Effectiveness of Medical Student Counseling for Hospitalized Patients Addicted to Tobacco (MS-CHAT): a Randomized Controlled Trial

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ABSTRACT

BACKGROUND: Low-middle-income countries face an enormous burden of tobacco-related illnesses. Counseling for tobacco cessation increases the chance of achieving quit outcomes, yet it remains underutilized in healthcare settings.

OBJECTIVE: We tested the hypothesis that utilizing trained medical students to counsel hospitalized patients who use tobacco will lead to an increase in patient quit rates, while also improving medical student knowledge regarding smoking cessation counseling.

DESIGN: Investigator-initiated, two-armed, multicenter randomized controlled trial conducted in three medical schools in India.

PARTICIPANTS: Eligibility criteria included age 18–70 years, active admission to the hospital, and current smoking.

INTERVENTION: A medical student–guided smoking cessation program, initiated in hospitalized patients and continued for 2 months after discharge.

MAIN MEASURES: The primary outcome was self-reported 7-day point prevalence of smoking cessation at 6 months. Changes in medical student knowledge were assessed using a pre- and post-questionnaire delivered prior to and 12 months after training.

KEY RESULTS: Among 688 patients randomized across three medical schools, 343 were assigned to the intervention group and 345 to the control group. After 6 months of follow up, the primary outcome occurred in 188 patients (54.8%) in the intervention group, and 145 patients (42.0%) in the control group (absolute difference, 12.8%; relative risk, 1.67; 95% confidence interval, 1.24–2.26; $p<0.001$). Among 70 medical students for whom data was available, knowledge increased from a mean score of 14.8 (±0.8) (out of a maximum score of 25) at baseline to a score of 18.1 (±0.8) at 12 months, an absolute mean difference of 3.3 (95% CI, 2.3–4.3; $p<0.001$).

CONCLUSIONS: Medical students can be trained to effectively provide smoking cessation counseling to hospitalized patients. Incorporating this program into the medical curriculum can provide experiential training to medical students while improving patient quit rates.

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KEY WORDS: smoking; tobacco; cessation; counseling; medical students; hospitalization

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INTRODUCTION

There are 1.1 billion smokers worldwide, 80% of whom live in low- and middle-income countries (LMIC).[1] After China, India has the second largest number of smokers, with an estimated 99 million smokers in 2016.[2] The MPOWER package, as well as India's National Tobacco Control Programme (NTCP) guideline, recommends that all patients should be asked about tobacco consumption and primary care systems should provide tobacco cessation counseling.[3] Despite this, provision of tobacco cessation services in India and elsewhere remains inadequate.[4–6]

Hospitalization is a major life event for many people. Counseling hospitalized patients is most effective if started during hospitalization and continued in the outpatient setting by hospital staff for at least a month after discharge.[7,8] Moreover, the efficacy of a smoking cessation intervention does not appear to vary by admitting diagnosis, making it potentially effective in all hospitalized smokers.[7] Despite this, there remains a significant gap in the implementation of this practice in LMIC.[9] A significant barrier to adoption has been human resource

and funding constraints, as the intervention is often delivered by research nurses in a study setting, making translation to routine clinical practice challenging. There is an increasing focus on low-cost scalable tobacco cessation interventions in LMIC like India.[10,11]

On the other hand, physicians in India and elsewhere have reported receiving inadequate training in tobacco cessation counseling and lack confidence in this skill.[12–15] Lack of confidence in counseling can diminish belief in its effectiveness, and lead to underutilization of this skill.[16] Medical school training in India is 5.5 years and includes comprehensive training in clinical medicine as well as program development (e.g., running community health clinics and vaccination drives). Medical schools have classically offered only didactic-based instruction on tobacco use, with little experiential learning in performing counseling.[9,17] In 2019, The Medical Council of India (MCI) updated its guidelines for medical education to incorporate competency-based training. The document references that medical students should be able to "Describe, discuss, and counsel patients appropriately on smoking cessation."[18] The mode of education and minimum number of patients needed for competence are not specified. Furthermore, there is a paucity of data on the actual implementation of these changes in medical school curricula. Potential barriers to such implementation include competing priorities, lack of available trained faculty, and limited resources available to schools. Prior attempts have been made at developing a tobacco cessation curriculum for medical colleges in India. One such curriculum was shown to improve confidence and uptake of tobacco cessation counseling among students; however, patient outcomes were not studied.[19] Our goal was to expand on these findings by training medical students to adopt the practice of tobacco cessation counseling at a formative stage, thereby improving the uptake of this skill by physicians (including physicians in training).[20–22]

We designed a study to test the hypothesis that utilizing trained medical students to counsel hospitalized smokers will lead to an increase in patient quit rates, while also improving medical student knowledge regarding smoking cessation counseling.

