

# Zwakala Ndoda: a cluster and individually randomised aimed at improving testing, linkage and adherence to treatment for hard-to reach men in KwaZulu-Natal, South Africa

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## Study protocol

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## Abstract

**Background** Men in sub-Saharan Africa are less likely than women to get tested for HIV, less likely to present for treatment, less likely to be maintained in treatment, more likely to have detectable viral load, more likely to transmit HIV with unprotected intercourse, and more likely to progress to AIDS and die sooner from HIV. The ultimate objective of this research is to provide evidence-based strategies to improve HIV testing and treatment of HIV-infected men.

**Methods** This study is being conducted in the Greater Edendale Area and Vulindlela region in KwaZulu-Natal, South Africa. It is a two-stage design of a cluster-randomised trial and an individual randomised trial to test how structural and individual-level interventions address the demand-side factors that affect HIV testing and treatment for hard-to-reach, high-risk men. It combines male-focused mobilization, community-based mobile HIV Testing Services and a small incentive to determine if the strategies singly and in combination can result in more men diagnosed with HIV, and more men linked to and maintained in care with undetectable viral load.

**Discussion** A priority for sub-Saharan Africa is developing and evaluating novel and cost-effective strategies for identifying hard-to-reach groups such as men, linking them to HIV testing and care services and maintaining them in care to the point of viral suppression. We propose a combination prevention intervention that addresses men's individual, interpersonal, and structural barriers to testing and care. This includes male-led mobilization to encourage uptake of testing and treatment; male-focused testing venues; male-only counselors; developing counseling models that are flexible and responsive to men; and strategies for adhering to clinic visits without missing work and navigating the health care system. By thoughtfully combining male-focused mobilization, testing and addressing some of the barriers to male engagement with health facilities, this study hopes to add to the growing evidence based about how to reach, test, link and maintain a hard to reach group such as men in HIV treatment and care services.

## Background

Men in sub-Saharan Africa are less likely than women to get tested for HIV, less likely to present for treatment, less likely to be maintained in treatment and have undetectable viral load (VL), more likely to progress to AIDS and die sooner from HIV [1-5]. Currently, uptake of testing, linkage, and treatment falls below the levels required to decrease new infections in high-prevalence countries such as South Africa. All available analyses demonstrate that fewer than 17% of HIV-positive individuals in South Africa know that they have HIV, are linked to care, and are maintained in care to reach viral load suppression [6]. Doubling antiretroviral therapy (ART) coverage, even to 35-40%, could reduce HIV infections by up to 40% [7]. The effects are even greater in high-prevalence areas such as KwaZulu-Natal (KZN) [7, 8]. Strategies for engaging the general population, and particularly hard-to-reach groups such as men [2, 4] through all steps of the treatment cascade are critical to epidemic control efforts in South Africa.

Several factors contribute to why men are a hard to reach population. HIV prevention and treatment programs have a blind spot regarding men [1, 2, 9, 10]. More than thirty years into the epidemic, interventions and research focusing on the prevention and care needs of men are notably absent [1, 2, 9-12]. Our attention thus far on women and girls is without dispute. Gender inequality is a key driver which impacts women's health and access to HIV services and creates specific vulnerabilities for women to HIV infection [13, 14]. However, framing gender as women's health means we have failed to understand how gender affects and drives the burden of ill health for men [9]. When men are included in HIV prevention and treatment, the focus is frequently on men as the problem (i.e., as transmitters of HIV), with outcomes that focus specifically on improving women's health, not that of men [15, 16].

Male gender norms discourage men from engaging in testing and treatment [1, 11, 17, 18]. Unhealthy constructions of masculinity and male gender norms associated with toughness and control, sexual prowess, and heteronormativity as a way of asserting manhood can deter men from engaging with HIV services [2, 19-21]. Low testing and treatment engagement is fuelled by perceptions of HIV as a threat to notions of masculinity, thus preventing men from testing early enough, disclosing their status, acknowledging their symptoms, or engaging with HIV treatment services [22, 23]. In Malawi, masculine ideals that require men to portray an aura of respectability, financial success, and as providers for their families are barriers to men engaging with testing and treatment services when they should [5, 24].

Key barriers to male engagement in HIV prevention and treatment include social and structural factors. HIV-related stigma and fear of disclosure leads to delays in HIV testing and treatment as well as poor adherence to medication among men [24-28]. Fear of ART side effects, and misconceptions around the benefits of early diagnosis, care, and treatment can keep people who are living with HIV out of care [12, 29, 30]. Micro-structural factors such as poverty and employment migration keep men away from their partners and families for long periods of time [24]. This absence may make them more vulnerable to HIV infection due to sexual exposure and drug and alcohol use, and may delink them from local health services [3, 31, 32]. Further, health services are not considered male-friendly spaces, with operating hours that often clash with work obligations, and provider attitudes that may lack sensitivity to men's needs, further alienating them [29, 30, 33]. As a result, men have fewer opportunities and disproportionately poorer access to HIV prevention, care, and treatment services.

Existing evidence points to several strategies that could address male involvement in HIV prevention and treatment programmes. Community mobilisation has successfully changed gender inequitable norms through engaging men to question traditional masculinity and support each other to change social inequalities [34-39]. In our work in Project Accept NIMH/HPTN 043, HIV testing uptake was improved by changing community norms through enhanced community participation, raising community awareness, and partnership building [40, 41]. Community mobilising interventions have also demonstrated success in addressing stigma for marginalized populations, thus improving access to sexually transmitted illnesses (STI) care and treatment [42-44]. Programs that address male gender norms and masculinity constructions have a positive impact on men's and women's relationships, health, attitudes, and behaviour [35, 45-48]. Effective community mobilisation that addresses restrictive gender norms could motivate men to engage in testing, linkage to care and treatment.

