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Combining Text Messaging and Telephone Counseling to Increase Varenicline Adherence and Smoking Abstinence Among Cigarette Smokers Living with HIV: A Randomized Controlled Study

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Abstract

Smoking represents an important health risk for people living with HIV (PLHIV). Low adherence to smoking cessation pharmacotherapy may limit treatment effectiveness. In this study, 158 participants recruited from three HIV care centers in New York City were randomized to receive 12-weeks of varenicline (Chantix) either alone as standard care (SC) or in combination with text message (TM) support or TM plus cell phone-delivered adherence-focused motivational and behavioral therapy (ABT). Generalized linear mixed-effect models found a significant decline in varenicline adherence from week 1–12 across treatment groups. At 12-weeks, the probability of smoking abstinence was significantly higher in SC+TM+ABT than in SC. The study demonstrates the feasibility of delivering adherence-focused interventions to PLHIV who smoke. Findings suggest intensive behavioral support is an important component of an effective smoking cessation intervention for this population, and a focus on improving adherence self-efficacy may lead to more consistent adherence and higher smoking abstinence.

Keywords

HIV; Smoking cessation; Medication adherence; Text messaging; Telephone counseling

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Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

Introduction

People living with HIV (PLHIV) in the US are two to three times more likely to be current smokers (40–88 %) and significantly less likely to quit compared with the general population [1–3]. Due to treatment advances, PLHIV are living longer, making the issue of cigarette smoking in this population a major clinical concern. Tobacco-related illnesses, including cardiovascular disease and cancer, are now the leading causes of non HIV-related deaths among PLHIV [4, 5]. Cigarette smoking also places PLHIV at increased risk of unsuppressed viral load, low CD4 count, serious HIV-related co-morbidities and premature death [6, 7]. Despite the overwhelming burden of tobacco use, there is a lack of research demonstrating efficacious approaches to treating nicotine dependence in this population [8].

The few randomized controlled studies using varying combinations of medication and counseling have shown mixed results among PLHIV [8–17]. Five trials have found no difference between groups using different forms of behavioral therapy and nicotine-replacement therapy (NRT) [13–17]. In contrast, Vidrine et al. found that HIV- positive smokers randomized to 11 cell phone-delivered behavioral counseling sessions plus usual care (which included access to NRT) achieved significantly higher 3-month abstinence rates compared to standard care [11]. However, the effect was no longer significant at 6-months [12]. The current literature demonstrates the need to explore new approaches to increasing cessation rates among PLHIV

A key component of evidence-based smoking cessation treatment is pharmacotherapy. Higher rates of adherence are associated with a greater likelihood of smoking abstinence [8, 18–23]. However, similar to findings in the general population, adherence to smoking cessation pharmacotherapy among PLHIV is poor and declines over time [15, 16, 24–26]. Despite the significance of this problem, adherence to smoking cessation medications has received little attention in randomized clinical trials. Moreover, few studies have prospectively tested interventions to improve adherence to smoking cessation medication, and none have included PLHIV [27].

Innovative interventions that promote both adherence to cessation medications and provide intensive behavioral support (i.e., telephone counseling) are needed. Text messaging is particularly well suited to address behaviors like smoking. Text message interventions are able to interact with individuals in the context of the behavior [28, 29] and offer the opportunity to deliver medication reminders consistent with a patient’s dosing schedule. Two systematic reviews found increased cessation rates at 3 and/or 6 months for text message-based smoking cessation interventions that provided behavioral support [30, 31]. However, there are no smoking cessation studies in which text messages included both behavioral support and medication reminders and none of these studies included PLHIV. In addition, there are no studies that have tested interventions that combine telephone-delivered counseling with text messages to address barriers to adherence and cessation. The current literature suggests that more intensive support is needed to improve cessation outcomes in this population and therefore point to a potential advantage to combining these modes of behavioral support [11, 30].

In response to this research priority, we conducted a three-arm randomized controlled study that compared standard care with adherence-focused behavioral interventions through text messages alone or in combination with phone counseling. The goal of the study was to explore the feasibilty of each intervention component to facilitate adherence to varenicline (Chantix®) and 12-week smoking abstinence among smokers living with HIV.

