Corrections2Community:

Post-Release Retention in HIV Care for Ex-Inmates in South Africa

Short title: Corrections2Community

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Implementing Partner: The Aurum Institute, South Africa

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STUDY SUMMARY

Background: This is a pilot randomized clinical trial (RCT) study to demonstrate the feasibility and acceptability of a transition in care strategy to improve retention in HIV care and antiretroviral therapy (ART) adherence for ex-inmates in South Africa. Our prior studies have identified the need for a retention in care strategy by documenting the substantial attrition in HIV care following release from corrections to the community. Our approach is informed by a conceptual model of key barriers to the care transition developed from our prior work along with a behavioral explanatory model, the Behavioral Model for Vulnerable Populations.
The overarching goal of this study is to tailor and pilot a transition community adherence club (TCAC) strategy for HIV-positive individuals transitioning from correctional to community settings in South Africa. CACs represent an accepted HIV care delivery approach that is currently available to "stable" HIV patients in South Africa. CACs provide medication refills, a brief health screen, and health discussions in a group setting. Observational studies have found that CACs are more acceptable, lead to fewer missed visits and shorter visit times without queueing, and increase engagement in care. Improving engagement in care for HIV-positive ex-inmates could have an important impact on the HIV epidemic in South Africa, a country with the 11th highest global corrections population and an estimated HIV prevalence of 23% in corrections settings.

Aims: The aims of the study are to pilot a randomized clinical trial of a transition community adherence club (TCAC) versus traditional care to study feasibility, acceptability, and preliminary effectiveness using mixed methods.

Methods: This project is a pilot randomized clinical trial (RCT) to refine and test the feasibility, acceptability, and preliminary effectiveness of the TCAC. At the conclusion of the R34 grant period we will have a protocol and procedural manual ready for a full RCT powered for effectiveness.

Significance: The proposed study is consistent with NIH HIV/AIDS highest priority research and the South African National Strategic Plan on HIV, TB, and STIs 2017-2022. The research addresses the HIV/AIDS Research Priority of "retention and engagement in these services, and achievement and maintenance of optimal prevention and treatment responses." It also addresses "health disparities" through a focus on recently released inmates, a marginalized population. The proposal also fits with the South African National Strategic Plan prioritizing inmates as a key population for HIV services.

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Glossary of Terms

AIDS	Acquired Immuno-deficiency Syndrome
ART	Antiretroviral Therapy
CAC	Community Adherence Club
CAU	Care as Usual
CBO	Community Based Organization
CCD	Community Corrections Department
CCMDD	Central Chronic Medicine Dispensing and Distribution (system or service)
CRF	Case Report Form
DCS	Department of Correctional Services
DOH	South African Department of Health
HIV	Human Immunodeficiency Virus
LTFU	loss to follow up
NIH	National Institutes of Health
PHC	Primary Health Clinic
PIS	Participant Information Sheet
RCT	Randomized Clinical Trial
SA	South Africa
STI	Sexually Transmitted Illnesses
TB	Tuberculosis
TCAC	Transition Community Adherence Club

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1 INTRODUCTION

1.1 Background

HIV care in corrections: Inmates in most of the 240 correctional facilities in South Africa have on-site access to HIV care provided by the Department of Correctional Services (DCS). Voluntary HIV testing is provided at facility entry, routinely during testing 'campaigns,' and in the corrections clinics. In addition, as per South Africa HIV treatment guidelines (2016), all inmates living with HIV were eligible for ART regardless of CD4 count.[1] Within the correctional facilities, care engagement and adherence to medication are supported by inmate peer educators and inmate support groups. At the time of release from corrections, inmates are provided a referral letter that briefly summarizes their HIV care history and current medications. Inmates are released with between 15 and 90 days (median 30 days) supply of ART (Hoffmann unpublished data).

Barriers to the transition from corrections to community care: Post-release, ex-inmates are expected to use the referral letter to establish care with Department of Health (DoH) clinics. It is the responsibility of the ex-inmate to identify the clinic and the appropriate days to go, and to advocate for his or her care. There is no active follow-up provided by DCS or DoH to confirm a successful transition, nor is there specific coordination between the DCS and the DoH regarding the release of ex-inmates receiving HIV care. Because of the absence of formal communication between the DCS and the DoH there is no documentation of the transition of care from corrections to community care to inform patient care, care continuum indicators, or quality improvement. The impressive HIV care outcomes observed in correctional settings in South Africa drop off dramatically following release from corrections. Ex-inmates living with HIV encounter unique care transition challenges across the socio-ecological framework. Qualitative and quantitative research conducted by the PI (Hoffmann) and co-I (Charalambous) with 492 ex-inmates in South Africa, identified several important themes related to the transition in care among ex-inmates. These include the clinic experience, social capital, stigma, substance use (11% of participants with identified drug use), re-incarceration, and economic insecurity. Depression also affects the transition from corrections to community care in the United States, but has not been evaluated in this context in South Africa.[16-23] Substance use is another barrier to the care transition. Substance use itself interferes with care seeking due to increased impulsivity as well as diminished social capital.[24-26] As a result of these barriers, at 6-months following release, only 44% had continuity in antiretroviral therapy (Hoffmann unpublished data).

Barriers to care engagement in the general population in Africa: Experience with the general population living with HIV provides additional insight regarding potential barriers for ex-inmates. On the individual level of the socio-ecological model, knowledge of HIV, self-efficacy, fatalism,

and depression are all positively or negatively associated with care engagement.[27-29] On the interpersonal level, a network of supportive ties can assist with material and psychosocial support and provide encouragement to attend clinic, leading to increased engagement in care.[30-34] This type of supportive network can be characterized as individual (or micro) bonding social capital.[35-37] On the community level, enacted stigma is also associated with lower linkage to care and ART uptake.[38-40] On the clinic level[41] clinic enacted stigma compromises retention in care because people tend to avoid places associated with stigmatization. The combination of HIV stigma and ex-inmate stigma may be especially challenging for men who were diagnosed with HIV during incarceration and return from corrections marked by both stigmas. Stigmatization appears to be especially insidious in regard to the care continuum when it occurs at the clinic where the negative effect on engagement in care is stronger than from stigma experienced in the community or family.[42,43] Additional clinic level factors that are barriers include long waiting times, frequent visits, and the need to start queuing early in the morning.[31,42,44,45]

Transitional Community Adherence Clubs: During follow-up focus groups with these ex-inmates , several solutions were suggested to facilitate the transition from corrections to community care including non-stigmatizing support groups or community adherence clubs (CACs) composed of individuals with similar experiences, assistance with locating skills training or starting a job search, and more efficient and non-stigmatizing care. CACs represent an accepted HIV care delivery approach that is currently available to "stable" HIV patients in South Africa. Community adherence clubs provide medication refills, a brief health screen, and health discussions in a group setting. Observational studies have found that CACs are more acceptable, lead to fewer missed visits and shorter visit times without queueing, and increase engagement in care.[2-4] A tailored CAC for ex-inmates transitioning in care, here termed a transition community adherence club (TCAC), has the potential to simultaneously address multiple barriers at the individual, interpersonal, and care delivery levels.

