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Development, Assessment, and Outcomes of a Community-Based Model of Antiretroviral Care in Western Kenya Through a Cluster-Randomized Control Trial

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Objective: To develop and assess an alternative care model using community-based groups for people living with HIV and facilitate by lay personnel.

Methods: Geographic locations in the Academic Model Providing Access to Healthcare Kitale clinic catchment were randomized to standard of care versus a community-based care group (ART Co-op). Adults stable on antiretroviral therapy and virally suppressed were eligible. Research Assistant–led ART Co-ops met in the community every 3 months. Participants were seen in the HIV clinic only if referred. CD4 count and viral load were measured in clinic at enrollment and after 12 months. Retention, viral suppression, and clinic utilization were compared between groups using χ^2, Fisher exact, and Wilcoxon rank sum tests.

Results: At 12 months, there were no significant differences in mean CD4 count or viral load suppression. There was a significant difference in patient retention in assigned study group between the intervention and control group (81.6% vs 98.6%; $P < 0.001$), with a number of intervention patients withdrawing because of stigma, relocation, pregnancy, and work conflicts. All participants, however, were retained in an HIV care program for the study duration. The median number of clinic visits was lower for the intervention group than that for the control group (0 vs 3; $P < 0.001$).

Conclusions: Individuals retained in a community-based HIV care model had clinical outcomes equivalent to those receiving clinic-based care. This innovative model of HIV care addresses the problems of insufficient health care personnel and patient retention barriers, including time, distance, and cost to attend clinic, and has the potential for wider implementation.

Key Words: community, ART, adherence, retention, LMIC, RTC

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INTRODUCTION

There are approximately 38 million people living with HIV (PLHIV) worldwide.[1] Of those, nearly 70% reside in sub-Saharan Africa (SSA),[2] with 1.6 million in Kenya alone.[3] Nearly 68% of Kenyans living with HIV are on antiretroviral therapy (ART),[3] a number that is increasing as universal test and treat (initiation of ART regardless of a patient's CD4 count)[4] continues to be implemented in support of ambitious Joint United Nations Programme on HIV/AIDS targets of 90-90-90 [90% of PLHIV know their status, 90% of them are on ART, and 90% of those on ART are virally suppressed].[5,6] However, SSA commands only 3% of the world's health care providers and access to only 1% of the global health care expenditures.[7] With a profound shortage of infrastructure, most specifically trained medical personnel, meeting these delivery goals will be difficult.[8,9]

Frequently, geographic accessibility (distance to clinic and transportation availability and costs) and shortages in health care personnel (leading to excessive clinic wait times) were documented as barriers to retention in HIV care.[10–16] Then, in advance of their 2016 revised guidelines on HIV treatment and prevention, the WHO advised the implementation of differentiated care models for the delivery of HIV care.[17] The focus was on the types, locations, providers, and

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frequency of care delivery. Although a small number of programs, particularly in Southern Africa, had already started examining these types of care programs,[18–32] data on the full impact of these models on retention in HIV care and viral suppression remained limited at the time of study conception and initiation.

Care models using task shifting and/or decentralization of care into communities have been assessed in various settings. These have included use of community-based ART distribution sites managed by PLHIV trained to distribute ART and provide adherence counseling to stable patients[33]; home visits conducted by PLHIV to reduce the number of clinic visits [Selke[18]]; and adherence groups taking place under the guidance of lower-cadre health care workers instituted at clinic and community sites.[23,24] Médecins Sans Frontières in Mozambique encouraged the development of Community ART Groups (CAGs) that allow PLHIV to become active participants in their own care and the care of others by supporting ART distribution, promoting adherence, providing social support, and monitoring clinical status.[19,20,25] Retention in the CAGs was exceptionally high, with 97.5% patients remaining in care for a median follow-up period of 12.9 months. Although results pertaining to patient satisfaction and retention in care were positive, little is known about the durability of patients' ART regimens and viral suppression because of this care model.

The goal of this study was to address knowledge gaps related to task-shifting and community-based care models for HIV. As such, we designed the ART Co-ops model, a lay personnel–led community-based model of HIV care delivery, with inputs from PLHIV, the community, and local clinic staff. We sought to compare the ART Co-ops model to the existing clinic-based model of care, with a specific focus on retention in care, viral suppression, and clinic utilization.

