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An Algorithm Approach to Determining Smoking Cessation Treatment for Persons Living with HIV/AIDS: Results of a Pilot Trial

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Abstract

Background—Smoking now represents one of the biggest modifiable risk factors for disease and mortality in PLHIV. To produce significant changes in smoking rates among this population, treatments will need to be both acceptable to the larger segment of PLHIV smokers as well as feasible to implement in busy HIV clinics. The purpose of this study was to evaluate the feasibility and effects of a novel proactive algorithm-based intervention in an HIV/AIDS clinic.

Methods—PLHIV smokers (N =100) were proactively identified via their electronic medical records and were subsequently randomized at baseline to receive a 12-week pharmacotherapy-based algorithm treatment or treatment as usual. Participants were tracked in-person for 12-weeks. Participants provided information on smoking behaviors and associated constructs of cessation at each follow-up session.

Results—The findings revealed that many smokers reported utilizing prescribed medications when provided with a supply of cessation medication as determined by an algorithm. Compared to smokers receiving treatment as usual, PLHIV smokers prescribed these medications reported more quit attempts and greater reduction in smoking. Proxy measures of cessation readiness (e.g., motivation, self-efficacy) also favored participants receiving algorithm treatment.

Conclusions—This algorithm-derived treatment produced positive changes across a number of important clinical markers associated with smoking cessation. Given these promising findings coupled with the brief nature of this treatment, the overall pattern of results suggests strong potential for dissemination into clinical settings as well as significant promise for further advancing clinical health outcomes in this population.

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DECLARATION OF INTERESTS

None declared.

Keywords

HIV; AIDS; Smoking Cessation; Algorithm; Proactive

INTRODUCTION

People living with HIV (PLHIV) are currently losing more years of life due to smoking than to their HIV disease [1]. Continued smoking among PLHIV has unique and specific risks that promote more rapid development of cardiovascular disease, pulmonary disease, bacterial infections, malignancy, and other adverse health outcomes [2-4]. It is now estimated that smoking is responsible for over 60% of deaths among PLHIV [1]. The health implications of continued smoking in this population are widespread, as approximately 50-70% of PLHIV are current smokers, a rate that is approximately three times higher than the general population [5-7]. As a result, smoking now represents the most significant modifiable risk factor for disease and mortality in PLHIV.

While a broad spectrum of effective behavioral and pharmacological services are available to help these smokers quit, utilization of these evidence-based cessation treatments remains extremely low [8]. Utilization rates may be related to the *reactive* approach of our current health care model to smoking cessation. Specifically, current clinical practice relies on smokers to either request treatment services or depends on the provider to initiate a conversation about smoking cessation [9]. Unfortunately, since less than 10% of smokers are ready to quit in the immediate future, a reactive approach may result in significant missed opportunities to engage smokers in cessation efforts [10]. More recent trends in treatment-based studies have focused on expanding the reach of cessation efforts by proactively identifying smokers and offering intervention efforts [9]. Proactive components have included identifying smokers through clinical registries or online/published channels and providing mailed outreach of cessation aids, telephone counseling, etc. [9-11]. In studies with PLHIV, proactive approaches have shown good success, even when targeting unmotivated smokers [12-14].

The HIV/AIDS clinical setting remains a prominent point of healthcare contact for many PLHIV smokers. However, the successful integration of proactive models of care in this clinical setting will require that any cessation service offered dovetail easily with existing HIV/AIDS treatment regimens. Currently, very few HIV providers report receiving tobacco cessation treatment training and most report little time or confidence in their ability to assess and treat tobacco dependence during a routine clinical encounter [15]. Algorithm-based interventions have been shown to be an effective clinical tool that can be used in busy clinical settings as they concisely synthesize knowledge and provide greater guidance with treatment decisions by more clearly prioritizing which factors need to be considered when prescribing pharmacotherapy [16-19]. Algorithms also have the added advantage of allowing for greater flexibility in response to evolving patient needs [17, 18]. Although algorithms have been successfully developed to standardize and provide guidance for best practices in the treatment of many disorders [20, 21], they have rarely been integrated into the field of smoking cessation.

