A text message delivered smoking cessation intervention: Design and rationale of the *Text My Quit* Study

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A B S T R A C T

Introduction: Smoking cessation interventions delivered through mobile technologies offer promise as an effective intervention tool. However, most existing programs have not been empirically tested, were not developed with end-user participation, and/or do not address evidence-based cognitive and behavioral variables shown to enhance smoking cessation in clinical trials. In addition, many programs tested in research trials have required users to access the internet and/or a smartphone app to access all program features, limiting the potential reach of those programs.
Methods/design: This study is a randomized controlled trial testing the efficacy of the TMQ intervention for smoking cessation. All participants are randomly assigned to receive 12 weeks of either; (1) a tailored smoking-cessation intervention delivered 100% through text messaging (TMQ), or (2) non-smoking-related text messages serving as a control for contact and subject burden (Mojo). Assessments are conducted at baseline, 3- and 6-month follow-up. The primary outcome is prolonged abstinence using an intent-to-treat approach. To understand why TMQ may be more effective than Mojo, we will test several posited mechanisms of action (i.e., mediators) that may underlie intervention efficacy and will examine use of the TMQ integrated social support (ISS) network. At the end of treatment, semi-structured interviews will be conducted with TMQ participants.
Conclusions: This study will provide a rigorous test of an innovative smoking cessation program delivered 100% through text messages. Use of mixed methodologies will provide the opportunity to enhance our understanding of the user's experience with TMQ and identify areas for future enhancement and/or expansion.

1. Introduction

Cigarette smoking kills 480,000 Americans annually [1,2], exacerbates myriad diseases, and costs over $300 billion in healthcare and productivity losses annually [2–4]. Although effective medications and evidence-based behavioral cessation treatments exist [5], most smokers attempt to quit without any assistance [6–8]. Traditional treatment approaches can present numerous barriers including substantial costs, time commitments, and logistics such as travel and scheduling of appointments [9]. Additionally, the impact of quit-smoking medications is diminished by poor adherence [7,10,11]. Studies of nicotine replacement therapy (NRT) have found that smokers take NRT less frequently and for shorter durations than the recommended dosing [12,13]. To

effect significant reductions in smoking rates, innovative interventions and delivery systems are needed that address these barriers to reach smokers effectively and efficiently [14].

The use of mobile technology, particularly mobile phones, to deliver health-related interventions is rapidly expanding [15–19]. Mobile phones are used by over 95% of Americans across diverse demographic groups [20], and offer promise as a way to reach a broad population of smokers and provide treatment to them in their natural environment in a cost-effective way. Text messaging specifically is an extremely popular communication method. Over 80% of Americans use text messaging, and the vast majority of text-message users have unlimited texting included in with their phone plan [21–23]. Additionally, text messaging is available on virtually all mobile devices and can even be performed

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on devices without phone plans (e.g., iPads/iChat), making it an inexpensive delivery medium.

Research involving smoking cessation interventions delivered through text messaging has shown promise [24–27]. For example, Mason et al. [28] conducted a randomized trial on tobacco dependent adolescent smokers comparing motivational and social networking-based text messages related to quitting smoking (experimental condition) vs a control condition of general health-related (non-smoking) messages. At 6 months, participants assigned to the experimental condition were shown to decrease the number of cigarettes smoked per day over the previous 30 days compared to controls. Similarly, Abroms and colleagues [29] showed significant increases in smoking cessation among pregnant women given a text message delivered program compared to controls.

However, most commercially available programs have not been empirically tested, were not developed with end-user participation (which has been shown to improve usability and quality of mobile health interventions; [30,31]), and/or were not developed to include features shown to promote successful smoking cessation in previous clinical trials (i.e., are not evidence-based) [26,27]. In addition, most existing programs require users to access the internet, a voice-phone counselor, and/or a smartphone app to access the core program features. Given the ubiquity of texting as a preferred communication strategy [21–23] and its availability across devices, smoking cessation interventions delivered 100% through text messaging have the potential to significantly impact uptake and use of evidence-based treatments, improve medication adherence, and greatly improve smoking cessation success rates by reducing barriers to treatment access [14].

The goal of this study is to test the efficacy of TMQ; a 12 week, evidence-based, tailored smoking-cessation intervention delivered 100% through text messaging. This paper describes the design and rationale of this randomized controlled trial.

