STUDY PROTOCOL

TITLE OF STUDY:
iQuit Mindfully: A Randomized Controlled Trial of Mindfulness-based Smoking Cessation Enhanced with Mobile Technology

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PRÉCIS

Study Title
iQuit Mindfully: A Randomized Controlled Trial of Mindfulness-based Smoking Cessation Enhanced with Mobile Technology

Objectives
The proposed study is a pilot investigation of mindfulness-based smoking cessation incorporating between-session text messaging ("iQuit Mindfully"). This will be the first known study to use text messaging to enhance mindfulness treatment.

Design and Outcomes
Participants will be randomly assigned to one of two groups: Mindfulness-based Addiction Treatment (MBAT) or iQuit Mindfully (MBAT with the addition of between-session text messages). Primary outcomes for this development and feasibility study are: 1) feasibility (e.g., attrition, engagement, participant ratings), 2) determining best practice for implementing and refining the text-messaging intervention (e.g., how many texts per day and at what times of day; which types of messages are most helpful; ways of increasing adherence), and 3) an estimate of effect size (based on smoking cessation in iQuit Mindfully vs. MBAT without text messaging).

Interventions and Duration
All participants will receive in-person group treatment based on the 8-week MBAT protocol (Wetter et al., 2009) in addition to nicotine patch therapy and self-help materials. Participants assigned to iQuit Mindfully will receive additional support via text messaging. Assessments will occur at baseline, at each of the weekly in-person visits, at end of treatment, and at 1-month follow-up.

Sample Size and Population
Participants will include English-speaking adult smokers (ages 18-65). Recruitment will target a racially/ethnically diverse sample of individuals with relatively low income levels. Participants (projected $N = 70$) will be randomly assigned to "iQuit Mindfully" (with text messaging) or MBAT (without text messaging). Approximately 10-15 participants will be enrolled per cohort, resulting in 6 cohorts (3 of each treatment).

1. STUDY OBJECTIVES

Primary outcomes for this development and feasibility study are: 1) feasibility (e.g., attrition, engagement, participant ratings; specific definitions of these outcomes are described in section 9), 2) determining best practice for implementing and refining the text-messaging intervention (e.g., how many texts per day and at what times of day; which types of messages are most helpful; ways of increasing adherence), and 3) an estimate of effect size (based on smoking cessation in iQuit Mindfully vs. MBAT). Effect sizes will be of greater importance than statistical significance, given that this is a feasibility study. Secondary analyses will include: 1) effects of treatment conditions on average number of cigarettes smoked per day; 2) effects of treatment on weekly mindfulness practice; 3) effects of treatment on self-reported levels of mindfulness, affect, self-efficacy, coping, dependence, and withdrawal symptoms; and 4) associations between number of sessions attended, weekly mindfulness practice, and abstinence.

2. BACKGROUND AND RATIONALE

Background and Significance

Tobacco use is the leading cause of preventable morbidity and mortality in the U.S. (CDC, 2008; Mokdad, Marks, Stroup, & Gerberding, 2004; USDHHS, 2010). Although most smokers indicate interest in quitting, only 6% quit each year (CDC, 2011b). Mindfulness-based interventions show promise for improving smoking cessation (Brewer et al., 2011; Davis, Fleming, Bonus, & Baker, 2007). For example, research suggests that participants receiving mindfulness training are over 5 times more likely to be abstinent at 17 weeks post-treatment, compared to standard treatment (Brewer et al., 2011). However, although between-session mindfulness practice is thought to be integral in producing benefits (Grow et al., 2015), participants do not always practice mindfulness in daily life (Vettese, Toneatto, Stea, Nguyen, & Wang, 2009). Fortunately, mobile health technology presents unique opportunities for mindfulness research and intervention. Between-session text messaging might be an effective means to encourage participants to use mindfulness techniques in the moments when they need them most, thus enhancing treatment effectiveness.

Enhancing the effectiveness of smoking cessation treatments is especially critical for underserved populations (i.e., members of racial/ethnic minority groups and individuals with low socioeconomic status [SES]), who often have greater difficulty quitting smoking and experience profound tobacco-related health disparities (CDC, 2011a, 2011b; Fagan, Moolchan, Lawrence, Fernander, & Ponder, 2007; Honjo, Tsutsumi, Kawachi, & Kawakami, 2006). Mobile technology is revolutionizing healthcare and might be used to enhance mindfulness-based interventions for smoking cessation in these populations.

Mindfulness

Mindfulness is defined as purposeful, present-focused attention with an attitude of acceptance and non-judgment (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006; Kabat-Zinn, 1990, 1994). Mindfulness is linked to improved mood, less anxiety and stress (Baer et al., 2006; Brown & Ryan, 2003; Smith et al., 2011), and lower stress reactivity (Bullis, Boe, Asnaani, & Hofmann, 2013).

Among smokers, mindfulness predicts lower negative affect and perceived stress (Adams et al., 2015; Waters et al., 2009), higher expectancies regarding ability to regulate emotions without smoking (Vidrine et al., 2009), and lower nicotine dependence (Vidrine et al., 2009). Brewer et al. (2011) found that in a diverse sample, mindfulness training for smoking cessation produced over 5 times better abstinence rates than standard treatment (31% vs. 6% at 17-week follow-up). In another diverse sample, Vidrine et al. (2016) found that although mindfulness treatment did not differ from cognitive-behavioral therapy (CBT) or usual care in terms of post-treatment abstinence from smoking,

mindfulness was superior in promoting lapse recovery. Among participants who were not abstinent at end of treatment, those who received mindfulness were more likely to regain abstinence by 1 week post-treatment, and this trend approached significance at 23 weeks. Mindfulness may be effective for preventing lapses from transitioning to full-blown relapses. Another study found that African American smokers with greater mindfulness were more likely to quit and to recover abstinence after an early lapse (Heppner et al., 2016). Tang, Tang, and Posner (2013) found that among current smokers, 2 weeks of mindfulness meditation produced a 60% reduction in smoking compared to a relaxation control.

