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Protocol

Scaling up tobacco control in India: a protocol for a hybrid III cluster randomized trial comparing smartphone to in-person training to implement a tobacco control program for school teachers

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ABSTRACT

Background: Low-and middle-income countries (LMICs) face increasing tobacco-related deaths. India is second in global tobacco use, with 29% adult users. Logistical challenges with in-person training in LMICs limit scale-up of tobacco control evidence-based interventions (EBIs). The Tobacco Free Teachers-Tobacco Free Society (TFT-TFS) program was previously shown to help teachers quit tobacco and schools adopt tobacco control policies. We are comparing smartphone-based training to in-person training to scale up the TFT-TFS program.
Methods: Hybrid III cluster-randomized comparative effectiveness trial, involving 200 high schools and high secondary schools in Madhya Pradesh, India. To implement the TFT-TFS program, researchers randomly assigned schools to either smartphone-based (n=110 schools) or in-person (n=90 schools) training arms. Trained teachers from both arms implement the program in their respective schools. We will examine differences in program implementation, reach, and effectiveness between schools from the two arms. Post-implementation mixed-methods will employ the consolidated framework for implementation research (CFIR) to identify contextual factors influencing implementation.
Conclusions: This study will scientifically and economically evaluate smartphone-based training to expand the use of EBIs for tobacco control in LMICs. Analyzing the contextual influences on TFT-TFS use in each training program will allow this work to create actionable guidance for education departments and groups involved in implementing smartphone-based training. These findings will help the CFIR strengthen its evidence on how to implement tobacco control EBIs successfully in low-resource environments.
Trial Registration: This study is registered at ClinicalTrials.gov ID: NCT05500235.

Keywords: Tobacco control, Smartphones, Training, Schools, LMICs, India

INTRODUCTION

By 2030, globally, tobacco use is projected to cause 8 million annual deaths, with 80% in low- and middle-income countries (LMICs).[1] India, the second largest tobacco consumer with the highest rate of oral cancer, sees about 1.2 million tobacco-related deaths yearly.[1-3] To reduce tobacco-related deaths in India and other LMICs, evidence-based interventions (EBIs) such as Tobacco Free Teachers-Tobacco-Free Society (TFT-TFS) must be successfully implemented.[4] A cluster-randomized evaluation in the Bihar School Teachers' study involved 72 government schools across 10 districts, proved the TFT-TFS program's effectiveness. Post-intervention, teachers in the intervention schools showed higher

adjusted quit rates than control schools (50% versus 15%, p<0.001). The benefits were sustained for six months (19% versus 7%, p=0.06), and stricter tobacco control policies were implemented in the intervention schools (OR=3.26; CI: 2.35, 4.54) than control schools.[4,5]

Smartphone-based learning provides a scalable solution for training program implementers, especially in resource-poor environments, which addressing the limitations of traditional in-person training including differences in training methodologies, expertise, and knowledge of subject matter compromise content quality and fidelity.[6,7] This approach leverages the growth of mobile learning, utilizing interactive features like "learning across multiple contexts", using personal electronic devices", facilitated by easy audio-visuals, peer-instructors engagement opportunities, real-time data tracking, and faster and cost-effective digital content sharing.[8-10] Smartphone-based learning is used in Indian government sectors, but not for school-based tobacco control.

With smartphone-based learning advantages and widespread use in India (i.e., over 90% smartphone ownership, and strong rural penetration), we are studying smartphone-based training's effectiveness for TFT-TFS program in two districts in Madhya Pradesh (MP), India.[11] In this study, the "program-in-charge", a term commonly used in MP, refers to the TFT-TFS implementers, usually school principals or their designees.

