Health-Related Quality of Life and Associated Characteristics among Men Who Have Sex with Men and Transgender Women with HIV in Lima, Peru

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A thesis

Submitted in partial fulfillment of the

Requirements for the degree of

Master of Public Health

University of Washington

2019

Committee:

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Program Authorized to Offer Degree:

Global Health

University of Washington

Abstract

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Background: Clinical care for people living with HIV (PLWH) increasingly incorporates quality of life considerations due to advances in HIV treatment and decline in HIV-related mortality. Men who have sex with men (MSM) and transgender women (TW) constitute the majority of new HIV infections in Lima, Peru, and there is currently limited research evaluating health-related quality of life (HRQOL) determinants in these populations.

Methods: We analyzed differences in health-related quality of life between HIV-positive participants from the Sables study who were randomized to either initiate antiretroviral therapy (ART) immediately or to defer ART for 24 weeks after HIV diagnosis. Items from the Short Form (SF)-12 survey were evaluated as individual HRQOL outcomes, and generalized linear

model with bivariate and multivariate logistic analyses were used to assess the relationship between HRQOL, demographic characteristics and baseline CD4 count.

Results: The results of bivariate analyses indicated that participants who initiated ART immediately were more likely to report better general health at 48 weeks post HIV diagnosis (prevalence ratio (PR): 1.11, 95% confidence interval (CI) [1.01, 1.21]). Multivariate analyses revealed participants who reported higher HIV-related aversive coping at 48 weeks were more likely to report more limitations with moderate physical activities (adjusted prevalence ratio (APR): 0.86, 95% CI [0.77, 0.97]) and with climbing several flights of stairs (APR: 0.89, 95% CI [0.80, 0.99]), increased limitations with social functioning (APR: 0.70, 95% CI [0.58, 0.85]), elevated psychological distress (APR: 0.73, 95% CI [0.58. 0.92]), and more role limitations due to physical health (APR: 0.89, 95% CI [0.80, 0.99]). Baseline CD4 count of 500 cells/uL or higher was found to be associated with less psychological distress (APR: 1.36, 95% CI [1.01, 1.83]) and less interference on normal work due to pain (APR: 1.37, 95% CI [1.01, 1.88]).

Conclusions: Among HIV-positive MSM and TW participants in Lima, Peru, self-perceived general health status at 48 weeks was greater in the immediate ART arm compared to those who deferred ART for 6 months after HIV diagnosis. One year after HIV diagnosis, higher HIV-related aversive coping was associated with worse HRQOL outcomes. Higher CD4 count at diagnosis was associated with less psychological distress 1 year after HIV diagnosis.

INTRODUCTION

As a result of advances in HIV treatment in the last three decades and a decline in HIV-related mortality, therapeutic focus has expanded to include mental health and overall wellbeing in people living with HIV (PLWH).[1] Health-related quality of life (HRQOL) is a multifactorial concept that encompasses physical, psychological, and social functioning and perceptions of general wellbeing related to impacts of a disease and its treatment.[2] For chronic diseases like HIV, assessing HRQOL is becoming an integral aspect of post-diagnosis follow-up care. Previous evidence suggests associations between HRQOL in PLWH and ART adherence, substance use, and risky sexual behaviors.[3] Compared with the general population, PLWH have also been observed to have overall lower HRQOL.[4,5]

Optimizing retention in HIV care increases the likelihood of therapeutic success, as poor retention is associated with ART non-adherence, and poor health outcomes including failure to suppress HIV viral load, reduced CD4 counts, and ART resistance.[6] While studies have shown that immediate initiation of ART reduces HIV- and AIDS-related morbidity and mortality, as well as HIV transmission, few studies that have examined how the timing of ART initiation may affect quality of life.[7-9] To date, only one study has compared immediate and delayed post-diagnosis treatment initiation on self-assessed physical, mental, and general health status of PLWH. This study found that HRQOL was higher among individuals who initiated ART upon diagnosis, compared to those whose treatment was deferred until their CD4 count fell below 350 cells/uL.[8]

In Lima, HIV prevalence is greater than 10% among MSM[10] and as high as 30% among TW,[11] whereas the prevalence in the general population is less than 1%.[10] MSM and TW also make up the majority of new HIV diagnoses in Peru. Research suggests that poor mental HRQOL is independently associated with unprotected sex among MSM.[12] Given the relationship between poor HRQOL and high risk behaviors, surveying the HRQOL of MSM populations can not only provide valuable feedback on their physical health, mental health, and social functioning based on their own perceptions, but can also lead to more effective and targeted interventions.[13] Until recently, most studies related to HRQOL have examined the role of HRQOL in HIV prevention. Little research has been done on the determinants of HRQOL among MSM and TW post HIV diagnosis.

The relationship between post-HIV diagnosis aversive coping strategies and HRQOL among MSM and TW has also not been well-characterized in the literature. PLWH often develop adaptive and aversive coping mechanisms, which are cognitive and behavioral responses to the stress of managing a chronic disease.[14] Aversive coping strategies, including substance use, disengagement and diagnosis denial, have been shown to be associated with depressed mood,[14] lower HRQOL,[15] lower odds of linkage to care,[16] and act as mediators for the effect of stigma on mental health post-HIV diagnosis.[17] Scrutiny of aversive coping among PLWH can identify opportunities for early interventions and help clinicians prevent future adverse mental health outcomes.

The proposed study evaluated 1) the effect of immediate versus deferred ART initiation on HRQOL and 2) the effect of demographic and clinical characteristics on HRQOL in the Sabes cohort of HIV-positive MSM and TW in Lima, Peru. We hypothesized that participants who initiated ART immediately post HIV diagnosis would have better HRQOL compared to participants who deferred ART initiation for 24 weeks, and that education level, social support, and baseline CD4 count would be associated with better HRQOL, and aversive coping would be associated with worse HRQOL. Taken together, the associations identified in this study provide clinically applicable considerations relating to peri-HIV-diagnosis factors (immediacy of ART initiation and CD4 count) to the trajectory of perceived physical and mental wellbeing in a cohort of MSM and TW during the first year after their HIV diagnosis.

