Sustained Sexual Behavior Change After Acute HIV Diagnosis in Malawi

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Background: Identification of acute HIV infection (AHI) allows for important opportunities for HIV prevention through behavior change and biomedical intervention. Here, we evaluate changes in sexual risk behaviors among persons with AHI enrolled in a combined behavioral and biomedical intervention designed to reduce onward transmission of HIV.

Methods: Participants were randomized to standard HIV counseling, a multisession behavioral intervention, or a multisession behavioral intervention plus antiretrovirals. Sexual behaviors were assessed periodically over 1 year.

Results: Four weeks after diagnosis, the predicted probability of reporting multiple sexual partners decreased from 24% to 9%, and the probability of reporting unprotected sex decreased from 71% to 27%. These declines in sexual risk behaviors were sustained over follow-up irrespective of study arm.

Conclusions: Diagnosis of AHI alone may be sufficient to achieve immediate and sustained behavior change during this highly infectious period.

Identification of acute HIV infection (AHI) allows for important opportunities for HIV prevention. Acute HIV infection, comprising the first few weeks of HIV infection before antibody development,[1] is characterized by increased infectiousness due to high viral burden and per-virion infectivity.[2–4] Immediate linkage to care and initiation of antiretrovirals (ARVs) during AHI may improve immune function,[5–8] limit the size of the HIV reservoir,[9–11] and reduce transmission risk through viral suppression.[7,12,13] Diagnosis during AHI can also lead to important transmission prevention benefits through infection awareness and subsequent behavior change.[14–16] Although AHI accounts for a relative minority (2%–10%) of new diagnoses in settings where AHI testing has been performed,[17] interventions during this period of heightened infectiousness can have a disproportionate impact on population-level HIV spread.[18]

Interventions aimed at rapidly decreasing risky sexual behaviors during the brief acute window are especially critical among persons with AHI because even immediate ARV initiation does not instantaneously reduce viral load.[19–21] In Malawi, where an estimated 10% of the adult population is HIV infected and 38% of all new heterosexually acquired infections may be due to contact with persons with AHI,[18] diagnosis during the acute window in combination with risk reduction education or counseling is associated with a rapid reduction in self-reported transmission risk behaviors.[22,23] However, the extent to which behavior change is sustained beyond the immediate post-diagnosis phase is unknown.

In this investigation, we evaluate both the immediate and sustained changes in sexual risk behaviors among persons with AHI enrolled in a combined behavioral and biomedical intervention designed to reduce onward transmission of HIV over a 1-year period.

METHODS

Study Design and Index Recruitment

This investigation was part of a trial that evaluated the feasibility and acceptability of a behavioral intervention (BI) and short-term ARV use among persons diagnosed as having AHI in Lilongwe, Malawi (ClinicalTrials.gov No. NCT01450189).[24] Recruitment was from 2 HIV testing and counseling centers and 2 sexually transmitted infections clinics. Primary study participants (index participants) were persons 18 years or older with AHI enrolled between June 2012 and January 2014.

Routine HIV testing using standard serial rapid testing was offered with Alere Determine HIV-1/2 (Alere, Inc, Waltham, MA) and Uni-Gold Recombigen HIV-1/2 (Trinity Biotech, Bray, Ireland) rapid antibody tests, as per Malawi national guidelines. Persons who tested positive for established (antibody-positive) HIV infection were referred to a nearby facility for routine HIV care. Persons who tested HIV-antibody (Ab) negative or Ab discordant were offered screening for AHI using a pooled HIV RNA polymerase chain reaction algorithm.[25] Acute HIV infection was defined as Ab-negative or Ab-discordant rapid tests with detectable HIV RNA. Persons found to have AHI were traced and asked to return to the clinic, where they were counseled on their results and provided additional information on AHI. At the time of AHI screening, a short questionnaire was administered to assess eligibility. Full eligibility criteria and detailed screening procedures have been published elsewhere.[24] Irrespective of eligibility status or the decision to enroll in the study, all persons with AHI were referred for routine HIV care.

Eligible patients with AHI were offered enrollment and randomized in a 1:2:2 ratio (blocked randomization with block sizes of five, stratified by sex) to 1 of 3 groups: (1) standard counseling

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Acknowledgments: The authors extend their gratitude to those who participated in this study, as well as the staff at the Lighthouse Trust and UNC Project Malawi who assisted with study activities.

