The Coach Mpilo Study Protocol

Title: The Coach Mpilo Study: evaluation of a peer-led intervention to promote engagement in HIV care for men living with HIV in South Africa

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Project Summary

Developed in South Africa using extensive input from community members and healthcare professionals, Coach Mpilo is a peer support intervention that was designed to improve health outcomes for men living with HIV. Coach Mpilo engages men living with HIV as coaches who provide support to their peers and help them address psychosocial barriers in accessing and staying in HIV care.

The peers employed by Coach Mpilo provide individualized assistance to men who are struggling with medication adherence and clinic visits, focusing on specific barriers ranging from knowledge about the benefits of HIV treatment, stigma, mental health, and social isolation.

Through a randomised control trial, this project will (1) determine the impact of the Coach Mpilo intervention on retention in HIV care, viral suppression, HIV treatment adherence, mental health, HIV stigma, and economic status; (2) identify populations of men who may not benefit from the intervention and require alternative support; and (3) assess the intervention's cost-effectiveness.

Background

Increasing treatment coverage among men living with HIV can not only improve men's health outcomes but also reduce HIV transmission and enhance efforts to end the HIV epidemic. Despite universal access to free antiretroviral therapy (ART), high rates of AIDS-related mortality and HIV incidence persist due to delayed ART uptake and ART retention in many African countries. In South Africa, the country with the world's largest HIV epidemic, the largest gaps in ART coverage are found among men:[1,2] 80% of women are receiving ART compared to only 68% of men.[3] Although >90% of men living with HIV are aware of their status, >30% of men living with HIV are not engaged in care.[4–6] Large gaps in ART coverage persist despite significant health system changes aimed at making it easier to obtain and stay on treatment, such as multi-month drug dispensing and offering ART collection points external to clinics and convenient for recipients of care.

As of December 2023, UNAIDS estimated that 761,000 men aged ≥15 years in South Africa were living with HIV but not on ART. An estimated 25,000 AIDS related deaths occurred among men aged ≥15 years, the vast majority being preventable by HIV treatment. Furthermore, a recent study shows that if gender equality in viral submission had been achieved in 2018 (i.e. men had the same viral suppression rates as women), there would have been 51% fewer new HIV cases in women.

A recent systematic review of reasons for disengagement from antiretroviral care in low- or middle-income countries found that common reasons for disengagement included socio-economic factors (e.g. inadequate income), lack of social support, and unexpected events (such as death of family and friends)[7] - all of which are more common in resource poor settings. This finding is consistent with other studies in South Africa indicating that the poorest people in

the population continue to bear a higher burden of HIV/AIDS despite free ART available from public health facilities.

Improving engagement in HIV care among men would reduce HIV-related morbidity and mortality while potentially generating a number of other benefits as well: improved health and well-being, strengthened family structures (e.g., from fewer children losing parents), increased economic productivity, reduced burden on health systems and accompanying cost savings through treatment (for example) of fewer people living with HIV and fewer opportunistic infections.

The Intervention - Coach Mpilo

When HIV care recipients miss a clinic visit, the standard of care (SOC) in South Africa is for healthcare workers to contact them by text and/or phone and then to conduct a home visit if necessary. Phone calls are made by lay counsellors/linkage officers and home visit attempts are made by community health workers/linkage officers. The majority of individuals conducting this tracing are female and not living with HIV.[8] The large proportion of individuals currently not on ART indicates that the SOC alone has been inadequate for re-engaging people in HIV care.

Created by Population Services International (PSI) and Matchboxology, Coach Mpilo employs ‘coaches’ (a term found to resonate in formative research with men and the concept of ‘getting back in the game’) to work 1-on-1 with men living with HIV (‘players’) and tailor support for each man to help him re-engage and stay in care. Coaches provide support for a period of up to six months, during which they engage with clients about once every week, with greater contact as needed based on the complexity of challenges faced.

The Coach Mpilo intervention has two innovative features that differentiate it from the SOC. (1) **Tailored support.** Coach Mpilo provides one-on-one, in-person support tailored to the individual needs of men living with HIV. As such, it may address the complex and varying psychosocial barriers to HIV care that traditional clinic-based interventions typically overlook. (2) **Utilization of peer mentors.** Coach Mpilo employs men living openly with HIV as coaches. This leverages the coaches’ personal experiences to create a safe and supportive environment for clients and provide relatable support. Since men living with HIV face acute psychosocial barriers, including a deep feeling of social isolation driven by not knowing other men living with HIV, access to mentors who are also living with HIV can help overcome the barriers to sustained engagement in HIV care.

Coaches are usually recruited into a full-time paid position from the same communities where both they and their clients reside. They receive a one-week structured training with a training team that includes a clinical psychologist with counselling expertise. The goal of the training is to empower coaches to be knowledgeable about HIV and ART; understand the fears and challenges men face; identify barriers to ART retention; provide guidance and support using various tools and techniques (e.g., motivational interviewing, explaining ART in layperson terms); and understand how to conduct themselves as coaches. The customized curriculum

draws on accredited HIV counseling and testing content. The training also includes interpersonal communication, mentorship, methods to establish trust, guidance on how to help men develop coping and problem-solving skills, and strategies for dealing with specific barriers to care.

Coaches also receive regular on-the-job support from a squad manager, including on counselling and mentoring.

Theory of Change

Coach Mpilo was motivated by three insights from formative research: (1) HIV leaves many men anxious and afraid, and in need of reassurance. (2) Many men do not believe it is possible to live a long, healthy, 'normal' life with HIV. (3) Many men want support in coping with HIV but see no sources that feel safe and relatable.

Coach Mpilo is designed to increase motivation for ART by increasing the perceived benefits and reducing perceived risk of ART, increasing self-efficacy (Health Belief Model); and changing perceived social norms around ART (Theory of Behaviour Change). The intervention helps men follow through with intentions via cues to action (Health Belief Model) and by creating an enabling environment. We describe each of these pathways below:

Increased perceived benefits and reduced perceived risks: As positive role models living a healthy life on ART, coaches reframe men's mental models about what life might be like on ART. They demonstrate that you can be healthy on ART and life does not need to change due to HIV. As such, they counter fears of rejection by family and friends, and loss of status. ART is reframed as something for healthy and strong men, thus countering beliefs that ART is only for the sick.

Increased self-efficacy: Coaches' personal experiences and training on strategies to overcome practical barriers to HIV care may increase men's agency and belief in their ability to re-engage and stay on ART. In addition, through changing the mental model to one in which men living with HIV are loved, valued and productive, Coach Mpilo reduces internalised stigma and further increases self-efficacy.