This paper outlines a protocol for a comparative effectiveness trial to compare smartphone-based and in-person TFT-TFS program training in two MP districts. This study compares program fidelity, reach, efficacy (regarding tobacco cessation), and cost, and identifies factors influencing TFT-TFS program implementation. Smartphone-based training is hypothesized to be non-inferior to in-person training in terms of program implementation and teachers' tobacco cessation, and that it will be more cost-effective with wider reach. The study will provide insights into expanding tobacco control EBIs in schools across India and other LMICs and utilizing smartphone-based training for other public health initiatives in resource-limited settings.

METHODS

Study design

This study compares smartphone-based and in-person training effectiveness for TFT-TFS program, using a Hybrid-III cluster-randomized trial in MP schools.[12] The study will assess implementation as primary outcome (fidelity, reach, and cost) and program effectiveness (cessation) as secondary outcome.

This study compares two training methods for program-in-charges in 200 (out of 484) randomly selected schools across two of MP's 55 districts. They were trained based on their assigned arms (see Implementation strategies) and implemented the TFT-TFS program for six months, tracking implementation, participation (reach), and cost (in terms of time) via TFT-TFS smartphone app. Using mixed-methods, the study assesses implementation factors in schools' post-implementation.[13]

Reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework defined implementation outcomes and consolidated framework for implementation research (CFIR)[15] identified influencing factors.[14] Our implementation study reporting followed CONSORT and StaRI guidelines.[16,17] The study protocols were approved by the Harvard T.H. Chan School of Public Health Office of Regulatory Affairs and Research Compliance (IRB20-2157) and the Healis-Sekhsaria Institute for Public Health Institutional Ethics Committee.

Study setting

This study was conducted in MP, India in collaboration with the state Department of Education (DoE) and the MP Voluntary Health Association (MPVHA). The DoE mandates smartphone use for all school staff's routine schoolwork, creating the infrastructure to train program-in-charges in the TFT-TFS program using smartphones. MP, India's second-largest state, had a population of over 72 million in 2011.[18] About 34% of adults (50% males, 17% females) and 21% of school staff (28% males, 8% females in MP either smoke and/or use SLT; with gutkha and khaini being the most prevalent SLT products.[19-21] The study districts have populations of 2,185,793 (51% males) and 1,563,715 (52% males).[18] These districts were selected based on high tobacco use (~ 60% males and ~7% females, a mix of urban, rural and tribal populations, proximity to MPVHA, and good road infrastructure.[22]

Study population, sample, and randomization

We randomly selected 200 high schools (HS: classes 1-8) and higher secondary schools (HSS: classes 1-12) from two districts. Random assignment and ≥eight teachers were required for school eligibility. We used a 55:45 ratios to assign 200 schools to smartphone-based training arm (n=110 schools) or in-person training arm (n=90 schools) after a pre-implementation assessment.

Sample size rationale

To test non-inferiority, we aimed for 80% power, using a -15% margin and a 5% significance level. It used an 80% implementation rate, considering school clustering with an ICC of 0.05 (derived from our prior study).[4] A 15% difference was significant, considering public health and sampling error. Thus, if the lower bound of the 90% confidence interval is -15% or higher, the smartphone-based training is non-inferior. The study has 80% power to detect non-inferiority in cessation rates, even though the sample size focused on implementation (primary outcome).

