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THE STATE UNIVERSITY
OF NEW JERSEY

STUDY INFORMATION

Title of Project: Addressing tobacco among those at socioeconomic disadvantage

Principal Investigator:

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1.0 Research Introduction

1.1 Purpose/Specific Aims

The purpose of the current investigation is to examine strategies for encouraging smokers at socioeconomic disadvantage in New Brunswick, New Jersey to quit in a randomized clinical trial. Tobacco use is a substantial problem for individuals at socioeconomic disadvantage (SED). While smoking prevalence has decreased across the United States over the past several decades, this decrease has not occurred at all levels of socioeconomic status. Those at lower socioeconomic status smoke at higher rates than those at higher socioeconomic status (Tucker-`Seeley et al., 2015).

A. Objectives

In order to examine strategies for encouraging smoking cessation in socioeconomically disadvantaged smokers, we will randomize self-identified smokers interested in our study to one of three intervention conditions: (1) Brief motivational interviewing (MI) and referral to the NJ quitline and local Tobacco Dependence Program, (2) provision of a two-week supply of nicotine replacement patch and nicotine lozenge (NRT sampling) and referral to the NJ quitline and local Tobacco Dependence Program, or (3) referral only. This randomized controlled trial will allow for a direct comparison of three brief and easy to implement treatment conditions in relation to various cigarette smoking outcomes.

B. Hypotheses / Research Question(s)

Brief advice to quit (i.e., referral), brief motivational interviewing, and nicotine replacement therapy are recommended approaches to promote smoking cessation and reduce health disparities in low-income smokers (Fiore et al., 2008). However, as compared to referring participants to the NJ Quitline, we expect brief MI and provision of NRT to be superior in terms of: (1) Increasing motivation to quit; (2) increasing self-efficacy to quit; (3) setting a quit date; (4) making a cessation attempt; (5) and achieving initial abstinence.

1.2 Research Significance *(Briefly describe the following in 500 words or less):*

A disproportionate number of individuals who use tobacco are from low socioeconomic status (Tucker-Seeley et al., 2015). By reaching smokers at socioecondomic disadvantage who may not initially be interested in seeking cessation services and prompting quit attempts in this population, we can have a positive impact on public health.

Brief motivational interviewing is a psychosocial intervention designed to promote behavioral change and recommended as part of the clinical practice guidelines for smoking cessation (Fiore, 2008), in particular for populations with low motivation to quit. This intervention assumes clients are motivated and have the ability to quit. By avoiding direct advice or convincing, the therapist carefully uses a series of techniques to illicit intrinsic motivation from the client to change. Although MI presumably is designed to affect motivation, thereby eliciting behavioral change, mechanisms research does not support this relationship and instead suggest that a therapist's ability to engage the client in 'change talk,' i.e., talk about what it would look like to engage in different behaviors, is central to a favorable outcome. Whereas meta-analytic reviews of MI indicate relatively small effect sizes, a recent meta-analytic review that examined the combined effect of brief MI (i.e., <60 minutes) found that it was significantly related to long-term cessation (d=.33). A similar significant effect for follow-up was found that MI that was not combined with pharmacotherapy (d=.21).

Clinical practice guidelines additionally recommend the provision of NRT to enhance smoking cessation (Fiore et al., 2008) via reduction in nicotine withdrawal. Meta-analytic reviews generally provide support for the efficacy of NRT in promoting cessation, but are somewhat mixed. More recently, combination NRT is emerging as a preferred method that provides smokers with constant nicotine replacement (e.g., via the nicotine patch) as well as relief for 'breakthrough' cravings via the addition of gum or lozenge (Carpenter et al., 2013).

1.3 Research Design and Methods

Overview: We will conduct a pilot randomized clinical trial in which socioeconomically disadvantaged smokers receiving services at a New Brunswick, NJ based agency (e.g., New Brunswick Housing Authority (NBHA) or Elijah's Promise) are randomized to one of two brief interventions designed to enhance motivation to quit smoking (see Study Interventions below) or to a control group. Participants will be re-contacted at one-month by a research assistant who is blind to the condition to which the participant was allocated to assess number of quit attempts and abstinence from cigarettes.

Participant Recruitment and Screening: In collaboration with staff at the New Brunswick, NJ based community partners, we will use flyers to advertise and will recruit daily smokers receiving services at a New Brunswick, NJ based agency. Interested participants will complete a brief in-person or telephone screening where they will be assessed by trained study personnel who will determine initial eligibility. Participants must be between the age of 19 and 65, must self-report being a daily smoker and provide biochemical verification of smoking status (expired breath carbon monoxide reading >5). Assessing carbon monoxide to verify smoking status is a common approach in tobacco use studies.

