

NIH Public Access

Author Manuscript

J Acquir Immune Defic Syndr. Author manuscript; available in PMC 2014 September 01

Published in final edited form as:

J Acquir Immune Defic Syndr. 2013 September 1; 64(1): e1-e8. doi:10.1097/QAI.0b013e31829b567d.

High HIV testing uptake and linkage to care in a novel program of home_based HIV counseling and testing with facilitated referral in KwaZulu-Natal, South Africa

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Introduction

South Africa has the greatest number of persons living with HIV infection of any nation [1], yet only approximately 50% of adults in South Africa are aware of their HIV serostatus [2]. Antiretroviral therapy (ART) can significantly reduce HIV transmission and infectiousness [3, 4]. However, in order to achieve a population reduction in HIV incidence with ART, very high levels of HIV testing, linkages to HIV care, uptake of ART, and sustained adherence to ART will be needed to significantly reduce HIV infectiousness [5].

New HIV testing strategies will be required to approach the target of universal knowledge of HIV status. Home-based counseling and testing (HBCT) involves the delivery of HIV counseling and testing by lay counselors to adults in their homes. HBCT was pioneered in a district-wide program in rural southwestern Uganda from 2004 through 2007, in which 62% of households were tested with 91% HIV testing uptake [6] with a significant increase in reported disclosure of HIV test results and safer sexual behaviors [7]. HBCT has been successfully implemented in several other localities in the region including Botswana [8], Zambia [9], Kenya [10], Malawi [11, 12] and South Africa [13, 14] demonstrating high testing uptake in diverse sub-Saharan settings and high acceptability. By bringing HIV testing to peoples' homes in resource-limited settings, HBCT reaches previously untested persons who are unaware of their HIV infection [6, 9, 13, 15].

Despite the success of HBCT in achieving high testing uptake, the high drop-out in sub-Saharan African countries at each step of the engagement-in-care cascade is increasingly recognized, with challenges in achieving high uptake of CD4 testing and linkages to ART, sustained adherence, and viral suppression, particularly for those who are asymptomatic with higher CD4 counts [16–18]. While HBCT reaches individuals with higher CD4 counts

^{*}Heidi van Rooyen and Ruanne V. Barnabas contributed equally to the writing of this article <u>Conflicts of Interest</u>

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There are no conflicts of interest.

and asymptomatic disease [19, 20], knowledge of HIV serostatus alone is not sufficient to get sustained engagement into care. In a previous district-wide HBCT study in Uganda that tested 264,966 participants and identified 11,359 (4.3%) HIV-positive individuals, only 11% initiated ART [21]. Late presentation results in lower treatment ART response rates, higher mortality, higher treatment costs, and, by increasing the duration not on ART, also likely contributes to increased HIV transmission rates [17, 20]. Strategies to efficiently link newly-identified HIV-infected persons into care and assess their eligibility for ART are needed.

We conducted an assessment of a novel adaptation of HBCT that included point-of-care CD4 testing and facilitated referrals to HIV care ('HBCT-Plus') in rural KwaZulu-Natal (KZN), to determine whether this model achieved 1) high HIV testing coverage, 2) identified HIV infected persons who are unaware of their HIV serostatus, 3) reduced potential barriers to engagement in HIV care, and 4) reduced HIV infectiousness through high uptake of and adherence to ART.

Methods

Research Setting and Procedures

The study was conducted from March 2011 to March 2012 in the Vulindlela subdistrict of the Umgungundlovu District, KwaZulu-Natal (KZN), South Africa, which is characterized by high unemployment and low per capita income (under USD \$2 per day). HIV prevalence in KZN was 15.3% among 15–24 yr olds and 23.5% among 25 yr olds in the 2008 National HIV Prevalence Survey [2].

The study area was a geographically distinct area of contiguous households within walking distance of a primary health center and an ART care center. After consultation with local leaders, community mobilization activities were conducted to prepare members for the study. Community mobilizers informed households about the study, completed household enumeration, identified eligible resident household members over the age of 18 and assessed optimal delivery times for HBCT. Participants were eligible to participate if they resided in the household, which was defined as spending two nights per week in the household. Known HIV-positive participants were considered eligible for the study.