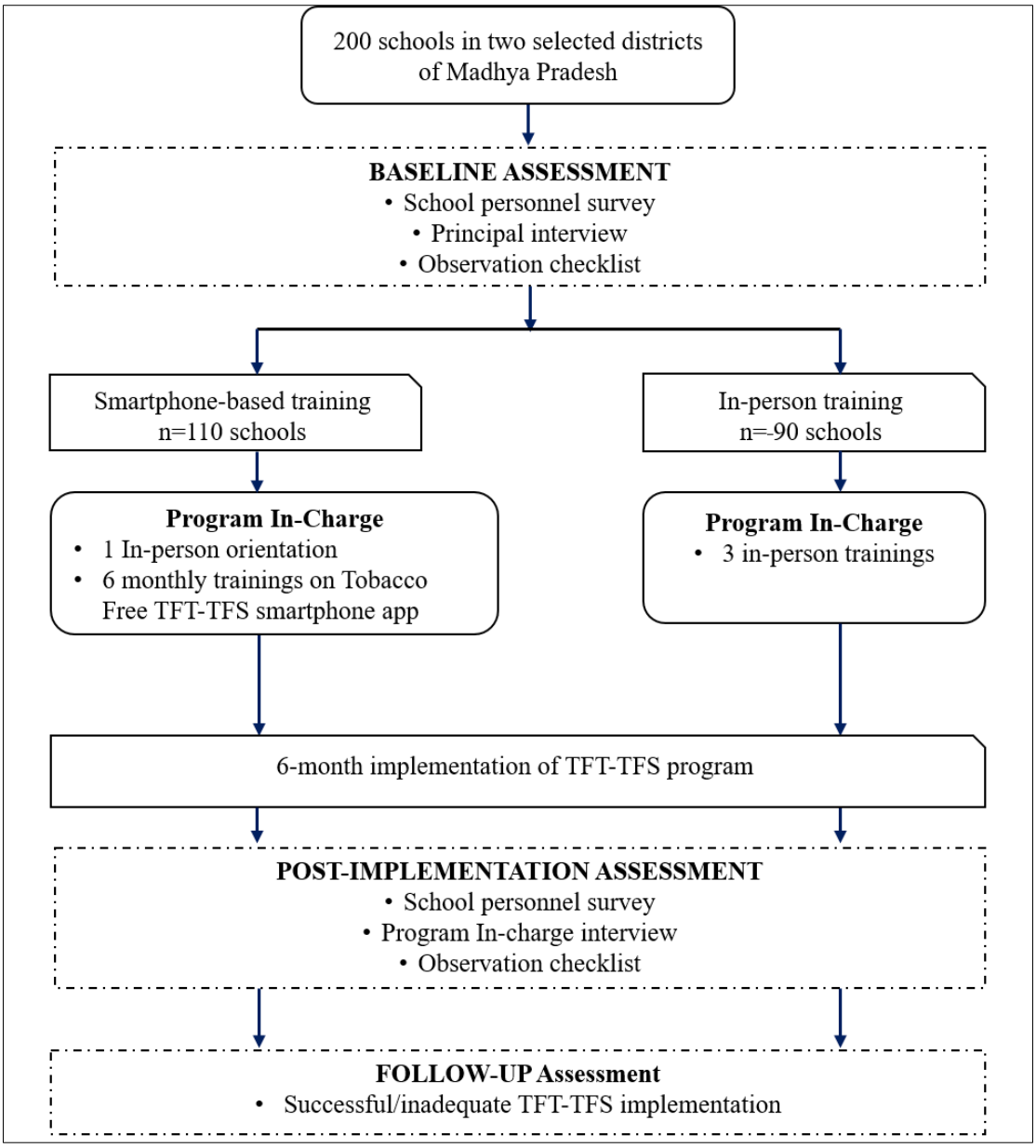

Figure 1: CONSORT flow diagram of cluster randomized trial: scaling up tobacco control in India.

Evidence-based intervention

The TFT-TFS program for teachers runs for six months of an academic year during school hours. Both training curriculum teaches program-in-charge how to implement the TFT-TFS program. TFT-TFS promotes a tobacco-free environment with six monthly themes, starting with an orientation session plus: teachers as role models; health effects of tobacco; motivation to quit tobacco use; skills to quit tobacco; dealing with withdrawal; and maintenance and celebration. The program encourages teachers to share information about tobacco harms and help others quit. TFT-TFS integrates these themes via four core components: six theme-based printed posters displayed monthly; theme-based monthly group discussions with teachers led by the program-in-charges; distribution of self-help "quit" booklets and referrals to available district resources for cessation; and display and implementation of the school tobacco-control policy.