In the current randomized pilot clinical trial, we tested a proactive model of smoking cessation care versus usual care. We used clinical registry information to identify smoking status, and through the assistance of an algorithm, proactively offered these smokers different forms of pharmacotherapy regardless of baseline motivation to quit or not. The main purpose of this study was to determine if proactively identified smokers who received algorithm-directed intervention at their HIV appointment would alter behaviors associated with smoking cessation compared to participants who received treatment as usual.

METHODS

Participant Recruitment and Eligibility

One hundred and thirty four participants were approached to participate in this study and 102 participants provided informed consent (see Supplemental Figure 1 for study flow). Two participants were excluded after consent; one was not receiving medical care at the clinic and the other participant tested negative for cotinine and was not smoking. Participants were enrolled in the study if they were at least 19 years of age (the legal age of adulthood in Alabama), receiving their HIV care at the clinic and not anticipating moving or changing clinics over the next six months, smoking at least five cigarettes per day for the past month, tested positive for cotinine, and living in an unrestricted environment that allowed smoking. Participants were excluded if they were pregnant or nursing, not English speaking, or had cognitive impairment such that they could not provide informed consent.

All patients at the University of Alabama at Birmingham (UAB) 1917 HIV clinic completed patient reported outcomes (PROs) every six months as part of routine clinical care and included in these measures was a question that determined smoking status. We identified potential participants through their most recent responses on the PROs. Participants who indicated current smoking during their last clinic visit were approached by their medical provider to determine if they were interested in being in this study. Research staff were available in the clinic two days per week and enrolled all consenting participants during their clinic visit. Participants who were not able to be enrolled during their clinic visit were scheduled for a baseline visit during the following week.

A total of 100 participants were deemed eligible to participate in the study and were subsequently randomized to receive either Algorithm-derived treatment (AT) for smoking cessation or Treatment as Usual (TAU) which was smoking cessation assistance from their medical provider when the patient was ready to quit

Procedures

All enrolled participants completed baseline assessments which included demographic, smoking history, and psychological constructs such as motivation and abstinence self-efficacy. Participants also completed the Fagerström Test of Cigarette Dependence (FTCD^[22]) and the Minnesota Nicotine Withdrawal Scale (MNWS^[23]) which assessed dependence on cigarettes and nicotine withdrawal, respectively. The Thoughts About Abstinence questionnaire (TAA^[24]) was administered to assess motivation, abstinence self-efficacy, perceived difficulty of quitting, and goal for smoking. Goal for smoking was

assessed using a multiple choice answer option ranging from complete lifelong abstinence to reduction in smoking to no change in smoking behavior. All measures were self-reported surveys completed by participants during their visit.

These measures were combined with other measures of interest in the patient's PRO. This included a measure of depressive symptoms [Patient Health Questionnaire-Depression (PHQ-9D)], panic symptoms [Patient Health Questionnaire-Anxiety (PHQ-A)], tobacco, alcohol and other drug use [Alcohol Smoking, and Substance Involvement Screening Test (WHO ASSIST v3.0)], and hazardous alcohol use [3-item Alcohol Use Disorders Identification Test (AUDIT-C). Nadir CD4 count, Viral Load, and chronic medical conditions were extracted from the clinical database for all participants as well as smokers who were seen in clinic but did not enroll in the study. In addition to completing demographic information, during the baseline visit, regardless of treatment group or abstinence goal, all participants received one standard 20 minute smoking cessation counseling at baseline provided by the research staff that discussed behavioral strategies for cutting down or reducing smoking. Research staff had a bachelor's level education and did not possess any specific training in smoking cessation other than a brief training to review common strategies used for smoking cessation used in this intervention. The strategies that were covered during the sessions included reviewing the importance of quitting, strategies to avoid or cope with high risk situations, and preparing to quit including telling friends and family their intention to quit and removing smoking paraphernalia and tobacco products from the home. The importance of using pharmacotherapy to assist with cessation was discussed with all participants.

