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Pilot Testing a Digital Intervention to Improve Smoking Cessation in Persons With Serious Mental Illness

Study Protocol

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Lay Summary

We have adapted a digital intervention both to the needs of SMI smokers and to being introduced in the inpatient psychiatric setting through a collaboration between experts in SMI and the Truth Initiative, a pre-eminent tobacco control organization. We have built upon a well-established, evidence-based, cessation website, BecomeAnEX.org (EX), that offers individualized quit plans, an active social community, text and email messaging support, and digital coaching. Integrating input from different stakeholders, we will develop adaptations so that EX components and language are in line with principles of mental health recovery and will successfully engage SMI smokers with digital coaching that will support the use of other EX services. We developed integrated procedures for identifying hospitalized SMI smokers and registering them with EX. In this study, we will conduct a randomized pilot trial with N=90 SMI smokers recruited during psychiatric hospitalization. Study participants will be randomized to usual care + EX-SMI or usual care only (brief counseling and quitline referral) and followed for 3 months. We will examine the feasibility/acceptability of EX-SMI, obtain initial estimates of efficacy, and measure impact on target mechanisms.

Background

Smoking is a leading cause of early mortality in people with SMI. About 50% of people with SMI smoke, more than 3x the prevalence in the general adult US population. People with SMI die on average 10-15 years earlier than those in the general population. Smoking is the most important risk factor for elevated mortality in schizophrenia and is associated with lower quality of life and less life satisfaction. People with SMI are less likely to be screened for tobacco use or offered cessation services. In addition to its physical health benefits, cessation is associated with reduced psychiatric symptoms in SMI. Effective cessation services are essential for reducing cancer mortality and improving the lifespan of SMI patients.

Psychiatric hospitalization is an ideal time to initiate cessation treatment. Hospital admissions for SMI are common with more than 1.2 million inpatient stays for schizophrenia and mood disorders per year in the US. Hospitalization represents a critical window of opportunity for delivering cessation services. All patients experience (required) abstinence, are available for counseling, can try cessation medications in a supportive setting, and are not exposed to usual cues for smoking. Center for Medicare and Medicaid Services (CMS) guidelines recommend cessation services be provided for all hospitalized patients including those on psychiatric units. Abstinence during hospitalization does not adversely impact psychiatric symptoms and is associated with greater motivation to quit. Many inpatients report recent quit attempts, overall attitudes towards smoking are negative among those who are hospitalized, motivation to quit is no lower among those with SMI who are hospitalized than those without a mental health disorder, and openness to quitting improves during an inpatient stay. The challenge is engaging SMI smokers in cessation treatment to maintain abstinence post-discharge. CMS guidelines require offering cessation referrals at discharge, which is usually satisfied by referral to a tobacco quitline. Unfortunately, most SMI patients do not access quitline services. Data from the Sheppard Pratt Hospital collected by Dr. Dickerson show that only 17% of smokers accept a referral to the state quitline at discharge; of those, only 15% later connected with a quitline counselor (i.e., only 3 in 100 referrals result in quitline use). While 34% accepted a prescription for NRT at discharge, it is not known how many

actually obtain NRT. For those that do accept a quitline referral, brief counseling offered by quitlines is not as effective with SMI smokers. As a result, despite reporting a desire to remain abstinent, most SMI smokers do not receive cessation services after discharge, and almost all return to smoking. The first weeks and months following hospital discharge are a critical time for sustaining abstinence as patients return to environments that do not support abstinence and typically do not have immediate access to cessation services. Introducing hospitalized SMI patients to cessation services that can be easily accessed when they leave the hospital offers the best chance of converting initial abstinence while in the hospital into sustained abstinence in the community. Identifying the best way to do this has been elusive. Referral to telephone quitlines at inpatient discharge is largely not effective for SMI smokers. In most cases, there is no transition plan at discharge for cessation services and these are left to the outpatient setting. There, interventions have relied on the Ask-Advise-Refer (AAR) model of tobacco dependence treatment in which healthcare providers Ask about smoking status, Advise a smoker to quit, and Refer to available cessation resources such as quitlines and local programs. However, there is little follow-up with advice to quit or the referral and most smokers passively referred to treatment fail to follow through. Studies that have tried to extend cessation services after discharge have examined multicomponent programs that provide combinations of telephone counseling, self-help manuals, community support, and in-person counseling. While some programs yield greater abstinence than no treatment controls or quitline referral, such programs generally rely on person hours to deliver services and do not build on existing hospital systems. As a result, they are difficult to deliver in a way that is scalable within large facilities and across treatment systems and sustainable over time. Other treatment models are needed to address cessation in SMI smokers.

