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A Clinical Trial to Examine Disparities in Quitting between African American and White Adult Smokers: Design, Accrual, and Baseline Characteristics

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TRIAL STATUS

The final participant was enrolled in May 2015. The active treatment and follow-up phases are ongoing, with the final week 26 follow-up visit scheduled for November 2015. Outcomes data have not been examined and will not be available until June 2016.

COMPETING INTERESTS

Pfizer Global Pharmaceuticals provided study medication but played no role in the design or conduct of the study or in interpretation and analysis of the data (WS953655). Dr. Benowitz has served as a paid consultant to Pfizer as a member of its smoking cessation medication advisory board and also as an unpaid scientific advisor to Pfizer regarding a multi-site international clinical trial that has been conducted on the safety of varenicline for smoking cessation. Dr. Tyndale has served as a paid consultant to Apotex.

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Abstract

BACKGROUND—African Americans smoke fewer cigarettes per day than Whites but experience greater smoking attributable morbidity and mortality. African American-White differences may also exist in cessation but rigorously designed studies have not been conducted to empirically answer this question.

METHODS/DESIGN—Quit2Live is, to our knowledge, the first head-to-head trial designed with the primary aim of examining African American-White disparities in quitting smoking. Secondary aims are to identify mechanisms that mediate and/or moderate the relationship between race and quitting. The study is ongoing. Study aims are accomplished through a 5-year prospective cohort intervention study designed to recruit equal numbers of African Americans (n=224) and Whites (n=224) stratified on age (< 40, ≥ 40) and gender, key factors known to impact cessation, and all within a restricted income range (≤ 400% federal poverty level). All participants will receive 12 weeks of varenicline in combination smoking cessation counseling. The primary outcome is cotinine-verified 7-day point prevalence abstinence from smoking at week 26. Secondary outcomes are cotinine-verified 7-day point prevalence abstinence from smoking at weeks 4 and 12.

DISCUSSION—Findings from Quit2Live will not only address if African American-White disparities in quitting smoking exist but, more importantly, will examine mechanisms underlying the difference. Attention to proximal, modifiable mechanisms (e.g., adherence, response to treatment, depression, stress) maximizes Quit2Live's potential to inform practice. Findings will provide an empirically-derived approach that will guide researchers and clinicians in identifying specific factors to address to improve cessation outcomes and reduce tobacco-related morbidity and mortality in African American and White smokers.

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Keywords

Smoking cessation; African American; White; disparities; varenicline

Racial and ethnic disparities in smoking-related disease and death are well-documented. African Americans use fewer cigarettes per day than White Americans [1–3], yet they have the highest incidence rates for all cancers combined, higher overall cancer mortality rates, and twice the rate of premature death attributable to cardiovascular disease compared to Whites [4, 5]. African American smokers also have a 43–55% higher relative risk of

smoking-attributable lung cancer compared to Whites and are at higher risk for nearly all smoking-related chronic diseases [6–8].

There are many purported reasons for the higher tobacco-related disease burden in African American smokers. On average, African Americans take in 30% more nicotine per cigarette smoked [9] and are exposed to higher levels of select lung carcinogens (e.g., 1-hydroxypyrene) at lower levels of smoking compared to Whites [10]. Greater exposure per cigarette smoked may be due, in part, to the preference for menthol cigarettes among African American smokers. Menthol has a cooling sensation that reduces the irritant quality of cigarette smoke and may facilitate deeper inhalation and greater exposure to nicotine [11]. Another plausible reason for the higher tobacco-related disease burden is that, although African Americans are more likely to attempt to quit smoking in a given year, they are less successful [12, 3].

The decreased likelihood of success for African American smokers has been attributed to the fact that they are less likely than Whites to receive provider advice/assistance to quit [13–16] and to be prescribed smoking cessation pharmacotherapy to aid in their attempts [17, 12, 18]; however disparities in smoking cessation have persisted for African American smokers in clinical trials where pharmacotherapy and quitting assistance have been provided [19–22]. To-date, no known trials have been conducted with the *primary aim* of prospectively examining African American-White differences in cessation. Existing trials have often enrolled unequal proportions of African American and White smokers and, because examination of racial differences in cessation was not the primary aim, were underpowered to make such comparisons [19, 22]. Others have relied on self-reported abstinence [23, 24], which is prone to misreporting and overestimation of abstinence [25–28], reported abstinence at early (e.g., Weeks 1–4) but not later time points (e.g., Week 26) [29, 30], or been conducted in special treatment settings (e.g., Veterans Affairs patients, smokers in the criminal justice system) which limits generalizability of the findings [23, 31]. Existing studies have also not been stratified by race on age or gender or ensured recruitment of African American and White smokers of comparable socioeconomic status (SES) [20, 21], all key factors known to impact smoking cessation [32, 24, 33–38]. Mechanisms underlying African American-White differences in quitting are also not well understood. Multiple factors, including demographic (e.g., socioeconomic status) [29, 33, 36, 37] and smoking characteristics (e.g., menthol, nicotine intake) [39–42], adherence and/or response to treatment (e.g., reductions in withdrawal, craving) [18, 17, 27, 31, 43], psychosocial (e.g., psychological distress, perceived and contextual disadvantage, stress) [44–46, 24, 47–53], and biological factors linked to nicotine metabolic inactivation (e.g., CYP2A6, 3hydroxycotinine/cotinine) [54–58] have been studied as they relate to cessation in African Americans and Whites, separately, but few studies have explored the relative importance of these factors in explaining African American-White differences in quitting.

