

The Process of Adapting the Evidence-Based Treatment for Tobacco Dependence for Smokers of Lower Socioeconomic Status

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Abstract

Introduction: Tobacco use is the leading cause of preventable death and disease and contributes significantly to socioeconomic health disparities. The prevalence of smoking among individuals of lower socioeconomic status (SES) in the US, many of whom are African American (AA), is three to four times greater than the prevalence of smoking among individuals of higher SES. The disparity in tobacco dependence treatment outcomes between lower and higher SES smokers contributes to tobacco-related health disparities and calls for adapting evidence-based treatment to more fully meet the needs of lower SES smokers.

Aims: We sought to adapt the evidence-based treatment for tobacco dependence using recommended frameworks for adapting evidence-based treatments.

Methods: We systematically applied the recommended steps for adapting evidence-based treatments described by Barrera and Castro and Lau. The steps included information gathering, preliminary adaptation design, preliminary adaptation tests, and adaptation refinement. We also applied the PEN-3 Model for incorporating AA values and experiences into treatment approaches and a community-engaged approach.

Results/Findings: Findings from each step in the process contributed to the results. The final results were incorporated into a revised treatment called the RITCh Study Tobacco Dependence Treatment Manual and Toolkit.

Conclusions: To our knowledge, this is the first adaptation of evidence-based treatment for tobacco dependence that has systematically applied these recommended frameworks. The efficacy of the treatment to reduce treatment outcome disparities is now being examined in a randomized controlled trial in which the revised treatment is being compared with a standard, individualized cognitive-behavioral approach.

Keywords: Cultural adaptation; Evidence-based treatments; Tobacco dependence; Smoking cessation

Introduction

Tobacco dependence is the greatest cause of preventable death and disease in the United States [1,2] and a significant contributor to socioeconomic health disparities [1,3-6]. While motivation and attempts to quit smoking show few socioeconomic differences, smokers of lower socioeconomic status (SES) are less likely to achieve long term abstinence once they begin smoking [7-15]. Standard evidence-based treatments for tobacco dependence attract lower SES smokers [16-20]; however, there are significant socioeconomic disparities in treatment retention and long-term treatment outcomes even when treatment adherence, clinical, environmental, and demographic factors are accounted for [17-24]. Estimates indicate that the highest SES smokers are at least twice as likely to achieve long-term abstinence as the lowest SES smokers after treatment regardless of treatment modality [18,20].

In health research, SES is a broad construct describing relative access to basic resources required to achieve and/or maintain good health [25,26]. Conceptual models propose that health disparities emerge because of higher levels of stress, less access to physical and environmental resources, greater environmental constraints, fewer affective and cognitive resources, and poorer health behaviors [25,27-29]. Consistent with these models, SES is empirically related to achieving abstinence from smoking through complex reciprocal relations among numerous clinical and environmental factors including stress, coping resources, psychological factors, exposure to other smokers, and use of treatment resources [30-35]. In the US, ethnic minority status

affects access to the basic resources to achieve and maintain good health, but the magnitude of socioeconomic disparities within ethnic minority groups is greater than between groups; thus, the effects of ethnic minority status on health are often reduced or eliminated after statistically adjusting for socioeconomic factors [36-38]. Nonetheless, in the US and elsewhere, ethnic minority groups tend to live in different social and physical environments and ethnic minority status includes a constellation of stressors separate from and additive to SES [36]. Moreover, ethnic minority status affects SES, but SES does not affect ethnic minority status, and thus, statistically adjusting for SES has the effect of over-controlling for the causal effects of ethnic minority status on health [26,36,39]. African Americans are the largest ethnic minority group in the US, have some of the highest poverty and smoking prevalence rates, and are among those smokers who respond

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less robustly to evidence-based tobacco dependence treatment [40,41]. These relations indicate the need to address tobacco-related health disparities within the context of both socioeconomic and ethnic minority disparities [36].

Adaptations to evidence-based treatments are indicated when groups show differences in engagement and/or treatment outcomes [42,43]. Adaptation of the standard evidence-based treatment for tobacco dependence is indicated because it is less effective at retaining lower SES smokers in treatment and demonstrates significant socioeconomic disparities in abstinence outcomes. Adapting interventions for particular groups has been shown to increase treatment engagement and the salience of treatment strategies for participants [44,45], but existing attempts to adapt tobacco dependence treatment for African Americans are limited because they utilized only print materials [46-48], or were not evaluated with controlled and/or comparable methods [49,50]. Additionally, although many treatment providers offer specialized protocols for “ethnic populations” [51], there is considerable confusion about when to implement protocols for African American smokers relative to individuals’ racial identities, acculturation status, and experience, and there is no evidence that these protocols reduce treatment outcome disparities [22,52]. Furthermore, given the associations among SES, African American ethnic minority status, and tobacco use, adaptations aimed solely at addressing relevant ethnic minority cultural issues are unlikely to address the significant socioeconomic factors associated with disparities experienced by many African Americans (i.e., socioeconomic stress, access to resources, environmental constraints, affective and cognitive resources). This evidence supports the need to adapt the standard evidence-based treatment for tobacco dependence to more fully meet the needs of lower SES groups and incorporate the needs of African American groups as well.