1.2 Study objectives

The overarching goal of this study is to tailor and pilot a transition community adherence club (TCAC) strategy for HIV-positive individuals transitioning from correctional to community settings in South Africa. The current proposal will allow for developing and piloting of the TCAC strategy to assess the feasibility for a fully powered effectiveness randomized clinical trial (RCT) comparing the TCAC to traditional care with a primary outcome of being in care with an undetectable viral load six months after release.

The primary objectives of this study are:

1. To assess the feasibility of implementing TCACs and of endpoint ascertainment

2. To assess the effectiveness of TCACs compared to care as usual by the differences in proportions of self-reported care at six months following corrections release.
3. To assess the acceptability of TCACs to ex-inmate participants and to implementing staff

The secondary objectives of this study are:

1. To assess the effectiveness of TCACs compared to care as usual with regards to:
   - Verified in care at six months
   - Time to linkage to care
   - Linkage to care within 90 days of corrections release
   - HIV RNA <400 c/mL at six months
   - Social capital score change
   - Stigma index score change
   - Employment or self-employment

1.3 Significance

This study fits with the South African National Strategic Plan prioritizing inmates as a key population for HIV services, particularly the priority of care continuity for this population. The study is also. is consistent with NIH HIV/AIDS highest priority research and the South African National Strategic Plan on HIV, TB, and STIs 2017-2022. The research addresses the HIV/AIDS Research Priority of "retention and engagement in these services, and achievement and maintenance of optimal prevention and treatment responses." It also addresses "health disparities" through a focus on recently released inmates, a marginalized population.

2 METHODS

2.1 Study design

This is a pilot randomized clinical trial (RCT) to refine and test the feasibility, acceptability, and preliminary effectiveness of TCACs.

2.2 Study setting

This pilot operational research study will be conducted in Gauteng Province. Recruitment will occur within correctional facilities of the Department of Correctional Services (DCS) (expected Kgosi Mampuru II and Modderbee). The activities within the correctional facilities and in the Districts will build on ongoing Aurum Institute service delivery and research projects.
All study interventions will occur following release in either Ekurhuleni District, Tshwane District or Johannesburg District.

2.2.1 Correctional Facilities

Kgosi Mampuru II Correctional Centre is sub-divided into 4 centres namely: awaiting trial offenders sentenced male offenders, sentenced female offenders, and a maximum security centre. The Correctional Facility has a population of approximately 8,900 offenders. Modderbee Correctional Centre is sub-divided into 3 centres namely: awaiting trial offenders, medium security centre and a maximum security centre. The correctional facility has an estimated population of 6460 offenders. It also has two satellite centres (Devon and Nigel Correctional Centres) that accommodate inmates who are about to be released and those who have short to mid-term sentences, respectively. In all the selected study facilities, each centre has its own primary health clinic (PHC) which provides TB treatment services, and in addition, different sections share one main hospital in which the ART clinic is located and where ART patients receive care. Offenders from each section are allocated a specific day in the week to attend the ART clinic in an effort to avoid mixing of offenders from different centres.

2.2.2 Description of the geographical areas of study implementation

Ekurhuleni District: This is one of the 6 districts of Gauteng province of South Africa and the fourth largest Metropolitan municipality in South Africa. The district had an approximate population of 2.8 million people (City of Ekurhuleni Annual Report 2010-2011). In the last HIV antenatal survey conducted in 2010, Ekurhuleni had the highest HIV prevalence in the province (34.0%) compared to other districts (Department of Health, 2010).

Tshwane District: This is one of the 6 districts of Gauteng province of South Africa and includes Pretoria. The total population of Tshwane is 2.9 million people.

Johannesburg District: This is one of the 6 districts of Gauteng province of South Africa. The total population is 4.4 million and total area is 1,645 km^2.

2.2.3 Rationale for selecting geographical areas of study implementation

We selected the correctional facilities based on a long-standing working relationship between the PI, Aurum Institute, and these facilities. This has included a prior study of linkage to care following corrections release and health systems strengthening work. The districts have been selected because they are the three districts to which the majority of inmates from these correctional centers are released to.

2.3 Study Population

The population is comprised of adult (≥18 years old) corrections inmates, either male or female, with known HIV infection and are receiving ART within the correctional facility and are expected to be released back into the community within 3 months of study enrollment.

2.3.1 Inclusion criteria

- Currently incarcerated (either an offender (sentenced inmates) or awaiting trial inmate (un-sentenced)
- Housed at Modderbee or Kgosi Mampuru II Correctional Centres (including participating satellite centres)
- Diagnosed with HIV
- Currently receiving ART
- Anticipated release or trial date within 3 months of study enrollment
- Self-report expected to reside within Ekurhuleni ,Tshwane, or Johannesburg districts of Gauteng Province and within proximity to one of the TCAC sites (within 20km, 45 minute travel time, or two local taxi minibus rides)
- Agree to post-discharge follow-up
- Medically stable based on DCS health assessment
- On ART for >3 months at the expected time of corrections release

2.3.2 Exclusion criteria

- <18 years of age
- Failure to provide informed consent to be followed up by study staff after release

2.4 Sampling scheme

2.4.1 Participant recruitment and informed consent

In liaison with DCS health staff, study staff will develop a line list of offenders on ART which will be updated regularly to identify potentially eligible and newly enrolled offenders initiated on ART. Individuals referred by DCS staff to the study team will be provided a brief description of the study in the correctional facility clinic. For those still interested in learning more, the study team member will proceed with the informed consent process including describing inclusion and exclusion criteria; post-release follow-up procedures including telephonic or home contact, clinical record review, and blood draw for viral load ascertainment at 6 months; the two study arms; and the randomization procedure. Consecutive offenders from the study sites who meet inclusion criteria and agree to be part of the study will be asked to provide written informed consent. Within the correctional facility, all the offenders who meet the inclusion criteria will be

invited to participate (Appendix A: EL001 Screening, eligibility and Enrolment). This process will take place between 1 week and 3 months prior to release.

2.4.2 Randomization

We will perform individual randomization blocked by correctional facility. Study staff will open numbered envelopes with the allocation following enrollment. Participants will be randomized 1:2 to either the standard of care or the TCAC using sequential envelopes with study arm determination sealed inside (blocked by study site and based on random number generation). Participants and members of the research team recruiting and implementing the strategy will be unmasked to randomization assignment due to the behavioral nature of the strategy and need for team members to explain the study arm procedures to participants. Study assignments will be masked to staff performing outcome assessments and the investigators until all outcome data have been collected.

2.5 Pre-release study procedures

All participants will have a baseline demographic, health, and incarceration history questionnaire. In addition the ASSIST substance use tool, social capital questionnaire, and stigma index will be used with all participants. Participants will have a second pre-release contact with study staff if release is more than one week from enrollment. The purpose of this visit will be to review the study, the allocation arm, and to encourage linking to care following release.