2. Methods

2.1. Study design

This study is a 2-arm randomized controlled clinical trial comparing participants randomly assigned to either; (1) a smoking-cessation intervention delivered 100% through text messaging (TMQ), or (2) a comparison condition (Mojo) that controls for contact time and subject burden between study arms by providing general motivational messages that are not smoking-related (e.g., "If you have the will, you will find the means" "Pitch to win by being prepared, positive, and passionate"). In addition, all participants receive a link with the same self-help material at study enrollment (*American Cancer Society Guide to Quitting Smoking;* [32]), and the phone number to the national quitline (*1-800-QUIT-NOW*). Assessments are conducted at baseline, 3- and 6-month follow-up. Post-intervention qualitative interviews will be conducted with study participants in the TMQ intervention arm to enhance our understanding of the user's experience with TMQ and identify areas for future enhancement and/or expansion.

All study procedures and materials including advertisements, consent forms and procedures were reviewed and approved by the Miriam Hospital (TMH) Clinical Research Review Board (TMH IRB registration: #00000482); and a core group from the research team will provide ongoing monitoring during the trial.

2.2. Research goals and hypotheses

The primary aim of this study is to test the relative efficacy of the TMQ intervention plus self-help manual compared to a contact-control (Mojo) plus the same self-help manual. The primary outcome for this study is prolonged abstinence at 6-month follow-up. We hypothesize that participants given the TMQ intervention will show significantly higher prolonged abstinence rates compared to those given the contact-

control program. We will also examine the use of the TMQ integrated social support (ISS) network among TMQ participants and test whether use of the ISS network predicts successful quitting. We hypothesize that among TMQ participants, increased use of the ISS network will be positively associated with smoking abstinence at follow-up.

A secondary aim of the study is to examine potential mechanisms of action (i.e., mediators) underlying the efficacy of TMQ for smoking cessation. This comparison is important for understanding why the TMQ intervention may be more efficacious than Mojo, and to understand how TMQ may act on different behavioral and cognitive mechanisms. We hypothesize that motivation, readiness, and confidence in quitting smoking, along with self-efficacy and social support for quitting smoking, will mediate the effect of treatment assignment on smoking outcomes at follow-up. These psychosocial factors are well-established and have been robust predictors of successful smoking cessation in previous studies [33–36] and the TMQ intervention was designed to address these constructs. We will also examine potential moderator variables to look for differences in outcomes by participant characteristics (e.g., age, gender, nicotine dependence, mobile phone affinity, baseline smoking rate) to determine if TMQ is more effective for different subgroups of participants (i.e., heavy versus light smokers).

2.3. Sample size and power calculations

Our primary hypothesis is that significantly more TMQ participants will achieve smoking abstinence versus controls. In our pilot, the abstinence rate at 6-month follow-up among individuals given a contact-control program was 5% using an intention-to-treat (ITT) approach that imputed positive smoking status to non-respondents (i.e., missing data = smoking) [37]. The current study uses a similar control group, and we thus estimate that abstinence rates at 6-months will be 5% among controls. The estimate of effect size for the TMQ group is also based on our previous pilot [37]. In that pilot, at 6-months follow-up, the ITT abstinence rate among active intervention participants was 20%. However, since those data were obtained on a relatively small sample ($n = 30$), to ensure we have ample statistical power to detect differences between groups in the present study, we conservatively estimate the 6-month smoking abstinence rate for the TMQ arm at 15%.

A power analysis of the primary aim indicated that a sample size of 280 participants (140 per group) is needed for a two-sided test at an alpha level of significance of 0.05 to achieve 80% power to detect differences in the ITT cessation rate of 15% for the TMQ group versus 5% for the Mojo group. The hypothesized difference (15% vs. 5%) is equivalent to a Cohen's h of 0.34, a standardized effect size for proportions, developed by Cohen [38] and interpreted as intermediate between a small (0.20) and medium (0.50) effect size.

2.4. Statistical power for secondary and mediation analyses

In general, secondary analyses that use the complete sample ($n = 280$) will have similar power as the primary analyses, that is, 80% power for a two-sided test at the alpha = 0.05 level to detect standardized deviation differences of 0.34. In our pilot study [37], we had found the average effect size difference between treatment groups for the secondary variables at 6-months follow-up to be a standardized difference of 0.42 in favor of the intervention group, and thus we expect to have sufficient power to detect differences among secondary variables in the present study. With respect to power for the mediation analyses, we are primarily concerned with the indirect effect from the independent variable (IV) to the mediator (M) to the dependent variable (DV). This is generally noted as the product of path coefficients or parameters from the IV to M and from M to DV, which we denote as a and b, respectively, and their product or indirect (mediated) effect as $a*b$. For any single mediator model that we will examine, prior to a more complex multiple mediator model, our overall sample size ($n = 280$) has > 80% power under multiple conditions of values for a, b

and the resulting indirect effect $a*b$. Specifically, this will be the case if both a and b each have a minimum standardized parameter value of 0.26 or greater, equivalent to a small to medium effect size for a regression coefficient. The indirect effects will be analyzed using a bias-corrected percentile-based bootstrap approach [39].

