

Protocol: Acceptance and Commitment Therapy for Tobacco Cessation Initiated in a Psychiatric Partial Hospital

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BACKGROUND

There is a significant disparity in tobacco use among those living with mental illness. Individuals with mental illness are more likely to use tobacco, smoke more cigarettes per day, and experience more difficulty quitting than those without mental illness.¹⁻⁴ Individuals living with serious mental illness (SMI, a mental illness meeting DSM criteria and resulting in substantial functional impairment,⁵ e.g., schizophrenia) die, on average, 20-25 years earlier than those without; these deaths are, in large part, attributable to smoking related diseases.⁶⁻⁸ Despite similar levels of motivation to quit, tobacco use in individuals without mental illness is declining while tobacco use in those with mental illness has remained steady.^{4,9,10} These steady tobacco use rates indicate that either existing treatments do not work for smokers with mental illness or that effective treatments are not reaching these individuals.

There is a knowledge deficit as to which treatments work for smokers with mental illness. Individuals with SMI are excluded from the majority of clinical trials, so many treatments have not been tested with this population.^{11,12} However, there has been research to support the use of provider intervention, pharmacotherapy, and mental health-tailored telephone counseling with smokers with mental illness.¹³⁻¹⁵ In contrast, public health campaigns and other population level interventions aimed at the general population are not effective for smokers with mental illness.¹⁶

Mental health providers do not systematically address smoking. Mental health providers, have among the lowest levels of intervention around tobacco use of any healthcare providers.^{11,14} Among psychiatrists, rates of intervention around tobacco use have actually declined over time.¹⁷ Treatment models that encourage intervention with tobacco use in mental health treatment settings are needed.

Partial hospitalization is an excellent and underused opportunity to engage patients in tobacco treatment. Inpatient hospital systems provide a good setting to initiate intervention with tobacco use because, unlike private practice, they provide a closed system of providers who see large numbers of patients. By training a few clinicians to intervene and having a system for follow-up, tobacco treatment initiated in this setting could reach a large number of patients. Individuals hospitalized in a psychiatric hospital report high levels of motivation to quit.^{18,19} Two clinical trials of a computerized, stage-based, tobacco cessation treatment administered in inpatient psychiatry found that smokers were interested in tobacco treatment (recruitment rates 69-79%) and that those in the intervention group were more likely to be abstinent following hospitalization than usual care.^{20,21} Post-discharge abstinence rates were low, but increased over time. No safety concerns were found.

Partial hospital programs provide intensive day treatment for individuals in acute psychiatric distress. PHPs are prevalent; in 2010, there were over 400 programs nationwide.²² Partial hospitals may be an even better place to intervene with tobacco use than inpatient units because: (1) like inpatient psychiatry, there is a closed system of providers who can be trained; (2) patients are accessible; (3) patients are more stable in their illness than inpatients and therefore may be more able to accept and benefit from smoking cessation interventions; (4) partial hospital programs provide a context that allows for goal setting and restructuring of patients' home environments; (5) patients spend the day on a smoke free campus which may reduce opportunities to smoke and provide practice managing cravings; (6) patients go home at night and are encouraged to practice skills that they have learned in their home environment.

Acceptance and Commitment Therapy (ACT) is a promising treatment strategy for smokers living with SMI. ACT is a third wave cognitive behavioral therapy with two key components: (1) acceptance of unpleasant thoughts, feelings or sensations, and (2) commitment to values-guided action despite discomfort. ACT is a general psychotherapeutic approach that has been used successfully to treat a variety of mental health diagnoses including anxiety, depression, and psychosis.^{23,24}

Several pilot studies show promise for ACT as a treatment for tobacco dependence, including one showing favorable results compared to traditional cognitive behavioral approaches.²⁵⁻²⁸ To date, no large scale (fully powered) trials have been completed on the use of ACT for tobacco cessation.

