

# A Pilot Community-Based Intensive Smoking Cessation Intervention in African Americans: Feasibility, Acceptability and Early Outcome Indicators

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Few intensive and community-based smoking cessation treatment programs have been designed for African-American smokers, a group who experiences numerous health disparities associated with cigarette smoking. The purpose of this study was to examine the feasibility, acceptability and biochemically verified early outcome indicators in a community-based comprehensive smoking cessation program in 50 urban, low- and middle-income African-American smokers. The intervention was an intensive six-session group program delivered in the community and a one-month supply of the transdermal nicotine patch. Results showed 74% of enrolled participants completed the program and 51% of participants were highly adherent to patch use guidelines. Intent-to-treat analyses revealed that 34% of participants were biochemically confirmed as having quit smoking at one month post quit date. Smoking urges and depressive symptoms also declined significantly during the first month. At three- and six-month follow-up, biochemically confirmed quit rates were 22% and 18%, respectively. Adherence to nicotine patch use, higher ratings of the perceived helpfulness of self-monitoring tasks (wrap sheets) and lower depression scores at baseline all significantly predicted quitting success during the first month of treatment (all  $p$ 's < 0.05). Larger studies are warranted to examine targeted treatment elements and individual difference factors to enhance cessation outcomes in African-American smokers.

**Key words:** tobacco ■ African Americans

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## INTRODUCTION

Cigarette smoking is recognized as the single most preventable cause of premature death in the United States.<sup>1</sup> Despite the evidence linking cigarette smoking to cancers of the lung, larynx, oral cavity, esophagus and kidney,<sup>2</sup> approximately 22% of all African-American and Caucasian adults currently smoke cigarettes.<sup>3</sup> Over the past two decades, key differences in the smoking topography and rates of smoking cessation in African Americans and Caucasians have been observed. For example, African-American smokers tend to prefer mentholated cigarettes<sup>4,5</sup> and high-tar and nicotine-yield cigarettes.<sup>6</sup> African Americans also metabolize both nicotine and cotinine (a metabolite of nicotine) more slowly than Caucasian smokers.<sup>5,7,8</sup> Combined, these factors may contribute to greater difficulty in quitting smoking<sup>9</sup> and significantly more adverse health consequences associated with smoking compared with Caucasian or other ethnic minority groups.<sup>5,10</sup>

In addition to differences in smoking topography, African Americans are also less likely than other racial groups to engage in formal smoking cessation interventions.<sup>11</sup> Compared to Caucasian smokers, African-American smokers report a higher desire to quit smoking<sup>4</sup> and are more likely to have quit smoking for  $\geq 1$  day during the previous year;<sup>12</sup> however, their longer-term quit rates are approximately 34% lower.<sup>13,14</sup> Despite racial differences in smoking topography and outcome, the majority of published research in this area is descriptive in nature, with far less research focused on clinical trials within underserved African-American smokers. The few intervention studies that have been conducted have yielded mixed results in terms of feasibility and outcome, which

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may be due to differences across studies in terms of sample characteristics or to differences in study methodology and treatment approach.

Experimental and quasiexperimental studies using psychosocial, behavioral or community-based intervention (without pharmacotherapy) in African-American smokers have largely shown low quit rates, and many have lacked biochemical verification of self-report quit status. While one study showed decreased smoking prevalence in African-American communities receiving a long-term (24-month) neighborhood wellness and nonsmoking campaign compared to demographically similar control communities, the absolute behavioral change was relatively modest, i.e., a smoking prevalence decline of 7% in the intervention communities compared with a decline of 1% in the nonintervention communities.<sup>15</sup> Tailored self-help materials and telephone counseling in African Americans have been shown to significantly increase the number of quit attempts and frequency of using smoking cessation strategies compared with a control condition, but short-term quit rates may not differ.<sup>16,17</sup> However, for some treatments, benefits may not be seen until a later interval, as in the Orleans et al.<sup>16</sup> study: an opportunistic one-year follow-up in the last cohort revealed that intent-to-treat quit rates were higher in the targeted intervention versus standard group (15% vs. 9%, respectively). Given the geographic diversity and large-scale nature of these studies, verifying self-report through biochemical measures was not available or deemed feasible. Other research has indicated no advantage of community-wide, church-based or other targeted interventions in African-American smokers compared with either no intervention or minimal intervention.<sup>18,19</sup> It has been suggested that cessation outcomes may be more favorable in underserved African Americans by using methods that employ direct contact and face-to-face approaches than in impersonal approaches.<sup>20</sup>

