





Community-based HIV self-testing: a cluster-randomised trial of supply-side financial incentives and time-trend analysis of linkage to antiretroviral therapy in Zimbabwe

Euphemia Lindelwe Sibanda ^{1,2} Melissa Neuman ³ Mary Tumushime,¹ Collin Mangenah ¹ Karin Hatzold,⁴ Constanca Watadzaushe,¹ Miriam N Mutseta,⁵ Jeffrey Dirawo,¹ Sue Napierala,⁶ Getrude Ncube,⁷ Fern Terris-Prestholt,⁸ Miriam Taegtmeier,² Cheryl Johnson,⁹ Katherine L Fielding,¹⁰ Helen A Weiss,¹⁰ Elizabeth Corbett,^{11,12} Frances M Cowan ^{1,2}

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For numbered affiliations see end of article.

Correspondence to

Euphemia Lindelwe Sibanda; euphemia@ceshhar.co.zw

ABSTRACT

Background HIV self-testing (HIVST) requires linkage to post-test services to maximise its benefits. We evaluated effect of supply-side incentivisation on linkage following community-based HIVST and evaluated time-trends in facility-based antiretroviral therapy (ART) initiations.

Methods From August 2016 to August 2017 community-based distributors (CBDs) in 38 rural Zimbabwean communities distributed HIVST door-to-door in 19–25 day campaigns. Communities were allocated (1:1) using constrained randomisation to either one-off US\$50 remuneration per CBD (non-incentive arm), or US\$50 plus US\$0.20 incentive per client visiting mobile-outreach services (conditional-incentive arm). The primary outcome, assessed by population survey 6 weeks later, was self-reported uptake of any clinic service, analysed with random-effects logistic regression. Separately, non-randomised difference-in-differences in monthly ART initiations were analysed for three time periods (6 months baseline; HIVST campaign; 3 months after) at public clinics with (40 clinics) and without (124 clinics) HIVST distribution in catchment area.

Findings A total of 445 conditional-incentive CBDs distributed 39 205 HIVST kits (mean/CBD: 88; 95% CI: 85 to 92) and 447 non-incentive CBDs distributed 41 173 kits (mean/CBD: 93; 95% CI: 89 to 96). Survey participation was 7146/8566 (83.4%), with 3593 (50.3%) reporting self-testing including 1305 (18.3%) previously untested individuals. Use of clinic services post-HIVST was similar in conditional-incentive (1062/3698, 28.7%) and non-incentive (1075/3448, 31.2%) arms (adjusted risk ratio (aRR) 0.94, 95% CI: 0.86 to 1.03). Confirmatory testing by newly diagnosed/untreated HIVST+clients was, however, higher (conditional-incentive: 25/33, 75.8% vs non-incentive: 20/40, 50.0%: aRR: 1.59, 95% CI:

WHAT IS ALREADY KNOWN?

- ⇒ HIV self-testing increases uptake of HIV testing using a range of delivery models.
- ⇒ Linking to post-test services will increase benefits and cost effectiveness of HIV self-testing.
- ⇒ Demand-side incentives increase linkage to post-test services but the role of supply-side incentives is less clear.
- ⇒ We investigated whether supply-side incentives increase linkage to post-test services during community-based distribution of HIV self-test kits.

WHAT ARE THE NEW FINDINGS?

- ⇒ Community-based, door-to-door distribution of HIV self-test kits improved testing coverage.
- ⇒ Supply-side incentives for test kit distributors did not increase post-test service uptake.
- ⇒ In a post-hoc analysis supply-side incentives for HIV self-test kit distributors increased uptake of confirmatory testing among newly diagnosed HIV positive self-testers.
- ⇒ Community-based, door-to-door distribution of HIV self-tests was associated with a 27% increase in antiretroviral therapy initiations at nearby health facilities.

WHAT DO THE NEW FINDINGS IMPLY?

- ⇒ Community-based, door-to-door delivery of HIV self-test kits is feasible and scalable.
- ⇒ Future research should aim to optimise the nature and size of incentives to increase uptake and linkage while weighing the benefits and costs.

1.05 to 2.39). In total, 12 808 ART initiations occurred, with no baseline or postcampaign differences between initiation rates in HIVST versus non-HIVST clinics, but initiation rates increased from 7.31 to 9.59 initiations

per month in HIVST clinics during distribution, aRR: 1.27, 95% CI 1.17 to 1.39.

Conclusions Community-based HIVST campaigns achieved high testing uptake, temporally associated with increased demand for ART. Small supply-side incentives did not affect general clinic usage but may have increased confirmatory testing for newly diagnosed HIVST positive participants.

Trial registration number PACTR201607001701788.

INTRODUCTION

HIV testing services (HTS) are a key entry point for HIV prevention and treatment services. Despite major investment in HTS, an estimated 21% of people living with HIV (PLHIV) globally were unaware of their status in 2018.¹ HIV self-testing (HIVST), whereby an individual uses a rapid diagnostic test to collect their own sample (oral or blood), performs the test and interprets the result, is recommended by WHO.² It is highly acceptable,^{3–7} safe and can be highly accurate.^{8–10} Adding HIVST to clinic-based HTS can increase coverage and frequency of HIV testing, including among those less well-served by more traditional HTS approaches, such as rural populations, men, young people and key populations (sex workers, men having sex with men, transgender people, prisoners and people who inject drugs).^{11–15} Projections suggest that 4.6% of all 360 million HIV tests used each year globally will be self-tests by 2020, with higher percentages of 10%–35% in Kenya, Malawi, Zambia, Zimbabwe and South Africa.¹⁶

