Study Protocol

CareConekta: a pilot study of a smartphone app to improve engagement in postpartum HIV care in South Africa

Version 7.0

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CareConekta: Mobile health for a mobile population

Project Period: 05/10/2019 – 03/31/2022

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- FWA00024139 (Vanderbilt University)
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ClinicalTrials.gov study number: NCT03836625

Study sponsor: National Institute of Mental Health (R34 MH118028)

Protocol summary

CareConekta: a pilot study of a smartphone app to improve engagement in postpartum HIV care in South Africa

Study aims:
Aim 1: Characterize mobility among South African women during the peripartum period and its impact on engagement in HIV care.

- **Aim 1a.** To use GPS location data from CareConekta and spatial analysis to characterize peripartum mobility within the complete observational cohort (n=200), including the frequency, distance, and timing.
- **Aim 1b.** To assess the association between mobility and engagement in HIV care for mother (retention in care and viral suppression six months after delivery) and infant (completion of routine early infant diagnosis).

Aim 2: Evaluate enhanced CareConekta as an intervention to improve engagement in HIV care.

- **Aim 2a.** To assess the acceptability and feasibility of the standard and enhanced app, with a focus on identifying user preference and implementation outcomes.
- **Aim 2b.** To evaluate the initial efficacy of the enhanced CareConekta intervention, using notifications and staff contact to improve engagement in HIV care, by assessing the association between study arm and engagement in HIV care at six-months postpartum.

Sample size: 200 participants

Study population: Adult (≥18 years), HIV-positive, pregnant (≥28 weeks) women attending antenatal services at the study site

Participating site: Gugulethu Midwife Obstetric Unit, Cape Town, South Africa

Study design:
Hybrid pilot trial assessing efficacy as well as feasibility and acceptability

Study timeline: August 2019 – July 2022 (approximately)

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ABSTRACT
South Africa is home to the world's largest antiretroviral therapy (ART) program, but sustaining high engagement along the HIV care continuum has proven challenging in the country and throughout the wider region. Population mobility is common in South Africa, but important research gaps exist describing this mobility and its impact on engagement in HIV care. Postpartum women and their infants in South Africa are known to be at high risk of dropping out of HIV care after delivery and are frequently mobile. We recently developed a beta version of a smartphone application (app) – CareConekta – that detects a user's smartphone location to allow for prospective characterization of mobility. Through this three-year award, we propose to adapt and test CareConekta to conduct essential formative work on mobility and evaluate an intervention – the CareConekta app plus text notifications and phone calls and/or WhatsApp messages – to facilitate engagement in HIV care during times of mobility. During the three-year project period, our primary objective is to evaluate the acceptability, feasibility, and initial efficacy of using CareConekta as an intervention to improve engagement in HIV care. Our secondary objective is to characterize mobility among South African women during the peripartum period and its impact on engagement in HIV care. We will enroll 200 eligible women at the Gugulethu Midwife Obstetric Unit in Cape Town, South Africa. This work will provide critical information about mobility during the peripartum period and the impact on engagement in HIV care, and piloting an intervention to improve engagement. This study will lay the necessary groundwork for a larger efficacy trial of the intervention within different geographic settings.

INTRODUCTION
With more than seven million HIV-infected people,[1] South Africa is home to more people living with HIV than any other country in the world,[2] and their national ART program is the world's largest.[2] South Africa adopted a "treat all" policy to provide ART to all HIV-positive people, regardless of CD4+ cell count, in September 2016.[3] Expanded ART availability has dramatically altered the health and quality of life of people living with HIV/AIDS, with an estimated life expectancy gain of 11.3 years between 2003 and 2011 due to ART[4] and a 77% decrease in HIV transmission in stable serodiscordant couples.[5] However, the rapid scale-up of the national ART program has put tremendous pressure on the limited resources of a public health sector that is hurrying to meet this immense need, and despite widespread availability of ART, over 135,000 people died of AIDS-related causes in 2016 in South Africa.[1] HIV and tuberculosis (usually exacerbated by HIV) are the top two causes of death among women ages 15-44 in South Africa.[6] The potential for improved health through expanded ART availability will only be realized if individuals sustain engagement in HIV care.

Black African women of reproductive age (ages 20-34) are the population most heavily affected by the South African HIV epidemic, with 31.6% prevalence.[7] Access to ART for all HIV-positive pregnant women through Option B+ has helped to reduce mother-to-child transmission of HIV to the point where near-elimination is now thought possible.[8] Despite this astounding achievement, there is mounting evidence that women who initiate ART during pregnancy may be at very high risk of loss to follow-up (LTFU),[9–12] with re-engagement in routine HIV care after delivery a particular concern.[13,14] The problem of patient LTFU within the public sector in South Africa has been well documented.[15,16] Our earlier research conducted in South Africa found that 25.2% of women pregnant at ART initiation were LTFU after one year, compared to 15.8% of men and 11.1% of non-pregnant women.[10] Our work also has helped to pinpoint the timing of LTFU to after delivery: among women diagnosed with HIV during antenatal care in Johannesburg, 47.9% were lost within six months of delivery;[13] in Cape Town, disengagement was over twice as frequent in the postpartum period as during antenatal care.[17]