METHODS

Study setting and participants

The Sabes study (evaluation of an expanded treatment-as-prevention intervention among MSM and TW in Lima, Peru), is a collaborative project between researchers in the U.S. and Peru.[18] Between 2013 and 2015, 3336 participants were recruited and referred to outpatient primary care clinics Lima, Peru for study enrollment and HIV screening as the first phase (Step1) of the study (Figure 1). Peer educators also enrolled participants from previously identified social venues such as saunas, sex work areas, discotheques, bars, and beauty parlors. Eligibility criteria included assigned male sex at birth, reported sexual contact with one or more male partners in the previous 12 months, 18 years of age or older, unaware of personal HIV status, and were considered at heightened risk for HIV infection. Of the 2682 MSM and TW who were HIV-uninfected but high-risk for HIV acquisition at screening, 2109 of them agreed to return for follow-up and monthly HIV testing for up to 2 years in the second phase (Step 2) of the study (Figure 1). Of the 248 eligible participants who acquired HIV during the follow-up period, 216 of them were enrolled into a randomized study of timing of ART initiation between 2013 and 2016. To be eligible for the randomized ART initiation study, individuals had to have either acute (HIV seronegative and HIV RNA positive) or recent (HIV seropositive with a documented prior negative HIV test in the past 3 months) infection, be ART-naïve, have normal renal and liver functions, and provide informed consent. Those who met these inclusion criteria and agreed to participate were subsequently enrolled into the third phase (Step 3) of the study (Figure 1). At enrollment, participants were randomized 1:1, with stratification by acute/recent HIV status, to start ART immediately or to defer ART initiation by 24 weeks (henceforth referred to as "immediate or "deferred" ART). Participants received either co-formulated tenofovir disoproxil fumarate 300mg/emtricitabine 200mg/efavirenz 600mg (TDF/FTC/EFV) or tenofovir disoproxil fumarate 300mg/emtricitabine 200mg/cobicistat 150mg/ elvitegravir 150mg (TDF/FTC/c/EVG). One hundred five and 111 study participants were randomized to the immediate and deferred arm, respectively. ART was offered prior to 24 weeks for any deferred arm participant who reached the Peruvian criteria for ART initiation (CD4 count ≤350 cells/uL before December 2014; ≤500 cells/uL thereafter), or by clinician discretion, generally for symptomatic acute

retroviral syndrome or low CD4 count. Switching to alternative WHO-recommended ART regimens was allowed if virologic failure, ART toxicity or intolerance were detected. All study participants were followed for 48 weeks and then linked to the Peruvian Ministry of Health for continued no-cost HIV care at the completion of the study.

This study was approved by the Institutional Review Board at the Fred Hutchinson Cancer Research Center and the Bioethics Committee at IMPACTA Salud y Educación. All study participants provided written consent in Spanish, their preferred language, to participate in this study. Implementation of the study was authorized by the Peruvian National Institute of Health, and the study is registered with ClinicalTrials.gov (https://clinicaltrials.gov/; trial NCT01815580).

Variables

During the initial HIV screening visit at Step 1, participants answered questions pertaining to the following demographic characteristics: age, education level, sexual orientation, gender identity, and race.

The SF-12, a shortened version of the SF-36 Health Survey, is a health-related quality of life survey instrument that was used to capture our outcome of interest at 48 weeks. It consists of 12 questions that measure eight health domains to assess participants' physical and mental health components. Physical health-related domains include General Health, Physical Functioning, Role-Physical (measures role limitations due to physical health issues), and Body Pain. Mental health-related scales include Vitality, Social Functioning, Role-Emotional (evaluates role limitations due to emotional health), and Mental Health. This instrument has been used across a number of chronic conditions but physical- and mental- composite summary scores have not been validated in MSM and TW populations in Peru. Therefore, each question of the questionnaire was assessed individually. The survey was administered at the following 3 time points of the study: enrollment, week 24, and week 48, but only responses at week 48 were included in our analyses. Responses to the questionnaire items were dichotomized to address the skewness of the outcome variable.

At randomization and 48 weeks post-diagnosis study visits, we collected responses to the eleven subscales from Carver's Brief COPE scale to assess participants' coping styles in relation to how they were managing their HIV diagnosis. Options for each question range from 1 ("I have not done this at all" to 4 ("I have been doing this a lot"). Items for these subscales were summed, such that greater summary scores indicated greater frequency of using a particular type of coping style. We created a summary variable for aversive coping, based on factor analysis which included the following coping items: denial (I've been saying to myself this isn't real); substance use ("I drank alcohol or used drugs to feel better"); and behavioral disengagement ("I didn't confront the situation I found myself in"). Higher values of the aversive coping variable indicate higher levels of aversive coping.

CD4 count was measured at enrollment and dichotomized for our analyses (<500 cells/uL or

≥500 cells/uL). We created a dichotomous variable for experience of an ART-related adverse event. Self-reported social support at 48 weeks was measured using 5 items from the RAND Social Support scale, which assessed if participants had people who showed them love and affection, who could help them with daily tasks or chores, who could purchase medications, who could provide transportation, and who could provide financial assistance if they needed it.

Analysis

For the first component of our study, we compared HRQOL between the study arms with an intent-to-treat analysis. A separate model for each of the 12 SF-12 items was used to obtain prevalence ratios comparing immediate and deferred arms.

For the second component of our study, we conducted bivariate analyses to identify associations between HRQOL and social support at the 48-week study clinic visit, aversive coping at baseline and 48 weeks, experience of ART-related adverse events, and baseline CD4 count. Similar to the first component, we used each of the SF-12 items in individual models to obtain prevalence ratios. All participants who completed all SF-12 items were included in the analytic sample, but participants with missing data on predictors of interest were excluded from final models.

Then, we used a backward stepwise approach to identify the covariates associated with HRQOL. We identified education level, baseline CD4, ART-related adverse events, aversive coping at baseline and week 48, and social support at week 48 a priori as covariates of interest. Associations with p values less than 0.2 were considered for inclusion in multivariate models using generalized linear model with logistic regression. Aversive coping at baseline or week 48 were assessed individually in all models. All statistical analysis was performed in STATA version 15.1 (Statacorp, College Station, TX). Two-sided statistical tests were performed at an alpha level of 0.05.

RESULTS

Study population

Of a total 256 eligible participants with acute or recent HIV infections, 216 participants were enrolled in the study cohort. Participants were randomized to receive either immediate ART (n=105; 37 acute and 69 recent infections), or to deferred ART (n=111; 34 acute and 77 recent infections). Baseline demographic and clinical characteristics are summarized in Table 2, and were similar for the immediate and deferred groups. Participants in the immediate arm initiated ART at a mean of 1 day post diagnosis (range 0-6 days) and 106 deferred participants initiated ART at a mean of 22.6 weeks (range 0-28.6 weeks). Thirty-two participants who were randomized to deferred ART initiation began ART prior to 24 weeks.

