Original Investigation

Effect of Optional Home Initiation of HIV Care Following HIV Self-testing on Antiretroviral Therapy Initiation Among Adults in Malawi
A Randomized Clinical Trial

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IMPORTANCE Self-testing for HIV infection may contribute to early diagnosis of HIV, but without necessarily increasing antiretroviral therapy (ART) initiation.

OBJECTIVE To investigate whether offering optional home initiation of HIV care after HIV self-testing might increase demand for ART initiation, compared with HIV self-testing accompanied by facility-based services only.

DESIGN, SETTING, AND PARTICIPANTS Cluster randomized trial conducted in Blantyre, Malawi, between January 30 and November 5, 2012, using restricted 1:1 randomization of 14 community health worker catchment areas. Participants were all adult (≥16 years) residents (n = 16 660) who received access to home HIV self-testing through resident volunteers. This was a second-stage randomization of clusters allocated to the HIV self-testing group of a parent trial.

INTERVENTIONS Clusters were randomly allocated to facility-based care or optional home initiation of HIV care (including 2 weeks of ART if eligible) for participants reporting positive HIV self-test results.

MAIN OUTCOMES AND MEASURES The preplanned primary outcome compared between groups the proportion of all adult residents who initiated ART within the first 6 months of HIV self-testing availability. Secondary outcomes were uptake of HIV self-testing, reporting of positive HIV self-test results, and rates of loss from ART at 6 months.

RESULTS A significantly greater proportion of adults in the home group initiated ART (181/8194, 2.2%) compared with the facility group (63/8466, 0.7%; risk ratio [RR], 2.94, 95% CI, 2.10-4.12; *P* < .001). Uptake of HIV self-testing was high in both the home (5287/8194, 64.9%) and facility groups (4433/8466, 52.7%; RR, 1.23; 95% CI, 0.96-1.58; *P* = .10). Significantly more adults reported positive HIV self-test results in the home group (490/8194 [6.0%] vs the facility group, 278/8466 [3.3%]; RR, 1.86; 95% CI, 1.16-2.97; *P* = .006). After 6 months, 52 of 181 ART initiators (28.7%) and 15 of 63 ART initiators (23.8%) in the home and facility groups, respectively, were lost from ART (adjusted incidence rate ratio, 1.18; 95% CI, 0.62-2.25, *P* = .57).

CONCLUSIONS AND RELEVANCE Among Malawian adults offered HIV self-testing, optional home initiation of care compared with standard HIV care resulted in a significant increase in the proportion of adults initiating ART.

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In 2012, an estimated 35 million individuals were infected with the human immunodeficiency virus (HIV).[1] Antiretroviral therapy (ART) substantially reduces the risk of onward HIV transmission as well as greatly reducing morbidity and mortality,[2,3] raising hopes that high uptake of annual HIV testing and early initiation of ART could improve HIV prevention as well as care.[4,5]

Achieving high coverage of HIV testing is a major challenge. Surveys in 15 sub-Saharan African countries between 2009 and 2012 show that only 20.0% of women and 20.5% of men were tested for HIV in the previous year.[6] Once tested, individuals need to access care and prevention services to maximize the individual and public health benefits of knowledge of HIV status. However, only one-fifth of patients link into care without any periods of loss to follow-up.[7-9]

Self-testing for HIV infection is a novel approach that is highly acceptable in Malawi and the United States.[10,11] Self-testing for HIV has been defined as individuals performing and interpreting their HIV test in private,[12] a process that could overcome barriers to conventional facility-based and community-based HIV testing, which lack privacy and convenience.[13,14] However, no studies in high HIV prevalence settings have investigated linkage into HIV care after HIV self-testing. Home initiation of HIV care has not previously been investigated, although home continuation of ART was noninferior to facility-based services in a Ugandan trial.[15]

We therefore tested the hypothesis that offering optional home initiation of HIV care after HIV self-testing might increase population-level uptake of ART and increase willingness to test and to report positive results compared with HIV self-testing accompanied by facility-based services only.