The vast majority of smoking cessation studies in African Americans have not included FDA-approved pharmacotherapy, despite their indication in the Clinical Practice Guidelines.<sup>11</sup> In the only double-blind placebo-controlled trial of nicotine patch (with no counseling) in African-American smokers,<sup>21</sup> end-of-treatment quit rates were significantly better with active patch improved short-term quit rates at end of treatment (22% vs. 14% placebo at 10 weeks), but at six-month follow-up, the difference between groups was no longer significant (17% vs. 12%, respectively) and biochemical verification was not used. Nicotine replacement combined with intensive psychosocial treatments in urban or public housing African-American smokers have yielded mixed results. In two studies, nicotine patch combined with either intensive behavioral empowerment<sup>22</sup> or culturally targeted materials<sup>23</sup> have produced generally favorable quit rates (14–18%, and 27% at six months, respectively, biochemically verified), similar to those reported in Caucasian smokers.<sup>24–26</sup> However, results from another study with

nicotine gum and motivational interviewing did not produce favorable quit rates at a similar follow-up interval (7–9% quit rates at six months).<sup>27</sup> Finally, a large-scale double-blind, placebo-controlled study of bupropion with brief motivational counseling showed significantly increased biochemically verified quit rates at six months (21% bupropion vs. 14% on placebo).<sup>28</sup> Adjunct pharmacotherapy may improve other outcomes besides smoking quit rates, as depressive symptoms also significantly decreased with bupropion treatment. In general, the majority of studies in African Americans have indicated favorable response to FDA-approved smoking cessation treatments; however, little is known about external validity (i.e., interest in using and/or compliance) since agreement to use the particular pharmacological adjunct is usually required for participation.

In summary, while there are numerous descriptive studies of features of African-American smokers<sup>29,30</sup> there is a relative dearth of studies examining practice guideline-based interventions in this subgroup. As such, the development and evaluation of the acceptability, feasibility and objectively verified behavioral outcomes within smoking cessation programs for African-American smokers are needed. Moreover, particularly in socioeconomically disadvantaged African-American women, lack of access and relevance of mainstream clinic-based treatments may underlie their low participation in organized cessation trials.<sup>19,31</sup> Programs centered within ethnic minority communities may help to reduce this potential barrier to access and comfort within cessation programs.<sup>32</sup> Therefore, the primary aims of this pilot study were to: 1) assess the feasibility and acceptability of a community-based, comprehensive group smoking cessation program consistent with practice guidelines in African Americans; 2) examine one-, three- and six-month point-prevalent quit rates and other smoking-related outcomes; and 3) explore potential predictors of treatment success.

## METHODS

### Participants

The sample consisted of 50 African-American adult smokers (45 female) with intention to quit smoking and who met eligibility criteria. The study inclusion criteria were: African-American adults between the ages of 18–65, smoke a minimum of one cigarette daily for a duration of  $\geq 1$  years, education level of  $>9$ th grade, English speaking, ability to read and write at the  $\geq 6$ th grade level, and have a stable residence and telephone contact number.

### Procedure

Participants were recruited as part of larger community-/school-based campaign to prevent smoking in elementary school children in predominantly African-American communities on the south side of Chicago. According to the U.S. Census (2000)<sup>33</sup> in these commu-

nities, 94.2–97.8% of residents identified themselves as African American/black. Flyers were distributed to local school children to give to their parents as well as placed in local community organizations and physician offices. Smokers interested in quitting were first screened over the telephone to determine their eligibility to participate in this study. The interview took approximately 10 minutes and consisted of standard background questions (demographics, smoking and health).

Subjects meeting general eligibility criteria on the telephone were invited to an orientation and screening session at one of six community locations (described below) one week prior to the start of the first treatment session. The purpose of this initial orientation session was to explain the study rationale, procedures and confidentiality issues. After the study was fully explained, candidates interested in participating (approximately 80% of attendees at the orientation) gave written informed consent. This was followed by a short interview with a trained assistant as well as a brief physical assessment by the study physician (Orman) to determine suitability for nicotine replacement, if interested. Candidates were excluded (n=3) from participation for current untreated major psychiatric or substance use disorder. The latter criteria were determined from a modified structured clinical interview for DSM-IV<sup>34</sup> as well as a general health and substance use patterns questionnaire. Appropriate feedback and referrals were provided to those candidates determined to be ineligible for the study. The study protocol was approved by the University of Chicago institutional review board.