3. Study procedures

3.1. Data security

To maximize potential intervention reach and maintain cultural consistency with technology-delivered interventions, study enrollment and all assessments are conducted online. To ensure the safety and security of participant data, we will use REDCap (Research Electronic Data Capture) [40] to administer study assessments. All study data are collected and managed using REDCap hosted by the HIPAA-compliant, hospital-based server for our research institution, the Miriam Hospital. REDCap is a secure, web-based application designed to support data capture for research and provides: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. Security for communications with the optional counselor (Section 5.1.1.3 below) must rely on the underlying security of the device, which also provides security for access to user's other applications (e.g., banking applications) that require security. SMS is highly proprietary. Other items are secured and authenticated to ensure data is encrypted when in transit and when at rest.

3.2. Recruitment and screening

Because the study is conducted online and via text messages, recruitment is not limited by geographic location. Since we are hoping to recruit a sample of smokers from the general population, recruitment methods include posting advertisements online on social media websites such as Craigslist or Facebook, as well as through flyers targeted at a variety of venues including pharmacies, grocery stores, and churches. These methods have proven successful in our previous studies [37,41,42]. In addition, we will be reviewing the hospital's electronic health records for patients who tentatively match the eligibility criteria (i.e. current smoker). Patients who appear eligible by e-chart review will be invited via email to be screened for study enrollment.

All advertisements provide a brief description of the study and include both the URL for the study's dedicated website (*www.TextMyQuit. com*) and phone number, allowing individuals to access information about the study by phone or internet. For those calling by phone, study staff briefly explain the study procedures and provide interested callers with an emailed secure link to the study URL. The study website provides a brief description of the study with an option to continue to the online screener. Individuals interested in determining if they are eligible to participate will respond to several multiple choice questions. Upon completion of the screener, the REDCap system is programmed to calculate eligibility based on responses to specific questions related to our eligibility criteria (i.e. must be over the age of 18, daily smoker, etc.) and informs the individual of their results (eligible/not eligible). Eligible individuals must be 18 years of age or older, smoke at least 1 cigarette per day, use text messaging at least weekly and be interested in quitting smoking within the next 30 days. They must also have a valid mailing address and phone that can send and receive voice calls. Persons are excluded if they have signs of current drug abuse as measured by the CAGE-AID [43], are unable to read and write fluently in English or are currently enrolled in a quit-smoking program or are using medications to quit smoking. Ineligible individuals are provided with resources for other programs for quitting smoking that are available in different delivery modalities (e.g., online, text message, voice-phone/ quit lines, etc.) as alternatives.

3.3. Informed consent, enrollment and randomization

Eligible individuals are invited to click-through to the next set of REDCap pages that contain the consent documents. These pages provide details about the study (purpose, design & risks) and staff contact information for those with further questions. As part of the consenting process, individuals also answer a series of true/false questions to ensure they understand the fundamentals of enrolling in a research study (e.g., this is a research study, your information is confidential, and you may withdraw at any time). The consent document is also available in pdf format for participants to print out and keep for their records. Finally, individuals are prompted to answer yes or no to the statement, "I electronically consent to participate in this study."

After providing electronic consent, participants complete study registration (i.e. name, address, cell phone number) and respond to questions related to nicotine dependence measured by the Fagerström Test for Nicotine Dependence (FTND) [44] for randomization purposes. Upon completion, the REDCap system sends an automated email notifying study staff that there is a completed registration form ready to be verified. The verification process includes reviewing responses from the participant's screener to ensure eligibility, verifying that the cell phone number provided at registration can send and receive calls and verifying the mailing address provided is valid in the official USPS address database. If any of the information provided by the participant is unable to be verified, study staff email and/or phone the participant to provide corrected information or withdraw them from the study. Once verified, the participant's information is entered into a research tracking system for assessment reminders and compensation payments.

The randomization scheme was designed by the study statistician prior to the start of recruitment and is stratified based on gender and level of nicotine dependence (FTND) to help ensure relatively equal distribution within treatment groups of gender and individuals high/ low in nicotine dependence. The randomization scheme is resident on the study REDCap website. This REDCap randomization module issues randomization assignments and does not allow study investigators to access the assignment sequence or to alter the sequence during the study. Immediately after randomization, participants are notified by automated email regarding which group they have been assigned to (TMQ or Mojo) and are given instructions to activate their TMQ or Mojo text messages by texting the word "enroll" to the appropriate text enrollment phone number (TMQ or Mojo). All participants were also provided the ACS Guide to Quitting Smoking [32] as a downloadable link at this time. Study staffs use an administrative portal online to verify that the participant has activated their randomization group (TMQ or Mojo) text messages and then emails the participant their first compensation payment and a link to the post-enrollment baseline survey, which completes the enrollment process.

