A Culturally Targeted Smoking Cessation/HIV Medication Adherence

Intervention for African American MSM

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DISSERTATION

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This dissertation is dedicated to my mother. I would not have gotten anywhere in
my life without you.
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# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>CHAPTER</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.  INTRODUCTION</td>
<td>1</td>
</tr>
<tr>
<td>A. Overview</td>
<td>1</td>
</tr>
<tr>
<td>B. The Present Study</td>
<td>11</td>
</tr>
<tr>
<td>C. Specific Aims</td>
<td>12</td>
</tr>
<tr>
<td>II. METHOD</td>
<td>13</td>
</tr>
<tr>
<td>A. Recruitment and Retention</td>
<td>13</td>
</tr>
<tr>
<td>B. Phase 1</td>
<td>14</td>
</tr>
<tr>
<td>C. Phase 2</td>
<td>15</td>
</tr>
<tr>
<td>1. Setting</td>
<td>16</td>
</tr>
<tr>
<td>2. Intervention materials and curriculum</td>
<td>16</td>
</tr>
<tr>
<td>3. Treatment Flow</td>
<td>17</td>
</tr>
<tr>
<td>4. Intervention staff and training</td>
<td>18</td>
</tr>
<tr>
<td>D. Measures</td>
<td>19</td>
</tr>
<tr>
<td>III. RESULTS</td>
<td>22</td>
</tr>
<tr>
<td>A. Focus Groups</td>
<td>22</td>
</tr>
<tr>
<td>1. Barriers to smoking cessation</td>
<td>24</td>
</tr>
<tr>
<td>2. Facilitators of smoking cessation</td>
<td>29</td>
</tr>
<tr>
<td>3. Barriers to medication adherence</td>
<td>33</td>
</tr>
<tr>
<td>4. Facilitators of medication adherence</td>
<td>36</td>
</tr>
<tr>
<td>B. Intervention Development</td>
<td>36</td>
</tr>
<tr>
<td>C. Pilot</td>
<td>41</td>
</tr>
<tr>
<td>1. Feasibility analyses</td>
<td>41</td>
</tr>
<tr>
<td>2. Demographics</td>
<td>43</td>
</tr>
<tr>
<td>3. Acceptability</td>
<td>47</td>
</tr>
<tr>
<td>4. Treatment outcomes: Smoking</td>
<td>47</td>
</tr>
<tr>
<td>5. Treatment outcomes: Medication adherence</td>
<td>49</td>
</tr>
<tr>
<td>IV. DISCUSSION</td>
<td>51</td>
</tr>
<tr>
<td>1. Lessons learned</td>
<td>53</td>
</tr>
<tr>
<td>2. Limitations</td>
<td>56</td>
</tr>
<tr>
<td>3. Conclusion</td>
<td>58</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>60</td>
</tr>
<tr>
<td>APPENDICES</td>
<td>79</td>
</tr>
<tr>
<td>Appendix A</td>
<td>80</td>
</tr>
<tr>
<td>Appendix B</td>
<td>83</td>
</tr>
<tr>
<td>Appendix C</td>
<td>98</td>
</tr>
<tr>
<td>Appendix D</td>
<td>103</td>
</tr>
<tr>
<td>Appendix E</td>
<td>107</td>
</tr>
</tbody>
</table>
TABLE OF CONTENTS CONTINUED

Appendix F ................................................................. 113
VITA ............................................................................. 117
# LIST OF TABLES

<table>
<thead>
<tr>
<th>TABLE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. DEMOGRAPHICS</td>
<td>23</td>
</tr>
<tr>
<td>II. FOCUS GROUP RATINGS OF INTERVENTION</td>
<td>41</td>
</tr>
<tr>
<td>III. PARTICIPANT DEMOGRAPHICS AT BASELINE</td>
<td>45</td>
</tr>
<tr>
<td>IV. SMOKING CHARACTERISTICS</td>
<td>46</td>
</tr>
<tr>
<td>V. MEDICATION ADHERENCE CHARACTERISTICS</td>
<td>46</td>
</tr>
<tr>
<td>VI. MEAN DAILY CIGARETTE USE, CO READINGS, AND SMOKING RELATED VARIABLES OVER TIME</td>
<td>49</td>
</tr>
<tr>
<td>VII. MEDICATION ADHERENCE OVER TIME</td>
<td>50</td>
</tr>
</tbody>
</table>
# LIST OF FIGURES

<table>
<thead>
<tr>
<th>FIGURE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Treatment flow</td>
<td>17</td>
</tr>
<tr>
<td>2. Standard and culturally targeted intervention elements</td>
<td>38</td>
</tr>
<tr>
<td>3. Participant flow</td>
<td>42</td>
</tr>
</tbody>
</table>
LIST OF ABBREVIATIONS

MSM  Men who have Sex with Men
SUMMARY

African American men who have sex with men (MSM) accounted for the highest rate of HIV infections and AIDS cases in the US. African American HIV-infected MSM also report lower levels of antiretroviral adherence than Caucasian MSM. Poor medication adherence is associated with poor outcomes, including progression of HIV to AIDS and increased mortality as well as increasing infectivity in an unprotected sexual encounter. The negative effects of medication non-adherence are likely exacerbated by additional health behaviors, such as tobacco use. Tobacco use is more common among MSM than in the general population. Several factors may make African American HIV-infected MSM more vulnerable to the negative effects of tobacco use than other HIV-infected populations including access to healthcare, lower medication adherence, and higher rates of comorbid health factors such as diabetes and high blood pressure. The purpose of this study was to develop and assess the feasibility and acceptability of a group-based culturally targeted intervention for African American HIV-infected men to address both smoking cessation and HIV antiretroviral adherence. During the development phase of the study, focus groups suggested several distinct barriers to and facilitators of smoking cessation and medication adherence for this vulnerable population. These themes were incorporated into a single intervention based on an established smoking cessation intervention (Courage to Quit, King & Riley, 2001) and a treatment adherence intervention (Treatment Advocacy Program, McKirnan, Tolous-Shams, & Courtenay-Quirk, 2010). Pilot study (n=10) findings suggested the intervention was acceptable to participants. Eighty percent of participants came to more than half the intervention visits and the 1-month and 3-month follow-ups. Three of the eight participants that attended
SUMMARY

follow-ups reported biochemically verified quit rates at the 3-month follow-up. All participants that attended the follow-ups reported medication adherence rates above 95% at the 3-month follow-up. Findings from this formative study suggest this culturally targeted intervention can be effective for both smoking cessation and medication adherence. However, significant structural barriers to recruitment negatively affected the feasibility of this intervention. Future studies of this intervention should be deeply integrated in an establish clinic that serves African American HIV-infected men. Community-based organizations should be engaged for effective recruitment strategies and community education.
I. Introduction

A. Overview

Medication adherence among African-American men who have sex with men

Men who have sex with men (MSM) continue to have a disproportionately high rate of HIV infection, accounting for approximately 45% of new HIV diagnoses in the Chicago area (Christiansen & Benbow, 2005). Despite only comprising 12% of the total US population, African Americans account for 44% of all people living with HIV (CDC, 2011). In 2010, African American MSM accounted for the highest rate of HIV infections and AIDS cases in the US (CDC, 2011). The prevalence of HIV among African American MSM is some ten times higher than that of Caucasian MSM (CDC, 2011). HIV-infected African American men also show elevated rates of tobacco use and have the poorest treatment outcomes of HIV-infected populations (CDC, 2008).

Successful antiretroviral treatment requires strict adherence to the treatment regimen (Department of Health and Human Services, 2014). Antiretroviral drugs prevent HIV from replicating through a number of mechanisms, all of which require steady blood levels of the drug. Unlike other chronic conditions such as diabetes or hypertension, where significant clinical effects can be seen at 70 – 80% regimen adherence, HIV regimens require a very high level of adherence (90-95%) for full effectiveness (Bangsberg, 2006; Ho, Bryson, & Rumsfeld, 2009; Paterson et al., 2000).

Poor adherence to HIV treatment allows the virus to quickly replicate, leaving patients susceptible to opportunistic infections and some cancers, as well as further destruction of the immune system. A key element of HIV treatment (and treatments for other infectious diseases, e.g., tuberculosis) is the development of medication resistance
Partial or inconsistent dosing of antiretroviral drugs allows more virulent and medication resistant strains of the virus to proliferate (Department of Health and Human Services, 2014). Poor medication adherence is associated with poor outcomes, including progression of HIV to AIDS and increased mortality (Arnsten et al., 2001; Howard et al., 2002; McNabb et al., 2001; Hogg et al., 2002) as well as increasing infectivity in an unprotected sexual encounter (Suzanna, Matthias, Monika, Zwahlen, & Low, 2009; Wilson et al., 2008).

While pinpointing exact rates of adherence among African American and Caucasian MSM is difficult, in several studies African American MSM reported lower levels of adherence than did Caucasian MSM (Beer, Oster, Mattson, & Skarbinski, 2014; Hall, Holtgrave, Tang, & Rhodes, 2013; Halkitis et al., 2003; Halkitis, Palamar, & Mukherjee, 2008; Johnson et al., 2003). Proposed psychological factors underlying this health disparity include lack of self-efficacy for coping with HIV and managing medications, substance use, intimate partner violence, and structural barriers including lack of access to care and tenuous housing (Beer et al., 2014; Berger, Ferrans, & Lashley, 2001; Levy et al., 2014). This lower adherence leads to an increased amount of HIV in the bloodstream (higher “viral load”), making the onset of AIDS quicker and sexual encounters more likely to transmit the virus.

Poorer treatment adherence among African American MSM increases the likelihood of drug-resistant strains of HIV in the population. Interventions to increase adherence in this population are desperately needed. While some interventions have addressed treatment adherence among HIV-infected MSM in general (McKirnan, Tolou-Shams, & Courtenay-Quirk, 2010; McPhereson-Baker et al., 2000; Purcell et al., 2007),
there is a paucity of research specifically addressing African American MSM. The negative effects of medication non-adherence are likely exacerbated by additional health behaviors, such as tobacco use.

*Tobacco use among HIV-infected African-American MSM*

As the survival time of HIV-infected individuals increases, general health promotion is an emerging area of need. Tobacco use is more common among MSM than in the general population (Alvy et al., 2011; Gruskin, Greenwood, Matevia, Pollak, & Bye, 2007; McKirnan et al., 2006; Ryan, Wortley, Easton, Pederson, & Greenwood, 2001; Tang et al., 2004). Smoking is generally elevated among HIV-infected individuals (Webb, Vanable, Carey, & Blair, 2007), and HIV-infected MSM in particular (Robinson, Brown, & Moody-Thomas, 2014; Stall, Greenwood, Acree, Paul, & Coates, 1999).

Overall, African-American men smoke at about the same rate as Caucasians, although African-Americans show greater likelihood of lung cancer despite smoking fewer cigarettes on average (American Lung Association, 2014; Garrett et al., 2011). There are few – and mixed – findings concerning African-American versus Caucasian smoking rates specifically for HIV-infected MSM (Webb et al., 2007). Although no evidence demonstrates that African-American HIV-infected MSM smoke more than their Caucasian counterparts, several factors may make them more vulnerable to the negative effects of tobacco use than other HIV-infected populations. These include lower access to healthcare (Alvy et al., 2011; McKirnan et al., 2013), lower medication adherence (Hall, Holtgrave, Tang, & Rhodes, 2013; Halkitis et al., 2003; Halkitis, Palamar, & Mukherjee, 2008; Johnson et al., 2003), and higher rates of comorbid health factors such as diabetes (Krauskopf et al., 2013) and high blood pressure (Krauskopf et al., 2013; Seaberg et al.,
2005). Underlying psychosocial factors that lead to increased smoking among MSM generally include cultural acceptability, depression, alcohol use, and minority stress (Hamilton & Mahalik, 2009; Offen, Smith, & Malone, 2008; Matthews, Vargas, Kuhns, Shappiva, & King, 2014; McKirnan et al., 2006).

Approximately 50% to 70% of HIV-infected individuals report smoking (Mamary, Bahrs, & Martinez, 2002; Webb et al., 2007; Tesoriero, Gieryic, Carrascal, & Lavigne, 2010). HIV-infected populations are particularly vulnerable for the negative health outcomes of smoking. Tobacco use among HIV-infected people has been associated with a number of poor health outcomes such as mortality and increased incidence of AIDS defining illnesses (Clifford et al., 2005; Crothers et al., 2005; Miguez-Burbano et al., 2005). Smoking increases the risk of developing AIDS and non-AIDS related cancers including cervical, anal, lung, and neck cancers (Palefsky et al., 1999; Palefsky, Shiboski, & Moss, 1994; Tirreli et al., 2000). Additionally, HIV-infected people are at increased risk for developing cardiovascular disease; smoking significantly increases this risk in HIV-infected individuals receiving prolonged antiretroviral treatment (Islam, Wu, Jansson, & Wilson, 2012; Petoumeno et al., 2011). Smoking may also reduce the benefits of antiretroviral medications (Clifford et al., 2005).

The clinical significance of reducing smoking among African American MSM who are infected with HIV is further underscored when one considers the association of smoking with immunological changes and risk for certain infections, including the non-HIV sexually transmitted infections, and human papilloma virus (HPV), which is associated with anal cancer (Palefsky et al., 1999). The additional psychosocial variables associated with smoking in this population combined with poor outcomes and increased
mortality rates indicate that smoking cessation and HIV medication adherence clearly need to be addressed in a single, culturally targeted intervention for this population.

_Mechanisms of tobacco use and medication adherence_

A significant behavior change, such as quitting smoking or starting an effortful medication regimen, can be highly stressful (Bock et al. 2014; Davis, Manley, Goldberg, Smith, & Jorenby, 2014; Matthews et al., 2014; McKirnan et al., 2010). Smoking cessation requires the inhibition of highly automatic, very rewarding behaviors (Matthews et al. 2013; Darlow & Lobel, 2012). In contrast, an HIV diagnosis requires that new behaviors be formed to adhere to a difficult antiretroviral regimen (McKirnan et al., 2010). The stress associated with interrupting or creating automatic health behaviors can be aversive (Bock et al., 2014; Davis et al., 2014; Matthews et al., 2014).

Receiving an HIV diagnosis requires both psychological adjustment and the development of new coping mechanisms. Strategies for coping with illness may be viewed as falling into two broad categories: Instrumental (or active) and avoidant (affective) coping (Folkman & Lazarus, 1986; Smith et al., 2001). Instrumental coping consists of active, positive strategies such as information seeking, cognitive restructuring, and problem-solving (Kotze, Visser, Makin, Sikkema, & Forsyth, 2013). These positive strategies are associated with increases in positive emotions (Folkman & Lazarus, 1988). Instrumental coping strategies are associated with positive outcomes in HIV treatment and decreased psychosocial stress associated with an HIV diagnosis (Chida & Vedhara, 2009; Deichert, Fekete, Boarts, Druley, & Delahanty, 2008; Kraaij et al., 2008).

Deichert et al. (2008) used the Ways of Coping Scale (Folkman & Lazarus, 1986) to measure active coping in an HIV-infected population, and found active coping to be
associated with positive affect, self reports of improved health, and less depression. The Ways of Coping Scale assesses 13 coping mechanisms including, but not limited to, seeking social support, accepting responsibility, planful problem solving, and positive reappraisal (Folkman & Lazarus, 1986). Kraaij et al. (2008) found that cognitive coping mechanisms such as positive refocusing, reappraisal of values, goal reevaluation, and goal reengagement were negatively associated with depression and anxiety in HIV-infected MSM. In their review of 37 articles, Chida & Vedhara (2009) concluded that active coping strategies among HIV-infected people were directly associated with less psychosocial stressors and slower HIV disease progression compared to avoidant coping strategies.

People employing avoidant coping strategies may disengage from treatment to lessen the negative affect associated with an HIV diagnosis; they will use strategies such as denial and distraction (Chida & Vedhara, 2009; Deichert et al., 2008). Avoidant coping, such as catastrophizing about diagnosis and blaming others for one’s HIV status, is associated with poor outcomes including non-adherence to antiretroviral treatment, increased substance use, and HIV disease progression (Kraaij et al., 2008; Pence et al., 2008; Vervoort, Grypdonck, de Grauwe, Hoepelman, & Borleffs, 2009). Avoidant coping is also associated with using smoking as a coping mechanism (Bricker, Schiff, & Comstock, 2011); many smokers report their tobacco use helps them cope with stressors (Alvy et al., 2011; Kassel, Stroud, & Paronis, 2003; Matthews et al., 2014; McKee et al., 2011) and serves a number of other functions such as promoting sociability (Matthews et al., 2014). Thus, it is particularly important for any intervention to increase medication adherence and promote smoking cessation to teach instrumental coping strategies.
Self-efficacy has long been associated with instrumental coping with health changes (Alvy et al. 2011; Heitzmann et al., 2011; Phillip, Merluzzi, Zhang, & Heitzmann, 2013; Bandura, 1998). Coping self-efficacy, defined here as the self-perception that one has the capability to cope with stress associated with health changes, is associated with improvements in health outcomes and quality of life for a variety of conditions: e.g., cancer (Philip et al., 2013); multiple sclerosis (Ng et al., 2013); and heart failure (Graven & Grant, 2013). Smoking cessation interventions that enhance self-efficacy to make behavior change have also demonstrated success (Fiore et al., 2008; Hyde, Hankins, Deale, & Marteau, 2008; Matthews, Conrad, Kuhns, Vargas, & King, 2013; O’Hea et al., 2004). Clearly, increasing self-efficacy by teaching instrumental coping strategies is necessary for an intervention promoting smoking cessation and medication adherence.