After baseline assessments, research staff asked questions according to the Algorithm to determine pharmacotherapy selection (see Figure 1 for a schematic of the algorithm). All participants were initially asked if they were interested in quitting smoking today or in the next 30 days. If the participant said "yes," they were then asked if they were willing to take a medication that they would have to take by mouth twice per day. Since varenicline has been shown to have superior quit rates over other single pharmacotherapy agents, it was selected as the first line of treatment for patients willing to take a medication twice per day and wanting cessation[25]. If varenicline was contraindicated (e.g., severe renal impairment), bupropion was the second agent for patients who were interested in quitting and willing to take a medication. Single NRT was the third agent if varenicline or bupropion were not appropriate, with nicotine patch as the first line NRT offered. In terms of preference for NRT, lozenge was offered as the second NRT option, gum was the third, inhaler was fourth, and nicotine nasal spray was the last option for NRT. The order of NRT within the algorithm was based upon patient familiarity and number of clinical trials supporting their use[26]. Clinical trials have also supported the use of combination NRT (e.g., patch and lozenge) [27], and this was offered to participants who made an unsuccessful quit attempt with NRT in the past. Similarly, among participants not interested in quitting, they too were offered NRT, if no contraindications existed. Participants were told they could use the NRT to practice quitting, in situations in which they were not allowed to smoke, or to reduce their smoking. The delivery of NRT to this sample was predicated upon recent findings that NRT can serve as an external cue to positively shift quitting momentum and ultimately trigger action [10, 11]. After a period of four weeks,

participants who continued to smoke and were initially prescribed a single agent were then offered an additional pharmacotherapy agent, generally nicotine lozenge for acute nicotine cravings, to aid in cessation. While the algorithm questions were asked by study staff, the study physician or clinic provider approved all medications for participants.

Following the baseline, participants entered a 12-week follow-up period, during which in-person assessments were made at weeks 2, 4, 8, and 12 (end of treatment). Final follow-up was at 1 month post-treatment. During each of the assessment periods, study staff collected data about several primary measures of interest, which included reduction in smoking behavior as measured by number of cigarettes smoked per day (cpd) and any 24-hr quit attempt, per Centers for Disease Control and Prevention definition [28]. We also collected secondary measures of interest focused on process measures of cessation including abstinence self-efficacy, motivation to quit, perceived difficulty of quitting; the latter constructs were assessed using a single-item 0-10 measure and were derived from the TAA questionnaire. Additionally, at each assessment period, we assessed uptake of pharmacotherapy resources, as provided by us or purchased independently [yes/no].

Statistical Analyses

Chi-square and analysis of variance were used to determine equivalence between groups on baseline characteristics. Generalized Estimating Equations (GEE) models were used to determine the effect of the intervention across study time points for both our primary measures of interest, i.e., changes in smoking behaviors and quit attempts, as well as the process measure of cessation including self-efficacy to quit, motivation to quit, perceived difficulty of quitting, and uptake of pharmacotherapy resources. Main effects of these variables as well as interaction terms were examined across time. An intent-to-treat analysis was conducted and all missing values were coded as smoking.

RESULTS

Baseline comparisons between Algorithm and Treatment as Usual

Tables 1 and 2 presents a summary of baseline characteristics for both groups. Overall, no differences between groups were detected for demographic, psychosocial or smoking history variables. About two thirds reported a goal of lifelong abstinence from smoking.

Medication Use and Adherence

Participants randomized to Algorithm Treatment most often received nicotine patch (38%), followed by varenicline (36%), combination NRT (nicotine patch and lozenge; 12%), bupropion (10%), or lozenge (4%). At week 4, over half of participants (52%) were offered a second pharmacotherapy agent as they had not made a quit attempt and were still smoking; specifically, they were given nicotine lozenges to cope with acute cravings. Thus, 89% of participants receiving nicotine patches added lozenge, 40% of bupropion smokers added lozenges, and 39% of participants who received varenicline added lozenge. Overall, slightly over half (57.1%) of the participants who received medication took the medication as prescribed.