3.4. Data collection

Study data are collected during initial eligibility screening, at enrollment, and at follow-ups conducted at 3- and 6-months (see Table 1).

During the 3-month intervention period, participants also complete periodic brief assessments, sent through text messages, about their smoking status on their quit day and multiple times weekly for two weeks thereafter. Participants will receive an automated email from the REDCap system that provides a link to follow-up survey assessments 3- and 6-months after activating their text messages. Participants will have a two-week window in which to complete these follow-up assessments. The REDCap system sends automatic notifications to study staff when a survey is completed. Staff will regularly monitor the REDCap to see if participants had yet to complete a follow-up assessment. During this two-week window, staff will reach out to these participants up to three times (text message, email, phone call) to remind them to complete their follow-up assessents before their online follow-up assessment is deactivated. This is done to prevent participants form

Table 1
Measures and schedule.

	Baseline	Weekly	Month-3	Month-6
Smoking outcomes				
Smoking Status (7PPA)	s, x	x	x	x
Saliva Cotinine			x	x
Smoking covariates				
Smoking History	x			
Cigarette Scavenging	x		x	x
Fagerstrom Nicotine Dependence (FTND)	x		x	x
Use of NRT/Quit smoking medications	x		x	x
Readiness, Confidence & Motivation	x		x	x
Smoking Situation Temptations (SST)	x		x	x
Smoking Risk Perception	x		x	x
Social Support for Quitting (SSQ) (family/friends)	x		x	x
Online Social Support			x	x
Decisional Balance	x		x	x
Other covariates				
Demographics	x			
Center for Epidemiologic Studies Depression Scale (CESD-10)	x		x	x
Pittsburg Sleep Quality Index (PSQI)	x		x	x
Mobile Phone Affinity Scale (MPAS)	x			
Process measures & program evaluation				
Customer Satisfaction Evaluation			x	
Interviews			x	

S = screening.

completing follow-up assessments outside of this two-week window.

Participants who report 7-day point prevalence smoking abstinence (7PPA) at either follow-up (and no use of other nicotine products) are mailed a kit with instructions to provide a saliva sample for cotinine assay. Kits are sent via overnight mail with return postage and packaging to ensure speedy return at no cost and minimal inconvenience to participants. Samples are shipped from our institute via overnight containers using dry ice to preserve samples during shipping. Salivva cotinine is highly stable at normal temperatures [45] and any delays by mail should not adversely affect it. Reliability of self-report is typically high [46] and importantly, should not differ between experimental conditions. Assays are conducted by Salimetrics laboratories. Samples are considered positive for nicotine if they exceed 10 mg/ml).

4. Covariates and outcome measures

4.1. Smoking outcome measures

Self-report of 7PPA and date of last cigarette smoked asere assessed weekly during the intervention period and at both follow-ups. At 3- and 6-months follow-up, self-reported abstinence of at least 7 days is verified with saliva cotinine. Cotinine values below 10 mg/ml are indicative of no smoking for the previous seven days [47,48]. Individuals whose saliva sample exceeds10 mg/ml are counted as smokers.

4.2. Smoking-related covariates

Covariates include smoking history and current smoking behaviors, nicotine dependence, readiness, confidence and motivation for quitting, social support for quitting, perceived risks of smoking, the pros and cons of smoking and temptations to smoke in various situations.

The smoking history questionnaire consists of 13 items including age started smoking, current smoking rate, previous quit attempts and use of quit smoking medications and the presence of any smoking-related rules at home. A 5-item survey developed in our previous studies also asks about cigarette scavenging behaviors (e.g., *In the past 30 days,*

did you smoke a cigarette butt previously smoked by someone else) [49,50]. Nicotine dependence is assessed using the Fagerström Test for Nicotine Dependence (FTND) [44]. We also assess current use of quit-smoking medications among participants in the TMQ group (type, frequency of use, and dosing patterns) weekly throughout the trial. These data enable the TMQ medication management program to provide personalized feedback concerning appropriate medication use and reminders to enhance compliance with, and proper use of quit-smoking medications. Readiness, confidence and motivation to quit smoking are measured at baseline and follow-up using three items answered on a 10-point scale from "not at all" to "extremely" [51].

