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Complete List of Authors:	NAKIGANDA, LYDIA; Lund University, Social medicine and Global Health Division Asamoah, Benedict ; Lund University, Department of Clinical Sciences, Malmö, Division of Social Medicine and Global Health Kagaayi, Joseph; Rakai Health Sciences Program Nalugoda, Fred; Rakai Health Sciences Program Serwadda, David; Makerere University School of Public Health, Kampala Uganda Sewankambo, Nelson; Makerere University College of Health Sciences, Gray, Ronald; John Hopkins University, Bloomberg, School of Public Health, USA. Ndyanabo, Anthony; Rakai Health Sciences Program Nakigozi, Gertrude; Rakai Health Sciences Program
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Author:

1. *Lydia Jacenta Nakiganda[1] lydianakiganda85@gmail.com
2. *Benedict Oppong Asamoah[1] benedict_oppong.asamoah@med.lu.se
3. Joseph Kagaayi[2] jkagayi@rhsp.org
4. Fred Nalugoda[2] fnalugoda@rhsp.org
5. David Serwadda[3] dserwada@infocom.co.ug
6. Nelson Sewakambo[4] sewankam@infocom.co.ug
7. Ronald Gray[5] rgray4@jhu.edu
8. Anthony Ndyanabo[2] andyanabo@rhsp.org
9. *Gertrude Nakigozi[2] ftrudie@rhsp.org

Corresponding author:

Lydia Jacenta Nakiganda
Spangatan 37B, lgh 1103, 21153, Malmo, Sweden
lydianakiganda85@gmail.com

Institutions and departments:

[1]Social Medicine and Global Health, Department of Clinical Sciences, Malmö, Lund University, Sweden.

[2]Rakai Health Sciences Program, Uganda,

[3]Makerere University School of Public Health, Kampala Uganda

[4]Makerere University College of Health Sciences, Kampala Uganda

[5]John Hopkins University, Bloomberg, School of Public Health, USA.

Risky sexual behaviours among pre-ART and ART experienced HIV-infected persons in Rakai, Uganda

Abstract:

Objectives:

To compare risky sexual behaviours among patients on ART (ART experienced) and patients not initiated on ART (ART naïve) and assess predictors of risky sexual behaviours among HIV infected patients in rural Rakai district, Uganda.

Study Design:

This is a Cross-sectional study that derived data from Rakai community cohort study (RCCS) data base between 2013 and 2014. A structured questionnaire was used for data collection. Stepwise logistic regression was used to estimate the adjusted odds ratios (adjOR) of risky sexual behaviors associated with ART treatment status.

Study setting:

This study was conducted in Rakai district, located in south western Uganda. The data for this study was extracted from the Rakai Community Cohort Study (RCCS). RCCS is a open prospective cohort of approximately 15,000 consenting participants aged 15-49 years.

Participants:

HIV positive Participants aged between 18-49 that had sex at least once a month with any partner (sexually active) prior to the start of the study.

Main Outcome Measures: Inconsistent/no condom use in the last 12 months, Alcohol use at last sex, two or more sexual partners.

Results;

ART naïve participants were more likely to report inconsistent/no condom use (OR=1.74, 95% CI 1.11-2.73) and more likely to drink alcohol at last sex (OR= 1.65, 95% CI 1.11-2.46), compared to ART experienced patients. Inconsistent/no condom use and alcohol use with sex were more frequent in males than females (adjOR=1.47, 95 % CI 0.90-2.41, and 1.80, 95% CI

1.18-2.74), respectively. ART treatment status (P=0.031), marital status (P=0.016) and occupation level (P=0.009) are positively associated with inconsistent condom use.

Conclusion

ART naïve patients were more likely to exhibit risky sexual behaviours than the ART experienced patients. Risk reduction counselling should be provided for pre-ART patients in HIV care.

Keywords: Antiretroviral therapy; Sexual behaviour; HIV transmission; HIV; Uganda

Strength and Limitations of the study:

- The use of data from a prospective population-based study cohort with a high participation rate of over 90% that captured a representative sample of the sexually active HIV positive population in 54 surveyed communities makes the findings generalizable and applicable country wide in an HIV positive population.
- However, Sexual risk behaviour estimates are based on self-reported measures, which are subject to social desirability and recall bias.
- Reporting condom use in the last 12 months may not always accurately characterize patient's overall condom use due to the long periods of measurement.
- This study did not consider the time element; CD4 cell count and calendar years as well as time on ART, which may be factors that correlated with risk sexual behaviour.
- The period of observation was restricted to one survey round which may not necessarily give accurate changes in exposure time measurements.

Introduction:

The effective and improved access of antiretroviral therapy (ART) has led to declines in morbidity and mortality among people living with HIV (PLHIV) (1,2). This is because ART is highly effective in reducing plasma levels of HIV RNA and reducing incidence of HIV related opportunistic infections (3,4) especially on good adherence for sustained viral suppression (5). Thus, A number of people living with HIV now live longer and live a better life (6).

Improvements in their physical health and increased survival that follow ART may be accompanied by an increase in sexual desire and activity. With increased sexual activity, PLHIV continue to be at risk of acquiring new strains and transmiting HIV to to others. Increased unprotected sexual activity may also come from optimistic beliefs as people perceive HIV to be a manageable chronic disease (7) and not life threatening (8,9). These optimistic beliefs have been associated with increased risky sexual behaviours among PLHIV (10).

Risky sexual behaviours continue to be reported among PLHIV in Uganda (11-14) thus the danger of transmitting drug resistant strains especially among persons with incomplete viral suppression has already been observed (15). Early sexual debut, multiple sexual partnerships, limited and inconsistent condom use, sex under the influence of alchol, childhood marriages and transactional cross-generational sex constitute the main risky behaviours currently driving the HIV epidemic in Uganda (16-18).

It is estimated that about 7–17% of new cases of HIV infection in high-income countries (19) and 4.8–6.8% in low and middle-income countries (20) carry at least one major drug resistance mutation. These resistant strains require second-line ART regimes which are prohibitively expensive in low-income countries. There is a risk of re-infection with drug resistant strains, which impairs immunity with poorer clinical outcomes (21). Therefore, understanding risky sexual behaviours among people living with HIV is important for designing interventions to promote secondary HIV prevention strategies.

In Uganda, ART is provided to all patients with a confirmed HIV diagnosis and CD4 count below 500 cells/mm3, or at time of diagnosis among sex workers, fisher-folk, pregnant mothers, those infected with TB, children less than 15 years and sero-discordant couples, per the Ugandan Ministry of Health Guidelines (22). Uganda's ART treatment coverage is still suboptimal with only about 775,212 patients out of ~1.5 million infected persons (51%) on ART by 2015 (23) . Due to the increasing availability of ART in Uganda, many more HIV positives are expected to survive or live longer so changes in risky sexual behaviours among people living with HIV could have an impact on the epidemic.

Largely, people diagnosed as HIV positive and referred for HIV care but are not yet started on antiretroviral treatment (ART naive) have received less attention. Most of the reviews done in Uganda have investigated risky sexual behaviours more on people already enrolled on ART (ART experienced) (24-26) leaving out those that have not been enrolled on ART (ART naïve). This comparison remains largely undocumented. This study therefore compares risky sexual behaviours among ART naïve and ART experienced and explores the predictors of risky sexual behaviour among PLHIV attending an HIV treatment and care program in Rakai.

Methods:

This cross sectional study was conducted among HIV positive patients in Rakai, a rural district located in southwestern Uganda. Rakai district has a population of 518,008, with 80% of the population being agriculturalists (37). The data for this study was extracted from the Rakai Community Cohort Study (RCCS). RCCS is a prospective cohort which has been described previously (39,40). It is an open population-based cohort of approximately 15,000 consenting participants aged 15-49 years with an overall adult HIV prevalence of 13% (38). Serosurveys have been conducted every 12-20 months since 1994. Structured Interviews are administered by same sex interviewers and participants provide blood samples for HIV serology and diagnosis of other sexually transmitted infections. Interviews establish information on socio-demographic characteristics, sexual behaviours, health and contextual characteristics. In this cross sectional study data were from Round 15 (2013-2014).

Eligibility criteria

Participants were eligible to participate in the study if they had tested HIV positive, were on ART or were ART naïve but in care, and had sex at at least once a month with any partner (sexually active).

Variables;

The outcome variables in this study were risky sexual behaviours. Risky sexual behaviours in this study are described as any sexual behaviour that increases the likehood of contracting an STI or HIV. In this study; two or more sexual partners, alcohol use at last sex, inconsistent condom use in the last 12 months are described as risky sexual behaviours. The independent variables included sociodemographics and ART treatment Status.

Dependent/ outcome variables;

Inconsistent/no condom use was defined from a question about frequency of condom use in the last 12 months. The response alternatives were dichotomized as consistent condom use and inconsistent/no condom use for those who responded that they 'sometimes' or 'never" used condoms. Alcohol use at last sex was dichotomized as 'yes' and 'No'.. Two or more sexual partners were defined as having either serial or concomitant partners within the past 12 months.Risky sex was described as those participants that either used condoms inconsistently, drank alcohol at last sex or had two or more sexual partners in the last 12 months.

Independent Variables;

Previous studies (27-29) identified several predictors associated with risky sexual behaviours among HIV Positive people. These variable were expected to correlate with risky behaviours among HIV positive people . These included; ART treatment status which was recorded as ART naïve; people diagnosed as HIV positive and referred for HIV care but are not yet started on antiretroviral treatment or ART experienced status; people already enrolled on ART. Education level classified as primary school level/did not attend school or secondary level or higher. Current marital status was categorized as currently married or unmarried. Age was grouped into

3 categories; 18-24, 25-34 and 35-50 years. Occupation was dichotomized into agriculture or any other.

Ethical consideration:

The Rakai Community cohort study (RCCS) was approved by the Research and Ethics Committee of the Uganda Virus Research Institute, the Uganda National Council of Science and Technology and US-based Western IRB. Written informed consent was obtained from all research participants.

Statistical methods

Contingency tables were used for bivariate analyses to examine associations between outcome variables (sexual behaviors) and co-variates, and chi square tests used for statistical inference. All co-variates statistically significant in bivariate analyses were included in the multivariable analyses. Multivariable logistic regression was used to estimate adjusted odds ratios (adjOR) and 95% Confidence Intervals (CI) using stepwise selection. Statistical significance was based on a p-value less than 0.05. Statistical analyses used IBM SPSS statistics version 21.

Results:

Table 1 describes the characteristics of the study participants stratified by ARV treatment status. There were 341 (66%) females and 176 (34%) males. The majority of participants were married (67.5%) agriculturalists. 55.7% had primary or no education (72.9%), and 55.7% were between 35-50 years of age. The mean age of the respondents was 35.6 years (SD=6.67).

ART naïve participants reported a higher percentage of inconsistent or no condom use (85.8%) compared to ART experienced (78.1%) and the difference was statistically significant (p=0.031). Alcohol use at last sex was reported by ART experienced (22.5%) and ART naïve participants (32.5%; p=0.012). Having 2 or more sexual partners were similar among ART experienced (19.4%) and ART-naïve persons 18.3% (p=0.756), while somewhat more ART naïve participants did not use condoms at last sex compared to ART experienced participants (72.1% vs 64.7%, respectively; p=0.081).

For the bivariate analyses (Table 2), inconsistent/no condom use was higher among the ART naive) compared to the ART experienced participants (OR=1.69, 95% CI 1.04 – 2.73), and inconsistent/no condom use was more frequent among women compared to men (65.9 % vs 34.1% p=0.932). Agriculturalists were more likely to report no or inconsistent condom use than other occupations (OR=1.80, 95% CI 1.15 – 2.80). Additionally, ART naïve participants had higher odds of drinking alcohol at last sex compared to the ART naïve participants (OR=1.65, 95% CI 1.11 – 2.46) (Table 3). Men were more likely to use alcohol at last sex compared to women (OR=3.40, 95% CI 2.26 – 5.12) (Table 3).

Three predictor variables (Table 2) were significantly associated with inconsistent condom use; ART treatment status (P=0.031), marital status (P=0.016) and occupation level (P=0.009).

In the final multivariate model (Table 4), the association between inconsistent condom use and ART treatment status remained statistically significant after adjusting for age, occupation and marital status (adj OR = 1.47 95% CI 0.90 – 2.41, model 4). Age and sex were significantly associated with alcohol use with sex (adjOR = 3.47 95 % CI 2.30-5.23), age (OR = 3.34 95% CI 0.74 – 15.03) (Table 5)

Discussion:

Findings from this study reveal pre-ART participants having slightly increasing odds of practicing risky sexual behaviours compared to participants on ART This is similar to other studies done that showed that ART naïve patients were more likely to practice risky sexual behaviours than the ART experienced patients (14,30). These differences could be attributed to the differences in counselling intensity, health education and follow-ups given to patients on ART more frequently than ART naïve patients (patients on ART are required to visit the clinic more frequently than those on ART.

Overall, almost eighty-one percent of study participants reported inconsistent condom use, which indicates high numbers of unsafe sex among HIV positive people. This highlights the dangers of continued HIV transmission despite the increasing ART roll out, which therefore calls for the focus on increasing awareness and motivation of condom use among HIV positive patients. Additionally, inconsistent condom use was more likely among ART naïve patients, a finding

similar to earlier studies in Uganda (14) Kenya (31) (40) and South Africa(30). These findings could be explained by the repeated, increasing counselling sessions given to ART experienced patients as they visit ART clinics for refills and medical check-ups more often than the ART naïve patients that are less likely to present themselves at clinics for HIV care.

Inconsistent condom use was higher among women than in men (65.9% vs 34.1%) in this study. This is similar to studies done in Italy and India that showed incosistence condom use prevalence at 44.3 % and and 44.3 % respectively (32,33) HIV positive women. This could reflect the limitations of female bargaining power within sexual relationships. A central feature of Ugandan society is gender inequality, with women occupying subordinate roles both in economic activities and in decision-making. Women are not culturally empowered to negotiate sexually related issues and this pattern of male control of sexual decision-making was also noted in Uganda and Rwanda (34,35). However, inconsistent condom use in this group could also be attributed to the desire to have children. Studies (36,37) have shown reproductive desires play a significant role among HIV positive women. Therefore, these gender differences highlight a need for better understanding and incorporating gender dynamics in secondary prevention strategies in order to meet the specific needs of both women and men.

We observed almost 26% of HIV positive patients drank alcohol before sex. This is a health concern because alcohol use among HIV positives has been associated with decreased adherence to ARV(38,39) increased risk of hepatic injury (40) and reduced patient's ability to practice safer sex(41) Additionally, ART naïve participants were more likely to use alcohol at last sex compared to ART experienced participants. This could be explained by the fact that once people are started on ART, they are advised not to take alcohol to preserve the integrity of their liver, so that the ARVs are well processed in the body. Another reason could be the guidelines and adherence support counselling given by health workers when on ART. This is line with a study that reported decreased alcohol consumption after ART initiation(42)and higher odds of alcohol use during the pre-ART period(43).

Males were three times more likely to drink alcohol at last sex in this study. This could be attributed to the common social values and masculine norms of the acceptance of male drinking in society.. This is related to ugandan study that reported 41% of males use alcohol before sex (44). It is recommended that alcohol abuse and its consequences should be a key factor in

secondary prevention interventions. Health care providers should screen their HIV patients for alcohol use problems and initiate interventions that can reduce alcohol related problems among people living with HIV. More research is needed to find and test different behavioural, social and biomedical interventions for alcohol related problems among people living with HIV.