2.5.1 Care-as-usual (CAU) study arm

Participants will have a pre-release session with a study team member. The goal of the session is to review study procedures, review contact from the study team or contacting the study team following release, update any changes in contact information, and to encourage post-release linkage to care. This session will occur 1 – 2 weeks prior to release. Per DCS routine, at release, participants will receive a referral letter form the DCS health services and will be dispensed ART (the duration ranges from 30-90 days and is determined by the DCS staff) prior to release.

2.5.2 TCAC study arm

Participants will have a pre-release session with a study team member. The goal of the session is to review contact from the study team or contacting the study team following release, update any changes in contact information, and to encourage post-release linkage to care. In addition, participants will be reminded of the location and timing of the TCAC session that they have been assigned to and will be provided a contact number for a TCAC facilitator. At release the TCAC arm will also receive a referral letter describing ART regimen and a supply of ART (per DCS routine).

2.6 Verification of release

Study staff will work with DCS health and security officials to, (1) verify whether participants have been released based on the release dates provided at study enrollment, and (2) identify inmates released without study staff knowledge.

2.7 Post release follow-up

The tracing of participants will primarily be based on the tracing plan developed with the participant during the in-correctional facility contact sessions (Appendix A: AD001 Locator and Tracing Plan). The tracing plan will contain information on alternative addresses at which the participant anticipates staying after release, if they plan to be at the same address in 3 months and 6 months, names and contacts of next of kin (part of informed consent), telephone numbers, and study staff contact information. After the participant has been released, study staff will also liaise with Community Corrections Department (CCD) staff to obtain extra information on where the participant is actually released to. The following strategies for tracing will be performed:

- Participants will be educated to telephonically contact a study team member within 15 days of release; for which they will receive a small incentive in the range of a ZAR 20 - 50 (US$3-7) airtime vouchers. Offenders will be instructed to send “call-me” messages to an allocated study cell-phone number that the case manager can access and respond to, thereby making the calls free for the ex-offenders.
- In the event that participants fail to initiate contact, study staff will use available contact information from the tracing plan or CCD staff to contact released offenders at the determined follow-up time points.
- If no contact is made via participant or study staff initiation, the case worker will work with CCD staff (who have contact details for all paroled individuals) to contact the released offender.

2.7.1 First post-release contact

The first contact with participants post-release will be conducted during 1-15 days after the participant’s release. The purpose of this visit is to verify if the participant’s contact details provided are still applicable and to find out the geographical area where the participant was released and remind the participant of study procedures. All participants will be reminded about the importance of linking into care. Following the first contact standard *“hello, are you well?”* messages will be sent every 2 weeks to maintain connection with the participant.

2.7.2 Ascertainment of linkage to care

Study staff will contact participants to ascertain care status and update contact information at 30, 90 and 182 days from release. Follow up will primarily be telephonic and will rely on participant self-report. The scheduled visit windows are: Day 30 (from 20-70 days), Day 90 (from 71-150 days), and Day 182 (from 151 – 245). The last contact attempt will be made on Day 246. At the Day 182 visit, participants will be asked for in-person contact that will occur either at research offices or at a site convenient to the participant. This study visit will be used to ascertain visit status, socio-demographic data, and to complete surveys on stigma, social capital, and care satisfaction. In addition, a whole blood sample (8mL) will be obtained for HIV RNA quantification (viral load) if there are no clinic obtained HIV RNA results from within 60 days or 182 days post-release. Refer to schedule of CRFs for data collection tools used at each study visit.

Table 1: Scheduled visit windows

Visit name	Period
Day 30	20 – 70 days
Day 90	71-150 days
Day 182	151 – 245 days
Day 246 (last contact attempt)	246 days

2.7.3 Care verification

Clinical records will be accessed to determine linkage to care status, timing of linkage to care, ART continuation, retention in care, and HIV RNA results. This will be done through reviewing paper clinic charts, electronic clinic data (tier.net), and electronic laboratory data (NHLS Trackcare system). Linkage between participants and records will be based on matching surname, first name, date of birth, sex, and appropriate date range.

2.7.4 Viral loads at 6 months

Participants in the TCAC arm will have 6 month viral loads obtained at the TCAC. Participants in the care as usual (CAU) arm will have a specimen (2mL) drawn at 6 months for viral load assessment.

2.8 TCAC post-release procedures

2.8.1 TCAC post release contact

Post-release, a study team member will make contact with the participant within 1 week to update contact details and to review attendance at TCAC sessions.

2.8.2 TCAC structure

TCACs will provide all the standard services the Department of Health provides for regular community adherence clubs. Similar to community adherence clubs, the TCACs will be affiliated with a clinic and provide visit and medication distribution to the clinic for monitoring and reporting purposes. Routine community adherence club activities include:

- Documentation of visits
- Symptom screen
- Distributing prepacked medications
- Routine laboratory monitoring

TCACs will have a standard structure divided into four parts with each session lasting approximately two hours. Attendance and medication pick-up at the session will be recorded by the facilitator using an electronic attendance log.

2.8.3 TCAC frequency and duration

Unlike standard community adherence clubs, participants will be requested to attend monthly sessions. If a TCAC session is missed, the facilitator will send a text message to ask how he or she is doing and to remind him or her of the TCAC sessions. If a participant misses a TCAC session they will have 1 week to collect the pre-packaged medications at the home clinic (in accordance with standard Community Adherence Club protocols). If the member collects the medications from the clinic he or she can return to the TCAC. If a participant misses TCAC sessions for 2 consecutive months, he or she will be considered out of care and will be referred to the local clinic for medication pick-up and medication evaluation. The TCAC facilitator will be responsible for contacting a participant and letting him or her know the care plan.

2.8.4 TCAC eligibility

All study participants assigned to the TCAC arm will be eligible for the TCAC. This includes individuals who may not meet community adherence club eligibility criteria. The reason for this approach is that, at present, there is low linkage to care from corrections. Furthermore, those individuals with the greatest adherence and clinic attendance challenges are hypothesized to benefit the most from the TCAC interventions. Thus all released inmates who meet the enrollment criteria will be eligible for TCACs – this is a critical component of the study.

2.8.5 TCAC confidentiality

Confidentiality rules will be reviewed for each member at their initial TCAC visit. In addition, each member will be asked to sign a pledge of confidentiality to re-enforce the importance of confidentiality. This approach was used successfully by study team members in prior community adherence club research.

2.8.6 TCAC Facilitation

The TCAC will have two facilitators:

- An ex-inmate peer trained in the TCAC facilitation approach, content, and health evaluation.
- A social worker, trained in the facilitation approach, and health evaluation

2.8.7 TCAC medical support

Phlebotomy will be provided at TCAC sessions for routine laboratory testing as needed by a professional nurse (registered nurse equivalent). For clinic referrals, a standard symptom and vital sign algorithm will be used for care triage [Appendix – Medical Assessment CRF]. Any participant meeting concern for unmanaged acute or chronic illness will be referred to the local clinic and will be assisted to reach the clinic.

2.8.8 TCAC content

A schematic intervention-impact diagram is shown below in Figure 1.