The current clinical trial, Quit2Live, is designed explicitly to address these gaps. Quit2Live uses a stratified design to recruit an equal number of African American and White smokers across gender and age, provides the same treatment to all participants (varenicline plus counseling), and will biochemically confirm smoking status at multiple time points. In addition, because the majority of US adult smokers are of lower socioeconomic status [32]

and lower socioeconomic status adversely impacts cessation [59], Quit2Live recruits participants within a restricted income range [≤ 400% federal poverty level (FPL)]. This paper describes the study design, enrollment, and baseline characteristics of participants in the trial.

METHODS

Study design

Quit2Live is a 5-year prospective cohort intervention study, stratified on race (African American, White) and, within race, on age (< 40, ≥ 40) and gender, with the primary aim of examining differences in quitting between African American and White smokers and secondary aims of identifying mechanisms (e.g., demographic, smoking, treatment process, psychosocial, and biological factors) that explain the relationship between race and quitting. All participants will receive 12 weeks of varenicline in combination with 6 sessions of smoking cessation counseling. Because women and younger smokers are less likely to quit smoking than their male or older counterparts [34, 35, 38], Quit2Live will stratify on these factors, along with race, to ensure recruitment of African American and White smokers who are comparable on key covariates known to impact cessation. Using the stratified design, 56 participants will be recruited into each of the 2 race by age and gender cohorts. The schedule of enrollment, intervention, and assessment activities is displayed in Table 1. The primary outcome is cotinine-verified 7-day point prevalence smoking abstinence at month 6. All study visits will be completed at Swope Health Central, a Federally Qualified Health Center located in Kansas City, Missouri. Methods of recruitment, screening, enrollment, and retention are identical and do not vary by race. Study procedures are approved and monitored by the University of Kansas Medical Center (KUMC) IRB (#00001602).

Recruitment

Recruitment started in February 2013 and ended in May 2015. Final 6-month follow-up will be completed in November 2015. Participants are recruited through clinic- and community-based efforts, including fliers, physician letters, radio, television, and social media ads, and word-of- mouth referrals from current and former participants.

Eligibility

Eligible participants are non-Hispanic African American or White adults, 18 years of age or older who smoke 3–20 cigarettes per day on 25 days or more during the preceding month, and are interested in quitting smoking, taking varenicline for 3 months, have a functioning telephone, and are willing to complete all study-related requirements. Individuals are excluded if they have a medical contraindication for varenicline, which includes being pregnant or breastfeeding, renal impairment, currently taking the blood thinner warfarin, history of panic or anxiety disorder, psychosis, bipolar disorder, or an eating disorder, being treated for depression in the last year, receiving treatment for alcohol or other drugs in the past year, known allergy or sensitivity to varenicline, being treated for a heart attack or any acute cardiovascular event in the past two months, and/or being diagnosed with angina or arrhythmia in the past two months. Individuals are also excluded if they have used a tobacco product other than cigarettes (e.g., cigars, cigarillos, smokeless tobacco) in the past 30 days,

are planning to move from the Kansas City area during the 6 month study period, have used varenicline in the preceding three months, are unwilling to refrain from use of other smoking cessation pharmacotherapies during the study period, have unstable housing (e.g., lived in a shelter, on the street, or in a detoxification center), or another smoker in the household is enrolled in the study. Varenicline carries an FDA black box warning for neuropsychiatric complications (i.e., depressed mood, suicidal behavior), therefore, the Patient Health Questionaire-2, a commonly used depression screener [60, 61], is administered to all individuals. Those scoring 3 or higher are excluded because of concern that varenicline could exacerbate underlying depressive symptoms. Participants are also excluded if the total yearly income for all people in their household places them at > 400% of the FPL [62].