A reactive (positive) HIVST result needs confirmatory testing to provide an HIV-positive diagnosis followed by prompt linkage into HIV care.² A negative HIVST result (which does not need confirmatory testing) provides an opportunity for HIV prevention, such as voluntary medical male circumcision (VMMC), pre-exposure prophylaxis and use of condoms. Ensuring linkage following HIVST is essential for maximising health outcomes and cost-effectiveness.¹⁷ Evidence to date has been limited, but trials suggest that supportive linkage strategies are needed, including home-based antiretroviral therapy (ART) initiation¹⁸ and financial incentives provided to HIVST clients,¹⁹ among other strategies.²⁰ However, the role of financial incentives for providers ('supply-side' incentives) has not previously been investigated for effectiveness on the later stages of the HIV care cascade (linkage and retention) (The HIV care cascade is the series of stages an HIV positive person goes through from HIV testing through to treatment initiation and viral suppression).²¹

The formative work that we conducted in non-trial sites showed that community-based HIVST is an acceptable and feasible model for providing HIVST.⁴ Here we report results from a cluster-randomised trial investigating conditional supply-side incentives

given to lay community-based distributors (CBDs) to promote linkage to services following HIVST.

METHODS

Population and setting

We conducted the study in Zimbabwe, a country with an HIV prevalence of 14.1%.¹² At the time of the study, Zimbabwe had already adopted HIVST into policy although self-tests were not yet widely available. Eight districts took part: Buhera, Bulilima, Chivi, Gutu, Gweru, Masvingo, Mazowe and Mberengwa, where the study unit was a ward (subdistrict administrative unit). We used administrative maps of the districts (online supplemental appendix 1) to select 44 out of a possible 254 wards with geographic separation. The number of districts was informed by the sample size: we continued to include new districts until we reached 44 eligible wards.

Starting with a randomly selected ward at the boundary of the district, we systematically worked through each map to select additional wards while ensuring that each was at least 15 km away from its nearest neighbour/s. The districts were chosen because of the presence of Population Services International (PSI) outreach clinics that deliver services, including standard HIV testing services, screening for TB, diabetes and hypertension, family planning and VMMC (Implementation of HIVST distribution was carried out by Unitaid/PSI as part of the Self Testing Africa Initiative²²). Within each district, there were public sector primary health clinics providing a range of services including provider-delivered HIV testing and treatment services. PSI worked closely with these facilities to prepare them to receive individuals who had self-tested and were linking for different services according to self-test results.

HIVST intervention in study communities (wards)

PSI Zimbabwe identified, recruited and trained CBDs from each ward to distribute HIVST kits. Selection of CBDs was informed by community leaders, who recommended individuals whom they felt were suitable distributors based on previous experience of working with HIV programmes, community work, literacy levels and good standing in the community, hence CBDs were a heterogeneous group with different backgrounds and levels of experience. PSI provided CBDs with a 2-day training in HIV testing, supporting others to use HIVST kits, providing information to promote and support linkage to appropriate post-test services, use of data capture tools and the study protocol. Each village (smallest subunit of a ward that varies in size but typically has about 100 households) had one or two CBDs depending on size. Over four to 4–6 weeks, CBDs conducted door-to-door visits offering oral fluid self-test kits to all household members ≥ 16 years old (the Ministry of Health-prescribed minimum age for consenting to HIV testing). Kits were only given to individuals providing verbal consent for self-testing. CBDs recorded distribution data onto computer tablets. They

advised clients to seek further HIV services as needed from PSI outreach clinics and/or local primary clinics. Kit recipients were given a toll-free helpline number that they could use as needed.

PSI staff provided outreach clinic services described above (Population and Setting) soon after starting and completing HIVST distribution, and provided support and supervision to CBDs throughout the campaign, including checks for implementation fidelity which were done through unannounced spot checks (CBDs were informed these would happen during their training).

Study design and modification

The initial protocol was a factorial design²³ whereby the 44 out of a possible 254 wards (clusters) were randomly allocated (1:1:1:1) to four arms. HIVST was distributed across all arms. All arms included fixed CBD stipends of US\$50 paid after an anticipated four to 4–6 weeks of HIVST distribution and either: (i) conditional incentives for CBDs (US\$0.20 for each person who linked to post-test services at PSI outreach site), (ii) conditional incentives and demand-side (transport assistance) incentives for clients confirmed HIV positive to facilitate

linkage to treatment, (iii) transport assistance for clients confirmed HIV positive and (iv) neither conditional incentives for CBDs nor transport assistance (figure 1).

The initial primary outcome was uptake of any health service at PSI clinics following distribution of self-test kits. However, on implementation (Mberengwa District), two major problems became apparent: first, transport assistance for recently diagnosed HIV patients had become standard of care, thus precluding evaluation of this intervention. Second, linkage data showed much higher than anticipated use of non-PSI clinics.

Hence, in consultation with our Technical Advisory Group (TAG), the demand-side incentive was dropped, and primary and secondary outcomes were redefined around endline survey data that did not require direct capture of clinic use. The six Mberengwa district clusters were dropped from analysis, leaving 38 wards in their original allocation for a two-arm cluster-randomised trial comparing fixed stipend only versus fixed stipend plus conditional incentives. The fixed stipend is standard practice for PSI community-based interventions.