METHODS

Study Design

We conducted a cluster-randomized control trial (RCT) to compare the outcomes of PLHIV enrolled in a community-based care group model with those receiving standard of care at an HIV clinic in western Kenya. The study was approved by the Indiana University Institutional Review Board, the Moi University College of Health Sciences, and Moi Teaching and Referral Hospital Institutional Research and Ethics Committee. The study was also reviewed in accordance with the Centers for Disease Control and Prevention human research protection procedures and was determined to be research, but Centers for Disease Control and Prevention investigators did not interact with human subjects or have access to identifiable data or specimens for research purposes.

Study Site

This study was undertaken through the Academic Model Providing Access to Healthcare (AMPATH) program in Kenya. AMPATH is a multidimensional care program established in 2001 with a long-standing emphasis on HIV care, with more than 160,000 patients in active care.[34,35] Patients enrolled were from Trans-Nzoia County, an area of 2500 square kilometers and a population >800,000 people in western Kenya. The county is subdivided into 5 subcounties and 57 sublocations (the smallest geographic identifiers within the area). The Kitale AMPATH clinic, located within Kitale District Hospital, supports the Trans-Nzoia catchment area, providing care and treatment services to more than 19,000 PLHIV.

Study Population

Patients were eligible for study if they were aged 18 years or older, were living with HIV on ART for ≥6 months, had a CD4 count ≥200 cells/μL, and had an undetectable viral load (VL) (<40 copies/mL) at the time of enrollment. Of the 57 sublocations in the county, 25 were excluded because of insufficient numbers of active patients attending the AMPATH clinic to form a community group within the enrollment period, resulting in patients residing in 32 sublocations who were eligible for the study. Patients were excluded from participation if they were pregnant or had an active opportunistic infection. Women who became pregnant while in the study were withdrawn and referred to the antenatal clinic as per the clinic's standard of care.

Description of the Intervention

Formative Process Informing Final Study Design

Before initiating the RCT, we gathered information from community stakeholders through key informant interviews and focus group discussions. Findings were used to refine the proposed model in such a way as to promote community and patient acceptance of and engagement in a community-based model of HIV care and treatment. A description of this work is detailed in a separate article.[36]

Selection and Training of Research Assistants

Four lay persons were hired as research assistants (RAs) with duties consistent with those of community health volunteers (CHVs).[37] We chose to use RAs instead of CHVs for this study because of the need to maintain rigorous records and adhere to study data collection protocols that would be outside of the scope of training for a CHV.

These individuals were selected from candidates living within the Kitale AMPATH clinic catchment area, had a high school diploma, were literate/fluent in Kiswahili and English, and were chosen with the input from village chiefs and county health officials. RA training included completion of the AMPATH HIV training curriculum and the AMPATH CHV curriculum. Study-specific training included instruction in recognizing the signs and symptoms that should prompt patient referral to the clinic (either during a group meeting or when contacted between meetings). RAs also underwent practical training in the clinic for 4 weeks, which included practice in measuring vital signs, obtaining a review of systems, and observing the ART distribution system.

Once in the field, the study's clinical officer (CO; equivalent to a physician's assistant in the United States)

observed the RAs first Co-op meeting, provided feedback, and completed a monthly performance evaluation for each RA, assessing history-taking skills, clinical judgment, documentation, and interactions with patients and staff. Remediation plans and reinforcement of expectations were instituted if an RA was identified as unsatisfactory.

Randomization of Sublocations

Of the 32 sublocations included, 4 contiguous sublocations with small population sizes were combined into 2 groups for a total of 30 geographic sites (15 per study arm). Sublocation randomization was stratified based on the distance (in kilometers) from the AMPATH Kitale clinic, with equivalent groups at each distance placed in each study arm. Participants were approached consecutively by study staff to participate in the study. After providing study consent, participants were informed of their assignment to the control or intervention arm. A patient sublocation data form was used to track the number of patients enrolling from each sublocation. When a sublocation's enrollment reached a maximum of 15 members, enrollment in that sublocation was stopped. Groups were formed by the study staff, and participants did not contribute to the groups' recruitment or formation; thus, participants may or may not have known other participants in their group before the study. Each RA supervised 3–4 community-based care groups.

Control Group (Standard of Care) Continuation of Care

The control group continued their HIV care at the AMPATH Kitale clinic as per the standard of care (Table 1). This consisted of clinic visits (generally every 3 months) where patients were assessed by a nurse and CO and were issued ART prescriptions. Control group patients were asked to check in with the study team at every clinic contact to confirm attendance. Patients missing appointments were tracked as described further.

