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Adherence to tobacco dependence treatment among HIV-infected smokers

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Abstract

High prevalence of tobacco use and low success in quitting remain significant problems for reducing disease burden among HIV-infected persons. This study's purpose was to examine participant responsiveness and tobacco dependence treatment adherence and their influences on tobacco abstinence among HIV-infected patients. This non-randomized study included HIV-infected smokers 18 years of age or older, who smoked at least 5 cigarettes per day, and had an interest in quitting smoking in the next 30 days. HIV-infected smokers ($n = 247$) received a 12-week tobacco dependence treatment intervention that included pharmacotherapy and telephone counseling. Younger age and non-White race were associated with lower adherence to pharmacotherapy. Younger age, non-White race, and increased monthly binge drinking were associated with lower adherence to telephone counseling. High participant responsiveness was associated with adherence to pharmacotherapy, counseling, and abstinence. Development and testing of interventions to improve adherence to evidence-based tobacco dependence treatment is warranted.

Keywords

HIV; tobacco dependence treatment; smoking cessation; adherence; participant responsiveness

Introduction

The success of potent combination antiretroviral therapy (ART) has drastically improved life-expectancy of individuals infected with the human immunodeficiency virus (HIV) (1); thus, HIV has become a “treatable” chronic disease. For HIV-infected patients on ART, non-AIDS-related conditions such as pulmonary complications, malignancies, and cardiac disease have emerged as major causes of morbidity and mortality (2–7). Bacterial pneumonia is the most common pulmonary-related complication associated with smoking among those with HIV infection (8). Compared to former smokers, current smokers infected with HIV have a much greater chance of developing bacterial pneumonia, emphasizing the importance of quitting smoking for this population (9–11). Additional pulmonary complications include lower respiratory tract infections and COPD (2,6). HIV infection and smoking each independently contribute to an increased risk of developing lung cancer (4). Other comorbid conditions that adversely affect persons living with HIV include cardiovascular disease, including myocardial infarction (12–14). As each of these illnesses are associated with tobacco use, smoking cessation has become an important target for prevention and reduction of disease burden among HIV-infected persons (1,15). Additionally, smoking cessation had been shown to decrease acute myocardial infarction rates among persons living with HIV (16,17). Of note, the prevalence of current smoking among persons living with HIV is reported in the range of 40%–85% (18–23). These estimates are significantly higher than rates of smoking in the general U.S. adult population.

The United States Public Health Service (USPHS) Clinical Practice Guideline *Treating Tobacco Use and Dependence* has provided recommendations for effective tobacco dependence treatment for all smokers, including those with HIV infection (24). The USPHS Guideline, now in its third update, consists of the systematic review of approximately 8,700 research articles that address the assessment and treatment recommendations for tobacco dependence. It provides key strategies and recommendations designed to assist clinicians in how to deliver effective evidence-based tobacco dependence treatment (24). Treatment recommendations include adherence to cognitive-behavioral counseling and pharmacotherapy (e.g., nicotine replacement therapy, bupropion, or varenicline), and skills training. Unfortunately, the efficacy of tobacco dependence treatment among HIV-infected smokers is modest. To date, only two long-term randomized controlled studies have been conducted (25,26). Both trials included cognitive-behavioral counseling along with pharmacotherapy in the form of nicotine replacement. The quit rates reported from these trials were mixed (5% vs. 20%) and may partially be explained by differences in how abstinence was measured at 12 months post-intervention (18–22,27). To better understand the relationship among counseling, pharmacotherapy, and long-term abstinence from smoking, this study assessed the adherence to treatment among HIV-infected smokers enrolled in a cessation trial.

Conceptual Rationale

Several studies have shown that greater adherence to tobacco dependence treatment (e.g., pharmacotherapy and behavioral counseling) is significantly associated with successful quitting (28–30). *Adherence* is defined as the extent to which a person’s behavior (i.e.,

following a diet, making lifestyles changes, etc.) corresponds with recommendations from a health care provider (31). Although an intervention may be delivered as planned, patients do not always fully adhere to the prescribed intervention, thus limiting its efficacy. *Participant responsiveness*, a term referring to the level of engagement and enthusiasm a participant has for an intervention, may influence adherence and treatment outcomes (32–34). Antiretroviral therapy (ART) adherence has been widely examined among HIV-infected patients. Factors such as current smoking, drug and alcohol abuse, depression, self-identifying as Black or Hispanic, unemployment, time since HIV infection diagnosis, higher CD4 counts, and self-perception of poor health have each been associated with lower ART adherence (35–42).

