRR**	**95% CI**
(A) Retained at 12 months postpartum												
Moved	1.09	0.88 – 1.34	1.10	0.94 – 1.28	1.06	0.86 – 1.29	1.09	0.94 – 1.26	1.11	0.95 – 1.30	1.12	0.99 – 1.28
Age	1.01	0.99 – 1.02	1.01	1.00 – 1.02	1.01	0.99 – 1.02	1.01	1.00 – 1.02	1.01	0.99 – 1.02	1.01	1.00 – 1.02
Married/cohabiting	1.17	1.05 – 1.30	1.20	1.08 – 1.32	1.17	1.05 – 1.30	1.20	1.08 – 1.32	1.17	1.05 – 1.30	1.20	1.09 – 1.33
Socioeconomic Status (Low)	1	(ref)	1	(ref)	1	(ref)	1	(ref)	1	(ref)	1	(ref)
Moderate	1.19	1.01 – 1.39	1.23	1.04 – 1.45	1.19	1.01 – 1.39	1.23	1.04 – 1.45	1.19	1.01 – 1.39	1.24	1.04 – 1.47
High	1.09	0.92 – 1.28	1.18	0.99 – 1.39	1.09	0.92 – 1.28	1.17	0.99 – 1.39	1.09	0.92 – 1.28	1.71	0.99 – 1.39
CD4 count at baseline (<200)	1	(ref)	-	-	1	(ref)	-	-	1	(ref)	-	-
200-350	0.98	0.83 – 1.16	-	-	0.98	0.83 – 1.16	-	-	0.98	0.83 – 1.16	-	-
350-500	0.99	0.84 – 1.18	-	-	0.99	0.84 – 1.18	-	-	0.99	0.84 – 1.18	-	-
>500	0.90	0.74 – 1.08	-	-	0.90	0.74 – 1.08	-	-	0.90	0.74 – 1.08	-	-
Design effect (intervention vs control arm)	1.17	1.04 – 1.31	1.20	1.09 – 1.33	1.17	1.04 – 1.31	1.20	1.09 – 1.32	1.17	1.04 – 1.31	1.20	1.09 – 1.32
(B) Retained at 4 years postpartum												
Moved	0.59	0.20 – 1.72	0.57	0.20 – 1.67	0.82	0.45 – 1.47	0.83	0.47 – 1.47	0.88	0.61 – 1.27	0.84	0.58 – 1.21
Age	0.99	0.99 – 1.01	-	-	0.99	0.99 – 1.01	-	-	0.99	0.99 – 1.01	-	-
Married/cohabiting	1.06	0.91 – 1.23	-	-	1.06	0.91 – 1.23	-	-	1.06	0.91 – 1.23	-	-
Currently pregnant	1.35	1.13 – 1.60	1.54	1.20 – 1.98	1.35	1.13 – 1.60	1.52	1.18 – 1.97	1.35	1.13 – 1.60	1.53	1.21 – 1.94
Socioeconomic Status (Low)	1	(ref)	1	(ref)	1	(ref)	1	(ref)	1	(ref)	1	(ref)
Moderate	1.22	0.99 – 1.51	1.27	1.04 – 1.54	1.22	0.99 – 1.51	1.25	1.02 – 1.52	1.22	0.99 – 1.51	1.23	1.02 – 1.49
High	1.30	1.06 – 1.58	1.39	1.14 – 1.69	1.30	1.06 – 1.58	1.38	1.13 – 1.67	1.30	1.06 – 1.58	1.34	1.11 – 1.62
CD4 count at baseline (<200)	1	(ref)	1	(ref)	1	(ref)	1	(ref)	1	(ref)	1	(ref)
200-350	0.99	0.82 -1.19	1.08	0.88 – 1.32	0.99	0.82 -1.19	1.08	0.88 – 1.33	0.99	0.82 -1.19	1.09	0.89 – 1.33
350-500	0.83	0.66 – 1.04	0.90	0.81 – 1.13	0.83	0.66 – 1.04	0.90	0.71 – 1.14	0.83	0.66 – 1.04	0.89	0.71 – 1.13
>500	0.75	0.59 – 0.95	0.79	0.63 – 0.98	0.75	0.59 – 0.95	0.79	0.64 – 0.99	0.75	0.59 – 0.95	0.79	0.64 – 0.98
Design effect (intervention vs control arm)	1.02	0.88 – 1.19	1.03	0.88 – 1.19	1.02	0.88 – 1.19	1.03	0.88 – 1.19	1.02	0.88 – 1.19	1.03	0.89 – 1.20

Discussion

This study describes the mobility patterns and HIV treatment outcomes of postpartum women who initiated lifelong ART during their pregnancy and were followed for up to 4 years postpartum. Overall, movement was common and mostly occurred in the first 12 months postpartum, with 28% of women reporting having moved to a different location at least once during the postpartum period. This analysis suggests that movement was not associated with viral suppression or retention in care at 4 years postpartum. At 12 months postpartum, women who had moved within 3, 6 or 12 months of the VL measurement were more likely to be virally suppressed compared to women who had not moved. No associations between mobility and VL at 4 years, or retention at either time point, were observed. These findings highlight high levels of viraemia and non-retention at both 12 months and 4 years postpartum, however mobility does not appear to be a key determinant of this specifically at 4 years postpartum.

Our finding that movement following delivery is a common occurrence among women living with HIV supports previous studies that have shown mobility in the postpartum period, mostly occurring right after the delivery of the baby [2,6–8,13,22]. Clouse and colleagues' [6] study among South African peripartum women found that nearly all of their participants planned to travel after delivery. Our findings suggest a key reason for movement is to seek care and help with the baby from family, which is consistent with the findings of previous studies on postpartum mobility and loss to follow up (LTFU) [6,13,22].

Despite the concerning levels of viraemia at 12 months and 4 years postpartum (34% and 44%, respectively), moving does not appear to be associated with worse viral load outcomes in our study. The only significant association was that movement within 3, 6 or 12 months of the VL measurement at 12 months postpartum increased the likelihood of being suppressed. The observed difference in proportions were however very low (7%, 8% and 12% mobility in the suppressed versus 4%, 6% and 9% in the unsuppressed). In contrast, previous studies have shown movement to be associated with suboptimal treatment adherence and poor treatment outcomes including being less likely to be suppressed [3,21,23–26]. One explanation may be the focus on different populations, with these studies focusing on migrant populations who mostly travelled for work.

There were great variations in the definitions for mobility used in these studies, with mobility being defined as either permanent or temporary migration, cross-border migration, and frequent migration. This variation in definitions of mobility in literature has been shown to contribute to the inconsistent findings on mobility and its impact on HIV treatment outcomes [5,21].

The association between mobility and viral suppression at 12 months postpartum may be linked to the main reported reason for moving which was to seek help with care for the baby from family. While some studies have shown this to be a hindrance to adequate engagement with HIV care, family support has also been shown to be an important facilitator [20,27]. Support from the family has been shown to be an enabler of ART adherence, mainly by helping women with domestic tasks and caring for the baby thereby making it possible for them to attend their clinic appointments [20,27]. We hypothesize that women who moved for support with the child may have also received social support to remain in HIV care.

High levels of non-retention at 12 months and 4 years postpartum (21% versus 32%) were observed in this analysis. Despite these findings, movement in the postpartum period was not associated with retention in care for our participants. Nonetheless, these high levels of non-retention reflect previous observations that women are at high risk of disengagement from care particularly following delivery [13,20,22,28,29]. Studies on retention among postpartum women have shown that moving may increase the risk of disengagement from care [9,13,28,30,31]. Although mobility was not associated with poor retention in care in this study, the high levels of non-retention found warrants further effort to ensure continuity of care for mobile populations.

Previous literature on postpartum women's engagement with HIV care has shown that following delivery mothers often emphasize care for the infant over care for the mother, overlooking the importance of continuous care for themselves [6,7]. Pregnancy and ANC has are important points for entry and re-entry into HIV services [32–34]. Our findings showed that women who were pregnant at 4 years postpartum were more likely to be virally suppressed and retained in care. This adds to previous findings that women are more likely to be adherent to ART and retained in care throughout pregnancy in order to protect their baby but then discontinuing care in the postpartum period [7]. Another predictor of viral suppression in this study was older age. This supports the

extensive evidence that younger women have an increased risk of poor treatment outcomes [9,10,20,31].

When interpreting these findings, it is important to consider several limitations. The main limitation of these results is that all data collected on the primary exposure (mobility) was self-reported by study participants. Participants had to report their mobility over the 4 year period following delivery, therefore this data may be susceptible to recall bias and could have led to errors in recalling movement and the timing thereof. Analyses using different windows of having moved within 3, 6 and 12 months of the outcome measurement was done in an attempt to address some of the bias that could have arisen. While these women were recruited from a large primary care clinic in Cape Town and these findings may be generalizable to similar settings, they do not necessarily reflect the mobility and HIV care experiences of women in other areas in South Africa or sub-Saharan Africa. It is important to note that the retention data was limited to women who did not move out of the Western Cape. This data was drawn from routine medical records obtained from the Western Cape Department of Health's Provincial Health Data Centre, which is only able to link participants' healthcare access across public facilities in the Western Cape [18]. Therefore, estimates of LTFU may not represent true disengagement from care and could result in an underestimation of retention, specifically for women who are required to transfer care in the postpartum period.

This study contributes to the scarce literature on postpartum women's mobility and how it effects their HIV care engagement and treatment outcomes. It is important to provide more insight on the role that postpartum mobility plays in terms of engagement with care, as consistent retention in care is a significant challenge in South Africa, specifically for postpartum women [6]. Continuous engagement in care for postpartum women is of great importance as HIV requires lifelong treatment and high treatment adherence in order to prevent treatment failure [16,35]. These findings show that movement following delivery is common, but this did not seem to disrupt engagement in HIV care. This study's findings emphasize the need for further research on postpartum mobility and its impact on women's treatment outcomes and retention in care in order for healthcare facilities to adequately consider movement and adapt care for this population.

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Supporting Information

Additional supplementary tables may be found in the appendix section of this article (Appendix G).

Table 1. Bivariate statistics of covariates of 353 postpartum women living with HIV who initiated ART during pregnancy. This table is grouped by whether they had moved within 6 months of the viral load visit or not during the postpartum period at approximately 12 months and 4 years following delivery. The characteristics were measured at baseline and 4 years postpartum for the two groups, respectively.

Table 2. Bivariate statistics of covariates of 349 postpartum women living with HIV who initiated ART during pregnancy. This table is grouped by whether they were virally suppressed (VL ≤50 copies/mL) or not during the postpartum period at approximately 12 months and 4 years following delivery.

