Original Research Paper

Volume - 16 | Issue - 11 | November - 2026 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Mental Health Nursing

FEASIBILITY AND ACCEPTABILITY OF A STRUCTURED BRIEF INTERVENTION MODULE DELIVERED BY TRAINED PSYCHIATRIC NURSES FOR ADULT SMOKELESS TOBACCO (SLT) USERS IN COMMUNITY SETTINGS: A PILOT RANDOMIZED TRIAL

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ABSTRACT

Background: Smokeless tobacco (SLT) use remains a major public health concern, particularly in community settings with limited access to structured cessation interventions and lack of awareness among general population. Psychiatric nurses, with expertise in substance use and behavioural disorders, are well positioned to deliver brief interventions and train primary healthcare workers. Therefore, the present pilot randomized controlled trial (RCT) aimed to assess the feasibility of a community-based structured brief intervention module and supplementary materials.**Methods:** Two villages under a selected Block Primary Health Centre (PHC) were randomly assigned to intervention and waitlist control groups using a lottery method. Eight eligible participants (aged 18–60 years) were recruited from randomly selected households using computer-generated random number tables. The pilot sample was determined using a thumb rule of recruiting 10% of the main RCT sample size and allocated in a 1:1 ratio. The intervention group was followed for three months, while the waitlist control group was followed for two months. Following baseline assessment, intervention arm received a structured brief intervention, followed by one post-test assessment and a booster session at one-month intervals. The waitlist control group received brief advice followed by a post-test assessment at one-month. Feasibility outcomes assessed included recruitment process, retention, acceptability, and intervention fidelity. Results: Recruitment and retention were achieved at 100%, confirming feasibility of recruitment protocol in the community setting. All participants completed the intervention which showed acceptability and also found content was culturally relevant to their SLT use behaviours. The supplementary self-help calendar was particularly valued, enabling participants to monitor and report frequency of use post-intervention. **Conclusions:** The study demonstrated feasibility, acceptability, and practicality of the nurse-delivered brief intervention module. These findings provide a foundation for scaling up to a larger RCT to evaluate effectiveness of community-based brief intervention module in enhancing abstinence period among adult SLT users.

KEYWORDS : Smokeless Tobacco User, Brief Intervention, Community Setting, Feasibility And Acceptability

INTRODUCTION

Smokeless tobacco (SLT) use remains a significant public health concern, particularly in low- and middle-income countries, where diverse tobacco products are socially acceptable and widely consumed. SLT products contain nicotine and are associated with serious adverse health effects including oral diseases and cancers. The Global Adult Tobacco Survey (GATS-2) reported that 21.4% of adults aged 15 years and above in India used SLT, with a higher prevalence in rural (24.6%) than urban areas (15.2%).[1] Policy review and analysis of GATS-2 data shows that 21.4% of Indian adults (apprx. 199.4 million) use SLT, out of which 29.6% of men and 12.8% of women.[2] Across South-East Asian countries, SLT consumption is 1.2 to 8 times higher in rural populations and 1.5 to 17 times higher among the poorest socioeconomic group compared to wealthier urban cohorts.[3] These findings highlight the need for accessible cessation interventions, particularly in community settings.

Brief interventions provide a practical approach to tobacco cessation by incorporating assessment, advice, motivation, and behavioural support into routine healthcare encounters. The World Health Organization recommends behavioural interventions to support tobacco cessation, emphasizing the role of healthcare providers in delivering cessation assistance.[4] Psychiatric nurses, with expertise in substance-use assessment, therapeutic communication, and behaviour change, are well positioned to deliver such interventions. Their involvement may also help extend cessation support to primary healthcare and community settings where access to specialized services is limited.

However, before evaluating the effectiveness of a structured intervention in a larger trial, its feasibility and acceptability need to be established. Pilot randomized controlled trials help assess recruitment, retention, intervention delivery, follow-up procedures, and the suitability of study materials. These preliminary findings can guide refinement of the intervention and inform the design of a definitive trial.

Therefore, the present pilot randomized controlled trial aimed to assess the feasibility, acceptability, and practicality of a researcher-developed, structured brief intervention module and supplementary materials among adult SLT users in a community setting under a selected Block Primary Health Centre in Assam. The study also explored the acceptability of the intervention's content and the usefulness of a self-help calendar for monitoring tobacco-use behaviour. The findings were intended to inform a larger RCT evaluating the effectiveness of the intervention in enhancing the abstinence period among adult SLT users.

METHODS

Research Approach and Design

A quantitative research approach was adopted for the present study and the study was a two-arm, parallel-group pilot randomized controlled feasibility trial.