Methods

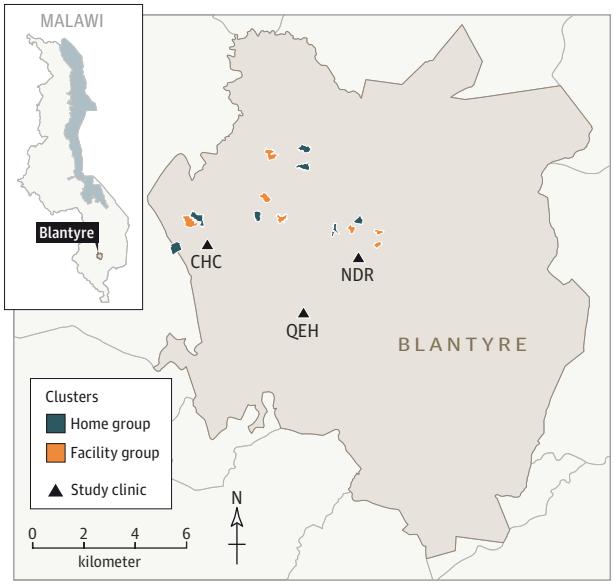
This was a second-stage randomization of clusters allocated to the HIV self-testing group of a parent study, which was a cluster randomized trial comparing health outcomes achieved under HIV self-testing vs standard-of-care HIV testing (with 14 vs 14 clusters in each group of the parent trial).[16] The present study was a cluster randomized trial using the 14 community health worker catchment areas allocated to receive HIV self-testing in the parent trial. These 14 clusters underwent restricted randomization into 2 groups: HIV self-testing followed by optional home initiation of HIV care or HIV self-testing accompanied by facility-based HIV care.

Participants and Study Setting

There are 26 administrative wards in Blantyre, Malawi. Three wards (Ndirande, Likhabula, and Chilomoni) were selected as the study site. They were all located in the northwest area of the city and comprised high-density urban neighborhoods. Comprehensive HIV care (including ART) was only available at 3 health facilities (Ndirande and Chilomoni Health Centres and Queen Elizabeth Central Hospital).

Between April and June 2011, 14 of a possible 73 community health worker catchment area clusters (5 in Ndirande, 6 in Likhabula, and 3 in Chilomoni) (**Figure 1**) were selected purposely to ensure sufficient distance and separation between cluster boundaries to reduce risk of contamination.[17] Clusters that were delineated by natural boundaries (rivers, roads, forests, etc) were preferentially selected. Boundaries of selected clusters were defined by study research assistants and Ministry of Health community health workers walking the boundary of each community health worker's catchment area recording coordinates with global positioning satellite receivers (eTrex Legend HCx, Garmin International). All households within clusters were enumerated by research assistants recruited from clusters, and a sociodemographic questionnaire was performed with the head of each household, or if unavailable, an adult household representative.

Figure 1. Location of Study Clusters and Allocation



Lake Malawi is shown in light blue. CHC indicates Chilomoni Health Center; NDR, Ndirande Health Center; QEH, Queen Elizabeth Central Hospital.

The research ethics committees of the College of Medicine, University of Malawi, Liverpool School of Tropical Medicine, and London School of Hygiene and Tropical Medicine approved the study. All participants provided written informed consent (or a witnessed thumbprint if illiterate) for HIV self-testing and separately for home initiation of care.

Interventions

Two volunteer counselors from each cluster, selected using participatory methods,[18] were trained in HIV testing. Prior to HIV self-testing availability, counselors in all 14 clusters promoted the availability of HIV self-testing by door-to-door visits and leafleting. Between January 30, 2012, and November 5, 2012, oral HIV test kits (OraQuick Advance Rapid HIV-1/2 antibody test, OraSure Technologies) were distributed to adult residents requesting HIV self-testing from the counselors' home (1 kit per resident per year), with pretest information about HIV self-testing, counseling, and demonstration of kit use. Participants were asked to self-test in the privacy of their

own house and to return the used test kit in person to the counselor in a sealed envelope. Participants were not required to report self-test results to the counselor; if they declined to do so, they received generic posttest counseling. Participants who reported self-test results received results-based counseling. Counselors recorded numbers of HIV self-test kits distributed and positive results.

