Implementation Science to reduce the disparity in tobacco treatment among individuals with serious mental illness (IS-RAISE)

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1. Background and rationale

Individuals with SMI have a much higher smoking prevalence (60% vs. 15%)[1-5] and die 25 years earlier compared to the general population.[6] Despite the fact that SMI patients express interest in and have success with evidence-based smoking cessation treatment,[7-10] inadequate provision of treatment in community mental health centers (CMHCs) contributes to high smoking prevalence and related health consequences among the mentally ill.[11-14]

Patients with serious mental illness (SMI) receive care in Community Mental Health Center (CMHC) settings and psychiatry clinics, and they frequently smoke and suffer from smoking-related harms.[4-6] Growing evidence shows that patients with SMI respond to smoking cessation treatment. [15, 16] Despite the profound health costs associated with smoking in SMI patients and evidence that smoking cessation is effective in this population, [7, 8, 10] evidence-based treatment (EBT) for smoking cessation remains infrequently provided in CMHCs, [11-13]which represents a missed opportunity to reduce the morbidity and mortality associated with smoking in this highly affected population. This treatment gap exists in CMHCs in our region.

Our study addresses a critical need for real-world interventions that can function in CMHCs and psychiatry clinics to address these medically underserved communities. If successful, this will result in a model that has potential to be disseminated to other under-resourced CMHC settings. This study will test an intervention that has the potential to make improvements in tobacco treatment and ultimately reduce cancer in the SMI patients. For this trial we will recruit broadly at Washington University Psychiatry Clinics. These clinics predominately serve SMI patients.

2. Objectives

Aim 1: test the effect of nudges to quit on patient receipt of tobacco treatment.
The investigators hypothesize patient receipt of tobacco cessation treatment such as medication and counseling will be higher after delivery of nudges to quit over usual care.

Aim 2, the investigators will test the effect of nudges to quit on smoking behaviors.
The investigators hypothesize that smoking behaviors will decrease and quitting behaviors will increase in the nudges to quit group compared to usual care.

Aim 3, the investigators will evaluate the feasibility and preliminary effect of this pilot project for a future R01 proposal to systematically evaluate this multilevel intervention adapted for CMHCs and psychiatry clinics.

3. Participant selection

3.1 Eligibility Criteria

Inclusion Criteria:

1. Patient of participating clinic
2. Current smoker, ≥5 cigarettes per day
3. Age 18 years or older
4. Can speak and understand English

Exclusion Criteria:

1. Active use or receipt of smoking cessation medication or smoking cessation counseling (within the past 30 days)

3.2 Inclusion of women and minorities

Women and members of all races and ethnic groups are eligible for this study.

4. Recruitment and informed consent

Research team members plan to recruit, consent, and enroll patients of the participating clinics into the study.

4.1 Recruitment

A study team member will identify patients who are potentially eligible via Epic or patient list provided by clinic and will:
1. Mail the individual a letter and/or flyer inviting the individual to participate in the study. A phone number and email address will be provided for the individual to indicate interest in the study to the study team.
2. Call the potential participant. A study team member will use a verbal script to describe the study, and address any questions the potential participant may have.
3. Send an invitation via MyChart to participants, if applicable.
4. Patients will be recruited by fliers posted in the clinic (with clinic prior approval).

If participants are interested in the study they will be screened for eligibility using a script and a research team member will collect eligibility information and consent as approved by IRB.

4.2 Informed Consent

Participants will have the opportunity to give consent verbally over the phone without documentation of signature or in person with documentation of signature at a study location outside of the clinic. If consent is attained over the phone, the study team member will review the consent, obtain verbal consent, and mail a copy to the participant. If consent is attained in person, a research member will review the paper information consent. We will ask the patient to indicate participation by signed consent form. There will be an opportunity for the participant to ask the research team questions and the study team will document assent, including questions asked, using the consent documentation instrument in REDcap. The research team member who discusses the consent with the participant will document the conversation. After any questions are addressed

and the consent is complete, a copy of the consent will be delivered to the participant. To reduce the possibility for coercion, participants will have as much time as they desire to consider enrolling in the study including the opportunity to thoroughly review the consent materials with knowledgeable members of the research team, and with family and/or friends as appropriate and sufficient time to have all questions answered.

5. Registration procedures

This study will register summary accrual statistics to the Siteman Cancer Center OnCore Database. On a quarterly basis, accrual should be grouped according to the demographic data collected. Demographic information includes gender, age, ethnicity, and race. If any piece of demographic information was not collected for those categories, choose unknown.

