

Reducing racial/ethnic tobacco cessation disparities via cognitive behavioral therapy: Design of a dualsite randomized controlled trial

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ABSTRACT

Racial/ethnic disparities in tobacco cessation are such that U.S. minorities have greater difficulty quitting compared to White non-Hispanics. Group differences in distress (i.e., perceived stress and depressive symptoms) may contribute to cessation disparities. The allostasis model of health suggests that the toll of chronic stress experienced by racial/ethnic minorities may lead to dysregulation of the physiological stress system and drug use. Previous research suggests that group cognitive behavioral therapy (CBT) for tobacco cessation addresses distress as a modifiable mechanism and has the potential to reduce/eliminate disparities. The present study is a dualsite randomized controlled trial aimed at evaluating the efficacy of group CBT in eliminating racial/ethnic differences in smoking cessation and distress. The study utilizes a [2 (intervention: group CBT or group general health education [GHE]) × 3 (race/ethnicity: African American/Black, Hispanic, White)] factorial design by randomizing 225 adult smokers from the community. Both interventions provide eight counseling sessions and eight weeks of nicotine patch therapy. Assessments occur at the end-of-therapy, and at 3-, 6-, and 12-months. Generalized longitudinal mixed modeling will be used to test our primary abstinence outcome, biochemically-confirmed 7-day point prevalence abstinence at 12-months. We hypothesize that group CBT will reduce or eliminate racial/ethnic differences in perceived stress, depressive symptoms, and smoking cessation compared to group GHE. We also hypothesize that reductions in physiological distress, assessed by salivary cortisol, will mediate racial/ethnic group differences in smoking cessation, particularly among racial/ethnic minorities. This study has implications for eliminating disparities in psychosocial factors related to tobacco use and cessation.

Trial registration: [Clinicaltrials.gov/NCT02511236](https://clinicaltrials.gov/ct2/show/study/NCT02511236). Registered on July 27, 2015.

1. Background

African Americans and Hispanics in the United States (U.S.) experience greater difficulty becoming tobacco-free compared to White smokers [1]. This disparity might be partially mediated by distress processes (i.e., stress and depressive symptoms), which are well established barriers to tobacco cessation. Distress can be manifested through both physiological and psychosocial pathways. Chronic activation of the neuroendocrine system due to persistent stress exposure can lead to dysregulation of adaptive physiological stress responses, known as allostatic load [2]. Psychosocial problems, such as family discord, perceived discrimination, financial problems, and employment

concerns, may also lead to distress and are positively associated with persistent smoking [3]. Depressive symptoms and perceived stress appear to be greater among treatment-seeking racial/ethnic minority smokers compared to Whites [4].

The literature on distress processes among racial/ethnic minority smokers is limited. Allostatic load appears to be greater among African Americans compared to Whites and is hypothesized to influence drug use and health [5]. Among African Americans, depressive symptoms [6], and stressors such as racial discrimination [7], work-family conflict, relationship distress, perceived social inequity, and daily stressful events are positively related to current smoking [8] and smoking intensity [9]. High perceived stress also inhibits cessation among African

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Americans, particularly among those seeking-treatment [10,11]. The distress-smoking relationship among Hispanics is less clear. Initial evidence suggests that stress may be positively related to smoking intensity [12], but not cessation [6,13]. Racial/ethnic discrimination, however, is a specific type of stressor that reduces the likelihood of cessation among Hispanics [14]. Additional research is needed to elucidate the impact of distress on racial/ethnic disparities in tobacco cessation.

We previously examined racial/ethnic differences in distress among treatment-seeking smokers [15]. At baseline, African Americans and Hispanics reported elevated distress compared to Whites. Over the course of group cognitive behavioral therapy (CBT) for cessation, significant distress reductions were observed among the racial/ethnic minorities, resulting in no differences across groups at the end-of-therapy (EOT). And in contrast to previous research [1], cessation rates were comparable across racial/ethnic groups. Findings from that study suggested that group CBT is associated with improving distress among racial/ethnic minority smokers, and may eliminate disparities in cessation rates. Additional research is needed to test the causal role of distress reduction during group CBT in eliminating tobacco cessation disparities.