All participants who had positive results on self-testing could self-refer or be referred by counselors to study clinics where study nurses performed confirmatory HIV testing, tuberculosis (TB) screening (and provided isoniazid preventive therapy [IPT] if eligible), World Health Organization (WHO) staging, and CD4 cell counts; provided cotrimoxazole; and made onward referral for ART initiation (routine ART clinics within the same facility) if eligible (CD4 cell count <350/μL, WHO stage 3 or 4, pregnant, or breastfeeding).[19]

In the 7 clusters allocated to the home group, at the same time during which HIV self-testing was being promoted, counselors additionally promoted (verbally and with leaflets) the availability of home services during the door-to-door visits. The counselors provided a second leaflet and verbal information on home services to participants when attending the counselor's home to request HIV self-testing. Counselors organized home visits by study nurses for participants reporting a positive HIV self-test result and requesting home initiation of care. Nurses visited each participant twice (first visit within 3 days and second visit within 7 days) to carry out confirmatory HIV testing, WHO staging, CD4 cell count (venous blood for laboratory testing), and TB screening (with IPT if eligible) and to provide 2 weeks of ART if the participant was eligible. Participants were provided with completed ART registration cards and a follow-up appointment at their nearest HIV care clinic.

Adult ART initiations during the study period were ascertained by (1) recording home ART initiations and (2) interviewing all adults who initiated ART at any of the 3 clinics serving the study population and using printed satellite maps marked with cluster boundaries and local landmarks, followed if necessary by a home visit, to establish cluster residence.[20] Data from clinic registers and treatment cards were extracted for the 6 months following ART initiation in all identified study residents, without reference to group. Self-reported adherence was assessed by questionnaire at 3 points after ART initiation (at 2-4 weeks, 3 months, and 6 months) using the AIDS Clinical Trials Group adherence questionnaire.[21]

Outcomes

The primary outcome compared between groups was the cumulative incidence of ART initiation among all adult cluster residents (regardless of HIV status, ART eligibility, site of HIV testing, or ART initiation) during the first 6 months of HIV self-testing availability. The secondary outcomes compared the cumulative incidence of taking an HIV self-testing kit (regardless of whether used), reporting a positive HIV self-test result to counselors, and loss from ART by 6 months (with participants recorded as still taking ART or transferred out to another clinic classified as retained).

Sample Size

We assumed that adult HIV prevalence was 18.5%,[10] 50% of HIV-positive self-testing adults would report a positive result to counselors, and 5% of the adult population would initiate ART over 6 months in the facility group. A mean cluster population of 1200 adults in 14 clusters provided 80% power at a 5% level of significance to detect a risk ratio (RR) of 1.5 between groups of the adult population who initiated ART, with a coefficient of variation k = .20.[17]

Randomization and Masking

Clusters were randomized at a public meeting after restricting possible allocations to ensure that for each of the 3 wards, the difference in the number of clusters allocated to each group would be no more than 2 (providing 2100 unique allocation patterns). Community representatives drew colored balls from an opaque bag held above eye level to select the distribution of clusters and group allocation. Counselors and residents were not masked to the intervention, but investigator blinding was maintained until the final analysis.

