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Title

Feasibility randomised controlled trial of face-to-face counselling and mobile phone messages compared to usual care for smokeless tobacco cessation in Indian primary care: Project CERTAIN

Authors

Rajmohan Panda, MD, Research division, Public Health Foundation of India, New Delhi, India.

Rumana Omar, PhD, Department of Statistical Science, University College London, London, UK.

Rachael Hunter, MSc, Department of Primary Care and Population Health, University College London, London, UK.

Supriya Lahoti[1], MPH, Research division, Public Health Foundation of India, New Delhi, India.

Rajath R Prabhu[2], MSc, Research division, Public Health Foundation of India, New Delhi, India.

Victoria Vickerstaff, PhD, PRIMENT Clinical Trials Unit, Research Department of Primary Care and Population Health, University College London, London, UK.

Durga Madhab Satapathy, MD, Department of Community Medicine, MKCG Medical College, Berhampur, Odisha, India.

Sangeeta Das[3], MD, Department of Community Medicine, MKCG Medical College, Berhampur, Odisha, India.

Irwin Nazareth, PhD, Department of Primary Care and Population Health, University College London, London, UK.

Corresponding author: Supriya Lahoti, Research division, Public Health Foundation of India, Unit No. 316, District Centre Saket, New Delhi-110017, India. supriyalahoti23@gmail.com. Contact no: +919920939123

Keywords Smokeless tobacco, cessation, low- and- middle income countries (LMIC), primary health care, feasibility study

Word count: 4197

Current affiliations:
[1] Supriya Lahoti, Consultant, Extension for Community Healthcare Outcomes (ECHO) India, Okhla phase III, New Delhi, India.
[2] Rajath R Prabhu, Senior Executive- Medical Content Writer, HexaHealth, Gurugram, Haryana, India
[3] Sangeeta Das, Associate Professor, Department of Community Medicine, SJMCH, Puri, India

ABSTRACT

Introduction

Smokeless tobacco (SLT) use in low- and middle-income countries (LMICs) has adverse health consequences. We hypothesize that it is feasible to test an intervention of mobile phone messages and face-to-face counselling session for SLT cessation in India.

Methods

We conducted an exploratory, individual parallel two group, randomised controlled trial (RCT), with baseline -and end-point (three months from randomisation) assessments in urban primary health centres in Odisha, India. A total of 250 current (i.e., users in the last three months) SLT users or dual users (i.e., smokers and SLT users) were recruited to the trial (125 in each group). Participants were randomised to either routine care, face-to-face counselling, and reminder mobile messages or routine care only. The primary outcomes were to assess the feasibility of running a full RCT including recruitment, compliance, and retention.

Results

A total seven (77.8%) out of nine primary care centres took part in the trial. Out of the 315 SLT users invited to participate, 250 provided consent and were randomised [79.4% (95% CI: 74.5, 83.7)]. Out of the 250 randomised SLT users, 238 [95% (95% CI: 91.8, 97.5)] were followed up at three months (117 in the intervention group and 121 in the control group). Of the participants in the intervention group, 74 (63.8%) reported that they received the mobile messages.

Conclusions

This exploratory trial demonstrated the feasibility of delivering and evaluating an intervention of mobile phone messages and face-to-face counselling for SLT users in Indian primary care in a full randomised trial

IMPLICATIONS

- This study found that combining mobile messages with face-to-face counselling for smokeless tobacco users visiting primary health care settings in India is feasible in terms of recruitment of users, compliance with the intervention, and retention of study participants within the trial.
- The biochemically verified smokeless tobacco abstinence rate was higher in the intervention group compared with the control group
- There was poor agreement between self-reported tobacco cessation and the measured salivary cotinine in smokeless tobacco users.
- The findings support the feasibility and acceptability of the intervention signalling the need for a larger clinical trial to test effectiveness of the intervention.

INTRODUCTION

Smokeless tobacco (SLT) is chewed, inhaled nasally, or placed in the oral cavity[1]. SLT use is prevalent in the World Health Organization (WHO) South-east Asia region and more than 250 of the 300 million global SLT users live there[2]. SLT products contain nicotine and carcinogenic nitrosamines in varying amounts[3] and is associated with a higher risk of premature morbidity and mortality[4]. The Global Adult Tobacco Survey, 2016-17 (GATS 2) identified 199.4 million SLT users in India which is two-fold higher than the 99.5 million smokers[5]. Most of these SLT users live in the eastern and north-eastern Indian states that have the poorest health indicators in the country[5,6]. Odisha, is one of the eastern states with 42.9% SLT users, double that of the national average of 21.4%[5]. The widespread availability of unregulated SLT products, socio-cultural acceptance of SLT use, and early age of initiation are among some of the factors responsible for the high burden of SLT[7–9].

Primary healthcare is best placed to promote tobacco cessation in India[10]. However, time constraints, lack of training and competing priorities mean that primary care physicians (PCPs) offer limited cessation advice and counselling to patients[11]. Interventions offered in primary care have the potential to identify SLT users with an early stage of use and who are unaware of the risks and hence not motivated to quit[12]. Mobile health (mHealth) solutions through text messages can offer support enhancing PCPs' efforts and improving participation in tobacco cessation programmes. The interventions with small effect sizes also result in a substantial impact on the population as a whole[13].