While adherence to ART has been widely examined, little attention has been given to *adherence* and *participant responsiveness* to tobacco dependence treatment in the context of HIV. Known barriers that interfere with smoking cessation attempts among HIV-infected smokers include poverty and disadvantage, less education, less social support, history of mood disorders, and alcohol abuse (43–45). Known predictors of adherence to tobacco dependence treatment among a healthy population include older age, fewer cigarettes smoked per day, and early success at quitting (46). We propose that the biopsychosocial characteristics and context of HIV-infected participants (e.g., demographics, tobacco use characteristics, mental health history, social support, and alcohol use) as well as participant responsiveness will influence adherence to tobacco dependence treatment and smoking abstinence among HIV-infected individuals (Figure I). Unless the patient receives the full dosage and therapeutic benefit of the pharmacotherapy and behavioral counseling, he or she will be less likely to achieve abstinence.

The purpose of this study was to examine participant responsiveness and tobacco dependence treatment adherence and their associations with tobacco abstinence. The research questions are: (1) What baseline characteristics are associated with patient adherence to a tobacco dependence treatment intervention at 12 weeks? (2) Is participant responsiveness associated with patient adherence to a tobacco dependence treatment intervention? (3) Is patient adherence to a tobacco dependence treatment intervention associated with abstinence at 12 weeks and 12 months?

METHODS

Design

This study was conducted as part of the Lung HIV study, a multi-site (8 sites) study funded by the National Heart, Lung, and Blood Institute (R01HL090313-01) conducted to characterize HIV-associated lung infections and complications in the era of combination ART (47). Longitudinal changes in lung function among HIV-infected smokers who quit, as compared to those who continued to smoke, was the focus of our clinical center site. Our study used a one-group longitudinal design. Specific to our site, all participants were HIV-infected smokers at baseline and were exposed to intensive tobacco dependence treatment to achieve the highest number of participants who successfully quit smoking. Participants were not randomized to treatment. All participants received the most efficacious therapy available based on the USPHS Clinical Practice Guideline *Treating Tobacco Use and Dependence* (i.e., cognitive-behavioral therapy plus appropriate pharmacotherapy) (24).

Setting and Sample

Eligibility for this study included being HIV-infected, being 18 years of age or older, smoking at least 5 cigarettes per day, having an interest in quitting smoking in the next 30 days, and giving informed consent. A convenience sample was recruited from the AIDS Clinical Trials Unit and the Infectious Diseases clinics at the institution and in community-based agencies. This study was approved by the institution's Institutional Review Board. The study visits were conducted at a separate location from the recruitment clinics.

Procedure

At study entry, each participant completed a baseline questionnaire and provided a saliva sample for cotinine analysis. Cotinine, the major metabolite of nicotine, is considered the "gold standard" measure of exposure to nicotine and serves as an excellent biomarker for confirming smoking status (48). Next, the participant completed the first visit with the study nurse. At this time, the nurse: (1) screened the participant for the appropriate pharmacotherapy (defined below in Intervention) and provided a 4-week supply of the selected pharmacotherapy; (2) provided encouragement for quitting smoking; (3) negotiated a quit date with the participant (within 2 weeks); (4) discussed how to prepare for the upcoming quit date; and (5) made arrangements for the subsequent weekly telephone counseling. The remaining eight weeks of pharmacotherapy were picked up by the participant in person or mailed to a home address.

Intervention

The 12-week intervention was based upon the USPHS Clinical Practice Guideline *Treating Tobacco Use and Dependence* (24). It was comprised of pharmacotherapy and weekly telephone counseling provided by an advanced practice nurse experienced in delivering tobacco dependence treatment (24). To ensure continuity, the same study nurse delivered all of the counseling calls to each participant. Pharmacotherapy included varenicline or NRT and was administered for 12 weeks. Varenicline use with behavioral counseling has resulted in the highest quit rates for a general population of smokers (24,49,50). Several comorbid conditions are contraindications in the use of varenicline, such as a psychiatric history significant for schizophrenia, bipolar disorder, and depression (49). The institution's IRB required the participant's past psychiatric history in order to dispense varenicline, given the U.S. Food and Drug Administration (FDA) black box warning of the safe administration of varenicline (51). Further, each participant's medication list was verified for psychotropic medication by the advanced practice nurse prior to dispensing any medication. NRT use with patch plus ad libitum gum has also been shown to increase the success of quitting. Because of its documented efficacy (24), participants were placed on varenicline if there was no self-reported history of mental illness (i.e., schizophrenia, bipolar disorder) or baseline Beck Depression Inventory (BDI) score ≥ 20 (administered at baseline). The varenicline dose, which was started one week prior to quitting, was 0.5 mg per day on days 1–3, 0.5 mg twice daily on days 4–7, and 1 mg twice daily for another 11 weeks. NRT included a daily 21-mg patch plus 4-mg ad libitum gum (up to 24 pieces of gum per day). If a participant experienced any side effects from the 21-mg patch that were believed to be related to the dose of NRT, then the patch dose was decreased to 14 or 7 mg.