Implementation strategies: In-person and smartphone-based training

The TFT-TFS training aims to equip teachers with: knowledge about the TFT-TFS program, tobacco use, its dangers, and cessation; skills implementing TFT-TFS, including program planning, teacher engagement, and tracking implementation progress; and strategies for overcoming implementation challenges, such as scheduling convenient times and locations for monthly group discussions for teachers.[23]

In-person training model were based on previously tested the training-of-trainers approach in Bihar DoE

infrastructure.[24] This involved training 46 cluster coordinators, who then trained and supported 219 headmasters in implementing TFT-TFS program in their schools.[24] This interactive training, built on principles of adult and situated learning, incorporated technique demonstrations, role playing, group discussions, and opportunities for practice and feedback—elements crucial for effective training, especially in LMICs.[25,26]

Smartphone-based training is through the TFT-TFS app, which uses the mobile numbers of designated school program in-charges and participating teachers for login. For program in-charges, the app gamifies program training with orientation and six Monthly theme-based modules. It adapts TFT-TFS' training materials into culturally relevant modules for MP, using India's kite festival to symbolize collaboration and friendly competition. The app content is presented as a kite, with each part representing a TFT-TFS theme, guiding program-in-charges through animated audio-visuals, quizzes with instant feedback, and unlocking new kite colors upon completion of core program components for each theme, culminating in a fully colored kite upon program completion.

The teachers' version of the app encourages them to become tobacco-free ambassadors by uploading photos/videos of their monthly activities, such as sharing information about tobacco harms and supporting others to quit. This boosts the competitive ranking of schools and promotes implementation. This gamified feature promotes healthy competition among schools and tracks teachers' engagement.

Procedures, measures, and analyses (by study aims)

Aim 1: Evaluate the fidelity, reach, effectiveness, and cost of the smartphone-based and in-person training models for implementing TFT-TFS, as detailed in Figure 2.

Following standard DoE procedures, officials introduce the TFT-TFS program to principals, highlighting its alignment with institutional goals. This study is supported by the National Cancer Institute of the National Institutes of Health, Division of Cancer Control and Population Sciences (DCCPS), Grant Number: 1R01CA248910-01A1 and encouraging program-in-charge's active participation.

In-person arm receives DoE leadership endorsement via a letter of support.

Smartphone-based arm receives DoE leadership endorsement via a letter of support and video in the TFT-TFS app. Ongoing video and text messages will remind the program-in-charges of the benefits for their schools and communities that will encourage them to continue with the TFT-TFS program.

The in-person arm training has three face-to-face sessions. Session 1: held at the start of the academic year, introducing the TFT-TFS program, themes 1 and 2, the use of printed materials, and guiding program in-charges on tracking progress using the TFT-TFS app. Session 2: shares successes, addresses challenges encountered in themes 1 and 2, and covers themes 3 and 4. Session 3: share successes, addresses challenges encountered in themes 1-4, and covers themes 5 and 6. All training were scheduled at convenient times and locations.

The smartphone arm training structure uses one in-person orientation and six app-led thematic sessions. Study staff orient program-in-charges to the TFT-TFS program, TFT-TFS app, and progress tracking within the app at the start of the academic year. Program-in-charges then receive six-monthly training on their TFT-TFS app—one per theme—covering how to implement the program's four core components. The app provides anytime/anywhere access and self-paced learning, featuring: short thematic audio-visuals with instant feedback quizzes; technique demonstrations (e.g., leading a group discussion with teachers); guidance on helping someone quit; and the school's progress with others.

In-person arm, encouraged program-in-charges to share knowledge and experiences with peers during each training.

Smartphone-based arm, program-in-charges participate in a study moderated TFT-TFS WhatsApp group for dialogue, peer learning, and support.[27]

Implementing TFT-TFS program monthly

Program-in-charges in both arms will: display monthly themed posters, lead thematic group discussions during breaks, staff meetings, or School Management Committee meetings with principals, teachers, and parents, distribute quit booklets to all teachers, and display a school tobacco-control policy.

