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Pulling the network together: quasi-experimental trial of a patient-defined support network intervention for promoting engagement in HIV care and medication adherence on Mfangano Island, Kenya

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Abstract

Background—Despite progress in the global scale-up of antiretroviral therapy, sustained engagement in HIV care remains challenging. Social capital is an important factor for sustained engagement, but interventions designed to harness this powerful social force are uncommon.

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Methods—We conducted a quasi-experimental study evaluating the impact of the Microclinic social network intervention on engagement in HIV care and medication adherence on Mfangano Island, Kenya. The intervention was introduced into 1 of 4 similar communities served by this clinic; comparisons were made between communities using an intention-to-treat analysis. Microclinics, composed of patient-defined support networks, participated in ten bi-weekly discussion sessions covering topics ranging from HIV biology to group support, as well as group HIV status disclosure. Nevirapine concentrations in hair were measured pre-and-post study.

Results—113 (74%) intervention community participants joined a microclinic group, 86% of whom participated in group HIV status disclosure. Over 22-months of follow-up, intervention community participants experienced one-half the rate of ≥ 90-day clinic absence as those in control communities (adjusted hazard ratio 0.48, 95%CI 0.25–0.92). Nevirapine hair levels declined in both study arms; in adjusted linear regression analysis, the decline was 6.7 ng/mg less severe in the intervention arm than control arm (95% CI −2.7 to 16.1).

Conclusions—The microclinic intervention is a promising and feasible community-based strategy to improve long-term engagement in HIV care and possibly medication adherence. Reducing treatment interruptions using a social network approach has important implications for individual patient virologic suppression, morbidity and mortality, and for broader community empowerment and engagement in healthcare.

INTRODUCTION

As HIV treatment programs scale up across resource-limited settings, unprecedented numbers of patients are newly initiating antiretroviral therapy (ART) each year. In 2012, nearly 1.3 million patients started ART in sub-Saharan Africa alone.[1] Despite this substantial progress, consistent and long-lasting engagement in HIV care remains a major challenge. Applying best- and worst-case 3-year retention scenarios, an estimated 200,000 to 450,000 of those newly initiated on therapy in sub-Saharan Africa during 2012 will have discontinued treatment by 2015.[2,3]

Given the magnitude of the retention challenge, there is considerable interest in understanding factors that help patients maintain consistent engagement in care over time.[4] One large ethnographic study across three sub-Saharan African countries identified access to social capital as a key facilitator of adherence to therapy.[5] Findings from that study, and others, indicate that patient support networks provide necessary psychosocial and material resources for maintaining engagement in HIV care and adherence to therapy.[4,6] In return, supporters expect ‘good adherence’, providing positive peer pressure for health-sustaining behaviors.

However, social capital can be difficult for HIV-infected individuals to access when seeking support for HIV treatment.[4,7] Status disclosure is often avoided due to fear of the real and perceived ways that disclosure can affect social standing, livelihoods, and relationships.[4,8,9] Consequently, many people living with HIV navigate treatment in secret,[10–12] leading to diverse negative consequences on maintenance of therapy over time.[4,13]

Social interventions to promote the exchange of social capital have been previously developed to improve retention in HIV care and adherence to medications. Some ART programs encourage patients to identify a 'treatment supporter' – a trusted individual who can provide psychosocial support and assistance with clinic appointments and medication-taking.[14–20] Patient support groups, another common intervention, allow patients to exchange knowledge and experiences with fellow patients.[21,22] Evidence suggests that these interventions may reduce stigma and facilitate disclosure.[23] However, by focusing exclusively on a single treatment supporter or a group of patient peers, these interventions may not fully utilize the pre-existing social infrastructure that patients engage with throughout daily life.