The Social Support for Quitting Questionnaire (SSQ) [52] contains six items measuring the degree of support for quitting smoking from both family members and friends. The SSQ includes three additional questions concerning the number of current smokers and successful quitters among the participant's family and friends, and the participant's expectations regarding how supportive, or unsupportive these individuals would be of the participant's efforts to quit smoking. We will also examine support obtained through online social networks using the scale developed by Graham and collagues [53]. Temptation to smoke under a variety of circumstances is measured using the short form 9-item Smoking Situations Temptations (SST) scale [54]. The SST has three sub-scales assessing temptations related to habit, negative affect, and social situations. The pros and cons of smoking are assessed using the short-form of the Smoking Decisional Balance (SDB) Scale [55]. Perceived risk related to smoking is measured by four items developed in previous studies [56]. These questions ask participants their beliefs regarding whether they have an illness that is caused or made worse by smoking, how they compare their health to that of an average smoker of the same age, how their overall health is affected by smoking, and to what degree quitting smoking would improve their health.

4.3. Other covariates

Demographic information including age, gender, education level, employment status, household income, race, ethnicity and maritial status were all collected at baseline. Symptoms associated with depression are assessed using the Center for Epidemiological Studies Depression Scale (CESD-10) [57], and the 17-Item Pittsburgh Sleep Quality Index (PSQI) is used to assess the duration and quality of sleep [58]. The individual's relationship with their mobile phone may affect how TMQ participants interact with, and react to, an intervention delivered through text messaging. Therefore, at baseline we administer the 24-item Mobile Phone Affinity Scale (MPAS) developed by Bock and Colleagues [59].

4.4. Process measures

Studies of smoking cessation internet programs have shown that user engagement with an online intervention (e.g., sending or posting messages to other users online) predicts success in quitting [60,61]. Similarly, some studies of text message-delivered smoking cessation interventions also show that increased engagement is associated with sucessful abstinence [62–64]. To assess engagment in this study, all participants, regardless of randomization assignment, are sent a single bi-weekly survey question through text message that requests a response. We define program engagment as the number of responses to these texted questions, along with other indicators (e.g., frequency of using the group-text social support feature) to assess engagement. Additionally, dt 3-month follow-up, participants also complete consumer satisfaction evaluations to indicate their degree of satisfaction with their program (TMQ or Mojo).

4.5. Quality control and assurance

De-identified participant data will be collected and managed using

the REDCap electronic data capture tools. [40] REDCap is housed at a secure data center location dedicated to Information Services and is continuously manned. Servers are backed up daily and monitored for hardware failures. As in previous studies, a manual of procedures and codebook will be developed during the initial study start-up period that explicitly describe the procedures related to intervention delivery, data collection, and quality assurance.

Programming for the TMQ system included creating of a User Interface (UI) that consisted of an administrative portal allowing study and programming staff to monitor functioning of the system and conduct testing for de-bugging purposes. Prior to the launch of the study, staff enrolled as fake participants to allow testing of the UI software and ensure that randomization assignments were following protocol and that text messages were delivered appropriately. Study staff also monitored the integrated social support network (ISS) chat room function and participant text message delivery through the UI software.

4.6. Qualitative research

After completion of the 3-month assessment, semi-structured interviews will be conducted with twenty-five participants randomized to the TMQ intervention. Interview questions are designed to enrich our understanding of the ways in which individuals use the TMQ program during their attempt to quit smoking, and to highlight areas of improvement needed for future development. Interview questions ask about participants' reactions to the TMQ program overall and for specific details of their reactions to receiving study texts. Questions also ask whether the content of the messages was appropriate to the specific circumstances of their quit attempt, for example, did the messages make sense based on whether they were using medications, were currently quit, or if they relapsed. We also ask whether and how the participant responded to any of the messages and whether there are other topics they would have wanted addressed by the texts that were not included. Importantly, we also enquire about participants' use of specific TMQ program components such as the medication management system, the TMQ integrated social support (ISS) network, and the live counselor *"CONNECT"* feature. Finally, to inform future commercialization plans for TMQ, we ask participants how much they would be willing to pay for the TMQ service, at what intervals (e.g., monthly, yearly), for how long, and would they be willing to use it as part of an employer- or healthcare provider-sponsored program.

Interviews will be audio recorded and reviewed for key content, which will then be summarized and entered into a framework matrix for analysis. Analysis of these interviews will explore difference between TMQ participants at 3-months on the following; smoking status, use of the TMQ ISS system, use of the medication management system, engagement with the system (based on number of responses to texts), and use of a live counselor. An applied thematic analysis [65] will be conducted using the framework matrix tool in NVivo 11 qualitative data analysis software.

