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A community mobilization intervention to improve engagement in HIV testing, linkage to care, and retention in care in South Africa: a cluster-randomized controlled trial

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SAL, AP, DP, RT, MKD, TN, KK, and ST conceptualized the study and designed the research. SAL, AP, KK, LPM, and JP secured funding. SAL, AP, AG, DP, DR, NH, JP, and RT designed the intervention components. RM, AJ, DR, and RW supervised intervention training, implementation, and monitoring. RM and DR supervised the mobilization team. CWK, FXGO, RW, KK, and ST designed the clinic data system for data capture and matching to the census and supervised clinic and census data collection. MKD conducted data management with CWK; MKD conducted data analysis with input from TN, SAL, and AP. MKD and TN have full access to the data and have verified the underlying data and all analyses. SAL led manuscript development with content support from MKD, AP, TN, KK, and ST. All authors have read, reviewed, contributed to, and approved the final manuscript for publication.

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Summary

Background: Community Mobilization (CM), engaging communities in a process to collectively enact change, could improve HIV testing and care engagement. We assessed whether CM increased HIV testing, linkage to, and retention in care over time in intervention relative to control communities.

Methods: Fifteen communities in Mpumalanga, South Africa were randomized to either a CM intervention engaging residents to address social barriers to HIV testing and treatment or to control. Implementation occurred from August 2015-July 2018. Outcomes included quarterly rates of HIV testing, linkage to care, and retention in care documented from health facility records among 18-49 year-old residents of intervention and control communities over the three years

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of study. Intention-to-treat analyses employed generalized estimating equations stratified by sex. ClinicalTrials.gov number NCT02197793.

Findings: Residents in eight intervention communities (N=20,544) and seven control communities (N=17,848) contributed data. Among men, HIV testing increased quarterly by 12·1% (Relative Change (RC):1·121, 95%CI:1·099-1·143) in intervention communities and 9·5% (RC:1·095, 95%CI:1·075-1·114) in control communities; differences by arm were marginally significant (exponentiated interaction coefficient:1·024, 95%CI:0·997-1·052, p-value=0·078). Among women, HIV testing increased quarterly by 10·6% (RC:1·106, 95%CI:1·097-1·114) in intervention and 9·3% (RC:1·093, 95%CI:1·084-1·102) in control communities; increases were greater in intervention communities (exponentiated interaction coefficient:1·012, 95%CI:1·001-1·023, p-value=0·043). Quarterly linkage increased significantly among intervention community women (RC:1·013, 95%CI:1·002-1·023) only. Quarterly retention fell among women in both arms; however, reductions were tempered among intervention women (exponentiated interaction coefficient:1·003, 95%CI:<1·000-1·006, p-value=0·062). No significant differences were detected in linkage or retention among men.

Interpretation: CM was associated with modest improvements in select trial outcomes. The sum of these incremental, quarterly improvements achieved by addressing social barriers to HIV care engagement can impact epidemic control. However, achieving optimal impacts will likely require integrated efforts addressing both social barriers through CM and provision of improved service delivery.

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Introduction

HIV transmission can be decreased by reducing undiagnosed infections and expanding early and consistent use of antiretroviral therapy (ART). Treatment as Prevention (TasP) has been proposed as key to ending the HIV epidemic.[1,2] To activate TasP in high prevalence countries, testing and care must be accessible and community members must be motivated to know their status, start ART, and maintain ART adherence. South Africa introduced ART initiation regardless of CD4 count in September 2016,[3] however, only an estimated 52% of men and 64% of women living with HIV in 2017 were on ART, and only 43% and 58% had achieved viral suppression.[4]

Community Mobilization (CM) could improve testing uptake and linkage to and retention in care by addressing key social barriers to HIV care engagement, including poor community awareness or understanding of HIV care (treatment literacy); fear and stigma associated with infection, clinic attendance and disclosure; lack of social support for care engagement; and gender norms deterring men from accessing care.[5] Defined as collective promotion of action towards social change around a shared concern by a group or community,[6] CM has reduced high risk sexual behavior[7] and improved HIV testing[8,9] by changing community norms through enhanced community participation and awareness.[10]

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UNAIDS designates CM as a critical enabler, an activity that is necessary to support program effectiveness.[11] However, CM strategies for linkage and retention in HIV care have not been rigorously evaluated as a standalone intervention, independent of multi-component efforts to increase access to care (e.g. large initiatives such as BCPP,[12] PopART[13] and SEARCH[14]). Because CM programs can produce normative change, there is potential to improve HIV outcomes for entire communities. To address the gap around rigorous CM evaluations, we conducted a cluster randomized trial to evaluate a theory-based CM intervention addressing known social barriers to engagement in HIV care.[15] The intervention sought to increase HIV testing uptake, thereby decreasing undiagnosed infections, and to improve HIV care engagement among adults aged 18-49 years, with the goal of reducing new infections and improving health outcomes among those living with HIV. Specifically, we hypothesized that residents in villages randomized to CM would have higher rates of HIV testing, higher rates of linkage to care, and higher rates of retention relative to control community residents.