India with the second-largest mobile phone user base (1145.5 million) in both, rural and urban settings[14], offers an opportunity for delivering a behaviour change program for tobacco cessation. Evidence indicates that the mHealth automated text-messaging interventions targeting smokers can increase the quit rates by 50% to 60% compared to minimal support for smoking cessation[15]. Cohort studies in India on SLT cessation show clinical benefits of behavioural interventions with risk ratios (RRs) ranging from 1.80 (95% CI: 0.77, 4.25) to 2.79 (95% CI: 2.36, 3.29) and quit rates between 20% and 40%[16]. The effectiveness research,

however, of mobile message-based interventions for SLT are restricted to high-income countries (HICs)[17,18]. These few studies have been conducted in specific populations such as male and white or veterans, thus limiting their generalizability. Little is known of the feasibility of delivering tobacco cessation mobile messages for SLT users in LMICs. This exploratory trial aimed to assess the feasibility and acceptability of delivering face-to-face counselling coupled with mobile phone messages to SLT users visiting primary care clinics in India, to inform an effectiveness trial. The specific objectives of this trial were to assess the proportion of primary care attendees approached to participate in the RCT that:

1. Consent to randomisation;
2. when randomised to the intervention comply with it;
3. can be approached at three months after randomisation for follow up data;
4. have data missing on research assessments administered at baseline and three months.

METHODS

Trial design and setting

This study is an exploratory, individual parallel two-group, randomised controlled trial, with baseline and end-point assessments. The study protocol of the CERTAIN (Counselling intErvention foR smokeless Tobacco cessAtion in INdian primary care) trial was published previously[19]. From nine urban primary health centres (UPHCs) approached to take part in the trial, in Berhampur city of Ganjam district of Odisha, two UPHCs were unable to participate due to the COVID-19 pandemic. Due to the pandemic restrictions, the outcomes could not be measured at six months as originally planned and both the intervention and control groups were followed up for three months (end-point).

Trial participants

People visiting the UPHCs were eligible for this trial if they were current (i.e., users in the last three months) SLT or dual users (i.e., smokers and SLT users), ≥18 years, possessed a mobile phone with a valid contact number and offered consent to take part. Those who did not have

the mental capacity to consent, or had an illness limiting their adherence or follow-up in the study were excluded.

Recruitment

Between July and August 2021, patients visiting the UPHCs for treatment were approached and screened by a research co-ordinator. A record of all patients screened was maintained at each UPHC. Those eligible were given a Participant Information Sheet (PIS) with detailed description of the study (a summary of both study groups and expectations for participation) in the local language- Odiya. They were also offered the opportunity to discuss the study with the research co-ordinator. The participant's signature was used to document informed consent. One copy of the PIS and consent sheet was given to the participant and one copy was maintained in their study file. Those participants who consented and underwent the baseline assessment by the research co-ordinator, were then referred for allocation to intervention and control study groups.

Study groups

Control group

Participants in the control group received "routine care" delivered by a PCP at the UPHC over one to two minutes[20,21]. All physicians in India are expected to briefly counsel their patients to quit tobacco. Therefore, routine care would include the treating physician doing the first 2As i.e., 'Ask' and 'Advice'[20] of the 5A's approach[22]. Under 'Ask', the physician asked about consumption of SLT and under 'Advice', the physician provided participants with clear, customised information regarding the advantages of full abstinence.

Intervention group

A single ten-minute face-to-face counselling was delivered by a practice-based counsellor and included brief standardized advice to participants. In addition to 'Ask' and 'Advice', the counselling also included the other components of the 5As approach i.e., 'Assess' their willingness to 'quit now'; 'Assist' them by providing behavioural support for cessation and/or

prescribing pharmacotherapy (wherever required); and 'Arrange' a follow-up visit to review progress and support cessation efforts. This was followed by mobile phone messages that included an initial welcome message encouraging participants to stop using tobacco after 48 hours of having received the counselling. This was followed by messages delivered three times/week over the next three months. Each follow-up message included behavioural support for quitting; information about the health hazards of tobacco use, and benefits of quitting, and coping strategies for withdrawal symptoms[23]. The messages were developed from formative research work[23] and based on the Trans theoretical model (TTM)[24]. The messages were tailored according to the stage of change of each user. A total of 36 messages were sent of which 20 were text, eight were audio, and pictorial each.

Outcomes

The primary outcomes included:

1. Proportion of SLT users approached, consenting to be randomised.
2. Proportion of randomised SLT users adhering to the intervention.
3. Proportion of SLT users on whom follow-up data was collected at three months.

We also assessed the feasibility of collecting the primary outcomes to be used in the main trial. They were included as the secondary outcomes of this trial below:

1. 'Self-reported tobacco abstinence' at seven days verified by a salivary cotinine test
2. Self-reported motivation and intention to quit
3. Resource use and costs to be used in an economic evaluation in a full trial

At baseline, socio-demographic details such as age, gender, educational level, and economic status were recorded. Variables related to tobacco consumption including the status of tobacco use, data on quit attempts, and challenges were collected at baseline and at end-point on paper by trained investigators who remained blinded to the group assignment. The data was monitored by a supervisor and inconsistencies in the data were resolved by verification with the participants. The data was entered in a database developed in MS Access

(Microsoft Office 2019) with a time-stamped audit trail that recorded entries, modifications, and deletions in the records.

Self-reported tobacco abstinence was recorded using the question "What is the longest period of time you have quit and remained tobacco-free?". Salivary cotinine was used to validate the self-reported tobacco abstinence at end-point. Participants in the intervention and control groups were approached to provide a sample of saliva which was collected through passive drooling. Collection, transportation, and disposition of the biological samples and the kit were handled by the research team at each study site. A visual interpretation of colour developed on the rapid test kit (cotinine ≥50ng/ml) was considered a confirmation of tobacco abstinence.