Community-based HIV Testing Services (HTS) optimize the treatment cascade by bringing testing closer to men [and women] thereby increasing demand. HTS both mobile and home-based, has expanded the geographic coverage and reach of HTS (in both urban and rural locations) and addressed some of the convenience factors—time, costs, distance—typically associated with health facility HTS [49-54]. Our work and others have shown that community mobilisation, coupled with mobile HTS targeted at venues frequented by men, can have a significant impact on increasing male engagement in treatment and prevention [11, 34, 49].

Economic incentives (EI) could address structural barriers to HIV testing for men [55]. A review assessing the effects of incentives on HIV/STI testing uptake demonstrated higher rates of uptake in the incentivized group in all seven studies [55]. In rural Malawi, Thornton examined a demand-side EI to randomise cash vouchers redeemable for HIV test results return, and found that the incentive nearly doubled uptake of HIV testing [56, 57]. A study in Cape Town, South Africa found that greater proportions of the men who received an incentive (a ~US\$10 food voucher) were first-time testers (60.1% vs. 42.0%) and had advanced disease (14.9% vs. 7.5%) compared with men testing at the non-incentivized clinic services [58]. Finally, incentives in community-based settings [58-60] demonstrated more significant differences in uptake rates compared to incentives offered in clinical settings [61-63]. With demonstrated successes in other areas of health [64-68], including HIV, community-based incentives may encourage more men to take up testing [55, 58].

Once tested positive for HIV, individuals need to be effectively linked to care, treatment, and support services for early initiation of ART and sustained engagement in care. The drop-off that occurs at each step in the treatment cascade results in an estimated 2% to 30% of those tested retained in care [69, 70]. There is a gendered slant to the treatment cascade: men are more likely to interrupt treatment [5], be lost to follow-up on ART [12, 16] present for treatment later and often start ART with more advanced HIV disease [5, 16] and experience additional complications than women [1]. Community-based testing and point-of-care (POC) diagnostics for HIV could address some of these challenges. The approach is able to effectively identify HIV-positive persons earlier in the course of their disease course, and link people to care [71, 72]. A recent systematic review found that people using POC testing were more likely to both receive a CD4+ T-cell (CD4) result and start ART compared to those relying on laboratory-based methods [73]. In a South African study comparing two linkage-to-care strategies (mobile HTS referral letter versus laboratory CD4 count), the most commonly stated barrier to linkage was accessing public health care facilities during working hours and/or not getting time off work (41.4%) [71].

Community-based testing and treatment approaches that actively engage men and their communities, promotes men's involvement, and is responsive to their needs are essential for developing effective responses to the epidemic in high-prevalence sub-Saharan Africa. This paper describes the protocol for the *Zwakala Ndoda* (an *isiZulu* term inviting men to participate) study designed to respond to these needs in an area of extremely high HIV prevalence and incidence viz., KwaZulu-Natal, South Africa. Our study innovatively combines an evidence-based testing strategy (male-focused mobilization, community-based mobile HTS and a small incentive) with proven, effective linkage-to-care strategies in one model. Our rigorous design allows us to test the individual and combined effects of novel strategies for HIV testing, linkage, and maintenance in care.

## Methods

### Study setting

This study is being conducted in the Greater Edendale Area (GEA) and Vulindlela region in KZN, South Africa. The area has a combined population of nearly 400,000 people spanning 20 municipal wards characterized by low population density, few infrastructure and developmental resources, high HIV prevalence (31%), high unemployment and low per capita income (under US\$2 per day)[25]. The population is primarily black African (99.3%). Nine of the wards fall under the tribal authority of a traditional leader or chief. Health services are provided through seven health facilities – Edendale Hospital, the main referral facility; two primary health clinics and three satellite primary health clinics.

### Study aims

The study combines the best of three strategies (male-focused mobilisation, community-based mobile HTS and a small incentive) to determine if the strategies singly and in combination can result in more men diagnosed with HIV, and more men linked to and maintained in care with undetectable VL. The specific aims are as follows:

Aim 1: To test the hypothesis, in a cluster randomised design, that men-centred mobilisation and testing strategies plus a small incentive will result in a substantially higher proportion of men getting tested for HIV (difference at least 30%).

Aim 2: To test the hypothesis, in an individual randomised design, that POC CD4 testing combined with personalised linkage to care (PLC) will result in a higher proportion of HIV-positive men linked to and maintained in care with undetectable VL than POC alone, and that both will be superior to standard of care.

Aim 3: To integrate the outcomes of the structural and individual level interventions and evaluate the joint effect of the structural and individual-level interventions on the percentage of HIV-positive men who are effectively treated (tested, linked to care and maintained with undetectable VL).

### **Research Design**

This is a two-stage design of a cluster-randomised trial and an individual randomised trial to test how structural and individual-level interventions address the demand-side factors that affect HIV testing and treatment for hard-to-reach, high-risk men. A Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) are presented in Figure 1 and Additional file 1.

#### **Cluster Randomised Study**

Eight (8) communities of approximately 5,000 persons (4 intervention and 4 control communities) from the GEA and Vulindlela regions will be selected with an equal mix of rural and peri-urban communities to ensure greater generalisability of the intervention in different settings. Each of the communities will be randomised to men-centred mobilisation and testing strategies plus a small incentive, or the control condition. Randomisation will be performed by the statistical centre in a restricted way, so that four communities are assigned to each arm. Randomisation code will be written in R and will use the Mersenne-Twister random number generator with seed derived from current system time.

