

A brief behavioral intervention promotes integration of mCessation with India's TB elimination program

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ABSTRACT

INTRODUCTION India is experiencing the dual epidemics of tuberculosis (TB) and tobacco use. Efforts at the integration of smoking cessation services with standard TB care are thwarted by the paucity of tobacco cessation services. The objective of the study was to assess the feasibility of integrating the freely available mCessation service (MCS) with India's National TB Elimination Program using a brief behavioral intervention package (BBPMC-TB), and to assess its effectiveness in enabling tobacco cessation among patients with pulmonary TB (PTB).

METHODS This was a quasi-experimental study conducted from December 2020 to February 2021 among patients with TB on anti-tubercular therapy that were current tobacco users living in Delhi, India. All consenting patients were administered the BBPMC-TB telephonically by a trained field investigator.

RESULTS We enrolled a total of 132 male patients with PTB who were current tobacco users having a median 10 years (IQR: 3.25–12) of completed education. After the application of the BBPMC-TB, a total of 96 (72.7%) participants enrolled in the MCS. On bivariate analysis, participants of a higher educational level were more likely to enroll for the MCS ($p=0.003$). On follow-up 30 days after baseline assessment, quit defined as absence of any tobacco use in the previous 7 days, was reported by 24 (21.24%) of 113 smokers.

CONCLUSIONS The BBPMC-TB was highly effective in promoting enrolment of patients with TB with MCS, although post-intervention quit rates after application of intervention were comparable irrespective of the participant's MCS enrolment status.

INTRODUCTION

Tobacco smoking significantly increases the risk of adverse treatment outcomes and recurrent disease among patients with pulmonary tuberculosis (PTB)^{1,2}. Assessing tobacco use in patients with PTB along with the provision of tobacco cessation services is a key requirement of TB control and elimination programs³. India is experiencing the dual burden of high TB and tobacco use. Efforts at the integration of smoking cessation services with standard TB care are thwarted by the paucity of tobacco cessation services⁴. Despite the institution of mandatory screening of all patients with PTB for tobacco use during initiation to treatment through the National TB Elimination Program (NTEP), a large proportion of tobacco users fail to quit at the end of their TB treatment despite their willingness to quit⁵. Moreover, a significant proportion of tobacco smokers reduce smoking during their TB (DOTS) treatment but switch to smokeless forms of tobacco associated with a higher all-cause mortality and increasing the risk of persistent dual use after the completion of their treatment^{6,7}.

There is growing recognition of the effectiveness of tailored mobile phone text-message based smoking cessation services worldwide⁸. mCessation is a free-of-

cost smoking cessation service run by the government of India that sends tailored text-messages to the users who register for it, by giving a missed call to a toll-free number. The mCessation service (MCS) in the general population has shown high self-reported tobacco quit rates but relatively low enrolment status due to decreased awareness of the service among Indian tobacco users⁹. However, it has been previously demonstrated that a brief behavioral intervention package (BBPMC) opportunistically implemented in low-resource outpatient clinic settings was highly effective in increasing enrolment, of patients using tobacco, into the MCS¹⁰. We hypothesized, that a similar intervention, tailored for tobacco using patients with PTB (BBPMC-TB) can promote their enrolment into the MCS and improve their chances of quitting tobacco.

The study objectives were to ascertain the feasibility of integrating the mCessation service (MCS) with the NTEP using a brief behavioral intervention package and to assess its effectiveness in enabling tobacco cessation among patients with pulmonary TB (PTB).

METHODS

We conducted a quasi-experimental study (single-arm trial)

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among bacteriologically confirmed adult patients with PTB undergoing anti-tubercular therapy and who were current tobacco users (either smoking or smokeless forms). Patients were included if they owned a mobile phone and who reported having the ability to read mobile text-messages in either English or Hindi, the local language. Patients who quit tobacco >1 month ago were excluded. The study duration was from December 2020 to February 2021. Existing or past users of the mCessation service (MCS) were excluded. The participants were selected from an existing patient database and contacted by phone to assess their eligibility and their consent towards study enrolment. Information was collected through an interview schedule related to their tobacco use habits.

