

Challenges and Opportunities for Smokeless Tobacco Cessation During Covid 19: learnings from a Feasibility trial in India

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Abstract:

The use of smokeless tobacco (SLT) is detrimental at any time, however, its usage during Covid 19 has proved to be more harmful in increasing the spread of the virus. The pandemic has also affected the efforts that were being made for SLT cessation. Understanding the various challenges and facilitating factors of smokeless tobacco cessation during the pandemic is imperative. This paper highlights the key challenges and opportunities of implementing a feasibility trial on SLT cessation amidst Covid 19 in India.

Keywords: Smokeless tobacco; Covid 19; cessation, feasibility trial; opportunities; and challenges

1. Introduction

As per the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA) under the Centre for Disease Control and Prevention (CDC), Smokeless Tobacco is defined as “any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity.” A wide range of products such as naswar, gutkha, khaini, zarda, mainpuri and betel quid is common in South and Southeast Asia, which may either be prepared commercially or at home¹. Concerns have been raised for SLT control and there is a need of developing an integrated policy, including cessation service⁴.

1.1 Smokeless tobacco cessation trial

A feasibility SLT cessation trial was conducted in the urban settings of India in parallel with Bangladesh and Pakistan under the project ASTRA (Addressing Smokeless Tobacco and Building Research Capacity in South Asia)⁵. The trial is funded by the National Institute of Health Research, U.K. It has been implemented to explore and demonstrate the feasibility of delivering pharmacological and behaviour intervention for SLT cessation.

2 Methods

The trial was conducted at the National Institute of Cancer Prevention and Research (NICPR), Noida, India. Besides providing specialized diagnostic referral services, the Institute aims to undertake research for the development of preventive and therapeutic approaches for the diagnosis of cancer in community settings. The primary objectives involved (Recruitment, randomisation and retention) in which exclusive SLT usage age above 18

years was recruited and then followed up for SLT cessation at 6, 12 and 26 weeks.

The study was conducted to demonstrate the feasibility of delivering a combination of interventions including behavioural Change Intervention for SLT Cessation and Nicotine Replacement Therapy alone and in combination and very brief advice.

2.2 Intervention timeline

The initial screening was started in January-March 2020 (Figure 1) to enrol the exclusive SLT users at the National Institute of Cancer Prevention and Research, Indian Council of Medical Research located in Delhi National Capital Region, Noida, India. The SLT users who agreed to participate could not enrol themselves at the facility due to the Covid-19 preventive lockdown initiated on March 23, 2020, across the country. Therefore, these SLT users were contacted again in September 2020 for their willingness to participate but due to a huge gap in time, migration of participants and other reasons, the screening for trial participation was restarted in the last week of Sept 2020. Information regarding the clients visiting the facility was gathered again, afresh. The 6th and 12th-week follow-ups were done in the month of November and December 2020, respectively. The 26th-week follow-ups were scheduled in April 2021 which got further delayed due to the second wave and second state-wise lockdown. The 26th-week follow-ups were then done over calls in April-June 2021 whereas the final assessment including saliva samples was collected in August 2021 when the second lockdown got over.

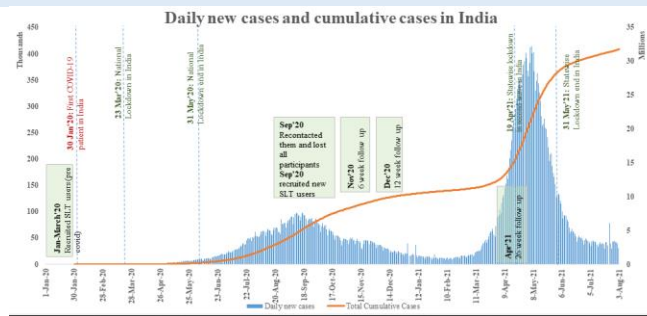


Figure 1: Daily new cases and cumulative cases in India

2.3 Recruitment, Randomisation and Response rate of the study

A total of 126 participants were screened to find 44 exclusive SLT users wherein 62.7 % (n=79) were found ineligible to meet the exclusion criteria. Seven per cent (n=3) did not provide their consent. A total of 44 clients was further randomised into 4 arms (11 in each arm). Out of the 44 eligible exclusive SLT users, Males (n=35) and females (n=9) exclusive SLT users were included, and the response rate was good; ranging from 95 % (n= 42) while implementing the intervention and 4.5 % (n=2) dropping out of the study by their choice and their unavailability. Most of the participants were studied up to secondary education and graduation and were working as daily wagers, and skilled labours including tailors, drivers and caddies.

As a part of the intervention, treatment was divided into four arms.