Sample size

Based on the primary outcomes of recruitment and attrition to this exploratory trial, 250 participants (125 participants per group) were required to estimate an anticipated proportion of 50% recruitment of participants with a 95% CI of 44% to 57% and 20% attrition at follow-up with a 95% CI of 15% to 25%. The sample size was calculated based on estimating proportions with a specified level of precision as measured by the width of the 95% CI using the Sample Size Tables for Clinical Studies software[25].

Randomisation

Randomisation was stratified by practice site (UPHCs) using random permuted blocks of varying block sizes from 4 to 10. A 1:1 allocation of individual participants to the intervention or control group was done by an independent statistician who was not involved with the core research group. This list was then mailed to an independent staff member employed by the implementation partner- MKCG Medical College, Berhampur, Odisha. The independent staff member after receiving the randomisation numbers from UCL assigned a unique identification number to each of the consented participants and maintained a list of those participants allocated to the respective study groups. This list was sent to a randomisation co-ordinator who was not part of the core research team in India. The core research team in India and UK were masked to allocation of study groups and outcome measurements.

Data analysis

Statistical analysis

Participant characteristics were summarised using mean and standard deviation (SD) or median and interquartile range for continuous variables, and number & percentages for the categorical variables. The proportion recruited and lost to follow-up were estimated with 95% confidence intervals (CI). The extent of missing data for each variable and the percentage of participants adhering to the intervention were reported. Attrition levels by randomised group and the characteristics of participants lost to follow-up were also reported. As part of the secondary analyses logistic regression models were used to estimate the intervention effects with 95% CI for tobacco abstinence, and self-reported motivation and intention to quit after adjusting for the stratification factor (UPHC) and baseline values of the outcome, when available. Kappa statistics were computed to examine the agreement between the salivary cotinine test and self-reported abstinence. The secondary outcomes analyses were done on an intention to treat (participants as randomised with available outcome data) basis. All analyses were done using STATA software version 17 (StataCorp. 2019. Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC).

Economic evaluation

The intervention was costed based on information provided by the trial team, excluding research related costs. Health care resource use was costed based on a published micro-costing of health care services in the North of India[26]. All costs are reported in Rupees (1 Rupee is equal to 0.012 United States Dollars). Regression analysis adjusting for baseline was used to estimate the mean incremental difference in costs between intervention and control groups.

RESULTS

The characteristics of the participants such as tobacco use and quit attempts by treatment group were balanced at baseline (Table 1). Figure 1 (CONSORT diagram) details the flow of participants through the trial.

The characteristics of the participants were: average age 47.2 (SD 14.4) years; gender (male 73% versus female 27%); over quarter with no formal education and 175 (70%) above the poverty line[27]. The mean age of using tobacco for the first time was 26.3 years (SD 12.2). One in five, 56 (23%), had attempted to quit in the last 12 months. Only nine (3.6%) reported having ever received counselling, NRT, prescription medicine, traditional medicine and telephone support. More than half, 137 (55%) had qwerty phones whereas the rest 113 (45%) had smartphones.

Primary outcomes

1. Recruitment

   i) Primary care centres: A total of nine UPHCs were approached to take part and seven (77.8%) agreed.

   ii) SLT users: We approached 315 eligible participants and 250 SLT users consented, achieving a recruitment rate of 79.4% (95% CI: 74.5, 83.7). The 65 eligible participants who declined to participate cited reasons such as disinterest, no permanent mobile number due to migration, and busy work schedules.

2. Compliance

Compliance data was obtained from 116 (93%) of the 125 participants of the intervention group. In total 109 (94%) participants received some mobile phone messages on quitting tobacco (a combination of text, pictorial, and audio). Out of these 109, 74 participants (63.8%) received all the 36 messages. An additional, 35 (30.2%) participants received some of the messages. 12% of the 30.2% did not receive audio and pictorial messages. Seven (6%) participants were unsure. Of the 74 (63.8%) participants that reported they received the messages, 15 (20.3%) were abstinent at three months as measured using the salivary cotinine. Similarly, of the 42 (36.2%) participants who reported that either they did not receive the message or didn't know, seven (16.7%) were abstinent at three months as measured using the salivary cotinine

3. Follow-up rate

Out of the 250 randomised, 238, 95% (95% CI: 91.8, 97.5) were followed through at three months (117 in the intervention group and 121 in the control group).

4. Missing data

Follow up data at three months could not be collected from 12 (eight in the intervention and four in the control group) participants (4.8%, 95% CI: 2.5, 8.2).

Secondary outcomes:

1. Self-reported tobacco abstinence confirmed by a salivary cotinine test

At the end-point, 238 out of 250 participants (95%) provided consent and saliva sample for biochemical verification of tobacco abstinence. Forty (17%) participants tested negative for salivary cotinine, of which 22 (18.8%; 95% CI: 11.7, 25.9) were in intervention and 18 (14.9%; 95% CI: 8.5, 21.2) in the control group. The difference in the proportions between the groups was found to be 3.9% (95% CI: -5.6, 13.4).

Seventy-one (31.2%) reported being tobacco-free for at least a week at follow up, of which 33 (29.7%) were in the intervention group and 38 (32.7%) were in the control group (Table 2). However, 10/71 (14.1%) indicated that they were abstinent for more than three months (i.e., the time of recruitment to the study), of which three (2.7%) were in the intervention and seven (6%) were in the control group. More than three-fourth of the participants, 198 (83%) said that they had decreased tobacco use after their last counselling session, of which 91 (77.8%) were in the intervention and 108 (88.4%) were in the control group. The two most common reasons reported for quitting or decreasing tobacco consumption were tobacco use may damage health (123 (51%)) and physician's advice (99 (42%)).