Smoking Outcomes

As shown in Supplemental Table 1, a significant interaction between treatment by time was found for number of cigarettes smoked per day such that smokers who received AT reduced the number of cpd across time relative to the TAU (AT: 10 cpd reduction vs. TAU: 6 cpd from baseline to one month follow-up; see Figure 2). Similarly, across the follow-up period, the proportion of participants reporting 24-hour quit attempts was significantly higher for participants who received AT compared to TAU participants (50% vs. 38%). Finally, more participants who received AT used medication for smoking cessation compared to TAU (81% vs. 23% overall; see Supplemental Table 1). GEE analyses showed a significant interaction for treatment across time for medication utilization, such that AT and TAU reported similar past use of smoking cessation pharmacotherapies at baseline; however, AT participants reported increased utilization of medications while TAU reported a decrease in use of medications across time (see Figure 3).

Given the high percentage of participants who reported use of other tobacco products, particularly cigars and cigarillos, we examined the use of any other tobacco product during the past week across time by treatment group using GEE analysis. We found no significant interaction between time and treatment, and no main effect of treatment. However, there was a significant main effect of time such that during the intervention period, use of these products increased for both groups, with 7% reporting use of another tobacco product (primarily cigars/cigarillos) at Baseline and increasing to 17% at Weeks 4 and 8 and dropping back to 6% by Week 16 (Wald Chi-Square=14.7; $p=0.012$).

Measures of Cessation Readiness

GEE models testing changes in motivation, self-efficacy, and perceptions of quitting difficulty and revealed significant main effects for treatment group for all constructs, such that participants assigned to AT group reported higher levels of motivation ($M=8.93$ vs. 8.61 ; $p=0.015$) and abstinence self-efficacy ($M=8.69$ vs. 8.14 ; $p<0.001$) and lower levels of perceptions of quitting difficulty ($M=4.65$ vs. 5.46 ; $p<0.001$) as compared to participants assigned to TAU over time (see Supplemental Table 2).

Comparison of Sample to Clinic Population

Given the largely proactive nature of recruitment for this study, we wanted to ensure that participants recruited in our study were representative of the larger population of PLHIV being treated in the clinic. Specifically, we compared individuals who participated in this study to smokers who were seen in the clinic during the recruitment time but who were not approached to be in the study ($n=100$, $n=356$; Supplemental Table 3). Study participants were older at the time of the study as well as older when they first were diagnosed with HIV. Female and African American participants were over-represented in the intervention relative to smokers in the HIV clinic. Study participants had a higher Nadir CD4 count compared to smokers in the clinic. Finally, participants in the intervention were more likely to be currently using cocaine but were less likely to engage in risky alcohol use compared to clinic smokers. No differences were found between study and non-study participants on all other PROs and no significant differences were found among individuals in the Algorithm group compared to TAU participants on any of these variables.

DISCUSSION

This is the first randomized pilot clinical trial to examine the implementation and delivery of a novel proactive algorithm-based intervention among PLHIV smokers engaged in HIV medical care. The findings demonstrate that our intervention was well integrated into the clinic setting and that the provision of active treatments to smokers receiving treatment in an HIV setting can produce important clinical changes, including reduced cigarette consumption, elevated levels of abstinence self-efficacy and motivation and diminished perception of difficulty for quitting, compared to participants receiving usual care. Importantly, these findings were inclusive of both motivated and unmotivated smokers. The overall evidence from this pilot is promising and has strong potential for dissemination into clinical settings.

Smoking is increasingly becoming the most important modifiable risk factor for morbidity and mortality among PLHIV and therefore it is unequivocal that smoking cessation becomes a top priority for HIV care providers. Unfortunately, the complexity of HIV management often renders smoking cessation a lower priority among providers, who otherwise lack the training and confidence to initiate cessation initiatives, particularly counseling-based cessation services [29]. While counseling services have significant merit, counseling is also often time-intensive and not compatible with a busy and often over-burdened HIV clinical setting. The algorithm protocol presented herein offers an alternative method for more easily incorporating smoking cessation efforts into clinical encounters [19]. Specifically, this easy-to-follow tool provides clinicians with a brief and succinct pathway for treatment selection decisions and thereby lends itself to being utilized during even brief clinical encounters [19]. In addition to being time-efficient, this tool capitalizes on other components of optimal health care, including patient customization [17]. The latter is particularly important for an HIV population, many of whom face unique barriers to smoking cessation given high rates of comorbid drug and alcohol use and mental illness [30]. These factors not only make cessation more challenging but also render some cessation resources inappropriate, e.g., bupropion for patients with a history of bipolar disorder [31]