Conflicts of Interest and Sources of Funding: This work was funded by the National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases (R01 AI083059) and supported by the UNC Center for AIDS Research, an NIH-funded program (P30 AI50410). S.E.R. was supported by the NIH/National Institute of Mental Health (F30 MH098731) and NIH/National Institute of General Medical Sciences (T32 GM008719). D.K.P. was supported by the NIH/National Institute of Allergy and Infectious Diseases (T32 AI070114). No conflicts of interest were declared.

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Received for publication March 9, 2018, and accepted May 15, 2018.
DOI: 10.1097/OLQ.0000000000000873

(SC), (2) a multisession BI, and (3) the same multisession BI plus a short-course of ARVs (BIA). Participants randomized to the SC group received a standard posttest counseling session that encouraged behaviors to reduce transmission risk and were provided information on AHI.

In addition to SC, participants randomized to the BI and BIA arms received 4 motivational interviewing counseling sessions and 1 "booster" session over an 8-week period. The patient-centered sessions were based on the IMB Model, which has been shown to reduce sexual risk behaviors among people living with HIV.[22,26] Each session was designed to provide participants with the tools needed to abstain or practice protected sex during the brief AHI period, while also planning for long-term behavioral risk reduction. Participants randomized to the BIA group were also provided a 12-week course of ARVs (raltegravir [400 mg orally twice a day] and emtricitabine/tenofovir [FTC/TDF; 200/300 mg orally once a day]) and completed supplementary counseling on potential adverse effects and the importance of ARV adherence.

This trial was approved by the Biomedical Institutional Review Board of the University of North Carolina at Chapel Hill and the National Health Sciences Research Committee of Malawi. Written informed consent was obtained from all participants.

Data Collection and Follow-Up

Study enrollment occurred after participants were traced and notified of their acute status, approximately 1 week after screening. Baseline questionnaires were completed at study enrollment in English or Chichewa using audio computer-assisted self-interview software. Participants in all study arms also completed questionnaires at weeks 1, 2, 4, 8, 12, 19, 26, 39, and 52. Questionnaires collected information on demographics (baseline), sexual risk behaviors in the last month (baseline and week 4 onward), and knowledge of acute and established HIV infection (baseline). Detailed information on demographics and sexual risk behaviors for up to 5 sexual partners was also collected at each study visit.

Outcomes

The primary aim of this analysis was to describe changes in sexual risk behaviors after AHI diagnosis across all index participants, with a secondary focus on assessing changes by intervention arm. Specifically, we assessed 2 dichotomous variables at each visit: (1) vaginal sex with multiple (>1) partners in the preceding month (yes/no) and (2) any unprotected vaginal sex in the preceding month (yes/no). We also descriptively assessed the proportion of participants reporting sex with steady versus casual partners in the preceding month at each time point.

Statistical Analyses

In baseline analyses, characteristics for enrolled participants were evaluated overall and by study arm. In longitudinal analyses, we used generalized estimating equations with a logistic link to assess whether there had been an overall decline after baseline in the proportions of participants reporting (1) multiple sexual partners and (2) any unprotected sex. We fit a model for each outcome, specifying time since diagnosis as the only explanatory variable. Robust variance estimators with an exchangeable correlation matrix were used to account for within-subject correlation.[27] We calculated predicted probabilities and 95% confidence intervals (CIs) for each outcome at weeks 4, 8, 12, 19, 26, 39, and 52. In secondary analyses, we included intervention status as an additional explanatory variable in both models. Because of sparse data, we combined persons in the BI and BIA arms to compare outcomes between persons who did and did not receive the BI (i.e., BI or BIA intervention vs. SC). No adjustment variables were included given the study's randomized design, and intent-to-treat analyses were used to assess both outcomes.

Additional analyses were also conducted to assess trends over time in the proportions reporting steady versus casual partners, overall and by intervention status. All statistical analyses were performed using SAS statistical software (version 9.4; Cary, NC).

RESULTS

Baseline Characteristics

Among 9171 persons testing Ab negative or Ab discordant for HIV infection between June 2012 and January 2014, 59 (0.6%) were diagnosed as having AHI.[24] Of the 59 persons with AHI, 46 (78%) were enrolled in the study and randomized to 1 of the 3 study arms (9 SC, 18 BI, 19 BIA). The median time between initial AHI screening and study enrollment was 7 days (interquartile range [IQR], 6–11 days; Table 1).

