

# **Zambian Peer Educators for HIV Self-Testing: a randomized study of testing provision to female sex workers in Zambia**

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## Note to readers

This impact evaluation has been submitted in partial fulfilment of the requirements of grant TW2.2.15 issued under Thematic Window 2. This version is being published online as it was received. A copy-edited and formatted version will be available in the 3ie Impact Evaluation Report Series in the near future. All content is the sole responsibility of the authors and does not represent the opinions of 3ie, its donors or its board of commissioners. Any errors and omissions are the sole responsibility of the authors. All affiliations of the authors listed in the title page are those that were in effect at the time the report was accepted. Any comments or queries should be directed to the corresponding author, Catherine Oldenburg at [catherine.oldenburg@ucsf.edu](mailto:catherine.oldenburg@ucsf.edu)

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## Summary

HIV testing is the critical first step for realization of the 90-90-90 targets, which aim to have 90% of people living with HIV aware of their status, 90% linked to care, and 90% virally suppressed. However, HIV testing among female sex workers (FSWs) in sub-Saharan Africa remains below the 90% target. HIV self-testing may be a strategy to increase HIV testing among FSW, but careful evaluation of FSW-specific interventions is needed before the intervention can be implemented at scale. The objective of this study was thus to evaluate 1) the effectiveness of HIV self-test provision compared to standard of care HIV testing for increasing HIV testing coverage among FSW and 2) the effectiveness of two delivery models for HIV self-test provision.

This study was a cluster randomized trial conducted in three transit towns in Zambia: Livingstone, Chirundu, and Kapiri Mposhi. Eligible FSWs were recruited by a peer educator. FSW-peer educator groups were randomized in a 1:1:1 ratio to one of three groups: 1) standard-of-care, which consisted of referral to existing HIV testing facilities (N=53 peer educators; N=320 participants); 2) direct delivery of an HIV self-test kit from the peer educator to the participant (N=53 peer educators; N=316 participants); or 3) distribution of a coupon from the peer educator, which could be used to collect an HIV self-test kit at a participating distribution point (N=54 peer educators; N=329 participants). The primary outcome was HIV testing during the one-month period following the first peer educator intervention. Secondary outcomes included HIV testing in the past month at the four-month visit, HIV self-test use in the self-testing arms, linkage to care, and antiretroviral therapy (ART) initiation.

Between September and October 2016, 965 participants were enrolled in the study. Of these, 886 had follow-up data at one month and 898 at four months. At one month, 94.9% and 84.4% of participants in the delivery and coupon arms reported testing for the past month, compared to 88.5% in the standard-of-care arm (delivery versus standard-of-care  $P=0.10$  and coupon versus standard-of-care  $P=0.29$ ). Participants in the delivery arm were significantly more likely to report testing for HIV in the past month compared to the coupon arm ( $P=0.005$ ). At four months, 84.1%, 79.8%, and 75.1% of participants reported testing for HIV in the past month in the delivery, coupon, and standard-of-care arms. There were no statistically significant differences in HIV testing at four months. At one month, participants in the delivery arm were more likely to report using the HIV self-test compared to the coupon arm (98.3% vs 86.3%,  $P=0.001$ ), but there was no difference in use at four months (89.8% vs 89.3%,  $P=0.88$ ). Although more participants in the standard-of-care arm reported linking to care at one month (74.6% versus 51.0% delivery and 52.8% coupon) and four months (85.7% versus 71.6% delivery and 76.6% coupon), there were no statistically significant differences. There were no statistically significant differences in ART initiation at one or four months. There were three reports of intimate partner violence related to HIV self-testing.

Although HIV self-testing did not increase HIV testing, high reported use of HIV self-tests indicate that it is acceptable to FSWs in Zambia. Although directly providing the HIV self-test may increase use in the short-term, delivery models utilizing distribution via

existing distribution points (e.g., clinics or pharmacies) will likely be successful in distributing kits.

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## 1. Introduction

Achieving high HIV testing coverage is essential for realizing the first step of the UNAIDS 90-90-90 target of diagnosing 90% of all people living with HIV by 2020 and for engaging in HIV prevention for individuals who are HIV-uninfected. (UNAIDS 2014; Nunn et al. 2017) In December 2016, the World Health Organization (WHO) released guidelines related to HIV self-testing (World Health Organization, 2016; World Health Organization, 2015), recommending that HIV self-testing be offered in addition to standard HIV testing services to help achieve realization of this target and as an entry point into HIV prevention services for those testing negative. In particular, the guidelines recognize the importance of development of new approaches such as HIV self-testing for members of key populations, who frequently have lower uptake of HIV testing services due to multilevel factors such as healthcare provider stigma (Bodkin et al. 2015; King et al. 2013) or lack of legal protection.(Oldenburg et al. 2016) Female sex workers (FSW) are a key population that are at elevated risk of HIV infection in sub-Saharan Africa.(Baral et al. 2012) FSW have unique barriers to engagement in all steps of the HIV care cascade, including barriers and facilitators to HIV testing.(Chanda et al. 2017) Evaluating interventions developed specifically for this population is therefore essential prior to their implementation.

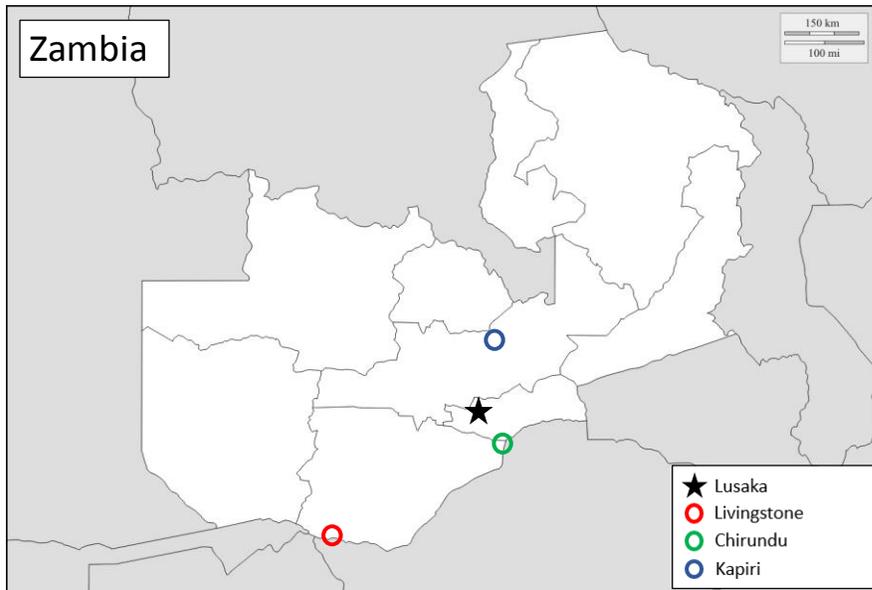
Oral HIV self-testing has been shown to be acceptable in diverse populations globally, and provision of HIV self-tests has been shown to increase HIV testing compared to standard testing services in some populations.(Stevens et al. 2017; Jamil et al. 2017; Masters et al. 2016; Johnson et al. 2017) A cohort study among FSW in Kenya found that 71% of participants used an HIV self-test after it was made available to them, but did not include a comparison group for standard testing services.(Thirumurthy et al. 2016) FSW are disproportionately affected by the HIV epidemic globally(Baral et al. 2012), including in generalized epidemic settings. Current recommendations for HIV testing among FSW include testing every three months. Although there are limited data on the HIV care continuum for FSW, available estimates suggest that all indicators are far behind the 90-90-90 target.(Gupta & Granich 2017; Cowan et al. 2017; Schwartz et al. 2016) Novel technologies, such as HIV self-testing, may help close the gap between current HIV testing coverage among FSW and the 90% coverage target.