*Techniques to change key study variables*

An intervention technique that appears to be effective in facilitating self-efficacy and instrumental coping for health care change is motivational interviewing (King & Riley, 2001; O’Hea et al., 2004; Louwagie, Okuyemi, & Ayo-Yusuf, 2014). Motivational interviewing has been shown to be an effective intervention for a range of health behaviors, including medication adherence (Cooperman et al., 2012; Miller, 2012; Raja, McKirnan, & Glick, 2007, Vanable, Ostrow, & McKirnan, 2003), increasing exercise and improving diet in cardiovascular patients (Miller, 2012), and improving diabetes management (Chen, Creedy, Lin, & Wollin, 2011).

Motivational interviewing, developed initially by Miller (1983), is a patient-centered approach that focuses on a patient’s perceptions, motivations, and values to
resolve ambivalence toward behavior change (Miller, 2004). Behavior change is difficult: It requires individuals to forgo immediate and concrete rewards associated with pleasure of the addictive substance or risky behavior, for the longer-term, more abstract health benefits of lessening or quitting the behavior (Murphy et al., 2012a; Murphy et al., 2012b). A core premise of motivational interviewing is that ambivalence about behavior change inhibits change attempts (Miller, 1983). This is particularly salient for smoking; many maladies associated with tobacco use, such as emphysema (Morse & Rosas, 2014), occur typically after an extended period of smoking and are often discounted for the immediate pleasures associated with smoking (Mitchell & Wilson, 2012). Motivational interviewing assumes that individuals ultimately have values for health and well-being that are consistent with behavior change, hence the initiation of change requires a clear articulation of those longer-term values or motivations. Promoting change with behavioral strategies in a non-judgmental fashion while articulating client long-term values is at the core of motivational interviewing (Miller, 2004).

In smoking cessation interventions using motivational interviewing, counselors express empathy for patients’ ambivalence by eliciting motivations for both smoking cessation and continuation (Heckman, Egleston, & Hoffman, 2010; Riley & King, 2001). Counselors assess whether smoking is congruent or incongruent with patients’ long-term core values (Heckman et al., 2010). Motivational interviewing, in combination with specific behavioral strategies, addresses this incongruence and focuses on increasing an individual’s self-efficacy for meeting long-term goals. Motivational interviewing has been shown to be effective in lessening smoking among HIV-infected populations in
three pilot studies (Heckman et al., 2010; Manuel, Lum, Hengl, & Sorensen, 2013; Matthews et al., 2013).

Motivational Interviewing attempts to resolve patients’ ambivalence via a “small gains” approach. Positive feedback about reaching initial, even small behavioral goals is hoped to increase self-efficacy for larger changes. I hypothesized that experiencing success with behavior change with either smoking cessation or increased medication adherence should increase patients’ general self-efficacy for effectively coping with their health condition. This increase in self-efficacy should allow a person to engage in increased instrumental coping. This will create a self-sustaining loop: Increased self-efficacy with smoking or medication adherence increases the occurrence of instrumental coping. This increase in instrumental coping and continued success with making a behavior change will then increase self-efficacy.

For this study I developed and conducted a pilot test of a health behavior intervention to simultaneously target medication adherence and smoking cessation among HIV-infected African American MSM. The intervention draws on motivational interviewing techniques to decrease ambivalence, increase positive change motivation, and clarify behavioral goals.

*Previous tobacco cessation and medication adherence interventions*

Despite the need for smoking cessation targeted to the needs of African American HIV-infected men, little research has been conducted to address the needs of this group. Intervention development for smoking cessation for HIV-infected individuals is limited primarily to pilot studies (Moscou-Jackson, Commodore-Mensah, Farley, & DiGiacomo, 2014; Matthews et al., 2013). Generally, smoking cessation interventions that delivered
motivational interviewing, that were composed of several structured sessions, and that promoted access to targeted care were found to be effective (Moscou-Jackson et al., 2014).

Recent research suggests that culturally targeting a smoking cessation intervention for HIV-infected African American MSM leads to significantly better outcomes (Matthews et al., 2013; Matthews et al., 2014). Courage to Quit (CTQ) is a group-based smoking cessation intervention steeped in motivational interviewing developed at the University of Chicago, currently being administered by the Respiratory Health Association of Metropolitan Chicago (King & Riley, 2001). In Project Exhale, CTQ was targeted for HIV-infected African American MSM in conjunction with nicotine replacement therapy (NRT) using cultural targeting techniques set by Kreuter et al. (2003). In the small pilot-study, approximately 24% of participants had successfully quit at 3-month follow up and there was a significant reduction in number of cigarettes among the remainder of the participants (Matthews et al., 2013). This quit rate is comparable to the quit rates in the general population of smokers that use the standard version of CTQ (Respiratory Health Association of Metropolitan Chicago, 2014).

Given the many barriers to smoking cessation among HIV-infected African-American MSM, raising their quit rates to baseline quit rates of the general population suggests the culturally targeted curriculum is effective in reducing smoking disparities experienced by African American MSM. The culturally targeted Project Exhale CTQ curriculum was implemented in this project with additional information from new focus groups and combined with an HIV medication adherence intervention.
Medication adherence interventions for African Americans and MSM

Intervention content addressing medication adherence will be drawn from the Treatment Advocacy Program (TAP), conducted by my advisor, Dr. David McKirnan (McKirnan, Tolou-Shams, & Courtenay-Quirk, 2010). The intervention, based on motivational interviewing, education, and peer support, is designed to increase HIV medication adherence and overall coping with HIV. A version of TAP has been specifically targeted for low-income African American men and women (Raja, McKirnan, & Glick, 2007).

B. The Present Study

This study proposed to develop and pilot-test a culturally targeted intervention for smoking cessation and HIV medication adherence among African American HIV-infected MSM that have reported difficulty with medication adherence. I specifically limited my sample to men that have reported difficulty with medication adherence to capture men that may benefit most from the intervention. These participants will likely describe barriers to and side effects of medications with this eligibility criterion.

Recent studies suggest that addressing multiple health behaviors simultaneously will increase successful outcomes (Prochaska & Sallis, 2004; Prochaska, Spring, & Nigg, 2008); increasing self-efficacy and self-regulatory capacity for changing one health behavior may increase capacity for changing other health behaviors (Bandura, 2004; Schwarzer, 1999). In this light, I anticipated that providing self-efficacy and coping skills to reduce smoking should bolster skills and confidence in adhering to HIV medication, and vice versa.
C. **Specific Aims**

This study developed and evaluated the feasibility and efficacy of a culturally targeted intervention to promote smoking cessation and treatment adherence among African American men who have sex with men. This intervention targeted men who have demonstrated difficulty with antiretroviral medications (defined as reporting missing or skipping doses or generally struggling with taking medications) and are current smokers (More than 5 packs in lifetime AND past year smoking AND 4 or more days per week). Secondary aims were to examine individual and cultural variables that underlie any effects of the intervention.

*Aim 1: Identify culturally specific barriers and facilitators of smoking cessation and HIV medication adherence among HIV-infected African American men who have sex with men.*

*Aim 2: Develop a culturally targeted intervention that addresses HIV medication adherence and smoking cessation.*

*Aim 3: Conduct a pilot-test of the intervention to assess its acceptability and feasibility.*
II. Method

This study consisted of two phases; a six-month developmental phase consisting of focus groups and cultural adaptation of the intervention, and an 11-month pilot phase to evaluate the feasibility and effectiveness of the targeted program.

A. Recruitment & Retention

The main recruitment venue was the primary care clinic at Howard Brown Health Center (HBHC). I also recruited at the UIC Infectious Diseases Clinic. I used passive (flyers, word of mouth), and active recruitment (presence at HBHC Clinic, HBHC study database, presence at LGBT and African American events).

Both clinics posted IRB approved flyers on site. Medical staff at HBHC, primarily medical assistants and nurses, invited smokers to fill out a form indicating their interest in smoking cessation services. Potential participants were given the option to indicate interest in the present study on this form. These forms were then filed in lockboxes for study staff to pick up. Potential participants were called to complete the 10-15 minute screening interview designed to collect demographic information, contact information, general medical condition, antiretroviral medication use, and smoking history. Potential participants recruited using passive methods called a dedicated research phone line at HBHC to undergo the screening protocol. During Phase I, eligible and interested individuals were given an appointment for a focus group. During Phase II, eligible participants were given a time to complete baseline screening measures.

Participants received a $25 stipend for participating in a focus group. To increase retention in the pilot phase, participants received $25 for completing study measures at baseline and the 1- and 3- month follow-up sessions. Participants also received a weekly
stipend of $5 for each intervention session to cover expenses associated with transportation, totaling $105 for participants that attended all intervention sessions and follow-up interviews.

B. **Phase 1**

Eligibility criteria for the focus groups include; 1) Self identify as gay, bisexual, or a man who has sex with men, 2) Assigned male sex at birth and identify as male, 3) HIV-positive (self-report), 4) Have an active antiretroviral medication prescription, 5) African American, 6) Age 18-65 7) Current cigarette smoker (More than 5 packs in lifetime AND past year smoking AND 4 or more days per week). Participants were screened over the phone according to these criteria using a Screening Guide (Appendix A). Eligible participants were invited to participate in either the first focus group or both the first and second focus groups. Participants completed a questionnaire assessing demographic information, smoking history, medication history, and substance use history (Appendix B) prior to the focus groups beginning. Every participant completed the questionnaire at the first focus group. Participants in the second group were required to complete the questionnaire only if they did not participate in the first focus group. Both focus groups were recorded.

I facilitated the first focus group using a discussion guide (Appendix C) to assess the medication adherence and smoking cessation needs of this community. The goal of this group was to address basic smoking and medication adherence knowledge, culturally-specific norms, barriers, triggers, and stressors associated both with smoking and with difficulties adhering to HIV medications. In addition to a needs assessment for smoking and medication adherence, I addressed participants’ experience with previous
interventions or training for HIV adherence or smoking, and their perspective on addressing two major adherence tasks simultaneously.

I conducted a content analysis of these in-session notes to code for themes relevant to cultural barriers to and facilitators of smoking cessation and HIV medication adherence. Previous research conducted by the project applicant co-sponsors and the information attained from focus groups was then combined to alter the existing CTQ protocol using established cultural targeting techniques by Kreuter et al. (2003).

The culturally targeted curriculum was presented to another focus group to review acceptability and cultural applicability (e.g., Matthews et al., 2014). I facilitated the second focus group using a discussion guide (Appendix D) to assess the targeted intervention. Specifically, I presented exercises for participants to evaluate their usefulness, ease of understanding, how much they were liked, and how motivating the exercise was in quitting smoking and promoting medication adherence.

C. **Phase 2**

Eligibility criteria for the pilot study included; 1) Self identify as gay, bisexual, or a man who has sex with men, 2) Assigned male sex at birth and currently identify as a male, 3) HIV-infected (self-report), 4) Have an active antiretroviral medication prescription, 5) Demonstrated difficulty with antiretroviral medications, defined as reporting missing or skipping doses or generally struggling with taking medications, 6) African American, 7) Age 18-65 8) Current cigarette smoker (More than 5 packs in lifetime, past year smoking, and 4 or more days per week), 9) Desire to quit smoking (self-report rating of interest in quitting at least a 7 on a 10-point scale), 10) Agree to using nicotine replacement therapy (NRT) patches, 11) No contraindications to use of
NRT (cardiovascular disease, uncontrolled hypertension) or prior adverse reactions to NRT, 12) Currently have a primary care provider, and, 13) Agree to carbon monoxide breath monitor screening.

**Setting:** The project was conducted in the Department of Research at Howard Brown Health Center (HBHC). HBHC is the largest LGBT focused health and research center in the United States. HBHC has a fully functioning primary care clinic that regularly sees large numbers of our target population. HBHC has conducted research among high-risk, multi-ethnic HIV-infected MSM.

**Intervention materials and curriculum:** The intervention consisted of an individual counseling session at baseline, 6 group sessions, 4 support calls from the clinicians leading the group sessions, and follow-ups at 1- and 3-months. The individual session consisted of a motivational interview (Miller & Rollnick, 2002), where the participant articulated his personal values and goals for smoking cessation, medication adherence, and generally coping with HIV. The purpose of this session was to assist the participant in developing specific behavioral goals to address in the group sessions. The purpose of the support phone calls was to reiterate treatment adherence and smoking cessation goals, address barriers and trigger situations experienced between group sessions, answer participant questions, and to encourage participant attendance to group sessions.

Participants received treatment manuals that contain the complete curriculum. These workbooks included worksheets to help them identify barriers to smoking cessation and medication treatment adherence, triggers for smoking, and information
about health behavior change. In addition, participants were provided with nicotine replacement therapy (NRT) in the form of patches or gum.

_Treatment Flow:_

1. **Phone Screening**
2. **Baseline**
   - Completion of MI component
3. **Session 1**
4. **Session 2**
5. **Session 3**
   - 1 week of NRT
6. **Session 4**
   - 1 week of NRT
7. **Session 5**
   - 2 weeks of NRT
8. **Session 6/1-month follow-up**
   - 2 weeks of NRT
9. **3-month follow-up**

_Figure 1. Treatment flow._
Treatment flow is illustrated in Figure 1. Participants were screened by phone using a Screening Guide (Appendix E) to assess eligibility based on the above criteria. After screening, eligible participants were invited to completed a baseline interview to complete initial study measures and to establish full eligibility based on medical criteria (e.g., no contraindications to NRT, medication non-adherent, and CO level). I administered the motivational interviewing component to eligible participants during this visit to assess participant values regarding smoking cessation. I simultaneously worked to increase their motivation for medication adherence and smoking cessation based on these values.

Eligible participants were invited to participate in the intervention. Participants waited approximately 3 – 4 weeks for a group of an appropriate size to form (minimum n = 5) before the initiation of a group. Treatment components of the groups are described below in Results and can be seen in Figure 2. Participants received 4 support phone calls throughout the intervention at the time points illustrated in Figure 1.

NRT was initiated at Session 3 for 6 weeks total. Participants received 1 week of NRT at sessions 3 and 4. Two weeks of NRT were given to participants at session 5 due to a skip week between sessions 5 and 6. This skip week was included to give participants experience in practicing skills discussed in the intervention until that point. Participants received their final two weeks of NRT at session 6.

*Intervention staff and training:* M.A. level clinicians facilitated the group sessions. These clinicians were trained at the Respiratory Health Association of Metropolitan Chicago in the standard CTQ curriculum. They then received training in
HIV medication and adherence issues from the study clinician (a nurse recruited from the primary care clinic at HBHC).

D. Measures

*Smoking Quit Rates* were collected at every session. **Point Prevalence smoking quit rates** were derived from data obtained from Time Line Follow-Back interviews (TLFB; Brown et al., 1998; $\alpha = .80$). The TLFB is a widely used and valid interview-derived measure to assess quantities of substance use over time. Point prevalence was used as the main cessation outcome measure, and is defined as no smoking (not even a puff). At the baseline and 6-month follow-ups, this was assessed during the thirty days prior to the assessment. At the session-by-session visits, this was assessed 7 days prior to the assessment. The TLFB also facilitates measurement of continuous abstinence (abstinence period that began on quit date) and prolonged abstinence (long-term abstainers that initially slip, i.e., no smoking in the past 30 days).

**Biochemical verification** of smoking status at each weekly study visit and at post-intervention follow-up was obtained by an expired air CO breath test (Smokerlyzer, Bedfont Corp., Medford, NJ; $\alpha = .81$, sensitivity = 78%, specificity = 91%).

**Smoking Related Psychosocial variables** were collected at every session. I used The Minnesota Nicotine Withdrawal Scale (MNWS; Hughes & Hatsukami, 1986; $\alpha = .80-.85$) to determine withdrawal symptoms. It consists of eight items closely related to the DSM IV criteria for nicotine withdrawal. **The Brief Questionnaire of Smoking Urges** (B-QSU; Cox, Tiffany, & Christen, 2001; $\alpha = .89$) was used to measure urges to smoke at each visit. It is a reliable and valid 10-item shorter version of the Questionnaire of Smoking Urges (Tiffany & Drobes, 1991).
Participants completed a *Modified Time-Line Follow Back* interview (TLFB) at each visit for alcohol intake. Standardized interview techniques (i.e., use of anchor points, and other reminders to aid in recall) will be used to increase the reliability of participants’ recall. *The Smoking Abstinence Self-efficacy Scale* (DiClemente, 1981; $\alpha = 85.89$) was used to assess each participant's level of confidence in his/her ability to refrain from smoking when confronted with challenging situations. *Stage of Readiness for Smoking Cessation* was collected at baseline and 1- and 3-month follow-ups. I used The Contemplation Ladder (Biener & Abrams, 1991) to measure desire to quit. *HIV Medication Adherence Outcomes* was collected at every session. I used a 7-item adherence and adherence barriers scale commonly used in short assessments of HIV treatment adherence (McKirnan, Tolou-Shams, & Courtenay-Quirk, 2010). I administered TLFB interviews to assess day-by-day medication adherence.

I measured *Psychosocial Stress* at baseline and 1- and 3- month follow-ups using the *Perceived Stress Scale* (PSS; Cohen, Kamarck, & Mermelstein, 1983). The PSS is a 4-item reliable and valid questionnaire of one’s perceptions of the valence and impact of interpersonal and general stressors over the last month. Prior research has shown high PSS scores are associated with greater nicotine dependency and lower self-efficacy in quitting, both of which may impact cessation outcome. *Background Characteristics* were collected at baseline. *Demographic* questions include age, education, income, relationship status. Each participant completed the *Fagerstrom Test for Nicotine Dependence* (Heatherton, Kozlowski, Frecker, & Fagerstrom, 2006; $\alpha = .61$). I administered the *Michigan Alcohol Screening Test* (MAST;
Selzer, 1971) and the Drug Abuse Screening Test (DAST; Skinner, 1982). Participants also completed a baseline expired-air carbon monoxide test.