Although the overall pattern of results suggests that the algorithm protocol is both feasible and produced encouraging results, this study has a number of limitations inherent in the design. As a pilot study, our sample was small and therefore we had insufficient power to detect more desired clinical outcomes, e.g., prolonged abstinence. Nonetheless, we did focus on other well-established process measures of cessation [32] which we believe to be an important, and cost-efficient, first step for studies focused on initially establishing feasibility [33]. In light of our promising results, however, the next steps should include randomized clinical trials utilizing larger samples and targeting more rigorous clinical outcomes over a greater period of time. In addition, due to the pilot nature of this project and limited funding, research staff could only be in the clinic during two days for active recruitment and were not available to approach all eligible participants. However, our study sample was fairly similar to the clinic sample, though females and African American smokers were over represented relative to rates in the clinic. However, this is likely a strength of our study, particularly given the general lack of representation of minority patient populations in current HIV treatment studies [34]. Sociodemographic differences in the prevalence of HIV/AIDS are

well-established, often with African Americans bearing the greatest burden and demonstrating differences in treatment responsiveness. Finally, some participants were unable to be seen after their regularly scheduled appointment and scheduled their appointment outside of this time to do the study. Unfortunately, this was not tracked so it is impossible to determine how this may have impacted our results.

In conclusion, this trial provides evidence that a proactive, algorithm-based protocol was effective in producing changes across a number of important clinical markers associated with smoking cessation [32]. In order for a smoking intervention to produce meaningful changes in population-level cessation rates, it must not only demonstrate potential for efficacy but also be able to reach a large proportion of smokers [35]. As the capacity to more easily identify smokers via electronic medical records continues to grow, the use of proactive initiatives will represent an excellent approach in which to increase smokers' access to evidence-based cessation resources [9]. Beyond improvements in reach, proactive initiatives circumvent several barriers associated with physician-delivered smoking cessation including lack of time and interest, biases about smokers' motivation and racial/ethnic background [9]. Combined, these advantages suggest strong potential to further advance clinical health outcomes in this population.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Key point

This is the first randomized pilot clinical trial to examine the implementation of a novel proactive algorithm-based intervention among PLHIV smokers engaged in HIV medical care. The intervention produced positive changes across several important clinical markers associated with smoking cessation.

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Figure 1.
Algorithmic Treatment of Smoking Cessation

Figure 2.
Interaction between Treatment across Time for Average Number of Cigarettes Smoked Per Day (N = 100)

Figure 3.
Interaction between Treatment across Time for Medication Utilization

Table 1

Demographic Characteristics (N = 100)

Variable	Total (n=100)	AT (n=50)	TAU (n=50)	p-value
Age, M (SD)	46.2 (8.7)	46.4 (7.8)	46.2 (8.6)	0.895
Race, %				
African American	75	72	78	0.419
White	25	28	22	
Sex, %				
Male	71	70	72	0.488
Female	29	30	28	
Marital Status, %				
Never Married	56	56	57	0.981
Married	10	10	10	
Divorced/Separated	27	28	26	
Widow	7	6	8	
Education Level, %				
<HS	30	30	30	1.000
HS/GED	30	30	30	
>HS	40	40	40	
Received Mental Health Treatment, %				
Yes	57	62	52	0.313
No	43	38	48	
Received Substance Abuse Treatment, %				
Yes	69	67	71	0.726
No	31	33	29	

Note: AT = Algorithm Treatment, TAU = Treatment As Usual, SD = Standard Deviation, HS = High School, GED = General Educational Development. Age comparison with treatment group was calculated using ANOVA while all other comparisons were done using Chi-Square analyses.