To address this gap, we adapted a social network-based intervention known as 'microclinics' that has previously been applied to address diabetes and other chronic diseases in other low-resource settings.[24,25] Microclinics are informal social networks empowered to support chronic disease management and prevention. Randomized trials of the microclinic model have demonstrated reductions in hemoglobin A1C levels and body mass indices for diabetic patients in Jordan[26,27] and in rural Kentucky.[24] Hypothesizing that a combined stigma reduction and social network empowerment intervention would result in improved HIV treatment outcomes[28], we developed a novel adaptation of microclinics to encompass groups of mixed HIV-infected and HIV-uninfected individuals in rural Kenya. We conducted a quasi-experimental trial to evaluate the impact of microclinics on engagement in HIV care and medication adherence among patients in this setting.

METHODS

Study population and setting

This study was conducted at Sena Health Center, the largest of six public-sector health facilities and dispensaries on Lake Victoria's Mfangano Island. Mfangano is located within Homa Bay County, the most HIV-affected county in Kenya, with an estimated adult prevalence of 27%.[29] Mfangano has a population of approximately 21,000 and is divided into four administrative sub-locations of roughly equal size. The Sena Health Center is located on the boundary between the East and North sub-locations and over 90% of patients at Sena reside in one of these two locations. Adult patients at the Sena Health Center were eligible to participate if they were Mfangano residents and had initiated ART prior to or during the study enrollment period from November 2011 – February 2012. The study was approved by the Kenya Medical Research Institute Ethical Review Committee and the University of California, San Francisco Committee for Human Subjects Research. The study protocol is registered at ClinicalTrials.gov (NCT01912521). Written informed consent was obtained prior to study enrollment.

Design and intervention

We conducted a quasi-experimental study with the intervention administered within the Mfangano East sub-location and the remaining three sub-locations serving as control. For this pilot study, Mfangano East was selected as the intervention community out of convenience because the implementing organization, the Organic Health Response, is

located within Mfangano East. Thus, Sena Health Center patients who lived in East comprised the intervention group and those residing in the remaining three neighboring sub-locations comprised the control group. We used an intention-to-treat analysis with treatment assignment based on sub-location of residence rather than intervention uptake. As secondary analysis, we also conducted as-treated analyses based on intervention participation.

After enrolling patients on ART at the Sena Health Center in the study, those living in the intervention community were invited to form 'microclinic' groups. These microclinic groups were intended to contain 5–15 close family, friends or other members of the patient's social support system, irrespective of these individuals' HIV status. CHWs and study staff worked with 'seed' individuals (i.e. study participants on ART) to identify microclinic group members. In some cases, several 'seed' individuals and their networks were combined into one microclinic group, based on CHW catchment area. Additionally, pre-existing community groups were also invited to form microclinic groups and participate in the intervention. At the time of group formation, all microclinic participants underwent confidential individual HIV counseling and testing.

Once formed, microclinics were assigned a CHW coordinator and facilitator, and were guided through a series of ten discussion sessions over a period of five months. Sessions were scheduled every two weeks at a time and location of each group's choosing and lasted 2–3 hours each. CHWs participated in a 3–4 hour 'train-the-trainer' workshop prior to each session to learn the games, role-plays and didactic components of each session, ask questions, and discuss with fellow CHWs prior to delivering the material to microclinic groups. CHWs were paid a stipend to compensate their role in microclinic coordination.

Over the course of the ten group discussion sessions, major intervention components included 1) health education to promote knowledge of HIV prevention and treatment; 2) promotion of group support through discussions of confidentiality, HIV status disclosure, and encouragement of group support for adherence and clinic attendance; and 3) outreach to promote HIV testing and clinic enrollment within the community. At the conclusion of the ten sessions, groups were invited to participate in voluntary group HIV testing, allowing microclinic members to disclose their HIV status to one another. Participants were followed for 18 months after initiation of the intervention to ascertain treatment outcomes.

Measurements

Study staff conducted surveys and chart review to measure baseline demographic and clinical characteristics (Table 1). At baseline and immediately post-intervention, we measured perceived community (attributable) stigma[30], HIV-related knowledge[31] and social support[32]. Study staff also collected small hair samples for measurement of ART concentration, using previously described procedures.[33] Hair samples were shipped at room temperature to a UCSF lab (the Drug Studies Unit) in San Francisco for analysis by liquid chromatography/tandem mass spectrometry (LC-MS/MS).[34,35]

We also collected clinic visit dates and corresponding next scheduled appointment dates from clinic records. For participants who were lost to follow-up, we conducted active patient tracing at the end of study follow-up, as well as review of records at other clinics on

Mfangano to ascertain whether the patient had transferred, died, or simply discontinued clinical care. We assumed that patients who could not be located and were not in care at another clinic within Mfangano were disengaged from care. For patients in care at another Mfangano facility, we continued chart review at those facilities following the transfer.