Program Evaluation measures were collected at the 1-month follow-up. I used the Therapist and Program Rating Scales (King et al., personal communication) to assess subject’s response to the intervention as possible covariates in response to the main measures of the study. Both scales were used in Project Exhale and in the development of Courage to Quit. In both Project Exhale and Courage to Quit, there was a positive association between program completion and positive ratings of therapist and program assessment.
III. Results

A. Focus Groups

*Analysis:* I conducted a content analysis of the transcription of the first focus group (n = 4) to code for themes relevant to cultural barriers to and facilitators of smoking cessation and HIV medication adherence. The accuracy of this transcription was verified by myself and an RA listening to the audio recording while reading the transcription. Content analysis was completed using QSR International’s NVivo Version 10 (2012), a software package designed specifically for qualitative analyses. Previous research completed by this student’s sponsor informed the process of thematic (Matthews et al., 2014). We used a thematic analysis of the first focus group to develop materials for the Project Adhere intervention. Specific themes are discussed below.

*Demographics:* The two focus groups were composed of 11 individuals total. The full demographic characteristics of focus group participants are displayed in Table 1.
Table I. Demographics

<table>
<thead>
<tr>
<th>Characteristic (n=11)</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (M, SD)</strong></td>
<td>41 (13.74)</td>
</tr>
<tr>
<td><strong>n</strong></td>
<td>3</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
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</tr>
<tr>
<td>Single, Never Married</td>
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</tr>
<tr>
<td>Steady Relationship</td>
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</tr>
<tr>
<td>Married, Long-term</td>
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</tr>
<tr>
<td>Relationship</td>
<td>2</td>
</tr>
<tr>
<td>Separated/Divorced</td>
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</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Romantic Partner Preference</strong></td>
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</tr>
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<td>Same Sex</td>
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</tr>
<tr>
<td>Both Sexes</td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Education</strong></td>
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<td>High School/GED</td>
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<td>Associates/Some College</td>
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<tr>
<td>Post Graduate Degree</td>
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<tr>
<td></td>
<td></td>
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<tr>
<td><strong>Employment Level</strong></td>
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<td>Unemployed</td>
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<td>Student</td>
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<tr>
<td>Part-time</td>
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</tr>
<tr>
<td>Other</td>
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<td></td>
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<td><strong>Health Status</strong></td>
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<td>Fair</td>
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<td>Good</td>
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<tr>
<td>Very Good</td>
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<tr>
<td>Excellent</td>
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</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cigarettes Smoked Daily M(SD)</strong></td>
<td>8.63 (5.48)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Days Per Week Alcohol Use</strong></td>
<td></td>
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<tr>
<td>Do not drink</td>
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</tr>
<tr>
<td>Less than 3 times monthly</td>
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<tr>
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</tr>
<tr>
<td>Daily</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Number drinks each sitting M(SD)</strong></td>
<td>2.89 (2.17)</td>
</tr>
</tbody>
</table>
Barriers to smoking cessation.

Several distinct barriers to smoking cessation were discerned during the focus group including: cultural acceptance, environmental factors, distrust of medications, emotional factors, and other substance use.

Cultural Acceptance/Environmental Factors

“Personally I think it is more acceptable in the Black community than White or Latino community.”

“Where I grew I thought it was very acceptable because everybody associated it as cool and all of that stuff...”

“I know my personal family, we all grew up smoking.”

“If you are a smoker, you are considered cool [in the gay community].”

“If you are a smoker, we have something in common. It’s like an icebreaker.”

“My first puff was like 10, my mom “boy go in there and light this on the stove...”

“You don’t have to have money to buy cigarettes these days. You can buy them off the street.”

“That is one of the easiest and most convenient addictions and cheapest.”

“It’s real easy to find loose squares on the streets.”

Generally, participants viewed smoking as normative in the African American community when compared to other populations. One participant even noted he believes smoking to be more prevalent in the Black community compared to White and Latino communities. Potentially, this perception itself could be a barrier to smoking cessation for these men. Most participants reported being reared in families where adults smoked cigarettes, and tried smoking at fairly early ages. One participant reported smoking as
early as 10 and others started at 13 or 14. Participants universally reported smoking mentholated cigarettes, reporting they are the “Black” cigarettes.

Epidemiological studies consistently show smoking rates among African Americans to be similar to that of Caucasians (American Lung Association, 2011; CDC, 2015). The mean number of cigarettes smoked per day by African Americans is actually less than that of Caucasians (American Lung Association, 2011). However, populations of lower SES have higher rates of smoking than those of higher SES (American Lung Association, 2011; American Lung Association, 2014; Businelle et al., 2010; Hiscock, Bauld, Amos, Fidler, & Munafo, 2012) and African American smokers report similar levels of nicotine addiction to Caucasians (St. Helen, Dempsey, Wilson, Jacob, & Benowitz, 2013). As the focus group participants were lower SES, their perception that smoking is prevalent in their community could be more influenced by SES than race.

While the cost of cigarettes is generally seen as a facilitator for smoking cessation, participants noted the ease and relative cheapness with which one can buy loose cigarettes on the street. This is consistent with research showing a greater prevalence of loose cigarette purchasing among African Americans compared to Caucasians (Smith et al. 2007; Stillman, Bone, Milam, Ma, & Hoke, 2014).

In addition to these men being African American, which has its own barriers to smoking cessation, these men are also part of the gay community and may be subject to additional barriers. Men noted it was easier to meet others and “hook up” as a smoker because smoking serves as a type of icebreaker. Despite the prolific PSAs about the ill effects of smoking on one’s health, one individual noted that smoking was still considered “cool.” While the ability to meet individuals within the “community” of
smokers was noted, others noted that they would not date someone who did not smoke. This participant did not want to be “bothered” by a significant other that would encourage him to quit smoking. Matthews and colleagues (2014) also found these patterns.

Insights for intervention development from these focus group data included:
- Focus on education regarding the targeting of minority by the tobacco industry;
- Addressing the importance smoking might have in participants’ formative years; including cognitive and behavioral skills to manage their environments; and the importance of supportive social networks not based on smoking (see Figure 2 for the incorporation of all insights into the intervention).

**Distrust of medications**

“I mean, I wouldn’t do, like, the Chantix thing... because of my lack of knowledge for it.”

“Another thing like the Chantix commercial, ok we can help you stop, but side-effects like upset stomach.”

“You have to check with the doctor to make sure that none of them interact with your current medication. It’s just too much.”

“I don’t want to put [the patch on] my body I can stop on my own.”

“I’m already used to taking a pill for the rest of my life [HIV medication]. I’m not going to take another pill for something I can quit on my own.”

Consistent with similar findings among low SES African American populations for other healthcare needs (Bogart et al., in press; Dale, Bogart, Wagner, Galvan, Klein, in press; Kalichman, Eaton, Kalichman, & Cherry, in press), distrust in medications and the medical system appears to lead to lower willingness to engage the healthcare system for smoking cessation among this group of men.
Participants reported “treatment fatigue”; their current medication regimens appeared to overburden them. They were wary of adding another medication to their daily routine. Treatment fatigue is common among those with chronic conditions (Heckman, Mathew, & Carpenter, 2015), including HIV-infected individuals (Claborn, Meier, Miller, & Leffingwell, 2015; Claborn, Miller, & Meier, 2015; Thielman et al., 2014) and is directly associated with medication non-adherence (Heckman et al., 2015; Thielman et al., 2014). Thus, the addition of a medication that may not be perceived as needed, such as smoking cessation medications, may be seen as unnecessary burden.

Insights for intervention development from these focus group data included: Addressing misbeliefs regarding smoking cessation products; proper management of smoking cessation product side effects; and the importance of linking HIV care to smoking cessation.

**Emotional Factors**

“I don’t have to deal with this. It’s the calming effect that cigarettes have.”

“What got me off track was because of my mom, the drama queen. When you with family, it’s always something.”

“It stops so much stress. It’s a habit.”

“It’s a stress reliever, gives you an appetite.”

“You feel good… I want to light up.”

Consistent with other populations, cigarettes serve as a source of stress relief for this group of men. Themes of avoidant coping arose during focus groups, suggesting that smoking does not actually assist with them stressor at hand, but gives them a break to figure out a strategy to deal with the stressor or to avoid the stressor entirely. While the
association of stress and smoking is not unique to African American MSM smokers, it may enhanced by the increased stressors these men typically face in comparison to other populations (Bogart, Wagner, Galvan, Landrine, & Klein, 2011; Radcliffe et al., 2010; Wohl et al., 2013).

This intervention included cognitive behavioral strategies to address stress such as diaphragmatic breathing, cognitive restructuring, distraction skills, pleasurable activity scheduling, and refusal skills.

**Other Substances**

“At 13, I smoked a joint and then after smoking the joint, the two people I was smoking the joint with was like take a puff of the cigarette”

“You feel good. Drinking a beer. I want to light up.”

“When I used to smoke me a joint, that would be the best time to smoke.”

“I don’t smoke until I drink. When I drink, I go get my cigarettes.”

“I wake up, smoke weed, and then light up a cigarette.”

Many individuals associated cannabis use with simultaneous tobacco use. In fact, the first time one individual smoked cigarettes was in the context of cannabis use. These two substances appear to be highly entwined in this group of men. Similar to cannabis use, alcohol use lowers inhibitions, serves as a trigger for smoking, and increases the automaticity of smoking behaviors. Research indicates these barriers to smoking cessation are not unique to these men, and in fact, are more generally more common in socioeconomically disadvantaged groups (de Silva, Samarasinghe, & Hanwella, 2011; Twyman et al., 2016).
While this intervention did not focus on cannabis cessation, I addressed the similarity of behaviors in smoking both cannabis and smoking cigarettes. Automaticity was addressed in terms of alcohol use and smoking, particularly within the context of social interactions.

**Facilitators of smoking cessation.**

Several distinct facilitators of smoking cessation were discerned during the focus group including: health, cost, knowledge of effects, shifting social norms, and medical providers.

**Health/Appearance**

“Have you guys seen the PSA from TV where they showed the consequences for smoking? These be real people, real patients who caught cancer, tracheotomy in their neck, and they couldn’t breathe.”

“Health, they told me years ago I had mild emphysema... I’m not the person I was twenty years ago.”

“It’s not good for your teeth, gum, skin, breathe. It gets in your clothes.”

“...even on the Oprah show they have the age define the one that smoked and the one that didn’t. They showed the progression of ten years later what the cigarette did...”

“I have emphysema. My breathing is not what it used to be. I’m a tennis player. That’s over.”

“I’m tired of coughing all the time, snoring.”

“I don’t smoke if I know I got a job interview... I don’t want to go into the office somewhere smelling like cigarette smoke.”
Participants identified several common health reasons to quit smoking. (Gierisch et al., 2012; Matthews et al., 2013; Uppal, Shahab, Britton, & Ratschen, 2013). They were generally aware of the negative long-term health effects of smoking and seemed particularly sensitive to chronic illnesses associated. Of note, while participants were aware that the purpose of the focus group was to create an intervention specifically for HIV-infected men like themselves, they did not note specific health dangers of smoking on HIV prognosis. They tended to conceptualize the health effects of smoking as problems for all smokers.

Participants appeared focused on the effect of smoking on physical appearance. The awareness of others’ perceptions of smokers was particularly striking. Thus, participants would shower and/or make efforts to not smoke before important events such as job interviews. They appeared to be worried about the social consequences of smoking, not only for their occupational lives, but their personal and dating lives. Physical appearance is commonly rated as an important facilitator of smoking cessation (Matthews et al., 2014).

The intervention provided education on specific health maladies that African American HIV-infected MSM that smoke are at risk for in Session 1 of the intervention.

Cost

“They want Newport $8 or $10 a pack.”

“What are some reasons [I] want to quit? Cost.”

“You don’t have to have money to buy cigarettes these days. You can buy them off the street.”

“That is one of the easiest and most convenient addictions and cheapest.”
“It’s real easy to find loose squares on the streets.”

Participants noted the high cost of cigarettes as a facilitator of smoking cessation. However, participants also noted the relevant ease with which they can find cheaper single cigarettes, or “loose squares,” on the streets of their neighborhoods. This is not only a culturally relevant facilitator, but is particularly relevant since these participants are mostly unemployed and, thus, have limited resources to spend on cigarettes. While research advocates for the raising of taxes as a deterrent to cigarette use among low-income populations in general, “loosies” will remain a way for this population to attain relatively cheap cigarettes. The practice of regular refusal skills should help participants meet their smoke free goals when faced with an environment in which loose cigarettes are readily available.

Medical Providers

“Every appointment, [my doctor] checks in with me about smoking.”

“[My doctor] kind of recognized the fact that I wasn’t smoking. A few things she brought to my attention. My blood pressure was the main thing.”

“My doctor suggested Bitch to Quit... and the patches”

“[My doctor] actually wants to know why I am back to smoking.”

Although distrust of medications for smoking cessation emerged as a barrier, participants did voice that having medical providers consistently ask them about smoking, offer counseling on smoking cessation medications and behaviorally based interventions, and point out successes, can be facilitator for smoking cessation.

Regular follow-up and a strong alliance with a provider generally improves health outcomes (Trevino, Fasciano, & Prigerson, 2013). Despite being members of a highly
disenfranchised community, these men obviously have providers that are consistently checking in with them. Possibly, the necessity of them returning for HIV medication evaluations and renewals promotes a close relationship with their doctors. Research suggests that a medical provider simply asking about smoking behaviors and offering smoking cessation advice improves long-term cessation rates (Anczak & Nogler, 2003; Aveyard, Begh, Parsons, West, 2012; Park et al., 2015).

During Session 2, a registered nurse provided medical expertise regarding the patch and its potential side effects. Facilitators also encouraged participants to discuss any smoking cessation medications with their providers to best boost their chances at successful cessation.

**Shifting social norms**

“I have not seen any cigarette commercials since I can’t remember.”

“I find it less acceptable because of the education we know that it does and what tobacco companies have targeted poor people and then because there is a health issue that really define now that links to throat cancers and all these other things that are linked to cigarettes.”

“I say it has shifted a different way because we know that it is not healthy for you.”

“It’s funny, because If I got into a relationship I would not date you if you didn’t smoke and I am not going to sit here and you judge me because of something I do.”

While participants generally believe that smoking is more acceptable and prevalent in the African American community, they also recognize that norms regarding smoking have shifted. Smoking has become a less acceptable behavior due to public policy and environmental restrictions (Cummings & Proctor, 2014). Improved education
regarding the ill effects of smoking has led to the severe restriction of smoking in public places.

Participants also noted shifting social norms in the gay community generally. Participants described a smaller dating pool due to their smoking. Older participants lamented the absence of smoking from restaurants and bars. As noted above, participants feel the need to hide their smoking behaviors from prospective employers because they do not want to deal with the possible bias against smokers. The extra stress associated with these perceptions may serve as a facilitator of smoking cessation. This shift within the gay community is particularly salient. Advertisements targeting the gay community historically emphasized freedom of choice in deciding to smoke (Matthews et al., 2013). Such advertisements are less prevalent currently.

The intervention used awareness of shifting social norms to enhance motivation to quit smoking. We instructed participants to weigh pros and cons of continued smoking versus smoking cessation by focusing on the aspects of shifting social norms that make smoking more difficult.

Barriers to medication adherence.

Several distinct barriers to medication adherence were discerned during the focus group including: community support, multiple medications, and side effects.

Community Support

“I don’t have that kind of support.”

“Hell naw.”

“If I told you my status, I don’t know how you can add value to my life.”

“...in the real world, people you interact with... ain’t none of their business.”
Participants generally reported a lack of support for their medication adherence and coping with HIV. While individuals in their immediate social circles, family or friends, may know about their diagnosis, participants did not see how those individuals could help them manage their HIV or their medications. Some men did not want that kind of support, indicating their HIV is a personal manner. This is particularly important, as social support is linked to improved medication adherence among HIV-infected African Americans (Edwards, 2006; Wohl et al., 2011). Participant’s perceptions that social support is not available or even desirable may reflect the lack of cultural acceptance of HIV in the African American community.

To address this, the intervention included a module on seeking social support, including a structured role play exercise. Participants also received a sheet to be given to their social network offering ideas on how to offer social support.

**Multiple Medications**

“There was a time when like, when I had several pills to take several times of the day. I wasn’t taking it.”

“I was doing this, that, and the other and medication wasn’t with me.”

“I didn’t really want to carry [medications] with me.”

“My roommate takes like 5 pills twice a day and there are times when he forgets to take medicine or he will sleep pass the time for his first medication. He’ll take his night medication but he done missed the first dose of medication.”

“That would scare the hell out of me because I am not only missing one, but I am missing five.”

Similar to interventions for any chronic disease, the more complex the regimen, the less likely one is to adhere to the treatment regimen (Airoldi et al., 2010; Bangsberg,
Ragland, Monk, & Deeks, 2010). Thus, the importance of the breakthrough of one-a-day anti retroviral medication cannot be overstated. Some individuals in the focus group had experience taking multiple medications at multiple times throughout the day and they reported great difficulty with maintaining adherence to these regimens. Participants reported it was difficult to carry multiple doses with them, thus it made it easier to ignore their middle of the day dosages. Thus, this is an important issue to address in the intervention.

Strategies taught to be adherent in the intervention included setting phone reminders, making environmental cues, and using pillboxes (provided to each participant).

**Side effects**

“For me, it’s very hard because I have to take mine on an empty stomach.”

“The first mess they had me on made me feel awful.”

“Atripla can give you really bad nightmares.”

“Like he said about the diarrhea thing, I have that with my medication, too.”

Participants reported common side effects of HIV medications as barriers to adherence. Management of medication side effects is essential in the treatment of HIV. Common side effects include nausea, tiredness, vomiting, diarrhea, headache, fever, muscle pain, and dizziness (NIH, 2016). Finding the regimen that has the best treatment outcomes combined with the least side effects promotes increased adherence. However, when these side effects occur, they can be very discouraging to patients. Planning for possible side effects, depending on the medications prescribed, can make these side
effects more tolerable. The intervention contained a list of common side effects and evidence-based interventions to manage the side effects.