The specific aim of this study was to adapt a well-established, evidence-based treatment for tobacco dependence to more fully meet the needs of smokers of lower SES, many of whom are African American, with the overall goal of preparing a revised treatment to be compared with the standard treatment in a randomized trial. Two relevant and prominent frameworks for adapting interventions were applied to the development of the revised treatment: The framework developed by Barrera and Castro and Lau [42,43], and the PEN-3 Model [53,54]. The Barrera and Castro framework is specifically designed to adapt evidence-based treatments for disparate groups. The logical framework of adaptation includes a systematic step-by-step process. The first phase is information gathering; the second, preliminary adaptation; the third, preliminary adaptation tests; and finally adaptation refinement [42,43]. The PEN-3 Model is specifically designed to incorporate African American values and experiences into treatment approaches [53,54]. The PEN-3 Model includes three dimensions a) understanding the role of the individual within the family, extended family, neighborhood, and community; b) recognizing perceptions, enablers, and nurturers; and c) evaluating the cultural appropriateness of the intervention. Perceptions are knowledge, attitudes, values, and beliefs that facilitate or hinder personal motivation to engage in an intervention. Enablers are societal, systematic, or structural influences that enhance or create barriers to engaging in an intervention. Nurturers are reinforcing factors provided by others (e.g., interventionists, peers, family, employers, religious leaders, etc.). Perceptions, enablers, and nurturers that lead to improved health status are positive; that are inconsistent with the mainstream, but have no harmful health consequences are exotic; and that lead to harmful health consequences are negative. These frameworks provided the structure and rationale for the methods and procedures described in this study.

Methods

We began with a well-established, manual-driven, multicomponent cognitive-behavioral treatment for tobacco dependence with which we had considerable experience and expertise. We sought to maintain the same amount of treatment contact in the revised treatment as the standard treatment to maintain comparability for a planned randomized controlled trial. The adaptation procedures were conducted in four Phases: 1) information gathering, 2) preliminary adaptation design, 3) preliminary adaptation tests, and 4) adaptation refinement. The PEN-3 Model was used in Phase 2 to ensure that the interventions were adapted with systematic consideration of relevant values and experiences. Phases 2-4 were guided by community-based participatory research principles, as described by Israel [55]. This study was approved by the Institutional Review Board at the City College of New York.

The standard evidence-based treatment

The standard treatment was developed and refined over the course of 30 years at the University of Mississippi Medical Center/GV (Sonny) Montgomery VA Medical Center. This manual-driven, multicomponent cognitive behavioral treatment for tobacco dependence has been delivered in multiple modalities (i.e., group, individual, and telephone), used in numerous studies [17-20,56-59], and is considered comprehensive, well-established, and consistent with the Public Health Service Clinical Practice Guideline [22]. When delivered in the group treatment modality, the treatment consists of 6 weekly closed-group 60-minute sessions with 5-10 participants. The treatment includes an overview of the biopsychosocial underpinnings of tobacco dependence and the trigger-urge-response cycle, scheduled gradual rate reduction, self-monitoring, stimulus control, problem-solving, conflict management, cigarette refusal training, enhancing social support, goal setting, relapse prevention, and stress management.

Phase 1: Information gathering: The objective of this phase was to identify factors that, if addressed, have theoretical and/or empirical support for reducing the disparity in treatment outcomes [42,43]. The research team reviewed conceptual models of socioeconomic and tobacco use disparities [12,25,28,30-35,60] and the findings associated with disparities in tobacco dependence treatment outcomes [17,18,20,58,61,62]. We identified eight modifiable factors associated with socioeconomic disparities that were prominent in both theoretical frameworks and treatment outcome studies: stress and stress management, negative affect regulation, smoking in response to negative affect, delay discounting, locus of control, impulsiveness, smoking policies in the home, and treatment utilization (e.g., medication and session attendance).

Phase 2: Preliminary adaptation design: The objective of this phase was to incorporate the factors identified in the first phase into a draft of the revised treatment manual [42,43]. Barrera and Castro (2006) indicate that this phase provides a good opportunity to incorporate qualitative research from community experts and potential participants [42]. Preliminary procedures for adaptation took place in two steps: 1) clinical adaptations addressing the eight modifiable factors selected in Phase 1, and 2) cultural adaptations addressing relevant perceptions, enablers, and nurturers using the PEN-3 Model.