## Intervention Protocol

The study took place at six intervention sites in predominantly African-American communities on the south side of Chicago (four elementary schools, one community center and one church). All participants were scheduled to attend six two-hour weekly study visits and follow-up interviews at three- and six months. Upon arrival, subjects completed questionnaires and a brief interview with a research assistant, provided an expired air carbon monoxide (CO) sample (Smokerlyzer®, Bedfont, Medford, NJ) and received their weekly supply of nicotine patches. These procedures took approximately 30 minutes and were immediately followed by a behavioral therapy group counseling session. The quit date was targeted for the third week (session 3) of the intervention.

**Nicotine replacement therapy.** Consistent with treatment practice guidelines,<sup>12,35</sup> nicotine replacement therapy, in the form of transdermal nicotine patch, was offered to interested participants who met health criteria (not currently pregnant or breastfeeding and no previous adverse patch reaction).

Participants were given complimentary samples of the nicotine patch (Nicoderm CQ,® GlaxoSmithKline, Pittsburgh, PA) distributed at each session by study staff throughout the first month of treatment. The study physi-

cian determined patch dose and duration, in conjunction with manufacturer recommendations: heavier smokers ( $\geq 15$  cigs daily) received 21 mg daily for two weeks, then 14 mg for one week, and then 7 mg for one week; moderate smokers (10–14 cigarettes daily) received 14 mg daily for two weeks, then 7 mg for one week; lighter smokers ( $\leq 9$  cigarettes daily) received 7 mg daily for two weeks. Nicotine replacement was initiated on the morning of the quit date. The study physician attended  $\geq 1$  post quit date counseling session per intervention group to answer questions and was also available by 24-hour pager.

**Behavioral counseling.** The smoking cessation intervention was delivered in a group format, with each session lasting approximately 75–90 minutes. Sessions were led by one of five trained master's-level clinicians involved in the study. Their ethnic backgrounds were as follows: one biracial female, one Hispanic female, two non-Hispanic white females, and one non-Hispanic white male. The groups followed a semistructured manual (© King & Riley, 2001),<sup>36</sup> which incorporates treatment elements from the Freedom from Smoking program,<sup>37</sup> the Clinical Practice Guidelines for Treating Tobacco Use and Dependence,<sup>12</sup> and *The Tobacco Dependence Treatment Handbook: A Guide to Best Practices*.<sup>38</sup> This treatment approach, combined with nicotine patch, has been used in prior studies with general adult and college student samples in prior studies and has yielded six-month point-prevalence quit rates ranging from 19–35%.<sup>39,40</sup>

The first two treatment sessions focused on increasing participant's behavioral and motivational skills in preparation for quit day. A smoking self-monitoring tool called "wrap sheets" was introduced in the first session and continued through the second session. This technique included a small recording sheet to wrap around the cigarette pack and note the number of cigarettes and situations and moods preceding each cigarette. These sessions also consisted of modules on positive health and financial gains of quitting smoking, identifying and creating plans for triggers and a motivational decisional balance sheet. The third group treatment session (the quit date) included a review of participants' smoking cessation experiences, modules on craving and withdrawal and an emergency plan for setbacks.<sup>41</sup> Finally, sessions 4–6 were comprised of group discussion and modules on high-risk situations and cognitive techniques to deal with rationalizing smoking. Those completing treatment received a \$40 gift card during the last session for their time in completing questionnaires and interviews and were eligible for a \$75 gift card raffle. Noncompleters received prorated compensation.

**Posttreatment follow-up.** Follow-up study visits were conducted three and six months after the quit date. The format of the follow-up interviews and data collection procedures was similar to the treatment sessions, where each participant completed the same question-

naires and interviews on smoking behaviors and mood (as during treatment) and expired CO levels were taken. In most cases, the therapist was available to answer any questions and review experiences since the end of active treatment. For attending follow-ups, participants were given a \$40 gift card and were eligible for a \$25 gift card raffle. Subjects completing the follow-up by mail or telephone were given a \$10 gift card. All attempts were made to obtain CO readings on these participants as well; however, if unavailable, they were conservatively classified as relapsed.

## Measures

**Background and smoking characteristics.** During the orientation session, participants completed questionnaires assessing demographics, health history and smoking behaviors. Nicotine dependence was assessed by the Fagerström Test for Nicotine Dependence (FTND),<sup>42</sup> a six-item scale summed to yield a score of 0–10 (severe nicotine dependence). Scores of <5 indicate a low level of dependence, scores of 5–7 a moderate level and scores of >7 high level of dependence ( $\alpha=0.68$ ). Stage of change was assessed by the Smoking Contemplation Ladder,<sup>43</sup> a 10-point scale based on the Prochaska and DiClemente Stage of Change model,<sup>44,45</sup> with higher scores indicating greater readiness and intention to make behavioral change.