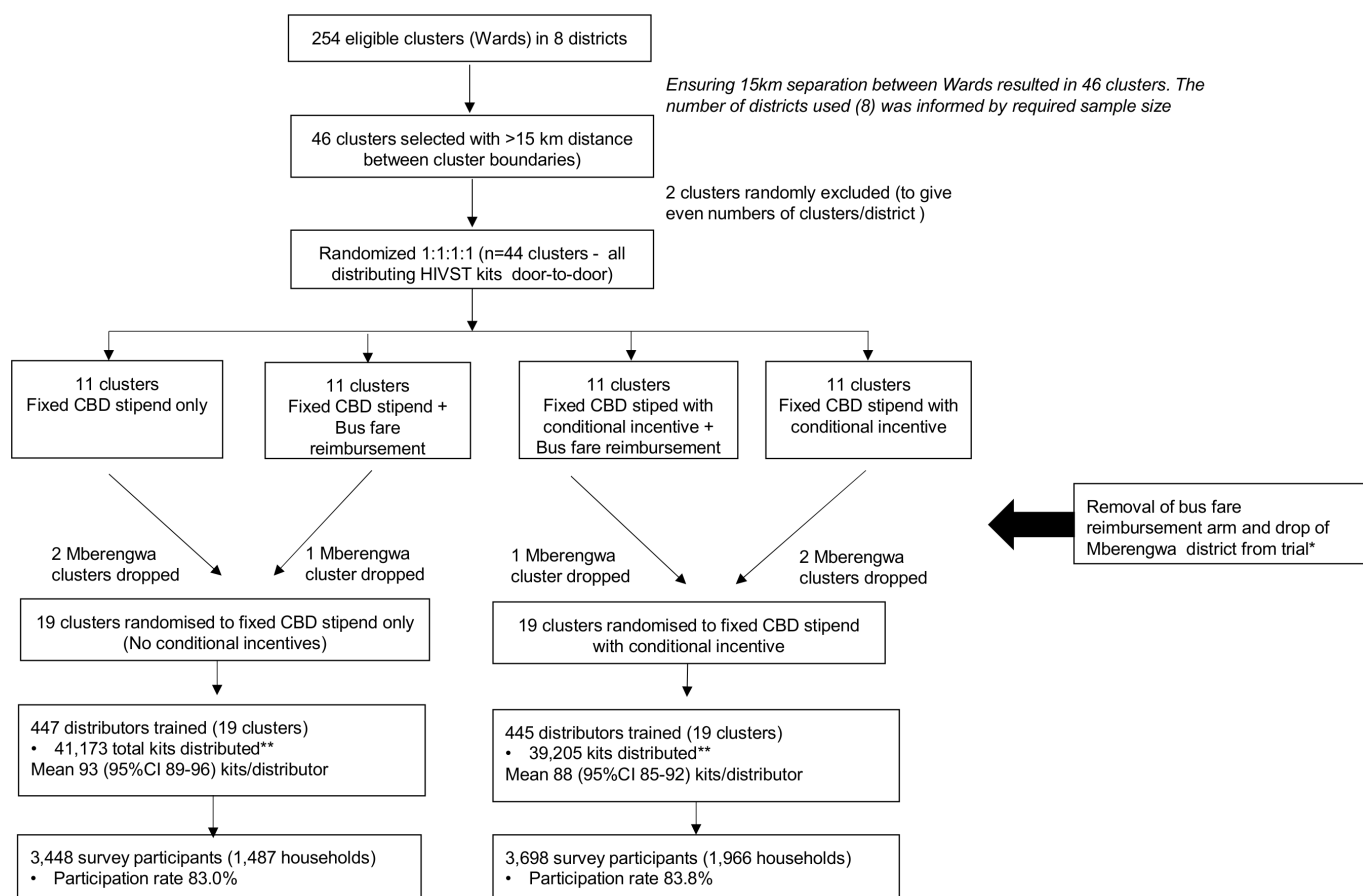


Figure 1 Trial profile. *The initial design was a 2x2 factorial trial with two interventions: conditional incentives for CBDs and bus fare reimbursements to support linkage to care for clients testing HIV positive. However, during implementation in the first six clusters (in one District, Mberengwa), transport support for clients testing positive became standard of care, thus precluding evaluation of the intervention. We therefore dropped the bus fare reimbursement intervention after consultation with the Technical Advisory Group. This left 38 clusters in seven districts with their distributor-incentive allocation intact. **No figures provided by one distributor in each arm. CBDs, community-based distributors

The conditional incentive amount (\$0.20 per client attending PSI clinic services, including non-HIV services) was determined through consultation between researchers and programme implementers, aiming for an amount that was affordable and thus scalable, yet high enough to motivate desired behaviour but low enough to minimise the risk of unethical behaviour (such as forced testing, false clients) among CBDs. To give a sense of the value, at the time of the study, a loaf of bread cost \$0.70–\$0.90 and a local one-way bus ticket cost \$0.20–\$0.50.

Administration of incentives was based on counting appointment cards provided to each HIVST client that were redeemed by PSI mobile clinic staff. Client self-reports were also accepted from clients who could not produce appointment cards but had a convincing account of having self-tested, for example, requests for confirmatory testing and/or production of used kits. Since CBDs operated in defined geographic areas, the residence of the client could be used to identify the CBD.

In addition to the trial, we conducted a before-during-after time-series analysis of ART initiations in clinic catchment areas receiving and not receiving HIVST, described below.