After obtaining individualized, written informed consent, participants were administered a standardized questionnaire about demographics, sexual behavior, and history of HIV testing using the mobile phone software Mobenzi ResearcherTM (Durban, South Africa). HBCT was then performed, with standardized, risk reduction pre- and post-test counseling messages. Counseling and HIV testing were conducted by lay counselors or enrolled nurse assistants in a separate room in the house or privately outside the house. If a couple participated, they were counseled and tested separately, with facilitated disclosure provided with their consent.

For persons found to be HIV seropositive, an additional questionnaire was administered about sexual behavior, HIV testing and knowledge, HIV clinic visits, ART initiation, opportunistic infection prophylaxis and symptoms suggestive of tuberculosis (TB), sexually transmitted infections (STIs) and advanced HIV. Point-of-care CD4 testing was conducted in the home at the same visit when a positive rapid HIV test was obtained, and results were used to determine whether the person was eligible for ART under South African ART initiation guidelines (CD4 200 count and CD4 350 if pregnant or co-infected with TB). ART initiation guidelines changed to CD4 350 cells/µL in August 2011, and study counseling messages and analysis plans were updated. The importance of accessing treatment was emphasized and the participant was encouraged to visit their local clinic as soon as possible. HIV-infected persons were counseled on the process of clinic screening, treatment initiation and adherence so that they were adequately prepared on arrival at the

clinic. Participants were compensated with a food parcel for their time but did not receive financial incentives or transport compensation to attend the HIV clinic. The date of the participant's HIV test, point-of-care CD4 test result and STI, TB and advanced HIV symptoms were provided in a referral letter to HIV clinics to facilitate referral for ART eligibility assessment.

Follow-up visits of HIV-infected persons were conducted at 1, 3 and 6 months to assess uptake of clinic visits and ART initiation and counsel about HIV care and ART adherence. At follow-up visits, study staff completed standardized questionnaires on mobile phones capturing linkage to and retention in HIV care information. Assessment and uptake of HIV care involved a review of HIV care documentation (e.g., registration card from HIV care clinic) and recording of medications (e.g., HIV care medications and ART). Participants were asked about social harms at every visit. At the baseline and 6 month visit, a plasma sample was obtained for HIV viral load testing.

HIV testing was conducted using blood obtained by finger-stick tested using rapid serologic tests (SD Bio-Line HIV ½ Rapid Test (Standard Diagnostics Inc.) and HIV ½ Gold Screening Test (G-Ocean, according to South African guidelines. All rapid HIV test results were confirmed by collecting a dry blood sample for ELISA testing using the Vironostika Uniform II Plus O (bioMerieux), to provide quality control for the field-based HIV rapid testing. Point-of-care CD4 testing (Alere, PIMATM) was done using a fingerstick specimen. To validate the performance of the point-of-care CD4 testing, a paired venous sample was obtained for flow cytometry (Facs CaliburTM) and for viral load testing. Plasma HIV viral load testing was done using a bDNA assay (NuclisensTM).

Ethical approval was obtained from the University of Washington Human Subjects Division and the Human Sciences Research Council Research Ethics Committee.

Data analysis

Completed surveys were encrypted on the mobile phone and stored in a non-human readable format. The mobile device securely stored and backed up data daily. Data entry was validated by weekly checks on all the data. In addition, the mobile phone software tracked completed surveys and provided a follow-up visit schedule for study staff. Lab data, CD4 count and viral load results were provided by the lab electronically and merged with the questionnaire data.

Summary statistics were used to describe uptake of testing and linkage to care among eligible participants in the enrollment, baseline characteristics and follow-up tables. Medians and interquartile ranges (IQRs) were also calculated for continuous variables (i.e., age and CD4 cell count). CD4 counts measured by flow cytometry (gold standard test) and point-of-care test were compared by Bland-Altman analysis [22]. The cumulative probability and time to clinic visits and ART initiation was analyzed by Kaplan-Meier methods. Linear regression analysis was used to identify predictors of visiting an HIV clinic and ART initiation. The potential predictors considered included socio-demographic variables, CD4 counts, partner characteristics and reported symptoms. Mean viral load at baseline and 6 months were compared with a paired t-test. Proportion with viral load <1,000 copies/mL, condom use and ART use at baseline and 6 months were compared using the McNemar's test [23]. The data were analyzed using Stata/SE software version 10 (StataCorp LP, Texas, USA) and SAS version 9.2.