Even though HIV self-testing may reduce some barriers to HIV testing, such as healthcare provider stigma, low access to or uptake of HIV self-testing would limit its ability to improve HIV testing coverage. Here, we test two delivery mechanisms of providing HIV self-testing to urban-based FSW in Zambia compared to standard HIV testing – *delivery* of HIVST (direct distribution of an oral HIVST from the peer educator), and *coupon* (a coupon for collection of an oral HIVST from a health clinic/pharmacy) – compared to standard-of-care HIV testing. We hypothesized that the active approach of peer-based HIVST *delivery* would perform better in terms of HIV testing and HIV status knowledge than the more passive *coupon* approach. We further hypothesized that both types of HIV self-test kit provision would lead to significantly improved recent HIV testing and better HIV status knowledge compared to standard testing.

## 2. Background/Context

### 2.1 Context

This study was conducted in three transit towns in Zambia: Livingstone, Chirundu, and Kapiri Mposhi (**Figure 1**).



**Figure 1.** Study site locations

Chirundu and Livingstone are located on the Zambia-Zimbabwe border, and are a major transportation points for people and goods. Kapiri Mposhi is north of the capital, Lusaka, and is a transit hub, with a large weigh station where many truckers stop for the night or longer. Study headquarters and coordination for the three sites was located in the capital, Lusaka. Sex work is effectively illegal in Zambia, which can limit access to HIV testing and other preventative services.

### 2.2 Intervention

In all study arms, participants completed 4 peer educator intervention visits that consisted of HIV risk reduction counseling, condom distribution, and information on where to get HIV testing. Peer educators were current or former sex workers who were recruited by sex work organizations operating in each of the study communities. The first intervention was a group-based intervention, and all subsequent interventions were one-on-one meetings between the peer educator and participant. All intervention visits happened at a time and place that was convenient and private for the participants and the peer educator. The group-based intervention was scheduled by the peer educator and was an informal meeting where the peer educator shared information with participants, and they could ask questions. The individual intervention visits were

informal check-ins that the peer educators conducted with each participant at a place of their choosing. A standardized intervention guide was developed for all peer educator intervention visits. Appendix A displays an overview of the study intervention and time points.

In the delivery arm, peer educators distributed two HIV self-test kits: one at the first peer educator visit, and a second one three months after the first peer educator visit. Each test distribution consisted of a single OraQuick ADVANCE Rapid HIV-1/2 Antibody test (OraSure Technologies, Bethlehem PA) with the manufacturer's instructions in English, Nyanja, Bemba, and Tonga. The HIV self-test is a rapid test that detects antibodies to HIV-1 and HIV-2 in the oral mucosa using an oral swab. The test gives results in 20 minutes, with a single line on the test indicating a negative result and two lines indicating a positive result. The instructions were both a pictorial and written step-by-step guide for using the test and interpreting results. Peer educators were trained on use of the oral HIV self-test and shared this information with participants. To preserve participant confidentiality, there was no HIV status requirement for distribution of the second HIV self-test kit.

In the coupon arm, peer educators distributed coupons which participants could use to collect an OraQuick HIV self-test at one of several participating distribution sites which were health clinics or pharmacies. There was no change in the health facility with regards to hours of operation or staffing. Existing staff were briefly trained on study procedures and the use of the OraQuick HIV self-test. Participants were required to bring to the coupon to the distribution site, which was exchanged for a single HIV self-test. The coupon did not include any identifying information related to the study or information that could potentially identify the participant as a sex worker. However, staff members at the distribution sites were aware that the study was specifically for sex workers. As with the delivery arm, peer educators distributed one coupon at the first peer educator visit and a second three months after the first peer educator visit. The content of the test and instructions provided to participants were identical. As with the delivery arm, there was no HIV status requirement for distribution of the second coupon.

In the standard testing arm, peer educators only provided information about existing HIV testing services. Identical information was provided to participants in the delivery and coupon arms.

Peer educators provided information to all participants about where to get a confirmatory test and link to care if they tested positive. While peer educators were available should participants have questions or need support, participants tested for HIV at a time and place of their own choosing and were not required to disclose their status to anyone. A 24-hour hotline was made available to participants in all arms. The hotline was developed specifically for the study and was staffed by research assistants in shifts, and available 24 hours a day 7 days a week. Participants were instructed to call the hotline if they needed help with HIV testing (including using the HIV self-test), experienced any adverse events such as intimate partner violence, and/or needed other assistance.

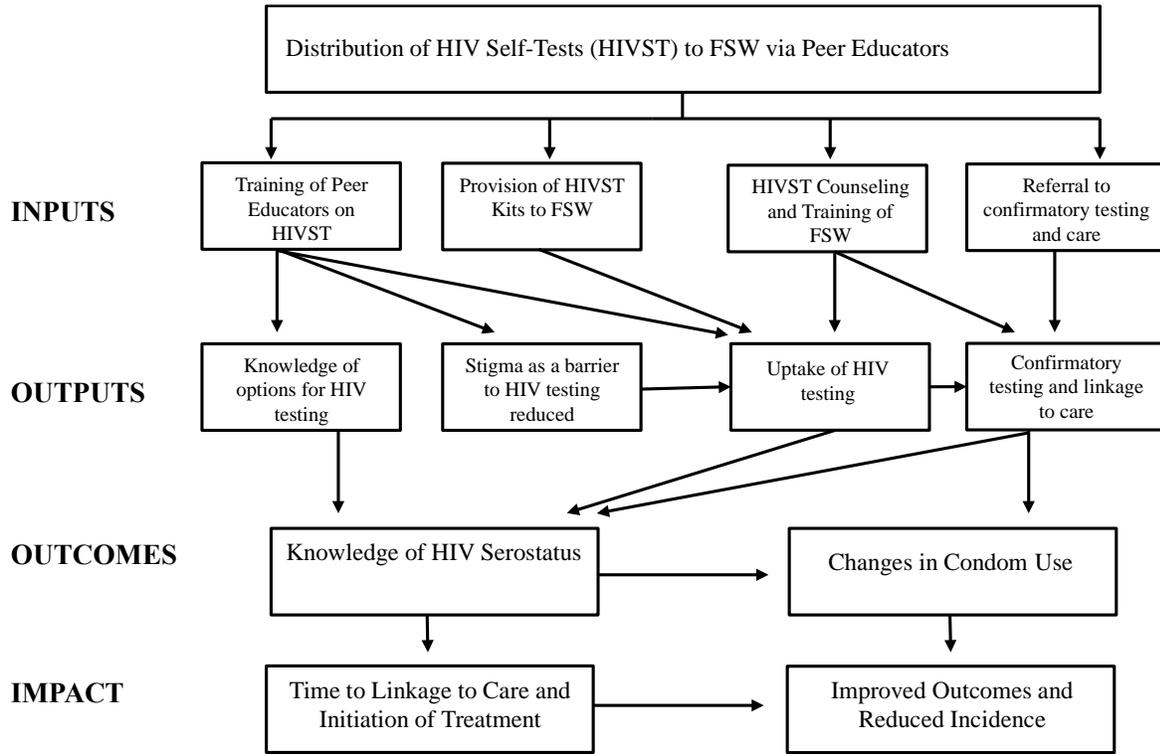
## 2.3 Theory of Change

The intervention tested in the ZEST study, and data collected throughout the course of the study, was guided *a priori* by a theory of change developed through mental models and deductive development. (Funnell & Rogers 2011) Mental models involve understanding how key stakeholders believe a program will achieve the desired outcome. We discussed with a variety of stakeholders, including programmatic implementers, researchers, and sex workers, their thoughts on how HIV self-testing might work to improve HIV testing coverage in the FSW community in Zambia. Deductive development includes logical analysis of the literature and experiences with the intervention that may inform how it is working. We consulted the relevant literature on HIV self-testing in key populations. Based on these exercises, we theorized that the distribution of HIV self-test kits via peer educators would lead to improved status knowledge by reducing barriers to HIV testing such as stigma or hours of clinic operation (Figure 2). Enacted or perceived sex work stigma from healthcare providers and from the community may be addressed by HIVST, by allowing individuals to test for HIV in private without fear of being seen in the clinic and without fear of judgment from providers. This would lead to improved uptake of HIV testing, which would lead to improved knowledge of status and ultimately reduce time to linkage to care. However, it is also possible that a community-based intervention such as HIVST could be unsuccessful if individuals are concerned about others discovering their HIV status.