Statistical Analysis

Primary outcomes were engagement in HIV care and change in antiretroviral drug concentration in hair from baseline to immediately post-intervention. We evaluated engagement in care in two different ways, namely 1) time to first 90-day clinic absence following a missed visit and 2) time spent adhering to clinic visit schedules (termed 'time in care'). Secondary outcomes included changes in HIV-related stigma, HIV knowledge, and reports of social support.

We used logistic regression, with a test for overall effect for categorical variables with more than two categories, to compare distribution of baseline characteristics between study arms. Because nevirapine (NVP) was the most prevalent drug taken by study participants (88% at baseline and 84% at post-intervention), and because the means and ranges of hair concentrations differs for each drug, we restricted our hair sample analysis to NVP users.[36] We computed the difference in hair NVP concentrations from baseline to immediately after completion of the intervention. Patients who were not taking NVP or who did not donate hair for analysis at one or both time points were excluded from analysis. We used univariable and multivariable linear regression to compare changes in NVP hair levels between study arms.

We calculated gaps in care by determining the number of days between a missed visit and the date of return to any clinic on Mfangano; participants were censored on the date of death or transfer to a health facility outside Mfangano Island. Thus 90-day disengagement indicates missing an appointment by ≥ 90 days and not known to have first transferred or died. 'Time in care' constituted the proportion of time participants spent adhering to their scheduled appointment dates, and was calculated as follows:

$$\frac{\text{Total time eligible for care} - \text{sum of gaps in care}}{\text{Total time eligible for care}}$$

Total time eligible for care was calculated from the date of study enrollment until the date of censoring or study closure. We compared time to 90-day disengagement between study arms using Cox proportional hazards. We evaluated the proportional hazards assumption both graphically and using formal testing with Schoenfeld residuals. We also computed the cumulative incidence function using death as a competing event, and displayed differences between groups graphically.[37] We used linear regression to compare differences in time in care between study arms. To enhance interpretability, we converted model-derived estimates to days per person-year by multiplying by 365.25. To address potential non-normality of the residuals, we used bootstrapping with 10,000 replications and cluster resampling to evaluate the degree to which potential non-normality of residuals impacted standard errors.

Though primary analysis was conducted using intention to treat, we also performed sensitivity analyses excluding individuals in the intervention arm who did not join a microclinic group. For each model, we used robust standard errors, which accounted for non-independence resulting from the clustered nature of the intervention. In multivariate models, we adjusted for baseline factors reasonably thought to confound the relationship between community of residence and study outcomes. These included age, sex, monthly household income, walking distance to the Sena Health Center, stigma score, HIV-related knowledge, social support, CD4 count, WHO stage and time since ART initiation. Predictors with p-values <0.1 were retained in an intermediate model and each predictor was readded and included in the final model only if the addition changed the estimated intervention effect by ≥ +/−10%.

In addition to the primary study outcomes, we used univariable linear regression to evaluate intervention impact on changes in perceived stigma, HIV-related knowledge, and social support.