Mobile Technology to Enhance Mindfulness Intervention Effectiveness. Mindfulness-based treatments (e.g., mindfulness-based stress reduction [MBSR] (Kabat-Zinn, 1990, 1994)) encourage participants to practice mindfulness between sessions, and consistent home practice appears to be a key factor in bringing about therapeutic outcomes (Vettese et al., 2009). However, mastering a new skill in treatment does not necessarily mean that it will translate to real-life situations, and a consistent barrier to treatment success occurs when individuals fail to practice mindfulness in daily life. In a recent trial of mindfulness-based smoking cessation, frequency of between-session mindfulness practice was relatively low (Vidrine et al., 2016). In my clinical experience, patients often realize in hindsight that using a particular strategy would have been helpful, but the strategy did not come to mind in that stressful moment (even with the best of intentions). When participants provide information on emotions, smoking urges, and situational circumstances, tailored in-the-moment strategies can be provided through text messages. By prompting participants to practice mindfulness in their daily lives, text-messaging interventions might increase skill level, self-efficacy, and the likelihood that the skill will become part of daily routines (Heron & Smyth, 2010).

Several researchers have implemented text message-based smoking cessation interventions with success, although none have included mindfulness (Abroms et al., 2012; Borland, Balmford, & Benda, 2013; Free et al., 2011; Obermayer, Riley, Asif, & Jean-Mary, 2004; Riley, Obermayer, & Jean-Mary, 2008; Rodgers et al., 2005). A recent review concluded that mobile phone interventions for smoking cessation nearly doubled the likelihood of quitting up to 6 month follow-up, compared to usual care (Whittaker et al., 2012). Research supports text messaging for promoting several health outcomes, including weight loss and diabetes management (Cole-Lewis & Kershaw, 2010; Fjeldsoe, Marshall, & Miller, 2009; Krishna, Boren, & Balas, 2009). These programs are cost-effective and beneficial across age and racial/ethnic groups (Cole-Lewis & Kershaw, 2010; Guerriero et al., 2012).

Focus on Underserved Populations. Disproportionately high rates of smoking are found in low-SES populations (CDC, 2011a). Compared to other racial/ethnic groups, African Americans tend to have greater difficulty quitting smoking and higher incidence and mortality rates for diseases associated with smoking (CDC, 2011b; Cooper et al., 2000; Fagan et al., 2007; Irvin Vidrine, Reitzel, & Wetter, 2009). The leading causes of death among Latinos (i.e., cancer, cardiovascular disease) are related to smoking (Heron, 2012). The majority of research on mindfulness has focused on higher-SES and Caucasian populations. Although mindfulness shows promise with respect to regulating emotion and promoting smoking cessation in diverse groups (Brewer et al., 2011; Szanton, Wenzel, Connolly, & Piferi, 2011), much work is needed to explore possible benefits and underlying mechanisms in these populations. Text messaging may be particularly effective for targeting low-SES and racial/ethnic minority populations. Latinos and individuals living in poverty are especially likely to have only wireless phones (Blumberg & Luke, 2013). In a Pew Research Center study, mean numbers of texts per day for Caucasians, African Americans, and Latinos were 31.2 (median 10), 70.1 (median 20), and 48.9 (median 20), respectively. Whereas mean number of texts per day among individuals with > college education was 23.8 (median 10), those with < high school education texted 58.7 (median 20) times per day (Smith, 2011). Furthermore, text messaging does not require a Smartphone, making it a highly feasible mode of intervention in low-income populations.

The proposed study is a pilot investigation of mindfulness-based smoking cessation incorporating between-session text messaging ("iQuit Mindfully"). This will be the first known study to use text messaging to enhance mindfulness treatment.

3. STUDY DESIGN

In this randomized clinical trial, participants will be randomly assigned to one of two groups: Mindfulness-based Addiction Treatment (MBAT) or iQuit Mindfully (MBAT with the addition of between-session text messages).

Primary outcomes for this development and feasibility study are: 1) feasibility (e.g., attrition, engagement, participant ratings), 2) determining best practice for implementing and refining the text-messaging intervention (e.g., how many texts per day and at what times of day; which types of messages are most helpful; ways of increasing adherence), and 3) an estimate of effect size (based on smoking cessation in iQuit Mindfully vs. MBAT without text messaging).

Secondary analyses will include: 1) effects of treatment conditions on average number of cigarettes smoked per day; 2) effects of treatment on weekly mindfulness practice; 3) effects of treatment on self-reported levels of mindfulness, affect, self-efficacy, coping, dependence, and withdrawal symptoms; and 4) associations between number of sessions attended, weekly mindfulness practice, and abstinence.

Participants will include English-speaking adult smokers (ages 18-65). Recruitment will target a racially/ethnically diverse sample of individuals with relatively low income levels. Participants (projected $N = 70$) will be randomly assigned to "iQuit Mindfully" (with text messaging) or MBAT (without text messaging; see details of interventions in section 5 below). Approximately 10-15 participants will be enrolled per cohort, resulting in 6 cohorts (3 of each treatment).