Arm1: (Very brief advice + Self-help material)/2-3 min counselling

Arm 2: Nicotine Replacement Therapy + Very brief advice + Self-help material

Arm 3: Behaviour Change Intervention for SLT Cessation + Very brief advice +Self-help material

Arm 4: Behaviour Change Intervention for SLT Cessation + Nicotine Replacement Therapy

Implications of the study: The study was conducted to assess the impact of the pandemic on the implementation of an SLT cessation trial in India. This paper provides unique insights into the challenges of this trial and presents viable solutions to ease the conduct of trials during the current Covid-19 pandemic and future preparedness. While considering future pandemic preparedness, we need a coordinated strategy to have realistic, investigator-led clinical trials. Flexibilities are required in terms of travel barriers to adhering to compliance and trial conduct. We need to rely more on virtual conversations which can be monitored through online support to ensure fidelity to the intervention protocol.

3. Results

Covid -19 has brought many challenges in the implementation of SLT cessation i.e., constraints related to recruitment, intervention, issues with SLT users, delayed follow-ups, relapse due to external advice and loss of follow-ups. Besides all the challenges Covid 19 has also been seen as an opportunity in intensifying the knowledge related to the adverse health impact of SLT and the benefits of quitting.

1. Challenges in recruitment

The recruitment process was delayed due to the stringent lockdown in India. To convince the SLT users to participate in the trial was one of the most challenging tasks. Though Carbon monoxide (CO) monitoring was done to exclude smokers, identifying the exclusive SLT users was challenging as most of them were found to be smoking in combination with using SLT. Residents of Other states (Migrants) visiting their family for temporary stay could not be enrolled. SLT users who used to visit their hometown for a

longer duration were excluded from the trial to adhere to the protocol timeline.

2. Challenges related to delivering SLT cessation intervention

Taking saliva samples during the peak in the number of daily Covid cases (Sept 2020) was difficult and clients were reluctant to give saliva samples due to the fear of getting infected. Study participants were then ensured of following Covid appropriate behaviour to avoid the spread of infection.

SLT users were found to be reluctant in setting a quit date, especially in arms 1 and 3 in which NRT was not given as SLT users were mostly looking for some medication to quit. As per the protocol in arms 2 and 4, the clients should be given NRT only after fixing the quit date, however, most of them were impatient and asked for NRT in the first meeting with the cessation advisor, assuring them to quit tobacco immediately. This tends to bypass the quiet session altogether. Hence arriving at the quiet session for only BISCA (Behavioural support interventions for smokeless tobacco cessation) clients without NRT was a bit difficult. NRT was accepted by the SLT users as a substitute for SLT. Adverse events about the quit attempts and use of NRT included excessive salivation and increased or decreased tooth sensitivity for hot and cold and flavoured food items.

3) Challenges associated with compliance between men and women

Men

Most of the male SLT users were found to be consuming SLT to remain active during night shifts to fulfil occupational demands. Higher dependency was seen among the daily wagers and skilled labourers including drivers and tailors. Among all the prevailing myths, improved concentration, ease in bowel movement and avoiding sleep were quite common. Some dropouts failed to comply with the trial protocol due to busy schedules and some also feared that their social image will get affected.

Loss of income: Employment and livelihoods have taken huge hits due to the enormous uncertainties created by Covid 19 pandemic and lockdown. Labour in India has been cornered in the unparalleled crisis is well documented [6]. Recruited participants were mostly belonging to the low socio-economic background. The lockdown further increased the financial crunch and restricted the movement of the study participants. Many study participants lost their jobs, due to which they could not afford the travel expenses to visit the clinic. To overcome all these issues, transport facilities were provided to study participants later.

Reverse Migration: Due to the unprecedented lockdown and loss of livelihood in the cities made a large number of migrants returned to their villages[7]. Some users were highly impacted by the lockdown as they lost their jobs and went back to their hometowns and did not return. Few users also reported visiting their hometown for disease treatment and pursuing farming.

Sharing Mobile phones among family members and friends: Some SLT users were sharing their mobile phones with their children to support virtual

online classes. Some SLT users were sharing their mobile with neighbours. Therefore, it was difficult to contact and communicate with them.

Relapse due to external advice: There has been evidence of strong belief in the sacred use of SLT by traditional healers⁸. Similar findings were obtained in the present study where SLT users who went back to their hometown started consuming SLT again due to the advice given by the traditional healer to chew tobacco for toothache problems. However, some users also quit SLT from the healings offered by traditional healers.