Most of the ACT for smoking cessation studies have included only non-psychiatric populations. ACT may be particularly well-suited for tobacco cessation in patients with psychiatric comorbidities as: (1) ACT treatments can also be applied to treat mental health symptoms allowing for a consistent treatment framework across diagnosis, (2) the hypothesized mechanism of change (i.e., willingness to experience distress and discomfort in order to live a valued life) may be particularly relevant for smokers with psychiatric comorbidities, who are more dependent and have more severe withdrawal symptoms (i.e., they will experience more

discomfort than average when quitting).²⁹⁻³² There have been two, small, uncontrolled, feasibility studies of ACT for smoking cessation in patients with mental illness. These studies found ACT for tobacco cessation to be feasible in smokers with bipolar disorder and posttraumatic stress disorder.^{33,34} There have been no controlled trials of ACT for smoking cessation in patients with psychiatric comorbidities. More work is needed to assess the feasibility of applying the ACT treatment approach to tobacco cessation treatment with smokers with SMI, particularly among those in acute psychiatric episodes.

SUBJECT RECRUITMENT: Source. Participants will be recruited from the Rhode Island Hospital (RIH), Psychiatric Partial Hospitalization program (PHP; See letter from Dr. Zimmerman, Medical Director of the program). This day treatment program (8AM-2PM) employs the principles of ACT via four group sessions, and individual meetings with both a psychologist and a psychiatrist.

Sample size. We propose a sample size of 20 smokers per group because the primary aim of the R03 grant mechanism is to assess initial feasibility. We will oversample men such that 50% of the sample is male. Based on the current census of the PHP, we anticipate 240 smokers will be seen over the 8-month recruitment period, making it feasible to recruit 40 smokers.

Inclusion criteria. Participants will be male and female, current daily smokers, \geq age 18, have regular telephone access, and are able to read and write English.

Exclusion criteria will be: current use of tobacco cessation treatment (bupropion prescribed for a psychiatric indication will be permitted). In order to participate in the PHP, patients must speak English (as groups are offered in English only). If participants would like the nicotine patch, they must be free of medical contraindications to the nicotine patch (unless a medical provider gives approval; contraindications include recent (<2 weeks) myocardial infarction, serious underlying arrhythmias, serious or worsening angina pectoris, and pregnancy or breastfeeding).

PROCEDURES:

Recruitment. Participants will be recruited during PHP treatment. As standard clinical care, all patients are screened for smoking status upon admission. Current daily smokers will be informed about the study at that time and invited to be screened for participation. All women of childbearing potential who would like the nicotine patch will complete a pregnancy test prior to inclusion into the study. Eligible and interested participants will complete an enrollment/pre-quit visit while enrolled in the PHP, which includes a baseline assessment, random assignment to a condition, the first counseling session and 4 weeks of nicotine patches (to be started on the quit day). The enrollment visit can be on the same day as the first pre-quit visit counseling but doesn't need to be. Participants will then complete a second pre-quit counseling session (within one week of the pre-quit session but before discharge). If the participant is to be discharged before their first or second counseling session, the counselor will choose one of the following options in order of preference ((1) complete the second counseling session early but not on the same day as the first counseling session, (2) have the patient return to the partial hospital program location for the first or second counseling session, (3) complete the counseling session by phone and mail materials distributed during the counseling session). Following the second counseling session, participants will continue in their assigned post-discharge intervention consisting of up to 5 Quitline or ACT telephone sessions.

Study outcomes will be assessed at the end of the counseling treatment at an in-person visit 5 weeks after their visit 2 date OR 24 hours after the last counseling session by a research staff member, whichever is later. As an incentive for completion of the follow-up assessment, those in either group who complete this visit will receive \$20 compensation and an additional 4 weeks of the nicotine patch. We will try to schedule visits around existing appointments in the hospital system to increase compliance.

Randomization will use block randomization, unknown to the counselor or the participant. In order to balance any benefit of bupropion treatment in combination with the nicotine patch across treatment conditions, randomization will be stratified by bupropion use.

Participant payment. Participants will be paid \$20 for the enrollment/pre-quit visit and \$20 for the follow-up assessment visit. If the first counseling session happens by phone, participants will be paid for the assessment with a mailed gift card with a \$20 value, instead of \$20 cash. Participants will be paid \$5 per telephone counseling session completed. Payment for the counseling sessions will be paid at the follow-up visit and is contingent on follow-up visit attendance.

Interventions.

Nicotine patch. All participants will receive usual psychiatric care plus an offer of the nicotine patch (up to 8 weeks), dosed per package instructions. At the second pre-quit session, participants will be instructed on patch use. The first 4 weeks of patch will be distributed at enrollment and the second 4 weeks will be distributed at the follow-up visit.