Methods

Study design and participants

The Community Mobilization for Treatment as Prevention (CM TasP) trial, also called *Tsima ra rihanyu* ("working together to plow the fields for health") occurred between August 1st 2015 and July 31st, 2018 in the Agincourt sub-district of rural Mpumalanga Province, South Africa. The Health and Socio-Demographic Surveillance System (Agincourt HDSS) has run an annual census for over 25 years, maintaining a detailed database and sampling frame.[16] There are now approximately 20,000 households and 117,000 individuals in the Agincourt HDSS study area's 31 villages. HIV prevalence in the area was over 45% among 35–39 year olds in 2010-2011.[17] We used a cluster randomized design, appropriate for interventions delivered at the community-level; villages were the randomization unit and were eligible if they had been fully enumerated in 2014, had not been included in previous mobilization activities, and included over 500 permanent adult (18-49) residents. The 15 eligible communities were randomized to either the intervention (n=8) or a control (n=7) condition (Figure 1). The intervention consisted of a community-based mobilizing strategy, including workshops, activities, leadership and stakeholder engagement, and training a cadre of community volunteers, with the goal of stimulating critical thinking around HIV and encouraging HIV testing and care.[15]

Rates of HIV testing, linkage to, and retention in HIV care were measured by linking the longitudinal population-based HDSS census data to an area-wide health facility-based electronic clinical tracking system (HDSS-Clinic Link). HDSS-Clinic Link is used in all nine sub-district primary care facilities and was initiated in one additional facility on the HDSS border that serves study communities (Figure 1). All HIV-related clinical services received across the 10 clinics were recorded among all consenting HDSS residents visiting the clinics during the study period.

This study also included cross-sectional population-representative surveys conducted in 2014 and 2018, prior to and following the intervention, in order to measure social barriers to testing and care and to obtain intervention exposure levels. Procedures for the community

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surveys have been described previously.[15] Written informed consent for extraction of clinical data and participation in community surveys was obtained from all participants. All procedures were approved by the Institutional Review Boards at the University of North Carolina-Chapel Hill and the University of California-San Francisco, the Human Research Ethics Committee (Medical) at the University of the Witwatersrand and the Mpumalanga Provincial Department of Health and Social Development Research Committee, South Africa. The full study protocol has been published.[15]

Randomization and masking

Villages were allocated to intervention or control using balanced (covariate constrained) randomization to minimize differences in key covariates at baseline between trial arms.[18] These covariates included population size, distance to closest health facility (measured by taxi fare), average socio-economic status (SES) based on household assets, proportion of temporary migrants in the village, proportion of female-headed households, and mean community mobilization score,[19] collected during the population-based survey in 2014.

Village leaders were consulted about the trial and consented for their villages to participate. Final village allocation was revealed at a public community event, where a community volunteer picked the winning randomization scheme from 50 randomly generated balanced combinations.

Procedures

The *Tsima* mobilization model adheres to the theory that social barriers necessitate social change solutions—those which move beyond service provision and instead engage communities in a process to dialogue about barriers to health and collectively act to change these. Therefore, our intervention addresses social barriers to care engagement derived from the literature[5] and our formative research,[20] specifically, poor treatment literacy; fear and stigma associated with HIV infection; lack of social support to engage in testing and care; and gender norms that deter men from accessing care. These issues are addressed by implementing activities that map onto six CM domains distilled from the social sciences literature and validated in the study area:[6,19] (1) a shared issue or concern that is the target of change, (2) community sensitization or building of critical consciousness, (3) an organizational structure with links to groups/networks, (4) leadership (individual and/or institutional), (5) collective activities/actions, and (6) community cohesion. These domains represent community factors integral to social change that must be addressed or modified for mobilization to occur and to have sustained impacts on behaviors, social norms, and health outcomes. *Tsima* intervention content was anchored in the theoretical framework (see Appendix page 4).[15]

The *Tsima* intervention was conducted in partnership with Sonke Gender Justice, a South African non-governmental organization (NGO) dedicated to activism and health programming at the intersection of HIV and gender equity. Implementation was conducted by a team of 16 community mobilizers selected from intervention communities. The mobilizers conducted over 16 community-based activities adapted from past collaborative mobilization work[21] or newly developed for this trial. Additionally, five intensive two-

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day workshop agendas were adapted[21] or developed, in total comprising seven themes and 50 modules.[22] Community-based activities and workshop curricula were pilot tested and refined before commencing the trial. Mobilizers underwent extensive training on the study protocol and conduct of intervention activities, including how to form, train, and manage community action teams (CATs) comprised of community volunteers who co-led mobilization efforts in their villages. The team engaged regularly with community leaders and stakeholders in support of the intervention. Meetings included annual community goal-setting workshops in each intervention village to discuss the current state of HIV testing and care outcomes in their community, establish community goals, and renew commitments and partnerships.

Each intervention village CM team had specified monthly targets for completion of a minimum number of activities, 2-day workshops leadership engagement efforts and CAT meetings monthly. Project targets aimed to engage 60% of village residents in at least one activity by year three of the intervention and were routinely monitored using case report forms completed by the mobilization team and entered into the project monitoring system.[15]

Outcomes

Outcome data originates from the electronic health facility data collected through HDSS-Clinic Link. Every adult accessing study clinics from August 2105–July 2018 was approached to consent to linkage of their census and clinical data files; fewer than 5% declined to consent. For trial analyses, we created a record for every resident of the 15 study villages aged 18-49 and linked clinical data to their census record, treating the entire 18-49-year old population (approximately 38,000) in the area as an open cohort. We conservatively assumed no clinic visits were made if none were captured. Individuals were excluded from the population at the time they either moved out of the study area or were documented as deceased.

