



# Rationale and design of a study to test the effectiveness of a combined community health worker and text messaging-based intervention for smoking cessation in India (Project MUKTI)

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**Background:** Nearly 275 million individuals in India consume tobacco every day, with more than 1 million dying annually as a result. Few people in India have access to smoking cessation services, an essential component of combating tobacco use globally. We hypothesize that a strategy of systematic community health worker (CHW) based counseling that covers eligible people who smoke in a geographical area, combined with text messaging support, will result in improved quit rates.

**Methods:** The study is a cluster randomized controlled trial that will be conducted at 2 sites in India. Sixteen clusters will be randomized into either an intervention or control arm. A total of 560 smokers between the age of 18 and 70 will be recruited from their home through CHWs. Smokers at all stages of change will be offered the intervention, which is based on the transtheoretical model of change.

**Results:** Pre-contemplative participants will be offered health education and motivational interviewing through CHWs. They will also be offered a low frequency form of text messaging, focused on health education and the benefits of quitting. Participants who are actively contemplating quitting smoking will be offered a more intensive intervention, with more frequent visits by CHWs and more intensive text messaging support. Contemplative participants will be encouraged to set a quit date, and all participants will be assessed periodically for stage of change to provide the appropriate intervention. Participants who set a quit date will be encouraged to use NRT to help with quitting. Control group participants are provided with brief smoking cessation advice only, at the start of the trial. The primary outcome will be self-reported abstinence for the past 14 days, biochemically verified by exhaled CO levels (cut-off 10 ppm) assessed at the end of 1 year of the intervention.

**Conclusions:** We will test whether a CHW-based intervention that incorporates motivational interviewing, text messaging and supportive counseling can prove effective in systematically helping smokers quit.

**Keywords:** Smoking cessation; mhealth; community health workers; motivational interviewing

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## Introduction

Tobacco use contributes to more than a million deaths in India annually, ranking as the second leading cause of disability adjusted life years (DALYs) in the country (1,2). Moreover, unlike high income countries, the prevalence of tobacco use continues to rise, especially in young people (3). Other low- and middle-income countries suffer a similar situation (4). Providing adequate smoking cessation services is a part of the MPOWER package, which is a set of six measures advocated by the World Health Organization (WHO) to reduce tobacco use globally (5). While India has made progress in regulating tobacco (by signing the WHO framework convention on tobacco control (FCTC), amongst others), provision of smoking cessation services to tobacco users has been wholly inadequate (6).

There is, therefore, an urgent need to develop models of tobacco cessation treatment that are effective, inexpensive, scalable and culturally acceptable. Community health workers (CHWs) have a successful track record in improving maternal health and various communicable disease imperatives (7). CHWs are lay community members who are trained in specific areas, and are primarily aimed at bridging the gap between traditional healthcare providers and patients. More recently, they have been used in noncommunicable diseases such as hypertension and diabetes with encouraging results, raising the question whether they could be effective in promoting quitting from tobacco (8). A brief community outreach intervention delivered by CHWs has previously been shown to increase tobacco cessation in India (9). However, the effect size was small. We have previously tested a CHW based approach to providing smoking cessation support for tobacco users in their homes (10). The study was based on the transtheoretical model of change, with contemplative participants receiving more intensive intervention from CHWs, as compared to precontemplative participants. At the end of 2 years of intervention, there was no significant difference between the intervention and control groups (11). Given that prior literature shows a direct relationship between the dose of a tobacco cessation intervention and results, we posited that inadequate hours of patient contact with CHWs may have partly driven the null findings. Since the ability of CHWs to spend time on tobacco related activities is finite, we hypothesized that supplementing a CHW led approach to smoking cessation with text messaging through

a mobile device may lead to increased rates of quitting tobacco. Previous studies have shown that text messaging-based solutions can improve quit rates of tobacco use in various populations (12). However, effectiveness of text messaging for smoking cessation has mostly been evaluated in high income countries and include only those who are contemplating quitting (13). While the transtheoretical model provides a construct to frame the intervention, traditional interventions have not achieved much success with precontemplative participants. Therefore, employing motivational interviewing techniques for precontemplative participants may help a greater proportion progress to the contemplative stage (14). Multiple studies have shown that motivational interviewing can increase quit rates of tobacco use, though no study has specifically employed CHWs to deliver motivational interviewing (15). Hence, tailoring the appropriate intervention to an individual's stage of change can potentially result in higher quit rates.