We hypothesized that the direct delivery of an HIV self-test would overcome the majority of barriers to HIV testing faced by FSW by not requiring them to visit a healthcare provider, thus removing stigma-related barriers to HIV testing. We hypothesized that the coupon delivery arm would increase HIV testing coverage by increasing options for how individuals test for HIV. Increasing options could improve testing coverage, as some individuals who would not feel comfortable testing with a provider may feel comfortable collecting a test kit and testing for HIV on their own.

Several assumptions were required at each level of the causal chain. First, we assume that all inputs have the hypothesized effects on the outputs. For example, we assume that training peer educators would reduce stigma as a barrier to HIV testing, which could occur through a variety of pathways. If availability of peer educators of HIV self-testing did not influence stigma as a barrier to HIV testing, then it is possible that the intervention would not have the desired effect of improving HIV testing, and ultimately impacts such as reducing time to initiation of ART and reduced HIV incidence.

**Figure 2.** Theory of change



## 2.4 Timeframe

Enrollment occurred from September-October 2016 and the final follow-up visit was conducted in February 2017.

## 2.5 Primary and secondary outcomes

The primary outcome was past one-month HIV testing measured via self-report at the one month study visit. Secondary outcomes included recent HIV testing at the four-month visit, use of the HIV self-test kit, linkage to care, ART initiation, and safety endpoints including intimate partner violence. **Table 2** lists each endpoint and its operationalization.

**Table 2.** Study endpoints

Endpoint	Operationalization
<i>Primary Effectiveness Endpoint</i>	
Tested for HIV in the past month, one month time point	<ul style="list-style-type: none"> <li>Recent HIV testing measured by asking participants when they last tested and where (in all arms of the study)</li> </ul>
<i>Secondary Effectiveness Endpoints</i>	
Tested for HIV in the past month, four month time point	<ul style="list-style-type: none"> <li>Recent HIV testing measured by asking participants when they last tested and where (in all arms of the study)</li> </ul>
Use of HIV self-test	<ul style="list-style-type: none"> <li>Measured by buying back unused HIV self-tests at four-month visit</li> <li>At the conclusion of the study, participants were offered a small financial incentive (~USD\$1) to return any unused HIV self-test kits, which was framed as a study closing procedure</li> </ul>
Linkage to care and ART initiation	<ul style="list-style-type: none"> <li>Measured by asking participants who reported a positive HIV test at their most recent test 1) if they had sought care for HIV, and 2) if they were currently receiving antiretroviral therapy for HIV</li> </ul>
Correct knowledge of HIV status	<ul style="list-style-type: none"> <li>Participants were asked if they currently knew their HIV status, and to take their best guess of their current HIV status (positive or negative)</li> <li>Participants were then offered a rapid HIV test to confirm HIV status</li> <li>Participants were told that they would receive a small financial reward (~USD\$5) for correctly guessing their status, although all participants received the reward for participating in the exercise</li> </ul>
<i>Safety Endpoints</i>	
Misuse of HIV self-tests	<ul style="list-style-type: none"> <li>Including difficulty conducting the test (i.e., mistakes in taking the test, incorrect use of components of the test), difficulty reading the test</li> </ul>

	<ul style="list-style-type: none"> <li>▪ Identified through interview and ongoing consultation with peer educators</li> </ul>
Intimate partner violence	<ul style="list-style-type: none"> <li>▪ Measured through surveillance and interviews by research assistants</li> <li>▪ Any intimate partner violence (including verbal, physical, or sexual) will be documented and reported</li> </ul>

## 2.6 Implementation

Research assistant training occurred in July 2016. The planned study start date was in August 2016, but due to national elections implementation was postponed until September 2016. Recruitment was completed over an approximately 3-week period and occurred faster than anticipated. There were no issues with recruitment or enrollment and women were eager to participate in the study. Intervention implementation occurred according to the protocol. There were no issues with self-test kit procurement, distribution, or supply. No corrective actions occurred during the course of the study as there were no deviations from the protocol.

## 3. Data and Methods

### 3.1 Ethics

Ethical approval was obtained from the Institutional Review Boards at the Harvard T.H. Chan School of Public Health in Boston, MA, USA and ERES Converge in Lusaka, Zambia. Written informed consent was obtained from all study participants.

### 3.2 Data Collection

#### 3.2.1 Sample Size Considerations

Sample size determination was based on the primary endpoint, testing for HIV in the past month at the one-month visit. Power calculations were performed using methods for cluster randomized trials, with the peer educator-participant group as the randomization unit. Based on previous data from FSW in Livingstone and Chirundu (Family Health International 2006; Corridors of Hope Southern Africa 2005), we assumed that 50% of participants would have tested in the previous month in the standard of care arm, and assumed 20% loss to follow-up. We estimated 50 peer educators per arm (150 total) and 6 participants per peer educator (900 total) would yield 89% power to detect a risk ratio of 1.3 for recent testing, assuming a type I error probability of 0.05 and an intracluster correlation of 0.03. During enrollment, 10 additional peer educators were recruited, yielding a total of 160 peer educators and 965 participants.

### 3.2.2 Recruitment and Randomization

Participants were recruited in Kapiri Mposhi, Chirundu, or Livingstone, Zambia by peer educators working in their town of residence. Peer educators were current or former FSW who had been recruited and trained by study staff prior to study initiation; many had formally worked as peer educators for previous FSW implementation projects in their region. Peer educators recruited participants based on their social networks. Peer educators informed potential participants and gave them the contact information for research assistants. Potential participants called study staff for assessment of eligibility, and were screened by a research assistant via phone, and then if eligible, were formally screened and enrolled in person. A phone screening was conducted prior to the formal in person screening and enrollment to improve resource efficiency and decrease the number of individuals screened in person who were ineligible. The target enrollment was six study participants per peer educator.

Peer educator-participant groups were randomized as a unit in a 1:1:1 fashion to one of the three study arms: 1) direct delivery of the HIV self-test from the peer educator to the participant (henceforth, *delivery*), 2) distribution of a coupon from the peer educator to the participant that could be used for collection of an HIV self-test from a fixed distribution point (henceforth, *coupon*), or 3) referral to standard testing (henceforth, *standard-of-care*). In our previously-published protocol (Oldenburg et al. 2017), the terms used to describe these three groups were direct (delivery), fixed (coupon), and standard (standard-of-care). Group randomization occurred after each participant in the group had completed their baseline study assessment. The randomization list was generated in R (Version 3.3.1, The R Foundation for Statistical Computing, Vienna, Austria) in random blocks of size 3, 6, and 9 and stratified by study site (Kapiri, Chirundu, or Livingstone). Randomized study assignments for each peer educator were placed in an opaque envelope, which was opened by the peer educator and a study staff member once all participants in the peer educator's group had been enrolled. Because of the nature of the intervention, the study was not masked, however the peer educator's study arm assignment was concealed until all participants in her group had been enrolled.

### 3.2.3 Sampling

Eligible participants were 18 years of age or older at the time of enrollment, had exchanged sex (vaginal, oral, and/or anal) for money or goods at least once in the past month, self-reported an HIV-uninfected status and had not had an HIV test in the previous three months or self-reported that their HIV status was unknown, and were permanent residents of their study town of enrollment (Kapiri, Chirundu, or Livingstone). **Table 3** lists the full inclusion and exclusion criteria for the study.