1.1. The present study

This dualsite randomized controlled trial (RCT) is designed to evaluate (1) the effects of group CBT on perceived stress and depressive symptoms among racially/ethnically diverse tobacco smokers; (2) the efficacy of CBT for eliminating cessation disparities; and (3) physiological distress as an underlying mechanism for the effects of CBT on cessation disparities. We hypothesize that group CBT will reduce racial/ethnic differences in psychosocial distress, and tobacco cessation compared to a group general health education (GHE) control group. We also hypothesize that reductions in physiological distress will mediate racial/ethnic group differences in smoking cessation. If the hypotheses are supported, this study will fill an important gap in the literature, and provide insight on interventions and mechanisms to address cessation disparities and related illnesses.

2. Methods/design

This study has been approved by Institutional Review Boards serving the University of Miami and the Moffitt Cancer Center. The study is a 2 (group intervention: CBT for tobacco cessation or GHE) \times 3 (race/ethnicity: African American/Black, Hispanic [any race], and White) dualsite RCT, using stratified random assignment [by race/ethnicity and sex] at each study site. The CBT condition receives 8-sessions of an evidence-based group therapy, which utilizes cognitive and behavioral smoking cessation techniques identified by contemporary smoking cessation and relapse prevention models. The GHE condition receives 8-sessions of didactic health education focusing on tobacco-related morbidity. Both conditions receive 8 weeks of adjuvant nicotine patch therapy. The primary outcomes are biochemically-confirmed 7-day point-prevalence abstinence (ppa), which will be assessed over a 12-month follow-up period, and change in perceived distress pre- to post-intervention. The mediating role of physiological distress is considered exploratory. Fig. 1 illustrates the flow of participants through the study.

2.1. Participants

The two recruitment sites are the South Florida and Tampa Bay metropolitan areas. Participants are recruited from the community using multiple strategies, including flyers, media-based advertisements (newspaper, radio, Internet, public transportation), physician offices, and social media websites (e.g., Facebook). Inclusion criteria are (1) self-identification as African American/Black, Hispanic (any race), or

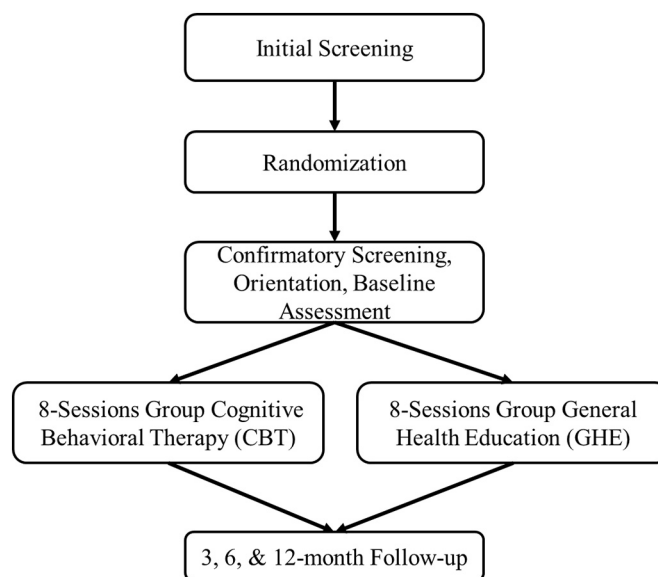


Fig. 1. Study design.

non-Hispanic White; (2) smoke at least five cigarettes/day or expired carbon monoxide (CO) of at least 8 ppm; (3) 18 years and older; and (4) speak/read English. Exclusions include having contraindications for nicotine patch therapy, cognitive or major mental health impairment that inhibits group treatment (e.g., schizophrenia), currently receiving smoking cessation treatment, active alcoholism or illicit drug use, and inability to attend sessions. Ineligible respondents are referred to a local cessation program or the Florida tobacco quitline (<http://tobaccofreeflorida.com/>).

2.2. Randomization

Simple randomization is used to determine the sequence of CBT and GHE groups and to counterbalance cohorts across time. Stratified random sampling by race/ethnicity and sex is used to generate randomization codes in blocks of 60 at each site. Eligible participants are randomly assigned in a 1:1 ratio, and those who provide informed consent are enrolled in the trial. Participants are not informed of their study condition; they are informed that they will receive a supportive group-based tobacco cessation intervention combined with nicotine replacement therapy.

2.3. Procedures

Screening occurs over the telephone or in person. Eligible participants attend an orientation meeting, eight intervention sessions, and 3-, 6-, and 12-months group reunions/assessments (Fig. 1). Reminder calls, emails, and text-messages are used to encourage attendance at orientation and each intervention session.