In relation to other studies in sub-Saharan Africa (45-47) this study found that participants with primary or lower level education were more likely to use condoms inconsistently. This could be explained by the fact that participants with higher education are more likely to have higher knowledge of HIV/AIDS and are more informed in addition usually there are more likely to seek more information and medical care that would protect them from re-infection.

Sex and age are significant predictors of risk sexual behaviors among HIV positive patients (P=< 0.001) in this study. This is related to studies done before that have either identified sex or age as significant predictors of risky sexual behaviours (27,30,48).

Methodological considerations;

The use of data from a prospective population-based study cohort with a high participation rate of over 90%, that captured a representative sample of the sexually active HIV positive population in 54 surveyed communities in rural Rakai was a notable strength. However this study had limitiations; Firstly, this was a cross sectional study and could not derive causal inferences. Secondly, Sexual risk behaviour estimates are based on self-reported measures, which are subject to social desirability and recall bias. The sensitivity of some of these questions and responses may lead to bias because of stigma and privacy concerns. However, a study done in Uganda showed large cohort studies have correlations between behavioural self-reported measures and HIV infection and thus suggesting recall bias does not necessarily conceal key associations(49). Thirdly, reporting condom use in the last 12 months may not always accurately characterize patient's overall condom use due to the long periods of measurement. The frequency of condom use as well as recalling sexual encounters in the last 12-18 months since the last survey done might affect people's ability to accurately answer and remember details of sexual encounters. However, findings from other shorter time periods do not necessarily differ from the findings of this study which maybe a minor factor (50). Fourthly, This study did not consider the time element; CD4 cell count and calendar years as well as time on ART which may be factors

that correlated with risk sexual behaviour. In addition, the period of observation was restricted to one survey round which may not necessarily give accurate changes in exposure time measurements.

Conclusion:

In general, this study reveals pre-ART participants having slightly increasing odds of risky sexual behaviours compared to the participants on ART. We predict these differences could be attributed to the variability in counselling intensity, health education and follow-ups offered to patients on ART. These findings reveal the need to improve positive prevention programming in Uganda.

Focused interventions such as risk reduction counselling and education programmes are required to be incorporated in HIV care and treatment programs and emphasis should be laid on counselling to avoid re-infections, alcohol abuse and including gender dynamics as part of these interventions. The roll out of ART should not be considered as a single preventive intervention but should be facilitated with other elements such as psychosocial support, mental health services, nutrition and family planning to ensure a successful HIV fight. Better understanding of the underlying mechanisms and correlates of such high-risk sexual behavior among persons living with HIV/AIDS remains a priority for researchers and public health professionals alike.

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Tables;

Table 1; Baseline socio demographic and sexual behaviour characteristics for 517 participants in a longitudinal cohort study of People living with HIV in a rural district, Rakai, Uganda

Characteristics	Overall (%)	ART Naive (%)	ART Experienced (%)	P-Value*
Overall		197 (38.1)	320 (61.9)	
Sex				
Female	341(66.0)	130 (66.0)	211 (65.9)	0.990
Male	176 (34.0)	67 (34.0)	109 (34.1)	
Age (years)				
Mean (SD)	35.55 (6.48)	36.34 (6.25)	34.27 (6.60)	< 0.001
Median (IQR)	35.0 (31-40)	37 (30-41)	34 (30-39)	
Age group (years)				
18-24	23 (4.4)	13 (6.6)	10 (43.5)	0.004
25-34	206 (39.8)	91 (46.2)	115 (35.9)	
35-50	288 (55.7)	93 (47.2)	195 (60.9)	
Marital status				
Married	349 (67.5)	137 (69.5)	212 (66.3)	0.438
Not Married	168 (32.5)	60 (30.5)	108 (33.8)	
Main Occupation				
Agriculture/housework	288 (55.7)	113 (57.4)	175 (54.7)	0.552
Other occupation	229 (44.3)	84 (42.6)	145 (45.3)	
Education level				
Primary or lower	377 (72.9)	137 (69.5)	240 (75.0)	0.175
Secondary or higher	140 (27.1)	60 (30.5)	80 (25.0)	
Alcohol use at last sex				
Yes	136 (26.3)	64 (32.5)	72 (22.5)	0.012
No	381 (73.7)	133 (67.5)	248 (77.5)	
Condom Use in last 12 months				
Consistent	98 (19.0)	28 (14.2)	70 (21.9)	0.031
Inconsistent	419 (81.0)	169 (85.8)	250 (78.1)	
No of sexual partners				
1 partner	419 (81.0)	161 (81.7)	258 (80.6)	0.756
2 or more partners	98 (19.0)	36 (18.3)	62 (19.4)	
Condom use at last sex				
Yes	168 (32.5)	55 (27.9)	113 (35.3)	0.081
No	349 (67.5)	142 (72.1)	207 (64.7)	

Table 2. Association (crude odds ratios, 95% Confidence Intervals) between sociodemographic factors, ART treatment status and inconsistent condom use in a sample of 517 HIV positive patients in Rakai; results of logistic regression.

	Consistent n (%)	*Inconsistent/no condome use n (%)*	*Crude ORs (95% CI)*	*P value*
ART treatment status				
ART naïve	28 (28.6)	169 (40.3)	1.69 (1.04-2.73)	0.031
ART experienced	70 (71.4)	250 (59.7)	1 (ref group)	
Sex				
Male	33 (33.7)	143 (34.1)	1.02 (0.64-1.62)	0.932
Female	65 (66.3)	276 (65.9)	1 (ref group)	
Age				
25-34	26 (26.5)	180 (43.0)	0.32 (0.041-2.43)	0.268
35-50	71 (72.4)	217 (51.8)	0.13 (0.02-1.04)	0.056
18-24	1 (4.3)	22 (5.3)	1 (ref group)	
Marital status				
Married	56 (57.1)	293 (69.9)	1.74 (1.11-2.73)	0.016
Not married	42 (42.9)	126 (30.1)	1 (ref group	
Education level				
Primary level	68 (69.4)	309 (73.7)	1.23 (0.76-2.00)	0.383
Secondary level	30 (30.6)	110 (26.3)	1 (ref group)	
Occupation level				
Agriculture/housework	43 (43.9)	245 (58.5)	1.80 (1.15-2.80)	0.009
Other occupation	55 (56.1)	174 (41.5)	1 (ref group)	

Table 3; Association (crude odds ratios, 95% Confidence Intervals) between sociodemographic factors, ART treatment status and alcohol use at last sex in a sample of 517 HIV positive patients in Rakai; results of logistic regression

	Alcohol use Yes n (%)	*Alcohol use No n (%)*	*Crude ORs (95% CI)*	*P value*
ART treatment status				
ART naive	64 (47.1)	133 (34.9)	1.65 (1.11-2.46)	0.013
ART experienced	72 (52.9)	248 (65.1)	(ref)	
Sex				
Male	75 (55.1)	101 (26.5)	3.40 (2.26-5.12)	< 0.001
Female	61 (44.9)	280 (73.5)	ref	

Age				
35-50	82 (60.3)	206 (54.1)	4.18 (0.95-18.22)	0.057
25-34	52 (38.2)	154 (40.4)	3.54 (0.80-15.63)	0.095
18-24	2 (1.5)	21 (5.5)	ref	
Marital status				
Married	92 (67.6)	257 (67.5)	1.0 (0.66-1.53)	0.967
Not married	44 (32.4)	124 (32.4)	ref	
Education level				
Primary level	106 (77.9)	271 (71.1)	1.43 (0.90-2.27)	0.126
Secondary level	30 (22.1)	110 (28.9)	ref	
Occupation level				
Agriculture/housework	70 (51.5)	218 (57.2)	0.79 (0.53-1.17)	0.247
Other occupation	66 (48.5)	163 (42.8)	ref	

Table 4; Association (adjusted odds ratio, 95% Confidence Interval) between inconsistent/no condom use and ART treatment status among 517 HIV positive patients in Rakai; results of multivariate logistic regressions

	Model 1 OR (95% CI)	**Model 2 OR (95% CI)**	**Model 3 OR (95% CI)**	**Model 4 OR (95% CI)**
ART Treatment Status				
ART naive	1.69 (1.04-2.73)	1.51 (0.92-2.46)	1.48 (0.90-2.42)	1.47 (0.90-2.41)
ART experienced	ref	ref	ref	ref
Age				
35-50		0.15 (0.02-1.15)	0.15 (0.02-1.21)	0.16 (0.02-1.23)
25-34		0.33 (0.43-2.55)	0.34 (0.04-2.72)	0.35 (0.04-2.77)
18-24		ref	ref	ref
Occupation level				
Agriculture/housework			1.79 (1.14-2.81)	1.71 (1.00-2.53)
Other occupation	ref	ref	ref	ref
Marital status				
Married				1.59 (1.00-2.53)
Not married				ref

Model 1: unadjusted model
Model 2: adjusted for age
Model 3: adjusted for age, Occupation
Model 4 Adjusted for age, occupation & marital status;

Table 5: Association (adjusted odds ratio, 95% Confidence Interval) between alcohol use at last sex and ART treatment status among 517 HIV positive patients in Rakai; results of multivariate logistic regression

	Model 1 OR (95% CI)	**Model 2 OR (95% CI)**	**Model 3 OR (95% CI)**
ART Treatment Status			
ART naive	1.65 (1.11-2.46)	1.72 (1.14-2.61)	1.80 (1.18-2.74)

ART Experienced	ref	ref	ref
Sex			
Male		3.47 (2.30-5.23)	3.29 (2.17-4.99)
Female		ref	ref
Age			
35-50			3.34 (0.74-15.03)
25-34			2.95 (0.65-13.35)
18-24			ref

Model 1: unadjusted model
Model 2: adjusted for sex
Model 3: adjusted for age, sex

Funding and competing interests:

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors. The authors declare no competing interests exist and this study and manuscript preparation had no funding attached.

Author's Contributions:

LNJ conceptualized the study, designed, analyzed and drafted the first version of the manuscript. BOA and GN were involved in the analysis, interpretation and critical review of the manuscript. JK, FN, DS, NS were involved in revising the article critically for important intellectual content. RN edited and approved the final version to be published. AN was involved in the acquisition of data, data analysis and interpretation of the data.

Data sharing statement:

The data sets used for this study are available on request from the Rakai Community Cohort Study Data base at Rakai Health Sciences Program. (www.rhsp.org)

Strength and Limitations of the study:

- The use of data from a prospective population-based study cohort with a high participation rate of over 90% that captured a representative sample of the sexually active HIV positive population in 54 surveyed communities makes the findings generalizable and applicable country wide in an HIV positive population.
- However, Sexual risk behaviour estimates are based on self-reported measures, which are subject to social desirability and recall bias.
- Reporting condom use in the last 12 months may not always accurately characterize patient's overall condom use due to the long periods of measurement.
- This study did not consider the time element; CD4 cell count and calendar years as well as time on ART, which may be factors that correlated with risk sexual behaviour.
- The period of observation was restricted to one survey round which may not necessarily give accurate changes in exposure time measurements.

CONTRIBUTORSHIP STATEMENT:

LNJ conceptualized the study, designed, analyzed and drafted the first version of the manuscript. BOA and GN were involved in the analysis, interpretation and critical review of the manuscript. JK, FN, DS, NS were involved in revising the article critically for important intellectual content. RN edited and approved the final version to be published. AN was involved in the acquisition of data, data analysis and interpretation of the data.

Authors

1. Lydia Jacenta Nakiganda (LJN)
2. Benedict Oppong Asamoah (BOA)
3. Joseph Kagaayi (JK)
4. Fred Nalugoda (FN)
5. David Serwadda (DS)
6. Nelson Sewakambo (NS)
7. Ronald Gray (RG)
8. Anthony Ndyanabo (AN)
9. Gertrude Nakigozi (GN)

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*

Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any pre-specified hypotheses	5
Methods			**5**
Study design	4	Present key elements of study design early in the paper	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*6*
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	6-7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7
		(*b*) Describe any methods used to examine subgroups and interactions	7
		(*c*) Explain how missing data were addressed	7
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	7

		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
Results			7-8
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	7-8
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7-8
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	8
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10
Generalisability	21	Discuss the generalisability (external validity) of the study results	10
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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A cross-sectional comparative study of risky sexual behaviours among pre-ART and ART experienced HIV infected persons in rural Rakai, Uganda

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Complete List of Authors:	NAKIGANDA, LYDIA; Lund University, Social medicine and Global Health Division Asamoah, Benedict ; Lund University, Department of Clinical Sciences, Malmö, Division of Social Medicine and Global Health Kagaayi, Joseph; Rakai Health Sciences Program Nalugoda, Fred; Rakai Health Sciences Program Serwadda, David; Makerere University School of Public Health, Kampala Uganda Sewankambo, Nelson; Makerere University College of Health Sciences, Gray, Ronald; John Hopkins University, Bloomberg, School of Public Health, USA. Ndyanabo, Anthony; Rakai Health Sciences Program Nakigozi, Gertrude; Rakai Health Sciences Program
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A cross- sectional comparative study of risky sexual behaviours among pre-ART and ART experienced HIV infected persons in rural Rakai, Uganda

Author:

1. Lydia Jacenta Nakiganda[1] lydianakiganda85@gmail.com
2. Benedict Oppong Asamoah[2] benedict_oppong.asamoah@med.lu.se
3. Joseph Kagaayi[3] jkagayi@rhsp.org
4. Fred Nalugoda[3] fnalugoda@rhsp.org
5. David Serwadda[4] dserwada@infocom.co.ug
6. Nelson Sewakambo[5] sewankam@infocom.co.ug
7. Ronald Gray[6] rgray4@jhu.edu
8. Anthony Ndyanabo[3] andyanabo@rhsp.org
9. Gertrude Nakigozi[3] ftrudie@rhsp.org

Corresponding author:

Lydia Jacenta Nakiganda
Spangatan 37B, lgh 1103, 21153, Malmo, Sweden
lydianakiganda85@gmail.com

Institutions and departments:

[1]International Master Programme in Public Health, Faculty of Medicine, Lund University, CRC, Jan Waldenströms gata 35, 205 02 Malmö, Sweden

[2]Social Medicine and Global Health, Department of Clinical Sciences, Malmö, Lund University, Sweden.

[3]Rakai Health Sciences Program, Uganda,

[4]Makerere University School of Public Health, Kampala Uganda

[5]Makerere University College of Health Sciences, Kampala Uganda

[6]John Hopkins University, Bloomberg, School of Public Health, USA.

A cross-sectional comparative study of risky sexual behaviours among pre-ART and ART experienced HIV infected persons in rural Rakai, Uganda

Abstract:

Objectives:

To compare risky sexual behaviours among persons on ART (ART experienced) and persons not initiated on ART (ART naïve) and assess predictors of risky sexual behaviours among HIV-infected patients in rural Rakai district, Uganda.

Study Design:

This is a cross-sectional study that derived data from Rakai Community Cohort Study (RCCS) database collected between 2013 and 2014. A structured questionnaire was used for data collection. Stepwise logistic regression was used to estimate the adjusted odds ratios (adjOR)) for the association between risky sexual behaviors associated and ART treatment status.

Study setting:

This study was conducted in Rakai district, located in south western Uganda. The data for this study was extracted from the Rakai Community Cohort Study (RCCS). RCCS is a open prospective cohort of approximately 15,000 consenting participants aged 15–49 years.

Participants:

HIV positive participants aged between 18–49 that had sex at least once a month prior to the start with any partner (sexually active) prior to the start of the study.

Main Outcome Measures: Inconsistent/no condom use in the last 12 months, alcohol use at last sex, and two or more sexual partners.

