NYU Langone Health

Official Title:	Clinical Reminder Changes to Increase Smoking Cessation Treatment in Outpatient Psychiatry
NCT Number:	NCT04071795
Study Number:	19-00813
Document Type:	Study Protocol and Statistical Analysis Plan
Date of the Document:	• July 11, 2019

Title: Clinical reminder changes to increase smoking cessation treatment in outpatient psychiatry

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NYULH Study Number:	S19-00813
Funding Sponsor:	National Institute on Drug Abuse (NIDA)
ClinicalTrials.gov Number	

Initial version: 6/21/2019

Statement of Compliance

This study will be conducted in accordance with the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), any other applicable US government research regulations, and institutional research policies and procedures. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

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Protocol Summary

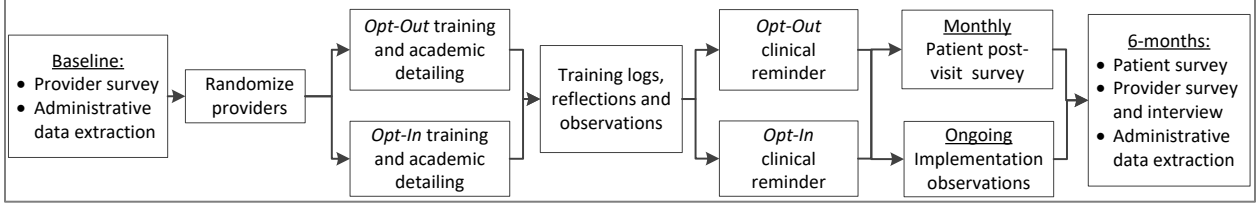
Title	Clinical reminder changes to increase smoking cessation treatment in outpatient psychiatry
Short Title	Clinical reminder changes to increase smoking cessation treatment in outpatient psychiatry
Brief Summary	This study will use a scientifically robust, mixed-methods, two-arm cluster-randomized study design. We will implement a tobacco use clinical reminder for outpatient psychiatrists practicing at the VA New York Harbor Healthcare System (N = 20). Half of the psychiatrists will receive a reminder that encourages the psychiatrist to offer cessation medications and referral to cessation counseling to patients interested in quitting (Opt-In Reminder). The other half will receive a clinical reminder that includes a standing NRT order and a referral to cessation counseling that will automatically generate unless the provider actively opts-out (Opt-Out Reminder). Prior to implementation of the reminders, psychiatrists in both arms will receive a one-hour training on tobacco treatment and individual education outreach to demonstrate the clinical reminder and answer questions (academic detailing).
Phase	N/A
Objectives	1: Estimate the effects of an Opt-Out versus Opt-In Tobacco Treatment System on the proportion of mental health patients who are screened and treated for tobacco use by their psychiatrist. 2: Assess intervention fidelity, provider perceptions, and barriers and facilitators to implementation. 3: Estimate the effect of the Opt-Out Reminder versus the Opt-In Reminder on the use of cessation treatment and self-reported abstinence among mental health patients who smoke.
Methodology	Two-arm cluster-randomized study design.
Endpoint	The primary endpoint is provider rates of screening and treating their patients for tobacco use in the first 6 months of implementation.
Study Duration	3 years
Participant Duration	6 months
Duration of behavioral intervention	6 months
Population	VA Psychiatrists and psychiatric patients who smoke
Study Site	VA NY Harbor Healthcare System (No recruitment or consenting will take place at NYULH.)
Number of participants	20 psychiatrists and 400 patients. Subjects are not NYULH employees or patients.

Description of Study Intervention/Procedure	Half of the psychiatrists will receive a reminder that encourages the psychiatrist to offer cessation medications and referral to cessation counseling to patients interested in quitting (Opt-In Reminder). The other half will receive a clinical reminder that includes a standing NRT order and a referral to cessation counseling that will automatically generate unless the provider actively opts-out (Opt-Out Reminder). Prior to implementation of the reminders, psychiatrists in both arms will receive a one-hour training on tobacco treatment and individual education outreach to demonstrate the clinical reminder and answer questions (academic detailing).
Reference Therapy	The newly tailored opt-out reminder will be compared with the current “opt-in” National reminder.
Key Procedures	1. Psychiatrist training and academic detailing 2. Provider survey at baseline and 6 months post implementation 3. Patient survey post-visit and 6 months after post-visit 4. Semi-structured interview with a subsample (n=12-14) of psychiatrists (6-7 per arm) at 1 year

Statistical Analysis	Objective 1: Based on administrative data, we will categorize the proportion of patients seen by a participating psychiatrist in each group who were: (1) screened for tobacco use by the psychiatrist, (2) among smokers, received a cessation medication prescription from the psychiatrist, and (3) among smokers, referred to cessation counseling by the psychiatrist. We will use generalized linear mixed effect models (GLMMs) to compare these screening and treatment rates between groups Objective 2: For intervention fidelity, we will use descriptive statistics to summarize the patient post-visit survey data to calculate the proportion of patients seen by a participating psychiatrist in each study arm who were asked about smoking, offered medications, offered counseling referral, and (among those offered) the proportion of patients who accepted medications and referral. We will also summarize training fidelity logs (the proportion of psychiatrists who attended the trainings and received an academic detailing session). To assess provider perceptions quantitatively, we will summarize provider survey data using descriptive statistics (means, standard deviations) to understand providers' attitudes and beliefs regarding treating their patients for tobacco. Objective 3: We will use a similar analytic approach as in Aim 1. We will first categorize each patient as: (1) having achieved or not achieved 7-day abstinence 6 months after their psychiatry visit and (2) having used or not use any type of cessation treatment in the 6 months after their visit. This will estimate use of treatment and abstinence rates for each study arm. We will use GLMMs to compare these two outcomes between groups. Qualitative Interviews: We will use ATLAS.ti to organize and analyze qualitative data. We will develop, test and refine a coding scheme based on the TDF that allows for systematic identification and conceptual definition of the main themes and sub-themes in the transcripts, as well as the relationships among the themes following Strauss's process of content analysis

Schematic of Study Design

Figure 1. Study Design



1 Key Roles

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2 Introduction, Background Information and Scientific Rationale

2.1 Background Information and Relevant Literature

Smoking is a Significant Problem for Mental Health Patients

Smoking is the leading preventable cause of death in the U.S., responsible for over 440,000 deaths per year.[1] Mental health patients have rates of smoking that at are 2-4 times higher than those found in the general population,[2] and they smoke more heavily in terms of number of cigarettes smoked per day and a longer draw per cigarette.[3] This causes considerable health consequences for this already vulnerable population. Mortality from smoking-related cardiovascular disease is 2–6 times higher in persons with a mental health condition than the general, age-matched population.[4] Persons with serious mental illnesses die on average 25 years earlier than the general population, and 60% of this excess mortality risk is due to smoking-related illnesses.[5]

Effective Tobacco Treatments Exist for Mental Health Patients

Several effective tobacco treatments are available for smokers with and without a history of mental illness. The U.S. Public Health Service (PHS) and the American Psychiatric Association (APA) practice guidelines for the treatment of tobacco use include five nicotine replacement medications (NRT) and two non-nicotine medications (bupropion and varenicline).[6, 7] The PHS guidelines further recommend the combination of medications with behavioral therapy to produce the highest abstinence rates. Several studies, including two large randomized trials conducted by our team, support the effectiveness of telephone-based cessation counseling combined with NRT for smokers with mental health diagnoses.[8-10] Busy physicians who are unable to provide cessation counseling themselves can follow a brief 3A's approach to providing tobacco treatment to mental health patients by – *asking* patients about tobacco use, *advising* them to quit and *assisting* them with quitting by prescribing cessation medications and referring them to a counseling program.