[Bivariate analyses]

HRQOL by treatment arm

HRQOL component scores at study entry were similar in the immediate and deferred study arms (Table 4). Forty-eight weeks after HIV diagnosis, participants' sense of their general health status differed between the two groups. Participants who had been randomized to initiate ART immediately were 11% more likely to report "good or better overall health" compared to participants who were randomized to defer initiation of ART (PR: 1.11, 95% CI [1.01, 1.13]). There were no significant differences between the study arms for any of the other 11 HRQOL items.

Effect of education level on HRQOL

In bivariate models, education level at diagnosis was associated with participants' self-reported physical functioning 48 weeks post-diagnosis. Individuals who completed high school or more were more likely to report higher physical functioning compared to individuals who had not completed high school (Tables 9 & 10).

Effect of aversive coping on HRQOL

Higher aversive coping at baseline was found to be significantly associated with more limitations with moderate activities [PR: 0.62, 95% CI [0.44, 0.87], and with more limitations with climbing several flights of stairs [PR: 0.58, 95% CI [0.41, 0.82] at 48 weeks. Higher aversive coping scores at 48 weeks post HIV diagnosis were associated with more limitations with physical functioning (Table 9, 10). Participants who reported higher aversive coping at 48 weeks were also more likely to report limitations with social functioning (Table 7). Participants with higher aversive coping scores at 48 weeks also had a higher likelihood of reporting feeling "downhearted and blue" over the past week (Table 6).

Effect of social support on HRQOL

Participants who reported having people who cared about them "most or all of the time" or would "help them purchase medications most or all of the time" had a higher likelihood of not feeling "downhearted or blue" (Table 6). Participants who reported having people who cared about them "most or all of the time", people who would be able to "assist them with daily tasks or chores most or all of the time" and who could "help them purchase medications most or all of the time" were more likely to report experiencing no limitation in their social functioning compared to people who reported less social support (Table 7).

Effect of baseline CD4 and ART-related adverse events on HRQOL

Baseline CD4 level of 500 cells/uL or higher was associated with less likelihood of "feeling downhearted or blue" (Table 6). Participants who experienced any ART-related adverse event had a higher likelihood of expressing that "physical pain interfered with their normal work" compared to participants who did not experience any ART-related adverse events (Table 12).

[Multivariate analyses]

Using generalized linear model with multivariate logistic regressions to identify characteristics associated with HRQOL, we found that treatment arm was still associated with participants' self-perceived general health status (Table 8, 13). Higher education level and lower aversive coping scores at 48 weeks were independently associated with less limitations with physical activities (Table 13). Higher aversive coping scores at 48 weeks were also associated with increased likelihood of reporting feeling "less accomplished as a result of one's physical health," feeling "downhearted and blue," and having more limitations with social functioning. Higher CD4 levels at baseline was associated with lower likelihood of participants reporting "pain interfered with [their] normal work" and "feeling downhearted and blue." Having social support who could help purchase medications and who loved and cared for the participants were associated with less reports of "feeling downhearted and blue" and having limitations with social activities such as visiting with friends or relatives, respectively.

DISCUSSION

A secondary intent-to-treat analysis of the Sabes cohort of MSM and TW showed that timing of ART initiation had an impact on only 1 of 12 components of health-related QOL measures: participants' reports of their general health 48 weeks after HIV diagnosis. Participants who initiated ART immediately after HIV diagnosis were more likely to report "good or better general health" than individuals who deferred ART for 24 weeks after enrollment. Aversive coping 48 weeks after diagnosis across the whole sample was found to be associated with self-reported" role limitations due to physical health", "limitations with social activities", and "psychological distress" at 48 weeks, although aversive coping at baseline was not associated with HRQOL measures at 48 weeks post-diagnosis. Peri-diagnosis CD4 level was also associated with psychological distress and pain interference with normal work. Altogether, these results suggest that CD4 count predicts post-diagnosis HRQOL, that immediate initiation of ART has a negligible effect on post-diagnosis HRQOL, and that self-reported aversive coping predicts poorer HRQOL one year after HIV diagnosis.

Meaning of the study: possible mechanisms and implications for clinicians or policymakers

We hypothesized that that the timing of ART initiation among ART-naïve HIV-positive MSM and TW would have an impact on many aspects of their HRQOL. The relatively minimal impact of immediate ART initiation on 1-year post-diagnosis HRQOL could be explained by the Sabes study participants' relatively young age and overall good health at study enrollment. All participants had regular check-ins with counselors, and being engaged in this study might have had an overall positive effect on all participants' HRQOL regardless of the timing of their ART initiation.

We identified several other factors that were associated with components of the HRQOL survey. Notably, aversive coping at 48 weeks was positively associated with increased limitations with physical functioning such as moderate physical activity and climbing several flights of stairs, limitations with accomplishments and social functioning, as well as increased psychological

distress such as feeling depressed or anxious. Despite the fact that baseline aversive coping was not associated with HRQOL one year after HIV diagnosis when we controlled for other covariates, we posit that it is still an important indicator of future physical and mental quality of life. This finding also suggests that as individuals deal with the new diagnosis of a serious and chronic condition, knowing what their coping strategies are can be important for predicting long-term wellbeing.

Baseline CD4 count <500 cells/uL was found to be associated with increased psychological distress as well as increased limitations with normal work due to bodily pain one year after diagnosis. Previous research has highlighted the predictive value of pre-treatment CD4 count on HIV-related mortality. These findings suggest that CD4 count prior to ART initiation may be useful in decisions regarding screening and prevention measures for psychological distress in places where it is not part of routine care for MSM and TW with HIV.

Strengths and weaknesses of the study

This study had a number of strengths. Unlike most studies that have evaluated HRQOL among PLWH, Step 3 of the Sabes study was a randomized trial, which provided an unique opportunity to assess how timing of ART initiation and other variables impact HRQOL in a cohort of MSM and TW who have been randomized from baseline to follow up at 48 weeks.

The intent-to-treat analysis provided comparisons between participants who had immediate ART initiation and participants who had delayed ART initiation. To our knowledge, only one other study has evaluated the association between timing of ART initiation and quality of life[8]. While there have been some studies that assessed HRQOL among MSM in China, the United States, and Sweden, this study is the first to evaluate this important outcome in the HIV-positive MSM and TW populations in Peru.