Program materials

Schools get the TFT-TFS program implementation manual, six theme-based posters, self-help tobacco quit booklets, a sample school tobacco-control policy, and adoption instructions.

In-person arm group uses paper-based materials, including the six printed themed posters.

Smartphone-based arm group accesses all program materials digitally through the TFT-TFS app, except for the six printed themed posters.

Teacher materials

They include self-help quit booklets, the National Quit-Line number, and information about district cessation clinics. Teachers are encouraged to share TFT-TFS program information with students, families, and friends.

In-person arm, teachers get printed quit booklets from their program-in-charges.

Smartphone-based arm, teachers get a PDF version of the quit booklet on their smartphone from their program-in-charges.

Data collection

Both arms utilize identical data sources and methods (Table 1).

Program implementation in both arms was tracked using smartphone-based TFT-TFS app, where Program-in-charges recorded: completed activities with photos, the number of teachers participating in TFT-TFS group discussions, and time spent on TFT-TFS activities. Teachers in the smartphone-based training arm use the TFT-TFS app to track their individual efforts. The app provided real-time tracking of the TFT-TFS program, checked against the data from staff evaluation visits.

We evaluated all schools' pre-implementation (before randomizing schools) and post-implementation using the same data collection methods in both arms. All consent was verbal, as in prior Indian studies.[4,24]

School staff (principals, teachers, and non-teaching staff) completed self-administered smartphone-based surveys via Redcap links to assess tobacco use, cessation efforts, policy perceptions, information sharing and helping others quit. The survey also assesses TFT-TFS program knowledge and participation.

We interviewed Principals (pre-implementation)/program-in-charges (post-implementation) about tobacco policy adoption and control efforts. Interviews post-implementation also examine the ease/difficulty of implementing the TFT-TFS program and contextual factors influencing implementation, using the CFIR framework (innovation, inner/outer setting, and individuals).

Study staff used an observation checklist to record spit marks, tobacco wrappers, and policy implementation indicators in the pre-post evaluations. Post-implementation evaluation also included recording the TFT-TFS program posters and policies.[4,28]

Outcomes and data analysis

Program implementation will be assessed using: TFT-TFS app data, observation checklists, and staff survey data. We will measure success by evaluating the implementation of each program component and then determine the percentage of schools successfully implementing all four-core program components. Implementation success will be a binary measure (successful or inadequate). A school will be considered having a successful implementation if: teachers' discussions covered ≥three of six themes; cessation materials were distributed to all teachers; ≥four of six wall posters were posted; and the tobacco policy was posted. Schools not meeting these criteria are coded as inadequate. School will be the unit of analysis, and all implementation measures will be assessed at the school level. We will compare implementation success rates between two training arms by calculating the difference in proportions, using a 90% confidence interval. The null hypothesis will be rejected when the lower limit of the confidence interval exceeds the non-inferiority margin. Finally, we will validate the TFT-TFS app data by comparing it with study staff data collected during the evaluation visits.

The program impact on cessation (secondary outcome) will be assessed via a self-administered survey. School staff (principals, teachers, and other non-teaching staff) present during the pre-and post-implementation evaluations completed the surveys on their smartphones using a RedCap link.

Measures

We compared pre-and post-implementation self-reported data to determine the effectiveness of the TFT-TFS program.

Data analysis

A generalized linear mixed-effects model will analyze the data, accounting for the clustering of school staff. The post-implementation survey will dichotomize cessation into non-use and current use. We will use a binomial distribution with logit link to estimate cessation log-odds, considering the study arm and school random effect. This model calculates cessation probability differences and 90% confidence intervals. The smartphone arm cessation is non-inferior if the lower limit of the confidence interval is above -0.065. Since this test relies solely on the lower limit, the 90% confidence interval corresponds to a 5% error level. We will interpret the confidence interval for quit rate differences. Analyses will use R with lme4 package or SPSS.[29,30]

To assess cost, the program-in-charges meticulously documented the time dedicated to implement TFT-TFS program, including time spent preparing for and facilitating six-monthly group discussions. Study staff also tracked their time and resources utilization.