## Feasibility: Session Attendance and Adherence to Nicotine Replacement

Feasibility was assessed by the ability to recruit African-American smokers into the smoking intervention trial and percent completing the intervention and follow-up. Retention rates were considered adequate if they were consistent with the literature in African-American smokers, i.e., retention rates at end of intervention or follow-up range 52–87%.<sup>16,21-23,28,46</sup>

Adherence with nicotine patch was computed for each person as a ratio of the total number of patches reported taken divided by the total number of patches that were distributed. The maximum amount of patches over the four-week active treatment period was 29. Compliance was rated as either low (using <75% of distributed patches) or high (using >75% of patches). These distinctions were chosen to approximate patch use on the majority of days of treatment and to ensure relatively steady-state nicotine levels.<sup>47</sup>

## Acceptability: Program and Therapist Evaluation

Acceptability of the smoking cessation intervention was assessed by participants' self-reported ratings of the various program components and the therapist—both of which were completed at the end of the last treatment session. Ratings of the perceived helpfulness of the eight

main treatment elements in the study were assessed by a questionnaire using a Likert scale for each item (1 = not at all effective to 5 = extremely effective). The items were: self-monitoring “wrap sheets,” CO readings; strategies for triggers, such as avoid, alter and substitute; deep breathing; managing triggers sheets to list one's triggers and techniques used to cope with the trigger; discussing weight and health issues; managing feelings, such as being hungry, angry, lonely and tired (HALT); and “Stinking Thinking,” which was adapted from 12-step models of identifying rationalizations for drug use and employing alternative thoughts or cognitions about reasons not to smoke. Therapist competence was evaluated using a five-item questionnaire measuring participants' rating of the working alliance, communication, sharing feelings, ease of quitting without the therapist and the role of therapist in helping aid in smoking cessation. Each item was scored on a five-point Likert scale ranging from strongly disagree (1) to strongly agree (5). The average of the five items was used as the overall dependent measure of therapist competence.

## Outcome: Quit Rates

Smoking quit rates were determined from the Timeline Follow-Back,<sup>48</sup> a reliable and valid calendar interview method to assess daily cigarette consumption.<sup>49-51</sup> Past studies with the TLFB have shown good split-half reliability between two 15-day time periods ( $r=0.97$ ;  $p<0.01$ ). Quitting was defined as last seven-day point-prevalence of not smoking even a puff in each period measured (one-, three- and six-month post quit day). CO levels <6 ppm confirmed self-reported status. If CO was higher than this level or a CO sample was not provided, then the participant was conservatively classified as relapsed.

## Outcome: Urges, Withdrawal and Depression

**Smoking urges.** At each weekly study visit, participants completed the 10-item Brief Questionnaire on Smoking Urges (B-QSU),<sup>52</sup> which is a valid and reliable questionnaire measuring smoking urges (Cronbach's alpha = 0.93–0.96). Participants responded to each item using Likert scales for each item, scored from 1 (strongly disagree) to 7 (strongly agree). Higher scores indicate stronger smoking urges.

**Tobacco withdrawal.** Withdrawal symptoms were measured by a modified version of the Withdrawal Symptom Checklist,<sup>53</sup> which was the total summary score of the following seven symptoms: depressed or sad mood, insomnia, irritability, anxiety, difficulty concentrating, restlessness and appetite increase. These symptoms are identical to seven of the eight DSM-IV criteria for nicotine withdrawal (except for heart rate increase).<sup>54</sup> Each item was rated using a Likert scale ranging from 0 (none) to 4 (severe). Total scores range from 0–32, with higher

scores indicating more tobacco withdrawal symptoms.

**Depressive symptoms.** Depressive symptoms were measured by the Beck Depression Inventory (BDI).<sup>55</sup> The BDI is a 21-question, multiple-choice self-report inventory for measuring the severity of depression. Each symptom is rated on a four-point intensity scale, and scores are summed to give a total ranging from 0–63: higher scores represent more severe depression with scores >16 considered to be indicative of clinically significant levels of depression ( $\alpha=0.81$ ).