2.4. Orientation and intervention session format

A detailed manual is followed for each in-person contact. Participants attend nine meetings over five weeks, starting with orientation (90–120 min) during the week prior to session 1. Orientation explains the study's purpose, format, and procedures. It also provides an overview of the health consequences of tobacco smoking, and elicits participants' reasons for seeking cessation assistance. Written informed consent and the baseline assessment are completed during orientation. Participants are not informed of their randomized study condition.

Eight intervention sessions occur over four weeks, including four sessions during week 1, two sessions during week 2, one session during

week 3, and the final session in week 4. Session duration approximates 90–120 min, depending on the number of participants. Groups are led by trained interventionists (doctoral level psychologists, clinical psychology, and public health graduate students) supervised by clinical psychologists. To limit therapist characteristics and effectiveness as potentially confounding variables, interventionists (at least bachelor's degree level, with backgrounds in psychology and/or public health) are trained by the PI to conduct group sessions for both study conditions (with ongoing supervision). Incentives for assessment completion include \$20 at baseline, \$40 at EOT, \$40 at 3-month, \$50 at 6-month, and \$50 at 12-months.

2.5. Intervention conditions

2.5.1. Group cognitive behavioral therapy for smoking cessation (CBT)

This intervention is based on an established program, which has demonstrated efficacy in middle class White smokers [16], and more recently, in racially/ethnically diverse and lower income samples [15,17]. The CBT intervention incorporates biobehavioral influences (e.g., the impact of physiological dependence and addictive behaviors), the stress-coping relationship (e.g., smoking in response to perceived distress), and social cognitive factors (e.g., self-efficacy). Therapeutic techniques used to deliver the content include rapport building, cognitive restructuring, cognitive reappraisal, and psychoeducation. Sessions cover topics such as the health effects of smoking, addiction and dependence, the process of nicotine withdrawal and associated symptoms, preparing for quit day, the economic cost of tobacco smoking, coping response training, dealing with stress and negative mood, decision making, weight management, abstinence violation, gaining a new identity, social support, and lifestyle changes (Table 1).

2.5.2. General health education (GHE)

This condition is designed as an active control. The GHE intervention teaches participants about tobacco-related medical conditions, and seeks to empower participants to self-advocate for health. Each session includes didactic information on a specific tobacco-associated morbidity, such as heart disease, diabetes, hypertension, colorectal cancer, and respiratory diseases (Table 1). Content is delivered via PowerPoint slide presentations and covers the prevalence, etiology, basic

pathology, symptom patterns, and treatment of the conditions. To encourage group interaction, learning, discussion, and personal relevance, questions are raised by the interventionists to activate prior knowledge, connect the topic to participants' lives, and demonstrate the association with tobacco smoking. Smoking cessation specific topics are mentioned only in session 1 where participants are provided with a handout describing suggestions for tobacco cessation, which is discussed briefly. No other specific behavioral cessation advice is offered in subsequent sessions. Participants are allowed to share feelings regarding smoking (if they self-disclose) and are encouraged to adhere to the nicotine patch recommendation.

2.5.3. Nicotine replacement therapy

Participants in both study conditions receive 8-weeks of nicotine patch therapy. Transdermal nicotine patches are safe, effective, and available over-the-counter. Consistent with the tobacco clinical practice guidelines [18], participants receive four weeks at 21 mg, 2 weeks at 14 mg, and 2 weeks at 7 mg, with dosages adjusted by daily smoking intensity.

2.6. Intervention integrity

Intervention manuals are used for both CBT and GHE groups. Sessions are audio or video recorded and discussed during supervision meetings with a clinical psychologist. Approximately 25% of sessions are randomly selected for fidelity assessments. Detailed quality assurance checklists for each session were developed to indicate topic coverage (Yes, adequate; Yes, but inadequate coverage; or No). The Kappa statistic will evaluate inter-rater reliability.

2.7. Assessments

2.7.1. Baseline

The baseline measures include sociodemographics (self-reported race, ethnicity, sex, age, education, occupation, marital status), medical history, body mass index, sleep quality, and alcohol use frequency and intensity per occasion (Table 2). Tobacco smoking history and nicotine dependence are assessed using the Fagerström Test for Nicotine Dependence (FTND) [19], with additional items assessing the use of

Table 1
Overview of group intervention conditions.