Consenting participants were administered the BBPMC-TB phone by a trained female field investigator lasting typically ten minutes. The investigator informed the patients that persistent tobacco use could cause further complications and reduce their chances of getting completely cured of the TB disease. Furthermore, they were explained the benefits of tobacco cessation potentially achieved as early as six weeks from quitting and emphasized the need to quit tobacco completely to achieve better health and treatment outcomes. Finally, they were informed of the availability of the MCS, the mode of utilization, and their willingness to register for the service. Those participants that were willing to enroll for the MCS were registered through the online portal by the investigator or themselves, by placing a missed call on a toll-free number as per the participant's preference.

The primary outcome of the study was the proportion of tobacco using patients with PTB who enrolled in the mCessation service after the administration of the BBPMC-TB. The secondary outcome was the tobacco quit rates at 1 month following the baseline assessment.

Outcome assessment was through verification of the MCS registration status 48–72 hours later through another phone call to the participants who enrolled. Tobacco use and quit status was ascertained by phone at follow-up at 1 month, in all the participants.

Operationally, current tobacco use was defined as the use of any tobacco products in the previous 7 days irrespective of quantity, while quit was defined through self-report of tobacco cessation along with the absence of use of any tobacco products in the previous 7 days.

The sample size was 118, estimated by considering 30% enrolment in the MCP after administration of the BBPMC-TB compared to routine 10% enrolment in its absence, at 80% power, 95% confidence levels, and 5% significance level. The data were analyzed with IBM SPSS 25 (Armonk, NY: IBM Corp). McNemar's test for used to assess significance of difference between paired categorical variables and the chi-squared test for unpaired categorical variables. A $p < 0.05$ was considered statistically significant.

The study was exempted from full review by the Institutional Ethical Committee and was prospectively

registered with the Clinical Trial Registry of India. Due to the COVID-19 pandemic, informed verbal consent was taken during the phone interview, and written consent was obtained only when the patients visited the DOTS facility for collecting their refill on a future date.

RESULTS

We enrolled a total of 132 male patients with PTB on anti-tubercular therapy after exclusion of 18 patients who were either illiterate or could not read text-messages. The median (IQR) age of the participants was 33.5 years (24.2–46.5), and the median (IQR) years of completed education was 10 years (3.25–12).

All the participants were current users of tobacco products. There were 113 (85.6%) tobacco smokers including 84 (63.6%) cigarette users, and 48 (36.4%) bidi users (local South Asian cigarette made of rolled tobacco leaves) including 19 (14.4%) using both. There were 61 (46.2%) smokeless tobacco users including 42 (31.8%) dual users. The median (IQR) duration of smoking and smokeless tobacco use was 8 years (3–20) and 3 years (2–5) amongst tobacco smokers and smokeless tobacco users, respectively.

The knowledge that tobacco smoking causes cancer was reported verbatim by 115 (87.1%) participants. Moreover, the awareness that tobacco smoking could reduce the chances of successful TB treatment outcomes was correctly reported by 81 (61.4%) participants.

One hundred and six (80.3%) participants reported having been advised to quit tobacco use at the time of initiation with anti-tubercular treatment, and 102 (77.3%) were provided with the information to access a quitline, which was utilized by 10 (9.8%) of these participants. A quit attempt after diagnosis of TB was reported by 81 (61.4%) participants with use of smokeless tobacco reported as the most (28.4%) common mode of smoking cessation, corroborating the evidence from other surveys⁶.

Ten (7.6%) participants were aware of the MCS at baseline. After the application of the BBPMC-TB, a total of 96 (72.7%) participants enrolled in the MCS. The reasons for non-registration were the lack of perceived usefulness in quitting tobacco ($n=9$; 6.6%), lack of current intention to quit tobacco ($n=17$; 12.9%), and difficulty in reading text-messages ($n=10$; 7.6%). On bivariate analysis, participants of a higher educational level were more likely to enroll for the MCS ($p=0.003$), a finding also observed in the general population¹⁰.

At follow-up after 30 days from baseline, the median (IQR) number of days of tobacco smoking reported in the previous 7 days was 3 days (1–6). Quit defined as the absence of tobacco smoking in the previous 7 days was observed in 24 (21.2%) of the 113 smokers originally at baseline. Among the only smokeless tobacco users ($n=19$), 3 (15.8%) of the 19 resumed smoking during the same interval while 8 (42.1%) quit smokeless tobacco use (Table 1).