Perceived social norms: Coaches are connected to a network of men living with HIV and are trained to instill that retention on ART is the subjective norm in their community (i.e. it is what most men do). This can serve as a motivator to initiate and stay on treatment.

Cue to action: Direct advice from coaches will act as a cue to action and strategies coaches are trained on will help clients overcome practical barriers to HIV treatment. This can motivate men to take specific actions such as going for their next clinic appointment.

Creating an enabling environment: Coaches are trained to support disclosure of HIV status. Through disclosure, social support will be strengthened (with accompanying reduced social isolation and improved mental well-being) and facilitate retention in care.

Study setting

We will conduct the study in KwaZulu-Natal (KZN), the province in South Africa with the highest adult HIV prevalence: 16%[6]-24%[9] (model estimates), 22% (survey estimates).[10] The study will be conducted in about six primary healthcare facilities based in the eThekwini Metropolitan Municipality, which includes the city of Durban and surrounding towns. eThekwini is densely populated (~4 million people) and consists of urban, semi-urban, and rural areas, along with townships and informal settlements. eThekwini has an HIV prevalence of 20.6% (Fig. 1A) and an estimated 631,994 people living with HIV and 228,987 men living with HIV.[9] Within KwaZulu-Natal province, eThekwini has the greatest number of people living with HIV, the greatest number of men living with HIV who are not on ART - 51,092 (Fig. 1B) - and the greatest number of HIV tests conducted annually.[11]

Selection of clinics: The clinics where the study will take place are supported by the Health Systems Trust (HST), a South African non-governmental organization focused on strengthening health systems and improving equitable access to care. HST and the KZN Department of Health have agreed to collaborate on the final selection of clinics. The selection of clinics will take into consideration, among other factors: a) the number of men living with HIV who have missed clinic appointments, b) the quality of clinic outcome data that can be obtained, c) the suitability and safety for community-based study enrolment and data collection. To ensure these decisions are made with the most accurate information, we aim to make the final decisions on clinics as close to the start of fieldwork as logistically feasible.

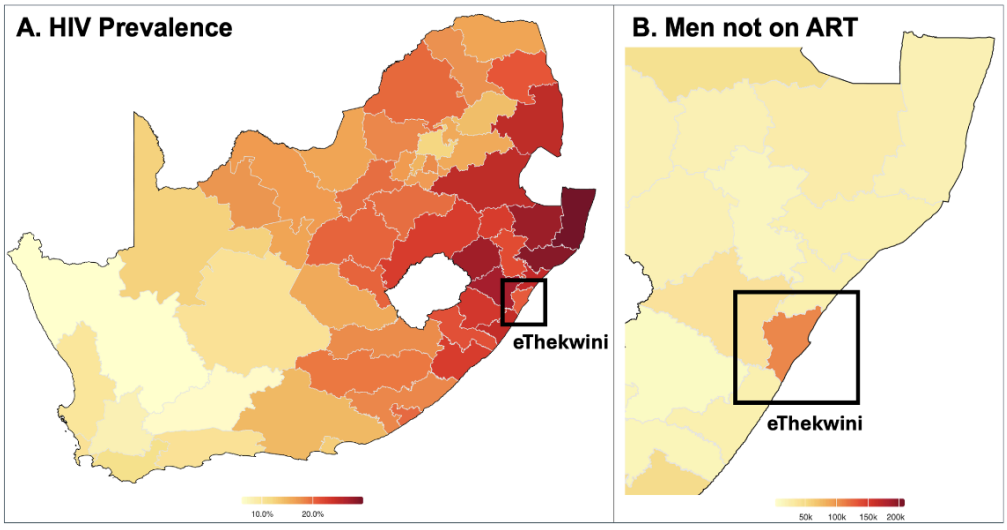

Figure 1. (A) HIV prevalence among adults in South Africa in 2023; (B) Number of men living with HIV and not on ART in districts in KwaZulu-Natal Province (Source: Naomi Spectrum, Sept. 2023)

Aim 1: Determine the effects of Coach Mpilo on retention in care among men living with HIV

In partnership with the Department of Health in KwaZulu-Natal Province, HST and Matchboxology, a South African organisation that designs health and social programs, we will conduct a randomised controlled trial (RCT) with men living with HIV who have dropped out of HIV care (i.e., having missed a clinic appointment by >28 days).

Recruitment: Our study staff will be trained by HST as Linkage Officers. As Linkage Officers, they will support clinics by encouraging people living with HIV to return to, and remain in, HIV care. Linkage Officers are endorsed by the Department of Health and will be integrated into the clinic team to support men who have missed clinic appointments.

The clinic will assist the Linkage Officers by providing a list of all men who have missed an appointment by >28 days. The physical clinic files for these individuals will be used to confirm that the individuals on the list have not visited the clinic for their latest appointment. Linkage Officers will then contact the men who have missed clinic appointments via telephone, encourage return to care, and ask to meet privately at local venues. The Linkage Officers will encourage return to HIV care - for all men on the list. At the in-person meeting the Linkage Officers will invite eligible participants to enrol in the study.

Inclusion criteria: Men living with HIV must meet the following criteria: (a) aged ≥18 years; (b) previously receiving HIV care at the study clinic; (c) missed their most recent ART clinic appointment by >28 days, (d) not planning to relocate to another region within the next 12 months; (e) able and willing to provide informed consent; (f) not currently taking ART. Importantly, agreement to be contacted by a coach (if selected) is not an eligibility criterion as our goal is to obtain generalizable evidence of the overall effectiveness of the Coach Mpilo program (uptake of communication with coaches will be explored in Aim 2).

Consenting process: Study staff will review the informed consent form with men who meet the inclusion criteria and answer any questions that men may have about study participation. The consent form (see Appendix A) includes a brief description of the Coach Mpilo intervention and the goals of the study. Staff will also obtain consent to review clinic records for participants. Those who provide informed consent and meet criteria for enrollment will proceed to randomization.

Data collection

Baseline survey: Study staff will administer a baseline questionnaire to obtain information on, among other things, participants' demographic characteristics, socio-economic status, health behaviour (HIV testing history, sexual behaviour, alcohol use), future outlook, internalized stigma and mental health. The baseline survey is found in Appendix B.

Follow-up survey: Study staff will contact participants at six months and administer an in-person

follow-up survey; many of the questions administered at baseline will be assessed again. The follow-up survey is found in Appendix C.