## DATA ANALYSIS

Data were analyzed by Statistica® and SAS® software packages. Descriptive variables were summarized into mean and SEM or frequency data, as appropriate. Changes in withdrawal, craving and depressive symptoms were analyzed by repeated measures analyses of variance with time as the within-subject factor. To identify predictors of quit status from the quit date through four weeks at the end of treatment, a Generalized Estimating Equations (GEE) model with a logit link function was fitted for each variable of interest while controlling for the effect of time. The advantage of GEE approach is that it considers the within-subject correlation, and it uses a sandwich estimating method to provide flexibility

in specifying the correlation structure to obtain correct standard error of estimated coefficients.<sup>56</sup> Factors examined in GEE analyses were based on empirical studies of predictors of cessation outcome, i.e., subject characteristics (BDI score at baseline) and smoking factors (cigarettes smoked daily, FTND scores, number of prior quit attempts and nicotine patch adherence). Exploratory analyses were conducted to examine the role of age and education levels as well as therapist and program factors to cessation outcome. Predictor variables that were significant from the individual GEE analyses were then included in a multivariate model to examine the role of each factor after removing the variance attributed to the other factors. Given the multiple comparisons, adjustment of significance level to reduce the type-1 error was considered. However, the adjustment was not undertaken since these analyses were deemed exploratory, the sample size was small, and there would be risks of increasing type-2 error and missing real association.<sup>57</sup>

## RESULTS

### Sample Characteristics

A total of seven intervention groups (N=50) were conducted over the two-year study period, with an average of

**Table 1. Demographic and smoking characteristics of sample (N=50)**

#### Demographics

Age (Range 27–64 Years)	44.5 (1.4)
Education (Range 11–16 Years)	13.0 (.3)
Race (African American)	100% (50)
Sex (Female)	90% (45)
Employment Status	
% full-time employed	60% (30)
% part-time employed	10% (5)
% unemployed	30% (15)
Annual Household Income	
<\$20,000	42% (21)
\$20,000–\$60,000	42% (21)
≥\$60,000	16% (8)
Relationship Status	
Unmarried/single	34% (17)
Married	32% (16)
Separated/divorced/widowed	28% (14)

#### Smoking Variables

Cigarettes Smoked per Day	14.3 (1.3)
Smoking Duration (Years)	21.1 (1.5)
Cigarette Type (Mentholated)	86% (43)
Age of Initiation (Years)	17.7 (0.6)
Prior Quit Attempts	2.4 (0.3)
Contemplation Ladder Scores (1–10)	
Contemplation (range 3–6)	16% (n=8)
Preparation or action stages (≥7)	84% (n=42)
Fagerström Test of Nicotine Dependence (0–10)	5.0 (0.3)
Carbon Monoxide Level at Baseline (ppm)	15.7 (1.3)

Data are mean ( $\pm$  SEM) or % (N)

seven members per group (range 2–12). As seen in Table 1, the majority of the sample was middle aged ( $M=44.5$  years), women (90%), with at least a high-school education ( $M=13.0$  years). Approximately 32% of the sample was married, 70% were employed either full or part-time and 58% reported a household income of  $\geq \$20,000$  per year. Participants smoked an average of 14 cigarettes per day for 21 years, with the majority (86%) preferring mentholated cigarettes. On average, participants initiated smoking at 17.7 years old, and they averaged 2.4 prior quit attempts. Participants were moderately dependent smokers as indexed by FTND scores and baseline CO levels (Table 1). Results from the Contemplation Ladder questionnaire revealed that the majority of participants (84%,  $n=42$ ) were in the preparation or action stages (i.e.,  $>7$  on the 10-point scale).

### Feasibility: Attendance and Adherence

Results showed that 74% ( $n=37$ ) of the participants who enrolled in the study completed study treatment sessions (i.e., attended  $>5$  of the six sessions). Completion rates for the three- and six-month follow-up interviews were 64% ( $n=32$ ) and 56% ( $n=28$ ), respectively. The majority of the participants (86%,  $n=43$ ) initiated nicotine patch use, with 58% starting with the 21 mg dose, 35% starting with 14 mg, and the remaining 7% starting with 7 mg. More than half of these participants (51%,  $n=22/43$ ) were highly adherent during the first month,

i.e., used  $\geq 75\%$  of the patches they received. Ad-hoc reasons cited for patch discontinuation included mild side effects (i.e., sleep problems, skin irritation, etc.) or personal feelings that the patch was no longer needed.