The average participant was 25 years of age (IQR, 22–32 years). Consistent with the proportion of men and women identified with AHI, most participants were male (28/46; 61%). More than two thirds were married or living with a steady partner. Nearly all participants in the SC arm (8/9; 89%) were married or living with a steady partner compared with 12 (67%) of 18 in the BI arm and 13 (68%) of 19 in the BIA arm.

Behavioral Intervention

Most (30/37; 81%) participants in the BI and BIA arms completed all 4 behavioral sessions, and median time to session completion (excluding the booster session) was 16 days (IQR, 14–18 days). Loss to follow-up was observed across all arms. At week 26, 80% of participants were still retained in the study (SC, 89%; BI, 78%; BIA, 79%). By week 52, 59% were retained (SC, 67%; BI, 56%; BIA, 58%).

Multiple Sexual Partners

At baseline, approximately a quarter of all participants (12/45; 27%) reported multiple partners in the previous month (Table 1). The proportion of participants reporting multiple partners in the last month was highest in the BI arm (6/17; 35%) and lowest in the SC arm (1/9; 11%). Compared with those not reporting multiple partners in the last month, a greater proportion of participants reporting multiple partners in the last month were male (9/12 [75%] vs. 19/33 [58%]) and married or living with a partner (10/12 [83%] vs. 22/33 [67%]).

On the basis of our observation of an immediate, substantial decrease in the proportion of participants reporting multiple partners in the last month, followed by a comparatively slower decline thereafter, we included a linear spline term beginning at week 4 to model changes over the study period (Fig. 1A). At baseline, the predicted probability of reporting multiple partners was 24% (95% CI, 15%–38%). At week 4, the predicted probability decreased to 9% (95% CI, 5%–17%). By the end of follow-up, the predicted probability of reporting multiple partners was 3% (95% CI, 1%–8%). In secondary analysis, a dichotomized term for intervention status (intervention vs. SC) was not associated with reporting of multiple partnerships in the last month; however, precision was low.

Unprotected Sex

At baseline, nearly all participants (32/45; 71%) reported one or more acts of unprotected vaginal sex in the past month

TABLE 1. Baseline Demographics and Sexual Risk Behaviors Among Patients with AHI (N = 46)

Characteristic	Overall (N = 46), Median (IQR)	SC (n = 9), Median (IQR)	BI (n = 18), Median (IQR)	BIA (n = 19), Median (IQR)
Age, years	25.0 (22–32)	32.0 (26–38)	24.5 (23–29)	25.0 (22–30)
Time between screening and receipt of results, days	7.0 (6–11)	7.0 (5–7)	7.0 (6–11)	9.0 (7–12)
No. sexual acts, last month	5.5 (1–12)	4.0 (1–7)	6.0 (2–15)	6.0 (1–14)
	n (%)	n (%)	n (%)	n (%)
Sex				
Male	28 (60.9)	5 (55.6)	11 (61.1)	12 (63.2)
Female	18 (39.1)	4 (44.4)	7 (38.9)	7 (36.8)
Married or living with a steady partner				
Yes	33 (71.7)	8 (88.9)	12 (66.7)	13 (68.4)
No	13 (28.3)	1 (11.1)	6 (33.3)	6 (31.6)
Education				
≤Primary completed	26 (56.5)	6 (66.7)	8 (44.4)	12 (63.1)
Some secondary	12 (26.1)	1 (11.1)	5 (27.8)	6 (31.6)
≥Secondary completed	8 (17.4)	2 (22.2)	5 (27.8)	1 (5.3)
Employment status				
Employed	30 (65.2)	7 (77.8)	11 (61.1)	12 (63.2)
Not employed	16 (34.8)	2 (22.2)	7 (38.9)	7 (36.8)
Total partners, last 3 months*				
≤1	25 (55.6)	5 (55.6)	7 (41.2)	13 (68.4)
>1	20 (44.4)	4 (44.4)	10 (58.8)	6 (31.6)
Total partners, last month*				
≤1	33 (73.3)	8 (88.9)	11 (64.7)	14 (73.7)
>1	12 (26.7)	1 (11.1)	6 (35.3)	5 (26.3)
Total partners since screening				
≤1	41 (89.1)	9 (100)	15 (83.3)	17 (89.5)
>1	5 (10.9)	0 (0)	3 (16.7)	2 (10.5)
Unprotected sex, last month*				
No	13 (28.9)	2 (22.2)	5 (29.4)	6 (31.6)
Yes	32 (71.1)	7 (77.8)	12 (70.6)	13 (68.4)
Unprotected sex since screening*				
No	33 (73.3)	5 (55.6)	16 (48.5)	12 (63.2)
Yes	12 (26.7)	4 (44.4)	1 (5.9)	7 (36.8)

AHI indicates acute HIV infection; SC, standard counseling; BI, behavioral intervention; BIA, behavioral intervention plus treatment; IQR, interquartile range.