The study will take place at Georgia State University in Atlanta, GA. All participants will receive in-person group treatment based on the 8-week MBAT protocol (Wetter et al., 2009) in addition to nicotine patch therapy and self-help materials. Assessments will occur at baseline, at each of the weekly in-person visits, at end of treatment, and at 1-month follow-up.

4. SELECTION AND ENROLLMENT OF PARTICIPANTS

Participants will include English-speaking adult smokers (ages 18-65). Recruitment will target a racially/ethnically diverse sample of individuals with relatively low income levels.

Inclusion Criteria

Inclusion criteria are:

- age 18-65 years
- current smoker with history of $\geq$5 cigarettes/day for past year (and CO $\geq$6 ppm*; participants will not be excluded for use of e-cigarettes)
- motivated to quit within next 30 days
- valid home address in the greater Atlanta area
- functioning telephone number
- own a mobile phone with text messaging capacity
- can speak, read, and write in English
- marginal/adequate health literacy (at least a sixth-grade level as determined by the Rapid Estimate of Adult Literacy in Medicine [REALM]; Davis et al., 1991)

*Expired carbon monoxide (CO) will be used for biochemical confirmation of smoking status because it is a simple and noninvasive method that is commonly used in smoking research. Dr. Spears and/or research assistants (who have been trained by Dr. Spears on CO testing procedures) will administer CO testing. Participants are asked to take a deep breath in, hold their breath for 15 seconds, and then expire into the disposable mouthpiece on the CO monitor. Although some studies have employed cutoff values of 8-10 parts per million (ppm), a growing body of research suggests that values of 8-10ppm misclassify a large number of smokers as non-smokers (e.g., Javors et al., 2005; Raiff et al., 2010). A cutoff value of 6 was chosen for the present study because it has been associated with good sensitivity and specificity (Middleton & Morice, 2000) and has been used successfully in recent research (Vidrine et al., 2016).

Exclusion Criteria

Exclusion criteria are:

- contraindication for nicotine patch
- active substance abuse/dependence
- regular use of tobacco products other than cigarettes
- current use of tobacco cessation medications
- pregnancy or lactation
- household member enrolled in the study
- current diagnosis of schizophrenia or bipolar disorder, or use of antipsychotic medications
- Score of $\geq$3 on PHQ-2 depression screening instrument (indicating high likelihood of clinically significant depressive symptoms)

Study Enrollment Procedures

Participants will be recruited through flyers (posted at venues including the GSU campus, local hospitals/community health centers, near MARTA and bus stops, community centers and shelters, etc.) and through print media in local newspapers and on buses and trains. The research team will stimulate recruitment by giving presentations, talking with staff, providing study information, and supplying flyers at local clinics and community organizations in Atlanta, GA. Dr. Spears and research staff will also visit primary care practices and health fairs to provide study information and enhance recruitment. Participants will also be recruited through online sources (e.g., Craigslist, listservs) and by word of mouth.

Participants (projected *N* = 70) will be randomly assigned to “iQuit Mindfully” (with text messaging) or MBAT (without text messaging). Approximately 10-15 participants will be enrolled per cohort, resulting in 6 cohorts (3 of each treatment).

Randomization. Randomization will take place at the end of the baseline session, after baseline assessments have been administered. Block randomization will be used achieve balance in the number of assignments to each treatment group. This form of randomization can be conducted within each stratum (i.e., stratified permutated block design) in efforts to achieve both covariate balance and treatment balance (Hedden, Woolson, & Malcolm, 2006). Thus, in the present study stratified permutated block design will be used, and it will be most important to stratify on variables expected to interact with the text messaging intervention to predict smoking cessation. Given that younger adults typically send and receive more text messages than older adults, age is an important stratification factor. Data from the Pew Research Center indicate that mean number of texts sent/received per day is 87.7 among people aged 18-29; 27 texts/day among people ages 30-49; 11.4 texts/day among those aged 50-64; and 4.7 texts/day among those 65 and older. Thus, stratification will be based on ages 18-49 vs. 50-65 (this cutoff is consistent with the Pew Center data and also lines up with data

from Dr. Wetter's randomized controlled trial of mindfulness-based smoking cessation treatment, in which approximately 50% of participants were 49 or younger.)

5. STUDY INTERVENTIONS

In-Person Treatment for all participants will follow the Mindfulness-Based Addiction Treatment (MBAT) group protocol (Wetter et al., 2009). MBAT groups will only contain study participants (i.e., MBAT groups will not involve existing classes apart from the study). Studies of mindfulness treatments have typically utilized a group format (Keng, Smoski, & Robins, 2011; Roemer & Orsillo, 2003), and the approaches in this study are particularly well suited to a group format. Not only may the group format facilitate the acquisition of skills through observational learning and practice, but it may also increase participants' willingness to explore different practices more than they would have on their own. Thus, we chose to include group treatment (rather than delivering the entire treatment via text-messaging, which would lack important aspects of group treatment). All participants receive nicotine replacement therapy (NRT) and self-help materials in addition to MBAT. Participants receive nicotine patch therapy because the patch is the most widely used pharmacotherapy for smoking cessation and the *Treating Tobacco Use and Dependence Clinical Practice Guideline* identified the patch as a frontline therapy.(Fiore et al., 2000; Fiore et al., 2008) Compared to bupropion and varenicline, the patch is safer, better tolerated, and available over-the-counter.