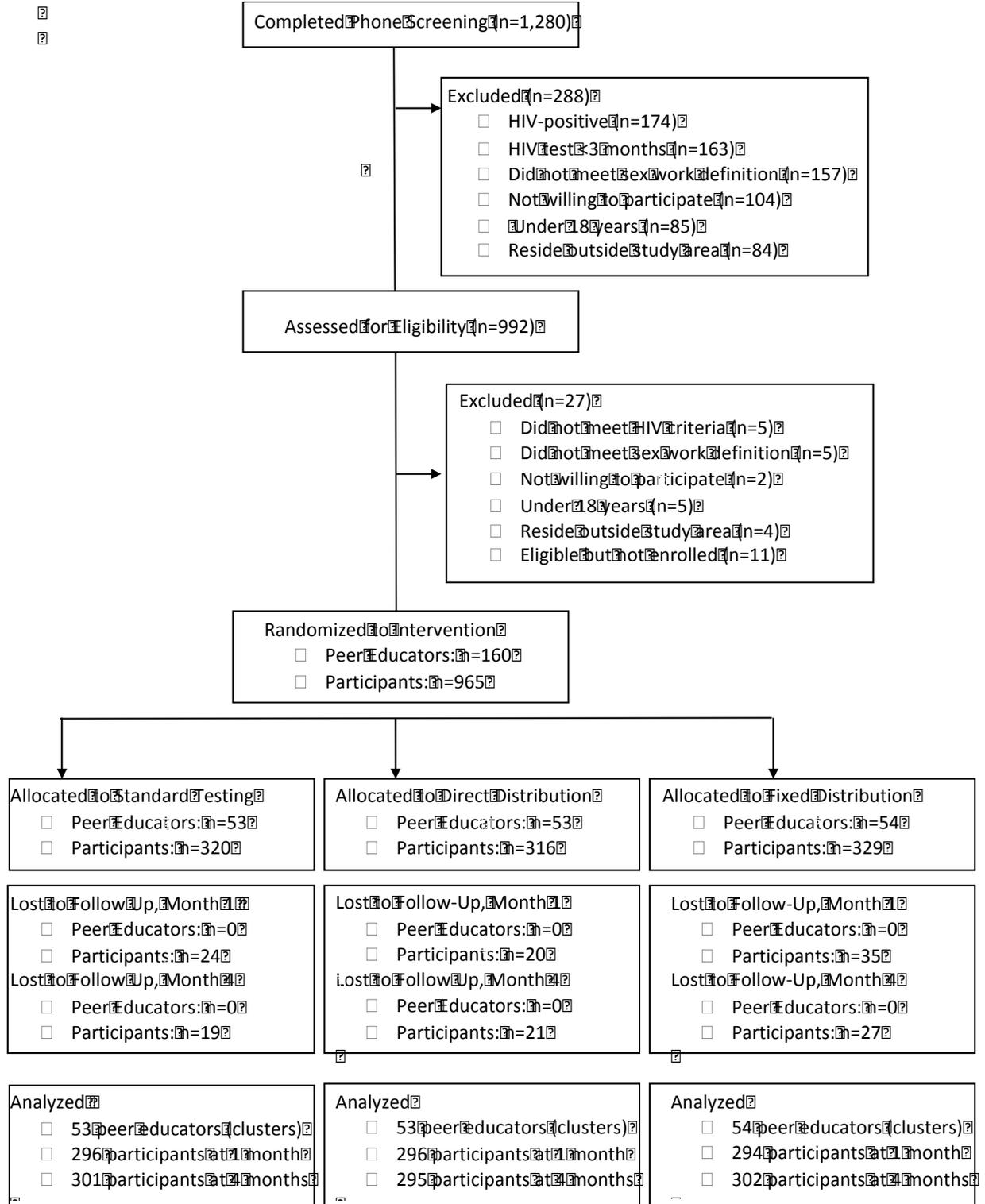
**Figure 2** displays the flow of study participants. Of 1,280 women who were screened via phone, 992 completed an in-person eligibility screen and 965 were enrolled and randomized in the study by 160 peer educators. Common reasons for exclusion were self-reporting to be living with HIV (N=163) and not meeting the sex work definition

(N=157). A total of 160 peer educator and participant groups were randomized to one of the three study arms. Follow-up was 91.8% at one month and 93.1% at four months. At one month, 92.5% in the standard, 93.7% in the direct delivery, and 89.4% in the coupon arms were retained in the study. At four months, 94.1% in the standard, 93.4% in the direct delivery, and 91.8% in the coupon arms were retained in the study. Differences in retention by arm were not statistically significant.

**Table 3.** Inclusion and exclusion criteria

<i><b>Inclusion criteria</b></i>	<i><b>Exclusion criteria</b></i>
<ul style="list-style-type: none"> <li>• 18 years or older at enrollment</li> <li>• Reports exchanging sex (vaginal, oral, and/or anal) for money or goods at least once in the past month</li> </ul>	<ul style="list-style-type: none"> <li>• Less than 18 years at enrollment</li> <li>• Has not exchanged any form of sex in the past month</li> </ul>
<ul style="list-style-type: none"> <li>• Self-reported HIV negative and no recent HIV test (&lt;3 months) OR HIV status unknown</li> </ul>	<ul style="list-style-type: none"> <li>• Self-reported to be living with HIV</li> <li>• Self-reported HIV negative but tested in the within the last 3 months</li> </ul>
<ul style="list-style-type: none"> <li>• Permeant residence in the study town of enrollment (Livingstone, Chirundu, Kapiri)</li> </ul>	<ul style="list-style-type: none"> <li>• Planning to move out of the geographical area within 4 months</li> <li>• Living in the PopART catchment area (Livingstone only)</li> </ul>
<ul style="list-style-type: none"> <li>• Willing to participate in peer education sessions and study assessments over 4-month study period</li> </ul>	<ul style="list-style-type: none"> <li>• Meets inclusion criteria but does not wish to participate</li> </ul>
	<ul style="list-style-type: none"> <li>• Concurrently participating in another HIV prevention study</li> </ul>

**Figure 3. Study flow diagram**



**3.2.4 Data Collection Methods**

Data were collected via face-to-face interview on a tablet using the cloud-based platform CommCare (Dimagi, Inc, Cambridge, MA). All interviews were conducted by a trained research assistant. Research assistants participated in a one-week training on the study, which included training in confidentiality and building rapport with participants.

To avoid differential participation by study arm, the baseline questionnaire was completed prior to randomization. Two baseline questionnaires were administered, at one and four months after the first peer educator intervention visit. Participants received approximately USD\$5 in compensation for their time for participating in each interview.

### *3.2.5 Quality Control*

Data were reviewed on a daily basis during each data collection round and data reports were generated that included inconsistencies or other data cleaning issues. The reports were emailed to the study coordinator, based in Lusaka, and each site coordinator. Weekly phone calls were held with study staff to review ongoing progress.

### *3.2.6 Challenges*

During the one-month time point, there was an interruption in data collection due to an issue with study funds. This caused a several week delay in follow-up visits, which complicated the measurement of the primary outcome due to its dependence on timing (any testing in the month prior to the one-month visit). A non-prespecified secondary outcome was therefore conducted assessing testing in the previous 3 months, as participants were asked 1) if they had ever tested for HIV, and 2) how long ago their most recent HIV test was. Ensuring and projecting the flow of study funds and prompt communication in the case of a similar issues should mitigate issues like this from occurring in the future.

## **3.3 Statistical Methods**

All analyses were intention-to-treat. Our pre-specified primary outcome was the proportion of participants reporting testing for HIV in the previous one month as measured at the one-month visit. Our pre-specified analysis was a mixed-effects multilevel regression model to account for clustering by peer educator and study site. To estimate risk ratios, we used a mixed-effects generalized linear model with a Poisson distribution, log link, and robust error term (Zou 2004), with a fixed effect for randomization arm and study site and a random effect for peer educator group. Secondary analyses with dichotomous variables, including past one-month testing at the four-month visit, correct knowledge of HIV status, linkage to care, and use of ART, were modeled with an identical model. Use of the HIV self-test kit was compared between the two intervention arms (delivery and coupon). This model was identical to that used for the primary outcome, with the exception that the term for study arm contained only two levels (delivery or coupon). A similar model was used for being offered the test kit or coupon and taking the test kit or coupon. As a sensitivity analysis, we calculated the proportion of participants within each peer educator group reporting

each outcome, and compared the proportions across study arm using a linear regression model with a term for study arm and for site. This model avoids the need to model the covariance structure by analyzing at the unit of randomization (the peer educator). Finally, we compared the effect of HIV self-testing either via delivery or coupon versus standard testing by pooling participants in the delivery and coupon arms in a non-pre-specified secondary analysis.