Table 3. Bivariate statistics of covariates of 349 postpartum women living with HIV who initiated ART during pregnancy. This table is grouped by whether they were virally suppressed (VL ≤1000 copies/mL) or not during the postpartum period at approximately 12 months and 4 years following delivery.

Table 4. Bivariate statistics of covariates of 315 postpartum women living with HIV who initiated ART during pregnancy (Restricted to women who did not report moving out of the Western Cape). This table is grouped by whether they were retained in HIV care or not during the postpartum period at approximately 12 months and 4 years following delivery.

PART C: APPENDICES

Appendix A: Demographic and Medical History Questionnaire (LACE Study)

LACE: Demographics & Medical History
V3.0 30 June 2017

PID: L - __ __ __ __ - __ __

		Visit Date: __ __/__ __ __/__ __ __ __
1.	Ingaba ufudukele kwelinye ikhaya emva kokuba sithethile nawe? Have you moved to a different home since we last spoke to you?	Hayi/No=0 Ewe/Yes =1
2.	Ingaba uyitshintshile inombolo yakho yomnxeba emva kokuba sithethile nawe? Have you changed your cell phone number(s) since we last spoke to you?	Hayi/No=0 Ewe/Yes =1
3.	Ingaba ukhona omnye umntu esingaqhagamshelana naye ukuba sifuna wena malunga nomba ongxamisekileyo? Is there anyone else that we can contact if we are looking for you in the event of an emergency?	Hayi/No=0 Ewe/Yes =1
Mbuzi-mibuzo – Nceda ukhumbule ukuhlaziya inkcukacha zaye wonke umthathi-nxaxheba ***Interviewer - Please remember to update locator information for ALL participants***		
Ngoku sizokubuza umibuzo embalwa: We are now going to ask you a few questions:		
4.	Leliphi ibanga eliphezulu oligqibileyo esikolweni/ ezifundweni zakho? What is the highest level of schooling/education that you have completed?	Inqanaba/Grade:_____ Ibanga/Standard:_____ Imfundo ephezulu/ Postsecondary:_____
5.	Ingaba uyafunda okanye uyasebenza ngoku? Are you currently working and or studying?	Hayi/No = 0 → **SKIP to Q7** Ewe/Yes = 1
6.	Ukuba ewe, yeyiphi kwezi zilandelayo ekuchaza ngcono? Khetha ibenye kuphela If yes, which of one the following best describes what you do? Choose one only	Uphangela isigxina = 1 Employed full-time Uphangela manqapha-nqapha=2 Employed part-time Umsebenzi onjengokuthengisa endlini/esitalatweni = 3 Informal job/hawker Uhamba isikolo/ungumfundi = 4 Attending school/learner Ufunda kwiziko lemfundo enomsila = 5 Attending tertiary education facility
7.	Ngowuphi UNDOQO ongenisa imali endlini yakho? Khetha ibenye kuphela What is the MAJOR source of income for your household? Choose one only	Akekho = 0 None Umsebenzi osisigxina = 1 Full-time employment Umsebenzi wamanqapha-nqapha = 2 Part-time employment Umsebenzi ozenzela wona = 3 Informal employment

Page 1 of 13

			Isibonelelo sokukhubazeka = 4 Disability grant Isibonelelo sentlalontle = 5 Social grant Pension = 6 Esobudala Esinye isibonelelo = 7,: ___ Other grant Cacisa uhlobo/specify type: _____ Enye = 8 Other Cacisa/specify:_____ Andazi = 9 Don't know
8.	Uhlala kwikhaya elinjani? What kind of home do you live in?		Ityotyombe/uhlaliso olungahlelwanga = 1 Shack/informal dwelling Indlu yesitena = 2 Formal house Iflethi/indlu kamasipala = 3 Flat/council home Enye = 4 Other Cacisa/specify:_____
9.	Ingaba indlu yakho inazo ezinto zilandelayo: Funda uze uphendule malunga nazo zonke Does your house have the following?: Read and answer for all	a. Indlu yangasese engaphakathi A toilet inside	Hayi/No=0 Ewe/Yes =1
		b. Amanzi empompo ngaphakathi endlini Running water inside	Hayi/No=0 Ewe/Yes =1
		c. Umbane ngaphakathi endlini Electricity inside	Hayi/No=0 Ewe/Yes =1
		d. Isikhenkcezisi A refrigerator	Hayi/No=0 Ewe/Yes =1
		e. Umnxeba A telephone	Hayi/No=0 Ewe/Yes =1
		f. Umabonakude A television	Hayi/No=0 Ewe/Yes =1
10.	Ukuquka isiqu sakho, bangaphi abantu (abadala nabantwana) abahlala endlini yakho? Including yourself, how many people (adults and children) live in your house?		# labantu/ # of people: _____
11.	Bangaphi abantu abadala (abakwiminyaka eyi 16 okanye ngaphezulu), ukuquka wena, abahlala endlini yakho? How many adults (aged 16 or older), including you, live in your house?		# labantu abadala/ # of adults:_____

Initials of counsellor: _____

12.	Bangaphi abantwana (abakwiminyaka eyi 15 nangaphantsi) abahlala endlini yakho? How many children (aged 15 and under) live in your house?	# Labantwana/ # of children: _____
13.	Wakhulelwa amatyeli amangaphi (kuquka nesi isisu, ukuba ukhulelwe)? How many times have you been pregnant (including current pregnancy if pregnant)?	# lokukhulelwa/ # of pregnancies: _____
14.	Bangaphi abantwana obazeleyo? How many children have you given birth to?	# Labantwana/ # of children: _____ → **If 0, SKIP to Q19**
15.	Bangaphi abaphilayo kwaba bantwana? How many of these children are living?	# Labantwana/ # of children: _____
16.	Bangaphi abahlala nawe? How many of these children currently live with you?	# Labantwana/ # of children: _____
17.	Bangaphi kwaba bantwana abanentsholongwane ka gawulayo? How many of your children have tested HIV-positive?	# labantwana abanentsholongwane kagawulayo/ # of HIV-positive children: _____
18.	Bangaphi kwaba bantwana abanentsholongwane kagawulayo abaphilayo ngoku? How many of these children who have tested HIV- positive are currently living?	# labantwana abanentsholongwane kagawulayo abaphilayo ngoku/ # of HIV-positive children currently alive: __
19.	Kwezinyanga zilishumi elinesibini zidlulileyo, ingaba ubukhe wathunyelwa kulo naliphi na iziko lezempilo malunga nolunye ukhathalelo lwempilo ngaphandle kweli lakho lesisiqhelo lwe HIV/ART (umzekelo, GF Jooste or Groote Schuur)? In the past 12 months, have you been referred to any health facility for <u>medical care other than your routine HIV/ART care</u> (e.g. GF Jooste or Groote Schuur)?	Hayi/No = 0 → SKIP to Q20 Ewe/Yes = 1

	a) Wathunyelwa phi? Where were you referred?	b) Yayisesiphi isigulo? What was the diagnosis?	c) Ingaba walala esibhedlele Did you sleep in the hospital	d) Walala intsuku ezingaphi esibhedlele? How many nights were you in hospital?	e) Kwakunini? Nceda unikezele ngomhla lowo When was this? Please give approximate date
i.			Hayi/No = 0 Ewe/Yes = 1		Day: __ __ Month: __ __ __ Year: __ __ __ __
ii.			Hayi/No = 0 Ewe/Yes = 1		Day: __ __ Month: __ __ __ Year: __ __ __ __
iii.			Hayi/No = 0 Ewe/Yes = 1		Day: __ __ Month: __ __ __ Year: __ __ __ __

	a) Wathunyelwa phi? Where were you referred?	b) Yayisesiphi isigulo? What was the diagnosis?	c) Ingaba walala esibhedlele Did you sleep in the hospital	d) Walala intsuku ezingaphi esibhedlele? How many nights were you in hospital?	e) Kwakunini? Nceda unikezele ngomhla lowo When was this? Please give approximate date
iv.			Hayi/No = 0 Ewe/Yes = 1		Day: __ __ Month: __ __ __ Year: __ __ __ __
v.			Hayi/No = 0 Ewe/Yes = 1		Day: __ __ Month: __ __ __ Year: __ __ __ __
vi.			Hayi/No = 0 Ewe/Yes = 1		Day: __ __ Month: __ __ __ Year: __ __ __ __
vii.			Hayi/No = 0 Ewe/Yes = 1		Day: __ __ Month: __ __ __ Year: __ __ __ __
viii.			Hayi/No = 0 Ewe/Yes = 1		Day: __ __ Month: __ __ __ Year: __ __ __ __
ix.			Hayi/No = 0 Ewe/Yes = 1		Day: __ __ Month: __ __ __ Year: __ __ __ __
x.			Hayi/No = 0 Ewe/Yes = 1		Day: __ __ Month: __ __ __ Year: __ __ __ __
20.	Kwezi nyanga zilishumi elinesibini zidlulileyo, ingaba uggirha okanye unesi wakhe wakuxelela ukuba une TB? In the past 12 months, has a doctor or nurse told you that you have TB?			Hayi/No = 0 → SKIP to Q25 Ewe/Yes = 1	
21.	Wafumanisa nini ngesi sigulo? When did you receive this diagnosis?			Day: __ __ Month: __ __ __ Year: __ __ __ __	

