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Title of Research Project: Self-Control and Adult Cigarette Smokers

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BACKGROUND/SIGNIFICANCE

Cigarette smoking is the single largest preventable cause of morbidity and mortality in Western countries [1]. The majority of smokers want to quit, but are unable to succeed at long term abstinence [2, 3]. The pharmacological and behavioral treatments with the best clinical outcomes still leave more than two-thirds of smokers unsuccessful at abstinence[3]. Further, while recent advances have been made in pharmacological treatments [4], few behavioral smoking treatments have been introduced [5, 6].

Self-control is "the capacity for altering one's own responses…to support the pursuit of long-term goals" [7] (p. 351). Self-control requires deliberate and conscious personal effort [7]. As both a trait (individual differences in personality) and state (which represents situational fluctuations), self-control plays an important role in self-regulation activities [8-12]. Self-control is a promising but underexplored area for behavioral treatment development.

Self-control is a key mechanistic factor in addictive behaviors, including the inability to stop using nicotine and other addictive substances [13-15]. Self-control is a limited resource that becomes depleted when used. This depletion impairs the continued use of self-control [7, 11, 16].

For example, the depletion of self-control makes it more difficult for one to resist smoking cigarettes [17], eating sweets [18], and consuming alcohol [19]. Extremely high and enduring levels of self-control are required to resist smoking during a quit attempt in the face of intense withdrawal symptoms, environmental and emotional triggers, and the desire to smoke [2, 15]. The majority of smokers are unable to maintain self-control and relapse to smoking within days of the quit attempt [2]. The inability to maintain a high and constant level of self-control plays a critical role in smoking cessation failure.

While self-control becomes weakened through use, it can be strengthened through practice. Given that impaired self-control has a detrimental effect on smoking cessation outcomes, increasing self-control through practice may help smokers resist smoking, thereby improving cessation outcomes [13, 14, 17]. Different tasks that demand self-control appear to share a common resource [16] suggesting that improving self-control related to one behavior can have a positive impact on self-control related to another behavior. In fact, a body of research has shown that paradigms involving the daily practice of general self-control tasks (e.g., avoiding sweets, using the non-dominant hand) improves both state and trait self-control [7, 12, 20-23]. Self-control is crucial in the success of smoking cessation efforts and can be strengthened with practice; however, self-control remains an understudied area in the field of smoking.

Only one study has used the self-control paradigm described above to test the impact of strengthening self-control on smoking behavior. Muraven [24] randomly assigned 122 smokers to practice either a general self-control task (Avoiding Sweets, Hand-Grip) or a control task (keeping a diary of sweets, math problems) daily for 2 weeks prior to a smoking quit attempt. Participants who practiced general self-control tasks, compared to control tasks, had a greater mean number of days before relapsing to smoking (Self-Control Tasks, Ms=12.10 and 12.32; Control Tasks, Ms=7.43 and 6.90; $p<0.05$) and were more likely to be abstinent from smoking at the end of one month (Self-Control Tasks, 27%; Control Tasks, 12%, $p<0.05$). While it can be hypothesized that self-control improvement led to a decreased likelihood of smoking lapse, Muraven [24] did not assess changes in self-control over the practice period. Further, general self-control tasks (e.g., instructing smokers to avoid sweets) were used rather than one focused on smoking (e.g., instructing smokers to avoid smoking). A self-control task that is specific to smoking could yield stronger outcomes than a self-control task not related to smoking due to the match between the target of the self-control practice and the target behavior. The self-control procedure holds promise for cessation efforts; however, a self-control task focused on smoking has yet to be tested to determine its impact on smoking behavior.

The purpose of this pilot study is to examine a smoking-related self-control task and smoking behavior in adult smokers who are not motivated to quit smoking. Information from this study will be used to design a larger trial to examine the impact of self-control task practice on smoking quit outcomes in treatment-seeking smokers (smoking reduction, smoking cessation).