5. Interventions

5.1. TMQ intervention

TMQ provides 12 weeks of text messages are based on constructs derived from Social Cognitive Theory (e.g., self-efficacy, social support, etc.) [66], and are tailored to the participant's motivational readiness for quitting smoking [67] and current smoking status. The TMQ program was designed with guidance from the research literature on smoking cessation, the national treatment guidelines for tobacco dependence [5], and qualitative data from participants in our pilot RCT study [37,68]. Formative work in the pilot showed that users wanted program control and flexibility, including the ability to start the program on their quit day, and to change their quit day and/or recycle through the program [37,68]. As a result, three "tracks" were

developed: "Prepare", "Quit" and "Not Ready".

The "Prepare" track is designed for individuals who set a target quit date (TQD) within 30 days and consists of once-daily messages targeted to help the individual prepare for quit day. To avoid redundancy, variations on these messages were created for a "Prepare-2" track designed for individuals who had relapsed after quitting during the program and were starting again with a new TQD. The "Quit" track consists of messages starting on participant's selected TQD that are delivered four times daily during quit weeks 1 and 2, then twice daily during weeks 3 and 4, and once daily during weeks 7 and 8. Finally, the "Not Ready" track is designed for those who have relapsed during the program but are not yet ready to set another quit date. These messages focus on increasing motivation to try again and encouraging the participant to set another quit date.

While the core program begins up to 4 weeks prior to quit day and continues through 8-weeks after quit day ("Quit" track), the total length of the program can extend beyond 12 weeks if participants relapse and recycle through the program (e.g., setting a new quit date or entering the "Not Ready" track). Allowing for relapse and recycle is important and is consistent with national tobacco treatment guidelines [5,69] that regard tobacco dependence as a chronic condition that may need repeated attempts before permanent cessation is achieved.

5.1.1. TMQ additional features
5.1.1.1. TMQ keywords.
Several participant-controlled "on demand" key words were created in the TMQ system based on formative work done in the pilot. Participants can text the key word "*CRAVE*" and immediately receive additional messages focusing on strategies to cope with cravings. Those who have smoked after their targeted quit day, can text the key word "*SLIP*" to receive additional messages focused on getting back on track before a full relapse to regular smoking occurs.

Any time after their targeted quit day, if a participant feels that he or she has relapsed and needs to leave the "quit" part of the program, he or she can text *"TQD start"* and the program sends a response text asking if they are ready to set a new quit date. If they respond "yes", the participant enters the new target quit date and the "Prepare-2" track messages begin. If not, the participant is re-started in the "Not Ready" track. Likewise, participants can text "*LETSQUIT*" to the TMQ system and will be started on the "Quit" track in which day 1 equals quit day. This is useful for individuals who decide to advance their quit day (i.e., "today's the day!"), or wish to start the program on their quit day. Users can also stop the program by texting the key word "*STOP*". For purposes of this research study, those who text "*STOP*" will be contacted by study staff to determine whether the person wants to stop treatment but continue to participate in the study for assessments, or wishes to withdraw from the overall study. Participants can text "*KEYWORD*" to receive a list of the system commands to remind them of the function of each word. At enrollment, participants are emailed and texted the full list of key words applicable to their randomization assignment.

5.1.1.2. TMQ integrated peer-to peer network (ISS).
Participants in our formative study [68] expressed strong desire for social support from peers within the program. To create a more naturalistic peer support network modeled after the way people use online social networks, we designed TMQ Integrated Social Support (ISS) network so that individual users can reach out to other users by texting the key word "*CHAT START.*" Participants who text "*CHAT START*" are added to a group text where they are able interact with other study members in a typical group text conversation. The TMQ program randomly assigns users to chat groups and provides a username (e.g., "blue-river") to facilitate identification of group text participants while maintaining individual anonymity. The individual's actual name and phone number are protected by the ISS system, thus allowing participants to text each other for support while maintaining the privacy of their actual name and phone number. Once a group chat has been initiated, participants can offer support by texting to the entire group or they can address one

member by their user name (e.g. "@blue-river"). Participants can opt out of this feature at any time by texting "CHAT STOP". In addition, we provide instructions to individuals in the TMQ arm that include explicit language informing them that, although their real name and phone number are not accessible to other individuals in their ISS group, if they provide their name, phone number or any other identifying information on a group text, it will be visible to all other members of the group.

5.1.1.3. TMQ live counseling. Participants can also text the term "*CONNECT*" to the TMQ system to receive a call from a live smoking cessation counselor. Trained smoking cessation counselors are available to provide individual counseling and advice as requested by study participants. To ensure that TMQ is completely accessible through text messaging the TMQ counselor is available through texting, but is also accessible through voice-phone, Google Chat, Skype and other communication platforms depending on user preference.