A challenge to ensuring a continuity of HIV care is that the fragmented health care system is not adapted for a mobile population. Patients considered LTFU actually may have switched facilities on

their own as "silent transfers," which typically are not recognized due to unlinked data across facilities.[18–20] This misclassification makes it very difficult to accurately assess the effectiveness of national ART programs. Mobility as a potential barrier to engagement in HIV care has been noted in Kenya,[21,22] Lesotho,[23] Zambia,[24] and the US[25]. South Africa's population is highly mobile; the most typical pattern is of circular, within-border migration between rural and urban areas, with the mobile individual keeping strong ties to the rural areas by sending remittances to their family and returning to the rural area for holidays and family events, and upon retirement, illness, or during lapses in employment.[26] Postpartum women in South Africa are likely to be a particularly mobile group, due to a tradition of returning to one's rural home after delivery to receive care from family members.[12,27,28] Our recent formative work at three sites in Johannesburg found that among 150 peripartum, HIV-positive women interviewed, 44% planned to travel around delivery – typically after delivery – to stay with family, sometimes leaving the infant in the care of family while the mother returned to work in Johannesburg (manuscript under review). HIV-exposed infants – even if HIV-uninfected – are at higher risk of mortality than HIV-unexposed infants[29] and require attentive follow-up. With no way of tracking mobility, it is difficult to intervene appropriately to ensure continuity of HIV care for mother and infant.

Cell phones are as common in South Africa as they are in the US,[30] according to a recent Pew Research study that found that 89% of adults in South Africa owned a cell phone.[30] Our own research among pregnant, HIV-positive women attending public antenatal care in Johannesburg found that phone ownership was ubiquitous, phone sharing was uncommon (94% did not share), and the median time with the current phone number was three years.[31] Additionally, smartphone use is increasing rapidly; a 2015 survey found that half of South African respondents owned a smartphone.[32] While this does not represent complete saturation, South Africa is rapidly adopting increasingly sophisticated mobile phones; thus, it is the most appropriate country in the African region to develop and test mHealth interventions, and lessons learned there will be relevant throughout the continent as other countries similarly adopt new technologies. mHealth interventions, particularly short message service (SMS) interventions, have been shown to improve adherence to ART[33,34] and patient retention.[35,36] Global positioning system (GPS) technology has been used successfully to track subject location in several studies, mostly in developed countries.[37–39]

In summary, a better understanding of mobility patterns and the impact of mobility on HIV engagement is urgently needed – particularly among postpartum women. Given high LTFU and unlinked data systems in many settings, mHealth technology offers an opportunity to intervene at the critical moment and to improve continuity of care among a highly mobile population.

CareConekta smartphone app and preliminary studies

In 2017, through a small grant from the Tennessee Center for AIDS Research (TN CFAR), we conducted formative research on smartphone use among our target population: peripartum, HIV-positive women at the proposed study site. Through focus group discussions (Vanderbilt IRB approval: 161805; UCT HREC approval: 792/2016), respondents told us they had few issues with data connectivity and privacy while using smartphones, and they were highly enthusiastic about mHealth interventions.[40] We also identified that over half of HIV-positive pregnant women we sampled owned a smartphone, the WhatsApp messaging app is very popular and widely-used, and about 90% of phones used the Android operating system.[40] We specifically asked participants about tracking their mobility for research purposes, and acceptability was high, noting that clinics could use an individual's location to help them find a new facility when traveling.

Based on this formative information, and through the same TN CFAR pilot funding, we developed a beta version of the app that we will now adapt and pilot: CareConekta. This smartphone app uses

the phone's GPS to prospectively characterize mobility and intervene in real-time. The beta version app was developed in collaboration between the current study team (Dr. Clouse, Dr. Myer, Ms. Phillips) and Dr. Martin Were of Vanderbilt University Medical Center's Department of Biomedical Informatics.

STUDY AIMS

Aim 1: Characterize mobility among South African women during the peripartum period and its impact on engagement in HIV care.

> **Aim 1a.** To use GPS location data from CareConekta and spatial analysis to characterize peripartum mobility within the complete observational cohort (n=200), including the frequency, distance, and timing.
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STUDY DESIGN

Hybrid pilot trial assessing efficacy as well as feasibility and acceptability

STUDY SITE

The study site for participant enrollment is the Gugulethu Midwife Obstetric Unit (MOU), based at the Gugulethu Community Health Centre near Cape Town, South Africa. The MOU serves Gugulethu as well as the surrounding informal settlements, and is often attended by women who come from the Eastern Cape to have their babies in Cape Town, resulting in travel to and from the Eastern Cape during pregnancy and postpartum.[41] The local antenatal HIV prevalence is high (~30%), and the mother-to-child HIV transmission rate is estimated at 2-4%.[42] The MOU team has helped to deliver HIV care and treatment services in this setting since 2003 and has a history of successful ART service delivery and research in partnership with the provincial government. Dr. Myer and Ms. Phillips have conducted studies at the MOU since 2006.[43]

ABOUT CARECONEKTA

CareConekta, developed in parallel with a series of focus group discussions, is a novel smartphone app that uses GPS to identify the user's location to record location coordinates meet two primary functions: (1) to allow the participant to locate ART facilities in South Africa that are near her current location, and (2) to trace mobility prospectively. We employ an algorithm on the mobile application to reliably determine when a participant has traveled outside the study area. If the participant travels more than 50 km outside the study area for more than 7 days, the app will automatically notify the participant of available care facilities near her new location, and will provide the facility address and phone number, if available. The notifications will be available to both English and isiXhosa-language speakers (the predominant languages of the region).