Results;

ART naïve participants were more likely to report inconsistent/no condom use (OR=1.74, 95% CI 1.11–2.73) and more likely to drink alcohol at last sex (OR= 1.65, 95% CI 1.11–2.46), compared to ART experienced patients. Inconsistent/no condom use and alcohol use with sex were more frequent in males than females (adjOR=1.47, 95 % CI 0.90–2.41, and 1.80, 95% CI

1.18–2.74), respectively. ART treatment status (P=0.031), marital status (P=0.016) and occupation level (P=0.009) are positively associated with inconsistent condom use.

Conclusion

ART naïve patients were more likely to exhibit risky sexual behaviours than the ART experienced patients. Risk reduction counselling should be provided for pre-ART patients in HIV care.

Keywords: Antiretroviral therapy; Sexual behaviour; HIV transmission; HIV; Uganda

Strength and Limitations of the study:

- The use of data from a prospective population-based study cohort with a high participation rate of over 90% that captured a representative sample of the sexually active HIV positive population in 54 surveyed communities makes the findings generalizable.
- Sexual risk behaviour estimates are based on self-reported measures, which are subject to social desirability and recall bias.
- Reporting condom use in the last 12 months may not always accurately characterize participant's overall condom use due to the long periods of measurement.
- This study did not consider the time element; CD4 cell count and calendar years as well as time on ART, which may be factors that correlate with risk sexual behaviour.
- The period of observation was restricted to one survey round which may not necessarily give accurate changes in exposure time measurements.

Introduction:

Improved access to effective antiretroviral therapy (ART) has led to declines in morbidity and mortality rates among people living with HIV (PLHIV) (1,2). ART is highly effective in reducing plasma levels of HIV RNA and reducing incidence of HIV related opportunistic infections (3,4), hence people living with HIV on ART now live longer and have reduced morbidity (5,6). Despite the beneficial effects of ART, risk of transmission is not completely eliminated, in particular for those who do not have complete viral suppression, and transmission from those with undetectable viral load has been documented (7,8).

The beneficial effects of ART; the slow disease progression and reduced viral load has been associated with optimism as HIV positive people perceive HIV as no longer life threatening (9,10) and many are aware that with treatment, HIV can be a chronic manageable disease (11,12). This optimism has been associated with increases in risky sexual behaviours (i.e., sexual behaviours that have increased likelihood of HIV transmission) (9,13,14). In addition, the general physical health improvement and increased survival that follow ART may be accompanied by an increase in sexual desire and activity (15,16). This can lead to onward HIV transmission.

Although ART prevents HIV transmission through reduced infectivity (4), there could be an offset brought about by risk sexual behaviours (17). Cell associated genital HIV shedding may occur in people with low HIV viral load (18,19) allowing for potential transmission of drug resistant strains (20). HIV transmission from people on ART will usually depend on the effectiveness of ART in reducing viral load and the efficiency of ART programs in reducing risky sexual behaviours .

Worldwide, risky sexual behaviours continue to be reported among PLHIV (21-24) increasing chances of transmission of drug resistant strains from HIV-infected persons with incomplete viral suppression (20). It is estimated that about 7–17% of newly infected persons in high-income countries (25) and 4.8–6.8% in low and middle-income countries (26) carry at least one major drug resistance mutation. These resistant strains are not responsive to first line ARV therapy (20,27), and require second-line ART regimes which are prohibitively expensive in low-income countries. In addition, there is a risk of superinfection with drug resistant strains that has

been reported among PLHIV (28,29). Therefore, understanding risky sexual behaviours among HIV positive persons is of great public health importance especially in designing secondary HIV prevention strategies.

Risky sexual behaviours have been reported among PLHIV in Uganda (15,30-32). Early sexual debut, multiple sexual partnerships, limited and inconsistent condom use, sex under the influence of alcohol, childhood marriages and transactional cross-generational sex constitute the main risky behaviours currently driving the HIV epidemic in Uganda (33-35). In Uganda, ART is provided to all patients with a confirmed HIV diagnosis and CD4 count below 500 cells/mm^3, or at time of diagnosis among sex workers, fisher-folk, pregnant mothers, those infected with TB, children less than 15 years and sero-discordant couples, per the Ugandan Ministry of Health uidelines (36). While in Kenya and Tanzania ART treatment coverage is at 59% and 53% respectively (37), Uganda's ART treatment coverage is still suboptimal with only about 775,212 patients out of ~1.5 million infected persons (51%) on ART as of 2015 (38). Due to the increasing availability of ART in Uganda, an increasing number of PLHIV can be expected to live extended periods, so changes in risky sexual behaviours among people living with HIV could have an impact on HIV transmission.

The characteristics and behaviours of people diagnosed as HIV positive and referred for HIV care but are not yet started on antiretroviral treatment (ART naive) have received less attention. Most of the reviews done in Uganda have investigated risky sexual behaviours focused more on people already enrolled on ART (ART experienced) (30,39,40), and have not done so for those not enrolled on ART (ART naïve). The comparison between these two groups remains largely undocumented. This study therefore compares risky sexual behaviours among ART naïve and ART experienced and explores the predictors of risky sexual behaviour among PLHIV attending an HIV treatment and care program in Rakai.

Conceptual framework:

In summary, the conceptual framework (Supplemantary Figure 1) illustrates the possible factors for PLHIV to engage in risky sexual behaviour. In understanding these various factors influencing risky sexual behaviour, this model suggests two sets of characteristics; distal factors

and proximate factors. The distal factors (age, educational level, occupation, socioeconomic status, gender, ARV treatment status) and proximate factors (intensity of counselling, frequent health education, medical check-ups) are considered as independent factors affecting risky sexual behaviours which is the dependent variable (outcome). Intensity of counselling, frequent health education and continued medical check-ups could predict risky sexual behaviours. This has been seen in studies conducted in other low-income settings that predict intensity of behavioural change counselling and health education (41,42), medical check-ups and frequent hospital visits (43) as factors in the reduction of risky sexual behaviours among people living with HIV.

Using this conceptual framework, it is hypothesized that ART experienced persons (those on ART) are more likely to drink alcohol at last sex, have multiple sexual partners and use condoms inconsistently with any sexual partner. Thus it is predicted that proximate factors will moderate the differences in the risky sexual behaviours between ART naïve and ART experienced persons.

Methods:

This cross-sectional study was conducted among HIV positive persons in Rakai, a rural district located in southwestern Uganda. Rakai district has a population of 518,008, with 80% of the population being agriculturalists (44). The data for this study was extracted from the Rakai Community Cohort Study (RCCS). RCCS is a prospective cohort which has been described previously (45,46). It is an open population-based cohort of approximately 15,000 consenting participants aged 15-49 years with an overall adult HIV prevalence of 13% (47). Serosurveys have been conducted every 12-20 months since 1994. Structured interviews are administered by same sex interviewers and participants provide blood samples for HIV serology and diagnosis of other sexually transmitted infections. Interviews establish information on socio-demographic characteristics, sexual behaviours, health and contextual characteristics. In this cross-sectional study, data were from Round 15 (2013-2014).

Eligibility criteria

Participants were eligible to participate in the study if they had tested HIV positive, were on ART or were ART naïve but in care, and had sex at at least once a month prior to the start of the

study with any partner (sexually active). Only HIV-sero-concordants were included in this study irrespective of marital status

Variables;

The outcome variables in this study were risky sexual behaviours. Risky sexual behaviours in this study are described as any sexual behaviour that increases the likehood of contracting an STI or HIV. In this study; two or more sexual partners, alcohol use at last sex, inconsistent condom use in the last 12 months are described as risky sexual behaviours. The independent variables included sociodemographics and ART treatment status.

Dependent/ outcome variables;

Inconsistent/no condom use was defined from a question about frequency of condom use in the last 12 months. The response alternatives were dichotomized as consistent condom use and inconsistent/no condom use for those who responded that they 'sometimes' or 'never" used condoms. Alcohol use at last sex was dichotomized as 'yes' and 'no'. Two or more sexual partners were defined as having either serial or concomitant partners within the past 12 months.Risky sex was described as those participants that either used condoms inconsistently, drank alcohol at last sex or had two or more sexual partners in the last 12 months.

Independent Variables;

Previous studies (48-50) identified several predictors associated with risky sexual behaviours among PLHIV. These variables were expected to correlate with risky behaviours among PLHIV.. These included: ART treatment status which was recorded as ART naïve; people diagnosed as HIV positive and referred for HIV care but are not yet started on antiretroviral treatment or ART experienced status; people already enrolled on ART. Education level classified as primary school level/did not attend school or secondary level or higher. Current marital status was categorized as currently married or unmarried. Age was grouped into 3 categories; 18-24, 25-34 and 35-50 years. Occupation was dichotomized into agriculture or any other.

Ethical consideration:

The Rakai Community Cohort Study (RCCS) was approved by the Research and Ethics Committee of the Uganda Virus Research Institute, the Uganda National Council of Science and

Technology and US-based Western IRB. Written informed consent was obtained from all research participants.

Statistical methods

Contingency tables were used for bivariate analyses to examine associations between outcome variables (sexual behaviors) and co-variates, and chi square tests used for statistical inference. All co-variates statistically significant in bivariate analyses were included in the multivariable analyses. Multivariable logistic regression was used to estimate adjusted odds ratios (adjOR) and 95% confidence intervals (CI) using stepwise selection. Statistical significance was based on a p-value less than 0.05. Statistical analyses used IBM SPSS statistics version 21.

Results:

Table 1 describes the characteristics of the study participants stratified by ARV treatment status. There were 341 (66%) females and 176 (34%) males. The majority of participants were married (67.5%), agriculturalists 55.7%, had primary or no education (72.9%), and 55.7% were between 35-50 years of age. The mean age of the respondents was 35.6 years (SD=6.67).

ART naïve participants reported a higher percentage of inconsistent or no condom use (85.8%) compared to ART experienced (78.1%) and the difference was statistically significant (p=0.031). Alcohol use at last sex was reported by ART experienced (22.5%) and ART naïve participants (32.5%; p=0.012). Having 2 or more sexual partners were similar among ART experienced (19.4%) and ART-naïve persons 18.3% (p=0.756), while somewhat more ART naïve participants did not use condoms at last sex compared to ART experienced participants (72.1% vs 64.7%, respectively; p=0.081).

For the bivariate analyses (Table 2), inconsistent/no condom use was higher among the ART naive compared to the ART experienced participants (OR=1.69, 95% CI 1.04 – 2.73), and inconsistent/no condom use was more frequent among women compared to men (65.9 % vs 34.1% p=0.932). Agriculturalists were more likely to report no or inconsistent condom use than other occupations (OR=1.80, 95% CI 1.15 – 2.80). Additionally, ART naïve participants had higher odds of drinking alcohol at last sex compared to the ART naïve participants (OR=1.65,

95% CI 1.11 – 2.46) (Table 3). Men were more likely to use alcohol at last sex compared to women (OR=3.40, 95% CI 2.26 – 5.12) (Table 3).

Three predictor variables (Table 2) were significantly associated with inconsistent condom use; ART treatment status (P=0.031), marital status (P=0.016) and occupation level (P=0.009).

In the final multivariate model (Table 4), the association between inconsistent condom use and ART treatment status remained statistically significant after adjusting for age, occupation and marital status (adj OR = 1.47 95% CI 0.90 – 2.41, model 4). Age and sex were significantly associated with alcohol use with sex (adjOR = 3.47 95 % CI 2.30-5.23), age (OR = 3.34 95% CI 0.74 – 15.03) (Table 5)

Discussion:

Findings from this study reveal pre-ART participants having slightly increasing odds of practicing risky sexual behaviours compared to participants on ART. This is similar to other studies done that showed ART naïve patients were more likely to practice risky sexual behaviours than the ART experienced patients (15,51). These differences could be attributed to the differences in counselling intensity, health education and follow-ups given to patients on ART more frequently than ART naïve patients (patients on ART are required to visit the clinic more frequently than those on ART).

Sex and age are significant predictors of risk sexual behaviors among HIV positive patients (P=< 0.001) in this study. This is related to studies done before that have either identified sex or age as significant predictors of risky sexual behaviours (50-52).

Overall, almost 81% (overall) of study participants reported inconsistent condom use, which indicates high prevalence of unsafe sex among HIV positive people. This highlights the dangers of continued HIV transmission despite the increasing ART roll out. Therefore, this calls for increasing awareness and motivation of condom use among HIV positive patients. Additionally, inconsistent condom use was more likely among ART naïve patients, a finding similar to earlier studies in Uganda (15) Kenya (53) and South Africa (51). These findings could be explained by the repeated, increasing counselling sessions given to ART experienced patients, as they visit ART clinics for refills and medical check-ups more often than ART naïve patients who are seen less frequently at clinics for HIV care.

Inconsistent condom use was higher among women than in men (65.9% vs 34.1%) in this study. This is similar to studies done in Italy that showed almost 44.3% of HIV positive women were incosistence condom users (54) . This could reflect the limitations of female bargaining power within sexual relationships. A central feature of Ugandan society is gender inequality, with women occupying subordinate roles both in economic activities and in decision-making. Women are not culturally empowered to negotiate sexually related issues and this pattern of male control of sexual decision-making was also noted in Uganda and Rwanda (55,56). However, inconsistent condom use in this group could also be attributed to the desire to have children. Studies (57,58) have shown reproductive desires play a significant role in the lives of HIV positive women. Therefore, these gender differences highlight a need for better understanding and incorporating gender dynamics in secondary prevention strategies in order to meet the specific needs of both women and men.

We observed almost 26% of HIV positive patients drank alcohol before sex. This is a health concern because alcohol use among HIV positives has been associated with decreased adherence to ARV (59,60) and reduced patient's ability to practice safer sex (61) . Additionally, ART naïve participants were more likely to use alcohol at last sex compared to ART experienced participants. This could be explained by the fact that once people are started on ART, they are advised not to take alcohol to preserve the integrity of their liver (62,63), so that the ARVs are well processed in the body. Another reason could be the guidelines and adherence support counselling given by health workers when on ART. This is line with a study that reported decreased alcohol consumption after ART initiation (64) and higher odds of alcohol use during the pre-ART period (32).

Males were three times more likely to drink alcohol at last sex in this study. This could be attributed to the common social values and the acceptance of male drinking in society. A Ugandan study reported 41% of males use alcohol before sex (65). It is recommended that addressing alcohol abuse should be a key focus in secondary prevention interventions. Health care providers should screen their HIV patients for alcohol use problems and initiate interventions that can reduce alcohol related problems among people living with HIV. More research is needed to find and test different behavioural, social and biomedical interventions for alcohol related problems among people living with HIV.

In relation to other studies in sub-Saharan Africa (66-68) this study found that participants with primary or lower level education were more likely to use condoms inconsistently. This could be explained by the fact that participants with higher education are more likely to have higher knowledge of HIV and are more informed. Sex and age are significant predictors of risk sexual behaviors among HIV positive participants (P=< 0.001) in this study. This is consistent with earlier studies that have either identified sex or age as significant predictors of risky sexual behaviours (50-52).