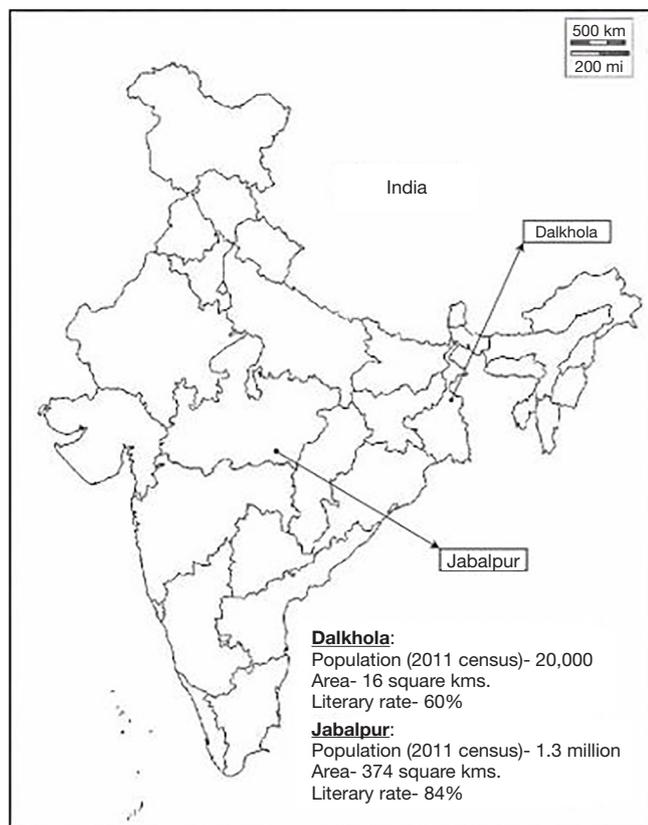
We therefore hypothesized that a home based CHW led approach to smoking cessation, incorporating motivational interviewing and accompanied by text messaging, would lead to increased quit rates amongst users of smoked tobacco in India.

## Methods

The design, implementation and reporting of the study follows recommendations from the 'Ottawa Statement on Ethical Design and Conduct of Cluster Randomized Trials' (16). The study protocol received approval from the institutional review board of University Hospitals Cleveland Medical Center, USA and Society for the Promotion of Ethical Clinical Trials (SPECT), an independent review committee in New Delhi, India. All trial participants provided written informed consent and the trial was registered in the clinicaltrials.gov database (registration number- NCT03495622).

### *Study design*

Project multi-unit kit for tobacco intervention (MUKTI) is a two armed, parallel, cluster randomized controlled trial conducted in two sites in India—Dalkhola and Jabalpur (*Figure 1*). Dalkhola is a town in eastern India, with a population of around 20,000 people and a literacy rate of 60%. Jabalpur, on the other hand, is a city in central India, with a population of 1.2 million and a literacy rate of 84%. The average national literacy rate is 74% (17).



**Figure 1** Study sites.

### *Study population*

Adults aged 18 to 70 years, who live in either of the two study sites and smoke daily, will be recruited into the study by the CHW. Home based screening will be conducted by the CHW assigned to each geographical cluster, using the voter list of the area as a guide. Among the screened individuals, those who smoke cigarettes or bidis daily (self-reported) and have access to a mobile phone will be recruited into the study. Bidis are inexpensive, hand rolled cigarettes commonly used in India. Screening will continue until she reaches the target study population of 35 participants in each cluster.

Exclusion criteria include those who are bed-bound because of an acute illness or a chronic condition. Participants who have significant disabilities that would prevent them from participating in the study in a meaningful way such as being blind, deaf or intellectually disabled will be excluded from the study. Illiterate participants will not be excluded, as long as they have access to a cellphone and a family member who can read out text messages to them. The CHW will have

discretionary power to exclude any individual who may not be able to participate in the study and will also exclude those who may not be available for follow up in the following year.