Screening and Consent

Interested individuals contact us by telephone and are screened for eligibility by study staff. Those who are provisionally eligible after the phone screening are scheduled for final, in-person eligibility screening, which consists of pregnancy testing on women who are not post-menopausal or sterilized, assessment of willingness to use birth control to avoid pregnancy while taking varenicline among these same women, and assessment of active suicidal ideation over the preceding two weeks. Individuals who are eligible following final, in-person screening participate in a consenting interview conducted by study staff. Those providing written informed consent are enrolled into the study and immediately participate in baseline (Week 0) activities (described below).

Intervention

The intervention consists of 12 weeks of varenicline, six smoking cessation counseling sessions, and a behaviorally-oriented smoking cessation guide that was designed to be used in conjunction with counseling.

Varenicline—Varenicline was chosen because it is the most effective of the currently approved first-line smoking cessation monotherapies [63]. More importantly, however, is that a very small proportion of participants enrolled in existing varenicline trials have been racial/ethnic minorities and cessation outcomes in these trials have not been reported by race. Our group conducted a small pilot trial of varenicline for cessation in African American moderate to heavy smokers (> 10 cigarettes per day) and found modest quit rates at Week 12 compared to rates found for predominately White smokers in published clinical trials (24% versus 49%) [64–66]. Fully powered clinical trials have been conducted examining the efficacy of other first-line medication for smoking cessation in African American smokers (e.g., bupropion, nicotine gum and patch; [27, 25, 67, 68]) but, to our knowledge, this is the first large-scale study examining varenicline as a cessation aid in African American smokers.

At baseline (Week 0), a research counselor gives each participant a 4-week supply of varenicline and instructions on titrating up to the full dose following standard dosing guidelines (0.5 mg once daily on Days 1–3, 0.5 mg twice daily on Days 4–7, and 1 mg twice daily on Day 8 through Week 12). Participants are encouraged to initiate varenicline the day after their baseline visit (Day 1) and to set a target quit date for one week later (Day 8).

Varenicline is dispensed in 30-day pill boxes at Weeks 0, 4, 8 to aid participants in taking their medication as prescribed [66, 69], to assist staff with monitoring medication adherence, and to enhance retention at the Week 4 and 8 study visits. One week of extra medication is included in the pill box to ensure that participants do not run out of varenicline before the refill visit. Varenicline is discontinued and the safety re-evaluated in participants reporting a serious adverse event that is deemed likely or possibly related to the medication (e.g., suicidal ideation or behavior).

Counseling—Participants receive smoking cessation counseling sessions in person at Weeks 0 (baseline), 4, 8, and 12 and by phone at Weeks 1 and 16. Trained counseling staff follow the current *Tobacco Use and Dependence Clinical Practice Guidelines* and give clear advice to stop smoking, provide assistance with quitting, and arrange follow-up [70]. The baseline counseling session provides participants information on the proper use of varenicline. It also addresses the health risks and benefits of quitting and assists participants in identifying triggers and developing a quit plan. Follow-up counseling sessions are tailored to participant's smoking status. For those who report quitting, sessions focus on strategies for preventing relapse, including alternatives to smoking and identifying and managing stressors that could lead to relapse. For those who report continued smoking, sessions focus on exploring barriers to quitting, discussing problems that lead to relapse/continued smoking, and reaffirming a quit date and plan. All counseling sessions are recorded for quality control purposes. The baseline session lasts 30 minutes, on average, with follow-up sessions averaging 15 minutes. Counseling fidelity is monitored by a licensed psychologist during biweekly counseling supervision meetings.

Written Materials—Participants receive the *Quit2Live Stop Smoking Guide* at baseline. The 30-page guide has been designed to go hand-in-hand with counseling and includes information on the health consequences of tobacco use, benefits of quitting, specific strategies to promote abstinence such as making a quit plan, obtaining social support, identifying reasons for quitting and activities that could take the place of smoking, strategies for dealing with urges, managing withdrawal and craving, coping with a lapse, and relapse prevention, instructions on medication use and tips for managing common medication side effects. Versions of the guide have been used successfully in three of our previous smoking cessation studies [25, 27, 66].

Retention

Study staff contact participants one week prior to each study visit via phone, text, email and postcards. For any missed session, participants receive up to 6 additional contacts to facilitate rescheduling. Participants are given a $30 gift card at Weeks 0 and 4, a $20 gift card at Week 8, and a $40 gift card at Week 12, and a $60 gift card at Week 26 in appreciation for their time and participation. Remuneration is based on session attendance and not on smoking status. Participants also receive a study t-shirt and water bottle at Weeks 1 and 16, respectively in appreciation for their time.

Outcome and Study Measures

Baseline demographic, smoking history, treatment process, psychosocial, and biological measures were selected based on those that have been found to be predictive of smoking cessation in African American and White smokers in previous studies and/or those that have been speculated to account for African American-White differences in quitting (e.g., menthol, nicotine dependence, cigarettes per day). Only those baseline measures included in the current paper are summarized below. A full list of the measures by time point is provided in Table 2.