RESULTS

Of 426 eligible clinic patients, 369 (87%) enrolled in the study (Figure 1). Baseline characteristics were similar between communities, though intervention community participants tended to live closer to the clinic and have higher baseline CD4 cell counts (Table 1). Within the intervention community, 44 microclinic groups were formed. The median (range) microclinic group was 13 members in size (4–18), 78% female (0–100%) and 33% HIV-infected (0–86%). Thirty-four groups contained a study participant on ART, nine groups contained members who were HIV-infected but not yet on ART, and one group was composed entirely of HIV-uninfected individuals (note, some groups did not contain a study participant on ART because we allowed pre-existing groups to also form microclinics). In total, 113 (74%) of the 153 intervention community study participants on ART and 423 members of their social support networks participated in a microclinic. Four control community study participants also participated in a microclinic group. Thus, standard errors for all models were adjusted for 286 clusters, namely 212 control arm participants who did not join a microclinic, 40 intervention arm participants who did not join a microclinic and 34 microclinic groups containing 117 study participants on ART from both intervention and control study arms. Microclinic participation was excellent; 110/113 (97%) of intervention arm study participants remained active group members at the end of the 10 sessions, based on CHW report, with study staff verification. Further, 86% of both patients on ART (97/113) and their social support network members (364/423) attended voluntary group counseling, testing and disclosure. Twenty one percent (75/364) of support network members who participated in the group disclosure were HIV-infected, but had not yet started ART. Clinic data was not available for these participants, and thus we were not able to determine whether they were enrolled in clinical care. HIV status of group members who did not participate in group testing and disclosure was not available.

Medication adherence

The acceptability of hair collection was 95% (350 of 369) at study baseline and 99% (338 of the 340 remaining in the study) at 6-month follow-up. One hundred and eleven (73%) intervention arm participants and 162 (75%) control arm participants were taking NVP and had hair samples collected at both baseline and 6-month study visits. Mean NVP levels decreased in both cohorts, from 82.9 to 77.4 ng/mg (change: −5.5, SD 42.4) in the intervention community and 93.4 to 81.0 ng/mg (change: −12.4, SD 38.8) in the control community (n=273). In univariable linear regression, the decline in NVP hair concentrations over the course of the intervention was 6.9 ng/mg less in the intervention arm compared to the control arm (95% CI −2.5 to 16.2). Because both groups experienced decreases in NVP hair concentrations, this represented a non-statistically significant smaller decrease in the intervention arm in comparison to control. In multivariable modeling, only age was retained as a potential confounder; estimates remained similar (effect size 6.7 ng/mg, 95% CI −2.7 to 16.1).

In as-treated analysis, comparing those who joined a microclinic group in the intervention arm to all participants in the control arm, decrease in NVP hair concentration was 11.1 ng/mg (95% CI 1.3 to 21.0) less in the intervention group than control. Multivariable analysis, including age, yielded similar results (effect size 11.3 ng/mg, 95% CI 1.4 to 21.1).

Disengagement from care

After study enrollment, participants were followed for 22 months or until the date of death or transfer to a health facility outside Mfangano Island. Most participants were retained in care by the end of follow-up (Figure 1), however over the course of follow-up, 11% of intervention arm participants intervention arm and 20% of those in the control arm experienced a clinic absence of ≥ 90-days. Incidence rates of 90-day disengagement were 6.8 per 100 person-years in the intervention group (95%CI 4.2–10.9) and 12.9 (95%CI 9.6–17.3) in the control. Using an unadjusted Cox proportional hazard model, participants in the intervention arm had one-half the rate of ≥ 90-day clinic absence as those in the control arm (HR 0.53, 95% CI 0.28–1.02) (Table 2). Adjusted analysis, including time since ART initiation and distance to the health center, yielded similar results (adjusted (a)HR 0.48, 95% CI 0.25–0.92). We plotted the cumulative incidence of 90-day disengagement, treating death as a competing event, to visually represent disengagement occurrence over the study period (Figure 2). Notably, the first four months of follow-up were contemporaneous with group formation and the intervention itself did not begin until month five. Cumulative incidence curves suggest a difference in disengagement that begins approximately two months after initiation of the intervention.

Time in care

To further characterize engagement in care over time, we measured the proportion of time participants spent adhering to clinic appointment schedules (*time in care*). During study follow-up, the average time in care was 86.2% in the intervention community and 81.6% in the control community, an absolute difference of 4.6% (95% CI 1.3% to 8.5%) (Table 3). This is equivalent to an increase of 17 days ‘in care’ per patient-year (95% CI 3–31 days) among patients in the intervention arm. In multivariable linear regression, adjusting for time

since ART initiation, distance from clinic and baseline stigma, the intervention community experienced a 6.0% absolute increase in time in care (95% CI 3.4 to 8.6%), an increase of 22 days 'in care' per patient-year (95% CI 10 to 34 days). Confidence intervals were not substantively changed when recalculated using the bootstrap method (data not shown).