Methods

Study Design

We conducted a three-arm randomized controlled study in which participants were randomized to receive 12 weeks of varenicline either alone as standard care (SC) or in combination with one of two adherence-focused support options: twice daily text message (TM) support, or TM plus seven telephone-delivered adherence-focused motivational and behavioral therapy sessions (ABT). The goal of the study was to test the feasibility and potential efficacy of text messaging alone and in combination with telephone counseling for varenicline adherence and was not designed to be a definitive test of the intervention although the sample size is larger than in a typical pilot study. As part of standard care, all participants also received a self-help information sheet, tailored to PLHIV who smoke with frequently asked questions about using varenicline, and a wallet card with the New York State Quitline number. Participants in all three arms could choose to use their own phone or a study provided cell phone during the 12 weeks of intervention period. The study phone provided unlimited text messaging and 250 min for telephone calls. Research staff monitored the study phone accounts and refilled them with additional minutes as needed. The study has been approved by New York University School of Medicine Institutional Review Board.

Setting and Participants

Between July 2013 and March 2014, we recruited and screened study participants for eligibility in the waiting area of three HIV care centers affiliated with St. Luke's-Roosevelt Hospital Spencer Cox Centers for Health, located in New York City. Smokers were eligible if they were 18 years or older and diagnosed with HIV, smoked ≥5 cigarettes daily in the past week, were willing to quit within the next 2 weeks, and were cleared by their physician for varenicline use (i.e., did not have major depression, schizophrenia or bipolar disorder, unstable cardiovascular disease or renal impairment). Individuals were excluded if they did not speak or read English, were pregnant or nursing, using another FDA-approved smoking cessation medication, had suicidal/homicidal ideations or a PHQ 9 depression score >5, and either a substantial to severe drug use disorder defined as a score of ≥6 on the drug abuse screening test-10 and/or a hazardous or active alcohol use disorder defined as ≥7 for men and ≥5 for women on the alcohol use disorders identification test-consumption (AUDIT-C) [32, 33]. All eligible participants who gave informed consent were scheduled for a baseline visit at New York University School of Medicine. To reduce post-randomization attrition, participants were randomized to one of the three study groups at baseline instead of at enrollment. Randomization was stratified by number of cigarettes smoked per day at baseline (5–10 and >10 cigarettes/-day). A total of 841 patients were screened for eligibility

and 158 were randomized (Fig. 1). Participants returned for follow-up visits at 1, 4, 8 and, 12 weeks postrandomization.

Measures

Baseline Measures—Nicotine dependence was evaluated using the Heaviness of Smoking Index, which contains a four category-scoring scheme for "time to the first cigarette of the day" and "average daily consumption of cigarettes" (range 0–6) [34]. Alcohol and drug use were measured using the AUDIT-C [35], and the drug use disorders identification test (DUDIT) [36]. To measure beliefs and attitudes (motivation), we adapted Fucito's 6-item beliefs and attitudes about bupropion measure which uses a 5-point Likert scale [25]. The 8-item varenicline information scale was adapted from The LifeWindows Information Motivation Behavioral Skills Adherence Assessment Questionnaire and was assessed on a 5-point Likert scale (1 = strongly disagree, 5 = strongly agree) [37]. We also measured varenicline adherence self-efficacy using a 17-item survey using a 4-point Likert scale (1 = not at all sure, 4 = extremely sure), with 12 items adapted from the Medication Adherence Self-Efficacy Scale (MASES) and 5 items from the Adherence Self-Efficacy Scale (ASES) [38, 39]. All negative questions were reverse coded before data analysis. To test internal consistency of the adapted scales, Cronbach's alpha was calculated based on all participants who completed the baseline survey (n = 159, Crobach's α = .86 for varenicline beliefs and attitudes measurement, Crobach's α = .65 for varenicline information scale, Cronbach's α = .92 for varenicline adherence self-efficacy measurement).

Adherence—Consistent with previous studies, adherence was defined as taking ≥80 % of prescribed varenicline since last visit, as determined by pill count and was assessed at 1, 4, 8 and 12 week follow up visits [22, 40–42]. Participants who did not bring their medication bottles for pill count or who did not come back for follow-up visits were considered non-adherent (intent-to-treat approach). Five participants became ineligible for varenicline during the course of intervention due to other medical reasons unrelated to varenicline use but were included in the analysis as per the intent to treat approach.