Smoking Abstinence—The primary endpoint is cotinine-verified 7-day point prevalence smoking abstinence, defined as no cigarettes for the previous 7 days at Week 26. The recommended cut-off of 15ng/ml for salivary cotinine will be used to differentiate smokers from non-smokers [26]. Secondary endpoints will be salivary cotinine verified-7 day point prevalence abstinence at Weeks 4 and 12 (end of drug).

Demographic Measures—Baseline demographic measures include participant age, gender, marital/partner status, employment status, health insurance status, educational level [71], income [72], perceived health [73], height, weight, waist circumference, and body mass index [74].

Smoking Measures—Baseline assessment of smoking history includes number of cigarettes smoked per day (cpd), type of cigarette smoked (menthol versus non-menthol), age when started smoking regularly, length of the longest quit attempt [75], social influences on smoking [76], and time to the first cigarette of the day, a marker of nicotine dependence [77].

Treatment Process Measures—Baseline treatment process measures include nicotine withdrawal [78], craving [79], and the reinforcing effects of nicotine [80].

Psychosocial Measures—Baseline psychosocial measures include perceived stress [81], discrimination [82], race consciousness [83], financial strain [24], symptoms of depression and anxiety [60, 84], proneness to psychological distress [85], distrust of others [86], perceived social status [87], perceived neighborhood problems, perceived neighborhood social cohesion and trust [88, 89], and overall life satisfaction [90].

Data Analysis

Sample Size Justification—The primary outcome is cotinine-verified 7-day point prevalence abstinence from smoking at month 6. Based on data from existing varenicline trials [91, 66], we postulate a 28% cessation rate in White and a 15% cessation rate in African American participants. The current sample size of 224 African American and 224 White participants provides 90% power to detect a difference in cessation with a type I error rate of 0.05 using a two-sample, two-tailed Chi-square test.

Primary Analyses—To accomplish the study's primary aim of examining differences in smoking cessation between African American and White smokers, we will compare the

cotinine verified 7-day point prevalence abstinence rates at Week 26 between African Americans and Whites using the chi-square test. Our research hypothesis is that African Americans will have significantly lower cotinine-verified 7-day abstinence from smoking at Week 26 than Whites. For our primary comparison, those lost to follow-up will be treated as smokers. We also will look at completers only and will utilize multiple imputation techniques to ensure valid comparisons between the two groups if the loss to follow-up does not appear random. Given this is not a randomized study, we will also utilize multiple logistic regression to compare the 7-day point prevalence abstinence rates between African Americans and Whites adjusting for our stratification variables (age, gender) along with baseline level of smoking. We will examine both main effects and pairwise interactions effects and determine if the expected difference between African Americans and Whites still exists in the presence of these other factors. Interactions not significant at the 0.10 level will be dropped from the model. To evaluate secondary endpoints, we will compare cotinine-verified 7-day point prevalence abstinence rates between African Americans and Whites at Week 12 (end of drug) using the same methods as above.

Analysis for the Current Paper—In this paper we provide descriptive summaries of baseline (Week 0) demographic, smoking, treatment process, and psychosocial characteristics using frequencies and percentages for categorical variables and means and standard deviations for quantitative variables. Baseline differences in these factors by race were computed using independent samples *t* tests for continuous variables and chi-square tests for discrete variables. Time to accrual and eligibility and enrollment rates were also computed within each of the eight strata. Future manuscripts will present findings on primary and secondary outcomes and explanatory mechanistic factors.

RESULTS

Recruitment Flow

Fifty-six participants have been recruited into seven of the eight race, age, and gender strata. A coding error resulted in an additional White male < 40 being enrolled (n=57), bringing the sample total to 224 African American and 225 White smokers. An overview of accrual into the study and screening, eligibility, and enrollment data for all strata is provided in Figures 1 and 2, respectively. African American women ≥ 40 were the first group to be fully enrolled; all 56 were enrolled in 4 months and 19 days. Despite having only a moderate eligibility rate compared to the other groups (52.1% of those screened were eligible), African American women ≥ 40 had the highest enrollment rates; 2.7 individuals were screened to enroll 1 and 71.8% of those who were eligible kept their baseline appointment and were enrolled, which contributed to their rapid accrual. Conversely, African American men < 40 were the last group to be enrolled, taking 26 months and 21 days. Interestingly, while this group had the highest eligibility rate (59.6% of those screened were eligible), they also had the lowest enrollment rates; 4 individuals were screened to enroll 1 and 58.8% of those who were eligible did *not* keep their baseline appointment, which contributed to their slow accrual relative to the other stratum. Accrual for the remaining stratum ranged from 12 months, 17 days for White women < 40 to 23 months, 30 days for White men ≥ 40.

