Quality of Life of HIV Patients in a Rural Area of Western Uganda: Impact of a Community-Based Antiretroviral Treatment Program

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Abstract: *Objective:* Community-based antiretroviral treatment (CBART) programs should aim to achieve positive quality of life outcomes. The purpose of this study was to investigate changes in the health related quality of life (HRQOL) outcomes of patients in a CBART program supported by community volunteers in one sub-county in western Uganda located 50 km from the nearest urban centre.

Methods: We administered a translated version of the MOS-HIV survey and collected clinical data at baseline and after one year from 130 patients. Inclusion criteria included residency in the sub-county, eighteen years of age or, treatment-naïve, eligible for ART based on CD4 cell count <200 cells/mm3 or WHO clinical stage 3 or 4, and willing to accept daily treatment support by family/friends and to be visited by a community volunteer weekly. We assessed changes in physical health (PHS) and mental health (MHS) summary scores and examined associations between patient characteristics and changes in HRQOL.

Results: After one year, we observed significant increases in mean PHS (42.7 to 50.1; $p<0.01$) and MHS (43.5 to 49.5; $p<0.01$) scores. Lower age ($p<0.01$) and lower baseline PHS scores ($p<0.01$) were associated with increases in PHS scores and lower age ($p=0.03$) and lower baseline MHS scores ($p<0.01$) were associated with increases in MHS scores. Fifteen patients (12%) had reductions in their HRQOL after one year which were not associated with patient or clinical characteristics, including virological suppression.

Conclusions: The observed improvements in HRQOL demonstrate that positive treatment outcomes can be achieved in CBART programs in rural Uganda. However, some patients appear to experience declines in their overall well-being, despite achieving virological suppression. HRQOL surveys can be useful in identifying these patients, who may require additional attention and support to achieve the full benefits of ART.

Keywords: Antiretroviral therapy, HIV/AIDS, quality of Life, Uganda, rural health services, community based treatment.

INTRODUCTION

Initiatives to scale up access to antiretroviral treatment (ART) have achieved reasonable success. At the end of 2007, 3 million people globally were receiving ART of an estimated 9.7 million that needed treatment [1]. However, this still represents coverage rates of only 30%. Most gains in scaling up access have been made by treating those that were the easiest to reach [1]. The current challenge for programs that are trying to achieve universal access is reaching populations not already being served by existing clinics and programs. This includes populations living in rural and remote locations. Typically, ART programs are situated in hospitals or clinics in urban and semi-urban locations where physicians and physical infrastructure are available to deliver and monitor ART. However, these programs are located far from rural populations, creating challenges for rural HIV patients to access treatment. Specifically, studies have found that the distance to travel to a clinic was the major barrier to accessing health services [2, 3] including ART [4]. Rural areas typically have weaker capacities to manage health programs including fewer trained health workers (especially physicians) and higher costs of service delivery [5] and are thus greatly underserved by ART programs [6].

In Uganda, efforts to scale-up ART have reached approximately 27% to 40% of those needing therapy [7]. However, since approximately 80-90% of Ugandans live in rural areas [8], it will be necessary to increase access to this population if universal coverage is to be achieved. To bring treatment closer to these rural populations, new models of treatment delivery will be necessary to overcome the weaker capacities to deliver ART in rural areas without compromising quality of care. Experiences have shown that a community-based approach can be utilized to provide effective treatment to rural communities [9].