Abstinence—Self-reported 7-day point prevalence smoking abstinence was verified by a carbon monoxide (CO) <8 ppm and measured at 1, 4, 8, and 12 weeks. Participants with missing data due to loss-to-follow-up or withdrawal/discharge from the study were considered as non-abstinent (intent-to-treat approach).

Intervention Components

The text messaging and phone counseling interventions were guided by the information-motivation-behavioral skills model (IMB) of antiretroviral adherence [43]. This model incorporates factors from social cognitive theory and the theory of planned behavior that are associated with medication adherence and smoking abstinence [39, 44, 45]. It posits that adherence-related self-efficacy (*behavioral skills*), *information/knowledge* about the treatment, and positive attitudes and beliefs towards adherence (*motivation*) are critical determinants of medication adherence [46, 47].

The behavioral intervention components were designed to address factors hypothesized by the IMB model to influence the primary study outcomes of varenicline adherence and smoking cessation [48, 49]. Details about each intervention component are described below.

Varenicline—At baseline, participants were given a one-week supply of varenicline, and at each subsequent visit they were given enough to last until the next visit for a total of 12-weeks of treatment. We titrated the dosage of varenicline in the first week: .5 mg once daily for days 1–3, then .5 mg twice daily for days 4–7, followed by 1.0 mg twice daily from day 8 until week 12.

Text Messaging—The text messaging protocol was designed to address both medication adherence and tobacco cessation themes. Messages created by our study team were based on IMB constructs including motivation, social support, and expectancies and findings from previous studies testing the efficacy of text message interventions for tobacco cessation [50, 51]. We also drew from the National Cancer Institute's QuitNowTXT library [52] and from a previous HIV-medication adherence study. [53] In addition, studies of adherence to HIV-related medications have found that "simply forgetting" is the most common self-reported reason for non-adherence [49]. Therefore, text messages that specifically prompted adherence were included daily. Based on findings from formative research, described in a previous publication, we developed a text library that included 168 text messages to ensure that each message was not repeated [54]. Each day participants in the two TM arms received one adherence-focused message and one IMB smoking cessation-themed message, at the time of their own choice.

ABT Phone Sessions—The seven-session standardized manual combined the principles of cognitive behavioral therapy with motivational interviewing techniques [18, 55–57]. The planning and quit date counseling sessions were approximately 30 min each, and the five follow-up sessions were scheduled 2 days, and then 2, 4, 6, and 10 weeks after the quit date, each lasting about 20 min. During the planning session, the counselor provided an overview of the program, discussed the effects of smoking on PLHIV, elicited the participant's barriers and facilitators to quitting, and developed a quit plan. On the quit day, status of quit was assessed. The counselor discussed with the participant about withdrawal symptoms, external and internal triggers, high risk situations, and coping strategies. The five follow-up sessions were intended to maintain adherence to medication, to help prevent relapse, and to help those who relapse to make a quick recovery and resume quitting. All counselors had a master's degree and were either a licensed clinical social worker or mental health counselor, or certified tobacco treatment specialist. Prior to the intervention, the counselors completed 4 days of training on the counseling manual with a member of the International Motivational Interviewing Network of Trainers organization. To prevent a decay of counseling skills, counselors also received ongoing coaching on their skills from the trainer.

Treatment Fidelity—Treatment fidelity was based on the expanded Lichtenstein treatment fidelity model developed by the Office of Behavioral Social Sciences Research Behavior Change Consortium [58]. Counselors completed a checklist indicating topics covered during the counseling sessions and recorded process notes after each session. All telephone sessions

were audio-recorded and archived for systematic sampling of 10 % of the sessions and subsequently coded in order to assess adherence to the counseling manual using the Behavior Change Counseling Index [59]. Counselors were considered adherent if they scored an average score ≥3 on the index (range 1 [not at all]–4 [a great extent]). The average score across counselors throughout the 12-week period was three. Treatment fidelity measures also included number of completed counseling sessions and self-reported frequency of reading text messages.