Therapists. There will be between 1 and 3 therapists (depending on therapist schedules). Minimum therapist qualifications are: 1) completion of master's degree or equivalent in counseling, psychology, social work, or related field; 2) daily mindfulness practice; 3) experience teaching stress reduction or body-centered awareness disciplines in a group setting; and 4) completion of formal training in mindfulness (e.g., the 7-day residential Professional Training Program in Mindfulness-Based Stress Reduction or the 5-day Mindfulness-Based Cognitive Therapy professional training). Sessions will be audio-recorded in order to allow for assessment of treatment fidelity. After each session, audio recordings will be uploaded onto a secure server and deleted from the recorder. The server is managed by Georgia State University, password-protected, and available only to research personnel who have completed training in research with human subjects. Dr. Spears will randomly select two sessions from each group and rate adherence to the protocol using a modified version of the MBCT Adherence Scale (Segal, Teasdale, Williams, & Gemar, 2002; reference to depression will be replaced with reference to smoking). Each item is rated on a 0 to 2 point scale (0 = no evidence for item, 1 = slight evidence, 2 = definite evidence). For any items rated as 0 or 1, Dr. Spears will conduct further training with the study therapist.

Nicotine Patch Therapy. Patch therapy (beginning the week before quit day) for participants who smoke >10 cigarettes/day will consist of 4 weeks of 21 mg patches, 1 week of 14 mg patches, and 1 week of 7 mg patches. Patch therapy for participants who smoke 5-10 cigarettes/day will consist of 4 weeks of 14 mg patches and 2 weeks of 7 mg patches. Patch dispensation will occur at weekly visits. Participants receive only the number of patches necessary to last until the next study visit plus several extra patches should a patch fall off, become torn, or should the visit be delayed. Based on our previous research, providing participants with only enough patches to last until the subsequent visit improves compliance.

Self-Help Materials. All participants will also be given evidence-based self-help materials for smoking cessation (based on the *Treating Tobacco Use and Dependence Clinical Practice Guideline* (Fiore et al., 2008).

MBAT Overview. Group treatment will strictly follow the MBAT protocol developed and used by Dr. Wetter. MBAT closely follows Mindfulness-based Cognitive Therapy (MBCT) procedures, but

replaces the depression-related material with nicotine dependence-related material. MBAT consists of 8 weekly 2-hour sessions (Wetter et al., 2009). The core aims are to help participants: 1) become more aware of thoughts, feelings, and sensations from moment to moment, 2) develop a different way of relating to thoughts, feelings, and sensations, and 3) obtain the ability to disengage attention and choose skillful responses to thoughts, feelings, and situations. In order to provide additional support on the quit date and encourage further mindfulness practice, session 5 (quit date) will be an extended 4-hour session.

MBAT emphasizes daily practice in several forms: formal sitting meditation, body scan meditation, walking meditation, eating meditation, and gentle yoga. Each of these practices shares a focus on awareness of the breath. By offering a menu of practices, differing preferences and learning styles can be accommodated. The quit day is scheduled for Session 5. Sessions 5-8 focus on continued development of awareness of the present, along with expansion of techniques for dealing with problematic thoughts, feelings, and situations. The group leader will have: 1) at least a master's degree or equivalent in counseling, psychology, social work, or a related field; 2) a regular personal mindfulness practice; 3) experience teaching mindfulness in a group setting; and 4) completion of training in teaching mindfulness.

Text Messages. Participants in the iQuit Mindfully condition will receive text messages on each day between treatment sessions. These messages are based on the MBAT protocol, the Text2Quit program led by Dr. Abroms (Abroms et al., 2012), and the SmokefreeTXT program developed by the National Cancer Institute (some of the messages are directly from the SmokeFreeTXT library). The content and frequency of messages were revised based on focus groups in low-income, racially diverse smokers. Text messages will remind participants to practice mindfulness (e.g., reminders for informal practice, such as awareness of the breath throughout the day, and reminders for formal practice such as the body scan and sitting meditation). Text messages will also remind participants of their personal reasons to quit as well as specific strategies to aid in cessation (e.g., reminders to get rid of cues to smoke, reach out for social support, and use cognitive-behavioral strategies taught in MBAT).

Participants will receive approximately 2 messages per day during Week 1, 3/day during Week 2, 4/day during Week 3, 5/day during Week 4, 6/day during Week 5, 4/day during Week 6, and 3/day during Week 7 (these numbers could be revised based on participant feedback). In addition, as in Text2Quit and SmokefreeTXT, participants will be able to text specified words to request help. Specifically, they may text CRAVE, STRESS, or SLIP at any point to receive additional text message support for coping with cravings, stress, or smoking lapses, respectively. Participants will also receive a relatively small number of texts (1-3 per week; exact number to be determined based on pilot project) during the 1-month follow-up period, and they will also have the opportunity to text keywords (CRAVE, STRESS, SLIP) during this time.

Mobile Commons, a service that supports the development and implementation of automated SMS applications, will be used to build the automated text message system and send and receive the text messages. Participants will receive text messages and will also have the option of texting CRAVE, STRESS, or SLIP.

Adherence. Adherence is defined as the number of intervention sessions attended and amount of mindfulness practice between sessions. Secondary analyses will examine associations between these adherence variables and abstinence outcomes.

Financial Compensation and Retention Procedures. Participants will be compensated for each of the 9 in-person visits in which they complete assessments after baseline (8 treatment sessions and 1 follow-up; $25 for assessments at session 1-4 and 6-7 visits; $40 for session 5 assessment; $50 for post-treatment assessment; and $50 for follow-up assessment (assessments on session 5, post-

treatment, and follow-up are longer than other sessions and thus associated with higher compensation). Participants will be compensated with $10 for completing at least 7 of the 10 daily assessments around the quit date (to be paid at session 6 visit). The maximum compensation per participant will be $300. Other procedures to increase adherence include: 1) reminder phone calls and letters, 2) requiring a phone number and valid home address so that participants can be contacted, and 3) obtaining names, addresses, and phone numbers of up to three collaterals who can provide information on participants' whereabouts if necessary. Written permission to contact the collaterals will be obtained from participants. Participants who do not attend in-person assessment visits will be contacted via phone, email, text message, and/or mail to reschedule or (if not able to reschedule) provide self-reported smoking status and feedback about the program/reasons for discontinuation.