22.	Wafumanisa phi ngesi sigulo? Where did you receive this diagnosis?		Igama le klinikhi/ Name of clinic:	
23.	Yayiphi emzimbeni wakho iTB (e.g, kwimiphunga, kwenye indawo)? Where in your body was the TB (e.g, lungs, other location)?		Indawo emzimbeni/ Place in body:	
24.	Walufumana na unyango lwe TB? Did you receive treatment for TB?		Hayi/No = 0 Ewe/Yes = 1	
25.	Njengoko waye wafunyaniswa unentsholongwane kagawulayo, ingaba ukhona na umntu owathi wamxelela ngesimo sakho sentsholongwane kagawulayo? Since you were diagnosed with HIV, have you told anyone about your HIV-status?		Hayi/No = 0 → SKIP to Q28 Ewe/Yes = 1	
26.	Nceda uphendule lombuzo malunga nelungu ngalinye losapho elikhankanywe ngezantsi Please answer this question for each of the family members listed below.	i. Ingaba bahlala kunye nawe? Do they live with you? *Ukuba konyulwe uN/A, ungamphenduli u ii no iii malunga nalomntu* *If NA selected, do not answer ii and iii for that person*	ii. Ingaba bayayazi na ukuba unentsholongwane ka gawulayo? Do they know you are HIV positive?	iii. Ingaba bayayazi na ukuba usebenzisa i ART? Do they know if you are taking ART?
a.	Umyeni/iqabane Husband/partner	Hayi/No = 0 Ewe/Yes = 1 N/A=9	Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
b.	Umama Mother	Hayi/No = 0 Ewe/Yes = 1 N/A=9	Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
c.	Utata Father	Hayi/No = 0 Ewe/Yes = 1 N/A=9	Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
d.	Usisi Sister	Hayi/No = 0 Ewe/Yes = 1 N/A=9	Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
e.	Ubhuti Brother	Hayi/No = 0 Ewe/Yes = 1 N/A=9	Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
f.	Intombi Daughter	Hayi/No = 0 Ewe/Yes = 1 N/A=9	Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
g.	Unyana Son	Hayi/No = 0 Ewe/Yes = 1 N/A=9	Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
h.	Umalume Uncle	Hayi/No = 0 Ewe/Yes = 1 N/A=9	Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
i.	Uanti Aunt	Hayi/No = 0 Ewe/Yes = 1 N/A=9	Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
j.	Umzala oyindoda Male cousin	Hayi/No = 0 Ewe/Yes = 1 N/A=9	Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1

k.	Umzala ongumfazi Female cousin	Hayi/No = 0 Ewe/Yes = 1 N/A=9	Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
l.	Amanye amalungu osapho angamadoda Other male family member	Hayi/No = 0 Ewe/Yes = 1 N/A=9	Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
m.	Amanye amalungu osapho angabafazi Other female family member	Hayi/No = 0 Ewe/Yes = 1 N/A=9	Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
27.	Ngaphandle kwamalungu osapho akhankanywe ngasentla, ngubani omnye owathi wamxelela ngesimo sakho sentsholongwane ka gawulayo? (funda uze uphendule malunga nazo zonke) Aside from family members listed above, who else have you told about your HIV status <u>since your HIV diagnosis</u>? (read and answer for all)		i. Ingaba bayayazi na ukuba unentsholongwane ka gawulayo Do they know you are HIV positive?	ii. Ingaba bayayazi na ukuba usebenzisa iART? Do they know if you are taking ART?
a.	Iingcali zempilo Health professionals		Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
b.	Iqela lenkxaso Support group		Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
c.	Iqabane owabelana nalo ngesondo ongahlali nalo A sexual partner who does not live with you		Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
d.	Abahlobo Friends		Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
e.	Umthandazeli Spiritual leader		Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
f.	Umqeshi wangoku okanye owayesakuba ngumqeshi wakho Current or former employer		Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
g.	Ukuphumela elubala ekuhlaleni Public disclosure/ community		Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
h.	Enye/Other Cacisa/ specify: _____		Hayi/No = 0 Ewe/Yes = 1	Hayi/No = 0 Ewe/Yes = 1
28.	Ingaba ukhona umntu othandana naye ngoku? Are you currently in a relationship?		Hayi/No = 0 → SKIP to Q33 Ewe/Yes = 1	
29.	Ungabuchaza uthini ubudlelwane onabo neqabane lakho ngoku? How would you describe your current relationship?		Utshatile = 1 Married Awutshatanga, nihlala kunye = 2 Not married, living together Utshatile, anihlali kunye = 3 Married, not living together Awutshatanga, anihlali kunye = 4 Not married, not living together Enye/Other = 5 Cacisa/specify:_____	
30.	Unexesha elingakanani uthandana neqabane lakho ngoku? How long have you been in this relationship?		Ixesha kwi/ Duration in: Nyanga/ Months _____ Iminyaka/ Years: _____	

31.	Ingaba iqabane lakho ngoku lingutata womnye wabantwana bakho? (ukuquka nomkhulelweyo ukuba ukhulelwe) Is your current partner the parent of any of your children? (including current pregnancy if pregnant)		Hayi/No = 0 Ewe/Yes = 1
32.	Ingaba iqabane onalo ngoku, iseleliya qabane owawunalo ngelaxesha wawubeleka umntwana wakho kuphando lwe MCHART ? Is your current partner the same partner you had when you delivered your baby in the MCHART study?		Hayi/No = 0 Ewe/Yes = 1
33.	Ingaba unabo ubudlelwane, okanye amaqabane othi wabelane nabo ngesondo ngelilixa ungathandani nabo? (nokuba awuthandani namntu ngoku)? Do you have relationships/sexual partners with any other people (even if you are not currently in a relationship)?		Hayi/No = 0 → SKIP to Q35 Ewe/Yes = 1
34.	Sithini isimo sobunye ubudlelwane onabo? Phawula zonke ezifanelekileyo What is the nature of your other relationship(s)? Mark all that apply.	a. Umyeni/utshatile Spouse/ married	Hayi/No = 0 Ewe/Yes = 1
		b. Iqabane Boyfriend	Hayi/No = 0 Ewe/Yes = 1
		c. Iqabane elingesosigxina/ Elobusuku obunye Casual Partner/One Night Stands	Hayi/No = 0 Ewe/Yes = 1
		d. Enye/other Cacisa/specify:	Hayi/No = 0 Ewe/Yes = 1

35.	Bangaphi abantu okhe wathandana nabo emva kokuba umntwana wakho ezelwe ngexesha lophando lwe MCH-ART? (ukuquka iqabane onalo ngoku ukuba unaye umntu othandana naye)
	How many relationships have you had since your baby was born during the MCH-ART study? (Including your current partner if you are in a relationship)
			# lobudlelwane/ # of relationships: _____
			Usekobabudlelwane = 999
			Still in the same relationship

36.	Ingaba usebenzisa iART ngoku? Are you currently taking ART?		Hayi/No = 0 Ewe/Yes = 1
37.	Wayigqibela ngoluphi usuku nexesha iART? When was the last day and time you took ART?		Time:__ __ Day: __ __ Month: __ __ __ Year: __ __ __ __
a.	Ingaba ubuyisebenzisile iART kwezintsuku zisixhenxe zidlulileyo? Have you taken ART at all in the last 7days?		Hayi/No = 0 Ewe/Yes = 1 → SKIP to Q38
b.	Ukuba hayi, ngoba kutheni? If No, why not?		Isizathu Reason

38.	Ingaba ubhalisile kwi klinikhi ye ART ngoku? *waya eklikhini kwezinyanga zintathu zidlulileyo Are you currently enrolled in an ART Clinic? *attended a clinic in the last 3 months	Hayi/No = 0 Ewe/Yes = 1 → SKIP to Q40
39.	Ukuba hayi, sithini isizathu esibangela ukuba ube awubhalisanga kwi klinikhi ye ART? Ungazidwelisa zibeliqela izizathu. If no, what is the reason that you are no longer enrolled in an ART clinic? You can list more than one reason.	1._____ 2._____ 3._____ 4._____ 5._____ → SKIP to Q47
40.	Ukuba ewe, yeyiphi iklinikhi ohamba kuyo? If yes, which clinic do you currently attend?	Igama leklinikhi/ Clinic name:
41.	Uya njani eklinikhi kukhathalelo lwakho lwesiqhelo? How do you usually travel to the clinic for routine care	Ngemoto eqeshiweyo = 1 Hired car Ngemoto yam = 2 My own car Ngeteksi =3 Taxi Ngebhasi = 4 Bus Ndihamba ngenyawo = 5 Walk Enye/other = 6 Cacisa/specify: _____
42.	Kukuthatha ixesha elingakanani ukufika eklinikhi? How long does it usually take you to get to the clinic?	Imizuzu/minutes: _____ Iyure/hours: _____
43.	Ubhatala malini yokukhwela isithuthi? How much do you usually pay for transport?	IRandi/Rand: _____
44.	Ingaba emsebenzini kufuneka uthathe ikhefu lokuya eklinikhi? Do you have to take time off work to go to the clinic?	Hayi/No = 0 Ewe/Yes = 1
45.	Ingaba kufuneka wenze amalungiselelo akhethekileyo wabantu abazogada umntwana/abantwana bakho? Do you have to make special arrangements for people to watch your child/children?	Hayi/No= 0 → SKIP to Q47 Ewe/Yes = 1 Andinabantwana = 2 → SKIP to Q47 Don't have any children

Initials of counsellor: _____

46.	Ingaba uyambhatala umntu ogada umntwana wakho ukuze ukwazi ukuya eklinikhi? Do you pay someone to watch your child so you can go to the clinic?		Hayi/No = 0 Ewe/Yes = 1
47.	Kwezinyanga zilishumi elinesibini zidlulileyo ingaba ubukhe wathetha nomniki-nkonzo eklinikhi/esibhedlela malunga nokhathalelo lwakho lwentsholongwane kagawulayo? In the past 12 months have you spoken to a counsellor at the clinic/ hospital about your HIV care?		Hayi/No= 0 → SKIP to Q48 Ewe/Yes = 1
a.	Ukuba EWE, wayaphi? If Yes, where did you go?		Igama leklinikhi/ Clinic name:
b.	Kwezinyanga zilishumi elinesibini zidlulileyo mangaphi amatyeli othe wolulekwa ngawo? In the past 12 months how many times have you been counselled?		# lamaxesha/ # of times: _____
c.	Ingaba wathetha nabani ngelixesha lolu loluleko? nomluleki, nomongikazi okanye nogqirha) Who did you speak to during this counselling? (counsellor, nurse, doctor)		
d.	Wathetha ngantoni ngelixesha lolu loluleko? What did you talk about during this counselling?		
48.	Xa uye kutyelelo lwakho lwesiqhelo lwe ART, ingaba umkhathaleli wempilo uyakubuza malunga: When you attend your routine ART care visit, does a health care provider ask you about:	a) Indlela otya ngawo amachiza Medication adherence	Hayi/No = 0 Ewe/Yes = 1
		b) Ngempilo yakho Your health	Hayi/No = 0 Ewe/Yes = 1
		c) Impilo yomntwana Child health	Hayi/No = 0 Ewe/Yes = 1
		d) Ukondliwa komntwana Child feeding	Hayi/No = 0 Ewe/Yes = 1
		e) Ucwangcwiso losapho Family planning	Hayi/No = 0 Ewe/Yes = 1
49.	Ingaba umntwana wakho uyaya na eklinikhi malunga nogonyo/utyelelo lwesiqhelo lokhathalelo lwabantwana? Is your child attending a clinic for immunizations/routine well baby care?		Hayi/No= 0 → SKIP to Q51 Ewe/Yes = 1 Umntwana wasweleka/ Child died = 2 → SKIP to Q55
50.	Ukuba ewe, kweyiphi iklinikhi? If yes, which clinic?		Igama leklinikhi/Clinic name: →SKIP to Q52
51.	Ukuba hayi, ngoba kutheni? Ungadwelisa izizathu ezininzi. If no, why not? You can list more than one reason.		1._____ 2._____