Tobacco Use is Under-Screened and Under-Treated in Outpatient Psychiatry

In 1996, the APA released guidelines for the treatment of nicotine dependence that recommended routine tobacco screening and treatment of psychiatric patients. Despite these recommendations, as well as the availability and need for effective cessation treatment among mental health patients, psychiatrists do not routinely screen or treat their patients for smoking.[11, 12] In a recent study, we used data from the National Ambulatory Medical Care Survey to analyze a national sample of outpatient psychiatry visits in the U.S. from 2006–2010. Results showed that only 60% of outpatient psychiatry visits included screening for tobacco use.[11] Moreover, psychiatrists provided cessation counseling or referral to only 23% of mental health patients known to be smokers. Of particular concern is that psychiatrists prescribed cessation medications to less than 1% of these patients.

Multiple Barriers Exist to Increasing Tobacco Treatment in Psychiatry that have not been Adequately Addressed in Prior Research

The literature and our work have identified several barriers toward screening and treating mental health patients for smoking. Mental health providers often view tobacco cessation as a low priority for their patients,[13, 14] and many psychiatrists receive no training in tobacco cessation treatment in medical school or residency.[14] In a prior study, we implemented a telephone care program for smokers in Veterans Health Administration (VA) mental health clinics[15] and conducted semi-structured interviews with mental health providers to understand barriers toward referring patients to the program. These discussions revealed treatment barriers at multiple levels, including low organizational prioritization of tobacco control in psychiatry, lack of clarification for psychiatrists about their role in treating tobacco, lack of training and comfort among psychiatrists in treating tobacco, provider attitudes that smoking may benefit their patients or cessation may be harmful, and lack of treatment engagement by patients. Although some work has been done to improve tobacco training for psychiatrists,[16] there is a paucity of research on how to best implement tobacco treatment in mental health care. Our research aims to fill this role.

Current Tobacco Treatment Systems Can Perpetuate Barriers to Tobacco Treatment for Vulnerable Populations

Health care systems currently use a ‘no treatment’ default for tobacco, such that providers must actively choose (opt-in) to treat their patients who express interest in quitting and patients must actively opt to receive treatment. A failure to act by either provider or patient results in a failure to treat. *Default bias theory* and experimental evidence within the field of behavioral economics posits that humans have a bias to accept customary (*status quo*) or default options even in the presence of superior alternatives.[17, 18] Thus, in settings and populations for which tobacco treatment is uncommon or discouraged (such as psychiatry visits), an opt-in treatment approach may actually reinforce the status quo to not treat.

2.2 Rationale

Changing to an Opt-Out Tobacco Treatment System Should Increase Treatment Rates

In recognizing that opt-in treatment approaches can introduce or reinforce systematic barriers to treatment, there has been a call in the literature to change tobacco treatment within health care settings to an opt-out system, where tobacco treatment is defaulted (i.e., automatically initiated) unless the provider or patient actively declines.[19] Research has shown that restructuring default options can significantly affect health-related choices and behavior.[20] Opt-out systems have been successful at modifying employee retirement plan contributions[21] and at dramatically improving rates of organ donation and HIV screening,[22] and preliminary evidence from an observational study suggests opt-out systems may increase the rate of cessation treatment referrals in maternity clinics.[23] Thus far, this approach has not been tested as a means to

improve the treatment of tobacco use in a psychiatric setting, and questions remain as to the acceptability and effectiveness of the approach. Our proposed study aims to fill these clinical and scientific knowledge gaps.

2.3 Potential Risks & Benefits

2.3.1 Known Potential Risks

Risk
There is minimal risk associated with being involved with this study. One risk all participants may face is a breach in confidentiality; however, multiple safeguards are in place to ensure information security. In the event of a breach, project staff immediately report the incident to the PI, who would report the incident to the ISO and Privacy Officer as appropriate. The PI would also review and update the study's standard operating procedures if needed and re-train staff to avoid incident recurrence.

There will be no penalty or change in treatment if a psychiatrist declines to participate in the study. All psychiatrists are free to choose to participate or not. Any staff that does not participate will continue to treat patients exactly as they normally would, and their employment or advancement will be in no way negatively affected.

Protection Against Risks
Subjects will be protected against risks through all the information security safeguards put in place by VANYHHS. Patient information will be kept confidential and well protected.

2.3.2 Known Potential Benefits

Potential Benefits to Subjects
The findings from this study will help inform future research and healthcare delivery at the VHA, and could lead to better implementation and treatment for tobacco dependence, with the potential to reduce smoking and its associated harms.

3 Objectives and Purpose

3.1 Primary Objectives

1. To estimate the effects of an Opt-Out versus Opt-In Tobacco Treatment System on the proportion of mental health patients who are screened and treated for tobacco use by their psychiatrist.
    a. *Hypothesis: An opt-out approach will be more effective at increasing tobacco screenings, NRT prescriptions and referrals to cessation counseling.*

2. To assess intervention fidelity, provider perceptions of the Opt-Out System, and barriers and facilitators to implementation of the Opt-Out System.

3. To estimate the effects of an Opt-Out versus Opt-In Tobacco Treatment System on use of cessation treatment and abstinence among mental health patients who smoke.

a. *Hypothesis: An opt-out approach will be more effective at increasing use of cessation treatment and abstinence.*

3.2 Secondary Objectives (if applicable)

Secondary outcomes will include patient use of cessation treatment and self-reported 7-day abstinence at 6 months. We will also measure intervention fidelity and provider perceptions of the intervention components.

4 Study Design and Endpoints

4.1 Description of Study Design

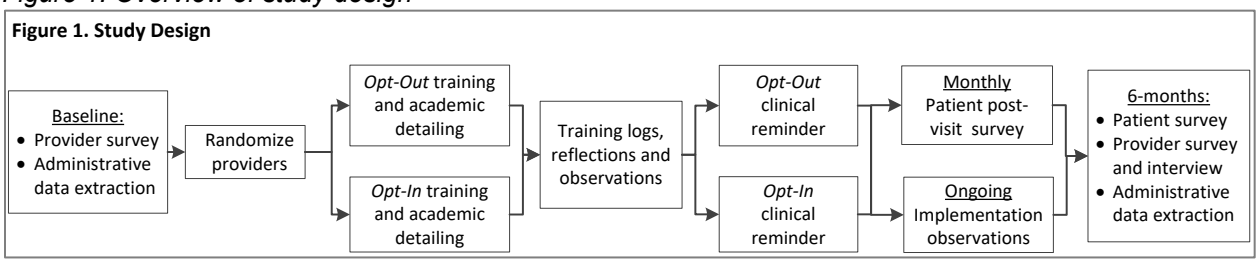
This study will use a scientifically robust, mixed-methods, two-arm cluster-randomized study design. Study subjects are not NYULH employees or patients. We will implement a tobacco use clinical reminder for outpatient psychiatrists practicing at the VA New York Harbor Healthcare System (N = 20). Half of the psychiatrists will receive a reminder that encourages the psychiatrist to offer cessation medications and referral to cessation counseling to patients interested in quitting (Opt-In Reminder). The other half will receive a clinical reminder that includes a standing NRT order and a referral to cessation counseling that will automatically generate unless the provider actively opts-out (Opt-Out Reminder). Prior to implementation of the reminders, psychiatrists in both arms will receive a one-hour training on tobacco treatment and individual education outreach to demonstrate the clinical reminder and answer questions (academic detailing).