An estimated 22,400 individuals with HIV reside in Kabarole district in southwestern Uganda [10]. HIV prevalence in the district is 11.6% [10] which is above the national average of 6.4% [11]. In 2006, our team, in conjunction with the Kabarole Health District, implemented a community-based ART (CBART) program in a rural sub-county located 50 kilometres from the nearest hospital-based ART program. Very few individuals from this sub-county

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were receiving ART in 2006 due to the cost of travelling to the urban-based ART program every month. The CBART program operates within an existing primary health care clinic (a Health Centre III) and provides ART using free drugs provided by the Ugandan government to a catchment area of 25,000 rural residents. Health workers (2 clinical officers and 1 nurse and 2 counsellors) at this Health Centre III were trained using the Uganda Guidelines for ART [12]. As these health workers already had a heavy workload in delivering primary health care services, we engaged local community volunteers as well as patient-identified treatment partners to assist with the regular monitoring of treatment. Community volunteers visited patients weekly and monitored adverse effects of treatment as well as treatment adherence through pill counts. Patients whose adherence was irregular were provided counselling by the volunteers while those with adverse effects were referred to the health centre. In addition, volunteers delivered drugs to their patients on a monthly basis. A recent study from Uganda has shown that ART may be delivered safely without intense clinical and laboratory monitoring, provided that there is a minimum level of reliable clinical follow-up [13], something that we aimed to do using trained volunteers who could refer patients with adverse effects to trained non-physician health workers. Volunteers were not paid, but were provided incentives and tools to assist them with their work including bicycles and appropriate rainwear. Treatment partners helped remind patients to take their tablets twice daily and documented that the patient had taken their medications. After six months on treatment, clinical outcomes for patients in our CBART program were positive, with 85% of CBART patients achieving viral suppression as measured by HIV-1 RNA viral loads of <400 copies/ml. This was comparable to clinical outcomes of the urban hospital-based program [14].

While ART has been shown to increase the life expectancy of HIV infected patients, ART should at the same time aim to improve the quality of life of these patients [15]. An improvement in quality of life, especially health related quality of life (HRQOL), which encompasses functional status and well-being influenced by treatment [16], has been identified as an important outcome in the treatment of chronic illnesses such as HIV/AIDS [17-19]. Though studies have shown that HRQOL does improve for patients on ART in both low and high income countries [20-24], little is known about HRQOL outcomes of ART programs based in rural areas and specifically in CBART programs where community resources such as community volunteers are engaged to support the distribution and monitoring of treatment. HRQOL can be used to gain additional insights into patient well-being that go beyond clinical measures typically used by ART programs and can help identify opportunities to enhance treatment to create more comprehensive and effective HIV care programs that ensure patients acquire the maximum benefits of ART [19, 25]. In addition, since HIV has social and structural determinants and outcomes, it is appropriate to go beyond clinical outcomes in research and to look at broader aspects of patient well-being and quality of life [25, 26].

OBJECTIVES

The purpose of this study is to investigate changes in the HRQOL of patients in the CBART program through an assessment of changes in patient-reported HRQOL after 12 months on treatment in the program and how patient characteristics, both demographic and clinical, are associated with these changes.

METHODS

This study was part of a larger prospective cohort study looking at the treatment of patients in a CBART program. Between March 2006 and May 2007, individuals who tested HIV-positive and who met the study eligibility criteria (described below) were recruited into the CBART program and study and started on combination ART. Study eligibility criteria included: residency in the sub-county, being eighteen years of age or older at the initiation of treatment, treatment-naïve, eligible for ART according to the Uganda National ART guidelines (CD4 cell count <200 cells/mm^3 or WHO clinical stage 3 or 4), and willing to accept daily treatment support by family/friends and to be visited by a community volunteer weekly. The first line treatment consisted of stavudine, lamivudine, and nevirapine (or efavirenz for patients also on rifampicin) taken twice daily. All patients were also prescribed daily co-trimoxazole. Patients were enrolled sequentially as they presented to the clinic for treatment until the end of the enrolment period.

HRQOL was measured using a version of the Medical Outcomes Study HIV Health Survey (MOS-HIV) translated into Rutooro, the common language spoken in our study area.