Several limitations should be considered when interpreting the results of this study. First, the intent-to-treat analysis included all participants randomized to immediate or deferred ART, regardless of timing of their actual ART initiation. This may have attenuated the true measures of association due to cross-over. Because the total cross-over during the trial was below 30% (percentage of participants from deferred ART group who initiated ART earlier than 24 weeks), we expect the dilutional impact to be relatively small. Although the SF-12 survey has been used in certain populations as a metric of quality of life, calculations using component summary scores have not been previously validated in the MSM or TW populations in Peru. Because of this limitation, we decided to assess the questions of the survey individually and therefore did not determine physical or mental composite scores for this cohort. Additionally, our analysis is not necessarily generalizable to the whole MSM and TW populations in Lima. MSM and TW participants were enrolled while visiting participating clinics, or by peer-educators who visited previously identified social venues, and TW who used estrogens or antiandrogens in the previous 3 months were excluded from the trial. Additionally, the Sabes study targeted a subset of MSM and TW who were at particularly high risk of HIV acquisition. Nevertheless, these results provide important insight into the relationship between ART initiation and other covariates associated with HRQOL among MSM and TW in high risk groups.

Comparison to other studies

The only other study to have examined the impact of timing of ART initiation on HRQOL is the START trial, which randomized healthy ART naïve PLWH with >500 CD4 cells/uL from 35 countries to immediate versus deferred ART and found modest but significant improvements in HRQOL in the immediate ART arm. In contrast, our results showed no variations between the two groups in any HRQOL metrics except for the participants' self-assessment of their general health status. Both trials randomized ART-naïve, HIV-positive participants to either immediate ART initiation or deferred ART initiation and HRQOL was measured in both using the SF-12 questionnaire. However, there are several noteworthy differences in these study designs. First, the START trial enrolled adult PLWH from 35 countries, whereas the Sabes study enrolled MSM and TW in Lima, Peru. Second, participants randomized to the deferred group in the START trial did not receive ART until their CD4 count decreased to <350 cells/uL or until the development of AIDS or another condition requiring ART, whereas Sabes participants in the deferred arm received ART after 24 weeks regardless of their CD4 count. Since CD4 count is a measure of immune system functioning and might impact general health, individuals with lower CD4 might also have lower HRQOL as a result. Third, the START trial analyzed 3 HRQOL outcomes, including general health, the physical component summary score, and the mental component summary score, which are weighted averages based on responses to all SF-12 items and standardized to have a mean score of 50 and a standard deviation of 10 in a U.S. reference population. Instead of utilizing the physical and mental component summary scores, we analyzed the individual items from the SF-12 as 12 individual QOL outcomes. Because the SF-12 has not been validated in our study population, this was considered the best approach for minimizing bias. Similar to the START trial, our analysis detected that participants in the immediate ART group had better perceived general health 48 months after diagnosis than those in the deferred ART group. However, the START trial reported changes in all QOL measures from baseline whereas we analyzed differences between the two groups at baseline and at week-48 follow up cross-sectionally.

Unanswered questions and future research

The antiretroviral medications used in this study included either co-formulated tenofovir disoproxil fumarate 300mg/emtricitabine 200mg/efavirenz 600mg (TDF/FTC/EFV) or tenofovir disoproxil fumarate 300mg/emtricitabine 200mg/cobicistat 150mg/elvitegravir 150mg (TDF/FTC/c/EVG). Our analysis showed that all of the study participants were exposed to efavirenz, an antiretroviral medication known to have associated neuropsychiatric effects.[19] Studies have shown that dolutegravir (DTG) is superior to efavirenz among treatment naïve individuals, and a systematic review has shown that DTG-based regimens are better tolerated and are more protective against medication discontinuation due to adverse events when compared to efavirenz-containing regimens.[20] Future studies using DTG-based therapies will have the opportunity to assess if a different ART regimen can influence HRQOL among this population. Future studies should also evaluate potential mental health interventions aimed at decreasing aversive coping among MSM and TW with HIV on HRQOL metrics.

CONCLUSION

In this secondary analysis of a randomized trial of ART-naïve MSM and TW participants in Lima, Peru, no HRQOL differences were observed in participants immediately initiating ART following HIV diagnosis compared to those who deferred treatment for 6 months, except for self-reported general health status. Education level, peri-diagnosis CD4 count, aversive coping at 48 weeks post-diagnosis, and social support at 48 weeks were all associated with HRQOL components at 48 weeks after HIV diagnosis.

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Figure 1. Sabes Study Procedures