Intervention Group Design

Intervention participants were invited to a group organizational meeting at the clinic to form their ART Co-op. Study staff facilitated participant introductions, selection of a group leader, discussion of group objectives, selection of a meeting time and place, and introduction of the group RA. All participants gave verbal agreement to maintain confidentiality.

ART Co-op meetings were held every 3 months at a date, time, and location selected by the group members (such as a church, community building, or local clinic). Co-op members were scheduled for only 1 clinic appointment, with laboratory studies at study exit at week 48. Before each meeting, the study CO wrote a 3-month ART and prophylactic drug prescription individualized for each Co-op patient, which were dispensed by the clinic pharmacist in a paper bag with the patient's study number.

The goals of the ART Co-op meetings were to reinforce adherence, distribute medications, offer condoms, and address issues of importance to the ART Co-op members. The RA coordinated the meeting, but the organization and discussions were driven by the group members. At each meeting, pill counts and calculation of the percentage of ART and prophylaxis pills missed were performed, and ART Co-op members who underwent a symptom screen (cough, vomiting, diarrhea, headache, weakness, and rash) were weighed. A positive symptom screen triggered additional assessments (temperature, blood pressure, and oxygen saturation), and referrals were made to the CO based on preestablished criteria. Participants with >5% missed pills were counseled on adherence by the RA. Any participant missing >10% of their pills was referred to the clinic for formal adherence counseling.

TABLE 1. Services Provided Within Each Study Arm

	Control (Standard of Care)	Intervention (ART Co-Ops)
Care location	HIV care clinic	Community (group choice)
Frequency of visits	Per provider (usual 1–4 mo RTC)	Every 3 mo
Providers	CO	Research assistant
	Nurse	Clinical officer by referral
	Pharmacist	Pharmacist by referral
Available services	Nursing triage—vital signs	RA triage—vital signs
	Clinician evaluation	Review of systems
	Pharmacy	ART delivery
Clinical consultations	Every visit	By RA, CO, or self-referral only
Ancillary services	At HIV care clinic	By RA, CO, or self-referral to HIV care clinic
Social work		
Psychosocial		
Nutrition		
ART pickup location	HIV care clinic pharmacy	ART Co-op meeting
ART refill frequency	Every 1–4 mo per RTC	Every 3 mo
LTFU tracking	Phone call initiated within 7 d after missed appointment by clinic staff	Phone call initiated on the day of the group meeting by RA

RTC, return to clinic.

Communication Between the ART Co-Ops and the Clinic

Patient data from community meetings were recorded in the ART Co-op logbook. Information collected included weight, vital signs, symptom screen, pill counts, clinic or other service referral, and confirmation of ART distribution. The RA reviewed the groups' logbooks with the study CO after every Co-op meeting to identify trends, patient issues, and data discrepancies. The COs documented their recommendations in the logbook and, if any urgent issues were identified, instituted appropriate action. After 1 month in the field, the CO was able to give favorable evaluations to all 4 RAs and transition them to every 4-month evaluations for the duration of the project.

Referrals and Clinic Visits

Co-op participant clinic referral was triggered in 1 of 3 ways: (1) RA referral for a positive symptom screen (eg, new or persistent cough, vomiting, or diarrhea), abnormal vital sign (temperature $\geq$38.0°C and oxygen saturation $<$93%), or a red flag (eg, pregnancy, domestic violence, and $>$10% missed ART); (2) patient requested referral; and (3) CO referral at the time of group logbook review. Individuals flagged by the CO were contacted by phone or in person and asked to come to the clinic for further review.

Lost to Follow-Up Tracking

Control patients who missed a regularly scheduled clinic appointment were contacted 7 days after the missed appointment by clinic staff, as per the standard of care. Intervention patients missing their ART Co-op meeting were immediately phoned by the RA and asked to join the meeting in progress or arrange to meet the following day in the community at an agreed upon location. A home visit was initiated for Co-op members who could not be located by phone within 7 business days of the meeting.

Data Collection and Management

Electronic point-of-care data collection forms were used for all clinic visits, and all laboratory data were automatically transmitted into the AMPATH Medical Records System.[38,39] All data from the ART Co-op logbook and study laboratories were entered into a REDCap database by a trained data manager using AMPATH standard data quality procedures.