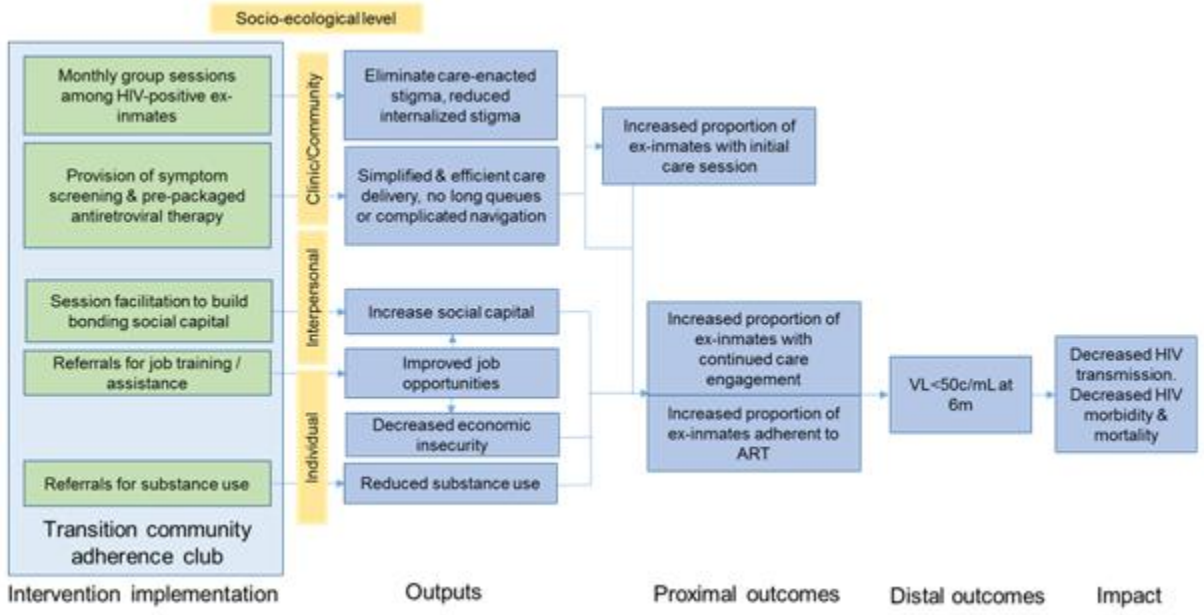

Figure 1: Intervention impact model

Part 1: Group discussion and group cognitive behavioral training.

The first 45-60 minutes will involve facilitated discussions among participants related to issues salient to the group. The facilitation of these sessions will seek to teach cognitive behavioral approaches. These approaches can be applied by a participant toward what is most salient to him or her. This may include managing depression, harm reduction, or medication adherence. The overall method is through group cognitive behavioral therapy.

Each session will include discussion on topics of salience to the group such as substance use, alcohol use, ART adherence, family and community relationships, and employment readiness. Facilitation will seek to have participation and involvement from all group members in sharing experiences, strategies, and resources.

Part 2: Individual symptom screen and medication distribution.

This is expected to take 15-20 minutes. Participants will be called by the facilitators for individual symptom screen and medication distribution (60 day supply as is provided in standard community adherence clubs). Based on the symptom screen, participants may be referred for further evaluation at a local clinic.

Part 3: Snacks/lunch: 15 – 20 minutes

Part 4: Life skills training

This will use a structured curriculum delivered by the facilitators or invited guest speakers. Topics will include: sustainable livelihoods[5,6], with sessions and materials on education/bursaries, finding and maintaining jobs, income generation, and saving and emergency funds; transitional support[7-9], with sessions and materials on transitional needs, transitional planning, and incarceration stigma and disclosure; and HIV care and treatment, with sessions and materials on HIV/AIDS, medication adherence, nutrition, treatment as prevention, and HIV stigma and disclosure. These skills training will partially use material adapted from ongoing routine programs in South Africa (e.g. Stepping Stones).

2.8.9 Schedule of TCAC medical evaluations

In addition to the standard structured group activities, there is a list of individual activities focused on health assessment and ART management and based on duration from release. These components are as follows:

1. First session: Health and ART history review, ASSIST substance use (alcohol and other drugs) screen, PHQ-9 depression screen, social capital, and stigma screens. The results of these tools will be used for guiding referrals and session services. This screening will occur on arrival at the TCAC session.
2. Every session: At every session the following will be performed: symptom screen, weight measurement. An algorithm for action or non-action will be developed. Based on the

algorithm, study staff may collect sputum, or refer participants to a primary care clinic based on the symptom screen and weight.

3. At 6 months: Laboratory assessment with HIV RNA, creatinine, and CD4 count. In addition, starting at 6 months, participants will be evaluated for transition to standard services including community adherence club, community chronic medication distribution, or clinic medication fast lanes.

2.8.10 Ad-hoc participant specific components

- Ad hoc counselling or case management / social work needs
- Care documentation: standard DoH stationary will be used to record TCAC attendance, symptom screen, and medication receipt.
- Missed visits: Any participant not reporting to a session and not collecting medication within 1 week will be reported to the dispensing clinic and will be contacted by the facilitator (either telephonically or with a home visit

2.8.11 TCAC completion & transition to regular differentiated care

At the end of 6 months individuals will be encouraged to join the appropriate DoH differentiated care model. These include standard clinic care, clinic fast lanes, community dispensing of chronic care medications, and standard community adherence clubs. The model will depend on the determination of the clinic.

2.9 Outcomes and Ascertainment

2.9.1 Feasibility of TCACs

The goal of this assessment is both to evaluate the feasibility of implementing the TCAC and of endpoint ascertainment for a larger clinical trial of TCAC implementation.

Specific feasibility considerations are:

1) The proportion of participants who are able to navigate to the TCAC as defined by success with intended first TCAC visit
2) Success of the study team to ascertain six month linkage to care status
3) Ability to use social capital and stigma index tools and assess HIV RNA level at six months.

Success will be based on *a priori* targets of ≥90% of those attempting to attend a TCAC session able to find the location, successful follow-up of ≥75% of participants, and viral load ascertainment for ≥95% of participants in care.

Table 2: Feasibility Indicators

Numerator	Denominator	Measure

Number with first TCAC visit	Total in TCAC arm	Proportion
Number in TCAC arm with visit first to a clinic (not TCAC)	Total in TCAC arm	Proportion
Number in TCAC at 6 months (at least 2 visits)	Number with first TCAC visits	Proportion
Number in TCAC at 6 months	Number in TCAC arm	Proportion
Number with no more than two missed visits in 6 months	Number in TCAC arm	Proportion
Proportion of all participants with successful 6month care ascertainment assessed	All study participants	Proportion
Proportion of all participants with 6 m social capital questionnaire and stigma scale	All study participants	Proportion
Proportion among those in care with 6m VL ascertainment	All study participants	Proportion

2.9.2 Effectiveness of TCACs

Primary outcome: The primary outcome of this assessment is the proportion of participants with self-reported care at 6 months either in TCAC or DoH clinical care. Self-reported care at 6 months will be defined as – having at least two post-release HIV care visits 90 days apart with the last visit between 5 and 7 months from release. We will perform an analysis of retention in care at 6 months among all randomized individuals as an intent to treat analysis.