Clinic records: We will obtain participants' health outcome data from electronic clinic data via TIER.Net (South Africa's national electronic HIV/TB monitoring system), to assess individual- and facility-level outcomes related to HIV. Where necessary for confirmation we will also retrieve data from physical clinic files. With consent from participants, we will use the participants folder number to match to their Tier.Net data at the clinic or subdistrict level. In cases of missing, mismatched, or duplicate folder numbers, fallback matching strategies may be applied using combination variables such as names, mobile phone number, year of birth, and only within data security constraints. We will conduct periodic validation and deduplication processes to improve linkage accuracy and reduce error. In addition, participants' data on laboratory tests relevant for HIV care (including viral load tests) will be requested from the National Health Laboratory Services (NHLS). All data will be handled in accordance with ethics approvals and national data protection standards. The study team will report linkage rates and assess potential bias due to non-linkage in the final analysis.

Coach Log Book: To collect data on the engagement between coaches and their clients, the coaches will maintain a log book of the dates, duration and mode (e.g., in-person, telephone call, WhatsApp messages) of contact with clients.

Randomization: Following the baseline survey, participants will be randomized (1:1) to a control group that receives the SOC and an intervention group that receives SOC plus the Coach Mpilo intervention. For the SOC, participants will receive the standard in-person tracking and tracing support as per the South African National Guidelines for individuals living with HIV who have missed clinic appointments. For the intervention group, participants will be informed about the potential support from a Coach. They will be provided with the details of their assigned coach and contact details for them to reach out to the Coach. In addition, permission will be obtained to provide their contact details to the Coach so that the Coach can initiate contact with them.

Outcomes: The primary outcome will be retention in HIV care at 12 months, defined as attending a follow-up clinic visit on or before 12 months and obtaining adequate ART refills for a supply of medications at 12 months post study enrolment. Studying this outcome will address an important question about whether time-limited, resource-intensive interventions like Coach Mpilo have a durable effect on participants' health outcomes. The outcome also features prominently in cost-effectiveness modeling that we will undertake.

Secondary outcomes will include retention in care at 6 months; viral suppression (<50 copies/ml) at 6 and 12 months; and adherence over 6 and 12 months using proportion of days covered (PDC). In addition, we will examine outcomes measured in the 6-month follow-up survey: HIV-status disclosure, mental health, internalized stigma, self-esteem, employment and social isolation.

Analyses: Primary analysis: We will conduct intention-to-treat analysis and estimate a logistic regression model that includes clinic fixed effects and month of enrollment, and controls for baseline participant characteristics that are significantly different between study groups.

Secondary analyses: We will repeat the primary analyses for each secondary outcome. Analysis of six-month outcomes will indicate whether Coach Mpilo has promising immediate effects on participants' health and well-being. Analyses of outcomes such as mental health, social isolation, and future orientation will provide insights on potential mechanisms by which the Coach Mpilo intervention may affect men's health.

Sample size and power calculations: We determined the target sample size based on statistical power to detect a clinically relevant effect of the intervention on the primary outcome of retention in care. We anticipate that Coach Mpilo will increase re-engagement and retention in HIV care (the primary outcome) by 10 percentage points. The Coach Mpilo pilot study found that 88% of men with coaches missed no clinic visits in their first seven months on ART, and 95% of men remained in care at seven months. This indicates 18-25% higher retention in care compared to several studies in South Africa that have found 30% drop out of care in the first six months of treatment.[2,4,5] Given potential biases in the pilot data - there was no control group, data was self-report and not disaggregated by engagement in care at baseline - we hypothesize the intervention will increase retention in care by at least 10 percentage points. We performed power calculations under varying scenarios of the primary outcome in the control group. Based on existing data from clinics and prior research, we anticipate retention in care at 12 months to be 40-60%.[12,13] With a sample size of 786 participants and 50% retention in care at 12 months, we will have 80% power to detect a difference of 10 percentage points between study groups. As a result, we will aim to recruit about 800 participants in the Aim 1 trial.

We also anticipate the intervention to: 1) improve mental health by reducing internalised stigma, increasing social support, and increasing hope; 2) reduce fears associated with living with HIV; 3) encourage HIV status disclosure.

Aim 2: **Identify the populations of men who are *not* reached by and do not respond to Coach Mpilo**

In the intervention group, we will measure intervention uptake and amount of engagement participants have with a coach. Primary quantitative analysis will assess the determinants of uptake within the intervention group to advance the limited evidence on sub-groups that are typically missed by peer-led interventions and therefore require different types of support. Qualitative interviews will also be conducted to better understand program uptake and engagement with a coach.

Participants: Aim 2 will be conducted with data collected from coaches and from Aim 1 trial participants.

Follow-up procedures and data collection: In-depth interviews (IDIs) with participants in the intervention arm who decline a coach. We will conduct about 15 IDIs with men who decline the

support of a coach to understand reasons they did not engage with a coach. IDIs will be conducted at about 6 months, when engagement with a coach will have ended. Stratified sampling (by study facility) will ensure representation across the different settings, with participants from different clinics randomly selected and with the final sample determined using saturation analysis. Interviews will follow a semi-structured agenda exploring the following themes: (1) perceptions of health support for men; (2) ART history and experience on ART, including reasons for stopping treatment and restarting treatment; (3) understanding of the Coach Mpilo program and peer-led support more generally; (4) the decision to not accept the offer of a coach, including reasons and feelings about the decision; (5) barriers to ART retention, including stigma, disclosure, and support systems; (6) other strategies used to support ART retention (e.g., do they not need a coach because they have other strategies). The semi-structured IDI guide is found in Appendix D.

IDIs with participants in the intervention arm who initially accept support from a Coach but then decline further support. We will conduct about 15 IDIs with men who, after initial engagement, decline the support of a coach. This will be in order to understand reasons they chose to end engagements with a coach. IDIs will be conducted at about 6 months. Stratified sampling (by study facility) will ensure representation across the different settings, with participants from different clinics randomly selected and with the final sample determined using saturation analysis. Interviews will follow a semi-structured agenda exploring the following themes: (1) reaction to diagnosis; (2) ART decision making; (3) understanding of the Coach Mpilo program and peer-led support more generally; (4) the initial decision to accept the offer of a coach, including reasons and feelings about the decision; (5) the decision to end support from a coach, including reasons and feelings about the decision; (6) barriers to ART retention, including stigma, disclosure, and support systems; (7) other strategies used to support ART retention (e.g., did they find that they did not need a coach because they have other strategies?). The semi-structured IDI guide is found in Appendix E.