5.1.1.4. TMQ medication management system. Using medications to assist with quitting smoking greatly increases chances of success [5]. However, the impact of medications is diminished by poor adherence. The TMQ medication management program provides assistance at four levels: 1) recommending the use of FDA approved quit-smoking medications; 2) providing educational texts about medications; 3) information about dealing with common side effects, and; 4) providing a system of dosing and refill reminders to help smokers who are using medications to use them correctly and adhere to FDA dosage recommendations and medication refill schedules.

Upon first activation participants assigned to the TMQ intervention are sent a text asking if they plan to use medications such as nicotine replacement and/or Chantix (varenicline), Zyban or Wellbutrin (bupropion) to help them quit smoking. Those who indicate they will use a medication are asked to verify which medication and to text the system when they start that medication. Those who indicate they have not yet obtained their planned medication(s) are texted reminders to fill prescriptions and/or purchase NRT as appropriate in accordance with their selected quit day. Participants who are not using medications can text "MEDS" at any time during the intervention if they want to begin using medication(s) to assist in their quitting.

5.2. Mojo (control condition)

Individuals assigned to Mojo receive text messages for 12 weeks to equalize contact time between study arms. These participants are sent a program of general motivational messages (e.g., "*Things work out best for those who make the best of things*") that are not smoking-related and do not address smoking cessation. The purpose of the Mojo control texts is to provide a partial control for the frequency of intervention contacts and subject burden. These messages are sent on the same schedule as the TMQ program messages; that is, once daily up to 30 days before their targeted quit day (although these messages do not specifically prepare individuals for quit day), then 4 times daily during the first week after quit day, tapering thereafter. In our pilot these texts were highly acceptable and rated highly by participants [37].

6. Participant compensation

The participant retention plan includes incentives (participant payments) structured to encourage completion of all assessments but which are not contingent on smoking status. Participants are compensated with online gift cards in values of $40 (baseline/screening), $40 (3-month follow up) and $50 (6-month follow up). Those reporting 7-day PPA at both 3- and 6-months follow-up are compensated with an additional $20 gift card for returning the saliva sample kit. Additionally, individuals who participate in the in-depth interviews at the 3-month follow-up are compensated with a $50 gift card.

7. Planned analyses

Although randomization should equalize group characteristics, preliminary analyses will examine comparability of participants in the TMQ and Mojo groups at baseline on demographic, smoking history, behavioral and psychosocial characteristics using chi-square tests or analysis of variance (ANOVA), depending on the specific variable characteristics (categorical or continuous). We will examine the distributional properties of continuously-scaled variables to determine if normalizing transformations should be applied before conducting further analyses. If group differences at baseline are found for any variables, we will evaluate them and statistically control them in outcome analyses.

Consistent with the primary aim of the study, we will conduct a logistic regression analysis that will compare the rate of prolonged abstinence at 6-month follow-up between the TMQ and Mojo conditions. For this analysis we will use the intention-to-treat (ITT) principle, in which participants with missing data are counted as smokers, to calculate treatment effects [39]. Smoking will be measured as a dichotomous outcome variable, measured by self-report of no smoking for the past 7 days at each follow-up interval, with biochemical verification of abstinence (saliva cotinine) to validate the accuracy of self-report.

Secondary analysis will include the examination of potential mediators on treatment effect. Specifically, we will examine whether the effect of TMQ is mediated by several variables including motivation/readiness/confidence to quit smoking or stay quit, smoking self-efficacy and social support. There are many approaches to mediation analysis [70], and we will implement a Structural Equation Modeling (SEM) approach using Mplus Version 8.1 [71] for these analyses. Mplus accommodates the evaluation of simple and complex multivariate models of mediation (multiple mediators with multiple variable indicators) across time, and the use and statistical evaluation of the parameter estimates of continuous mediators to predict categorical outcomes. We will also investigate for the effects of treatment assignment on smoking cessation that may be dependent on values of possible moderator variables, including household income, age, sex, nicotine dependence, mobile phone affinity, and smoking rate at baseline. These moderator analyses will consist of entering interaction terms (moderator variable x treatment condition) in to a series of logistic regression analyses [72].