Data collection was interrupted during the one-month visit after approximately 80% of participants had completed their assessment, and was delayed for approximately one month. Participants who were interviewed late who tested during the first month of the study therefore would have responded that their most recent test was more than one month ago. As a non-pre-specified sensitivity analysis, we therefore assessed HIV testing in the previous 3 months as measured at the one-month visit. Given that participants were not eligible to participate if they had tested in the three months prior to enrollment, past three-month testing captures testing while in this study for all participants.

We assessed heterogeneity in treatment effects by study site (Livingstone, Kapiri Mposhi, and Chirundu) and by HIV testing history (ever/never). Effect modification was assessed by including a treatment arm by effect modifier variable interaction term in a model that was otherwise identical to the primary model.

We assessed differences in loss to follow-up with a mixed-effects generalized linear model with a Poisson distribution, log link, and robust error term, with a fixed effect for randomization arm and study site and a random effect for peer educator group.

The pre-specified primary analysis was a complete-case. All tests were two-sided with no adjustments for multiple comparisons. All analyses were conducted in Stata 14.1 (StataCorp, College Station, TX).

### **3.4 Cost Effectiveness Methodology**

We calculated the incremental cost effectiveness of HIV self-testing delivery models using administrative data collected on costs and evidence generated from the trial on the effectiveness of HIV self-test delivery directly or via facility collection. We calculated the incremental cost-effectiveness for the following outcomes: any HIV testing (at one month and at four months), and repeat testing (at four months).

We took the provider perspective of a non-governmental organization (NGO) with an existing FSW peer educator program and accounted for all running costs, including materials and salaries. Materials costs included HIV testing referral cards, coupons, and HIV self-tests. The oral HIV self-tests in this study were purchased from OraSure for approximately USD\$5.90/test (including shipping and tax). We additionally included costs related to car hire and airtime. We did not include start-up costs related to recruiting and training FSW peer educators in the cost-effectiveness analysis.

## 4. Results

### 4.1 Baseline Data

Baseline characteristics were balanced between the three groups (**Table 4**). Approximately half of participants were enrolled in Livingstone, and a quarter each in Kapiri Mposhi and Chirundu.

**Table 4.** Baseline descriptive characteristics by randomization arm

	<b>Standard-of-Care Testing (N=320)</b>	<b>Direct HIV Self-Test Delivery (N=322)</b>	<b>HIV Self-Test Coupon (N=323)</b>
Age (median, IQR)	25 (22 to 31)	25 (21 to 30)	25 (21 to 30)
Site			
Livingstone	156 (48.8%)	162 (51.3%)	162 (49.2%)
Kapiri	87 (27.2%)	76 (24.1%)	82 (24.9%)
Chirundu	77 (24.1%)	78 (24.7%)	85 (25.8%)
Have a primary partner	203 (63.6%)	171 (54.1%)	202 (61.0%)
Can read and write	226 (70.9%)	243 (77.1%)	253 (77.9%)
Education			
No formal education	53 (16.6%)	30 (9.5%)	25 (7.5%)
Primary/Junior	129 (40.3%)	152 (48.1%)	169 (51.5%)
Secondary	131 (40.9%)	128 (40.5%)	130 (39.6%)
Vocational	6 (1.9%)	6 (1.9%)	1 (0.3%)
Tertiary	1 (0.3%)	0	3 (0.9%)
Mobile phone ownership	271 (84.7%)	265 (83.9%)	284 (86.3%)
Monthly income			
No income	81 (25.8%)	58 (18.7%)	63 (19.4%)
<250 kwacha <sup>1</sup>	40 (12.7%)	32 (10.3%)	51 (15.7%)
251-500 kwacha <sup>1</sup>	75 (23.9%)	86 (27.7%)	74 (22.8%)
501-1000 kwacha <sup>1</sup>	74 (23.6%)	82 (26.4%)	90 (27.8%)
1001-1500 kwacha <sup>1</sup>	17 (5.4%)	30 (9.7%)	26 (8.0%)
>1500 kwacha <sup>1</sup>	27 (8.6%)	23 (7.4%)	20 (6.2%)
Years in sex work (median, IQR)	5 (3 to 10)	5 (3 to 10)	5 (3 to 8)
Inconsistent condom use with clients	231 (75.2%)	236 (78.7%)	228 (71.0%)
Timing of last HIV test			
>3-6 months	131 (42.3%)	94 (29.8%)	152 (47.1%)
>6-12 months	69 (22.3%)	95 (30.2%)	76 (23.5%)
>12-24 months	18 (5.8%)	26 (8.3%)	26 (8.1%)
>24 months	17 (5.5%)	24 (7.6%)	24 (7.4%)
Never tested	75 (24.2%)	76 (24.1%)	45 (13.9%)
Intimate partner violence, past 12 mo			
Physical	165 (51.6%)	150 (50.8%)	168 (51.1%)
Sexual	148 (46.4%)	157 (49.7%)	144 (43.8%)
Any	196 (61.4%)	194 (61.4%)	199 (60.5%)

## 4.2 Primary Outcome

The results of the primary outcome are listed in **Table 5**. At one month, 88.5%, 94.9%, and 84.4% of participants in the standard, delivery, and coupon arms reported testing for HIV in the past month. At four months, 75.1%, 84.1%, and 79.8% of participants reported testing for HIV in the past month. Compared to the standard arm, participants in the delivery arm were 1.07 times as likely to test for HIV (RR 1.07, 95% CI 0.99 to 1.15,  $P=0.10$ ) and participants in the coupon arm were 0.95 times as likely to test for HIV (RR 0.95, 95% CI 0.86 to 1.05,  $P=0.29$ ). At 4 months, participants in the delivery arm were 1.11 times as likely to test for HIV (RR 1.11, 95% CI 0.98 to 1.27,  $P=0.11$ ) compared to the standard arm and participants in the coupon arm were 1.06 times as likely to test for HIV (RR 1.06, 95% CI 0.92 to 1.22,  $P=0.42$ ) compared to the standard arm. None of these differences were statistically significant. In a sensitivity analysis which assessed HIV testing in the past 3 months at the one-month visit to account for delayed data collection, participants in the coupon arm were less likely to test for HIV compared to those in the standard arm ( $P=0.01$ ). Compared to the coupon arm, participants were more likely to test for HIV at one month in the delivery arm (RR 1.13, 95% CI 1.04 to 1.22,  $P=0.005$ ) but there was no difference at four months (RR 1.05, 95% CI 0.94 to 1.18,  $P=0.40$ ).

**Table 5.** HIV Testing and Linkage to Care at One and Four Months by Study Arm.

	One Month				Four Months			
	Standard-of-Care (N=296)	Delivery (N=296)	Coupon (N=294)	P-value	Standard-of-Care (N=301)	Delivery (N=295)	Coupon (N=302)	P-value
Self-report tested for HIV in past one month	262 (88.5%)	280 (94.9%)	248 (84.4%)	0.10 <sup>1</sup> 0.29 <sup>2</sup>	226 (75.1%)	248 (84.1%)	241 (79.8%)	0.11 <sup>1</sup> 0.42 <sup>2</sup>
Self-report tested for HIV in past three months**	290 (98.0%)	288 (97.6%)	271 (92.2%)	0.83 <sup>1</sup> 0.01 <sup>2</sup>	n/a	n/a	n/a	
Self-report positive status at last test	59 (20.5%)	49 (16.7%)	36 (12.4%)	0.24 <sup>1</sup> 0.04 <sup>2</sup>	84 (28.2%)	74 (25.3%)	77 (25.7%)	0.59 <sup>1</sup> 0.60 <sup>2</sup>
Self-report linked to care (among those self-reporting positive status)	44 (74.6%)	25 (51.0%)	19 (52.8%)	0.07 <sup>1</sup> 0.12 <sup>2</sup>	72 (85.7%)	53 (71.6%)	59 (76.6%)	0.13 <sup>1</sup> 0.17 <sup>2</sup>
Self-report on ART (among those self-reporting positive status)	27 (46.6%)	11 (22.5%)	9 (25.0%)	0.09 <sup>1</sup> 0.21 <sup>2</sup>	54 (64.3%)	35 (48.0%)	44 (57.1%)	0.17 <sup>1</sup> 0.39 <sup>2</sup>
Correctly identified HIV status <sup>3</sup>	n/a	n/a	n/a	n/a	192 (86.9%)	222 (90.2%)	194 (90.2%)	0.30 <sup>1</sup> 0.30 <sup>2</sup>
Reported intimate partner violence resulting from self-testing	n/a	1 (0.3%)	1 (0.3%)		n/a	1 (0.3%)	0	