We will use VA administrative data extracted on all patient visits with a participating psychiatrist 6 months before and after implementation to calculate the study's primary outcomes: 1) the percent of patients screened for smoking, 2) the percent of smokers prescribed a cessation medication and 2) the percent of smokers referred to counseling. To assess intervention fidelity, we will use training logs to track psychiatrist attendance at group and academic detailing trainings. Over the intervention period, we will also conduct post-visit surveys with a cluster sample of 400 patients (20 per psychiatrist) to assess psychiatrist fidelity to the 3 A's approach. At the end of the intervention period, we will conduct semi-structured interviews with 12-14 psychiatrists (6-7/arm) asking about their perceptions of the intervention components. We will also analyze implementation observations (e.g., training observations, reflection memos) and documents (e.g., meeting minutes) for implementation barriers and facilitators. At six months, we will survey the clustered 400-patient sample again to evaluate the study's secondary outcomes: 1) patient use of cessation treatment in the prior 6 months and 2) self-reported 7-day abstinence at 6 months.

One month before implementation of the provider training and reminders, all psychiatrists in the facility will be notified of the study at a required staff meeting. Psychiatrists will have the option at the meeting to ask questions and have the opportunity to opt-out of study participation. Psychiatrists will also have the opportunity to ask questions one-on-one with Drs. Rogers and Sherman before deciding whether to participate. Psychiatrist turn-over is low at the facility; however, during recruitment we will ask psychiatrists if they plan to leave in the next 6 months and only enroll those who have no plans to leave. When Dr. Sherman used this approach to provider participation in a study implementing a new tobacco treatment model in VA NYHHS primary care clinics, 50 of 51 primary care providers participated.[24] In the ongoing CHORD study, led by Dr. Schwartz, no primary care providers opted out of participation. We conservatively anticipate that 20 of 24 psychiatrists at the VA NYHHS will participate.

Psychiatrists who do not opt-out of participation will be randomized to one of the two study arms, stratified by their patient panel size and by the number of patients who smoke (captured as a health factor in the EHR) in their prior-year panel. Randomization will be supervised by the study's statistician. Psychiatrists who opt-out of study participation will receive the opt-in clinical reminder as a part of their routine care, but their performance will not be included in study analyses.

Figure 1. Overview of study design



4.2 Study Endpoints

4.2.1 Primary Study Endpoints

The study's primary outcomes will measure provider rates of screening and treating their patients for tobacco use in the first 6 months of implementation: 1) the percent of patients screened for tobacco, 2) the percent of smokers prescribed a cessation medication, and 3) the percent of smokers referred to cessation counseling.

5 Study Enrollment and Withdrawal

5.1 Inclusion Criteria

Study subjects are not NYULH employees or patients. In order to be eligible to participate in this study, an individual must meet all of the following criteria:

A. Psychiatrists
    1. Works in outpatient psychiatry at the VA New York Harbor Healthcare System and has no plans to leave in the next 6 months
B. VA patient Post-Visit Survey Population (NOT NYULH Patients)
    1. Had a visit with a psychiatrist included in the study
    2. Current smoker

5.2 Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

A. Outpatient Psychiatrists
    1. None
B. Patient Post-Visit Survey Population
    1. Non-English speaking

5.3 Vulnerable Subjects

Outpatient Psychiatrists (VA staff) will be included in this study.

5.4 Strategies for Recruitment and Retention

Data Sources

Method of Subject Identification and Recruitment

A. Psychiatrists (n=20)
    a. All outpatient psychiatrists at the VA NYHHS (based on administrative records) will be identified and notified of the study via a regular department meeting. Psychiatrists will have the opportunity to ask questions one-on-one with Drs. Rogers and Sherman before deciding whether to participate. Psychiatrist turn-over is low at the facility; however, during recruitment we will ask psychiatrists if they plan to leave in the next 6 months and only enroll those who have no plans to leave.
    b. *Semi-Structured Interview Recruitment:* We will use two methods to recruit psychiatrists for interviews. First, we will have a sign-up sheet during the training sessions and academic detailing sessions requesting volunteers. If we do not obtain our desired sample size using this method, we will employ the second approach of sending an email (with up to two follow-up emails and/or calls) notifying psychiatrists of the interview portion of the study with instructions on how to contact study staff if interested. A trained interviewer will follow an interview guide with a set of pre-specified questions and follow-up probes. All interviews will be audio-taped.
B. Patient Post-Visit Survey Population (n=400)
    c. To identify and recruit patients for the surveys, we will use the EHR to identify a list of patients seen by a participating psychiatrist on the day we run the EHR query. We will take a random selection of 5-10 male patients (depending on response rate) and all female patients (to increase representativeness of women) per psychiatrist at each monthly assessment point to reach out to for a survey. We aim to complete post-visit surveys with 20 patients per psychiatrist over the intervention period (N=200/arm).

AIM 1 Measures: Tobacco Screening, Prescriptions and Treatment Referrals

Table 2 on page 9 of the protocol outlines our measures, data sources and data collection schedule for the study. Our assessment plan for Aim 1 is to use VA administrative data to estimate and compare the effect of the Opt-Out versus Opt-In treatment systems on the percent of all patients screened and treated for tobacco use by their psychiatrist during the study's intervention period. The VA uses a fully electronic health record system that documents diagnostic and procedural data from all outpatient and inpatient encounters. The VA's Informatics and Computing Infrastructure (VINCI) allows VA-affiliated researchers to query encounter data and has data analysts available to assist investigators with data selection. We will work with VINCI programmers to identify all patients seen by a participating psychiatrist in the six months before and after implementation of the clinical reminder. We will then ask VINCI programmers to calculate the percent of these patients who were screened for tobacco use by the psychiatrist, and then among smoking patients, the percent prescribed at least one cessation medication and the percent who were referred to the local cessation program.

