Study title: Just Kwit: Mobile Intervention for Tobacco Cessation

NCT: NCT03538678

Document created: Feb 1, 2021. The protocol below represents the study as approved by the University of Pittsburgh IRB, originally on April 2, 2019, with the latest modifications approved on June 6, 2019.

Objectives: This project will study feasibility of a smartphone-based app for tobacco cessation delivered to young adults. It will formally assess usability of a leading online tobacco cessation app using a Patient-Centered Outcomes Research (PCOR) approach. It will include a formal and thorough process evaluation of use of the Kwit smartphone app. It will include work with the Tobacco Treatment Service (TTS) to assess the usability of integrating Kwit into its program. Systematic qualitative data analysis will culminate with delineation of specific ways in which to refine the app, the existing research plan, and to facilitate ultimate translation of the intervention into practice.

Design: This is an experimental unblinded randomized controlled trial. Participants will be equally allocated in 1:1 ratio between intervention (app) and control (standard of care). Fixed allocation, stratified randomization will be used to have equal distribution of gender in both treatment and control groups, as literature suggests men and women respond differently to tobacco cessation interventions. Allocation concealment will be managed by disconnecting the randomization process (by a statistician) and recruitment (research assistant). Recruiter will not know the (pre-determined) assignment of each participant until immediately after consent to participate.

Participants will be contacted one month after discharge to answer a survey about their current smoking habits through their preferred form of communication. A reminder will be sent to the participant 1 day prior to the follow-up to notify them of the upcoming survey. Experimental arm participants will also be asked about their experience using the smartphone app. If participants do not respond after the 30-day followup, 2 additional attempts will be made at 30+1 days, and 30+7 days. After 2 weeks with no response, a final attempt will be made by phone (30+14 days).

If participants do not complete a follow-up by the end of their study period, we will contact them by phone in order to find out why they were not able to complete the follow-up. We will ask a single open-ended question.

Methods: Individual participants are in-patients at UPMC Presbyterian/Montefiore Hospitals. Tobacco Treatment Service (TTS) members provide tobacco counseling for in-patients that are smokers. Dr. Chu or an assistant on his team will accompany the TTS counselor to meet the patient. At the completion of the TTS counseling session, patients will be asked if they are interested in further discussing tobacco cessation. If the patient is interested, the researcher will begin describing the study and the consent process.

Once participants have consented to the study, they will be asked to complete a brief 10 minute survey about their smoking habits. If they are randomized to the control arm, they will be given usual care for follow-up after hospital discharge, including access to the Pennsylvania Quitline as well as information about cessation. If they are randomized to the experimental arm, the study coordinator will describe the smartphone app that will be used in the study. The coordinator will also assist in installing the app on the patient's phone. One month after discharge, participants in both arms will be contacted to complete a follow-up survey to assess

their smoking behavior. Participants in the experimental arm will be asked additional questions about their experience in using the smartphone app. The follow-up survey should take approximately 15 minutes and will take place either online, in-person, or over the phone.

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Statistical considerations: This is a pilot to gather feasibility data in using a mobile app for tobacco cessation. As no statistical analysis is being conducted, there is no statistical need for a specific number of subjects being interviewed. The use of 40 patients is based on recommended numbers for mobile application feasibility studies.