The MOS-HIV survey is a brief, but comprehensive health status measure for studies of HIV/AIDS. The MOS-HIV instrument has been identified as an appropriate tool to measure HRQOL for those living with AIDS [18, 27], is a valid and reliable instrument to measure changes in HRQOL due to treatment [28] and is highly sensitive to changes in functional and mental status [29]. The questionnaire consists of 35 questions which assess 11 domains of health including general health perceptions, pain, physical functioning, role functioning, social functioning, mental health, energy/ fatigue, cognitive function, health distress, health transition and overall quality of life. Current recommendations are that research on HRQOL should ensure support for the HRQOL instrument's reliability and validity in the study population's local context [30]. To ensure that our survey met these conditions, we chose to translate the Luganda version of the MOS-HIV survey used in a previous study in Uganda [31] into Rutooro. The Luganda version of the MOS-HIV is a culturally adapted version of the original MOS-HIV and has also been shown to be a valid and reliable instrument for measuring HRQOL in the Ugandan context [31-33]. The main outcomes of interest were changes in the physical health (PHS) and mental health (MHS) summary scores, though changes in the 11 MOS-HIV domain scores were also analyzed. Scores for each domain were calculated and transformed to have a range from 0 to 100 with a higher score indicating better quality of life status. PHS and MHS scores were calculated from individual domain scores [28] and standardized to have a mean of 50 and a standard deviation of 10 using standard methods described elsewhere [28]. The translated MOS-HIV questionnaire was administered by trained research assistants at a baseline point (2 to 12 weeks after initiation of ART) and subsequently at

12 months after the initiation of ART. In addition, we collected information on patient demographics (age, sex, education, and occupation), WHO clinical stage and CD4 cell count at baseline (Becton Dickinson®) as well as HIV-1 RNA levels at baseline and after 12 months (Cobas Amplicor HIV-1 Monitor test, Roche Molecular Systems®). We defined virological suppression after one year as an HIV-1 RNA viral load of <400 copies/ml (this is the lowest level of detection for the Cobas Amplicor HIV-1 Monitor test we used). In this study, only summary virological suppression data have been presented; additional detailed findings will be described in a forthcoming paper.

Data were entered into an MS Access database and entries were checked by a second research assistant who compared the data in the database to the data in the survey forms. Data were then extracted and analyzed using SAS® (version 9.1; SAS Institute Inc., Cary, NC) and STATA IC 10 (College Station, TX). We tabulated baseline patient demographic and clinical characteristics and compared characteristics between study patients and those excluded from the study using Wilcoxon rank sum tests (normal approximation) for continuous variables and χ^2 tests for categorical variables. We used paired t-tests to examine differences in baseline and 12-month summary and domain scores. We used the same tests to analyze differences in PHS and MHS scores for patients whose PHS and MHS scores decreased by 5 points or more (as this change is considered to be clinically significant [33, 34]) at 12 months compared to baseline as well as for patients who did not achieve viral suppression compared to those who did. We used Fisher's exact tests to compare baseline demographic characteristics of patients whose PHS and MHS scores decreased to those patients whose PHS and MHS scores increased or remain unchanged. For all analyses, two-sided p-values which were <0.05 were considered to be statistically significant.

We developed two multiple linear regression models: one with change in PHS as the dependant variable and one with change in MHS as the dependant variable. We considered all measured patient baseline demographic and clinical characteristics as potential explanatory variables. In addition, we considered baseline PHS and baseline MHS in the models of change in PHS and change in MHS, respectively. All variables that had a p-value of <0.20 in unadjusted linear regression models were selected for inclusion in the multiple linear regression models. Though sex, age and WHO stage were not statistically significant in the linear regression models, we forced these variables into the final multiple linear regression models based on *a priori* considerations of the relevance of these variables to the outcomes.

The University of Alberta's Health Research Ethics Board provided ethical approval for the study. In Uganda, approval for the study was obtained from the Uganda National Council of Science and Technology and by the Ethical Review Committee of the School of Public Health, Makerere University, Kampala. Each participant provided informed, signed consent before enrollment in the study.