Tobacco abstinence measured using the salivary cotinine showed a trend towards abstinence in the intervention group (OR 1.33, 95% CI: 0.67, 2.62; p=0.419). However, based on self-reported abstinence, those in the intervention group had a lower trend towards abstinence (OR 0.87, 95% CI: 0.49, 1.52; p=0.623) (Table 3). There was 73% observed agreement

between the self-reported question and the salivary cotinine test and the Cohen's kappa agreement was 0.291.

2. Self-reported motivation and intention to quit

At three months follow up, it was found that the majority of participants, 152 (64%) were willing to quit tobacco in the next 30 days, of which 68 (58%) were in the intervention group and 84 (70%) were in the control group. Of the 85 (36%) who were not willing to quit in the next 30 days, 61 (72%) were willing to quit in the next three months, of which 33 (67.3%) were in the intervention group and 28 (77.8%) were in the control group.

Regression analyses indicated a reduced trend in the intervention group's willingness to quit in 30 days (OR 0.61; 95% CI: 0.35, 1.04; p=0.071) and willingness to quit in the next three months (OR 0.45; 95% CI: 0.19, 1.10; p=0.080) (Supplementary material, Table 1).

Participant experiences of the intervention

From a total of 117 participants in the intervention group, 116 completed the supplementary questionnaire documenting their experience of receiving the intervention (Supplementary Material, Table 2). The majority 111 (97%) had never received mobile tobacco cessation messages in the past. Of those participants who received the intervention, 63 (55%) found the messaging useful and easy to understand. A question regarding the reasons for participation in the intervention where multiple responses were allowed identified that the three main reasons were on account of physician advice (81 (70%)), counsellor advice (56 (48%)), and family suggestions (26 (22%)). Sixty-six (58%) said they will use mobile phone-based tobacco cessation in the future and 75 (65%) said they would recommend it to others.

Cost of the intervention

Detailed information on the cost of the intervention is reported in the Supplementary Material, Table 3. The intervention cost 1230 Rupees ($14.76) per participant for ongoing costs, including physician training, if the intervention were to be rolled out in new areas. Fixed sunk

costs, costs that are unlikely to be incurred again as part of the intervention, such as development of the intervention, was 2798 Rupees ($33.58) per participant.

Wider health care costs

Descriptive statistics for the health care resource use and costs are reported in the Supplementary Material, Tables 4, 5. Overall, there was little missing data in completing the questions, with the most of missing data due to loss to follow-up. The mean total health care cost was 355 Rupees (SD 527) ($4.26) per participant in the intervention group and 263 Rupees (SD 453) ($3.16) per participant in the control group, with out-of-pocket costs, costs incurred directly by participants, making up the majority of the costs. After adjusting for baseline imbalances, the mean incremental cost of the intervention compared to control group was 75 Rupees (95% CI: 48, 201) ($0.90) excluding the cost of the intervention.

DISCUSSION

This is the first study to establish the feasibility and acceptability of a complex intervention of face-to-face counselling coupled with mobile messaging for SLT users visiting primary health care settings in India. We recruited 250 SLT users from seven UPHCs over three weeks in 2021. Our findings highlight that this intervention was well rated by the participants who received it and the trial was feasible in terms of recruitment (79.4%), compliance with the intervention (63.8%), and retention within the trial (95%) at three months. There was negligible missing data at baseline and end-point. This included data on measures of health care resource use.

Seven out of nine UPHCs participated in the study, indicating that SLT cessation was a priority for both, clinicians as well as health program managers. The identification and selection of SLT users by a screening process was simple and fast, which helped achieve a high recruitment rate. We achieved a high follow-up by making a maximum of five telephone call reminders from the Urban Primary Health Centres (UPHC) to each participant asking them to visit the UPHC. No payment for participation was provided to the participant. We compensated

the participant for their time and travel in the form of 100 Rupees ($1.20). Other factors contributing to the high recruitment and retention rates were the strong partnerships with the local teaching hospital and training and advocacy with physicians and counsellors working in the UPHCs.

The study was designed to assess feasibility and not powered for assessing tobacco cessation. The biochemically verified SLT abstinence rate in our trial showed a trend towards the intervention group (18.8%) compared with the control group (14.9%). Various measures are used to ascertain tobacco abstinence in clinical and epidemiological practice. Biochemical verification of tobacco use through cotinine a major metabolite of nicotine, in saliva, urine or blood increases scientific rigor and is recommended in clinical trials of tobacco cessation[28,29]. There was poor agreement between self-reported tobacco cessation and the measured salivary cotinine of just under 0.3 Cohen's kappa. Other studies from India have reported mixed results on the agreement between self-reported and biochemically verified tobacco abstinence[30–32] with one study indicating a poor sensitivity of 36% and a positive predictive value of 73% for self-report of tobacco abstinence[31]. A review of several multisite smoking cessation RCTs conducted on hospital patients in the USA also reported high rates (40%) of failed biochemical verification of self-reported abstinence[33]. Based on our findings, the self-report in this Indian population would suggest the need to adopt solely salivary cotinine as a more accurate outcome in future clinical trials on tobacco cessation.