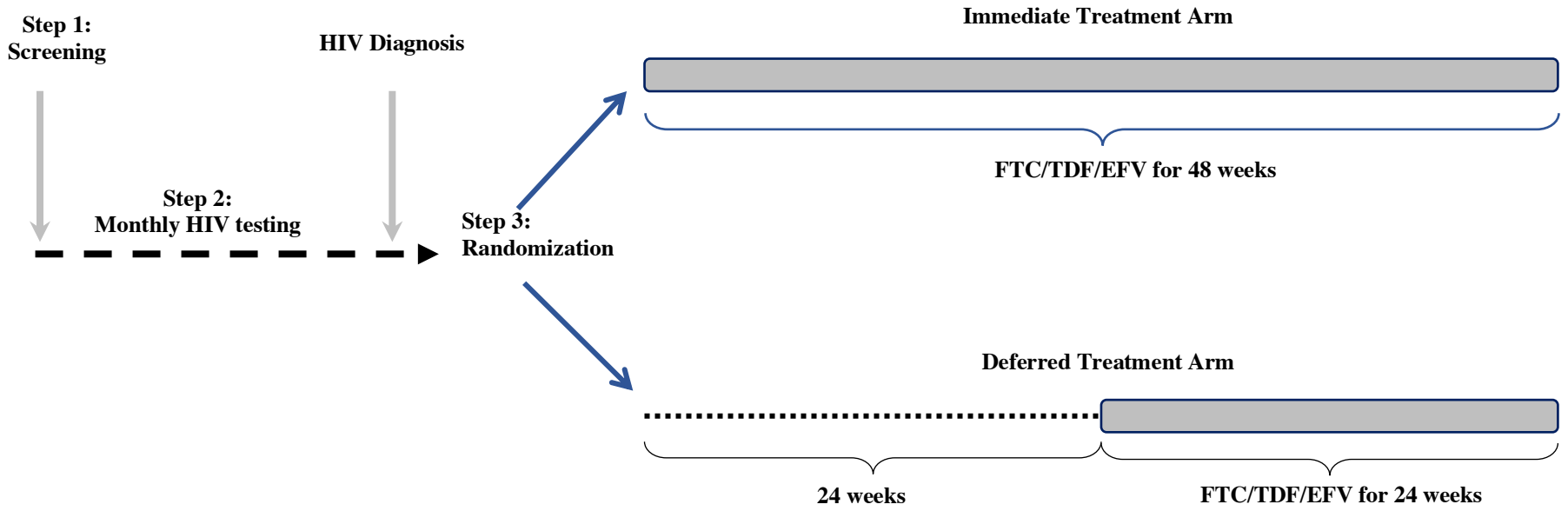

Figure 2. Diagram for Participants in the Sabes Study ART Initiation Trial

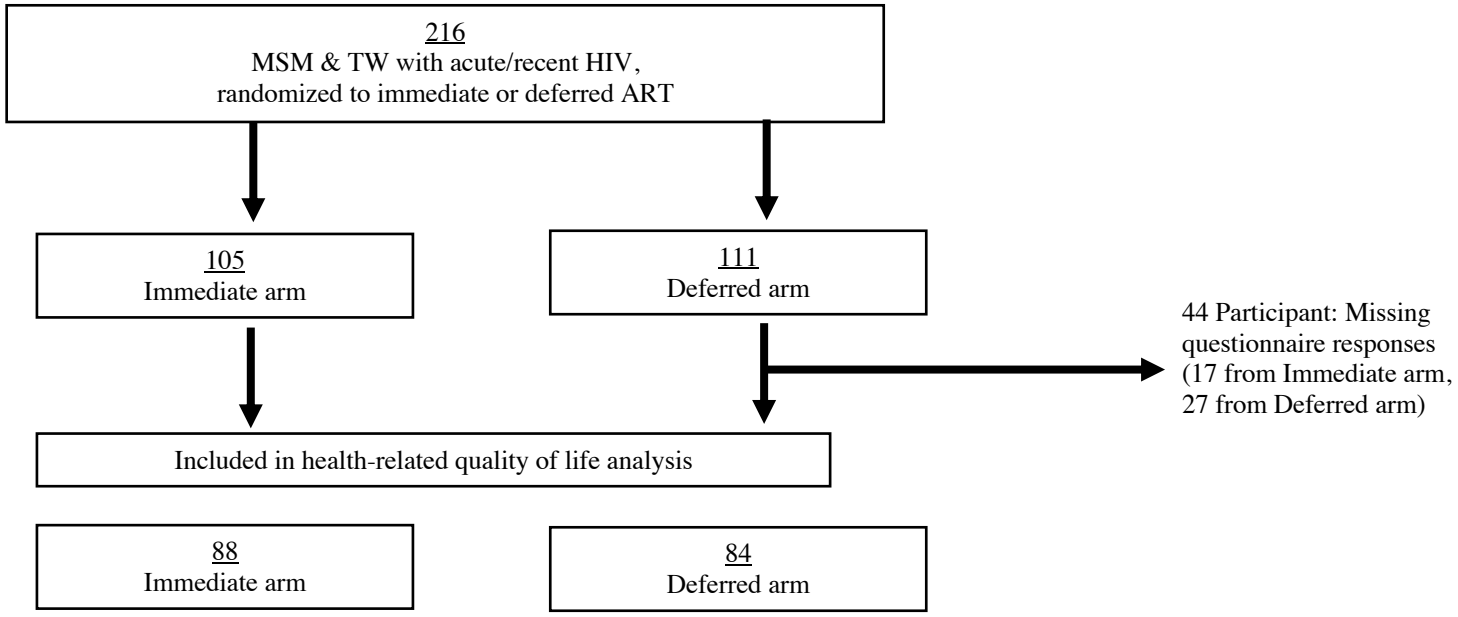

Table 1. Sabes Study Predictors and Outcome

		Variables
Outcome		Health-related quality of life at 48 weeks
Predictors	Enrollment	Demographic characteristics, study arm (immediate vs. deferred ART); CD4; aversive coping
	48 Weeks	Aversive coping; social support (-care, -chores, -medication, -transport, -money)

Table 2. Characteristics of Sabes Participants at the Time of Their Enrollment Visit (N=216)					
	Immediate (N=105)		Deferred (N=111)		
Characteristic	**N**	**%**	**N**	**%**	**P-value**
Age (Mean, SD)	27.8	7.3	26.6	6.8	0.19
Race[a]					
White	9	9.1	10	9.3	0.32
Black	1	1.0	0	0.0	
Indigenous	4	4.0	1	0.9	
Mestizo	61	61.6	70	64.8	
Asian	0	0.0	2	1.9	
Other/Mixed	1	1.0	4	3.7	
Not Reported	23	23.2	21	19.4	
Gender					
Male	87	82.9	89	80.2	0.12
Female	4	3.8	0	0.0	
Transgender	3	2.9	10	9.0	
Not Reported	11	10.5	12	10.8	
Sexual Orientation					
Heterosexual	3	2.9	5	4.5	0.80
Homosexual	65	61.9	64	57.7	
Bisexual	19	18.1	23	20.7	
Transgender	7	6.7	8	7.2	
Other	2	1.9	1	0.9	
Not Reported	9	8.6	10	9.0	
Education					
High School or Less	20	20.2	36	33.3	0.13
Some Technical School or University	35	35.4	38	35.2	
Complete Technical School, University, or Higher	35	35.4	28	25.9	
Not Reported	9	9.1	6	5.6	
HIV Diagnosis					
Acute	37	35.2	34	30.6	0.47
Recent	68	64.8	77	69.4	
Baseline CD4 Level (Mean, SD)	431.7	207.7	433.7	211.9	0.94
Baseline Log Transformed Viral Load (Mean, SD)	13.4	2.7	13.2	2.2	0.73

[a]Categories for race are mutually exclusive. All participants are Hispanic
[b]Baseline CD4 was dichotomized to <500 cells/uL or ≥500 cells/uL

Table 3. Self-Reported Quality of Life Metrics among MSM and TW Participating in the Sabes Study (N=216) at Enrollment