Randomisation and masking

Under the original study design, 44 clusters were randomly allocated to one of four arms. Randomisation was restricted by district and proximity to a health facility²⁴ using Stata V.15.1. From more than 7.5 billion ways of randomising 44 clusters to four arms, we randomly selected 100 000 on which we applied the restriction criteria. This produced 32 629 eligible allocations from which we randomly selected 1000. During a public randomisation ceremony, we randomly selected one of these allocations.

Although distributors were not masked to study arm, clients receiving HIVST did not know that there were differences in the way distributors were paid, and all analyses used masked data (study arms were anonymised) with unmasking only after analysis of the primary outcome was finalised.

Outcomes

Population-based survey

The primary outcome was the proportion of survey participants who self-reported having accessed any clinic services from PSI outreach or local clinic visits since the start of HIVST kit distribution in their cluster, regardless of whether they had self-tested or not. This was assessed through response to the question ‘Since about six weeks ago (when CBDs came to your area to distribute self-test kits), have you been to a clinic or HIV testing facility for any service that you wanted for yourself?’. The outcome included non-HIV services such as hypertension, diabetes screening and family planning services to prevent unintended disclosure of HIV status.

Secondary outcomes were the proportion of survey participants self-reporting that they had:

1. Used an HIVST kit (all respondents).
2. Accessed confirmatory testing (for respondents who stated having self-tested positive only).
3. Initiated ART (for respondents who stated having self-tested positive only).
4. Self-tested HIV-negative and had VMMC (for previously uncircumcised male respondents only).

Outcome evaluation

Population-based surveys

Six to 8 weeks after completion of HIVST kit distribution, a population-based survey was conducted in four randomly selected National Census Office Enumeration Areas (EA) in each cluster. Within each EA, 50% of households were randomly selected using Open Data Kit,²⁵ and all members of selected households aged ≥ 16 years were invited to participate, with written informed consent. Questionnaires used Audio Computer Assisted Self Interview (ACASI) on electronic tablets (male/female participants listened to male/female voices, respectively) and included demographic details; history of HIV testing and ART; access to, use and results of self-testing and uptake of any health services including confirmatory testing and ART following kit distribution.

The survey was conducted at population level (rather than restricted to individuals who received HIVST kits) because we wanted to determine HIVST uptake and population level impact of the interventions.

ART clinic data extraction for before–during–after time series analysis

Catchment areas (defined and published at health facilities) of all public sector facilities providing ART in each district were mapped in relation to wards of both trial arms and categorised into clinics with and without catchment-area HIVST distribution. Numbers of ART initiations per month were extracted from clinic registers for the period 6 months before HIVST distribution, during distribution, and 3 months following completion of distribution. For clinics without catchment-area HIVST, we matched the before–during timepoints to those of the closest trial ward.

Time series evaluations can be affected by concurrent campaigns/initiatives, but during the trial, PSI were the only organisation partnering Ministry of Health to provide HIV testing services in the selected study districts (and were the only provider of HIVST in the country).

Before–during–after study

Differences in ART initiation rates for public sector health facilities were defined by time period (before, during and after) of HIVST distribution, using preintervention initiation rates as the baseline for each clinic, and comparing during–after time trends between facilities with and without catchment-area HIVST distribution.

Statistical methods

Study power

Following protocol amendment to the two-arm design, the study power was recalculated, having initially been based on differences in demand for PSI outreach services. Using standard methodology,²⁶ and assuming 200 postintervention survey participants per cluster, an intercluster coefficient of variation (k) of 0.3, and 10% uptake of any clinic service (as informed by a previous survey) among postintervention survey participants in the least effective arm, then 38 clusters would provide >90% power to detect a 50% difference between arms, from an assumed 10%–15%.

Analysis of population-based survey data

The statistical analysis plan was finalised for the two-arm (modified intention-to-treat) trial before data collection ended. Analysis used Stata V.15.1.²⁷ We conducted logistic regression of individual-level data, with random effects adjustment to account for the cluster²⁶ to estimate prevalence ratios and differences by arm, and their associated 95% CI.²⁸ A permutation test incorporating the restriction criteria used for randomisation was used to estimate the primary outcome p-value.

The primary and secondary analyses were adjusted for imbalance by arm in a priori variables, with educational attainment, household food insecurity and mental distress meeting these criteria. Household food insecurity was defined by ≥ 2 affirmative responses to three questions, one from each domain of the Household Food Insecurity Access Scale.²⁹ Risk of mental distress was defined by a score of ≥ 9 on the locally validated Shona Symptom Questionnaire.³⁰

Sub-group analyses used data stratified by sex, age, food insecurity and mental distress. Sensitivity analyses, accounting for clustering at both the ward and household levels are shown in online supplemental appendix 2.

Analysis of ART clinic data

Generalised estimation equations were used to analyse relationships between ART initiation and campaign period, and to test for differences between clinics with and without catchment-area HIVST distribution, and between trial arms. We fitted separate models assessing rate differences and rate ratios. For both models, we assumed ART initiations were Poisson distributed. In both analyses, we adjusted for district (fixed effect), observation days (offset), preintervention clinic testing rates (average number of post-test counselling sessions per month, modelled as quadratic) and calendar month (fixed effect).

Ethical considerations and governance

As the conditional incentive intervention carried minimal risk to participants, no interim analyses were planned. An independent TAG met every 6 months to review progress.

Patient and public involvement

Before the trial, we conducted formative research including qualitative studies and discrete choice experiments where we obtained communities' preferences for door-to-door distribution of HIV self-tests.^{4 31} We used these findings to refine the HIVST distribution strategy. During the trial, as part of community entry activities, the study team met with community leaders in each ward to seek their consent for involvement of their communities and their guidance in the selection of CBDs. At the end of the study, community meetings were held to discuss research findings and get views on what worked well/less well during the intervention.