STUDY DESIGN

This pilot study will have a between-subjects design. All participants will be asked to complete two study appointments. First, they will complete a baseline appointment where they will review consent procedures. Participants who complete the consent forms will then be asked to fill out measures of demographics, smoking, and self-control. Smoking will be confirmed using expired breath carbon monoxide (CO) levels taken using a CO monitor. At that appointment participants will be randomly assigned to complete one of two self-control tasks: a task that is related to smoking (e.g., giving instructions to delay smoking when they have a craving) or a task that is not related to smoking (e.g., participants will be instructed to try to maintain the best posture possible (e.g., sit up straight, walk with good posture) as much as possible throughout each day [20]). Random assignment will be done using a random number generator and 50% of participants will be assigned to the smoking task while the other 50% will be assigned to the non-smoking task. Study staff will received standardized instructions to read to each participant about the task that they are assigned to practice during the week. Participants will be asked to practice their assigned self-control task every day for a week and to complete a brief series of questions about the effort and time spent practicing the task that day along with the number of cigarettes they smoked that day. After one week, participants will return for the second study appointment where they will report on their effort and time spent practicing the self-control tasks and complete additional measures of smoking and self-control. Study staff will be asked to complete a checklist to be sure that all parts of the two study appointments have been completed.

Measures

Independent Variables

Demographics, mood, and individual difference variables. Participants will be asked to report demographics including age, gender, race, ethnicity, sexual orientation, and education as well as past-week mood. In addition, past-three month racial and ethnic discrimination will be assessed using the 17-item Perceived Ethnic Discrimination Questionnaire (PEDQ; [25]).

Current Smoking Behavior. Questions related to smoking behavior will include age of smoking onset, frequency and quantity of cigarette smoking, use of non-cigarette tobacco products, nicotine dependence (Fagerström Test for Nicotine Dependence, FTND, [26]), and motivation to quit smoking (Thoughts About Abstinence Scale, TAAS, [27]). Beliefs about quitting smoking will be assessed using the Perceived Risks and Benefits Questionnaire [28].

Self-Control. Aspects of self-control will be measured using the Self-Control Scale [9], the Delaying Gratification Scale [29], the Barrett Impulsiveness Scale, and the Distress Tolerance Scale. The hand-grip will be used as a behavioral measure of self-control (see below for more details).

Dependent Variables

The first dependent variable for this study will be the change in self-control from the first study appointment to the second appointment. Change in self-control will be primarily measured behaviorally using the hand-grip procedure. The hand-grip is a measure of self-control rather than one of bodily strength (e.g., [30]) and the most commonly used dependent measure in self-control research [11]. Following the procedure used in other self-control studies (e.g., [20, 31]), participants will be instructed to squeeze a hand-grip exerciser as long as possible and research staff will use a stopwatch to time the length of time that the hand-grip is squeezed. A wad of paper will be inserted between the handles of the hand-grip and timing will stop when the paper falls from the hand-grip indicating that the participant has released the hand-grip. The hand-grip will be held before and after a thought suppression exercise that is meant to diminish self-control in order to control for individual hand strength (see [20]). Self-control will be measured as the difference in the length of time holding the hand-grip before and after the thought suppression exercise. Change in self-control due to task practice will be measured as [self-control at the second study appointment] minus [self-control at the first study appointment]. Secondary measures of self-control change will be calculated using self-report questions of self-control ability.

The second dependent variable will be the change in cigarettes smoked per day from the first study appointment to the second study appointment. Average number of cigarettes smoked per day will be assessed by self-report at each of the study appointments using a standard timeline followback procedure [32, 33].

Additional Measures

Research staff will be asked to complete a checklist to ensure that all parts of the study appointments have been completed.

STUDY POPULATION

Participants in this study will be 150 adults who are current cigarette smokers. Data from Muraven (1999) in a general population of smokers suggested a medium effect size (d=0.59) for practicing self-control tasks and large effects (d range: 2.2-3.4) for the impact of practicing self-control tasks on smoking behavior. Using G*Power, it was calculated that recruiting 80 participants (40 who practice a smoking-related task and 40 who practice a non-smoking-related task) will provide more than 80% power to detect a medium effect size difference between the task conditions.

Inclusion Criteria: To be eligible, participants must:
1. Be adults who are 18 years of age or older
2. Currently smoke ≥10 cigarettes per day biochemically confirmed by an expired breath carbon monoxide (CO) level ≥8
3. Report that they are not currently attempting to quit smoking and not currently receiving smoking cessation treatment (e.g., counseling, nicotine replacement therapy, bupropion, varenicline)
4. Have the capacity to give informed consent
5. Be English- or Spanish-speaking.

Children under the age of 18, non-English or non-Spanish speakers, and those who do not have the capacity to consent will be excluded from this study.

