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## Brief Report

# Proactively Offered Text Messages and Mailed Nicotine Replacement Therapy for Smokers in Primary Care Practices: A Pilot Randomized Trial

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## Abstract

**Introduction:** Proactive, population health cessation programs can guide efforts to reach smokers outside of the clinic to encourage quit attempts and treatment use.

**Aims and Methods:** This study aimed to measure trial feasibility and preliminary effects of a proactive intervention offering text messages (TM) and/or mailed nicotine replacement therapy (NRT) to smokers in primary care clinics. From 2017 to 2019 we performed a pilot randomized trial comparing brief telephone advice (control: BA), TM, 2 weeks of mailed NRT, or both interventions (TM + NRT). Patients were identified using electronic health records and contacted proactively by telephone to assess interest in the study. We compared quit attempts, treatment use, and cessation in the intervention arms with BA.

**Results:** Of 986 patients contacted, 153 (16%) enrolled (mean age 53 years, 57% female, 76% white, 11% black, 8% Hispanic, 52% insured by Medicaid) and 144 (94%) completed the 12-week assessment. On average, patients in the TM arms received 159 messages (99.4% sent, 0.6% failed), sent 19 messages, and stayed in the program for 61 days. In all groups, a majority of patients reported quit attempts (BA 67% vs. TM 86% [ $p = .07$ ], NRT 81% [ $p = .18$ ], TM + NRT 79% [ $p = .21$ ]) and NRT use (BA 51% vs. NRT 83% [ $p = .007$ ], TM 65% [ $p = .25$ ], TM + NRT 76% [ $p = .03$ ]). Effect estimates for reported 7-day abstinence were BA 10% versus TM 26% ( $p = .09$ ), NRT 28% ( $p = .06$ ), and TM + NRT 23% ( $p = .14$ ).

**Conclusions:** Proactively offering TM or mailed nicotine medications was feasible among primary care smokers and a promising approach to promote quit attempts and short-term abstinence.

**Implications:** Proactive intervention programs to promote quit attempts outside of office visits among smokers enrolled in primary care practices are needed. TM have potential to engage smokers not planning to quit or to support smokers to make a planned quit attempt. This pilot study demonstrates the feasibility of testing a proactive treatment model including TM and/or mailed NRT to promote quit attempts, treatment use, and cessation among nontreatment-seeking smokers in primary care.

**ClinicalTrials.gov Identifier:** NCT03174158.

## Introduction

Only 31% of US smokers use any evidence-based treatment when they try to quit.<sup>1</sup> Health care systems could address this treatment gap; however, the visit-based model in which primary care providers deliver a brief intervention during a visit relies on smokers to seek out treatment or busy primary care providers taking the initiative and having enough time during a visit.<sup>2</sup> Proactive population health models capitalize on the ability of electronic health records to identify smokers who can be contacted by phone and mail and offered help between clinic visits,<sup>3-10</sup> but these models have not been widely adopted. Community-based text message (TM) treatment models also show promise,<sup>11-19</sup> but trials of TM for smokers in health care settings using office-based or treatment-seeking models have produced mixed results.<sup>20-25</sup> Interventions combining these elements, population health, and TM, have not been tested in primary care.

In this pilot study, we assessed the feasibility of a randomized trial and preliminary effects of proactive outreach with brief telephone coaching, a free sample of mailed nicotine replacement therapy (NRT), and TM among nontreatment-seeking primary care patients who smoke.

## Materials and Methods

### Study Design

We conducted a 12-week unblinded four-arm pilot randomized trial (NCT03174158). The design is described in detail elsewhere.<sup>26</sup> The study compared proactively offered interventions among primary care patients: (1) brief advice by telephone (BA) as a control, (2) TM tailored to quit readiness (TM), (3) a 2-week supply of NRT by mail (NRT), or (4) both TM and NRT (TM + NRT). The Partners Healthcare Institutional Review Board approved the study in July 2017.

### Study Population and Recruitment

Inclusion criteria were as follows: adult ( $\geq 18$  years), daily smoker, able to read and speak English, office visit within the last 2 years, and mobile number documented in electronic health records. Exclusion criteria included: contraindications to NRT (eg, serious adverse reaction to NRT or unstable cardiac conditions), nonworking mobile number, inability to participate in consent, and use of cessation treatments in the past 30 days.

Patients were identified from a Primary Care Practice Based Research Network<sup>27</sup> with smoking status based on structured health maintenance fields and problem lists. Lists of potentially eligible smokers were generated, and primary care provider approval obtained. To expedite recruitment, we also accepted provider referrals and advertised on an internal research recruitment website. Eligible patients were verbally consented.