**Facilitators of medication adherence.**

**Social support**

“I don’t need you to baby me, I just need you to understand what the situation is.”

“I told my circle... the people I normally hang around with, just because anything can happen...”

Participants were more interested in having individuals that were aware of the diagnosis and the practical day-to-day and emergency difficulties this might present. This is consistent with the information stated under community support as a barrier to medication adherence. However, while participants did not connect social support with medication adherence specifically, they did note it was important for those close to them to understand their diagnosis at a basic level.

The intervention included a module to assist participants in asking for needed social support. This included worksheets and roleplaying exercises.

**B. Intervention Development**

The intervention was developed using the PEN-3 model of theoretical behaviors, a model developed to place culture at the center of health behavior change and disease prevention (Airhihenbuwa, 1989). This formulation was influenced by Matthews and colleagues earlier work during the creation of the intervention this project is based on (Matthews et al., 2009). The purpose of the PEN-3 model is to use the framework of culture to understand people’s perspectives on and relationships with health (Airhihenbuwa, 1989; Airhihenbuwa et al., 2009). The PEN-3 model consists of 3
dimensions that address not only the negative factors that culture may contribute to health behaviors, but also the positive factors (Airhihenbuwa et al., 2009). This, in effect, reduces the view of race and/or culture as “pathology.” The three dimensions of the Pen-3 model are: 1) Persons, Extended family, and Neighborhoods, that is, the specific targets of the intervention or social change; 2) Perceptions, Enablers, and Nurturers, identifying the facilitators and barriers to health behavior change; and 3) Positive, Existential, and Negative behaviors, referring to specific strategies and skills for behavior change.

The PEN-3 model has been used in multiple studies to culturally tailor interventions (Airhihenbuwa et al., 2009; Crowdery, Parker, & Thompson, 2010; Iwelunmor, Newsome, & Airhihenbuwa, 2014; Purcell & Cutchen, 2013). This model recognizes that specific cultural beliefs, experiences, and expectations need inform interventions to make them relevant to minority populations. While the use of general messages promoting health may be effective, the disparities that often exist between minorities and Caucasians suggests more can be done to make interventions relevant to minorities.

For the first step of the PEN-3 model, I identified the specific population to intervene on. The population of interest for this study is HIV-infected African American MSM. Regarding neighborhood, most of these men live on South and West sides of Chicago. I partnered with community organizations (Howard Brown Health Center and Project Brotherhood) that serve these men to recruit them. Other men were informed of the study through word-of-mouth referrals from men that had participated in other larger smoking cessation intervention studies.
For the second step of the PEN-3 model I conducted focus groups to identify specific barriers and facilitators for both smoking cessation and medication adherence to inform the standard intervention. Assessing these views and perceptions is important to culturally target an intervention to make it relevant for the population of interest. Further, I included culturally relevant images, culturally relevant messages, and statistics specific to these men in the intervention materials to further increase the salience of the materials for participants. Content gathered from the focus groups was integrated into the standard intervention as illustrated in Figure 2.

<table>
<thead>
<tr>
<th>Session</th>
<th>Standard Elements</th>
<th>Targeted Elements</th>
</tr>
</thead>
</table>
| Individual Session | • Motivational interviewing and needs assessment  
  • Basic HIV and smoking education  
  • Importance of HIV medication adherence | • Coping with HIV  
  • Combined effect of HIV and smoking on health  
  • Personal barriers and support needs |
| Session 1      | • Welcome participants and answer program questions  
  • Health and financial benefits of quitting  
  • Nicotine replacement information | • Orientation; smoking rates among HIV+ and African American MSM  
  • Health beliefs, values and motivation for smoking cessation and treatment adherence  
  • Relationship between African Americans and Big Tobacco  
  • Structural reasons it is difficult to change  
  • Health risks of smoking while HIV-infected |
| Session 2      | • Motivation enhancement  
  • Relaxation techniques  
  • Behavioral preparations for quit day  
  • Peer support roleplay  
  • RN informational visit | • Afrocentric motivations to quit and adhere to medications gathered from focus groups  
  • Nicotine replacement and adherence information: Dispelling myths and promoting alliance with PCP |
| Session 3 | • Quit day  
  • Techniques for coping with cravings  
  • Treating withdrawal and emergency plans if setbacks | • Emphasis on how quitting and treatment adherence will help participants reach their HIV-related health goals  
  • Medication adherence techniques |
|---|---|---|
| Session 4 | • Long-term goal setting  
  • Strategies to counter “high-risk” situations for smoking relapse  
  • Weight gain in quitting smoking | • Positive self-image as a non-smoker and Person living with HIV/AIDS  
  • Strategies for obtaining support for quitting and medication adherence  
  • Culturally relevant motivational and coping sources  
  • Connection of smoking with socialization with other African American MSM |
| Session 5 | • Assertive communication  
  • Coping strategies for long-term maintenance  
  • Stress management | • Smoking cessation as an act of resistance against tobacco company targeting  
  • Positive medication adherence outcomes  
  • Issues of weight and body image in the MSM community  
  • Building supportive social networks |
| Session 6 | • Relapse prevention  
  • Review of prior topics  
  • Future strategies and celebration | • Individual and community pride and self-worth  
  • Supportive social networks revisited |

Figure 2. Standard and culturally targeted intervention elements

For the third step of PEN-3, I integrated and modified content from Project Exhale (Matthews et al., 2014) and the Treatment Advocacy Program (McKirnan et al., 2010) to identify specific cognitive behavioral strategies and skills to jointly promote smoking cessation and medication adherence within this population. Strategies included identifying triggers for smoking and cues for medication adherence that are specific to
this subculture. Common behavioral strategies for smoking triggers include avoiding, altering, or substituting the trigger (King & Riley, 2001). I addressed distinctive environmental triggers for smoking in this population, including lax norms for smoking among African-American HIV-infected MSM, the increased stress of having multiple minority status, and the easy availability of “loosies” on the street. I also addressed common thought patterns associated with smoking (i.e. “I deserve a treat.” “I can just have one.”). I included education regarding smoking cessation and antiretroviral medications to address distrust and misinformation expressed during focus groups. The intervention also emphasized communication with support networks as sources of strength to achieve their overall health goals. Figure 2 illustrates the primary differences between the culturally targeted intervention and the standard intervention.

The intervention was evaluated in a second focus group (n = 7) using standard face-valid measures (King et al., personal communication) for acceptability, usefulness, and cultural relevance. Participants rated 21 exercises targeted for this intervention for their usefulness, ease of understanding, how much they were liked, and how motivating the exercise was. These domains were rated on a scale of 1 – 10 with higher scores indicating stronger positive ratings. All scores for the 21 exercises were combined for a general overall exercise ratings score. As seen in Table 3, participants generally thought all exercises were useful, easy to understand, were motivating, and liked the exercises.

Participants also rated the intervention overall in terms of cultural relevance and psycho-education (on a Likert Scale, with lower scores indicating participants feel they would learn a lot more) and how much they believe the intervention could help them quit smoking and become adherent to their medication regimen (on a scale of 1 – 4 with
higher scores indicating positive ratings). Participants felt the intervention was relevant to them and their smoking cessation and medication adherence needs. Moreover, they felt the intervention would help them achieve their smoking cessation and medication adherence goals.

Table II. Focus group ratings of the intervention.

<table>
<thead>
<tr>
<th>Exercise Ratings</th>
<th>M(SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Useful</td>
<td>8.58(.43)</td>
</tr>
<tr>
<td>Easy to Understand</td>
<td>8.58(.58)</td>
</tr>
<tr>
<td>Like exercise</td>
<td>8.43(.83)</td>
</tr>
<tr>
<td>Motivating</td>
<td>8.10(.68)</td>
</tr>
<tr>
<td>Relevance</td>
<td>1.20(.22)</td>
</tr>
<tr>
<td>Help Achieve Goals</td>
<td>3.79(.20)</td>
</tr>
</tbody>
</table>

C. **Pilot**

*Feasibility analyses*

Approximately a third of potential participants were recruited through the Howard Brown Health Center clinic or website. Eight participants were recruited by word of mouth. Five were recruited by flyers. One participant was recruited through the UIC Infectious Diseases Clinic. Thirty individuals met eligibility criteria to participate in a baseline screening to establish full eligibility for the study. Eleven individuals were not eligible at phone screening due to being medication adherent. The other 10 did not meet
race, gender, sexual orientation, and medical requirements. The CONSORT diagram is given in Figure 3 below.

Figure 3. Participant flow
Recruitment took place over a 9-month period. Fifty-one total potential participants were screened for a rate of approximately 6 participants screened per a month. Approximately a third of potential participants were recruited through either the Howard Brown clinic or Howard Brown website. Eight participants were recruited by word of mouth. Five were recruited by flyers. One participant was recruited through the UIC Infectious Diseases Clinic. Thirty individuals met eligibility criteria to participate in a baseline screening to establish full eligibility for the study. Eleven individuals were not eligible at phone screening due to being medication adherent. The other 10 did not meet race, gender, sexual orientation, and medical requirements.

Twenty-three total individuals attended baseline. Of those twenty-three individuals, 15 were eligible to enroll in the study. Of the 8 individuals ineligible for the study at baseline, 4 were adherent to their antiretroviral medications and 4 did not meet the cut-off for expired breath carbon monoxide measurement. Ten out of 15 eligible participants attended Session 1 and 8 of those individuals attended more than half the sessions and the 1- and 3-month follow-ups.

Demographics

Participant characteristics at baseline are shown in Table 3. Participants were approximately 47 years old. They varied in education level from high school graduate to obtaining a master’s degree. Generally, they were very low income and did not maintain full-time employment. Cannabis use was high among this population, with 60% of participants reporting they used cannabis in the past year. The overall sample endorsed likely alcohol use disorder on the SMAST and a low-level drug use disorder on the DAST.
Smoking behaviors are displayed in Table 4. Participants smoked 7 cigarettes per day and had expired CO levels suggesting they were regular smokers. Eighty percent of participants smoked mentholated cigarettes. Scores on the Fagerstrom Test of Nicotine Dependence, Brief Questionnaire of Smoking Urges, and the Minnesota Nicotine Withdrawal Scale indicated mild to moderate degrees of physical dependence on nicotine. Participants had moderate levels of readiness to quit smoking and smoking abstinence self-efficacy. Participants generally tried quitting 2 to 3 times.
<table>
<thead>
<tr>
<th></th>
<th>N=10</th>
<th>M(SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td>47.20(8.98)</td>
</tr>
<tr>
<td><strong>Preference in romantic partner</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Same Sex</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Both Sexes</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td><strong>Education (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full time</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Part time</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Other (student, etc.)</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single, never married</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Married/Long-term partner</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Separated/Divorce</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Income</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than $15,000</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>$15,000 or more</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td><strong>Psychosocial Characteristics</strong></td>
<td>M(SD)</td>
<td></td>
</tr>
<tr>
<td>Perceived Stress Scale</td>
<td>6.00(3.40)</td>
<td></td>
</tr>
<tr>
<td>SMAST Alcohol (drinks per day)</td>
<td>3.7(1.95)</td>
<td></td>
</tr>
<tr>
<td>DAST Marijuana (past year)</td>
<td>n</td>
<td></td>
</tr>
<tr>
<td>Opiates (past year)</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Stimulants (past year)</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Tranquilizers (past year)</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>
Table IV. Smoking characteristics.

<table>
<thead>
<tr>
<th></th>
<th>M(SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expired Breath CO</td>
<td>21.90(7.82)</td>
</tr>
<tr>
<td>Cigarettes smoked per day</td>
<td>7.16(3.94)</td>
</tr>
<tr>
<td>Fagerstrom Test of Nicotine Dependence</td>
<td>4.60(2.17)</td>
</tr>
<tr>
<td>Brief Questionnaire of Smoking Urges</td>
<td>32.60(13.83)</td>
</tr>
<tr>
<td>Smoking Abstinence Self-Efficacy</td>
<td>21.30(5.58)</td>
</tr>
<tr>
<td>Readiness to Quit</td>
<td>6.70(1.34)</td>
</tr>
<tr>
<td>Minnesota Nicotine Withdrawal Scale</td>
<td>1.39(0.84)</td>
</tr>
<tr>
<td>Number of serious quit attempts</td>
<td>2.56(1.59)</td>
</tr>
</tbody>
</table>

n
Mentholated cigarette use
Other
  Cigars        4
  Pipe tobacco  2

Smoking cessation methods used
  Group Counseling 2
  Cold turkey      5
  Nicotine Replacement 5

1Taken from session 1

Medication behaviors are displayed in Table 5. Participants were taking approximately 76% of their prescribed daily HIV medications and endorsed moderate levels of medication non-adherence behaviors.

Table V. Medication adherence characteristics.

<table>
<thead>
<tr>
<th></th>
<th>M(SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of medications</td>
<td>2.3(0.95)</td>
</tr>
<tr>
<td>Number of daily pills prescribed</td>
<td>2.6(0.97)</td>
</tr>
<tr>
<td>Current level of adherence (%)</td>
<td>76.33(28.22)</td>
</tr>
<tr>
<td>Medication Adherence Rating Scale</td>
<td>3.00(2.87)</td>
</tr>
</tbody>
</table>
Acceptability

Ratings of the program (0 – 5 scale) were generally high at the end of treatment including: feeling the sessions helped them quit smoking and take meds, thought the facilitators worked well with participants, ability to share feelings in group, feeling the group facilitators were competent, satisfied with the intervention, getting the kind of program they wanted, recommending program to a friend, satisfaction with the amount of help offered during the program, and overall quality of the intervention. Mean rating of the overall program was 4.25, SD = .57.

Treatment Outcomes: Smoking

The pilot nature of this study did not allow for in-depth analyses. I assessed the key outcomes of mean number of daily cigarettes and expired breath CO readings from baseline to the 1- and 3-month follow-ups using repeated measures ANOVA. Table 6 displays these results. At 1-month follow-up, there was a significant reduction in mean number of daily cigarettes smoked (F(1,7) = 21.69, p < .00). This was maintained through the 3-month follow-up (F(1,7) = 20.83, p < .00). In contrast, there was not a significant reduction in expired breath CO readings at either 1-month (F(1,7) = 2.11, p = .19) or 3-month follow-ups (F(1,7) = 1.48, p = .26). Per self-report Time Line Follow-Back (TLFB), 3 participants (37.5%) reported complete cessation at the 1-month follow-up while 4 (50%) reported complete cessation at the 3-month follow-up. However, when looking at expired breath CO-verified quit rates, defined as CO reading below 8 ppm, two of eight participants (25%) fell below this threshold at the 1-month follow-up. Three of eight participants (37.5%) fell below this threshold at the 3-month follow-up.
There was not a significant change in smoking self-efficacy from baseline to 1-month (F(1,7) = 2.70, p = .14) or 3-month follow-ups (F(1,7) = .92, p = .14). Nor did perceived stress levels change from baseline to follow-ups (1-month: F(1,7) = 3.61, p = .10; 3-month: F(1,7) = 2.09, p = .19). However, ratings of smoking urges decreased significantly from baseline to the 1-month follow-up (F(1,7) = 10.68, p = .01), suggesting participants were experiencing a low urge to smoke. This was maintained at the 3-month follow-up, F(1,7) = 8.5, p = .02. Similarly, ratings of nicotine withdrawal significantly reduced from baseline to 1-month follow-up, F(1,7) = 8.30, p = .02, suggesting minimal withdrawal symptoms were being experienced at this time. While nicotine withdrawal was reduced at the 3-month follow-up, it was not significantly different from baseline, F(1,7) = 3.97, p = .09. Participants’ readiness to quit increased from baseline to the 1-month follow-up, F(1,6) = 10.50, p = .02, suggesting participants had either quit smoking or had significantly cut back. This was maintained at the 3-month follow-up, F(1,7) = 10.43, p = .01. These findings were expected based on previous research (Matthews et al., 2014, Matthews et al., 2009).
Table VI. Mean daily cigarette use, CO readings, and smoking-related psychosocial variables over time.

<table>
<thead>
<tr>
<th></th>
<th>M(SD)</th>
<th>Baseline</th>
<th>1-month</th>
<th>3-month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily Cigarettes</td>
<td>7.38(4.42)</td>
<td>.72(.73)*</td>
<td>1.34(1.72)*</td>
<td></td>
</tr>
<tr>
<td>CO Reading (ppm)</td>
<td>20(7.62)</td>
<td>14.75(7.27)</td>
<td>14.75(10.17)</td>
<td></td>
</tr>
<tr>
<td>Smoking Abstinence Self-Efficacy</td>
<td>20.13(5.64)</td>
<td>25.13(6.27)</td>
<td>23.75(8.46)</td>
<td></td>
</tr>
<tr>
<td>Perceived Stress Scale</td>
<td>6.38(2.88)</td>
<td>8.38(1.30)</td>
<td>8.63(2.20)</td>
<td></td>
</tr>
<tr>
<td>Brief Questionnaire of Smoking Urges</td>
<td>32(12.71)</td>
<td>16.50(9.10)*</td>
<td>16.88(9.45)*</td>
<td></td>
</tr>
<tr>
<td>Minnesota Nicotine Withdrawal Scale</td>
<td>1.45(.87)</td>
<td>.58(.50)*</td>
<td>.73(.67)*</td>
<td></td>
</tr>
<tr>
<td>Readiness to Quit</td>
<td>6.63(1.51)</td>
<td>8.50(.53)*</td>
<td>8.57(.79)*</td>
<td></td>
</tr>
</tbody>
</table>

n = 8

Self-reported Quit       | 3 (37.5%)      | 4 (50%)   |
CO2 Verified Quit         | 2 (25%)        | 3 (37.5%) |

*p<.05

Treatment Outcomes: Medication Adherence

The primary outcome for the medication adherence was the percentage of prescribed pills participants reported taking on the TLFB. As indicated in Table 7, there was a trend toward an increase in the proportion of pills taken from baseline to 1-month follow-up (F(1,7) = 4.54, p = .07). This trend is maintained at the 3-month follow-up (F(1,7) = 4.07, p = .08). I feel these trends to be meaningful, given the very small sample size. At 1-month follow-up, patients reported 100% adherence, up from 76.25% at baseline. This trend is maintained at the 3-month follow-up. As 90% adherence is generally accepted as the standard at which HIV antiretroviral medication is most effective (Bangsberg, 2006), I used that as a cutoff point to determine which participants were adherent to their medications across time. Only 1 participant had an adherence rate over 90% at baseline. At the 1-month and 3-month follow-ups, all participants reported adherence rates over 90%.
Consistent with an increase with participants’ increased adherence, their ratings of medication non-adherence on a face-valid measure trended toward significance at the 1-month follow-up ($F(1,7) = 4.2, p = .08$) and was maintained at the 3-month ($F(1,7) = 3.89, p = .09$) follow-up. In general, despite the very small sample size, the results show a clear trend toward improved medication adherence.