1. In OnCore, navigate to the PC Console for this study and enter the dates of the quarter for which you are entering accrual statistics. (These dates must be inclusive of the same year, e.g. 1/1/2020 – 3/31/2020, not 12/31/2019 – 3/31/2020.)
2. Then, enter the accrual number for any subjects who are in the same demographic groups of race, ethnicity, gender, and age group. For example, if you have accrued two white non-Hispanic males in their 50s, you will enter that demographic as an accrual group of 2. If you have also accrued an Asian female in her 40s, you will enter her as a separate accrual group (you would enter "1" for the accrual number.)
3. In addition, you will enter "Research Center" in the drop-down field for "Internal Accruing Reporting Group" and "No disease" in the drop-down field for "Disease Site."

Complete instructions can be accessed in the OnCore Users' Manual:
https://cbmiapps.wustl.edu/confluence/display/OSS/6.+Summary+Accruals

6. Methods

6.1 Study overview

The overarching goal of this pilot project is to reduce the disparity in the treatment of tobacco use among patients at psychiatry clinics with low burden, multi-level implementation strategies, a important need reflected in existing evidence and a recent survey of community needs. The investigators propose a pilot randomized trial of 60 patients. Patients will be randomized with 1:1 allocation to usual care vs. intervention "Nudges to Quit".

TRIAL OVERVIEW	Recruit, Screen, Consent	Baseline	Follow Up	Follow Up
Timeline	Prior to baseline	Day 0	Month 3	Month 6
Location	Phone	Zoom/ Phone/ Study Lab	Zoom/ Phone/ Study Lab	Zoom/ Phone/ Study Lab
Remuneration	-	$50	$50	$50
COMMUNICATIONS				

Mail Recruitment Letters/ Call to recruit/ Flyers	X			
ADMINISTRATIVE				
Screening/ Eligibility Check	X	X		
Informed Consent	X	X		
Contact Information		X		
ASSESSMENTS AND DATA				
Demographics		X		
Smoking History/Status		X	X	X
Smoking Treatment History and Interest		X	X	X
Bioverified point prevalence abstinence (patients reporting abstinence)			X	
Use of Nicotine and Tobacco		X	X	X
FTND		X	X	X
WSWS		X	X	X
Credibility, Acceptablity and Expectancy		X	X	X
Readiness to Quit		X	X	X

FTND= Fagerström Test for Nicotine Dependence, WSWS= Wisconsin Smoking Withdrawal Scale; NTQ - Nudges to Quit; UC- usual care

6.2 Patient participation

Patients who participate will be asked to complete 3 assessments either over the phone, in person on paper or via secure redcap questionnaire administered by a research team member. Patients will be asked to complete a pre-appointment tobacco treatment needs assessment (baseline). This assessment will collect demographic, smoking, and treatment information about the patient (see trial overview table), and in part will be used as decision support for their provider via nudge creation. If patients are randomized to nudges to quit their provider will receive the nudge within one week post pre-appointment tobacco treatment needs assessment. At three month and three six months, the study team will assess tobacco treatment and smoking behaviors such as readiness to quit, smoking abstinence, smoking quantity, and quit attempts. If patients are randomized to usual care, the provider will receive the nudge following three month assessment.

These assessments will occur at study visits outside of regular clinic visits.

6.3 Enrollment

Patients will be randomized after completion of baseline assessment to either usual care or "nudges to quit". Once randomization occurs, the participant will be considered enrolled.

6.4 Intervention:

Nudges to Quit-

a. Patient:

i. Content: Patients will receive a basic handout (example attached) for patient education on evidence-based Guideline-recommended tobacco treatment and a nudge report based on patient reported treatment needs (example attached).
ii. *Delivery methods:*
    a. *Mailed and Email Delivery:* A patient handout and patient nudge to quit mailed and/or emailed (password protected with pin number, if emailed) to participants.
    b. Verbal Delivery: A study team member will deliver the patient nudge with a brief coaching interaction based on the public health service guidelines and 5A's approach.
iii. Timing: We will deliver the intervention report on the day of or <=7 days of the baseline visit. A booster intervention report will be mailed and/or emailed in 1 month following the baseline visit.

b. Provider :

i. Content: Providers will receive a nudge report (example attached) based on patient reported treatment needs. For example, providers will receive a nudge message informing them of their patients' cigarettes smoked per day, interest in medication and free smoking cessation programs, and guidance on what they can do to help their patient. Attached to the message will be a triage card that encourages providers to give advice and refer. Triage cards will also correspond to patient interest profiles.
ii. Delivery Methods: The providers of the participants will be sent via secure email and/or inbasket message.
iii. Timing: We will deliver the intervention report on the day of or <=7 days of the baseline visit. A booster intervention report will be mailed and/or emailed in ~1 month following the baseline visit.