We will also perform an eligible for 6 month follow-up analysis. This analysis will exclude:

- Not released within 3 months of enrollment
- Re-incarcerated within 6 months of release
- Died within 6 months of release
- Withdrew participation within 6 months of release

Secondary outcomes: We will also evaluate the effectiveness of TCACs compared to care-as-usual for the following secondary outcomes:

1. Verified in care at six months
2. Time to linkage to care
3. Linkage to care within 90 days of corrections release
4. HIV RNA <400 c/mL at 6 months - Viral load data at 6 months will be based on routinely collected viral load data (clinic records and the electronic National Health Laboratory System to determine 6 month viral load outcomes, successfully applied in prior studies) augmented by viral loads obtained by the study when 6 month viral load data are not available.
5. Social capital score change
6. Stigma index score change
7. Employment or self-employment

Table 3: Effectiveness outcomes

Primary outcome	Self-reported in care at six months by arm	Test of proportions (chi-square)
Secondary outcomes	Self-reported linkage to care by 90 days by arm	Test of proportions (chi-square)
	Clinical record verified in care at six months by arm	Test of proportions (chi-square)
	HIV RNA <400c/mL for those in care by arm	Test of proportions (chi-square)
	Social capital score by arm	Test of medians (Wilcoxon rank sum)
	Stigma index score by arm	Test of medians (Wilcoxon rank sum)
	Employed or self-employed by arm	Test of proportions (chi-square)

2.9.3 Acceptability

Participant in-depth interviews: We will interview up to 36 participants recruited through a purposive sampling strategy to obtain a maximum variation sample by strategy arm, transition in care status, timing of ART initiation, and age group. In-depth interviews will be conducted by trained experienced research assistants in the participant's preferred language (e.g., Sepedi, isiZulu, isiXhosa, and Sesotho). Interviews will explore:

- Perceptions of the care model they were assigned to
- Interactions with other patients (either at a TCAC or traditional care)
- Family and relationship status, housing stability, and sources of support (financial, social, emotional)
- Experiences with HIV and other (non-HIV and non-allopathic) service providers, including perceived or experienced stigma related to their HIV or ex-inmate status, and v) ideas about what services they still need.

Staff and TCAC facilitator in-depth interviews: We will interview approximately 12 staff members involved in TCAC referral, implementation, or coordination (sample size based on the anticipated number of individuals to have substantial involvement in transition in care in facilities and the community). Interviews will explore: i) Comfort with referring to TCAC and ii) adaptability of TCAC to routine operations.

3 Drugs/substances/devices

Study participants will receive standard-of-care (SOC) ARV (anti-retroviral) drugs to treat HIV infection that will be dispensed at the DoH primary care clinics or pre-packed by Department of Health primary care clinics.

4 Study statistics

4.1 Sample size

As a study of feasibility and acceptability we have selected a sample size that, based on prior experience, can easily be recruited within 6 months. From the most recent prior work, we recruited approximately 35 inmates per month (approximately 2% declined participation). Over a 6 month period this would result in 210 *released* inmates. To be conservative, we will seek to recruit only 50% of the recruitment rate of the prior study, representing a total of 60 participants into the standard of care and 120 in the TCAC arm. We will continue recruiting until we have reached 180 released inmates.

Table 4 : Sample size for TCAC evaluation

Arm	Sample size
Care as usual	60
TCAC	120

Recruiting 120 in the TCAC arm will provide four TCACs with 12-20 participants each (assuming 40 to 66% successful transition in care to TCACs among participants in that arm). The 1:2 enrollment provides a greater population in the TCAC arm for assessing acceptability. This sample size has an 80% power with an alpha of 0.05 to identify an approximate difference in proportion meeting the primary outcome (in care with an undetectable viral load at 6 months) of 0.24 (e.g. 0.25 versus 0.49 meeting the primary outcome) assuming successful outcome ascertainment for 78% of participants (our success in a prior study) (Figure 2). We note that this is not an effectiveness study and we present these calculations purely to illustrate the power.

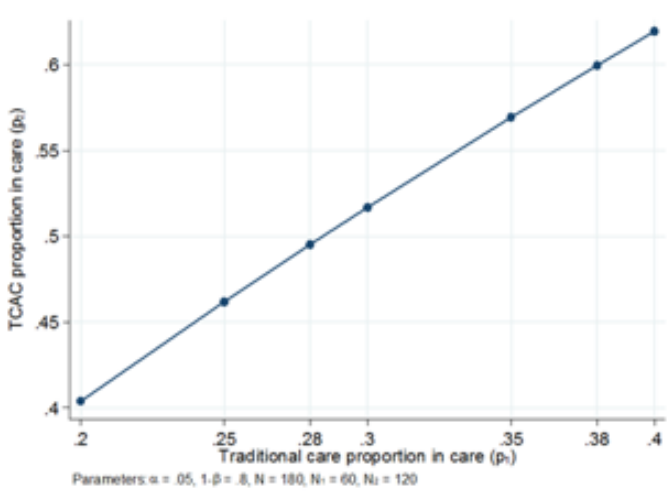

Figure 2: Proportions in care in CAU and TCAC that study is powered to detect with alpha of 0.05

4.2 Analysis

4.2.1 Feasibility

Success will be based on *a priori* targets of ≥90% of those attempting to attend a TCAC session able to find the location, successful follow-up of ≥75% of participants (based on the challenging nature of follow-up of this population our prior work with 75% follow-up), and viral load ascertainment for ≥95% of participants in care.

4.2.2 Effectiveness

Effectiveness will be based on intention to treat comparing CAU and intervention group outcomes using assessed using mixed effects logistic regression with correctional facility included as a mixed effect.

4.2.3 Acceptability

All audio-recorded interviews will be transcribed and translated into English (as necessary). Transcripts will be uploaded into MAXQDA software for coding and analysis. All documents will first be coded by participant stratification (engaged vs. not engaged in care) and personal characteristics to allow for a search of documents and comparisons that explore differences among participants, regional patterns, and clinic specific characteristics. This will be followed by inductive and deductive coding based on a coding guide that reflects key analytic concepts, including stigma, social capital, and access to health care.
Qualitative analysis will proceed by first listing variations in care experiences among study participants, and then explore similarities and differences in these experiences between

different types of patients. Particular attention will be paid to how participants in the TCAC arm talk about HIV care, stigma management, and the role of the TCAC in addressing these issues. Qualitative analysis will then explore the positive and negative experiences with health care providers; who they identify as trustworthy; and how they describe the role of family, friends, community members, and health care providers in supporting or impeding their efforts to access health care. Analysis will also assess whether participants have unmet needs and barriers to services, including level of comfort receiving services in different settings, experience navigating health and social service bureaucracies, instances of failure to follow up with care, and continuing unmet needs.