Phase 2: Step 1: Clinical adaptations: We systematically adapted the standard treatment manual to incorporate interventions addressing the eight factors identified in Phase 1. Table 1 provides a detailed description of the revisions incorporated to address each of the eight factors. In addition, a specific technique, behavioral rehearsal, is explicitly introduced as an important strategy in the first session and

Clinical or Environmental Factor	Revisions to specific intervention components
<p>Stress: Increased emphasis is placed on stress management. Stress management is introduced earlier in treatment, and discussed during every treatment session. The management of particular stressors associated with restriction of resources and /or of being of minority status are explicitly explored.</p>	<ol style="list-style-type: none"> 1. Stress management is introduced and given greater emphasis as a primary component of treatment. 2. Stress is more explicitly discussed as a precursor to relapse. 3. Cognitive restructuring is used to <ol style="list-style-type: none"> a. facilitate understanding of a cognitive-behavioral conceptualization of stress and stress management earlier in treatment b. frame the relationship between stress and locus of control c. frame the relationship between stress and negative affect d. explicitly introduce negative affect as a powerful cue for smoking. 4. Relaxation training is introduced in the first session instead of the third session, normalized, modeled, rehearsed in every session. 5. Relaxation is practiced in session at the beginning of sessions 2-6 instead of the end of sessions 4-6. 6. Relaxation homework is assigned for sessions 1-6 instead of 3-6. 7. Goal setting includes more directive relation training practice goals and reviews of daily practice. 8. Self-reinforcement is discussed as a stress management strategy, discussed in the third instead of the fifth session, and emphasized by repeating the concept in sessions 3-6 in a directive manner. 9. Everyday discrimination and micro-aggressions are explicitly discussed as stressors. 10. Financial stress is explicitly discussed. 11. Strategies for managing interpersonal conflict are more concise and directive. 12. Strategies for maintaining good health (nutrition, exercise, sleep) are explicitly linked to stress management and delivered in a more concise manner. 13. The belief that smoking alleviates stress is explicitly countered.
<p>Negative affect: Proactive emphasis on recognizing and managing negative affect.</p>	<ol style="list-style-type: none"> 1. Managing negative affect is introduced as a primary component of treatment in first session instead of the third session and linked to stress and stress management in every session. 2. Cognitive restructuring is used to <ol style="list-style-type: none"> a. frame the relationship between stress and negative affect b. frame stress management as a method of managing negative affect c. frame negative affect as affected by the environment and changeable by the individual. 3. Self-reinforcement is discussed as a strategy for managing negative affect. 4. Moderate exercise is discussed as a method to manage negative affect. 5. Strategies for maintaining good health (nutrition, exercise, sleep) are linked to managing negative affect and delivered in a more concise manner.
<p>Smoking in response to negative affect: Proactive, explicit emphasis on recognizing and managing negative affect as a cue to smoke and a risk for relapse.</p>	<ol style="list-style-type: none"> 1. Cognitive restructuring is used to frame negative affect as a cue to smoke. 2. Negative affect is explicitly discussed as a precursor to relapse. 3. Negative affect is normalized as a cue to smoke. 4. Participants are encouraged to manage negative affect as they would any other cue to smoke.
<p>Discounting the value of delayed rewards: New explicit emphasis placed on recognizing and choosing long-term versus immediate rewards.</p>	<ol style="list-style-type: none"> 1. Shifting one's focus to long-term rewards is introduced as a primary component of treatment. 2. Immediate challenges are reframed to place them in the context of long-term relapse prevention. 3. Situations in which one can wait for a larger reward later are identified. 4. Foregoing selected short-term rewards for larger rewards later are encouraged. 5. Behavioral rehearsal is used to practice waiting for a larger reward. 6. Self-reinforcement strategies without long-term consequences are encouraged. 7. Specific goals are developed for waiting for larger rewards. 8. Problem-solving and conflict management are framed to decrease delay discounting. 9. Future thinking is encouraged by incorporating an episodic future thinking goal-setting exercise.
<p>Locus of control: New proactive emphasis placed on supporting perceived personal control.</p>	<ol style="list-style-type: none"> 1. Shifting perceptions of control from an external to internal focus is introduced as a primary component of treatment. 2. The discussion of willpower is framed to shift perception of control from an external to an internal focus. 3. Locus of control is linked to stress and stress management. 4. Wording throughout manual was revised to more strongly encourage an internal locus of control. 5. Perceived personal control is incorporated into framing of stress management, problem-solving, impulsivity, negative affect, and smoking in response to negative affect. 6. Locus of control is discussed in the context of faith-based beliefs in a new exercise discussing a common parable, "Getting into the boat."
<p>Impulsiveness: New explicit emphasis placed on identifying and addressing impulsive decision-making.</p>	<ol style="list-style-type: none"> 1. Impulsive decision-making is introduced as a primary component of treatment in first session. 2. Impulsive decision-making is linked to stress and stress management. 3. The cue-urge-response cycle is framed as sometimes being automatic and impulsive. 4. The management of situations where impulsive decision-making might occur are explicitly discussed. 5. Behavioral rehearsal is used to help anticipate and practice alternative responses to situations that elicit impulsive decision-making. 6. Specific goals are developed for self-monitoring of impulsive decision-making. 7. Problem-solving and conflict management are framed to decrease impulsive decision-making. 8. Self-reinforcement strategies are encouraged as a means of countering impulsive decision-making.
<p>Smoking policies in the home: New explicit emphasis placed on developing smoking policies in the home.</p>	<ol style="list-style-type: none"> 1. Managing smokers in one's environment introduced in first session as a primary component of treatment in the first session. 2. Increased emphasis on managing smokers in one's environment. 3. New content on benefits of smoke-free policies in the home. 4. Barriers to establishing smoke-free policies in the home are explicitly discussed. 5. Rights as a non-smoker are discussed in the fourth instead of the fifth session.