		3._____ 4._____ 5._____
52.	Ingaba uhlala nawe umntwana wakho ngoku? Does your child currently live with you?	Hayi/No = 0 Ewe/Yes = 1 → SKIP to Q55
53.	Ukuba hayi, uhlala nabani umntwana wakho? (ubudlelwane emntwaneni e.g: umhakhulu, u-anti) If no, who does the child stay with? (relationship to child eg: grandmother, aunt)	
54.	Uhlala phi umntwana? Where does the child live?	Igama ledolophu & iphondo/ Name of town & province:
55.	Wagqibela nini ukuya exesheni? When was your last menstrual period?	Day: __ __ Month: __ __ __ Year: __ __ __ __ Andiqinisekanga/ Unsure = 9
56.	Ingaba ukhulelwe na ngoku? Are you pregnant at the moment?	Hayi/No= 0 → SKIP to Q58 Ewe/Yes = 1 Andiqinisekanga/Not sure = 2 → SKIP to Q58
57.	Ingaba selwazisiwe ukhulelo? Has the pregnancy been confirmed?	Hayi / No = 0 →DO PREGNANCY TEST NOW Ewe/Yes = 1
Ngoku sizokubuza imibuzo embalwa ngamaxesha othe wanohambo olungaphandle kwekhaya lakho elise Kapa. We will now ask you a few questions about any times you have travelled away from your home in Cape Town.		
58.	Kwezi nyanga zilishumi elinesibini zidlulileyo, ingaba wakhe wachitha intsuku ezintathu nangaphezulu uhambele ngaphandle kwekhaya lakho lesiqhelo? In the past 12 months, have you ever spent three or more nights traveling away from your usual house?	Hayi/No= 0 → END HERE Ewe/Yes = 1
59.	Kwezi nyanga zilishumi elinesibini zidlulileyo, mangaphi amaxesha owathi watyelela ngawo ngaphandle kwekhaya lakho lesiqhelo ubuncinane intsuku ezintathu? In the past 12 months, how many times have you travelled away from your usual home for at least three nights?	Ixesha elinye – amaxesha amabini = 1 1 to 2 times Amaxesha amathathu – amaxesha amahlanu = 2 3 to 5 times Ngaphezu kwamaxesha amahlanu = 3 More than 5 times

60.	Lingakanani elona xesha lide ukude ekhaya? What was the longest period you were away from home?	a) _____ iintsuku/ days b) _____ iiveki/weeks c) _____ iinyanga/months OR d) Wafuduka isigxina/ Relocated permanently
61.	a) Xa wawuhambele, ingaba wawuhambele kwi When you have travelled, did you travel to:	Kwindawo enye oko/idolophu = 1 Always the same place/town Kwindawo ezizinizi/idolophu/iphondo = 2 More than one place/town/province
	b) Wawuhambele phi, dwelisa indawo ezininzi kangangoko kufanelekileyo? (Idolophu, Iphondo) Where did you travel to, list as many places as apply? (Town, Province)	i. _____ ii. _____ iii. _____ iv. _____
62.	a) Abanye abantu bafumanisa kunzima ukusebenzisa amayeza abo xa bengekho ekhaya, ngoku ubungekho kwixesha elidlulileyo, ingaba wawukhe wafumana ubunzima bokusebenzisa amayeza akho? Some people find it difficult to take their treatment while away from home, when you were away the last time, did you have any difficulties taking your treatment?	Hayi/No = 0 → SKIP to Q63 Ewe/Yes = 1

	b) Zintoni ezenza kwanzima? (Biyela konke okufanelekileyo) What things made it difficult? (Circle all the apply)	Ndalibala ukuphatha ipilisi zam I forgot to carry my pills	Hayi/No = 0 Ewe/Yes = 1
		Ndandixakekile ndaze ndalibala ukuthatha ipilisi zam I was busy and forgot to take my pills	Hayi/No = 0 Ewe/Yes = 1
		Ndandihlala nabantu ababengasazi isimo sam I stayed with people who did not know my status	Hayi/No = 0 Ewe/Yes = 1
		Ndaye ndaphelelwa ngamayeza I ran out of medication	Hayi/No = 0 Ewe/Yes = 1
		Intsuku zokuhlala kwam zaye zanda ndingalindelanga My length of stay extended unexpectedly	Hayi/No = 0 Ewe/Yes = 1
		Ezinye izinto/Any other things? Cacisa/Specify:	Hayi/No = 0 Ewe/Yes = 1

PID: L - __ __ __ __ - __ __

63.	Ingaba wawukhe waya kwi ART klinikhi ngaphandle kwale uhamba kuyo yesiqhelo ngoku wawungekho khaya? Have you ever attended an ART clinic other than your usual clinic while you were away from home?		Hayi/No = 0 Ewe/Yes = 1
64.	a) Ingaba wawukhe wafumana ulongezo lwe ART ngexesha owangekho khaya? Did you ever receive an ART top up while you were away from home?		Hayi/No = 0 → SKIP to Q65 Ewe/Yes = 1
	b) Ukuba ewe, wawafumana phi amayeza? If yes, where did you get the treatment from?		Klinikhi/Clinic = 1 Igama leklinikhi /Clinic name_____ Umhlobo/ilungu losapho = 2 Friend/family member Enye/Other = 3 Cacisa/Specify:_____
65.	a) Ingaba wakhe wayifumana ileta esuka kwiklinikhi yakho yesiqhelo ikuthumela kwenye iklinikhi ngelixesha wawungekho khaya? Did you ever receive a transfer letter from your routine ART clinic to receive care at another clinic when you went away?		Hayi/No = 0 Ewe/Yes = 1 → END HERE
	b) Ukuba hayi, kwakutheni (biyela konke okufanelekileyo)? If no, why not? (circle all that apply)	i. Ndandinamayeza oneleyo ngexesha endandizohamba I had enough treatment for the time I was going to be away	Hayi/No = 0 Ewe/Yes = 1
		ii. Ndandingayazi ukuba kwakufuneka ndifumnane ileta endithumela kwenye iklinikhi ye ART I did not know I would need a transfer letter to receive ART from another clinic	Hayi/No = 0 Ewe/Yes = 1
		iii. Ndahamba ngequbuliso kwaye zange ndibenalo ithuba lokuyocela ileta eklinikhi I left unexpectedly and did not have time to go to the clinic for a letter	Hayi/No = 0 Ewe/Yes = 1
		iv. I klinikhi yam yesiqhelo yandinika iART eyoneleyo yokundijonga ngexesha endandingekho ngalo My usual clinic gave me enough ART to see me through the time I was away	Hayi/No = 0 Ewe/Yes = 1
		v. Ndaya eklinikhi ndayozama ukufumana ileta kodwa zange ndiyifumane ileta endithumelayo I went to the clinic to try to get a letter but was not able to get a transfer letter	Hayi/No = 0 Ewe/Yes = 1
		vi. Esinye isizathu sokungafumani ileta ekuthumelayo Any other reason you did not get a transfer letter: Cacisa/Specify:	Hayi/No = 0 Ewe/Yes = 1

Date completed: __ __ /__ __ __ / __ __ __ __	Signed counsellor completing CRF: _____

QC stamp:	Data capturer stamp:

LACE: Maternal movement table
V2.0 22 February 2017

PID: L - __ __ __ __ - __ __

A	**Ukufuduka kukamama** Imiqathango yetafile: Singathanda ukukubuza ngokuhamba /ngokufuduka kwakho emva kokubeleka usana ukuvavanyo lweMCH-ART. Sizakugcwalisa itafile engezantsi. Wawuhlala phi ngexesha ubeleka usana lwakho kwi MCH-ART? **Maternal relocation** **Instructions for table:** We would like to ask you about **your movement/relocation after the baby was born** in the MCH-ART study. We will complete the table below. Where were you living at the time you delivered your baby in the MCH-ART study?

Umzekelo/ Example:

	Ukuqala kwexesha **Start of time period**	**Ubude bexesha** **Duration**	**Igama ledolophu, iphondo** **Name of suburb, province**	**Inyanga/unyaka wokufuduka** **Month/year relocated**	**Isizathu sokufuduka** **Reason for relocating**
1	Right after delivery	1 year	Lower crossroads, WC	June 2014	Moved to stay with family
2	June 2014	6 months	Butterworth, EC	Dec 2014	Moved back for work
3	Dec 2014	Current	Gugulethu, WC	NA	Still living here

	a) Ukuqala kwexesha **Start of time period**	**b) Ubude bexesha** **Duration**	**c) Igama ledolophu, iphondo** **Name of suburb, province**	**d) Inyanga/unyaka wokufuduka** **Month/year relocated**	**e) Isizathu sokufuduka** **Reason for relocating**
1	Right after delivery of baby in MCH-ART			D: __ M: ___ Y: ____	
2				D: __ M: ___ Y: ____	
3				D: __ M: ___ Y: ____	
4				D: __ M: ___ Y: ____	
5				D: __ M: ___ Y: ____	
6				D: __ M: ___ Y: ____	
7				D: __ M: ___ Y: ____	
8				D: __ M: ___ Y: ____	
9				D: __ M: ___ Y: ____	
10				D: __ M: ___ Y: ____	

Appendix C: University of Cape Town Protocol Approval for MCH-ART Study

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	Signature removed	Date Signed	19/10/2019

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	15 October 2019		
HREC REF Number	451/2012	Current Ethics Approval was granted until	30 October 2019
Protocol title	Strategies to optimize antiretroviral therapy services for maternal & child health: the MCH-ART study		
Protocol number (if applicable)	NA		
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.	HREC REF 194/2013: Estimation of delivery dates using obstetric ultrasound in the MCH-ART study HREC 550/2015: Childbearing, family planning and relationships among women living with HIV in Gugulethu, Cape Town		
Principal Investigator	Landon Myer		

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

HUMAN RESEARCH ETHICS COMMITTEE
18 OCT 2019
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

Appendix D: University of Cape Town Protocol Approval for LACE Study

HUMAN RESEARCH ETHICS COMMITTEE
21 MAY 2019
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30.04.2020
☐ Not approved	See attached comments		
Signature Chairperson of the HREC	Signature Removed	Date Signed	22/5/2019

Comments to PI from the HREC
Ph to go for re deviation document

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	17 May 2019		
HREC REF Number	866/2016	Current Ethics Approval was granted until	30 Jan 2019
Protocol title	Long-term Adherence and Care Engagement (LACE): A supplement to the MCH-ART protocol		
Protocol number (if applicable)			
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.			
Principal Investigator	Prof Landon Myer		
Department / Office Internal Mail Address	Office 5.43 Level 5 Falmouth Building		

1.1 Does this protocol receive US Federal funding?	✓ Yes	☐ No

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

Appendix E: University of Cape Town Protocol Approval for secondary analysis of MCH-ART and LACE data

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

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

03 June 2020

HREC REF: 185/2020

Dr T Phillips
School of Public Health & Family Medicine
Office 5.38, Level 5
Falmouth Building-FHS
Email: tammy.phillips@uct.ac.za
Student: Mzrrob001@myuct.ac.za

Dear Dr Phillips

PROJECT TITLE: PATTERNS OF MOBILITY AND THE EFFECT OF MOBILITY ON VIRAL SUPPRESSION AND RETENTION AMONG POSTPARTUM WOMEN LIVING WITH HIV IN SOUTH AFRICA (MPHIL DEGREE - MISS ROBYN MAZRIEL)

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.