Results

Enrollment characteristics

Between March 2011 to March 2012, 282 households were enumerated, in which 739 adults resided in the households. Of the 282 households, 76 household heads were ineligible for the study, primarily because they did not sleep in the household at least 2 nights per week, in part due to migratory labor practices. Of the remaining 205 households, 18 households reported more than one household head, 111 (59%) and 76 (41%) households reported a female and male head of the household, respectively. Of the resident adults, 671 (91%) provided informed consent and were tested for HIV, with 51 adults (7%) declining participation, 13 (2%) not present during HBCT visits and 4 (1%) not being able to provide consent (Table 1). The most common reported reason for declining participation was not ready for HIV testing (28%). Overall, 222 (33%) of participants tested were male and 214 (32%) were tested for the first time. Two hundred and one (30%) HIV-infected participants were identified through HBCT, of whom 73 (36%) were newly identified as HIV-infected.

Within these households, 71 couples were enumerated, 58 of which both partners were tested for HIV; 48 couples had concordant HIV status (43 concordant negative and 5 concordant positive), and 10 couples tested serodiscordant for HIV.

Two participants had indeterminate rapid HIV test results; both were known HIV-infected individuals on ART and were confirmed HIV-positive by ELISA on phlebotomy specimens. The remaining rapid HIV test results were confirmed by ELISA on dried blood spots with 100% agreement.

Baseline characteristics of HIV-infected participants

The demographic characteristics of the HIV-infected participants are shown in Table 2. The median age of participants was 34 years (interquartile range (IQR) of 27 to 43 years), of whom 36% were older than 30 years of age and 82% were female. Sixty (30%) reported being employed and 35 (17%) reported cohabiting with their partner. Of the 164 HIV-infected females, the majority (52%) did not know their HIV partner's status, and 22% reported having an HIV-infected or probably HIV-infected partner. Of the 128 participants who reported knowing their HIV-infected status when tested through HBCT, the median time since HIV diagnosis was 33 months (IQR 7 – 60 months). One hundred and eighteen individuals (92% of those who knew they were HIV-positive) reported that a CD4 count blood specimen had been previously drawn, of which only 61 (52%) had received their result. We did not obtain self-reported nadir CD4 counts for participants were on ART at baseline and 4 reported concurrent treatment for TB co-infection. Fifteen (83%) of the 18 HIV-infected persons with CD4 200 cells/ μ L who were eligible for ART by the former South African guidelines were not on ART at the HBCT visit.

Among the 201 HIV-infected participants, the most common reported symptoms were substantial weight loss (N=67; 33%), poor appetite (N=60; 30%) and fever (N=48; 24%). In screening for TB symptoms, 36 participants (18%) reported having 3 symptoms of cough, fever, night sweats and loss of appetite [24]. Fifty eight participants (29%) reported having STI symptoms (i.e, penile or vaginal discharge, genital sores, and/or dysuria).

Agreement between point-of-care and laboratory based CD4 testing

Of the 201 HIV-infected participants, 193 (96%) had a point-of-care CD4 test in addition to confirmatory CD4 testing by flow cytometry (the gold standard test). The median CD4 count at baseline by point-of-care CD4 testing was 435 cells/ μ L (IQR 297 – 591 cells/ μ L)

and by flow cytometry was 423 cells/ μ L (IQR 282 cells/ μ L - 591 cells/ μ L). Among ART naïve participants, 66 (33%) had a CD4 count 350 cells/ μ L. There was high agreement between the point-of-care and flow cytometry CD4 test results; the mean difference between point-of-care and flow cytometry CD4 testing was 16 cells/ μ L (CI: -1 to 32 cells/ μ L) by Bland-Altman analysis (Figure 1).