RESULTS

In total, 185 patients were enrolled in the CBART program. After one year, 28 had died and an additional 22 were lost to follow-up; these patients were excluded from the analyses. Two patients were accidentally missed in the one year MOS-HIV survey and three patients provided incomplete data on their surveys and were also excluded from the analyses. Of the 130 patients remaining in this study, 62% were female and 38% were male (Table **1**). Many (42%) were married and most (65%) were employed in farming or non-professional work activities. The median age was 35 (interquartile range (IQR)=30-43) years. Most patients (80%) were either WHO Clinical Stage 3 (n=90) or 4 (n=15) at the initiation of treatment. The median baseline CD4 cell count was 144 (IQR=92-209) cells/mm^3 and the median baseline HIV-1 RNA viral load was 5.2 (IQR=4.6-5.6) $\log_{10}$ copies/ml (Table **1**). Compared to the 130 study patients, the 55 excluded patients were more likely to be single (25% *vs* 10.0%, p=0.01) and less likely to be widowed (11% *vs* 25%, p=0.04), but did not differ significantly from the study patients with respect to other baseline characteristics (age, sex, WHO clinical stage, education level, occupation, viral load, or CD4 cell count) or baseline HRQOL scores.

Table 1. Baseline Characteristics of Study Patients (n=130)

Sex, n (%)	
Male	50 (38)
Female	80 (62)
Age in years, median (IQR)	35 (30-43)
Marital status, n (%)	
Married	55 (42)
Single	13 (10)
Divorced or separated	29 (22)
Widowed	33 (25)
Education level, n (%)	
None	40 (31)
Primary	76 (58)
Secondary or post-secondary	14 (11)
Occupation, n (%)	
Unemployed/Housewife	28 (22)
Non-professional/Farmer	84 (65)
Professional/Businessperson	18 (14)
WHO clinical stage, n (%)	
1	10 (8)
2	15 (12)
3	90 (69)
4	15 (12)
CD4 cell count (cells/mm^3), median (IQR)	144 (92-209)
HIV RNA, ($\log_{10}$ copies/ml), median (IQR) (n=120)	5.2 (4.6-5.6)

At baseline, mean MOS-HIV summary scores were 42.7 points for PHS and 43.5 points for MHS (Table **2**). Mean baseline MOS-HIV domain scores ranged from 37.0 to 74.2 points. The lowest mean domain score was for general health perceptions (37.0 points) while the highest were for health

Table 2. Changes in MOS-HIV Subscales and Summary Scores Between Baseline and 12 Months (n=130)

Domain	Baseline		12 months		Difference		P-Value
	Mean	SD	Mean	SD	Mean	SD	
PHS	42.7	12.4	50.1	9.2	7.5	15.4	<0.01
MHS	43.5	11.7	49.5	8.4	6.0	13.6	<0.01
General health perceptions	37.0	21.6	45.9	19.4	8.8	28.4	<0.01
Pain	52.6	25.4	65.7	22.2	13.2	33.7	<0.01
Quality of life	55.0	23.4	65.4	19.3	10.4	28.7	<0.01
Role functioning	65.4	44.0	83.5	33.8	18.1	53.2	<0.01
Social functioning	64.3	31.5	79.4	22.0	15.1	38.3	<0.01
Vitality	53.3	22.7	64.7	17.0	11.4	28.0	<0.01
Mental health	61.5	20.2	70.3	15.3	8.8	24.2	<0.01
Health distress	60.0	27.1	73.3	17.4	13.4	29.3	<0.01
Cognitive functioning	72.6	25.5	83.5	17.7	11.0	31.2	<0.01
Health transition	74.2	22.4	84.8	17.7	10.6	28.3	<0.01
Physical functioning	65.0	27.6	84.5	21.4	19.6	32.1	<0.01

transition (74.2 points) and cognitive functioning (72.6 points). Patients experienced a mean increase of 7.5 points in PHS and 6.0 points in MHS scores after 12 months on ART (Table **2**). The largest increases were in the mean scores for physical functioning (19.6 points), role functioning (18.1 points) and social functioning (15.1 points). The smallest increases were in the mean scores for general health perceptions (8.8 points) and mental health (8.8 points). Changes in all domain scores and the two summary scores after 12 months were statistically significant (Table **2**).