IDIs with participants in the intervention arm who are supported by a coach. We will conduct about 15 IDIs with participants who receive support from a coach to understand engagement with coaches and elicit insights on reasons why the intervention may have worked for some participants but not others. IDIs will be conducted shortly after the 6-month follow-up survey (i.e. after support from a coach has ended). Stratified sampling (by level of engagement with a coach) will be used to include men whose engagement with a coach is minimal (1-2 sessions) and more substantial (>4 sessions). Interviews will follow a semi-structured agenda exploring the following themes: (1) perceptions of health support for men; (2) ART history and experience on ART, including reasons for stopping treatment and restarting treatment; (3) reasons for accepting support from a coach; (4) experience and perceptions of the Coach Mpilo program, including expectations, whether these were met and perceived role of coaches; (5) level and type of engagement with coaches; (6) barriers to retention in care – with a focus on stigma, disclosure and social support – and coaches' role in overcoming them; (7) perceived efficacy of the intervention on Aim 1 outcomes. The semi-structured IDI guide is found in Appendix E.

IDIs with coaches who deliver the Coach Mpilo program. We will conduct IDIs with all coaches (about N=7) involved in the study to gain insights on their engagement with participants. IDIs will be conducted soon after the intervention stops being implemented as part of the study.

Interviews will follow a semi-structured agenda exploring the following themes: (1) reasons for being a coach; (2) experience and perceptions of the Coach Mpilo program, including level of satisfaction with the intervention; (3) engagement with clients, including how the level of engagement with each client was determined, the most common and effective modes of engagement, and assessments of when support was no longer needed; (4) main barriers to retention in care faced by clients and approaches to address these, including whether coaches were equipped/supported to address clients' needs and ability to tailor engagements for specific needs; (5) perceived efficacy of the intervention on Aim 1 outcomes; (6) perceptions of how the Coach Mpilo program can be improved.

IDI procedures and data management. We will obtain written informed consent before IDIs. IDIs will be conducted by trained interviewers, in participants' preferred language (Zulu/English), and in a private and safe location. Procedures for data quality assurance will include: (1) careful design of IDI guides; (2) extensive interviewer training; and (3) immediate analysis of data to inform improvements for subsequent interviews. IDIs will last approximately 1-1.5 hours and be recorded using a digital voice recorder. Audio files will be translated and transcribed verbatim by a transcriptionist. After transcription, the study team will edit out any personal identifying information. Participants will receive ZAR200 (USD11.50) in grocery vouchers for completion of the IDI.

Analyses: Primary quantitative analysis. Among Aim 1 intervention group participants we will evaluate factors associated with declining the offer of a coach using logistic regression, with independent variables including socioeconomic and demographic characteristics, local clinic, internalized stigma, HIV-status denial, symptoms of mental distress and ART readiness. Secondary within-group analyses of retention on ART using unsupervised machine-learning clustering methods will be conducted to determine the populations of men whose outcomes are least improved by engagement with a coach.[14] We will analyze the composition of each cluster and the association between sub-group classification and the outcome of receiving the intervention but not being retained on ART, i.e. who does not respond well to the program?

Qualitative data analysis. We will conduct ongoing saturation analyses, based on iterative coding during data collection. Transcriptions will be checked for accuracy and entered into Dedoose. We will also enter all observational notes as memos. Data analysis will be iterative, and include both deductive and inductive approaches to thematic analysis. To ensure accurate interpretation, we will conduct independent reviews of transcripts to generate an overarching thematic framework for data interpretation. The investigators will compare frameworks for consistency and discrepancies. Data will be re-examined, allowing for discussion and making interconnections between research questions, coding categories, and raw data.

Expected outcomes. Findings from Aim 2 will advance our understanding of the uptake and impact of peer-led interventions for people living with HIV. Crucially, we will identify populations of men who do not respond to the Coach Mpilo program. We will gain insights from both recipients of the intervention and coaches on perceived efficacy and underlying mechanisms for intervention effects determined in Aim 1. Findings will inform intervention scale-up and modifications to the program for maximum impact.

IDI quality assurance: We will monitor depth of discussions through immediate review of interview materials, and if necessary, refine probes in the IDI guides, and conduct additional interviewer training.

Aim 3: **Assess the cost-effectiveness of the Coach Mpilo program**

To inform strategic policy decisions about the scale-up of Coach Mpilo, and how it compares in cost and cost-effectiveness against current standard of care treatment, as well as other HIV interventions, we will conduct an economic evaluation. We will collect cost-related data and resource utilization data to construct cost estimates for both arms. These data will be combined with retention in care data from Aim 1 to determine average costs per client retained in care and incremental cost per additional person retained. As part of the analysis, we will conduct a sub-analysis to adjust the cost estimates to reflect implementation in a routine care setting, excluding research-related expenses such as start-up and study-specific costs. This will provide more realistic national-level scale-up cost estimates for Coach Mpilo. Epidemiological modeling based on effectiveness estimates from Aim 1, will use the Thembisa model[15] to estimate several long-term health outcomes, including life years saved and HIV infections averted due to onward transmission. These long-term health outcomes will form the basis to estimate the cost-effectiveness analysis of Coach Mpilo. To compare Coach Mpilo to other HIV prevention and treatment options in South Africa with the broader aim of informing strategic policy decisions, we will incorporate our estimates into the South Africa HIV Investment Case, a prominent initiative that assesses the relative cost-effectiveness of different HIV interventions and aims to inform government of the optimal mix of interventions that also accounts for allocative efficiency.

Cost and resource use data sources

A detailed overview of individual cost categories, their associated expenditures, and required resources is provided below, with a consolidated summary presented in Table 1.

Start-up costs

Information on the cost of training of coaches and other personnel or volunteers involved in Coach Mpilo will be obtained from Matchboxology. This information will include the number of participants attending the training (for the economic costing, the opportunity cost of their time will be based on their salary), the total cost of organising a workshop and the number of workshops held. The cost per person trained will consider expenses related to the development of training materials, refreshments, office supplies, facilitator, etc.

Staff costs

Staff costs will be based on public sector clinic staff salaries (from Department of Public Service and Administration), and implementer's records of coaches' and squad manager salaries. Staff who do not provide direct patient care, but who support the running of the programme, such as admin staff, will also be included. Time spent by coaches in engaging with intervention recipients will be determined through log-books maintained by the coaches during intervention implementation, presented in Appendix F. Time spent with patients at clinic-level will be sourced

from existing time and motion data for patients on treatment in studies previously conducted by HE^{2}RO.

Laboratory costs

Laboratory test costs will be sourced from the National Health Laboratory Service (NHLS), while quantities of tests will be sourced from a combination of client medical records at the clinic, data from TIER.Net and latest ART guidelines.