Methodological considerations:

The use of data from a prospective population-based study cohort with a high participation rate of over 90%, that captured a representative sample of the sexually active HIV positive population in 54 surveyed communities in rural Rakai was a notable strength. However this study had limitiations; Firstly, this was a cross-sectional study and could not derive causal inferences. Secondly, sexual risk behaviour estimates are based on self-reported measures, which are subject to social desirability and recall bias. The sensitivity of some of these questions and responses may lead to bias because of stigma and privacy concerns. However, a study done in Uganda showed large cohort studies have correlations between behavioural self-reported measures and HIV infection and thus suggest that recall bias does not necessarily conceal key associations (69) and it is less likely that these potential biases would impact differences between the two groups. Thirdly, reporting condom use in the last 12 months may not always accurately characterize patient's overall condom use due to the long periods of measurement. The frequency of condom use as well as recalling sexual encounters in the last 12-18 months since the last survey done might affect people's ability to accurately answer and remember details of sexual encounters. However, findings from other shorter time periods do not necessarily differ from the findings of this study which maybe a minor factor (70). Fourthly, this study did not consider the time element; CD4 cell count and calendar years as well as time on ART which may be factors that correlated with risk sexual behaviour. In addition, the period of observation was restricted to one survey round which may not necessarily give accurate changes in exposure time measurements.

Conclusion:

This study indicates that pre-ART participants have slightly increased odds of risky sexual behaviours compared to participants on ART. These differences may be attributed to the variability in counselling intensity, health education and follow-ups offered to patients on ART. Though findings reveal higher odds of risky sexual behaviours among pre- ART positive people, rates of risky behavior are high for both groups, and positive prevention programs should be able to target both groups.

Focused interventions such as risk reduction counselling and education programmes are required to be incorporated in HIV care and treatment programs and emphasis should be laid on counselling to avoid re-infections, alcohol abuse and including gender dynamics as part of these interventions. The roll out of ART should not be considered as a single preventive intervention but should be facilitated with other elements such as psychosocial support, mental health services, nutrition and family planning to ensure a successful HIV fight. Better understanding of the underlying mechanisms and correlates of such high-risk sexual behavior among persons living with HIV remains a priority for researchers and public health professionals alike.

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Author's Contributions:

LNJ conceptualized the study, designed, analyzed and drafted the first version of the manuscript. BOA and GN were involved in the analysis, interpretation and critical review of the manuscript. JK, FN, DS, NS were involved in revising the article critically for important intellectual content. RN edited and approved the final version to be published. AN was involved in the acquisition of data, data analysis and interpretation of the data.

Data sharing statement:

The data sets used for this study are available on request from the Rakai Community Cohort Study Data base at Rakai Health Sciences Program. (www.rhsp.org)

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Table 1; Baseline socio demographic and sexual behaviour characteristics for 517 participants in a longitudinal cohort study of People living with HIV in a rural district, Rakai, Uganda

Characteristics	Overall (%)	ART Naive (%)	ART Experienced (%)	P-value*
Overall		197 (38.1)	320 (61.9)	
Sex				
Female	341(66.0)	130 (66.0)	211 (65.9)	0.990
Male	176 (34.0)	67 (34.0)	109 (34.1)	
Age (years)				
Mean (SD)	35.55 (6.48)	36.34 (6.25)	34.27 (6.60)	< 0.001
Median (IQR)	35.0 (31-40)	37 (30-41)	34 (30-39)	
Age group (years)				
18-24	23 (4.4)	13 (6.6)	10) (3.1)	0.004
25-34	206 (39.8)	91 (46.2)	115 (35.9)	
35-50	288 (55.7)	93 (47.2)	195 (60.9)	
Marital status				
Married	349 (67.5)	137 (69.5)	212 (66.3)	0.438
Not Married	168 (32.5)	60 (30.5)	108 (33.8)	
Main Occupation				
Agriculture/housework	288 (55.7)	113 (57.4)	175 (54.7)	0.552
Other occupation	229 (44.3)	84 (42.6)	145 (45.3)	
Education level				
Primary or lower	377 (72.9)	137 (69.5)	240 (75.0)	0.175
Secondary or higher	140 (27.1)	60 (30.5)	80 (25.0)	
Alcohol use at last sex				
Yes	136 (26.3)	64 (32.5)	72 (22.5)	0.012
No	381 (73.7)	133 (67.5)	248 (77.5)	
Condom Use in last 12 months				
Consistent	98 (19.0)	28 (14.2)	70 (21.9)	0.031
Inconsistent	419 (81.0)	169 (85.8)	250 (78.1)	
No of sexual partners				
1 partner	419 (81.0)	161 (81.7)	258 (80.6)	0.756
2 or more partners	98 (19.0)	36 (18.3)	62 (19.4)	
Condom use at last sex				
Yes	168 (32.5)	55 (27.9)	113 (35.3)	0.081
No	349 (67.5)	142 (72.1)	207 (64.7)	

*P-value from chi-square test

Table 2. Association (crude odds ratios, 95% Confidence Intervals) between sociodemographic factors, ART treatment status and inconsistent condom use in a sample of 517 HIV positive patients in Rakai; results of logistic regression.

	Consistent n (%)	*Inconsistent/no condom use n (%)*	*Crude ORs (95% CI)*	*P-value**
ART treatment status				
ART naïve	28 (28.6)	169 (40.3)	1.69 (1.04-2.73)	0.031
ART experienced	70 (71.4)	250 (59.7)	1 (ref group)	
Sex				
Male	33 (33.7)	143 (34.1)	1.02 (0.64-1.62)	0.932
Female	65 (66.3)	276 (65.9)	1 (ref group)	
Age				
25-34	26 (26.5)	180 (43.0)	0.32 (0.041-2.43)	0.268
35-50	71 (72.4)	217 (51.8)	0.13 (0.02-1.04)	0.056
18-24	1 (4.3)	22 (5.3)	1 (ref group)	
Marital status				
Married	56 (57.1)	293 (69.9)	1.74 (1.11-2.73)	0.016
Not married	42 (42.9)	126 (30.1)	1 (ref group	
Education level				
Primary level	68 (69.4)	309 (73.7)	1.23 (0.76-2.00)	0.383
Secondary level	30 (30.6)	110 (26.3)	1 (ref group)	
Occupation level				
Agriculture/housework	43 (43.9)	245 (58.5)	1.80 (1.15-2.80)	0.009
Other occupation	55 (56.1)	174 (41.5)	1 (ref group)	

*P-value from chi-square test

Table 3; Association (crude odds ratios, 95% Confidence Intervals) between sociodemographic factors, ART treatment status and alcohol use at last sex in a sample of 517 HIV positive patients in Rakai; results of logistic regression

	Alcohol use Yes n (%)	*Alcohol use No n (%)*	*Crude ORs (95% CI)*	*Pvalue**
ART treatment status				
ART naive	64 (47.1)	133 (34.9)	1.65 (1.11-2.46)	0.013
ART experienced	72 (52.9)	248 (65.1)	(ref)	
Sex				
Male	75 (55.1)	101 (26.5)	3.40 (2.26-5.12)	< 0.001
Female	61 (44.9)	280 (73.5)	ref	
Age				
35-50	82 (60.3)	206 (54.1)	4.18 (0.95-18.22)	0.057
25-34	52 (38.2)	154 (40.4)	3.54 (0.80-15.63)	0.095
18-24	2 (1.5)	21 (5.5)	ref	
Marital status				
Married	92 (67.6)	257 (67.5)	1.0 (0.66-1.53)	0.967
Not married	44 (32.4)	124 (32.4)	ref	
Education level				
Primary level	106 (77.9)	271 (71.1)	1.43 (0.90-2.27)	0.126
Secondary level	30 (22.1)	110 (28.9)	ref	
Occupation level				
Agriculture/housework	70 (51.5)	218 (57.2)	0.79 (0.53-1.17)	0.247
Other occupation	66 (48.5)	163 (42.8)	ref	

*P-value from chi-square test

Table 4; Association (adjusted odds ratio, 95% Confidence Interval) between inconsistent/no condom use and ART treatment status among 517 HIV positive patients in Rakai; results of multivariate logistic regressions

	Unadjusted OR (95% CI) (Model 1)	Adjusted for age OR (95% CI) (Model 2)	Adjusted for age, occupation OR (95% CI) (Model 3)	Ajusted for age, occupation& marital status OR (95% CI) (Model 4)
ART Treatment Status				
ART naive	1.69 (1.04-2.73)	1.51 (0.92-2.46)	1.48 (0.90-2.42)	1.47 (0.90-2.41)
ART experienced	ref	ref	ref	ref
Age				
35-50		0.15 (0.02-1.15)	0.15 (0.02-1.21)	0.16 (0.02-1.23)
25-34		0.33 (0.43-2.55)	0.34 (0.04-2.72)	0.35 (0.04-2.77)
18-24		ref	ref	ref
Occupation level				
Agriculture/housework			1.79 (1.14-2.81)	1.71 (1.00-2.53)
Other occupation	ref	ref	ref	ref
Marital status				
Married				1.59 (1.00-2.53)
Not married				ref

Model 1: unadjusted model
Model 2: adjusted for age
Model 3: adjusted for age, occupation
Model 4 Adjusted for age, occupation & marital status;

Table 5: Association (adjusted odds ratio, 95% Confidence Interval) between alcohol use at last sex and ART treatment status among 517 HIV positive patients in Rakai; results of multivariate logistic regression

	Unadjusted OR (95% CI) (Model 1)	Adjusted for sex OR (95% CI) (Model 2)	Adjusted for age & sex OR (95% CI) (Model 3)
ART Treatment Status			
ART naive	1.65 (1.11-2.46)	1.72 (1.14-2.61)	1.80 (1.18-2.74)
ART Experienced	ref	ref	ref
Sex			
Male		3.47 (2.30-5.23)	3.29 (2.17-4.99)
Female		ref	ref
Age			
35-50			3.34 (0.74-15.03)
25-34			2.95 (0.65-13.35)
18-24			ref

Model 1: unadjusted model
Model 2: adjusted for sex
Model 3: adjusted for age, sex

Conceptual Framework:

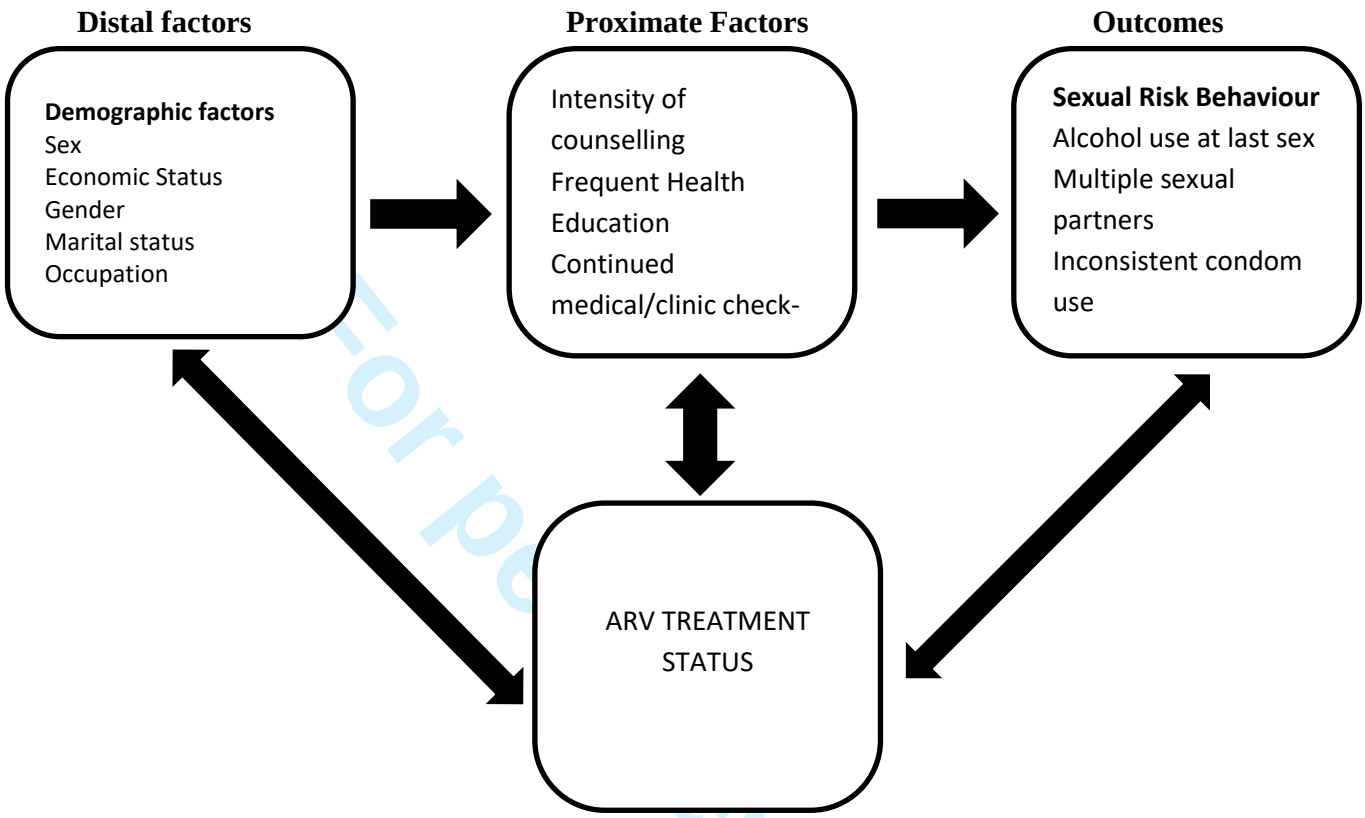

Figure 1: Conceptual framework showing the relationship between factors that may contribute to differences in sexual risk behaviours among HIV positive persons in rural Rakai, Uganda

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*

Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any pre-specified hypotheses	5
Methods			**5**
Study design	4	Present key elements of study design early in the paper	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*6*
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	6-7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7
		(*b*) Describe any methods used to examine subgroups and interactions	7
		(*c*) Explain how missing data were addressed	7
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	7

		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
Results			7-8
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	7-8
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7-8
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	8
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10
Generalisability	21	Discuss the generalisability (external validity) of the study results	10
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

A cross-sectional comparative study of risky sexual behaviours among HIV infected persons initiated and waiting to start antiretroviral therapy in rural Rakai, Uganda.

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A cross-sectional comparative study of risky sexual behaviours among HIV infected persons initiated and waiting to start antiretroviral therapy in rural Rakai, Uganda.

Author:

1. Lydia Jacenta Nakiganda[1] lydianakiganda85@gmail.com
2. Benedict Oppong Asamoah[2] benedict_oppong.asamoah@med.lu.se
3. Joseph Kagaayi[3] jkagayi@rhsp.org
4. Fred Nalugoda[3] fnalugoda@rhsp.org
5. David Serwadda[4] dserwada@infocom.co.ug
6. Nelson Sewakambo[5] sewankam@infocom.co.ug
7. Ronald Gray[6] rgray4@jhu.edu
8. Anthony Ndyanabo[3] andyanabo@rhsp.org
9. Richard Muwanika[3] rmuwanika@rhsp.org
10. Gertrude Nakigozi[3] ftrudie@rhsp.org

Corresponding author:

Lydia Jacenta Nakiganda
Spangatan 37B, lgh 1103, 21153, Malmo, Sweden
lydianakiganda85@gmail.com

Institutions and departments:

[1]International Master Programme in Public Health, Faculty of Medicine, Lund University, CRC, Jan Waldenströms gata 35, 205 02 Malmö, Sweden

[2]Social Medicine and Global Health, Department of Clinical Sciences, Malmö, Lund University, Sweden.

[3]Rakai Health Sciences Program, Uganda,

[4]Makerere University School of Public Health, Kampala Uganda

[5]Makerere University College of Health Sciences, Kampala Uganda

[6]John Hopkins University, Bloomberg, School of Public Health, USA.

A cross-sectional comparative study of risky sexual behaviours among HIV infected persons initiated and waiting to start antiretroviral therapy in rural Rakai, Uganda.

Abstract:

Objectives:

To compare risky sexual behaviours between HIV positive persons initiated on ART (ART experienced) and persons waiting to start on ART (ART naive) and assess predictors of risky sexual behaviours among HIV- infected patients in rural Rakai district, Uganda.