Measures

The study meticulously tracked these costs: study staff time related to delivering TFT-TFS program (e.g., training and supporting schools); training expenses, encompassing food and venue rentals, and TFT-TFS app maintenance, including personnel time, recorded on log sheets. School expenses included program-in-charges: travel time and costs to attend training sessions, recorded on attendance sheets; time spent on training and program implementation

activities, tracked on TFT-TFS app. Development costs for both arms were excluded, only the production costs of printed materials were tracked.

Analysis

Sum the individual components to find the implementation cost. We will analyze the total costs against components, rural/urban school location, and school size. These cost findings will describe and project program expenditures for scaling up the TFT-TFS program in other districts of MP and other Indian states. This data will help the DoE plan its budget and resources allocation.

To assess reach, we will use data from two sources: TFT-TFS app-based program tracking, which monitors the number of teachers involved in monthly thematic group discussions; and a school personnel survey where teachers self-report their participation in the program. The survey will assess how often teachers share TFT-TFS information and if they encourage quitting. Teachers in the smartphone-based training arm also recorded their monthly activities.

Measures

Reach is measured by the average teachers' participation in monthly thematic group discussions. This will be based on the TFT-TFS app tracking data and the school surveys (note: although we will assess how often teachers share TFT-TFS information, this study's scope excludes measuring the program's impact on tobacco cessation among students, parents, or community members).

Analysis

The null hypothesis will be rejected when the lower limit of the confidence interval exceeds the non-inferiority margin.

Aim 2: Determine factors influencing program implementation after smartphone-based versus in-person training

A mixed-methods study will follow after the program has been put into practice. We want to know what causes implementation differences after program-in-charges were trained either with the smartphone-based or in-person training. Factors impacting TFT-TFS implementation were selected based on prior works.[24,31,32] These are relevant to the DoE and will help us scale-up the program later. We are looking at factors from four domains of the CFIR framework: innovation (the duration of smartphone-based training for implementing the TFT-TFS program, time and scope of orienting the principals on the smartphone-based training, design quality/packaging of TFT-TFS components, and complexity in the interactive smartphone-based training strategy); inner setting (alignment of the TFT-TFS program with the schools' processes and tobacco control efforts); outer setting (needs and resources related to tobacco control and leadership support for successful TFT-TFS training and implementation); and individuals (participants' knowledge and beliefs about the need for effective implementation of the TFT-TFS program).[15]

Quantitative measures were added to the program-in-charges' interviews to analyze implementation differences.[33] We are also comparing schools with and without successful TFT-TFS program implementation using the cross-case comparison method.[34] We interviewed the program-in-charges and held focus groups with teachers to identify implementation facilitators and barriers. This will help us understand the TFT-TFS program's context and effectiveness.

We will collect, examine, and combine both quantitative and qualitative data. We will use CFIR constructs to develop survey questions for the quantitative data.[15] We adapted existing measures and changed open-ended questions into closed-ended questions using Likert scales.[33] Interviews with all 200 program-in-charges will provide this data after the TFT-TFS program be in place. Quantitative data will be analyzed using averages, standard deviations (or medians and the IQR, depending on the data's spread), and frequencies to compare implementation outcomes. We will then build a multivariable generalized linear model linking implementation success to CFIR constructs and school characteristics. We will include the program-in-charge's gender in our analysis.

We interviewed program-in-charges from purposefully chosen 32 schools across both arms. These schools represent three different implementation scenarios: schools that successfully implemented five to six themes monthly; schools that successfully implemented six themes under five months; and schools with inadequate implementation.