6. STUDY PROCEDURES

Screening Evaluation and Consenting Procedure

Telephone Screening. Interested individuals will be given a detailed description of the study over the phone. The voluntary nature of the study will be emphasized, and it will be made clear that if they decide not to participate, there will be no repercussions. Research staff will read the telephone consent form to potential participants and answer any questions. After provision of verbal informed consent (a Waiver of Documentation of Consent has been included in the GSU IRB protocol), the research staff member will document verbal consent and sign and date the consent form. Potential participants will then be screened for inclusion/exclusion and answer questions about demographic information. Eligible individuals who are interested in participating will be scheduled for an initial in-person session. Participants will receive a reminder telephone call, text, and/or email on the day before their scheduled session.

In-Person Baseline Visit and Consent Procedure. Following the phone screen, interested individuals will attend an in-person session to finalize eligibility, engage in further discussion about the study, and provide written informed consent.

Before in-person assessment of eligibility criteria, participants will review the consent form for in-person screening. Study personnel will offer an opportunity for participants to ask questions and have them answered, the consent form for in-person screening will be signed and dated by the participant and staff member, and a copy of this form will be given to the participants. Then, in order to confirm eligibility, participants will provide a breath sample for assessment of expired carbon monoxide. Health literacy will be assessed with the Rapid Estimate of Adult Literacy in Medicine (REALM; Davis et al., 1991), and for the proposed study participants who have at least a sixth-grade level will be eligible. Individuals who decline or are ineligible will be given self-help materials and referral to other cessation programs. In addition, potential participants will complete the Patient Health Questionnaire-2 (PHQ-2; Kroenke, Spitzer, & Williams, 2003; Lowe, Kroenke, & Grafe, 2005) and answer a question regarding psychotic disorders in order to screen for clinically significant depressive symptoms and psychotic disorders, respectively. Individuals who are not eligible for these reasons will be provided with appropriate mental health referrals in addition to smoking cessation referrals.

Next, the research staff will engage eligible individuals in a discussion of pros and cons of participating, as well as participants' ambivalence about behavior change and research participation (these methods have been suggested to improve retention; Goldberg & Kiernan, 2005).

For eligible individuals who are interested in participating, study personnel will initiate the informed consent process which will include: 1) A thorough review of the Informed Consent Form (ICF), particularly study procedures; 2) Study personnel will offer an opportunity for participants to ask

questions and have them answered; 3) The ICF will be signed and dated by the participant and staff member; and 4) A copy of the ICF will be given to the participants.

Study personnel will explain the text messaging procedures in detail and send a test message to the participant, who will respond and ask any questions. Participants will indicate when they typically wake up and when they typically go to bed. This information will be used so that text messages will only be sent during the hours specified by each individual participant.

Individuals who would like to participate and express informed consent will then be asked to complete questionnaires. Descriptions of the assessments are provided below:

- The *Telephone Screening* assesses eligibility criteria and demographic characteristics, including age, race, ethnicity, education, employment, and income.
- *Tobacco History* assesses onset of regular smoking, previous quit attempts, abstinence history, smoking rate, and partner smoking status. This includes the *Heaviness of Smoking Index* comprises two items from the *Fagerström Test for Nicotine Dependence* (FTND) (Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991): self-reported average number of cigarettes smoked per day and time to first cigarette upon waking ("time to first cigarette"). The HSI is a strong indicator of nicotine dependence (Kozlowski, Porter, Orleans, Pope, & Heatherton, 1994).
- The *Rapid Estimate of Adult Literacy in Medicine* (REALM)(Davis et al., 1991) is a rapid screening instrument that is used to assess health literacy. It takes 2-3 minutes to administer and score and is highly correlated with comprehensive literacy diagnostic instruments. Individuals are classified as having limited (≤6th grade reading level; REALM=0 to 44), marginal (7th- to 8th-grade reading level; REALM=45 to 60), or adequate (≥9th grade reading level; REALM=61 to 66) health literacy skills. Participants with scores $\leq$44 will be excluded from the proposed study.
- In order to assess for *current psychotic disorders*, participants will be asked, "Do you have a current diagnosis of Schizophrenia or Bipolar Disorder or take anti-psychotic medications such as Haldol or Thorazine?". Individuals who answer affirmatively will not be eligible but will be provided with appropriate mental health referrals.
- The *Patient Health Questionnaire-2* (PHQ-2; Kroenke et al., 2003; Lowe et al., 2005) is a 2-item questionnaire designed to screen for symptoms of depression. Participants are asked, "Over the last 2 weeks, how often have you been bothered by the following problems?": "feeling down, depressed or hopeless" and "little interest or pleasure in doing things." These items (which correspond to the two core diagnostic criteria for Major Depressive Disorder; APA, 2013) are rated on a 0-3 scale (0 = not at all, 3 = nearly every day). Individuals with scores of 3 or above (which has been identified as the cut-off for obtaining optimal sensitivity and specificity for identifying depressive disorders; Kroenke et al., 2003; Lowe et al., 2005) will not be eligible but will be provided with appropriate mental health referrals.
- *Smoking Status (SRNT)* surveys tobacco use, use of other tobacco products, and nicotine replacement medications. The questionnaire also collects data on the use of other tobacco products and nicotine replacement medications as determined by the participant's time point in the protocol (e.g., based upon the date the participant quits smoking) (Hughes et al., 2003). Point prevalence abstinence (i.e., no smoking during past week) will be self-reported and biochemically confirmed by CO<6ppm.
- The *Brief Wisconsin Dependence Motives Questionnaire* (Smith, Piper et al., 2011) is a 37-item measures that yields an overall dependence score and subscale scores for other dimensions (i.e., cognitive enhancement, affective enhancement, automaticity, affiliative

attachment, loss of control, craving, cue exposure/associative processes, social/environmental goals, taste/sensory processes, weight control, tolerance).