Analysis

Baseline characteristics were described. Varenicline adherence and smoking abstinence outcomes at each time point were compared among three treatment groups using Chi square tests and Fisher's exact tests. To investigate predictors of varenicline adherence and of smoking abstinence, two generalized linear mixed-effect models (GLMMs) were estimated, with repeated measurements nested under individual participants and randomly varying intercept coefficients. Variables that demonstrated group differences at baseline or known association with outcomes based on literature were chosen as covariates. In the model of varenicline adherence, treatment condition, time, baseline adherence self-efficacy, as well as the interaction term between time and treatment condition were included as predictors. Living in independent housing, on which there was a moderate imbalance across treatment arms despite randomization, was also included. In the model of smoking abstinence, treatment condition, time, varenicline adherence, baseline heaviness of smoking, living in independent housing, as well as the interaction term between time and treatment condition were included. In both models, the time variable was coded to contrast weeks 1 and 12. All analysis was conducted in version 14 of Stata [60], with *xtmelogit* used to fit GLMMs. Variance explained by the fixed and random effects in each GLMM was calculated [61]. Significance tests, including comparisons between specific treatment arms, were made without adjustments to p-values.

Power Analysis

Because this study was not meant to provide a definitive test of intervention efficacy, analyses relied on effect size calculation, confidence intervals and patterns of results in addition to null hypothesis significance testing. Nevertheless, a priori power calculations were undertaken to provide some idea of the magnitude of effects that could be reliably detected using conventional tests of significance for the proposed sample size. With a sample size of 50 participants per group that were deemed feasible to recruit, power is 80 % to detect an increase in the proportion with good varenicline adherence from 50 % (taking ≥80 % of prescribed varenicline) in the standard care condition to 77 % in one of the enhanced treatment conditions. This increase corresponds to an odds ratio of 3.29.

Results

Sample Demographics

Over 80 % of the sample was either Non Hispanic Black or Hispanic of any race, predominantly males in their mid 40 s and over 70 % were currently unemployed (Table 1).

At baseline, over half of the participants smoked their first cigarette within 5 min after waking, and on average smoked 15 cigarettes per day.

Intervention Feasibility

Recruitment and Retention—Figure 1 shows the CONSORT diagram. Among 841 individuals who were screened, 195 (23.2 %) were enrolled in the study and 158 (18.8 %) were randomized to one of three treatment arms. The overall retention rate was 72.2 % at 12 weeks. There was no difference in retention across treatment groups at any time point (data not shown; $p = 1.00$ at week 1, $p = .93$ at week 4, $p = .40$ at week 8, $p = .57$ at week 12; Chi square test).

Treatment Exposure—Among participants who completed week 12 surveys, 78.4 % ($n = 29$) in the SC+TM arm and 66.7 % ($n = 24$) in the SC+TM+ABT arm reported having always or usually read the intervention text messages (data not shown; $p = .26$; Chi square test). On average, participants in the SC+TM+ABT arm completed 4.25 of the seven counseling sessions (data not shown; $n = 51$, $SD = 2.42$).

Estimates of Efficacy for Adherence and Abstinence Outcomes

Varenicline Adherence and Smoking Abstinence at Weeks 1, 4, 8 and 12—Adherence and abstinence outcomes at each follow-up time point were compared across three arms, without adjusting for other factors (Table 2). No difference was found in varenicline adherence across treatment groups at any time point. At week 8, the abstinence rate among SC+TM+ABT was significantly higher (17.7 %) than the SC+TM (5.7 %) and SC groups (3.7 %) ($p = .03$). At week 12, the SC+TM+ABT group had a higher abstinence rate (15.7 %) compared with SC (5.7 %,) and SC+TM (3.7 %,) groups; however, the difference was only marginally significant ($p = .07$). Taking ≥80 % doses for at least two study visits in a row was associated with increased odds (data not shown, OR 11.33, $p = .007$, Fisher's exact test) of smoking abstinence at week 12.

Longitudinal Modeling on Varenicline Adherence and Smoking Abstinence—Longitudinal modeling of varenicline adherence (Table 3) shows adherence decreased significantly from week 1 to week 12 (OR .09, $p < .001$). The trajectory of varenicline adherence over time did not differ across the three arms (data not shown, $p = .50$). Higher adherence self-efficacy at baseline was associated with significant increased odds of adherence (OR 2.20, $p < .001$). Fixed effects alone explained 19 % of the variance in adherence while the whole model (fixed and random effects) explained 64 % of the variance in adherence (data not shown).