The top three reasons for ineligibility, overall, are use of non-cigarette tobacco products (e.g., hand-rolled cigarettes, cigarillos; 20.5%), followed by medical contraindications to varenicline (20.2%) and smoking ≤ 2 or ≥ 21 cpd (14.2%). Other primary reasons for ineligibility include > 400% FPL (7.3%), a pharmacotherapy assisted quit attempt in the past 3 months (5.7%), unstable housing (2.4%), smoking on < 25 days in past 30 (2.1%), refusal to sign informed consent (1.5%), and no phone number to be reached for counseling calls (1.4%).

Baseline Characteristics

Participant baseline characteristics, including differences by race, are presented in Table 3. African American participants have lower educational attainment, are less likely to be employed, have lower overall household incomes and percent federal poverty levels, and are less likely to own their home compared to White. With respect to smoking and treatment process characteristics, African Americans are more likely than White to smoke menthol cigarettes, to smoke fewer cigarettes per day and to start smoking later in life. While African American and White smokers note similar amounts of nicotine dependence and withdrawal and craving for cigarettes, they report differences on two of the five reinforcing effects of nicotine subscales: African American smokers have more aversion to smoking (e.g., dizziness, nausea) and less craving reduction immediately following a cigarette. In terms of psychosocial characteristics, African American smokers have higher perceived stress and depression and lower satisfaction with life compared to White. Despite experiencing an equivalent number of situations of everyday discrimination, African American encounter situations more frequently and they are more likely to think about/be conscious of their race than White. Finally, African American participants are more distrustful of the intentions of others' and they report more problems in their neighborhood (e.g., noise, vandalism, safety) and less connectedness between neighbors.

DISCUSSION

Quit2Live is the first known prospective head-to-head trial, stratified on race, gender, and age, to explicitly examine whether disparities in cessation exist between African American and White smokers while concurrently exploring demographic, smoking, treatment process, psychosocial, and biological mechanisms to explain the expected disparity. Quit2Live will also be the first fully powered trial to report cessation outcomes for African Americans treated with varenicline and will answer important questions regarding the efficacy of varenicline for this understudied but prevalent subgroup of smokers.

Baseline differences in smoking [42, 3], socioeconomic [92, 93], and psychosocial characteristics [94, 82, 95] are largely consistent with differences identified between African Americans and Whites in previous studies. What is not known, and what will be addressed through the study's secondary aims, is how the factors in this study independently and *jointly* moderate and/or mediate the relationship between race and cessation. The selection of variables across demographic, smoking, treatment process, psychosocial, and biological domains offers a comprehensive approach that is strongly grounded in the literature. Our analytic plan will allow us to model each domain independently (e.g., race → demographic

factors → cessation) and, if multiple mediators and/or moderators are identified, to examine the interrelationship of factors across demographic, smoking, treatment process, psychosocial, and biological domains. In addition, we are conducting assessments at multiple time points, which will allow for the examination of how factors differ at baseline and change over time for African American and White and how these differences are related to cessation. Few longitudinal comparisons have been conducted to provide evidence of differences in factors that facilitate quitting for African American and White [29, 30].

In summary, Quit2Live addresses an important public health problem, health disparities in relation to smoking. This prospective stratified cohort design will move the field beyond descriptive, post-hoc analyses. Findings from this study will not only examine if African American- White disparities in quitting exist but, more importantly, will identify mechanisms underlying the difference, including interrelationships of factors across domains. Attention to many proximal, modifiable factors (e.g., adherence, response to treatment, depression, stress, peer/family smoking norms) further enhances the potential of our findings to inform practice by moving the field away from a generic focus on race toward an empirically derived approach that will guide researchers in identifying specific factors to address to improve cessation outcomes and reduce tobacco-related morbidity and mortality in future studies with African American.

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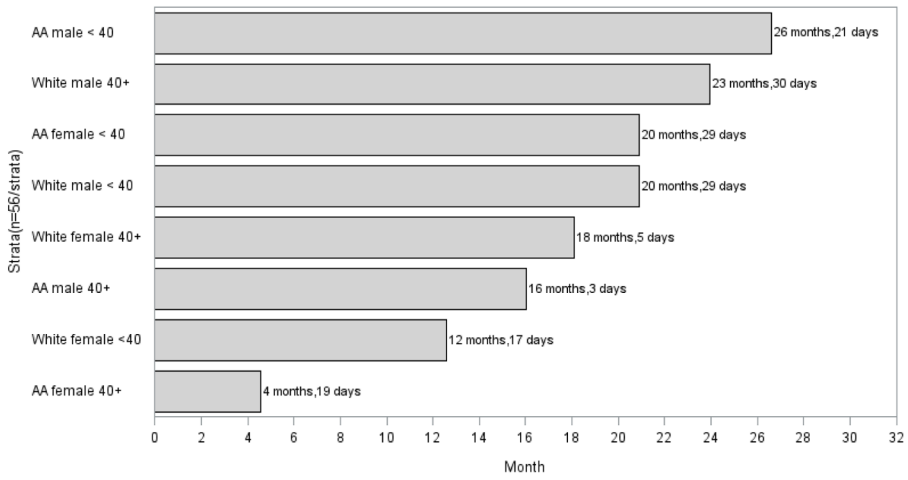

Figure 1.