Counseling consisted of weekly telephone calls provided by the nurse at the participant's convenience. Discussion topics were compiled in a manual and included: self-monitoring of tobacco consumption behaviors; adherence to and side effects of pharmacotherapy; integration of tobacco cessation into daily living; coping with triggers; withdrawal symptomatology; seeking assistance with mood management; access to social support; and reinforcement of motivational messages about quitting tobacco use (e.g., relevance to disease status, risks to health, and rewards of quitting) (52). The first counseling meeting included an overview of most of the discussion topics in the counseling manual. Weekly discussion topics depended on the participant's successes and challenges during the previous week and on the participant's current needs. Potential topics for the counseling session included cultivating other interests than tobacco use and a support system; rewards and incentives for quitting; and techniques for managing social situations, stress, and weight gain. The participant was given a toll-free telephone number to contact the nurse if questions or problems arose in between counseling calls. The participant was asked to provide a secondary contact in case the nurse was unable to reach the participant at the initially provided phone number (e.g., if the phone number was disconnected). At 12 weeks, the participant completed a follow-up questionnaire (in person); this visit was conducted by study personnel other than the study nurse.

Several aspects of the study methods supported fidelity of the treatment delivery. The advanced practice nurses had prior experience delivering tobacco dependence treatment. The weekly intervention content was placed in a study manual for the study nurses to refer to for each weekly counseling call. The nurses completed an intervention checklist after each participant's weekly call which documented topics that were discussed. The nurses met at least monthly to review compliance with intervention delivery.

Measures

Baseline Characteristics—A questionnaire completed by the participant at baseline provided a measure of participant characteristics, including:

Sociodemographic factors measured with six items that assessed self-reported: (1) age; (2) gender; (3) race; (4) education level; (5) marital/partner status; and (6) household income.

Tobacco-related factors included self-reported: (1) cigarettes per day, a measure of consumption (10, 11–20, or 21); (2) previous quit attempts, at least one 24-hour quit attempt in past year (yes/no); (3) living with other smokers/other smokers in household (yes/no); (4) nicotine dependence measured with the Fagerström Test of Nicotine Dependence (53), a 6-item questionnaire that continues to be the gold standard measure used in tobacco studies (24); and (5) decisional balance (54). The construct of decisional balance was first described by Velicer as a measure of motivation to quit smoking. The measure includes two 10-item subscales: (1) the pros of smoking and (2) the cons of smoking. Item responses range from 1 = *not important* to 5 = *extremely important*. Each subscale's responses are summed to obtain total subscale scores. Both scales have good internal consistency scores: 0.87 (pros) and 0.90 (cons) (54). To derive a decisional balance score, the cons scale score is subtracted from the pros scale score (54).

Mental health and health-related factors were measured with: (1) self-reported past diagnosis of depression (yes/no); (2) self-reported past diagnosis of bipolar disorder (yes/no); (3) self-reported past diagnosis of schizophrenia (yes/no); (4) Beck Depression Inventory (BDI), a 21-item measure of depressive symptomatology with good reliability and validity (55); and (5) the SF-8 Health Survey, which measures health status with a 4-week recall and includes 4 items relating to physical health and 4 items relating to mental health; each item has either a 5- or 6-point response range. This measure has good reliability and validity, and a higher sum score indicates better health (56–58).

Perceived support was measured with the following two questions: (1) “In general, how satisfied are you with overall support you get from your friends and family members?” with response options of: *very dissatisfied*, *somewhat dissatisfied*, *somewhat satisfied*, and *very satisfied*; and (2) “To what extent do your friends and family members encourage and/or help you to quit smoking?” with response options of: *not at all*, *a little*, *somewhat*, and *a lot*.

Alcohol use was measured with a single item that assessed the participant’s self-reported binge drinking behavior, defined as having six or more drinks on one occasion at least monthly (yes/no) (59).

Content of Counseling Calls—The number of topics discussed during each call, out of a total of 16 possible topics, was recorded by the nurse at the end of each call. Weeks where there was not a call were assigned 0 topics. The average number of topics per call, over the 12 calls, was calculated for each respondent.

Pharmacotherapy Selection—Pharmacotherapy selection was recorded by the study nurse: varenicline or NRT.

Patient Adherence—Patient adherence to the tobacco dependence treatment protocol was assessed by the following two measures.

Adherence to the pharmacotherapy was defined as the proportion of weeks that pharmacotherapy was taken as prescribed out of 12 weeks. Patient adherence to the tobacco dependence treatment protocol was measured by self-reported use of pharmacotherapy collected by the nurse during the weekly calls (range 1–12 weeks), calculated as a dichotomous variable 80% versus < 80% of 12 weeks of drug taken as prescribed. Eighty percent or greater adherence to a prescribed medical treatment is considered a good outcome for medication adherence (31,60–62).

Patient adherence to tobacco dependence counseling calls was defined as the number of completed calls out of 11 planned calls.