Competitive sales have reduced the costs of mobile phones, making it accessible and affordable for even low-income populations in LMICs. In this study, 45% of participants had smartphones and the rest 55% had qwerty phones. In 2015, the Government of India had initiated an "mCessation" service (MCS) in which text messages were used for motivating and supporting tobacco users to quit. Lack of awareness of this service resulted in a low enrolment (only 2.1 million of 275 million tobacco users registered as of 2019)[34,35]. We found that 97% of the participants in the intervention group in our study had never heard or been offered mobile phone-based counselling for tobacco cessation. The MCS is available in the Hindi and English

languages and therefore its reach is limited for regional language populations. The beneficiaries need to register to avail the MCS thus making it a requirement to having a preexisting intention to quit tobacco. Since the MCS includes only text messages, the ability to read is an important pre-cursor to utilise this service. We, therefore, developed the mobile messages and did not use the existing MCS for the intervention group

In our study out of the 116 intervention group participants who responded to the questionnaire commenting on the intervention they received, the majority of 74 (63.8%) participants reported that they had received all the mobile messages. Studies in India have documented various challenges in mobile-based interventions which have included financial burden of receiving text messages, fatigue[36] and connectivity issues[37]. This can be one of the main challenges for ensuring compliance with the intervention

Most participants reported that the prime motivation for participation was the advice of the physician or the counsellor. Another study in a primary healthcare facility in Delhi, found that a brief two-minute behavioural intervention by a physician significantly promoted participation in the mCessation service among male adult tobacco users[38]. At the end-point of this study, the participants reported that the two main reasons for quitting or decreasing their SLT use was advice from physicians or being counselled that tobacco may damage their health. Currently only 20% of SLT users in Odisha are being asked to quit by their health care providers[5]. Interventions that built capacity in primary care can substantially improve quit rates[10]. In the absence of a tobacco cessation intervention, only 7% of SLT users in Odisha reported that they were planning to quit within the next 30 days[5]. We found that in the intervention group, 58% of participants were willing to quit SLT in the next 30 days. A behavioural interventional study in 2017 conducted in Rajasthan and Odisha found higher odds of intention to quit (OR 3.06; 95% CI: 1.35, 6.98) amongst SLT users in the intervention group than in the control[40]. Our study has suggested that cessation rates can be improved by the use of mobile phone messages.

Our study has shown that it is feasible to collect health care resource use data as part of the trial for the purposes of an economic evaluation alongside an RCT, noting that a large majority are out-of-pocket costs. Whether it is possible to project outcomes beyond the duration of the trial to estimate the long-term health impact is unclear. There is a significant risk of oral cancer in particular due to SLT[41], but the reduction in risk of oral cancer following a SLT quit intervention is difficult to quantify in the absence of data. The cost of the intervention at 1230 Rupees ($14.76) per participant is quite high, but would reduce significantly with a larger number of people using the intervention as the costs can be spread over more people.

Strengths and Limitations

The strengths of this study include the successful recruitment and follow-up of SLT users. The study also supported the use of biochemical verification of self-reported abstinence outcomes, consistent with other studies[30]. Limitations of this study include lack of data on the number of users ineligible to participate in the trial according to each eligibility criterion. Second, we do not have data on exact levels of non-compliance with the mobile message intervention i.e., what type of messages (text, audio, or pictorial) were not received by 30.2% participants. Third, we did not capture information regarding message fatigue or the financial burden of receiving mobile messages. There is a dearth of high-quality unit costs for health care services in India. Lastly, we considered this intervention of counselling and mobile messages to be a very low risk and did not specifically set out to assess safety or adverse events.

CONCLUSION

This feasibility trial successfully recruited most of the primary care sites that were approached to participate. It achieved the target sample and was able to randomise and follow-up participants across intervention and control groups with negligible missing data on all research outcomes. Further research is needed to understand the challenges associated with receiving mobile messages.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ACKNOWLEDGEMENTS

The authors wish to thank Dr Sithun Kumar Patro and senior residents of MKCG Medical College for their dedication in collecting data and appropriate follow-up of patients.

CONFLICT OF INTERESTS

None declared.

ETHICAL CONSIDERATION

Ethics approval was obtained from the Institutional Ethical Committee at Public Health Foundation of India (PHFI) (ref: TRC-IEC-391/19; dated May 29, 2019). At the national level, ethical clearance was obtained from the Health Ministry's Screening Committee (HMSC), led by the Indian Council of Medical Research (ICMR) (ref: 2019-3581; dated December 11, 2019). Also, local level approval was obtained from the Odisha State Ethics Board (ref: 191/PMU/187/17; dated November 14, 2019). In the UK, ethical clearance was obtained by the UCL Research Ethics Committee (ref: 5686/001, dated October 1, 2019). The study was registered at Clinical Trials Registry India (reference number CTRI/2019/05/019484) dated May 31, 2019. All the participants (participating in both the phases in this study) were provided with a participant information sheet (PIS), providing details of the study. Following this, voluntary written consent for participation were taken from them (Appendix B) All the data that was collected for the study was stripped of any personal identifiers and the data was stored in PHFI's data repository. The data was only accessible to the principal investigator and trial team analysing the data. To ensure confidentiality, data shared to project team members was blinded for any identifying participant information.

FUNDING

Research reported in this publication was funded by the Department of Health and Social Care (DHSC), the Foreign, Commonwealth & Development Office (FCDO), the Medical Research

Council (MRC) and Wellcome Joint Global Health Trials Initiative (ref: MR/P021166/1). This research work is sponsored by University College London, Gower Street, London, WC1E 6BT, UK. IN was in receipt of the grant.