#### **Individual Randomised Study**

A sample of 440 HIV-positive men identified through mobile HTS at baseline will be randomised to either standard-of-care referral to ART or POC CD4 testing combined with personalised linkage to care. Randomisation sequence will be generated in advance by the statistical centre, using the Mersenne-Twister random number generator with seed derived from current system time. Randomization assignments will be placed into sealed tamper-proof numbered envelopes according to the generated sequence and released to study counsellors in small batches. The envelopes will be used in the assigned order to reveal randomization results for individual participants. Lost or misplaced envelopes will be registered and tracked. The randomization sequence will be fully non-predictable.

#### *Blinding*

Due to the nature of the interventions, neither community-randomised nor individual-randomised intervention assignments are blinded to everyone. However, the laboratory results are completely blinded. The study statistician cannot be blinded because the intervention assignments were created by him and is also part of a team that conducts an unblinded review of process outcomes such as enrolment and dropouts in the study. Nevertheless the data processing and analysis will be done in the same impartial way in both intervention groups.

#### **Research Ethics Approval and Data Safety Monitoring**

The Institutional Review Board of the University of California, Los Angeles (UCLA, 00003962) and the Research Ethics Committee of the Human Sciences Research Council in South Africa (HSRC, REC 3/18/02/15) have approved the study and oversee adherence to the study protocol over time. A six-member Data Safety and Monitoring Board (DSMB), consisting of local and international experts, will monitor the implementation of the trial. National, provincial, district, and municipal health authorities approved the study and its protocol, and set the conditions of the standard care practice.

The DSMB will review the effectiveness and scientific validity of the study. The DSMB will provide their evaluation feedback to the principal investigators and study sponsor assessing interim analyses on enrolment progress, protocol fidelity and participant safety. Concurrently, enrolment progress is reported each trimester directly to the study sponsor. On-going harms and adverse monitoring is overseen by the local

institutional research ethics (REC) committee. A Community Advisory Board consisting of community stakeholders, representatives and leaders has been constituted for this study. Quarterly meetings are held with a Community Advisory Board (CAB) consisting of 25 local stakeholders who serve as liaison between research staff and the community, advising on study policies and keeping the community informed of progress. CAB members and study personnel have been trained to identify and report incidents of social harm and adverse events that may occur in the community to the study project manager. Regular feedback meetings are conducted with health authorities. The study project manager is responsible for logging, assessing and actioning any appropriate remedial steps (onward referral, staff re-training, community messaging etc.), reporting to the local REC and maintaining a register of incidents, if any, for the DSMB. The study will engage with participants' preferred clinics for a formal feedback and update meeting on post-trial care. The study team will engage with the department of health and local health facilities to create a database of options (community based re-supply, active support groups and accredited health system partners). The study team will share this information with participants and facilitate access to programmes the participants may be eligible, with referral to active support groups and adherence clubs.

## **Research activities and procedures**

### **Male-Focused Community Outreach and Mobilization (Component 1)**

The community outreach team engage traditional leaders and key governmental and local stakeholders to obtain permission to conduct the study in the communities. Information is provided about the study aims and objectives, and the rationale for including men in the intervention. The team identifies formal (e.g. community halls and churches) and informal social venues (e.g. transport hubs and sporting events) in each of the study communities where men are mobilised to participate in the study. At both venues, four community-based mobilisers (CBMs) conduct activities such as dialogues, social games and distribute pamphlets and edutainment to encourage men to test and link to treatment (see Table 1). Through these social networks, early adopters are identified and encouraged to test. Some of the early adopters are invited to be community champions (CC). Community champions work with study staff to identify other men in their networks who are invited to participate in the intervention. These formal spaces are used for mobilisation activities but also as possible spaces where mobile HIV testing is conducted. In addition, men identified through these venues are given information about the mobile HTS schedule and venues.

In addition to recruiting men to testing through formal and informal venues, CBMs go from house to house in the study communities to talk to men about healthy living and the importance of screening for HIV and other diseases. These CBM's also visit busy road intersections and talk with people who are passing by and distribute study information using pamphlets and appointment cards. In both these instances, men are provided information regarding when testing is likely to happen in their communities.

### **Male-focused and delivered mobile HTS (Component 2)**

The mobile HIV testing services teams coordinate with community mobiliser teams to ensure that testing happens according to the testing schedule. Copies of the testing schedule are distributed to community working groups, community-based outreach volunteers, local police stations, local health centres, and other community centres deemed appropriate by the study team.

Two HTS teams (4 male nurse counsellors and 1 driver per team) deliver easy-to-access mobile HIV testing through two mobile caravans. A mobile HTS team circulates through a range of male-centred locations in the community on a regular schedule of days and times suitable for men. Two teams serve the four intervention communities, with each team being responsible for two intervention communities over the course of the intervention. The team is supervised by a Counsellor Supervisor.

Community mobilisers are stationed in the vicinity of the men-centred spaces and engage men individually and in groups about the study. Mobilizers also inform men that a small incentive of R50 cell phone airtime (approximately US\$5) would be received at completion of testing, regardless of HIV status. Other men in the vicinity of the mobile facility, but not necessarily frequenting the venues, are also encouraged to test by study staff. Recruited men are handed over to the study counsellor at the mobile caravan for a fuller explanation of the study, informed consent and completion of the HTS process.