Stigma decreased by 25% relative to baseline in the intervention community and was unchanged in the control community, with a difference in change scores between groups of −1.6 units on a 17-unit scale (95% CI −2.4 to −0.8, Table S1). There was no difference in change in HIV-related knowledge between groups. Social support increased slightly in the intervention community, though the change within the intervention arm represented only a 2% relative increase from baseline.

DISCUSSION

Microclinics improved community-wide engagement in HIV care among patients on ART. Patients residing in the intervention community had one-half the rate of 90-day gaps in care as control participants. Those in the intervention community also spent a larger proportion of time adherent to clinic schedules. The observed 6% increase in time in care in the multivariable model is equivalent to a three-week reduction, per patient-year, in the delay between missed visits and subsequent return to clinic.

We also observed increases in hair NVP concentrations in intervention community participants relative to controls, though this improvement was not statistically significant. The confidence interval of our observed estimates for change in NVP hair concentrations was wide and included the possibility of either no true effect or an effect large enough to be beneficial for many patients, based on comparison of NVP changes to virologic suppression in another study.[36] As-treated results suggested that the intervention might exert a protective effect on declining hair drug levels over time. However, this analysis is subject to potentially substantial selection bias and should be regarded with caution. Absolute NVP hair concentrations are difficult to interpret clinically, especially since this rural Kenyan cohort had baseline mean concentrations that were over two times higher than US-based cohorts.[33,36] However, the within-individual differences over a relatively short period of time likely reflect changes in adherence, rather than alterations in pharmacokinetics.[38]

We propose that the microclinic intervention impacts the above clinical processes by reducing HIV-related stigma and, thus, lowering the 'activation energy' required for engaging social networks in the treatment process. The resulting increase in access to social capital for HIV treatment support could explain our observed improvements in clinic appointment adherence and possible medication adherence.[5] Our observation that HIV-related stigma decreased, while overall social support and HIV-related knowledge remained relatively unchanged, may support this hypothesis.

Microclinics build on key strengths of existing social interventions for promoting engagement in HIV care, including treatment supporters and patient support groups. Whereas treatment supporters promote status disclosure and reduce stigma through a single supportive relationship,[23] microclinics provide this degree of support by means of patient's

broader social network. In addition, microclinics also promote the role of 'expert patients' commonly found in patient support group interventions.[39] By encouraging group members to be both supported by and supporters of other group members, the microclinic model facilitates group empowerment and may represent a more socially-relevant approach to chronic disease management than more individual-oriented approaches.[4]

Though most participants who met our definition of disengagement eventually returned to care, we observed a substantial reduction in long gaps in care in the intervention community. Recent work by Ware and colleagues highlights a pathway from missing a clinic visit to 'disengaging' from care that includes, as intermediary steps, developing a 'reluctance to return' and subsequent feelings of decreased connectedness to care.[40] In our study, missed visits were very common, with over 90% of participants missing at least one visit by more than three days over the course of follow-up and no significant difference between study arms (data not shown). It is possible that microclinic participation either prevented development of 'reluctance to return' following a missed visit or prevented this reluctance from eroding ultimate feelings of connection to care, though further study is needed to understand how the microclinic intervention interacts with these concepts.

These results bolster empiric support for microclinics as an effective model for chronic disease management. Microclinic interventions to address diabetes have demonstrated beneficial effects not only for 'index' diabetes patients, but also for members of their social networks – arguably individuals who are also at high risk for developing diabetes due to shared genetic, environmental and behavioral risk factors.[24,26] Similarly, this intervention holds potential for improving care not only for individuals who are on ART, but also for improving engagement in care by those who have not yet sought HIV care. Still other HIV-uninfected group members may benefit from increased knowledge, motivation and group support for preventing HIV. This multi-level social network effect may be especially important among high prevalence populations.