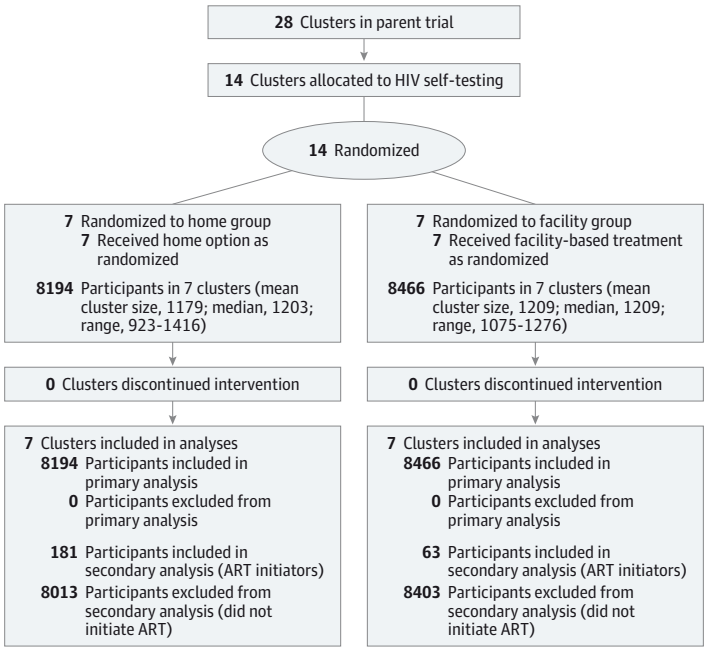
Statistical Methods and Cost Analysis

For the primary and secondary outcomes, analysis was done by intention to treat. CONSORT guidelines were followed in reporting preplanned study outcomes (eMethods 1 in the Supplement).[22] The cluster-level proportions of residents who initiated ART, took an HIV self-test kit, and reported a positive HIV self-test result in each intervention group were compared using the t test, with the unadjusted RR calculated as the ratio of cluster-averaged means using the method described by Hayes and Moulton.[17] The analysis was adjusted for death reported in households in the year preceding enumeration. Because data on these outcomes were not linked to individuals and were collected and analyzed at the cluster level, there were no missing data to take into account in the analysis.

A separate analysis was used to assess rates of loss from ART with the denominator being adult residents who initiated ART. The ART initiators whose treatment records indicated that they were still taking ART or had transferred to another ART clinic were classified as retained on ART. The ART initiators whose treatment records indicated that they had died or defaulted from ART were classified as lost to ART.[23] No ART initiators had missing data for ART outcome. Cluster-level rates of loss from ART in each group were compared using the t test, with the unadjusted rate ratio calculated as the ratio of cluster-averaged means and with subsequent adjustment for sex, age, pregnancy status, CD4 cell count strata, and WHO stage. The 3 of 244 participants (1.2%) for whom WHO stage was missing were not included in this adjusted analysis. Under national treatment guidelines, CD4 cell count was not indicated for pregnant women and individuals in WHO stage 3 or 4 and was not measured prior to ART initiation in facilities. Therefore, for the 69 of 244 individuals (28.3%) without CD4 cell count results, a category for missing was constructed.

Characteristics of ART initiators were compared between groups using χ^2 tests for categorical characteristics and Kruskal-Wallis tests for continuous characteristics. Differ-

Figure 2. Flowchart of HIV Self-testing and ART Initiation in Malawi



ART indicates antiretroviral therapy.

ences in adherence between the 2 groups were compared using χ^2 tests. Tests were 2-sided and a P value of ≤.05 was considered significant. Stata version 12.1 (StataCorp) was used for analysis.

A partial cost analysis was undertaken of the home ART initiation service from a programmatic perspective (eMethods 2 in the Supplement).[24] The cost estimates do not include the costs of facility-based assessment and initiation or downstream HIV care costs.

Results

The 14 clusters enumerated between April and June 2011 had a combined adult population of 16 660, with 8194 adults resident in 3213 households in the home group and 8466 adults resident in 3397 households in the facility group (**Figure 2**). Characteristics were well balanced between groups (**Table 1**), apart from reported household deaths in the previous year (home group: 131/8194, 4.1%; facility group: 81/8466, 2.4%).