Participants consent for on-site point of care procedures for HIV and non-communicable diseases (NCDs) screening using rapid and point of care tests. No specimen are retained for HIV and NCDs testing. In the event of a discordant HIV test result, Dry Blood Spot (DBS) specimen will be collected from the participant for a laboratory confirmatory test to confirm serostatus. No specimen are retained for confirmatory tests. Participants who are eligible for enrolment (HIV positive and not on antiretroviral treatment), who consent to enrolment provide a DBS for baseline viral load measures. Consent is provided for participants to be re-contacted at 3 and 6 months for study contact visits, and for an exit visit at 9 months post enrolment where participant exist survey data and end line viral load will be collected. Participants consent for their data to be stored and for secondary use of their data if such use is approved by the REC.

After consent is obtained, the study counsellor completes the utilization form on the mobile phone. The form includes basic socio-demographic information as well information about previous testing behaviour, and engagement in HIV treatment and prevention and related health activities. If the male is not willing to participate, he will still complete the utilisation form to allow for comparison of participants with non-participants.

### **Brief risk-reduction counselling**

In our Uganda study we showed that briefer modes of HIV risk-reduction counseling are likely to be equally effective as extended counseling and testing [74]. We adapted this briefer risk-reduction counselling method (between 10-23 minutes) by incorporating appropriate messages into the counselling that would addresses men's masculinity concerns and gender beliefs about testing and treatment (See Table 2 for a breakdown of each session). The approach is male-friendly: we provide services to men in their social spaces and at their convenience; sessions are shorter and tailored to address their particular concerns; men do not have to wait in long queues and all screening services are offered by male counsellors.

During the pre-test counselling session, the counsellor explains the clinical and prevention benefits of testing, the right to refuse, the follow-up services that will be offered, and, in the event of a positive test result, the importance of disclosure to others who may have been exposed to HIV infection. If the patient has never tested for HIV, the counsellor explains why it is important to know one's HIV status and then offers the test.

Post-test counselling is tailored to the outcome of the test (positive/negative) and retain key messages (e.g., disclosure and partner testing, risk reduction, linkage to care, availability of care). The HIV-positive patient counselling session focuses on emotional support, HIV risk reduction, disclosure of HIV status, follow-up care available and referral; and partner notification and testing. Counselling for the HIV-negative patient focuses on HIV risk reduction, disclosure of HIV status, and partner notification and testing.

### **HIV Testing**

HIV testing is conducted using blood collected by finger-stick with a sterile lancet and using a serial testing algorithm for rapid testing according to 2015 South African National HIV Test Services guidelines [75]. All specimens are first tested with one assay (Test 1 or screening test) and specimens that are non-reactive are considered HIV-negative and reported as such. Any specimens that are reactive on the first assay (Test 1) are tested again using a different assay (Test 2 or confirmatory test). For specimens that are reactive on both the first and the second assays, results are reported as HIV-positive. Specimens that are reactive on the first assay but non-reactive on the second assay will receive an ELISA laboratory test and be recorded as discordant. In the case of discordant results, the individual is given the schedule of mobile HTS testing locations and asked to return in seven days [7] for their HIV results.

Participants are triaged according to their HIV test result. HIV-negative participants will have completed their visit, as they are not eligible for further study participation and if required, referrals to relevant services are made. Study counsellors will explain to HIV-positive men in the intervention communities that they are eligible for the randomisation and the next phase of the study, if interested. All HIV-positive participants are asked for locator information (addresses and alternate/additional contact phone numbers) so if randomised into the PLC arm they can be contacted. Permission is obtained to call and/or text the participant to arrange and keep in contact for PLC.

### **Non-Communicable Disease Screening**

In order to destigmatise HIV testing for men, a variety of NCDs screening services are provided alongside the screening for HIV. Procedures for hypertension, diabetes, obesity and STI are explained to interested men, the relevant tests conducted and results provided. Appropriate information on these conditions as well as follow-up referrals are made to nearby health facilities if further care is indicated.

### **Control Communities**

Control communities receive the current standard of care HTS services. All primary health care facilities in South Africa provide client-initiated counselling and testing (CICT) and provider-initiated counselling and testing (PICT). CICT involves individuals or couples/sexual partners actively seeking HIV testing and counselling at a facility that offers these services, while PICT is initiated and recommended by health care providers to all clients attending health care facilities as a standard component of medical care. All counselling includes the provision of pre-test information sessions conducted with groups, couples, or individuals, the HIV test itself, and post-test counselling. The standard of care also involves the promotion of HTS through flyers in clinics, and the service is offered free of charge during office hours, predominantly on weekdays.

### **Quality assurance of HTS**

Rapid, on-site HIV testing has the potential to be a useful and advantageous testing strategy in community-based or outreach settings. The intervention performs HIV testing according to the South African national rapid testing algorithms with on-going external quality assessment (EQA). All staff are fully trained in performing the rapid testing algorithm. CD4 counts are done by POC tests with on-going EQA. Viral load testing are done at a laboratory with EQA participation. Training in rapid testing technology was done as part of the 10-day counselling course for counsellors.

In addition to covering all of the didactic portions of the counselling and testing process, counsellors practice using the test kits themselves with known HIV-positive and HIV-negative sera to ensure that they are performing and reading the tests correctly. Counsellors also practiced with mock patients under the supervision of the counsellor supervisor. Supervisors periodically observe counsellors in the HTS process, using a standardized checklist, to ensure that all parts of the procedure are being followed. Counsellors are recertified bi-annually with panels of HIV-positive and HIV-negative sera. They are expected to achieve 100% correct results; if they fail to do so, the counsellor is taken out of the study, retrained and recertified, and monitored closely to ensure correct adherence to testing protocols. We also conduct daily test kit validation to ensure quality test results. For each mobile unit, we conduct a known positive and known negative validation. We expect perfect concordance of results. If we do not achieve this, the batch is identified and set aside. A new batch of test kits will be validated and used for further testing.