At 12-weeks, pairwise comparisons of the three intervention conditions suggest the probability of smoking abstinence was significantly higher in SC+TM+ABT than in SC (OR 5.51, $p = .05$). Adherence to varenicline at the same visit (OR 2.01, $p = .13$) and baseline smoking heaviness (OR .61, $p = .09$) were not associated with smoking abstinence. Fixed effects alone explained 14 % of the variance in abstinence while the whole model explained 64 % of the variance in abstinence (data not shown).

Discussion

The study demonstrated success in recruiting and retaining a racially diverse sample of cigarette smokers living with HIV in a smoking cessation trial. The medium to high level of treatment exposure reported by study participants confirmed the feasibility of implementing text messaging and phone counseling interventions with this vulnerable population. Although the objective of the study was not to draw definitive conclusions about intervention efficacy and the limited sample size did not allow precise estimates of intervention effects on outcomes, below we discuss interval estimates of intervention effects on varenicline adherence and smoking abstinence to identify strengths and weaknesses of the intervention design and to inform future studies.

Adherence

We found significant and similar declines in adherence over time across all three-study arms despite the addition of adherence-focused content in the text messaging and combined text and telephone counseling intervention arms. While confidence intervals for the effect of adding text messaging or text-messaging plus counseling include potential impacts on adherence with clinical and public health significance, even the upper limits of those intervals suggest modest effects of those enhancements to standard care (i.e., odds of good adherence multiplied by 3.5 at most). A 2015 Cochrane review also found limited evidence that interventions focused on improving adherence to smoking cessation medications enhanced adherence when added to behavioral support for smoking abstinence [62]. However, among the five studies reviewed, none included the use of text messaging. In contrast to our findings, text reminders have been shown to be effective in increasing adherence to antiretroviral therapy (ART) [27]. A recent meta-analysis of eight studies found text messaging yielded significantly higher rates of adherence to ART than control conditions. Larger effects were associated with interventions that used bidirectional communication, included personalized message content and were matched to the dosing schedule [27]. The current study used a unidirectional text message protocol that was not tailored to any individual characteristics, which may, in part, explain why effects on adherence were not stronger [63, 64]. Moreover, text reminders alone may not fully address the myriad social, economic and medical challenges of PLHIV, including an already complex medical regimen that may contribute to low rates of adherence to cessation medications [1, 65]. Notably, the addition of telephone counseling did not enhance adherence. However, our fidelity assessments indicated more than 75 % of the sessions did not focus significant time on this issue; rather, the counselor emphasized increasing motivation and behavioral support for cessation. Our findings do point to the potential for improving adherence self-efficacy as a strategy for increasing adherence to smoking cessation medications. Consistent with studies of ART adherence, adherence self-efficacy was a strong predictor of more consistent use of varenicline [46].

Together the literature, and findings from this study, suggests the need for further research to explore whether components of mobile-based phone interventions that are effective for increasing ART adherence can be applied to cessation pharmacotherapy. In addition, studies are needed that explore the impact of more consistent attention to adherence as part of

counseling interventions with a specific focus on building adherence self-efficacy. Finally, to make progress in this area, studies should apply conceptual models that may help delineate how these interventions work to improve adherence [27].

Smoking Abstinence

In addition to the text message to remind participants to take varenicline, we sent daily messages that offered behavioral support for quitting informed by the IMB model. In contrast to previous studies of mobile phone interventions to increase cessation this component of the text intervention did not appear to improve cessation rates. A Cochrane review of five studies using mobile phone interventions reported increased quit rates at 6 months [30]. None of the studies included PLHIV. Again, differences in design elements may explain the discrepancy. Unlike these previous studies, the text delivered behavioral support was not customized, did not allow bidirectional interaction and did not vary in intensity. These factors appear to be important components of an effective text message cessation intervention.

Although the telephone counseling did not improve adherence rates, there was evidence of an effect on cessation. In the longitudinal model, the addition of cell phone delivered counseling was associated with significantly improved cessation rates even after controlling for varenicline adherence, suggesting an impact of the counseling's emphasis on increasing motivation and behavioral support for cessation, other than improving adherence. The positive impact of telephone counseling is consistent with Vidrine et. al's study in PLHIV, as are the relatively low quit rates [11, 66]. Based on the literature to date, more intensive counseling appears effective; however, rates of cessation are low and no studies to date have found evidence of long-term efficacy [12]. The longitudinal analysis did not demonstrate an association between adherence and abstinence. However, in combined analysis, participants who were more consistently adherent to the prescribed dose (≥80 % prescribed doses for at least two visits in a row) were significantly more likely to achieve 12 week smoking abstinence, pointing to a potential role for adherence focused interventions as a part of a comprehensive approach to smoking cessation in this population.