	Immediate (n=88)		Deferred (n=84)				
	n[a]	%[a]	n[a]	%[a]	p-value[b]	PR[c]	95% CI[d]
Good or better health	80	82	96	89	0.15	0.92	(0.82, 1.03)
No limitations with moderate activities[f]	62	63	62	57	0.39	1.10	(0.88, 1.38)
No limitations with climbing several flights of stairs	65	66	64	59	0.30	1.12	(0.91, 1.38)
Did not feel less accomplished due to physical health[e]	67	68	75	69	0.87	0.98	(0.82, 1.18)
No limitations in work or daily activities due to physical health[e]	72	74	81	75	0.80	0.98	(0.83, 1.15)
Did not feel less accomplished due to mental health[e]	66	67	77	71	0.54	0.95	(0.79, 1.13)
Did not work less carefully due to mental health[e]	68	69	76	70	0.88	0.99	(0.82, 1.18)
Pain did not interfere with normal work[e]	40	41	44	41	0.99	1.00	(0.72, 1.39)
Felt calm and peaceful[e]	42	43	54	50	0.34	0.87	(0.64, 1.16)
Had abundant energy[e]	31	32	45	42	0.16	0.77	(0.53, 1.11)
Did not feel downhearted and blue[e]	35	36	50	46	0.14	0.78	(0.56, 1.09)
Did not feel social activities were limited by health[e]	51	53	60	56	0.67	0.95	(0.73, 1.22)

[a] Do not include participants who did not complete survey instrument at baseline
[b] P-values refer to the bivariate association
[c] PR: unadjusted prevalence ratio
[d] CI: confidence interval
[e] Participants were asked to answer questions pertaining to their experiences in the previous week
[f] i.e. moving a table, pushing a vacuum cleaner, bowling, or playing golf
[g] may not add up to total value due to small numbers of missing value

Table 4. Self-Reported HRQOL among MSM and TW in the Sabes Study (N=216) at 48 weeks Post-HIV diagnosis

	Immediate (n=105)		Deferred (n=111)				
	n[a]	%[a]	n[a]	%[a]	p-value[b]	PR[c]	95% CI[d]
Good or better health	84	95	72	86	**0.033**	1.11	(1.01, 1.13)
No limitations with moderate activities[f]	66	75	64	76	0.86	0.98	(0.83, 1.17)
No limitations with climbing several flights of stairs	66	75	63	75	1.00	1.00	(0.84, 1.19)
Did not feel less accomplished due to physical health[e]	65	74	64	76	0.73	0.97	(0.82, 1.15)
No limitations in work or daily activities due to physical health[e]	69	78	71	85	0.30	0.93	(0.80, 1.07)
Did not feel less accomplished due to mental health[e]	70	80	63	75	0.48	1.06	(0.90, 1.25)
Did not work less carefully due to mental health[e]	66	75	69	82	0.26	0.91	(0.78, 1.07)
Pain did not interfere with normal work[e]	52	59	49	58	0.92	1.01	(0.79, 1.30)
Felt calm and peaceful[e]	51	58	48	57	0.92	1.01	(0.78, 1.31)
Had abundant energy[e]	38	43	44	52	0.23	0.82	(0.60, 1.13)
Did not feel downhearted and blue[e]	41	47	39	46	0.98	1.00	(0.73, 1.38)
Did not feel social activities were limited by health[e]	53	60	47	56	0.57	1.08	(0.83, 1.39)

[a] Do not include participants who did not complete survey instrument at 48 weeks
[b] P-values refer to the bivariate association.
[c] PR: unadjusted prevalence ratio
[d] CI: confidence interval
[e] Participants were asked to answer questions pertaining to their experiences in the previous week
[f] i.e. moving a table, pushing a vacuum cleaner, bowling, or playing golf
[g] may not add up to total value due to small numbers of missing value

Table 6. HRQOL question assessing "How much of the time did you feel downhearted and blue in the past week" and predictors of interest

Variables	Level	Some of the time		None of the time		PR[a]	P value[b]
		n	%	n	%		
Study arm	Deferred	45	49	39	49		0.98
	Immediate	47	51	41	51		
Age	<25	38	41	37	46		0.51
	≥25	54	59	43	54		
Education	Some high school or less	20	24	22	29		0.46
	Completed high school or more	64	76	54	71		
Baseline CD4	<500	67	73	47	59	1.38	0.05
	≥500	25	27	33	41		
ART-related A/E	No	53	87	40	78		0.24
	Yes	8	13	11	22		
Aversive coping, week48 (mean, SD)		0.27	1.06	-0.26	0.87	0.71	<0.001
Social support-care, week48[c]	<half of time	65	71	42	52	1.49	0.014
	Most/all the time	27	29	38	48		
Social support-chores, week48[d]	<half of time	70	76	41	51	1.73	<0.001
	Most/all the time	22	24	39	49		
Social support-medications, week48[e]	<half of time	78	85	54	68	1.59	0.007
	Most/all the time	14	15	26	32		
Social support-transport, week48[f]	<half of time	76	83	58	72	1.34	0.11
	Most/all the time	16	17	22	28		
Social support-money, week48[g]	<half of time	79	86	61	76	1.36	0.11
	Most/all the time	13	14	19	24		

[a] PR: unadjusted prevalence ratio, ones with associations tested in multivariate models were included
[b] P-values refer to the bivariate association.
[c] Social support question that asked participants if they had people who cared about them less than half of the time or most/all of the time
[d] Social support question that asked participants if they had people who helped them with chores less than half of the time or most/all of the time
[e] Social support question that asked participants if they had people who could help them purchase necessary medications less than half of the time or most/all of the time
[f] Social support question that asked participants if they had people who could provide them transportation less than half of the time or most/all of the time
[g] Social support question that asked participants if they had people who could provide them monetary assistance less than half of the time or most/all of the time

Table 7. HRQOL question assessing "How much of the time did you feel limited with social activities due to physical and mental health in the past week" and predictors of interest

Variables	Level	Some of the time		None of the time		PR	P value
		n	%	n	%		
Study arm	Deferred	37	51.4	47	47		0.57
	Immediate	35	48.6	53	53		
Age	<25	33	45.8	42	42		0.62
	≥25	39	54.2	58	58		
Education	Some high school or less	17	25	25	27		0.76
	Completed high school or more	51	75	67	73		
Baseline CD4	<500	52	72.2	62	62	1.20	0.16
	≥500	20	27.8	38	38		
ART-related A/E	No	43	84	50	82		0.76
	Yes	8	16	11	18		
Aversive coping, week48 (mean, SD)		0.43	1.09	-0.27	0.84	0.70	<0.001
Social support-care, week48	<half of time	52	72.2	55	55	1.35	0.022
	Most/all the time	20	27.8	45	45		
Social support-chores, week48	<half of time	52	72.2	59	59	1.26	0.074
	Most/all the time	20	27.8	41	41		
Social support-medications, week48	<half of time	59	81.9	73	73	1.22	0.17
	Most/all the time	13	18.1	27	27		
Social support-transport, week48	<half of time	56	77.8	78	78		0.97
	Most/all the time	16	22.2	22	22		
Social support-money, week48	<half of time	62	86.1	78	78	1.23	0.18
	Most/all the time	10	13.9	22	22		