Through the TN CFAR award, we conducted a proof-of-concept study by enrolling four participants at the proposed study site and following them for 90 days (Vanderbilt IRB approval: 170510; UCT HREC: 227/2017; ClinicalTrials.gov: 170510). We identified technological issues to address in order to

maximize the compatibility of CareConekta for the local context. Namely, we would like to transfer CareConekta's development architecture from the Ionic platform to native Android, so that we can ensure that CareConekta is compatible with all Android phones, which represents most smartphones in use by the population at the proposed study clinic. We will then be ready to pilot CareConekta to explore mobility and its impact on HIV care, and to conduct a preliminary evaluation of the enhanced CareConekta intervention.

STUDY POPULATION

Adult (≥18 years), HIV-positive, pregnant (≥28 weeks) women who 1) own a smartphone that meets the technical requirements, 2) are willing to opt-in to installation of CareConekta on her personal phone and mobility tracking, 3) demonstrate basic smartphone-level literacy, and 4) are willing to be randomized.

Technical requirements

For the purposes of this study, a smartphone will be defined as a mobile phone device with a touchscreen interface and internet and GPS capabilities. CareConekta is only available for phones using the Android operating system, version 5.0 or later. In our preliminary work, nearly 90% of smartphones of women approached for study participation used the Android system. Cell phone service providers must be one of the following: Vodacom, Cell-C, Telkom, or MTN. The phone must be able to demonstrate that it can use GPS by opening a map app, such as Google Maps, and finding current location. The phone must be capable of holding a battery charge; phones will be ineligible if they need to be charged more than twice per day on average (by self report).

INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria:

- ≥18 years old
- HIV-positive
- Pregnant (≥28 weeks gestation)
- Able to speak and understand isiXhosa and/or English
- Currently own a smartphone that meets the technical requirements of the app
- Willing to opt-in to installation of the app on her personal phone and to mobility tracking
- Able to demonstrate basic smartphone-level literacy
- Willing to be randomized

Exclusion criteria:

- Currently enrolled in another research study which may impact on the study outcomes

STUDY TIMELINE

Study activities will occur from August 2019 – July 2022 (approximately)

Human subjects' participation will begin with recruitment and enrollment in approximately Q3 of Y1, following the adaptation and revision of the CareConekta smartphone app.

Activity	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Study preparation												
IRB approval and renewal												
ClinicalTrials.gov registration												
Develop study instruments and REDCap database												
Adapt CareConetka smartphone app												
Confirm eligibility, recruit and consent participants												
Enrollment questionniare												
Participant follow-up												
Follow-up questionnaire												
File review												
Data analysis												
Manuscript preparation												
R01 submisson and revision												

STUDY DESIGN

Sample Size

We will enroll 200 participants.

For this pilot trial formal sample size estimation was not conducted. The sample size was reached based on the feasible enrolment from the study site within the study timeline. Approximately 4,000 women seek antenatal care at the MOU annually; ~30% of these are HIV-positive, about 1 200 per year, or 100 per month. Our formative work (HREC REF 792/2016 and 227/2017) showed that over half of these women own smartphones. If we conservatively estimate that 30% of all pregnant, HIV-positive women seeking antenatal care each month will be eligible and interested which equals 30 participants enrolled per month. We anticipate that it will take approximately seven months to reach our enrolment target of 200 participants (see Timeline above).

Based on our earlier work in South Africa and at the study site, we estimate that 25% of the participants will engage in long-distance travel during the study period. A sample size of 200 allows us to characterize the mobility experiences of 50 women who travel and explore differences with those who do not. While we do not anticipate having sufficient power to detect statistically significant differences between groups in Aims 2b, the information gained through this pilot study will inform sample sizes for larger future studies should this pilot show promise.

Study arms

- **Control arm (n=100):** Participants will receive standard CareConekta, which will track their mobility and allow the participant to look up new ART facilities upon request.
- **Intervention arm (n=100):** Participants will receive standard CareConekta with the following additions:
    - text notifications of nearby ART facilities when they have traveled >50 km from the study site for >7 days
    - phone call(s) and/or WhatsApp message(s) from study staff when they have traveled >50 km from the study site for >7 days. The study staff calls and messages will ask about medication supply and will provide assistance with nearby facilities, if requested. The study staff member who conducts interviews will not deliver the intervention calls and/or messages.

STUDY PROCEDURES

This study will consist of two face-to-face study visits as well as abstraction of routine medical records. The details of each visit are described below.