1.3.1 Biochemical verification

To confirm smoker status, expired breath carbon monoxide (CO) levels (also commonly collected in tobacco dependence treatment studies) will be assessed with a carbon monoxide monitor and CO reading in parts per million (ppm) will be recorded. The carbon monoxide monitor used will be the Bedfont Scientific Ltd. Micro+ Smokerlyzer. The Micro+ Smokerlyzer is a hand-held, battery powered instrument which uses electrochemical technology to sample the gas and a microprocessor to convert the output from the sensor to a carbon monoxide (CO) concentration. The result and menus are displayed on a color LCD and an accompanying buzzer sounds in response to the CO level. The instrument is controlled using a touch screen operation and has a USB link to a computer to download readings.

The Micro+ uses a breath sampling D-Piece with integrated bacterial and viral filter and a one-way valve designed to maximize infection control. Each patient uses a fresh mouthpiece for each breath sample. The D-Piece may be reused or replaced as required.

The patient is asked to hold their breath for a 15 second countdown. This is displayed on the screen of the device. At the end of the breath hold, the patient blows gently into the Micro+ expiring as much of the breath in their lungs as possible. The reading on the device shall rise until the peak reading is held on the display.

A research assistant will provide instructions on how to use the CO monitor and will record the results at visit 1 and one-month follow-up appointments. The study PI is accountable for the device.

Exclusion criteria include taking FDA approved smoking cessation or anti-psychotic medications, self-reported medical issues of potential concern to nicotine replacement therapy users (i.e., unstable angina pectoris, myocardial infarction, or significant cardiac arrthymia (including atrial fibrillation) in the past 30 days), or self-reported pending legal issues with potential to result in incarceration. Additionally, women must state in writing that they are not pregnant or nursing, planning on becoming pregnant in the next two months, and that they are using effective birth control.

Visit 1: Following the initial phone screen study staff will arrange to meet with eligible participants to administer additional measures as well as the brief intervention. In addition to verifying inclusion/exclusion criteria as well as smoking status, participants will be asked to complete a questionnaire battery online using a laptop provided by study staff, and a brief interview to further assess motivation and confidence to quit, substance use, physical health, and mental health status and history, as well as smoking cessation history.

Study Interventions: Next, we will use a block randomization procedure to allocate participants to one of three groups: A *single session motivational intervention (MI),* which will include a 30-minute therapy session designed to enhance motivation to quit smoking, followed by a referral to the NJ State Quitline and local Tobacco Dependence Program; (2) An *NRT sample intervention,* which will include free two-week supplies of nicotine patches and nicotine lozenge with instructions for proper use and a referral to the NJ State Quitline and local Tobacco Dependence Program, or (3) An *assessment and referral only control.*

Block randomization is a procedure in which participants are randomly allocated to intervention groups within blocks such that an equal number are assigned to each intervention. We will use the Sealed Envelope Ltd. 2017 application to electronically develop a list of 60 allocation outcomes using a block randomization procedure with 3 intervention groups and block sizes of 3, 6, and 9. The study coordinator will use this list to inform study therapists of the intervention to which participants were assigned.

Upon completion of the intervention, participants will be scheduled for a one-month follow-up visit with a research assistant. Participants will be reminded of their appointment via text, phone, and email 48 and 24 hours prior.

One-month Follow-up: Participants will be asked to complete a brief online survey once again, and smoking status will be verified via self-report and carbon monoxide analysis of breath sample. Staff will also conduct brief interviews to assess main outcomes of interest.

1.4 Preliminary Data

Drs. Steinberg and Leyro have committed their academic careers to research on tobacco use and dependence. In addition to academic research, Dr. Steinberg was Director of the Mercer County Tobacco Program from 2005–2010 where in addition to providing smoking cessation services, he partnered with community organizations in Mercer County to increase awareness of the consequences of smoking and to increase the uptake of tobacco dependence treatment services.

Dr. Steinberg recently published data on a motivational interviewing intervention (Steinberg et al., 2016) similar to the one proposed in the current application in which he found smokers with schizophrenia receiving a single-session motivational interviewing intervention were significantly more likely than those receiving an educational intervention to make a quit attempt. In addition, Dr. Leyro recently published research indicating that clinical management of nicotine withdrawal of severely mentally ill smokers on smoke-free inpatient units is enhanced by offering NRT directly upon admission; these findings support the exploration of our NRT in smokers who live in newly smoke-free public housing units.

1.5 Sample Size Justification

We have a target N of 60 smokers (n=20/treatment condition). In terms of race/ethnicity, we anticipate our sample will be reflective of cigarette smokers living in the greater New Brunswick, NJ area: We expect to enroll two participants weekly in order to meet our target N. Estimating that 50% of the sample will make quit attempt during the course of the study, our main outcome of interest, this is adequate to group differences with 95% confidence (CI: 0.38, 0.61).

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

Our IV of interest is treatment assignment; please see section 1.3 for a description of the study interventions.