### *Randomization*

Randomization will be done at the level of the geographical cluster at the 2 sites. Dalkhola and Jabalpur are geographically divided into 14 and 30 wards, respectively. Each ward consists of smaller regions. Using the voter list as a reference, these regions are combined to form clusters of approximately equal population sizes. We will select a total of 16 clusters for the study, 12 from Dalkhola and 4 from Jabalpur. From these 16 clusters, 8 clusters will be randomly assigned to the intervention group, and 8 clusters assigned to the control group. A computer-generated sequence will be used for randomization. Post randomization, if a randomly selected control cluster is adjacent to an intervention cluster, we will exclude the control cluster and randomly choose a new control cluster from the remaining clusters. This is done to avoid contamination of the control group. Once the cluster randomization is finalized, CHWs will start the screening process.

### *The community health worker*

The role of CHWs in controlling non-communicable diseases is a growing area of interest but their utility in smoking cessation interventions is yet to be fully defined. Furthermore, their ability to utilize motivational interviewing to elicit change has not been previously studied. We have previously described our selection and training processes for CHWs (18). Briefly, our CHWs are recruited through a written test and interview. Once selected, they are trained to provide care for hypertension and diabetes, in addition to smoking cessation. For smoking cessation, they are given a 1-week training session that focuses on didactics, role play, practicing skills and learning motivational interviewing. A 40-page training book serves as the template for learning. CHWs are also provided a flipbook, and trained in utilizing it for patient education. The CHW finishes training when their overall performance during training is judged by the instructor to be satisfactory. Once fieldwork starts, there is a supervisor whose role is to monitor the work of the CHW using a pre-defined quality checklist to uphold the fidelity of the intervention. These supervisors, in turn, are in regular communication with study investigators (<http://fp.amegroups.cn/cms/mhealth.2019.05.04-1.pdf>).

## *mHealth—TxT pro program*

### **Development of the mHealth delivery system**

To develop a cost-effective, evidence-based text messaging intervention, we used an existing open source software called RapidPro to develop messaging flows for each stage of behavior change (19). Each messaging flow is triggered by a code word sent by the participant. Given that text messages are delivered solely through the software, with no human mediation, we restricted bidirectional messaging to certain code words that can trigger messaging flows. This will provide a feeling of control to the participant who can decide the type of messages they receive based on their readiness to change. For instance, a previously pre-contemplative participant who is now contemplating quitting can send the words ‘ready for MUKTI’ which triggers the contemplative message flow. This will reduce the passivity of a unidirectional messaging intervention.

### **Development of the text messages**

The content of the messages was obtained from a large bank of messages that had been previously used in an Australian trial (20). These messages were modified to suit the needs of our target population. The modified messages were reviewed by multiple study personnel, sample patients and community health workers until all team members agreed upon the final text messages. Over the course of one month, a random sample of these modified messages were delivered through the RapidPro software to evaluate the feasibility of the intervention. Qualitative feedback was obtained from the participants and further changes to the content was made accordingly. Once finalized, the messages were divided into different ‘sets’, to be delivered at different ‘phases’ of the intervention. In addition, through random messages interspersed in the program, participants will be informed of the methods of opting out of the program or contacting their CHW. All messages were translated to Bengali (Dalkhola) and Hindi (Jabalpur). Sample text messages are shown in *Table 1*.

### **Assistance messages**

Participants who abstain from smoking, after their preset ‘quit date’, will be provided with a list of code words which can be used to trigger a set of pre-defined assistance messages. Code words such as ‘TEMPT’ or ‘STRESS’ can be sent by the participant which will activate a flow of messages to be delivered over a span of 15 minutes. The goal of these messages is to provide 24-hour assistance and distract an

individual from the instant urge to smoke a cigarette/bidi.

### **Delivery of messages**

The intervention software is built to deliver messages randomly between 10AM and 9PM on each day. The number of messages delivered in each week is pre-determined, with a greater number of messages delivered over the weekend. The participants will incur no charge to receive messages. However, depending on their network plan, they may incur a one-time small charge on sending the prespecified code word to trigger the intervention flow.