The three primary outcomes for this study include: testing, linkage, and retention. HIV testing was defined as provider administered HIV testing among residents of negative or unknown status. Linkage to care following a positive test was defined as evidence of treatment initiation within 90 days. For the few not eligible for treatment in the first year of the study, prior to implementation of universal treatment in September 2016, linkage was defined as evidence of a CD4 test or clinical follow-up within 3 months of testing positive. Among those who had obtained any treatment in the past year, individuals were considered retained if they were currently on treatment or did not default from medication. Treatment default is defined as a lapse in medication coverage of 90 days.[23] For the few HIV patients who were not ART eligible in the first year of the study, retention was defined as having a CD4 or viral load test every six months. Clinical services were assessed continuously and then parsed into three-month windows for analytic purposes, with each outcome operationalized as binary variable (tested/untested; linked/unlinked; retained/not retained) per three-month window. Though we initially defined the HIV testing outcome using a 12 month period,[15] we chose to assess testing in three-month windows given lack of a 12 month look-back period during the first quarters of the study.

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As a post-hoc summary outcome measure, we computed the unconditional composite testing and care cascade estimates derived from the UNAIDS 90-90-90 (now 95-95-95) indicators in the intervention and control communities at endline, including the proportion of all residents living with HIV with known status, on treatment, and virally suppressed.[24] Viral suppression was defined as viral load <400 copies/ml per South African guidelines. Denominators (total proportion of men and women who are HIV positive) were calculated using age-specific estimates for Mpumalanga Province from the national Thembisa model.[25] Given the nature of intervention activities, harms were passively reported.

Statistical Analysis

We determined sample size by using minimum detectable differences for cluster randomized trials.[18] We conservatively assumed an intraclass correlation (ICC)=.05 (survey data from 2012 indicated an intra-class correlation of 0.014 for HIV testing); HIV prevalence=30%, linkage=60%, retention=50% in control communities; and 30,000 adults (6,000 on treatment), alpha=5%, and power=80%, we had power to detect a 19% or greater difference.[15]

Primary analyses follow an intent-to-treat (ITT) approach stratified by gender, including terms for intervention group, time, and the group-by-time interaction to assess changes in testing, linkage, and retention in the intervention villages as compared to control villages. The model was structured with time in three-month increments, with time coefficients calculated for intervention and control groups separately. Therefore, each time-by arm-coefficient represents the *relative change* (RC) over a three month time period within the specified group. Interaction coefficients, which are exponentiated to align with other components of the model, represent the difference in outcomes (or slopes) over time between study arms.

Models were fitted using Generalized Estimating Equations (GEE), clustering by individual repeated measures using an exchangeable correlation structure and treating village as a covariate in order to assess marginal changes in outcomes by arm over time. As linkage to care was recorded once for each resident, we used GEE models clustered by village for this outcome. A log link and poisson distribution were used to model these binary outcomes (testing, linkage, and retention). Baseline characteristics were compared by arm using cluster-adjusted two group comparison methods (e.g., Rao-Scott chi-square) to assess balance between randomization arms. Alpha was pre-specified at .05 for all hypothesis tests of main effects. Missing data were assumed to be covariate-dependent.[26] Aforementioned analyses were conducted using SAS version 9.4 (SAS Institute, Cary NC). We compared the 90-90-90 indicators by arm at the end of the study using chi-square tests to assess differences in both overall 90-90-90 indicators and cluster-adjusted values that account for variability in village-specific estimates.

Because the first quarter of data collection was coincident with team training and HDSS-Clinic Link data capture system refinements, we excluded first quarter data. We also excluded the last quarter from main analyses due to a partial clinic strike from May-July 2018, which resulted in inconsistent service availability. We conducted a sensitivity analysis, re-running our models including all quarters of the study data. Because our modeling

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approach for HIV testing and retention clustered at the individual level, assuming no variability in time effect between villages, we also conducted sensitivity analyses in M*plus* 8.1 (Muthén and Muthén, Los Angeles, CA) using random effects models allowing for variance in slopes between villages.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Trial Registration: trials.gov: NCT02197793 Registered July 21, 2014.

Results

A total of 38,300 individuals aged 18-49 were resident in the 15 study villages during the study period and thus contributed to the analysis (Figure 2). Overall, 20,544 contributed time in an intervention village and 17,848 to a control village (92 contributed to both). There were 15,112 adult study village residents who received health services during the study (41% in intervention and 38% in control communities, p<0·001); of these, 81% were successfully linked to a census record in a study village (83% in intervention; 80% in control, p=0·025.) For the approximately 19% of individuals receiving care and not linked to a census record, potentially due to new residency not yet captured in the census, we utilized self-reported village residence to assign intervention status.

Intervention and control village resident demographics, including sex, age, mean SES, and mean education, were similar at baseline (Table 1). Men comprised approximately 49% of the population and those ages 18-29, 30-39, and 40-49 years comprised 52%, 30%, and 18% of the target population, respectively (Table 1). Village characteristics did not substantively differ between intervention and control villages. At endline, 66% of intervention and 18% of control village residents reported knowing about the Tsima intervention, with 45% in intervention and 7% in control villages reporting participation in an intervention activity. Monitoring data revealed that we reached the target of 60% cumulative coverage with at least one activity in seven of eight villages; the remaining village reached 52% coverage. All villages met cumulative targets for the numbers of activities offered, three met the cumulative target for number of 2-day workshops, and five met the cumulative target for number of leadership engagement activities (see Appendix pages 5-7).