To examine the effect that use of the ISS feature may have on smoking cessation, we will initially examine this using correlation analyses, either Pearson r or Spearman rho, depending on the distribution of this variable (the number of instances of ISS use). We will examine this correlation at the primary outcome (6 months), and at 3 months. We will also enter the number of ISS texts as a covariate within a logistic regression analysis to examine and calculate at each follow-up the increased odds of smoking cessation for each additional ISS text sent. We will also assess the effect of increased ISS engagement in a longitudinal framework using generalized estimating equations (GEE) to compare for any change in cessation across time. Lastly, should we find a significant proportion of the TMQ group do not engage with the ISS, we will examine within both a logistic regression and GEE analysis framework, the odds of smoking cessation for participants within the TMQ group who do versus do not engage in the ISS group text feature.

Additionally, we will also conduct a longitudinal analysis that will examine outcomes between groups at 3- and 6-months follow-up. We will use an ITT approach that imputes smoking status to missing data, and we will use GEE approach of Zeger & Liang with robust standard errors [73]. The longitudinal analysis will also allow us to compare smoking cessation outcomes over time within and between groups. The GEE approach is highly flexible for modeling trend analyses that allow for an alternate way to present intervention effectiveness (comparing group trends over time). GEE analysis can also accommodate covariates (e.g., initial smoking rate, NRT use, etc.) and missing data under certain assumptions, thus allowing the maximum use of existing data for

detecting treatment effects.

Finally, we will examine the effect of treatment group on other smoking-related outcome measures (e.g., 24-h quit, prolonged abstinence). Analyses will fall into 3 types based on the type of dependent variable: 1) multiple logistic regression, 2) analysis of variance or covariance (ANOVA, ANCOVA), and 3) survival analysis. We will employ multiple logistic regression with appropriate covariates to analyze the effects of treatment on variables with categorical outcomes such as achievement of a 24-h quit. ANOVA or ANCOVA analyses will use baseline values as covariates where appropriate, to examine the effects of treatment on continuously-scaled variables, such as the number of 24-h quit attempts and total days abstinent. Survival analyses, using a proportional hazards regression approach [74,75] will be used to investigate treatment effects on time to first lapse/relapse and time to first quit after setting a quit-date.

8. Summary

The use of mobile technology, particularly mobile phones, to deliver health-related interventions is rapidly expanding [15–19,24–27]. Text-messaging specifically has shown promise as an effective tobacco intervention delivery tool [24–27]. Of the randomized controlled trials conducted to date, text messaging has produced significantly higher cessation rates than control conditions [26]. Text messaging has also produced significantly higher quit rates compared to smartphone apps [76]. However, the full potential for text message delivered smoking interventions is not yet well established due to numerous limitations to existing studies and programs. These shortcomings include very brief (e.g., 6 weeks) follow-up periods, absence of comparison or control conditions, and/or lack of control for number or intensity of contacts between control and intervention conditions [27,77,78]. Few studies have used biochemical validation of self-reported smoking cessation [37,79], and commercially available programs are often not evidence-based [26]. In addition, most programs require users to access the internet, a voice-phone counselor and/or a smartphone app in order to access all features of those programs. As with all research studies, this study has several limitations. Firstly, participants cannot be blinded to the intervention. We have employed several features to minimize bias including using a randomized controlled design, provision of a minimal self-help intervention (quit smoking guide, national hotline) to both study conditions and use of an online system for collection of study assessment data, thus ensuring that assessments are free from investigator bias. Second, incentives were provided to increase the likelihood that participants will remain in the study through final follow up. This may result in higher or different user patterns than might be seen in a commercial roll-out of this program in which incentives are not offered, but which also does not employ research-related surveys. Third, because the program allows users to relapse and re-start the program, including re-setting their targeted quit date, it is not possible to assess all users at the same within-program time interval. That is, the 8-week follow up is timed for 8 weeks after baseline, at which point some users may have been quit smoking for 8 weeks (assuming they started the program within 1 day of quit day), while others may have just restarted the program in the Prepare or Not Ready track. Analyses will examine differences in patterns of use of the program and duration of the program based on quit status at each follow up. Lastly, the ISS system functions like a group text-chat but protects privacy by using an internet program that mediates text messages by providing a user-name rather than the user's phone number. There is no capability for users to reach out to each other individually apart from the group ISS. We will not be able to determine how individuals may have responded if they had been able to contact each other individually for support in quitting.

Despite these limitations, if successful, the TMQ program would bring an effective, evidence-based, quit-smoking program to the commercial marketplace. An effective, text-message delivered program may have important public health significance since text message interventions are easily disseminated, highly scalable, have broad reach into the population and across diverse groups, and may be particularly appealing to younger smokers, who have the most health benefit to gain by quitting smoking and who typically under-utilize traditional health care services [80]. Thus, bringing a high-quality, evidence-based program that is 100% accessible through text messaging to market may assist in improving smoking cessation rates broadly and help to improve the health of the nation.

Acknowledgements

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