Enrollment visit procedures

Recruitment and assessment of eligibility criteria

Each week during the study recruitment period, study staff will review the list of upcoming appointments at the study site to assess who may be eligible for study participation. Pregnant women attending routine antenatal care services at the Gugulethu Community Health Centre will be approached by trained study recruiters and given brief information about the pilot study. If they are interested, they will be screened to ensure they meet the eligibility criteria using an eligibility checklist. If eligible, they also will be shown a demonstration of CareConekta and its functionality prior to the informed consent process. Text message-level literacy will be demonstrated by reading aloud the text, "I can look up a new clinic on the phone," in either English or isiXhosa.

Selection of study participants in an equitable manner

The selection of participants will be equitable in relation to the research purpose and setting because any interested woman attending antenatal services at the study clinic who meets the eligibility criteria will be invited to enroll. Pregnant women will be limited by gestational age to the third trimester to allow for a nine-month total follow-up time within the time constraints of this three-year grant. In South Africa, most women present for their first antenatal visit around 20 weeks gestation or later,[13,44,45] and attendance for antenatal visits is generally high,[13,17] so we do not believe there will be substantial bias introduced by enrolling women later in pregnancy. isiXhosa is the predominant language in the region of the study site, and English also is widely spoken, so we do not anticipate excluding potential participants due to language. Basic smartphone-level literacy will be required of participants in order to assess the impact of messages. However, we anticipate that most women who own a smartphone already have a basic smartphone-level literacy ability. We acknowledge that women who own a smartphone may be different than those who do not, in terms of employment, education, or other factors. Besides the additional financial resources needed to provide phones, we want to be able to assess CareConekta in existing phones for maximal impact. If women already have a smartphone (over half of the population), providing a second phone for study purposes is redundant and burdensome. For women who do not already own a smartphone, we are concerned with ethical implications of providing such a highly-desired item as a smartphone in terms of possible coercion for study participation, the impact it may have on relationships between participants and partners and/or friends, and the potential for disclosure for participating in an HIV-related study.

In order to assess differences between our cohort of smartphone users and the general population assessed for eligibility, we will collect four demographic indicators at the time of recruitment: age, education, employment and nationality. These will be collected anonymously prior to study enrollment or the collection of any identifying data.

Informed consent

All women who meet the eligibility criteria and are interested in participating in the study will undergo written informed consent, which will be available in English and isiXhosa. The consent form will confirm the eligible woman's understanding of the study procedures and her informed willingness to participate. The key messages of the informed consent process will include: 1) a description of the study goals and procedures, 2) voluntary participation in the study, 3) confidentiality and privacy with use of the app and study data, 4) the right to withdraw at any time, and 5) the standard of care received at the MOU or any other healthcare facility will not differ according to participation in the study. Specifically, we will request written informed consent for installation of the app, location tracking, data collection, medical record review (participant and infant), one blood draw, and re-contacting by study staff.

Once the consent form has been explained to the participant, any questions she may have will be answered. If the participant agrees to provide consent for participation, she will indicate this with her signature on the consent form. If she does not wish to participate or does not provide her consent for all the activities, she will not sign the consent form and will not be enrolled. A second copy of the form will be provided for her to sign as well and keep. The study staff member who administered the form will provide his or her name, signature and date as a witness to the signing. Signed informed consent forms will be stored in binders within a locked office and only accessible by study staff.

Linkage information and study ID assignment
After the informed consent is signed, the participant will be assigned a study ID number. The master list of study ID numbers linked with participants' names and MOU clinic file numbers will be kept in a password-protected file, accessible only by designated study staff. In order to re-contact the participant and access her medical records, we will collect identifying information on a separate paper-based linkage form, including contact information, name, study number, clinic record number, phone number, national identification number, address, date of birth, and we will also update this form with infant information, when available. As is standard practice for research studies at the study site, the participant may also provide details for an alternative contact person in the event that we are unable to reach the participant after multiple attempts. No details about the participant will be shared with the alternative contact; study staff simply will ask that the participant return to the clinic when she can. Identifiers and study details will only be linked on the linkage form which will be stored in a locked cabinet in the study office.

Randomization
Randomization will occur after study ID assignment and will follow a dynamic permuted block design. All participants will be randomized 1:1 to the control or intervention arms. Randomization numbers will be generated prior to the start of the study, and placed in sequentially numbered opaque envelopes. Randomization envelopes will be stored in a locked cabinet in the study office at the study site that will be accessed by the study coordinator when a participant is fully consented, with independent documentation of the participant ID number, randomization date, and randomization assignment.

Enrollment questionnaire
Following randomization, study staff will complete a face-to-face questionnaire with each participant. Responses will be recorded directly into a password-protected REDCap database by an interviewer using a tablet computer or laptop. The questionnaire will collect information on demographic characteristics, smartphone type and usage preferences, barriers and facilitators to engagement in HIV care, and travel intentions. Response options primarily will be categorical, with open-ended questions to allow for deeper elaboration. Questionnaire data collected will identify participant responses by study ID, not by names or identifiable data.

App installation
After the enrollment questionnaire, the participant will be invited to install the app on her own phone, with assistance available from study staff. The app will be provided free of charge. The participant will enter her phone number into the app during installation, which will be automatically confirmed through a one-time PIN.