HIV testing uptake was assessed among all 36,747 residents not known to be HIV positive at study start. Among men, HIV testing at baseline was higher in control villages. Uptake increased significantly by quarter in both arms over the three years of the program. The 12·1% increase in testing uptake per quarter in the intervention arm (intervention RC 1·121, 95% CI: 1·099-1·143) was greater than the 9·5% increase in the control arm (control RC 1·095, 95% CI: 1·075-1·114), resulting in a marginally significant difference between arms (interaction coefficient 1·024, 95% CI: 0·997-1·052 p-value=0·078) (Figure 3; Appendix page 1). Testing uptake among men tripled over the course of the study, but started and remained quite low; just under 6% of the male population accessed testing in the final year of the study, up from 2% in the first year. Among women, HIV testing was higher

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in control villages at baseline and increased in both arms significantly over time, with testing uptake increasing by 10·6% (intervention RC 1·106, 95% CI: 1·097-1·114) and 9.3% (control RC 1·093, 95% CI: 1·084-1·102) per quarter. Increases in testing were higher in intervention vs. control village women (interaction coefficient 1·012, 95% CI: 1·000-1·023, p-value=0·043) (Figure 3; Appendix page 1). The annual proportion of women testing in intervention villages increased from 12·19% to 25·27% from years one to three, compared to an increase of 13·59% to 22·88% in control villages. (Figure 3)

Linkage to care within 90 days was assessed among those testing positive, with 367 men and 992 women contributing to the linkage analysis. Linkage did not differ significantly by arm at baseline and did change significantly over time for men in intervention communities (RC 0·985, 95% CI: 0·958-1·012), but did significantly decrease for men in control communities (RC 0·977, 95% CI: 0·954-1.002). (Figure 3; Appendix page 1). Among women, linkage rates improved significantly by approximately 1·3% per quarter in the intervention arm (RC 1·013, 95% CI 1·002-1·023), with no observed increased in the control arm (RC 1·00, 95% CI 0·981-1·020), however, the difference over time by arm was not statistically significant. (interaction coefficient 1·013, 95% CI: 0·990-1·035, p-value=0·267) (Figure 3; Appendix page 1).

Retention estimates are based on care and treatment visits among adults in care in the past year. Thus, estimates of retention started at almost 100% in quarter one. Over time, an increasing number of adults were eligible for the retention analysis as more care was documented in HDSS-Clinic Link. At study start, 615 adults were known to be in care in control communities and 928 adults were in care in intervention communities. Retention significantly dropped over time, as those known to have been in care began to default. As a result, despite more people being diagnosed and initiating treatment over time, the retention analyses show reductions in retention (Figure 3; Appendix page 1). Men in intervention and control villages defaulted at a rate of approximately 2% per quarter in both arms (intervention RC 0·981, 95% CI: 0·977-0·985; control RC 0·979, 95% CI: 0·973-0·984). Among women, rates of retention were marginally better in the intervention villages (RC 0·981, 95% CI: 0·979-0·984) as compared to control villages (RC 0·978, 95% CI: 0·976-0·981), with some indication of less default among intervention community women (interaction coefficient 1·003, 95% CI: >1·000 - 1·006; p-value=0·062) (Figure 3; Appendix page 1). By the end of the study period 83% of women in intervention villages were retained vs. 81% of women in control villages (Figure 3), a small but important difference at the population-level, resulting in 2086 adults aged 18-49 retained in care in the intervention communities and 1599 retained in control communities.

Finally, in assessing our summary outcome measure, there were notable differences between intervention and control communities in the composite 90-90-90 indicators in the final year of the study (Figure 4). As compared to control community men, Intervention community men were more likely to know their status (44·9% vs. 36·9%), be on ART (26·1% vs 20·4%) and be virally suppressed (19·8% vs. 14·3%). Similar differences were observed between intervention and control community women in known status (68·3% vs. 64.0%), being on treatment (44·1% vs. 39·2%) and viral suppression (33·6% vs 30·7%). While all differences were significant when comparing intervention and control communities overall (Figure 4),

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statistical significance was attenuated when using cluster-adjusted estimates, such that only differences in viral suppression among men remained significant. In absolute terms these proportions translate into 200 more residents who are virally suppressed in the intervention communities vs. the control communities, which could lead to stark differences in rates of new infections.

Sensitivity analyses including all quarters of the study data did not change findings appreciably, with the exception that the rate of testing among intervention community men was statistically higher than that of control community men (p-value=0.033; data not shown). Sensitivity analyses using random effects models indicated little to no appreciable variation in village slopes, and, though these models yielded similar coefficients to the GEE model, confidence intervals included the null (Appendix pages 2 and 3). There were no reports of adverse events or social harms during the study.

Discussion

To our knowledge, this is the first trial specifically designed to assess whether a community mobilization intervention addressing social barriers to HIV service uptake and promoting treatment as prevention increases rates of HIV testing, linkage to and retention in care. Using a cluster-randomized design, we identified modest but significant improvements in testing uptake among women in intervention communities relative to control communities, with marginal evidence of increased testing among men and retention in care among women in intervention relative to control communities. We also noted improvements in linkage among women in intervention communities, but not in control communities. Impacts for each individual outcome are modest and perhaps insufficient to warrant the cost of a CM approach for any single outcome. However, the sum of these incremental improvements resulted in meaningful differences at the population level at the end of the three-year study, as evidenced in the improved 90-90-90 indicators in intervention community residents.

HIV testing in the study communities started at much lower rates than those reported in national survey data which were utilized for power calculations, with only about 2·34% of males and 13·01% of women presenting for HIV testing in year one. It is likely that some HIV tests were not recorded; negative test results are particularly vulnerable to this. We also suspect that HIV testing is over-reported in survey data. Nonetheless, testing uptake increased significantly for men and women in intervention communities and for men in control communities, with the increase being greater among intervention versus control community women in main analysis, though effects were attenuated in the random effects sensitivity analyses. Differences between intervention and control community men were marginally significant in main analyses, significant in sensitivity analyses including first and last quarters, and not significant in the random effects sensitivity analyses.