<sup>1</sup>P-value for direct arm versus standard arm; <sup>2</sup>P-value for fixed arm versus standard arm; <sup>3</sup>N=682 due to non-participation in the assessment, measured via asking participant to report HIV status and confirming with a rapid test; \*\*NOTE: Due to an interruption in data collection during the one-month visit, some visits were conducted >1 month after the first peer educator visit, and thus some participants reported that they had not had an HIV test in the past month but they had had an HIV test since their peer educator visit. Note that past one-month HIV testing is the pre-specified primary outcome.

## 4.3 Secondary Outcomes

### 4.3.1 Linkage to Care and Antiretroviral Therapy Initiation

Linkage to care and ART initiation outcomes are listed in **Table 5**. At one month, among 144 individuals who reported that their most recent HIV test was positive, 74.6% in the standard, 51.0% in the delivery arm, and 52.8% in the coupon arm reported linking to care, and 46.6% in the standard, 22.5% in the delivery, and 25.0% in the coupon arm reported initiating ART. At four months, among 235 women reporting that their most recent HIV test was positive, 85.7% in the standard, 71.6% in the delivery, and 76.6% in the coupon arm reported linking to care, and 64.3% in the standard, 48.0% in the delivery, and 57.1% in the fixed arm reported starting ART. None of these differences were statistically significant.

### 4.3.2 HIV status knowledge

At four months, there was no difference in HIV status knowledge between arms (Table 5). In the standard arm, 86.9% of individuals correctly identified their HIV status, compared to 90.2% in the delivery and 90.2% in the coupon arms.

### 4.3.3 HIV self-test use

HIV self-test use outcomes are listed in **Table 6**. At one month, 98.3% of participants reported using the HIV self-test kit in the direct delivery arm compared to 86.3% in the coupon arm ( $P=0.001$ ). There was no difference between HIV self-test arms in HIV self-test use at four months (89.8% in the direct delivery arm compared to 89.3% in the coupon arm).

### 4.3.4 Hotline use

Forty-three (4.9%) of participants called the hotline prior to the one-month visit and 20 (2.2%) participants called the hotline prior to the four-month visit. Common reasons for calling the hotline included help with accessing HIV testing (25.6% at one month, 20.0% at four months), HIV self-test use help (13.9% at one month, 5% at four months), and accessing non-HIV healthcare (37.2% at one month, 10% at four months).

**Table 6.** HIV Self-Test Kit Distribution and Use at One and Four Months by Study Arm.

	One Month			Four Months		
	Delivery (N=289)	Coupon (N=285)	P- value <sup>1</sup>	Delivery (N=295)	Coupon (N=299)	P- value <sup>1</sup>
Offered coupon/test by peer educator	285 (98.6%)	273 (95.5%)	0.17	284 (96.3%)	293 (98.0%)	0.20
Took coupon/test from peer educator	285 (98.6%)	272 (95.1%)	0.17	284 (96.3%)	291 (97.3%)	0.52
Collected test kit <sup>2</sup>	285 (100%)	258 (90.2%)	0.003	284 (100%)	280 (93.7%)	0.003
Used HIV self-test	284 (98.3%)	246 (86.3%)	0.001	265 (89.8%)	266 (89.3%)	0.88
Used HIV self-test, among those who had the kit	284 (99.7%)	246 (95.7%)	0.01	265 (93.3%)	266 (95.3%)	0.45
Number of kits used during study						
0	n/a	n/a	n/a	0	4 (1.4%)	0.75
1				45 (15.4%)	44 (15.4%)	
2				246 (84.3%)	238 (83.2%)	
Number of tests returned <sup>3</sup>						
0	n/a	n/a	n/a	224 (84.4%)	231 (87.8%)	0.38
1				24 (8.8%)	18 (6.8%)	
2				24 (8.8%)	14 (5.3%)	

<sup>1</sup>Multilevel mixed effects generalized linear model with study arm and site as a fixed effects and peer educator a random effect; <sup>2</sup>By default, all participants in the delivery arm collected the kit as it was directly handed to them by the peer educator; <sup>3</sup>Measured via incentivized collection at the end of the study

#### **4.4 Adverse Events**

Four instances of intimate partner violence related to study participation were reported during the study, two in the delivery arm and two in the coupon arm. Three participants reported physical violence following their partner learning of their HIV self-test use, and one reported physical and sexual violence following the partner learning about her engagement in sex work. One death was reported in the delivery arm, which was not related to study participation. No other adverse events were reported during the study.

#### **4.5 Effect Modification**

Subgroup analyses for past-month HIV testing, HIV self-test use, and HIV status knowledge were conducted by study site (Livingstone, Kapiri, and Chirundu) and history of HIV testing (ever versus never). There was evidence of effect modification by study site at one month for both use of the HIV self-test and past one-month HIV testing. At four months, there was effect modification by study site in past one-month HIV testing. Models of effect modification appeared to show evidence of differential effects of the intervention arms in different study settings, although the study was not powered to detect effect modification. In general, effects were larger in Livingstone and Kapiri and there was no effect of the intervention in Chirundu. For example at four months, the only site where there was a statistically significant effect of the intervention was in the direct delivery arm compared to standard-of-care in Livingstone ( $P=0.04$ ). However, this comparison is not statistically significant after correction for multiple comparisons. There was no evidence of effect modification for any outcome by HIV testing history.

**Table 7.** Intervention efficacy by subgroup of participants, one month

<b>Used HIV Self-Test</b>						
	<b>Standard</b>	<b>Direct</b>	<b>Fixed</b>	<b>Risk Ratio (95% CI)</b>	<b>P-value</b>	<b>P-value for interaction</b>
<b>Site</b>						
Livingstone	n/a	146 (98.0%)	121 (85.2%)	1.15 (1.03 to 1.29)	0.02	0.001
Kapiri	n/a	65 (94.2%)	50 (72.5%)	1.30 (1.00 to 1.69)	0.05	
Chirundu	n/a	73 (100%)	75 (100%)	n/a	n/a	
<b>HIV Testing</b>						
Ever	n/a	219 (99.1%)	213 (87.3%)	1.13 (1.06 to 1.21)	<0.001	0.70
Never	n/a	64 (92.8%)	32 (78.1%)	1.19 (0.90 to 1.58)	0.21	
<b>Tested in Past One Month</b>						
<b>Site</b>						
Livingstone	133 (93.7%)	142 (94.0%)	125 (85.6%)	D: 1.00 (0.92 to 1.10) F: 0.91 (0.81 to 1.03)	0.93 0.13	<0.001
Kapiri	55 (69.6%)	65 (91.6%)	46 (64.8%)	D: 1.31 (0.99 to 1.75) F: 0.93 (0.62 to 1.39)	0.06 0.72	
Chirundu	74 (98.7%)	73 (100%)	77 (100%)	D: 1.01 (0.99 to 1.04) F: 1.01 (0.99 to 1.04)	0.30 0.30	
<b>HIV Testing</b>						
Ever	190 (88.0%)	212 (95.9%)	216 (86.4%)	D: 1.07 (0.99 to 1.17) F: 0.97 (0.88 to 1.07)	0.11 0.54	0.40
Never	69 (92.0%)	67 (91.8%)	21 (72.1%)	D: 1.04 (0.92 to 1.17) F: 0.81 (0.61 to 1.07)	0.56 0.14	