This study has several limitations, including the quasi-experimental design and our inability to assess impact on downstream health outcomes. Though treatment assignment was not randomized, we compared outcomes among populations that were qualitatively and quantitatively highly similar at baseline. Additionally, our intention to treat analysis eliminated the confounding that occurs when patients with lower risk of poor outcomes are also more likely to participate in a social intervention of this type. Viral load was cost-prohibitive in this early phase trial, and our study design was not intended to evaluate impact on mortality. However, others have shown that gaps in clinical HIV care predict subsequent virologic failure, morbidity and mortality.[41] Our successful efforts to ascertain outcomes for nearly all study participants through active tracing also increase our confidence that observed gaps are reflective of true treatment interruptions. Our time in care measure, the proportion of time patients adhered to their clinic appointment schedules, further supports our observation that patients attended appointments more regularly and with less delay in the intervention community.

CONCLUSION

The microclinic intervention holds promise as a feasible community-based strategy to improve long-term engagement in HIV care. The success of a social network approach on reducing treatment interruptions and improving engagement in care has important implications for improving virologic suppression, and subsequently decreasing morbidity, mortality and HIV transmission. Because of the way in which social networks are woven directly into the fabric of daily life, particularly in poor communities in resource-limited settings, this strategy may result in a more sustained and amplified effect than previously evaluated approaches and warrants further study.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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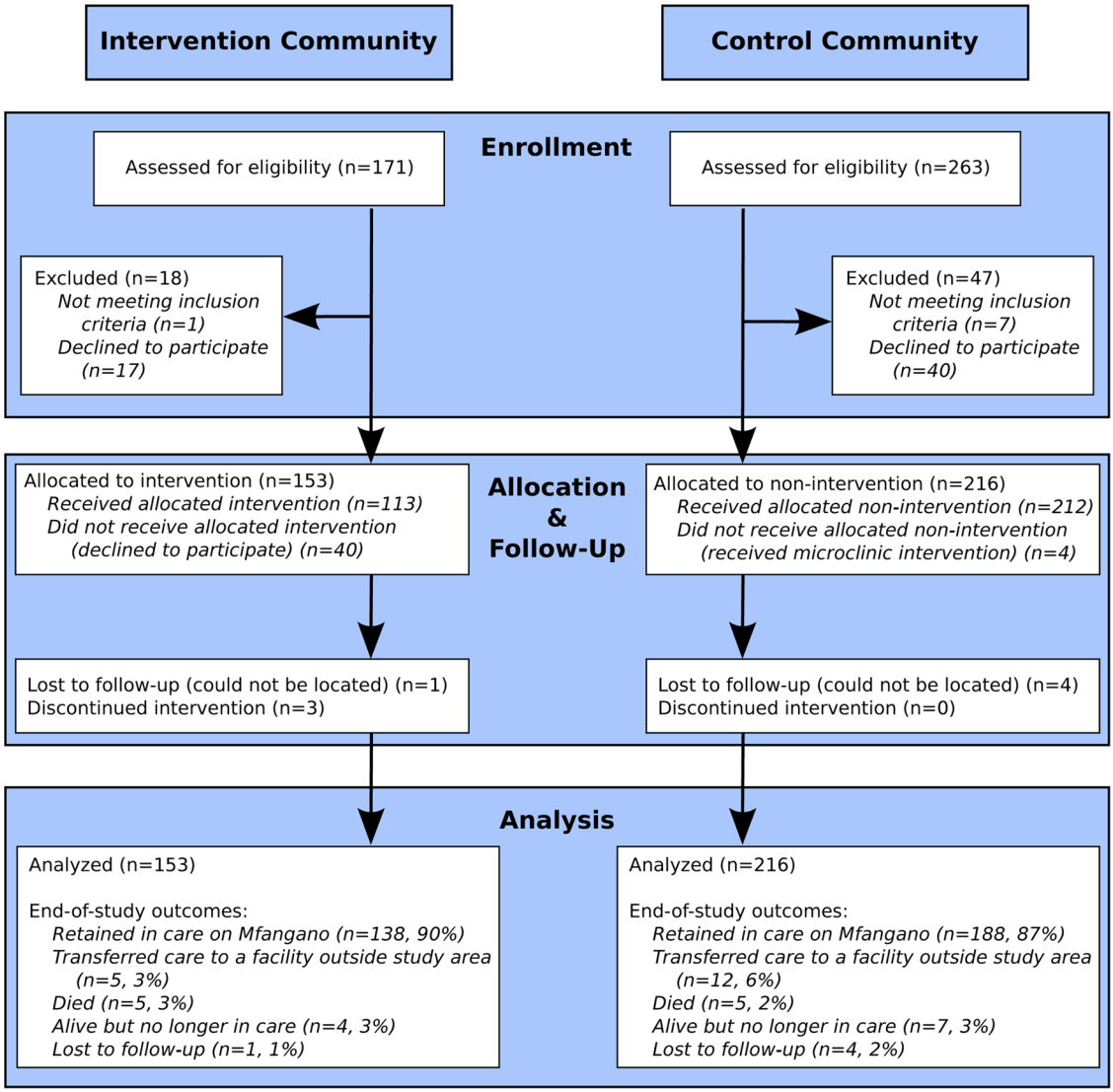