- The *Wisconsin Smoking Withdrawal Scale* (Welsch et al., 1999) includes subscales for anger, anxiety, sadness, concentration difficulty, craving, hunger, and sleep. All subscales have excellent internal consistency and validity (Wetter et al., 2000).
- The *Self-Efficacy Scale* assesses confidence for resisting smoking urges in specific types of situations (e.g., when feeling stressed, when with friends) (Condiotte & Lichtenstein, 1981) Subscales include negative affect, pleasure, social image, social influence, and diet. Scores are predictive of relapse (Cinciripini, Cinciripini, Wallfisch, Haque, & Van Vunakis, 1996).
- The *Mindful Attention Awareness Scale* (MAAS; Brown & Ryan, 2003) is a 15-item self-report measure of dispositional mindfulness that has shown good reliability and validity.(Brown & Ryan, 2003)
- The *Five-Factor Mindfulness Questionnaire- Short Form* (FFMQ-SF; Bohlmeijer, ten Klooster, Fledderus, Veehof, & Baer, 2011) is a 24-item self-report questionnaire of facets of dispositional mindfulness. The scale yields five factors: 1) Nonreactivity, 2) Observing, 3) Acting with Awareness, 4) Describing/Labeling with Words, and 5) Nonjudging of Experience. The FFMQ-SF correlates highly with the 39-item FFMQ and has comparable internal consistency and factor structure.
- Participants will fill out a *Weekly Mindfulness Practice Log* (Vidrine et al., 2016) to indicate how frequently they practice each of the mindfulness techniques taught in treatment.
- The *Perceived Stress Scale – Short Form* (Warttig, Forshaw, South, & White, 2013) is a 4-item self-report measure of the extent to which individuals view their lives as stressful. The scale shows good psychometric properties.
- The *Positive and Negative Affect Schedule* (PANAS (Watson, Clark, & Tellegen, 1988)) is a 20-item self-report measure of affective experience yielding two factors (Positive and Negative Affect) with strong psychometric properties (Watson et al., 1988).
- Participants in the iQuit Mindfully group will be asked to provide weekly feedback about their experiences receiving the text messages (*Weekly Text Message Feedback*), and both groups will complete *Final Program Evaluation*. Items will assess perceived helpfulness and acceptability of the in-person and text messaging portions of treatment and also solicit suggestions for improving future programs.

The maximum time between telephone screening and enrollment will be 1 month. The maximum time between baseline assessment (as well as randomization, which will occur right after baseline assessment) and start of treatment will be 1 month. However, we will employ a variety of strategies to ensure that these timeframes are as short as possible. For example, in order to reduce the time between telephone screening and baseline we will offer a variety of days and times for baseline assessment. We will also time our recruitment efforts around planned baseline assessments to maximize potential participants' interest (in order to prevent longer wait time to accrue a sufficient number of participants to start a group).

Daily Surveys around Quit Date. In order to gather more daily data about emotions, smoking, and mindfulness surrounding the quit date, all participants will be asked to complete a daily online survey for 10 days surrounding the quit date (Days 3, 2, 1 pre-quit, Quit Date, and Days 1-6 post-quit). Each morning, participants will be sent a link (via text, and also via email for participants who supply an email address) to an online survey including 8 questions about emotions, smoking, and mindfulness on the previous day.

Follow-Up Visit and Individual Interview. One month following the last treatment session, participants will attend an in-person follow-up visit in which they will complete questionnaires, provide expired CO samples, and complete an individual interview. Individual interviews will be conducted by trained research staff. All participants will be asked for their feedback about and suggestions for improving the intervention. In addition, interviews with iQuit Mindfully participants will involve more in-depth discussion of what participants liked/did not like about the texts, how they perceived the messages to be helpful/unhelpful, and their suggestions for improving the text-based program. Interviews will be audio-recorded with a digital voice recorder and transcribed verbatim.

Blinding

The majority of study personnel, including the PI, will be blinded to treatment condition until the database is locked. Limited staff will be unblinded to handle randomization codes, administer individual interviews (i.e., the graduate research assistant) and delivery of interventions (i.e., the study therapist). Once the algorithm for randomization has been prepared, the graduate research assistant will execute the randomization scheme. The graduate research assistant (unblinded) will also be responsible for preparing reports for data and safety monitoring, as well as conducting individual interviews (which requires knowledge of the participants' treatment conditions). Research personnel who are blinded to treatment condition will administer all assessments. For example, in order for participants to complete the post-treatment assessment, separate research personnel (who do not know the treatment condition) will arrive after the treatment ends and administer the assessments.

7. SAFETY ASSESSMENTS

Reporting of Adverse Events and Serious Adverse Events

An **adverse event (AE)** is defined as any unfavorable and unintended diagnosis, symptom, sign, syndrome or disease which either occurs during the study, having been absent at baseline, or if present at baseline, appears to worsen. Adverse events are to be recorded regardless of their relationship to the study intervention.