Linkage and retention indicators were slightly higher among intervention communities, with some evidence of increased linkage as well as less default among intervention women as compared to control community women. Importantly, while 1.3% quarterly increases in linkage appear modest, the end result of having approximately 85% of intervention women linked at the end of the study compared to 75% at the outset translates into substantive

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impacts at the population level. All 90-90-90 indicators were higher in intervention communities at endline. Notably, national 90-90-90 indicators are much higher than those in our study. For example, the 2017 National HIV Survey Summary, estimated that 78·0% and 88·9% of HIV-positive males and females, respectively, were aware of their status.[4] Estimates in this study are lower, and far below levels of testing and treatment uptake that would be needed to control the epidemic. However, there is no reason to believe that bias would be differential between intervention and control arms, as all residents attend the same set of nine clinics.

Improvements in the policy environment over the three years of the intervention may have reduced the likelihood of study impact across all indicators. Rates of HIV testing uptake are improving across sub-Saharan Africa, as demonstrated by increased testing uptake in control communities in this study, with increases attributed to testing campaigns and improved availability of testing and treatment. Universal treatment was implemented in September 2016, coinciding with the beginning of year two of our intervention, and it is likely a key factor in increases in treatment initiation in South Africa.[27,28] These policy gains likely had similar impacts on the concurrent test and treat trials, in which differences in available treatments between control and treatment arms were reduced.[12–14,29] Despite improving trends in treatment uptake, our data also indicate reductions in retention, which could represent default due to healthier individuals not adhering to treatment, or could be a result of the data structure with limited information on treatment (and retention) prior to the trial.

The large test and treat trials referenced above aimed to reduce community HIV incidence and collectively demonstrated moderate impacts.[30] The interventions largely focused on integrated HIV service delivery, but also used community outreach strategies, such as community health campaigns, to facilitate uptake of HIV testing and care. In contrast, our trial focused exclusively on community mobilization to address social barriers and encourage testing and treatment uptake at local clinics. We only facilitated service delivery when participants mobilized for community-based testing; such testing events occurred six times over the project's course. Our trial offers important evidence that on its own, community mobilization efforts that truly aim to change social understanding and social processes can yield improvements in testing and care engagement. However, we hypothesize that both supply, in the form of improved access to service delivery—e.g., shorter wait times, confidential services, extended ART prescriptions, and community-based care delivery for stable patients— and demand resulting from mobilizing communities to address social norms and action surrounding HIV—e.g., addressing stigma around HIV testing and ART, addressing ART literacy—should be integrated in future efforts to achieve greater impacts.

We hypothesize that Tsima successes result in part to addressing what is likely the most intractable barrier to engagement in care, HIV-related stigma, which is best addressed by changing social dynamics. Qualitative data from our trial found evidence that Tsima brought about improved treatment literacy and that understanding the benefits of early and consistent HIV treatment motivated participants to engage in testing and care by reducing stigma-related fears associated with a positive diagnosis.[31] Because stigma is unlikely to resolve by increasing service delivery alone,[32] less focus on stigma, could have played a role

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in diminishing the impact of some of the test and treat trials,[30] driving home the need for continued innovation in the field of stigma reduction. These innovations are most urgently needed for men, where entry to care through HIV testing continues to pose the greatest barrier to achieving national targets.[27] At our research site, men access health services at less than one tenth the frequency that women do.[33]

Limitations

This trial included a rigorous design to estimate population-level impacts of a community-based mobilization intervention. Nonetheless, there were some limitations. Some control village residents reported attending CM activities, which could attenuate effects. There were likely residents who received HIV testing services who went uncaptured. However, because potentially missing testing data would be non-differential between arms, it would most likely attenuate intervention effects. Additionally, based on our 2018 survey data, approximately 7% of those in care for HIV in the HDSS reported receiving treatment at a facility outside the study area. Because proportions receiving care elsewhere were equivalent between intervention and control communities on the survey, bias in comparative findings is unlikely; however, our 90-90-90 estimates across intervention and control communities could be biased downwards. In our models for the linkage to care outcomes, the number of clusters is modest (15) and may lead to underestimation of the standard error, even with robust error estimation. Finally, we do not know definitively what proportion of the population is living with HIV; as a result, we estimated the HIV positive population using age and sex specific prevalence estimates for the Province from the Thembisa model, which is utilized by the national program.[25]

Conclusions

Taken together, our results strengthen evidence that CM focused on treatment as prevention can improve the HIV care continuum. CM has at its core the building of community social resources to address inequities, disparities and injustices, and for communities to build their own responses to health, in this case HIV.[10] We believe that sustained improvements in HIV outcomes will require a purposeful emphasis on broad community capacity building, as community-wide improvements owing to social change have potential to be sustained. The potential impact can be most clearly demonstrated in the overall 90-90-90 findings, evidence that incremental improvements can impact the course of the national HIV epidemic.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Data Sharing

Data sharing requests will be considered by the study principal investigators upon written request to the corresponding author. Deidentified participant data or other prespecified data will be available subject to a written proposal and a signed data sharing agreement.