Drug costs

Drug costs, both ARV and non-ARV, will be sourced from the National Department of Health's (NDoH) Master Product Health List, which contains prices from national government tenders for all drugs available in the public sector. The quantities of drugs will be sourced from a combination of client medical records at the clinic, data from TIER.Net and latest ART guidelines.

Consumables and equipment

The cost of consumables will be obtained from facility and programme financial reports. The quantities of consumables will be estimated from facility and programme financial reports, or consultation with staff. Equipment (including furniture) costs will be sourced from government contracts or comparable market-related pricing, and adjusted for their standard working life to estimate a cost per month/visit. Equipment needed will be sourced through existing literature of costing studies based at clinics and through Matchboxology for coaches.

Building overheads and utilities

Buildings costs or annual rent equivalent, where applicable, will be estimated by using current replacement values based on Department of Health (DoH) building costs. The information on annual rent equivalent will be obtained from facility managers or partners where applicable. If this information is not available, rental costs will be estimated using market-related average rental cost per square meter. Utility costs (including telephone, water, gas and electricity costs, maintenance of vehicles, and transport costs) will be obtained from facility financial records. If not available, these costs will be estimated using data from existing studies conducted by HE^{2}RO on the cost of providing HIV treatment in similar settings.

Table 1: Cost data sources for prices and quantities

Resource	Cost source (prices)	Resource use source (quantities)
Personnel	***For clinics***: Department of Public Service and Administration government salaries. ***For coaches***: Matchboxology for salaries.	***For clinic resources***: Number of visits as recorded in TIER.Net and client records; existing time-in-motion studies for PHC ART care (HE2RO and others) ***For coaches***: Log-books for coach time

Resource	Cost source (prices)	Resource use source (quantities)
Drugs	NDoH Master Product Health List.	TIER.Net and client records to inform visits and dispensing, ART guidelines on dispensing, existing literature for non-ARV costs
Laboratory tests	NHLS	Tier.Net and client records to inform number of visits, ART guidelines to inform laboratory monitoring
Consumables	***For clinics***: National Treasury and NDOH contracts, clinic financial records ***For coaches***: Matchboxology for coaches.	**For clinics**: Clinic and programme financial reports, staff interviews **For coaches**: Matchboxology
Equipment	***For clinics***: National Treasury and NDOH contracts, clinic financial records, retail pricing ***For coaches***: Matchboxology for coaches.	***For clinics***: *Existing literature for clinics* ***For coaches***: Matchboxology for coaches.
Building/space overheads (incl utilities)	***For clinics***: Department of Health, clinic financial records, existing literature	***For clinics***: Clinic financial records, existing literature ***For coaches***: Matchboxology for coaches.
Other start-up costs	***Training for coaches*****:** Costs from Matchboxology	***Training for coaches*****:** Quantities from Matchboxology

Time horizon and discounting

The timeframe for the costs will be annual, with annualization of capital resources that provide benefits for more than one year. We will consider depreciation of equipment and building (cost allocation of a tangible asset over its useful life) using a discount rate of 5%. For the intermediary cost-effectiveness analysis, the time horizon will be 1 year, in line with the Aim 1 outcomes for Coach Mpilo. For long-term impact modelling and cost-effectiveness analysis, we will consider a 20-year time horizon. Costs and outcomes will be presented undiscounted over the 20-year time horizon, with sensitivity analyses applying different discount rates that are relevant to policymakers (commonly, 3% and the current repo rate as informed by the South African Reserve Bank).

Analyses

The analyses will be conducted in three phases:

1) **Cost analysis**: we will utilize a multiprong approach that incorporates top-down and bottom-up costing methodologies to construct a cost for both standard of care and Coach Mpilo arms.

2) **Cost-effectiveness analysis**: we will conduct both intermediate and long-term cost effectiveness analysis (using an HIV transmission model), comparing Coach Mpilo to standard of care.
3) **Integration into the HIV Investment Case**: we will compare the cost-effectiveness of Coach Mpilo to other HIV prevention and treatment options in South Africa to inform strategic policy decisions for the South African government.

As a first step for (1), we will identify all the relevant providers and activities involved in the delivery of treatment in both arms. This will include an analysis of expense records of each provider, and as needed, we will engage in informal, conversational consultations with clinic staff involved in implementation and management. These discussions will focus on operational workflows, resource use, and time allocation, and are intended to support accurate costing. This in turn will guide any adaptation of the cost data collection tools. The research team will combine top-down and bottom-up costing approaches, as well as supplemented data from existing literature and HE^{2}RO studies where needed (see Table 1), to estimate the costs of treatment under both standard of care and Coach Mpilo arms. For (2), we will combine effectiveness estimates from Aim 1 to construct intermediary cost-effectiveness estimates (cost per person retained in care, incremental cost per additional person retained), as well as conduct long-term modelling of the impact on the HIV epidemic (incremental cost per life year saved, incremental cost per HIV infection averted). For the modelling, we will use a deterministic, compartmental HIV transmission model (Thembisa[15]) to estimate the long-term impact of a hypothetical national scale up of Coach Mpilo compared to standard of care. Modeled rates of ART interruption in men will be modified to reflect the observed impact of the intervention. The Thembisa model is an integrated HIV and demographic model that has been developed specifically for the South African HIV epidemic and has been used extensively in South Africa to support HIV policy, planning, budgeting and program evaluation. We will include our study data in the widely-used South African HIV Investment Case, thus enabling us to directly compare the cost-effectiveness of Coach Mpilo to other HIV prevention and treatment interventions currently being implemented in South Africa.

Outcomes: We will estimate the total cost and average cost per person in treatment, and the cost per person successfully retained in HIV care at 12 months for both the Coach Mpilo and the standard of care study arms. Additional outcomes will include the intermediary cost-effectiveness outcomes of incremental cost per additional participant retained, and long-term cost-effectiveness outcomes from modelling work will include incremental cost per life year saved and incremental cost per HIV infection averted.

Expected outcomes: Our findings will add to the limited evidence on the cost-effectiveness of peer-led interventions for people living with HIV. They will also indicate the role of peer-led interventions in closing the gender gap in ART coverage and viral suppression rates. Finally, they will be directly useful for decisions about whether to allocate scarce resources to Coach Mpilo, or whether the use of the intervention should be more narrowly targeted to specific population segments.

Aim 4: **Assess the acceptability, feasibility and fidelity of the Coach Mpilo program**

To inform intervention refinements and policy decisions on the scale-up of Coach Mpilo and peer-led interventions more generally, we will quantitatively and qualitatively assess implementation outcomes alongside effectiveness and cost-effectiveness of the intervention. Implementation outcomes are viewed as important for evaluation of complex health interventions in research and practice,[16] providing indications into the implementation process as preconditions for attaining intended intervention engagement and health outcomes.[17] Table 2 outlines implementation outcome-specific conceptual and definitional distinctions as well as proposed methods to measure these outcomes.

