Public Health in Practice 9 (2025) 100581

Contents lists available at ScienceDirect

Public Health in Practice

journal homepage: www.sciencedirect.com/journal/public-health-in-practice

Efficacy of shared decision making in tobacco cessation among health facilities of Haryana, India – A double blinded, parallel group Randomized Controlled trial Protocol

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ARTICLE INFO

Keywords:
Shared decision making
Tobacco cessation
Randomized controlled trial
Tobacco cessation center

ABSTRACT

Background: Shared decision-making (SDM) incorporates evidence, patient values, and preferences into medical decision-making. SDM and decision aids might promote health professional engagement and patient knowledge of tobacco cessation therapy, improving usage and results. The SDM facilitates talks that lead to better-informed judgements that align with patients' priorities, unlike individual decision-making. Thus, the study will attempt to identify the efficacy of shared decision making in tobacco dependence treatment.

Methods: 1) **Design**: a two-arm parallel group randomized controlled trial (RCT) 2) **Setting:** Three selected government health centers of Haryana, India. 3) **Participants:** 596 tobacco users aged ≥18 visiting the outpatient department/Tobacco cessation centers (TCC) of selected health centers. 4) **Intervention and Comparator:** The intervention group will receive shared decision process for prescribing pharmacotherapy (Nicotine replacement therapy, Bupropion) using specially designed decision aid based on three-talk model for tobacco cessation, while the control group will get standard care. 5) **Measurements:** Primary outcomes include urinary cotinine analysis for evaluating 7-day point prevalence abstinence. Secondary outcomes include patient satisfaction questionnaire PSQ-18 score, cumulative days of tobacco abstinence, self-reported number of quit attempts, and the rate of withdrawal. The outcomes such as change in behavior status i.e. tobacco cessation will be compared between the intervention and the comparator groups. When comparing the two groups, differences between proportions will be assessed by chi-square test, differences between means with *t*-test. An intention to treat analysis will be done when comparing outcomes in both arms.

Discussion: SDM in tobacco cessation therapies in healthcare settings is understudied, thereby this study looks at comparable interventions in different settings to add to the evidence. This suggests that this study on SDM in tobacco cessation therapy, which includes healthcare professionals, aims to assist patients in making evidence- and value-based medical decisions.

Trial registration: This protocol has been registered under the registration number CTRI/2022/10/046793 with the Clinical Trials Registry in India.

1. Background

Smoking causes most cancers and numerous chronic disorders like asthma, coronary artery disease, and stroke. Tobacco caused 8.71 million deaths in 2019, 15.41 % of all deaths. Additionally, it caused 229.77 million disability-adjusted life years (DALYs), or 9.07 % of worldwide DALYs [1]. To be accomplished by 2025, the World Health Organization (WHO) has set nine global targets for noncommunicable diseases (NCDs). By 2025, these objectives include a 30 % reduction in the prevalence of current tobacco use [2]. According to the 2016–17 Global Adult Tobacco Survey (GATS)-2, 10.38 % (99.5 million) of Indians smoked and 21.38 % (199.4 million) used smokeless tobacco [3]. Approximately 23.6 % of individuals in Haryana alone were presently consuming tobacco in any form, which is a significantly higher rate [3].

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https://doi.org/10.1016/j.puhip.2024.100581
Received 21 April 2024; Received in revised form 10 September 2024; Accepted 11 September 2024
Available online 22 December 2024

Smoker's desire to stop, but just 4 % succeed without help [4]. To address tobacco use and dependency, promoting evidence-based tobacco cessation treatment is crucial as healthcare regulations change. Moreover, healthcare experts' guidance increased quit rates by 66 % [5]. Empathetic, individualized tobacco cessation intervention programs with long-term support and follow-up are the best preventive measures doctors can give tobacco users for many diseases [6]. Patients may quit smoking using programs that target severe nicotine dependency, urgency, fatalistic ideas about cessation benefits, and tobacco users in the social network [7]. Although there are many ways to help smokers quit and reap the health benefits, most relapse or need numerous interventions to quit permanently [8].

Article 14 of the WHO FCTC addresses tobacco dependence, cessation, and demand reduction [9]. The Cigarettes and Other Tobacco Products Act (COTPA) of 2003 in India regulates trade, commerce, manufacturing, supply, and distribution and prohibits cigarette advertising [10]. In 2008, the National Tobacco Control Program (NTCP) started to execute COTPA [5]. Under the NTCP, the Indian government established Tobacco Cessation Centers (TCC) in district hospitals and provided free pharmacotherapy and counselling services at these clinics [11].

Guidelines for tobacco cessation include behavioral and pharmacological interventions [12]. Pharmacotherapy has been shown to be effective in aiding smoking cessation. The most efficacious initial interventions include nicotine replacement therapy (NRT) and bupropion [12]. In-person provision of different modalities, particularly in hospitals, encourages patients to discontinue [5]. But less than one-fifth of smokers get help quitting on any given outpatient visit [13]. One study found that only 14 % of inpatient smokers received a cessation prescription and 12 % were referred for follow-up [13]. Unfortunately, smokers must opt in for each counselling and pharmaceutical component of evidence-based therapy, so few get both [13].

The Agency for Healthcare Research and Quality (AHRQ) describes shared decision making (SDM) as patient-centered care that empowers patients to make health decisions. First, informed customers will ask questions and express their thoughts about their ailments and treatment options. Second, doctors will consider patients' goals and preferences when giving therapy advice [14]. SDM helps patients understand their options and their pros and cons, and their goals and treatment preferences guide decisions [14]. The main purpose of SDM is to ensure that people make informed health decisions. Ultimately, more independent people emerge with a stronger sense of commitment and responsibility for their health [15].