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Tables

Table 1. Demographic characteristics of tobacco users

Characteristics*	**Control (n=125)**	**Intervention (n=125)**	**Total (n=250)**
Age (years), mean (SD)	46.9 (14.7)	47.5 (14.1)	47.2 (14.4)
Gender			
Male	88(70.4)	93(75.0)	181 (72.7)
Female	37 (29.6)	31 (25.0)	68 (27.3)
Education			
No Formal Schooling	35(28.0)	33(26.6)	68(27.3)
Primary Schooling or less	40(32)	36(29.1)	76(30.5)
Secondary Schooling and above	50(40)	55(44.4)	105(42.1)
Place of Residence			
Rural Area	8 (6.4)	3(2.4)	11(4.4)
Urban/Semi Urban Area	117(93.6)	121(97.6)	238(95.6)
Economic status			
Above Poverty Line	38(30.4)	37(29.6)	75(30.0)
Below Poverty Line	87(69.6)	88(70.4)	175(70.0)
Type of tobacco use			
Smokeless	122(97.6)	123(98.4)	245(98.0)
Both (smoking and smokeless)	3(2.4)	2(1.6)	5(2.0)
Age at first tobacco use (years), mean (SD)	27.8 (12.9)	24.8(11.3)	26.3(12.2)
Number of quit attempts during the past 12 months			
0	94(75.8)	99(79.2)	193(77.5)
1 to 5	27(21.8)	24(19.2)	51(20.5)
5 to 10	1(0.8)	2(1.6)	3(1.2)
>10	2(1.6)	0(0.0)	2(0.8)
Use of counselling, including at a smoking cessation clinic			
Yes	1(0.8)	0(0.0)	1(0.4)
No	124(99.2)	122(100.0)	246(99.6)
Use of nicotine replacement therapy (NRT), such as the gum			
Yes	0(0.0)	1(0.8)	1(0.4)
No	125(100.0)	121(99.2)	246(99.6)
Use of other prescription medications, for example Bupropion			
Yes	1(0.8)	0(0.0)	1(0.4)
No	124(99.2)	122(100.0)	246(99.6)
Use of traditional medicines			
Yes	3(2.4)	3(2.5)	6(2.4)
No	122(97.6)	119(97.5)	241(97.6)
Use of a cessation or an anti-tobacco telephone support line			
No	125(100.0)	122(100.0)	247(100.0)
*n (%) unless specified otherwise			

Table 2. Tobacco use outcome measures at three months

Indicators*	**Treatment**					
	Control n =121		**Intervention n = 117**		**Total n = 238**	
Salivary Cotinine Test Result						
Positive (cotinine detected)	103	(85.1)	95	(81.2)	198	(83.2)
Negative (insufficient detected)	18	(14.9)	22	(18.8)	40	(16.8)
Remained tobacco-free in the past 3 months (n=227)						
Less than 24 hours	42	(36.2)	49	(44.1)	91	(40.1)
24 hours	17	(14.7)	7	(6.3)	24	(10.6)
2 – 6 days	19	(16.4)	22	(19.8)	41	(18.1)
7 days / a week	11	(9.5)	12	(10.8)	23	(10.1)
8 – 30 days	12	(10.3)	6	(5.4)	18	(7.9)
Between 1 month and 3 months	8	(6.9)	12	(10.8)	20	(8.8)
More than 3 months	7	(6.0)	3	(2.7)	10	(4.4)
Decreased tobacco use since last counselling						
Yes	107	(88.4)	91	(77.8)	198	(83.2)
No	14	(11.6)	26	(22.2)	40	(16.8)
Experience any withdrawal symptoms						
Yes	18	(14.9)	25	(21.4)	43	(18.1)
No	102	(84.3)	92	(78.6)	194	(81.5)
Refused	1	(0.8)	0	(0.0)	1	(0.4)
Reasons for quitting/decreasing use						
Tobacco use might damage my health	64	(52.9)	59	(50.4)	123	(51.7)
Fewer places now where smokeless is permitted	7	(5.8)	5	(4.3)	12	(5)
Ads about the health risks of tobacco made me stop	9	(7.4)	9	(7.7)	18	(7.6)
Warning labels on tobacco packet made me stop	5	(4.1)	4	(3.4)	9	(3.8)
Example for children by quitting tobacco use	1	(0.8)	4	(3.4)	5	(2.1)
Close friends and family members	48	(39.7)	43	(36.8)	91	(38.2)
Disapproved of my tobacco use habits	11	(9.1)	12	(10.3)	23	(9.7)
Advised by a doctor to quit tobacco use	52	(43)	47	(40.2)	99	(41.6)
Advised received through mobile health counselling	25	(2x0.7)	33	(28.2)	58	(24.4)
Willingness to quit tobacco in the next 30 days						
Yes	84	(70.0)	68	(58.1)	152	(64.1)
No	36	(30.0)	49	(41.9)	85	(35.9)
Willingness to quit tobacco in the next 3 months						
Yes	28	(77.8)	33	(67.3)	61	(71.8)
No	8	(22.2)	16	(32.7)	24	(28.2)
*n (%) unless specified otherwise						

Table 3. Logistic regression models for tobacco abstinence

Indicator	Odds Ratio	95% Confidence Interval
Self-reported abstinence	0.87	(0.49, 1.52)
Salivary cotinine results	1.33	(0.67, 2.62)

Table 4. Logistic regression models for willingness to quit

Indicator	Odds Ratio	95% Confidence Interval
Willing to quit in 30 days	0.61	(0.35, 1.04)
Willing to quit in three months	0.45	(0.19, 1.10)