Linkage to HIV care and uptake of ART

Of the HIV-infected participants, 197 (99%), 199 (100%) and 196 (100%) of completed their month 1, 3 and 6 follow-up visits respectively. Three participants died during the study and 2 withdrew. Participants who reported ever visiting an HIV clinic increased from 116 (57%) at baseline to 196 (96%) at 6 months (Figure 2a; p<0.0001). The cumulative probability of ART initiation by 3 months among those meeting South African guidelines was 86% (Figure 2b).

Overall, 64 participants (32%) reported ART use at baseline and 36 participants initiated ART during the study. Of the 36 who initiated ART, 12 had a baseline CD4 count 200 and 10, 10 and 4 had a CD4 count 201–350, 351–500 and >500 cells/ μ L respectively. Clinical reasons for initiation ART at higher CD4 counts included pregnancy and TB-co-infection. Due to the time to complete clinic staging for ART initiation, 60% of individuals were on ART for less than 3 months when the exit viral load was measured.

Among the 196 participants for whom viral load measures were available at baseline and 6 months, mean HIV viral load decreased by 0.31 log₁₀ copies/mL (p=0.009). Among the participants with CD4 200 cells/µL (N=15) and CD4 350 cells/µL (N=62), mean HIV viral load decreased by 2.46 log₁₀ copies/mL (p=<0.001) and 0.79 log₁₀ copies/mL (p=0.003) respectively (Table 3). Among the 132 participants not on ART at baseline, 36 of whom initiated ART during the study, HIV viral load decreased by 0.49 log₁₀ copies/mL (p=0.009). For the 12 participants eligible for ART (CD4 200 cells/µL) at baseline who were not on ART, 11 initiated ART and mean HIV viral load by 3.23 log₁₀ copies/mL (p=0.009). The percentage of all HIV-positive participants with HIV viral load < 1,000 copies/mL increased from 50% at baseline to 55% at month 6 (p=0.21). For participants with a CD4 count 200 cells/µL, the percentage with viral load <1,000 copies/mL increased from 20% to 80% (p=0.01) and for those with 350 cells/µL, increased from 44% to 63% (p=0.02). Of the 137 participants not on ART at enrollment, 37 (27%) had baseline viral load < 1,000 copies/mL load < 1,000 copies/mL despite reporting that they were not currently on ART.

Because rates of clinic visits and ART initiation among those eligible were very high, regression analysis did not identify predictors for clinic visit (data not shown). In univariate analysis, CD4 count, age and reporting any HIV related symptom were significantly correlated to ART initiation. However, in the final multivariate model, only baseline CD4 count predicted ART initiation.

The mean number of sex partners reported by HIV-infected partners at baseline and six months did not change (mean = 1.1, standard deviation 0.40) but reported condom use at last sex increased significantly, from 44% at baseline to 68% at the 6 month visit (p<0.0001) (Table 3). There was no statistically significant difference in condom use by ART initiation during the study. Of the 58 couples were both partners were tested for HIV, 95% mutually disclosed their status.

There was one reported case of social harm; a participant temporarily lost their income and residence but returned to live at home with support within 3 months.

Discussion

This pilot of HBCT integrated with same day point-of-care CD4 testing and follow-up (HBCT-Plus) in KwaZulu-Natal, South Africa demonstrates very high uptake of HIV testing in a setting with HIV prevalence of 30%. The field performance of the point-of-care CD4 test was excellent in comparison to CD4 testing through flow cytometry on a venous sample. Point-of-care CD4 testing and lay counselor follow-up achieved almost universal linkage to HIV care and ART initiation following South African guidelines. Our findings demonstrate that HBCT can achieve very high levels of knowledge of HIV serostatus, HIV care linkage, and uptake of ART, all of which will be necessary to achieve a population impact of ART as prevention. Notably, six months after HBCT implementation, we observed a significant decrease in mean HIV viral load among the HIV positive persons identified through HBCT-Plus and an increase in the proportion with viral load <1,000 copies/mL among those participants eligible for ART. South African guidelines for ART changed during the six month follow-up period, with 46.8% (22 out of 47 participants with CD4 350 cells/µL at baseline) of HIV-infected persons with CD4 350 initiating ART during the follow-up. Thus, the reduction in viral load and infectiousness we observed is a conservative measure of the program's impact, given the expanding ART guidelines in South Africa and relatively short (six month) follow-up interval.