METHODS

The study protocol received approval from the Institutional Review Board at University Hospitals/Case Western Reserve University and each participating medical school in India. All study participants provided written, informed consent in their native language. The study is registered on ClinicalTrials.gov (NCT03521466). The study materials are attached in the supplement and study data can be made available on contacting the corresponding author. PS had full access to all the data in the study and takes responsibility for its integrity.

Study Design and Setting

This was an open-label, parallel-group, two-armed randomized controlled trial with 1:1 concealed allocation. Patients were the unit of randomization. It was conducted at three sites in India, from December 2018 to November 2020. Participating sites in India included PSG Institute of Medical Sciences and Research, Coimbatore; Government Calicut Medical College, Calicut; and DM WIMS Medical College, Wayanad. The study coordinating center was at University Hospitals, Case Western Reserve University, in Cleveland, Ohio.

Participants

Eligibility criteria included age 18–70 years, current hospital admission, current smoking (cigarettes and/or bidis), or report of having smoked in the last 4 weeks prior to admission (to account for changes in behavior during illness).

Exclusion criteria included patients using only non-smoked tobacco and those who self-reported daily alcohol use or daily drug use. There were patients deemed unable to follow up, either because of distance from the hospital (> 10 km) or lack of telephone, unable to understand spoken language, or to have medical/psychiatric conditions rendering them incapable of interacting with providers. Patients currently participating in another tobacco cessation program or those already enrolled in this trial during a prior hospitalization were excluded.

Trial Procedures

Second-year students from participating medical schools volunteered for the study. These medical schools train between 150 and 250 students per year who are introduced to clinical rotations in the second year. The training was conducted in English by DS using a training module adapted from the WHO guide for tobacco cessation counselors.[23] Training consisted of the following components: (a) a 3-h didactic lecture; (b) structured group role-playing scenarios for 2 h, with peer and proctor feedback; (c) interactive booster sessions conducted during the trial phase to support patient counseling.[24] Following training, students were asked to complete a 15-item knowledge and attitude questionnaire with scores ranging from 0 to 25 (available in Supplementary Materials).[23,26] These questionnaires had previously been pilot-tested for face and content validity using a separate group of students. Only students obtaining a minimum test score (40%) proceeded to counsel patients, with a total of 84 students enrolled. The questionnaire was re-administered

to students at 6 weeks, and 12 months after training to assess change in knowledge over time.

A study coordinator screened all patients admitted to the general medicine, respiratory, and cardiology wards in the hospital. Eligible patients were stratified based on the medical school and block randomized into an intervention or control group using a block size of 20. Opaque envelopes developed by the research team were used for randomization. Patients in the intervention group were assigned to individual students by the coordinator. Participating medical students offered individual face-to-face counseling to patients in the intervention group once during their hospitalization (recommended duration of 15–20 min in a private room). Counseling was performed in the patient's preferred language. They were allowed to recommend tobacco cessation pharmacotherapy (NRT), but not allowed to prescribe it. The patient could request the treating team for a prescription or purchase NRT over the counter at any pharmacy. The study group did not provide financial support for pharmacotherapy.

The medical students then followed up with their patients after discharge to provide 3–5 sessions of approximately 15 min, maintaining notes in a formatted workbook. The students met with the proctor (DS) for periodic booster sessions via video call starting at 6 weeks after the first training session. At these sessions, basic concepts were reinforced, and clinical scenarios discussed. The structure of the intervention is shown in Fig. 1.

In the control group, smoking cessation advice and NRT prescription were left to the discretion of the treating physician, to reflect usual care. The coordinator met with the patient once during their hospitalization to collect baseline data.