Table VII. Medication adherence over time

<table>
<thead>
<tr>
<th>M(SD)</th>
<th>Baseline</th>
<th>1-month</th>
<th>3-month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily pills taken (%)</td>
<td>76.25%(31.54%)</td>
<td>100%(0%)*</td>
<td>99.17%(1.54%)*</td>
</tr>
<tr>
<td>Medication Adherence Rating Scale</td>
<td>3.25 (3.15)</td>
<td>.63(.92)</td>
<td>1.00(.76)</td>
</tr>
</tbody>
</table>

n = 8
>90% adherent               1   8   8

*p<.0
IV. Discussion

African American HIV-infected MSM continue to experience poor health outcomes compared to their Caucasian counterparts. This can be partially attributed to lower rates of antiretroviral adherence. Moreover, smoking is particularly harmful for HIV-infected individuals. These harmful effects are particularly strong among HIV-infected people with lower rates of medication adherence. These individuals are more likely to develop AIDS, experience a reduced quality of life and, and endure an increased incidence AIDS defining illnesses (Clifford et al., 2005; Crothers et al., 2005; Islam, Wu, Jansson, & Wilson, 2012; Miguez-Burbano et al., 2005).

I developed an intervention to address the confluence of these target behaviors to reduce health disparities this population experiences. Culturally targeted health interventions (Matthews et al., 2014; Moscou-Jackson et al., 2014; Raja et al., 2007) and interventions designed to address multiple health behaviors (Prochaska & Sallis, 2004; Prochaska et al., 2008) have shown effectiveness in addressing key health behaviors. This study is distinctive in that it is the first study to address both medication adherence and smoking cessation among HIV-infected African American MSM.

This was a systematic, formative research study to develop and test the feasibility of a compound smoking cessation and medication adherence intervention for this population. Another strength is the retention of participants that came to the first intervention session and the use of CO monitors to biochemically very quit rates. Despite the very small sample size, this study has implications for future research in the delivery of culturally targeted interventions for multiple health behaviors generally and specifically to HIV-infected African American MSM.
One aim of this study was to examine barriers to and facilitators of smoking cessation among this specific group on men. While participants identified several barriers (eg. emotional factors, other substances) and facilitators (eg. health, cost) of smoking cessation that were not unique to this population, they also identified several distinctive factors that were taken into account in the creation of the intervention. A main factor associated with smoking within this population of men was the cultural acceptability of smoking among their home communities. We attempted to address the perception of cigarette use as “normal” in their home communities using cognitive strategies to improve cessation rates. Moreover, one of the ways we addressed the environment these men live in was to address availability of “loosies” on the street using behavioral and roleplay strategies may help individuals be successful in their smoking cessation goals. These barriers to smoking cessation were consistent with a previous study conducted by Matthews and colleagues (2014) looking at a similar population and should be addressed in future interventions for these men. Focus groups also revealed the need of increased education regarding the negative effects of smoking specifically for individuals living with HIV and to dispel myths regarding smoking cessation medications.

A facilitator of smoking cessation that stood out in particular was the role of medical providers. Participants spoke of the importance of medical providers regularly asking about their smoking status. This is particularly important from an intervention standpoint as evidence points to long-term reductions in smoking among individuals that are simply asked about their smoking status at medical visits (Anczak & Nogler, 2003; Aveyard et al., 2012; Park et al., 2015). Ensuring that providers are trained in cultural
competence and also asking about smoking status would likely lead to long-term cessation within this group of men.

A significant barrier to medication adherence was the lack of community support for coping with HIV. While the research suggests social support is associated with improved medication adherence (Edwards, 2006; Wohl et al., 2011), these men felt that HIV is a personal matter and did not perceive the benefits of having support regarding their HIV. A macro-level intervention could be instituted to promote discussion of status and how to support loved ones. If trained educators delivered this intervention at trusted forums, such as churches, this may increase the salience of the intervention. Participants also voiced the importance of provider trust in their HIV care. As stated above, having regular doctor visits is associated with improved outcomes on overall health measures.

Another aim for this study was to conduct a pilot test of the intervention to assess feasibility and acceptability. Generally, participants found the intervention to be acceptable. They gave the intervention high ratings in domains including: feeling the sessions helped them quit smoking and take meds, thought the facilitators worked well with participants, ability to share feelings in group, feeling the group facilitators were competent, satisfied with the intervention, getting the kind of program they wanted, recommending program to a friend, satisfaction with the amount of help offered during the program, and overall quality of the intervention.

Lessons learned

Feasibility was assessed using recruitment and retention rates. While 51 participants were screened in approximately 6 months, similar to Project Exhale (Matthews et al., 2013), only 20% of those individuals screened eligible and came to the
first session of the intervention. Only 59% of individuals screened over the phone were eligible for an in-person baseline-screening interview. This is in contrast to Project Exhale (Matthews et al., 2013). Eligibility criteria may have been too stringent for medication adherence, thus resulting in a lower n.

To be fully feasible this intervention approach must directly address difficulties with recruitment. Recruitment efforts would benefit from more input from the community regarding the content of recruitment materials such as ads, flyers, and announcements, and the methods used to recruit individuals in clinic settings. Future studies would include an assessment of this information in focus groups. An intervention like this depends on the buy-in from medical providers in medical settings that serve African American HIV-infected MSM. This includes not only endorsement from the individual(s) in charge of the medical setting, but also systematic training of providers that are likely to be informing potential participants of the study. Physicians are often very busy in these settings and asking them to increase their load to include recruitment may not be successful. However, medical assistants and nurses conduct most of the clinical interviewing regarding health behaviors and generally spend more time with patients. Training them in recruitment strategies would likely greatly increase recruitment and retention.

Future studies could make a point to include the involvement of more community-based organizations that serve African American HIV-infected MSM. While this study took place in an LGBT clinic, it may be more effective to run this through organizations that are based in the communities that this population resides. Moreover, the
organizations likely have the trust of the community, thus their endorsement and buy-in would likely increase recruitment.

Once participants enrolled in the study and initiated treatment, retention was good. Eighty percent of participants attended more than 3 sessions and the 1-month and 3-month follow-ups. This was similar to the retention rate in Project Exhale (Matthews et al., 2013). This high retention rate demonstrates that once you get participants enrolled and initiate the intervention, they find the intervention materials acceptable. Despite numerous psychosocial difficulties, these participants persevered in their visits. Twenty-five percent of participants had CO-verified quit rates at the 1-month follow-up. This increased to 37.5% at the 3-month follow-up. While the sample size is small, these quit rates compare favorably to other studies (Matthews et al., 2013; Matthews et al., 2009;). Consistent with participants achieving cessation at the 1-month and 3-month follow-ups, there were statistically significant changes to a number of psychosocial variables related to smoking including smoking urges, nicotine withdrawal, and readiness to quit smoking.

There were also significant increases in treatment adherence. At baseline, only one participant was taking more than 90% of their antiretroviral medications. However, at 1-month follow-up, all participants reported 100% adherence. This was generally maintained at the 3-month follow-up. Consistent with this, participants’ ratings on a face-valid measure of adherence improved.

Despite the small sample size, these findings suggest that using a culturally-tailed group-based intervention for HIV-infected African American MSM smokers to address two significant health behaviors is acceptable to participants once they are enrolled, and shows some evidence of effectiveness on both behavioral outcomes.
Limitations

The study had several limitations. The foremost was my inability to gain full collaboration with the clinics that serve this population, as described above. As a consequence, the small sample size makes this study underpowered and not generalizable.

I was only able to conduct one focus group during the earliest formative phase of the study. Ideally, several focus groups should be run to attain a more robust picture of the barriers and facilitators of smoking cessation and medication adherence African American HIV-infected MSM experience. A larger and more representative sample of these men in focus groups may yield different or more robust results. While I was able to assess smoking quit rates biochemically using expired breath CO monitors, I had no such measure for medication adherence. This study would benefit from longer follow-ups to allow for the ability to test meaningful changes in viral load and to see if smoking cessation results attained in this study maintained over time.

A key recruitment difficulty was potential participants not understanding the eligibility criteria for this study. Participants were explicitly told the purpose of the study at the initiation of the phone screening. However, as demonstrated in the CONSORT flowchart in Figure 3, 41% of individuals were ineligible at phone screen for various reasons. Half those individuals were medication adherent, suggesting they did not understand that having difficulties with medication adherence was an eligibility criterion. This is despite the screener containing specific language indicating the intervention was for those that were medication non-adherence. More qualitative formative work focusing on effective screening and recruitment language around medication adherence may have
ameliorated this effect. Understandably, the concept of smoking and quitting smoking is more straightforward than the concept of medication adherence. This need for education surrounding topics of adherence could be addressed more readily in medical settings serving this disenfranchised population.

As emphasized above, to truly engage these men in an intervention like this, it is imperative to have medical providers on board and promoting the study. To that end, buying out the time of medical providers might be the most effective way of increasing enrollment. Anecdotally, the most effective individuals in recruitment from these clinics were medical assistants. They have more time to spend with patients and generally complete screenings that assess for smoking status and treatment adherence.

While we offered nicotine replacement patches with this study, future studies may want to consider offering Zyban or Chantix. Incorporating one of these pills into their medication adherence education and training may be more useful and salient for these men than nicotine replacement patches. Making the intervention focus on one medication behavior, adherence to pills, would possibly make it easier for participants to adhere to HIV antiretrovirals and smoking cessation medications. An intervention that focuses on pill adherence could facilitate effective treatment for both smoking cessation and HIV. The intervention would focus on increasing the automaticity of pill taking behaviors, thus improving outcomes for both smoking cessation and HIV. Clearly, this consistency of pill taking could benefit this vulnerable population of men.

While the need for intervention on these two behaviors is obvious within this community, smoking cessation and HIV medication adherence may seem like two unrelated health behaviors to potential participants. Anecdotally, participants seemed
more interested in smoking cessation than medication adherence. Thus, facilitators had to consistently link how these two behaviors were related and how important medication adherence is to overall health. Perhaps framing this as a whole health intervention will ameliorate this difficulty.

Conclusion

Given the clear health disparity between African-American and Caucasian HIV-infected MSM, innovative interventions to address their specific health needs continue to be needed. Data from this formative study suggests that culturally targeting an existing intervention can be successful in reducing both smoking and medication non-compliance among these men. Participants found this intervention to be acceptable, as indicated by the retention rate once they initiated the intervention. However, future improvements in recruitment strategies will greatly help the feasibility of further testing of this intervention on a larger scale.

Further refinement of recruitment strategies may be achieved in several ways. Emphasis needs to be placed on engaging community members and community-based organizations in effective recruitment strategies and community education. There should be a focus on defining adherence for African American HIV-infected MSM and educating them on the importance of adherence. Community-based organizations can contribute greatly to educating these men. Community members can also provide more information for focused recruitment strategies that would appeal to other African American HIV-infected MSM. Future research should fully integrate into clinical settings with medical providers as direct stakeholders in the intervention to improve recruitment and increase the buy-in of this vulnerable population. Furthermore, biochemical
verification of medication adherence and a longer follow-up period should be included in
the next iteration of this study to corroborate self-report pill counts.
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APPENDICES
APPENDIX A

Screening Tool for MSM Smoking/HIV Medication Adherence Project Focus Group

Thank you for calling about our combined smoking cessation/HIV medication adherence study. My name is (name) and I’m one of the staff members working on the smoking cessation and HIV medication adherence research project, which is being conducted here in Chicago by Howard Brown Health Center and the University of Illinois at Chicago.

The purpose of this study is to learn more about the needs of HIV+ African American MSM who are current smokers. The information that we receive will be used to develop smoking cessation and HIV medication adherence materials that are targeted to the specific needs of HIV+ African American MSM smokers. If you are eligible, we would schedule you to participate in a focus group interview to be conducted at Howard Brown Health Center. The focus group will last approximately 90 minutes and will include other HIV+ MSM smokers. You will be compensated $25 for your time. Prior to the focus group you will be asked to complete a brief survey about yourself, your smoking habits, and your HIV medication adherence. Sensitive and/or personal issues will be discussed during the focus group. All information that you provide on the survey and during the focus group will be kept confidential.

All the information you provide in the study questionnaires will be treated as confidential. Your screening data may be retained for the larger main study. If you agree, you may be contacted to see if you are interested in participating in that study in the future.

If you are ineligible, you have the option to indicate whether your contact information can be saved for future Howard Brown Health Center studies. With your permission, only your contact information will be kept in a file in a locked cabinet separate from the rest of the study data so that you are not linked to this study. You will be re-screened and re-consented for any future studies based on that study’s IRB approved protocol should you choose to participate in them.

Do you have any questions about the study at this point? _________________

In order to determine if you are eligible for this study, I will need to ask you a few questions. Do you have a few minutes right now to answer these questions?

Are you interested in seeing if you are eligible for the study? _________________

How did you hear about this study?

☐ Flyer
☐ Street outreach
☐ Club outreach
Eligibility Questions:

What is your sex? Specifically, what sex were you assigned at birth?

☐ Male  ☐ Female
   ☐ Eligible  ☐ Ineligible

What is your gender?

☐ Male  ☐ Female  ☐ Transgender
   ☐ Eligible  ☐ Ineligible

What is your age? ____________ (If not 18-65, go to ineligibility statement)

What is your HIV status? ____________ (If Positive, Eligible; If Negative, Ineligible skip to ineligibility statement)

Do you currently have prescriptions for antiretroviral medications (HIV medications)?

☐ Yes  ☐ No (ineligible, go to ineligibility statement)
   ☐ Eligible  ☐ Ineligible

What is your race? ____________ (if not African American or black, ineligible, skip to ineligibility statement)

Are your current sexual partners men, women or both?: ____________

Have you smoked any cigarettes at all in the past ONE YEAR?

☐ No  ☐ Yes

Have you ever smoked 100 cigarettes (5 packs) or more in your life?

☐ No  ☐ Yes

** If “No” to both Questions, skip to ineligibility statement***
3. In past ONE YEAR:
   a. How many days per week, on average, did you smoke cigarettes?
      □ Daily
      □ 5-6 days a week
      □ 3-4 days a week
      □ 1-2 days a week
      □ Less than 3 times a month
      □ Have not smoked in past one year

   ** If “less than 3 times a month,” skip to ineligibility statement**

DON’T READ TO PARTICIPANT: Determine if eligible based on guidelines for age, race, HIV status, MSM, HIV medication, and smoking status.

If eligible:
You are eligible to be in our study.
Are you still interested in participating in the study? ____________

Are you available to participate in any of the following focus group days and times? ____________

May I have your phone number so that I may contact you if necessary? ____________

Do you have an e-mail address that you would like to share with me? ____________ If ineligible:
Sorry, but you do not meet the eligibility requirements for this study. Thank you very much for your interest in our study. We conduct many different types of studies here at Howard Brown. Would you like for us to keep your contact information on file so that we can call you if we have another study you may be interested in?

□ No
□ Yes (if yes, record separately for Department wait list)

Interviewer: IF SUBJECT DOES NOT AGREE TO HAVE THEIR CONTACT INFORMATION SAVED FOR FUTURE STUDIES, INFORM THE SUBJECT THAT THE SCREENING AND CONTACT INFORMATION JUST COLLECTED WILL BE SHREDDED IMMEDIATELY. IF PARTICIPANT AGREES TO HAVE THEIR CONTACT INFORMATION SAVED FOR FUTURE STUDIES, INFORM THEM THAT THEIR CONTACT INFORMATION WILL BE SAVED AND STORED IN A FILE AND LOCKED CABINET SEPARATE FROM THE STUDY DATA, AND THEIR SCREENING INFORMATION WILL BE SHREDDED IMMEDIATELY. IMMEDIATELY SHRED SCREENING DOCUMENT IN BOTH CASES.
APPENDIX B

Focus Group Questionnaire

Demographics

1. What is your age? __________________

2. What is your sex?
   □ Male
   □ Female

3. What is your ethnicity?
   □ Hispanic or Latino
   □ Not Hispanic or Latino

4. What do you consider to be your race?
   □ American Indian / Alaska Native
   □ Asian
   □ Native Hawaiian / Other Pacific Islander
   □ Black / African American
   □ White
   □ More than one race

5. What is your current marital status?
   □ Single, Never Married, not in steady relationship
   □ Single, Never Married, in a steady relationship
   □ Married or Living with long-term, committed partner
   □ Living with significant other
   □ Separated or Divorced
   □ Widowed

6. What is your preference in your intimate/romantic partners?
   □ Opposite Sex
   □ Same Sex
   □ Both Sexes
   □ Do not wish to answer
7. How many years of schooling have you COMPLETED?