### **Recruitment**

Recruitment will be done by the CHW, who will visit every household and interview all potential participants listed in the voter’s list. She will also determine the participant’s stage of behavior change by asking them if they would be willing to quit smoking in the next 30 days. Those who answer “Yes or maybe” to this question will be deemed to be contemplative by the CHW and those who respond “No” will be considered pre-contemplative.

### **Intervention**

#### **Rationale and structure**

The intervention is tailored to each participant’s stage of behavior change, determined by the CHW at the first home visit. All participants will have the option of choosing between an intervention involving regular text messages combined with scheduled CHW house visits or CHW visits only with no text messages. The intervention structure is described in *Figure 2*.

#### **Precontemplation**

The CHW, at the time of enrollment, will explain the features and benefits of the TxT Pro program and offers this intervention to all participants who are pre-contemplative about quitting smoking. Regardless of their interest in the TxT Pro program, each pre-contemplative participant will receive a CHW visit every 2 months. The CHW will utilize techniques of health education (using a flipbook) and motivational interviewing to communicate with participants, with the goal of transitioning them into becoming contemplative about quitting smoking. In the first couple of visits, she will focus on health education, and then transition to a motivational interviewing- based approach in subsequent visits.

**Table 1** Sample text messages

Message category (based on phase of behavior change)	Examples
Motivation phase	<p>Cigarettes are more stimulating than relaxing; even one increases your heart rate and blood pressure. They don't really help you to relax.</p> <p>Reframe how you think about quitting—try to view not smoking as a good thing and something you want to do, rather than as a sacrifice.</p> <p>You should set a date to quit soon. It is common to have mixed feelings about quitting, but remember smoking is harming your health and fitness.</p> <p>Ask any friends or acquaintances who've quit what helped them; everyone's smoking habit is different, but some things they did might prove useful to you.</p> <p>After quitting, your senses of taste and smell begin to improve. Your breath, hair and clothes will smell fresher, and you will have more energy.</p> <p>The best approach to quitting is to quit suddenly, on a set quit date. Cutting down over time can actually make things harder.</p> <p>It's common to make several attempts to quit before quitting for good. Each attempt is a stepping stone that gets you closer to success.</p> <p>To reduce cravings first thing in the morning, have a bath at the time you would have smoked. This can delay the first craving you get.</p> <p>Withdrawal symptoms can be unpleasant, but see them as a positive. They're proof that your body is adjusting to being without the harmful chemicals in tobacco.</p>
Preparation phase	<p>Nicotine gum helps prevent or reduce cravings to smoke, so consider using it if you feel you're struggling.</p> <p>This evening, treat yourself to something you will enjoy, as a reward for getting through the day without smoking.</p> <p>After only 2 days of quitting, your taste buds and sense of smell begin to improve. Can you notice it yet?</p> <p>There are 2 main tasks once you quit: Dealing with cravings to smoke and coming to enjoy and value life as a non-smoker.</p> <p>Congratulations on quitting! You're taking control of your health, you're taking control of your addiction and you're taking control of your life.</p> <p>Day 2 is often the hardest. Renew your resolve to stay quit and have coping strategies ready. Treat it as a challenge.</p>
Post quit day month 1	<p>Most people find that cravings rarely last for more than 5 minutes, so the trick is to distract yourself with ANYTHING until they go.</p> <p>No one will be offended if you refuse an offer of a cigarette. Practice saying 'No thanks, I don't smoke any more' in case you are offered one.</p> <p>Don't fall for the "just one" thought; just one is one too many. It's likely you'll wake your addiction up and soon it'll be wanting more and more.</p> <p>Don't focus on what you miss about smoking; switch those thoughts off as soon as they occur.</p> <p>Avoid thinking too far ahead; get through one craving at a time.</p>
Post quit day month 2–6	<p>You might notice smokers looking as if they're enjoying a smoke, but remind yourself, they're just feeding their addiction, while you're recovering from yours.</p> <p>Being a nonsmoker is one of the best gifts you've ever given yourself. Soon you'll experience improved health and fitness, if you haven't already noticed it.</p> <p>Keep reminding yourself of how safe your family feels now that you're doing the best thing for your health and long life.</p> <p>Keep practicing walking away from stressors, breathe deeply, exercise and thoughts about smoking will eventually fade for good.</p> <p>At this point people often have the thought "I've come this far, just one won't hurt" and end up relapsing. Remember, nonsmokers don't need "just one".</p>