Role of the funding source

The funder did not influence the study design, protocol writing process, implementation decisions, data analysis and data interpretation. The corresponding author has full access to data.

RESULTS

Between August 2016 and August 2017, 445 CBDs in the conditional incentive arm and 447 CBDs in the no incentive arm distributed a mean of 88 (CI: 85 to 92) and 93 (CI: 89 to 96) kits each, respectively. The total distributed per arm was 39 205 and 41 173 (figure 1). Populations sizes were similar by arms, with harmonic means of 3993 (CI: 2881 to 6501) and 4796 (CI: 4020 to 5944) in HIVST and non-HIVST communities, respectively (based on 2012 census data). Distribution was carried out over 19 days (range 19–25 days) per cluster, with a median of 2313 (IQR: 1403–2521) kits distributed per cluster in the conditional incentive arm and 2071 (1646–2616) in the no incentives arm. In total, 171 (38.4%) CBDs in conditional incentive arm were given conditional incentives, with incentive amounts ranging from \$0.20 to \$6.00 (median \$0.80), corresponding to 1–30 clients linked per CBD.

The postintervention survey included 7146 participants from 3813 households, with a response rate of 83.8% in the conditional incentive arm and 83.0% in the no incentive arm. Participant characteristics were largely comparable between arms (table 1), although small imbalances by arm in food insecurity, education and mental distress were adjusted for in subsequent analyses.

Overall, 6335 (88.7%) of participants had ever tested for HIV (table 2), and 5838 (81.7%) had ever heard of HIVST. Of note, 4039 (56.5%) of those who had heard of HIVST had taken a self-test kit during HIVST distribution, and 3593 (89.0% of kit recipients) reported having self-tested. The overall population uptake of HIVST was 50.3% (3593/7146). Uptake varied relatively little by arm, age or sex, with 46.2% of young people (age 16–25 years) and 46.5% of men reporting having self-tested. Among self-testers, 36.3% (1305/3593) reported that HIVST was their first ever HIV test; this represented 18.3% of the overall sample.

Table 1 Characteristics of respondents in household surveys

	Conditional incentive		No incentive		Total	
	No.		No.		No.	
Clusters (no.)	19		19		38	
Households (no.)	1966		1847		3813	
Respondents (no.)	3698		3448		7146	
Mean respondents per cluster (geometric)	182.49		177.72		180.09	
	Mean	SD	Mean	SD	Mean	SD
Household characteristics						
Adult respondents per household (mean/SD)	1.73	0.89	1.71	0.92	1.72	0.9
Adolescent respondents per household (mean/SD)	0.15	0.4	0.16	0.39	0.15	0.39
	No.	%	No.	%	No.	%
Household wealth quintile (no./%)						
Poorest	505	25.69	529	28.64	1034	27.12
Second	312	15.87	294	15.92	606	15.89
Middle	419	21.31	336	18.19	755	19.8
Fourth	373	18.97	347	18.79	720	18.88
Least poor	357	18.16	341	18.46	698	18.31
Household food insecurity (no./%)	1190	60.53	1103	59.72	2293	60.14
	Mean	SD	Mean	SD	Mean	SD
Individual characteristics						
Age (mean/SD)	39.2	18.4	38.8	18	39	18.2
	No.	%	No.	%	No.	%
Age in groups						
16–19 years	591	16	513	14.9	1104	15.5
20–29 years	799	21.6	778	22.6	1577	22.1
30–39 years	718	19.4	706	20.5	1424	20
40–49 years	532	14.4	528	15.3	1060	14.9
50–59 years	428	11.6	360	10.5	788	11
60 years and older	625	16.9	558	16.2	1183	16.6
Male (no./%)	1414	38.2	1353	39.2	2767	38.7
Marital status (no./%)						
Married or living as married	2169	58.7	2071	60.1	4240	59.3
Never married	853	23.1	764	22.2	1617	22.6
Widowed/separated/divorced	676	18.3	613	17.8	1289	18
Highest level of education (no./%)						
None or primary only	1664	45	1428	41.4	3092	43.3
Some secondary	1008	27.3	903	26.2	1911	26.7
O-levels complete	856	23.1	942	27.3	1798	25.2
A-level and higher	170	4.6	175	5.1	345	4.8
Able to read a newspaper or letter (no./%)	570	15.4	583	16.9	1153	16.1
Religion (no./%)						
Apostolic	1230	33.3	1220	35.4	2450	34.3
Other Christian denomination	1115	30.1	1128	32.8	2243	31.4
Other, including no religion	1353	36.6	1100	31.9	2453	34.3
Receives regular salary (no./%)	570	15.4	583	16.9	1153	16.1

Continued

Table 1 Continued

	No.	%	No.	%	No.	%
SSQ* \geq 9 (no./%)	1599	43.2	1622	47	3221	45.1
Ever tested for HIV (no./%)	3236	87.5	3099	89.9	6335	88.7
Self-reported HIV+ (no./%)	450	12.2	377	10.9	827	11.6
Self-reported current ART use, among HIV+ (no./%)*	388	86.2	319	84.6	707	85.5

*Shona Symptom Questionnaire.
ART, antiretroviral therapy.

Effect of conditional incentives

Uptake of HIVST

There were 1770 (47.9%) and 1823 (52.9%) participants who reported self-testing in the conditional incentives and no incentives arms, respectively, giving an adjusted prevalence ratio (aPR) 0.91 (95%CI: 0.80 to 1.02).