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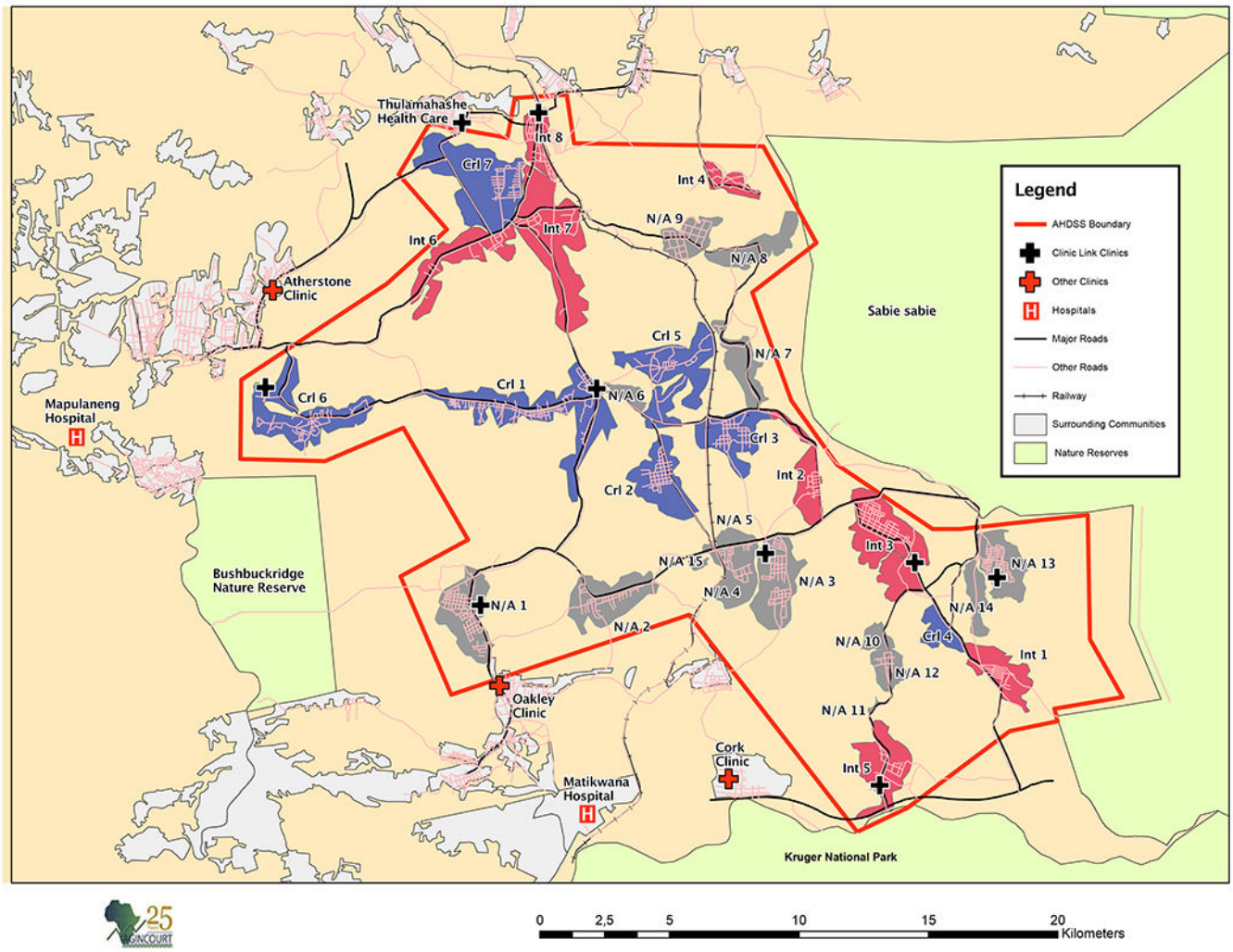


Figure 1:

Agincourt HDSS Study Area Map.

Intervention villages displayed in pick and denoted with “Int 1-8”; Control villages displayed in purple and denoted with “Crl 1-7”. All area villages not included in this study displayed in grey and denoted with “N/A 1-15”

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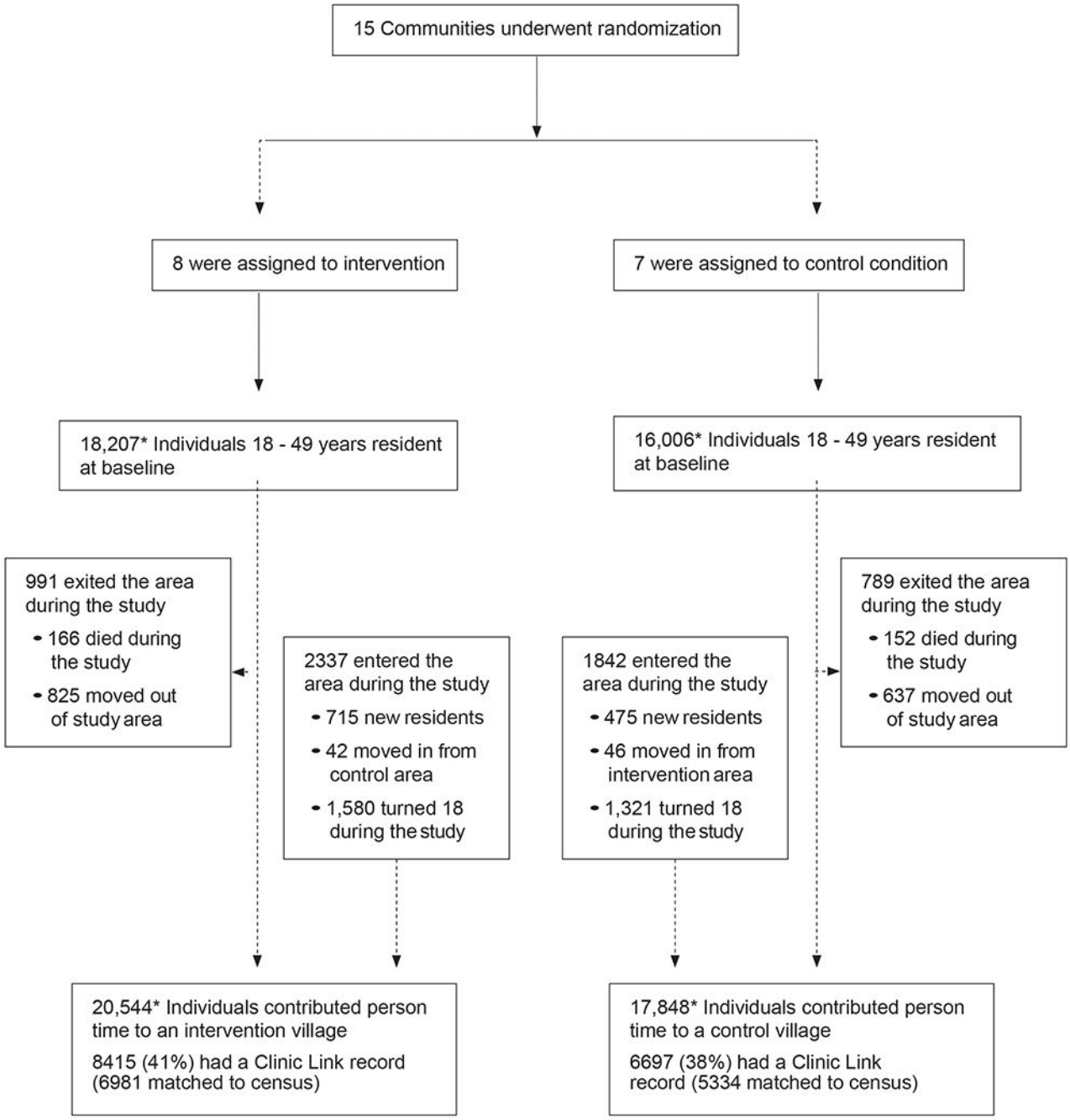