Qualitative data collection

We conducted face-to-face interviews with the program-in-charges after implementing TFT-TFS to explore factors related to the CFIR constructs. These interviews delve into: implementation experiences via open-ended questions; perceptions of strategies used to promote the TFT-TFS app-based program tracking; and solutions to any training challenges.[35] We also asked program-in-charges to suggest solutions to implementation challenges and recommendations for future improvements.

Qualitative data analysis

All interviews will be transcribed and translated into English. The N'Vivo template with CFIR codes will be used for coding.[15] The data will be coded independently by two study staff members (one in India and one in the US).[36] Codes will be compared, resolving differences through discussion. Data will be aggregated and summarized in a

memo template. We will allow for the inclusion of emergent themes beyond CFIR codes to capture unanticipated determinants.[37] Framework analysis enhances the credibility and relevance of findings, especially for multidisciplinary teams.[38]

Comparing study findings

We will present qualitative and quantitative data for each CFIR construct, along with the mean number of components, cessation rates, costs, and reach. We will then synthesize the program-in-charges' proposed solutions to challenges and share suggestions with principals and district-level representatives. For instance, if leadership engagement is identified as a key factor, the study team will collaborate with principals and officials to develop recommendations for how DoE at different levels can show their support for TFT-TFS through monthly meetings, District newsletters, and other communication channels. This analysis will allow cross-school comparisons.