*n = 45; 1 index patient randomized to the BI arm missing sexual behaviors.

(Table 1), with similar proportions across intervention arms. Compared with participants who did not report unprotected sex, a greater proportion of participants reporting unprotected sex were male (21/32 [66%] vs. 7/13 [54%]) and married or living with a spouse or partner (26/32 [71%] vs. 7/13 [54%]).

As with our assessment of multiple partners, we observed an immediate decrease in the proportion of participants reporting unprotected sex in the last month, followed by a much slower decline. We similarly included a linear spline term beginning at week 4 to model changes in unprotected sex over the study period (Fig. 1B). We observed a sharp decrease in unprotected sex at week 4 (predicted probability, 27% [95% CI, 19%–39%]) relative to baseline (predicted probability, 71% [95% CI, 57%–83%]). After week 4, the predicted probability of unprotected sex remained relatively constant; at the end of follow-up, the predicted probability of unprotected sex in the previous month was 20% (95% CI, 10%–36%). In secondary analysis, a dichotomized term for intervention status (intervention vs. SC) was not associated with reporting of unprotected sex in the last month. Precision was low.

Sex with Steady and Casual Partners

At baseline, more than half of participants (23/45; 51%) reported sex with one or more steady partners (e.g., spouse or live-in boyfriend/girlfriend) in the previous month, and 20 (44%) of 45 reported sex with one or more casual partners (e.g., non–live-in boyfriend/girlfriend or other partner outside an established relationship; Table 2). Results were similarly by intervention arm.

Although the proportion of participants reporting sex with a steady partner remained relatively constant over follow-up, we observed a consistent decrease in the proportion of participants reporting sex with a casual partner. By week 4, the proportion reporting sex with a casual partner decreased to 22% (from 44% at baseline). By the end of follow-up, this proportion had decreased to just 4%. When assessed by intervention status, this trend persisted in both the combined intervention arm and the SC arm.

DISCUSSION

We conducted a longitudinal study of 46 persons who had been diagnosed as having AHI in Lilongwe, Malawi. This study's prospective design, which included frequent and detailed assessments of sexual risk behaviors over 1 year, was uniquely suited to measure behavior change after diagnosis. We found a decrease in sexual risk behaviors after AHI diagnosis that was sustained for the remainder of the 1-year follow-up period.

Immediately decreasing sexual risk behavior in persons with AHI is critical given the high probability of transmission during this period. Even among persons who are linked to care and treated during the acute window, transmission efficiency via unprotected sex remains high until viral suppression is achieved.[17,19,20] In