Figure 2:

Trial Population.

Individuals were included in the analyses if they resided in a study village at any point during the study. *92 individuals moved during the study and contributed to both intervention and control arm outcomes during the study

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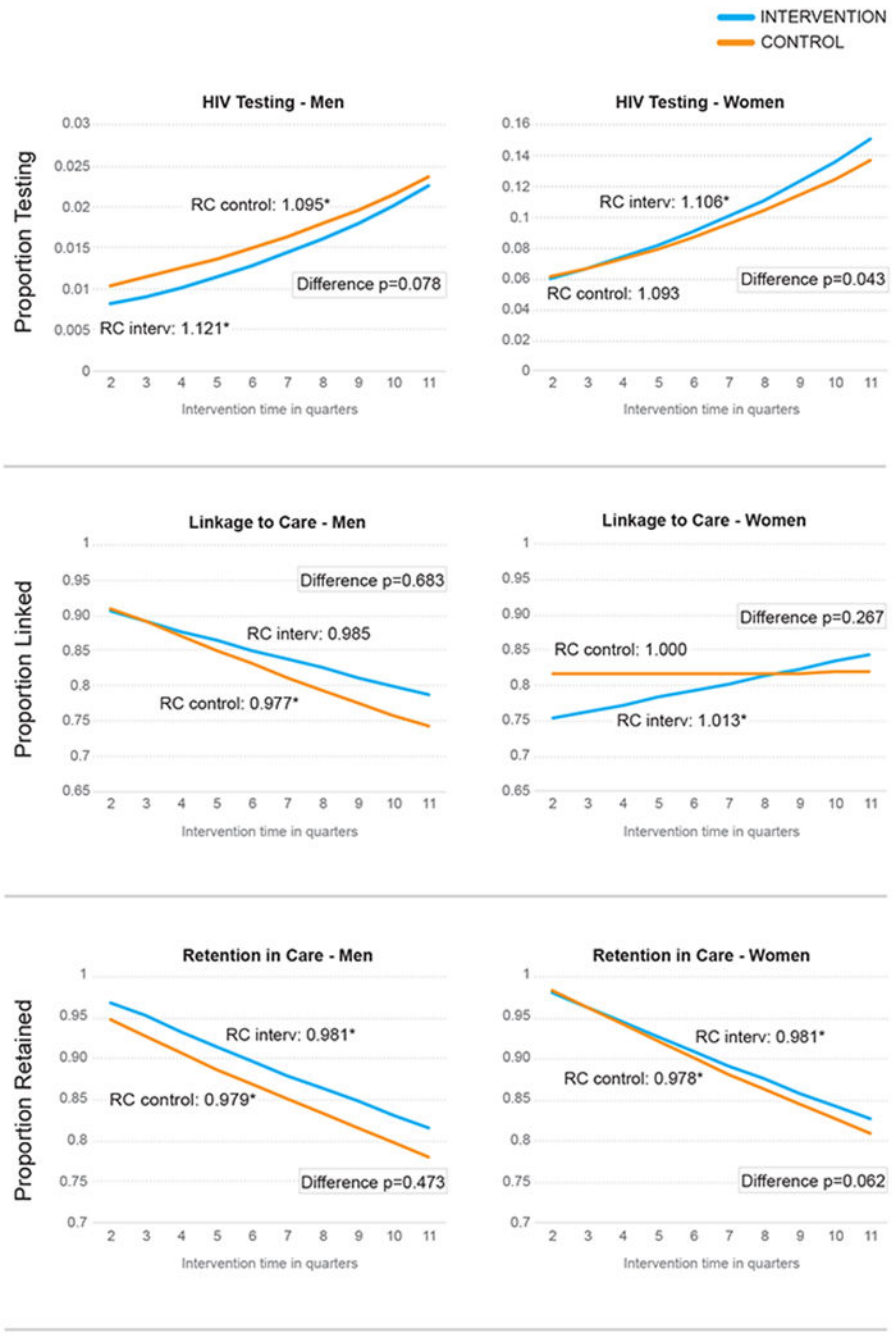


Figure 3:

Primary Intent To Treat Analyses for A: HIV Testing, B: Linkage to Care, C: Retention in Care, stratified by sex.