Reimbursement
After all the above steps are complete, the enrollment visit will conclude with providing the participant R150 reimbursement for transport and missed opportunity costs. Payment will be made in cash and/or grocery vouchers and will be recorded in a reimbursement log. Data charges to

compensate for data used by the app will be reverse-billed to the study and will not be the responsibility of participants.

Interim procedures

Interim procedures for participants in the intervention arm

Participants in the intervention arm will receive text notifications of nearby ART facilities when they have traveled >50 km from the study site for >7 days. They also will receive phone call(s) and/or WhatsApp messages from study staff to when they have met this travel threshold. The study staff calls and messages will provide adherence support and assistance with connecting to nearby facilities, if requested. Messages will be written at an 8th-grade reading level or lower. All contact attempts (successful or not) will be recorded on a contact log.

Other notifications

Participants in both arms may receive notifications via the CareConekta app that are unrelated to linkage to ART care and nearby health facilities. Such notifications may include reminders to keep the app installed on the phone or messages about the raffle incentive (see below). There is no charge to the participant for receiving notifications.

Follow-up phone call

We will contact all participants by phone approximately one week after the expected delivery date to determine current location, and infant name and date of birth. This contact may take place in person at the study site if the participant is attending a regularly scheduled visit. We are including this step due the difficulty of tracing infant outcomes and linking mother-child dyads without infant date of birth and name. This information will be recorded on a CRF and captured in REDCap. A minimum of three contact attempts will be made for each participant. All contact attempts (successful or not) will be recorded on a contact log.

Mobility data

Mobility data will be collected throughout the follow-up period. Geospatial coordinates will be recorded with a timestamp. Upon bulk extraction of these data, we will import location information as decimal degree coordinates into ArcMap spatial analysis software. Data charges related to the app are reverse-billed through our app development consultants to ensure timely transmission of data with no cost to participants.

Weekly raffle incentive

To encourage participants to keep the CareConekta app installed on their phone and the GPS function enabled throughout the entire study period, we will offer an incentive: a weekly raffle of one 200MB data bundle (worth approximately $4). Participants will be eligible to enter the raffle if their phone sent GPS coordinates at least once per day for the prior week. Winners will be randomly selected among all eligible participants using a randomization code automated in STATA. The weekly raffle incentive will only apply to participants enrolled from October 2020 onwards and who have signed version 5.0 or later of the Informed Consent document. There is no limit to the number of times a participant may win the raffle.

Six-month postpartum follow-up visit procedures

Recontacting participant

All participants will be recontacted six months postpartum to return to the study site for a one-time visit. A minimum of three contact attempts by phone and/or home visit will be made for each participant. All contact attempts (successful or not) will be recorded on a contact log.

Follow-up questionnaire

Study staff will complete a face-to-face questionnaire with each participant. This follow-up questionnaire will include reasons for overall acceptability of CareConekta (standard or enhanced), reasons for travel and clinic switching, and barriers and facilitators to care since the start of the study. Response options primarily will be categorical, with open-ended questions to allow for deeper elaboration. Additional questions will be asked of participants in the intervention arm regarding acceptability and feasibility of the intervention. Responses will be recorded directly into a REDCap database by an interviewer using a tablet computer or laptop. This questionnaire may be conducted telephonically.

Viral load testing and potential blood draw
In routine care in this setting, viral load tests are to be repeated every three months in pregnancy and every six months during breastfeeding, so we expect that most women will have a routine viral load completed before six months postpartum. To avoid additional blood draws for the participant, at the follow-up visit, the study staff will check NHLS to determine the most recent viral load test. If the participant has had no viral load test within 3 months prior to the six-month study follow-up visit, a blood draw for viral load will be conducted by the clinical staff at the Gugulethu CHC. A clinic nurse will collect 5 ml of venous blood, which will be transported daily to the National Health Laboratory Services (NHLS) for HIV viral load testing (Abbott Molecular RealTime HIV-1 assay (Abbott Molecular, Illinois, USA). We will not recontact participants about viral load results unless participants are on ART and the viral load result indicates lack of viral suppression. In that case, results will be made available to participants over the phone (or in person, at participant's wish) with appropriate referrals. For all participants, viral load results will be captured using the participants provincial folder number into the NHLS database, as is standard practice for routine laboratory results in South Africa.

Uninstall app
During the follow-up visit, the CareConekta app will be uninstalled from each participant's phone.

Reimbursement
After all the above steps are complete, the enrollment visit will conclude with providing the participant R150 reimbursement for transport and missed opportunity costs. Payment will be made in cash and/or grocery vouchers and will be recorded in a reimbursement log.

File review activities
Electronic and paper files will be reviewed after the participant's final visit to assess engagement in HIV care. If the participant fails to return for a final visit, files will be reviewed a minimum of seven months after estimated delivery. Electronic data on health facility visits and pharmacy dispensing, including facility recorded deaths, will be requested the Provincial Health Data Centre of the Western Cape Department of Health by providing a list of folder numbers of women who have consented and enrolled in the study. These data include all public health facilities in the Western Cape Province, which is the location of the study site. Laboratory records, including viral loads, from any South African facility will be abstracted from the NHLS database. Participants in both arms who are lost from the study at the time of study close will be traced through staff outreach and electronic/paper medical records. Informed consent will include permission to link with electronic medical records.