Primary Outcome

Between January 30, 2012, and November 5, 2012, 244 cluster resident adults initiated ART during 6 months of HIV self-testing availability. The cumulative incidence of ART initiation was significantly higher in the home group (181/8194, 2.2% of residents) compared with the facility group (63/8466, 0.7% of residents; RR, 2.94; 95% CI, 2.10-4.12; P < .001) (**Table 2**). After adjusting for reported household mortality at baseline, the effect of availability of home care initiation remained statistically significant (adjusted RR, 2.44; 95% CI, 1.61-3.68; P < .001).

Of the 181 residents initiating ART in the home group, 116 (64.0%) initiated at home and 65 (36%) initiated at 1 of the 3 health facilities. The difference between groups in ART initiation was maintained throughout the analysis period (**Figure 3**).

Secondary Outcomes

During the 6 months of availability, a total of 9720 of 16 660 adult residents (58.3%) took an HIV self-test kit. There was no significant difference in uptake between the home (5278/8194, 64.9%) and facility groups (4433/8466, 52.7%; RR, 1.23; 95% CI, 0.96-1.58; P = .10). Participants in the home group (490/8194, 6.0%) were significantly more likely to report a positive HIV self-test result than facility group participants (278/8466, 3.3%; RR, 1.86; 95% CI, 1.16-2.97; P = .006).

Home ART initiators had significantly higher median CD4 cell counts compared with facility initiators (eTable 1 in the Supplement): median CD4 cell count at ART initiation was highest among home initiators in the home group (219/μL, interquartile range [IQR], 135-305) compared with facility initiators in the home group (154/μL, IQR, 116-249) and the facility group (187/μL, IQR, 100-256; P = .04).

Loss From ART Over 6 Months

After 6 months, 52 of 181 participants (28.7%; 30/116 [25.9%] home initiators and 22/65 [33.8%] facility initiators) who initiated ART in the home group and 15 of 63 participants (23.8%) in the facility group were lost from ART. Treatment records showed that 5 of 181 (2.8%) and 1 of 63 (1.6%) ART initiators in the home and facility groups died, respectively. In unadjusted analysis, the rate of loss from ART was higher in ART initiators in the home group (63.4/1000 person-months; 95% CI, 42.7-84.1) than in the facility group (53.5/1000 person-

Table 1. Baseline Characteristics

	Home Group	Facility Group
No. of clusters	7	7
No. of households	3213	3397
No. of adults (aged ≥16 y)	8194	8466
Cluster Characteristics		
Adults per cluster, mean (range), No.	1179 (923-1416)	1209 (1075-1276)
Population density per cluster, persons per m^2, mean (range)	0.016 (0.009-0.030)	0.024 (0.010-0.044)
Household Characteristics		
Adults per household, mean (SD), No.	2.55 (1.26)	2.48 (1.17)
Children per household, mean (SD), No.	1.96 (1.58)	1.93 (1.54)
Household wealth quintile, No. (%)[a]		
1 (poorest)	730 (23.3)	806 (24.3)
2 (poorer than average)	656 (21.0)	703 (21.2)
3 (average)	599 (19.2)	696 (21.0)
4 (wealthier than average)	602 (19.2)	589 (17.8)
5 (least poor)	540 (17.3)	518 (15.6)
Death in household in year preceding enumeration, No. (%)	131 (4.1)	81 (2.4)
Individual Characteristics (Adults Only)		
Age, mean (SD), y	30.4 (11.8)	30.2 (11.4)
Age group, y, No. (%)		
16-19	1312 (16.1)	1227 (14.5)
20-29	3312 (40.5)	3556 (42.1)
30-39	2113 (25.9)	2267 (26.8)
40-49	785 (9.6)	788 (9.3)
50-59	363 (4.4)	355 (4.2)
≥60	285 (3.5)	255 (3.0)
Male, No. (%)[b]	4252 (52.5)	4399 (52.6)
Marital status, No. (%)[c]		
Married or cohabiting	5031 (62.8)	5293 (64.4)
Never married	2441 (30.5)	2403 (29.2)
Widowed, separated, or divorced	535 (6.7)	524 (6.4)
Ever lost a spouse, No. (%)[d]	378 (4.7)	373 (4.5)
Highest level of education, No. (%)[e]		
No schooling	217 (2.7)	237 (2.9)
Primary	3168 (39.7)	3214 (38.7)
Secondary, no MSCE	2389 (30.0)	2863 (34.5)
Secondary with MSCE	1564 (19.6)	1465 (17.6)
Higher	635 (8.0)	520 (6.3)

Abbreviation: MSCE: Malawi secondary certificate of education.