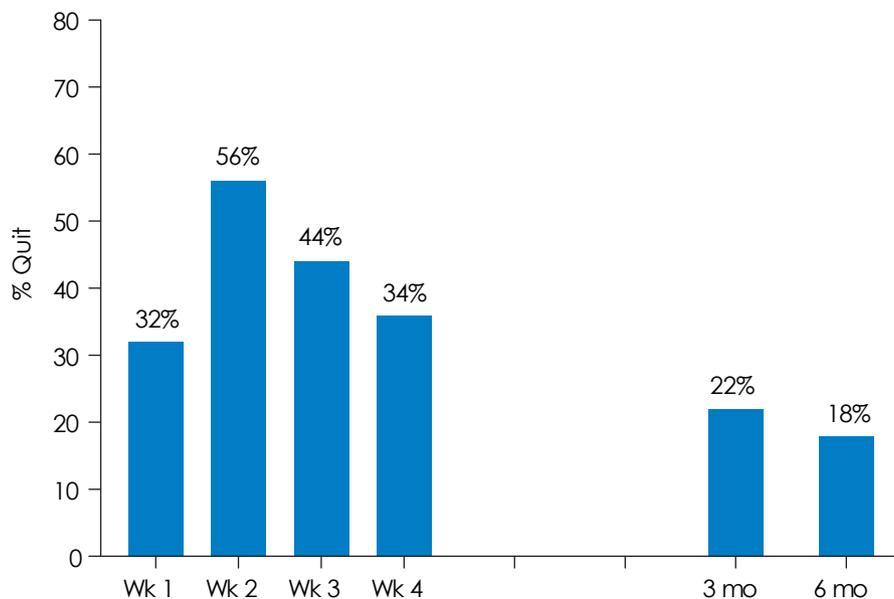
### Acceptability: Program and Therapist Evaluation

Participant ratings of the perceived helpfulness of the eight program elements varied. Self-monitoring wrap sheets had the lowest perceived helpfulness ratings (29% of the participants rated it as very effective to extremely effective, i.e., a 4 or 5 on the five-point scale), and deep breathing had the highest ratings (71% rated it as very effective to extremely effective). The other six elements (CO, avoid-alter-substitute, weight and health, etc.) were intermediate, i.e., 47–68% of participants rated these elements as very to extremely effective. In terms of therapist ratings, the majority of participants (82%) agreed or strongly agreed that their therapist was highly competent (i.e., average rating of  $\geq 4$  on the five-point scale). Therapist competency ratings did not differ based on therapist sex or race/ethnicity.

### Outcome: Quit Rates

Using intent-to-treat analyses, self-reported point-prevalence quit rate at one month was 36% ( $n=18/50$ ). Since confirmation of quit status by CO breath test was not available for one subject, the official biochemically confirmed quit rate was 34% ( $n=17/50$ ). Examin-

**Figure 1. Biochemically confirmed point prevalence quit rates**



Point-prevalence quit rates through the first four weeks of treatment. Point prevalence is defined as not smoking even one puff during the seven days prior to the assessment and confirmed by expired air CO  $\leq 6$  PPM.

ing the week-by-week variation revealed that the peak biochemically confirmed quit rates were observed two weeks after the quit date (56%;  $n = 28/50$ ) (Figure 1). At three- and six-month follow-up, biochemically confirmed point-prevalence quit rates at follow-up were 22% (11/50) and 18% (9/50).

### Outcome: Withdrawal, Craving and Depression in Early Stages of Treatment

Withdrawal symptoms scores as assessed by the Minnesota Withdrawal Scale were generally in the low-to-moderate range and did not significantly decrease from the quit date through the end of the first month of treatment [ $X = 3.98 + 0.5$  to  $3.2 + 0.6$ ],  $p = ns$ ]. However, ratings of smoking urges from the Brief Questionnaire of Smoking Urges scale showed a significant decline over the first month of treatment [baseline =  $30.4 + 2.3$  to one month =  $18.7 + 2.2$ ,  $F(1, 39) = 18.62$ ,  $p < 0.001$ ]. BDI scores also significantly decreased during the first month of treatment [ $X = 7.9 + 1.1$  to  $2.5 + 0.5$ ,  $F(1, 40) = 19.16$ ,  $p < 0.0001$ ].

### Predictors of Quit Status

Results of analyses examining the relationships among demographic, smoking, and treatment factors to quit rates revealed that lower depression scores [ $\beta(SE) = -0.06 (0.03)$ ,  $p < 0.05$ ], higher nicotine patch adherence [ $\beta(SE) = 0.80 (0.33)$ ,  $p = 0.02$ ] and higher perceived helpfulness ratings of wrap sheets [ $\beta(SE) = 0.40 (0.18)$ ,  $p = 0.02$ ] all significantly predicted quitting success during the first month of treatment. However, when each of the three variables were included in an overall model, no single factor was predictive of smoking cessation except that the effect of perceived helpfulness ratings of wrap sheets was marginally significant [ $\beta(SE) = 0.33 (0.19)$ ,  $p = 0.08$ ]. This was likely due to the high intercorrelation among some of these variables (for instance, wrap sheets rating with depression,  $r = -0.38$ ;  $p = 0.02$ ; wrap sheets and patch adherence,  $r = 0.31$ ;  $p = 0.06$ ) and the relatively small sample size in the study.