Table of schedule of measures

Item for completion	Enrolment	Early postpartum phone call	6 months postpartum
Eligibility Checklist	x		
Informed Consent	x		
Linkage form	x	x child details	
Randomisation log	x		
Demographics and medical history	x		x
Maternal mobility (past and planned)	x		x
Maternal clinic switching	x		x
Perceived barriers and facilitators of engagement in care	x		x
Depression (PHQ-4)	x		x
Alcohol and drug use (AUDIT-C and DUDIT Q1)	x		x
Patient provider relationship scale	x		x
ART adherence	x		x
WHO VAW (intimate partner violence)	x		
Social impact scale (stigma)	x		
Availability of social support	x		
Life events (trauma)			x
Infant health			x
Child mobility			x
Acceptability of CareConekta			x
Impact of COVID-19 & lockdown of HIV care and mobility			x
Laboratory tests			
HIV viral load*			x
Record review			
Antenatal and obstetric information	x	x	x
ART pharmacy records	x	x	x
Maternal laboratory results	x	x	x
Child HIV testing		x	x

* If no routine viral load result found in the three months before the study visit

DATA COLLECTION AND STORAGE

Data collection methods

Data will be collected in three ways:

- Face-to-face enrollment and follow-up questionnaires

- Medical record review (electronic and paper file records) to determine participant engagement in HIV care
- Electronic app usage and mobility data

Questionnaire data
Questionnaire responses will be recorded directly into a REDCap database by an interviewer using a tablet computer. The study team has extensive experience building and using REDCap databases. The database will be password-protected with access limited to the members of the study team. All questionnaire data will be converted to SAS, STATA or SPSS for data analysis. All databases will be password-protected with access restricted to the members of the study team. All questionnaire data will be stored on the University of Cape Town secure network drive and any files sent for transcription or review will be sent as password-protected encrypted files or through a secure file share program, such as the REDCap's Send-It secure data transfer application. The encrypted REDCap data servers will be housed at Vanderbilt University Medical Center.

Study document storage
All hard copies of study documents, including signed consent forms, linkage forms, and logs will be stored in locked cabinets in the study office with only the study team having access to the data. For increased protection, the linkage form and signed consent forms will stored separately from other study documents.

Smartphone data
The transmission and storage of sensitive participant information will follow best practices regarding smartphone app confidentiality. All information collected by CareConekta, including location, device ID and timestamp, will be encrypted and transmitted to secure study servers using the secure https protocol. Time-stamped GPS coordinates will be stored in a longitudinal history. Electronic mobility data will be stored on a back-end storage system at the South African Medical Research Council (MRC) that meets Health Normative Standards Framework guidelines, which call for restricted access, and the separation of patient demographics and health data. The user reference (unique ID or demographic information of the patient) is separated from the user's cell number and phone ID, as well as separated from the location information for security and purposes.

Destruction of data
All identifiable data, including linkage forms and signed informed consent forms, will be destroyed five years after the study is completed and closed with the IRB.

ANALYSIS PLAN AND STUDY OUTCOMES
Aim 1a. To use GPS location data from CareConekta and spatial analysis to characterize peripartum mobility within the complete observational cohort (n=200), including the frequency, distance, and timing.

Outcome: Mobility within the study period
We will use data from all 200 participants to describe mobility within a complete observational cohort. In order to assess mobility comprehensively, we will use multiple data sources: time- and date-stamp data as well as geographic location data from CareConekta, participant self-report during questionnaires, and electronic medical records during the file review. Participant questionnaire data and medical record data will be exported from REDCap, and mobility data from CareConekta will be imported from .csv files to SAS for data analysis. To assess the primary outcome of interest, we will report the number of participants who travel during the study period (defined as >50 km for >7 days), over the denominator of all participants. Among those who travel, we will report the median and interquartile range number of trips during the study period and will determine timing and

frequency of travel as it relates to delivery date, which will be obtained from participant questionnaire and/or medical records. Median and interquartile range duration of travel will be reported in days, and we will also assess temporicity (frequency of trips x duration of trips). Reasons for travel will be obtained from the enrollment and follow-up questionnaire and will be grouped by theme, such as family, work, housing, and education.

For a more detailed assessment of mobility, we will use ArcMap to geographically place all locations in which participants were recorded during the study period. We will plot origin and destination locations on a map of South Africa, and neighboring countries (if necessary). We will connect origin and destination locations using ArcMap's XY-to-line tool, and will use a spherical calculator to estimate the distance between origin and destination. The geographic data will be used in conjunction with the novel metrics of mobility developed by Dr. Camlin, which are reflective of the complex forms of mobility in sub-Saharan Africa. For example, we will apply geopolitical boundaries to location codes so that measures of internal migration and localized mobility within and across those boundaries can be estimated, such as inter- and intra-provincial mobility. We also will map mobility flow according to origin and destination pairs, classified by geopolitical categories. We will thereby demonstrate how geographic data can be used to characterize the mobility of populations – providing a vital alternative to survey measures – in order to measure the impacts of that mobility on care cascade outcomes, with broad applicability to the measurement of its impact on other health outcomes. We also will conduct a secondary analysis to validate whether self-reported anticipated travel matches data collected from the CareConekta app.