	CBT	GHE
Orientation	Introductions, program explanation, structure of sessions, Baseline assessment, Biochemical Verification (BV), Health and smoking, motivation and goals	Same as in the CBT condition
Session 1	Agenda Setting (AS), Review of Quit Plan, Addiction/Withdrawal, Coping Response Training (CRT) model, Motivation, Nicotine Patch Use, Behavioral Contract (BC), BV	AS, Hypertension: Description, Risk Factors, Symptoms, Diagnosis, Prevention, Treatment, Talking to Your Doctor, TNP Use
Session 2	AS, Review of Quit Plan/Progress, PR, Benefits of Quitting, Withdrawal and Time Course, Cognitive Behavioral Coping Responses, BC, BV	AS, Heart Disease and Heart Attacks: Description, Risk Factors, Symptoms, Diagnosis, Treatment, Talking to Your Doctor, TNP Use
Session 3	AS, Review of Quit Plan/Progress, Benefits of Quitting, Stress and Smoking, Alcohol Use, Cognitive Reframing, High Cost of Smoking, Anticipatory Planning (AP), Responding to Lapses, BC, BV, TNP Use	AS, Type II Diabetes: Description, Risk Factors, Symptoms, Diagnosis, Prevention, Treatment, Talking to Your Doctor, TNP Use
Session 4	AS, Review of Quit Plan/Progress, Negative Affect and Smoking, Behavioral Activation, Withdrawal, Cognitive Restructuring, Decision Making, Apparently Irrelevant Decisions, AP, BC, BV, TNP	AS, Stroke: Description, Risk Factors, Symptoms, Diagnosis, Prevention, Treatment, Talking to Your Doctor, TNP Use
Session 5	AS, Review of Quit Plan/Progress, Withdrawal, Personal High-Risk Situations, Relapse Prevention, Health Effects, Abstinence Violation Effect, AP, BC, BV, TNP Use	AS, Colon and Rectal Cancer: Description, Risk Factors, Symptoms, Diagnosis, Prevention, Treatment, Talking to Your Doctor, TNP Use
Session 6	AS, Review of Quit Plan/Progress, Benefits of Quitting, Weight and Smoking Cessation, TNP Use, Individual High-Risk Situations, Environmental Re-design, AP, BC, BV, TNP Use	AS, Respiratory Conditions and Asthma: Description, Risk Factors, Symptoms, Diagnosis, Prevention, Treatment, Talking to Your Doctor, TNP Use
Session 7	AS, Review of Quit Plan/Progress, Termination Planning, Smoking and Motivation, Lifestyle Change, Social Support, Relaxation Training, AP, BC, BV, TNP Use	AS, Lung Cancer: Description, Risk Factors, Symptoms, Diagnosis, Prevention, Treatment, Talking to Your Doctor, TNP Use
Session 8	AS, Review of Quit Plan/Progress, Reflection, Long-term Trip-Ups, Review CRT Model, Withdrawal, Relapse Prevention, AP, BC, BV, TNP Use, EOT assessment	AS, Sensory Conditions, Vision, Hearing, and Taste: Description, Risk Factors, Symptoms, Diagnosis, Prevention, Treatment, Talking to Your Doctor, TNP Use, EOT assessment

Table 2
Measures administered at each time point.

Measure	Baseline	Intra-Treatment	EOT	3, 6, 12-Month Follow-Up
Demographics				
Tobacco Smoking History, and Nicotine Dependence [19]				
Perceived Stress [20, 21]				
Depressive Symptoms [22]				
Ethnic Discrimination [23]				
Nicotine Withdrawal and Smoking Urges [24, 25]				
Intervention Evaluations [17]				
Group Climate [27]				
Breath CO				
Saliva Cotinine				
Saliva Cortisol				
Nicotine Patch Use				
Tobacco Use [26]				

electronic cigarettes and other tobacco products. Psychosocial assessments include the Perceived Stress Scale [20,21], Center for Epidemiological Studies Depression Scale [22], and the General Ethnic Discrimination Scale [23].

2.7.2. Intra-intervention

At each group session, assessments include weight, breath carbon monoxide (CO), the Minnesota Withdrawal Scale, and the Questionnaire of Smoking Urges-Brief Scale [24,25]. Participants also record number of cigarettes per day and nicotine patch use since the previous session using timeline follow-back calendars [26].

2.7.3. End-of-therapy (EOT)

At session 8, measures include perceived stress, depressive symptoms, nicotine withdrawal, height, and weight. Participants also rate the intervention using a scale developed in a previous study [17], and complete the Group Climate Questionnaire [27].

2.7.4. Bio-verification of smoking status

Saliva cotinine levels are assessed at baseline, and to confirm self-reported cessation at the 3-, 6-, and 12-month follow-ups, with ≥ 7 ng/ml distinguishing smokers from nonsmokers [28]. Breath CO testing occurs at each in-person meeting, with levels of ≥ 8 ppm distinguishing smokers from nonsmokers [29].