### Randomization

We used block randomization stratified by primary care practice, and readiness to quit in the next 30 days (yes/no). Randomization was automated using REDCap (Research Electronic Data Capture)<sup>28</sup> and the upcoming assignment sequence was not viewable by the staff informing participants of their assignment. After assignment, staff and participants were not blinded.

### Study Interventions

#### Brief Advice

All participants were given 3–5 minutes of scripted advice that included discussion of smoking cessation medications, insurance

benefits, the state quitline, and local resources including in-person coaching in some practices.

#### Mailed NRT

Participants randomized to the NRT and TM + NRT arms were offered 14 nicotine patches at the 21 or 14 mg dose and/or 72 full size lozenges at the 4 or 2 mg dose (dosed per package instructions). Medications were mailed from the hospital outpatient pharmacy.

#### GetReady2Quit TM Intervention

Smokers randomized to the TM or TM + NRT arms had their mobile numbers and first names entered into a web-based TM platform (Mobile Commons, Upland Software, Austin, TX). Both TM and TM + NRT received the same text messaging program. Message volume was consistent with previously tested TM interventions and based on patient feedback.<sup>29,30</sup> Message content was tailored for readiness to quit, as described elsewhere.<sup>30</sup> Briefly, messages were created from three sources: (1) content from SmokefreeTXT that was adapted for primary care patients, (2) novel messages encouraging practice quit attempts, and (3) novel messages promoting medication use based on the Information-Motivation-Behavioral Skills model.<sup>31</sup> Participants who were ready to quit in the next 30 days were asked to enter a quit date and sent from 0 to 5 messages per day over 12 weeks with the most messages in the 2 weeks after the quit date when risk for relapse is greatest.<sup>32</sup> Content included motivational advice, behavioral tips, health benefits, medication information, social supports, local resources, and interactive messages assessing mood, cravings, medication use, and quit success. Participants who were not ready to quit were sent motivational messages and advice to practice quitting at a volume of 0–5 messages per day with message volume tapering over 5 weeks. Users could switch between the ready to quit and not ready to quit content each week.

### Data Collection

#### Quantitative Data

Survey data were collected by telephone or email using REDCap<sup>28</sup> at one-, two-, six-, and 12-week post-enrollment. Participants who reported abstinence at 12 weeks were asked to provide exhaled carbon monoxide measurement (using coVita | Bedfont Micro+ Smokerlyzer) in person at their practice or a clinical research center. TM user engagement was collected in the web-based platform.

### Outcomes

#### Feasibility

Trial feasibility was assessed by the proportion of patients reached, eligible, and enrolled. Follow-up and retention were compared by study arm.

#### Fidelity

Fidelity of the TM intervention was based on number of messages received by participants and proportion sent among those intended. Fidelity of the NRT intervention was assessed by self-reported receipt of mailed medication.

#### Engagement

TM engagement was measured using data from the web-based TM program. NRT engagement was measured in the NRT and TM + NRT arms with two measures: total days of NRT used and total milligrams used over 2 weeks. We assessed overall satisfaction with study treatments with a 4-item Likert scale.

**Table 1.** Text Message Fidelity and Treatment Engagement Outcomes by Study Arm

	BA	NRT	TM	TM + NRT
	N = 39	N = 36	N = 39	N = 39
	Mean [SD]			
Text message fidelity				
No. of text messages sent to patient	—	—	160.4 [54.5]	158.0 [72.0]
Text message engagement				
Days in text message program <sup>a</sup>	—	—	63.7 [19.5]	59.2 [24.0]
No. of text messages sent from patient	—	—	17.4 [11.9]	19.6 [22.4]
HELP requests sent by patient	—	—	0.4 [0.7]	0.2 [0.7]
No. of URL links clicked	—	—	3.8 [8.0]	2.1 [3.9]
Proportion URL links clicked/links sent	—	—	21.8 [49.2]	13.7 [28.2]
NRT engagement				
Week 1 milligrams of NRT	—	33.8 (54.8)	—	22.3 (45.8)
Week 2 milligrams of NRT	—	84.2 (81.2)	—	58.0 (91.3)
Days of NRT use, weeks 1 and 2	—	5.3 (4.4)	—	3.3 (4.3)

BA = brief advice; NRT = nicotine replacement therapy; TM = text messages; TM + NRT = text messages and nicotine replacement therapy.

<sup>a</sup>Days from enrollment in program until user texted STOP or program ended.