Aim 1b. To assess the association between mobility and engagement in HIV care for mother (retention in care and viral suppression six months after delivery) and infant (completion of routine early infant diagnosis).

Outcome: Impact of mobility on engagement in HIV care in the absence of the intervention
We will limit the analysis to the control arm only to explore the impact of mobility on engagement in HIV care in the absence of intervention. We will report baseline participant characteristics as collected on the questionnaire. We will report proportions and 95% confidence intervals for categorical variables and medians and interquartile ranges for continuous variables. Open-ended questions will be reviewed for key themes. Themes will be abstracted and quantified.

To assess engagement in HIV care, we will report retention in care, which will be assessed at the six-month postpartum point and defined as no documented HIV-specific contact with any healthcare facility (including medication pick-ups) for >3 months. We also will report viral suppression six months after delivery, using thresholds of ≤50 and ≤1000 copies/ml. Additionally, we will report vertical HIV transmission and completion of the routine 10-week infant PCR test.

We will fit a series of models of mobility metrics on outcomes. For one, we will use a dichotomous exposure of mobility (any travel >50 km: yes/no), we will use Cox proportional hazard regression models to estimate the association of mobility on these outcomes, and will produce adjusted hazard ratios and 95% confidence intervals for retention in care and achieving viral suppression. We also will identify other predictors of engagement in HIV care. We will produce crude Kaplan-Meier curves to time to loss to follow-up and time to viral suppression by mobility group. Additionally, we will perform sensitivity analyses to explore how the estimated effect size changes when using varying cut-off points to define mobility.

Aim 2a. To assess the acceptability and feasibility of the standard and enhanced app, with a focus on identifying user preference and implementation outcomes.

Outcome: Acceptability and feasibility of CareConekta
Acceptability and feasibility data will be collected among all 200 participants. Those in the intervention arm will receive additional questions related to the enhanced app features. The outcomes selected for analysis in Aim 3a correspond with the Technology Acceptance Model for Resource-Limited Settings (TAM-RLS) framework, which was designed to draw attention to end-user acceptability as a predictor of mHealth technology adoption in low-resource settings.[46] We will report proportions and 95% confidence intervals for categorical variables and medians and interquartile ranges for continuous variables. For open-ended questions, we will create a list of categorical themes that emerge over multiple readings and calculate the proportions for the response categories. We will select key illustrative quotes for each theme.

Aim 2b. To evaluate the initial efficacy of the enhanced CareConekta intervention, using notifications and staff contact to improve engagement in HIV care, by assessing the association between study arm and engagement in HIV care at six-months postpartum.

Outcome: Efficacy of the intervention
The overall efficacy analysis will include participants in both arms (n=200). To assess overall cohort engagement in HIV care, we will report retention in care, which will be assessed at the six-month postpartum point and defined as no documented HIV-specific contact with any healthcare facility (including medication pick-ups) for >3 months. We also will report viral suppression six months after delivery based on the viral load test closest to the six-month period, using thresholds of ≤50 and ≤1000 copies/ml. Additionally, we will report vertical HIV transmission and completion of the routine 10-week infant PCR test.

Study arm assignment is the primary exposure of interest. We will use Cox proportional hazard regression models to estimate the association of study arm assignment on these outcomes, and will produce adjusted hazard ratios and 95% confidence intervals for retention in care and achieving viral suppression by study arm. We also will identify other predictors of engagement in HIV care. We will produce crude Kaplan-Meier curves to time to loss to follow-up and time to viral suppression by study arm. In a secondary analysis, we will perform an as-treated analysis using self-reported data regarding actually reading the notifications and/or WhatsApp messages or staff phone calls to analyze the effect of receiving the intervention.

HUMAN SUBJECTS' PROTECTION
Ethical review process
The research protocol will be reviewed by the Institutional Review Boards at Vanderbilt University; the University of California, San Francisco; and the University of Cape Town in South Africa. All research activities will occur in South Africa. All procedures will conform to U.S. and South African ethical standards for human subjects' research.

Informed consent
Informed consent will be obtained for all participants as described in the "Informed Consent" section above.

Privacy and confidentiality
Certainly the concept of tracing an individual's personal location is one that must address substantial protections of human subjects. First, our formative research with potential users in focus group discussions specifically addressed issues of privacy regarding a mobility-tracing app and notifications. For both issues, we found high acceptability.

While we feel that our formative research clearly indicates initial acceptability of mobility tracing and notifications, we have designed this work with a strong commitment to offering the highest level of protection of our participants' privacy and confidentiality. First, the location data of interest is at the macro-level, showing movement between towns, cities or regions, not at the micro-level, showing specific whereabouts. Thus, to protect participants' privacy, the transmitted location information will be made "fuzzy" by transmitting a random location within 1 km of each participant's exact location. Any participant's exact location within that radius will be unknown. All information collected by the app, including location, device ID and timestamp, will be transmitted to secure study servers using the secure https protocol. The participant's numerical study ID number will be used during installation; and no identifiable participant information will be recorded in the app.