Consequently, complete tobacco quit status was reported

Table 1. Factors associated with enrolment in the MCP at baseline (N=132)

Variables	Total n (%)	Enrolled for MCP (n=96) n (%)	OR (95% CI)	p		
Age (years)						
<33.5 (Ref.)	66 (50.0)	51 (77.3)	1	0.243		
≥33.5	66 (50.0)	45 (68.2)	0.63 (0.29–1.4)			
Education level (years)						
<10 (Ref.)	59 (45.4)	36 (60.0)	1	0.003		
≥10	71 (54.6)	60 (83.3)	3.3 (1.5–7.5)			
Duration of ATT (months)						
≤2 (Ref.)	26 (19.7)	21 (80.8)	1	0.308		
≥3	106 (80.3)	75 (70.8)	0.6 (0.2–1.7)			
Current tobacco use type						
Smoking only (Ref.)	113 (85.6)	54 (47.8)	1	0.559		
Smokeless only	19 (14.4)	14 (73.7)	0.9 (0.3–2.8)			
Dual user	42 (31.8)	28 (66.7)	0.63 (0.27–1.5)			
Duration tobacco use (years)						
<8.5 (Ref.)	66 (50.0)	49 (74.2)	1	0.696		
≥8.5	66 (50.0)	47 (71.2)	0.86 (0.4–1.8)			
Intention to quit						
Yes	81 (61.4)	62 (76.5)	1.6 (0.7–3.5)	0.217		
No (Ref.)	51 (38.6)	34 (66.6)	1			
Tobacco use	MCP enrolled (n=96)		p	MCP not enrolled (n=36)		p
	Baseline n (%)	Endline n (%)		Baseline n (%)	Endline n (%)	
Tobacco smoking use	82 (85.4)	67 (69.8)	0.0011	31 (86.1)	25 (69.4)	0.014
Smokeless tobacco use	42 (43.7)	20 (20.8)	<0.001	19 (52.8)	5 (13.9)	<0.001

by 19 (14.4%) participants at follow-up. The proportion of participants who quit tobacco was lower in the MCP enrolled 12 (12.5%; n=96) compared to the MCP non-enrolled group 7 (19.4%; n=36) but this difference was not statistically significant (p=0.311).

DISCUSSION

The present study generates preliminary evidence towards the successful integration of the MCS with the National TB Elimination Program (NTEP) to promote tobacco cessation through the application of a brief behavioral intervention package which is highly scalable and is likely to require minimal training or costs. Implementation research towards the viability of training of DOTS providers, TB surveillance officers, and frontline health workers (ASHAs) towards the successful administration of BBPMC-TB and achievement of the MCS-NTEP integration in diverse real-world settings is thereby warranted. Understanding the associated barriers and challenges in mainstreaming and synergizing the MCS-

NTEP integration also require further evaluation.

Limitations

There were certain study limitations including the small sample size, absence of female participants, short duration of follow-up, and the lack of participants having multi-drug resistant tuberculosis. Moreover, we could not enroll patients who were unable to read text messages.

CONCLUSIONS

Comparable levels of tobacco quit rates were observed in the patients irrespective of their MCS enrolment status, indicating the need for objective measurement of tobacco cessation using biochemical parameters to overcome the potential limitation due to the social desirability bias. Future studies should also assess the long-term tobacco quit rates in patients with PTB to accurately estimate the effectiveness of these interventions for combating the TB and tobacco syndemic prevalent in India.

CONFLICTS OF INTEREST

The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none was reported.

FUNDING

There was no source of funding for this research.

ETHICAL APPROVAL AND INFORMED CONSENT

The study was reviewed and exempted from ethical approval by the Institutional Ethical Committee and was prospectively registered with the Clinical Trial Registry of India (CTRI/2020/09/028061). Informed verbal consent was obtained during the phone interviews, and written consent was obtained when the patients visited the DOTS facility for collecting their refill on a future date.

DATA AVAILABILITY

The data supporting this research are available from the authors on reasonable request.

PROVENANCE AND PEER REVIEW

Not commissioned; externally peer reviewed.

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