Time to Accrual by Strata*

*Time to accrual was calculated as the time between when the study opened for enrollment through when the last participant was enrolled into each stratum. Recruitment for all groups began on February 4, 2013.

AA=African American

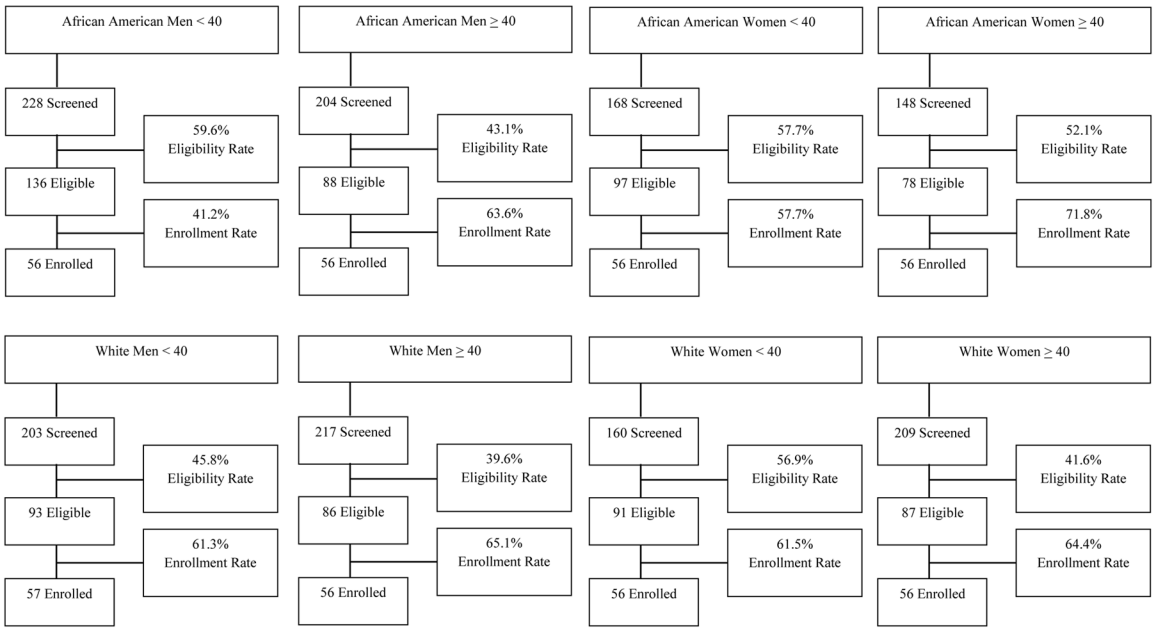

Figure 2.

Participant Flow During Screening and Enrollment by Strata

Eligibility Rate = eligible/screened, Enrollment Rate = enrolled/eligible

Table 1

Schedule of enrollment, intervention, and assessment activities

	STUDY PERIOD							
	Screening	Enroll-ment	Follow-up Visits in Weeks					
TIMEPOINT	*-14 to -1 days prior to Wk 0*	**Wk 0**	*1*	*4*	*8*	*12* *End of drug*	*16* *End of counseling*	*26* *End of Study*
ENROLLMENT:								
Eligibility phone screen	X							
Final eligibility screening (pregnancy test, suicidal ideation assessment)		X						
Informed consent		X						
Allocation[a]		X						
INTERVENTIONS:								
Varenicline dispensed[b]		X●———	———	———	———●			
Counseling[c]		X	X	X	X	X	X	
ASSESSMENTS:								
Surveys[d]		X	X	X	X	X	X	X
Outcome Variable								
Cotinine-verified quitting				X		X		X Primary endpoint
Biological Samples								
Total nicotine equivalents		X						
Nicotine metabolite ratio (3HC/COT) phenotype		X						
CYP2A6 genotype (nicotine metabolism genotype)		X						
Varenicline steady-state levels				X				

[a] All participants were allocated to receive the same treatment

[b] A 4-week supply of varenicline was dispensed at the Week 0, 4, and 8 in-person visits