<p>Treatment utilization: New emphasis placed on increasing the positive valence of treatment.</p>	<ol style="list-style-type: none"> 1. Treatment participation is introduced as a primary component of treatment in the first session. 2. Increased emphasis is placed on <ol style="list-style-type: none"> a. increasing the positive valence of treatment by <ol style="list-style-type: none"> i. focusing on participant attachment to the group, ii. reinforcing attendance, iii. reinforcing personal responsibility for others in group before every session, iv. ensuring participants receive positive feedback from group members through a structured exercise at the beginning of each session, and v. sending “we missed you” postcards signed by all participants to participants who miss sessions; b. in-session behavioral rehearsal of new skills and behaviors to <ol style="list-style-type: none"> i. encourage skill development, ii. normalize new behaviors, and iii. increase probability that new skills and behaviors are utilized outside of treatment. 3. Self-reinforcement strategies are encouraged as a means of providing reinforcement for new skills and behaviors and increase the probability that these skills and behaviors are utilized outside of treatment 4. Increased emphasis is placed on proper use of the nicotine patch.
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Table 1: Clinical and environmental factors associated with disparities in tobacco dependence treatment outcomes and addressed in the revised treatment.

more frequently utilized throughout treatment as the emphasis is placed on generating, rehearsing, and evaluating specific strategies as well as encouraging engagement. New laboratory research was applied in the development of an episodic future thinking goal setting exercise used to reduce delay discounting [63]. The health education component in first session and two traditional relapse prevention exercises focused on the Abstinence Violation Effect [64] were deleted.

Phase 2: Step 2, Cultural adaptations: Community consultants led the research team in procedures for adapting the treatment manual from Phase 2, step 1 using the PEN-3 Model. The community consultants included an unemployed African American woman, living in the New York City metropolitan area who was in recovery from cancer and who had been experiencing significant financial hardship for an extended period of time. Her perspective was informed by having been treated with the standard treatment. She had successfully maintained abstinence from smoking after treatment with the standard tobacco dependence treatment for three years. The second and third community consultants were two veteran community health advocates and experts in understanding lower income and African American community perspectives. These experts were from the Arkansas Mississippi Delta and are co-investigators on this study and included an African American woman (NC) who was the director Walnut Street Works, Inc., a non-profit community health organization and a white woman (MO) who is a community health advocate with Walnut Street Work, Inc. and a pastor. To facilitate the systematic application of the PEN-3 model, the research team developed worksheets that cross-listed components of the PEN-3 Model with each intervention component through-out the revised manual. While acknowledging the role of the individual, the extended family, the neighborhood, and the community, the research team completed the worksheets commenting on perceptions, enablers, and nurturers and then determining whether the perceptions, enablers, and nurturers were positive, exotic, or negative. After reviewing all the intervention components in each of the six treatment sessions, the community consultants were asked: How can we incorporate themes relevant to people of limited means? How can we incorporate themes relevant to African Americans? Is there enough detail (i.e., choices for tailoring) in terms of socio-culturally specific triggers, smoking contexts, barriers to cessation?

The feedback from the community consultants was extensive. The consultants provided numerous comments and recommendations that sometimes involved completely re-structuring the manner in which intervention components were delivered in order to improve the acceptability, suitability, and/or tolerability of the interventions. Table 2 gives a description of the perceptions, enablers, and nurturers for

each intervention strategy and revisions suggested by the community consultants. Overall, the consultants endorsed the use of an overall theme of viewing helpful ideas, interventions, and strategies as “tools,” and overtly highlighted opportunities to enhance a sense of personal control. They recommended that we develop a culturally congruent participant workbook and call it a “Toolkit” to be provided in a binder with pockets to help participants organize and preserve information about the process of quitting for reference at a later date. Suggestions for the Toolkit included a review of material presented in the treatment sessions, tracking sheets, and information about health risks of smoking and benefits of quitting, obtaining support from others, stress management ideas, and myths about using nicotine replacement, etc. They suggested that the Toolkit include positive messages and images relatable to lower SES and African American communities. This feedback was incorporated into the revised treatment manual.

Phase 3: Preliminary adaptation tests: The objectives of this phase were to determine if the revised treatment could be delivered in six one-hour closed-group treatment sessions to ensure comparability with the standard treatment in the clinical trial; to ensure that the revised treatment was acceptable and understandable to participants; and to identify and discuss difficulties with implementation, program content, and/or activities [42]. Pilot studies with small groups followed by a qualitative inquiry are often used to assess program elements from participants’ perspectives as well as gather suggestions for improvement [42]. Qualitative information was also gathered from the treatment provider and the focus group facilitators. Thus, we administered the revised treatment to two pilot study groups and then invited the group participants to participate in a focus group to obtain feedback. Throughout the process, we sought to reduce demand characteristics by minimizing the amount of personal data collected from participants, using community members to facilitate the focus groups, and ensuring no university presence during the focus groups.