B. Dependent Variables or Outcome Measures

Our DVs of interest are as follows: (1) pre-treatment to one-month follow-up change in (1a) motivation to quit (i.e., motivation), (1b) readiness to quit, and (1c) confidence in quitting; (2) setting a quit date (yes/no); (3) making a cessation attempt (yes/no); (4) days of self-reported abstinence, and (5) achieving initial CO verified abstinence (yes/no).

1.7 Drugs/Devices/Biologics

1) *Nicotine replacement therapy.* Nicotine patch and nicotine lozenge are accepted, FDA approved treatments for nicotine dependence. Both are available over-the-counter (OTC) without a prescription. Study participants will be provided with information written at a 6th grade level describing the proper use of the nicotine patch and lozenge, including a description of common side effects. To minimize adverse events, we are excluding smokers with potential contraindications (see *Participants* section within *Methods* above).
   a) *Storage and accountability.* We will store nicotine replacement therapy (NRT) in original packaging (box containing 2-week supply) in locked cabinets in a room with locked doors at 317 George Street; Suite 105; New Brunswick, NJ and at Institute for Health, Rutgers, The State University of New Jersey 112 Paterson Street, Rm 212, New Brunswick, NJ 08901-1293. We will document temperature of the room weekly using a min/max thermometer.
      a. *Transferring medication.* Research coordinators, Jessica Ortiz and Mindy Kibbey, will arrange to transfer medication between research laboratory sites as needed. Jessica and Mindy will be the only people who transfer medication between sites, arranging with one another to pick up or drop off the medication.
   b) *Inventory.* We will use an NRT inventory log to document the Lot # and Expiration date of each box of NRT.
   c) *Dispensing NRT.* We will use an NRT dispensing log to document which boxes of NRT are provided to which subjects (listed by subject number only), by whom, and on what date. We will not collect unused portions of the NRT because it is not common practice to specify a time limit by which participants are required to use the NRT.
      a. In the event NRT is stored at the Institute for Health, the research coordinators will arrange to pick up the medication or to drop off the medication at 317 George Street; Suite 105; New Brunswick, NJ for research subjects.

1.8 Primary Specimen Collection

A. N/A

B. N/A

C. N/A

D. N/A

E. N/A

1.9 Interviews, Focus Groups, or Surveys
A. Administration
Following consent, study staff will first verify each participant's smoking status via expired breath carbon monoxide (CO > 5ppm). Participants will complete a questionnaire battery online via Qualtrics, using a laptop computer or tablet provided by study staff (see Table 1 below). If any participant indicates high levels of depression, we will provide phone numbers and a recommendation to contact Rutgers University Behavioral Health Care or the Rutgers RWJMS Department of Psychiatry outpatient practice.

Timing and Frequency: Following an initial phone screen, participants will be visited by study staff for an in-person session that will last approximately 60-90 minutes (including assessment and intervention). After randomization and Visit-1 study procedures are completed, they will be scheduled for a final follow-up visit to occur approximately one-month later.

Location: Study participation will take place at the Rutgers RWJMS Division of Addiction Psychiatry / Tobacco Research & Intervention lab, at the New Brunswick Housing Authority offices and / or housing units, or on the premises of the non-profit agency, Elijah's Promise, depending on study patient preference.

Procedures for Audio Recording: Participants will be asked permission to allow study staff to audio record their intervention as part of the research study, by signing the "Agreement to Audio Record" at the end of the consent form. Participants do not have to agree to be recorded in order to participate in the main part of the study. The recording(s) will be used for clinical supervision, to validate the integrity of the counseling intervention, and potentially to later examine the relationship between what is said during the sessions and various clinical outcomes. The recording(s) will include the participant ID number and date of the research appointment. Digital audio files will be stored on password protected computers and the files themselves will be password protected and encrypted using the Advanced Encryption Standard 256 method (AES-256). Files will be linked with each participant's ID number. Files will be destroyed 6 years after the protocol is closed.

B. Study Instruments
Below, please find details regarding questionnaire and interview administration.

Measures List

Online Measures (Qualtrics)

1**) Demographic Questionnaire**: To obtain basic social support information as well as descriptive information including age, race, ethnicity, marital and SES status. Additionally, we will ask the place where they are completing the survey.

2) **Fagerström Test for Cigarette Dependence** (FTCD; Fagerström, 2012): 6-item scale use to evaluate the quantity of cigarette consumption, the compulsion to use, and nicotine dependence. The measure

has both yes/no items (scored as 1 or 0) and multiple-choice items (scored from 0-3). These scores are then summed to give a total score from 1-10 where the higher the score the more intense subject's the nicotine dependence is.

3) **Smoking History Questionnaire** (SHQ;Bonn-Miller & Zvolensky, 2005): 30-item questionnaire used to assess participants smoking history and patterns of use. Items pertain to smoking rate, age of onset of smoking initiation, and years being a daily smoker.