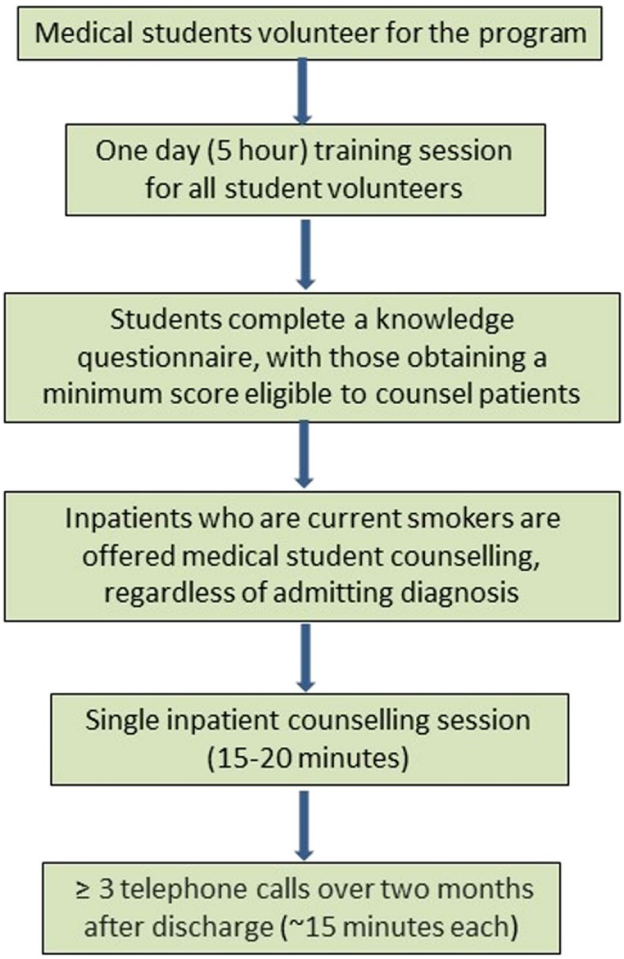

Figure 1 Structure of the Medical Student Counseling for Hospitalized patients Addicted to Tobacco (MS-CHAT) intervention.

Data Collection and Analysis

A study coordinator, blinded to group assignment, collected follow-up information from patients in both groups, in their preferred language, at 2 and 6 months after enrollment. Study data were entered into REDCap, and analyzed in Cleveland, Ohio, by an independent statistician blinded to group assignment.[27] A detailed description of the study design has been previously published.[28]

Monitoring the Fidelity of the Intervention

The individual site principal investigators (PIs) were closely involved in routinely monitoring the student and coordinator workbooks. During the booster sessions, students were randomly selected for an in-depth discussion of patient scenarios. All data was entered at the site of collection into REDCap and monitored for fidelity. The site coordinators were trained periodically and had routine contact with the coordinating center. The entire team met regularly for appraisal on study progress and review of data. When the protocol had to be modified during the COVID-19 pandemic, the changes were reported to the IRB immediately.

Outcomes

The planned primary outcome measure was biochemically verified 7-day quit rate at 6 months from enrollment. The criterion for a verified quit attempt was an exhaled CO level of < 10 PPM. Patients who claimed to have stopped smoking (not a single puff in the last 7 days) at 6 months received verification with an exhaled breath carbon monoxide (CO) test. Due to the COVID-19 pandemic starting March 2020, the majority of patients could not undergo confirmatory testing with an exhaled breath CO test, due to restrictions on in-person visits as well as risks posed by the breath test itself. However, follow-up procedures remained identical in both groups, and self-reported 7-day quit status (which is a part of the Russell Standard) was used as the primary outcome.[29,30] A key secondary outcome was a change in medical student knowledge between baseline and 12-month questionnaires. Other secondary outcomes are reported below and in Table 3.

Sample Size

We calculated the sample size with a power of 85% and α of 0.05 to detect a 10% absolute difference in the primary outcome, assuming a control quit rate of 20%.[31] We assumed an attrition rate of 20%. Based on these measures, we calculated a sample size of 830 patients, equally divided between the two study groups.

Statistical Analysis

The primary outcome was analyzed by an intention-to-treat approach. Patients lost to follow-up at any time point were considered to be smoking at the end of the study. At 6 months, cessation rates were compared using univariate hierarchical logistic regression accounting for clustering at sites by including it in the model as a random effect. Similar regression tests were used to estimate the per protocol analysis, which included all patients who received the full dose of the intervention (inpatient visit + ≥ 3 phone calls). We also performed additional prespecified subgroup analysis based on age, FTND, admitting diagnosis (cardiorespiratory vs other), medical student knowledge score (< 15 and ≥ 15), and prior quit attempts. All subgroup analyses were also performed by accounting for clustering at sites. The mean student knowledge score at baseline and 12 months after training was compared using the paired *t*-test. Prior to analysis, individual missing values within any of the 15-item "student knowledge questionnaire" were imputed. Given that all medical students at the 3 study sites were trained by the same study personnel, we anticipated that variation in student knowledge regarding smoking cessation and counseling will be dependent on the site of training. Hence, all missing student scores were imputed by using the mean score for the particular question at the given study site. To avoid excessive imputation, students with missing data in > 10/15 questions were excluded from the analysis.