Participants: Pilot study participants were recruited into one of two pilot study groups by flyers placed in the West Harlem community and word of mouth. Inclusion criteria included: a) smoking cigarettes daily, b) expressing a desire to quit smoking in the next 30 days, c) no regular use of other tobacco products, d) age 18 years or older, e) willing to comply with study commitments, and f) able to engage in treatment. The exclusion criteria included: a) any contra-indication for use of the nicotine patch (i.e., uncontrolled high blood pressure, allergic reaction to patch adhesive, pregnancy, etc.), b) current use of medications for smoking cessation (bupropion, varenicline, or any form of nicotine replacement), c) consumption of more than 20 alcoholic drinks per week, and d) current symptoms that would prohibit engagement in

Intervention Strategy	Perceptions, Enablers, Nurturers	Suggested Revision
Description of intervention components throughout the treatment.	<ul style="list-style-type: none"> Negative perception. Participants are likely to have multiple beliefs about clinical language that will hinder their motivation to engage in treatment. 	<ul style="list-style-type: none"> Use everyday language and metaphors. Examples include using the term "tool" instead of strategy; using the term "Big picture versus right-now thinking" when describing impulsive choices and long-term rewards; using change or improve instead of "manage" especially with regard to people. Don't expect participants to learn therapy language, learn the language they use to describe what is needed.
Pre-session assessment of motivation, self-efficacy, cigarettes per day, carbon monoxide levels, and progress toward goals.	<ul style="list-style-type: none"> Negative perception. Participants are likely to have multiple negative beliefs about impersonally completing forms prior to receiving services that will hinder their motivation to engage in treatment and foster an external locus of control. 	<ul style="list-style-type: none"> Re-name the process of collecting and discussing pre-session assessment data to Feedback. Provide a copy of the feedback form to participants. Do not collect pre-session assessments before the first session. Instead, describe how the participants can use the Feedback information during the first session, demonstrate how to use the carbon monoxide monitor in session, prepare participants to complete the Feedback forms on their own prior to the rest of the sessions. Have a rotating in-group leader to assist with the collection of Feedback prior to sessions 2-6.
Preparing for abstinence after the group; countering beliefs that group is like a class; encouraging conceptualization of treatment as changing thoughts, behaviors, and feelings.	<ul style="list-style-type: none"> Negative perceptions. Negative value placed on interactions that have no continuity beyond the 6 sessions; no relevant concrete materials to share with others. 	<ul style="list-style-type: none"> Develop a culturally relevant and complementary "Toolkit" with pockets to enable collection of related materials and for Feedback sheets.
Quit date set for session 3	<ul style="list-style-type: none"> Negative perception. Multiple negative beliefs and attitudes about having a specified quit date that will hinder motivation to engage in treatment and foster an external locus of control. 	<ul style="list-style-type: none"> Reinforce the notion of preparation as part of the quitting process. Discuss the quit date as part of the quitting process and a target or a goal to work toward.
Multiple interventions to increase internal locus of control	<ul style="list-style-type: none"> Negative perception. Multiple negative beliefs about fate and the role of faith in one's life. Culturally accepted to have no control over circumstances or to place the locus of control in a higher power. Negative enabler. Multiple systemic influences that reinforce and encourage an externally focused locus of control. Negative perception. Willpower is a personality defect and is not under one's control. Negative perception. Willpower is provided by a higher power. 	<ul style="list-style-type: none"> Help them to see what controls they actually have. This can be associated with stress management as well. Use 'tools' analogy. Having the right tools was associated with more personal control and an internal locus of control.
Increase positive valence of treatment, reinforce attendance, and reinforce contributions to the group.	<ul style="list-style-type: none"> Negative perception. Negative beliefs about the importance of attendance. Negative perception. Negative beliefs about being "second-class" citizens. Positive perception. Positive beliefs about responsibility and respect for others that can be extended to the importance of attending and contributing to group. 	<ul style="list-style-type: none"> Use introductions to establish commonalities. Overtly discuss feelings of being second-class citizens. Establish group norms that reinforce participant contributions and the value of contributions and participation. Have participants actively give and receive positive feedback to each other. Develop group guidelines that reinforce attendance, individual contributions, helping others, and respecting group members. Reinforce attendance at the beginning of each session. Reinforce individual contributions throughout treatment.
Diaphragmatic breathing to manage stress and negative affect	<ul style="list-style-type: none"> Positive perception. Intervention is consistent with preference for behavioral interventions and practice of faith and prayer. Negative perception. Allowing stress to "get to you" is a personality defect. 	<ul style="list-style-type: none"> Normalize the experience of stress, the experience of negative affect, as well as the experience of relaxation. Encourage practice as much as possible.
Nicotine replacement	<ul style="list-style-type: none"> Negative perception. Lack of trust in medications. 	<ul style="list-style-type: none"> Have group facilitator and participants unwrap and apply a patch in session. Provide proactive explanations to questions about patch use. Provide information to counter common myths about nicotine patches.
Review and inform participants about limits of confidentiality.	<ul style="list-style-type: none"> Negative perception. Descriptions such as this (i.e., limits of rights) is often associated with institutions like the police, child protective services, lawyers, etc. and might hinder motivation for group participation. Positive perception. The term "respect" includes culturally congruent responsibilities or expectations for maintaining confidentiality in appropriate contexts and might facilitate motivation for group participation. 	<ul style="list-style-type: none"> Discuss confidentiality in terms of respect for others and keeping everyone's business private.
Triggers include negative affect and significant stressors related to having limited resources and suffering from discrimination.	<ul style="list-style-type: none"> Negative perception. These types of distress are sometimes embarrassing and often discussed only in the context of close family and friends. Positive nurturer. Overtly discussing these issues in a group setting might normalize the experience and reinforce the notion that these topics are important to talk about when trying to quit. 	<ul style="list-style-type: none"> Tailor the trigger-urge-response cycle exercise in the first session to overtly include situations of financial stress, discrimination, and feelings of loss of control, and negative affect including anger and frustration.