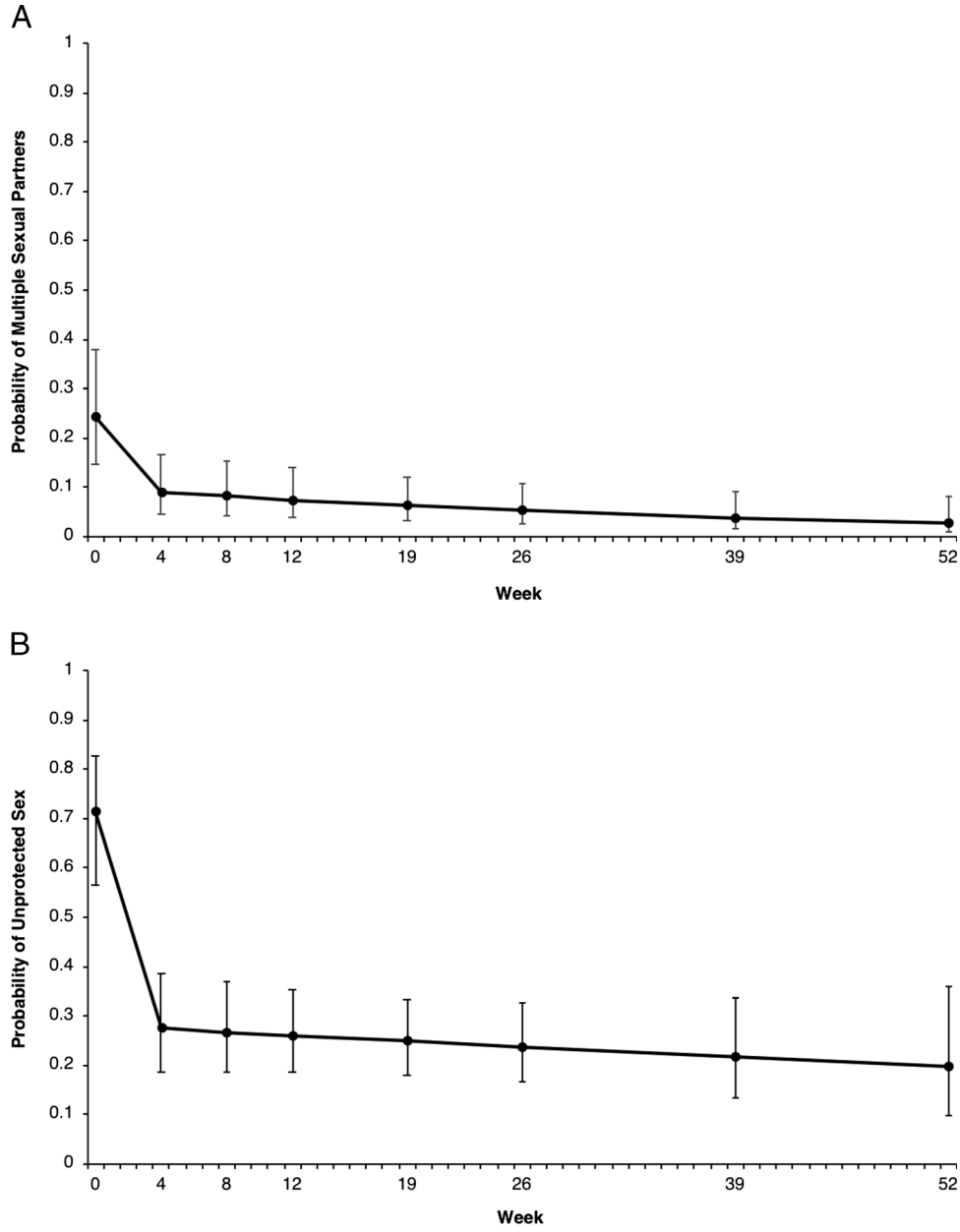

Figure 1. A, Unadjusted predicted probability of multiple sexual partners (95% CIs). B, Unadjusted predicted probability of any unprotected sex (95% CIs). Predicted probabilities were calculated using generalized estimating equation modeling. Panel A depicts predicted probability of reporting multiple (>1) sex partners over the 52-week study period. There was a decrease in the predicted probability of reporting multiple sex partners by week 4 (ranging from 24% at baseline to 9% at week 4), which was sustained over time. Panel B depicts the predicted probability of having unprotected over the 52-week study period. By week 4, the predicted probability of unprotected sex steeply declined (from 71% at baseline to 27% at week 4). This decrease was sustained over time. Precision was limited.

our study, participants reduced their probability of having multiple partners and decreased their overall probability of unprotected sex within 4 weeks of learning their acute status.

Among persons with multiple partners, concurrent partnerships and consecutive partnerships separated by short temporal gaps are thought to facilitate the spread of HIV and STIs.[28] A formal assessment of concurrency was beyond the scope of this analysis. However, most participants in our study were either married or living with a partner, and almost half reported sex with multiple partners in the months preceding AHI diagnosis. The probability of reporting multiple partners in the past month dropped from 24% at baseline to just 3% at 52 weeks, and the proportion of participants reporting sex with casual partners sharply declined. However, we observed a high proportion of loss to follow-up at 52 weeks, and it may be possible that participants who were lost to follow-up were more likely to report sex with multiple partners or casual partners than those that were retained.