All analyses were performed using R software v3.5.2 and STATA 16.1 with a two-way significance level of < 0.05.

Role of the Funding Source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. All authors had full access to the data in the study and had final responsibility for the decision to submit for publication.

RESULTS

Baseline Characteristics

Baseline characteristics of patients are in Table 1 and CONSORT diagram in Fig. 2. The characteristics of the patients at baseline were similar in the two groups. Nearly half the patients were admitted with a cardiorespiratory diagnosis (48%). A majority of patients had not made a prior quit attempt (55%), and reported use of concomitant smokeless tobacco was low. Twenty-four patients died during follow-up (3.5%), 14 in the intervention group and 10 in the control group. A total of 35 patients (10.2%) in the intervention group and 29 (8.4%) in the control group were lost to follow-up or declined to participate.

Table 1 Demographics and Baseline Characteristics

	Intervention $N = 343$	Control $N = 345$
Age, years	51.7 ± 11.4	51.9 ± 11.7
Sex, male	341 (99.4)	343 (99.4)
Education		
None or pre-secondary school	47 (13.7)	52 (15.1)
Secondary school	201 (58.6)	206 (59.7)
Post-secondary school	93 (27.1)	86 (24.9)
Employed	305 (88.9)	314 (91)
Married	307 (89.5)	327 (94.8)
Admitting diagnosis		
Cardiorespiratory	169 (49.3)	164 (47.5)
Gastrointestinal/liver	40 (11.7)	50 (14.5)
Infections	32 (9.3)	40 (11.6)
Cancer	0	2 (0.5)
Others	100 (29.2)	88 (25.5)
Cigarettes, per day		
Median (IQR)	6 (9)	6 (9)
Mean ± SD	8 ± 7.9	8 ± 7.9
Bidis, per day		
Median (IQR)	10 (17.3)	10 (18)
Mean ± SD	12 ± 11.8	12 ± 11.9
Smokeless tobacco users	14 (4.1)	26 (7.5)
FTND score	4 ± 2.2	4 ± 2.2
Prior quit attempts		
Mean ± SD	1 ± 7.2	1 ± 7.1
Median (IQR)	0 (1)	0 (1)

FTND, the Fagerström Test for Nicotine Dependence. FTND scores range from 1 to 10, with higher scores indicating higher levels of nicotine dependence

Categorical variables are presented as counts (column percentage) and continuous variables are presented as mean ± standard deviation (SD)

Primary Outcome

At the end of 6 months of follow-up, 333 out of 688 enrolled patients achieved the primary outcome of 7-day quit status (48.4%). A higher proportion of patients randomized to the intervention group reported smoking cessation (54.8%, $n = 188$), compared to those in the control group (42.0%, $n = 145$), with an absolute difference in cessation rate of 12.8% (RR 1.67, 95% CI 1.24, 2.26; $p < 0.001$; Table 2).

Among 188 patients in the intervention arm who reported smoking cessation at 6 months, 44/188 (23.4%) underwent biochemical verification with a confirmatory rate of 97.7% (43/44). In the control group, 35/145 (24.1%) underwent biochemical verification with a confirmatory rate of 94.3% (33/35).