Figure 1. CONSORT Diagram

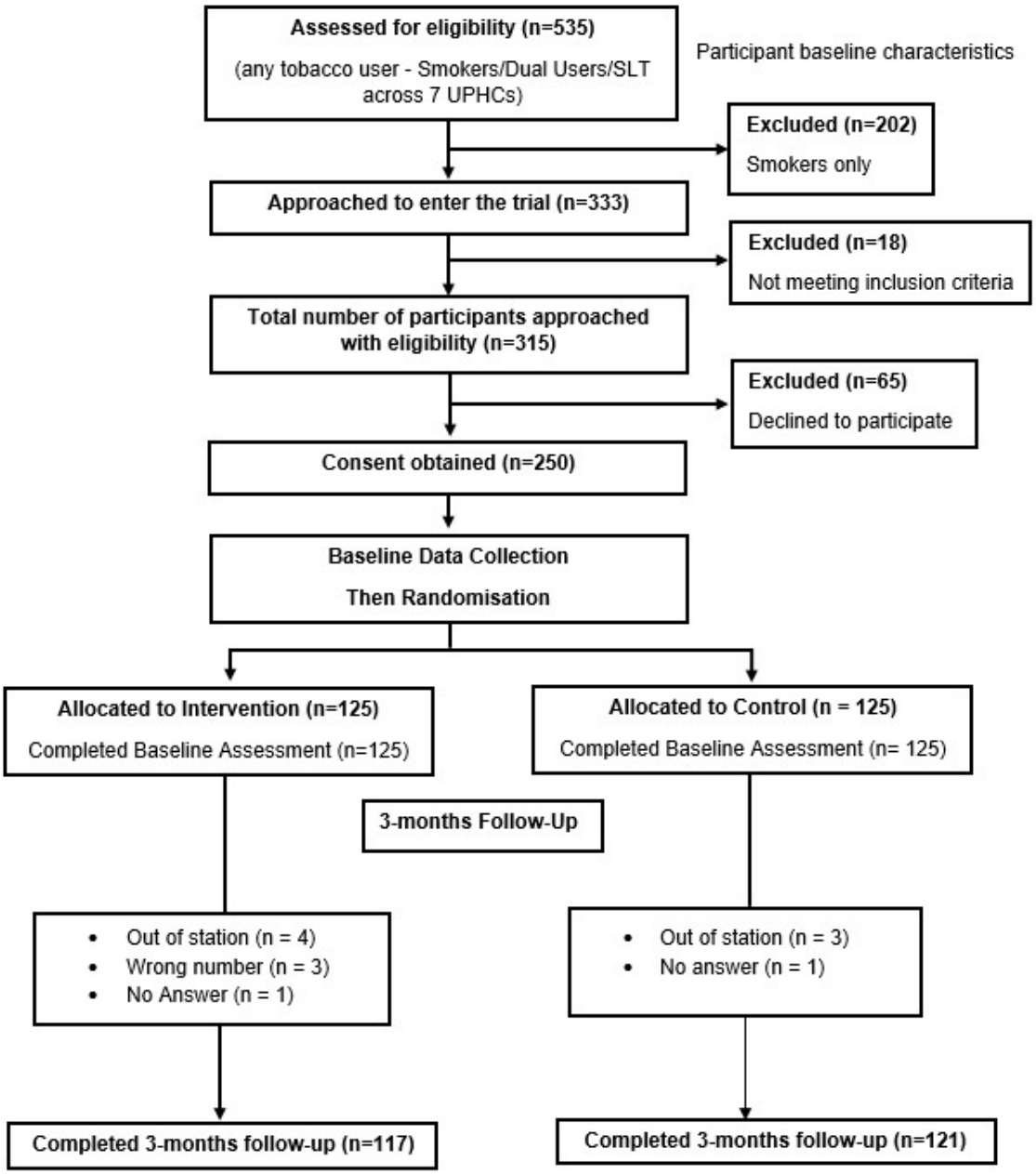

FIGURE LEGEND

Figure 1. CONSORT flow diagram showing participant flow through each stage of the exploratory randomized controlled trial (eligibility, enrolment, intervention allocation, and follow-up).

Supplementary Tables

Supplementary Material Table 1. Logistic regression models for willingness to quit

Indicator	Odds Ratio	95% Confidence Interval
Willing to quit in 30 days	0.61	(0.35, 1.04)
Willing to quit in three months	0.45	(0.19, 1.10)

Supplementary Material Table 2. Experiences of the intervention

Indicators	**(n=116)**	
	N (%)	
Compliance with the intervention		
Yes	74	(63.8)
No	35	(30.2)
Don't Know	7	(6.0)
Frequency of calls and messages adequate		
Yes	57	(49.1)
No	35	(30.2)
Don't Know	19	(16.4)
Refused	5	(4.3)
Motivated you to quit tobacco?		
Yes	59	(50.9)
No	38	(32.8)
Don't Know	10	(8.6)
Refused	9	(7.8)
Easy to understand?		
Yes	63	(54.8)
No	35	(30.4)
Don't Know	13	(11.3)
Refused	4	(3.5)
Useful?		
Yes	64	(55.2)
No	34	(29.3)
Don't Know	14	(12.1)
Refused	4	(3.4)
Relevant to your condition?		
Yes	59	(50.9)
No	34	(29.3)
Don't Know	17	(14.7)
Refused	6	(5.2)
Duration of messages adequate?		
Yes	49	(42.2)
No	37	(31.9)
Don't Know	18	(15.5)
Refused	12	(10.3)
Recommend to others?		
Yes	75	(64.7)
No	23	(19.8)
Don't Know	16	(13.8)
Refused	2	(1.7)
Cause any inconvenience?		
Yes	15	(13.2)
No	87	(76.3)
Don't Know	5	(4.4)
Refused	7	(6.1)
Subscribe to mobile phone-based counselling in future?		
Yes	66	(57.9)
No	42	(36.8)
Don't Know	5	(4.4)
Refused	1	(0.9)

Part of mobile phone-based counselling in the past?		
Yes	4	(3.5)
No	111	(96.5)
Motivation to participate in the intervention		
Doctor's Advice	81	(69.8)
Counsellor’s Advice	56	(48.3)
I wanted to quit tobacco	22	(19)
Interesting/Innovative Concept	3	(2.6)
Family pressure/suggestion	26	(22.4)
Friends Advice	6	(5.2)
Past/Current recipient	1	(0.9)
Prefer mobile calls or mobile messages?		
Mobile Calls	36	(32.1)
Mobile Messages	37	(33.0)
Both	25	(22.3)
Don't Know	11	(9.8)
Refused	3	(2.7)
Prefer mobile phone over face-to-face counselling?		
Yes	30	(29.7)
No	71	(70.3)
Overall satisfaction		
Satisfied	96	(86.5)
Not Satisfied	2	(1.8)
Uncertain	13	(11.7)

Supplementary Material Table 3. Cost of the intervention in Rupees.