[a] PR: unadjusted prevalence ratio, ones with associations tested in multivariate models were included
[b] P-values refer to the bivariate association.
[c] Social support question that asked participants if they had people who cared about them less than half of the time or most/all of the time
[d] Social support question that asked participants if they had people who helped them with chores less than half of the time or most/all of the time
[e] Social support question that asked participants if they had people who could help them purchase necessary medications less than half of the time or most/all of the time
[f] Social support question that asked participants if they had people who could provide them transportation less than half of the time or most/all of the time
[g] Social support question that asked participants if they had people who could provide them monetary assistance less than half of the time or most/all of the time

Table 8. HRQOL question assessing "In general how would you characterize your health" and predictors of interest

Variables	Level	Poor/Fair		Good/Excellent		P value
		n	%	n	%	
Study arm	Deferred	12	75	72	46.2	0.028
	Immediate	4	25	84	53.8	
Age	<25	4	25	71	45.5	0.12
	≥25	12	72	85	54.5	
Education	Some high school or less	5	33.3	37	25.5	0.51
	Completed high school or more	10	66.7	108	74.5	
Baseline CD4	<500	8	50	106	67.9	0.15
	≥500	8	50	50	32.1	
ART-related A/E	No	9	90	84	82.4	0.54
	Yes	1	10	18	17.6	
Aversive coping, week48 (mean, SD)		0.45	1.26	-0.02	0.98	0.078
Social support-care, week48[b]	<half of time	11	68.8	96	61.5	0.57
	Most/all the time	5	31.2	60	38.5	
Social support-chores, week48[c]	<half of time	9	56.2	102	65.4	0.47
	Most/all the time	7	43.8	54	34.6	
Social support-medications, week48[d]	<half of time	11	68.8	121	77.6	0.43
	Most/all the time	5	31.2	35	22.4	
Social support-transport, week48[e]	<half of time	10	62.5	124	79.5	0.12
	Most/all the time	6	37.5	32	20.5	
Social support-money, week48[f]	<half of time	14	87.5	126	80.8	0.51
	Most/all the time	2	12.5	30	19.2	

[a] P-values refer to the bivariate association.
[b] Social support question that asked participants if they had people who cared about them less than half of the time or most/all of the time
[c] Social support question that asked participants if they had people who helped them with chores less than half of the time or most/all of the time
[d] Social support question that asked participants if they had people who could help them purchase necessary medications less than half of the time or most/all of the time
[e] Social support question that asked participants if they had people who could provide them transportation less than half of the time or most/all of the time
[f] Social support question that asked participants if they had people who could provide them monetary assistance less than half of the time or most/all of the time

Table 9. HRQOL Question Assessing "Does your health now limit you in moderate activities such as moving a table, pushing a vacuum cleaner, bowling, or playing golf" and Predictors of Interest

Variables	Level	Limited		Not limited		PR[a]	P value[b]
		n	%	n	%		
Study arm	Deferred	20	47.6	64	49.2		0.86
	Immediate	22	52.4	66	50.8		
Age	<25	26	61.9	49	37.7	1.29	0.006
	≥25	16	38.1	81	62.3		
Education	Some high school or less	16	43.2	26	21.1	1.33	0.007
	Completed high school or more	21	56.8	97	78.9		
Baseline CD4	<500	28	66.7	86	66.2		0.95
	≥500	14	33.3	44	33.8		
ART-related A/E	No	26	84	67	83		0.88
	Yes	5	16	14	17		
Aversive coping, week48 (mean, SD)		0.51	1.11	-0.13	0.93	0.84	<0.001
Social support-care, week48	<half of time	26	61.9	81	62.3		0.96
	Most/all the time	16	38.1	49	37.7		
Social support-chores, week48	<half of time	27	64.3	84	64.6		0.97
	Most/all the time	15	35.7	46	35.4		
Social support-medications, week48	<half of time	33	78.6	99	76.2		0.75
	Most/all the time	9	21.4	31	23.8		
Social support-transport, week48	<half of time	31	73.8	103	79.2		0.46
	Most/all the time	11	26.2	27	20.8		
Social support-money, week48	<half of time	34	81	106	81.5		0.93
	Most/all the time	8	19	24	18.5		

[a] PR: unadjusted prevalence ratio, ones with associations tested in multivariate models were included
[b] P-values refer to the bivariate association.
[c] Social support question that asked participants if they had people who cared about them less than half of the time or most/all of the time
[d] Social support question that asked participants if they had people who helped them with chores less than half of the time or most/all of the time
[e] Social support question that asked participants if they had people who could help them purchase necessary medications less than half of the time or most/all of the time
[f] Social support question that asked participants if they had people who could provide them transportation less than half of the time or most/all of the time
[g] Social support question that asked participants if they had people who could provide them monetary assistance less than half of the time or most/all of the time

Table 10. HRQOL Question Assessing "Does your health now limit you in climbing several flights of stairs" and Predictors of Interest

Variables	Level	Limited		Not limited		PR[a]	P value[b]
		n	%	n	%		
Study arm	Deferred	21	48.8	63	48.8		1.00
	Immediate	22	51.2	66	51.2		
Age	<25	24	55.8	51	39.5	1.93	0.062
	≥25	19	44.2	78	60.5		
Education	Some high school or less	17	44.7	25	20.5	1.38	0.003
	Completed high school or more	21	55.3	97	79.5		
Baseline CD4	<500	30	69.8	84	65.1		0.58
	≥500	13	30.2	45	34.9		
ART-related A/E	No	28	85	65	82		0.74
	Yes	5	15	14	18		
Aversive coping, week48 (mean, SD)		0.44	0.44	-0.12	0.95	0.86	0.002
Social support-care, week48	<half of time	25	58.1	82	63.6		0.53
	Most/all the time	18	41.9	47	36.4		
Social support-chores, week48	<half of time	28	65.1	83	64.3		0.93
	Most/all the time	15	34.9	46	35.7		
Social support-medications, week48	<half of time	33	76.7	99	76.7		1.00
	Most/all the time	10	23.3	30	23.3		
Social support-transport, week48	<half of time	32	74.4	102	79.1		0.52
	Most/all the time	11	25.6	27	20.9		
Social support-money, week48	<half of time	37	86	103	79.8		0.37
	Most/all the time	6	14	26	20.2		