Statistical Analysis

Data were analyzed using STATA v.15 (Stata Corp 2017; College Station, TX). The main outcome was retention in HIV care (participant seen within 3 months of their last scheduled clinic visit or Co-op meeting) and viral suppression at 12 months. Median and interquartile range (IQR) were estimated for continuous variables, and frequencies and percentages were calculated for categorical variables. The main analysis presented reflects the per-protocol results where patients who were not retained in their preassigned intervention arm (Co-ops or standard of care) were excluded. Complete case analyses of participants retained in care at 12 months were performed. The χ^2 test was used to assess associations between categorical variables in bivariate analyses. The Fisher exact test was used when the expected cell counts were small (ie, expected count was $<$5). The Wilcoxon rank sum test was used in cases where normality assumption was not tenable. A P value less than 0.05 was considered statistically significant.

An intent-to-treat analysis is also presented. We assigned a series of viral suppression rates to subjects who were not retained in the intervention arm (nonretention was minimal in the control arm). Such scenarios included assigning, among nonretained Co-ops subjects, the same rate of viral suppression as in the control arm (given that virtually all transferred to standard care after discontinuing from the study). We also assigned the viral suppression rates observed in the intervention arm. The point estimate resulting from these simulations. Empirical confidence intervals (the values bound by the 2.5th and 97.5th percentiles of the 1000 simulated P values) were also produced.

RESULTS

Eligible Patients

A total of 513 patients met demographic eligibility criteria for the study, with 420 patients fulfilling laboratory criteria (Fig. 1). Participants were enrolled and followed up from October 2016 to February 2018. Of the enrolled individuals, 213 resided in the control sublocations and 207 in the intervention sublocations. There were no statistical differences in baseline characteristics between the 2 groups (Table 2). Most participants were women (78%) (adult female patients enrollment at Kitale clinic in 2017 was 67.2%), with a median age of 46 years (IQR 38–53). Most participants had no education (43%) or a primary education only (33%). Per protocol, all participants had an undetectable baseline VL, most were on a first-line ART regimen (96%), and the median CD4 count was 583 cells/μL.

Patient Withdrawals

There were 37 withdrawals from the intervention group (from 13/15 sublocations) and 3 withdrawals from the control group during the study. Five of the intervention withdrawals and the 2 control withdrawals were due to women becoming pregnant and transferring to specialized peripartum care. One intervention patient switched to clinic care without notifying study staff, and 1 control patient requested withdrawal from the study at the first return visit but remained at the clinic for HIV care. Of the remaining withdrawals from the Co-ops group, 15 took place before group formation, 9 before the first group meeting, and 8 after the first group meeting (from 7 different sublocations with supervision evenly distributed among RAs). Causes of the intervention withdrawals included the following: 3 administrative withdrawals (wrong sublocation assignment and group over enrollment); 12 patient relocations outside of the intervention sublocation; 6 work or other schedule conflicts; 3 patient-initiated withdrawals