Digital interventions are an ideal way to deliver effective cessation services after inpatient discharge. More than 12 million smokers search online every year for assistance in quitting. Internet interventions that are interactive and tailored have been shown to increase abstinence in numerous meta-analyses. They can overcome many practical barriers to continuity of services from inpatient to outpatient care. Many of their components are automated meaning that sustained intervention can be delivered in a way that is scalable and cost-efficient. They can incorporate evidence-based practices such as assistance setting a quit date, creating a quit plan, identifying triggers and developing coping strategies, and provision of NRT. Proactive prompts and reminders through text messaging and email can increase medication adherence. Text messaging has been shown to increase both short- and long-term abstinence. Moreover, digital programs are even more effective when blended with human support. This support can be provided by clinicians or coaches and can be delivered by phone, email, or via digital coaching. Digital programs offer contact with an online social network for 24/7 peer support and encouragement from others engaged in quitting and maintaining abstinence. Importantly, digital interventions offer options and allow for a tailored, personalized experience based on user needs and preferences. For SMI smokers, human support via digital coaching can foster a trusting relationship where symptom and safety issues can be thoroughly addressed.

Technology use is common and digital interventions are used by persons with SMI. The majority of individuals with SMI own cellphones, 50% own smartphones, and most use text message and social media. Persons with SMI regularly access the internet to obtain health information: over 58% in one

survey reported accessing the internet daily and 54% reported accessing it more than once per day. and can use smartphone applications and other types of digital interventions. These data support the feasibility of reaching SMI smokers via digital interventions.

Digital interventions for smoking cessation need to be customized for SMI smokers. SMI smokers find existing web-based cessation tools and resources poorly matched to their needs. Other interventions are focused on increasing motivation to quit but continue to rely on clinicians to deliver cessation services. Currently, there is no digital cessation program that addresses the needs of SMI smokers. In addition, there have been only limited efforts to help SMI smokers who have quit while in the hospital to maintain abstinence after discharge and none that are digital. An effective program could be adapted to meet this need.

The program we will be adapting is called BecomeAnEX (“EX”). EX is a well-established, multimodal, evidence-based digital intervention for smoking cessation developed by Truth Initiative in collaboration with Mayo Clinic in 2008. Since it launched, EX has helped more than 800,000 users and has been at the center of a large, federally-funded research portfolio that has demonstrated its effectiveness in promoting cessation. Developed in collaboration with Mayo Clinic’s Nicotine Dependence Center, core components of EX represent “pull” components (i.e., those that require the user to initiate use) and “push” components (i.e., those that proactively deliver the intervention to drive ongoing engagement). It is accessible on any web-enabled device and does not require a separate app. The EX website educates smokers and provides tools to enhance self-efficacy for quitting through a series of interactive components. The EX Community is a large, thriving online social network of current and former smokers that has been active for over 10 years. The EX text messaging program is a fully-automated system that has been integrated into the website and delivers personalized and dynamically tailored information and support based on how the participant has (or has not) engaged with the program. Text messages encourage the use of live chat and provide medication-specific support for NRT adherence. The existing text message program will be one element that will be tailored to the needs of SMI smokers. EX Coaching via live chat is grounded in the Mayo Clinic model for treating tobacco dependence and evidence-based coaching principles. EX Coaches have years of experience helping thousands of people quit smoking. Through Truth Initiative’s longstanding partnership with Mayo Clinic, EX Coaches are supervised by Mayo Clinic clinicians and follow coaching and safety protocols adapted from Mayo Clinic. Coaches help participants set a quit date and develop a quit smoking plan, build confidence and motivation for quitting, choose medication and understand the importance of adherence, and build skills to avoid relapse. A scheduling application and push notifications facilitate repeat usage of live chat. NRT decision support is provided by EX Coaches, who coordinate NRT delivery directly to a smoker’s home. EX has been at the center of a large research portfolio for over 10 years. Key findings are: 1) smokers who use NRT, interactive tools for quitting, and participate in the EX Community are more than 4x as likely to be abstinent as smokers who only visit the website in analyses that controlled for potential self-selection bias; 2) smokers who participated in the online social network were significantly more likely to be abstinent than those who never visited the community, with a significant effect demonstrated for both active participation (i.e., posting) as well as passive participation; 3) smokers with anxiety, depression, or alcohol use disorder had lower overall quit rates than those without, but greater levels of engagement on