[a] PR: unadjusted prevalence ratio, ones with associations tested in multivariate models were included
[b] P-values refer to the bivariate association.
[c] Social support question that asked participants if they had people who cared about them less than half of the time or most/all of the time
[d] Social support question that asked participants if they had people who helped them with chores less than half of the time or most/all of the time
[e] Social support question that asked participants if they had people who could help them purchase necessary medications less than half of the time or most/all of the time
[f] Social support question that asked participants if they had people who could provide them transportation less than half of the time or most/all of the time
[g] Social support question that asked participants if they had people who could provide them monetary assistance less than half of the time or most/all of the time

Table 11. HRQOL Question Assessing "Have you accomplished less than you would like in your work or other regular daily activities as a result of feeling depressed or anxious" and Predictors of Interest

Variables	Level	Yes		No		P value[a]
		n	%	n	%	
Study arm	Deferred	21	53.8	63	47.4	0.48
	Immediate	18	46.2	70	52.6	
Age	<25	17	43.6	58	43.6	1.00
	≥25	22	56.4	75	56.4	
Education	Some high school or less	10	27	32	26	0.90
	Completed high school or more	27	73	91	74	
Baseline CD4	<500	27	69.2	87	65.4	0.66
	≥500	12	30.8	46	34.6	
ART-related A/E	No	26	81	67	84	0.75
	Yes	6	19	13	16	
Aversive coping, week48 (mean, SD)		0.35	1.12	-0.07	0.96	0.023
Social support-care, week48	<half of time	26	66.7	81	60.9	0.51
	Most/all the time	13	33.3	52	39.1	
Social support-chores, week48	<half of time	26	66.7	85	63.9	0.75
	Most/all the time	13	33.3	48	36.1	
Social support-medications, week48	<half of time	32	82.1	100	75.2	037
	Most/all the time	7	17.9	33	24.8	
Social support-transport, week48	<half of time	32	82.1	102	76.7	0.48
	Most/all the time	7	17.9	31	23.3	
Social support-money, week48	<half of time	35	89.7	105	78.9	0.13
	Most/all the time	4	10.3	28	21.1	

[a] P-values refer to the bivariate association.
[b] Social support question that asked participants if they had people who cared about them less than half of the time or most/all of the time
[c] Social support question that asked participants if they had people who helped them with chores less than half of the time or most/all of the time
[d] Social support question that asked participants if they had people who could help them purchase necessary medications less than half of the time or most/all of the time
[e] Social support question that asked participants if they had people who could provide them transportation less than half of the time or most/all of the time
[f] Social support question that asked participants if they had people who could provide them monetary assistance less than half of the time or most/all of the time

Table 12. HRQOL Question Assessing "How much did pain interfere with your normal work (including work outside the home and housework in the past week" and Predictors of Interest

Variables	Level	Some		Not at all		P value
		n	%	n	%	
Study arm	Deferred	35	49.3	49	48.5	0.92
	Immediate	36	50.7	52	51.5	
Age	<25	33	46.5	42	41.6	0.52
	≥25	38	53.5	59	58.4	
Education	Some high school or less	16	24	26	28	0.56
	Completed high school or more	51	76	67	72	
Baseline CD4	<500	52	73.2	62	61.4	0.11
	≥500	19	26.8	39	38.6	
ART-related A/E	No	45	92	48	76	0.029
	Yes	4	8	15	24	
Aversive coping, week48 (mean, SD)		0.15	0.98	-0.07	1.03	0.16
Social support-care, week48	<half of time	49	69	58	57.4	0.12
	Most/all the time	22	31	43	42.6	
Social support-chores, week48	<half of time	43	60.6	68	67.3	0.36
	Most/all the time	28	39.4	33	32.7	
Social support-medications, week48	<half of time	52	73.2	80	79.2	0.36
	Most/all the time	19	26.8	21	20.8	
Social support-transport, week48	<half of time	53	74.6	81	80.2	039
	Most/all the time	18	25.4	20	19.8	
Social support-money, week48	<half of time	57	80	83	82.2	0.75
	Most/all the time	14	20	18	17.8	

[a] P-values refer to the bivariate association.
[b] Social support question that asked participants if they had people who cared about them less than half of the time or most/all of the time
[c] Social support question that asked participants if they had people who helped them with chores less than half of the time or most/all of the time
[d] Social support question that asked participants if they had people who could help them purchase necessary medications less than half of the time or most/all of the time
[e] Social support question that asked participants if they had people who could provide them transportation less than half of the time or most/all of the time
[f] Social support question that asked participants if they had people who could provide them monetary assistance less than half of the time or most/all of the time

Table 13. Multivariate Analyses Showing Statistically Significant Associations Between HRQOL Metrics and Study Arm, Education Level, Baseline CD4 Count, as well as Aversive Coping and Social Support at 48 Weeks

	Arm		Edu		CD4		AC		SS-1[c]		SS-3[d]	
	PR[a]	P[b]	PR[a]	P[b]	PR[a]	P[b]	PR	P[b]	PR	P[b]	PR	P[b]
Good or better health	1.11	0.03										
No limitations with moderate activities			1.29	<0.05			0.86	0.01				
No limitations with climbing stairs			1.35	0.03			0.89	0.04				
Did not feel less accomplished due to physical health[e]							0.89	0.03				
No limitations in work/activities due to physical health[e]												
Did not feel less accomplished due to mental health[e]												
Did not work less carefully due to mental health[e]												
Pain did not interfere with normal work[e]					1.37	0.05						
Felt calm and peaceful[e]												
Had abundant energy[e]												
Did not feel downhearted and blue[e]					1.36	<0.05	0.73	<0.01			1.54	<0.01
Did not feel social activities were limited by health							0.71	<0.001	1.28	0.03		

[a] PR: adjusted prevalence ratio
[b] p: - refer to p-values of multivariate associations
[c] SS-1: a social support question that asked participants whether they had people who cared about them less than half of the time or most/all of the time
[d] SS-3: a social support question that asked participants whether they had people who could help them purchase necessary medications less than half of the time or most/all of the time
[e] Participants were asked to answer questions pertaining to their experiences in the previous week