### **Personalised Linkage to Care (Component 3)**

In this third component of the intervention, HIV-positive men are randomised into two arms: 1) standard of care HIV follow-up 2) versus POC CD4 testing with male-centred PLC.

#### *POC CD4 testing with male-centred PLC*

HIV positive participants randomised into the PLC phase of the study receive POC CD4 testing. The study nurse conducts same-day CD4 testing by taking a small blood sample obtained from the participant's fingertip by a lancet. The date of the HIV and CD4 test and symptoms reported by the participant are provided in a one-page letter to the clinic to facilitate ART initiation. At the end of the counselling session, the nurse counsellor schedules a follow-up visit for the participant and their study assigned PLC clinic-based champion (CBC). The clinic-based champion coordinates schedules with the participant and visits the HIV clinic with the participant within 2 weeks of enrolment. PLC services are tailored for individual clients and include pro-active case-management counselling to discuss and reduce barriers to linkage to care, adherence and the importance of disclosure. It also comprises clinic champion accompaniment of the participant to help them navigate the health systems, and extended hours access to the ART clinic.

#### **Accompaniment to the HIV clinic by the clinic-based champion**

The PLC clinic-based champion discusses with the participant the usual means of travel to the clinic and encourages the participant to attend the clinic. As appropriate, the champion may travel with the participant to the clinic by public transport or meet the participant at the clinic. At the clinic accompaniment visit, clinic-based champions answer questions and provide support for HIV care. If several accompaniment visits are required before linking to care, the CBC may make these visits with the participant.

#### **Extended Clinic Hours for Men (Happy Hour)**

The PLC team leader negotiates with health services to ensure that extended hours of operation for obtaining ART and services are made available to PLC participants who have conflicting engagements during regular HIV clinic hours. This service (called happy hour) is already provided to young people by the Department of Health. A sample of clinics are opened once a week during 17h00-20h00 especially to cater for men. This male only HIV service allows the PLC participants to feel more comfortable in accessing services and discussing their questions and concerns more freely with the staff at the after-hours HIV clinic. The after-hours HIV clinic will offer all services normally available at a standard HIC clinic during regular work hours including HIV testing, counselling, ART medicines.

#### **Regular follow-ups by the clinic-based champion**

Further follow-up visits may be scheduled for 3 and 6 months after the initial visit, if the participant has not established care at an HIV clinic. At the follow-up visits, clinic-based champions answer questions about barriers to care, difficulties with adherence and provide support for HIV care. Participants complete a questionnaire on their experience accessing care, including barriers to care, risk behaviour, HIV clinical care and knowledge of HIV treatment and prevention. Examination of HIV care documentation (e.g., registration card from HIV care clinic) and recording of medications (e.g., HIV care medications and ART) takes place.

CBC also link men to appropriate referrals and support, including arranging opportunities for men to come together for support groups with other men to talk about and discuss issues of disclosure, adherence and retention in care.

### **HIV standard of care**

HIV positive men randomized into the standard of care arm are referred to the study counsellor. All participants who get assigned to standard of care receive HIV and NCDs testing results slip that is used as referral letter with all testing outcomes written on it. The lay counsellor provides information about HIV treatment and encourages the participant to visit the nearest clinic or any health care service of their choice for further clinical attention. Participants get information about being contacted telephonically at 3 and 6 months in preparation for the 9-month follow-up visit. The telephonic contact at 3 and 6 months is for tracking purposes to maintain contact with the participant. At 9 months, participant is invited to participate in another short survey and a DBS specimen collection again. Another consent process with participant is solicited at this point.

### **Study outcomes**

Aim 1: Outcome measures compare men-centred mobilisation and testing strategies in intervention communities to those in control communities.

#### *Primary outcomes:*

1. Proportion of men getting tested for HIV in the last 12 months. This is find out how many men have been tested for HIV in the last 12 months.

#### *Measurement of Aim 1 outcomes*

Conduct post-intervention assessments in intervention and control communities (n=1600, 8 communities x 200).

- Post-intervention random survey data (focusing on self-reported testing history, other wellness related data, health-seeking indicators etc.); and
- Specimen samples from men living in the study communities. We will be able to look at reported HIV status vs actual status.

Aim 2: Outcome measures compare enrolled participants assigned to PLC to those in standard care during the intervention.

#### *Primary outcomes:*

1. Proportion of men linked to care for first clinic visit in the last 9 months. This is to establish how many enrolled men accessed health care during the intervention.
2. Proportion who remained in care in the last 9 months. This is to establish how many enrolled men completed scheduled clinic visits during the intervention.
3. Proportion with undetectable viral load at exit. This establishes how many enrolled men have suppressed viral load at exit.

#### *Measurement of Aim 2 outcomes*

This uses information collected at 9 month exit interview:

- We will conduct facility level chart abstraction to confirm linkage to care for those enrolled in the study; and
- Laboratory DBS viral load assessment to establish viral suppression.

### **Theoretical Rationale**

Our combination prevention intervention is informed by the social-ecological framework which demonstrates how effective intervention can effectively address individual, socio-cultural, and program or health facility factors that influence individual health decisions. At the individual level, men's testing and treatment decisions require careful balancing of perceived benefits against constraints of adopting these health behaviours. Men report testing decisions as comprising a struggle between fears of the consequences of not testing (illness and death) and fears of the consequences of HIV testing (stigma and loss of status as a man). For men, there may also be fears that testing exposes their hidden sexual activities [1, 2]. Social-cultural factors affect men's decisions regarding health care [16]. Prevalent gender norms are important determinants of both decisions to undergo HTC for men and of subsequent progression through the HIV care pathway.