2.7.5. Salivary cortisol

Saliva samples for cortisol analyses are collected at baseline, the EOT, and at the 3-, 6-, and 12-month follow-ups. Participants are provided with the needed materials and trained in saliva collection procedures at orientation and prior to each assessment. They are asked to collect saliva four times throughout the day (waking, 30 min post-waking, 4 pm, and 6:30 pm), and to record hours of sleep, food consumption, and exercise within the past hour. Saliva samples are stored in the lab freezers. Immunoassay procedures are used to determine cortisol levels using the Salimetrics high sensitivity kit (State College, PA).

2.8. Statistical power

A priori sample size analyses were based on our previous research

[15,17]. This work observed large effect sizes when comparing changes in perceived stress by race/ethnicity (Cohen's $d = -0.67$, African Americans vs. Whites; Cohen's $d = -0.69$, Hispanics vs. Whites) and depressive symptoms from baseline to the EOT (Cohen's $d = -0.56$, African Americans vs. Whites; Cohen's $d = -0.47$, Hispanics vs. Whites) [15]. Based on these effect sizes and power = 0.80, this requires 60 participants per racial/ethnic group. We also observed medium to large effect sizes in previous research examining cessation rates following CBT in diverse samples, which found 51% 7-day ppa at the EOT in the CBT condition, and 27% in the GHE condition [17], and intent-to-treat 7-day ppa of 55% at the EOT, 38% at 3-months, 37% at 6-months, and 20% at 12-months [15]. Thus, we estimated small to medium effect sizes for cessation-specific associations among racial/ethnic categories by condition, Cohen's $w = 0.30$, $df = 5$, and power = 0.80, requiring 151 participants. Given the longitudinal study design, we are able to utilize statistical models for analyzing longitudinal data with repeated assessments (i.e., all observations included in a single model). Our final sample size target of 180 participants, will yield 720 observations (four smoking status assessments per participant) and power = 0.80 with two-sided significance level of 5% to evaluate interactions between intervention condition and race/ethnicity on cessation at 12-months (i.e., generalized linear mixed models).

2.9. Statistical analyses

Preliminary analyses will include descriptive statistics on baseline variables. Significant differences in demographic factors by condition and/or race/ethnicity (e.g., socioeconomic status, cotinine levels, body weight) will be controlled in subsequent analyses. Pattern mixture analyses will examine completion of assessments (i.e., missing data), and racial/ethnic differences in baseline characteristics using chi-squared and two-sided Wilcoxon and Kruskal-Wallis tests. Transformations of the data to meet statistical assumptions will be undertaken when indicated. Alpha will be set at 0.05, and for the exploratory analysis, adjusted using a Holm-Bonferroni correction. Given the longitudinal design of the trial, some attrition over the 13-months from baseline to the 12-month follow-up is anticipated. Missing values will be handled with maximum likelihood estimation. To examine the impact of CBT on perceived distress (hypothesis 1), analyses of covariance (adjusted for baseline variables) will test the effects of (a)

condition and (b) race/ethnicity on perceived stress and depressive symptoms. Difference scores will be compared to examine pre-to-post change in perceived stress and depressive symptoms. An interaction term will evaluate the variation in distress reported in each condition by race/ethnicity. To test the efficacy of CBT for eliminating smoking cessation disparities (hypothesis 2), generalized linear mixed models (GLMMs), adjusted for site and covariates (e.g., baseline differences), will test the effect of (a) intervention condition and (b) race/ethnicity on the primary cessation outcome, biochemically-confirmed 7-day ppa. Specifically, we will examine the 12-month longitudinal effect of treatment. GLMMs will also test interactions between condition, time, and race/ethnicity on 7-day ppa. GLMMs will adjust for correlated longitudinal assessment and correlation within study sites through random effects. Hierarchical logistic regression, controlling for covariates and clustering factors, will test intervention effects at the 6-month follow-up. Analyses of conditional indirect effects, or moderated mediation, will test changes in stress and depressive symptoms as mediators of the relationship between condition and smoking status (which are hypothesized to be moderated by race/ethnicity). For all tests, intent-to-treat analyses will be conducted. Finally, we will explore change in physiological distress as an underlying mechanism for the effects of CBT by race/ethnicity (hypothesis 3). Slopes of cortisol level (i.e., rate of change over the course of the day) will be computed for each participant and comparisons by race/ethnicity will be analyzed using analyses of covariance. Area under the curve (AUC) analyses will be conducted to measure the pitch of the diurnal cortisol slope. Distress reduction is indicated by a decreased AUC and an increase in the negative pitch of the diurnal slope. Salivary cortisol slopes will be examined as a mediator of the relationship between condition and smoking status in the overall sample and by race/ethnicity using moderated mediation techniques. All of the statistical analyses will be carried out using SAS (SAS Institute Inc., Cary, NC) or R (R Foundation for Statistical Computing, Vienna, Austria. <http://www.R-project.org/>) statistical softwares.