**Table 8.** Intervention efficacy by subgroup of participants, four months

Used HIV Self-Test						
	Standard	Direct	Fixed	Risk Ratio (95% CI)	P-value	P-value for interaction
<b>Site</b>						
Livingstone	n/a	142 (93.4%)	134 (88.7%)	1.05 (0.95 to 1.16)	0.31	0.62
Kapiri	n/a	57 (86.4%)	62 (88.6%)	0.98 (0.80 to 1.18)	0.80	
Chirundu	n/a	66 (85.7%)	70 (90.9%)	0.94 (0.80 to 1.11)	0.49	
<b>HIV Testing</b>						
Ever	n/a	200 (90.5%)	229 (90.2%)	1.02 (0.85 to 1.23)	0.82	0.84
Never	n/a	64 (87.7%)	37 (86.1%)	1.00 (0.93 to 1.09)	0.95	
Tested in Past One Month						
<b>Site</b>						
Livingstone	116 (81.1%)	142 (93.4%)	132 (87.4%)	D: 1.15 (1.01 to 1.32) F: 1.08 (0.93 to 1.26)	0.04 0.34	0.0004
Kapiri	58 (69.1%)	52 (78.8%)	56 (76.7%)	D: 1.14 (0.90 to 1.45) F: 1.11 (0.86 to 1.46)	0.29 0.42	
Chirundu	52 (70.3%)	54 (70.1%)	53 (68.0%)	D: 1.00 (0.66 to 1.52) F: 0.97 (0.63 to 1.47)	0.99 0.88	
<b>HIV Testing</b>						
Ever	161 (70.9%)	186 (84.2%)	205 (80.1%)	D: 1.19 (1.01 to 1.40) F: 1.13 (0.96 to 1.34)	0.04 0.14	0.12
Never	60 (87.0%)	61 (83.6%)	36 (80.0%)	D: 0.94 (0.84 to 1.08) F: 0.89 (0.75 to 1.06)	0.41 0.20	
Correct HIV Status						
<b>Site</b>						
Livingstone	111 (87.4%)	135 (93.1%)	113 (91.1%)	D: 1.07 (0.99 to 1.15) F: 1.04 (0.96 to 1.14)	0.11 0.35	0.18
Kapiri	31 (91.2%)	25 (71.4%)	28 (90.3%)	D: 0.78 (0.64 to 0.96) F: 0.99 (0.88 to 1.12)	0.02 0.88	
Chirundu	50 (83.3%)	62 (93.9%)	53 (88.3%)	D: 1.12 (0.96 to 1.32) F: 1.06 (0.90 to 1.25)	0.14 0.49	
<b>HIV Testing</b>						
Ever	142 (87.1%)	168 (90.3%)	165 (91.7%)	D: 1.03 (0.90 to 1.18) F: 0.94 (0.79 to 1.12)	0.66 0.51	0.56
Never	49 (87.5%)	53 (89.8%)	28 (82.4%)	D: 1.03 (0.97 to 1.11) F: 1.05 (0.98 to 1.12)	0.34 0.15	

## 4.6 Qualitative Results

Individual in-depth interviews and focus groups were conducted with study participants and peer educators, respectively, to help provide context for quantitative findings of the primary outcomes. In both in depth interviews and focus group discussions, barriers to HIV testing were related to stigma associated with going to HIV testing facilities and self-stigma related to HIV.

<b>Barriers to HIV testing</b>
<i>"I get afraid because am scared to be tested for HIV because I don't know if am being HIV negative or HIV positive. Because I have slept with a lot of man."</i> – Individual interview, 24-year-old participant
<i>"Others do have self-stigma, because she knows that she's a sex worker she says I can't go there, when I go there I will just test positive."</i> – Focus group discussion, peer educator
<i>"Others also fail to accept the results. Somebody decides to go and test but she is not sure or ready. It makes them to start imagining what could happen when tested positive. Before you have an HIV test, you need to be ready to accept the result."</i> – Focus group discussion, peer educator
<i>"It is difficult to test because some think if I get tested this same person testing me, will tell others "that's the one I tested she is sick of HIV."</i> – Focus group discussion, peer educator

Facilitators of HIV testing included pregnancy and knowing that they had increased risk related to HIV acquisition. Participants also discussed wanting to protect their male partners as a motivation for HIV testing.

<b>Facilitators of HIV testing</b>
<i>"We protect the men we have sex with not to contract HIV, that's why we often go for HIV testing."</i> - Individual interview, 19-year-old participant
<i>"In my view, it is not common among sex workers to test for HIV. Because just as my sister mention earlier that sex workers know the kind of work they are involved into, it's not common for them to test. Unless she is pregnant or she gets sick and goes to the hospital, they will be able to test her for HIV, and then she will know her HIV status."</i> – Focus group discussion, peer educator
<i>"She's a sex worker, she knows the kind of job she's doing. it's important to go for a test so that each person knows their status."</i> – Focus group discussion, peer educator

HIV self-testing was described by both peer educators and participants as a means to reduce stigma associated with visiting the clinic for HIV testing. This provided substantial motivation for participants to be interested in HIV self-testing.

<b>Motivations for HIV Self-Testing</b>
<p><i>“Yes, the main reason is as I explained, most of them are shy of going to the clinic for testing, therefore, this method of testing yourself is much better where you test yourself and you know the results for yourself.”</i> – Individual interview, 20-year-old participant</p>
<p><i>“I would know my HIV status by myself and I can even go to the hospital for medications.”</i> – Individual interview, 19-year-old participant</p>
<p><i>“Interviewer: Why is it good when testing by yourself? Participant: It is good because of the fact that it’s different from the ordinary testing. Interviewer: What else do you think about HIV/AIDS self testing? Participant: HIV self testing is nice like I said earlier because no one will see you.”</i> - Individual interview, 31-year-old participant</p>
<p><i>“Interviewer: How do you think HIV self-testing will be received by other sex workers in Zambia? Respondent: Yes it would be received well because sex workers are afraid of going for VCT so they test themselves at their own time then its better. And then if there is need to go to confirm at the clinic, then they go confirm.”</i> - Individual interview, 29-year-old participant</p>
<p><i>“Participant 1: I also think they can be interested because they will be the only one to know their HIV status whether positive or negative. Therefore, even when it comes to taking good care of herself, she will know best how and what to do when she gets sick or she is well. Participant 2: Just to add on what my sister has said, when a person tests herself and finds out that she is HIV positive, she can be forced to find out where people go when they test positive so as to know how best they can further help you. So she may be helped with a referral note to take with to the clinic and there after she can be going from time to time get medicine as known only to herself. So it can be easy.”</i> - Focus group discussion, peer educator</p>

Some peer educators reported concerns related to counseling following HIV self-testing, although these themes did not emerge in individual interviews.

*“Once you test yourself and find out that the result is positive, who will counsel you. It’s likely that you will have a lot of worries. What I’m thinking is that it could be better some body conducts a test on you and offers you counsel. It is better that way. Because at times you may test and discover you are HIV positive, and because you are alone in the room, you may begin to entertain suicidal thoughts and before you know it, you get poisonous staff and take your life, because there is nobody to counsel you.”*  
- Focus group discussion, peer educator

## 4.7 Cost Effectiveness

The cost of HIV self-testing interventions and standard of care arms at four months are shown in Table 9. The cost per participant in the standard of care arm was \$40.39. In the delivery arm, the cost per participant was \$53.70, and the cost per participant in the coupon arm was \$52.83. A breakdown of costs is in Table 9.

In a pseudopopulation of 1,000 FSWs, 64 additional FSWs tested for HIV with direct provision of the HIV self-test and 41 fewer tested with facility provision at one month. At four months, 90 additional FSW tested for HIV in the delivery arm and 47 additional tested in the facility collection arm. In the delivery arm, 294 additional FSWs tested for HIV twice, and 138 tested twice in the facility arm.