Not all patients had increases in their HRQOL. After 12 months, 93 (72%) patients had an increase in their PHS score and 84 (65%) had an increase in their MHS score; the remaining patients experienced either no change or a reduction in their PHS or MHS scores. Twenty seven patients (21%) had a decrease in both PHS and MHS scores after 12 months, while fifteen patients (12%) had a decrease of 5 points or more. For these 15 patients, the mean decrease in PHS scores was 15.3 points ($p<0.01$) and the mean decrease in MHS scores was 12.9 points ($p<0.01$). Baseline characteristics of patients who had decreases in their PHS and MHS scores were not different from those patients who did not see decreases in their HRQOL scores (Table **3**).

At 12 months, HIV-1 RNA viral load data were available for 129 patients; of these 117 (91%) achieved virological suppression. There were no statistical associations between changes in MHS or PHS and virological suppression at 12 months. The mean increase in PHS was 7.0 points for those who achieved virological suppression versus 11.1 points for those who did not achieve virological suppression ($p=0.38$). The mean increase in MHS was 5.4 points for those who achieved virological suppression versus 10.7 points for those who did not achieve virological suppression ($p=0.20$). While not statistically significant, the trend was for greater increases in PHS and MHS for those that did not achieve virological suppression compared to those that did. Further analyses revealed that, of the 12 patients who did not achieve virological suppression, only 1 patient had a decrease in both PHS and MHS scores; the remaining 11 patients all had increases in both their PHS and MHS scores.

In unadjusted linear regression analyses, we found no statistically significant associations between baseline patient characteristics (demographic or clinical) and change in PHS or MHS scores; however, baseline PHS scores and baseline MHS scores were significantly and inversely associated with a change in PHS ($p<0.01$) and change in MHS ($p<0.01$), respectively (Table **3**). In multiple linear regression analyses, only lower baseline PHS scores ($\beta=-1.01$, $p<0.01$) and younger age ($\beta=-0.25$, $p<0.01$) were associated with an increase in PHS scores and only lower baseline MHS scores ($\beta=-0.92$, $p<0.01$) and younger age ($\beta=-0.18$, $p=0.03$) were associated with an increase in MHS scores after 12 months (Table **4**). In a sub-analysis, multiple linear regression analyses that included only patients who had a decrease in their PHS and MHS scores (n=27) showed no statistically significant associations between the decrease in scores and their baseline characteristics (results not shown).

DISCUSSION

Patients enrolled in the CBART program had significant improvements in their HRQOL after 12 months of treatment. Mean scores in all MOS-HIV domains improved, and overall, mean PHS and MHS scores improved by more than 5 points, which is considered to be clinically significant [33, 34]. Notable improvements were seen in physical functioning, role functioning, and social functioning suggesting that patients were able to resume physical activities in their daily lives. Lesser improvements were seen for mental health and general health perceptions. These findings are similar to those reported in other developing

Table 3. Baseline Characteristics of Patients who had Unchanged or Improved HRQOL Compared to those whose HRQOL Decreased