[a] Missing values: home group: 86, facility group: 85.

[b] Missing values: home group: 7, facility group: 79.

[c] Missing values: home group: 163, facility group: 228.

[d] Missing values: home group: 180, facility group: 224.

[e] Missing values: home group: 197, facility group: 149.

months; 95% CI, 23.7-83.4), although not significant (incidence rate ratio [IRR], 1.18; 95% CI, 0.67-2.10). Adjusting for risk factors had little effect (adjusted IRR, 1.18; 95% CI, 0.62-2.25).

There were 201 ART initiators (82.4% of all ART initiations and 91.0% of initiators who returned for a subsequent clinic appointment) who completed the adherence questionnaire 2 to 4 weeks after ART initiation, 145 (59.4% of all ART initiators and 82.9% of individuals retained in care) who completed the questionnaire at 3 months, and 119 (48.8% of all ART initiators and 67.2% of individuals retained in care) who completed questionnaires at 6 months. Overall, of those with data available, 19 of 164 (11.6%) and 3 of 60 (5.0%) ART initiators in the home and facility groups, respectively, self-reported missing at least 1 dose of ART in the past 4 days at any assessment point (P = .14).

Cost Analysis

The total cost of the home-based ART service was US $20 005.24 (45 809.16 international dollars) (eTable 2 in the Supplement). The average cost per participant assessed was US $97.11 (222.37 international dollars), and the average cost per participant who initiated ART through the home service was US $172.46 (394.91 international dollars).

Discussion

The main finding of this cluster randomized trial was that population-level ART initiations were significantly increased (RR, 2.94; 95% CI, 2.10-4.12) by availability of home initiation of care. To our knowledge, this is the first study to investigate the effects of a comprehensive home-based HIV testing, eligibility

Table 2. Primary and Secondary Trial End Points[a]

	Home Group		Facility Group				
	No./Total No.	% or Rate per 1000 Person-Months (95% CI)	No./Total No.	% or Rate per 1000 Person-Months (95% CI)	Risk or Rate Ratio (95% CI)	*P* Value	k_O
Primary trial outcome: ART initiations							
Unadjusted[b]	181/8194[c]	2.2%	63/8466	0.7%	2.94 (2.10-4.12)	<.001	.15
Adjusted					2.44 (1.61-3.68)	<.001	
Secondary trial outcomes							
HIV self-tests	5287/8194	64.9%	4433/8466	52.7%	1.23 (0.96-1.58)	.10	.23
Reporting of HIV positive self-test results	490/8194	6.0%	278/8466	3.3%	1.86 (1.16-2.97)	.006	.50
Loss from ART if initiated ART							
Unadjusted	52/181	63.4 (42.7-84.1)	15/63	53.5 (23.7-83.4)	1.18 (0.67-2.10)	.52	
Adjusted					1.18 (0.62-2.25)	.57	

Abbreviations: ART, antiretroviral therapy; k_O, intracluster coefficient of variation in facility group; WHO, World Health Organization.