EX had a buffering effect on 3-month cessation outcomes; 4) exposure to positive sentiment about NRT in the EX Community significantly increased the likelihood of NRT use.

Study Procedures

1. Recruitment and Screening to Determine Eligibility. We will introduce the study to unit clinicians and accept referrals. First, we will review patients' medical records to confirm tobacco use, determine psychiatric diagnoses, and collect standard demographics. Then, we will receive approval from unit staff to approach patients that are sufficiently stable and cooperative to engage in the intervention. During the recruitment meeting with patients, we will ask the patient about smoking habits, interest in staying quit after discharging, and their use of computers and the internet. Screening data will be used to determine eligibility and will enable us to characterize the pool of individuals recruited to the study and assess the generalizability of our final sample.

2. Consent. Eligible patients will complete informed consent as detailed in Protocol Section 15. Participants will be asked to provide contact information, including an email address, phone number, mobile phone carrier, and mailing address following hospital discharge that will be used to contact the participant for the follow-up assessment.

3. Baseline assessment. The baseline assessment will be conducted in person during the inpatient hospitalization by research staff. The baseline assessment will include:

- Demographic Form
- Use of Computers, Internet, Email, and Access to Mobile Devices
- Brief Symptom Inventory 18
- Self-Report of Psychiatric Medications
- Smoking History Form (Baseline version) – assesses smoking, quitting, experiences with quitting, and confidence in ones ability to quit
- Smoking Cessation Services Use Form (Baseline version) – assesses what strategies participants have used to quit
- Mental Health and Substance Use Treatment Services Form (Baseline version)
- Use of Other Tobacco and Nicotine Delivery Products
- Timeline Follow-Back - quantifies cigarette smoking in the past 30 days
- Smoking in the Home and Social Network
- Heaviness of Smoking Index
- Abstinence-Related Motivational Engagement Scale – assesses degree of motivation to quit smoking
- Smoking Abstinence Self-Efficacy Scale – assesses confidence in not smoking in a range of situations
- Tobacco Cravings Questionnaire

Payment for the baseline assessment will be made by gift card.

If a participant discharges from the hospital before completing the Baseline assessment, they will be withdrawn from the study and not asked to participate in any other procedures.

4. Randomization. Following baseline assessment, participants will be randomly assigned to usual care + EX (referred to as "EX") or usual care only (referred to as Brief Counseling or "BC") using computer-generated randomization numbers and blocked randomization with sex as the stratification factor given sex/gender differences in SC.

4a. All participants will receive BC. Research staff will coordinate with the inpatient units to ensure that all participants have been assessed for smoking and advised to quit, and that nicotine replacement therapy has been offered and prescribed during the hospital stay. Brief tobacco cessation counseling will be provided in the context of EX-SMI for those assigned to it and for those assigned to BC using the Usual Care Outline. Research staff will also coordinate with the inpatient units to ensure that all participants are provided with a prescription for nicotine replacement therapy to use after discharge and a referral to the quitline.