Participant Responsiveness—Participant responsiveness was assessed by the study nurse on a weekly basis with three measures: the participant’s rapport with the nurse, the participant’s understanding of cessation topics, and the participant’s interest in quitting smoking. Each measure was assessed by the study nurse using response options of: 1 = *poor*; 2 = *fair*; 3 = *good*; and 4 = *excellent*, after concluding the telephone counseling call. The ratings for each of the three measures were averaged across visits and then summed to create

a composite measure of responsiveness (34). The composite measure was dichotomized (> 10.5 and ≤ 10.5) to differentiate between participants who received an average of excellent ratings across all responsive measures from those who did not. The cut-point of 10.5 was selected because this was the highest quartile of the composite measure, as reported by Hood and colleagues (34).

Smoking Abstinence—At the 3-month follow-up visit, if the participant reported no smoking or use of tobacco in the past 7 days, a saliva sample was collected to confirm abstinence, using a cotinine concentration of $< 15\text{ng/mL}$ as the cut-point (63). Carbon monoxide was used to determine abstinence among participants who reported current use of nicotine replacement, with $< 8\text{ ppm}$ used as a cut-point for abstinence (48). Cotinine (the major metabolite of nicotine) and carbon monoxide (a measure of combustion) are reliable and valid biomarkers for confirming abstinence from smoking (48). The number of 24-hour quit attempts in the past year is highly correlated with successful smoking abstinence and is an accepted secondary measure (64).

Statistical Analysis

Descriptive statistics were calculated for the demographic, smoking-related, mental health, health-related, social support, and binge drinking variables according to adherence to pharmacotherapy and counseling calls. The main analysis involved examining adherence to the outcome separately (i.e., pharmacotherapy and counseling calls). The methods for building a predictive model, proposed by Hosmer and Lemeshow (65), were used. First, univariate logistic regression models were fit to each outcome and assessed for statistical significance. Next, all variables that were significant at the $\alpha = 0.10$ level were entered into a full model. Then, variables that were not significant were removed one by one until all variables were significant at the $\alpha = 0.05$ level. Model fit was examined by evaluating the area under the receiver operating characteristic (ROC) curve and discrimination and calculating the Hosmer-Lemeshow statistic (65).

To determine whether patient adherence to pharmacotherapy and counseling were associated with cotinine-confirmed cessation and 24-hour quit attempts at 12 weeks and 12 months, two logistic regression models were fit. For each outcome, one model included adherence to pharmacotherapy as the primary predictor, and the other included adherence to calls as the primary predictor. The models included the covariates that were significant predictors of adherence in the primary analysis. A similar approach was used to examine the relationship between participant responsiveness and the patient adherence outcomes.

RESULTS

Three hundred sixty individuals inquired about the study; 36 did not meet one or more of the eligibility criteria, and 74 were eligible but refused to participate after learning the details of the study. Approximately half did not give a reason for refusal; of those who did, reasons were: not able to leave employment, no longer located in the area, and lack of transportation. Two hundred fifty participants enrolled in the tobacco dependence treatment protocol. A total of 247 were placed on either varenicline or NRT; those who declined pharmacotherapy ($n = 3$) were excluded from the analysis because compliance to pharmacotherapy could not

be assessed. A total of 114 (46%) participants completed at least 80% of calls and 80% of pharmacotherapy, whereas 82 (33%) participants did not, and the remaining 51 (21%) participants only completed either 80% of calls or 80% of pharmacotherapy (Figure II).

Of the participants who completed at least 80% of pharmacotherapy, 57% were given varenicline and of the participants who completed at least 80% of calls, 55% were given varenicline. Table I shows, according to adherence, a description of demographic, smoking-related, mental health, health-related and social support indicators, and alcohol use. Of note is that self-identified White participants ($n = 138$) were significantly more likely to have reported drug use in the last year than non-White participants (i.e., self-identified as Black, $n = 100$; self-identified as Other Race $n = 9$): 25.4% vs. 14.8%, respectively ($p < 0.05$). Most participants responded that they did not have much support from friends and family on their smoking cessation attempt and that they were not satisfied with their support. This was consistent whether or not they completed 80% of counseling calls or pharmacotherapy. The mean number of topics were similar for those who completed at least 80% of calls or pharmacotherapy and for those who completed less than 80% of calls or pharmacotherapy.

Univariate logistic regression models predicting the completion of 80% or more of calls or pharmacotherapy are shown in Table II. Age, race, education, history of bipolar disorder, household income, cigarettes smoked per day, and binge drinking each were independently associated with at least 80% adherence to pharmacotherapy or counseling calls. The final logistic regression models are presented in Table III. Older age and self-identifying as White were associated with completion of at least 80% of prescribed pharmacotherapy. Older age, self-identifying as White, and no binge drinking in the last month were associated with completion of at least 80% of the counseling calls. Confirmed cessation at 3 months was 19.4% and 10.2% at 12 months. The Spearman correlation between adherence to pharmacotherapy and calls = 0.71.

