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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.govNCT02511236. 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) × 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 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/).

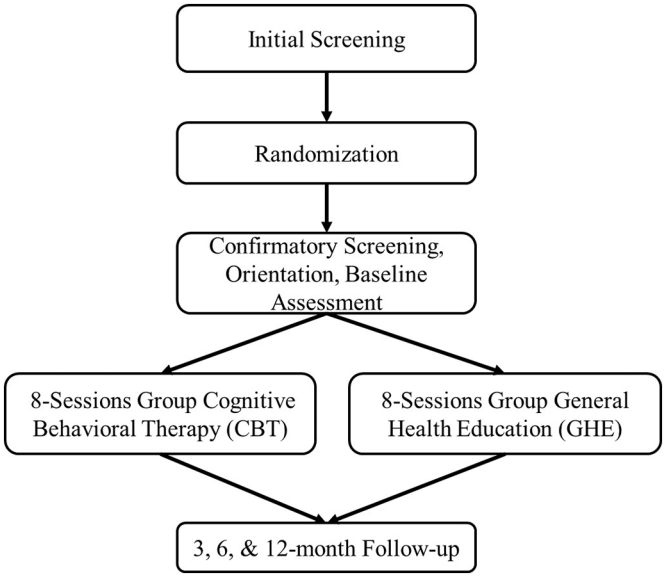

Fig. 1. Study design.

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