A **serious adverse event (SAE)** is defined as any untoward medical occurrence that results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly.

Dr. Spears will conduct daily oversight of participant safety, and will meet regularly with staff to review progress and discuss any problems or concerns. Adverse events that are not deemed "serious adverse events" will be included in the annual report to the mentors, Independent Monitoring Committee (IMC), and IRB. The IMC will state that they have reviewed all AE reports in the annual report.

SAEs that are unanticipated, serious, and possibly related to the study intervention will be reported to the IMC, IRB, and NCCIH in accordance with requirements. Georgia State University defines an unanticipated event as an event that was (1) unforeseen; (2) more likely than not related to the research; and (3) either caused harm to participants or others, or placed them at increased risk of harm. Unanticipated events include any harm or injury (physical, psychological, social or economic) or other unexpected events occurring during the course of participation in a research study. As required by the GSU IRB, Dr. Spears will report a summary of each unanticipated event to the IRB using the IRB Unanticipated Event form within 7 business days.

Unexpected fatal or life-threatening SAEs related to the intervention will also be reported to the NCCIH Program Officer, mentors, and IMC within 7 days. Other serious and unexpected AEs related to the intervention will be reported to the NCCIH Program Official within 15 days. Anticipated or unrelated SAEs will be handled in a less urgent manner but will be reported to the Independent Monitors, IRB, and NCCIH. In the annual AE summary, the Independent Monitoring Committee Report will state that they have reviewed all AE reports.

8. INTERVENTION DISCONTINUATION

This study will be stopped prior to its completion if: (1) the intervention is associated with adverse effects that call into question the safety of the intervention; (2) any new information becomes available during the trial that necessitates stopping the trial; or (3) other situations occur that might warrant stopping the trial.

9. STATISTICAL CONSIDERATIONS AND DATA ANALYSES

Primary outcomes for this development and feasibility study are: 1) feasibility (e.g., attrition, engagement, participant ratings), 2) determining best practice for implementing and refining the text-messaging intervention (e.g., how many texts per day and at what times of day; which types of messages are most helpful; ways of increasing adherence; these variables will be assessed through participant feedback in the individual interview and final program evaluation questionnaire), and 3) an estimate of effect size (based on smoking cessation in iQuit Mindfully vs. MBAT).

Approximately 35% attrition will be deemed acceptable (based on 34% attrition in Vidrine et al.'s (2016) trial of mindfulness-based smoking cessation treatment). Level of engagement will be determined based on: 1) the proportion of texts that participants indicate reading (we expect that at least 75% will read most or all texts, based on Abroms et al.'s (2012) findings); and 2) responses to interactive text messages (we expect that at least 85% of participants will respond to at least one of the interactive text messages or use the CRAVE, STRESS, or SLIP keywords at least once, based on Heminger et al.'s (2016) findings). In terms of participant ratings, we will focus on ratings of helpfulness of the text messages and the extent to which participants would recommend the text messaging program to others (rated on 1-10 scales; the minimum acceptable rating is 6).

Effect sizes will be of greater importance than statistical significance, given that this is a feasibility study. Smoking abstinence will be defined as self-reported complete abstinence for 7 days that is biochemically confirmed with expired carbon monoxide <6ppm. Chi-square tests and t-tests will be used to evaluate group differences.

Individual interviews will be transcribed verbatim. Transcripts will be managed and coded using QSR International's NVivo 10 software, a qualitative software analysis program that allows researchers to associate codes with portions of text, to search within and across codes for patterns, and to construct classifications of codes reflecting relationships within the data. Data coding and analysis will follow both inductive and deductive approaches. An initial set of codes will be developed from the interview topics and the conceptual framework, with additional codes identified from concepts that emerge from the data. The objective of the data coding process will be to capture as many concepts as possible and then to examine the relationships and patterns of the concepts within and across transcripts to identify conceptual linkages or themes (Ayres, Kavanaugh, & Knafl, 2003; Ryan & Bernard, 2003). Two independent coders will code the transcripts and then meet to discuss findings, resolve inconsistencies, and develop a preliminary coding scheme. Then the remaining transcripts will be independently coded (with regular meetings to refine the coding scheme as needed). This method of constant comparison will be used to identify themes within the data (Corbin & Strauss, 2008). This

approach involves comparing concepts across categories to identify links, patterns, connections, and differences.

10. DATA COLLECTION AND QUALITY ASSURANCE

During this study, psychosocial assessments and biochemical confirmation of smoking will be conducted at baseline and at regular intervals. All of the materials collected are for research purposes only, and data will be kept in strict confidence. Confidentiality will be ensured by use of identification codes. All data will be identified with a randomly generated identification code unique to the participant. The master list containing participant numbers and participants' names will be kept in a locked file, accessible to study staff only. Although participants will sign informed consent documents, these forms will be kept in a separate locked file and will never be connected to the study data. No names will ever be recorded on the questionnaires, which will be stored in a locked file cabinet and available only to the research personnel. Participants' names will not be used in the recorded interviews (participants will be asked not to use their names, and the interviewer also will not use their names during recorded interviews). These interviews will be transcribed and coded with participant ID numbers, and audio files will be deleted within one year after the completion of data collection.