3. Discussion

While CBT is considered the gold standard treatment for tobacco dependence, racial/ethnic minority smokers have been underrepresented in this literature. Only recently has an emerging literature found that CBT may be generalizable to minority smokers [15,17]. The primary innovations of this RCT include the focus on eliminating racial/ethnic disparities in cessation, and the consideration of biobehavioral distress processes as underlying mechanisms for cessation outcomes. The question here is not whether CBT works, but whether it works in the context of disparities. If our hypotheses are supported, findings will have implications for models of health disparity reduction and elimination, policies on access to care in underserved communities, and the development and dissemination of tobacco interventions designed for racial/ethnic minority populations.

Racial/ethnic disparities in tobacco cessation and health have shown little to no change decades after their initial documentation [30,31]. Clinical trials designed to test interventions and conduct trans-group comparisons are important to assess generalizability and to move the field forward. U.S. racial/ethnic minority smokers report high levels of multiple stressors (e.g., neighborhood, family, relationship and work stress, discrimination, financial concerns, discrimination, and childhood adversity) [8]. However, the tobacco literature has not adequately considered the roles of stress and depressive symptoms on cessation across racial/ethnic groups and none have done so in an RCT. Interventions that address these concerns have the potential to reduce or eliminate disparities in cessation. CBT-specific techniques may alleviate the high distress in treatment-seeking racial/ethnic minority smokers, thus facilitating equity in smoking cessation rates across populations [15].

The allostasis model of health describes the negative consequences

of chronically elevated distress, known as “weathering,” which contribute to racial health disparities [5]. Physiological distress is commonly assessed by cortisol level, a peripheral biomarker of neuroendocrine functioning. The literature on racial/ethnic differences in hypothalamic-pituitary-adrenal (HPA) axis is scant. However, there is initial evidence of dysregulation among African Americans, such as lower cortisol secretions following a common stressor [32] and flatter slopes throughout the day [5] compared to Whites, and lower awakening cortisol and a flatter slope compared to Hispanics [33]. This pattern suggests high cumulative stress exposure and hormonal dysregulation (i.e., allostatic load) [34]. Little is known about the links between tobacco cessation, the stress induced by nicotine withdrawal, and HPA axis functioning across racial/ethnic groups. This study will be the first to measure HPA functioning and investigate the relationship between stress and cessation among treatment-seeking, racially/ethnically diverse smokers.

There are a few challenges and potential limitations with this study. This is an intensive behavioral intervention that may not attract some smokers. As such, findings may be less generalizable to smokers who would prefer to quit without professional assistance or in the context of a formal cessation group. However, the interventions being tested are designed for smokers interested in cessation, and do not include the motivational components that might be important for ambivalent smokers or those not ready to make a quit attempt. Moreover, the interventions being tested do not address the needs of individuals with serious mental illnesses (e.g., schizophrenia or bipolar disorder), and thus may not generalize to this subset of smokers. The study is seeking to recruit equal proportions of White, African American, and Hispanic smokers, which could be a challenge. The demographics of the two study sites suggest that Hispanic participants will be enrolled primarily in South Florida, and the majority of white smokers will be recruited in Tampa Bay, Florida. Both locations are expected to enroll comparable proportions of African American participants. Careful attention to accrual of the target populations and moderately aggressive recruitment and retention strategies are necessary.

Notwithstanding the potential limitations, this study will make an important contribution to the literature. Taken together, the logic of the proposed study is that if baseline distress is elevated in racial/ethnic minority smokers (indicated by high perceived stress and depressive symptoms) and cortisol slope is flatter (indicating HPA dysregulation and susceptibility to health problems), and CBT lowers self-reported distress, then CBT (vs. GHE) will reduce disparities in smoking cessation as a function of reduced perceived and physiological distress in racial/ethnic minorities over time, whereas these distress changes will be less salient for Whites. If our hypotheses are supported, this trial will set the stage for larger scale studies to elucidate these relationships and reduce health disparities.

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