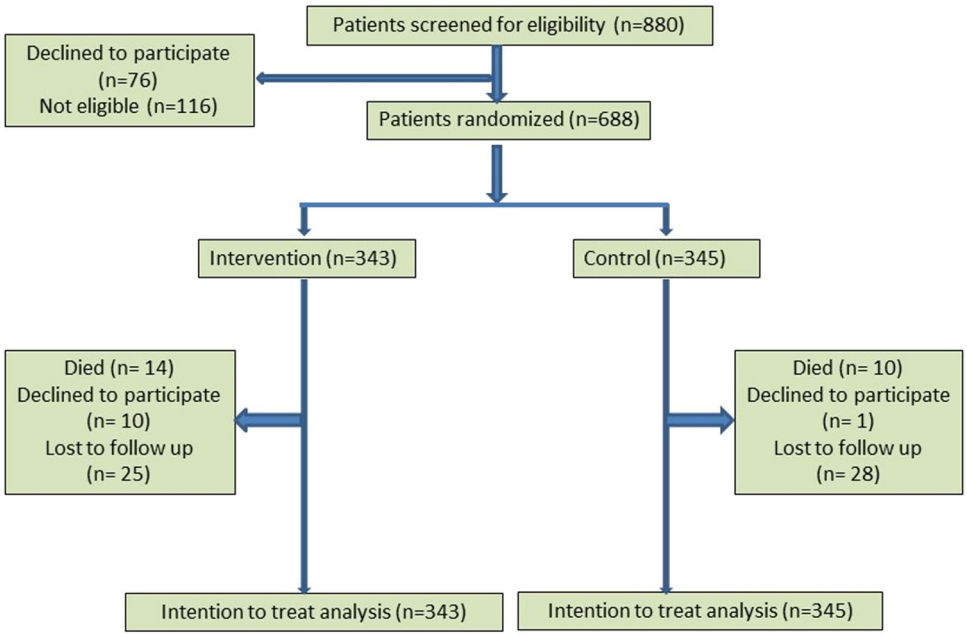

Figure 2 Participant flow through the study.

The full dose of the intervention was one inpatient and 3 subsequent phone calls. In the intervention arm, all patients received an inpatient counseling session, 67.9% of the patients received at least one phone call, and 39.1% received at least 3 phone calls. In the per protocol analysis, among those patients who received the protocol specified 3 phone calls (i.e., the full dose of the intervention), the quit rate was 67.9% (91/134), with a relative risk of 2.77 (95% CI 1.72, 4.46; $p < 0.001$; absolute difference of 25.9%).

Secondary Outcomes

Smoking cessation rates in different subgroups are shown in Table 3. Patients who were older, admitted with a non-cardiorespiratory diagnosis, and with no prior quit attempts at baseline had a higher chance of achieving smoking cessation at 6 months. Use of cessation pharmacotherapy was low in both groups. Among patients who did not achieve the primary outcome, 21/155 patients (13.5%) in the intervention group vs 28/200 (14%) in the control group achieved a 50% reduction in the number of cigarettes/bidis smoked in a week, measured 6 months after enrollment. Use of smokeless tobacco remained low at 6 months of follow-up (9 intervention vs 14 control).

Among the 84 students who participated in patient counseling, 14 students had missing data and were excluded from the analysis. Among the 70 students remaining, approximately 10% of the scores were missing at different time points. This data was imputed by using the mean score at that particular site. The scores ranged from 9 to 21 (maximum possible score 25) at baseline, with a mean of 14.8 ± 0.8 among all students. At the end of 12 months, the scores increased, ranging from 12 to 25 (maximum possible score 25) with a mean of 18.1 ± 0.8, an absolute mean difference of 3.3 (95% CI 2.3, 4.3, $p < 0.001$; Fig. 3).

Table 2 Primary Outcome: Smoking Cessation at 6 Months

Characteristics	Intervention Number (%)	Control Number (%)	Absolute difference (%)	RR (95% CI)	*p* value
Primary outcome: self-reported 7-day quit rate at 6-month follow-up visit	188/343 (54.8%)	145/345 (42.0%)	12.8	1.67 (1.24, 2.26)	<0.001
Per protocol analysis: self-reported 7-day quit rate at 6-month follow-up visit*	91/134 (67.9%)	145/345 (42.0%)	25.9	2.77 (1.72, 4.46)	<0.001
Biochemically verified 7-day quit rate at 6-month follow-up visit	43/44 (97.7)	33/35 (94.3)	N/A	–	–

RR, relative risk

*Only includes intervention group patients who received the full dose of the intervention (inpatient visit + ≥3 phone calls)