Social networks create powerful conduits for both support and discouragement for men on this pathway. The influences of other men in the social network regarding testing and treatment and how this feeds into ideas of masculinity as well as the influence of sexual partners, family members, and friends also factor into men's decisions regarding testing and treatment. Health facility factors also shape the individuals cost-benefit analysis of seeking and sustaining testing and treatment. The distance to medical services, financial and opportunity costs of travel, and the quality of care, such as waiting time and the attitude of providers, are all important factors in testing uptake and treatment compliance for men. Men thus formulate personal options and behavioural intentions while negotiating the social environment and the parameters of testing and treatment programs, and they do so against a broader structural environment that in much of sub-Saharan Africa includes entrenched poverty, food security, and weakened health systems [76]. Our multi-level intervention attempts to address all three levels that affect men's decision-making regarding testing and engagement in care.

### **Data management and adverse event reporting**

The assessments in the study are administered using electronic mobile data capture. The mobile data collection platform allows for offline data collection. Collected data is uploaded to the server once network connection is re-established. Checks are placed to ensure correct information has been entered. Data from laboratory testing (i.e. plasma HIV VL) is collected by participant ID number and merged into the database. Information from the questionnaires collected via the mobile phone is uploaded to a secured server. The de facto standard for securing network traffic is Secure Sockets Layering (SSL). This technology is fully supported by the handsets used in this study and ensures that all data transferred between the device and the server is encrypted.

Similarly, when reviewing, exporting or managing data all communications between browser and server are encrypted. All data is encrypted. Servers are secured by firewalls to prevent unauthorized access and denial of service attacks. Data is protected from virus threats using antivirus technology. The study database is backed up regularly. All personal identifying data will be destroyed 5 years after the study is completed, in compliance with the regulatory requirements of the study funder. The team is committed to ensuring that identifying data, including GPS, are secure until the time of destruction.

### **Quality Assurance**

To assure data accuracy and completeness, the mobile data collection platform is programmed to require data submission on all data fields. Skip patterns and logic branches are programmed to ensure that valid data is collected. Range checks are programmed on key fields to ensure data consistency. Operational data is collected for cross-check, data tracing and validation purposes. To assure data security, all hard-copy data is stored in locked cabinets in a locked office, and all electronic data is password protected and stored on a secure server in a secure facility. To ensure protocol compliance, the Project Director conducts periodic observations of study procedures [e.g., observing the informed consent process, a face-to-face interview, or HIV test counselling], conducts periodic "retraining" on key study procedures using role-plays during staff meetings, and produces a regular quality assurance report for the PI.

### **Data analysis**

Aim 1: Cluster-Randomised Component. We will test the hypothesis that the community-wide proportion of men who were tested for HIV in the past year is at least by 10 percentage points [on an absolute scale] larger in communities randomised to the active intervention compared to the standard-of-care arm. The analysis will be based on testing reports provided by men included in the post-intervention assessment. Empirical proportions of tested participants will be calculated for each community and compared between the study arms by a two-sample Welch t-test. We will test the hypothesis that the difference in proportions is less than or equal to 0.1 against the alternative that the difference is larger than 0.1 at the one-sided level of 0.05.

Power Calculations for Aim 1. We assumed 30% annual testing rates in the standard arm [similar to testing rates observed in Project ACCEPT in the community-based HTS arm in Vulindlela site] and between-community variance in testing rates 0.007 (estimated from Project ACCEPT's Vulindlela data). Then the sample size of 4 communities per arm, with 200 men sampled from each community, provides the following power for detecting intervention effects: power 0.05 for 10% difference (30% vs 40%, null hypothesis); power 0.36 for 20% difference (30% vs. 50%); power 0.86 for 30% difference (30% vs. 60%); power 0.95 for 35% difference (30% vs 65%). Thus the study is powered to detect differences in testing rates that are substantially larger than 20% and therefore likely to be of practical significance. The power for detecting differences of 30% or more is large enough to be reasonably certain that such effects are not missed.

Aim 2: Individually-Randomised Component. We will test the hypothesis that the proportion of HIV-positive men who were linked to care and maintained with undetectable VL 9 months after enrolment will be the same in the POC + PLC arm as in the standard-of-care arm. The analysis will be based on men who were randomised and who completed the follow up visit. We will use asymptotic tests for log odds ratios performed at the two-sided level of 0.05. Confidence intervals will be obtained by the same method.

## **Power Calculations for Aim 2.**

Assuming that the rates of linkage to care and undetectable VL are 33% in the standard arm and 50% in the POC + PLC arm (odds ratio 2.0), the sample size of 175 subjects per arm yields 88% power to detect the effect of POC + PLC over standard of care. Adjusting for 20% attrition yields the sample size of 220 per arm.

## **Secondary Analyses for Aim 2**

We will carefully investigate the effect on attrition on the primary analysis of Aim 2. We will compare the men who do and do not present for the final visit to assess potential bias in the analysis of the primary endpoint of Aim 2. We will evaluate the attrition effect by multiple imputation of missing data using baseline characteristics of the subjects. We will compare HIV-positive men identified in Aim 1 who do and do not enrol in the Aim 2 study.