Figure 1.
Participant flow

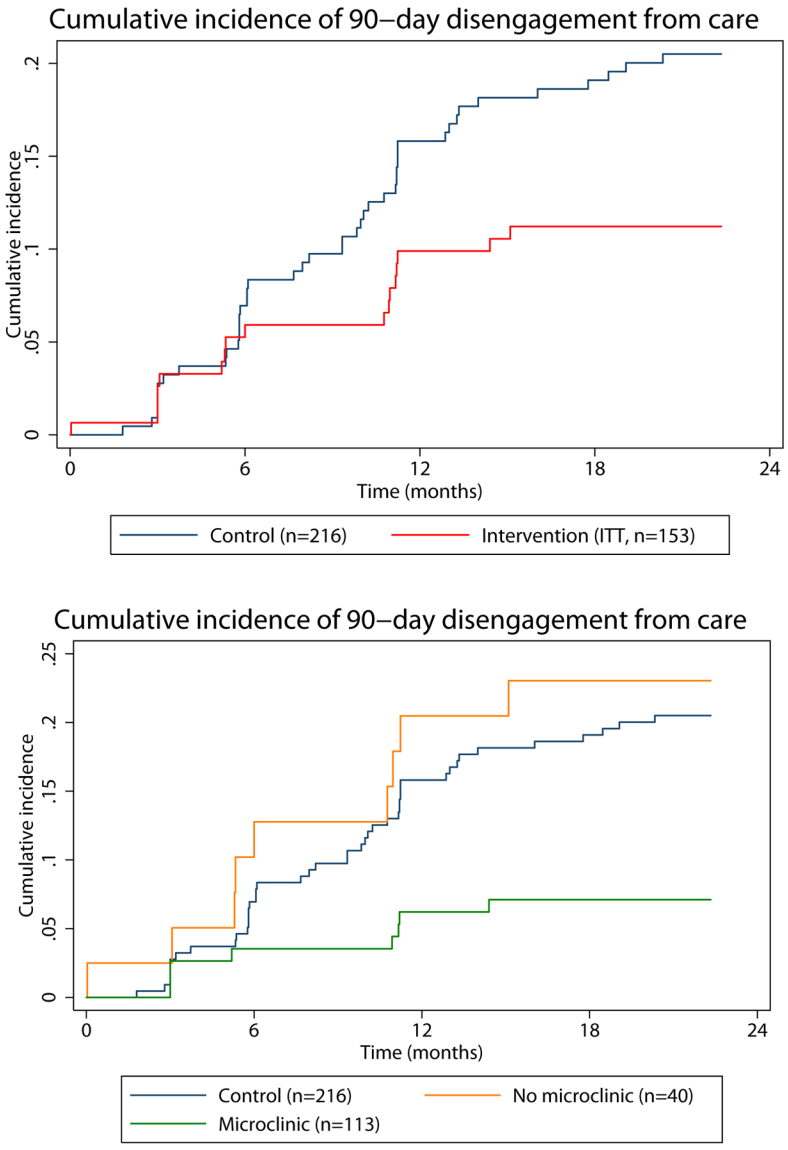

Figure 2. Cumulative incidence of 90-day disengagement from care

The intervention commenced at month 5 and ran through month 9. (A) Intention to treat analysis. (B) As treated analysis with green line representing intervention arm participants who joined microclinics and orange line representing intervention arm participants who did not join a microclinic.