Participant responsiveness, a composite measure of nurse rating of rapport and understanding and interest in cessation, was significantly associated with 80% or greater adherence with calls and with pharmacotherapy ($p < 0.01$). Sixty percent of participants ($n = 81$) who had high responsiveness to the intervention had adherence to the prescribed pharmacotherapy, and 78% ($n = 79$) who had low responsiveness did not have adherence to the pharmacotherapy. Of the participants who had high responsiveness to the intervention, 58% ($n = 77$) had adherence to the counseling calls, and 75% of participants ($n = 77$) who had low responsiveness did not have adherence to the counseling calls. Univariate logistic regression models predicted the completion of 80% or more of calls or pharmacotherapy based upon high and low responsiveness (OR = 5.07, CI = 2.89–8.89 [calls]; OR = 6.52, CI = 3.63–11.72 [pharmacotherapy]). High participant responsiveness was independently associated with at least 80% adherence to pharmacotherapy or counseling calls. High participant responsiveness was associated with abstinence at 12 weeks and 12 months (OR = 8.16 and OR = 4.33, respectively), both with a wide confidence intervals (Table IV).

Cotinine-confirmed abstinence at 12 weeks was associated with adherence to prescribed pharmacotherapy, and adherence to the weekly counseling calls was associated with cotinine-confirmed abstinence at 12 weeks (OR = 4.61, OR = 7.58; respectively), both with

wide confidence intervals. At 12 months, adherence to the weekly counseling calls was associated with cotinine-confirmed abstinence (OR = 5.91; Table V). At least one 24-hour quit attempt in the past year at the 12 month time point was associated with adherence to prescribed pharmacotherapy (OR = 2.41).

DISCUSSION

Smokers infected with HIV have a high susceptibility to the ill effects of continued smoking (1–6), and there is an exceedingly high prevalence of smoking among persons living with HIV (1,7–12). This makes quitting smoking an important health behavior change that could reduce disease burden among persons living with HIV (19). Gold-standard tobacco dependence treatment interventions are available; however, patients must adhere to the prescribed treatment to have the highest chance for success in quitting smoking (24). This study comprehensively examined factors associated with adherence to tobacco dependence treatment in the HIV-infected population. Our study found that younger age and non-White race were associated with lower adherence to pharmacotherapy, and lower adherence to telephone counseling was associated with younger age, non-White race, and increased monthly binge drinking. Participants who were enthusiastic and engaged in the intervention had better adherence to tobacco dependence treatment and were successful with smoking abstinence. Better adherence to telephone counseling resulted in higher biochemically confirmed smoking abstinence at 12 months.

Some of these findings are supported by previous work in healthy and HIV-infected populations. Increasing age is a known predictor of better adherence to tobacco dependence treatment, increased interest in quitting, and better adherence to antiretroviral therapy (46,66). Alcohol abuse is a known predictor of poor adherence to tobacco dependence treatment (67), continued smoking (24), and HIV medication adherence (37). It has been widely demonstrated that adherence to tobacco dependence treatment does predict smoking abstinence (24,68,69). To date, race has not been shown to predict adherence to tobacco dependence treatment (70). We did examine the data for significant differences among tobacco use characteristics with respect to race. In our study, self-identified White participants were significantly more likely to report pharmacotherapy use in the last year than non-White participants. Findings from several studies with large samples were mixed on whether race was a predictor of smoking abstinence. Daza and colleagues found that race and ethnicity were not predictive of abstinence; Fu and colleagues reported that Black smokers were less likely to be abstinent than White smokers; and a trend toward lower readiness to quit was observed for Black smokers by Shirley and colleagues (44,71,72). Despite these contrasts, some known predictors of smoking abstinence do differ by race. For example, Black smokers are less likely to have ever used NRT for smoking cessation than White smokers; however, when NRT was used, there were no differences among Black and White races when quitting smoking (72). On average, Black smokers smoke fewer cigarettes per day than White smokers (71). In a study examining misperceptions of NRT among racially and ethnically diverse smokers, lack of NRT use by Black smokers was attributed to suspicion of government and pharmaceutical industry oversight, lack of understanding of its effects and efficacy, and concern with safety (73).

Patients who had adherence to calls were seven times as likely to have quit smoking at 12 weeks, and those who did not have adherence to pharmacotherapy were almost five times as likely to quit smoking at 12 weeks. At 12 months, patients who had adherence to calls were almost six times as likely to quit smoking. While the USPHS Clinical Practice Guideline *Treating Tobacco Use and Dependence* treatment recommendations are evidence-based, *patient adherence* to the recommendations must occur for success. Our findings suggest that non-White race, younger age, and binge drinking are associated with poor adherence among HIV-infected participants. While race and age are not modifiable risk factors, testing interventions to improve adherence to tobacco dependence treatment with these at-risk demographic groups may increase successful smoking abstinence. Potential interventions targeting adherence may include: (1) use of electronic and/or social media for daily messaging for younger smokers; and (2) including lay educators with similar age and/or race of the target population for intervention delivery (74,75). Most participants did not feel adequate social support was provided by friends and family during the time preceding their cessation attempt and, importantly, found this lack of support dissatisfying. Perceived social support is an important predictor of smoking abstinence (76,77). Given the high smoking prevalence among persons infected with HIV, it may be important to encourage smokers who are interested in quitting to identify someone who will be supportive of their efforts to quit.