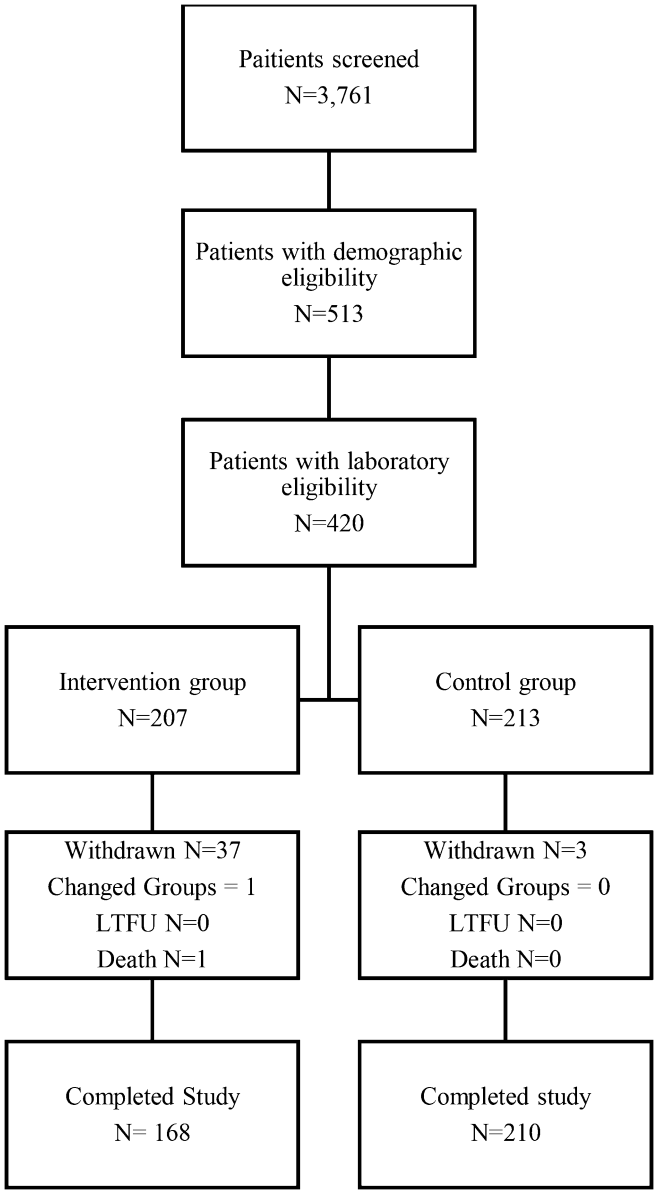

FIGURE 1. Enrollment cascade.

(patient not interested in continuing participation or unwilling to attend group); and 7 withdrawals (of which 5 were before group formation) with concerns about stigma from the patient or a family member.

Patient Outcomes

Per-Protocol Analysis

In the main (per-protocol) analysis, 169 of the 207 (81.6%) participants in the intervention group and 210 of the 213 (98.6%) in the control group were retained in their study assigned care program at the end of study ($P \leq 0.001$) (Table 3), and all patients in both groups (intervention 207; control 213) were verified to have been retained in HIV care and maintained on their enrollment ART regimen. This means that all subjects essentially transferred to the standard-of-care (control) group on discontinuation from the study.

One death occurred in the intervention arm, which was reported as due to gastroenteritis that was unreported to study staff and was determined not to be study related. Of those evaluable, 168 subjects (100%) in the intervention and 205 subjects (97.6%) in the control group had a VL <1000 copies/mL ($P = 0.06$) after 12 months of follow-up. When conservative VL criteria (undetectable VL) were used for analysis, 154 subjects (91.7%) of the intervention group and 196 (93.3%) of the control group met criteria for suppression (χ^2 test $P = 0.560$; Table 3). The median number of clinic visits was considerably lower for the intervention group than that for the control group (0 vs 3; $P < 0.001$). There were a total of 31 clinic visits by intervention patients during the 12-month study period. Participants in both groups remained immunologically stable and had no changes to their ART regimens during the study period. There was 1 hospitalization in the intervention group, which ultimately resulted in the 1 recorded death, and none in the control group.

Sensitivity Analyses

We performed 2 sensitivity analyses in lieu of an intent-to-treat analysis. We ran 1000 simulations where nonretained subjects in the intervention arm were assigned either the viral suppression rate observed in the retained individuals in the intervention group or the levels observed in the control group. For the less conservative criterion of viral suppression, defined as HIV VL <1000 copies/mL, the P value, assuming 100% viral suppression among intervention subjects, was 0.061. Note that there is no variability in this estimate because 100% of intervention subjects were suppressed. For the scenario where we assigned a 97.6% probability of viral suppression to nonretained subjects in the intervention group, the mean P value was 0.213 (95% empirical confidence interval 0.061 to 0.724).

The mean P value of 1000 simulated Pearson χ^2 P values associated with the more conservative definition of viral suppression (HIV VL < 40 copies/mL) was 0.673 (empirical 95% confidence interval 0.285 to 1.000) for the best-case scenario (93.3% viral suppression among non-retained subjects in the intervention group) and 0.602 (95% empirical confidence interval 0.218 to 1.000), respectively.