Table 1

Baseline characteristics of the 369 participants enrolled in the MIHNIS study

Characteristic	Control Communities (n=216)		Intervention Community (n=153)		p-value*
Female sex, n (%)	139	64%	97	63%	0.85
Age (yrs), mean (sd)	40	13	39	10	0.40
Monthly household income (USD), mean (SD)	45	49	56	78	0.09
Household size, mean (SD)	5.7	3.0	5.8	3.1	0.76
Level of education completed, n (%)					0.36
None	8	4%	12	8%	
Primary	140	65%	91	59%	
Secondary	56	26%	42	27%	
Post-secondary	12	6%	8	5%	
Marital Status, n (%)					0.11
Single/Never married	10	5%	3	2%	
Separated/Divorced	9	4%	15	10%	
Widowed	61	28%	39	25%	
Married	136	63%	96	63%	
Walking distance to health center, n (%)					<0.0001
<30 min	28	13%	75	49%	
30–60 min	80	37%	46	30%	
>1 hour	108	50%	32	21%	
Baseline stigma score (17-pt scale), mean(sd)†	6.6	3.4	6.9	3.5	0.38
Baseline HIV knowledge scale (18-pt scale), mean(sd)‡	14.8	2.3	14.9	2.0	0.42
Time since ART initiation (yrs), mean(SD)	2.7	1.8	2.8	1.9	0.50
Baseline CD4 count (cells/mm^3), mean(SD)	372	195	415	209	0.05

Characteristic	Control Communities (n=216)		Intervention Community (n=153)		p-value*
Baseline WHO stage					0.89
Stage I/II	103	49%	74	51%	
Stage III	76	36%	52	36%	
Stage IV	31	15%	19	13%	
Microclinic participation, n (%)	4	2%	113	74%	
Group VCT participation, n (%)	2	50%	97	86%	

*univariate logistic regression of continuousor categorical predictors against study arm

†larger value indicates greater perceived stigma

‡larger value indicates increased HIV-related knowledge

Table 2

Disengagement from care

Characteristic	Hazard ratio	95% CI*	p-value
Univariable model			
Intervention community	0.53	0.28–1.02	0.056
Multivariable model†			
Intervention community	0.48	0.25–0.92	0.026
Time since ART initiation	0.80	0.68–0.94	0.007
Walking distance to clinic			
<30 min	ref	ref	ref
30–60 min	0.60	0.30–1.17	0.13
>60 min	0.70	0.36–1.36	0.29

*95% CIs adjusted for clustering using robust standard errors (286 clusters)

†Other covariates considered but not selected: age, sex, monthly income, food insecurity, baseline stigma, baseline WHO stage, baseline CD4 count

Table 3

Time in care

Characteristic	Beta	95% CI*	p-value
Univariate model			
Intervention community	0.046	0.008–0.085	0.02
Multivariate model†			
Intervention community	0.060	0.027–0.093	<0.005
Time since ART initiation	0.015	0.005–0.025	0.004
Walking distance to clinic			
<30 min	ref	ref	ref
30–60 min	0.057	0.011–0.102	0.02
>60 min	0.039	−0.007–0.085	0.09
Attributable stigma‡	−0.004	−0.009–0.001	0.08

*95% CIs adjusted for clustering using robust standard errors (286 clusters)

†Other co-variates considered but not selected: age, sex, monthly income, food insecurity, baseline WHO stage, baseline CD4 count

‡Perceived stigma in the community, increased score indicates higher levels of perceived stigma