☐ 10 Degree ☐ 14 (Associates Degree) ☐ 18 (Masters Degree)
☐ 11 ☐ 15 ☐ 19
☐ 12 (High School or GED) ☐ 16 (College Graduate) ☐ 20
☐ 13 ☐ 17 ☐ 21 (PhD Degree)

8. Do you have a job currently (or in the last 6 months)?

☐ No, I am currently unemployed
☐ No, I am currently a homemaker
☐ No, I am currently a student
☐ Yes, odd jobs
☐ Yes, part-time
☐ Yes, full-time

9. Do you have health insurance coverage?

☐ Yes
☐ No

10. Would you say that your health is…

☐ Excellent
☐ Very Good
☐ Good
☐ Fair
☐ Poor

11. How long have you been HIV+?

________________

12. Are you currently under a doctor’s care for your HIV treatment?

☐ Yes
☐ No

13. Does your doctor know that you smoke?

☐ Yes
☐ No

14. Has your doctor advised you to quit smoking?

☐ Yes
☐ No
Substance Use

NICOTINE / CIGARETTE SMOKING PATTERNS:

15. Have you smoked any cigarettes at all in the past ONE YEAR?

☐ No
☐ Yes

16. Have you ever smoked 100 cigarettes (5 packs) or more in your life?

☐ No
☐ Yes

** If “No” to both Questions, discontinue questionnaire**

16. In past ONE YEAR:

a. How many days per week, on average, did you smoke cigarettes?
   
   ☐ Daily
   ☐ 5-6 days a week
   ☐ 3-4 days a week
   ☐ 1-2 days a week
   ☐ Less than 3 times a month
   ☐ Have not smoked in past one year

b. On average, how many cigarettes did you smoke on those days?

_______________ (# cigs)  ☐ Not applicable, have not smoked in past one year

18. In the past ONE YEAR, when drinking alcohol, what are your feelings of wanting to smoke a cigarette?

☐ No desire to smoke
☐ Mild desire to smoke
☐ Moderate desire to smoke
☐ Strong desire to smoke
☐ Not applicable, non-drinker

19. At what age did you have your first puff of a cigarette?

_______________ (Age)

20. At what age did you smoke your first full cigarette?

_______________ (Age)
21. At what age did you start smoking cigarettes on a monthly or more frequent basis?

________________ (Age)  □ Not applicable

**ALCOHOL CONSUMPTION PATTERNS:**

22. Have you drank any alcohol at all in the past ONE YEAR (including beer, wine, liquor, etc.)?

□ No  □ Yes

23. In past ONE YEAR:

   a. How many days per week, on average, did you drink alcohol?

□ Daily  □ 5-6 days a week  □ 3-4 days a week  □ 1-2 days a week  □ Less than 3 times a month  □ Have not had alcohol in past one year

   b. On average, how many drinks did you have on those days?

(1 drink = 12 oz. beer, 5 oz. wine, 1.5 oz. (shot) liquor)

________________ (# drinks)  □ Not applicable, have not drank alcohol in past one year

**SUBSTANCE USE PATTERNS:**

Cannabis (Pot, Marijuana, Hashish, Marinol):

24. Have you ever used Marijuana in your lifetime?

□ No  □ Yes, recreational use  □ Yes, but only as prescribed by physician

** If “No” to Question 16, skip to “Tranquilizers/Downers”**

25. Have you used Marijuana in the past ONE YEAR?

□ No  □ Yes
26. In past ONE YEAR:
   a. How many days per week, on average, did you use Marijuana?

   [ ] Daily
   [ ] 5-6 days a week
   [ ] 3-4 days a week
   [ ] 1-2 days a week
   [ ] Less than 3 times a month
   [ ] Have not used Marijuana in past one year

27. How many years did you/have you used Marijuana?

   ________________________ (# years)

28. What type of tobacco do you use most frequently?

   [ ] Cigarettes
   [ ] Cigars
   [ ] Smokeless Tobacco
   [ ] Pipe Tobacco

29. What brand of cigarettes do you smoke most frequently?

   ________________________________ (brand name)

30. Is the brand of cigarettes you smoke most frequently:

   [ ] Non-Menthol
   [ ] Menthol
   [ ] Don’t know

31. In the past ONE YEAR, have you used any of the following?

   a.) Cigars                      Yes  No
   b.) Smokeless Tobacco (dip, snuff, chew, etc.)  Yes  No
   c.) Pipe Tobacco                Yes  No
32. Since you started smoking, have you made any **serious** attempts to quit smoking and did so for 12 or more hours?

☐ No (Skip questions 33-35)
☐ Yes (Continue with questions 33-35)

33. Since you started smoking, how many times in your life have you made a **serious** attempt to quit smoking?

________________ (# times)

34. Since you started smoking, what was the longest period of time you were able to stay off cigarettes?

☐ 0 hours to 23 hours
☐ 24 hours and up to 1 week
☐ More than 1 week and up to 1 month
☐ More than 1 month up to 6 months
☐ More than 6 months and up to 1 year
☐ More than 1 year

35. In your attempts to quit smoking, what methods have you used? (Check all that apply.)

☐ Nicotine Replacement (Patch, gum, lozenge, nasal spray, inhaler)
☐ Zyban / Wellbutrin
☐ Group Counseling
☐ Individual Counseling
☐ Hypnosis, Acupuncture, Herbal Remedies, Laser methods
☐ “Cold Turkey”
☐ Other – Specify ___________________________________________________________

**SMOKING HOUSEHOLD / ENVIRONMENTAL**

36. How many adults live in your household currently? (include yourself, partners, etc.)

________________ (# adults)

37. How many adults in your household currently smoke? (include yourself)

________________ (# adults)

**A. PARTNER / SPOUSE:**

38. Do you currently have a partner/spouse?

☐ No (Skip questions 39-41)
☐ Yes (Continue with questions 39-41)
39. Does your partner/spouse know that you are a smoker?
    □ No
    □ Yes

40. Has your partner/spouse asked you to quit smoking?
    □ N/A – My partner/spouse does not know I smoke
    □ No
    □ Yes, sometimes
    □ Yes, frequently
    □ Yes, all the time

41. How often does your current partner/spouse smoke cigarettes?
    □ Non-smoker
    □ Ex-smoker (Not smoked in the past ONE YEAR)
    □ Occasional smoker (Less than Daily, or has smoked in past ONE YEAR)
    □ Regular smoker (Daily or nearly Daily)

B. CHILDREN:

42. Do you have any children?
    □ No (Skip questions 43-45)
    □ Yes (Continue with questions 43-45)

43. How many children do you have?
    ____________________ (# children)

44. Do one or more of your children know that you are a smoker?
    □ No
    □ Yes

45. Have one or more of your children asked you to quit smoking?
    □ N/A – My children do not know I smoke
    □ No
    □ Yes, sometimes
    □ Yes, frequently
    □ Yes, all the time
C. PARENTS:

46. Is/was your mother (or woman who raised you longest) a regular cigarette smoker?
   - No
   - No, not a cigarette smoker, but she used smokeless tobacco or cigars regularly
   - Yes, but she quit or is no longer a smoker
   - Yes, she currently smokes or never quit

47. Is/was your father (or man who raised you longest) a regular cigarette smoker?
   - No
   - No, not a cigarette smoker, but he used smokeless tobacco or cigars regularly
   - Yes, but he quit or is no longer a smoker
   - Yes, he currently smokes or never quit

48. Do either/or both of your parents know that you are a smoker?
   - No
   - Yes

49. Have your parents asked you to quit smoking?
   - N/A – My parents do not know I smoke
   - No
   - Yes, sometimes
   - Yes, frequently
   - Yes, all the time

D. FRIENDS / CO-WORKERS:

50. What percent of your close friends (i.e., those you interact with regularly) are current smokers?
   - N/A, I do not have close friends or regular contact with others socially
   - None / Few, 0 – 25%
   - Some, 26 – 50%
   - Many, 51 – 75%
   - Most or All, 76 – 100%

51. What percent of your co-workers (i.e., those you interact with regularly) are current smokers?
   - N/A, I do not work or have co-workers or regular contact with others at work
   - None / Few, 0 – 25%
   - Some, 26 – 50%
   - Many, 51 – 75%
   - Most or All, 76 – 100%
SMOKING HABITS

52. How soon after you wake up do you smoke your first cigarette?

☐ Within 5 minutes
☐ 6-30 minutes
☐ 31-60 minutes
☐ After 60 minutes

53. Do you find it difficult to refrain from smoking in places where forbidden, e.g. at the library, movie theater, church, etc...?

☐ Yes
☐ No

54. Which cigarette would you hate most to give up?

☐ First one in the morning
☐ Any of the others

55. How many cigarettes/day do you smoke?

☐ 31-40 or more cigarettes
☐ 21-30 cigarettes
☐ 11-20 cigarettes
☐ 10 or less cigarettes

56. Do you smoke more frequently during the first hours after waking than during the rest of the day?

☐ Yes
☐ No

57. Do you smoke if you are so ill that you are in bed most of the day?

☐ Yes
☐ No
### NON-SMOKING CONFIDENCE

**How confident are you that you would NOT smoke in the following situations?**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Not at all confident</th>
<th>Not very confident</th>
<th>Unsure/Don’t know</th>
<th>Very confident</th>
<th>Extremely confident</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>82.</strong></td>
<td>When things are just not going the way I want and I am frustrated.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>83.</strong></td>
<td>With my spouse or close friend who is smoking.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>84.</strong></td>
<td>When I am angry about something or someone.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>85.</strong></td>
<td>Over coffee while talking and relaxing.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>86.</strong></td>
<td>When I first get up in the morning.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>87.</strong></td>
<td>When I feel I need a lift.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>88.</strong></td>
<td>With friends at a party.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>89.</strong></td>
<td>When I am extremely anxious and stressed.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>90.</strong></td>
<td>When I realize I haven’t smoked for awhile.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
## SMOKING STAGES

Circle the number below that best represents where you are right now with your smoking?

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>I have quit smoking and I will never smoke again.</td>
</tr>
<tr>
<td>9</td>
<td>I have quit smoking, but I still worry about slipping back, so I need to keep working on living smoke-free.</td>
</tr>
<tr>
<td>8</td>
<td>I still smoke, but I have begun to change, like cutting back on the number of cigarettes I smoke. I am ready to set a quit date.</td>
</tr>
<tr>
<td>7</td>
<td>I definitely plan to quit smoking within the next 30 days.</td>
</tr>
<tr>
<td>6</td>
<td>I definitely plan to quit smoking in the next 6 months.</td>
</tr>
<tr>
<td>5</td>
<td>I often think about quitting smoking, but I have no plans to quit.</td>
</tr>
<tr>
<td>4</td>
<td>I sometimes think about quitting smoking, but I have no plans to quit.</td>
</tr>
<tr>
<td>3</td>
<td>I rarely think about quitting smoking, and I have no plans to quit.</td>
</tr>
<tr>
<td>2</td>
<td>I never think about quitting smoking, and I have no plans to quit.</td>
</tr>
<tr>
<td>1</td>
<td>I enjoy smoking and have decided not to quit smoking for my lifetime. I have no interest in quitting.</td>
</tr>
</tbody>
</table>
HIV Stigma Scale

This study asks about some of the social and emotional aspects of having HIV. For most of the questions, just circle the letters or numbers that go with your answer. There are no right or wrong answers. Feel free to write in comments as you go through the questions.

This first set of questions asks about some of your experiences, feelings, and opinions as to how people with HIV feel and how they are treated. Please do your best to answer each question.

For each item, circle your answer: Strongly disagree (SD), disagree (D), agree (A), or strongly agree (SA).

1. In many areas of my life, no one knows that I have HIV ........................................... SD D A SA
2. I feel guilty because I have HIV................................. SD D A SA
3. People’s attitudes about HIV make me feel worse about myself......................................................... SD D A SA
4. Telling someone I have HIV is risky............................... SD D A SA
5. People with HIV lose their jobs when their employers find out........................................ SD D A SA
6. I work hard to keep my HIV a secret.............................. SD D A SA
7. I feel I am not as good a person as others because I have HIV .......................................................... SD D A SA
8. I never feel ashamed of having HIV............................ SD D A SA
9. People with HIV are treated like outcasts .............. SD D A SA
10. Most people believe that a person who has HIV is dirty............................................................... SD D A SA
11. It is easier to avoid new friendships than worry about telling someone that I have HIV ................ SD D A SA
12. Having HIV makes me feel unclean............................... SD D A SA
13. Since learning I have HIV, I feel set apart and isolated from the rest of the world.......................... SD D A SA
14. Most people think that a person with HIV is disgusting.......................................................... SD D A SA
15. Having HIV makes me feel that I'm a bad person.. SD D A SA
16. Most people with HIV are rejected when others find out .......................................................... SD D A SA
17. I am very careful who I tell that I have HIV............ SD D A SA
18. Some people who know I have HIV have grown more distant .................................................. SD D A SA
19. Since learning I have HIV, I worry about people discriminating against me............................ SD D A SA
20. Most people are uncomfortable around someone with HIV......................................................... SD D A SA
21. I never feel the need to hide the fact that I have HIV ................................................................. SD D A SA
22. I worry that people may judge me when they learn I have HIV .................................................. SD D A SA
23. Having HIV in my body is disgusting to me............ SD D A SA

Many of the items in this next section assume that you have told other people that you have HIV, or that others know. This may not be true for you. If the item refers to something that has not actually happened to you, please imagine yourself in that situation. Then give your answer ("strongly disagree (SD), "disagree (D)," "agree (A)," "strongly agree (SA)") based on how you think you would feel or how you think others would react to you.

24. I have been hurt by how people reacted to learning I have HIV .................................................. SD D A SA
25. I worry that people who know I have HIV will tell others........................................................... SD D A SA
26. I regret having told some people that I have HIV.. SD D A SA
<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>27.</td>
<td>As a rule, telling others that I have HIV has been a mistake.</td>
<td>SD D A SA</td>
</tr>
<tr>
<td>28.</td>
<td>Some people avoid touching me once they know I have HIV.</td>
<td>SD D A SA</td>
</tr>
<tr>
<td>29.</td>
<td>People I care about stopped calling after learning I have HIV.</td>
<td>SD D A SA</td>
</tr>
<tr>
<td>30.</td>
<td>People have told me that getting HIV is what I deserve for how I lived my life.</td>
<td>SD D A SA</td>
</tr>
<tr>
<td>31.</td>
<td>Some people close to me are afraid others will reject them if it becomes known that I have HIV.</td>
<td>SD D A SA</td>
</tr>
<tr>
<td>32.</td>
<td>People don't want me around their children once they know I have HIV.</td>
<td>SD D A SA</td>
</tr>
<tr>
<td>33.</td>
<td>People have physically backed away from me when they learn I have HIV.</td>
<td>SD D A SA</td>
</tr>
<tr>
<td>34.</td>
<td>Some people act as though it's my fault I have HIV.</td>
<td>SD D A SA</td>
</tr>
<tr>
<td>35.</td>
<td>I have stopped socializing with some people because of their reactions to my having HIV.</td>
<td>SD D A SA</td>
</tr>
<tr>
<td>36.</td>
<td>I have lost friends by telling them I have HIV.</td>
<td>SD D A SA</td>
</tr>
<tr>
<td>37.</td>
<td>I have told people close to me to keep the fact that I have HIV a secret.</td>
<td>SD D A SA</td>
</tr>
<tr>
<td>38.</td>
<td>People who know I have HIV tend to ignore my good points.</td>
<td>SD D A SA</td>
</tr>
<tr>
<td>39.</td>
<td>People seem afraid of me once they learn I have HIV.</td>
<td>SD D A SA</td>
</tr>
<tr>
<td>40.</td>
<td>When people learn you have HIV, they look for flaws in your character.</td>
<td>SD D A SA</td>
</tr>
</tbody>
</table>
Medication Adherence Rating Scale

1. Do you ever forget to take your medication?  
   Yes   No

2. Are you careless at times about taking medication?  
   Yes   No

3. When you feel better, do you sometimes stop taking your medication?  
   Yes   No

4. Sometimes if you feel worse when you take the medicine, do you stop taking it?  
   Yes   No

5. I take my medication only when I'm sick.  
   Yes   No

6. It is unnatural for my body to be controlled by medication.  
   Yes   No

7. By staying on medication, I can prevent getting sick.  
   Yes   No
APPENDIX C

MSM Smoking Cessation/HIV Medication Adherence Focus Group
Curriculum Creation Discussion Guide

I. Introduction:
Welcome, Thanks for coming and agreeing to talk with us today in this focus group.

Moderator: Remember to also introduce yourself and any other members of the team that are assisting or who are present.

- Orientation to the setting and procedures: A focus group is an open, confidential discussion about a specific topic. We ask that each of the members of this focus group respect the privacy of the other members. Keep in mind that there are no correct answers to the questions that we will be asking and each of us is entitled to our own opinions. The focus groups will be taped (with your consent) so we can write the report. However, no identifying information will be used in any reports. The topic today will be about community sources of health information.

- Framing script: “During our time together, we will be discussing questions about your health and health behaviors with a particular interest in your smoking experiences. In addition, we will be discussing your experiences with HIV medications. In focus groups, we will also explore reasons why you may smoke and what types of things that would help you start thinking about quitting. We will also discuss any difficulties you’ve been having staying adherent to your HIV medications. Finally, we will ask you to help us think about what might be some of the most important components of a combined smoking cessation and HIV medication adherence treatment program to make it relevant to individuals like yourselves.

- Time constraints: We are interested in hearing about your experiences. Because we have a lot of ground to cover, part of my responsibility will be to keep us on schedule. Occasionally, I may have to shift topics before everyone has had an opportunity to share. However, if time permits, we’ll come back to any unfinished topics.