We will use Sekhon's 2017 Theoretical Framework for Acceptability (TFA)[18] to assess the feasibility and acceptability of the intervention, informing interpretation of effectiveness overall (Aim 1), for sub-groups (Aim 2), and cost-effectiveness (Aim 3) by describing how acceptable the intervention is and how feasible the intervention is to deliver, from different stakeholder perspectives, and by describing the fidelity of the intervention.

Table 2. Aim 4 Qualitative and quantitative implementation science methods: conceptual and theoretical distinctions

Implementation outcome	**Intervention stakeholder**	**Measures**	**Analysis**
Acceptability[17,18] *"The perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory"*	Participants	Baseline survey - prospective acceptability, assessing values alignment and ethicality Follow-up survey - retrospective acceptability, using AIM and CSQ-8, coach uptake and retention in the coach program	Descriptive analysis Deductive and inductive thematic analysis
	Coaches	Participant IDIs Coach IDIs	

Implementation outcome	Intervention stakeholder	Measures	Analysis
Feasibility[17] *"The extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting."*	Participants Coaches Squad managers	Participant IDIs Coach IDIs Coach logs Coach-to-Coach Whatsapp group Adaptation logs	Descriptive analysis Deductive and inductive thematic analysis
Fidelity[17] "*The extent to which the intervention is delivered as intended"*	Participants Coaches Squad managers	Participant IDIs Coach IDIs Coach logs Coach-to-Coach Whatsapp group Debriefing Adaptation logs	Deductive and inductive thematic analysis

Participants: Aim 4 will be conducted with quantitative and qualitative data collected from trial participants (Aim 1 and 2) coaches (Aim 2) and from the Squad Manager.

Procedures and data collection: We will collect both i) primary quantitative survey data at baseline and six month follow-up (through Aim 1 survey instruments); ii) primary qualitative data from intervention arm participants that decline a coach, participants who are supported by a coach at six-month follow up, and coaches immediately after the intervention stops being implemented (through Aim 2 IDI instruments); iii) routine administrative data during intervention preparation and implementation. Sampling, consenting process and data collection procedures for primary data are described in Aim 1 and 2. Quantitative: At baseline, we will assess participants' affective attitude and values alignment to understand prospective acceptability. In the follow up survey with intervention arm participants, we will use the Acceptability of Intervention Measure (AIM)[19], and the Client Satisfaction Questionnaire (CSQ-8).[20,21] AIM and CSQ are widely used instruments with published data on reliability and validity.[21] Results from the AIM and CSQ-8 can be compared with intervention feedback from IDIs with participants. In addition, data from the baseline survey will be used to assess potential determinants of intervention acceptability (AIM and CSQ-8) measured in the 6 month follow-up study. Consenting process and data management procedures will follow those laid out in Aim 1. Qualitative: **Follow-up in-depth-interviews** described in Aim 2 include topics which answer our implementation research questions, focusing on retrospective acceptability (the semi-structured IDI guide is found in Appendices D and E). **Coach log:** an existing routine administrative data collection tool has been adapted to focus on implementation choices, their determinants, and

coach-participant relationship quality. **Adaptation log**: an existing routine administrative data tool on implementation adaptations and their determinants will be used, completed by Squad Managers who hold regular meetings with individual coaches and collectively with the entire coach cohort. **Coach-to-Coach WhatsApp Group:** the implementing partner routinely establishes a WhatsApp group used by Coaches and the Squad Manager (i.e. not including any clients/participants). Data from this group will include challenges Coaches are facing and solutions suggested by other coaches. Coach phone numbers and any other identifying information derived from these communications will be treated as confidential, stored securely, and handled in accordance with the study's data management plan. **Training observations:** an existing routine administrative data tool will be used to collect semi-structured observations at the initial coach training and at a refresher training after two months of implementation. **Monthly and quarterly implementation reports and follow-up discussions**: these reports will be developed by Population Services International and Matchboxology, providing both quantitative data on reach and their own observations on fidelity, reach, mechanisms of change and implementation strategies and determinants. Monthly reports will be accompanied with a follow-up discussion conducted in English, transcribed through AI transcriptions.

Analysis: Quantitative analysis. Among Aim 1 intervention group participants, we will conduct descriptive analysis of data from the AIM and CSQ-8 scales and linear regression analysis to assess what factors at baseline were associated with these scales. Qualitative data analysis. We will conduct ongoing saturation analyses, based on iterative coding during data collection. Transcriptions will be checked for accuracy and uploaded into Dedoose qualitative analysis software. We will also enter all observational notes as memos. Data analysis will be iterative, and include both deductive and inductive approaches to thematic analysis. Deductive analysis will engage topics from our instruments in interpreting and organising data and we will use the Theoretical Domains Framework (TDF) for mapping and reporting implementation-related themes. The TDF is used extensively in implementation science, and is valuable in identifying barriers and facilitators to intervention implementation across 14 domains relevant to behaviour change.[22] To ensure accurate interpretation, we will conduct independent reviews of transcripts to contribute to the study's overarching thematic framework for data interpretation. The investigators will compare frameworks for consistency and discrepancies. Data will be re-examined, allowing for discussion and making interconnections between research questions, coding categories, and raw data. Data integration: Analysis of data from this multi-method aim will require integration of multiple data sources. We will follow a triangulation protocol, ensuring systematic integration of data analysis, examining and responding to completeness, convergence, dissonance and silence across findings.[23–25] Qualitative findings will be compared with quantitative findings from descriptive analysis, aiming to identify inferences or draw conclusions at the point of interpretation, and at the point of reporting in a synthesis or discussion section of our publications.[26]

Expected outcomes. Findings from Aim 4 will advance our understanding of how the Coach Mpilo intervention is adopted, delivered, adapted and sustained in this new study setting and context. Evaluating feasibility, acceptability and fidelity will improve our ability to interpret whether results reflect the effectiveness of the Coach Mpilo intervention itself as well as whether

and how changes in delivery influence these outcomes, to guide improvements, scale-up, and policy decisions.

Quality assurance: We will monitor depth of discussions and observational memos through immediate review of interview materials, and if necessary, refine probes and guidance in our instruments, and conduct additional interviewer and/or observer training.