Table 3 Secondary Outcomes: Smoking Cessation by Subgroups

Subgroup	Intervention	Control	Relative risk (95% CI)+	*p* value
Overall	188/343 (54.8)	145/345 (42.0)	1.67 (1.24, 2.26)	<0.001
Patient age				
≥50 years	129/219 (58.9)	91/209 (43.5)	1.84 (1.25, 2.70)	0.002
<50 years	59/120 (49.2)	51/131 (38.9)	1.52 (0.92, 2.50)	0.10
Admitting diagnosis				
Cardiorespiratory	103/169 (60.9)	86/164 (52.4)	1.44 (0.93, 2.24)	0.10
Other*	85/172 (49.4)	59/180 (32.8)	2.00 (1.30, 3.08)	0.002
FTND score				
≥4	61/102(59.8)	26/89 (29.2)	3.69 (1.99, 6.82)	<0.001
<4	50/90 (55.5)	42/105 (40.0)	1.87 (1.06, 3.32)	0.031
Prior quit attempts**				
None	121/209 (57.9)	69/172 (40.1)	2.05 (1.36, 3.09)	<0.001
≥One	64/125 (51.2)	76/164 (46.3)	1.20 (0.75, 1.92)	0.50
Medical student knowledge at baseline				
≥15	106/192 (55.2)	145/345 (42.0)	1.70 (1.19, 2.43)	0.003
<15	18/37 (48.6)	145/345 (42.0)	1.31 (0.66, 2.58)	0.40

RR, relative risk

+Adjusted for clustering at sites

*Includes gastrointestinal/liver, infections, cancer, and other reasons for admission

**Excluded patients who reported >10 prior quit attempts

DISCUSSION

In hospitalized patients, smoking cessation counseling by trained medical students led to a 12% absolute increase in quit rates over usual care, while increasing medical student knowledge regarding smoking cessation counseling. There are several strengths of this simple, low-cost, scalable intervention. First, the intervention makes smoking cessation services convenient and accessible to patients. Second, consistent with the convenience, there are zero out of pocket costs for patients for counseling by medical students, regardless of the health system. This is particularly relevant for healthcare systems in many LMICs (including India), which have pay for service financing models.[32] Third, the intervention provides competency-based education on behavior change counseling and tobacco treatment to medical students, with a curriculum that meets the needs of the health system.[33,34] Fourth, with increasing focus on telemedicine, this is an evidence-based model for medical student education in telemedicine and its delivery in clinical practice. Implementing such a program requires trained educators, faculty champions at the

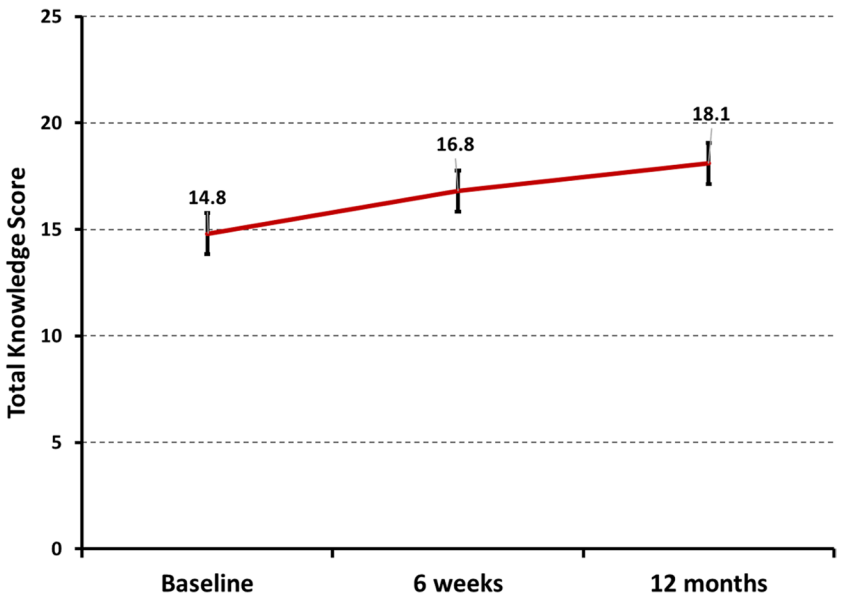

Figure 3 Change in medical student knowledge between baseline, 6 weeks, and 12 months. Total score is 25 and is based on 15 questions. Mean knowledge scores at baseline, 6 weeks, and 12 months are reported. A comparison was made between scores at baseline and 12 months with an absolute mean difference of 3.3% between the two time points. $p < 0.001$ for change from baseline to 12 months.

individual schools, and awareness among students. Costs associated with this program include training costs for medical students and staff to participate in the program.