Study Design:

This is a cross-sectional study that derived data from Rakai Community Cohort Study (RCCS) database collected between 2013 and 2014. A structured questionnaire was used for data collection. Stepwise logistic regression was used to estimate the adjusted odds ratios (adjOR)) for the association between risky sexual behaviors and ART treatment status.

Study setting:

This study was conducted in Rakai district, located in south western Uganda. The data for this study was extracted from the Rakai Community Cohort Study (RCCS). RCCS is a open prospective cohort of approximately 15,000 consenting participants aged 15–49 years.

Participants:

HIV positive participants aged between 18–49 that had sex at least once a month with any partner (sexually active) prior to the start of the study.

Main Outcome Measures: Inconsistent/no condom use in the last 12 months, alcohol use at last sex, and two or more sexual partners.

Results;

ART naive participants were more likely to report inconsistent/no condom use (OR=1.74, 95% CI 1.11–2.73) and more likely to drink alcohol at last sex (OR= 1.65, 95% CI 1.11–2.46),

compared to ART experienced patients. Inconsistent/no condom use and alcohol use with sex were more frequent in males than females (adjOR=1.47, 95 % CI 0.90–2.41, and 1.80, 95% CI 1.18–2.74) respectively. ART treatment status (P=0.03, P<0.001) was a significant predictor of risky sexual behaviours. Both marital status (P=0.016) and occupation level (P=0.009) were positively associated with inconsistent condom use while sex (P<0.001) correlated with alcohol use at last sex.

Conclusion

ART naive participants were more likely to exhibit risky sexual behaviours than the ART experienced participants. The intensity of risk reduction counselling should be increased for HIV positive persons waiting to start ART but already in HIV care.

Keywords: Antiretroviral therapy; Sexual behaviour; HIV transmission; HIV; Uganda

Strength and Limitations of the study:

- The use of data from a prospective population-based study cohort with a high participation rate of over 90% that captured a representative sample of the sexually active HIV positive population in 54 surveyed communities makes the findings generalizable.
- Risky sexual behaviours estimates are based on self-reported measures, which are subject to social desirability and recall bias.
- Reporting condom use in the last 12 months may not always accurately characterize participant's overall condom use due to the long periods of measurement.
- This study did not consider the time element; CD4 cell count and calendar years as well as time on ART, which may be factors that correlate with risk sexual behaviour.
- The period of observation was restricted to one survey round which may not necessarily give accurate changes in exposure time measurements.

Introduction:

Improved access to effective antiretroviral therapy (ART) has led to declines in morbidity and mortality rates among people living with HIV (PLHIV) (1,2). ART is highly effective in reducing plasma levels of HIV RNA and reducing incidence of HIV related opportunistic infections (3,4), hence people living with HIV on ART (ART experienced) now live longer (5,6). Despite the beneficial effects of ART, risk of transmission is not completely eliminated particularly for those who do not have complete viral suppression, and transmission from those with undetectable viral load has been documented (7,8).

The beneficial effects of ART; the slow disease progression and reduced viral load has been associated with optimism as HIV positive people perceive HIV as no longer life threatening (9,10) and many are aware that with treatment, HIV is a chronic manageable disease (11,12). This optimism has been associated with increases in risky sexual behaviours (i.e., sexual behaviours that have increased likelihood of HIV transmission) (9,13,14). In addition, the general physical health improvement and increased survival that follow ART may be accompanied by an increase in sexual desire and activity (15,16) which can lead to onward HIV transmission.

Although ART prevents HIV transmission through reduced infectivity (4), there could be an offset brought about by risk sexual behaviours (17). Cell associated genital HIV shedding may occur in people with low HIV viral load (18,19) allowing for potential transmission of drug resistant strains (20). HIV transmission from people on ART will usually depend on the effectiveness of ART in reducing viral load and the efficiency of ART programs in reducing risky sexual behaviours.

Worldwide, risky sexual behaviours continue to be reported among PLHIV (21-24) increasing chances of transmission of drug resistant strains from HIV-infected persons with incomplete viral suppression (20). It is estimated that about 7–17% of newly infected persons in high-income countries (25) and 4.8–6.8% in low and middle-income countries (26) carry at least one major drug resistance mutation. These resistant strains are not responsive to first line ARV therapy (20,27), and may require second-line ART regimes which are prohibitively expensive in

low-income countries. In addition, there is a risk of superinfection with drug resistant strains that has been reported among PLHIV (28,29). Therefore, understanding risky sexual behaviours among HIV positive persons is of great public health importance as it can provide useful insights in preventing further HIV transmission and enable PLHIV lead healthy lives.

Risky sexual behaviours have been reported among PLHIV in Uganda (15,30-32). Early sexual debut, multiple sexual partnerships, limited and inconsistent condom use, sex under the influence of alcohol, childhood marriages and transactional cross-generational sex constitute the main risky behaviours currently driving the HIV epidemic in Uganda (33-35). In Uganda, ART is provided to all patients with a confirmed HIV diagnosis and CD4 count below 500 cells/mm^3, or at time of diagnosis among sex workers, fisher-folk, pregnant mothers, those infected with TB, children less than 15 years and sero-discordant couples, per the Ugandan Ministry of Health guidelines (36). While in Kenya, ART treatment coverage is at 59% (37), Uganda's ART treatment coverage is still suboptimal with only about 775,212 patients out of ~1.5 million infected persons (51%) on ART as of 2015 (38). Due to the increasing availability of ART in Uganda, an increasing number of PLHIV are expected to live extended periods, so changes in their risky sexual behaviours could have an impact on HIV transmission.

The characteristics and behaviours of ART naïve (persons waiting to start ART) have received less attention maybe because they are not required to visit clinics oftenly for HIV care unlike the ART experienced persons (those on ART). Most of the reviews done in Uganda have investigated risky sexual behaviours focused more on people already enrolled on ART (30,39,40), and have not done so for those not yet started on ART. The comparison between these two groups remains largely undocumented.

This study therefore compares risky sexual behaviours among ART naïve and ART experienced persons and explores the potential predictors of risky sexual behaviours among PLHIV attending an HIV treatment and care program in Rakai.

Conceptual framework:

In summary, the conceptual framework (Supplemantary Figure 1) illustrates the possible factors for PLHIV to engage in risky sexual behaviour. In understanding these various factors

influencing risky sexual behaviour, this model suggests two sets of characteristics; distal factors and proximate factors. The distal factors (age, educational level, occupation, socioeconomic status, gender, ARV treatment status) and proximate factors (intensity of counselling, frequent health education, medical check-ups) are considered as independent factors affecting risky sexual behaviours which is the dependent variable (outcome). Intensity of counselling, frequent health education and continued medical check-ups could predict risky sexual behaviours. This has been seen in studies conducted in other low-income settings that predict intensity of behavioural change counselling and health education (41,42), medical check-ups and frequent hospital visits (43) as factors in the reduction of risky sexual behaviours among people living with HIV.

Using this conceptual framework, it is hypothesized that ART experienced persons (those on ART) are more likely to drink alcohol at last sex, have multiple sexual partners and use condoms inconsistently with any sexual partner. Thus it is predicted that proximate factors will moderate the differences in the risky sexual behaviours between ART naïve and ART experienced persons.

Methods:

This cross-sectional study was conducted among HIV positive persons in Rakai, a rural district located in southwestern Uganda. Rakai district has a population of 518,008, with 80% of the population being agriculturalists (44). The data for this study was extracted from the Rakai Community Cohort Study (RCCS). RCCS is a prospective cohort which has been described previously (45,46). It is an open population-based cohort of approximately 15,000 consenting participants aged 15-49 years with an overall adult HIV prevalence of 13% (47). Serosurveys have been conducted every 12-20 months since 1994. Structured interviews are administered by same sex interviewers and participants provide blood samples for HIV serology and diagnosis of other sexually transmitted infections. Interviews establish information on socio-demographic characteristics, sexual behaviours, health and contextual characteristics. In this cross-sectional study, data were from Round 15 (2013-2014).

Eligibility criteria

Participants were eligible to participate in the study if they had tested HIV positive, were on ART or were ART naive but in care, and had sex at least once a month with any partner (sexually active) prior to the start of the study. Only HIV-sero-concordants were included in this study irrespective of marital status

Variables;

The outcome variables in this study were risky sexual behaviours. Risky sexual behaviours in this study are described as any sexual behaviour that increases the likehood of contracting an STI or HIV. In this study; two or more sexual partners, alcohol use at last sex, inconsistent condom use in the last 12 months are described as risky sexual behaviours. The independent variables included socio-demographics and ART treatment status.

Dependent/ outcome variables;

Inconsistent/no condom use was defined from a question about frequency of condom use in the last 12 months. The response alternatives were dichotomized as consistent condom use and inconsistent/no condom use for those who responded that they 'sometimes' or 'never" used condoms. Alcohol use at last sex was dichotomized as 'yes' and 'no'. Two or more sexual partners were defined as having either serial or concomitant partners within the past 12 months. Risky sex was described as those participants that either used condoms inconsistently, drank alcohol at last sex or had two or more sexual partners in the last 12 months.

Independent Variables;

Previous studies (48-50) identified several predictors associated with risky sexual behaviours among PLHIV. In this study, these variables were expected to correlate with risky behaviours among PLHIV; ART treatment status which was recorded as ART naive; people diagnosed as HIV positive and referred for HIV care but are not yet started on antiretroviral treatment or ART experienced status; people already enrolled on ART. Education level classified as primary school level/did not attend school or secondary level or higher. Current marital status was categorized as currently married or unmarried. Age was grouped into 3 categories; 18-24, 25-34 and 35-50 years. Occupation was dichotomized into agriculture or any other occupation.

Ethical consideration:

The Rakai Community Cohort Study (RCCS) was approved by the Research and Ethics Committee of the Uganda Virus Research Institute, the Uganda National Council of Science and Technology and US-based Western IRB. Written informed consent was obtained from all research participants. For this study, no additional consent was needed as it is secondary data analysis.

Statistical methods

IBM SPSS statistics version 21 for windows was used for statistical analysis. Contingency tables were used for bivariate analyses to examine associations between outcome variables (sexual behaviors) and co-variates, and chi square tests used for statistical inference. All co-variates statistically significant in bivariate analyses were included in the multivariable analyses. Multivariable logistic regression was used to estimate adjusted odds ratios (adjOR) and 95% confidence intervals (CI) using stepwise selection and statistical significance was based on a p-value less than 0.05.

Results:

Table 1 describes the characteristics of the study participants stratified by ARV treatment status. There were 341 (66%) females and 176 (34%) males. The majority of participants were married (67.5%), agriculturalists 55.7%, had primary or no education (72.9%), and 55.7% were between 35-50 years of age. The mean age of the respondents was 35.6 years (SD=6.67).

ART naive participants reported a higher percentage of inconsistent or no condom use (85.8%) compared to ART experienced (78.1%) and the difference was statistically significant (p=0.031). Alcohol use at last sex was reported by ART experienced (22.5%) and ART naïve participants (32.5%; p=0.012). Having 2 or more sexual partners were similar among ART experienced (19.4%) and ART-naïve persons 18.3% (p=0.756), while somewhat more ART naïve participants did not use condoms at last sex compared to ART experienced participants (72.1% vs 64.7%, respectively; p=0.081).

For the bivariate analyses (Table 2), inconsistent/no condom use was higher among the ART naive compared to the ART experienced participants (OR=1.69, 95% CI 1.04 – 2.73), and

inconsistent/no condom use was more frequent among women compared to men (65.9 % vs 34.1% p=0.932). Agriculturalists were more likely to report no or inconsistent condom use than any other occupations (OR=1.80, 95% CI 1.15 – 2.80). Additionally, ART naïve participants had higher odds of drinking alcohol at last sex compared to ART experienced participants (OR=1.65, 95% CI 1.11 – 2.46) (Table 3). Men were more likely to use alcohol at last sex compared to women (OR=3.40, 95% CI 2.26 – 5.12) (Table 3).

Three predictor variables (Table 2) were significantly associated with inconsistent condom use; ART treatment status (P=0.031), marital status (P=0.016) and occupation level (P=0.009). Table 3 shows both sex (P < 0.001) and ART treatment status (P=0.013) as significant predictors in drinking alcohol at last sex.

In the final multivariate model (Table 4), the association between inconsistent condom use and ART treatment status remained statistically significant after adjusting for age, occupation and marital status (adj OR = 1.47 95% CI 0.90 – 2.41, model 4). Age and sex were significantly associated with alcohol use with sex (adjOR = 3.47 95 % CI 2.30-5.23), age (OR = 3.34 95% CI 0.74 – 15.03) (Table 5)

Discussion:

Findings from this study reveal ART naive participants having slightly increasing odds of practising risky sexual behaviours compared to participants on ART. This is similar to other studies done that showed ART naïve patients were more likely to practice risky sexual behaviours than the ART experienced patients (15,51). These differences could be attributed to the differences in counselling intensity, health education and follow-ups given to patients on ART more frequently than ART naive patients (patients on ART are required to visit the clinic more frequently than those on ART).

Sex and age are significant predictors of risk sexual behaviors among HIV positive patients (P=< 0.001) in this study. This is related to studies done before that have either identified sex or age as significant predictors of risky sexual behaviours (50-52).

Overall, almost 81% (overall) of study participants reported inconsistent condom use, which indicates high prevalence of unsafe sex among HIV positive people. This highlights the dangers of continued HIV transmission despite the increasing ART roll out. Therefore, this calls for

increasing awareness and motivation of condom use among HIV positive patients. Additionally, inconsistent condom use was more likely among ART naïve patients, a finding similar to earlier studies in Uganda (15) Kenya (53) and South Africa (51). These findings could be due to more secondary HIV prevention programs given to ART experienced patients as they visit ART clinics oftenly for refills and medical check-ups.

Inconsistent condom use was higher among women than in men (65.9% vs 34.1%) in this study. This is similar to studies done in Italy that showed almost 44.3% of HIV positive women were incosistence condom users (54). This could reflect the limitations of female bargaining power within sexual relationships. A central feature of Ugandan society is gender inequality, with women occupying subordinate roles both in economic activities and in decision-making. Women are not culturally empowered to negotiate sexually related issues and this pattern of male control of sexual decision-making was also noted in Uganda and Rwanda (55,56). However, inconsistent condom use in this group could also be attributed to the desire to have children. Studies (57,58) have shown reproductive desires play a significant role in the lives of HIV positive women. Therefore, these gender differences highlight a need for better understanding and incorporating gender dynamics in secondary prevention strategies in order to meet the specific needs of both women and men.

We observed almost 26% of HIV positive patients drank alcohol before sex. This is a health concern because alcohol use among HIV positives has been associated with decreased adherence to ARV (59,60) and reduced patient's ability to practice safer sex (61) . Additionally, ART naive participants were more likely to use alcohol at last sex compared to ART experienced participants. This could be explained by the fact that once people are started on ART, they are advised not to take or take limited alcohol to preserve the integrity of their liver (62,63), so that the ARVs are well processed in the body. Another reason could be the guidelines and adherence support counselling given by health workers when on ART. This is line with a study that reported decreased alcohol consumption after ART initiation (64) and higher odds of alcohol use during the pre-ART period (32).

Males were three times more likely to drink alcohol at last sex in this study. This could be attributed to the common social values and the acceptance of male drinking in society. A Ugandan study reported 41% of males use alcohol before sex (65). It is recommended that

addressing alcohol abuse should be a key focus in secondary prevention interventions. Health care providers should screen their HIV patients for alcohol use problems and initiate interventions that can reduce alcohol related problems among people living with HIV. More research is needed to find and test different behavioural, social and biomedical interventions for alcohol related problems among people living with HIV.