**Table 1** (continued)

Table 1 (continued)

Message category (based on phase of behavior change)	Examples
Relapse	<p>You tell us you have relapsed; however, you have proven you have the skills to quit. You can be confident you will eventually succeed. Having recently tried to quit, you will know in what situations you get cravings. You need to develop strategies to avoid smoking in these situations.</p> <p>Even if you don't feel ready to make another attempt now, take the time to think how you could have avoided relapsing. This will help you next time.</p> <p>Congratulations on making an attempt. With one more attempt to quit behind you, you're now closer to the one that will be permanent. Medication, when properly used, reduces the strength of cravings to smoke. Make sure you are giving yourself the best chance. If you had trouble with cravings on your previous attempt, you should consider Nicotine gum to control cravings.</p>
Pre-contemplative messages	<p>Is it hard to keep from smoking when others around you are smoking? If so, addiction is creeping up on you already. Quit now before addiction makes it harder.</p> <p>Try to push back the first cigarette of the day by an hour. If this is too hard, it is a sign of nicotine addiction. Quit now before addiction takes hold.</p> <p>It's rare for someone to be able to quit the first time they try (or even the second); it's very normal to make a number of attempts before quitting for good.</p> <p>All cigarettes are toxic. Smokers not only die younger (on average), they also suffer more years of disability than nonsmokers. Quitting will benefit your health at any age.</p> <p>Smoking causes wrinkles to develop earlier around the eyes and mouth, and can stain your fingers and teeth. It is harmful to your appearance.</p>
Emergency messages	
Stress	Try a minute of deep breathing, it can relax you: breathe in slowly to the count of 4, hold it for a count of 2 and breathe out slowly for 4; do this 5 times.
Social	Try to find some excuse to get out of the situation you are in. Going to the bathroom tends to work well. The craving will pass in a few minutes.
Tempt	If you can, call a friend and chat for a few minutes. The urge to smoke should soon pass.
Slip up	Go for a brisk walk if you can. Even short bursts of exercise help get rid of cravings and they also re-energize you. You're on a steep learning curve adjusting to being a nonsmoker. Don't be too hard on yourself, just recommit to staying stopped.