Enhanced Usual Care (EUC). Participants in the EUC condition will receive one in-person counseling sessions during the PHP and a second telephone session the week following: the first session will occur prior to the quit day and will focus on establishing a quit plan and instructing the participant on the use of the nicotine patch; the second session will occur prior to quit day and will assess for any difficulties using the nicotine patch. After the second session, participants will be electronically referred to the RI state quitline. This quitline offers an enrollment call and 5 proactive counseling telephone calls to those who enroll. Quitline staff make up to 3 attempts per call to reach users. Total scheduled counseling time offered is 120 minutes. If the participant is unexpectedly discharged before their first counseling visit, the counselor will choose one of the following options in order of preference ((1) complete the second counseling session early but not on the same day as the first counseling session, (2) have the patient return to the partial hospital program location for the first counseling session, (3) complete the counseling session by phone and mail materials distributed during the counseling session).

ACT Care (AC). Participants in the AC condition will receive one in-person and 6 telephone contacts delivered from an ACT framework. Sessions will last approximately 30 minutes. If the participant is unexpectedly discharged before their first counseling visit, the counselor will choose one of the following options in order of preference ((1) have the patient return to the partial hospital program location for the counseling session, (2) complete the counseling session by phone and mail materials distributed during the counseling session). This intervention is an adaptation of the in-person and telephone protocols developed by consultant Heffner to deliver an ACT-based smoking cessation treatment to patients with bipolar disorder.³³ This treatment was found to be feasible to deliver both in person (80% retention, 40% verified abstinence at end of treatment, 90% satisfied with treatment) and by telephone (67% retention, 33% verified abstinence, 100% satisfied with treatment).

The intervention targets the six core processes in ACT: acceptance, cognitive defusion, awareness of the present moment, self as context, defining values, and committed action towards values. In ACT, acceptance means increasing willingness to fully engage in all aspects of experience, as opposed to avoiding unpleasant experiences. Cognitive defusion refers to the separation of oneself from the content of one's thoughts, recognizing that cognition does not necessarily have to drive behavior (i.e., a patient can notice themselves having a thought and choose not to act on it). Awareness of the present moment means being fully in contact with the present moment rather than dwelling psychologically in the past or the future (e.g., rumination about past failures or worry about future challenges). Self as context refers to the awareness that there is a self, independent of the content of thoughts or experiences that acts as an observer of these events.

Defining values is the process of identifying what is meaningful to individuals. Finally, committed action means making concrete value driven behavior change (as opposed to behavior driven by avoidance). The intervention relies heavily on experiential in-session exercises and metaphors as a means of helping smokers learn in vivo to apply ACT principles to the task of quitting smoking.

Counselor training. Counselors with previous experience in ACT will be trained by consultant Dr. Heffner in the delivery of her ACT for smoking cessation protocol. Dr. Heffner will review mock sessions of the counselors delivering the treatment and offer feedback to ensure that the counselors are trained to criterion. Counseling

Table 2: Measures			
Construct	Measure	Enrollment	EOT
Feasibility	% smokers recruited	X	
	% participants completed follow-up		X
Acceptability	% counseling calls completed		X
	CSQ		X
Safety	Rehospitalization		X
	K6	X	X
Efficacy	Abstinence		X
	Cigarettes per day	X	X
	Quit attempts		X
Treatment Targets	AIS	X	X
	CTQ	X	X
Covariates	Demographics	X	
	Tobacco History	X	
	FTCD (Modified)	X	
	MSW	X	X
	Cessation treatment utilization		X

sessions will be audiorecorded and we will rate 10% of sessions for fidelity using a fidelity checklist. Quitline counselors are trained Tobacco Treatment Specialists.

Hennepin Healthcare Research Institute. Sandra Japuntich, Ph.D., is the MPI of the study. She will continue to be involved in the study at her new institution, Hennepin Healthcare Research Institute (HHRI). Her roles will include designing study manuals, protocols and assessments, supervising study counselors, listening to audiorecordings of counseling sessions and providing feedback to study counselors and monitoring study progress.

Measures.