Setting

The study was conducted in two randomly selected villages under Bihaguri Block Primary Health Centre (BPHC) of Sonitpur district, Assam, India. The two villages were selected for the study setting through lottery method and allocated to the experimental and waitlist control groups, respectively. As the study was conducted through home visit, house selection was performed using computer-generated random number tables.

Study Population

The study population included adult smokeless tobacco (SLT) users residing in the selected villages. Eligible participants were individuals aged 18 to 60 years and who were currently using SLT. Individuals who used only betel nut without tobacco, used other substances and had attended a tobacco-awareness programme in the past, or were seeking treatment for nicotine dependence were excluded from the study.

Sample Size

The pilot study included a total eight participants, representing 10% of the planned sample size for the main study. Among the total participants four were included in the experimental group and four in the waitlist control group, maintaining a 1:1 allocation ratio.

Sampling Technique

A random sampling technique was used to select eligible participants from the selected houses. Eligible individuals identified through the sampling process were recruited into the study, with four participants assigned to each study group.

Data Collection Tools

In the present study a 23-item self-structured sociodemographic proforma was used to collect demographic details of the study

participants. The six-item Fagerström Test for Nicotine Dependence–Smokeless Tobacco (FTND-ST), the eight-item Alcohol, Smoking and Substance Involvement Screening Test, Version 3.0 (ASSIST-V3.0), and the 32-item University of Rhode Island Change Assessment Scale (URICA) was also used.[5,6,7] In addition, three self-structured questionnaires were used- a six-item abstinence questionnaire to assess abstinence period of smokeless tobacco users, a 15-item perception questionnaire assessing perceptions regarding smokeless tobacco use, and a nine-item questionnaire assessing awareness of smokeless tobacco use. A self-help calendar was also provided to the participants as a supplementary tool to record their tobacco-use patterns during the intervention period by self.

Data Analysis

The collected data were entered and analysed using IBM Statistical Package for the Social Sciences (SPSS), V.26.

Descriptive statistics were used to summarise the data and assess the feasibility of the study procedures.

Data Collection procedure

Ethical approval for the study was obtained from the Institutional Ethics Committee (IEC) and administrative permission was taken from the Joint Director of Health Services of the selected district. The main study was also registered with the Clinical Trials Registry–India (CTRI). Following approval from joint director of health services, a list of villages/wards under the selected Block Primary Health Centre (PHC) was obtained and from that list two villages were randomly assigned to the intervention and waitlist control groups using the lottery method. Prior to data collection, gatekeeper consent was obtained from the respective village heads. Households were selected from the selected villages using random number tables and visited until the required number of eligible participants was achieved in each group. Individuals those meeting the inclusion and exclusion criteria were provided the participant information sheet, and written informed consent was obtained before enrolment for the study.

Description of intervention procedure and study sessions:

In the intervention group, the first home visit involved baseline assessment followed by the delivery of the structured brief intervention using 'Brief Intervention module for smokeless tobacco cessation'. The second home visit was considered as follow-up session and a post-test was conducted. The third home visit was subsequently considered as booster session to increase adherence to the quit decision. On the other hand, in the waitlist control group, the first home visit involved pretesting and simple advice regarding harmful consequences of smokeless tobacco use. During the second home visit, a post-test was administered.

RESULTS

Recruitment of Participants

A total of 17 households were visited across the two selected villages to recruit participants for the pilot study. Of these, nine individuals were not recruited because they did not meet the eligibility criteria, were unavailable during the home visit, or declined participation due to time constraints.

In Village A, nine households were visited. Two individuals were ineligible, and three were unavailable during the home visits. The remaining four participants were recruited into the intervention group. In Village B, eight households were visited. Three individuals were ineligible, and one declined participation due to time constraints. The remaining four participants were recruited into the waitlist control group.

Overall, eight participants were recruited, with four participants in the intervention group and four in the waitlist control group. The recruitment process demonstrated the feasibility of identifying and recruiting eligible participants through household visits in the selected community settings. [Table 1]

Screening and Eligibility of Participants

During the screening process, five individuals were excluded from participation based on the predefined eligibility criteria. In the intervention arm, two individuals were excluded one due to smoking tobacco dependence, with a Fagerström Test for Nicotine Dependence (FTND) score of 6, and one because the individual was younger than 18 years. In the waitlist control arm, three individuals were excluded: one because the individual was older than 60 years and two due to smoking tobacco dependence, with FTND scores of 5. [Table 2] Overall, the screening findings highlight the importance of assessing age eligibility and tobacco-use patterns before enrolment in the main study.