In relation to other studies in sub-Saharan Africa (66-68) this study found that participants with primary or lower level education were more likely to use condoms inconsistently. This could be explained by the fact that participants with higher education are more likely to have higher knowledge of HIV and are more informed.

Methodological considerations:

The use of data from a prospective population-based study cohort with a high participation rate of over 90%, that captured a representative sample of the sexually active HIV positive population in 54 surveyed communities in rural Rakai was a notable strength. However this study had limitiations; Firstly, this was a cross-sectional study and could not derive causal inferences. Secondly, sexual risk behaviour estimates are based on self-reported measures, which are subject to social desirability and recall bias. However, a study done in Uganda showed large cohort studies have correlations between behavioural self-reported measures and HIV infection and thus suggest that recall bias does not necessarily conceal key associations (69) thus it is less likely that these potential biases would impact differences between the two groups. Thirdly, reporting condom use in the last 12 months may not always accurately characterize patient's overall condom use due to the long periods of measurement. The frequency of condom use as well as recalling sexual encounters in the last 12-18 months since the last survey done might affect people's ability to accurately answer and remember details of sexual encounters. However, findings from other shorter time periods do not necessarily differ from the findings of this study which maybe a minor factor (70). Fourthly, this study did not consider the time element; CD4 cell count and calendar years as well as time on ART which may be factors that correlated with risk sexual behaviour. In addition, the period of observation was restricted to one survey round which may not necessarily give accurate changes in exposure time measurements.

Conclusion:

This study indicates that ART naive participants have slightly increased odds of risky sexual behaviours compared to participants on ART. These differences may be attributed to the variability in counselling intensity, health education and follow-ups offered to patients on ART. Though findings reveal higher odds of risky sexual behaviours among ART naive persons, rates of risky behavior are high for both groups, and positive prevention programs should be able to target both groups.

Focused interventions such as risk reduction counselling and education programmes are required to be incorporated in HIV care and treatment programs and emphasis should be laid on counselling to avoid re-infections and alcohol abuse. The roll out of ART should not be considered as a single preventive intervention but should be facilitated with other elements such as psychosocial support, gender dynamics, mental health services, nutrition and family planning to ensure a successful HIV fight. Better understanding of the underlying mechanisms and correlations of such high-risk sexual behavior among persons living with HIV remains a priority for researchers and public health professionals alike.

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Author's Contributions:

LNJ conceptualized the study, designed, analyzed and drafted the first version of the manuscript. BOA and GN were involved in the analysis, interpretation and critical review of the manuscript. JK, FN, DS, NS were involved in revising the article critically for important intellectual content. RN edited and approved the final version to be published. AN was involved in the acquisition of data, data analysis and interpretation of the data.

Data sharing statement:

The data sets used for this study are available on request from the Rakai Community Cohort Study Data base at Rakai Health Sciences Program. (www.rhsp.org)

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Table 1; Baseline socio demographic and sexual behaviour characteristics for 517 participants in a longitudinal cohort study of People living with HIV in a rural district, Rakai, Uganda

Characteristics	Overall (%)	ART Naive (%)	ART Experienced (%)	P-value*
Overall		197 (38.1)	320 (61.9)	
Sex				
Female	341(66.0)	130 (66.0)	211 (65.9)	0.990
Male	176 (34.0)	67 (34.0)	109 (34.1)	
Age (years)				
Mean (SD)	35.55 (6.48)	36.34 (6.25)	34.27 (6.60)	< 0.001
Median (IQR)	35.0 (31-40)	37 (30-41)	34 (30-39)	
Age group (years)				
18-24	23 (4.4)	13 (6.6)	10) (3.1)	0.004
25-34	206 (39.8)	91 (46.2)	115 (35.9)	
35-50	288 (55.7)	93 (47.2)	195 (60.9)	
Marital status				
Married	349 (67.5)	137 (69.5)	212 (66.3)	0.438
Not Married	168 (32.5)	60 (30.5)	108 (33.8)	
Main Occupation				
Agriculture/housework	288 (55.7)	113 (57.4)	175 (54.7)	0.552
Other occupation	229 (44.3)	84 (42.6)	145 (45.3)	
Education level				
Primary or lower	377 (72.9)	137 (69.5)	240 (75.0)	0.175
Secondary or higher	140 (27.1)	60 (30.5)	80 (25.0)	
Alcohol use at last sex				
Yes	136 (26.3)	64 (32.5)	72 (22.5)	0.012
No	381 (73.7)	133 (67.5)	248 (77.5)	
Condom Use in last 12 months				
Consistent	98 (19.0)	28 (14.2)	70 (21.9)	0.031
Inconsistent	419 (81.0)	169 (85.8)	250 (78.1)	
No of sexual partners				
1 partner	419 (81.0)	161 (81.7)	258 (80.6)	0.756
2 or more partners	98 (19.0)	36 (18.3)	62 (19.4)	
Condom use at last sex				
Yes	168 (32.5)	55 (27.9)	113 (35.3)	0.081
No	349 (67.5)	142 (72.1)	207 (64.7)	

*P-value from chi-square test

Table 2. Association (crude odds ratios, 95% Confidence Intervals) between sociodemographic factors, ART treatment status and inconsistent condom use in a sample of 517 HIV positive patients in Rakai; results of logistic regression.

	Consistent n (%)	*Inconsistent/no condom use n (%)*	*Crude ORs (95% CI)*	*P-value**
ART treatment status				
ART naïve	28 (28.6)	169 (40.3)	1.69 (1.04-2.73)	0.031
ART experienced	70 (71.4)	250 (59.7)	1 (ref group)	
Sex				
Male	33 (33.7)	143 (34.1)	1.02 (0.64-1.62)	0.932
Female	65 (66.3)	276 (65.9)	1 (ref group)	
Age				
25-34	26 (26.5)	180 (43.0)	0.32 (0.041-2.43)	0.268
35-50	71 (72.4)	217 (51.8)	0.13 (0.02-1.04)	0.056
18-24	1 (4.3)	22 (5.3)	1 (ref group)	
Marital status				
Married	56 (57.1)	293 (69.9)	1.74 (1.11-2.73)	0.016
Not married	42 (42.9)	126 (30.1)	1 (ref group	
Education level				
Primary level	68 (69.4)	309 (73.7)	1.23 (0.76-2.00)	0.383
Secondary level	30 (30.6)	110 (26.3)	1 (ref group)	
Occupation level				
Agriculture/housework	43 (43.9)	245 (58.5)	1.80 (1.15-2.80)	0.009
Other occupation	55 (56.1)	174 (41.5)	1 (ref group)	

*P-value from chi-square test

Table 3; Association (crude odds ratios, 95% Confidence Intervals) between sociodemographic factors, ART treatment status and alcohol use at last sex in a sample of 517 HIV positive patients in Rakai; results of logistic regression

	Alcohol use Yes n (%)	*Alcohol use No n (%)*	*Crude ORs (95% CI)*	*Pvalue**
ART treatment status				
ART naive	64 (47.1)	133 (34.9)	1.65 (1.11-2.46)	0.013
ART experienced	72 (52.9)	248 (65.1)	(ref)	
Sex				
Male	75 (55.1)	101 (26.5)	3.40 (2.26-5.12)	< 0.001
Female	61 (44.9)	280 (73.5)	ref	
Age				
35-50	82 (60.3)	206 (54.1)	4.18 (0.95-18.22)	0.057
25-34	52 (38.2)	154 (40.4)	3.54 (0.80-15.63)	0.095
18-24	2 (1.5)	21 (5.5)	ref	
Marital status				
Married	92 (67.6)	257 (67.5)	1.0 (0.66-1.53)	0.967
Not married	44 (32.4)	124 (32.4)	ref	
Education level				
Primary level	106 (77.9)	271 (71.1)	1.43 (0.90-2.27)	0.126
Secondary level	30 (22.1)	110 (28.9)	ref	
Occupation level				
Agriculture/housework	70 (51.5)	218 (57.2)	0.79 (0.53-1.17)	0.247
Other occupation	66 (48.5)	163 (42.8)	ref	

*P-value from chi-square test

Table 4; Association (adjusted odds ratio, 95% Confidence Interval) between inconsistent/no condom use and ART treatment status among 517 HIV positive patients in Rakai; results of multivariate logistic regressions

	Unadjusted OR (95% CI) (Model 1)	Adjusted for age OR (95% CI) (Model 2)	Adjusted for age, occupation OR (95% CI) (Model 3)	Ajusted for age, occupation& marital status OR (95% CI) (Model 4)
ART Treatment Status				
ART naive	1.69 (1.04-2.73)	1.51 (0.92-2.46)	1.48 (0.90-2.42)	1.47 (0.90-2.41)
ART experienced	ref	ref	ref	ref
Age				
35-50		0.15 (0.02-1.15)	0.15 (0.02-1.21)	0.16 (0.02-1.23)
25-34		0.33 (0.43-2.55)	0.34 (0.04-2.72)	0.35 (0.04-2.77)
18-24		ref	ref	ref
Occupation level				
Agriculture/housework			1.79 (1.14-2.81)	1.71 (1.00-2.53)
Other occupation	ref	ref	ref	ref
Marital status				
Married				1.59 (1.00-2.53)
Not married				ref

Model 1: unadjusted model
Model 2: adjusted for age
Model 3: adjusted for age, occupation
Model 4 Adjusted for age, occupation & marital status;

Table 5: Association (adjusted odds ratio, 95% Confidence Interval) between alcohol use at last sex and ART treatment status among 517 HIV positive patients in Rakai; results of multivariate logistic regression

	Unadjusted OR (95% CI) (Model 1)	Adjusted for sex OR (95% CI) (Model 2)	Adjusted for age & sex OR (95% CI) (Model 3)
ART Treatment Status			
ART naive	1.65 (1.11-2.46)	1.72 (1.14-2.61)	1.80 (1.18-2.74)
ART Experienced	ref	ref	ref
Sex			
Male		3.47 (2.30-5.23)	3.29 (2.17-4.99)
Female		ref	ref
Age			
35-50			3.34 (0.74-15.03)
25-34			2.95 (0.65-13.35)
18-24			ref

Model 1: unadjusted model
Model 2: adjusted for sex
Model 3: adjusted for age, sex

Conceptual Framework:

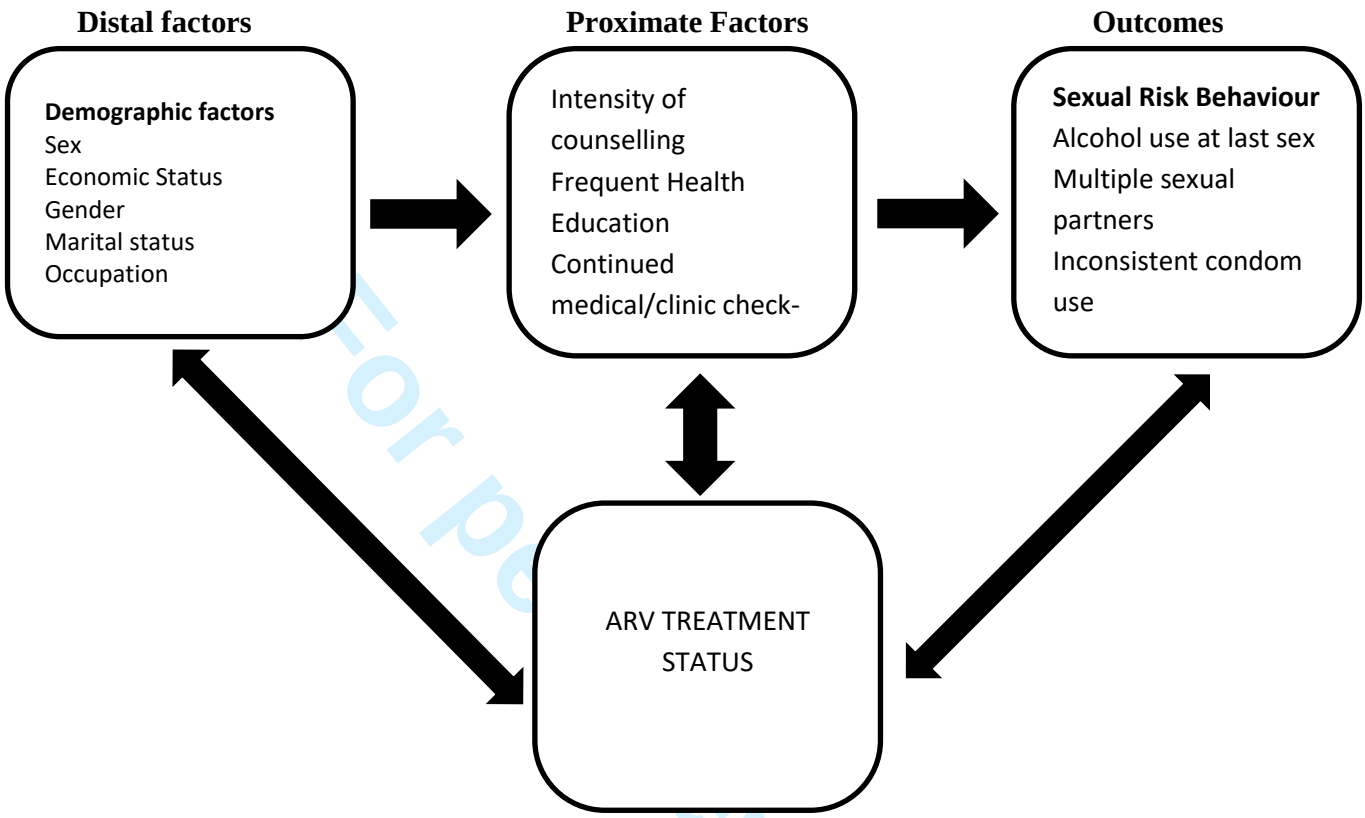

Figure 1: Conceptual framework showing the relationship between factors that may contribute to differences in sexual risk behaviours among HIV positive persons in rural Rakai, Uganda

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*

Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any pre-specified hypotheses	5
Methods			**5**
Study design	4	Present key elements of study design early in the paper	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*6*
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	6-7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7
		(*b*) Describe any methods used to examine subgroups and interactions	7
		(*c*) Explain how missing data were addressed	7
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	7

		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
Results			7-8
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	7-8
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7-8
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	8
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10
Generalisability	21	Discuss the generalisability (external validity) of the study results	10
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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A cross-sectional comparative study of risky sexual behaviours among HIV infected persons initiated and waiting to start antiretroviral therapy in rural Rakai, Uganda.

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A cross-sectional comparative study of risky sexual behaviours among HIV infected persons initiated and waiting to start antiretroviral therapy in rural Rakai, Uganda.

Author:

1. Lydia Jacenta Nakiganda[1] lydianakiganda85@gmail.com
2. Gertrude Nakigozi[2] ftrudie@rhsp.org
3. Joseph Kagaayi[2] jkagayi@rhsp.org
4. Fred Nalugoda[2] fnalugoda@rhsp.org
5. David Serwadda[3] dserwada@infocom.co.ug
6. Nelson Sewakambo[4] sewankam@infocom.co.ug
7. Ronald Gray[5] rgray4@jhu.edu
8. Anthony Ndyanabo[2] andyanabo@rhsp.org
9. Richard Muwanika[2] rmuwanika@rhsp.org
10. Benedict Oppong Asamoah[6] benedict_oppong.asamoah@med.lu.se

Corresponding author:

Lydia Jacenta Nakiganda
Spangatan 37B, lgh 1103, 21153, Malmo, Sweden
lydianakiganda85@gmail.com

Institutions and departments:

[1]International Master Programme in Public Health, Faculty of Medicine, Lund University, CRC, Jan Waldenströms gata 35, 205 02 Malmö, Sweden

[2]Rakai Health Sciences Program, Uganda,

[3]Makerere University School of Public Health, Kampala Uganda

[4]Makerere University College of Health Sciences, Kampala Uganda

[5]John Hopkins University, Bloomberg, School of Public Health, USA.