Women

Gender-related taboos: Screening at the National Institute of Cancer Research in Noida has found that the majority of the urban slum population consumed SLT. Gender variation in the form of tobacco and product-specific consumption has also indicated the importance of addressing subgroups of tobacco users⁹. The sense of fear of getting identified as a women SLT user was also observed in the study. Women seemed to hide their addiction due to the fear of being judged by the advisor. Women SLT users were also found to be anxious about the follow-ups as they didn't want to engage themselves for a longer duration. Transport facilities were provided to facilitate the women SLT users but they were reluctant to use these facilities due to fear of being identified as an SLT addicts in their community.

Sharing NRT doses: Recruited Women SLT users were found to be sharing the given NRT doses with their husbands to help them to quit who were also SLT users.

Less access to a mobile phone: India has one of the highest gender gaps in mobile phone access in the world¹⁰. Women's unequal use of mobile phones was also witnessed as one of the hindrances in completing the follow-ups. The number of women identified as consuming SLT was less, even if enrolled (mostly elderly) didn't have mobiles. Therefore, their son or daughter used to give their contact numbers. In such cases, conducting in-depth interviews and communicating to adhere to the follow-up timelines became difficult.

Ignorance regarding Gul Manjan usage: As per the cross-sectional study conducted in the peri-urban area in Noida, most of the Gul (a form of SLT) users were found to be females (86%). It was found to be used multiple times a day to get relief from dental pain due to dental caries.¹¹ Most of the women SLT users did not consider Gul manjan as one of the SLT products and its consumption as wrong practice as they didn't observe any harmful effects and symptoms associated with its use. Convincing them to quit Gul was challenging.

4. Opportunities for Smokeless tobacco cessation efforts amidst Covid 19 lockdown

The countrywide lockdown in 2020 was seen as an opportunity to quit SLT by some users. During the lockdown, the increased stay-at-home of study participants has led to the increased availability for follow-ups over calls as they had enough time to respond. Some clients also provided testimonies of their quit journey through social media. The unavailability and increased prices of tobacco products led to a decrease in the accessibility and affordability of Smokeless tobacco. Loss of income and decreased purchasing power also intensified the abstinence and SLT cessation efforts. In addition to these factors, family pressure and shifts in community norms have been also reported to facilitate quitting SLT¹². On the contrary, some SLT users reported that wearing masks has facilitated chewing tobacco at the workplace post-lockdown.

Covid 19 also triggered an improvement in the dissemination of public health information at a remarkable pace, particularly related to the vulnerability of tobacco users to co-morbidities and harm from SARS-CoV-2 infection¹². Using SLT may facilitate the spread of the Covid 19 disease through spitting. Considering this, there was a comprehensive ban on SLT and public spitting in India to contain Covid-19 Pandemic. NICPR drafted a document for banning spitting of Smokeless Tobacco products in public places during the

Covid-19 pandemic to prevent transmission. Following this, an appeal to the General Public from the Indian Council of Medical Research was issued advocating "Not to consume and spit Smokeless Tobacco in Public" on April 4, 2020. Twenty States and one Union Territory adhered to this and released notifications to ban SLT use and public spitting during Covid-19.

5. Conclusion

The global pandemic of Covid 19 has had a significant impact on the conduct of scientific research worldwide¹⁵, including the termination of 2000 trials registered on ClinTrials.gov¹⁶. The reported challenges included constraints related to recruitment, intervention delivery, compliance among SLT users, delayed follow-ups, relapse due to external advice and loss of follow-ups. Study participants were reluctant to adhere to the follow-up needed in the trial. The fear associated with testing positive for or having acquired Covid-19 was the major barrier to the 26th-week follow-ups. Besides all the challenges, Covid 19 has also been seen as an opportunity in intensifying smokeless tobacco cessation efforts. Although the follow-up sessions in-person were affected due to the Covid 19 crisis, few measures were adopted to continue the cessation trial in the light of preventive Covid 19 measures. Telephonic interviews were quite useful for conducting the final assessment and obtaining good-quality data. The trial was completed amidst the Covid-19 challenges. While considering future pandemic preparedness, we need a coordinated strategy to have realistic, investigator-led clinical trials. Flexibilities are required in terms of travel barriers to adhering to compliance and trial conduct. We need to rely more on virtual conversations which can be monitored through online support to ensure fidelity to the intervention protocol.

Although the follow-up sessions in person were affected due to the Covid 19 crisis. Few measures were adopted to continue the SLT cessation in the light of preventive Covid 19 measures. Telephonic interviews were quite useful for conducting the assessment and obtaining good-quality data. The study was completed amidst the Covid-19 challenges.

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Declaration of Interest:

None

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Data Availability Statement

The data underlying this article will be shared on reasonable request to the corresponding author.

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