Feasibility, acceptability and safety. Feasibility of recruitment and retention will be measured by the proportion of smokers seen in the program during the enrollment period who enroll during the recruitment period. The two existing studies of smoking cessation treatment provided in inpatient psychiatric hospitals reported 69-79% recruitment rate (of those meeting inclusion criteria) and 80% retention.^{21,36} Results in this range will be considered feasible. Feasibility of treatment delivery will be assessed by the number of completed visits in the ACT group. Previous studies of ACT for tobacco cessation have found approximately 65-67% of calls were completed.^{26,33} Results in this range will be considered feasible. Acceptability will be measured at end of treatment using the 8-item Client Satisfaction Questionnaire (CSQ),³⁷ a reliable and valid questionnaire developed to test health program acceptability. Safety. We will collect information on patient re-hospitalization via chart review and using questions from the 2016 National Health Interview Survey about visits to the emergency room and to the hospital.³⁸ In addition, we will assess for symptom exacerbation. In addition, we will measure global distress using the K6 scale, a measure of non-specific psychiatric distress that has been used in population samples to discriminate between samples with and without mental illness.⁴¹

Efficacy. Efficacy will be measured by 7-day point-prevalence tobacco abstinence at end of treatment, verified by an expired breath CO rating ≤ 6 ppm.^{42,43} Finally, we will assess number of serious quit attempts (>24 hours of intentional abstinence).

ACT treatment targets. ACT treatment targets will be measured at both in person visits and during the follow-up call. The two overarching constructs of ACT, acceptance, and commitment will be assessed. Acceptance, will be measured using the Avoidance Inflexibility Scale (AIS), a 13 item, Likert scale, assessing participants' responses to their internal stimuli, including smoking-related thoughts, feelings and physiological sensations.⁴⁵ Acceptance has been shown to account for the bulk of the treatment effect of ACT for tobacco cessation in previous studies.^{25,26} Commitment will be measured using the 8-item, Commitment to quitting scale (CTQ).⁴⁶

Covariates. Demographics. We will collect patient demographics (e.g., psychiatric diagnoses, age, race/ethnicity, and age) upon enrollment. Tobacco use history (e.g., number of cigarettes per day, number of years smoking) will be measured at enrollment. Nicotine dependence will be measured at enrollment via the first item of the Fagerström Test for Cigarette Dependence (FTCD),^{47,48}. Cigarette withdrawal will be measured at each of the in-person visits and at end of treatment using the Minnesota Nicotine Withdrawal Scale (MNWS), a 9-item self-report measure of DSM withdrawal symptoms.^{49,50} Nicotine patch use will be assessed at end of treatment. We will also assess use of other cessation medications (e.g., prn nicotine replacement, bupropion, varenicline) as well as use of tobacco cessation counseling (quitline, group, individual) during the trial.

BENEFITS:

Potential benefits for all participants include free treatment with the potential to increase the likelihood of smoking cessation, which could in turn prevent smoking related morbidity and mortality as well as improve the effectiveness of psychiatric medications. All participants will be offered the nicotine patch, an FDA-approved tobacco cessation pharmacotherapy, for free. By participating in the research, all participants will also benefit from knowing they may ultimately be helping others as they will have helped us test an intervention. The costs of participating in the research will be minimized through our extensive efforts to maintain confidentiality, reduce discomfort or distress, and minimize medical complications. Overall, it is expected that the potential benefits to participants in the proposed study will outweigh potential risks.

RISKS:

Nicotine patch side effects: All subjects who are ready to quit have no contraindications to the patch will be offered an 8-week supply of free nicotine patches. The nicotine patch has been in clinical use for almost 20

years. It is available over the counter and has been judged to be generally safe and efficacious with very few contraindications. If the participant has a medical contraindication to the nicotine patch (e.g., recent history of MI) he or she must obtain clearance from a medical provider in order to receive the patch from the study team (e.g., their PHP psychiatrist or their primary care provider). Initial dosing will follow package instructions. Study counselors will explain the patch's purpose, application, and side effects. Common side effects of the patch include local skin irritation at the site of the patch, nausea if the dose is too large or if the participant continues to smoke at a high level while using the patch, and disturbed and vivid dreams. Less common reactions include allergic reactions. A comprehensive meta-analysis of 129 studies involving 177,390 individuals concluded that there was no significant difference between Nicotine Replacement Therapy and placebo in prevalence of severe adverse events (SAEs) including suicidal ideation, heart attack, and mortality.⁵¹ Thus, the principal investigator of this study, Ernestine Jennings, Ph.D. expects the risk of using the nicotine patch in the current study be very minor. We will obtain a release to inform participants' psychiatric and primary care providers that they have enrolled in a tobacco cessation study and may have been started on the nicotine patch. Participants can call the study PI or their medical provider for information on managing side effects of the nicotine patch.