5 Data Management

Data will be collected to review study associated outcomes in order to evaluate the extent to which the case management goals and objectives are being met. To achieve this, data will be collected in the pre- and intervention study periods. In addition to this, data will also be collected to assess actual programme performance against planned activities.

5.1 Data collection tools

Table 5: List of data collection tools and intended use

Name of tool	Purpose	Schedule	Study arm
Visit Contact Documentation (AD001)	To collect and track information on all study contacts made with the participant during scheduled visit windows.	Pre-release Post-release	CAU TCAC
Pre-release locator Form (AD002)	To collect the participant's personal information important for identifying and contacting the participant for follow up after release.	Pre-release	CAU TCAC
Release Verification (AD003)	To verify participant release from the correctional facility and collect information of the documented date of release.	Post-release	CAU TCAC
Post-release locator Form (AD004)	To collect the participant's personal information important for identifying and contacting the participant for follow up after release.	Pre-release	CAU TCAC
Off Study (AD005)	To document discontinued participation in the study due to withdrawal, loss to follow up or end of the study procedures.	Pre-release Post-release	CAU TCAC
Screening, Eligibility & Enrolment (EL001)	To collect screen participant for eligibility, and collect enrolment information.	Pre-release	CAU TCAC

Baseline Demographics (DM001)	To collect participant demographic information at the time of enrolment	Pre-release	CAU TCAC
Demographics Follow-Up (DM002)	To update participant demographic information (where necessary) after correctional facility release.	Post-release	CAU TCAC
Pre-release Assessment (RK001)	To collect information on health and ART history, ASSIST substance use (alcohol and other drugs) screen, PHQ-9 depression screen, social capital, and stigma screens)	Pre-release	CAU TCAC
Post-release Assessment (RK002)	To collect information on health and ART history, ASSIST substance use (alcohol and other drugs) screen, PHQ-9 depression screen, social capital, and stigma screens)	Post-release	CAU - Day 30 visit TCAC– at first session
Routine Health Screening (RK003)	To closely monitor participant health status in order to guide referrals and session services following established study algorithms (includes symptom screen, and weight measurements).	Post-release	TCAC
Health Seeking (SS001)	To collect information on self-reported visits to access medical or non-medical HIV care and treatment services at any time after correctional centre release.	Post-release	CAU TCAC
Clinic Visit (SS002)	To collect details of self-reported participant clinic visits.	Post-release	CAU TCAC
No Clinic Visit (SS003)	To document the reasons for non-entry among participants who self-report that they have not gone to the clinic.	Post-release	CAU TCAC *Self-reporting no clinic visits.*
Post-entry (SS004)	To document information on additional clinic visits made by the participant after initial entry-into-care	Post-release	CAU TCAC *Self-reported clinic visits.*
Case note abstraction pre-release (FV001)	To abstract information on participant health and ART history reviews from correctional facility clinical management records.	Pre-release	CAU TCAC
Case note abstraction post-release (FV002)	To verify self-reported clinic visits or identify unreported clinic visits (among participants that cannot be contacted from electronic health record sources), and abstract information on participant health and clinic management in community clinics.	Pre-release	CAU TCAC

Laboratory Testing (LT001)	To document collection of lab specimens and results for HIV RNA, creatinine and CD4 counts.	Post-release	CAU TCAC
TCAC Transition (TR001)	To document transition of participants out of the TCAC.	Post-release	TCAC

5.2 Schedule of case report forms

Table 6: Schedule of data collection within correctional facility

Case Report Form	Form Code	Visits:	Visit 1 Enrolment	Visit 2 Pre-release
		Visit Code:	01.0	02.0
Screening, Eligibility & Enrolment	EL001		X	
Pre-release assessment	RK001		X	
Baseline Demographics	DM001		X	
Visit Contact Documentation	AD001		X	[X]
Pre-release Locator	AD002		X	
Case Note Abstraction Pre-release	FV001		[X]	[X]

X required CRF, [X] may be required if updated or as necessary

Table 7: Scheduled study visit windows for all participants after release from correctional facility

Case Report Form	Form Code	Visits:	Visit 3 Release	Visit 4 Post-release	Visit 5 Post-release	Visit 6 Post-release	Visit 7[1] Post-release
		Time since release:	0D	30D	900D	182D	90 days from time of entry
		Visit Code:	03.0	04.0	05.0	06.0	07.0
Release verification	AD003		X				
Post-release locator	AD004			[X]	[X]	[X]	
Demographics Follow-Up	DM002			[X]	[X]	[X]	
Health Seeking	SS001			[X]	[X]	[X]	
Clinic Visit	SS002			[X]	[X]	[X]	
HIV/TB Testing	SS003			[X]	[X]	[X]	

No Clinic Visit	SS004			[X]	[X]	[X]	
Post entry into care	SS005						X
Case Note Abstraction Post-release	FV002			[X]	[X]	[X]	[X]
Off Study	AD002			[X]	[X]	[X]	[X]

X required CRF, [X] may be required if updated or as necessary
Visit 7 only occurs if participant had entered into care by Visit 7

Table 8: Scheduled TCAC visits

		Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Routine Health Screening	RK003	X	X	X	X	X	X
TCAC Transition	TR001	[X]	[X]	[X]	[X]	[X]	[X]

X required CRF, [X] may be required if updated or as necessary

5.3 Database management

5.3.1 Structure of the database

This study will rely on two databases. One will be used to capture participant characteristics and outcomes (main database). The other database will be a study administrative database used for monitoring of corrections release and communication with participants following release (administrative database). Main study data will be captured into a secure web based REDCap™ (Research Electronic Data Capture) electronic database. The Redcap database provides; an intuitive interface for validated data entry; audit trails for tracking data manipulation and export procedures; automated export procedures for seamless data downloads to common statistical packages; and procedures for importing data from external sources. The administrative database will be developed within Microsoft Access. This database will have an Access frontend connected to a SQL-based server to allow for simultaneous access and data-entry from multiple sites. We will develop a separate database form within REDCap for each paper case report form (CRF). All fields will have appropriate range-checks for validation during data-entry. Field numbers and names in the database will correspond to numbers and names on the CRF. Trained data capturers or research assistants will manually input all data into the electronic database from the paper CRFs.
Data entry for the release and communication database will be maintained on a daily basis for real-time use of data. On the day of enrolment, the identification and contact details will be entered into the release and communication database. The release database will be updated

within seven days of the participant's expected release using either participant self-reported information or confirmed DCS release dates. Data entry validation and automatic range checks will be incorporated in most data fields to reduce data entry errors. In addition, a data monitor will compare approximately 10% of CRFs with data within the database. This will help to identify systematic errors. Such problems may lead to a review of a larger proportion of CRFs. In addition, bi-weekly electronic checks for inconsistencies within and across forms will be performed followed by CRF review of any data queries that are generated.

5.3.2 Database access

Access to the database (data entry, reporting, and extraction) is controlled by the Data Manager, Study Manager, and the REDCap Database Administrator. Study personnel requiring access to the database must complete required documentation and training prior to receiving the necessary username and password.