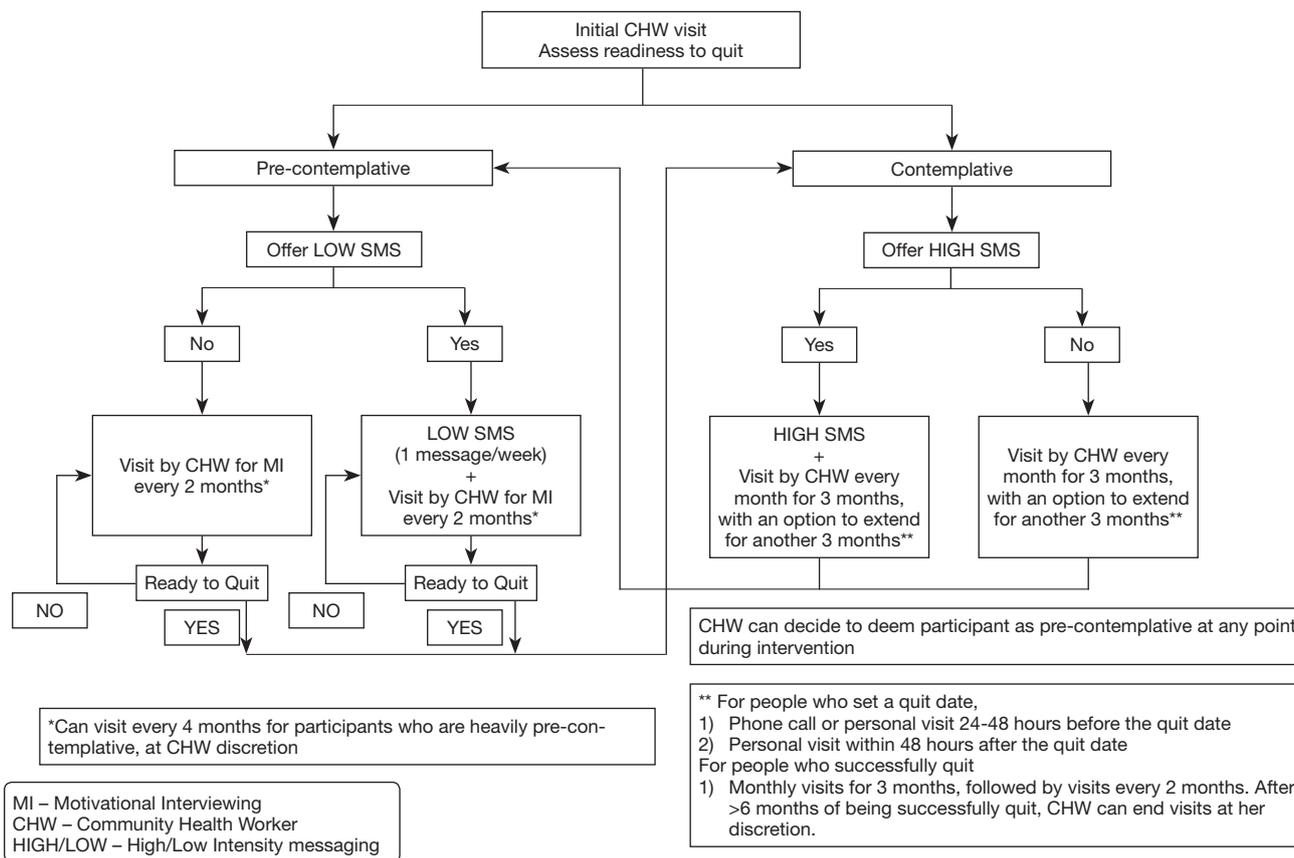


Figure 2 Structure of the intervention.

### Contemplation

All contemplative participants will be offered the TxT Pro program. Similar to the precontemplative group, each participant will be visited by a CHW (at an increased frequency of once a month for three months) regardless of their interest in the TxT Pro program. At the end of 3 months, if the participant hasn't quit smoking, the CHW can assign him to the precontemplative group or continue the intensive contemplation intervention for another 3 months, based on her judgment.

The text messages in this group will differ from those sent to precontemplative participants, and are delivered more frequently (Figure 3). Broadly, these messages are divided into four phases based on a participant's stage of behavior change, as described below.

#### Phase I (preparation & motivation)

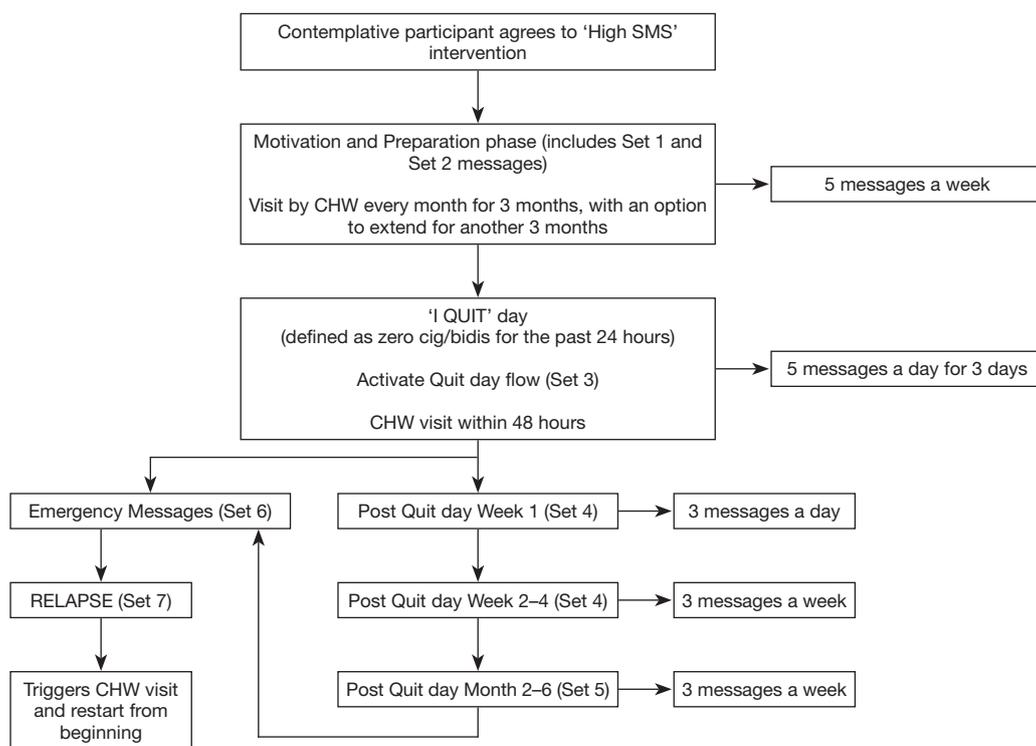
These messages contain a combination of motivational content, facts regarding smoking and the process of quitting. Participants will be provided with tips to prepare themselves for the process of smoking cessation. Each