Our findings suggest that in a low SES patient population with significant comorbidities the multisession telephone-delivered behavioral support intervention component, which employed principles of motivational interviewing and cognitive behavioral therapy, was an important factor in achieving cessation. While evidence on association between adherence and smoking abstinence was weak, interventions that are able to lead to more sustained adherence may still lead to improved cessation outcomes. Adherence self-efficacy predicted medication adherence, suggesting a possible direction for interventions designed to enhance adherence.

There were several limitations. First, this study was not meant to provide a definitive test of intervention efficacy. Although our results demonstrated intervention feasibility, a detailed analysis on qualitative data collected with participants (not presented in this paper) will help further identify facilitators and barriers to adherence and abstinence. Second, this analysis presents data at end of treatment (12 weeks). A longer follow up assessment is needed to assess if the higher rates of cessation in telephone counseling intervention arm persist.

Finally, as noted previously, the text message intervention lacked components that have been demonstrated to improve adherence rates in PLHIV.

In conclusion, the current study demonstrated the feasibility of delivering a smoking cessation intervention using text messaging in a HIV-positive group of smokers. Intensive behavioral support appears to be an important component of an effective smoking cessation intervention for PLHIV. Despite limitations in sample size and follow-up length, we observed trends in varenicline adherence and smoking abstinence worthy of further investigation. Future research needs to explore innovative approaches to delivering this support, including continuing to test the use of mobile-based interventions that address the multidimensional barriers to adherence and smoking abstinence and are tailored to the complex psychosocial needs of this vulnerable population.

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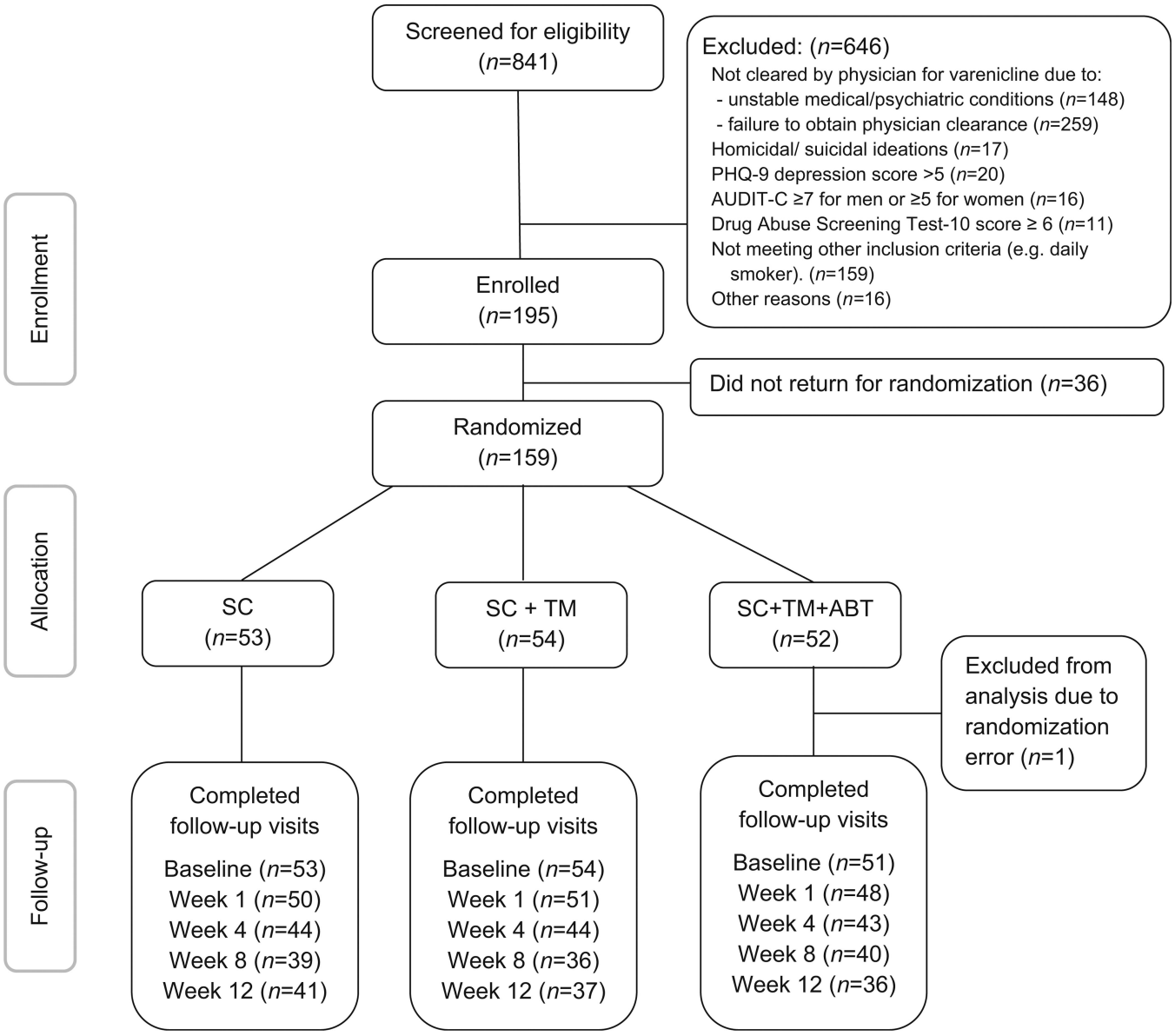