Low participant responsiveness was associated with less adherence to the prescribed tobacco dependence treatment and lower abstinence, suggesting that interest in quitting, understanding of salient cessation topics, and having a good rapport with the counseling nurse can have an important impact on the success of quitting smoking. Hood and colleagues have reported similar findings of higher participant responsiveness associated with abstinence in a rural female population (34).

There were several limitations related to the study measures, including: (1) pill counts and NRT product counts were not performed (i.e., a preferred method for verifying medication adherence); (2) weekly medication adherence relied on self-reported data only that was collected by the nurse interventionist; (3) a medication adherence questionnaire was not administered, so subjective reasons were not determined for lack of or low adherence; (4) psychiatric history data were self-reported by the participant and not corroborated with a medical record; (5) illicit drug use was assessed during the study; however, many participants refused to answer the illicit drug use questions and, due to the low number, these data were subsequently not included in the analyses; and (6) the number of participants who received the second supply of study medication via the mail versus in person was not able to be determined. Picking up the study medication in person may have influenced adherence. Limitations of the data collection and analysis included: (1) interpretation of missing data; (2) estimation of adherence; (3) bias associated with the participant responsiveness data collection by the nurse; and (4) change of variables from continuous to dichotomous. If a participant reported medication use during the week before and the week after a missed telephone counseling call, medication adherence was assumed for the week of the missed call. We did estimate adherence as a continuous outcome measure; however, due to low variability in the data, we chose to use 80% as a cut-point. Eighty percent or better adherence has been demonstrated as a good measure of adherence (31,61,62). There were no

formal measures of fidelity to the delivered intervention. As this intervention was a tailored approach, there was lack of standardization of each weekly content session; session topics were driven by the needs of the participant.

Logistic regression was the selected method for the statistical analysis because it is a frequently used statistical method when the outcome measure is dichotomous. This model may have overestimated the true relationship of the data. We also expect that there may be some collinearity between the independent and outcome variables.

CONCLUSION

The high prevalence of tobacco use and low success in quitting remains a clinically significant problem for the overall health and quality of life of HIV-infected persons. The USPHS offers an efficacious Clinical Practice Guideline *Treating Tobacco Use and Dependence*; however, *patient adherence* to the recommendations is necessary to improve successful abstinence. Further, patients must be engaged and responsive to the treatment. Future research in an HIV-infected population is needed to further examine why adherence to tobacco dependence treatment is affected by age and race and how participant responsiveness to the tobacco dependence treatment can be increased. Additional research should examine the impact of alcohol use and patient adherence to tobacco dependence treatment, with the potential to incorporate combined tobacco dependence treatment with alcohol reduction interventions. Development and testing are warranted of tailored interventions specific for this population that improve adherence to evidence-based tobacco dependence treatment for HIV-infected smokers and improving participant responsiveness. Future studies should incorporate rigorous methods for evaluating tobacco dependence medication adherence.

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Figure I. Conceptual relationship between adherence, patient responsiveness, tobacco dependence treatment and abstinence

Adapted from Hood et al. (34)

Figure II.
Participant adherence to counseling calls and drug

Table I

Baseline characteristics of participants by adherence and non-adherence to pharmacotherapy and tobacco dependence treatment calls ($n = 247$)