[a] For ART initiation, HIV self-tests, and reporting of positive HIV self-test results, denominators are total number of adult residents. For loss from ART, denominator is all adult cluster residents who initiated ART (regardless of site of HIV testing, or site of ART initiation) during first 6 months of HIV self-testing availability. Unadjusted proportions of adult residents initiating ART, taking HIV self-testing kits, and reporting positive HIV self-testing results were compared using the *t* test with the risk ratio calculated as the ratio of cluster-averaged means. Ninety-five percent CIs were calculated based on the *t* distribution and using a Taylor approximation to estimate the standard error of the log risk ratio. The analysis was adjusted for reported household death in the previous year using a logistic regression model to estimate cluster-specific predicted prevalence of the outcome (risk residuals), which were compared using the *t* test with the risk ratio calculated as the ratio of cluster-averaged risk residuals. For this adjusted analysis, 95% CIs and *P* values were calculated from the cluster-specific residuals based on the *t* distribution and using a Taylor approximation to estimate the standard error of the log risk ratio. Unadjusted rates of loss from ART among ART initiators were compared using the *t* test, with the rate ratio calculated as the ratio of cluster-averaged means. The analysis was adjusted for sex, age, pregnancy status, WHO clinical stage (1/2 or 3/4), and CD4 cell count strata (>350/μL, 201-350/μL, ≤200/μL, or missing [n = 69]) at ART initiation using a Poisson regression model to estimate cluster-specific prevalence of covariates (rate residuals), which were compared using the *t* test with the rate ratio calculated as the ratio of cluster-averaged rate residuals. For this adjusted analysis, 95% CIs and *P* values were calculated from the cluster-specific residuals based on the *t* distribution and using a Taylor approximation to estimate the standard error of the log rate ratio. Three individuals who had missing data for WHO clinical stage were excluded from this adjusted analysis.

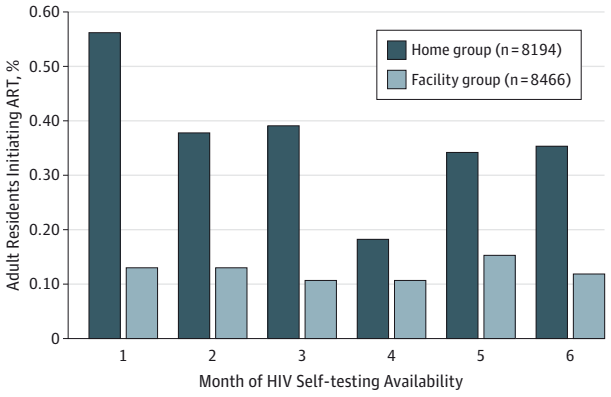
[b] Includes all ART initiations among cluster resident adults during the first 6 months of HIV self-testing availability, regardless of site of ART initiation (home or facility).

[c] Of the 181 residents initiating ART in the home group, 116 (64.0%) initiated at home and 65 (36%) initiated at 1 of the 3 health facilities.

assessment, and treatment initiation strategy. The uptake of HIV self-testing during the first 6 months of availability was high in both groups (58% overall). At a time when universal test and treat approaches to controlling the HIV epidemic are being considered,[4] home initiation of HIV care shows high promise as a simple strategy to improve uptake of ART when HIV self-testing is carried out at home.

The absolute difference between groups was 1.5% (2.2% − 0.7%) or, assuming adult HIV prevalence was 18.5% in both groups[10] and 76% of adults eligible for ART under 2010 WHO guidelines were taking ART at baseline,[1] an additional 7.9 per 100 HIV-infected adult residents (181/[8194 × 18.5%] − 63/[8466 × 18.5%]) and 33.0 per 100 ART-eligible HIV-infected adults (181/[8194 × 18.5% × 24%] − (63/[8466 × 18.5% × 24%]) initiated ART when both HIV self-testing and home initiation of HIV care were offered (detailed calculations in eTable 3 in the Supplement). We attribute this increase to removal of existing barriers to initial linkage to ART, including mistrust of routine clinic-based services and the intense pressure of time related to extreme poverty.[13,25] Reassuringly, offering the option of home initiation of HIV care did not simply shift ART initiations from health facilities to home: the rate of facility ART initiations was maintained between groups, while home initiations provided extra numbers.

Figure 3. Cluster Resident ART Initiations During 6 Months of HIV Self-testing Availability



ART indicates antiretroviral therapy.