ETHICAL CONSIDERATIONS

Ethical review

This study will be conducted in compliance with the protocol, applicable regulatory requirements (including POPIA), and ethical guidelines for research with human subjects in South Africa. Ethical oversight will be provided by the University of the Witwatersrand HREC (Medical), University of Cape Town HREC, and University of Pennsylvania IRB.

The protocol, information sheets, other requested documents, and any subsequent modifications will be reviewed and approved by the University of Witwatersrand, University of Cape Town, and University of Pennsylvania institutional review boards (IRBs) prior to starting this study. Subsequent to initial review and approval, the study team will submit progress reports as requested or required by the various IRBs.

All study staff will be trained in human subject's protection and study procedures to ensure that they understand both research confidentiality requirements and study confidentiality procedures.

Informed consent

Written informed consent will be required from all participants. As part of the informed consent process, potential participants will be given two copies of the Informed Consent Form, and a trained interviewer will review this document with them. It will contain: (1) the purpose and methods of the study, (2) alternatives to participation in the study, (3) procedures to protect confidentiality, (4) their rights to withdraw from the study at any time, (5) the fact that their non-participation will not have adverse effects, and (5) persons to contact if they have any questions about the study.

After reviewing the information, the study interviewer will ask follow-up questions to ensure that the informed consent process has been well understood by the potential participant and then ask her to sign the study copy of the written informed consent form (Appendix A). The signed copy will be retained for the study records, and the participant will be allowed to take the other copy, which can also be signed if they choose. In addition, a separate written informed consent process is in place for participants taking part in the in-depth interviews, which includes explicit consent for audio recording. The corresponding consent form is provided in Appendix H.

Study benefits

By taking part in this study, participants will not receive any direct benefits, aside from what is outlined in the study compensation section below. However, participation in this research could benefit the community as a whole. In this research we will evaluate an intervention to improve reengagement and retention in HIV care, which may in turn increase the health and well-being of people living with HIV and their families. This study will also potentially advance the science of peer-led programmes to improve health outcomes (HIV-related and beyond [e.g. Tuberculosis]).

Risks

This study poses low risk to participants. Participants will be offered the support of a Coach for 6-months. An information sheet provided to participants will make it clear that accepting or not accepting the offer of a Coach will in no way impact the care they receive in the public or private health care system. See Appendix A for an example of the information sheet on Coach Mpilo that participants will be provided.

There is always the possibility of a breach of confidentiality when conducting research. While this is acknowledged, there is very low likelihood because of the precautions that will be taken to protect confidentiality. If, however, confidentiality was breached it is possible that the data on the participant's HIV status and sexual history becomes public. For the participant this may result in stigmatisation and discrimination. To ensure participants confidentiality we will (1) ensure that the only study document that will contain an identifier is the written informed consent form, and this will be kept separate from other study data; (2) all data will be kept strictly confidential. All data files will be stored on password protected servers and devices that meet the requirements of local and international IRBs for secure data storage.

Participants have the option to withdraw from the study at any point should they feel uncomfortable or no longer be interested or willing to continue.

Study compensation

Participants will be reimbursed for their time and travel costs at minimum ZAR250 (~USD14.80) in grocery vouchers for study participation or in person visits. These grocery vouchers will be generated electronically and shared with the participant using only their cellphone number. This amount fairly compensates participants for their time and convenience; participants will not incur any study-related travel costs.

Safety and adverse events

There is the possibility that questions in the baseline survey asked to assess mental health may either give rise to some discomfort among participants or result in participants disclosing acute problems being experienced by themselves. To minimise risk and support participants should a case arise, study staff will be carefully trained on the standard operating procedure (SOP) for assessing and managing psychological risk. This is found in Appendix G. In addition, a referral form is available to facilitate appropriate psychosocial support for participants who request or

are identified as needing additional assistance (See Appendix I). Besides this risk, there are no other known safety or adverse events anticipated for participation in this study.

Privacy and confidentiality

The surveys will be conducted on handheld devices using survey software SurveyCTO and the SurveyCTO Collect application hosted by the University of Cape Town server. The devices will be encrypted and password protected so that, in the event of theft or loss, the information stored on these devices will not be accessible. Raw data will be loaded onto a secure SurveyCTO server via the cellular network. The data will be encrypted and only accessible by the research team. This study ensures all parties adhere to the Protection of Personal Information Act (POPIA). The data collected will be anonymous and a study ID will be assigned to participants.

Confidentiality measures will apply to all aspects of the study process from the time of first engaging with a participant at recruitment through to the data collection procedures. All study-related information will be stored securely. All paper-based participant information that includes any personal identifying information will be stored in locked file cabinets in areas with access control. Forms will be identified by a unique identification number to maintain participant confidentiality. All electronic databases will be secured with password-protected access systems. All folders will be encrypted using Cryptomator. Identifiers will be separated from the data that will be used for analysis and a key will be stored separate from the files for analysis. This key will be retained until the study results are finalized, at which point it will be destroyed. Participant study information will not be released without their written permission, except as necessary for monitoring by funders or local government authorities.

Study administration and data management

Study implementation will be directed by this protocol as well as study-specific procedures. Standard operating procedures will outline more detailed procedures for conducting this study. Regular meetings/teleconferences with investigators will occur to review study progress with corrective feedback supplied as necessary to implement the protocol.

This study ensures all parties adhere to the Protection of Private Information Act (POPIA). The study databases resulting from data collection will not contain identifying information and will be organised by assigned unique identifiers. All database files will also be password-protected, and only study staff will have access to the files. The study team based in South Africa and those outside of South Africa will be given access to the de-identified data through a Secure File Transfer Protocol (SFTP) link. All data will be managed by J-PAL's data management system.

All data will be captured and stored electronically through SurveyCTO which holds high data security features necessary for academic research. The electronic study records will be kept for ten years after study completion before destroying them.

Study monitoring

The study will be monitored by investigators and study managers from J-PAL, with additional support provided by collaborators from the University of Pennsylvania, and The University of The Witwatersrand. The study sponsor, The Fund for Innovation in Development (FID) will conduct auditing of study activities on an annual basis to ensure the scientific integrity of the study and to ensure the rights and protection of study participants. Monitoring and auditing activities may be conducted by:

- Staff (“internal”)
- Authorised representatives of the University of Pennsylvania, University of Cape Town and The University of The Witwatersrand

Participants will complete the study survey on SurveyCTO, which is an online database. There will be no paper based records. All data will be captured and stored electronically on SurveyCTO which holds high data security features necessary for academic research. The electronic study records will be kept for ten years after study completion before destroying them.

Vulnerable populations

We will enroll men living with HIV of consenting age (18 years and older). Participation will occur with full informed consent, confidentiality safeguards, and in collaboration with trusted community and health partners to minimize potential risk and ensure respect for participants’ dignity and autonomy.