### Quit Attempts, Treatment Use, and Smoking Cessation

We measured smoking outcomes for effect estimates but were not powered to assess differences in cessation. Our primary clinical outcome was one or more self-reported quit attempt(s) lasting 24 hours or longer. Biochemically validated cessation was defined as exhaled carbon monoxide  $\leq 9$  parts per million.

### Statistical Analysis

We compared each study arm to BA even though the study was akin to a 2 × 2 factorial design because our primary interest was the difference between each arm and the control group. We examined differential loss to follow-up by arm using chi-square tests. We used multivariable regression models to identify predictors of fidelity and engagement.

Power calculations are described elsewhere.<sup>26</sup> Briefly, we estimated that less than half of BA patients would make a quit attempt and that the relative risk of quit attempts among those receiving TM would be 1.8, slightly greater than the effect of TM on abstinence.<sup>5,14,15</sup>

We conducted an intention-to-treat analysis. Missing smoking outcomes were assumed to be negative (ie, no quit attempt, no medication use, still smoking, or carbon monoxide >9 ppm). Planned subgroup analysis included comparison of outcomes among those ready to quit and not ready to quit. We conducted sensitivity analyses using multiple imputation for missing smoking outcomes and excluding patients recruited by referral or advertisement. Statistical analyses were performed using SAS version 9.4 (Carey, NC).

### Results

Between November 2017 and January 2019, we contacted 988 primary care patients by telephone, of who 527 (53.4%) declined participation, 276 (27.9%) were ineligible, 32 (3.2%) were eligible but dropped out before randomization, and 153 (15.5%) were randomized (Supplementary Figure S1). Sample characteristics are shown in Supplementary Table S1.

### Feasibility and Fidelity Measures

#### Recruitment and Retention

Our sample included 127 patients (83.0%) recruited proactively, 3 (2.0%) patients referred by providers, and 23 (15.0%) patients recruited by advertisement. Overall, 144 participants (94.1%, 95% confidence interval 89.1, 97.3) completed the week 12 assessment with no differences by study arm (Supplementary Figure S1).

#### Intervention Fidelity

On average, the TM and TM + NRT arms received 159 messages (99.4% sent, 0.6% failed). All participants accepted the offer of mailed NRT and all reported receipt of medications.

#### Treatment Engagement

TM engagement did not differ in the TM and TM + NRT arms (Table 1). Nine (12%) participants texted STOP during the study. NRT engagement also did not differ in the NRT and TM + NRT arms (Table 1). TM and NRT engagement were not associated with demographics, insurance, education, tobacco use characteristics, psychiatric symptoms, alcohol, or other substance use. At 12 weeks, 117 of 144 (81.3%, 95% confidence interval 73.9, 87.3) were somewhat or very satisfied with treatment with no differences between arms.

### Smoking Outcomes

#### Evidence-Based Treatment Use

Compared with BA, participants in the NRT and TM + NRT arms more often reported using any NRT during the study (BA: 51.4%, NRT: 82.9%  $p = .007$ , TM: 64.9%  $p = .25$ , TM + NRT: 76.3%,  $p = .03$ ). Nineteen (12.4%) participants reported bupropion use, six (3.9%) reported varenicline use, and 44 (28.8%) reported using in-person or telephone counseling with no differences by study arm.

#### Quit Attempts and Cessation

Participants in the intervention arms more often reported quit attempts and short-term abstinence, but the differences were not statistically significant overall (Table 2). Sensitivity analysis using

**Table 2.** Quit Attempts and Smoking Abstinence by Study Arm

	BA	NRT	<i>p</i> <sup>a</sup>	TM	<i>p</i> <sup>a</sup>	TM + NRT	<i>p</i> <sup>a</sup>
	N (%) / mean [SD]						
Overall	N = 39	N = 36		N = 39		N = 39	
Quit attempt							
≥1 quit attempt(s) ≥24 hours	26 (66.7)	29 (80.6)	.18	33 (84.6)	.070	31 (79.5)	.21
Abstinence							
Week 12: 7-day reported abstinence	4 (10.3)	10 (27.8)	.060	10 (25.6)	.086	9 (23.1)	.14
Week 12: CO confirmed abstinence <sup>b</sup>	1 (2.6)	3 (8.3)	.29	3 (7.7)	.33	2 (5.1)	.56
Subgroup: ready to quit next 30 days	N = 32	N = 31		N = 33		N = 32	
Quit attempt							
≥1 quit attempt(s) ≥24 hours	20 (62.5)	26 (83.9)	.062	28 (84.8)	.046	27 (84.4)	.053
Abstinence							
Week 12: 7-day reported abstinence	3 (9.4)	10 (32.3)	.033	9 (27.2)	.074	8 (25.0)	.11
Week 12: CO confirmed abstinence <sup>b</sup>	1 (3.1)	3 (9.7)	.31	2 (6.1)	.58	2 (6.3)	.56
Subgroup: not ready to quit next 30 days	N = 6	N = 5		N = 6		N = 5	
Quit attempt							
≥1 quit attempt(s) ≥24 hours	5 (83.3)	3 (60.0)	— <sup>c</sup>	5 (83.3)	— <sup>c</sup>	4 (80.0)	— <sup>c</sup>
Abstinence							
Week 12: 7-day reported abstinence	0 (0.0)	0 (0.0)	— <sup>c</sup>	1 (16.7)	— <sup>c</sup>	1 (20.0)	— <sup>c</sup>
Week 12: CO confirmed abstinence <sup>b</sup>	0 (0.0)	0 (0.0)	— <sup>c</sup>	1 (16.7)	— <sup>c</sup>	0 (0.0)	— <sup>c</sup>