4b. Participants assigned to EX. These participants will learn how to use EX during hospitalization. While they are in the hospital, participants will be asked to complete two 45 minute meetings to learn how to use EX. In the first meeting, participants will be introduced to EX, assisted by research staff to register, and provided an opportunity to use its components on a tablet or smart-device. Study staff will take participants through all EX components and show them how to access the key features. The intent of this "practice period" is to familiarize participants with EX, to get participants comfortable with the program, and to allow them to ask questions. In the second meeting, study staff will guide the participant through procedures learned in the first session and allow participants to have extra practice and ask any remaining questions. If a participant discharges from the hospital before completing the EX-SMI Intervention, they will be contacted and given the opportunity to complete the Intervention by phone. If they do so, then they will also be able to participate in the follow-up assessments. At discharge, participants will be informed that additional NRT is available through interaction with an EX Digital coach.

5. Follow-up assessments. All participants will complete a 1-month follow-up assessment with research staff that will be conducted by telephone or secure Zoom video call. If the participant does not respond at the scheduled appointment time, the study staff member will leave a discreet phone message asking the participant to call back. Those participants who do not respond to this initial call after 24 hours will be called again until the participant is reached. If the participant is difficult to contact, the study staff member, in consultation with the study PI, will call the other contact numbers listed on the Locator Form.

Participants will also complete a 3-month follow up assessment either in-person on campus (737 West Lombard Street) or remotely (by phone or Zoom). One week before the assessment, we will contact the participant and ask them if they have smoked at all in the past week. If they report smoking in the past week, we will schedule the assessment by phone or Zoom. If they report that they

have not smoked in the past week, we will invite the participant to come in-person to complete questionnaires and an exhaled carbon monoxide test using a breathalyzer device. The CO test will be used for biochemical verification of smoking abstinence.

If abstinent participants are unable to come in-person for the full visit, we will complete the questionnaires by phone or Zoom and offer to bring them to campus for the CO test only. If they are unable to travel and live within 5 miles of UMMC, a study staff member will travel to the participant's home and complete the CO test outside.

The study team will pay for and arrange for transportation for participants who live within a 10 mile radius of UMMC for the 3 month follow-up.

In anticipation of some participants not completing a follow-up assessment by phone, Zoom, or in-person, the study team will call each participant once a week to complete a short, 4 question survey to ask about recent smoking, craving, and desire to stay quit. If the study team is unable to reach the participant, the survey will be sent via email or text message.

The follow-up assessments will include the measures listed below:

- Brief Symptom Inventory 18
- Self-Report of Psychiatric Medications
- Timeline Follow-Back
- Heaviness of Smoking Index
- Abstinence-Related Motivational Engagement Scale – assesses degree of motivation to quit smoking
- Smoking Abstinence Self-Efficacy Scale – assesses confidence in not smoking in a range of situations
- Tobacco Cravings Questionnaire
- Smoking History Form (Follow Up version)
- Smoking Cessation Services Use Form (Follow Up version)
- Mental Health and Substance Use Treatment Services Form (Follow Up version)
- EX Feedback Questionnaire
- Breath CO Test (3-month follow up only)

Payment for the follow-up assessments will be made by gift card.

For participants in the EX group, a study team member will also complete the Post-Intervention Qualitative Interview at one of the follow-up assessments. This is a brief interview in which will ask about their experience with EX.

Throughout the intervention period, a member of the study team will attempt to call participants in the EX group 2-4 times to ask if they have used the BecomeAnEx program and to help solve any

problems they may have encountered while using the site. These calls are designed to assist participants in using the program and do not include formal assessments or surveys.

During calls to participants, follow-up assessments, or digital coaching sessions, the study staff or coach may determine that a participant has thoughts or plans to harm themselves or others. If so, the staff member/coach will make a more detailed assessment via a structured protocol and, if there is an imminent risk of harm to self or others, the PI will be contacted and will proceed with a series of steps that may include: informing the participant's family member and/or primary mental health clinician; advising the participant to seek emergency treatment, or, in case of immediate and high risk, urgent situations, dialing 9-1-1.