Nicotine Withdrawal Symptoms After Quitting: There is a strong likelihood that most study participants who quit smoking will experience some nicotine withdrawal symptoms, including anxiety, restlessness, anger, irritability, sadness, problems concentrating, appetite change and weight gain, insomnia, and decreased heart rate. Generally, these reactions are temporary and pose no serious health risks.

Worsening of psychiatric symptoms and emergent suicidality. Available evidence suggests that quitting smoking has not been associated with increases in psychiatric symptoms among those with mental illness and may even result in improvement in psychiatric symptoms.^{20,52} However, this population is at high risk for additional acute psychiatric episodes.

Need for adjustment of psychiatric medication following cessation: Cessation in some patients on psychiatric medications (most notably antipsychotics, benzodiazepines, SSRIs, SNRIs and tricyclic antidepressants) can produce increased serum drug levels.⁵³ Medication doses will need to be monitored upon cessation to maintain the proper therapeutic dose.

Confidentiality or loss of privacy. We will collect potentially sensitive information about participants; if released inappropriately, participants may experience embarrassment or distress. The seriousness of the consequences would depend on the nature of the information revealed and to whom the information was revealed. Given the numerous steps we take to protect participant confidentiality, we think the risk of a breach of confidentiality is low.

Discomfort or distress when completing assessment and treatment procedures. Some participants may feel uncomfortable or distressed answering personal or private questions during assessment or treatment. In our previous studies, when individuals do report discomfort in these situations, it is mild. Participants will be informed at the beginning of each assessment that their participation is voluntary and they may refuse to answer any questions that make them uncomfortable or withdraw from the study at any time.

1. ADEQUACY OF PROTECTION AGAINST RISK

Recruitment and Informed Consent

Participants who appear to meet inclusion/exclusion criteria, will be informed about the study by partial hospital program research assistants. If they express interest, they will be screened for eligibility criteria by the research assistants. At first contact, all participants will first be given a brief verbal overview of the study. If participants agree to be screened and pass the screening questions based on inclusion/exclusion criteria they will be invited to participate, and will complete a contact information form. The participant will then be scheduled for a baseline assessment visit and counseling session. Written informed consent (including a description of the nature, purpose, risks, and benefits of the study) will be obtained from participants before initiating the baseline assessment. The voluntary nature of the study and the participant's right to withdrawal at any time will be stressed during the consent process; this information will be provided to participants in written form at the time of consent. As part of the consent process, to ensure comprehension, following the participant reading the consent form, we will verbally explain the study to the participant. All participant questions will be answered prior to obtaining written consent. Research assistants and study counselors will obtain consent.

PROTECTION AGAINST RISK:

Minimization of nicotine patch side effects: The nicotine patch is an over the counter medication with few serious side effects. However, participants will be screened for all contraindications to the patch. If a contraindication is present, they must obtain approval from a medical provider before participating. Participants will agree to consult with their outpatient medical providers regarding the safety of using the patch if their medical status changes after the patch is initially provided. Further, study counselors will explain the patch's purpose, application, and side effects, as well as how to use the patch in a manner that minimizes risk.

To minimize skin reactions, participants will be instructed to move the site of patch placement each day and to not repeat site use for at least one week. Patch dose may be adjusted downward if there is significant nausea or other reactions. Participants will be instructed to remove the patch before bed if it significantly interferes with sleep. Participants with severe side effects will be asked to discontinue patch use and contact their primary care provider before resuming.

Minimization of nicotine withdrawal symptoms after quitting: Participants that decide to use the nicotine patch will be told that it will reduce but not entirely eliminate withdrawal symptoms. Participants will be instructed to call their outpatient physician or psychiatrist in the case of severe withdrawal reactions. Withdrawal symptoms typically abate within 1 to 2 weeks of quitting and are not medically dangerous.