[c] Counseling sessions were conducted in person at Weeks 0, 4, 8, and 12 and by phone at Weeks 1 and 16

[d] See measures section and Table 2 for a description of each measure and the time point it was administered

Table 2

Quit2Live Measures at Each Time Point

	Eligibility	Baseline Week 0	Week 1	Week 4	Week 8	Week 12	Week 16	Week 26
Smoking Abstinence								
Cotinine				x		x		x
Demographic Measures								
Demographics	x	x						
Perceived health		x						
Body mass index		x		x		x		x
Waist circumference		x		x		x		x
Smoking Measures								
Smoking history		x						
Social influences		x						
Nicotine dependence		x						
Treatment Process Measures								
Withdrawal		x		x		x		x
Craving		x		x		x		x
Reinforcing effects of nicotine		x		x		x		x
Medication-related side effects			x	x	x	x	x	
Medication adherence (self-report)				x	x	x		
Medication adherence (steady-state)				x				
Psychosocial Measures								
Stress		x		x		x		x
Depressive symptoms	x	x		x		x		x
Anxiety symptoms		x		x		x		x
Financial strain		x						
Discrimination		x						
Race consciousness		x						
Perceived social status		x						
Proneness to psychological distress		x						

	Eligibility	Baseline Week 0	Week 1	Week 4	Week 8	Week 12	Week 16	Week 26
Distrust of others		x						
Satisfaction with life		x						
Neighborhood problems		x						
Neighborhood cohesion and trust		x						
Biological Measures								
Nicotine intake		x						
Nicotine metabolite ratio (3HC/COT)		x						
Nicotine metabolism genotype (CYP2A6)		x						
Varenicline steady-state levels				x				

Table 3

Baseline Participant Characteristics

	Range for Scale Scores[a]	African American (n=224)	White (n=225)	p-value[b]
DEMOGRAPHIC CHARACTERISTICS[c]				
Age, mean(SD)		42.4 (12.0)	40.5 (11.2)	0.0930
Gender, n (%)				
Female		112 (50.0%)	112 (49.8%)	0.9624
Male		112 (50.0%)	113 (50.2%)	
Cohabitation Status, n (%)				
Living alone		142 (63.4%)	115 (51.1%)	0.0085
Living with a partner		82 (36.6%)	110 (48.9%)	
Employment Status, n (%)				
Employed full-time		77 (34.4%)	142 (63.1%)	<0.0001*
Employed part-time		41 (18.3%)	29 (12.9%)	
Not currently employed		75 (33.5%)	28 (12.4%)	
Retired		11 (4.9%)	5 (2.2%)	
Student/Homemaker		20 (8.9%)	21 (9.3%)	
Education Level, n (%)				
Less than high school (HS) graduate		30 (13.4%)	14 (6.2%)	0.0027*
HS graduate or HS equivalent (GED)		64 (28.6%)	44 (19.6%)	
Some college or tech school		90 (40.2%)	116 (51.6%)	
College graduate or higher		40 (17.9%)	51 (22.7%)	
Health Insurance that Pays for Most Medical Care, n (%)				
No		107 (47.8%)	102 (45.3%)	0.6051
Yes		117 (52.2%)	123 (54.7%)	
Income, mean(SD)		$21,293 ($15,501)	$35,806 ($21,035)	<0.0001*
Number of people in household, including self		2.7 (1.6)	3.0 (1.8)	0.0716
Poverty level, n (%)				
≤100		115 (51.3%)	43 (19.1%)	<0.0001*
101–200		72 (32.1%)	87 (38.7%)	
201–250		15 (6.7%)	25 (11.1%)	
251–300		9 (4.0%)	27 (12.0%)	
301–400		13 (5.8%)	43 (19.1%)	
Housing, n (%)				
Own a home		38 (17.0%)	77 (34.2%)	<0.0001*
Rent or stay with others		186 (83.0%)	148 (65.8%)	
Perceived Health, n (%)				
Good, Fair, or Poor		125 (55.8%)	113 (50.2%)	0.2361
Very good/Excellent		99 (44.2%)	112 (49.8%)	
Height in inches, mean(SD)		66.8 (3.7)	66.8 (3.9)	0.9984
Weight in pounds, mean(SD)		195.3 (51.2)	182.9 (44.1)	0.0065