5.3.3 Locking of final database

The final study database is locked to changes after the clean file form has been signed. Final storage of the database is with the production folder structure together with all the Metadata, source data and the user written programs and the version of the system used to produce the database. The folder is given a special icon to show it is locked and the available choices are restricted to reading the data.

5.3.4 Data security

All paper study records (e.g. consent forms, screening logs) will be kept in a secure location accessible only to authorized study staff, investigators, and monitors. All CRFs will be identified with study ID numbers and will not contain personnel identifiers.

5.3.5 Study limitations

The proposed implementation research has the following limitations:

- The study depends on contact with incarcerated individuals following release. Such individuals may be more likely to come from unstable living situations and may be highly mobile, making follow up a challenge. However, our experience is that released offenders seek re-integration services and are required to provide accurate contact information for the purposes of compliance with parole. Thus we anticipate tracing a high percentage of released offenders.
- Participant self-report regarding lapses in medications and entry into care may introduce bias as participants may favour the most socially acceptable responses. Verification of self-reported entry-into-care using clinic records will be conducted, where possible, for all participants. Data abstraction forms will be submitted to health staff at the health centres

where participants will report to have linked (refer to out-of-correctional facility clinic data abstraction form).

- Follow up and observation of participants in the pre-intervention period (more frequent than current standard of care) may result in modified or improved participant outcomes because of the fact that they are being studies.
- Pre/post assessments that we intend to apply in this study are susceptible to secular trends and to differences in outcome ascertainment. We believe that secular trends in HIV care both in DCS centers and in the public sector will be minimal in terms of HIV care in correctional centers, care in the community, and the offender population. To account for potential population differences we will include disease state and personal characteristics in the logistic regression analysis.
- A low proportion participating would markedly reduce the generalizability of the results (pre and post-intervention). Our experience is with an interest and willingness of inmates to participate in studies. Thus we do not anticipate this to be a significant limitation.

6 Protection of human participants

6.1 Regulatory approvals

This study will be conducted according to Good Clinical Practice (GCP) guidelines and completed in compliance with international and local human subject research guidelines. Approvals will be sought from University of the Witwatersrand Human Research Ethics Committee, Ekurhuleni Research Committee and the Johns Hopkins University IRB.

6.2 Risks and benefits

- The nature of this research is focused on improving outcomes regarding a situation unique to incarcerated populations. The majority of potential benefit from research results will inform care for this vulnerable population. The risk posed by the components of this study are equal to or less than that of daily life. The primary risk will be of inadvertent disclosure of HIV status through contact with study staff after release from incarceration or participation in standard clinic care or transition community adherence clubs (TCACs) – risks present with obtaining public section HIV care in South Africa. While this risk is what is faced in public section care, it is of serious concern for the study and will be addressed through training of study staff not to indicate nature of contact to anyone except the participant or an individual that the participant specifically designates and by conducted TCAC meetings in a private space. In addition, as part of the assessment of the service delivery, at the end of participation we will ask about experiences, including inadvertent disclosure of HIV status.

- Disclosure to other TCAC members is unavoidable and intrinsically a component of the intervention. This aspect of the study will be clearly described to potential participants during the informed consent process.
- The other risk is that participants may have a delay in receiving higher level clinical services if they present to the TCAC with an acute illness. TCAC facilitators will make every effort to transport a participant to the relevant level of care (primary care clinic, hospital) based on symptom screening results. All symptom screen results and triage will be recorded and reviewed at least bi-weekly by the study team. We will be assessing for un-managed morbidity in both arms at each study follow-up (as a secondary outcome) to assess for any differences.
- All participants will be eligible for nominal compensation for contact with study staff (approximately US$ 2-3 in airtime or data bundle). Participants in the TCAC are may benefit from added services. Whether this will truly reduce the burden of care, increase social capital, and lead to improved care continuum outcomes is the object of study.

6.3 Additional ethical considerations

As a study recruiting institutionalized individuals (detainees) additional human subjects protections need to be considered. Notably, although recruitment will occur among detained individuals, all intervention services will be provided post-release. We believe we meet the seven requirements specified in 45 CFR 46 for approval of research involving detainees and offenders. These are described below:

1. Category of permissible research: Category iii research under 45 CFR 46.306(a) (2): Research on conditions particularly affecting prisoners (detainees and offenders).
   Post-release adjustment, including continued medical care, following prison release is a challenge uniquely faced by incarcerated populations. Thus this research focuses on a condition only affecting detainees and offenders.
2. No excessive inducements for participation.
   Detainees and offenders will not accrue any advantages due to participation in the research while incarcerated. Following release, participants will receive cell phone airtime to enable on-going two-way communication with the case management team. While we agree that this is a reimbursement for the costs associated with participation, we do not believe that it represents undue incentive or pressures to participate within the South African context. In addition, the potential harms of participation are approximately the same as encountered with daily life (risk of inadvertent disclosure in public clinic settings).
3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.

Risks for participation are negligible and commensurate with risks for non-prison volunteers enrolled in retention-in-care programs and studies. This study places participants at minimal risk and may provide benefit if it is successful in increasing continuation of HIV or TB care. The greatest risk to the participants is a breach of confidentiality regarding HIV / TB status or incarceration history. This risk will be minimized by: secure storage with limited access of all documents, use of unique identifiers on all study forms, and use of discreet language that does not refer to incarceration history or HIV or TB diagnoses by case managers and tracers when speaking with the participants either telephonically or in person.

4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.
   Participation will be open to all inmates receiving ART or TB treatment (without random or population-based selection). There will be no control or intervention by prison authorities regarding potential participation. The study takes on a quasi-experimental approach in which outcomes of offenders released in the pre-intervention phase are compared to those in the intervention phase. Therefore, assignment to intervention or non-intervention is solely dependent on the offenders release date or sample size required for, whichever comes first.
5. The information is presented in language that is understandable to the subject population.
   The Participant Information Sheet (PIS) and other study related communication is at the inmate level. Additionally, the PIS will be translated into 6 common local languages – Sesotho, isiXhosa, isiZulu, Setswana, Xitsonga, and Afrikaans. We have extensive experience working with inmate peer educator groups and communicating on other ways with inmates. Through this experience we believe that we will be able to explain the study at a level comprehensible to the inmate population.
6. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole.
   Parole boards will have no information on agreeing to participate or declining from participation in this research.
7. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact (45 CFR 46.305(a).
   The intervention occurs following release and is non-medical. We are not planning on any medical follow-up for participants. However, participants assigned to the non-intervention arm will be offered additional counselling if they fail to enter community care within 90 days. In addition, participant contact information will be available should the need arise for follow-up after study completion.