Minimization of risk from worsening of depression and emergent suicidality. There is no evidence indicating that participation in this trial will worsen depression or cause suicidality. In fact, other studies have found that quitting smoking is associated with improvements in psychiatric symptoms.^{20,52} However, given that participants will be enrolled during an acute psychiatric episode, it is likely that some participants will experience worsening of depression during this study. A minority may experience episodes of suicidal ideation. Thus, we will monitor and respond to these issues in an ethically sensitive manner.

As part of the Partial Hospital program, all patients are referred to a psychiatrist and a therapist upon discharge. We will obtain a release to inform these mental health providers that their patient is attempting to quit smoking and could experience symptom exacerbation. Participants will be informed that, in the case of symptom exacerbation, they should: (1) discuss the symptoms with their psychiatrist, therapist and/or primary care provider, (2) page Dr. Jennings, a licensed psychologist (Dr. Langdon, a licensed psychologist, will cover if Dr. Jennings is not available); or, if they pose an immediate risk to themselves or someone else, (3) call 911 or present to the nearest emergency room.

If a participant reports active suicidality (i.e., any recent suicidal attempts, suicidal gestures, or self-injurious behavior; any current plan or intent to engage in suicidal or self-injurious behavior) to any study staff at any time, the participant will be assessed by Dr. Jennings or Dr. Langdon, who will respond in an appropriate and ethical manner according to the standards of care for suicide prevention (e.g., referral to immediate emergency psychiatric care if danger to self is imminent).

Minimization of risk of inappropriate psychiatric medication dose upon cessation. Upon enrollment in the study, we will inform the patient's PHP psychiatrist of the patient's planned cessation attempt. A benefit of stopping smoking while in the PHP is that patients meet with their psychiatrists daily while in the program to monitor medication effects and side effects. In addition, we will obtain a release of information from the patients to their outpatient psychiatric provider and primary care provider. Upon enrollment, we will fax these providers a form letter indicating that the patient plans to attempt to stop smoking, their anticipated quit date, that they will be using the nicotine patch, and information on potential medication interactions with tobacco cessation.

Minimization of loss of confidentiality/privacy: All data and records will be safeguarded according to the strict privacy/confidentiality policies of The Miriam Hospital Institutional Review Board (IRB). Confidentiality will be maintained by numerically coding all data, disguising identifying information, and keeping data in secure electronic locations or locked in file drawers. All electronic data will be numerically coded and stored on a limited access server in a secure research space. All paper forms will be stored in locked file cabinets in a locked room. Names of participants will be stored separately. Participant information will be accessible only to research staff, who are pledged to confidentiality and complete training in the ethical conduct of research (i.e., both HIPAA and CITI trainings). Dr. Jennings will also personally train staff on maintenance of participant confidentiality. Identifying information will not be reported in any publication.

Minimization of discomfort or distress when completing assessment and treatment procedures: We will take three specific steps to reduce the possibility of discomfort or distress:

Study will be clearly explained. A detailed explanation of the study, including what study participation would involve, the nature of the questions participants will be asked to answer, the nature of measurements, the

nature of the intervention being tested, and the right to withdraw from the study at any time without penalty, will be provided to the participants, both verbally and in writing (through the informed consent form). Participants will be encouraged to ask questions about the study. Individuals who are uncomfortable answering these types of questions, assessments, or interventions likely will not choose to participate. Those who choose to participate but are very uncomfortable with the questions, assessments or interventions will be told that they can refuse these assessments or choose to withdrawal from the study.

Private setting. To help ensure clients' comfort, they will answer survey questions in a private setting. Thus, they should not be concerned that another individual would be able to observe these assessments.

Staff Training. All staff interacting with participants will be trained by Dr. Jennings to ask questions and complete assessments in a sensitive manner and be supportive to any participant experiencing discomfort or distress.

INFORMED CONSENT:

All participants will provide written, informed consent, before engaging in any study procedures. Participants will be given as much time as they need to provide consent, including taking the consent form home to read and enrolling at a later date (provided they still enroll while they are a patient in the partial hospital). The consent form will be explained fully by a member of the study staff before signing.