4) **Distress Tolerance Scale** (DTS; Simons & Gaher, 2005): 15-item scale used to assess participants' perception of their ability to tolerate mental distress. Items (e.g. "I can't handle feeling distressed or upset") answered on 5-point Likert-type scales ranging from (1) strongly agree to (5) strongly disagree evaluate participants' ability to experience and endure negative emotional states and includes scales that assess appraisal, tolerance, absorption, and regulation. This scale contains good psychometric properties, including high internal consistency. Because six of these items are included in the DII, below, this measure will be comprised of nine items.

5) **Distress Intolerance Index** (DII; McHugh & Otto 2011): 10 items (e.g. *I can't bear disturbing feelings*) rated on a five point Likert-type scale (0 = very little to 5 = very much for question 1, 1 = strongly agree to 5 = strongly disagree for questions 2-7, and 1 = absent to 5 = very strong for questions 8-10) assess individual differences in perceived capacity to withstand and tolerate general somatic and psychological distress.[102] One item is pulled from the Anxiety Sensitivity Index (ASI),[103] six items from the DTS,[104] eight items from the FDS[105] The DII demonstrates strong internal consistency reliability and concurrent validity, and evidence for construct validity.

6) **Generalized Anxiety Disorder** (**GAD-7**; Spitzer et al., 2006): 7-item index is a valid and efficient tool for screening for GAD and assessing its severity in clinical practice and research.

7) **Kessler Psychological Distress Scale (K6;** Kessler et al., 2002): This 6-item measure is a validated and brief index that is used to screen for the presence of mood and anxiety disorders.

8) **Snaith-Hamilton Pleasure Scale** (SHAPS; Snaith et al., 1995): 14-item measure used to assess the ability to experience pleasure from typically rewarding activities.[157] Participants rate the degree to which they believe that they would experience pleasure from hypothetical situations using a 4-point Likert type scale ranging from 0 = definitely agree to 3 = definitely disagree. The SHAPS appears to demonstrate good construct validity through its significant association with a latent dimension of anhedonia[158] and test-retest reliability.

9) **Change Questionnaire** (Miller & Johnson, 2008): Measures ratings of importance of quitting and confidence in quitting on a 10-point Likert-type scale from 0=Definitely Not to 10 = Definitely.

10) **McArthur Scale of Subjective Social Status** (Adler & Stewart, 2007): Self-report measure of an individual's sense of social status across different SES indicators. The scale is in a pictorial format, and presents the participant with a "social ladder" and asks them to place an "X" where they feel they fall. There are two separate social ladders that are presented to the participant. One is linked to traditional

SES factors, SES Ladder, while the other is linked to social standing within a community, Community Ladder.

11) **Readiness to Quit Ladder**: Single-item measure that includes ten response options that assess motivation to quit along a continuum. Options range from 10, "I have quit smoking and I will never smoke again", to 1, "I enjoy smoking and have decided not to quit smoking for my lifetime. I have no interest in quitting". As such, higher scores on this measure indicate higher readiness to quit.[95]

12) **Stages of Change Algorithm** (Prochaska, Velicer, DiClemente, & Fava, 1988): This three item measure is used to assess readiness for change (i.e., smoking cessation) and will be used to categorize participants into precontemplation (i.e., not thinking about quitting), contemplation (yes, within next 6 mo.), and preparation (i.e., yes, within the next 30 days). This will then be used to inform therapist provided brief motivational interviewing.

13) **Financial Strain Scale** (Pearlin, Menaghan, Lieberman, & Jullan, 1981): This 9-item measure will be used to assess participants' perceptions of financial strain. Subjective indices of financial strain, rather than using education or income as the primary indicators of socioeconomic status have the advantage of assessing perceived burden and interference. On this measure eight items are rated on a 3-point scale (1=no difficulty to 3-very great difficulty; e.g., How difficult is it to afford a home suitable for (yourself/your family?). The final item asks participants to report how much money they have left over at the end of each month.

14) **Subjective Financial Situation Scale** (Williams et al., 2016): This single item measure asks participants to describe their subjective view of their overall personal financial situation.

15) **Attitudes Toward Nicotine Replacement Therapy scale:** This measure assesses previous offering of nicotine replacement therapy (NRT), perceived advantages to NRT use, perceived side effects, and if relevant, reasons for not using NRT.

16) **Quitting Preparation and Actions Questionnaire.** This measure is used at followup only and assesses actions consistent with preparing for or making an attempt to quit smoking.

Pencil Paper Measures

1) **Initial screen:** This measure will allow us to determine if the participant is likely to meet inclusion criteria before we conduct a full baseline assessment.

2) **Timeline Followback** (Sobell & Sobell, 1992)**:** method of assessing substance use requires participants to retrospectively estimate their daily substance and alcohol use. For the purposes of our study, we will be assessing past month alcohol, nicotine, marijuana, and other substance use.