Questionnaire data (both in-person assessments and online surveys surrounding the quit date) will be collected using the REDCap (Research Electronic Data Capture) system available at Georgia State University. This will provide a secure way to collect and manage data, while avoiding potential issues with manual data entry. Georgia State University belongs to a consortium of institutional partners that work to maintain a software toolset and workflow methodology for electronic collection and management of research data. REDCap data collection projects rely on a study-specific data dictionary defined by the research team. REDCap also contains a Survey tool for building and managing online surveys. The research team can create and design surveys in a web browser and engage potential respondents using a variety of notification methods. Both REDCap and REDCap Survey systems provide secure, web-based applications that are flexible enough to be used for a variety of types of research, provide an intuitive interface for users to enter data and have real time validation rules (with automated data type and range checks) at the time of entry. These systems offer easy data manipulation with audit trails and reporting for monitoring, reporting, and querying patient records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). REDCap application is securely housed in Amazon AWS and managed by the Research Solutions department at Georgia State University. All web-based information transmission is encrypted and the data is encrypted at rest. Amazon AWS's data centers are state of the art nondescript and secured facilities. Data will be downloaded from REDCap into a secure server that is managed by Georgia State University, password-protected, and available only to research personnel who have completed training in research with human subjects.

Additional safeguards will include appropriate password protection and physical security for all computer systems and physical data. Personal names will not be stored in electronic data files. Physical data will be stored in a locked file cabinet and available only to the research personnel. The master list containing participant numbers and participants' names will be kept in a separate locked file, also accessible to study staff only.

The Mobile Commons platform maintains a high level of security control for sending and receiving text messages. The Mobile Commons HIPAA and Text Messaging Security White Paper indicates: "All Mobile Commons systems that transmit or store sensitive client information are housed in a secure data center facility that maintains a high standard of physical security controls…. The Mobile Commons information security program includes comprehensive technical security measures geared towards protecting the confidentiality, integrity, and availability of sensitive client data…. Authentication controls are in place for access to all systems and applications that deal with sensitive

client data. All activity regarding access to, and transmission of, this data is logged. Sessions are configured to timeout after a period of inactivity. All sensitive data, including PHI and authentication credentials for system and application access, are transmitted via encrypted protocols (SSL or SSHv2) when traversing public or untrusted networks. Strong encryption is used for sensitive data stored on Mobile Commons systems. Multiple layers of procedures and technical controls are in place to verify the identity of any person or entity seeking access to any sensitive client information" (https://www.mobilecommons.com/wp/wp-content/uploads/2014/07/Mobile-Commons-HIPAA-Text-Messaging-Security-White-Paper1.pdf).

11. PARTICIPANT RIGHTS AND CONFIDENTIALITY

Institutional Review Board (IRB) Review

This protocol and the informed consent documents and any subsequent modifications will be reviewed and approved by the Georgia State University IRB.

Informed Consent Forms

The consent forms describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation.

The informed consent process will include:
1) A thorough review of the Informed Consent Forms (ICF), particularly study procedures; 2) Study personnel will offer an opportunity for participants to ask questions and have them answered; 3) The ICF will be signed and dated by the participant and staff member; and
4) A copy of the ICF will be given to the participants. (For the consent process prior to telephone screening, the research staff will document participants' verbal consent after reviewing the ICF).

Participant Confidentiality

Participants will be assured that the information gathered from the study (including responses to questionnaires, text messages, and interview) will be kept confidential to the extent of the law, and that the findings of the study may be published, but that participants will not be identified. Upon enrollment, participants will receive an ID number. Assessment data will be linked to this number. Personal/identifying information, including consent forms, will be maintained separate ely from study assessment data. Although participants will sign informed consent documents, these forms will be kept in a separate locked file and will never be connected to the study data. Data will be stored on a secure server to protect the data and to prevent unauthorized access. Databases will be accessed only by members of the research staff who have met the IRB's requirements for training in Human Subjects' Protection.

Although participants' first names will be used in the text messages that participants receive (in efforts to increase the personalization of the text messaging, as suggested by our qualitative research to inform this intervention), their names will not be connected to any data that is stored in the Mobile Commons platform.

By virtue of participating in a treatment group with other people, participants' verbal responses during group treatment will be known to others in the group. Thus, we will request (in the consent form and verbally at the start of the group) that participants keep what they hear confidential. Of course, we cannot guarantee that the other members of the treatment group will maintain confidentiality of responses, and this is made clear in the consent form.

Participants' names will not be used in the recorded interviews. These interviews will be transcribed and coded with participant ID numbers, and audio files will be deleted within one year after the

completion of data collection.

Study Discontinuation

The study may be discontinued at any time by the IRB, NCCIH, or other government agencies as part of their duties to ensure that research participants are protected.

12. COMMITTEES

External oversight of participants' safety will be conducted by the members of the Independent Monitoring Committee (IMC): Sarah Bowen, Ph.D., Bradley N. Collins, Ph.D., and Danielle E. McCarthy, Ph.D. They are not part of the key personnel involved in this grant. Dr. Bowen, Assistant Professor of Psychology at Pacific University, has expertise in designing and conducting randomized controlled trials of mindfulness-based treatment for addictions. Dr. Collins, Associate Professor of Public Health at Temple University, has expertise in smoking cessation intervention research (with particular focus on low-income, racial minority and medically-underserved communities). Dr. McCarthy, Associate Director of Research at the University of Wisconsin Center for Tobacco Research and Intervention, has expertise in smoking cessation treatment and using mobile technology to examine momentary mechanisms underlying behavior change. Together, the IMC brings extensive knowledge and experience with regard to mindfulness-based treatments, randomized controlled trials, tobacco use and cessation, underserved populations, and mobile technology. The IMC will regularly review participant safety and assess study progress (including participant confidentiality, recruitment and retention, and data quality and management).

13. PUBLICATION OF RESEARCH FINDINGS

In accordance with NIH public access policy, final peer-reviewed journal manuscripts that arise from this study will be deposited to PubMed Central immediately upon acceptance for publication.

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