CONFIDENTIALITY OF DATA:

Data will be kept in locked cabinets in locked rooms and on secure, limited access servers behind The Miriam Hospital firewall. On survey documents and in the survey databases, participants are identified only by only numeric IDs, so the identity of participants is protected. The document connecting participant names to IDs will be kept separate from study data.

DATA AND SAFETY MONITORING PLAN:

Given that the proposed research is a single site, pilot RCT, with a very short duration of active participant contact and our expectation of a minimal risk designation, the proposed trial does not meet NIH criteria requiring establishment of a formal Data and Safety Monitoring Board. However, we have a detailed data and safety monitoring plan to ensure the safety of all participants and the validity and integrity of the data.

Monitoring.

Dr. Jennings (PI) will have primary responsibility for monitoring all participants. Any data or safety issues that arise will also be discussed with Dr. Jennifer Tidey, a senior investigator with extensive experience conducting tobacco cessation research with patients with mental illness, who will provide consultation. In addition, an independent faculty member will be recruited before the start of the study to serve as an independent reviewer. Drs. Jennings, Langdon, Tidey, and the independent reviewer will meet quarterly to review study progress and the occurrence of adverse events.

In addition, The Miriam Hospital IRB will initially approve the study. All needed changes or amendments to the IRB approved protocol will be submitted to the IRB in a timely manner. There will be no changes in protocol enacted until IRB approval of the new protocol is received.

Dr. Jennings will report all adverse events to The Miriam Hospital IRB within 24 hours. The funding institution will be informed in cases when any significant action is taken as a result of an adverse event or by direction of the IRB. Any serious adverse event (SAE), whether or not related to study intervention, will be reported to both the IRB and the funding institution. A summary of the SAEs that occurred during the previous year will be included in the annual progress reports to both the IRB and the funding institution.

Data.

All data and records will be safeguarded according to the policies of The Miriam Hospital IRB. As reviewed above, all participant records and assessment data from this study will be treated as confidential, including participant names and the fact they are participating in the study. All electronic data will be stored on secure, password protected servers. A file will be maintained that associates the subject's name with that subject's study identification number. This file will be kept in a secure, password-protected file, separate from the actual study data (e.g., screener and survey data). This study will use electronic data collection for all study data. However, consent forms will be paper forms. They will be stored in locked file cabinets in a locked room.

Long-term storage of these paper files will be at a facility that specializes in the storage of medical/research information. The destruction date of these files will be at least 6 years from the termination of the study and will be authorized by the PI.

Only the Principal Investigator, co-Investigator, and study staff will have access to data. The data entry system will require login identification and passwords in order to gain access to the data. All data are considered part of the subject's confidential record. All staff will receive ethics training and will be trained by Dr. Jennings (PI) in strict confidentiality procedures.

Every effort will be made to ensure that missing data are kept to a minimum. Data entry programs with range checking and response validation will be used for any data keypunched. Where appropriate, validation and range rules will be applied to the actual entry fields. Under supervision from the PI, the Data Systems Analyst will conduct error checking procedures and preliminary analyses on all data to ensure their accuracy. All data designated as primary outcome data will be subject to a 100% cross-referencing. All data files are automatically backed-up daily. All audits will be supervised and documented by the PI.

Only the Principal Investigator will give permission for the release of aggregated study data. No identifiable data will be released. Participants in the proposed research will be informed, during consent, that completely de-identified data (i.e., data that has been cleaned of all 18 types of HIPAA identifiers) will be available to other qualified researchers. Within 18 months of study completion, we will make datasets available to interested investigators who submit a written request to the PI. The only contingency on the use of the data will be that ethical guidelines be followed (e.g., only individuals who have completed a research ethics training course will have access to the data, the data will be stored securely). The NIH will be notified of transmissions of the data to interested investigators.

Education/Training.

All research personnel connected with this project will participate in mandatory education in human research subject protection. At the core of the self-directed training program is the tutorial provided through the Collaborative Institute Training Initiative (CITI) hosted by the University of Miami. All staff must complete online training in the protection of human research subjects and units specific to HIPAA regulations and compliance. To be certified, all staff must pass the CITI training every 3 years and the HIPAA unit annually. All investigators and staff on the present application have been certified and will maintain certification.

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