Potential risks of the proposed research to participants and others
There is always the possibility of a breach of confidentiality of study materials when conducting research. While this is acknowledged, there is very low likelihood because of the precautions that will be taken to protect confidentiality. Study staff will be trained on the expectations that they are not to disclose any information collected in the study to anyone outside the study team. All identifying information associated with the study participants will be maintained in locked storage cabinets and complex password-protected computers that themselves are kept in locked rooms or cabinets. All participants will be encouraged to contact the clinic staff, principal investigators, or other staff to report any undesirable conduct associated with the study. These reports will be brought to the attention of the PI.

In the unlikely event that a study participant experiences or is involved in criminal activity that may relate to CareConekta mobility or user data, we will comply with all local laws regarding data handover.

Another risk to participants is that an HIV-positive status may be discerned through disclosure of participation in the study. However, we will do everything possible to minimize the risk of disclosure. We only will communicate with participants outside of the study if they do not return for their follow-up visit. No communication, whether on the phone or by text message, will identify the participant as HIV-positive. Importantly, among participants in the intervention arm who receive notifications of new facilities and phone calls and/or WhatsApp messages, the study staff will not use HIV-specific language. To avoid the possibility of inadvertent disclosure, ART facilities will only be referred to generically as "clinics" and any reference to ART will be to "tablets," a common term for any medication that we demonstrated was acceptable in an earlier mHealth study in South Africa.44 We considered providing smartphones to all study participants, but felt that this might lead to inadvertent disclosure of HIV status through one's participation in the study, as well as potential issues related to coercion.

Additionally, discomfort or distress may arise from answering interview questions about behaviors or feelings. We will explain the nature of the questions to be asked during the consent process and all participants will be able to refuse to answer questions or terminate the interview at any time. Women who indicate psychological distress during study visits or interviews will be referred for support and counseling at the MOU. The interviews are designed to be supportive and non-confrontational and attempts will be made during administration of the study to minimize the discomfort of participants. Interviews will be conducted in private rooms with closed doors within the clinic that provide privacy for the participants. If an individual is uncomfortable during an interview, she will be reminded that she can terminate the interview and/or withdraw from the study at any time.

Risk to subjects will be minimized by: 1) training research staff in the ethical conduct of research; 2) strict protection of confidentiality by detailed standard operating procedures and on-site monitoring; 3) careful handling of sensitive data, procedures and processes in place to ensure data is securely stored and transferred; and 4) referral of participants to appropriate social and health services when necessary. The study site is well connected with the social worker and psychology services at the site as well as local non-governmental organizations providing counselling and support. While the potential risks to subjects are low, any social harm will be reported to the PI and a serious event will be reported to the Vanderbilt University and University of Cape Town IRBs within 48 hours of becoming aware of the event. Should any respondent experience discomfort or distress from participation in the study, we will provide the participant with the appropriate referral needed for follow-up and care.

Risk to subjects from participation in the study is minimal. All possible precautions will be taken to ensure complete confidentiality and protection of study participants. Given the minimal risk, the overall benefit of the study outweighs the risks.

Potential benefits of the proposed research to participants and others
The participants in the intervention arm who receive notifications while traveling may benefit from improved linkage to care while traveling and may have improved HIV-related outcomes. Moreover, the information obtained in this study will provide valuable information for future design and implementation of interventions aiming to improve retention in care among HIV-positive postpartum women. In addition, information obtained from participants will help inform our understanding of mobility among postpartum women and how it may contribute to HIV-positive women dropping out of care after pregnancy.

Data and safety monitoring plan
The study team will undergo extensive training prior to beginning the study, including training on issues of confidentiality. The PI has extensive experience with conducting research studies in South Africa and in training staff in the ethical application of research. In addition, the study team will be trained in ethical conduct of research.

The PI will monitor the study safety data on an ongoing basis. They will report to their IRBs and the South Africa HREC any breaches in confidentiality identified. In the event that a breach in confidentiality does occur, staff will be retrained on human subjects' protection and confidentiality if possible or removed from subject contact if the either the breach is too serious or if the PIs feel the staff member cannot be sufficiently retrained. Staff will be made aware of this condition on employment.

The PI will be responsible for reporting to the grant program director any action resulting in a temporary or permanent suspension of the research.

We will not convene a Data Safety Monitoring Board (DSMB) for this study.

Data accuracy and completeness
In addition to the co-investigators, the local South African study team will consist of a study coordinator, a site coordinator, and an interviewer/fieldworker. These team members will be trained in human subjects' research through the NIH's website or through a presentation developed by UCT faculty based on the NIH course, but adapted to the local context. Prior to contact with any subjects, all staff with participant interaction duties will be trained on the background and objectives of the study, procedures for obtaining informed consent, and correct administration of the questionnaire. Training will include procedures for minimizing risk to subjects, assuring data accuracy and protocol

compliance. The study team will also be asked to complete several practice interviews. To avoid bias and/or contamination, the study staff member who conducts interviews will not deliver the intervention calls and/or messages.

Participant remuneration

Following standards set by the University of Cape Town Research Ethics Committee, all participants will be reimbursed R150 (approximately US $10.50) per study visit (enrollment and follow-up) for transport and missed opportunity costs. There will be no participant reimbursement for routine care visits made between study visits.

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