Usual Care:

a. *Patient:*
    i. Content: Patients will receive a basic handout (example attached) for patient education on evidence-based Guideline-recommended tobacco treatment.
    ii. *Delivery Methods:*
        a. *1. Mailed and Email Delivery:* A patient handout and patient nudge to quit will be mailed and/or emailed (password protected with pin number, if emailed) to participants.
        b. *Verbal Delivery:* A study team member will deliver the patient nudge with a brief coaching interaction based on the public health service guidelines and 5A's approach.
    iii. Timing: We will deliver the intervention report on the day of or <=7 days of 3 month visit.
b. *Provider:* Providers will maintain their usual care without receiving any reports.

INTERVENTION	**Arm 1:** Nudges to Quit (NTQ)	**Arm 2:** UC
Patient level		
Patient Basic Handout (mail, email and verbal delivery by a research team member if applicable)	X	X

Patient Nudges to quit report (mail, email and verbal delivery by a research team member if applicable)	X	
Provider level (Patient will provide consent for us to send the report to their doctor)		
Provider Nudges to quit report (email and inbasket message, if applicable)	X	
Timing of intervention	**Baseline** (<=7 days within enrollment) and **Booster** (1 month)	**Baseline** (<=7 days within enrollment) and

1. Outcomes will be assessed at 3 months post-intervention.
2. After 3 months, patients in Arm 2 (UC) will receive NTQ intervention. Patients in Arm 1 will continue with their study participation with no change. This will allow the Arm 2: UC to receive the intervention at a delayed timing. This will allow additional secondary comparisons (e.g., patients assigned to the UC arm may have increased treatment as they transition from UC to NTQ intervention.)
3. At 6 months patients in both arms will receive the 6 month follow up assessment.

6.5 Remuneration
Patients will receive a $50 gift card for each assessment completed (3 assessments = $150).

6.6 Retrospective EHR query
De-identified EHR data will be queried, as approved by IRB. We will examine patient smoking prevalence, diagnosis codes, and proportion receiving tobacco treatment (medication and counseling) from EHR data. Data will be provided as approved by the Washington University Institutional review board.

7. Risks and Benefits
Participants may or may not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because knowledge generated from this research could advance the delivery of smoking cessation treatment.

Participation in this study does not entail any risks that are greater than those ordinarily encountered in daily life. It is possible that a participant will feel uncomfortable during the assessment. If that is the case, they can refuse to answer that particular question or discontinue the assessment altogether.

There is a risk of breach of confidentiality. All reasonable steps will be taken to ensure that patient privacy is maintained.

8. Regulatory and reporting requirements

We expect that the occurrence of a serious adverse event as it relates to these study interventions to be extremely rare. If a breach of confidentiality were to occur, it would be reported to QASMC and HRPO within 10 days of notification.

This study does not require QASMC audit or submission of DSM reports.
In case of severe adverse events requiring immediate attention the study team will have a call schedule to ensure an on-call clinician and a back-up clinician are always available for the study team for safety assessment. If both the on-call clinician and back up clinician cannot be reached, the staff will recommend the participant to contact their existing primary care doctor or psychiatrist or go to the emergency room for evaluation and refer the participant to crisis hotline or other community resources that may be beneficial to the participant.

9. Statistical Considerations

Aim 1: test the effect of nudges to quit on patient receipt of tobacco treatment.
The investigators hypothesize patient receipt of tobacco cessation treatment such as medication and counseling will be higher after delivery of nudges to quit over usual care.
Aim 1 analysis: We will compare the patient receipt of tobacco treatment for smoking cessation during at 6 months visit across the 2 arms. This pilot trial will be limited in statistical power due to its small sample size, but will provide important estimates for R01 proposal power calculations.

Aim 2, the investigators will test the effect of nudges to quit on smoking behaviors.
The investigators hypothesize that smoking behaviors will decrease and quitting behaviors will increase in the nudges to quit group compared to usual care. This pilot trial will be limited in statistical power due to its small sample size, but will provide important estimates for R01 proposal power calculations.

Aim 3, the investigators will evaluate the feasibility and preliminary effect of this pilot project for a future R01 proposal to systematically evaluate this multilevel intervention adapted for CMHCs. These data will inform the design of a future larger well powered trial to evaluate the multilevel intervention rigorously. Participant perspectives on acceptability of the intervention, collected during follow up visits, will be used to motivate this future work.

This is a pilot trial to evaluate feasibility and preliminary effects. No statistical tests will be pursued.

10. REFERENCES

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