Previous HBCT projects have shown that HBCT is acceptable, can achieve high coverage and almost universal knowledge of HIV status, and identifies HIV-infected persons previously unaware of their serostatus and at higher CD4 cell counts [6, 8–13, 20, 25–27]. In order to foster linkages to HIV care, our HBCT-Plus program used the same HBCT strategy coupled with point-of-care CD4 testing to facilitate the initial step in determination of ART eligibility, a critical step in the HIV testing and treatment 'cascade' [18, 28]. Study staff conducted a point-of-care CD4 test for HIV-infected persons when they were identified in HBCT, provided same day counseling about their CD4 result and the importance of HIV care, information about HIV care options, and a referral card. Point-of-care CD4 testing avoided the HIV-infected person having to make two clinic visits for phlebotomy followed by another visit in 1–2 week's time for CD4 test results and ART eligibility assessment. We demonstrated that the point-of-care CD4 testing was highly acceptable at the time of learning one was HIV-infected, feasible to be conducted in homes in a rural South African setting, facilitated specific counseling on HIV care and faster determination of ART eligibility, and had excellent agreement with a paired venous sample tested by flow cytometry. This builds on a prior observational study of point-of-care CD4 testing in Mozambique which demonstrated a reduction in loss to pre- treatment follow-up but did not change loss to follow-up between CD4 staging and ART initiation [29].

The high linkages to HIV care observed within 6 months of HBCT was in the context of point-of-care CD4 testing combined with follow-up visits by lay counselors at 1 and 3 months, who provided counseling and assessed HIV clinic attendance and ART initiation. As an objective measure of the prevention impact of HBCT and HIV care linkages with ART initiation based on South African ART guidelines, we compared HIV plasma viral load before and 6 months after HIV testing through the HBCT program. Our finding of decreased mean viral load among the HIV-infected persons identified through HBCT is encouraging since it was achieved in the context of the previous South Africa's new guideline of ART initiation at CD4 350 cells/ μ L began half way through the study, it was encouraging to observe a high proportion with viral load suppression among participants with CD4 350 cells/ μ L. Thus, with potential incomplete viral suppression due to 40% of participants initiating ART between the 3 month visit and the 6 month follow-up visit, when viral load was measured, and with incomplete coverage of ART among those with CD4 350 cells/ μ L

due to changing ART initiation guidelines in South Africa, our findings are likely an underestimate of the potential of HBCT to increase the proportion of persons with viral load <1,000 copies/mL.

Limitations of our study include the modest sample size and short follow-up interval of six months. The linkages to HIV care were facilitated by the clinic location within walking distance of study participants, and it will be important to evaluate this model in more remote areas with greater distances to clinics. A factor that may have influenced the high uptake of linkages to care was that most participants were seen by the same staff member at follow-up visits, which may have increased engagement in care. Lastly, clinic visits and ART initiation were confirmed by examination of the clinic card and ART medication bottles as clinic electronic health records (EHR) were not available. We did not measure ART in plasma of participants who reported not being on ART but had low viral load.

Cost-effectiveness analysis will be conducted of the program component costs for HBCT, point-of-care CD4 testing [30], and lay counselor follow-up relative to HIV care linkage, ART initiation, viral suppression as an objective measure of the public health benefit, and the projected clinical benefits of averted disability and mortality. A recent modeling paper estimated that with 90% annual HIV testing of adults and treatment by South African guidelines (CD4 350 cells/µL) costs of the program would break even within two years due to the savings of HIV cases averted [31]. Further, HBCT could be combined with other mobile testing strategies with demonstrated success at increasing testing uptake among youth and men who are not as readily reached through HBCT [32] and community mobilization and HIV testing campaigns [33]. Mathematical models of HIV in KwaZulu-Natal suggest that HBCT every 4 years with associated behavior change, uptake of ART uptake and medical male circumcision, could have a sustained impact on the epidemic [5]. HBCT could utilize an existing cadre of community health workers in South Africa and many other African countries to deliver integrated health care to communities, which would facilitate implementation of the HBCT strategy [34]. Combining this decentralized model of health care delivery, using point-of-care tests and more fully utilizing the capacity of electronic systems for health system monitoring and communication has the potential to be a powerful approach to increase ART uptake for HIV treatment and prevention.