	Unchanged or Improved HRQOL* (N=115)	Decreased HRQOL** (N=15)	P-Value***
Sex, n (%)			
Male	70 (60.9)	10 (66.7)	0.78
Female	45 (39.1)	5 (33.3)	
Age n (%)			0.79
18-35	61 (53.0)	7 (46.7)	
36+	54 (47.0)	8 (53.0)	
Marital status, n (%)			0.76
Married	49 (42.6)	6 (40.0)	
Single	12 (10.4)	1 (6.7)	
Divorced or separated	24 (20.9)	5 (33.3)	
Widowed	30 (26.1)	3 (20.0)	
Education level, n (%)			0.92
None	36 (31.3)	4 (26.7)	
Primary	66 (57.4)	10 (66.7)	
Secondary or post-secondary	13 (11.3)	1 (6.7)	
Occupation, n (%)			0.43
Unemployed/Housewife	23 (20.0)	5 (33.3)	
Non-professional/Farmer	75 (65.2)	9 (60.0)	
Professional/Businessperson	17 (14.8)	1 (6.7)	
WHO clinical stage, n (%)			0.15
1	9 (7.8)	1 (6.7)	
2	11 (9.6)	4 (26.7)	
3	80 (69.5)	10 (66.7)	
4	15 (13.0)	0 (0)	
Baseline CD4 cell count (cells/mm^3) n (%)			1.00
1-49	15 (13.0)	2 (13.3)	
50-99	21 (18.2)	2 (13.3)	
100+	79 (68.7)	11 (73.3)	
Baseline HIV RNA, (log_{10} copies/ml), n (%)			1.00
1-4.9	39 (36.8)	5 (35.7)	
5+	67 (63.2)	9 (64.3)	

*Change in PHS and MHS scores >-5 points between baseline and 12 months
**Change in PHS and MHS scores <-5 points between baseline and 12 months
***Fisher' exact test.

countries [35]. A study that looked at changes in the quality of life of rural patients in eastern Uganda after one year of ART observed larger increases in all domains and higher one-year scores in all but one domain (health transition) than we found [33]. In that study, PHS scores increased to 54.2 after one year (compared to 50.1 for our cohort) while MHS scores increased to 54.2 (compared to 49.5 for our cohort). Part of the reason for the observed higher scores in their study may have been the use of paid and trained staff to regularly monitor and counsel patients compared to our model, which used lay community volunteers who received basic training. Results from Rakai, in southeast Uganda, show that our one-year PHS and MHS scores are similar to those of HIV-negative women in that community [31], suggesting that the 12-month HRQOL scores observed in our patient cohort are similar to what would be expected among HIV-negative individuals in Uganda.

Our study found no statistically significant associations between most demographic and clinical baseline characteristics and change in PHS or MHS. A study looking at hospital patients in western Uganda similarly found no

Table 4. Factors Associated with Changes in PHS and MHS After 12 Months (n=130)