AIM 2 Measures: Fidelity, Provider Perceptions, and Implementation Barriers and Facilitators

Intervention Fidelity: We will use training logs and post-visit patient surveys to assess fidelity to the interventions:

1. Training Logs: We will log all training activities to capture the proportion of participating psychiatrists who attended the training sessions and received an academic detailing visit, and the content and length of the academic detailing visits.
2. Post-Visit Patient Surveys: Once a month during the 6-month intervention period we will survey a random sample of patients seen by a participating psychiatrist within 24 hours of their visit. The survey will ask patients whether their psychiatrist asked them about their smoking, and offered NRT and counseling, as well as the patient's sociodemographics, smoking behavior, cessation treatment use, and motivation to quit.

Provider Perceptions and Barriers/Facilitators to Implementation*:* We will use observations, provider surveys, and semi-structured interviews with psychiatrists to obtain rich data on psychiatrists' perceptions of the different intervention components (training, 3A's approach, opt-out and opt-in reminder) and implementation barriers/facilitators:

1. Observations: We will use an approach used by Dr. Rogers on a study evaluating the implementation of a novel intervention for diabetes patients to collect observations during the study related to provider perceptions of the intervention and implementation barriers/facilitators. During the group training sessions, the study coordinator will take notes and the trainers will complete reflection memos after each session that capture the psychiatrists' reactions to the training content, questions asked and any group discussion. The coordinator will also observe each academic detailing session and document psychiatrist reactions, comments and questions. The study investigators and coordinator will also use standardized reflection memos throughout the study to document issues that occur during and after implementation of the intervention components. All study meeting minutes (excluding confidential information) will be analyzed qualitatively for themes related to provider perceptions and barriers/facilitators.
2. Provider Survey: We will use a repeated measures design to conduct an email or paper survey with participating psychiatrists at baseline and 6 months assessing their attitudes, beliefs, motivations and intentions to treat tobacco. The survey will assess the following domains:
    a. Attitudes toward the opt-in or opt-out reminder – We will adapt the *Evidence-Based Practice Attitude Scale (EBPAS)*,44,45 which was designed to measure mental health provider attitudes toward a new evidence based practice (EBP) along four dimensions: (1) the Appeal of the EBP, (2) perceived Requirements to use the EBP, (3) Openness to use EBP and (4) perceived Divergence between the EBP and their regular practice. The scale's internal consistency reliability has been shown to be high-to-moderate. We will adapt the language of the scale to ask specifically about the study's interventions.
    b. Psychiatrists' perceived level of control in helping their patients quit smoking – Using questions adapted from the *Determinants of Implementation Behavior Questionnaire,46* we will ask psychiatrists to indicate their level of confidence in helping their patients quit tobacco on 7-point scales ranging from "Not at all confident" to "Extremely confident."
    c. Psychiatrists' subjective disciplinary norms in treating tobacco – We will use questions from the *Determinants of Implementation Behavior Questionnaire46* to ask psychiatrists to indicate their level of agreement on 7-point scales with the

statements: “Most of the psychiatrists in my department prescribe cessation medications for to their patients who smoke” and “Most psychiatrists in my department refer their patients who smoke to a smoking cessation program.”

d. Psychiatrists’ intrinsic and extrinsic motivations to treat – We will adapt two items from the *Treatment Self-regulation Questionnaire*[47] for smoking. Psychiatrists will be asked to rate on 7-point scales the level of truth to two statements related to the reasons they offer tobacco treatment to their patients. One statement will refer to a reason deriving from their personal beliefs about the importance of offering treatment. The second statement will refer to a reason deriving from the benefits the psychiatrist receives from the organization if he/she offers treatment.

e. Psychiatrists’ intentions to help their patients quit smoking – We will use a question adapted from the *Determinants of Implementation Behavior Questionnaire.*[46] Psychiatrists will respond to the statement “I intend to provide tobacco treatment to all my patients who smoke” on a 7-point scale ranging from “Agree completely” to “Disagree completely.”

3. Semi-structured Provider Interviews: Guided by the Proctor and CFIR models, we will conduct semi-structured interviews with 12-14 psychiatrists (6-7 per arm) assessing their views on the appropriateness, acceptability and sustainability of the intervention components, as well as how the clinic’s *inner setting* (e.g., culture, norms, workflow compatibility with the intervention), *outer setting* (e.g., VA policies, psychiatric professional associations), *psychiatrist characteristics* (e.g., beliefs about the intervention), and the *implementation process* (e.g., how providers were informed, who championed the intervention) may impact their views on appropriateness, acceptability and sustainability. We will also ask psychiatrists for their insights into challenges and successes encountered during their participation in the intervention components.

AIM 3 Measures: Patient Use of Cessation Treatment and Self-Reported Abstinence

We will also assess patient use of cessation treatment and tobacco abstinence 6 months after seeing a participating psychiatrist in the two arms. For this aim, we will conduct a follow-up telephone survey with the 400 cluster-sampled patients who completed a post-visit survey during the intervention period. The follow-up survey will ask patients to indicate whether they used a list of tobacco treatments in the prior 6 months, including all FDA-approved cessation medications, in-person cessation counseling, telephone cessation counseling, and a mobile texting cessation service. Consistent with guidelines for measuring abstinence in pragmatic trials, the survey will also assess 7-day point prevalence abstinence.48 Using methods that we have successfully used on prior research, we will make up to 10 attempts at different times of the day and month to reach patients by phone for a follow-up survey. Telephone non-respondents will be sent a survey in the mail with a pre-paid return envelope.

Other Measures: Patient Characteristics

Our patient surveys will collect additional information, including sociodemographics (age, gender, marital status, race/ethnicity, income), attitudes toward tobacco treatment using the *Attitudes Toward Nicotine Replacement Therapy Scale*49 adapted to ask about NRT and counseling, quitting self-efficacy using the *Smoking Self-Efficacy Questionnaire,*50 motivations to quit using a 0-10 scale, and smoking status and history using questions from the California Tobacco Survey. [51]

Table 2: Measures, Data Source and Collection Tool

Measures	Data Source	Timing	Aim
PRIMARY OUTCOMES			

Proportion of patients screened for smoking	EHR	6 months pre and post implementation	1
Proportion of smokers prescribed cessation medication	EHR	6 months pre and post implementation	1
Proportion of smokers referred for counseling	EHR	6 months pre and post implementation	1
SECONDARY OUTCOMES			
Patient use of cessation treatment	Patient post-visit survey and telephone follow-up survey	6 months before and after post-visit survey	3
Patient self-reported 7-day abstinence	Patient follow-up survey	6 months after post-visit survey	3
PROVIDER PERCEPTIONS			
Provider perceptions of the intervention	Provider interviews Training observations	6 months post-implementation Training period	2
Provider attitudes toward treatment, self-efficacy toward treatment,[46] treatment norms[46], motivation[7] and intention to treat[46]	Provider Survey	Baseline and 6 months post-implementation	2
IMPLEMENTATION BARRIERS AND FACILITATORS			
Barriers/facilitators toward implementation of the intervention components	Provider interviews Study observation logs	6 months post-implementation Intervention period	2

5.5 Duration of Study Participation

Both psychiatrists and patients will be participants for 6 months duration.

5.6 Total Number of Participants and Sites

Study subjects are not NYULH employees or patients.In total, this study plans to include 420 participants:

A. Psychiatrists (n=20)
B. Patient Cohort (n=400 smokers)

Participants will be recruited from the VA NY Harbor Healthcare System, at the Manhattan and Brooklyn campuses.