Feasibility of Study Procedures and Participant Engagement

The feasibility of the pilot randomized controlled trial was assessed across six domains: recruitment feasibility, randomization and allocation, retention and follow-up, intervention delivery, assessment tools and questionnaires, and participant engagement. [table 3]

Recruitment Feasibility

Recruitment through household visits was feasible in the selected community setting. However, multiple visits and flexible scheduling were required because some potential participants were unavailable during the initial home visits. These findings highlight the need for adequate time and flexible scheduling when recruiting participants for community-based research.

Randomization and Allocation

Random allocation of the two villages to the intervention and waitlist control arms was successfully carried out using the lottery method, and the study procedures were implemented as planned. However, the randomization process in the community setting was time-consuming, indicating the need for adequate planning and coordination before initiating a larger trial.

Retention and Follow-up

All eight participants completed the planned study sessions and follow-up assessments, resulting in a retention rate of 100%. Telephonic reminders were required to facilitate follow-up, highlighting the importance of maintaining communication with participants throughout the study.

Feasibility of Intervention Delivery

The brief intervention (BI) module was delivered as planned. Nevertheless, scheduling difficulties and environmental distractions during home visits presented challenges during intervention delivery. These findings suggest that flexible scheduling and arrangements for a suitable setting may help facilitate the delivery of the intervention in the main study.

Feasibility of Application of Assessment Tools and Questionnaires

The assessment tools and self-structured questionnaires were clear and understandable to participants, culturally appropriate, and easy to administer in the community home setting. No major challenges identified related to the tools or questionnaires during the pilot study, which supports their practical use under the study conditions.

Participant Engagement with the Self-Help Calendar

Participants in both groups were able to maintain the self-help calendar to monitor smokeless tobacco use and record their abstinence days. However, family members reported that participants required supervision to support adherence to self-monitoring. This finding suggests that clear instructions and demonstrations on using the self-help calendar may be helpful in the main trial.

Table 1: Participant recruitment and randomization by arm N= 8(4+4)

Villages	No. of houses visited	Reasons to not recruited in the study	No. of participants recruited	
			Intervention arm	Waitlist control arm
Village A	09	Non-eligible=02 • Unavailable during home visit=03	04	0
Village B	08	• Non-eligible=03 • Refused (time constraint) =01	0	04
Total	17	09	04	04

Table 2: Reasons that participates did not meet eligibility criteriaN= 5

Study Arms	Reason	Frequency
Intervention arm (n=02)	Smoking tobacco use	1
	Age less than 18 years	1

Waitlist control arm (n=03)	Age more than 60 years	1
	Smoking tobacco use	2

Table 3: Feasibility of Study Procedures and challenges identified

Domain	Findings from Pilot RCT	Challenges
Recruitment Feasibility	Recruitment through home visits was feasible.	Multiple visits and flexible scheduling were required due to participant unavailability.
Randomization & Allocation	Randomization of villages and allocation into intervention and waitlist control arms were successfully carried out, and the study protocol was followed as planned.	Randomization in community setting itself is a time-consuming procedure.
Retention & Follow-up	All participants in both groups completed all sessions, achieving a 100% retention rate and follow-up, indicating high compliance and acceptability.	• Required telephonic reminders multiple times • Potential risk of drop-out
Intervention Delivery	The Brief Intervention (BI) module was delivered as planned.	Scheduling difficulties and environmental distractions during home visits.
Tools & Questionnaires	The assessment tools and self-structured questionnaires were clear, culturally appropriate, and easy to administer in a community home setting.	Nil
Participant Engagement	Participants from both groups were able to maintain the self-help calendar effectively to monitor smokeless tobacco use and abstinence period.	Family members reported guidance required for self-monitoring adherence.

DISCUSSION

The present pilot RCT was conducted to assess the feasibility and acceptability of a structured brief intervention module delivered by trained psychiatric nurses to adult SLT users in community settings. The findings provide preliminary evidence regarding the practicality of recruiting participants, implementing the intervention through home visits, maintaining participant engagement throughout the study. In the present study, 17 households were visited and approached, of which eight participants consented to participate and hence were recruited and randomized equally into the intervention and waitlist control groups. The remaining individuals were not recruited because of ineligibility, unavailability, or refusal to participate [Table 3]. This finding aligns with community outreach literature in India. In a cluster RCT (BABAEX trial) showed that doorstep screening in low-income communities requires intensive field visit, where refusal and participant absence is mainly due to lack of interest and poor awareness, representing barriers to enrolment in study.[8] Nadkarni et al., also reported that nearly one third of participants enrolled in community based study were lost due to lack of interest prior to baseline assessment and also due to call back unavailability.[9] These highlight the importance of establishing effective community engagement strategies and ensuring the availability of eligible participants during household visits.