## DISCUSSION

Given the relative dearth of African-American participants in formal smoking cessation treatment programs, clinical practice guidelines have set forth priorities for increasing their enrollment and participation in efficacious treatments.<sup>11</sup> The treatment provided in this pilot study was consistent with practice guidelines and included intensive behavioral treatment as well as offering nicotine replacement to all eligible participants. In sum, the current study provides initial support for the feasibility and acceptability of a community-delivered comprehensive smoking cessation program in low- and middle-income, urban African-American smokers. In addition, the results indicate positive early outcome indicators of

this intervention in terms of quit rates (one-third quit at four weeks) as well as significant reductions in smoking urges and depressive symptoms during that interval.

Point-prevalence quit rates observed in the current study combining group behavioral therapy and nicotine patch (34% at four weeks, and 22% and 18% at three- and six-month follow-up, respectively) were higher than reported in prior studies of African-American smokers receiving less intensive counseling or no pharmacotherapy,<sup>29,30</sup> or receiving counseling and education with nicotine replacement in the form of gum (6% at eight weeks and 8% at six months).<sup>27</sup> Quit rates in the present study are comparable to another study utilizing a different adjunctive pharmacotherapy (bupropion) with motivational counseling with African-American smokers (36% at seven weeks and 22% at six months).<sup>28</sup> The highest quit rates in African Americans have been observed in a multicomponent intervention employing behavioral/empowerment counseling, nicotine patches, and social support and spiritual well-being counseling with community health workers for up to six months (49% at six weeks, 39% at six months).<sup>22</sup> Together, these results show promise for improving smoking cessation outcomes in low-to-middle-income African Americans. Intensive behavioral smoking cessation interventions combined with pharmacotherapy appear to yield higher cessation rates than less-intensive interventions, consistent with findings in non-African-American samples.<sup>11</sup>

In terms of feasibility, the majority of those who attended the orientation session (approximately 80%) enrolled in the study and, of those who enrolled, 74% completed treatment. While attendance rates were lower at three- and six-month follow-up (64% and 56%, respectively), retention of study participants was consistent with the extant literature involving African-American smokers.<sup>16,21-23,28,46</sup> Retaining African-American smokers for long-term follow-up will be essential for understanding factors associated with maintenance of smoking abstinence as well as relapse. The issue of extended retention is also particularly important in terms of codifying longer-term quit rates, as nonattendees and those unable to provide CO breath tests were conservatively classified as relapsed, which may result in some false negatives.<sup>58,59</sup> The highest retention rates in African-American smokers (i.e., 87% at six months) employed extended social support through six months at the time point when follow-up data were collected and financial compensations were distributed.<sup>22</sup> Such methods may provide a useful model for enhancing retention for future research in ethnic minority smokers. Therefore, taken together, the findings of the current study as well as prior studies suggest that a strong focus on retention strategies should be undertaken in future research. Potential approaches may include providing cost-effective maintenance programs such as involvement of community health workers, providing more frequent follow-up or booster sessions, and/

or providing greater monetary incentives after continued participation.

Acceptability of the intervention was established through positive evaluations of the program therapists. Ethnic matching of therapists and patients has been identified as an important component in successfully treating ethnic minorities.<sup>60</sup> Although the present study did not specifically match therapist race, ethnicity or sex to those of the participants, such factors did not appear to have an impact upon therapist competency ratings or quit rates. We may speculate that this was due, in part, by holding the treatment session in African-American settings, utilizing highly trained master's-level therapists, frequent supervision by a licensed psychologist (King), and addressing cultural competency as a part of therapist training and supervision. It remains to be seen if therapist sex, race or ethnicity matters in terms of acceptability or quit rates in trials utilizing not-as-highly trained providers or held in locations outside of African-American communities. Other research has focused on the issue of the cognitive match between therapists and patients.<sup>60</sup> Although there is a need to increase the ethnic diversity of treatment providers, equally important is a need for therapists to understand the cultural values and worldviews of their patients.<sup>60</sup> A good cognitive match between the participant and therapist combined with credible, empathic and competent counseling are likely as critical to treatment acceptability and outcomes as ethnic matching alone.