DISCUSSION

Retention in HIV care after 12 months in this RCT was equivalent between patients seen in community-based ART Co-ops and patients with standard-of-care clinic visits, with all patients in both study arms retained in HIV care and maintained on their enrollment ART regimen. High retention rates in nonclinic-based groups (adherence clubs) in South Africa surpassed those of standard of care,[40] and in Zambia, retention rates were high and surpassed those of a home-based care model.[41] However, in this study, the number of patients remaining in their assigned study group was significantly lower in the intervention group. This high rate of attrition within the

TABLE 2. Baseline Characteristics at Enrollment

	Total	Intervention (N = 207)	Control (N = 213)	
	Median (Q1, Q3)	Median (Q1, Q3)	Median (Q1, Q3)	*P*
Age, years	46 (38, 53)	46 (38, 54)	46 (38, 52)	0.654
CD4 count, cells/μL*	583 (431.5, 735)	585 (429, 731)	582 (435, 740)	0.800
Viral load, copies/mL	0 (0, 0)	0 (0, 0)	0 (0, 0)	—
	Total	**Intervention (N = 207)**	**Control (N = 213)**	
	Frequency (%)	**Frequency (%)**	**Frequency (%)**	***P***
Sex				0.362
Female	327 (77.9)	163 (78.7)	164 (77.0)	
Male	93 (22.1)	44 (21.3)	49 (23.0)	
Education level completed				0.934
None	180 (42.9)	91 (44)	89 (41.8)	
Primary	139 (33.1)	69 (33.3)	70 (32.9)	
Secondary	84 (20.0)	39 (18.8)	45 (21.1)	
Tertiary	17 (4.0)	8 (3.9)	9 (4.2)	
Marital status				0.889
Married/cohabiting	183 (43.6)	89 (43)	94 (44.1)	
Divorced/separated	76 (18.1)	39 (18.8)	37 (17.4)	
Widowed	144 (34.3)	72 (34.8)	72 (33.8)	
Never married	17 (4.0)	7 (3.4)	10 (4.7)	
ART regimen				0.166
First line	402 (95.7)	201 (97.1)	201 (94.4)	
Second line	18 (4.3)	6 (2.9)	12 (5.6)	
Duration on ART†	5.96 (2.95, 8.78)	5.75 (2.95, 8.76)	6.15 (3.04, 8.78)	0.821
Distance to clinic, km				0.164
0–1	162 (38.6)	75 (36.2)	87 (40.9)	
5	66 (15.7)	39 (18.8)	27 (12.7)	
10	38 (9.1)	23 (11.1)	15 (7.0)	
15	22 (5.2)	7 (3.4)	15 (7.0)	
20	103 (24.5)	49 (23.7)	54 (23.4)	
>25	29 (6.9)	14 (6.8)	15 (7.0)	

*Two CD4 counts missing at baseline.
†Two missing ART start dates.

Co-ops group, most of which occurred before the first community meeting, had several causes. First, stigma surrounding HIV positivity is still prevalent in many communities in Kenya.[42–44] This often manifests as participants being afraid of identification as HIV-positive in their community due to activities such as participating in locally held community-based care group meetings, thus resulting in their withdrawal before the first Co-ops meeting. In several cases, spouses or family members insisted on participants' withdrawal from the community group, likely also due to stigma and confidentiality concerns. Second, patients moving out of the designated group areas were common. Temporary relocation of people is not uncommon in Kenya, with many moving between rural and urban areas for work or moving to other areas with established family or social networks.[45,46] Finally, women in HIV care who become pregnant are monitored on a monthly basis per Kenyan national guidelines.[47] Although the guidelines did not exclude them from differentiated care,[48] the current practice of monthly evaluation and clinic-based ART distribution made Co-ops meetings redundant, and so women who became pregnant all chose not to continue their participation in their Co-op and attend antenatal care only. Children are not excluded from differentiated care per guidelines; however, these services are not currently available within our care

TABLE 3. Twelve-month Viral Load/CD4 and Patient Outcomes

	Intervention Freq (%)/Median (Q1, Q3)	Control Freq (%)/Median (Q1, Q3)	*P*
CD4 at 12 mo, cells/μL	N = 168	N = 207	0.123*
	557.5 (425, 699)	521.0 (408, 666)	
Viral load, copies/mL	N = 168	N = 209	0.068†
1000	0 (0.00)	5 (2.4)	
<1000	168 (100.0)	204 (97.6)	
Viral load, copies/mL	N = 168	N = 209	0.560†
>40	14 (8.3)	14 (6.7)	
<40	154 (91.7)	195 (93.3)	
Retained in study assigned care	169 (81.6)	210 (98.6)	<0.001*
Death	1 (0.5)	0 (0)	0.493†
Clinic visits	0 (0, 0)	3 (3, 4)	<0.001†

*χ^2 test.
†Fisher exact test.

system or within the ART Co-ops, leading to some women with children in HIV care to withdraw from their community group and return to clinic-based care. Although relocation and new pregnancy could not be anticipated by participants at enrollment, issues related to loss of confidentiality, group attendance requirements, and the ineligibility of children for group participation were clearly addressed during the consenting process. At the study's conclusion, all patients who withdrew for any reason were traced either by phone or through community visits and found to be active in the AMPATH Kitale clinic, prevention of mother-to-child transmission clinic, or a non-AMPATH clinic. Although ART Co-op groups were not the preferred venue of care for some patients, enrollment in the study did not negatively impact retention in HIV care as a whole.