In the present study, village-level random allocation and computer-generated random numbers for household selection was used, which demonstrates the operational feasibility of implementing a randomized recruitment procedure within a community setting.

A particularly encouraging finding was the retention of all eight participants throughout the intervention and follow-up period, resulting in a retention rate of 100%. This indicates that the study procedures were acceptable to the enrolled participants and that follow-up assessments could be completed within the community setting. Nevertheless, telephonic reminders were required to facilitate participant engagement and follow-up. This observation suggests that regular communication and reminders may be useful strategies for maintaining participant involvement in a future definitive trial. Likewise, Haokip et al., also highlighted in their study that mobile phone- and reminder-based contacts are highly effective strategies for boosting participant engagement and adherence in clinical and community settings.[10]

In this study, the structured brief intervention module was delivered by a trained psychiatric nurse as planned which in result demonstrating the practical feasibility of implementing a nurse-led tobacco cessation intervention through home visits. The use of trained psychiatric nurses may be particularly relevant in community settings where access to specialized tobacco cessation services is limited as psychiatric nurses possess skills in therapeutic communication, behavioural assessment and motivational enhancement, which may ultimately support the delivery of structured cessation interventions. WHO also recommends that evidence-based tobacco cessation interventions be delivered by healthcare providers in both clinical and community settings and emphasizes the importance of training healthcare professionals to provide cessation support.[4]

Furthermore, research on individualized tobacco cessation interventions among individuals with schizophrenia in India has also identified that psychiatric nurses are potential intervention providers, depending on sufficient workforce availability.[11]

In the present study, the self-structured brief intervention was designed to incorporate behavioural strategies and self-management techniques to support SLT users' efforts to enhance abstinence and complete cessation. The successful delivery of the intervention in the pilot study suggests that a structured and standardized module can be implemented within the existing community healthcare settings for wider reach.

However, scheduling difficulties and environmental distractions were encountered during intervention sessions indicate that the intervention may require careful planning regarding the timing of home visit, selection of location, and duration of sessions to ensure adequate participant engagement throughout the study. It also highlighted the need of maintaining flexibility in the delivery of community-based interventions.

The materials that used in the present study including the self-help calendar, were found clear and culturally appropriate for the participants. Similarly, in previous literatures culturally adapted self-help calendar was also used to support monitoring of SLT use.[12,13,14]

These studies also suggest that a culturally relevant self-help calendar may be a practical supplementary tool for community-based SLT cessation. However, it's independent contribution to abstinence cannot be established from the present pilot findings.

The present pilot RCT findings provide valuable information for planning a future definitive randomized controlled trial and which is very suggestive evidence for the future definitive RCT. The successful implementation of the methodology indicate that the study procedures were feasible in the selected community setting.

As the present study was designed primarily to evaluate feasibility and acceptability rather than to establish the effectiveness of the intervention, therefore, the findings should not be interpreted as evidence of the efficacy of the brief intervention module in increasing the abstinence period among SLT users.

Strengths and Limitations

One of the major strengths of the present study was the implementation of a structured psychiatric nurse-led intervention within a community setting using a randomized design, thereby demonstrating the potential applicability of nurse-led tobacco cessation strategies beyond specialized healthcare institutions. Furthermore, the complete retention of participants provided encouraging evidence regarding the acceptability of the study procedures.

However, due to small sample size, the findings are preliminary and cannot be generalized to the wider population of SLT users. In

addition, the recruitment trial was limited to a small number of households within the selected community, which may not adequately represent the recruitment challenges encountered in other settings.

CONCLUSION

The present pilot RCT demonstrated the preliminary feasibility and acceptability of implementing a structured brief intervention module delivered by trained psychiatric nurses among adult SLT users in a community setting. The successful intervention delivery and 100% retention provide encouraging findings regarding the practicality of the study procedures and methodology. The challenges identified during recruitment, intervention scheduling, and self-help calendar use offer important insights for refining the intervention and strengthening the study protocol. These findings support the need for a larger, adequately powered randomized controlled trial to establish the effectiveness of the intervention in enhancing the abstinence period among adult SLT users.

DECLARATIONS

Funding: Nil
Conflict of interest: Nil
Ethical approval: Approval obtained from Institutional Ethics Committee (IEC No. IEC/2024/02/03)

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