Our effect size for smoking cessation rates (RR 1.67, 1.24 to 2.26) is consistent with meta-analyses of previous trials in hospitalized patients (RR 1.37, 1.27 to 1.48).[7] Our subgroup analysis also showed results broadly consistent with the primary outcome, with no significant difference between subgroups. Notably, there was no significant difference in outcome by admitting diagnosis, which is consistent with the broader literature.[7] Our control group had a quit rate of 42%. This is higher than reported in prior studies of hospitalized patients (primarily from high-income countries in North America and Europe).[31] However, these rates are similar to the 50% quit rate reported in the control group of the multicenter Secondary Prevention of CoRonary Events After Discharge from hospital (SPREAD) trial that enrolled patients after an acute coronary syndrome in India.[35] Given that patients in countries like India incur higher out of pocket costs for a hospital admission, have a weaker social safety net, and present with a higher burden of symptoms, these patients may have a greater incentive to avoid future tobacco use.[36] However, this is speculative and needs to be validated in other studies from LMIC. Furthermore, the complete intervention (consisting of 1 inpatient visit plus 3 outpatient calls) was delivered to only 39% in the intervention group. Despite this, the intervention group had a significantly higher quit rate compared with control. This would suggest that a lower intensity of intervention may be sufficient in this population, similar to a prior report. [37] Brief interventions have the potential to expand access to these interventions with more intensive counseling reserved for those who need it. However, the existing evidence suggests that 3 follow-up phone calls are optimal and shorter schedules will need to be studied more rigorously.[38] With a high quit rate in the control group, the absolute benefits of the intervention are higher at a similar relative risk. For every 100 patients who receive the intervention, an estimated 13 additional patients will quit smoking, a number needed to treat 8. In addition, with a quit rate of > 50% in the intervention group, a medical student will see half their patients quit on average.

Our study had a low reported rate of smoked tobacco use among women, similar to a prior study.[37] This could be because smokeless tobacco is more common in Indian women and because of associated stigma in reporting use. [39] Furthermore, there is regional variation in the prevalence of smoked and smokeless tobacco use and this may offer another explanation for the low percentage of women smokers in our trial. [2] The use of NRT was low in our study, and use of bupropion and varenicline was non-existent. A large barrier to NRT usage remains local accessibility and high out of pocket costs.[32] The price of NRT in one study was 4.1 times the median amount spent on tobacco during the same period.[40] We did not provide subsidized or free NRT to replicate real-world conditions. However, given the well-established benefits of NRT, the effect size of the intervention can likely be further enhanced if NRT were to be made available at minimal or no cost.

This trial has several limitations. First, due to the COVID-19 pandemic, we had to modify our primary outcome from biochemically verified smoking cessation to self-reported smoking cessation at 6 months. We also had to stop enrolment at 688 patients. This may have led to overestimation of smoking cessation rates. However, outcome assessment was similar in both groups and outcome assessors were blinded to study assignment. Self-reported point prevalence of smoking cessation is part of the Russell Standard and has been used as the primary outcome in prior trials.[29,30] In addition, in the subset of patients who underwent biochemical verification, the results were largely concordant with self-reported quit status (96.2%, 76/79 patients). Second, our assessment of medical student outcomes was limited to assessing medical student knowledge at 12 months. Third, 12.8% of patients were not available for assessment of the primary outcome at 6 months after enrollment, due to either death (as reported by a family member) or loss to follow-up. However, given that loss to follow-up was numerically higher in the intervention group and these patients were considered to be smoking at the end of the study, any bias arising from this would favor the null hypothesis.

We show that provision of smoking cessation counseling to hospitalized patients through medical students, initiated as an inpatient and continued after discharge, can improve patient quit rates while increasing medical student knowledge. These findings provide a model for incorporating smoking cessation counseling in medical curricula. Further studies are needed to clarify the effect of a similar intervention on longer term patient quit outcomes, and student practice patterns. There is also the possibility of further refinement in the mode of medical student instruction as well as method and duration of counseling. It also remains to be tested if the skills acquired through a program such as MS-CHAT may enable medical students to provide counseling for other health behaviors.

Supplementary Information *The online version contains supplementary material available at https://doi.org/10.1007/s11606-023-08243-y.*

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Society to Enhance Health and Access to Treatments

Data Availability *The data that support the findings of this study can be made available from the first author (PS), upon reasonable request.*

Declarations

Conflict of Interest *The second author A. K. is the cofounder of SEHAT. There are no other competing interests.*

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