Managing smoking in the home, social situations, and reinforcing rights as a nonsmoker	<ul style="list-style-type: none"> Negative enabler. Individuals often do not have much control over or power to change situations in the social structures in which they live and work. Positive nurturer. Family and friends are likely to be supportive. Negative nurturer. Family and friends who smoke might not be supportive or might not know how to be supportive. 	<ul style="list-style-type: none"> Identify a social network with both positive and negative social influences. Clearly acknowledge situations in which individuals have a lack of control. Focus on positive aspects of relationships that provide both positive and negative social support. Develop methods within the social structure to encourage the type of support the individual needs.
Using religion and/or spirituality to support quitting	<ul style="list-style-type: none"> Positive perception. Faith is often valued and used to manage many personal challenges. Negative nurturer. Smoking is sometimes viewed as a sin and giving in to temptation and difficult to discuss with religious leaders. Negative perception. Faith is sometimes viewed as encouraging a passive, trusting approach (i.e., waiting for God to give you the power, inspiration, and/or means to quit). 	<ul style="list-style-type: none"> Discuss a common parable, "Getting into the Boat" . Invite participants to use religious/spiritual imagery during relaxation training.

Table 2: Summary of community consultants' review of intervention strategies in terms of the PEN-3 Model.

treatment (active psychotic disorder, acute major depressive episode, significantly cognitively impaired). Participants (n=25) were 100% African American and 48% male with a mean age of 44 years (SD 12.4). One participant also identified as Hispanic. Group one (n=13) was 38% male with a mean age of 51 years. Group two (n=12) was 58% male with a mean age of 55 years.

Procedure: Participants were screened for inclusion/exclusion criteria over the telephone and if eligible, scheduled for a pilot study group and consented immediately prior to the first treatment session. Treatment sessions were delivered to the pilot groups by an experienced tobacco dependence treatment provider (CS). Pilot sessions were timed. One week after completing the treatment sessions, participants were invited to discuss their experience of the treatment with their respective groups in one of two focus groups. Participants were compensated \$30 for each visit. Community-based participatory research principles and a democratic deliberative approach were used to pilot test the revised treatment. The democratic deliberative approach is widely used to understand a number of sensitive social questions [65,66]. The approach assumes that those most affected by use or nonuse of a program can most accurately answer questions pertaining to that program and acknowledges the importance of context in interpretation. Discussion must take place in a setting in which anonymity is supported and values are not judged. Two community consultants (NC and MO) with expertise in both community-based research and democratic deliberative methods facilitated the focus group discussions. This approach was chosen because it supports the study objectives and was the method of choice for the community partners. To reduce demand characteristics, university staff and team members were not present during the focus group discussions.

The questions used to initiate discussion were developed by the community consultants and included: *Was the treatment and the discussion understandable? Discuss the good and the bad of it. Was the treatment something that you feel you can apply in your life in terms of helping you to stop smoking? Were there ways you could apply it other than smoking? Was the treatment acceptable? Let's discuss what was good and bad about it. What would you add to the program and why? What worked most for you? What worked least for you? Would you sign up again without the stipend? Let's discuss common ground. As the last word about the treatment, anything you would like to share?* Responses were recorded in large text notes on newsprint and taped on the walls of the conference room for continuous review during the discussions. After the discussion group, the research team transcribed the notes from the newsprint and met as a team to extract relevant themes and recommend revisions.

Results: Eighteen (n=18) of the pilot group participants returned for focus groups. Focus group attendees were 56% male with a mean age of 53 (SD 13.5). Chi-square and analysis of variance indicated no significant sex and age differences among those who attended the focus groups and those who did not (sex: $\chi^2=1.47$, $df=1$, $p=.23$; age: $F=.054$, $df=1,23$, $p=.82$).

Was the treatment understandable and acceptable? Discuss the good and the bad of it. The participants uniformly reported that the treatment and the discussion were understandable and acceptable; that the treatment helped them to feel hopeful about quitting; and that being able to talk about quitting increased their desire to quit. Relaxation training was reported to be the most favorite and useful intervention component. Participants reported that they also liked the tips about quitting, the cinnamon toothpicks available during treatment, carbon monoxide monitoring, and the tips about managing stress. Some participants reported that they didn't realize how harmful smoking was to their health. The facilitators interpreted this to mean that even if the participants had been told about the health effects before, they felt ready to know and hear more about the health effects during treatment. Some participants reported that although they did not quit, they cut down significantly and planned to quit soon. Participants liked the idea of understanding triggers and of quitting gradually. They noted that learning about particular triggers including sex, eating, routines, alcohol, bowel movements, habits, and emotions were especially helpful. Most agreed that the discussions were good because the topics were debatable and their opinions were respected. Participants repeatedly acknowledged that each person had different story to tell and that they valued the effort made by the group leader to ensure that everyone and all efforts were viewed positively. They especially liked the acknowledgement that they weren't bad people because they smoked cigarettes or when they slipped or when they didn't meet their goals every week. They liked knowing that they were not alone in their struggle to quit. Participants reported that they liked having the participant workbook.