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

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

We acknowledge that the student: Miss Robyn Mazriel will also be involved in this study.

Please quote the HREC REF in all your correspondence.

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

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

HREC 185/2020sa

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

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

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

HREC 185/2020sa

Appendix F: Informed Consent Form for the LACE Study

LACE Informed Consent Form

TITLE OF RESEARCH: **Long-term Adherence and Care Engagement (LACE) study**

YINTONI INJONGO YOLU PHANDO?
Sisuka kwiYunivesithi yaseKapa ibambisene ne-ICAP ekwiYunivesithi yase Colombia. Ngaphambili, wathatha inxaxheba kuphando lweMCH-ART, apho siye sanolandelelwano lwakho nosana lwakho (olubelekwe ngo 2013-2014) lwade lwanenyanga ezili 12 ukuya kwezili 18.

Kweli ityeli uyacelwa uthathe inxaxheba kuphando olongezelelweyo lolandelelwano kwakolu phando lunye.

Injongo yolutyelelo lophando olongezelelweyo kukufunda banzi ngempilo yakho, neyomntwana wakho, ukhathalelo lwe HIV kananjalo nonyango othe walufumana kutyelelo lwakho lokugqibela lwe-MCH-ART. Singathanda ukuqonda ukuba unakekelo lwe HIV owawulufumene xa wawuse kwi MCH-ART iyichaphazele indlela ozinakekela ngayo njengokuba usana seluludala. Sinqwenela ukuqondisisa ezinye zezinto ezinokuthi zibenegalelo kukhathalelo lwakho lwentsholongwane ye-HIV kwaye nendlela ozinikela ngayo ekutyeni amachiza akho . Singathanda ukwazi ukuba singaxoxa njani namadoda malunga nokhathalelo lwe-HIV kwixa elizayo.

Siyayazi ukuba impilo kamama xa ekhulelwe, emva kokubeleka, naxa encancisa ingayichaphazela indlela umtwana wakhe aphuhla kwaye afunde ngayo. Sinqwenela ukuphanda ukuba abantwana abano mama abakhe bathatha amachiza e- HIV xa babekhulelwe nangelixa bencancisa; ingaba baphuhla njani kwiminyaka embalwa yokuqala ebomini babo. Le ngcombolo iyakusinceda sikwazi ukuphawula iingxaki ezinokwenzeka ekufundeni kubantwana abano omama abaphila ne- HIV. Injongo yoluxwebhu lwesivumelwano kukukunika ulwazi oluyakukunceda ukuze uthathe isigqibo malunga nokuba uyafuna na okanye akufuni ukuthatha inxaxheba.

WHAT IS THE PURPOSE OF THIS STUDY?
We are from the University of Cape Town and ICAP at Columbia University. Previously, you took part in the MCH-ART study where we followed you and your baby (who was born in 2013-2014) until the baby was 12-18 months old.

At this time, you are being asked to take part in an additional follow-up visit for this same study.

The purpose of this additional study visit is to learn more about your health and the health of your child as well as the HIV care and treatment you have received since the last MCH-ART study visit. We would like to understand how the HIV care you received when you were still in the MCH-ART study has impacted your HIV care now that your child is older. We would like to understand some of the other factors that may impact on your HIV care and adherence to HIV treatment. We would also like to know how we may be able to engage male partners in HIV care in the future.

We know that a mother's health during pregnancy, after delivery and during breastfeeding can affect how her child children develops and learns. We would like to investigate how children whose mothers took HIV drugs during pregnancy and breastfeeding develop during their first few years. This information will help to identify possible problems with learning in children whose mothers have HIV.

The purpose of this consent form is to give you information to help you decide if you want to take part in this additional study visit.

NDENZE NTONI UKUBA NDIYAVUMA UKUTHATHA INXAXHEBA?
Ukuba uyavuma ukuthatha inxaxheba, uyakucelwa ukuba usityelele kanye nomntwana wakho, ukuba kuyenzeka.

Njengakuvavanyo lwe MCH-ART, olutyelelo lohlukile kutyelelo lwakho lwesiqhelo lwasekliniki okulo lokhathalelo lwakho lwe -HIV. Olu tyelelo luya kuthatha iiyure ezi-2 ukuya kwezi-3, yaye kuyakuquka oku kulandelayo:

- Ukuphendula imibuzo emalunga nokhathalelo lwakho lweHIV lwakutsha nje, ukwazisa ngesimo sakho se-HIV, usetyenziso lwamachiza eHIV (kuquka imiphumela nonyamezelo kumachiza).
- Siyakukubuza imibuzo eyongezelelweyo malunga neHIV, ukudlakathiswa, nempilo yengqondo (kuquka ukusetyenziswa gwenxa kweziyobisi notywala), ucwangciso-ntsapho, inkqubo zokondliwa kweentsana, uhlukunyezo lwamaqabane ,impilo yabantwana nokhathalelo lwempilo nokuba uva kanjani ngokhathalelo lweHIV olufumanayo.
- Kuzakutsalwa igazi elingange 15mls (amatisipuni ama-3) engalweni yakho.
- Umlinganiselo wobunzima, ubude nobungakanani bomjikelo bomntla wengalo yomntwana wakho.
- Umlinganiselo wobude bakho, ubunzima nomjikelezo womphezulu wengalo yakho
- Uvavanyo lokuphuhla kwengqondo yomntwana wakho. Ngelixesha loluhlolo siyakukucela ukuba uzama ukukhumbula imidlalo yomntwana wakho kwaye siyakucela umntwana wakho enze izinto nje ezingaphi. Siyakuthi sihlole ke ukuba ingaba izakhono zakhe zonxibelelwano, izakhono zokushukumisa umzimba, izakhono zokusombulula ingxaki nezinye ke ezimalunga nokuphuhla kwakhe ngokwasemphefumlweni nangokwasekuhlaleni. Olu luvavanyo nje lokuhluza.Ukuba kungenzeka kubeko izinto ezixhalabisayo malunga nomntwana eziphawulweyo siya kumthumela esibhedlele ayekujongwa ziingcali.
- Ukongeza kule mimiselo ingasentla efana kakhulu nemimiselo yondwendwelo lophando lwe MCH-ART, sikwajonge nokukubuza malunga nezizinto zilandelayo ezazingabuzwanga kwi MCH-ART:

- Sizakukubuza imibuzo malunga nesimo seqabane lakho se -HIV, kunye nokuhlola.
- Sizakukubuza malunga nezimo ezidandathekisayo owathi mhlawumbi wahlangabezana nazo usengumntwana okanye kulonyaka udluleyo. Lemibuzo kungenzeka ibenzima ukuphenduleka kwaye ibuyise iinkumbulo ezibuhlungu. Njengeminye imibuzo, unakho ukwala ukuphendula nayiphi na imibuzo ongaziva ukhululekile ukuba ungayiphendula. Ukuba kuyenzeka uzive unqwenela ukuthetha banzi nomntu oqeqeshiweyo ngezizinto zakhwehlelayo, siya kuthi sikudlulisele kwi counsellor eqeqeshiweyo.

Qaphela: Igazi elitsalwe kolutyelelo liyakusetyenziswa ukujonga ubungakanani bentsholongwane(oku bubungakanani bentsholongwane egazini lakho)yaye ukuba kuyimfuneko, kukujonga ukuba ingaba I HIV esegazini lakho iyaxhathisa na kumachiza e HIV. Iziphumo zoluvavanyo ziyakwenziwa zifumaneke kuwe.

WHAT DO I HAVE TO DO IF I AGREE TO TAKE PART?
If you agree to take part, you will be asked to complete one additional study visit with your child, if possible.

As in the MCH-ART study, this visit is separate from the usual clinic visits that you have for HIV care. This visit will take 2-3 hours and will include the following:

- *Answer questions about your recent HIV-related health care, HIV disclosure, and use of HIV drugs (including side effects and adherence).*
- *We will ask you questions about HIV, stigma, and mental health (including drug and alcohol use), family planning, child feeding practices, partner violence, child health and health care and how you feel about the HIV care that you have received.*
- *Have approximately 15mLs (3 teaspoons) of blood drawn from your arm*
- *Measurement of weight, length and mid-upper arm circumference of your child*
- *Measurement of your height, weight and mid-upper arm circumference*
- *Neurodevelopmental assessment of your child. During this assessment we will ask you to recall your child's activities and we will ask you child to perform some simple tasks. We will assess his/her communication and motor skills, problem solving and social-emotional development. This is just a screening assessment. If any concerns are detected, we will refer your child for further evaluation.*
- *In addition to the measures above, which are all very similar to the measures in the MCH-ART study visits, we will also ask you about the following things which were not asked in the MCH-ART study:*
  - *We will ask you questions about your partner's HIV status and testing.*
  - *We will ask you about any traumatic events that you may have experienced when you were a child, or in the past year. These questions may be difficult to answer and bring*

back stressful memories. As with the other questions, you may refuse to answer any questions you do not feel comfortable answering. If you feel like you need to talk to someone more about these experiences, we will refer you to a trained counsellor.

NOTE: The blood that is drawn at this visit will be used to check your viral load (this is the amount of HIV in your blood) and if necessary, to check whether the HIV in your blood is resistant to any HIV medicines. Results from these tests will be made available to you. It will also be used to check for levels of HIV medicines in your blood. Results from these tests will not be made available.