The model is structured with time in three-month increments, with relative change (RC) calculated for intervention and control groups separately over time. Therefore each RC represents the relative change in the proportion of residents being tested, linked, and retained over three month time periods with (*) indicting significant changes. Interaction term p-values represent the significance testing for differences in rates of outcomes between arms.

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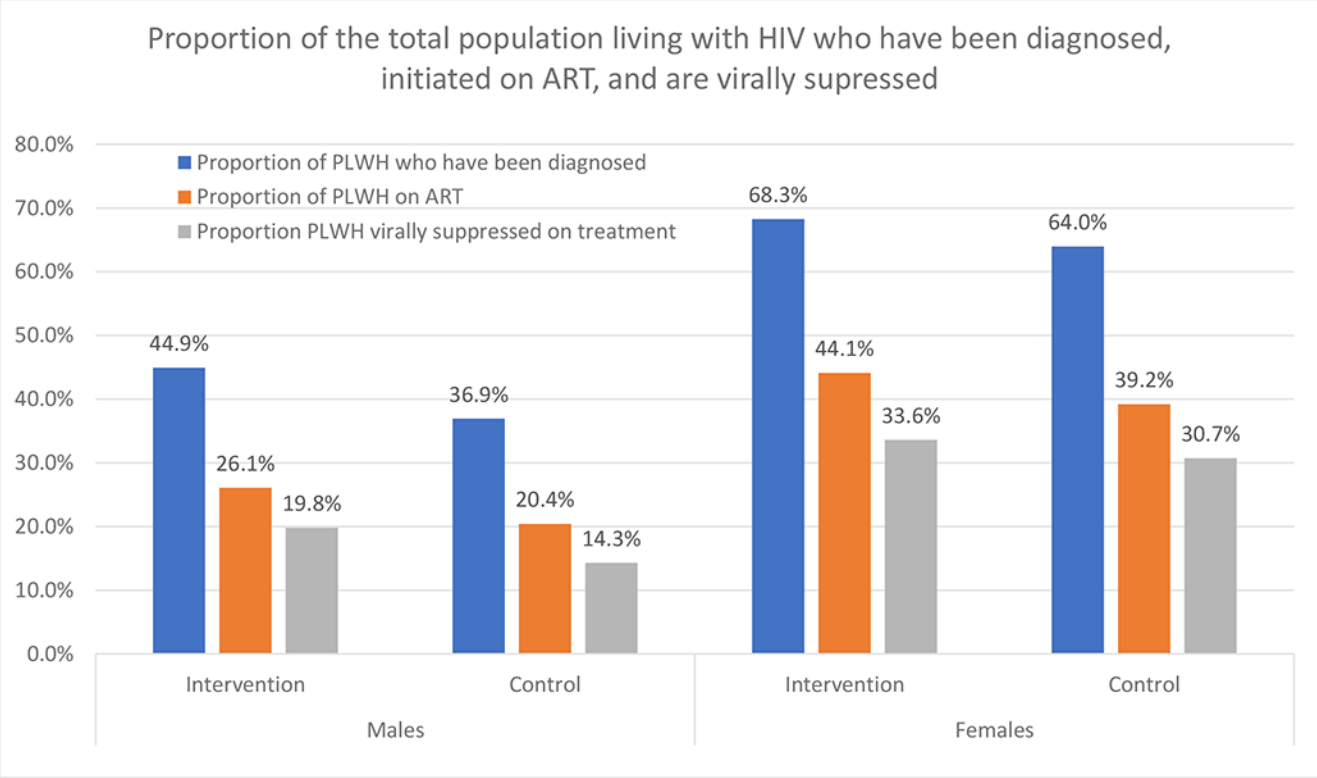


Figure 4: 90-90-90 indicators among all people living with HIV (PLWH) at the end of the trial, August 2018

Overall differences between intervention and control community men: known status, on ART, viral suppression ($p<0·001$; $p<0·001$; $p<0·001$, respectively) and intervention and control community women: known status, on ART, viral suppression ($p<0·001$; $p<0·001$; $p=0·016$, respectively).

Cluster-adjusted differences between intervention and control community men: known status, on ART, viral suppression ($p=0·15$; $p=0·14$; $p=0·032$, respectively) and intervention and control community women: known status, on ART, viral suppression ($p=0·54$; $p=0·34$; $p=0·45$, respectively).

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Table 1:

Characteristics of the Trial Population at Baseline

	Intervention (8 villages; N=18,207)		Control (7 villages; N=16,006)	
Resident Characteristics *	**N**	**%**	**N**	**%**
Sex				
Male	8917	49·0%	7936	49·6%
Female	9290	51·0%	8070	50·4%
Age group				
18 – 29 years	9501	52·2%	8337	52·1%
30 – 39 years	5391	29·6%	4847	30·3%
40 – 49 years	3315	18·2%	2822	17·6%
SES measured by household assets (mean, sd)	2·73	0·38	2·8	0·36
Years of education (mean, sd)	10·35	2·96	10·64	2·71
Village Characteristics*	**mean**	**sd**	**mean**	**sd**
Cost of taxi to nearest clinic from village center (ZAR)	11	3·8	10·6	1·5
Proportion temporary migrant	0·276	0·048	0·301	0·042
Proportion female headed households	0·426	0·037	0·426	0·020

* Population characteristics from the 2015 Agincourt Census; village characteristics represent village averages. Because 99.5% of the population is comprised of Black South Africans, race/ethnicity data is not captured.