3) **NRT Contraindication Checklist and Expired CO:** Participants will be screened for contraindications associated with NRT use, including: hypersensitivity to the active ingredient or any component of the NRT product, temperomandibular joint disease (should be excluded from using NRT gum), and active

gastric or duodenal ulcer (should be excluded from using NRT nasal spray) Any risks that may be associated with NRT are substantially outweighed by the dangers of continued smoking. Participants will provide expired breath carbon monoxide by blowing into the CO monitor to demonstrate smoker status (CO > 5ppm). CO levels will be documented on this form in parts per million (ppm).

4) **Adverse Events Questionnaires**: To be filled out by study staff during the follow-up visit with participants to assess AEs associated with quitting and use of NRT.

5) **Not Pregnant Form**: Using this form, women will state in writing that they are not pregnant or nursing, planning on becoming pregnant in the next two months, and that they are using effective birth control.

6) **Contact Form:** Participants will provide contact information to be used for scheduling appointments.

1.10 Timetable/Schedule of Events

	Jul 2017	Aug 2017	Sep 2017	Oct 2017	Nov 2017	Dec 2017	Jan 2018	Feb 2018	Mar 2018	Apr 2018	May 2018	Jun 2018
Rutgers / NBHA project meeting	X		X		X		X		X		X	X
Train study therapist & research asst.	X	X										
Recruit participants (N=60; 2/week)			X	X	X	X	X	X	X			
Complete follow up assessments				X	X	X	X	X	X	X		
Data analysis										X	X	

2.0 Project Management

2.1 Research Staff and Qualifications

Marc Steinberg, Ph.D. is a licensed clinical psychologist, a faculty member in the Rutgers RWJMS Department of Psychiatry, and director of the Tobacco Research & Intervention lab. His research focuses on tobacco dependence treatment, including tobacco dependence treatment development and tobacco use in vulnerable populations such as those with psychiatric comorbidity and lower socioeconomic status. Dr. Steinberg has been PI or Co-I for multiple randomized clinical trials of tobacco dependence treatments for high-risk smokers including RCTs of motivational interviewing, behavioral therapy, and of nicotine nasal spray for smokers with schizophrenia, of persistence-targeted smoking cessation in low SES smokers, and of varenicline for smokers not yet ready to quit.

Teresa M. Leyro, Ph.D. is a faculty in the Department of Psychology and director of the Affective and Biological Underpinnings of Substance Use and Anxiety lab. She has completed extensive research on processes that promote smoking and interfere with abstinence and has been a project coordinator and graduate and post-doctoral clinician on several randomized clinical trials of smoking cessation, including those that have employed nicotine replacement and motivational interviewing interventions. In addition, she is a licensed clinical psychologist in the state of New Jersey.

<u>Graduate Students:</u>
Benjamin Billingsley

Allison Borges
Min-Jeong Yang
Mark Varsella
Rachel Rosen

Graduate students have completed coursework and didactics in substance use treatment, cognitive behavioral therapy, and motivational interviewing. Students also have prior experience treating individuals with psychosocial impairment in the surrounding area. All graduate students have also interfaced with members of the community to facilitate completion of research projects focused on nicotine use. This includes, but is not limited to, structured clinical interviewing of research subjects and administration of behavioral tasks.

All graduate students have also completed online coursework on ethical research practices (e.g., HIPAA compliance).

Research Coordinator(s):
Jessica Ortiz. Ms. Ortiz is currently a research assistant/coordinator for a NIDA funded trial on smokers with schizophrenia. She has an undergraduate degree in psychology and has completed online coursework on ethical research practices (e.g., HIPAA compliance).

Mindy Kibbey. Ms. Kibbey is a research assistant/coordinator in Dr. Leyro's lab. She will also serve as a clinician for the current study. Like the above named graduate students, Ms. Kibbey has received extensive training in motivational interviewing and will receive ongoing supervision by the PI.

2.2 Resources Available
Facilities-Dr. Leyro has laboratory space at both the Institute for Health and Tillett Hall where RAs will prepare study materials, conduct phone screens, schedule participants, complete reminder calls/texts/emails, store study materials, and manage data entry. In addition, Dr. Steinberg has similar space located in the Division of Addiction Psychiatry, Rutgers RWJMS at 317 George Street in New Brunswick.

Medical Or Psychological Resources- Both Drs. Steinberg and Leyro are licensed clinical psychologists in the state of New Jersey and will assist in training study staff in the management of crisis intervention. In addition, they will be available 24/7 to field any questions/concerns study staff have regarding how to proceed in the event that participants experience unanticipated psychiatric distress during the course of the study.

Research Staff Training- All graduate students and research assistants will complete intensive training with the Drs. Leyro and Steinberg, including proper administration of each intervention condition and proper administration and management of nicotine replacement therapies. Training will include didactic instruction, as well as mock-administration of the interventions with structured feedback. All graduate students will also complete weekly supervision with Drs. Leyro and Steinberg.