BA = brief advice; CO = carbon monoxide; NRT = nicotine replacement therapy; TM = text messages; TM + NRT = nicotine replacement therapy and text messages.

<sup>a</sup>*p* values based on chi-square comparing interventions to BA control.

<sup>b</sup>Exhaled CO ≤9 parts per million captured by Covita Smokerlyzer Micro+pro.

<sup>c</sup>*p* values not calculated due to small numbers.

multiple imputation of missing outcome data and excluding patients recruited by advertisement or referral showed similar results. Among 128 (83.7%) participants ready to quit in the next 30 days, there were differences in quit attempts and abstinence compared with BA.

## Discussion

This trial demonstrates the feasibility of a proactive delivery model for TM and mailed NRT for nontreatment-seeking primary care patients who smoke. Our pilot results also highlight several potential modifications to strengthen the design of a larger scale trial of our intervention.

In our proactive treatment model, 16% of the patients contacted enrolled in the study. Although this uptake rate is similar to uptake with other proactive outreach models,<sup>6,8</sup> further work examining ways to nudge more patients to act could have a large population health impact. Engagement with the TM compared favorably to engagement with other research and programmatic TM interventions among nontreatment-seeking populations.<sup>33,34</sup> Despite the use of theory-based NRT adherence content in the TM, there was no suggestion of an additive effect between TM and mailed NRT on adherence or smoking outcomes. However, there are relatively few examples of effective interventions targeting smoking cessation medication adherence<sup>35</sup> to inform message content. In a larger trial, adding more behavior change techniques to our message content to support NRT adherence may prove more effective.

We did not find a difference in quit attempts or abstinence in our pilot study, but our self-reported 7-day abstinence rates were promising. Quit attempts and NRT use were more common among our

BA control than anticipated. The BA may have prompted patients to seek out additional treatment from their provider and this effect may have led to the high proportion of quit attempts and NRT use. In a larger trial, measuring provider engagement with cessation activities might clarify the impact of these proactive interventions on primary care cessation treatment seeking. The higher rates of quit attempts and cessation among the NRT group and TM group compared with the TM + NRT group, although not statistically significant, were also unexpected. The offer of NRT or TM alone may also have prompted patients to seek out additional treatments, while patients who were offered both interventions did not supplement their treatment package with other help. The most effective model may not be offering all assistance upfront, but rather letting patients choose or adapt their treatment package based on their needs.

## Limitations

We biochemically verified abstinence with in-person exhaled carbon monoxide in only 27% of self-reported quitters. In a larger study with long-term cessation, mailed anabasine among long-term NRT users or increasing incentive payments may improve sample return. Other limitations include our reliance on self-report for quit attempts and medication adherence data and the setting in a single health care system in a state with high insurance coverage that may not generalize to other settings.

## Conclusions

A trial of a proactive treatment model offering TM and/or mailed NRT was feasible with excellent retention and promising smoking

outcomes in a nontreatment-seeking primary care patient sample with high rates of comorbid psychiatric symptoms and substance use. Measures of treatment use and engagement with the TM provides encouragement that this may be a viable treatment model for primary care populations that is worthy of further study.

## Supplementary Material

A Contributorship Form detailing each author's specific involvement with this content, as well as any supplementary data, are available online at <https://academic.oup.com/ntr>.

Supplementary data are available at *Nicotine & Tobacco Research* online.

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## Declaration of Interests

GRK has a family financial interest in Dimagi Inc. NAR receives royalties from UpToDate, is an unpaid consultant for Pfizer, and a paid consultant for Achieve Life Sciences. LA has stock in Welltok Inc and receives royalties from the licensing of Text2Quit to Welltok Inc.

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