[6]Social Medicine and Global Health, Department of Clinical Sciences, Malmö, Lund University, Sweden.

A cross-sectional comparative study of risky sexual behaviours among HIV infected persons initiated and waiting to start antiretroviral therapy in rural Rakai, Uganda.

ABSTRACT

Objectives

To compare risky sexual behaviours between HIV positive persons initiated on ART (ART experienced) and persons waiting to start on ART (ART naive) and assess predictors of risky sexual behaviours among HIV-infected patients in rural Rakai district, Uganda.

Study Design

This is a cross-sectional study that used data from the Rakai Community Cohort Study (RCCS) database between 2013 and 2014. A structured questionnaire was used for data collection. We used stepwise logistic regression as an index to estimate the adjusted odds ratios (adjOR)) for the association between risky sexual behaviors and ART treatment status.

Study setting

This study was conducted in Rakai district, located in south western Uganda. The data for this study was extracted from the Rakai Community Cohort Study (RCCS). RCCS is an open prospective cohort of approximately 15,000 consenting participants aged 15–49 years.

Participants

HIV positive participants aged 18–49 years that had sex at least once a month with any partner prior to the start of the study.

Main Outcome Measures

Inconsistent/no condom use in the last 12 months, alcohol use at last sexual encounter, and two or more sexual partners.

Results

ART naive participants were more likely to report inconsistent condom use (OR=1.74, 95% CI 1.11–2.73) and more likely to drink alcohol at last sexual encounter (OR= 1.65, 95% CI 1.11–2.46), compared to ART experienced patients. ART treatment status (p<0.001) was a significant predictor of risky sexual behaviours. Both marital status (p=0.016) and occupation level (p=0.009) were positively associated with inconsistent condom use; while sex (p<0.001) correlated with alcohol use at last sexual encounter.

Conclusion

ART naive participants were more likely to exhibit risky sexual behaviours than the ART experienced participants. The intensity of risk reduction counselling should be increased for HIV positive persons waiting to start ART but already in HIV care.

Keywords: Antiretroviral therapy; Sexual behaviour; HIV transmission; HIV; Uganda

Strengths and Limitations of this study:

- Use of data from a prospective population-based study cohort, with a high participation rate of over 90%; capturing a representative sample of the sexually active HIV positive population in 54 surveyed communities. Findings are therefore generalizable and applicable to countrywide policies and interventions.
- Risky sexual behaviours estimates are based on self-reported measures, which are subject to social desirability and recall bias.
- Reporting condom use in the last 12 months may not always accurately characterize participant's overall condom use due to the long periods of measurement.
- This study did not consider the time element, CD4 cell count, calendar years, or time on ART, which may be factors that correlate with risky sexual behaviour.
- The period of observation was restricted to one survey per round, which may not necessarily give accurate changes in exposure time measurements.

INTRODUCTION

Improved access to effective antiretroviral therapy (ART) has led to declines in morbidity and mortality rates among people living with HIV (PLHIV).[1,2] ART is highly effective in reducing plasma levels of HIV RNA and reducing incidence of HIV related opportunistic infections,[3,4] hence people living with HIV and are on ART (ART experienced) now live longer.[5,6] Despite the beneficial effects of ART, risk of transmission is not completely eliminated, particularly for those who do not have complete viral suppression, or transmission from those where an undetectable viral load has been documented.[7,8]

Beneficial effects of ART include slower disease progression and reduced viral load, which has been met with optimism among HIV positive people, as they no longer perceive HIV as a life threatening ailment [9,10] and many are aware that with treatment, HIV is a chronic manageable disease.[11,12] This optimism has been associated with an increase in risky sexual behaviours.[9,13,14] In addition, the general physical health improvement and increased survival that follow ART may be accompanied by an increase in sexual desire and activity,[15,16] which can lead to onward HIV transmission. There could also be an offset brought about by risky sexual behaviours.[17] Cell associated genital HIV shedding may occur in people with low HIV viral load,[18,19] allowing for potential transmission of drug resistant strains.[20] HIV transmission from people on ART will usually depend on the effectiveness of ART in reducing viral load and the efficiency of ART programs in reducing risky sexual behaviours.

Worldwide, risky sexual behaviours continue to be reported among PLHIV,[21-24] increasing chances of transmission of drug resistant strains from HIV-infected persons with incomplete viral suppression.[20] It is estimated that about 7–17% of newly infected persons in high-income

countries [25] and 4.8–6.8% in low and middle-income countries [26] carry at least one major drug resistance mutation. These resistant strains are not responsive to first line ART therapy [20,27] and may require second-line ART regimes, which are prohibitively expensive in low-income countries. In addition, there is a risk of superinfection with drug resistant strains that has been reported among PLHIV.[28,29] Therefore, understanding risky sexual behaviours among HIV positive persons is of great public health importance as it can provide useful insights in preventing further HIV transmission and enable PLHIV to lead healthy lives.

Early sexual debut, multiple sexual partnerships, limited and inconsistent condom use, sex under the influence of alcohol, childhood marriages and transactional cross-generational sex constitute the main risky behaviours currently driving the HIV epidemic in Uganda.[30-32] In Uganda, ART is provided to all patients with a confirmed HIV diagnosis and CD4 count below 500 cells/mm^3, or at time of diagnosis among sex workers, fisher-folk, pregnant mothers, those infected with TB, children less than 15 years and serodiscordant couples, as per the Ugandan ministry of health guidelines.[33] While in Kenya, ART treatment coverage is at 59%,[34] Uganda's ART treatment coverage is still suboptimal with only about 775,212 patients out of ~1.5 million infected persons (51%) on ART as of 2015.[35] With improvements in access to ART and availability in Uganda, an increasing number of PLHIV are expected to live extended periods and healthier lives, so changes in their risky sexual behaviours could have an impact on HIV transmission.

However, the characteristics and behaviours of ART naive persons (waiting to start ART) have received less attention maybe because they are not required to visit clinics more often for HIV care unlike the ART experienced persons (those on ART). Most of the reviews done in Uganda have investigated risky sexual behaviours; with a focus on people already enrolled on ART[36-38]

leaving out those not yet started on ART. The comparison between these two groups remains largely undocumented.

This study therefore compares risky sexual behaviours among ART naïve and ART experienced persons and explores the potential predictors of risky sexual behaviours among PLHIV attending an HIV treatment and care program in Rakai.

Conceptual framework

In summary, the conceptual framework (Supplemantary Figure 1) illustrates the possible factors for PLHIV to engage in risky sexual behaviours. In understanding these various factors influencing risky sexual behaviours, this model suggests two sets of characteristics; distal factors and proximate factors. The distal factors (age, educational level, occupation, socioeconomic status, gender, ARV treatment status) and proximate factors (intensity of counselling, frequent health education, medical check-ups) are considered as independent factors affecting risky sexual behaviours which is the dependent variable (outcome). Intensity of counselling, frequent health education and continued medical check-ups could predict risky sexual behaviours. This has been seen in studies conducted in other low-income settings that predict intensity of behavioural change counselling and health education,[39,40] medical check-ups and frequent hospital visits as factors in the reduction of risky sexual behaviours among people living with HIV.

Using this conceptual framework, it is hypothesized that ART experienced persons (those on ART) are more likely to drink alcohol at their last sexual encounter, have multiple sexual partners and use condoms inconsistently with any sexual partner. Thus it is predicted that proximate factors will moderate the differences in the risky sexual behaviours between ART naïve and ART experienced persons.

METHODS

This cross-sectional study was conducted among HIV positive persons in Rakai, a rural district located in southwestern Uganda. Rakai district has a population of 518,008, with 80% of the population being agriculturalists.[41] The data for this study was extracted from the Rakai Community Cohort Study (RCCS). RCCS is a prospective cohort which has been described previously.[42,43] It is an open population-based cohort of approximately 15,000 consenting participants aged 15–49 years with an overall adult HIV prevalence of 13%.[44] Within this cohort, serosurveys have been conducted every 12–20 months since 1994. Structured interviews are administered by samesex interviewers and participants provide blood samples for HIV serology and diagnosis of other sexually transmitted infections. Interviews establish information on sociodemographic characteristics, sexual behaviours, health and contextual characteristics. In this cross-sectional study, data used was derived from round 15 (2013–2014).

Eligibility criteria

Participants were eligible to participate in the study if they had tested HIV positive, were on ART or were ART naive but in care, and had sex at least once a month with any partner (sexually active) prior to the start of the study. Only HIV seroconcordant persons were included in this study, irrespective of marital status.

Variables

The outcome variables in this study were risky sexual behaviours. Risky sexual behaviours in this study are described as any sexual behaviour that increases the likehood of contracting an STI or HIV. In this study; two or more sexual partners, alcohol use at last sexual encounter and

inconsistent condom use (in the last 12 months) are all described as risky sexual behaviours. The independent variables included; socio-demographics and ART treatment status.

Dependent/ outcome variables

Inconsistent/no condom use was defined from a question about frequency of condom use in the last 12 months. The response alternatives were dichotomized as consistent condom use and inconsistent/no condom use for those who responded that they 'sometimes' or 'never" used condoms. *Alcohol use at last sex* was dichotomized as 'yes' or 'no'. *Two or more sexual partners* were defined as having either serial or concomitant partners within the past 12 months. Risky sex was described as those participants that either used condoms inconsistently, drank alcohol at last sex or had two or more sexual partners in the last 12 months.

Independent Variables

Previous studies[45-47] identified several predictors associated with risky sexual behaviours among PLHIV. In this study, these variables were expected to correlate with risky behaviours among PLHIV; *ART treatment status* which was recorded as ART naive; people diagnosed as HIV positive and referred for HIV care but are not yet started on antiretroviral treatment or ART experienced status; people already enrolled on ART. *Education level* classified as primary school level/did not attend school or secondary level or higher. *Current marital status* was categorized as currently married or unmarried. *Age* was grouped into 3 categories; 18–24, 25–34 and 35–50 years. *Occupation* was dichotomized into agriculture or any other occupation.

Ethical consideration

The Rakai Community Cohort Study (RCCS) was approved by the Research and Ethics Committee of the Uganda Virus Research Institute, the Uganda National Council of Science and Technology and US-based Western IRB. Written informed consent was obtained from all research participants. For this study, no additional consent was needed as it is secondary data analysis.

Statistical methods

IBM SPSS statistics version 21 for windows was used for statistical analysis. Contingency tables were used for bivariate analyses to examine associations between outcome variables (sexual behaviors) and co-variates, and chi-square tests used for statistical inference. All co-variates statistically significant in bivariate analyses were included in the multivariable analyses. Multivariable logistic regression was used to estimate adjusted odds ratios (adjOR) and 95% confidence intervals (CI) using stepwise selection and statistical significance was based on a *p*-value less than 0.05.

RESULTS

Table 1 describes the characteristics of the study participants stratified by ARV treatment status. This study had 341 (66%) females and 176 (34%) males. The majority of participants were married (67.5%), agriculturalists (55.7%), had primary or no education (72.9%), and 55.7% were between 35–50 years of age. The mean age of the respondents was 35.6 years (SD=6.67).

ART naive participants reported a higher percentage of inconsistent or no condom use (85.8%) compared to ART experienced (78.1%) and the difference was statistically significant (p=0.031).

Alcohol use at last sexual encounter was reported by ART experienced (22.5%) and ART naïve participants (32.5%; p=0.012). Having 2 or more sexual partners was almost similar among ART experienced (19.4%) and ART-naïve persons 18.3% (p=0.756), while somewhat more ART naïve participants did not use condoms at last sex compared to ART experienced participants (72.1% vs 64.7%, respectively; p=0.081).

For the bivariate analyses (Table 2), inconsistent/no condom use was higher among the ART naive compared to the ART experienced participants (OR=1.69, 95% CI 1.04 – 2.73) and inconsistent/no condom use was more frequent among women compared to men (65.9 % vs 34.1% p=0.932). Agriculturalists were more likely to report no/inconsistent condom use than any other occupations (OR=1.80, 95% CI 1.15 – 2.80). Additionally, ART naive participants had higher odds of drinking alcohol at last sexual encounter compared to ART experienced participants (OR=1.65, 95% CI 1.11 – 2.46) (Table 3). Men were more likely to drink alcohol at last sexual encounter compared to women (OR=3.40, 95% CI 2.26 – 5.12) (Table 3).

Three predictor variables (Table 2) were significantly associated with inconsistent condom use; ART treatment status (p=0.031), marital status (p=0.016) and occupation level (p=0.009). Table 3 shows both sex ($p < 0.001$) and ART treatment status (p=0.013) as significant predictors in drinking alcohol at last sex.

In the final multivariate model (Table 4), the association between inconsistent condom use and ART treatment status remained statistically significant after adjusting for age, occupation and marital status (adj OR = 1.47 95% CI 0.90 – 2.41, model 4). Age and sex were significantly associated with alcohol consumption; with sex (adjOR = 3.47 95 % CI 2.30 – 5.23), age (OR = 3.34 95% CI 0.74 – 15.03) (Table 5)

DISCUSSIONS

Findings from this study reveal ART naive participants having slightly increasing odds of practising risky sexual behaviours compared to participants on ART. This is similar to other studies done that showed ART naïve patients were more likely to practice risky sexual behaviours than the ART experienced patients.[15,48] These differences could be attributed to the variability in counselling intensity, health education and follow-ups given to patients on ART, compared with ART naive patients (patients on ART are required to visit the clinic more frequently than those on ART).

Sex and age are significant predictors of risk sexual behaviors among HIV positive patients in this study. This is related to studies done before that have either identified sex or age as significant predictors of risky sexual behaviours.[45,48,49]

Almost 81% of participants within the study reported inconsistent condom use, which indicates high prevalence of unsafe sex among HIV positive people. This highlights the dangers of continued HIV transmission despite the increasing ART roll out. Therefore, these findings calls for increasing awareness and motivation of condom use among HIV positive patients. Additionally, inconsistent condom use was more likely among ART naïve patients, a finding similar to earlier studies in Uganda[15] Kenya[50] and South Africa.[48] These findings could be due to more secondary HIV prevention programs given to ART experienced patients as they visit ART clinics oftenly for refills and medical check-ups.

Inconsistent condom use was higher among women than in men (65.9% vs 34.1%) in this study. This is similar to studies done in Italy that showed almost 44.3% of HIV positive women were inconsistent condom users.[51] This could reflect the limitations of female bargaining power within

sexual relationships. A central feature of Ugandan society is gender inequality, with women occupying subordinate roles both in economic activities and in decision-making. Women are not culturally empowered to negotiate sexually related issues and this pattern of male control of sexual decision-making was also noted in Uganda and Rwanda.[52,53] However, inconsistent condom use in this group could also be attributed to the desire to have children. Studies[54,55] have shown reproductive desires play a significant role in the lives of HIV positive women. Therefore, these gender differences highlight a need of incorporating gender dynamics in secondary prevention strategies in order to meet the specific needs of both women and men.