Recruitment will end when approximately 20 psychiatrists and 400 smokers are enrolled.

No recruitment or consenting will take place at NYULH.

5.6.1 Reasons for Withdrawal or Termination

Participants are free to withdraw from participation in the study at any time upon request. An investigator may terminate participation in the study if:

- Any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

5.6.2 Handling of Participant Withdrawals or Termination

After a participant withdraws, the study will not conduct any additional follow-up with the participant. Participants who withdraw will not be replaced.

6 Behavioral/Social Intervention

6.1 All Participants

Both Arms: Psychiatrist Training and Academic Detailing

Since psychiatrists cite lack of training as barrier to providing smoking cessation treatment, both arms will receive a 1-hour training in helping their patients quit smoking. One hour was chosen based on the provider trainings held by Dr. Sherman (MPI), and to maximize feasibility and fidelity (e.g., psychiatrist attendance) of the training. We will provide this education to both study arms, because education alone is necessary but not sufficient to change provider behavior.[25]

Table 1: Psychiatrist training

Content Education	• Epidemiology of tobacco use in psychiatric patients • Tobacco treatment guidelines • Linking cessation to mental health treatment norms and outcomes • Common myths about smoking in mental health patients • 3A's model – ask, advise, assist • Pharmacological Aids (focus on PHS guidelines) • Counseling Strategies • Overview of local cessation program • Medication Interactions with smoking • Patient resistance (motivational interviewing demonstration)
Process Education	• How to use clinical reminder, order NRT and refer

The training will be a mix of content education and process education (Table 1). Our approach will be adapted from the one Dr. Sherman used to train primary care and mental health providers about depression[26] and the *Psychiatry Rx for Change* training program for psychiatry residents.[27] The lecture will include a 15-minute demonstration of motivational interviewing[28] (MI) in order to help psychiatrists provide brief motivational enhancement for patients resistant to treatment[29] (identified as a barrier in our prior psychiatrist interviews).

To reinforce provider self-efficacy in treating mental health patients for smoking, we will also implement academic detailing (educational outreach) for providers in both arms. Academic detailing has consistently shown improvements in provider behavior.[30] Two study investigators will make a brief outreach visit to each psychiatrist, at least one of whom will be a physician to answer any questions about cessation medications. The investigators will follow a script, using the seven steps recommended by the National Resource Center for Academic Detailing:[31] 1) The Introduction; 2) Needs Assessment; 3) Key Messages/Features/Benefits; 4) Understanding Barriers and Enablers; 5) Identifying and Handling Objections; 6) Summary; and 7) Close. The key message (Step 3) will include demonstration of the clinical reminder, review of the evidence for smoking cessation medications and how to prescribe them, and review of the role of the facility Health Promotion staff and how to contact them. Note that detailing will occur after randomization, so each psychiatrist will receive a detailing visit on the specific intervention to which he or she will be exposed.

6.1.1 Control Arm

Arm 1: OPT-IN Clinical Reminder

To increase actual and perceived behavior control and to increase perceived prioritization (disciplinary norms) of the treatment of psychiatric patients who smoke, we will implement a

tobacco clinical reminder embedded within the EHR. Tobacco use clinical reminders are a best practice recommended by the PHS tobacco treatment guidelines and are routinely tested and used to address tobacco in primary care settings.[6] All VA facilities currently use clinical reminders, which are adapted locally and can be adapted for specific individuals or groups of providers. We will adapt the clinical reminder currently in use in Primary Care Clinics at VA New York Harbor Healthcare System, to make it suitable for the treatment of psychiatric patients who smoke. As we have done previously, the reminder will be self-explanatory, and will walk providers through each step of the 3A's approach. The reminder will include the following domains:

1. *Ask and Advise* – Providers will be prompted to ask their patients if they currently use tobacco and advise the patient to quit and to use treatment if interested in quitting.

2. *Assist: Medications* – Providers will be able to order cessation medications by clicking a box associated with an order template embedded in the reminder. The VA already has pre-set ordering templates for NRT (patch, gum, and lozenge), bupropion, and varenicline. For the proposed study, we will set combination NRT (patch plus gum or lozenge) as the preferred medication.

3. *Assist: Referral to Counseling* – Providers will be able to refer patients to the local cessation counseling program by clicking a consult box embedded in the reminder. The consult will be sent to the facility's Health Behavior Coordinator who runs the local cessation program. Program staff will proactively contact the patient to offer group behavioral counseling or warm-transfer to the VA Quitline via 3-way call for telephone counseling.

4. *Assist: Handout* – The provider will be able to print out a handout for patients with: a) The local phone number for the VA NY Harbor Healthcare System Health Behavior Coordinator, b) Instructions for smoking cessation medications, and c) Information about the VA Quitline and text messaging service.

Completing the reminder will turn it off for nine months. The reminder will be specific for psychiatrists – i.e., it will only be turned off if completed by a psychiatrist. The Tobacco Use Cessation clinical reminder that primary care providers complete will still be in effect and will be completely separate from this psychiatry reminder.

6.1.2 Intervention Arm

<u>Arm 2: OPT-OUT Clinical Reminder</u>
Arm 2 will implement a clinical reminder that automatically initiates a standing order for NRT and referral to the cessation program at the time a smoker is identified. The psychiatrist will need to actively cancel the NRT and counseling orders in order to opt the patient out of treatment. The reminder will include the following domains:

1. *Ask and Advise* – Providers will be prompted to ask their patients if they currently use tobacco. Psychiatrists will be prompted to advise patients that the VA's goal is to help all patients quit by prescribing NRT and referring them to telephone tobacco cessation coaching.

2. *Assist: Automatic Medications* – As discussed above, the VA has pre-set ordering templates for NRT, bupropion and varenicline. For smoking patients, the psychiatrist will receive an alert that an order for combination NRT (patch plus gum) will be placed unless the provider cancels the order by clicking a box within the reminder.

3. *Assist: Automatic Referral to Counseling* – For smoking patients, the reminder will also automatically generate an electronic consult to the local smoking cessation program

(described above). The reminder will include a box to check if the psychiatrist *does not* want the Coordinator to follow up with the patient.

4. *Assist: Handout* – The reminder will initiate the printing of a patient handout with: The local contact number for the VA NY Harbor Healthcare System Health Behavior Coordinator, Instructions for smoking cessation medications, and Information about the VA Quitline and text messaging service. The psychiatrist can cancel the print-out by clicking a box within the reminder.

At each opt-out point (medications, counseling, handout), the psychiatrist will be asked to select the reason for cancellation: 1) the psychiatrist does not want to treat at this time, or 2) the patient refuses treatment. Completing the reminder will turn it off for 9 months, since the VA's national goal is to ensure that all smokers are offered medications, counseling and referral annually. The reminder will be specific for psychiatrists – i.e., it will only be turned off if completed by a psychiatrist. The Tobacco Use Cessation clinical reminder that primary care providers complete will remain in effect and will be separate from this psychiatry reminder.