Uptake of post-HIVST distribution services (primary outcome)

We found no evidence of a difference in uptake of post-HIVST services by arm with 1062 (28.7%) and 1075 (31.2%) clients in conditional incentive and no incentive arm, respectively, linked to any service (aPR=0.94; 95% CI: 0.86 to 1.03, permutation test $p=0.13$; [table 3](#)). The majority of participants who linked (1768/2137; 82.7%) visited the local clinic/hospital. The most commonly sought post-test services from the local clinic/hospital (multiple responses possible) were HIV testing and counselling (38.6%), treatment for an ailment (16.7%), routine clinic visit or prescription refill (12.2%), HIV care—CD4 cell count (12.1%) and family planning services (11.0%). Subgroup analysis showed no evidence of a difference in linkage to post-test services by arm, by gender, age, food insecurity or mental distress (online supplemental appendix 3). The cluster coefficient of variation, k , for uptake of post-test services was 0.05.

Other outcomes

We did not find evidence of a difference by arm for our secondary outcomes of linkage to PSI outreach services ([table 3](#)). The preset analyses of confirmatory testing and uptake of ART for participants with reactive self-tests were

dominated by retesting while already on ART ([table 3](#)), which was not the intention of this intervention. As such, we also present a post-hoc analysis excluding respondents who reported they were already on ART at the time of HIVST ([table 3](#)). This provides some evidence that individuals with newly diagnosed HIV were more likely to have attended for confirmatory testing in the conditional incentives arm (23/33, 75.8%) compared with the no incentive arm (20/40, 50.0%): aPR 1.59; 95% CI 1.05 to 2.39.

Effect of HIVST on ART clinic initiations

To determine the effect of HIVST on ART initiations, we extracted data from all 164 health facilities that provided ART in the study districts. Of these, 40 facilities served the 38 HIVST communities and recorded 3138 ART initiations, while 124 facilities were outside the catchment-area for HIVST distribution and reported 9670 ART initiations. Our data show that the average number of ART initiations per clinic day preintervention was similar between HIVST and non-HIVST health facilities. During the period of HIVST distribution, there was a difference in rate of ART initiations between HIVST distribution and non-HIVST areas; this difference disappeared after completion of HIVST distribution. Online supplemental appendix 4A summarises the number of ART initiations per month during the three periods before, during and after HIVST distribution in HIVST and non-HIVST communities: in HIVST communities, the number of ART initiations increased during the distribution period

Table 2 Coverage of self-testing after distribution

Characteristic	Conditional incentives	No incentives	Total
Respondents—number	3698	3448	7146
Ever tested for HIV	3236/3698 (87.5%)	3099/3448 (89.9%)	6335/7146 (88.7%)
Ever heard of HIV self-testing	2962/3698 (80.1%)	2876/3448 (83.4%)	5838/7146 (81.7%)
Received kit during intervention	1983/3698 (53.6%)	2056/3448 (59.6%)	4039/7146 (56.5%)
Used kit to self-test	1770/3698 (47.9%)	1823/3448 (52.9%)	3593/7146 (50.3%)
% First-time testers	642/3698 (17.4%)	663/3698 (19.2%)	1305/7146 (18.3%)
Overall coverage of self-testing	1770/3698 (47.9%)	1823/3448 (52.9%)	3593/7146 (50.3%)
Coverage among men	628/1414 (44.4%)	658/1353 (48.6%)	1286/2767 (46.5%)
Coverage among aged <25 years	463/1037 (44.7%)	456/952 (47.9%)	919/1989 (46.2%)

Table 3 Effect of CBD incentive on linkage to additional care and uptake of self-testing

	Conditional incentive		No incentive		Prevalence ratio	Prevalence difference		
	n/N	%	n/N	%		95% CI	P value	k
Primary outcome								
Linkage to any services	1062/3698	28.7	1075/3448	31.2	0.94 (0.86 to 1.03)	0.17	0.05	7146
Secondary outcomes and post-hoc analyses								
Uptake of self-testing	1770/3698	47.9	1823/3448	52.9	0.91 (0.80 to 1.02)	0.116	0.05	7146
Uptake of PSI outreach services	94/1770	5.3	106/1823	5.8	0.92 (0.68 to 1.24)	0.57	0.38	3593
Uptake of VMMC among men	19/854	2.2	12/853	1.4	1.76 (0.77 to 4.03)	0.186	0.74	1707
Uptake of confirmatory testing for reactive self-tests	88/157	56.1	72/132	54.5	1.02 (0.82 to 1.28)	0.845	*	289
Post-hoc analysis: uptake of confirmatory testing for reactive self-tests if not already on ART and or in HIV care	25/33	75.8	20/40	50	1.59 (1.05 to 2.39)	0.019	-	73
Initiation of ART among all participants who reported a reactive self-test result	15/157	9.6	12/132	9.1	1.03 (0.50 to 2.15)	0.932	1.36	289
Post-hoc analysis: uptake of ART among HIV-positive participants not previously in HIV care (ie, excluding those participants already on ART)	15/33	45.5	12/40	30	1.52 (0.48 to 4.81)	0.354	-	73

Adjusted models include adjustment for educational attainment (none/primary, some secondary, O-levels complete, A-levels and above), household food insecurity (moderate/severe food insecurity, no/mild food insecurity) and high SSQ (Shona Symptom Questionnaire) score (nine or higher).

ART, antiretroviral therapy; CBD, community-based distributors; PSI, Population Services International; VMMC, voluntary medical male circumcision .