Ukuhlolwa kweencwadi zazesibhedlele

Ngokuyinxalenye yoluphando, siyakujonga yaye sithathe iinkcukacha kwirekhodi zakho zesiqhelo zikagqirha, neerekhodi zomntwana obelekelwe kuvavanyo lwe MCH-ART. Oku kuyakuquka ezobelekiso, ikliniki yamachiza okuthomalalisa intsholongwane ka Gawulayo, iirekhodi zase lebhu nezasemayezeni. Ngenxa yokuba iikliniki zisebenzisa intlobo ezininzi zeefayile zezigulane, Singathanda ukufumana imvume yakho yokufikelela kuzo zonke iirekhodi zakho: ifayile zamaphepha, iirekhodi zase khemesti ne databases ezisetyenziswa ngombane kumaziko empilo eninokutyelela kuyo wena nomntwana wakho. Kwezi rekhodi, sinomdla wokufunda ngokhathalelo lwakho lwe-HIV nonyango olufumeneyo emva kokubeleka usana lwakho kuvavanyo lwakwa MCH-ART. Ekugqibeleni, sifuna ukufunda ngempilo nesimo somntwana wakho emva kokuba ebelekiwe. Sizakusebenzisa inombolo yakho yefolder yephondo ukufumana ezi rekhodi zikagqirha ekliniki okanye kwidatabase esebenza ngombane. Yonke idata esithi siphinde ukuyijonga, nesishwankathelo sayo iyimfihlelo yaye akukho gama lamthathi nxaxheba liya kushicilelwa kumaxwebhu ophando.

Review of medical records

As part of this study, we will also be looking at and taking information from your routine medical records, and the records of your child born in the MCH-ART study. This will including obstetric, ART clinic, laboratory and pharmacy records. Since clinics use many types of patient files, we would like your permission to access all your records: paper files, pharmacy records and electronic databases at the facilities you and your child may visit. From these records, we are interested in learning about the HIV care and treatment that you received after you delivered your baby in the MCH-Art study. Finally, we want to learn about your child's health status after delivery as well. We will use your and your child's provincial folder number to find these medical records in the clinic or electronic database. All data that we review and abstract is confidential and no participant names are recorded on study documents.

Imvume Ngotyando Lwesidumbu

Ukuba kungenzeka umntwana wakho ozelwe ngelixa uthatha inxaxheba koluphando lwakwa MCH-ART asweleke, siyakuthi sicele ukuba ugcwalise uxwebhu lwemibuzo nombhexeshi wodliwano ndlebe

onamava ukusinceda siqonde ukuba umntwana usweleke njani. Ukuba akuziva kakuhle yaye ukhetha ukungalugcwalisi uxwebhu lwemibuzo, uvumelekile ukuba wale ukukwenza oko.

Verbal Autopsy

In the event that your child born while you were in the MCH-ART study has passed away, we may ask you to complete a questionnaire with a trained interviewer to help us to understand how the child died. If you feel uncomfortable and would prefer not to complete the questionnaire, you can refuse to do so

Uqhagamshelwano Malunga Nophando Lwexesha Elizayo

Emva kokugqitywa kolutyelelo, kungenzeka siphinde siqhagamshelane nawe kwakhona kutyelelo lwakho olulandelayo okanye ngelinye ithuba kweli xesha lizayo ukujze uthathe inxaxheba kwizifundo ezingophando olongezelelweyo. Ngelo xesha uyakucelwa uphonononge yaye utyikitye enye ifomu yesivumelwano. Ukuba ucelwa uthathe inxaxheba kufundo ngophando kwixa elizayo, ungakhetha ukungathathi nxaxheba. Uyakucelwa unikeze ngenkcukacha zakho ukuze sikwazi ukuqhakamshelana nawe malunga nezifundo ezongezelelweyo zophando. Abasebenzi bophando bayakuthetha nawe ngeyona ndlela ingcono yokuqhagamshelana nawe.

Contact for future study

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

YEYIPHI IMINGCIPHEKO ELINDELEKILEYO?

Njengokuba sichazile ngentla ukuba kungenzeka uzive ungakhululekanga ukuyiphendula eminye imibuzo oyibuzwayo. Eminye yalemibuzo sizakubuza malunga namava anokuthi akuzisele iinkumbulo ezidandathekisayo. Unelungelo lokwala ukuphendula umbuzo ongafuniyo ukuwuphendula. Ukuba ngelixa ukudliwano ndlebe ikhona into ekwenza uzive unqwenela ukuthetha banzi nomntu oqeqeshiweyo ngezizinto zakwehlelayo, siyakuthi sikudlulisele kwindawo zecounselling Gugulethu Community Health Centre okanye imibutho enikisa ngeenkonzo zecounselling nezenkxaso.

Ukhona umngcipheko ekwabeleni ngeenkcukacha zakho buqu nolwazi ngezigulo zakho. Sizakucoselela siqiniseke ukuba zonke iimpendulo zakho sizigcina ngokunqabe kangangoko.

Ukutsalwa kwegazi kwenziwa ngokwesiqhelo Ngokufanayo nakukhathalelo lwempilo lwesiqhelo yaye ibonakalisa umngciphekwana wokungakhululeki ncam. Abasebenzi abanamava bayakutsala igazi phantsi kwemeko zococeko ukuze wena ukhuseleke kulemingcipheko.

WHAT ARE THE POTENTIAL RISKS?

As we mentioned above, you may feel uncomfortable about some of the personal questions you are asked. Some of the questions we ask about your past experiences may trigger difficult memories. You may refuse to answer any question that you do not want to answer. If anything raised during the interview makes you want to talk more with someone, we will refer you to counselling services either in the Gugulethu Community Health Centre or nearby organisations providing counselling and support services.

There is some risk in sharing personal 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 INZUZU ELINDELEKILEYO?

Akukho nzuzo ingqamene nawe ngqo ukuba uthatha inxaxheba kolu vavanyo, kodwa ukuba sifumanisa nayiphina na ingxaki yokhathalelo lwempilo lwakho nolomntwana ngexesha ukuvavanyo, siyakuqinisekisa ukuba uyakuthunyelwa kwiziko elililo lokhathalelo lwempilo. Ukongeza, ulwazi oluzuzwe kolu vavanyo lunganceda ukuphucula iinkonzo zamaziko amachiza okuthomalalisa iNtsholongwane kaGawulayo kubafazi abakhulelweyo nabasanda kubeleka abaphila nentshongwane kaGawulayo eKapa, eNtshona Koloni nakuMzantsi Afrika jikelele

WHAT ARE THE POTENTIAL BENEFITS?

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 child during the course of the study, we will make sure 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 and postpartum women in Cape Town, the Western Cape Province, and across South Africa.

YEYIPHI INDLELA EYENYE YOKUTHATHA INXAXHEBA?

Ayikho enye indlela ekuthatheni inxaxheba koluphando. Ukuba ugqiba ekubeni ungathathi nxaxheba, uyakuqhubeka ngokhathalelo lwakho lwesiqhelo.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

There is no alternative to taking part in this study. If you decide not to take part you will continue your routine care as usual.

KUTHIWANI NGEEMFIHLELO?

Ukuba uyavuma ukuthabatha inxaxheba, lonke ulwazi olungqamene nawe oluqokelelwe ngexesha lovavanyo, luyakugcinwa luyimfihlelo eluqilima. Igama lakho aliyi kubhalwa kwifomu yoluphando yaye aliyi kusetyenziswa ngokunxulumene nalo naluphina ulwazi okanye i-spesimeni sase lebhu eziqokelelwe njengenxalenye yoluphando.

Ngabasebenzi abayinxenye kuhlolo lwesiqhelo abavumelekileyo kule mathiriyeli kuphela. Aba balandelayo okanye/ne namaqela bakuba nakho ukujonga okanye bakope iirekhodi zakho zophando:

- Abaphandi, abasebenzi nezinye iingcaphephe eziyakube ziphononongauphando.
- Abasemagunyeni beYunivesithi yaseColumbia nabe Yunivesithi yase Kapa, kuquka neIRB okanye iKomiti yeEthics. I-IRB yikomiti eyenzelwe ukukhusela amalungelo nentlalontle yabantu ababandakanywa nophando.
- I-Ofisi yeHuman Research Protection (OHRP)
- Abaxhasi ngezimali bovavanyo, iNational Institutes of Health (NIH), kuquka nabantu bamaqumrhu abasebenza ne-NIH, bangaphinda bajonge iinkcukacha zakho ngokungqameneyo kodwa abasayikukopa ulwazi olunegama lakho kuzo.

Bonke abasebenzi abachaphazelekayo kuqokelelo nokuphathwa kwe data nabaphathi bayakufumana uqeqesho olukhethekilyo ngeemfihlelo.

Olu phando lukwakhuselwe nge Setifikethi Semfihlelo se National Institutes of Health. Abaphandi abanesi Setifikethi bangangabinako ukwazisa okanye basebenzise naluphina ulwazi olunokuthi luveze wena nakuyiphi kwezi zintlu zizinze kwi US-federal (apho kwenziwa khona imithetho kaRhulumente welo lizwe kuzo zonke izintlu zobuRhulumente balapho), ezobuzwe okanye ezentlalo yoluntu, ezolwaphulo-mthetho, ezolawulo, ezomthetho okanye nasiphina isenzo, izinto ozenza ngokufanele wena okanye ukuqhubeka, okanye zisetyenziswe nje ngobungqina ngaphandle kokuba wena unike imvume yokusetyenziswa koku.
Ulwazi lovavanyo olukhuselwe ngesi Setifikethi alunako ukwaziswa nakubani omnye onganxulumananga nolu phando ngaphandle, ukuba kukho kwi US-federal, isizwe, okanye umthetho woluntu odinga ukwaziswa; ukuba unike imvume yokwaziswa , kuquka nonyango lwakho ngamayeza; okanye ukuba oku kusetyenziselwa olunye uphando lwenzululwazi kweze sayensi, ngemvume yemiqathango yefederal ekhusela abantu abasetyenziselwa uphando.

Kanti nangezi nkqubo ne Setifikethi Semfihlelo esikhoyo, ukuba umsebenzi wovavanyo ufumanisa ukuba wena buqu usemngciphekweni okanye omnye umntu okanye impatho-mbi, okanye ukungahoywa komntwana, umsebenzi wophando uyakuxelela abasemagunyeni boqobo.

WHAT ABOUT CONFIDENTIALITY?