## **Aim 3: Integrating the outcomes of the structural and individual level interventions**

We will estimate the joint effect of the structural and individual-level interventions on the percentage of HIV-positive men who are effectively treated (tested, linked to care and maintained with undetectable VL) by estimating the percentage of HIV-positive men who have been tested in male-centred mobile HTS vs. control arms using data on HIV testing and HIV status of the post-intervention assessment participants from Aim 1, and estimating success rates of undetectable VL in SOC and POC + PLC arms in Aim 2 (adjusted for attrition if needed). These estimates will be multiplied to estimate overall success rates of undetectable VL among HIV-positive men in all four combinations of the two interventions. Confidence intervals will be also calculated. We will assume that the interventions do not interact with each other since each targets a different stage in the process leading to successful HIV treatment of HIV-positive men. Given population size and HIV prevalence, we will be able to estimate the number of men who would be identified, treated, and maintained on treatment under each of the possible intervention combinations. A sensitivity analysis will be performed to evaluate the impact of potential non-independence of intervention effects.

A full factorial design is not feasible because one of the interventions is applied at the community level and the other at the individual level, and success at the first of the interventions (being tested) is a condition of enrolment into the other intervention. This brings bias into the randomization of the community-level intervention. This design could only be conducted by randomizing whole communities to the four combinations of the interventions, but that would be too costly.

## **Cost-effectiveness analysis**

We will examine effectiveness in terms of: (1) behavioural changes resulting from HIV testing and counselling (which reduces HIV transmission and acquisition), (2) increases in life-expectancy and quality of life from engagement and retention in care, and (3) reductions in HIV transmission, and thus morbidity and mortality from downstream infections, derived from reduced HIV infectivity of those on ART. We will contrast standard of care versus exposure to (1) male-centred mobilization + mobile HTC and (2) combined POC CD4 + Personalized linkage to care. For each, we will use Bernoulli-Process models for HIV transmission, extension of life, and enhancement of quality of life.

## **Sensitivity Analysis**

We use Monte Carlo and Latin Hypercube simulations with @Risk™ software for sensitivity analyses. Confidence intervals and point estimates from study data will be fitted to distribution functions. Convergence will occur when the addition of model iterations changes the average and standard deviation of the output by less than 1.5%. Correlations between model parameters will be identified to better fit the model.

## **Discussion**

The ultimate objective of this research is to provide evidence-based strategies to improve treatment of HIV-infected men. A priority for sub-Saharan Africa is developing and evaluating novel and cost-effective strategies for identifying hard-to-reach groups such as men linking them to HIV testing and care services and maintaining them in care to the point of viral suppression [77]. In this study, we are combining the best of these strategies [male-centred community outreach and mobilisation followed by male-centred and delivered mobile HIV testing services plus a small incentive, and finally personalised linkage to care] to determine if the strategies singly and in combination can result in more men diagnosed with HIV, and more men linked to and maintained in care with undetectable VL.

A growing number of interventions are beginning to target men and boys in their prevention work and rigorously evaluating the impact, with mostly positive results [2, 16]. This study combines structural (community) and individual-level interventions and integrates the two to address our objective of maintenance in care to the point of viral suppression, adds to the few rigorous evaluations of male-focused interventions in South Africa.

Community-based testing and treatment approaches that actively engage men and their communities, promotes men's involvement, and is responsive to their needs are essential for developing effective responses to the epidemic in high-prevalence sub-Saharan Africa. Research increasingly shows that men prefer community-based events where they would have the opportunity to ask questions and where they can talk about the reality of their lives [48]. The low rates of treatment engagement in South Africa and KZN, in particular, could limit the potential impact for these novel treatment-based strategies to reach the communities where they are most needed [78].

A growing number of studies point to two reasons for men's low involvement in HIV services. The first relates to the gender inequalities and associated gender norms about masculinities that encourage men to act in ways that put themselves and their sexual partners at risk of contracting HIV [5, 16]. In South Africa, and other parts of sub-Saharan Africa, these include a range of male sexual behaviours and practices, such as an unwillingness to use condoms or get tested for HIV, as well as engagement in multiple and concurrent partnerships increase men's likelihood of contracting HIV and transmitting it to their female partners [3, 13, 79].

Addressing harmful gender norms that inform these practices by reaching out strategically to men may be one of the best ways to protect women [and men themselves] [3, 4]. By placing men at the centre of this study, we do not seek to exclude women but acknowledge that men and women may need different approaches to motivate HIV testing and linkage to and maintenance in care. Further, engaging men in testing and treatment could keep them healthy for longer periods, thus having a positive impact on the economic circumstances of their families, and potentially alleviating the care burden on women [9, 11].

The second factor for low male involvement in HIV prevention and care points to the need for improved health system policies [5], programmes and service delivery strategies to ensure better provision of HIV services to men [16]. Finally, when men are included in policies and programmes they are all too often seen only as the problem and as vectors of HIV [2]. As a result limited attention is placed on how men can be meaningful and supportive partners and how to effectively link men into the HIV prevention and care cascade. This study addresses this important gap by developing targeted strategies that engage men both as agents of change and as holders of the right to health, including especially HIV and AIDS services.

We propose a combination prevention intervention that addresses individual, interpersonal, and structural barriers to male involvement in testing and care and is responsive to their needs [30, 80, 81]. Our innovative male-centred combination prevention interventions include: (a) male-led mobilization to encourage uptake of testing and treatment; (b) male-focused testing venues convenient and accessible to men and their work obligations; (c) male-only counsellors who will counsel other men; (d) counselling and mobilization messaging that address gender norms and masculinity ideals – promoting the benefits of good health for earning income and supporting one's family, the importance of being a strong role model for children, especially sons; (e) developing counselling models that are flexible and responsive to men and their work demands; (f) ways to get support from fellow men; and (h) strategies for keeping clinic visits without missing work and navigating the health care system. By thoughtfully combining male-focused mobilization and testing and addressing some of the barriers to male engagement with health facilities, this study hopes to add to the growing evidence based about how to reach, test, link and maintain a hard to reach group such as men in HIV treatment and care services.