Activity	Total cost in Rupees	Cost per participant (n=125)
Fixed sunk costs		
Cost of flipbook for face-to-face intervention	104,760	
Development of mobile text messages	110,000	
Cost of development of mobile message application	135,000	
Total fixed sunk costs	349,760	2798
Ongoing costs		
Training for 12 primary care physicians and 25 counsellors.	50,000	
Counsellor delivering 10 minute face-to-face intervention	12,500	
Server cost	41,470	
Cost of recharging the messaging pack	49,792	
Total ongoing costs	153,762	1230
Total all costs	503,522	4,028

Supplementary Material Table 4. Health care resource use – percentage who used the resource

	Control				Treatment			
	n=125				n=125			
	n	%	missing - n	%	n	%	missing - n	%
Counselling								
Baseline	1	1%	0	0%	0	0%	3	2%
3 months	1	1%	4	3%	9	8%	8	6%
Nicotine replacement								
Baseline	0	0%	0	0%	1	1%	3	2%
3 months	2	2%	4	3%	1	1%	8	6%
Other prescription medications								
Baseline	1	1%	0	0%	0	0%	3	2%
3 months	0	0%	4	3%	0	0%	8	6%
Traditional Medicines								
Baseline	3	2%	0	0%	3	2%	3	2%
3 months	6	5%	4	3%	10	9%	8	6%
Cessation telephone line support								
Baseline	0	0%	0	0%	0	0%	3	2%
3 months	0	0%	4	3%	0	0%	8	6%
Other								
Baseline	8	6%	0	0%	9	7%	3	2%
3 months	5	4%	4	3%	5	4%	8	6%
Community Health Worker								
Baseline	20	16%	0	0%	24	19%	1	1%
3 months	3	2%	4	3%	9	8%	8	6%
Outpatient - PHC								
Baseline	37	30%	0	0%	42	34%	1	1%
3 months	44	36%	4	3%	59	50%	8	6%
Dental								
Baseline	4	3%	1	1%	7	6%	0	0%
3 months	7	6%	4	3%	8	7%	8	6%
Outpatient - CHC								
Baseline	5	4%	0	0%	7	6%	0	0%
3 months	5	4%	5	4%	2	2%	8	6%
Outpatient - District Hospital								
Baseline	11	9%	0	0%	9	7%	1	1%
3 months	9	8%	11	9%	14	13%	18	14%
Inpatient								
Baseline	1	1%	0	0%	1	1%	0	0%
3 months	0	0%	4	3%	0	0%	8	6%

Out of pocket expenditure for health care								
Baseline	8	6%	0	0%	17	14%	0	0%
3 months	26	21%	4	3%	28	24%	8	6%
Travel costs								
Baseline	4	3%	0	0%	4	3%	0	0%
3 months	9	7%	4	3%	4	3%	8	6%

Supplementary Material Table 5. Health care resource use – cost in Rupees.

	Control			Treatment		
	n=125			n=125		
	n	mean	SD	n	mean	SD
Community Health Worker						
Baseline	20	2.6	2	24	2.7	1.9
3 months	3	1	0	9	1.1	0.3
Outpatient - PHC						
Baseline	37	2.4	1.6	42	4.2	1.6
3 months	44	2.2	0.97	59	2.1	1.1
Dental						
Baseline	4	1.5	1	7	1.14	0.4
3 months	7	1.7	1.3	8	1.3	0.7
Outpatient - CHC						
Baseline	5	2	1	4	2.7	1.1
3 months	5	1.7	0.9	2	2	1.4
Outpatient - District Hospital						
Baseline	11	1.5	0.7	9	2	1.7
3 months	9	1.3	0.7	14	1.5	1.2
Total Health Care cost						
Baseline	125	167	326	125	240	524
3 months	121	155	234	117	202	249
Out of pocket costs						
Dental						
Baseline	0	0	0	2	3000	2828
3 months	1	400		3	183	28
Medication						
Baseline	8	1271	1615	13	1283	1898
3 months	25	463	386	27	626	534
Travel						
Baseline	4	90	74	3	60	40
3 months	9	123	57	4	108	65
Total out of pocket costs						
Baseline	125	105	269	125	143	368
3 months	121	109	273	117	153	378
Total combined costs						
Baseline	125	252	614	125	424	1236
3 months	121	263	453	117	355	527

* Mean for only those that used the resource.

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4-5
	2b	Specific objectives or research questions for pilot trial	5
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	5, 8
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	5, 6
	4b	Settings and locations where the data were collected	5,6
	4c	How participants were identified and consented	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6,7
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	7,8

	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	5
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	
Sample size	7a	Rationale for numbers in the pilot trial	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8,9
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8,6,9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	8,9
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	9, 10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Figure 1 10, 11
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1

Recruitment	14a	Dates defining the periods of recruitment and follow-up	5,6
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	10,11
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	10,11,12,13
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	16,17
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	13-16
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	17
Protocol	24	Where the pilot trial protocol can be accessed, if available	5, Reference no. 19

Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	17
	26	Ethical approval or approval by research review committee, confirmed with reference number	16, 17

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see www.consort-statement.org.