2.3 Research Sites
Research activities will occur at the offices of Rutgers RWJMS Division of Addiction Psychiatry, *Tobacco Research & Intervention* lab, the Rutgers Department of Psychology *Affective and Biological Underpinnings of Substance Use and Anxiety* lab, at New Brunswick Housing Authority offices and / or housing units, and at the New Brunswick non-profit agency, Elijah's Promise.

3.0 Multi-Site Research Communication & Coordination

N/A

3.1 Outside Research

N/A

4.0 Research Data Source/s

4.1 Primary Data-Subjects and Specimens

Research participants will be 60 daily socioeconomically disadvantaged smokers receiving services at a New Brunswick, NJ based agency. We will collect questionnaire data and expired breath carbon monoxide.

4.2 Subject Selection and Enrollment Considerations

A. Recruitment Details

Research assistants will post flyers and place leaflets at New Brunswick, NJ social service agencies and will work with staff at said agencies for help in connecting with potential participants.

B. Source of Subjects

Service agencies in New Brunswick, NJ (e.g., New Brunswick Housing Authority, Elijah's Promise).

C. Method to Identify Potential Subjects

Research assistants will post flyers and place leaflets at New Brunswick, NJ social service agencies and will work with staff at said agencies for help in connecting with potential participants. Participants responding to flyers or otherwise referred will complete a "pre-screen" to determine likely eligibility. Those passing the pre-screen will be invited to participate in the study and complete the full baseline battery during which eligibility will be confirmed.

D. Subject Screening

Interested participants will complete a brief in-person or telephone screening where they will be assessed by trained study personnel who will determine initial eligibility.

Inclusion Criteria

Participants must be between the age of 19 and 65, must self-report being a daily smoker and provide biochemical verification of smoking status (expired breath carbon monoxide reading >5), must be at socioeconomic disadvantage, defined as receiving services at a New Brunswick, NJ based social services agency (i.e., living in New Brunswick Housing Authority-run public housing units or requesting social services from the community social service agency, "Elijah's Promise"), and must be able to speak and read English.

Exclusion Criteria

Exclusion criteria include taking FDA approved smoking cessation or anti-psychotic medications, self-reported medical issues of potential concern to nicotine replacement users (i.e., See Table 1, e.g., unstable angina pectoris, myocardial infarction, or significant cardiac arrthymia (including atrial fibrillation) in the past 30 days), or self-reported pending legal issues with potential to result in incarceration. Additionally, using the not pregnant form, women must state in writing that they are not pregnant or nursing, planning on becoming pregnant in the next two months, and that they are using effective birth control.

E. Recruitment Materials

We will rely upon flyers and leaflets. Please see attachments. We additionally anticipate recruitment of participants via word-of-mouth.

4.3 Subject Randomization

We will use a block randomization procedure to allocate participants to one of three groups. Block randomization is a procedure in which participants are randomly allocated to interventions groups within blocks such that an equal number are assigned to each intervention. We will use the Sealed Envelope Ltd. 2017 application to

electronically develop a list of 60 allocation outcomes using a block randomization procedure with 3 intervention groups and block sizes of 3, 6, and 9. A research assistant will use this list to create envelopes for therapists to open (revealing allocation to intervention) after each participant provides informed consent and is deemed eligible to participate in the study.

4.4 Secondary Subjects
N/A

4.5 Number of Subjects
A. Total Number of Subjects
N=64

B. Require Number of Subjects to Complete Research
N=60

C. Feasibility Of Recruiting
We anticipate enrolling 2-3 participants weekly over the course of 7 months. Based on previous research conducted by the principal investigators, and the reports from staff at Elijah's Promise, this should be feasible.

4.6 Consent Procedures

A. Consent
All participants will provide written informed consent after being given the opportunity to read the consent form in full and to ask questions about the research. A research assistant will also sign the consent form as a witness.

B. Consent Process
Location of Consent Process
Verbal consent will be obtained for the initial phone screen. The PI or RA will first explain the purpose of the phone screen and limits of confidentiality and provide an overview of the study. If potential participants remain interested, they must verbally agree to phone screen completion.

During the initial in-person meeting at our research offices, or at the agency at which the participant is associated, study personnel will verbally go over the consent form including details regarding the procedure, time commitment, payment, risks/benefits, and option to discontinue at any time without penalty, and ask the participant questions to ensure they understand.

Individual Roles for Researchers Involved in Consent
PI supervised/trained graduate students and research assistants will complete all aspects of the consent procedures.

1. Consent Discussion Duration
Staff will go over details regarding the procedure, time commitment, payment, risks/benefits, and option to discontinue the study at any time without penalty. We anticipate that it will take participants 5 minutes to read the consent and up to an addition 5 for staff to review relevant information.

2. Coercion or Undue Influence

During the consent process, staff will make clear to participants that regardless of their ability to make a cessation attempt, they will receive full compensation, and that early termination will result in payment for the portion completed (i.e., visit 1 only), and will not result in loss of ability to participate in future research.