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

Only study staff and personnel involved in routine audits will have access to these materials. The following individuals and/or agencies will be able to look at and copy your research records:

- *The investigators, study staff and other professionals who may be evaluating the study.*
- *Authorities from Columbia University and the University of Cape Town, including the IRB or Ethics Committee. An IRB is a committee organized to protect the rights and welfare of people involved in research.*
- *The Office of Human Research Protection (OHRP)*
- *The study sponsor, National Institutes of Health (NIH), including persons or organizations working with NIH may review your data for accuracy but may not copy information with your name on it.*

All staff involved in data collection and management will get specific training in confidentiality.

This research is also covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use any information that may identify you in any US-based federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence unless you have consented for this use. Study information protected by this Certificate cannot be disclosed to anyone else who is not involved in this research except, if there is a US-federal, state, or local law that requires disclosure; if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Even with these procedures as well as the Certificate of Confidentiality in place, 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.

KWENZEKA NTONI XA NDINOKWENZAKALA NDITHATHA INXAXHEBA KOLUVAVANYO?

Akukho mayeza okulinga asetyenziswayo koluvavanyo yaye umngcipheko wokwenzakala ngenxa yothatho-nxaxheba usezantsi kakhulu. Nangona oluvavanyo lophando lukhuselwe yipolisi ye-inshorensi ethathwe yiDyunivesithi yaseKapa xa unokufumana umenzakalo womzimba kuba uthatha inxaxheba koluphando.

Le inshorensi iyakuhlawula zonke iindleko ezifanelekileyo zikagqirha ukunyanga ukwenzakala komzimba wakho ngokwe SA Good Clinical Practice Guidelines 2006. I-inshorensi iyakuhlawula ngaphandle kokuba ude ubenesiqinisekiso sokuba ngenene uphando lube negalelo kumenzakalo wakho emzimbeni.

Ungayicela ikopi yale miqathango kugqirha wophando.

I-inshorensi ayiyi kuwuhlawulela umonzakalo, ukuba, ngexesha lophando wenze oku kulandelayo:

- Akulandelanga imiqathango kamongikazi
- Awukhange uzikhathalele ngendlela eyiyo

Ukuba kwenzekile ngelishwa wonzakala i-inshorensi iyazibhatalela iindleko zoko, ngokwesiqhelo kulindeleke ukuba usamkele ngokugcweleyo isixa semali esiyakube sibhatelwe yi-inshorensi ukukhawulelana nemeko yakho yempilo. Noxa kunjalo, ukwamkela lomnyenyevu we-cover ye inshorensi ayithethi ukuba unikezele ilungelo lakho lokubanga malunga nezinye iilahleko eziphathelele kwimpathombi, oku ukwenza eNkundleni yase Mzantsi Afrika.

Kubaluleke kakhulu ukuba ulandele imiyalelo yabongikazi abakoluphando kwaye uchaze ngoko nangoko xa ukrokrela ukuba kukho umonzakalo emzimbeni ngokuphathelele koluphando.

WHAT HAPPENS IF I GET HURT TAKING PART IN THIS STUDY?

There are no experimental medicines being used in this study and risk of injury due to study participation is very low. However this research study is covered by an insurance policy taken out by the University of Cape Town if you suffer a bodily injury because you are taking part in the study.

The insurer will pay for all reasonable medical costs required to treat your bodily injury, according to the SA Good Clinical Practice Guidelines 2006. The insurer will pay without you having to prove that the research was responsible for your bodily injury. You may ask the study doctor for a copy of these guidelines.

The insurer will not pay for harm if, during the study, you:

- *Do not follow the study nurses' instructions*
- *Do not take reasonable care of yourself*

If you are harmed and the insurer pays for the necessary medical costs, usually you will be asked to accept that insurance payment as full settlement of the claim for medical costs. However, accepting this offer of insurance cover does not mean you give up your right to make a separate claim for other losses based on negligence, in a South African court.

It is important to follow the study nurses' instructions and to report straightaway if you suspect study related bodily harm.

IKHONA INTO ENDIYAKUYINIKWA NGOKUTHATHA INXAXHEBA?

Ekupheleni kolutyelelo, uyakunikwa ivawtsha zegrosari exabisa i-R150 ukukubulela ngexesha lakho negalelo lakho koluvavanyo nemali yokukhwela isithuthi. Wena nomntwana wakho niyakunikwa into etyiwayo. Uyakunikwa nesipho esincinci somntwana wakho.

WILL I BE GIVEN ANYTHING FOR TAKING PART?

At the end of this visit, you will be given R150 in grocery vouchers to thank you for your time and contribution to this study as well as money to cover your transport cost. Refreshments for you and your child will be provided. A small gift for your child will also be given to you.

IKHONA INTLAWULO?

Akukho ntlawulo ngokuba kolu vavanyo

ARE THERE ANY COSTS?

There is no cost for being in this study.

Ndingalushiya Uvavanyo? NDINGALUSHIYA UVAVANYO?

Unelungelo lokugqiba ekubeni ungathathi nxaxheba kolu vavanyo longezelelweyo, wale ukuphendula nayiphina imibuzo, okanye urhoxe kutyelelo nangaliphina ixesha ngaphandle kwesohlwayo. Ayiyikuba nafuthe kukhathalelo olufumana eGuguletu kliniki okanye naliphi elinye iziko lezempilo.

CAN I LEAVE THE STUDY?

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

UKUSETYENZISWA KWE SPESIMENI KWIXESHA ELIZAYO?

Ngemvume yakho, i-ml ezi-5 ezongezelelweyo zegazi ziyakuthathelwa uphando oluzayo lwe-HIV olungqamane ngempilo yosana kwakunye nokubeleka (oko kusenza i-20mls lilonke). Okwelithutyana, asikwazi ukukunika iinkcukacha zokuba olu vavanyo luya kuqhutywa nini, okanye ncakasana loluphi uphando esiyakuthanda ukulenza. Noxa kunjalo, uphando olongezelelweyo aluyi kwenziwa kusetyenziswa ezi sampulu zigciniweyo ngaphandle kwemvume eyiyo yekomiti yophando ye ethics ebandakanyeka koluphando.

Ukuba uyavuma ukuba sigcinele uphando lwexesha elizayo iisampulu zakho, ziyakugcinwa kwisikhenkcezisi esitshixwayo kangange minyaka emi 5. Xa kunokwenzeka sizisebenzise kwixesha elizayo iisampulu zegazi lakho, igama lakho naziphina izazisi aziyi kuqukwa kolu lwazi (ngokunjalo nayo yonke ingcombolo esiyiqokelele koluphando).

FUTURE USE OF SPECIMENS:

If you agree, an additional 5mLs of blood will be taken for future HIV and maternal and child health related research (making it 20mLs in total). At this time, we cannot provide details of when this testing may be conducted, or exactly what tests we would like to do. However, additional testing will not be done using these stored samples without the approval of the appropriate research ethics committees involved in this research.

If you agree to let us keep your stored samples for future research, they will be kept in a locked freezer for up to 5 years. If we do use the samples in the future, your name or other identifiers will not be included with this information (as with the rest of the information we collect for this study).

Nceda beka unobumba wegama ukubonakalisa ukuba unika imvume yokuba iispesimeni zakho zisetyenziswele uphando oluzayo. Ungahlala ukulo uvavanyo, nokuba ukhethe eyiphi.
Please initial below to indicate whether or not you give permission for your specimens to be used for future research. You may still remain in the study, no matter which you choose.

Imvume yokuba kugcinwe igazi lako:
Consent for storage of your blood:

_____(unobumba) Ndiyavuma ukuba igazi lam ligcinelwe uphando oluzayo
(initial) I agree to have my blood stored for future research.

_____(unobumba) **ANDIVUMI** ukuba igazi lam ligcinelwe ukusetyenziswa kwixesha elizayo
(initial) I do NOT agree to the storage of my blood for future use.

Unayo Eminye Imibuzo?
Ukuba kukho enye into engacacanga okanye ukuba ufuna ulwazi olungaphezulu, nceda sibuze, yaye siyakukunika.
Unayo imibuzo?
Do You Have Any Questions?
If there is anything that is unclear or if you need further information, please ask us and we will provide it.
Do you have any questions?

Ulwazi Olongezelelweyo:
Ukuba unayo eminye imibuzo okanye ezinye iingxaki ngexesha uthatha inxaxheba kolu phando, ungaqhagamshelana no:

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

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LACE Informed Consent Form

Igama lomsebenzi wophando_____
Staff member's name

_____ _____
Utyikityo sandla somsebenzi wophando Umhla
Signature of study staff *Date*

Ukuba ivolontiya alikwazi ukufunda okanye ukubhala xa licaciselwa ngophando kufuneka kujongwe lngqina elizimeleyo ukuqinisekisa indlela yotyikityo sivumelwano
If the volunteer is unable to read or write the entire counselling process must be observed by an independent witness who can then confirm the procedure once the she has given consent.

Ucinezelo lukabhontsi lwevolontiya:
Fingerprint of volunteer:

Ingqina:
Ndiyaqinisekisa ukuba ndizimele andingomnye wophando,ndikwangqina kwisivumelwano esicacisiweyo esenziwe ngolwimi llomthathi nxaxheba
Witness:
I confirm that I am independent of the study and that I witnessed the entire informed consent counselling process in the home language of the volunteer

Igama: _____
Name

_____ _____
Utyikityo sandla sengqina Umhla
Signature of witness *Date*

Enkosi
Thank you

Appendix G: Supporting Information - Supplementary Tables

Table 1. Bivariate statistics of covariates of 353 postpartum women living with HIV who initiated ART during pregnancy. This table is grouped by whether they had moved within 6 months of the viral load visit or not during the postpartum period at approximately 12 months and 4 years following delivery. The characteristics were measured at baseline and 4 years postpartum for the two groups, respectively.

	12 months postpartum			4 years postpartum		
Variable	**Moved**	**Did Not Moved**	**p-value**	**Moved**	**Did Not Move**	**p-value**
Age (mean and standard deviation)	30.14 (5.17)	30.04 (5.59)	0.929	31.23 (5.26)	32.58 (5.49)	0.351
Married/ cohabiting	12 (46)	123 (38)	0.423	5 (33)	140 (38)	0.701
Completed secondary school	3 (12)	78 (24)	0.255	2 (13)	90 (25)	0.538
Employed	9 (35)	124 (39)	0.694	6 (40)	158 (43)	0.808
Gravidity (median and IQR)	1 (1-2)	1 (1-2)	0.705	2 (1-3)	2.5 (2-3)	0.208
Diagnosed with HIV in this pregnancy	13 (50)	172 (53)	0.737	9 (60)	198 (54)	0.653
Currently Pregnant	0 (0)	2 (1)	1.000	1 (7)	20 (6)	0.580
Socioeconomic Status			0.080			0.758
Lowest	11 (42)	81 (25)		5 (33)	128 (35)	
Moderate	10 (39)	118 (37)		6 (40)	112 (31)	
Highest	5 (19)	123 (38)		4 (27)	126 (34)	
Formal housing	9 (35)	160 (50)	0.139	8 (53)	185 (51)	0.832
CD4 count at baseline			0.797			0.952
<200	6 (23)	51 (16)		2 (13)	59 (17)	
200-350	7 (27)	107 (34)		6 (40)	113 (32)	
350-500	6 (23)	75 (24)		3 (20)	90 (25)	
>500	7 (27)	80 (26)		4 (27)	95 (27)	

Table 2. Bivariate statistics of covariates of 349 postpartum women living with HIV who initiated ART during pregnancy. This table is grouped by whether they were virally suppressed (VL ≤50 copies/mL) or not during the postpartum period at approximately 12 months and 4 years following delivery.