Acceptability was also established by positive ratings of all eight treatment elements (half or more of the participants rated each of the elements as helpful). Although self-monitoring wrap sheets had the lowest perceived helpfulness rating of all the eight elements, higher ratings of perceived helpfulness for wrap sheets were associated with greater success in smoking cessation. This finding underscores the potential importance of behavioral strategies for increasing smoking cessation outcomes and preventing relapse.<sup>61</sup> Other expected predictors of positive outcome, such as greater adherence to nicotine patch and lower depressive symptoms, were also indicative of higher quit rates, supporting findings from past studies in general smokers.<sup>62-64</sup> Urban, low-income African-American women may be a particular high-risk group for depression, because of living under stressful conditions and perceptions of smoking for mood management.<sup>65</sup> Participants experiencing even subclinical depressive symptoms may be less able to engage in and benefit from treatment techniques that require behavioral activation.<sup>66</sup> The self-monitoring wrap sheets require concentration, attention to detail and perseverance, and these factors may account for the strong relationship between greater depressive symptoms and lower perceived helpfulness of wrap sheets, both of which related to lower success in quitting smoking.

There are several strengths to this study. First, this

study tested the initial outcome of a multicomponent treatment program, including nicotine patch and an intensive six-session group intervention utilizing cognitive, behavioral and motivational interviewing techniques. With only a few exceptions, the majority of prior studies in African-American smokers have not included a combination of behavioral treatment and pharmacotherapy. Second, the study employed biochemical verification of self-reported quit rates, which is an element missing in many past studies in African-American smokers. Third, the intervention was delivered in a community setting using novel recruitment approaches (e.g., school-based recruitment). Prior research indicates that a community-based approach may increase recruitment<sup>22,67</sup> and smoking cessation quit rates.<sup>22</sup>

Despite the considerable strengths of this study, there were several limitations which should be borne in mind when interpreting the findings. First, we conducted a single-group pilot study examining primarily feasibility and acceptability endpoints. As such, we did not include a control condition or randomize participants to the intervention. Both of these factors limit the internal validity of the study. Second, there may be limitations concerning the generalizability of our sample. Study participants were a convenience sample of unknown representation to African-American smokers in our catchment area. Further, the majority of participants were low- or middle-income, urban African Americans with at least a high school education, and we are unable to generalize the results of this study to rural African Americans or those at the lowest or highest levels of education or income. Consistent with the literature, the majority of participants were middle-aged African American women. The oversampling of women may be due to an artifact of our recruitment methods (e.g., school based) and that women are more likely than men to express a preference for formal smoking programs and groups.<sup>68</sup> Post-hoc analyses of the five males in the study revealed similar results to the overall sample: 60% (n=3/5) completed the first month of treatment and were highly adherent with the patch, with 40% (n=2/5) and 20% (n=1/5) having successfully quit at one and six months, respectively. Additional research is warranted to identify more effective recruitment techniques to encourage African-American men to enroll in smoking cessation treatment. Third, another limitation is the lack of a randomized study design to investigate the efficacy of patch versus a placebo or specific behavioral treatment components in African-American smokers. Such an investigation was beyond the scope of this initial pilot trial but would be important in future research. Fourth, future smoking cessation intervention studies should collect and analyze nicotine replacement patch adherence as a continuous variable, rather than as only a dichotomous variable. Although we chose this more conservative method, examining patch adherence as a con-

tinuous variable may be useful in terms of examining the range of nicotine replacement compliance to outcome. Fifth, although this intervention was highly acceptable to participants, long-term retention and cessation rates were modest. Studies show that culturally targeted interventions can improve recruitment and health outcomes with ethnic minorities.<sup>69</sup> Recent research<sup>23</sup> also points to the need to continue to develop culturally targeted interventions for African-American smokers, an area that our research team is currently pursuing.

In summary, there is a relative dearth of community-based, comprehensive smoking cessation interventions for African Americans. The National Medical Association recently reviewed this topic and set forth recommendations to improve cessation rate and reduce harmful effects of smoking in African Americans.<sup>70</sup> This pilot study makes an important first-step contribution to the literature on the feasibility, acceptability and early outcome indicators of a comprehensive community-based intervention in African-American smokers. Future smoking cessation studies in African Americans are needed to focus on early identification of depressive symptoms, techniques to enhance continued nicotine patch use, and potential targeted or culturally tailored treatment, as well as controlled randomized designs to examine specific factors that enhance smoking cessation in underserved African-American smokers.

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## AUTHOR'S NOTE

Although the term "African American" is used throughout this manuscript, the authors acknowledge that there is great heterogeneity within this classification. African American refers to those persons who self-identify as African American or black and whose ethnic origins can be traced to the black ethnic groups of Africa.

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