Characteristic	Completed 80% or more weeks of drug		Completed 80% or more weeks of calls	
	Yes ($n = 141$)	No ($n = 106$)	Yes ($n = 138$)	No ($n = 109$)
	57.1%	42.9%	55.9%	44.1%
Demographics				
Age ($n = 247$)	44.3 ± 8.9	40.1 ± 9.2	44.2 ± 9.3	40.4 ± 8.7
Gender				
Female ($n = 35$)	14.2%	14.2%	14.5%	13.8%
Male ($n = 212$)	85.8%	85.8%	85.5%	86.2%
Race				
White ($n = 138$)	62.9%	47.2%	63.5%	46.8%
Other ($n = 108$)	37.1%	52.8%	36.5%	53.2%
Education level				
< HS ($n = 36$)	10.6%	19.8%	10.1%	20.2%
HS or GED ($n = 60$)	23.4%	25.5%	22.5%	26.6%
HS ($n = 151$)	67.0%	54.7%	67.4%	53.2%
Current employment status				
Employed full-time or part-time ($n = 71$)	30.5%	26.4%	28.2%	29.3%
Unemployed or disabled ($n = 141$)	56.0%	58.5%	58.0%	56.0%
Other ($n = 35$)	13.5%	15.1%	13.8%	14.7%
Marital status				
Married or member of couple ($n = 59$)	26.6%	21.0%	24.8%	23.4%
Never married ($n = 129$)	50.4%	56.2%	53.3%	52.3%
Divorced/separated/widowed ($n = 56$)	23.0%	22.8%	21.9%	24.3%
Household income				
\$20,000 ($n = 145$)	53.2%	66.1%	53.6%	65.1%
> \$20,000 ($n = 83$)	35.5%	31.1%	36.2%	30.3%
Don't know/Refused to answer ($n = 19$)	11.4%	2.8%	10.2%	4.6%
Smoking-Related Variables				
Current cigarettes per day				
10 or less ($n = 61$)	19.3%	32.1%	21.2%	29.4%
11–20 ($n = 110$)	49.3%	38.7%	45.2%	44.0%
21 or more ($n = 75$)	31.4%	29.2%	38.6%	26.6%
At least one quit attempt in past year				
No ($n = 118$)	47.9%	49.5%	47.5%	50.0%
Yes ($n = 125$)	52.1%	50.5%	52.5%	50.0%
Other smokers in household				
No ($n = 85$)	36.2%	32.1%	32.6%	36.7%

Characteristic	Completed 80% or more weeks of drug		Completed 80% or more weeks of calls	
	Yes (<i>n</i> = 141)	No (<i>n</i> = 106)	Yes (<i>n</i> = 138)	No (<i>n</i> = 109)
	57.1%	42.9%	55.9%	44.1%
Yes (<i>n</i> = 162)	63.8%	67.9%	67.4%	63.3%
Fagerström Scale score (<i>n</i> = 236)	5.3 ± 2.2	5.1 ± 2.4	5.3 ± 2.3	5.0 ± 2.3
Baseline cotinine (ng/mL) (<i>n</i> = 221)	244 ± 196	265 ± 150	246 ± 187	263 ± 166
Decisional balance (<i>n</i> = 219)	-0.7 ± 13.1	1.5 ± 11.4	1.1 ± 13.2	-0.9 ± 11.3
Mental health & social support indicators				
History of depression				
No/DK (<i>n</i> = 115)	44.0%	50.5%	44.5%	50.5%
Yes (<i>n</i> = 131)	56.0%	49.5%	55.5%	49.5%
History of bipolar disorder				
No/DK (<i>n</i> = 196)	84.1%	75.5%	84.4%	75.2%
Yes (<i>n</i> = 48)	15.9%	24.5%	15.6%	24.8%
History of schizophrenia				
No/DK (<i>n</i> = 240)	97.8%	96.2%	97.8%	96.3%
Yes (<i>n</i> = 7)	2.2%	3.9%	2.2%	3.7%
Physical Component score (SF-8) (<i>n</i> = 230)	47.0 ± 9.7	47.0 ± 10.3	46.6 ± 9.8	47.3 ± 10.1
Mental Component score (SF-8) (<i>n</i> = 230)	45.3 ± 10.4	45.4 ± 11.4	45.3 ± 10.8	45.3 ± 11.0
Beck Depression Inventory score (<i>n</i> = 230)	10.7 ± 8.7	11.4 ± 8.7	10.8 ± 8.7	11.3 ± 8.7
Satisfaction with support for cessation				
Less than very satisfied (<i>n</i> = 165)	69.1%	65.1%	67.9%	66.7%
Very satisfied (<i>n</i> = 80)	30.9%	34.9%	32.1%	33.3%
Support from family/friends for cessation				
Not at all/a little/somewhat (<i>n</i> = 168)	68.6%	67.9%	68.8%	67.6%
A lot of support (<i>n</i> = 78)	31.4%	32.1%	31.2%	32.4%
Alcohol use				
Binge drinking at least monthly				
No (<i>n</i> = 184)	81.2%	69.9%	82.8%	68.2%
Yes (<i>n</i> = 57)	18.8%	30.1%	17.2%	31.8%
Drug choice				
NRT	42.6%	52.8%	44.9%	49.5%
Varenicline	57.4%	47.2%	55.1%	50.5%
Mean ± SD topics discussed during calls	6.6 ± 1.8	4.3 ± 1.9	6.8 ± 1.7	4.0 ± 1.6

Table II

Univariate logistic regression model results associated with adherence to pharmacotherapy and tobacco dependence treatment calls ($n = 247$)