participant will receive 5 messages a week, delivered at random time points spread throughout the week. During this period, participants will be encouraged to set a quit date and communicate their concerns regarding quitting with the CHW. This phase will continue until they set a quit date, at which point the CHW can transition them to phase II.

#### Phase II (action)

On the preset 'quit day', participants will be expected to have not smoked a single cigarette or bidi for the past 24 hours and inform the CHW by sending the words 'I QUIT' to the central number. This message will trigger two integrated events that are focused towards helping the participant stay quit.

First, it will trigger a predefined flow of messages that are designed to encourage the participant to stay quit. During the first 72 hours, they will receive a higher dose (5 messages/day) of text messages to provide additional support. The content of these messages ranges from being congratulatory to those that describe various positive effects



**Figure 3** Structure of ‘High SMS’.

of staying away from cigarettes/bidis. Second, it will also trigger a CHW house visit focused towards preventing early relapse. This visit will be within 48 hours of receiving the ‘I QUIT’ message, which is the period of maximum vulnerability for early relapse.

### Phase III (post quit)

Three days after quitting, the participant will be transitioned to the post quit phase. It will encompass an early phase (week 1) and a late phase (weeks 2–4). During this phase, the frequency of messages will be gradually decreased but the frequency of CHW house visits will be increased. The dose of messages will be slowly tapered down from 3 messages/day at the beginning to 3 messages/week at the end of the phase. This month-long phase has text messages and CHW visits that encourage sustained abstinence by reminding participants of all the physical, mental and financial benefits of smoking cessation.

This phase will also activate the ‘assistance messages’ which are a pre-defined set of messages that are designed to help participants to stay quit and prevent relapse. These messages are activated by certain code words sent by the participant at a time of need and can be activated at any part of the day.

### Phase IV (maintenance)

One month after the quit day, participants who are still quit will be transitioned to the maintenance phase. This phase continues for a duration of 6 months from the quit day and consists of 3 messages a week, coupled with monthly CHW visits to provide brief support and encouragement. These participants continue to have access to ‘assistance messages’ in this phase.

### Relapse

At any time after the quit day, if the participant relapses, they will be instructed to send the word ‘RELAPSE’ via a text message. The code word will trigger a set of pre-defined text messages addressing possible solutions for relapse. This will also trigger a CHW visit in the next few days who will examine the various possible causes of relapse and suggest a way forward. If the participant feels they are not ready to quit, the CHW will assign them to the pre-contemplative phase of the intervention.

### Access to nicotine replacement therapy

Apart from text messages and CHW home visits, participants will be encouraged to use nicotine replacement

therapy to help them during the quitting process. These medications will be made available to them through the CHWs, at market rates. Additionally, participants will also have the option of buying them over the counter. CHWs will be trained about the benefits and risk of NRT, which will also be communicated pictorially to patients through the smoking cessation flipbook used by the CHW.

### Control

Screening will be conducted in the same manner as in the intervention group. At the time of screening, all participants will receive brief verbal advice about the hazards of smoking and the benefits of smoking cessation. No further visits or support will be provided for the duration of the intervention.