- Questions or concerns: Does anyone have any questions at this point?

II. Icebreaker
Lead in: If there aren’t any additional questions, let’s get started by going around the room and introducing ourselves. Let’s have each person briefly tell us:
   a. What name you want to be called by
   b. Why you decided to participate in the focus group?

III. Smoking habits.
Let’s first talk about your first experiences with smoking tobacco.

- When did you start smoking and why?
- Are the reasons that you smoke now the same or different?
  - If different, what are your current reasons for smoking?

- Thinking about your smoking habits right now . . . When are you most likely to smoke? **ACTIVITY: Write responses on separate sheets of paper for each category.**
  - time, place, persons, feelings

- When are you least likely to smoke and why?

- What are your strongest and most consistent triggers for smoking? i.e., drinking, etc.
  - **Activity: Write on flipchart and see if group can rank order the triggers.**

**IV. Cultural identity**
We know that members of different cultural or racial groups may have different reasons for smoking. We know that African Americans, MSM and people who are HIV+ are more likely to be smokers.

- Were you aware of this information? Why do you think this is the case?
  - Think about the communities that you are a part of (your multiple identities). Do you think the reasons you smoke might be related to your membership in these communities?

**V. Minority Stress**
- We know that some members of minority groups such as AA, MSM and persons with HIV may face additional pressures in life because of prejudice and discrimination.

- Why might stress/discrimination/stigma contribute to higher smoking rates in:
  - AA
  - HIV+
  - MSM

**VI. Community Norms**
Sometimes members of different communities think and feel differently about tobacco use and smoking.

How acceptable is it to be a smoker in the various communities that you belong to? Think about:
  - AA community
  - MSM communities
  - HIV+ communities
  - Other important communities?
How about the people that you are close to?
   Do the people in your life smoke? (probe: friends, partners, family)
- How do the people in your life feel about your smoking?
  o Have they asked you to quit? Not smoke around them? Other actions?

VII. Knowledge
Let’s talk about what you know about smoking and health.
   - What are some of the risks associated with smoking in general?

   - What are some of the risks associated with smoking if you are HIV+?
     - Does smoking impact your HIV infection or treatment?

   - What are some of the risks associated with HIV medication nonadherence?

VIII. Attitudes about smoking cessation
- How easy or difficult do you feel it is to stop smoking if you wanted to?
  - What makes you feel this way?

- How often do you consider stopping smoking?
  o Have you tried to stop smoking since being diagnosed with HIV?

- What types of things make you want to quit?

- What types of things make you want to continue as a smoker?

- What would help motivate you to make a quit attempt?

IX. Smoking Cessation Treatments
People try to stop smoking using a number of different methods. In your opinion

- What do you think are some of the best ways to stop smoking?

- What are your thoughts about formal stop smoking treatment programs such as hotlines, groups, individual counseling, medications?
  o What have you heard about them?
  o What are the pros and cons of going to a stop smoking treatment program?

- How do you feel about using nicotine replacement or other types of medications for trying to stop? What are the pros and cons?
X. Patient provider communication about smoking
- Where do you receive the majority of your health care services?

- Has your current doctor ever asked if you smoke? Does he/she know that you smoke?

- Has your regular doctor ever talked to you about stopping smoking?
  - Has your provider ever recommended that you quit?

If yes, did your provider give you any information about how to quit? Have you tried to quit when asked to by your doctor? What worked? What didn’t.

XII. Barriers to smoking cessation - THIS MIGHT COME UP IN EARLIER SECTIONS AND CAN BE SKIPPED HERE.
Now I’d like to talk with you any barriers to stopping smoking?
- What are the things that have keep you from quitting smoking?
- Ask about
  o Lack of motivation
  o Stress
  o Lack of access to smoking cessation treatments
  o No LGBT specific smoking cessation programs
  o Costs - treatments or nicotine replacement
  o No support from family/friends
  o Not a health priority
  o Others?

XIII. Attitudes About HIV and HIV Medication Adherence
- Do you discuss your HIV status with your family and friends?
  o What do you think society thinks about people with HIV?

- How easy or difficult do you feel it is to stay adherent to HIV medications?
  o What are the things that make it difficult?
  o What have you done that has been successful to stay adherent?

- What types of things make you want to be medication adherent?

- What types of things make you want to be medication nonadherent?

- What would help motivate you to be medication adherent?

XIV. Patient Provider Communication About HIV Medication Adherence
- Does your doctor communicate to you in an effective manner the purposes and side effects of your medications?
- Does your regular doctor ask you about your HIV medication adherence regularly?
  - Have you felt comfortable enough with your doctor to disclose any difficulties with taking HIV meds?

- Has your regular doctor ever talked to you about the importance of staying adherent to HIV medications?

If yes, did your provider give you any information about medication adherence? Do you try to increase your HIV medication adherence asked to by your doctor? What worked? What didn’t?

XIII. Elements of a Successful Smoking and HIV Medication Adherence Cessation Program

- Now let’s talk about some of the things that you believe would be helpful in a smoking cessation and HIV medication adherence treatment program for individuals like yourself

- What type of focus, information, materials, how run, by whom?

- What type of supports do you need for quitting?

- What can we do to help you feel comfortable with a smoking cessation and medication adherence program?
  o AA
  o MSM
  o HIV+ individual

O.k., This completes are focus group session. Is there anything else that you would like to add or have us consider before we end?
I. Introduction:
Welcome, thanks for coming and agreeing to talk with us today in this focus group.

Moderator: Remember to also introduce yourself and any other members of the team that are assisting or who are present.
• Orientation to the setting and procedures: A focus group is an open, confidential discussion about a specific topic. We ask that each of the members of this focus group respect the privacy of the other members. Keep in mind that there are no correct answers to the questions that we will be asking and each of us is entitled to our own opinions. The focus groups will be taped (with your consent) so we can write the report. However, no identifying information will be used in any reports. The topic today will be about community sources of health information.
• Framing script: “During our time together, we will be reviewing intervention curriculum created to target smoking cessation and HIV medication adherence for men such as yourselves. We will discuss what you like about the curriculum, what you don’t like about it, and any suggestions you have to make it more relevant for you. In general, we may discuss questions about your health and health behaviors with a particular interest in your smoking and HIV medication adherence experiences. In addition, we will be discussing your experiences with HIV medications. In particular, we will discuss whether this intervention meets your specific needs for smoking cessation and HIV medication adherence.”
• Time constraints: We are interested in hearing about your opinions experiences. Because we have a lot of ground to cover, part of my responsibility will be to keep us on schedule. Occasionally, I may have to shift topics before everyone has had an opportunity to share. However, if time permits, we’ll come back to any unfinished topics.
• Questions or concerns: Does anyone have any questions at this point?

II. Icebreaker
Lead in: If there aren’t any additional questions, let’s get started by going around the room and introducing ourselves. Let’s have each person briefly tell us:
   a. What name you want to be called by
   b. Why you decided to participate in the focus group?

III. Introduction of Intervention
We know that African Americans, MSM and people who are HIV+ are more likely to be smokers. In fact, HIV+ African American MSM have some of the highest rates of smoking of any population. Additionally, HIV+ African American MSM have one of the poorest adherence rates to HIV medications.

V. Reasons for Higher Smoking Rates among HIV+ African American MSM
- We know that some members of minority groups such as AA, MSM and persons with HIV may face additional pressures in life because of prejudice and discrimination.
- Reasons behind higher smoking rates and poor HIV medication adherence among African American MSM
  - Stress due to discrimination, homophobia, and AIDS-phobia
  - Lack of access to stop smoking treatments and HIV medications
  - Lack of education about risks of smoking and poor HIV medication adherence
  - Community acceptance of smoking
  - Distrust of doctors
  - Targeting by the tobacco industry

VI. Unique Barriers to Smoking Cessation
- Cultural
  - Smoking is part of a masculine gay image
  - Everyone in the community smokes
- Attitudinal
  - It is impossible to quit smoking
- Social
  - Everyone I know smokes
- Behavioral
  - I smoke when I drink
- Emotional
  - I smoke because of stress
  - I smoke because I’m bored

VII. Unique Barriers to Medication Adherence
- Attitudinal
  - I’m going to die anyway
- Medication Management
  - Keeping track of my medications is difficult.
- Structural
  - I am don’t have a regular doctor.
- Behavioral
  - I don’t remember to take my medications when I’m out.
VII. Lack of Effective Treatments
- HIV+ African American MSM have less access to effective smoking and HIV medication adherence interventions
- Stop smoking treatment guidelines say that the best treatments are a combination of counseling, support, and nicotine replacement.
- Counseling and education have been found to be effective in increasing HIV medication adherence.

VIII. Targeted combined smoking cessation and medication adherence intervention
- We are developing a smoking cessation and medication adherence intervention specifically tailored for HIV+ African American MSM
- Doing a joint program because of the health complications that arise from comorbid smoking and medication nonadherence and recent literature suggesting targeting 2 health behaviors for change increases the likelihood of success
- Treatment focuses on the multiple barriers to quitting and staying adherent to HIV medication
  - Cultural
  - Emotional
  - Attitudinal
  - Environmental
  - Behavioral
  - Social
  - Structural
- What do you think about a targeted combined smoking cessation and HIV medication adherence program for HIV+ African American MSM?
- How comfortable would you be talking about smoking, medication adherence, and issues related to being:
  - African American
  - MSM
  - HIV+
- Did we capture your reasons for smoking?
- Did we capture your reasons for HIV medication non-adherence?
- How likely would you be to join a program like this?
- How likely would you be to use the nicotine replacement patch?

IX. Program Details
- The program is six sessions and includes:
  - 90 minutes of group therapy
  - Counseling and skill development
  - Social support for quitting and medication adherence
  - Nicotine replacement patch
O Pill boxes

Moderator: Take out curriculum and ask the questions below for each session.

X. Questions to ask about each session of the intervention.
- What do you think of the format of the group?
- What did you think of the topics covered in the session X?
- What did you think of the activities/materials for session X?

Moderator: Ask the group what they think the intervention should be named.

XI. Thank you!
- Receive stipend
- Sign up if you would like to be considered for the program
APPENDIX E

Screening Tool for African American MSM Smoking/HIV Medication Adherence Project

Thank you for calling about our smoking cessation/HIV medication adherence study. My name is (name) and I’m one of the staff members working on the smoking cessation research project, which is being conducted here in Chicago by Howard Brown Health Center and the University of Illinois at Chicago.

The purpose of the study is to test a targeted smoking cessation/HIV medication adherence intervention for HIV+ African American Men who have Sex with Men.

Are you interested in hearing more about the study?

☐ No (discontinue screening)
☐ Yes (continue)

If you are eligible for the study and decide to enroll, you would receive the targeted intervention and will attend 6 weekly group-based smoking cessation and HIV medication adherence counseling sessions. You will use the nicotine replacement patch for one month and be provided with pillboxes to help you manage your HIV medications. You will also complete study assessment questionnaires before the intervention begins, at the weekly smoking cessation sessions, and at 1 month and 3 months after your quit smoking date. The total enrollment time is approximately 6 months. You would receive $25 for completing the baseline enrollment visit, $5 for each weekly intervention session, $25 for the 1-month follow-up visit and $25 for the 3-month follow-up visit. The total compensation possible for participation in all research activities is $105. Due to the group-based nature of the intervention, no make-up sessions are possible if you are unable to attend one of the sessions. You will be given the written materials for any sessions you miss and encouraged to read over the information. However, you will be asked to come in to complete data collection for the missed session and to receive your nicotine replacement patch supply. You will be compensated for completing only data collection at the same rate for the session you missed. We encourage you to come in for future sessions, including the 1- and 3-month follow-ups, even if you miss any sessions.

All the information you provide in the study questionnaires will be treated as confidential. Your screening data may be retained for the larger main study. If you agree, you may be contacted to see if you are interested in participating in that study in the future.

If you are ineligible, you have the option to indicate whether your contact information can be saved for future Howard Brown Health Center studies. With
your permission, only your contact information will be kept in a file in a locked cabinet separate from the rest of the study data so that you are not linked to this study. You will be re-screened and re-consented for any future studies based on that study’s IRB approved protocol should you choose to participate in them.

Do you have any questions about the study at this point? ________________

In order to determine if you are eligible for this study, I will need to ask you a few questions. These questions will determine if you are eligible for the study and may be used later as part of our research for African American Men. Do I have your permission to ask you these questions?

☐ No (discontinue screening)
☐ Yes

First of all, how did you hear about the study?

☐ Posted flyer in community location (coffee shop, bar, etc.)
☐ Newspaper ad – Gay paper or magazine or newsletter
☐ Newspaper ad – Mainstream paper or magazine or newsletter
☐ Internet posting - Craig’s list, listserv, forwarded email, etc.
☐ Howard Brown – Research Website
☐ Howard Brown Clinic – posting in clinic or provider referral
☐ CORE Center – posting in clinic or provider referral
☐ I was contacted by HBHC because I was in another study
☐ Word of mouth – friend, other study participant, etc.
☐ Announcement at a community event
☐ Other: ________________________________

**Eligibility Questions:**

What is your age?:

☐ Under 18 (if under 18, ineligible)
☐ 18-65

☐ Eligible  ☐ Ineligible

What is your HIV status?:

☐ Positive
☐ Negative (ineligible, go to ineligibility statement)
☐ Never been tested/Don’t know (ineligible, go to ineligibility statement)

☐ Eligible  ☐ Ineligible

**Eligibility Criteria:**

- Age – 18-65
- HIV status – Positive, reported difficulty taking antiretroviral medications
- Race – Primarily identifies as Black or African American
Have you experienced difficulty taking your antiretroviral (HIV) medications? Eg. You miss or skip doses or you generally struggle taking your medications?

☐ Yes
☐ No (ineligible, go to ineligibility statement)
  ☐ Eligible  ☐ Ineligible

Do you currently have prescriptions for antiretroviral medications (HIV medications)?

☐ Yes
☐ No (ineligible, go to ineligibility statement)
  ☐ Eligible  ☐ Ineligible

Are you currently under a doctor’s care?

☐ Yes
☐ No (ineligible, go to ineligibility statement)
  ☐ Eligible  ☐ Ineligible

What is your race?: ______________

☐ African American/Black/Man of Color/Afro-American/Of African descent
☐ If Biracial, “Do you primarily identify as African American/Black or something else”
☐ If Latino “Do you primarily identify as African American/Black or something else?”
  ☐ Eligible  ☐ Ineligible

What is your sex? Specifically, what sex were you assigned at birth?

☐ Male
☐ Female
  ☐ Eligible  ☐ Ineligible

What is your gender?

☐ Male
☐ Female
☐ Transgender
  ☐ Eligible  ☐ Ineligible

What is your preference in your intimate/romantic partners?

☐ Opposite Sex
☐ Same Sex
☐ Both Sexes
☐ Do not wish to answer
  ☐ Eligible  ☐ Ineligible

Eligibility Criteria:

Sex – Male
Gender – Male
Sexual Orientation – MSM
Have you ever smoked 100 cigarettes (5 packs) or more in your life?

☐ No
☐ Yes

☐ Eligible  ☐ Ineligible

Have you smoked any cigarettes at all in the past ONE YEAR?

☐ No
☐ Yes

☐ Eligible  ☐ Ineligible

Thinking about the past year, about how many days per week did you smoke cigarettes?

☐ Daily
☐ 5-6 days a week
☐ 3-4 days a week
☐ 1-2 days a week
☐ Less than 3 times a month
☐ Have not smoked in past one year

☐ Eligible  ☐ Ineligible

On a scale of 0-10, how interested are you in quitting smoking?

No Interest ___________________________________________ Highest Interest

0 1 2 3 4 5 6 7 8 9 10

☐ Eligible  ☐ Ineligible

These next questions will collect some physical health information.

Do you have a history of adverse reaction to the Nicotine patch?

☐ No
☐ Yes

☐ Eligible  ☐ Ineligible

Eligibility Criteria:

Smoking – More than 5 packs in lifetime AND past year smoking AND 4 or more days per week

Interest in quitting – 7 or more

Do you have uncontrolled hypertension?

☐ No
☐ Yes

☐ Eligible  ☐ Ineligible

Eligibility Criteria:

Must answer “No” to all physical health questions
Do you have active coronary artery disease (hardening of the arteries)?

☐ No
☐ Yes
☐ Eligible  ☐ Ineligible

**ELIGIBILITY DETERMINATION: DON'T READ TO PARTICIPANT**

Caller is eligible for the study if met ALL eligibility questions above.

☐ Eligible  ☐ Ineligible

Reason(s) for Ineligibility: (check all that apply)

☐ Age
☐ Race
☐ HIV Status
☐ Gender
☐ Sexual Orientation
☐ Smoking Behaviors
☐ Interest in quitting
☐ Medical Reasons
☐ Currently using NRT

STUDY ENROLLMENT

Thank you for your time in answering these questions about yourself and your smoking.

IF ELIGIBLE:
You are eligible to be in our study.
Are you still interested in participating in the study? ______________

Check availability to participate in any of the group days and times? ______________ Date/time

Check availability to complete enrollment visit: ____________________ Date/time
May I collect some contact information so we can remind you about study visits? This information will be kept confidential by study staff. Do I have your permission to record this information?

☐ No
☐ Yes (if yes, fill out Study Locator Form)

Do you have an e-mail address that you would like to share with me? Fill out Study Locator

**IF INELIGIBLE:**
Sorry, but you do not meet the eligibility requirements for this study. Thank you very much for your interest in our study. We conduct many different types of studies here at Howard Brown. Would you like for us to keep your contact information on file so that we can call you if we have another study you may be interested in?