Table 2

Baseline Smoking Characteristics (N = 100)

Variable	Total (n=100)	AT (n =50)	TAU (n =50)	p-value
Age of First Smoking, M (SD)	16.0 (6.7)	15.8 (4.7)	16.3 (8.3)	0.699
Age at Onset of Daily Smoking, M (SD)	19.5 (6.9)	18.2 (5.2)	20.8 (8.1)	0.057
Average CPD, M (SD)	16.0 (8.9)	16.7 (9.6)	15.3 (8.2)	0.440
Highest CPD, M (SD)	21.2 (11.2)	20.7 (10.8)	21.7 (11.6)	0.635
Number of Cigarettes Smoked Today, M (SD)	5.5 (5.5)	5.5 (5.1)	5.6 (5.9)	0.843
Number of Cigarettes Smoked Yesterday, M (SD)	14.4 (8.7)	14.9 (8.3)	13.8 (9.2)	0.626
CO Level (ppm), M (SD)	18.0 (11.6)	19.1 (13.1)	16.8 (9.9)	0.341
FTCD (baseline), M (SD)	5.1 (2.1)	5.1 (2.0)	5.1 (2.2)	0.924
QSU (baseline), M (SD)	40.3 (17.4)	41.4 (17.7)	39.1 (17.3)	0.505
HHWS (baseline), M (SD)	12.8 (8.0)	13.3 (8.1)	12.3 (8.0)	0.559
Total Number of Years Smoking, M (SD)	26.9 (11.0)	26.8 (10.8)	27.0 (11.3)	0.919
Number of Past Quit Attempts, M (SD)	2.8 (10.6)	2.1 (4.2)	3.5 (14.4)	0.503
Longest Quit (months), M (SD)	15.5 (25.1)	16.5 (26.8)	14.5 (23.6)	0.731
Last Time Tried to Quit (months), M (SD)	19.8 (50.5)	28.7 (68.2)	10.7 (17.2)	0.077
Difficulty of Last Quit Attempt ^a , M (SD)	5.6 (2.2)	5.6 (2.3)	5.7 (2.2)	0.786
Percentage of Family Who Smoke, M (SD)	39.7 (36.7)	36.1 (37.4)	43.3 (35.9)	0.305
Percentage of Friends Who Smoke, M (SD)	57.0 (34.8)	54.9 (33.6)	59.0 (36.2)	0.512
Average Amount Spent on Cigarettes (weekly in dollars), M (SD)	\$33.9; 51.8	\$28.5; 20.1	\$38.9; 69.4	0.326
Abstinence Goal, %				
Complete Abstinence	66	62	70	0.398
Some other goal	34	38	30	
Thinking about Quitting Smoking, %				
Within 30 days	73	68	78	0.376
Within 6 months	26	30	22	
No, not considering quitting	1	2.0	0	
Family Member has Medical Problems Related to Smoking, %				
Yes	27	26	29	0.587
No	58	62	53	

Variable	Total (n=100)	AT (n =50)	TAU (n =50)	p-value
Do Not Know	15	12	18	
Family Member Died from Smoking, %				
Yes	32	24	40	0.170
No	55	64	46	
Do Not Know	13	12	14	
Personal Medical Problems from Smoking, %				
Yes	23	20	26	0.801
No	65	67	62	
Do Not Know	12	12	12	
Currently Living with a Smoker				
Yes	61	62	60	0.838
No	39	38	40	
Use of Menthol Cigarettes, %				
Yes	78	74	82	0.334
No	22	26	18	
Other Tobacco Products Used, %				
Cigars/cigarillos	26	34	18	0.068
Smokeless/Chew/Snus	9	8	10	0.727
Pipes	6	10	2	0.092

Note

^a 1-7 scale; 1= not difficult; 7=very difficult, AT= Algorithm Treatment, TAU = Treatment as Usual, CPD = Cigarettes per day, CO = carbon monoxide, FTCD = Fagerstrom Test of Cigarette Dependence, QSU = Questionnaire of Smoking Urges, HHWS = Hughes-Hatsukami Withdrawal Scale. ANOVAs were calculated for comparisons between continuous variables.