### Trial status

Screening and recruitment for the trial began on 30 August 2017. As of 30 November 2018, the study team has been in the field for 15 months with 4473 participants screened (4179 screened for NCDs and tested for HIV, 88 tested for HIV only, and 206 screened for NCDs only). 249 participants have been enrolled for the personalised linkage to care intervention trial within the study. It is expected that enrolment will continue until 30 April 2020.

## List Of Abbreviations

Antiretroviral therapy (ART)

CD4+ T-cell (CD4)

Client-initiated counselling and testing (CICT)

Clinic-based champion (CBC)

Community Advisory Board (CAB)  
Community based mobilisers (CBMs)  
Community champions (CC)  
Data Safety and Monitoring Board (DSMB)  
Dry Blood Spot (DBS)  
Economic incentives (EI)  
External quality assessment (EQA)  
Greater Edendale Area (GEA)  
HIV Testing Services (HTS)  
KwaZulu-Natal (KZN)  
Non-communicable diseases (NCDs)  
Personalized linkage to care (PLC)  
Point-of-care (POC)  
Provider-initiated counselling and testing (PICT)  
Secure Sockets Layering (SSL)  
Sexually transmitted illnesses (STI)  
Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)  
Viral load (VL)

## Declarations

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### *Availability of data and materials*

The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

### *Authors' contributions*

HVR, TC, MK, and MS designed the study. HVR and TC are the principal investigators on the study. HVR is the primary author of this manuscript. TM made significant contributions to the writing. HVR, TC, MK, MS, TM, PJ, TN commented on drafts of the manuscript. HVR, TC, MK, MS, TM, PJ, TN read and approved the final manuscript.

### *Ethics approval and consent to participate*

The trial design is covered within the ethics application and overall protocol of the *Zakwala Ndoda* study (**Protocol version 12 of 7 July 2015**). The Institutional Review Board of the University of California, Los Angeles (**UCLA, 00003962**) and the Research Ethics Committee of

the Human Sciences Research Council in South Africa (**HSRC, REC 3/18/02/15**) have approved the study and oversee adherence to the study protocol over time, and is a registered clinical trial under the National Institutes of Health, U.S National Libraries of Medicine, ClinicalTrials.gov (**NCT03794245**). All participants have to provide informed consent to participate in the study.

#### *Consent to publish*

Not Applicable

#### *Competing interests*

The authors declare that they have no competing interests.

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## Tables

**Table 1: Men-centred Mobilization Strategies**

Social Games and Entertainment	Different games are organized monthly per intervention community. These games include street soccer, field soccer, fun run/walk, card games etc. These also include screening of soccer games on a big screen in taverns if a community WIFI hot spot is available. While men participate in these games, health messages are distributed and testing is provided through the mobile van.
Men's dialogues	The team organizes dialogues as a safe space for men to discuss matters pertaining to their health. Men are encouraged to be open about issues concerning them. Video clips of topics such as "AIDS in our community, Living positive with HIV/AIDS, Phuza Wise, Help stop women abuse, Alcohol and you" developed by a local communications non-governmental organization called Soul City ( <a href="https://www.soulcity.org.za">https://www.soulcity.org.za</a> ) are played to prompt discussion about men and their health. HTS staff are available to provide testing before and after each dialogue.
Pamphlets	Large amount of pamphlets with study information are printed and distributed in taxi rank, taverns and sheebens, busy intersections, places of worships and many other social venues. Posters are also pasted at strategic venues where men are frequenting. Some of these posters provide general HIV testing FAQs and others are provide testing van schedule.

Table 2: Brief risk reduction counselling model

rotocol Component 1: Pre-Test Counselling	Minutes
. Introduction of HIV testing to patients	1-5
initial Session Time	Total 1-5
rotocol Component 2-4: Disclosure of HIV-Negative Results	Minutes
. Provide HIV-negative test result	1-2
. Develop risk reduction plan	1-2
. Discuss disclosure, discordance, and partner testing	1-2
econd Session Time	Total 3-6
rotocol Component 5-7: Disclosure of HIV-Positive Results	Minutes
. Provide HIV-positive test result and identify care resources	2-4
. Discuss disclosure, discordance, and partner testing	2-4
. Develop risk reduction plan	2-4
econd Session Time	Total 6-12

## Figures

	STUDY PERIOD						
	Enrolment	Allocation	Post-allocation			Close-out	
TIMEPOINT**	Screening	3-7 Days Post Screening	Baseline	Contact	Linkage	ART Initiation	9M Endline
<b>ENROLMENT:</b>							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
<b>INTERVENTIONS:</b>							
<i>Personalised Linkage to Care Group</i>						→	
<i>Referral to Primary Health Care Facility (SOC) Group</i>							
<b>ASSESSMENTS:</b>							
<i>Demographics, NCD assmt, Prior HIV testing, HIV Status, ART Status</i>	X		X			X	
<i>Demographics, Income, Testing history, Sexual Risk, Health seeking behavior, Challenges accessing care, HIV treatment and adherence indicators,</i>			X			X	
							X
			X				X

Figure 1

Zwakala Ndoda Intervention SPIRIT Schematic

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- AdditionalFile1.LinkagestoCareSPIRITChecklist.doc