We observed almost 26% of HIV positive patients consumed alcohol before sex. This is a health concern because alcohol consumption among HIV positive persons has been associated with decreased adherence to ARV,[56,57] reducing the patient's ability to practice safer sex.[58] Additionally, ART naive participants were more likely to consume alcohol at their last sexual encounter compared with ART experienced participants. This could be explained by the fact that once people are started on ART, they are advised not to drink or certainly take limited amounts of alcohol in order to preserve the integrity of their liver,[59,60] so that the ARVs are well processed in the body. Another reason could be the guidelines and adherence support counselling given by health workers when on ART. These findings are aligned with a study that reported decreased alcohol consumption after ART initiation[61] and higher odds of alcohol consumption during the pre-ART period.[21]

In this study, males were three times more likely to drink alcohol at their last sexual encounter. This could be attributed to the common social values and the acceptance of male drinking in society. A Ugandan study reported 41% of males consume alcohol before sex.[62] It is recommended that addressing alcohol abuse should be a key focus in secondary prevention

interventions. Health care providers should screen their HIV patients for alcohol use problems and initiate interventions that can reduce alcohol related problems among people living with HIV. More research is needed to find and test different behavioural, social and biomedical interventions for alcohol related problems among people living with HIV.

Compared with other studies in sub-Saharan Africa,[63-65] this study found that participants with primary or lower level education were more likely to use condoms inconsistently. This could be explained by the fact that participants with higher education are more likely to have higher knowledge of HIV and are more informed.

Methodological considerations

The use of data from a population based prospective cohort study with a high participation rate of over 90%, that captured a representative sample of the sexually active HIV positive population in 54 surveyed communities in rural Rakai communities makes the findings generalizable and applicable to countrywide policies and interventions. However this study had limitiations; Firstly, this was a cross-sectional study and could not derive causal inferences. Secondly, risky sexual behaviour estimates are based on self-reported measures, which are subject to social desirability and recall bias. However, a study done in Uganda showed large cohort studies have correlations between behavioural self-reported measures and HIV infection,thus suggesting that recall bias does not necessarily conceal key associations.[66] It is therefore less likely that these potential biases would impact differences between the two groups. Thirdly, reporting condom use in the last 12 months may not always accurately characterize patient's overall condom use due to the long periods of measurement. The frequency of condom use as well as recalling sexual encounters in the last 12–18 months since the last survey done

might affect people's ability to accurately answer and remember details of sexual encounters. However, findings from other shorter time periods do not necessarily differ from the findings of this study which maybe a minor factor.[67] Fourthly, this study did not consider the time element; CD4 cell count and calendar years as well as time on ART which may be factors that correlated with risky sexual behaviour. In addition, the period of observation was restricted to one survey round which may not necessarily give accurate changes in exposure time measurements.

CONCLUSION

This study indicates that ART naive participants have slightly increased odds of risky sexual behaviours compared to participants on ART. These differences may be attributed to the variability in counselling intensity, health education and follow-ups offered to patients on ART. Though findings reveal higher odds of risky sexual behaviours among ART naive persons, rates of risky behavior are high for both groups, and positive prevention programs should be able to target both groups.

Focused interventions such as risk reduction counselling and education programmes are required to be incorporated in HIV care and treatment programs and emphasis should be laid on counselling to avoid re-infections and alcohol abuse. The rollout of ART should not be considered as a single preventive intervention, but should be facilitated with other elements such as psychosocial support, gender dynamics, mental health services, nutrition and family planning to ensure a successful HIV fight. Better understanding of the underlying mechanisms and correlations of such high-risk sexual behavior among persons living with HIV remains a priority for researchers and public health professionals alike.

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Author's Contributions

LNJ conceptualized the study, designed, analyzed and drafted the first version of the manuscript. BOA and GN were involved in the analysis, interpretation and critical review of the manuscript. JK, FN, DS, NS were involved in revising the article critically for important intellectual content. RN edited and approved the final version to be published. AN was involved in the acquisition of data, data analysis and interpretation of the data.

Data sharing statement

The data sets used for this study are available on request from the Rakai Community Cohort Study Data base at Rakai Health Sciences Program. (www.rhsp.org)

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Table 1. Baseline socio demographic and sexual behaviour characteristics for 517 participants in a longitudinal cohort study of People living with HIV in a rural district, Rakai, Uganda

Characteristics	Overall (%)	ART Naive (%)	ART Experienced (%)	*p*-value*
Overall		197 (38.1)	320 (61.9)	
Sex				
Female	341(66.0)	130 (66.0)	211 (65.9)	0.990
Male	176 (34.0)	67 (34.0)	109 (34.1)	
Age (years)				
Mean (SD)	35.55 (6.48)	36.34 (6.25)	34.27 (6.60)	< 0.001
Median (IQR)	35.0 (31-40)	37 (30-41)	34 (30-39)	
Age group (years)				
18–24	23 (4.4)	13 (6.6)	10) (3.1)	0.004
25–34	206 (39.8)	91 (46.2)	115 (35.9)	
35–50	288 (55.7)	93 (47.2)	195 (60.9)	
Marital status				
Married	349 (67.5)	137 (69.5)	212 (66.3)	0.438
Not Married	168 (32.5)	60 (30.5)	108 (33.8)	
Main Occupation				
Agriculture/housework	288 (55.7)	113 (57.4)	175 (54.7)	0.552
Other occupation	229 (44.3)	84 (42.6)	145 (45.3)	
Education level				
Primary or lower	377 (72.9)	137 (69.5)	240 (75.0)	0.175
Secondary or higher	140 (27.1)	60 (30.5)	80 (25.0)	
Alcohol use at last sexual encounter				
Yes	136 (26.3)	64 (32.5)	72 (22.5)	0.012
No	381 (73.7)	133 (67.5)	248 (77.5)	
Condom Use in last 12 months				
Consistent	98 (19.0)	28 (14.2)	70 (21.9)	0.031
Inconsistent	419 (81.0)	169 (85.8)	250 (78.1)	
No of sexual partners				
1 partner	419 (81.0)	161 (81.7)	258 (80.6)	0.756
2 or more partners	98 (19.0)	36 (18.3)	62 (19.4)	
Condom use at last sexual encounter				

Yes	168 (32.5)	55 (27.9)	113 (35.3)	0.081
No	349 (67.5)	142 (72.1)	207 (64.7)	

*p-value from chi-square test

Table 2. Association (crude odds ratios, 95% Confidence Intervals) between sociodemographic factors, ART treatment status and inconsistent condom use in a sample of 517 HIV positive patients in Rakai; results of logistic regression.

	Consistent n (%)	*Inconsistent/no condom use n (%)*	*Crude ORs (95% CI)*	*P-value**
ART treatment status				
ART naïve	28 (28.6)	169 (40.3)	1.69 (1.04-2.73)	0.031
ART experienced	70 (71.4)	250 (59.7)	1 (ref group)	
Sex				
Male	33 (33.7)	143 (34.1)	1.02 (0.64-1.62)	0.932
Female	65 (66.3)	276 (65.9)	1 (ref group)	
Age				
25–34	26 (26.5)	180 (43.0)	0.32 (0.041-2.43)	0.268
35–50	71 (72.4)	217 (51.8)	0.13 (0.02-1.04)	0.056
18–24	1 (4.3)	22 (5.3)	1 (ref group)	
Marital status				
Married	56 (57.1)	293 (69.9)	1.74 (1.11-2.73)	0.016
Not married	42 (42.9)	126 (30.1)	1 (ref group	
Education level				
Primary level	68 (69.4)	309 (73.7)	1.23 (0.76-2.00)	0.383
Secondary level	30 (30.6)	110 (26.3)	1 (ref group)	
Occupation level				
Agriculture/housework	43 (43.9)	245 (58.5)	1.80 (1.15-2.80)	0.009
Other occupation	55 (56.1)	174 (41.5)	1 (ref group)	

*P-value from chi-square test

Table 3. Association (crude odds ratios, 95% Confidence Intervals) between sociodemographic factors, ART treatment status and alcohol use at last sexual encounter in a sample of 517 HIV positive patients in Rakai; results of logistic regression

	Alcohol use Yes n (%)	*Alcohol use No n (%)*	*Crude ORs (95% CI)*	*Pvalue**
ART treatment status				
ART naive	64 (47.1)	133 (34.9)	1.65 (1.11-2.46)	0.013
ART experienced	72 (52.9)	248 (65.1)	(ref)	
Sex				
Male	75 (55.1)	101 (26.5)	3.40 (2.26-5.12)	< 0.001
Female	61 (44.9)	280 (73.5)	ref	
Age				
35–50	82 (60.3)	206 (54.1)	4.18 (0.95-18.22)	0.057
25–34	52 (38.2)	154 (40.4)	3.54 (0.80-15.63)	0.095
18–24	2 (1.5)	21 (5.5)	ref	
Marital status				
Married	92 (67.6)	257 (67.5)	1.0 (0.66-1.53)	0.967
Not married	44 (32.4)	124 (32.4)	ref	
Education level				
Primary level	106 (77.9)	271 (71.1)	1.43 (0.90-2.27)	0.126
Secondary level	30 (22.1)	110 (28.9)	ref	
Occupation level				
Agriculture/housework	70 (51.5)	218 (57.2)	0.79 (0.53-1.17)	0.247
Other occupation	66 (48.5)	163 (42.8)	ref	

**p*-value from chi-square test

Table 4. Association (adjusted odds ratio, 95% Confidence Interval) between inconsistent/no condom use and ART treatment status among 517 HIV positive patients in Rakai; results of multivariate logistic regressions

	Unadjusted OR (95% CI) (Model 1)	Adjusted for age OR (95% CI) (Model 2)	Adjusted for age, occupation OR (95% CI) (Model 3)	Ajusted for age, occupation& marital status OR (95% CI) (Model 4)
ART Treatment Status				
ART naive	1.69 (1.04-2.73)	1.51 (0.92-2.46)	1.48 (0.90-2.42)	1.47 (0.90-2.47)
ART experienced	ref	ref	ref	ref
Age				
35–50		0.15 (0.02-1.15)	0.15 (0.02-1.21)	0.16 (0.02-1.23)
25–34		0.33 (0.43-2.55)	0.34 (0.04-2.72)	0.35 (0.04-2.71)
18–24		ref	ref	ref
Occupation level				
Agriculture/housework			1.79 (1.14-2.81)	1.71 (1.00-2.93)
Other occupation	ref	ref	ref	ref
Marital status				
Married				1.59 (1.00-2.53)
Not married				ref

Model 1: unadjusted model
Model 2: adjusted for age
Model 3: adjusted for age, occupation
Model 4 Adjusted for age, occupation & marital status

Table 5. Association (adjusted odds ratio, 95% Confidence Interval) between alcohol use at last sexual encounter and ART treatment status among 517 HIV positive patients in Rakai; results of multivariate logistic regression

	Unadjusted OR (95% CI) (Model 1)	Adjusted for sex OR (95% CI) (Model 2)	Adjusted for age & sex OR (95% CI) (Model 3)
ART Treatment Status			
ART naive	1.65 (1.11-2.46)	1.72 (1.14-2.61)	1.80 (1.18-2.74)
ART Experienced	ref	ref	ref
Sex			
Male		3.47 (2.30-5.23)	3.29 (2.17-4.99)
Female		ref	ref
Age			
35–50			3.34 (0.74-15.03)
25–34			2.95 (0.65-13.35)
18–24			ref

Model 1: unadjusted model
Model 2: adjusted for sex
Model 3: adjusted for age, sex

Conceptual Framework:

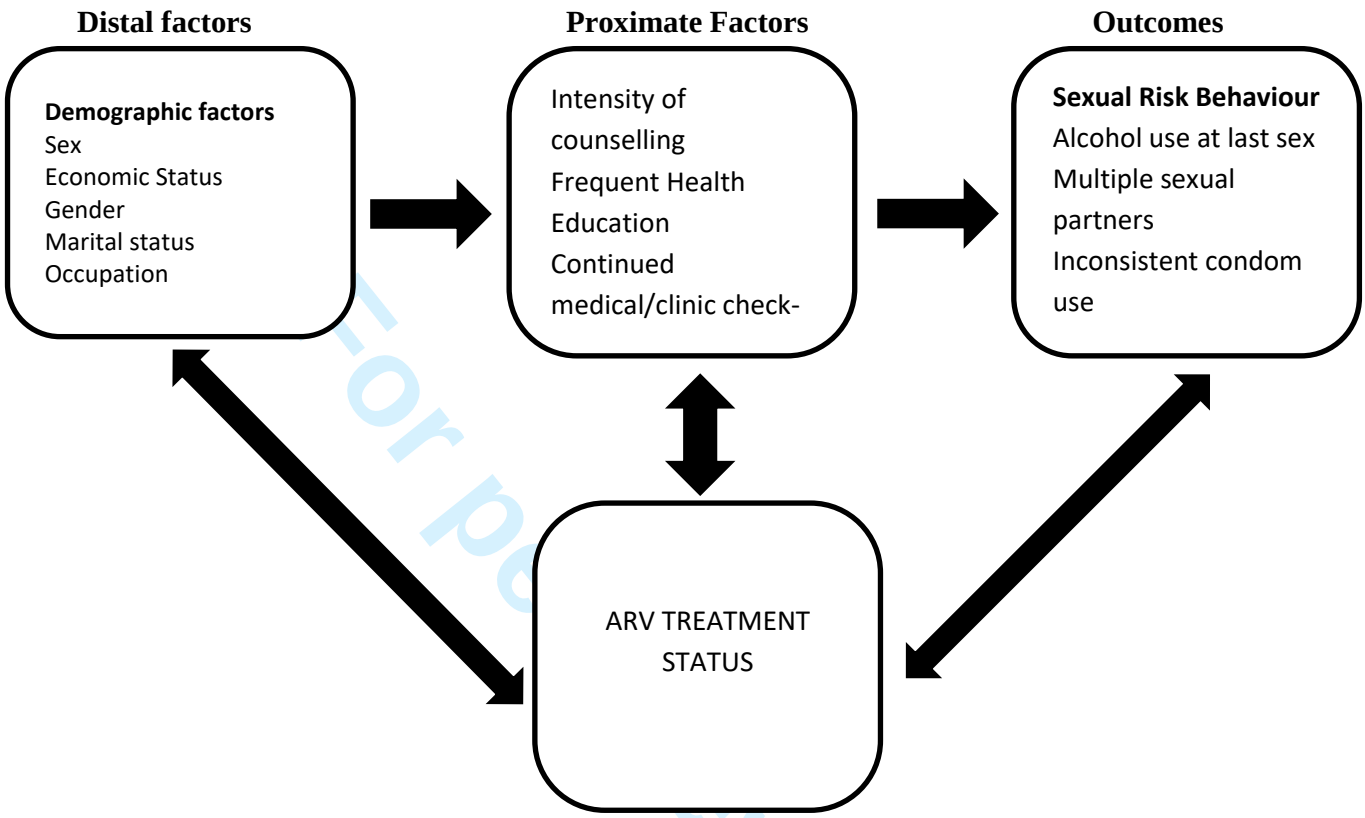

Figure 1: Conceptual framework showing the relationship between factors that may contribute to differences in sexual risk behaviours among HIV positive persons in rural Rakai, Uganda

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*

Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any pre-specified hypotheses	5/6
Methods			
Study design	4	Present key elements of study design early in the paper	8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	8
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	8
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	8/9
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8/9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*9*
Bias	9	Describe any efforts to address potential sources of bias	8/9
Study size	10	Explain how the study size was arrived at	8/9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	10
		(*c*) Explain how missing data were addressed	10
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	10

		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
Results			7-8
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10/11
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	10/11
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	10/11
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14
Generalisability	21	Discuss the generalisability (external validity) of the study results	14
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	16

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.