In summary, HBCT-Plus in rural KwaZulu-Natal achieved almost universal knowledge of HIV status, linkage to HIV care, and ART uptake following South African guidelines, which was achieved through point-of-care CD4 testing and lay counselor follow-up of HIVinfected persons. A significant reduction in plasma HIV levels was observed, which indicates potential public health benefit as well as clinical benefit of this strategy. Further evaluation of this model in diverse African settings should be undertaken to evaluate the impact and cost-effectiveness of HBCT and to inform national HIV treatment and prevention programs.

Acknowledgments

Sources of Funding: The authors acknowledge funding from the National Institutes of Health (NIH) 5 R01 AI083034, 3 R0 AI083034-02S2 and NIH Directors Award RC4 AI092552. RVB acknowledges funding form the Qatar National Research Fund (NPRP 08-068-3-024), NCRR/NIH (KL2 TR000421) and the Centers for AIDS Research (CFAR)/NIH (P30 AI027757).

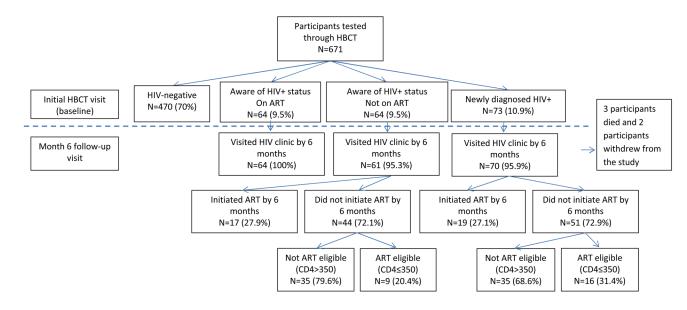
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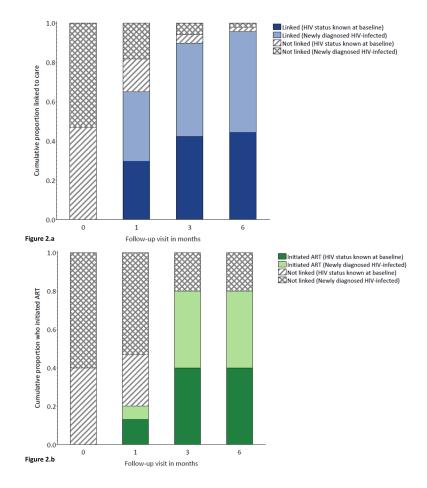
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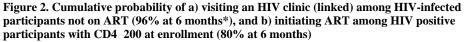
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*Six of the 201 HIV-infected participants identified at initial HBCT visit (baseline) did not visit an HIV clinic by 6 months. Of the 6 participants, 3 died, 2 withdrew from the study and 1 remained in follow-up but did not visit a clinic.

Table 1

Enrollment characteristics of adults approached through home-based counseling and testing (HBCT) in KwaZulu-Natal, South Africa

Enrollment characteristics of all subjects approached	Ν	Percent (%)
Households enrolled	281	
Households reporting one head of household	187	66
Female headed household	111	59
Households with children under 18 years	89	32
Adults living in households	739	
Adults not present at HBCT visit	13	2
Adults who refused HIV testing	51	7
Adults not able to consent	4	1
Adults consented and tested	671	91
Adults tested *(% of consented)	671	100
Adults who received HIV test results (% of tested)	671	100
Male	222	33
Female	449	67
First time tested	214	32
HIV-infected adults	201	30
Male (% of tested males)	37	17
Female (% of tested females)	164	37
HIV-infected pregnant females (% of HIV+ females)	2	1
Newly identified HIV infection (% of positives)	73	36

*Two participants had no HIV test result due to test indeterminate results (both were known HIV+ on ART).