Research material will only consist of self-report survey responses. No other materials (e.g., blood, tissue) will be collected.

PARTICIPANT RECRUITMENT

Potential participants will be recruited from the community using advertisements on multiple media including Craigslist, flyers, radio, newspaper, and television. The advertisement will include the phone number of the PI's research laboratory. Research staff will talk to potential participants by phone to assess initial inclusion criteria (e.g., confirm that they are older than 18, confirm that they currently smoke cigarettes), give a brief description of the study (e.g., that it will consist of two in-person appointments during which they will be asked to fill out questionnaires and to complete practice tasks at home between the appointments), answer questions, and schedule the in-person baseline appointment. Potential participants will have the chance to ask the research staff as many questions as they want and will have as much time as they want to decide if they would like to participate in the study. Participants will also be able to decline to participate in the study, to end their participation at any time, and to decline answering any specific questions on the survey. Participants who speak and read English will complete the study materials in English. Participants who speak and read Spanish will complete the study materials in Spanish and work with a member of the research staff who speaks Spanish.

INFORMED CONSENT

The Albert Einstein College of Medicine at Yeshiva University Documentation of Informed Consent and HIPAA Authorization will be used to obtain consent to participate in the research study. At the beginning of the first study appointment, potential participants will be consented in the PI's research laboratory with a member of the research staff. The staff member will read the consent form aloud with the participant. The participant will be encouraged to stop the staff member and ask questions along the way. In addition, the staff member will describe anything that seems unclear in more detail. After reading the consent form, the participant will be asked again if he/she has any questions. Any questions will be answered. Then the participant will be asked by the staff member whether he/she wishes to participate in the study. This procedure will enhance independent decision-making by never assuming the participant automatically wants to participate after reading the consent form.

RISK/BENEFIT

There are minimal risks associated with the study procedures which include attending two study appointments, completing questionnaires, and completing the hand-grip self-control assessment. There are also minimal risks associated with practicing the self-control tasks at home between the study appointments. Some of the survey questions (e.g., smoking, desire to quit smoking, mood) may cause stress. The research staff will be able to contact the Principal Investigator, a clinical psychologist who is licensed by the state of New York (License # 020388), by cell phone at any time that they are meeting with participants for the study with questions and/or concerns. Participants who report that they are interested in quitting smoking will receive information about quit smoking resources such as the phone number for the New York Smokers Quitline (1-866-NYQUITS; 1-866-697-8487).

Participants will receive $20 as payment for completing the first study appointment either in cash or gift cards (e.g., Amazon) and $40 for completing the second study appointment either in cash or gift cards (e.g., Amazon). The money for participant payments will come from the Principle Investigator's research funds through the Ferkauf Graduate School of Psychology.

DATA ANALYSIS

Differences in demographics, smoking behavior, mood, and self-control (assessed at the first study appointment) will be compared by practice task condition (smoking-related versus non-smoking-related). Variables that differ significantly between the two groups will be considered as covariates for all analyses.

Changes in self-control will be calculated by (1) the difference in the hand-grip procedure (in seconds) from the first study appointment to the second study appointment and (2) the difference in scores on the self-report questionnaires from the first study appointment to the second study appointment. Differences in self-control changes will be compared by practice task condition (smoking-related versus non-smoking-related).

Changes in the number of cigarettes smoked per day will be calculated by the difference in the average number of cigarettes smoked per day over the previous week as assessed at the first study appointment and the average number of cigarettes smoked per day over the previous week as assessed at the second study appointment. Differences in smoking changes will be compared by practice task condition (smoking-related versus non-smoking-related).

DATA QUALITY CONTROL AND DATABASE MANAGEMENT

Participants will be identified using participant numbers on all research materials. The Principal Investigator will maintain a master list with the participants' names and contact information. This data will be kept in a locked file cabinet in the Principal Investigator's office and will not be linked with any research material (which will be kept in binders labeled only with participant ID numbers in the research laboratory). The data obtained from this study may be published, but will not identify any participants by name. After surveys have been completed, data will be entered into data analysis programs (e.g., Excel, SPSS). Data will be cleaned by the PI and the research staff by checking for missing data and outliers. Data will be stored on password-protected computers. After the study is complete, the research data will be retained in compliance with state and national requirements. Data will continue to be protected by storage in locked file cabinets and password-protected computers (for entered data). Identifiable data will not be linked to or stored with non-identifiable research data.

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