3. Subject Understanding
In addition to providing written informed consent, participants must verbally indicate that they understand the study procedures and that they have no further questions.

4.7 Special Consent/Populations
N/A

4.8 Economic Burden and/or Compensation for Subjects
A. Expenses
N/A

B. Compensation/Incentives
Participants will be compensated $20 for their initial study visit and an additional $40 for completion of the follow-up visit. Participants must complete all questionnaires and participate in the discussion at the first appointment to receive the $20 at the first appointment and must complete all questionnaires at the second appointment 30 days later to receive the $40. Participants will receive the $20 for the first appointment even if they do not attend the second appointment.

4.9 Risks to Subjects
A. Description of Subject Risk
Risks are expected to be minimal for our proposed study procedures, and we do not anticipate that participants will experience any adverse consequences associated with participation in this research, aside from mild distress associated with answering questions about physical and mental health.

Telephone pre-screening and Pre-visit Questionnaires. Following a phone screen to determine basic eligibility requirements, participants will complete a battery of self-report indices as outlined above. Participants will be scheduled for their study appointment within one week.

B. Procedures for Risks to Embryo, Fetus, and/or Pregnant Subjects
N/A

C. Risks to Non-Subjects
N/A

D. Assessment of Social Behavior Considerations
Reasonably Foreseeable Risks
Study risks are minimal and include a small, temporary increase in distress as a result of the assessments; however, the methodologies employed have been utilized in many labs and clinical settings with hundreds of participants suffering from a range of psychopathology, and approved by as many IRBs.

Risk Of Imposing An Intervention On Subject With Existing Condition
N/A

Other Foreseeable Risks

Our research team employs standard procedures to ensure confidential information about study participation is not disclosed. All data are linked to an arbitrary 3-digit study ID unrelated to personal information. The file linking participants to their study ID will be stored in a password-protected file, located within a password-protected database on an encrypted computer. Only select trained laboratory personnel will have access to the file. All computer files or printed data used for analysis also will be de-identified. Consent forms and payment forms will be stored in a locked file cabinet separate from data in an office that is locked when not occupied. Participants' confidentiality also is protected by never associating a participant's name with results in any published or otherwise publicly presented report. Demographic information, including information about participants' age, ethnicity, education, marital status and employment status, will be reported using averages and percentages computed over multiple participants and never reported at the level of individual participants.

Observation And Sensitive Information
N/A

E. Minimizing Risks
Participants who indicate psychological distress during participation will be provided with several strategies to reduce distress as needed, including, distraction and deep breathing. Staff will conduct a thorough risk assessment with participants who report suicidal ideation or intent.

Any participants who report suicidal ideation or intent will be provided with information and phone numbers for three local options for mental health care: Rutgers University Behavioral Health Care (800-969-5300), Rutgers Health Psychiatry/Psychology Clinic (732-235-7647), and the Rutgers Psychological Clinic in (848-445-6111). In the unlikely event that a participant reports an imminent intent to harm themself, we will contact Acute Psychiatric Services (855-515-5700).

F. Certificate of Confidentiality
We have obtained a Certificate of Confidentiality from the National Institutes of Drug Abuse.

G. Potential Benefits to Subjects
Each of the three treatment conditions in our proposed project are associated with improved cessation outcomes, which may have a long-term positive impact on health and psychological well-being.

H. Provisions to Protect the Privacy Interests of Subjects
Participants will be asked to engage with trained research staff throughout the course of the study. However, if participants indicate a desire not to work with a particular staff member, we will oblige.

Our research team employs standard procedures to ensure confidential information about study participation is not disclosed. All data are linked to an arbitrary 3-digit study ID unrelated to personal information. The file linking participants to their study ID will be stored in a password-protected file, located within a password-protected database on an encrypted computer. Only select trained laboratory personnel will have access to the file. All computer files or printed data used for analysis also will be de-identified. Consent forms and payment forms will be stored in a locked file cabinet separate from data in an office that is locked when not occupied. Participants' confidentiality also is protected by never associating a participant's name with results in any published or otherwise publicly presented report. Demographic information, including information about participants' age, ethnicity, education, marital status and employment status, will be reported using averages and percentages computed over multiple participants and never reported at the level of individual participants.

I. Research Team Access To Subject Data

Only IRB approved staff will have access to participant data. All data will be coded by arbitrary study number to ensure confidentiality and will be stored in a locked filing cabinet or stored on the lab server where access will be password-protected. Data collected online will be de-identified (e.g., associated with an arbitrary study ID number) and only accessible to trained study personnel. Consent forms with identifying information (names) will be filed separately from actual study data in a separate locked filing cabinet. This cabinet the office in which it is kept will ensure that it is also double-locked.