Participant withdrawal

Participants can withdraw from the study at any point should they feel uncomfortable or no longer be interested or willing to continue.

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Appendix

Consent Form

Study title: The Coach Mpilo Study: evaluation of a peer-led intervention to promote engagement in HIV care for men living with HIV in South Africa
Principal Investigators: Dr. Brendan Maughan-Brown, Dr. Harsha Thirumurthy

Overview
Thank you for completing the first part of the screening process. I would now like to tell you more about the study we are running. If there are words or information that you do not understand or if you have any questions about this study please feel free to ask your questions at any time. It is important you fully understand this information and can make an informed choice about being in this study.

Why are we doing this research study?
This study is about HIV treatment (antiretrovirals or ARVs) in South Africa. This study wants to find ways to help more men with HIV restart treatment and continue taking it.
The goal of this study is to test a peer mentor program called Coach Mpilo. This program is designed to help men living with HIV who have stopped treatment to start again and keep going with their medication.

What happens in this research study?
This study is happening in KwaZulu-Natal. We are asking about 800 men to participate in this study. To join the study you must be over 18 years old, living with HIV, and not currently taking ARVs, the HIV medication.

If you agree to participate in this study you will be asked to answer questions in a survey. The surveys ask questions about you, your health, your knowledge about HIV, your experience with HIV treatment, and your thoughts about HIV treatment. This should take about 30-45 minutes to complete. As part of the study, we will also ask your permission to contact you over the phone or by SMS to either conduct an interview, send you a link to complete a survey on your phone, or invite you to meet with us in person to complete a follow-up survey. This follow-up survey will be shorter than the first survey and will include similar questions.

Some participants in the study will be randomly chosen to participate in the Coach Mpilo program. Those who are randomly chosen will be offered a peer mentor who can offer advice and support in accessing HIV treatment, taking medication and overcoming challenges living with HIV. The peer mentor will be a man living with HIV and taking ARVs. Those who are not randomly chosen to participate in the Coach Mpilo program will not be given a mentor, but will still be able to access the same clinic services and receive HIV treatment from their local clinic. The process of randomly choosing who will be given a mentor is done by a computer and is the same as drawing names out of a hat. This is done so that it is fair and everyone has the same chance of being chosen.

Why do we need information from your medical records?
We are also asking for your permission to link the information that you give us during the study with your clinic medical records over the course of this study. This will allow us to monitor your HIV treatment over time. To make this link, we will ask you your name and information needed to find your individual medical record. After we have linked your clinic records to the information we have collected we will make sure we remove your name or any other information that could identify you to protect your privacy. It will not be possible to identify you or any other individual patient from the information that is presented or reported from this study. If you do not wish to give us permission to link this questionnaire with your clinic records, you will not be able to participate in this study, but this will not affect any health care or services that you can access from the clinics.

Are there risks or discomforts from participating?
The main risk to participating in this study is the small risk of loss of confidentiality, meaning that your name and research study information may become known. However, the study team will take every measure to ensure that this does not happen, and will not tell or show anyone what you have said. Your name and other identifying information will be used only to find your clinic records, and not for any other purpose.

The other risk of this study is that some of the questions you are asked may make you feel uncomfortable or emotionally distressed. The study staff will make every effort to reduce your distress. You do not have to respond to any question unless you feel comfortable doing so. You can stop at any time if you prefer not to finish the questionnaire, and you can withdraw from the study at any time. If you become very distressed or uncomfortable during the interview, we will connect you with people who are trained to handle these types of issues.

Are there potential benefits from participating?
You will receive no direct benefit from taking part in this study. However, the information that you provide may help us to understand ways to improve healthcare services in South Africa and how to support patients in accessing HIV treatment. This means that your participation in the study may benefit your community as a whole.

What other choices do I have?
Your alternative is not to participate in this study. You will still be able to access HIV treatment from any clinic if you are not a part of the study.

Are there any costs or payments to me?
There are no costs to participate in the study. HIV treatment is free at your local clinic and available outside of participating in the study. After completing the study interview you will receive a grocery voucher valued at R250, to thank you for your time and effort in participating in the study.

How will my information be protected?
The information that we collect from this research project will be kept private. If you agree to

join the study, we will assign you a study number to use instead of your name so that we can protect your privacy. Your name and other identifying information is kept separately and securely from the other information collected. This means it will not be possible to identify you in any of the information released as part of this study.

We will keep your information safe. Paper files will be locked away, and electronic files will be protected with passwords and encryption. We will do our best to make sure your information stays private and secure.

Participant's rights
By consenting to be in this study, you do not give up any of your legal rights. Giving consent means that you have heard or read the information about this study; that you agree to participate; and that you give permission for us to access your clinic records over the course of this study (from the date that you sign this consent). You will be given a copy of this form and the signed consent form to keep if you wish.

Taking part in this study is voluntary. You can choose not to take part in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. If you decide not to take part or leave this study at any time, you will not suffer any penalty or lose any benefits to which you are entitled and it will not affect your care at any clinic in any way.

The researchers may decide to stop your participation in the study without your permission because they may decide that staying in the study will be bad for you, or the sponsor may stop the study.

Ethics Approval
This study protocol has been submitted to the University of Cape Town and the University of the Witwatersrand, Human Research Ethics Committee (HREC) and written approval has been granted by those committees. The study has been structured in accordance with the Declaration of Helsinki (last updated: October 2024), which deals with the recommendations guiding doctors in biomedical research involving human participants. A copy of each guideline may be obtained from me should you wish to review it.

Who can I talk to if I have questions?
If you have questions about the study you can ask them now. If you join the study, you can contact the researcher listed below if you have any questions.
[include researcher details]

CONSENT

Do you have any questions about the information provided in the information sheet? If you do, please discuss these with your interviewer before you sign this consent form.

If you do not have any more questions and agree to participate in the study, please sign this form stating that I have informed you of your rights as a participant and that you have agreed to participate in the research. By consenting to participate in this study you do not give up any of your legal rights. A copy of this form and the information sheet will be made available for you to keep if you wish. We thank you for your time.

[PARTICIPANT] I have read the information in the information sheet for this study (or it has been read to me). All my questions about my participation in the study have been answered. I freely consent to be in this research study.

Participant Name (Please print) Participant Signature/FingerprintDate (DD/MM/YYYY)/Time

_____ _____ _____

Interviewer Name (Please print) Interviewer Signature Date (DD/MM/YYYY)/Time

_____ _____ _____

Study copy	
Participant copy	
Ethics Reference No	