Participants reported that they would have liked more sessions per week and more sessions in general. They reported that they were engaged, that the hour went quickly, and that they had many more questions than could be answered during the six sessions. This appeared to be especially true of the nicotine patches. Participants reported that it "was good that patches were offered" even though they didn't think the patches "worked" or were a "good idea" and most participants didn't use them even though they agreed to use them when they enrolled. The facilitators interpreted the comments about patches to mean that participants didn't want to use patches because of previous experience, but might try patches later if they felt more comfortable. Some

participants reported that they were “scared of” the patches so didn’t even try them. Complaints about the patches included causing the “shakes,” making the “taste in my mouth disgusting,” or causing them to “break out.” One participant noted that, “If someone put a patch on you and you didn’t know it – you wouldn’t know it was there. It is a mental thing,” implying that they perceived the origin of the complaints about the patches to be psychological in nature. Nonetheless, participants agreed that there should have been more information about the patches in the treatment. They suggested that there be less time between sessions to provide support for using the patch and to talk about their concerns and what they felt. Participants reported that they would have liked to discuss “how to handle stress” more in-depth. They suggested “a whole session on a stress.” In addition, they reported that they would have liked to have used the participant workbook more during treatment and would like more written education about smoking and scientific facts about smoking. Participants agreed that the sidebar conversations and cell phone ringing and use during treatment were distracting. Some participants reported that they would have liked to have a celebration with food or snacks at some point during the treatment.

Were there ways you could apply it other than in smoking? Participants reported that there were some things they learned that they could apply to other areas of life including the practice of stopping and “thinking before behaving,” waking up earlier and meditating, planning the day out ahead of time, eating breakfast, deep breathing, exercising, being in the company of others with the same goals, and lifestyle changes in general. They reported that achieving a goal helped them to feel like they could achieve other goals and that the process of trying to quit helped them to “find out that your real friends are – a very positive thing.”

What would you add to the program and why? Participants reported that they would like to know more about electronic cigarettes, more sessions, more time to talk, and a list of other programs so they would get more support. One group also suggested detailed revisions to the Group Guidelines.

What worked the most and the least? Participants listed the “breathing exercises,” the coping skills, discussions during the feedback sessions, discussions about meeting their goals, discussions about faith, the carbon monoxide monitoring, and the everyday talk about quitting and sharing their progress toward quitting as working the most for them. Some did not think that others commenting on their personal smoking was helpful and reported that sometimes talking about smoking during treatment “made them want a cigarette more.”

Would you sign up again without the stipend? Participants uniformly reported that they would sign up again with or without the stipend, but the stipend was helpful. One participant reported that they were proud of the fact that they “didn’t buy cigarettes with the stipend.” When asked why they would participate again they reported the primary reasons would be “togetherness, engagement, support, and bonding.”

Common ground and last word: Participants agreed that the common ground included “the support from each other, togetherness, engagement, support, and bonding,” and “good to hear from peers.” During last words, participants in both groups asked whether it was possible for them to attend the treatment again. Some reported that they “would not have gotten this far with quitting without the sessions,” and “Would like to see what percent of people actually quit.” One participant apologized for having a bad attitude during the sessions, but noted that the sessions tended to “bring out the best of the people.” All felt that, “This was a good use of our time,” and “Will recommend it to others.” Most indicated that they will continue to try and quit

or stay quit. Most reported that they acquired “tools for life – stress management, planning, people who are committed to stopping,” and that “Tools that help you with life are the tools that lead to smoking cessation.” The final words included, “All these are life skills and life skills empower one to quit smoking.”

Phase 4: Adaptation refinement: The objective of this phase was to incorporate feedback from Phase 3 and develop a treatment manual that could be compared with the standard treatment for efficacy in a randomized control trial. The final phase of the adaptation included bringing the research team together to integrate findings from the adaptation test. Several components required revision. For example, during Phase 2, Step 2, community consultants suggested that we use a rotating within-group leader to facilitate preliminary group procedures and enhance the positive valence of treatment. This procedure did not function well and was eliminated during the refinement. The image of a tree for the social network identification exercise was found to be confusing and was replaced by a network-related image with circles representing individuals. As per the focus group recommendations, the Group Guidelines were revised. Procedures were revised to include review of the Group Guidelines prior to every session. The group size was limited to six participants to enable tobacco treatment specialists to address the complexity of participants’ presentations. The research team also revised the procedure for assessing carbon monoxide levels to encourage an internal locus of control. Instead of having staff administer the CO assessment to participants before each group session, participants are taught how to use the CO monitor in the first session. Every session thereafter, CO monitors are left out for participants to assess and record CO levels on their Feedback sheets prior to group. Finally, the language in the manual was further refined to be more accessible and reference to the Toolkit and other key factors like Personal Control and Keeping the Big Picture in Mind, were increased throughout treatment.