6.4 Consent

Written informed consent will be obtained from eligible participants while incarcerated and from health staff members and selected TCAC members prior to in depth interviews. The consent process will be done in a private area to ensure confidentiality. Informed written consent, using Ethics Committee/IRB-approved consent forms, will be obtained by trained study personnel prior to performing any study-specific procedures. Informed consent is a process that will be initiated prior to the individual's agreeing to participate in the study and will continue throughout the individual's study participation. Potential participants will receive information about risks and possible benefits of study participation, study objectives and procedures. Informed consent requires the legally effective signature or mark of the subject. A copy of the signed and dated informed consent document will be offered to each participant for his or her records. Another copy will be placed in the participant's corrections health file. The rights and welfare of the subjects will be protected by emphasizing to subjects that the treatment by clinicians will not be adversely affected if they decline to participate in this study, and that they may withdraw consent at any time. The investigator will retain a copy of the signed consent forms, which may be inspected at the monitor's/auditor's request. The investigator will promptly report to the Ethics Committee/IRB of all changes in the research activity and all unanticipated problems involving risks to human subjects or others, and will not make changes in the research without Ethics Committee/IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

The informed consent process will include a verbal review of the study, provision on participant information sheets in relevant languages (Sesotho, isiXhosa, isiZulu, Sepedi, and English), review of the information sheets, and answering and questions. Participants unable to read or write will be asked to make a mark or thumbprint in the presence of a witness (verbal consent will not be obtained). Only written informed consent will allow for study participation.

6.5 Clinical trials registration

The study will be registered with clinicaltrials.gov. Key study information and results will have open-access availability on the clinicaltrials.gov website. This is in accord with funder (NIH) regulations.

6.6 Confidentiality

All study records will be managed in a secure and confidential fashion. All records will be stored at the participating correctional centers and Aurum Head Office in locked filing cabinets and access to the records will be restricted to specified study team members. Case report forms and case management documents will be identified using the participant's study number only, with locator information stored separately.

6.7 Data safety and monitoring

A data safety and monitoring board will be established to review of the protocol and monitoring plan prior to commencement of enrollment into the RCT and meet virtually prior to commencing enrollment and then every 6 months to review of RCT progress, enrollment and outcomes data, and any potential adverse outcomes. The meetings will review safety to suggest procedural changes and study modifications. There will be no criteria for study termination based on effectiveness because this is a pilot feasibility study with a total sample size that may not allow clear assessment of difference. The DSMB will include 3-5 members including individuals with experience with corrections research, the corrections environment, and good clinical practice.

7 Project Governance and Management

7.1 Research team

- Dr. Christopher Hoffmann, MD, MPH, MSc is a clinician scientist, Associate Professor at Johns Hopkins University and a Senior Scientist at Aurum. He has been working with Aurum on operational research since 2005 and is experienced with study design and statistical analysis and has published over 80 articles related to HIV care and treatment issues. He was the PI on a recently completed study implemented by the Aurum Institute in correctional facilities in Gauteng, South Africa. Dr. Hoffmann will provide overall leadership for study implementation.
- Dr Jill Owczarzak PhD, is an Assistant Professor at Johns Hopkins she has extensive international experience in qualitative and quantitative assessment of complex social/behavioral interventions. She will lead qualitative components of the study.
- Dr Stefan Baral MD is an Associate Professor at Johns Hopkins University with substantial experience on interventions for key populations, assessments of stigma, and study management. He will leverage these skills to provide guidance and inputs on study design, implementation, and evaluation.
- Dr Colleen Hanrahan PhD is a Scientist at Johns Hopkins University with experience implementing and evaluating community adherence club interventions in South Africa.
- Dr. Salome Charalambous MBBCh, PhD, is the Director of Research at the Aurum Institute and has extensive experience leading research in collaboration with the DCS and the Department of Health. She will manage stakeholder engagement with the DCS and Department of Health for this study.
- Tonderai Mabuto, MSc is a Senior Program Manager for the Research Department with ten years' experience with pragmatic clinical trials and other studies. He led a prior study regarding linkage to care following corrections release as well as a clinical trial of accelerated linkage to care following HIV testing. He will provide on the ground coordination.

The study team (PI and co-Is) will meet biweekly to review study progress. The PI will meet weekly with Tonderai Mabuto to discuss operational aspects of the study implementation. Dr Owczarzak will meet as needed for qualitative analysis components. The PI will make 3 – 4 visits annually to study sites.

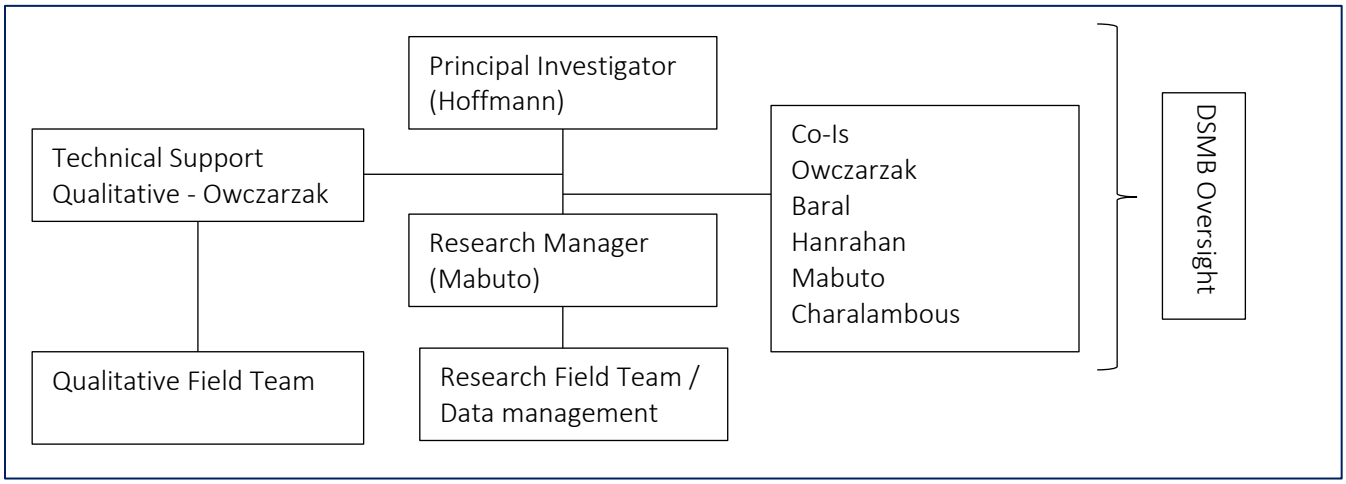

Figure 3: Project Management Structure

7.2 Publication policy

The research findings will be presented first to national stakeholders, and disseminated to stakeholders and participants in each province by means of local meetings. The results will be written up as one or more articles for submission to a suitable scientific journal.

7.3 Performance monitoring

The principal investigator will complete a monthly progress report that will facilitate monitoring of study progress and keeping the funders informed. These reports will capture vital information, such as IRB timelines, status of protocol development, enrolment figures, and any issues/delays that the PI may be experiencing.

8 Participant reimbursement

Participants will not receive payment for participation in the study but will receive reimbursement for time (and travel when needed) for study visits. Provision of food at the TCAC sessions is in line with food provision for people queueing at some public clinics.

9 Funding

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