4.10 Secondary Data – Records/Chart Reviews/Databases/Tissue Banks/etc.
N/A

4.11 Chart/Record Review Selection
N/A

4.12 Secondary Specimen Collection
N/A

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)
N/A

5.2 Family Educational Rights and Privacy Act (FERPA)
N/A

5.3 NJ Access to Medical Research Act
N/A

5.4 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)
N/A.

6.0 Research Data Protection and Reporting

6.1 Data Management and Confidentiality

A. Success of randomization will be checked via summary statistics of baseline demographic and psychosocial characteristics. Depending on the measurement scale of each variable, we will use either χ^2 or independent samples t-tests, corrected for unequal variances if indicated. Variables found to show significant baseline differences between groups will be included as covariates. Logistic regression analyses will be conducted to examine differences in dichotomous outcomes such as abstinence (yes/no), quit attempts (yes/no), and treatment seeking (yes/no). Because this is a small, pilot study, we will report effect sizes representing each of the two active interventions (MI and NRT sampling) as compared to the control intervention (referral only).

B. *Provide a power analysis. (As applicable, e.g. quantitative research).*
N/A. This is a small, pilot study. We will use the data collected in this study to estimate effect sizes for a larger NIH grant application.

C. *Describe the steps that will be taken secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.* The link between participants to their study ID will be stored in a password-protected file, located within a password-protected database on an encrypted computer. Only select trained laboratory personnel will have access to the file. All computer files or printed data used for analysis also

will be de-identified. Consent forms and payment forms will be stored in a locked file cabinet separate from data in an office (of Division of Addiction Psychiatry, 317 George Street, Suite 105, New Brunswick) that is locked when not occupied. All research personnel will complete CITI Human Subjects Research training and pass the CITI quizzes.

Additionally, we will obtain a Certificate of Confidentiality from the NIH

D. *Describe any procedures that will be used for quality control of collected data.*
Qualtrics and Excel databases will be created in such a way as to not allow for out of range data.

E. *Describe how data will be handled study-wide:*
Data (described in Table 1) will only be accessed and handled by IRB approved study personnel and kept in password protected databases. Dr. Steinberg is ultimately responsible for the receipt and transmission of all data. Paper copies of data (e.g., names on consent forms) collected at the New Brunswick Housing Authority will be brought immediately to Rutgers offices where they will be locked in a cabinet housed behind a locked door (of Division of Addiction Psychiatry, 317 George Street, Suite 105, New Brunswick).

6.2 Data Security
Our research team employs standard procedures to ensure confidential information about study participation is not disclosed. All data are linked to an arbitrary 3-digit study ID unrelated to personal information. The file linking participants to their study ID will be stored in a password-protected file, located within a password-protected database on an encrypted computer. Only select trained laboratory personnel will have access to the file. All computer files or printed data used for analysis also will be de-identified. Consent forms and payment forms will be stored in a locked file cabinet separate from data in an office that is locked when not occupied.

6.3 Data and Safety Monitoring
A. Periodic Data Evaluation
We conduct relevant interim data analyses at 1/3 (n=20), and 2/3 (n=40) of the way through data collection to examine differences between groups with respect to serious adverse events. If there is a significant difference in number of adverse events between groups, we will halt data collection and consult with the IRB.

B. Type of Data Evaluated
We will track reported adverse events using the Adverse Events Tracking log and categorize such events as mild, moderate and severe and take appropriate action accordingly, as determined by IRB guidelines for reporting. AEs and outcomes will be tracked using the Adverse Events Specifics log.

C. Collection of Safety Information
Participants will be queried regarding their experience of nicotine replacement at the follow-up session. Participants who report adverse events will be counseled on discontinuation.

D. Frequency Of Data Collection
We will collect data at baseline and at study follow-up.

E. Reviewer of Data
Data will be reviewed by the study coordinators, Ortiz and Kibbey, weekly, and by Drs. Steinberg and Leyro monthly.

F. Schedule Of Review Of Cumulative Data

Quality assurance of data will be assessed weekly by the study coordinators, Ortiz and Kibbey. They will alert to PIs to any discrepancies or observations that suggest risk of appropriate data management procedures.

G. Tests for Safety Data
Analysis of variance will be conducted to determine if there are statistically significant differences between the three groups with regards to serious adverse events.

H. Suspension of Research
If we found significant differences between groups with regards to serious adverse events, we would consult with the IRB to discuss suspending the research.

6.4 Reporting Results
A. Sharing of Results with Subjects
N/A

B. Individual Results
N/A

C. Aggregate Results
Participants will be told that published aggregate study results will be available to them upon their request by contacting the laboratory.

D. Professional Reporting
Data from our research will be presented at annual professional organization conferences (e.g., Society for Research on Nicotine and Tobacco) and published in peer-reviewed journals.

E. ClinicalTrials.Gov Registration And Data Reporting
We will register the trial with ClinicalTrials.gov

7.0 Data and/or Specimen Banking
N/A

8.0 Other Approvals/Authorizations
N/A

9.0 Bibliography
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