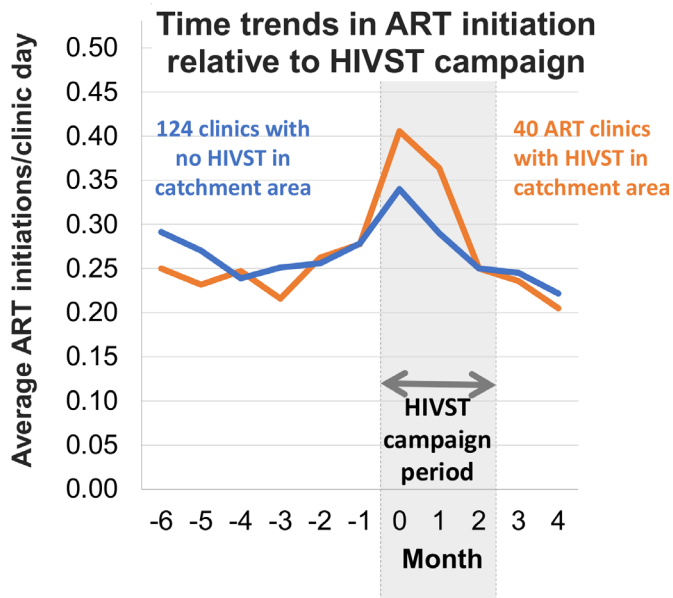


Figure 2 Trends in ART initiation rates before, during and after the HIVST campaign period.

from 7.31 to 9.59 initiations per month, then decreased thereafter to 6.53 initiations per month.

Figure 2 illustrates the change in ART initiation rates over time and interaction with HIVST, with the increase in ART initiation rates in HIVST communities corresponding to an adjusted ART initiation rate ratio of 1.27 (95% CI: 1.13 to 1.42). Details are given in online supplemental appendix 4B. Once HIVST distribution ended, the adjusted initiation rate ratio was 1.02 (95% CI: 0.88 to 1.18) compared with the preintervention period. There was no difference in ART initiation by trial arm post-HIVST distribution (data not shown).

DISCUSSION

In this pragmatic cluster-randomised trial, we found that community-based HIVST campaigns achieved high uptake of testing across both arms, including groups with historically low testing rates (men, young people) and those who had not tested previously. Using a separate quasi-experimental design, we showed that HIVST campaigns in both arms were associated with a 27% relative increase in ART initiation rates at nearby public health facilities, with return to pre-HIVST rates as soon as the campaign was over. There was, however, no evidence of additional benefit from providing kit distributors with a small linkage incentive (US\$0.20 per client linked) on top of a fixed stipend, with no evidence of a difference between arms on uptake of post-test services including ART or on HIVST uptake. Uptake of confirmatory testing was higher for newly diagnosed HIV-positive participants in the conditional incentive arm, but this finding was based on small numbers and was a post-hoc modification to the planned analysis to exclude clients who were using HIVST to re-test while on ART.

Our results add to the growing body of evidence showing that HIVST can increase uptake of HIV testing.¹⁵ Following HIVST distribution, 88.7% of participants surveyed reported ever testing for HIV, compared with 75% in the nationally representative Zimbabwe Public Health Impact Assessment conducted in the same year.¹² These data suggest that campaign style HIVST distribution can bring about a step change in knowledge of HIV status, with good uptake by men, young people and a substantial proportion being first-time testers. Of note, we found an increase in ART initiation immediately after commencement of HIVST distribution, with rates going back to previous levels after distribution stopped, showing the value of self-testing in achieving timely linkage.

Studies of community-based provider testing have shown longer times to linkage than suggested by our ART clinic-level data,^{32 33} for instance in the HIV Prevention Trials Network 071 trial (known as POPART) in Zambia and South Africa, the median time to linkage was 6 months. Data from our survey, conducted just 6 weeks after the HIVST campaign data, add support to more rapid linkage with most previously undiagnosed self-testers with reactive results having already confirmed them. It is plausible that reactive (positive) self-tests may tend to prompt more rapid action than reactive provider-tests, given the additional uncertainties regarding the result and likely desire for experienced in-person post-test counselling. Not only are reactive self-tests preliminary (unconfirmed by a second or third test kit), but self-testers acknowledge their own inexperience as a motivator for clinic confirmation when they get unexpected results.³⁴

A small conditional incentive of US\$0.20 per person taking up post-test services did not increase linkage overall although confirmatory testing of newly diagnosed HIV-positive HIVST clients appeared to have been increased. Existing literature has shown the effectiveness of demand-side incentives on engagement along the HIV cascade, including increasing linkage to HIV care and prevention following self-testing among male partners of women attending antenatal care clinics in Malawi.¹⁹ Importantly, the Malawi trial showed a dose-effect with US\$10 more effective than US\$3 in prompting post-HIVST clinic attendance.¹⁹ In contrast, uptake of HIVST by male partners, which was already 93% in the no-incentive arm—implying strong inherent motivation, was unaffected by incentivisation.¹⁹ Motivation was high in both arms of the current trial, with CBDs reporting pride in delivering an important and novel intervention to their community.³⁵ Motivation was also potentially driven by the \$50 base amount. We could not test a range of amounts for the conditional incentive due to time pressure and acknowledge that the amount may simply have been too low. We were constrained to test a small amount that was potentially scalable but with low risk of unintended consequences.