7 Study Procedures and Schedule

7.1.1 Study Specific Procedures

7.1.1.1 Psychiatrist training

One month before implementation of the provider training and reminders, all psychiatrists in the facility will be notified of the study at a required staff meeting.. Dr. Sherman will deliver a psychiatrist training adapted from Dr. Judith Prochaska, tailored for training psychiatrists on tobacco use cessation for mental health patients.

7.1.1.2 Provider Randomization and Baseline Survey.

Psychiatrists will be approached and given the opportunity to choose to participate in the study or opt out of participating. At this time, psychiatrists will also have the option to ask questions. Completion of the baseline survey during this point will serve as study assent and psychiatrist will then be randomized into the control group or the intervention group.

7.1.1.3 Intervention (Clinical Reminders)

Participants will be given the intervention components outlined in section 6.1 above.

Psychiatrists who do not opt-out of participation will be randomized to one of the two study arms, stratified by their patient panel size and by the number of patients who smoke (captured as a health factor in the EHR) in their prior-year panel. Psychiatrists in the control arm will receive a clinical reminder similar to the one they currently receive as mandated by national standard. Psychiatrists in the intervention arm will receive a modified clinical reminder that is tailored for an opt-out smoking cessation approach.

7.1.1.4 Post-Visit Patient Survey

Patient PHI, including names, phone numbers, mental and physical health information, and tobacco-related measures will be obtained through CPRS and patients who see a participating psychiatrist. Once a month during the 6-month intervention period we will survey a random sample of patients seen by a participating psychiatrist within 24 hours of their visit. The survey

will ask patients whether their psychiatrist asked them about their smoking, and offered NRT and counseling, as well as the patient's sociodemographics, smoking behavior, cessation treatment use, and motivation to quit.

7.1.1.5 Six Month Follow-up Psychiatrist Survey and Patient Survey

We will use a repeated measures design to conduct an email or paper survey with participating psychiatrists at baseline and 6 months assessing their attitudes, beliefs, motivations and intentions to treat tobacco. We will also assess patient use of cessation treatment and tobacco abstinence 6 months after seeing a participating psychiatrist in the two arms. For this aim, we will conduct a follow-up telephone survey with the 400 cluster-sampled patients who completed a post-visit survey during the intervention period

7.1.1.6 Follow-up Qualitative Interview with Psychiatrists

Guided by the Proctor and CFIR models, we will conduct semi-structured interviews with 12-14 psychiatrists (6-7 per arm) assessing their views on the appropriateness, acceptability and sustainability of the intervention components, as well as how the clinic's *inner setting* (e.g., culture, norms, workflow compatibility with the intervention), *outer setting* (e.g., VA policies, psychiatric professional associations), *psychiatrist characteristics* (e.g., beliefs about the intervention), and the *implementation process* (e.g., how providers were informed, who championed the intervention) may impact their views on appropriateness, acceptability and sustainability. We will also ask psychiatrists for their insights into challenges and successes encountered during their participation in the intervention components.

7.1.2 Standard of Care Study Procedures

Participants will receive their regular psychiatric care and tobacco treatment during the study. Study staff will not be involved in standard of care procedures.

8 Assessment of Safety

8.1.1 Definition of Adverse Events (AE)

An ***adverse event*** (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the course of the study. Intercurrent illnesses or injuries should be regarded as adverse events. Abnormal results of diagnostic procedures are considered to be adverse events if the abnormality:

- results in study withdrawal
- is associated with a serious adverse event
- is associated with clinical signs or symptoms
- leads to additional treatment or to further diagnostic tests
- is considered by the investigator to be of clinical significance

8.1.2 Definition of Serious Adverse Events (SAE)

Serious Adverse Event

Adverse events are classified as serious or non-serious. A ***serious adverse event*** is any AE that is:

- fatal
- life-threatening
- requires or prolongs hospital stay
- results in persistent or significant disability or incapacity
- a congenital anomaly or birth defect
- an important medical event

Important medical events are those that may not be immediately life threatening, but are clearly of major clinical significance. They may jeopardize the subject, and may require intervention to prevent one of the other serious outcomes noted above. For example, drug overdose or abuse, a seizure that did not result in in-patient hospitalization, or intensive treatment of bronchospasm in an emergency department would typically be considered serious.

All adverse events that do not meet any of the criteria for serious should be regarded as ***non-serious adverse events***.

8.1.3 Definition of Unanticipated Problems (UP)

Unanticipated Problems Involving Risk to Subjects or Others
Any incident, experience, or outcome that meets all of the following criteria:

- Unexpected in nature, severity, or frequency (i.e. not described in study-related documents such as the IRB-approved protocol or consent form, the investigators brochure, etc)
- Related or possibly related to participation in the research (i.e. possibly related means there is a reasonable possibility that the incident experience, or outcome may have been caused by the procedures involved in the research)
- Suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm).

8.2 Classification of an Adverse Event

8.2.1 Severity of Event

For AEs not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating.

8.2.2 Relationship to Study Intervention

The clinician's assessment of an AE's relationship to study intervention is part of the documentation process, but it is not a factor in determining what is or is not reported in the study. If there is any doubt as to whether a clinical observation is an AE, the event should be reported. All AEs must have their relationship to study intervention assessed. In a clinical trial, the study intervention must always be suspect. To help assess, the following guidelines are used.

- ***Related*** *– The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study intervention and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE.*
- ***Not Related*** *– There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.*

8.2.3 Expectedness

The PI will be responsible for determining whether an AE is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

8.3 Time Period and Frequency for Event Assessment

AEs and SAEs can be identified during any study procedure. When a study staff member learns of an AE or SAE, he or she will report it to the PI with 24 hours. All AEs, SAEs and Ups will be documented using standardized forms created for the study.

8.4 Reporting Procedures – Notifying the IRB

AEs, SAEs, and UPs will be reported to the IRB based on NYU SoM IRB reporting guidelines. The report will include:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an AE, SAE or UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the AE, SAE or UP.

The PI will complete and sign all reports.

9 Statistical Considerations

9.1 Statistical Hypotheses

We hypothesize that an opt-out approach will be more effective at increasing tobacco screenings, NRT prescriptions and referrals to cessation counseling.

9.2 Description of Statistical Methods

9.2.1 General Approach

We will first summarize survey and administrative data using descriptive statistics (means, medians, standard deviations, frequency distributions, and graphical displays) to characterize providers and patients treated by the providers in the two intervention arms.

9.2.2 Analysis of the Primary Efficacy Endpoint(s)

AIM 1: Estimate the effects of an Opt-Out versus Opt-In Tobacco Treatment System on the proportion of mental health patients who are screened and treated for tobacco use by their psychiatrist.

Based on administrative data, we will categorize the proportion of patients seen by a participating psychiatrist in each group who were: (1) screened for tobacco use by the psychiatrist, (2) among smokers, received a cessation medication prescription from the psychiatrist, and (3) among smokers, referred to cessation counseling by the psychiatrist. We will use generalized linear mixed effect models (GLMMs) to compare these screening and treatment rates between groups. For all analyses, sensitivity analyses will be used to evaluate the impact on results from missing data and subject dropout. Specifically, missingness will be handled by creating a separate category, or removed by multiple imputation (MI). An intent-to-treat (ITT) approach will be compared with a complete-case only method.