Results and Discussion

The final treatment manual and participant handbook are called the RITCh (Reducing Disparities in Tobacco Dependence Treatment Outcomes) Tobacco Dependence Treatment Manual and Toolkit. The manual comprises six 1-hour, closed group sessions, identical in terms of overall time of exposure to the standard treatment; however, the treatment components have been revised to address factors associated with the development and maintenance of the disparities associated with the standard treatment. The treatment appears to be understandable and acceptable to lower income individuals and African American individuals. To our knowledge, this is the first adaptation of evidence-based treatment for tobacco dependence that has systematically applied the well-accepted frameworks proposed by Barrera and Castro and Airhihenbuwa and used a community based participatory approach [43,55]. The revised treatment is currently being compared with the standard treatment in a randomized controlled trial. We expect the socioeconomic disparities in treatment outcomes from the standard treatment to be greater than the treatment outcome disparities from the revised treatment.

Whether or not the revised treatment is found to be more efficacious for lower SES groups, the results from the focus groups suggest that the RITCh Tobacco Dependence Treatment Manual and Toolkit are likely to be well received among many smokers. Many of the elements were refined, adapted, and sometimes instituted by community members invested in engaging the current population of smokers and particularly African Americans and perhaps other minority communities who might identify with the experiences of African Americans. The goal of

the participant workbook, the Toolkit, is to support relapse prevention by providing participants with adjunctive and supportive information as well as to serve as a tool to organize and preserve information about the process of quitting. It is designed to be provided in a 1-inch black binder with internal pockets to enable participants to save copies of their feedback sheets, goals, and other relevant information for reference at a later date. The Toolkit is organized by topic, reflects the new components in the treatment manual, and includes motivational quotes from notable African Americans, facts about African Americans and smoking, tracking charts and worksheets to be used during treatment, tips, and adjunctive information about goal setting, stress, lifestyle changes, and myths about nicotine replacement and tobacco use in general. The RITCh Treatment manual includes multiple references to the content in the Toolkit as well as how to use the Toolkit for relapse prevention. Although currently constructed to be delivered in groups, similar to the standard treatment, the revised treatment manual can be easily adapted to be delivered over the telephone or individually. Of note, there is nothing in the materials that precludes or excludes the experience of groups who are not of lower SES or African American.

We speculate that the revised treatment is likely to be acceptable, understandable, and address the needs of other groups who experience increased stress from discrimination, restricted resources, and/or struggles with negative affect as well as possess a perceived external locus and fewer positive expectations from treatment. Increased stress and restricted resources appear to cultivate an increased focus on the present that translate into increased impulsivity and delay discounting rates [67] all of which have been shown to affect cessation. These groups might include women, sexual minorities, and lower SES groups who are not of minority status.

Conclusions

Tobacco disparities are a significant contributor to socioeconomic and ethnic minority health disparities. Adaptation of the standard, intensive, evidence-based treatment for tobacco dependence is indicated because lower socioeconomic groups demonstrate significant disparities in treatment retention and outcomes. African Americans are disproportionately represented among lower socioeconomic groups and among smokers and thus adaptations must recognize and address the values, experiences, and concerns of African Americans.

The RITCh Treatment approach is important, distinctive, and relevantly addresses the current tobacco-related health disparities because it adapted an existing, well-established standard treatment to more fully address the needs of significant disparate groups in a manner consistent with the conceptual and empirical evidence as well as with significant input from community members who are likely to use the treatment and community partners who served to interpret and incorporate community values and experiences. This treatment is also distinctive and important because it is actively inclusive, does not preclude active participation among smokers from all walks of life, and is perhaps, given the current demographics of the smoking population, more relatable to more smokers than the standard treatment. For instance, the discussion about stress from everyday discrimination includes racial, socioeconomic, gender/sex, sexual minority, and other types of discrimination with the goal of helping participants become aware of and manage this significant source of stress. Moreover, the disparate groups for which this treatment has been adapted are fast becoming highly representative of the majority of smokers. Thus, there exists a rationale for adopting the revised treatment as a new standard, eliminating the problems inherent in using special protocols for special populations. In other words, we propose that creatively addressing

the conceptual and empirical underpinnings of disparities within a singular approach might be more effective at retaining and effectively treating smokers from disparate groups than offering special protocols for special groups.

The RITCh Tobacco Dependence Treatment Manual and Toolkit are currently being compared with the standard treatment and a generic participant workbook in a randomized control trial. We expect the RITCh Treatment to reduce long-term treatment outcome disparities and RITCh participants to demonstrate improvement on the eight modifiable factors associated with treatment outcome disparities (Table 1), but this is yet to be determined. If the RITCh Treatment is effective in reducing treatment outcome disparities, then perhaps the treatment can be further revised to more fully incorporate the needs of other groups including women, sexual minorities, and individuals with mental illness and substance use disorders.

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