No intervention patients had a VL >1000 copies/mL after 12 months. Another RCT evaluating community-based care in Kenya had PLHIV making monthly home-based assessments guided by handheld computers, with patients seen in clinic every 3 months showing no significant VL differences between the intervention and control. The intervention group had a detectable VL of only 8.5% versus 12.6% in the control group.[18] This trial, however, used a home-based care model for individual patients rather than a community group model. A 2016 meta-analysis with 11 RCT and 11 cohort studies (including studies from 8 SSA countries) analyzed community versus facility-based health care.[48] Results from 8 RCT examined in the analysis showed no statistically significant difference in virologic outcomes between community and facility-based care, as was seen with ART Co-ops.

Clinic utilization was dramatically decreased through the implementation of community-based care groups. Control patients had between 1 and 6 visits during the follow-up period. However, once enrolled in the study, only 31 intervention patients required an HIV clinic visit before their exit visit. Patients in both groups had visits to other non-HIV clinics and dispensaries near their homes for issues unrelated to HIV (eg, suspected malaria). This reduction in HIV clinic visits may decrease the workload for clinic staff by allowing them to see stable patients less often and have more time to address patients with nonsuppressed VL or complicated medical problems or those newly enrolling in care. Fewer clinic visits addressed patients' concerns around long waiting times and loss of time from work, school, home, or childcare due to frequent, often lengthy, and expensive travel.

Throughout the implementation and maintenance of the community-based care groups, some modifiable factors were identified, which could enhance sustainability and expansion of the model. Although nonhealth care personnel were used to do health screening of group members and deliver drugs, these responsibilities could be taken on by a group member with periodic reporting to a designated clinic staff member. Return visits to clinic on a yearly basis could be simplified to consist of a simple laboratory visit if there are no clinical, social, or adherence problems to address. Although extensive recording of patient's adherence, review of systems, and weight were kept by the group RA, these tasks could be assigned to group members to review with other members verbally at each meeting. Education at the clinic for group leaders could teach basic skills to identify patients who need clinic referrals.

This study was strengthened by its use of cluster randomization to assure that the sublocations included in each study arm were matched based on their distance to the clinic. In addition, the comparison of the intervention to a standard-of-care control group and the assessment of end-of-study VL suppression outcomes strengthen the findings. To enroll in the study, participants had to meet strict CD4 and VL inclusion criteria. The rigorous selection process excluded patients who were immunodeficient or who had detectable VLs (meeting standards for nonsuppression), limiting generalizability to such populations. Another weakness included the structured formation of community-based care groups based on the geographic location of the patient's home. This led to a forced group membership that may have contributed to the early attrition we saw in the intervention group. Although this allowed for the construction of an RCT with an emphasis on clinical outcomes, it likely contributed to a larger number of withdrawals than was seen in the CAGs in Mozambique.[19,20,25] Allowances were made for patients to return to their group and participate in the end-of-study clinic visit if they had left the area for a short time and returned. Finally, the study followed up patients for 12 months, but it is unknown whether a longer duration of follow-up would result in potentially different outcomes.

We found that community-based HIV care delivered in Kenya by trained lay personnel could provide safe and effective HIV care with VL suppression rates and retention-in-care rates equivalent to those seen in the standard-of-care clinic setting. These findings should assure care programs and providers that the guidelines

recommending the diversification of care models and the increased use of lay or lower-cadre health care workers in the community-based settings are effective models of HIV care. Continued work to decrease HIV stigma remains important to the success of such models. Community-based care will likely be crucial in the sustainability of ongoing HIV care with likely ongoing reductions in funding and in addressing threats to the traditional clinic-based care structure such as coronavirus disease 2019 (COVID-19). This innovative model of HIV care helps address the problems of insufficient health care personnel and the patient retention in HIV care barriers of time, distance, and cost to attend clinic and should be adapted for wider implementation.

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