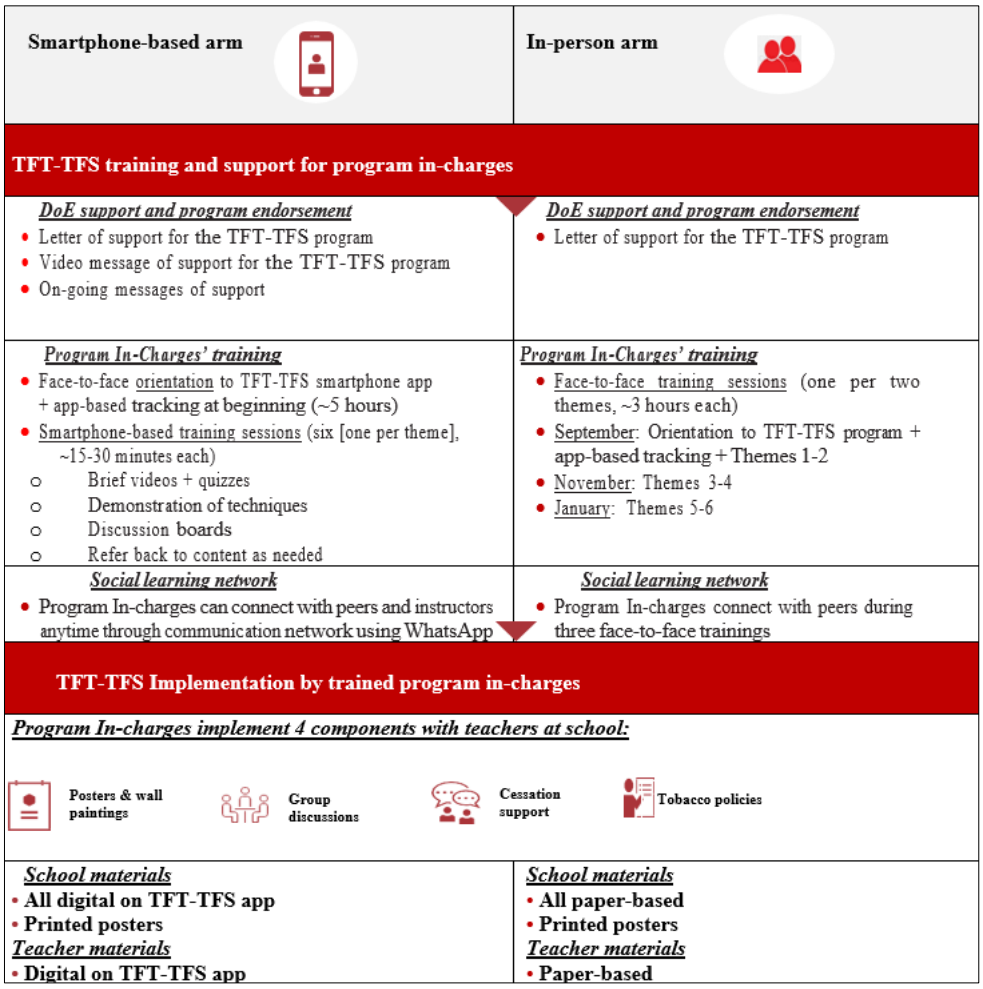

Figure 2: TFT-TFS training, support, and implementation.

Table 1: Measures summary.

Outcome	Measure	Data source
Program implementation	Implementation of 4 program components	School personnel surveys, observation checklist, TFT-TFS app-based program tracking
Tobacco cessation	School personnel self-report	School personnel surveys
Cost	Estimated time, resource use, and unit costs	TFT-TFS app-based program tracking, study staff tracking
Program reach	Teacher participation in TFT-TFS, teacher sharing information with others	TFT-TFS app-based program tracking, school personnel surveys
Factors affecting program implementation	Constructs from 4 CFIR domains (innovation, inner setting, outer setting, individuals	The program-in-charge interviews (n=200), the program-in-charge follow-up interviews (n=32)

DISCUSSION

LMICs are seeing a surge in tobacco-related deaths. Effective tobacco control is often hindered by logistical challenges of in-person training. This study compares smartphone-based training to traditional in-person training to see how they affect TFT-TFS in schools, focusing on implementation, reach, effectiveness, and cost. Contextual factors affecting TFT-TFS implementation will also be examined after each training. The findings will help DoE stakeholders understand the training models' impact on TFT-TFS implementation in schools. It will help build CFIR evidence on factors that influence the implementation of tobacco control strategies in low-resource settings.

To our knowledge, this is the first study to assess the use of smartphones for training school staff to deliver and monitor a tobacco control EBI. Considering that most teachers and principals in India own smartphones, both for work and personal use, this study will show the feasibility of smartphone-based training to improve tobacco control in Indian schools. Existing research primarily focuses on the effect of mobile learning on learners' attitudes, knowledge, and skills, not on program implementation or outcomes.[39]

We recognize this study's limitations, despite our prior India research. To address the possibility of school dropouts, we increased the sample size and involved the DoE to address school concerns. We will provide ongoing support for the TFT-TFS app because of the evolving nature of smartphone technology. Finally, we excluded the RE-AIM constructs of adoption and maintenance as study outcomes because: adoption decisions are made at the state level, where support is already in place from the DoE; and a maintenance study would require long-term tracking beyond the study's timeframe.[14]

Future research should explore smartphone use in training program implementers to address health issues like non-communicable diseases in LMICs. Teachers' use of smartphones to share tobacco control information needs further exploration. Finally, there is a potential to examine how gamification could enhance smartphone-based training user experience, engagement, and data collection, especially in LMICs.

CONCLUSION

This study compares smartphone and in-person training for implementing a tobacco control EBI, focusing on app-based real-time program tracking in low-resource settings. Our goal is to offer strong scientific and economic evidence for using smartphone to expand tobacco control EBIs training in LMICs. Our rigorous mixed-methods evaluation will show how training program implementers via smartphones affect program implementation and outcomes. The results could informe (schools and DoEs) tailored training to local contexts, identify implementation factors, and offer evidence for smartphone-based training models for Indian school staff. Ultimately, the study will determine if smartphone-based training can expand implementation of tobacco control EBIs and reduce tobacco use and related deaths in resource-constrained areas, including other LMICs.

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Conflict of interest: None declared
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