Table 2

Baseline characteristics of HIV-infected participants identified through home-based counseling and testing (HBCT)

		N (%)	Percent (%) or Median (Interquartile range, IQR)
Age		201	34 years (IQR: 27-43 years)
Age group	<=30 years	72	36
	> 30 years	129	64
Gender	Male	37	18
	Female	164	82
Education	Primary or less	58	29
	Secondary or more	143	71
Employed		60	30
Cohabiting		35	17
Sexually active		146	73
Number of current sex partners		146	1 (IQR: 1–1)
Condom use with last sex act	_	82	41
Number of children	1-3 children	93	46
	>3 children	13	7
CD4 count (cells/µl)		201	435 (IQR: 301–591)
CD4 groups	200 cells/µl	18	9
	201-350 cells/µ1	48	24
	351–500 cells/µl	58	29
	>500 cells/µl	77	38
HIV+ adults on ART at baseline HBCT visit (% of positives)		64	32
Partner HIV-infected	Yes*	45	22
	No	46	23
	Don't know	106	52
	Refused	6	3

*The answer "yes" includes 1 participant who responded "I think so".

^A The answer "no" includes 10 participants who answered "I don't think so".

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Change in behavior and viral load from study enrollment to 6 month follow-up visit among HIV-infected persons identified through home-based counseling and testing (HBCT)

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	z	Baseline [^] Median (IQR)	Month 6 Median (IQR)	Change over 6 months	p-value*
Behavior and uptake of care					
Number of sex partners (#2)	196	1.0 (0.0–1.0)	0.0 (1.0–1.0)	-0.08	0.03
	N	Baseline ^ N (%)	Month 6 N (%)	Change over 6 months	p-value *
Condom use during last sexual intercourse	186	81 (44)	127 (68)	25%	<0.001
Clinic visit among HIV+					
All	201	115 (57)	195 (97)	40%	<0.001
Aware of HIV+ status	128	108 (84)	125 (98)	13%	<0.001
Newly identified HIV+	73	7 (10)	70 (96)	86%	<0.001
ART use					
All participants	201	64 (32)	99 (49)	17%	<0.001
Aware of HIV+ status	128	64 (50)	80 (63)	13%	<0.001
ART eligible (CD4 200)	6	3 (33)	9 (100)	67%	***
Newly identified HIV+	73	0 (0)	19 (26)	26%	***
ART eligible (CD4 200)	6	0 (0)	6 (67)	67%	***
HIV viral load		Mear	Mean HIV viral load (log ₁₀ copies/mL)	ies/mL)	
	N	Baseline ^A viral load	Month 6 viral load	Change over 6 months	\mathbf{p} -value *
+AIH IIV	196	2.92	2.64	-0.28	0.02
HIV+ not on ART at baseline	132	3.74	3.30	-0.44	0.007
HIV+ on ART at baseline	64	1.24	1.30	0.06	0.624
CD4 200 (excluding HIV+ on ART at baseline)	12	4.93	1.70	-3.23	<0.001
CD4 201- 350 (excluding HIV+ on ART at baseline)	31	3.77	3.40	-0.36	0.29
Change in percent with viral suppression (<1,000 c/mL) from baseline to 6 months (%)) from	baseline to 6 months (%)			
+AIH IIV	196	50%	55%	5%	0.21
HIV+ with CD4 200	15	20%	80%	60%	0.01
HIV+ with CD4 201- 350	47	51%	57%	6%	0.55

 λ Baseline visit is the first HBCT vist at study enrollment.

 $_{\star}^{*}$ McNemar's test was used to calculate p-value for binary outcome and paired t-test was used to calculate p-value for continuous outcome.

 ** Three participants died and 2 withdrew from the study and were excluded from the follow-up analysis.

*** Cannot compute McNemar's p-value due to 0 cell counts (either none on ART at enrollment or none who had not initiated by 6 months).