	Range for Scale Scores[a]	African American (n=224)	White (n=225)	p-value[b]
BMI, mean(SD)		30.8 (8.1)	28.9 (7.1)	0.0074
Waist circumference in inches, mean(SD)		37.6 (6.7)	36.3 (6.2)	0.0410
SMOKING CHARACTERISTICS[d]				
Cigarettes per day, mean (SD)		12.5 (5.7)	16.9 (4.6)	<0.0001*
Age when you started smoking regularly, mean(SD)		18.5 (6.5)	16.5 (4.8)	<0.0002*
Menthol smoker, n (%)				
Non-Menthol		31 (13.8%)	166 (73.8%)	<0.0001*
Menthol		193 (86.2%)	59 (26.2%)	
Longest quit attempt in months, mean(SD)		24.8 (70.9)	25.3 (51.7)	0.9328
Time to first cigarette, n (%)				
After 30 minutes		47 (21.0%)	57 (25.3%)	0.2745
Within 30 minutes		177 (79.0%)	168 (74.7%)	
Number of your five best friends smoke, mean(SD)	0–5	2.9 (1.8)	2.7 (1.7)	0.2180
Number of smokers in the home(not including self), mean(SD)		0.6 (1.0)	0.6 (0.8)	0.8502
Partner smoking status, n (%)				
No partner/spouse		94 (42.0%)	78 (34.7%)	
Partner/spouse is a non-smoker		68 (30.4%)	69 (30.7%)	0.1899
Partner/spouse is a smoker		62 (27.6%)	78 (34.7%)	
TREATMENT PROCESS CHARACTERISTICS[e]				
Withdrawal, mean(SD)	0–32	5.3 (4.3)	5.2 (3.1)	0.8090
Craving, mean(SD)	4–28	14.1 (7.9)	15.3 (6.7)	0.0890
Reinforcing effects of nicotine, mean (SD)				
Smoking satisfaction	3–21	12.2 (4.9)	12.1 (4.5)	0.9108
Psychological reward	5–35	16.7 (7.2)	16.6 (7.3)	0.9034
Aversion	2–14	3.0 (1.9)	2.4 (1.2)	0.0004*
Enjoyment of respiratory tract sensations	1–7	3.2 (1.9)	3.0 (1.8)	0.4651
Craving reduction	1–7	4.8 (2.0)	5.4 (1.6)	0.0021*
PSYCHOSOCIAL CHARACTERISTICS[f]				
Perceived stress, mean(SD)	0–16	4.5 (2.7)	3.6 (2.3)	<0.0001*
Depression, mean(SD)	0–27	2.1 (3.4)	1.2 (1.8)	0.0006*
Anxiety, mean(SD)	0–21	3.0 (3.6)	2.1 (2.7)	0.0038
Financial strain, mean(SD)	8–24	15.6 (4.3)	14.6 (4.1)	0.0137
Perceived discrimination, mean (SD)				
# of situations encountered	0–5	2.7 (1.6)	2.6 (1.6)	0.3167
Frequency encountered	0–25	6.8 (5.4)	5.1 (4.1)	0.0003*
Race Consciousness, "*I think about my race…*", n (%)				
Never		109 (48.7%)	158 (70.2%)	<0.0001*
Once a year		25 (11.2%)	25 (11.1%)	

	Range for Scale Scores[a]	African American (n=224)	White (n=225)	p-value[b]
Once a month		22 (9.8%)	18 (8.0%)	
Once a week		14 (6.3%)	17 (7.6%)	
At least daily		54 (24.1%)	7 (3.1%)	
Perceived social status, mean(SD)	1–10	4.8 (1.5)	5.0 (1.5)	0.2444
Satisfaction with life, mean(SD)	5–35	20.1 (6.3)	23.8 (5.5)	<0.0001*
Personality factors, mean (SD)				
Cynicism/distrust of others' intentions	0–8	5.7 (1.6)	4.8 (1.7)	<0.0001*
Neuroticism/proneness to psychological distress	0–48	12.6 (7.1)	12.5 (6.3)	0.9396
Neighborhood disadvantage (self-reported), mean (SD)				
Social cohesion and trust	5–25	16.2 (4.7)	17.8 (4.5)	0.0003*
Neighborhood problems	10–30	15.5 (4.7)	13.5 (3.4)	<0.0001*

[a] Higher scores on each scale indicate more of the factor /trait – e.g., more withdrawal, more craving, greater reinforcing effects of nicotine, etc.

[b] Bonferroni corrections were applied to minimize the likelihood of a Type I error due to multiple testing. Variables with a p-value below the corrected Type I error rate for the category are considered significant and noted with an asterik.

[c] The Bonferroni correction for Demographic Characteristics sets the significance cut-off at $p < 0.0033$ (0.05/15)

[d] The Bonferroni correction for Smoking Characteristics sets the significance cut-off at $p < 0.0063$ (0.05/8)

[e] The Bonferroni correction for Treatment Process Characteristics sets the significance cut-off at $p < 0.0071$ (0.05/7)

[f] The Bonferroni correction for Psychosocial Characteristics sets the significance cut-off at $p < 0.0038$ (0.05/13)