	Change in PHS				Change in MHS			
	Unadjusted Linear Regression		Multivariate Regression		Unadjusted Linear Regression		Multivariate Regression	
	Coefficient (95% CI)	*p-Value*	*Coefficient (95% CI)*	*p-Value*	*Coefficient (95% CI)*	*p-Value*	*Coefficient (95% CI)*	*p-Value*
Baseline PHS	-0.99 (-1.13, -0.87)	*<0.01*	-1.01 (-1.13, -0.88)	*<0.01*	-	-	-	-
Baseline MHS	-	-	-	-	-0.92 (-1.05, -0.80)	*<0.01*	-0.92 (-1.05, -0.79)	*<0.01*
Age	-0.14 (-0.44, 0.16)	*0.36*	-0.25 (-0.43, -0.07)	*<0.01*	-0.15 (-0.41, 0.12)	*0.27*	-0.18 (-0.34, -0.02)	*0.03*
Sex								
Male	Ref		Ref		Ref		Ref	
Female	-0.18 (-5.68, 5.32)	*0.95*	1.89 (-1.42, 5.19)	*0.26*	-1.17 (-6.05, 3.71)	*0.64*	-0.45 (-3.50, 2.59)	*0.77*
WHO Stage								
1	Ref		Ref		Ref		Ref	
2	-6.16 (-18.39, 6.07)	*0.32*	-1.51 (-8.82, 5.80)	*0.68*	-4.46 (-15.40, 6.48)	*0.42*	-1.01 (-7.77, 5.76)	*0.77*
3	-0.77 (-10.76, 9.21)	*0.88*	1.65 (-4.38, 7.69)	*0.59*	-2.40 (-11.33, 6.54)	*0.60*	-1.63 (-3.98, 7.23)	*0.57*
4	7.90 (-4.33, 20.14)	*0.20*	2.41 (-4.96, 9.78)	*0.52*	5.14 (-5.81, 16.09)	*0.36*	2.65 (-4.15, 9.45)	*0.44*
Marital status								
Married	Ref		-	-	Ref		-	-
Single	0.86 (-8.55, 10.26)	*0.86*	-	-	1.48 (-6.88, 9.83)	*0.73*	-	-
Divorced/Separated	-1.99 (-8.99, 5.01)	*0.57*	-	-	-3.36 (-9.58, 2.86)	*0.29*	-	-
Widowed	3.59 (-3.13, 10.30)	*0.29*	-	-	1.30 (-4.67, 7.26)	*0.67*	-	-
Education Level								
None	Ref		-	-	Ref		-	-
Primary	-3.22 (-9.16, 2.71)	*0.29*	-	-	-2.64 (-7.93, 2.65)	*0.33*	-	-
Secondary/ Post-Sec	-6.37 (-15.80, 3.07)	*0.18*	-	-	-2.51 (-10.93, 5.91)	*0.56*	-	-
Occupation								
Unemployed	Ref		-	-	Ref		-	-
Non-Professional	1.99 (-4.61, 8.59)	*0.55*	-	-	1.51 (-4.42, 7.44)	*0.62*	-	-
Professional	-5.06 (-14.20, 4.08)	*0.28*	-	-	0.43 (-7.78, 8.64)	*0.92*	-	-
Baseline CD4 (cells/mm^3)	-0.01 (-0.03, 0.02)	*0.65*	-	-	0.01 (-0.02, 0.03)	*0.60*		
Baseline HIV-RNA (log_{10} copies/ml)	0.68 (-2.79, 4.15)	*0.70*	-	-	0.81 (-2.39, 4.00)	*0.62*		

associations between high and low values of PHS and MHS and the patient characteristics we evaluated [36]. The only exception, in our study, was patient age, where those who were younger had greater increases in their PHS and MHS scores. These increases would not be associated with clinical treatment outcomes as our study did not find any associations between age and clinical outcomes such as virological suppression or changes in CD4 cell counts (reported elsewhere) [14]. However, it is possible that younger patients are more optimistic and may have enhanced expectations of treatment which may have affected their physical and psychological recovery. Our study also found that lower baseline PHS and MHS scores were statistically significant predictors of higher increases in these scores after 12 months, findings which have been shown elsewhere [17]. This indicates that those with poor quality of life at the start of treatment improve more dramatically, and, after 12 months, end up with similar levels of quality of life as those who started with a relatively higher baseline quality of life. Similar findings were also observed by Strangl *et al.* in

eastern Uganda [33]. In our study, we found no associations between virological suppression and improvements in HRQOL. There is uncertainty around the association between clinical markers and quality of life; one study found a significant association between lower HIV-1 RNA viral load and higher quality of life [37] while other studies have found no such associations [18, 36, 38, 39].

We observed that 15 patients (12%) had a decrease in their PHS and MHS scores of more than 5 points. Decreases in HRQOL after starting on ART have been seen in studies in Europe by Murri *et al.*, in which 20-29% of Italian patients were found to have a decrease of 5 points in their MOS-HIV MHS and PHS scores after 6 months on treatment [17] and by Carrieri *et al.*, in which 27% of French patients were found to have decreases in their HRQOL after one year [21]. However, not much is known about decreases in HRQOL in the Ugandan or sub-Saharan African context. In our study, all but one of these 15 patients with a decrease in their HRQOL showed virological suppression after 12 months on treatment, indicating that despite being on treatment and achieving virological suppression, other factors in a patient's life can still lead to a diminished quality of life. A qualitative study that undertook a series of interviews with a random sample of patients and caregivers within our CBART program cohort found that patients on ART faced numerous and unexpected stresses, including concerns about the uncertainty of drug supply in the future, facing ongoing poverty, and ongoing issues related to stigma around the disease [40]. Another study in Uganda found that the quality of life of patients treated with ART was limited by factors such as pill burden, drug adverse effects, unemployment and poverty [41], as well as stigma for those that had not disclosed their HIV status [42]. Other studies in developing and developed countries have also identified negative outcomes of ART which could contribute to a patient's perception that their quality of life has decreased, including concerns about future drug adverse effects, managing treatment over the long-term, acceptance of the loss of certain aspects of quality of life, having to continue to hide an HIV-positive status, and psychological issues related to body image due to body fat redistribution while on treatment [43, 44].