	12 months postpartum			4 years postpartum		
Variable	**Virally Suppressed**	**Not Virally Suppressed**	**p-value**	**Virally Suppressed**	**Not Virally Suppressed**	**p-value**
Age (mean and standard deviation)	30.87 (5.48)	28.43 (5.45)	0.000	33.15 (5.19)	31.77 (5.74)	0.014
Moved within 6 months of outcome visit	18 (8)	7 (6)	0.537	8 (4)	7 (4)	0.910
Moved within 3 months of outcome visit	15 (7)	4 (4)	0.320	5 (2)	6 (4)	0.529
Moved within 12 months of outcome visit	28 (12)	10 (9)	0.312	12 (6)	20 (12)	0.040
Married/ cohabiting	95 (42)	38 (32)	0.092	91 (44)	53 (31)	0.010
Completed secondary school	59 (26)	23 (20)	0.193	55 (27)	36 (21)	0.223
Employed	97 (42)	38 (32)	0.066	99 (48)	64 (37)	0.042
Gravidity (median and IQR)	1 (1-2)	1 (1-2)	0.167	2 (2-3)	2 (2-3)	0.842
Diagnosed with HIV in this pregnancy	131 (57)	56 (48)	0.084	115 (56)	90 (53)	0.570
Currently Pregnant	1 (1)	1 (1)	0.547	15 (7)	5 (3)	0.068
Socioeconomic Status			0.003			0.458
Lowest	46 (20)	43 (36)		66 (32)	65 (38)	
Moderate	95 (42)	34 (29)		67 (32)	51 (30)	
Highest	88 (38)	41 (35)		74 (36)	55 (32)	
Formal housing	106 (46)	64 (54)	0.161	98 (47)	92 (54)	0.211
CD4 count at baseline			0.424			0.828
<200	33 (15)	22 (19)		33 (16)	28 (17)	
200-350	77 (35)	37 (32)		62 (31)	55 (33)	
350-500	49 (22)	32 (27)		55 (27)	38 (23)	
>500	62 (28)	26 (22)		53 (26)	45 (27)	

Table 3. Bivariate statistics of covariates of 349 postpartum women living with HIV who initiated ART during pregnancy. This table is grouped by whether they were virally suppressed (VL ≤1000 copies/mL) or not during the postpartum period at approximately 12 months and 4 years following delivery.

	12 months postpartum			4 years postpartum		
Variable	**Virally Suppressed**	**Not Virally Suppressed**	**p-value**	**Virally Suppressed**	**Not Virally Suppressed**	**p-value**
Age (mean and standard deviation)	30.66 (5.52)	28.24 (5.37)	0.000	32.94 (5.24)	31.76 (5.85)	0.044
Moved within 6 months of outcome visit	21 (8)	4 (5)	0.343	11 (5)	4 (3)	0.587
Moved within 3 months of outcome visit	17 (7)	2 (2)	0.176	8 (3)	3 (2)	0.753
Moved within 12 months of outcome visit	32 (13)	6 (7)	0.145	18 (7)	14 (10)	0.321
Married/ cohabiting	106 (41)	26 (30)	0.051	105 (43)	39 (29)	0.006
Completed secondary school	62 (24)	19 (22)	0.628	61 (25)	30 (22)	0.555
Employed	105 (41)	28 (32)	0.133	113 (47)	50 (37)	0.075
Gravidity (median and IQR)	1 (1-2)	1 (1-2)	0.132	3 (2-3)	2 (2-3)	0.375
Diagnosed with HIV in this pregnancy	147 (57)	38 (43)	0.023	137 (56)	68 (50)	0.261
Currently Pregnant	2 (1)	0 (0)	1.000	17 (7)	3 (2)	0.055
Socioeconomic Status			0.022			0.895
Lowest	57 (22)	32 (36)		83 (34)	48 (36)	
Moderate	103 (40)	25 (28)		75 (31)	43 (32)	
Highest	97 (38)	31 (35)		85 (35)	44 (33)	
Formal housing	119 (46)	50 (57)	0.089	115 (47)	75 (56)	0.125
CD4 count at baseline			0.089			0.898
<200	36 (15)	18 (21)		37 (16)	24 (18)	
200-350	85 (34)	29 (33)		75 (32)	42 (32)	
350-500	55 (22)	26 (30)		61 (26)	32 (24)	
>500	72 (29)	15 (17)		65 (27)	33 (25)	

Table 4. Bivariate statistics of covariates of 315 postpartum women living with HIV who initiated ART during pregnancy (Restricted to women who did not report moving out of the Western Cape). This table is grouped by whether they were retained in HIV care or not during the postpartum period at approximately 12 months and 4 years following delivery.

	12 months postpartum			4 years postpartum		
Variable	**Retained**	**Not Retained**	**p-value**	**Retained**	**Not Retained**	**p-value**
Age (mean and standard deviation)	30.21 (5.61)	29.10 (5.45)	0.164	32.53 (5.16)	32.57 (6.37)	0.943
Moved within 6 months of outcome visit	16 (7)	3 (5)	0.775	5 (2)	4 (4)	0.476
Moved within 3 months of outcome visit	13 (5)	2 (3)	0.744	2 (1)	3 (3)	0.333
Moved within 12 months of outcome visit	22 (9)	3 (5)	0.434	12 (6)	8 (8)	0.441
Married/ cohabiting	111 (44)	18 (26)	0.008	92 (42)	39 (38)	0.441
Completed secondary school	63 (25)	18 (26)	0.827	64 (29)	18 (18)	0.024
Employed	97 (38)	31 (45)	0.310	116 (53)	37 (36)	0.003
Gravidity (median and IQR)	1 (1-2)	1 (1-2)	0.166	2 (2-3)	2.5 (2-4)	0.291
Diagnosed with HIV in this pregnancy	131 (52)	41 (59)	0.247	112 (51)	60 (58)	0.270
Currently Pregnant	0 (0)	2 (1)	1.000	17 (8)	2 (2)	0.042
Socioeconomic Status			0.082			0.022
Lowest	58 (23)	23 (33)		58 (27)	43 (41)	
Moderate	95 (37)	17 (25)		71 (32)	30 (29)	
Highest	101 (40)	29 (42)		90 (41)	31 (30)	
Formal housing	131 (52)	36 (52)	0.930	106 (48)	55 (53)	0.452
CD4 count at baseline			0.550			0.022
<200	39 (16)	9 (13)		37 (17)	11 (11)	
200-350	83 (34)	21 (31)		79 (37)	25 (25)	
350-500	63 (26)	15 (22)		50 (23)	28 (28)	
>500	62 (25)	23 (34)		49 (23)	36 (36)	

Appendix H: Turnitin Originality Report

Reviewed and signed
off 28 June 2020
Tammy Phillips
Supervisor

Signature Removed

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by Robyn Mazriel

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13	Kirsty Brittain, Claude A. Mellins, Robert H. Remien, Tamsin K. Phillips, Allison Zerbe, Elaine J. Abrams, Landon Myer. "Impact of HIV-Status Disclosure on HIV Viral Load in Pregnant and Postpartum Women on Antiretroviral Therapy", JAIDS Journal of Acquired Immune Deficiency Syndromes, 2019 Publication	<1%
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15	Tamsin K. Phillips, Kemberlee Bonnet, Landon Myer, Sizakele Buthelezi, Zanele Rini, Jean Bassett, David Schlundt, Kate Clouse. "Acceptability of Interventions to Improve Engagement in HIV Care Among Pregnant and Postpartum Women at Two Urban Clinics in South Africa", Maternal and Child Health Journal, 2019 Publication	<1%
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27	Phillips, Tamsin, Margaret McNairy, Allison Zerbe, Landon Myer, and Elaine J. Abrams. "Postpartum transfer of care among HIV-infected women initiating antiretroviral therapy during pregnancy :", JAIDS Journal of Acquired Immune Deficiency Syndromes, 2015. Publication	<1%
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30	Zara Trafford, Yolanda Gomba, Christopher J. Colvin, Victoria O. Iyun et al. "Experiences of HIV-positive postpartum women and health workers involved with community-based antiretroviral therapy adherence clubs in Cape Town, South Africa", BMC Public Health, 2018 Publication	<1%
31	Kate Clouse, Constance Mongwenyana, Melda Musina, Dorah Bokaba, Lawrence Long, Mhairi Maskew, Aima Ahonkhai, Matthew P. Fox. "Acceptability and feasibility of a financial incentive intervention to improve retention in HIV care among pregnant women in	<1%

	Johannesburg, South Africa", AIDS Care, 2017 Publication	
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33	Submitted to University of Stellenbosch, South Africa Student Paper	<1%
34	Catriona A. Towriss, Tamsin K. Phillips, Kirsty Brittain, Allison Zerbe, Elaine J. Abrams, Landon Myer. "The injection or the injection? Restricted contraceptive choices among women living with HIV", Sexual and Reproductive Health Matters, 2019 Publication	<1%
35	Phepo Mogoba, Yolanda Gomba, Kirsty Brittain, Tamsin K. Phillips, Allison Zerbe, Landon Myer, Elaine J. Abrams. "Re-recruiting postpartum women living with HIV into a follow-up study in Cape Town, South Africa", BMC Research Notes, 2019 Publication	<1%
36	Submitted to London School of Hygiene and Tropical Medicine Student Paper	<1%

Appendix I: Journal Submission Guidelines for JIAS

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: 3500 words
Numbers of figures and tables: Unlimited
Additional files: Yes

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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

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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

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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

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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

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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

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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

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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.

Submitting authors are strongly encouraged to include data disaggregated by sex (and, whenever possible, by race) and provide a comprehensive 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.

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.

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.

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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.
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• **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

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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.

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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**.

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Submitting authors shall 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

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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.

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