AIM 2: Assess intervention fidelity, provider perceptions, and barriers and facilitators to implementation: For intervention fidelity, we will use descriptive statistics to summarize the patient post-visit survey data to calculate the proportion of patients seen by a participating psychiatrist in each study arm who were asked about smoking, offered medications, offered counseling referral, and (among those offered) the proportion of patients who accepted medications and referral. We will also summarize training fidelity logs (the proportion of psychiatrists who attended the trainings and received an academic detailing session). To assess provider perceptions quantitatively, we will summarize provider survey data using descriptive statistics (means, standard deviations) to understand providers' attitudes and beliefs regarding treating their patients for tobacco. For our qualitative data analysis (interviews, observations, reflection memos, meeting minutes), we will use a three-step coding process for each data source. First, two investigators will individually read a sub-sample of data (e.g., 3 interviews) to identify preliminary inductive codes, then meet to achieve consensus on coding the sub-sample and create the first draft of a code book. Second, the investigators will individually apply the codebook to a second sub-sample of data, and meet to achieve coding consensus on the second sub-sample to create final codebook for the data source. Third, once all data are coded, the investigators will meet to complete more focused coding to identify code clusters, relationships among codes, and common themes. Once all data sources are coded, we will also use group consensus meetings to look for themes across the four main data sources.

AIM 3: Estimate the effect of the Opt-Out Reminder versus the Opt-In Reminder on the use of cessation treatment and self-reported abstinence among mental health patients who smoke: We will use a similar analytic approach as in Aim 1. We will first categorize each patient as: (1) having achieved or not achieved 7-day abstinence 6 months after their psychiatry visit and (2) having used or not use any type of cessation treatment in the 6 months after their visit. This will estimate use of treatment and abstinence rates for each study arm. We will use GLMMs to compare these two outcomes between groups. Sensitivity analyses will be used to evaluate the impact on results

from missing data and subject dropout. An IIT approach will be compared with the complete-case only method, but our primary analysis will be the complete case analysis, as The North American Quitline Consortium has found this approach to be more accurate in representing true quit rates and recommends use of this calculation,52 as do other reviews.53

9.3 Sample Size

We aim to enroll all practicing psychiatrists at the VA New York Harbor Healthcare System, but have conservatively estimated that 20 will enroll. This sample will allow us to study provider behavior during approximately 4,000 unique patient visits over 6 months. We calculated the level of power this will provide us to find a significant group effect on the proportion of patients prescribed a cessation medication by their psychiatrist (primary outcome 2). Our power calculation varied the intraclass correlation (ICC) of 0.05-0.15 based on a cluster-randomized trial of preventive care in primary care practices.54 We estimate that 10% of patients in Arm 1 will receive a prescription.15 With the smallest ICC of 0.05, a type I error of 5%, and 80% power, 4,000 visits will provide us with enough power to detect a 21% or greater prescription rate in Arm 2. With the largest ICC of 0.15, a type I error of 5%, and 80% power, 4,000 visits will provide us with enough power to detect a 29% or greater prescription rate in Arm 2.

10 Ethics/Protection of Human Subjects

10.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with Regulations for the Protection of Human Subjects of Research codified in 45 CFR Part 46.

10.2 Institutional Review Board

The protocol, waiver applications, recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented.

10.3 Informed Consent Process

10.3.1 Consent/Assent and Other Informational Documents Provided to Participants

Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting intervention. The following consent materials are submitted with this protocol:

- Informed Consent (for psychiatrists) for qualitative interview
- Audio Recording Consent (for psychiatrists)
- Waiver of Documentation of Consent (Psychiatrist Study Population)
- Waiver of Documentation of Consent (Patient Post-Visit Survey Population)

A waiver of authorization and a waiver of consent and documentation of consent have been submitted for IRB approval.

10.3.2 Consent Procedures and Documentation

Psychiatrists will have the option to decline study participation at any point in the study. Psychiatrists who opt-out of study participation will receive the opt-in clinical reminder as part of their routine care, but their performance will not be included in study analyses. We will include a cover letter on the survey including all elements of informed consent. Completing the survey will serve as documentation of consent from psychiatrists for the baseline/6-month surveys. Psychiatrists face minimal risk by participating in this study and are able to withdraw at any time. During the consent process, subjects are able to express any questions or concerns with the research team. Research staff will request separate participant consent for participation in the qualitative interviews and for audio recording.

Patient Post-Visit Survey Population (n=400). We will obtain a waiver of HIPAA authorization to identify smokers through CPRS. We will obtain verbal consent from participants for completing the short post-visit survey, and thus will obtain a waiver of documentation of consent. The consent will cover the post-visit survey and consent to participate in a short survey 6 months later to assess their use of cessation treatment and abstinence outcomes. As the survey will be conducted over the phone, it will not be possible to have documented informed consent.

10.4 Participant and Data Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

The above information will be waived through a waiver of authorization for obtaining PHI, as well as a waiver of consent and documentation of consent for psychiatrists in the study.

10.4.1 Research Use of Stored Human Samples, Specimens, or Data

All electronic data will be stored on a secure VA research server (\\R04NYNNA/RNS21\NYN_Groups\Research). Only approved members of the research team will have access to the data and files in the research folder, which is housed In the VA NY Harbor Research drive. Additionally, all documents will be password protected. Data for this study will never be kept on a local hard drive. All hardcopy study materials, including consent forms, will be kept in a locked cabinet at the research coordinator's work space. All audio-recorded and transcribed data will be de-identified. The audio-recorders have been issued by the VA and have the necessary identification. Surveys filled out by participants will not contain any names or links to other identifiable information. Surveys will be anonymously entered into REDCap, a VA approved web application for storage and analysis.

Publications and presentations of the data will not allow identification of participants. All physical documents will be safely secured in a locked cabinet monitored by members of the research team in Room 15028DN at the Manhattan campus of VANYHHS.

11 Data Handling and Record Keeping

11.1 Data Collection and Management Responsibilities

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site PI. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All electronic data will be stored on a secure VA research server (\\R04NYNNA/RNS21\NYN_Groups\Research). The audio-recorders have been issued by the VA and have the necessary identification. Surveys filled out by participants will not contain any names or links to other identifiable information. Surveys will be anonymously entered into REDCap, a VA approved web application for storage and analysis.

11.2 Study Records Retention

Study documents will be retained for the longer of 3 years after close out or 5 years after final reporting/publication.

11.3 Publication and Data Sharing Policy

At the end of the study, the PI will make results of the research available to the research community and public at large by submitting at least one manuscript to a peer-reviewed journal reporting main findings and submitting at least one abstract for presentation at a national research conference. The PI (Dr. Rogers) will be responsible for resolving authorship issues. We plan to publish study results in respected peer-reviewed journals and present at national conferences.

12 Study Finances

12.1 Funding Source

This study is funded by the National Institute on Drug Addiction (NIDA).

12.2 Costs to the Participant

There are no costs associated with participating in this study.