### Outcome evaluation and follow up

All outcomes will be evaluated at the end of 1 year of the intervention. The primary outcome is biochemically verified [by exhaled carbon monoxide (CO) level] abstinence for the past 14 days. CO levels will be checked using a validated breath analyzer by the CHW at her final house visit. Those with a breath CO level of less than 10 ppm will be considered to have quit smoking successfully (21). Pre-specified secondary outcomes will include uptake rates of text messaging and variation in quit rates based on a participant's education and socio-economic status.

### Sample size and statistical analysis

The sample size determinations, or power analysis, account for lack of independence in observations due to the clustered study design, by multiplying the standard sample size calculation by the design effect,  $\{1+[(\text{average cluster size}-1)\times\text{ICC}]\}$ , where the ICC is the intra-cluster correlation coefficient. Sample sizes were calculated using a two-sided test,  $\alpha=0.05$  and power of 80%. Sixteen clusters will be chosen across 2 sites—12 in Dalkhola and 4 in Jabalpur. We fixed the number of clusters for each group at 8 based on our financial and technical capabilities. We used conservative estimates of the population prevalence of smoking to determine the number of participants required.

We used an ICC estimate of 0.04 based on a previous community-based smoking cessation study (22). CHW interventions in non-communicable diseases have usually had an attrition rate of 20–25%, due to the community-based nature of the intervention and broad inclusion criteria (23). We chose a slightly higher attrition rate of 30%, to ensure we had adequate power. We chose a minimum detection rate of 3.9% based on a prior study using CHWs that found a difference of 2.1% between the intervention and control groups (9). We adjusted that

upwards to 3.9% due to the longer duration and more intensive nature of the intervention in our study. We calculated that to achieve a minimum detectable difference of 3.9% in quit rates amongst intervention and control group, assuming a conservative ICC of 0.04 and 30% attrition, we would need an average of 35 participants in each of the 16 clusters. We therefore aim to enroll a total of 560 participants. The primary analysis of the study will be done by an intention to treat approach.

### Data management

All data collected by the CHWs will be entered at the field office into REDCAP (Research Electronic Data Capture), a secure web application for managing online databases. Only de-identified data will be accessed at University Hospitals of Cleveland, which is the coordinating center for the trial. The central phone, through which the software platform for text messaging is operational, will be securely stored in the field office at the 2 sites. Information from the phone will be accessible only to research personnel at each site.

### Limitations

Our study has a few limitations. Participants who smoke but don't have access to a cell phone are excluded from the trial. This may limit the eventual reach of our intervention. Second, we limited our intervention to smoked tobacco, though a substantial part of the population uses smokeless tobacco. If our intervention is successful, it could be suitably adapted to study its efficacy for quitting smokeless tobacco. Third, the control group participants will only receive brief advice at the start of the trial and no text messages. This places a limitation on differentiating the effect of the content of messages from the delivery of messages itself.

### Discussion

Our study has multiple strengths. To our knowledge, this is the first intervention to combine a CHW based approach to smoking cessation with text messaging. Second, the feasibility and efficacy of delivering motivational interviewing through CHWs for any health-related outcomes have not been examined previously. If successful, motivational interviewing through CHWs could be used for other health imperatives. Third, our intervention includes participants who are pre-contemplative about quitting smoking. Historically, this has been a challenging

population to treat. If successful, our intervention would create a holistic framework to help all people who smoke, and not just those willing to quit. Fourth, our trial design is real world and pragmatic, and would be generalizable and scalable to a large population of smokers- if successful.

Going forward, low- and middle-income countries are in dire need of models to provide smoking cessation support to an ever-increasing population of individuals who smoke. Our intervention provides a framework that covers all aspects of smoking cessation, and if successful, can be integrated into national CHW programs.

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### Footnote

*Conflicts of Interest:* The authors have no conflicts of interest to declare.

*Ethical Statement:* The study protocol received approval from the institutional review board of University Hospitals Cleveland Medical Center, USA and Society for the Promotion of Ethical Clinical Trials (SPECT), an independent review committee in New Delhi, India. All trial participants provided written informed consent and the trial was registered in the clinicaltrials.gov database (registration number- NCT03495622).

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