**Table 9.** Incremental cost effectiveness of HIV self-testing at four months

	<b>Delivery</b>	<b>Coupon</b>	<b>Standard</b>
<b>Number tested in population of 1,000</b>			
HIV testing, any (one month)	949	844	885
HIV testing, any (four months)	841	798	751
HIV tested twice	870	714	576
<b>Itemized running costs, USD</b>			
Self-test kits	4,044.80	4,211.2	0
Airtime	53	53	53
Peer educator costs	12,759.75	13,000.50	12,759.75
Hotline	98.24	102.28	99.48
Cumulative costs, USD	16,967.90	17,379.59	12,924.50
Total	53.70	52.83	40.39
Cost/participant			
Cost for population of 1000	53,700	52,830	40,390
<b>Incremental cost-effectiveness, USD</b>			
HIV testing, any (one month)	\$208	(\$303)	Ref
HIV testing, any (four months)	\$148	\$265	Ref
HIV tested twice	\$45	\$90	Ref

## 5. Discussion

Provision of HIV self-tests directly to participants via peer educators and via existing health facilities led to high uptake of HIV self-testing, although there was no difference in HIV testing across study arms. Overall, HIV testing was very common in this study. Although one in five participants reported at baseline that they had never tested for HIV, by four months all but one participant had tested for HIV via some form during the course of the study. HIV self-testing was highly accessed by individuals in the intervention arms, indicating that while its provision may not lead to greater rates of HIV testing, it is acceptable and accessible to participants.

Data from pre-study focus groups with peer educators found that multilevel stigma was an important barrier to HIV testing among FSW in these areas in Zambia.(Chanda et al. 2017) One reason for the lack of difference across study arms may be the availability of the peer educators in all intervention arms. Previous studies of peer educator interventions for FSW have generally shown that peer educators can reduce barriers to accessing healthcare.(Krishnamurthy et al. 2016; Onyango et al. 2016; Hoffman et al. 2013; Geibel et al. 2012; Morisky et al. 2010; Sarafian 2012) Having access to the peer educators may have allowed participants to have greater agency in seeking out any form of HIV testing (self-testing or traditional) by reducing some barriers to testing.

Intimate partner violence at baseline was very high. During the course of the study, there were three instances of intimate partner violence related to HIV self-testing. Intimate partner violence is a major concern with HIV self-testing, particularly among vulnerable populations such as FSW. The results of this study indicate that HIV self-testing is safe, although implementation programs should be aware of the potential for intimate partner violence following HIV self-testing.

Overall, linkage to care and ART initiation were lower in the HIV self-testing arms, but this difference was not statistically significant. The study was not specifically powered to detect a difference in linkage to care and ART initiation, and thus there may be true differences in linkage to care and ART initiation that could have significant implications for treatment as prevention strategies. However, both linkage to care and ART initiation increased substantially over time in all arms. By four months, ART initiation coverage in the standard testing arm approached previously-described estimates of ART coverage among FSW in Zimbabwe(Cowan et al. 2017) and exceeded a previous global estimate of 36% among FSW in low- and middle-income countries.(Mountain et al. 2014) In the HIV self-testing arms, the rapid increase in linkage to care and ART initiation, which approached the standard-of-care arm and exceeded previous global estimates, mitigates some concern related to linkage to care following HIV self-testing.(Bain et al. 2016) Access to a peer educator may have facilitated the high and rapidly increasing percentage of participants who reported linking to care and ART initiation.

Costing results indicate that it would cost approximately \$45 and \$90 for a repeat test for one additional person in the delivery and coupon arm, respectively. These results take the perspective of an NGO with an existing peer educator program, and thus do not represent the costs of programs that do not have established peer educator programs. These cost results may therefore not be generalizable to NGOs that are not already working with peer educators, and costs may be higher in such programs.

There are several limitations to consider when interpreting these results. The majority of outcomes in this study were self-reported, including HIV testing, linkage to care, and ART initiation outcomes. It is possible that participants' responses were influenced by social desirability bias. It is also possible that participants built rapport with research assistants over time, which could have changed social desirability bias over time. If participants were influenced by social desirability bias, this would likely have resulted in an overestimate of reported outcomes.

This study was conducted among FSW in three transit hubs in Zambia, in a population that has had relatively little prior involvement in HIV research. Compared to some settings, there are relatively few FSW-specific services available for participants in this region. This may in part explain the high uptake of any HIV testing: exposure to the peer educators was novel, and thus participants in all arms may have been encouraged to test for HIV. However, the results of this study may not be generalizable to FSW working in different contexts, for example, those working in capital cities where services are generally more widely available.

Overall, the results of this study indicate that HIV self-testing is acceptable, accessible, and safe for FSW in Zambia. Direct provision of an HIV self-test kit yielded the highest coverage of use and testing at one month, but this difference was gone by four months, indicating that over time a delivery model that uses traditional facilities may be effective for implementation of HIV self-testing in this population. This model may also be the most practical, given that it utilizes existing the existing health system.

## **6. Specific findings for policy and practice**

HIV self-testing was accessible and was highly used by participants, but it did not increase HIV testing relative to referral to standard HIV testing services. Although linkage to care and ART initiation were lower in the HIV self-testing arms compared to the standard of care arm, both linkage and ART initiation increased over time. Individuals in the coupon arm were less likely to test for HIV at one month compared to those in the direct delivery arm but this difference was gone by four months, indicating that there may be some short-term barriers to HIV self-testing that reduce over time. This indicates that the delivery model may matter in the short term, but once individuals have more time to adjust to the new technology, delivery of HIV self-testing via existing health systems infrastructure may be sufficient for implementation.

Key findings at each level include:

- *National:* As the government of Zambia considers HIV self-testing policy, our results indicate that HIV self-testing is accessible, acceptable, and safe for FSW in several contexts within Zambia. Only three instances of intimate partner violence related to HIV self-testing were reported, although background intimate partner violence levels were very high. While attention should be paid to the possibility of intimate partner violence, in general HIV self-testing does not appear to increase intimate partner violence.
- *Local:* From a supply chain and delivery perspective, while direct delivery of the HIV self-test removes many barriers from using the test and resulted in greater use in the short-term, provision of the HIV self-test via existing health facilities led to high uptake of the self-test kit over time. Given the complexity of direct delivery of HIV self-testing at scale, working with local health systems that are already in place likely will be sufficient for delivery of HIV self-testing.
- *Project:* Women were highly interested in participating in this study. There were no issues with enrollment, and loss to follow-up was minimal. While we anticipated that loss to follow-up would be a significant issue, over 90% of participants were retained in the study at four months. There were relatively few barriers to implementing the peer educator intervention, and women were eager to work as peer educators. However, the scalability of the peer educator program should be considered as there are costs involved in recruiting, training, and retaining peer educators.

## **Online appendixes**

Note to the readers: These appendixes are available online only. Please note that these have not been copy-edited or formatted.

Online appendix A: Overview of study procedures

[http://3ieimpact.org/media/filer\\_public/2018/06/28/tw2215-zambia-hivst-zest-appendix-a.pdf](http://3ieimpact.org/media/filer_public/2018/06/28/tw2215-zambia-hivst-zest-appendix-a.pdf)

Online appendix B: Baseline questionnaire

[http://3ieimpact.org/media/filer\\_public/2018/06/28/tw2215-zambia-hivst-zest-appendix-b.pdf](http://3ieimpact.org/media/filer_public/2018/06/28/tw2215-zambia-hivst-zest-appendix-b.pdf)

Online appendix C: One-month questionnaire

[http://3ieimpact.org/media/filer\\_public/2018/06/28/tw2215-zambia-hivst-zest-appendix-c.pdf](http://3ieimpact.org/media/filer_public/2018/06/28/tw2215-zambia-hivst-zest-appendix-c.pdf)

Appendix D: Four-month questionnaire

[http://3ieimpact.org/media/filer\\_public/2018/06/28/tw2215-zambia-hivst-zest-appendix-d.pdf](http://3ieimpact.org/media/filer_public/2018/06/28/tw2215-zambia-hivst-zest-appendix-d.pdf)

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