Measuring linkage is already challenging for standard provider-delivered HIV testing, but becomes more so

with self-testing with loss of provider-control over the test results.³⁶ Attempts to track cohorts of HIV self-testers and link individual HIVST clients to confirmatory testing and ART initiation events, as occurs for monitoring standard HIV testing services, may be futile. Even using more approximate triangulation approaches looking at initiation rates at health facilities may be undermined by clients failing to disclose previous testing episodes and results. Additionally, some clients may opt to initiate treatment in a different location from where they initially tested positive to maintain confidentiality. The lack of national unique patient identifiers which can be used to track individuals across facilities coupled with poor penetration of electronic medical record systems in many African settings adds to this challenge. Despite its limitation, the approach used here to infer linkage to care following HIVST through a time-series analysis, provides an effective, low cost alternative to evaluating the impact of HIVST, circumventing the difficulties of measuring linkage more directly, and is one that other programmes could consider if using similar high intensity campaigns aimed at high coverage.

The major strength of this study was the large-scale implementation of community-based HIVST, providing evidence on feasibility, coverage and linkage. The accompanying time-trend analysis showing increased clinic-level ART initiations associated with HIVST adds powerful support for HIVST-related health outcomes using methods that bypass the need for cohort tracking despite also showing no difference between incentive trial arms. PSI was the sole HIV testing partner operating in the study districts, allowing us to confidently exclude non-study interventions during the HIVST campaign period.

Limitations include potential bias from trial outcomes based on self-report, although we used ACASI to minimise this risk.³⁷ The trial deviated from the original design (see Methods section), dropping one of the two planned interventions (demand-side incentives) and redefining the way that the primary outcome was to be captured, which necessitated removal of one district (six clusters) from analysis postrandomisation. As randomisation was restricted by district, we retained balance between arms in the remaining clusters. People already on ART using HIVST to retest, which is common for a variety of reasons,^{8 38 39} outnumbered new HIV diagnoses in our endline survey necessitating post-hoc adaptation of confirmatory testing outcome. Retesting on ART has become more problematic for evaluation of routine HIV testing services, regionally, as countries approach 90-90-90 targets, and should be discouraged as far as possible. We acknowledge that our conclusions regarding conditional incentives would have been more robust had we been able to include prior dose-ranging studies. For the difference-in-differences analysis, clinic catchment areas were larger than HIVST clusters and not all newly diagnosed PLHIV will choose their local clinic for HIV services: one explanation for the smaller peak seen for

designated non-HIVST clinics during HIVST distribution (figure 2). As such, we may have underestimated the effect of HIVST campaigns on demand for ART.

In summary, community-based HIVST campaigns achieved a step change in uptake of HIV testing, including among men and young people who typically have poor testing uptake. HIVST was accompanied by a significant increase in clinic-based ART initiations during the campaign period. Delivery of HIVST by briefly trained community members was feasible, but a conditional financial incentive added little to their performance over a fixed stipend to distribute this novel technology, suggesting either high levels of inherent non-monetary motivators, or a subeffective incentive amount or a combination of these two. Given our post-hoc analysis showing higher linkage to confirmatory testing for newly diagnosed HIV-positive clients in the conditional incentive arm, future research should aim to optimise the nature and size of incentives to increase uptake and linkage while weighing the benefits and costs as highlighted in WHO guidance.⁴⁰

Author affiliations

¹CeSHHAR Zimbabwe, Harare, Zimbabwe

²Department of International Public Health, Liverpool School of Tropical Medicine, Liverpool, UK

³MRC Tropical Epidemiology Group, London School of Hygiene & Tropical Medicine, London, UK

⁴HIV and Tuberculosis, Population Services International Global, Washington, DC, USA

⁵Department of Sexual Reproductive Health Rights and Innovations, Population Services International Zimbabwe, Harare, Zimbabwe

⁶Women's Global Health Imperative, RTI International, Berkeley, California, USA

⁷HIV and TB Unit, Ministry of Health and Child Care, Harare, Zimbabwe

⁸Department of Global Health and Development, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine, London, UK

⁹HIV Department, Geneva, Switzerland

¹⁰Department of Infectious Disease Epidemiology, Faculty of Epidemiology and Population Health, London School of Hygiene & Tropical Medicine, London, UK

¹¹Department of Clinical Research, Faculty of Infectious and Tropical Diseases, London School of Hygiene and Tropical Medicine Faculty of Epidemiology and Public Health, London, UK

¹²Malawi-Liverpool Wellcome Trust Clinical Research Programme, Blantyre, Malawi

Twitter Euphemia Lindelwe Sibanda @Euphemia4, Collin Manganah

@cmanganah01, Miriam Taegtmeier @MiriamTaegtmeier and Cheryl Johnson @ccasejohn

Contributors Formulated the research study and design: FMC, EC, MTa, KH, CJ, ELS, GN, KLF, HAW, MN, FT-P. Informed development of data collection methods and collected data: FMC, EC, MTu, MTa, MN, JD, MNM, ELS, GN, CW. Analysed the data or contributed to the analysis: MN, ELS, HAW, KLF. Substantially provided intellectual input to the manuscript: FMC, EC, HAW, KH, FT-P, KLF, MTu, MTa, CJ, MN, MNM, CM, SN, CW.

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ORCID iDs

Euphemia Lindelwe Sibanda <http://orcid.org/0000-0003-1754-1076>

Melissa Neuman <http://orcid.org/0000-0002-8870-6504>

Collin Manganah <http://orcid.org/0000-0002-0733-0622>

Frances M Cowan <http://orcid.org/0000-0003-3087-4422>

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