12.3 Participant Reimbursements or Payments

Participants will be reimbursed for their time depending on their amount of participation:

A. Psychiatrists
    a. Psychiatrists will not be reimbursed for their l participation in using the studies modified clinical reminder or current clinical reminder (opt-in-versus-opt-out reminders) in the study, as their role will be to implement standard treatment of care.

b. Psychiatrists will be compensated $10 for each survey they complete, for up to $20.
c. Psychiatrists who participate in the semi-structured interviews will be paid $20 for their time.

B. Patient Post-Visit Survey Population
   a. Participants will be compensated $10 each for completing the post-visit survey and 6 month follow-up survey, for up to $20.

The study will adhere to NYULH human subject payment policy and allowable payment methods.

13 References

1. Centers for Disease, C. and Prevention, *Annual smoking-attributable mortality, years of potential life lost, and economic costs--United States, 1995-1999.* MMWR Morb Mortal Wkly Rep, 2002. **51**(14): p. 300-3.
2. Grant, B.F., et al., *Nicotine dependence and psychiatric disorders in the United States: results from the national epidemiologic survey on alcohol and related conditions.* Arch Gen Psychiatry, 2004. **61**(11): p. 1107-15.
3. Williams, J.M. and D. Ziedonis, *Addressing tobacco among individuals with a mental illness or an addiction.* Addict Behav, 2004. **29**(6): p. 1067-83.
4. Goff, D.C., et al., *Medical morbidity and mortality in schizophrenia: guidelines for psychiatrists.* J Clin Psychiatry, 2005. **66**(2): p. 183-94; quiz 147, 273-4.
5. Colton, C.W. and R.W. Manderscheid, *Congruencies in increased mortality rates, years of potential life lost, and causes of death among public mental health clients in eight states.* Prev Chronic Dis, 2006. **3**(2): p. A42.
6. *A clinical practice guideline for treating tobacco use and dependence: 2008 update. A U.S. Public Health Service report.* Am J Prev Med, 2008. **35**(2): p. 158-76.
7. *Practice guideline for the treatment of patients with nicotine dependence. American Psychiatric Association.* Am J Psychiatry, 1996. **153**(10 Suppl): p. 1-31.
8. Rogers, E.S., et al., *Telephone Smoking-Cessation Counseling for Smokers in Mental Health Clinics: A Patient-Randomized Controlled Trial.* Am J Prev Med, 2015.
9. Grossman, E., et al., *Effectiveness of smoking-cessation interventions for urban hospital patients: study protocol for a randomized controlled trial.* Trials, 2012. **13**: p. 126.
10. Lukowski, A.V., et al., *Quitline Outcomes for Smokers in 6 States: Rates of Successful Quitting Vary by Mental Health Status.* Nicotine Tob Res, 2015. **17**(8): p. 924-30.
11. Rogers, E. and S. Sherman, *Tobacco use screening and treatment by outpatient psychiatrists before and after release of the American Psychiatric Association treatment guidelines for nicotine dependence.* Am J Public Health, 2014. **104**(1): p. 90-5.
12. Montoya, I.D., et al., *Identification and treatment of patients with nicotine problems in routine clinical psychiatry practice.* Am J Addict, 2005. **14**(5): p. 441-54.
13. Schroeder, S.A. and C.D. Morris, *Confronting a neglected epidemic: tobacco cessation for persons with mental illnesses and substance abuse problems.* Annu Rev Public Health, 2010. **31**: p. 297-314 1p following 314.
14. Prochaska, J.J., et al., *Training in tobacco treatments in psychiatry: a national survey of psychiatry residency training directors.* Acad Psychiatry, 2006. **30**(5): p. 372-8.
15. Rogers, E., et al., *Telephone care coordination for smokers in VA mental health clinics: protocol for a hybrid type-2 effectiveness-implementation trial.* Addict Sci Clin Pract, 2013. **8**: p. 7.
16. Prochaska, J.J., et al., *Evaluation of an evidence-based tobacco treatment curriculum for psychiatry residency training programs.* Acad Psychiatry, 2008. **32**(6): p. 484-92.
17. Camerer, C.F., *Behavioral economics.* Curr Biol, 2014. **24**(18): p. R867-71.
18. Camerer, C., *Behavioral economics: reunifying psychology and economics.* Proc Natl Acad Sci U S A, 1999. **96**(19): p. 10575-7.
19. Richter, K.P. and E.F. Ellerbeck, *It's time to change the default for tobacco treatment.* Addiction, 2015. **110**(3): p. 381-6.

20. Loewenstein, G., T. Brennan, and K.G. Volpp, *Asymmetric paternalism to improve health behaviors.* JAMA, 2007. **298**(20): p. 2415-7.
21. B.C., M. and D. F.S., *The Power Of Suggestion: Inertia In 401(k) Participation And Savings Behavior.* Quarterly Journal of Economics, 2001. **v116**(4,Nov): p. 1149-1187.
22. Walmsley, S., *Opt in or opt out: what is optimal for prenatal screening for HIV infection?* Cmaj, 2003. **168**(6): p. 707-8.
23. Bauld, L., et al., *Implementation of routine biochemical validation and an 'opt out' referral pathway for smoking cessation in pregnancy.* Addiction, 2012. **107 Suppl 2**: p. 53-60.
24. Schwartz, M.D., et al., *Panel Management to Improve Smoking and Hypertension Outcomes by VA Primary Care Teams: A Cluster-Randomized Controlled Trial.* J Gen Intern Med, 2015.
25. Forsetlund, L., et al., *Continuing education meetings and workshops: effects on professional practice and health care outcomes.* Cochrane Database Syst Rev, 2009(2): p. CD003030.
26. Sherman, S.E., et al., *Teaching systems-based practice to primary care physicians to foster routine implementation of evidence-based depression care.* Acad Med, 2007. **82**(2): p. 168-75.
27. Prochaska, J.J., et al., *Designing for dissemination: development of an evidence-based tobacco treatment curriculum for psychiatry training programs.* J Am Psychiatr Nurses Assoc, 2009. **15**(1): p. 24-31.
28. Steinberg, M.L., et al., *Motivational interviewing with personalized feedback: a brief intervention for motivating smokers with schizophrenia to seek treatment for tobacco dependence.* J Consult Clin Psychol, 2004. **72**(4): p. 723-8.
29. Steinberg, M.L., et al., *An Adaptation of Motivational Interviewing Increases Quit Attempts in Smokers With Serious Mental Illness.* Nicotine Tob Res, 2016. **18**(3): p. 243-50.
30. O'Brien, M.A., et al., *Educational outreach visits: effects on professional practice and health care outcomes.* Cochrane Database Syst Rev, 2007(4): p. CD000409.
31. Farrell, S., et al., *Introductory Guide to Academic Detailing*. 2013, National Resource Center for Academic Detailing.

14 Appendices

A. Intervention Form
    a. Form A: Referral Form
    b. Form B: Opt-out Form
B. Smoking Cessation Handout
C. Patient Post-Visit Survey Verbal Consent Script
D. Brief Qualitative Interview Guide
E. Patient Post-Visit Survey