☐ No
☐ Yes (if yes, record separately for Department wait list)

**Interviewer: IF SUBJECT DOES NOT AGREE TO HAVE THEIR CONTACT INFORMATION SAVED FOR FUTURE STUDIES, INFORM THE SUBJECT THAT THE SCREENING AND CONTACT INFORMATION JUST COLLECTED WILL BE SHREDDED IMMEDIATELY. IF PARTICIPANT AGREES TO HAVE THEIR CONTACT INFORMATION SAVED FOR FUTURE STUDIES, INFORM THEM THAT THEIR CONTACT INFORMATION WILL BE SAVED AND STORED IN A FILE AND LOCKED CABINET SEPARATE FROM THE STUDY DATA, AND THEIR SCREENING INFORMATION WILL BE SHREDDED IMMEDIATELY. IMMEDIATELY SHRED SCREENING DOCUMENT IN BOTH CASES.**
APPENDIX F

UNIVERSITY OF ILLINOIS
AT CHICAGO

Office for the Protection of Research Subjects (OPRS)
Office of the Vice Chancellor for Research (MC 672)
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612

Approval Notice
Initial Review (Response To Deferred)

April 23, 2013

Kyle Jones, MA, BA
Psychology
Psychology
1007 W Harrison Street, M/C 285
Chicago, IL 60612
Phone: (312) 996-7885 / Fax: (312) 413-4122

RE: Protocol # 2013-0085
“Culturally Targeted Smoking Cessation/HIV Medication Adherence Intervention for African American HIV-positive Men who Have Sex With Men”

Dear Mr. Jones:

Your Initial Review (Response To Deferred) was reviewed and approved by the Convened review process on April 18, 2013. You may now begin your research.

Please note the following information about your approved research protocol:

This research has been determined to be no greater than minimal risk by the convened IRB, but will require convened review for Continuing Review and all substantive amendments due to the sensitivity of the data collected and the vulnerability of the subjects (20 copies required).

Please remember to submit a copy of IRB approval from the Howard Brown Health Center (HBHC) and the CORE Center prior to accessing/analyzing identifiable data and/or recruiting/enrolling subjects at the sites. Approval letters must be accompanied by an Amendment form when submitted to the UIC IRB.
Please remember to submit a copy of the grant/contract supporting this research. The grant/contract must be accompanied by an Amendment form when submitted to the UIC IRB.

Please remember to submit a revised Appendix P with additional research staff prior to their involvement in any research activities. Appendix P must be accompanied by an Amendment form when submitted to the UIC IRB.

Please remember to submit finalized data collection instruments prior to their use in the field. Finalized instruments must be accompanied by an Amendment form when submitted to the UIC IRB.

**Protocol Approval Period:** April 18, 2013 - April 18, 2014
**Approved Subject Enrollment #:** 70

**Additional Determinations for Research Involving Minors:** These determinations have not been made for this study since it has not been approved for enrollment of minors.

**Performance Sites:**
UIC, Respiratory Health Association of Metropolitan Chicago

**Sponsor:** National Institutes of Health

**PAF#:** 2013-00469

**Grant/Contract No:** Not available

**Grant/Contract Title:** A Smoking cessation/medication adherence intervention for African American MSM

**Research Protocol(s):**

a) Culturally Targeted Smoking Cessation and HIV Medication Adherence HIV-Positive MSM, Protocol; Version 3; 04/01/2013

**Recruitment Material(s):**

a) Focus Group Locator Form; Version 1; 01/04/2013

b) Pilot Phase Locator Form (no version #); 01/04/2013

c) Screening Tool for MSM Smoking/HIV Adherence Study, Focus Group; Version 3; 04/01/2013

d) Pilot Tear-Off Ad; Version 3; 04/01/2013

e) Pilot Ad; Version 3; 04/01/2013

f) Phase I Tear-Off Ad; Version 3; 04/01/2013

g) Study Provider Recruitment Script, Pilot Phase; Version 2; 04/01/2013

h) Study Provider Recruitment Script, Focus Groups; Version 2; 04/01/2013

i) Focus Group Ad; Version 3; 04/01/2013

j) Screening Tool for MSM Smoking HIV/Medication Adherence, Pilot; Version 3; 04/02/2013

**Informed Consent(s):**
a) Pilot Phase Consent; Version 4; 04/21/2013  
b) Focus Group Consent; Version 4; 04/21/2013  
c) A waiver of documentation of consent has been granted under 45 CFR 46.116(d)  
an alteration of consent has been granted under 45 CFR 46.116(d) for screening  
purposes only; minimal risk; written consent will be obtained at enrollment.

Your research meets the criteria for expedited review as defined in 45 CFR 46.110(b)(1)  
under the following specific category(ies):

(7) Research on individual or group characteristics or behavior (including but not limited  
to research on perception, cognition, motivation, identity, language, communication,  
cultural beliefs or practices and social behavior) or research employing survey, interview,  
oral history, focus group, program evaluation, human factors evaluation, or quality  
assurance methodologies.

Please note the Review History of this submission:

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<th>Submission Type</th>
<th>Review Process</th>
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Please remember to:

➔ Use your research protocol number (2013-0085) on any documents or  
correspondence with the IRB concerning your research protocol.

➔ Review and comply with all requirements on the enclosure,  
"UIC Investigator Responsibilities, Protection of Human Research Subjects"  
(http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0924.pdf)

Please note that the UIC IRB has the prerogative and authority to ask further  
questions, seek additional information, require further modifications, or monitor  
the conduct of your research and the consent process.

Please be aware that if the scope of work in the grant/project changes, the protocol  
must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need  
further help, please contact OPRS at (312) 996-1711 or me at (312) 355-0816. Please  
send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.
Sincerely,

Alison Santiago, MSW, MJ
IRB Coordinator, IRB # 2
Office for the Protection of Research

Enclosure(s):

1. **UIC Investigator Responsibilities, Protection of Human Research Subjects**
2. **Informed Consent Document(s):**
   a) Pilot Phase Consent; Version 4; 04/21/2013
   b) Focus Group Consent; Version 4; 04/21/2013
3. **Recruiting Material(s):**
   a) Focus Group Locator Form; Version 1; 01/04/2013
   b) Pilot Phase Locator Form (no version #); 01/04/2013
   c) Screening Tool for MSM Smoking/HIV Adherence Study, Focus Group; Version 3; 04/01/2013
   d) Pilot Tear-Off Ad; Version 3; 04/01/2013
   e) Pilot Ad; Version 3; 04/01/2013
   f) Phase I Tear-Off Ad; Version 3; 04/01/2013
   g) Study Provider Recruitment Script, Pilot Phase; Version 2; 04/01/2013
   h) Study Provider Recruitment Script, Focus Groups; Version 2; 04/01/2013
   i) Focus Group Ad; Version 3; 04/01/2013
   j) Screening Tool for MSM Smoking HIV/Medication Adherence, Pilot; Version 3; 04/02/2013

cc: Joe L. Martinez, Psychology, M/C 285
    Alicia K. Matthews (Faculty Advisor), Health Systems Science, M/C 802
    OVCR Administration, M/C 672
VITA

Kyle Jones, M.A.
852 W. Agatite Ave. #2· Chicago, IL 60640· kjones42@uic.edu · (916) 201-0921

EDUCATION

**Doctor of Philosophy** – Clinical Psychology Anticipated: August 2016
University of Illinois at Chicago – Chicago, IL
Dissertation: A Culturally Targeted Smoking Cessation/HIV Medication Adherence Intervention for African American Men who have Sex with Men

**Master of Arts** – Clinical Psychology October 2011
University of Illinois at Chicago – Chicago, IL

**Master of Arts** – Social Psychology May 2009
San Diego State University – San Diego, CA

**Bachelor of Arts** – Psychology May 2007
Pacific University – Forest Grove, OR

HONORS AND AWARDS

F31 DA035582-01 10/01/2013 – 09/30/2015
NIH/NIDA (Jones, PI)
$84,464
_A smoking cessation/medication adherence intervention for African American men who have Sex with men (MSM)_
The objective of the study is to develop and pilot a culturally targeted combined smoking cessation and antiretroviral medication adherence intervention for HIV-positive African American men who have sex with men.
**Role: Principal Investigator**

Facility Scholar Grant 12/01/2011 – 11/30/2012
The Institute for Research on Race and Public Policy at the University of Illinois at Chicago (Schewe, PI)
$10,000
_Effects of race, gender, and sexual orientation on experience of hate crimes in Chicago_ This purpose of this project was to assess the intersection of race and gender presentation on the experience of violence in the LGBT community.
**Role: Co-Investigator**
CLINICAL EXPERIENCE

Intern 06/29/2015 – 06/24/2016
Edward Hines, Jr. VA Hospital

Rotations (06/29/2015 – 12/25/2015)

Primary Care Behavioral Health
I served as a consult-liaison in fast-paced interdisciplinary primary care clinics. Additionally, I conducted brief evidence-based protocols in individual and group formats including: Cognitive Behavioral Therapy for Chronic Pain (CBT-CP), Acceptance and Commitment Therapy for Chronic Pain (ACT-CP), and Cognitive Behavioral Therapy for Insomnia (CBT-I). I conducted brief psychological intervention for various medical and psychological conditions requiring health behavior change such as diabetes, hypertension, obesity, smoking, affective disorders, binge eating disorder, sleep disorders, substance use and HIV/AIDS. My other responsibilities consisted of providing didactic presentations to medical professionals, trainees, and patients.

Supervisors: Erin Zerth, Ph.D., Jamie Mathews, Psy.D.

Spinal Cord Injury Service
I worked within a large multidisciplinary team providing psychological assessment, brief cognitive assessment, and psychological interventions to veterans with a range of spinal cord injuries and disorders. A key component of my responsibilities was to provide consultation to other providers to facilitate patient rehabilitation. I participated in staffings and presented behavioral management recommendations to other providers based on the results of psychological assessment. I conducted interventions on the inpatient unit focusing on adjustment to disability and illness, treatment compliance, affective disorders, personality disorders, and anxiety disorders. Additionally, I collaborated with other providers for treatment and discharge planning of inpatients.

Supervisor: Azi Ghaffari, Ph.D.

Rotations (12/28/2015 – 06/24/2016)

Blind Rehabilitation Center
I conducted psychological assessment and provided psychological intervention for visually impaired veterans participating in intensive blind rehabilitation training. I made recommendations to the interdisciplinary team based on brief psychological assessment to assist with rehabilitation planning. I developed expertise in the different etiologies of blindness and their associated psychopathology.

Solid Organ Transplant
As part of the Blind Rehabilitation Center rotation, I had the opportunity to conduct pre-surgical evaluations for solid organ transplant candidates. Behavioral characteristics of transplant patients are crucial to graft success, including potential adherence, substance abuse, social support for coping with a dramatic life change. I made recommendations for psychological support pre- and post-surgery to increase successful transplant outcomes.

Supervisor: Jennifer Kiebles, Ph.D.
Substance Abuse Residential Rehabilitation Treatment Program
I conducted individual and group interventions for patients enrolled in an intensive, structured residential substance use treatment program. Treatment modalities will include motivational interviewing and Cognitive Behavioral Therapy for Substance Use Disorders (CBT-SUD). Additionally, I conducted psychological assessments for newly admitted patients, ran psychoeducational groups and gained further consultation experience within an interdisciplinary team.
Supervisor: Amber Singh, Ph.D.

Extern 08/15/2014 – 05/15/2015
Advocate Lutheran General Hospital
Rehabilitation Psychology
I conducted brief inpatient cognitive screeners in the inpatient rehabilitation unit of a large private hospital. Patients primarily presented with traumatic brain injury, dementia, and spinal cord injury. Additionally, I conducted individual therapy sessions with former inpatients focusing on adjustment to disability, anxiety, and depression.
Supervisor: Mary Schmidt, Ph.D., ABPP

Extern 07/15/2013 – 05/31/2014
Edward Hines, Jr. VA Hospital
Primary Care Behavioral Health
I conducted brief structured individual and group therapy within Primary Care and Infectious Diseases clinics. The cases consisted of veterans presenting with minor to moderate depression and anxiety, pain disorders, and depression secondary to medical condition. I also worked with patients with chronic conditions, such as HIV/AIDS, diabetes, and hypertension, on treatment compliance. Additionally, I contributed to the creation of curriculum for an ongoing information session for the Nine Healthy Living Messages endorsed by the VA medical system.
Supervisors: Erin Zerth, Ph.D., Jamie Mathews, Psy.D.

Group Facilitator 09/01/2012 – 06/30/2015
Howard Brown Health Center
“Bitch to Quit”
I co-lead structured smoking cessation groups targeted for the lesbian, gay, bisexual, and transgender (LGBT) community as part of a large randomized NIH-funded study. This intervention took place at Howard Brown Health Center, one of the largest health and research centers in the United States for the LGBT community.
Supervisors: Alicia Matthews, Ph.D.

Extern 07/01/2012 – 06/30/2013
John H. Stroger Hospital of Cook County
Adult Outpatient Psychiatry
I conducted individual and group therapy at a large public hospital serving a primarily low-income population. Patients presented with a wide range of psychopathology including depression, anxiety, schizophrenia, and substance use disorders. Additionally, I
conducted brief inpatient cognitive evaluations. I also conducted co-therapy sessions in the pain clinic.

Supervisors: Gregory Davis, Ph.D., Stephen Clingerman, Ph.D., Linda Strozdas, Psy.D.

Extern 03/15/2010 – 06/15/2012
Office of Applied Psychological Services
University of Illinois at Chicago
I conducted individual therapy for mild to moderate depression and anxiety and psychological assessment at the outpatient clinic managed by the Department of Psychology at the University of Illinois at Chicago. My caseload consisted primarily of students and young adults.

Supervisors: Nancy Dassoff, Ph.D., Audrey Ruderman, Ph.D., Alicia Matthews, Ph.D., Maureen Stress, Ph.D.

RESEARCH EXPERIENCE

Principal Investigator 10/01/2013 – Present
University of Illinois at Chicago
Howard Brown Health Center
Manage recruitment, datasets, IRB correspondence, personnel, and finances for a pilot study of a culturally targeted combined smoking cessation and antiretroviral medication adherence intervention for HIV-positive African American men who have sex with men.

Supervisors: Alicia Matthews, Ph.D., David McKirnan, Ph.D.

Co-Investigator 01/01/2012 – 05/01/2013
Interdisciplinary Center for Research on Violence, University of Illinois at Chicago
Create a comprehensive report on the effects of the intersection of race, gender, and sexual orientation on the experience of violence among the LGBT community for the Chicago Commission on Human Relations. Responsibilities included data collection, maintenance of study datasets, and data analyses.

Supervisors: Paul Schewe, Ph.D., Alicia Matthews, Ph.D.

Graduate Research Assistant 07/01/2011 – 06/30/2015
University of Illinois at Chicago
Howard Brown Health Center
Responsibilities consist of qualitative coding, data management, data collection, data analysis, and recruitment coordination for a randomized clinical trial to test the effectiveness of a culturally targeted smoking cessation intervention for the lesbian, gay, bisexual, and transgendered community.

Supervisor: Alicia Matthews, Ph.D.

Recruitment Coordinator 06/01/2010 – 08/30/2010
Howard Brown Health Center
Recruitment coordination for a study designed to assess the effects of a HIV prevention intervention developed for young men who have sex with men.

Supervisors: Amy Johnson, M.A., Marco Hidalgo, M.A.
Graduate Research Assistant 01/01/2008 – 05/30/2008
San Diego State University
Purpose of project was to assess reaction time differences to Black versus White men who are carrying a gun or a similar sized object. Main responsibility was data collection. 
Supervisor: Melody Sadler, Ph.D.

Graduate Research Assistant 08/01/2007 – 05/30/2008
San Diego State University
Duties included scheduling participants and data collection for a project to assess implicit attitudes toward various ethnicities and gender.
Supervisor: Thierry Devos, Ph.D.

Undergraduate Research Assistant 08/01/2005 – 05/30/2007
Pacific University
Duties were data entry, basic analyses, and lab organization for a study to assess efficacy and effectiveness of an intervention designed to improve social skills in elementary school children.
Supervisor: Alyson Burns-Glover, Ph.D.

PEER-REVIEWED PUBLICATIONS:


PROFESSIONAL TALKS


Mathews, J., & Jones, K. (2013). Providing comprehensive healthcare to LGBT active duty service members and veterans following the repeal of “Don’t Ask, Don’t Tell.” Paper presented at the 2nd Annual Operation: Do Ask, Do Tell, Jesse Brown VA Medical Center, Chicago, IL.


INVITED TALKS


POSTER PRESENTATIONS

Jones, K., Matthews, A. K., Kuhns, L., & King, A. (2012). Culturally tailoring an established smoking cessation intervention to the LGBT community. Poster submitted for presentation at the 33rd Annual Meeting and Scientific Sessions of the Society of Behavioral Medicine, New Orleans, LA.


TEACHING EXPERIENCE

Teaching Assistant 08/15/2009 – 05/15/2015
University of Illinois at Chicago
• Introduction to Cognitive Behavioral Therapy
• Field Work in Applied Psychology
• Social Psychology
• Theories of Personality
• Abnormal Psychology
• Psychology of Women and Gender
• Sport Psychology
• Introduction to Psychology

Teaching Assistant 08/15/2008 – 05/15/2009
San Diego State University
• Introduction to Psychology
• Sensation and Perception

Teaching Assistant 01/15/2007 – 05/15/2007
Pacific University
• Social Psychology

Undergraduate Students Mentored
• John Hayes (Research Assistant, 2014 – 2015)
• Natalie Ross (Research Assistant, 2012 – 2013)
• Emmanuel Olivier (Research Assistant, 2012 – 2013)
• Davilyn Freeman (Research Assistant, 2011 – 2012)

PROFESSIONAL ORGANIZATIONS

Gay and Lesbian Medical Association 2013 - Present

Society of Behavioral Medicine 2011 - Present