Fig. 1.
Consort diagram

Table 1

Baseline characteristics

Baseline variable	Mean ± SD, *n* (%)			
	Total (*n* = 158)	**SC (*n* = 53)**	**SC+TM (*n* = 54)**	**SC+TM+ABT (*n* = 51)**
Age in years	46.79 ± 9.83	46.64 ± 10.77	46.00 ± 9.96	47.76 ± 8.74
Gender				
Female	29 (18.4 %)	10 (18.9 %)	10 (18.5 %)	9 (17.6 %)
Male	125 (79.1 %)	39 (73.6 %)	44 (81.5 %)	42 (82.4 %)
Transgender	4 (2.5 %)	4 (7.5 %)	0 (.0 %)	0 (.0 %)
Race/ethnicity				
Non-hispanic black	81 (51.3 %)	21 (39.6 %)	27 (50.0 %)	33 (64.7 %)
Non-hispanic white	21 (13.3 %)	9 (17.0 %)	7 (13.0 %)	5 (9.8 %)
Other non-hispanic	6 (3.8 %)	2 (3.8 %)	2 (3.7 %)	2 (3.9 %)
Hispanic of any race	50 (31.6 %)	21 (39.6 %)	18 (33.3 %)	11 (21.6 %)
Education				
<HS	35 (22.2 %)	6 (11.3 %)	15 (27.8 %)	14 (27.5 %)
HS degree or GED	46 (29.1 %)	19 (35.8 %)	10 (18.5 %)	17 (33.3 %)
Some college	52 (32.9 %)	19 (35.8 %)	21 (38.9 %)	12 (23.5 %)
College or post-graduate degree	25 (15.8 %)	9 (17.0 %)	8 (14.8 %)	8 (15.7 %)
Housing				
Independent apartment/house	132 (83.5 %)	49 (92.5 %)	38 (70.4 %)	45 (88.2 %)
Other type of housing	26 (16.5 %)	4 (7.5 %)	16 (29.6 %)	6 (11.8 %)
Employment status				
Employed	45 (28.5 %)	14 (26.4 %)	15 (27.8 %)	16 (31.4 %)
Unemployed	32 (20.3 %)	15 (28.3 %)	11 (20.4 %)	6 (11.8 %)
Unable to work or disabled	54 (34.2 %)	14 (26.4 %)	20 (37.0 %)	20 (39.2 %)
Other	27 (17.1 %)	10 (18.9 %)	8 (14.8 %)	9 (17.6 %)
Used study cell phone	101 (63.9 %)	28 (52.8 %)	36 (66.7 %)	37 (72.5 %)
Baseline number of cigarettes per day	14.8 ± 9.7	15.1 ± 10.1	14.2 ± 9.2	15.3 ± 9.9
Time to first cigarette				
5 min or less after waking	85 (53.8 %)	30 (56.6 %)	28 (51.9 %)	27 (52.9 %)
6–30 min after waking	55 (34.8 %)	18 (34.0 %)	17 (31.5 %)	20 (39.2 %)
>30 min after waking	18 (11.4 %)	5 (9.4 %)	9 (16.7 %)	4 (7.8 %)
Heaviness of Smoking Index	3.0 ± 1.2	3.2 ± 1.3	2.8 ± 1.2	3.1 ± 1.1
DUDIT	4.3 ± 6.5	4.4 ± 7.1	5.1 ± 7.2	3.2 ± 4.9
AUDIT-C	1.8 ± 1.8	1.9 ± 1.9	1.8 ± 1.9	1.7 ± 1.7
Beliefs and attitudes about varenicline[a]	4.3 ± .6	4.4 ± .5	4.3 ± .7	4.2 ± .6
Varenicline information scale[b]	34.9 ± 4.4	34.9 ± 4.1	34.9 ± 4.7	34.9 ± 4.4
Adherence self-efficacy[b]	55.6 ± 10.0	57.3 ± 8.6	54.9 ± 9.6	54.6 ± 11.5