Although HIV self-testing has been available for more than 20 years,[26] it has only recently been considered for use in national HIV testing programs.[27] Following US Food and Drug Administration approval for over-the-counter sale of an oral HIV self-test kit in 2012,[28] and 2 pilot studies from Kenya[29] and Malawi[10] showing high acceptability and uptake, there has been

renewed interest in HIV self-testing as a strategy for complementing existing HIV testing services.[27] Advantages of HIV self-testing include increased convenience and confidentiality compared with facility-based HIV testing.[10]

Economic analysis found the cost of home assessment per participant to be US $97.11 (222.37 international dollars) and the cost per individual initiated with ART to be US $172.46 (394.91 international dollars). This compares favorably with community-based HIV testing programs (US $7.77-$126.48 per individual tested)[11] and the annual costs of providing ART in facilities (US $857.84-$1165.47).[30] Patient costs were not considered in this analysis. However, home initiation of care will likely have savings for individuals who would otherwise incur substantial transport and opportunity costs. The costs of the HIV self-testing service, costs of facility-based initiation of care, and the differences in downstream management costs were not considered. The home-based service identified participants at significantly higher median CD4 cell counts, which will likely affect cost-effectiveness through prolonged survival,[31] reduced early HIV management costs,[32] and increased lifetime HIV treatment costs.

Loss from ART over 6 months was worse in the home group than in the facility group, although the differences were not statistically significant, and overall numbers of initiators were small, limiting power to identify anything other than large differences. Pooled across study groups, 72.5% of ART initiators were still taking ART at 6 months. This is below national HIV program estimates for Malawi (80% retained at 12 months[33]), although still within the range seen in other programs.[34] The study setting, with recruitment from urban slums, may have led to inclusion of a greater proportion of highly mobile individuals compared with other areas of the country. The trend toward poorer outcomes among ART initiators in the home group means that careful monitoring and treatment support should be provided for home ART initiators in future studies to avoid losing the initial population benefits of home ART initiation.

Perceived lack of confidentiality (which could be more pronounced in smaller or rural communities) has been cited as a potential barrier to uptake when HIV interventions are offered in the home, although in a previous trial of home continuation of ART after facility initiation, dropout due to stigma was extremely uncommon.[15] We overcame these potential difficulties by developing a partnership with the community (through volunteer counselors and community representative groups) and with participants by giving pretest information about the potential advantages and disadvantages of home initiation of HIV care. Regular meetings were held with community stakeholders where concerns could be raised and addressed. No incentives (financial or otherwise) were provided to participants or providers.

Limitations of the study include the need to use all adult cluster residents (not people living with HIV or ART-eligible adults) as our denominator. This reflects the lack of available cluster-level HIV prevalence and CD4 cell count data. However, ART initiation remained statistically significantly increased in the home group after adjusting for household mortality in the previous year, which could have been indicative of differences in HIV prevalence or ART coverage between study groups. To maintain privacy and confidentiality, individual HIV self-testing participants were not followed up as a cohort; reporting results was optional and not required. Therefore, we cannot estimate overall linkage into care after positive HIV self-testing or examine any given step of the HIV care pathway. Total numbers of ART initiations were small, meaning that larger studies are required to fully evaluate the possible trends toward worse retention of ART in the home initiation group. Initiators of ART were followed up for only a short period (6 months) and default from ART was not followed up by active tracing. Clinical outcomes of ART initiators (including causes of death) were not assessed at 6 months. Because HIV self-testing was implemented through neighborhood volunteers living close to participants, home initiation of HIV care was a highly feasible option in this situation and may not apply to other models of HIV self-testing delivery. Other models for encouraging linkage may need to be developed and ideally directly compared for effectiveness.

Conclusions

Among Malawian adults offered HIV self-testing, optional home initiation of care compared with standard HIV care resulted in a significant increase in the proportion of adults initiating ART.

ARTICLE INFORMATION

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