Participants in our study may have chosen to limit sexual encounters with casual partners after learning their HIV status, which may have contributed to the overall decline multiple partnerships. A decline in casual sexual partners and overall partner number among persons with AHI has previously been reported

TABLE 2. Steady* and Casual† Sex Partners in the Previous Month at Baseline, Week 4, Week 12, Week 26, Week 39, and Week 52 Among Patients With AHI (N = 46)‡

Characteristic	Baseline (N = 46), n (%)	Week 4 (n = 42), n (%)	Week 12 (n = 37), n (%)	Week 26 (n = 37), n (%)	Week 39 (n = 33), n (%)	Week 52 (n = 27), n (%)
Steady partners						
0	22 (48.9)	21 (50.0)	18 (48.7)	22 (59.5)	18 (54.6)	11 (44.0)
≥1	23 (51.1)	21 (50.0)	19 (51.4)	15 (40.5)	15 (45.5)	14 (56.0)
Casual partners						
0	25 (55.6)	32 (78.1)	31 (83.8)	31 (83.8)	26 (78.8)	24 (96.0)
≥1	20 (44.4)	9 (22.0)	6 (16.2)	6 (16.2)	7 (21.2)	1 (4.0)

AHI indicates acute HIV infection.

*A steady partner was defined as a spouse or live-in boyfriend/girlfriend.

†A casual partner was defined as a non–live-in boyfriend/girlfriend, sex worker, or other partner outside an established relationship.

‡Results may not add to column totals because of missing data.

in Malawi; however, the observation period for these prior changes did not extend past 6 months.[22] We have demonstrated that, coupled with standard risk reduction counseling, AHI diagnosis may be sufficient to initiate a reduction in sexual partners that is sustained over a 1-year period.

A sustained reduction in sexual partners is critical for HIV prevention, particularly among HIV-infected persons who engage in unprotected sex. In our study, despite a sharp decrease in unprotected sex that was sustained throughout follow-up, an estimated 20% of participants were still engaging in unprotected sex at the end of 1 year. Unfortunately, we did not have information to assess the HIV status of the partners with whom unprotected sex was occurring, so it is difficult to assess the transmission risk associated with these unprotected acts. However, the high HIV prevalence among referred partners (79%; unpublished data) suggests that participants who continually engaged in unprotected sex may well have done so with partners who were HIV positive.

Among persons with AHI, engaging in sexual activity with a long-term or committed partner (vs. a casual partner) is thought to reduce one's ability to negotiate condom use.[23] To maximize treatment as prevention, risk reduction strategies that advocate abstinence or consistent condom use with all partners should be strongly emphasized during the acute window, even in the presence of ARVs. For persons who continue to engage in unprotected sex, both during the acute window and after, immediate initiation of ARVs (potentially coupled with preexposure prophylaxis for HIV-negative partners) should be made a top priority for prevention.

Questionnaires were administered using audio computer-assisted self-interview software to increase efficiency during data collection and to minimize social desirability bias. To minimize out-of-range responses and missing data resulting from user error, robustness flags and checks were used during data collection and data cleaning to improve internal consistency. Still, some participants may have misreported their sexual behaviors.

Our study's design and the nature of our assessment tool precluded us from assessing specifically when participants initiated a relative decrease in their sexual risk behaviors in the 4 weeks after screening. Some participants may have decreased their sexual risk behaviors immediately after consenting to AHI screening, either to prevent potential transmission to their partners or for health-related reasons.

A secondary objective of this analysis was to determine if changes in sexual risk behaviors were associated with motivational interviewing (plus or minus treatment with ARVs) relative to standard risk reduction counseling. We noted few differences in sexual risk behaviors by intervention status, suggesting that diagnosis and SC can have powerful effects. However, the precision of our intervention-specific estimates was limited by the small size of—and substantial loss to follow-up in—the pilot study, and our findings should be interpreted with some caution. Furthermore, because all participants in this study received standard risk reduction counseling, we were unable to assess whether AHI diagnosis alone would have similarly decreased sexual risk behaviors.

Differences in demographics by study arm were also evident despite randomization, likely resulting from the small size of the pilot study population. To detect meaningful differences between intervention arms, a larger study would be necessary. Despite these limitations, our findings clearly suggest that early diagnosis, coupled with standard risk reduction counseling, may be sufficient to decrease sexual risk behaviors during and after the acute period.

Although identification of AHI remains challenging,[1,29] the transmission implications of AHI detection are substantial, and both newer technologies and targeted screening approaches can increase efficiency.[24,29,30] Our previous findings[24] suggest that AHI screening is both acceptable and feasible when incorporated into routine testing procedures. As Malawi and other countries with high HIV prevalence scale up initiation of ARVs irrespective of CD4 count, treatment as prevention will be most effective if persons with AHI are routinely identified and provided risk reduction strategies.[18] Early diagnosis and intervention during AHI can provide several years' worth of transmission prevention benefits beyond what can be achieved with diagnosis during established infection, suggesting that expanded efforts to implement AHI screening in at-risk populations should be a high priority.

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