[a] Mean score was used for beliefs and attitudes about varenicline scale

[b] Sum scores were used for adherence self-efficacy (MASES and ASES combined) and varenicline information scale

Table 2

Varenicline adherence and smoking abstinence by treatment arms at each visit

	SC	SC+TM	SC+TM+ABT	p-value[a]
Week 1				
Adherence rate	66.0 % (*n* = 35)	72.2 % (*n* = 39)	78.4 % (*n* = 40)	.37
Abstinence rate	1.9 % (*n* = 1)	7.4 % (*n* = 4)	.0 % (*n* = 0)	.13
Week 4				
Adherence rate	54.7 % (*n* = 29)	38.9 % (*n* = 21)	43.1 % (*n* = 22)	.24
Abstinence rate	11.3 % (*n* = 6)	18.5 % (*n* = 10)	13.7 % (*n* = 7)	.59
Week 8				
Adherence rate	35.9 % (*n* = 19)	37.0 % (*n* = 20)	35.3 % (*n* = 18)	.98
Abstinence rate	5.7 % (*n* = 3)	3.7 % (*n* = 2)	17.7 % (*n* = 9)	**.03**
Week 12				
Adherence rate	34.0 % (*n* = 18)	29.6 % (*n* = 16)	29.4 % (*n* = 15)	.85
Abstinence rate	5.7 % (*n* = 3)	3.7 % (*n* = 2)	15.7 % (*n* = 8)	.07

[a]Chi square tests were used for adherence rate and Fisher's exact tests were used for abstinence rate Bold value is statistically significant ($p < 0.05$)

Table 3

Longitudinal models on varenicline adherence and smoking abstinence

	Adherence			Abstinence		
	OR	***p*-value**	**95 % CI**	**OR**	***p*-value**	**95 % CI**
Treatment						
SC+TM[a]	0.87	.83	0.24, 3.09	0.62	.64	0.08, 4.54
SC+TM+ABT[b]	0.70	.59	0.20, 2.53	5.51	**.05**	0.99, 30.58
Time[c]	0.09	<**.001**	0.03, .25	1.53	.62	0.28, 8.37
Time*Treatment						
SC+TM	0.81	.78	0.19, 3.51	0.17	.14	0.02, 1.84
SC+TM+ABT	0.41	.26	0.09, 1.93	8.84	.07	0.84, 92.40
Adherence to varenicline at the same visit				2.01	.13	0.82, 4.90
Baseline heaviness of smoking Index				0.61	.09	0.35, 1.07
Baseline adherence self-efficacy[d]	2.20	<**.001**	1.43, 3.39			
Independent housing	1.02	.97	0.34, 3.08	6.13	.07	0.84, 44.96

Individuals' intercepts vary with a standard deviation of 2.04 (95 % *CI* 1.59–2.63) in the adherence model and 2.13 (95 % *CI* 1.43–3.18) in the abstinence model

Bold values are statistically significant ($p < 0.05$)

[a]The SC+TM treatment condition is compared with SC

[b]The SC+TM+ABT treatment condition is compared with SC

[c]Time variable is coded to contrast weeks 1 and 12

[d]Standardized scores were used for baseline heaviness of smoking index and adherence self-efficacy