FHIR-ed Up for Tobacco Cessation

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Unique Protocol

Objective:

The purpose of this research was to assess in a 30-day pilot test the acceptability and feasibility of *refresh,* a theoretically-grounded, mobile-optimized, and individualized, tobacco cessation native iOS app. *refresh* is designed for adult tobacco users. The app is tailored to the user's readiness to quit smoking and it leverages Fast Healthcare Interoperability (FHIR) and HealthKit API calls to import data from AppleHealth that is used to personalize app content.

Design:

As this was a Phase I study, it entailed a single group, pre-post pilot test of the *refresh* app.

The *refresh* app experience has various components, including:

- *Interactive activities* designed to increase smokers' readiness to quit. Activities include goal setting; cigarette log and savings tracker; a "Crush Cravings" gamified tool; mindfulness, self-reflection, seeking support, dealing with temptations, etc.;
- Tailored *text messages*;
- A personalized *actionable insight* transmitted to the patient's electronic health record (EHR) that can be used to guide a clinician's interaction around tobacco during a patient appointment. The actionable insight includes customized insight to the patient's stage of readiness, current smoking rate, goal, and app use, along with a brief, 20-second message matched to the patient's readiness to quit that the clinician could deliver.

Methods:

Recruitment for the 30-day pilot test began in March 2022. Potentially eligible patients (i.e., who had an indication of tobacco use in Epic and an upcoming regularly scheduled appointment for a visit with one of the participating clinicians in the next 30—45 days) were identified by the Rush University Medical Center research assistant (RA). The RA then sent a secure message through their patient portal in Epic (i.e., MyChart) with an invitation to take part in the refresh study on behalf of the clinician the patient was scheduled to see. Up to 2 reminders were sent via MyChart and 1 reminder was made by phone in advance of the appointment. All invitations directed potential participants to a Rush-branded landing page, which began with a brief overview of the study, followed by "Frequently Asked Questions" that address several elements of informed consent. The landing page also included a link to a brief (about 5 minute) secure screener.

The study eligibility criteria assessed in the secure screener were:

- having an upcoming appointment with a participating clinician
- being age 18 or older;
- being a current smoker;
- having an iPhone 6s or higher or an iPad;
- being willing and able to download a mobile app;
- being able to read and speak English

The screener excluded individuals who did not meet the study eligibility criteria. Individuals who screened out or who do not consent to study participation were thanked for their time.

Eligible participants were invited to provide informed consent. Those who provided informed consent completed a baseline assessment that assessed smoking history, current rate of tobacco use, psychosocial expectancies, self-efficacy, and readiness to quit smoking, tobacco products, and e-cigarettes. They were invited to download and use the app for 30 days. As a thank you for taking part, participants received a $25 gift card as a thank you for their time and were told that they could interact with the app as often as they like over the following 30 days. During that period, up to 11 re-engagement text and email messages were sent based on inactivity in the app.

In advance of the participant's next regularly scheduled appointment, data on the patient's readiness to quit, current smoking status, number of interactions with the app were synthesized into an actionable insight for their clinician that was combined with an evidence-based behavior change message that would be most helpful for the patient. This actionable insight was manually placed in the Epic pre-charting note before the visit by the Rush research assistant.

Participants received an email 30-days post-baseline to invite them to complete the follow-up assessment. Up to 9 emails and/or text reminders to complete the follow-up assessment were sent. Participants who failed to respond were called by a member of the study team and asked to complete the assessment by phone. Up to 2 attempts were made to reach them by phone. Participants received a $25 Amazon.com gift card as a thank you for completing the follow-up assessment. Fifty-one individuals participated in the pilot test.

The modification of aims (i.e., reduction in sample size from 100 to 50 participants) was requested by the PI and approved by our Program Officer on 12/21/22. Similarly, the manual placement of the actionable insight into the EHR was an approved aim modification for Phase I.

Simple descriptive statistics were calculated to describe the study sample and to evaluate app utilization and acceptability. Paired t-tests of pre-post differences on several key outcomes, including the primary outcome (psychosocial expectancies) were conducted, and responses to open-ended data qualitatively coded.