Our study is unique in that it looks at the outcomes of patients in a rural ART program managed by non-physician health workers and supported by community volunteers and treatment partners. While this model of treatment provides an opportunity for delivering ART to underserved populations living in rural areas using locally available resources, there may be characteristics of the model that may contribute to not realizing even higher levels of changes in HRQOL. Community volunteer visits can either be a source of psychosocial support for patients facing the reality of living with HIV/AIDS and life-long treatment, or may contribute to poorer HRQOL outcomes if their support does not provide some of the additional benefits that a trained physician could. Patients may also experience anxiety about disclosure of their HIV status to others by volunteers or by neighbours observing volunteer visits to their homes. However, while stigma around HIV/AIDS continues to exist and does affect the ability of volunteers to undertake their activities, stigma has been on the decline in western Uganda over the past few years [45]. In addition, the patients in this study consented to being visited by volunteers, which indicates that they had overcome some aspects of confidentiality or disclosure of their HIV status. Finally, there were more men than women volunteers in the CBART program with patients unable to be matched with the same gender of volunteer. This may have had a negative impact on single, widowed, and divorced women who may have been uncomfortable with having a male volunteer visit them regularly. Many of the factors above could not be assessed within the context of this study, but have provided our team with interesting questions to pursue for future research. What is known at this time, through patient interviews, is the strong sense of appreciation and positive value that patients put on the community volunteer support they receive. In addition, during these interviews, patients did not identify any gender-related issues related to treatment support by volunteers.

There were some other limitations in our study. Logistical challenges resulted in baseline scores being measured over a period of 2 to 12 weeks. Studies have shown that treatment effects and dramatic increases in quality of life can be observed by 12 weeks [25, 33]. Sensitivity analyses showed that, within our cohort, patients whose baseline HRQOL was measured between 2-4 weeks after starting treatment did have a larger increase in their summary and domain scores compared to those whose HRQOL was measured 5-12 weeks after treatment. This suggests that our baseline measures overestimated the quality of life at the early stages of treatment and that the true change in quality of life between the start of treatment and one-year following treatment may be higher than we reported. Finally, we could not assess whether certain characteristics of the CBART program, including the potential for stigma-related issues because of lay-person involvement in monitoring, impacted the level of changes seen in HRQOL.

CONCLUSIONS

A community-based approach that engages community support to deliver ART can achieve positive clinical as well as quality of life outcomes in resource-poor countries such as Uganda. However, for those patients whose quality of life does not improve or gets worse, virological markers may not be a good surrogate measure for capturing this in a setting where other factors independent of health status (notably factors related to poverty) may have strong influences on a patient's quality of life while on ART. Thus, HRQOL surveys can be useful in identifying patients who, despite achieving virological suppression, may require additional attention and support to achieve the full benefits of ART. We would therefore recommend: a) the development and adoption of simplified HRQOL instruments that can be easily administered and analyzed by local health care workers as part of routine monitoring of patients on ART; b) additional research on factors influencing the quality of life of patients treated with ART to further assist policy makers, clinicians and social workers to improve rural-based ART programs; c) expanding the role of the community volunteers

used in this program to provide psychosocial support for those whose quality of life decreases; and d) engaging the social welfare department in the district to work with the health care department to ensure that social support can be made available to those in rural-based ART programs.

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