Characteristic	Completed 80% or more weeks of drug OR (95% CI)	Completed 80% or more weeks of calls OR (95% CI)
Demographics		
Age	1.05 (1.02–1.08) ^b	1.05 (1.02–1.08) ^b
Gender		
Female	1.0	1.0
Male	1.00 (0.49–2.07)	0.94 (0.46–1.94)
Race		
White	1.0 ^b	1.0 ^b
Other	0.53 (0.32–0.88)	0.51 (0.30–0.84)
Education level		
< HS	1.0 ^a	1.0 ^b
HS or GED	1.71 (0.74–3.95)	1.68 (0.73–3.89)
HS	2.25 (1.07–4.70)	2.52 (1.20–5.31)
Current employment status		
Employed full-time or part-time	1.0	1.0
Unemployed or disabled	0.88 (0.46–1.48)	1.08 (0.61–1.91)
Other	0.77 (0.34–1.75)	0.97 (0.43–2.20)
Marital status		
Married or member of couple	1.0	1.0
Never married	0.71 (0.38–1.33)	0.96 (0.51–1.79)
Divorced/separated/widowed	0.79 (0.38–1.67)	0.85 (0.41–1.77)
Household income		
\$20,000	1.0 ^a	1.0
> \$20,000	0.71 (0.41–1.22)	0.69 (0.40–1.19)
Don't know/Refused to answer	3.52 (0.95–13.03)	1.85 (0.61–5.62)
Smoking-Related Variables		
Current cigarettes per day		
10 or less	1.0 ^a	1.0
11–20	2.12 (1.12–4.00)	1.43 (0.76–2.67)
21 or more	1.79 (0.90–3.54)	1.75 (0.88–3.47)
At least one quit attempt in past year		
No	1.0	1.0
Yes	1.07 (0.64–1.78)	1.11 (0.67–1.84)
Other smokers in household		
No	1.0	1.0
Yes	0.83 (0.49–1.42)	1.20 (0.71–2.03)
Fagerström Scale score	1.03 (0.93–1.15)	1.04 (0.94–1.17)

Characteristic	Completed 80% or more weeks of drug OR (95% CI)	Completed 80% or more weeks of calls OR (95% CI)
Baseline cotinine (ng/mL)	0.99 (0.99–1.00)	0.99 (0.99–1.00)
Decisional balance	0.99 (0.97–1.01)	1.01 (0.99–1.04)
Alcohol use		
Binge drinking at least monthly		
No	1.0 ^b	1.0 ^b
Yes	0.54 (0.30–0.98)	0.45 (0.24–0.82)
Drug choice		
NRT	1.0	1.0
Chantix	1.51 (0.91–2.51)	1.20 (0.73–1.99)

^a
 $p < 0.10$.

^b
 $p < 0.05$.

Table III

Final logistic regression model results^a associated with adherence to pharmacotherapy and tobacco dependence treatment calls ($n = 247$)

Characteristic	Completed 80% or more weeks of drug OR (95% CI)	Completed 80% or more weeks of calls OR (95% CI)
Demographics		
Age	1.06 (1.02–1.09)	1.04 (1.01–1.07)
Race		
White	1.0	1.0
Other	0.52 (0.31–0.89)	0.48 (0.28–0.83)
Alcohol use		
Binge drinking at least monthly		
No		1.0
Yes		0.53 (0.28–1.00)

^a All results presented are adjusted for the other variables in the model plus pharmacotherapy type.

Table IV

Multivariable logistic regression model results^a predicting cotinine-confirmed cessation at 12 weeks and 12 months ($n = 247$)

Models with High Responsiveness as Primary Predictor	OR (95% CI)
12-week cessation model	
Participant Responsiveness	
Low	1.0
High	8.16 (3.36–19.82)
12-month cessation model	
Participant Responsiveness	
Low	1.0
High	4.33 (1.51–12.44)

^aModels control for covariates that significantly predicted adherence to drug (age, race) or calls (age, race, binge drinking) plus pharmacotherapy type.

Table V

Multivariable logistic regression model results^a predicting cotinine-confirmed cessation and 24-hour quit attempts at 12 weeks and 12 months ($n = 247$)

	OR (95% CI)
12-week models	
Abstinence	
Adherence to 80% or more of drug	
No	1.0
Yes	4.61 (1.92–11.11)
Adherence to 80% or more of calls	
No	1.0
Yes	7.58 (2.78–20.66)
24-hour quit attempt	
Adherence to 80% or more of drug	
No	1.0
Yes	2.06 (0.61–6.96)
Adherence to 80% or more of calls	
No	1.0
Yes	3.11 (0.84–11.46)
12-month models	
Abstinence	
Adherence to 80% or more of drug	
No	1.0
Yes	1.99 (0.74–5.37)
Adherence to 80% or more of calls	
No	1.0
Yes	5.91 (1.66–21.02)
24-hour quit attempt	
Adherence to 80% or more of drug	
No	1.0
Yes	2.41 (1.01–5.77)
Adherence to 80% or more of calls	
No	1.0
Yes	1.87 (0.76–4.63)

^aModels control for covariates that significantly predicted adherence to drug (age, race) or calls (age, race, binge drinking) plus pharmacotherapy type.