Using decision aid with SDM conversations can improve treatment. The most widely tested SDM enhancement strategy is patient decision aids. Patients can use the best evidence to make informed healthcare choices with patient decision aid. They help patients build, clarify, and communicate their values when making values-based decisions with their healthcare professionals by providing balanced information about alternatives. Clinical interventions to promote SDM must be routine to be effective [14]. SDM and decision aids may increase physician engagement and patient smoking cessation therapy knowledge, enhancing treatment outcomes [16]. Collaborative decision-making is appropriate for preference-sensitive therapy like smoking cessation [16].

Additionally, decision aids have the potential to significantly advance education and accessibility to tobacco treatment [17]. Decision aids can improve nonpharmacological interventions during clinical encounters, especially for patients who are less motivated to change their behavior [18]. Utilizing in-visit decision aids may be a practical means of encouraging clinicians and patients to make decisions jointly concerning tobacco use [18]. These aids have demonstrated a significant enhancement in patient engagement during the decision-making process [19,20]. SDM in tobacco dependence treatment improves cessation outcomes and helps NTCP and other tobacco control efforts [21].

The existing smoking cessation techniques fail to consider the active involvement of patients in the decision-making process and rely solely on medical or behavioral interventions [22]. On the other hand, a paradigm shift toward SDM has the potential to influence patient empowerment, improve outcomes, and have an effect on tobacco cessation attempts [16]. However, current evidence indicates that the healthcare industry has not extensively adopted SDM [23]. Thus, we aim to assess the effectiveness of shared decision-making for tobacco cessation at the outpatient department or tobacco cessation center.

2. Objective

2.1. Primary objective

To compare the biochemically confirmed point prevalence of abstinence from tobacco among the SDM and standard of care (SOC) subjects at 6 months.

2.2. Secondary objectives

- To compare the cumulative days of abstinence from tobacco at the end of six months.
- To determine the change in knowledge of tobacco users with and without a SDM process.
- To ascertain the length of consultation and patient satisfaction in the process of tobacco cessation.

3. Methods

3.1. Hypothesis

Null Hypothesis: There will be no difference of point prevalence tobacco abstinence with shared decision-making process as compared to Usual Care/SOC.

Alternative Hypothesis: There will be a 20 % or above point prevalence tobacco abstinence with shared decision-making process as compared to Usual Care/SOC.

Study design and participant timeline: A superiority framework based RCT will compare two parallel groups with a 1:1 allocation ratio. Randomization will be done on patients. Participants will be recruited over a nine-month period, randomized, and followed up after three months. Patient process evaluations will occur after intervention and 6 months.

Study Area & setting: Geographically, Haryana ranks twenty-first in India with a total area of 44,212 km2. About 2.09 percent of India's population lives in its 22 districts, which number over 2.53 crore. Sub-Divisions, Tehsils, Sub-Tehsils, Blocks, urban, and rural areas make up each district. According to NFHS-5 which is recently published found that 29.1 % of men & 2.5 % of women use any kind of tobacco in Haryana [24]. India: Health of the Nation's States, The India State-Level Disease Burden Initiative, ranks tobacco use [8.4 %] as the 5th leading cause of death and disability in Haryana [25]. In terms of the burden of major tobacco-related disorders in Haryana, 60.99 % of DALY was accountable for NCDs in 2019 [25]. The study will be carried out at three tobacco cessation centers running at two tertiary health care centers and one community health center in Ambala district.

Specific program settings: The NTCP was initiated by the GoI during 2007–08 [11]. One of its primary objectives was to establish and enhance cessation facilities, which included the provision of pharmacological treatment facilities at the district level [11]. Tobacco Cessation Centre (TCC) have been established at the district level to offer complimentary pharmacotherapy and counselling services to patients. The NTCP has TCC in all 22 Haryana DTCC districts. TCC has outpatient care doctors who provide tobacco cessation services. One counsellor/psychologist provides psychological interventions.

Study Participants: The study population will be divided into two parallel groups in each of the study sites. Arm 1/Intervention group:

Shared decision process for prescribing pharmacotherapy (NRT, Bupropion) using decision aid for tobacco cessation. Arm 2/Control Group: Regular procedure for prescribing pharmacotherapy for tobacco cessation.

Participants will be eligible provided they [1] Visiting the outpatient department/TCC of selected Health Centers [2] are above 18 years of age [3] have a history of tobacco use during the last one or more years and willing to quit [4] Able to read and understand English or Hindi [5] Resident of the area under the jurisdiction of the selected health centers [6] Provide written consent for intervention and follow-up of 6 months in the study.

Participants will be excluded if they [1] are unable to understand any of the languages as mentioned above [2], Below 18 years of age [3], are already taking treatment for tobacco cessation, and [4] are mentally ill to accord informed consent for the study [5], Migrant patients will not be included.

Subjects will be excluded from the study if they [1] withdraw their consent voluntarily [2], fail to adhere to the study protocol, or [3] are unable to continue with the study due to migration or other factors. The rationale for discontinuation will be documented, and subsequent monitoring will not be pursued. Subjects who discontinue their involvement in the research will be classified as individuals who consume tobacco.

Sample size: The sample size of 248 for each arm was calculated at 95 % confidence interval using quit rate of 20.2 % [19] among participants receiving intervention for tobacco cessation using shared decision-making process. The total sample size of 496 is calculated but considering migration, lost to follow up, the sample size of 596 will be taken with 298 in each arm.

Enrollment: OPD/TCC patients will be screened about their history of tobacco use while filling out the case history form; if the patient is found to have a history of tobacco use, they will be further assessed as

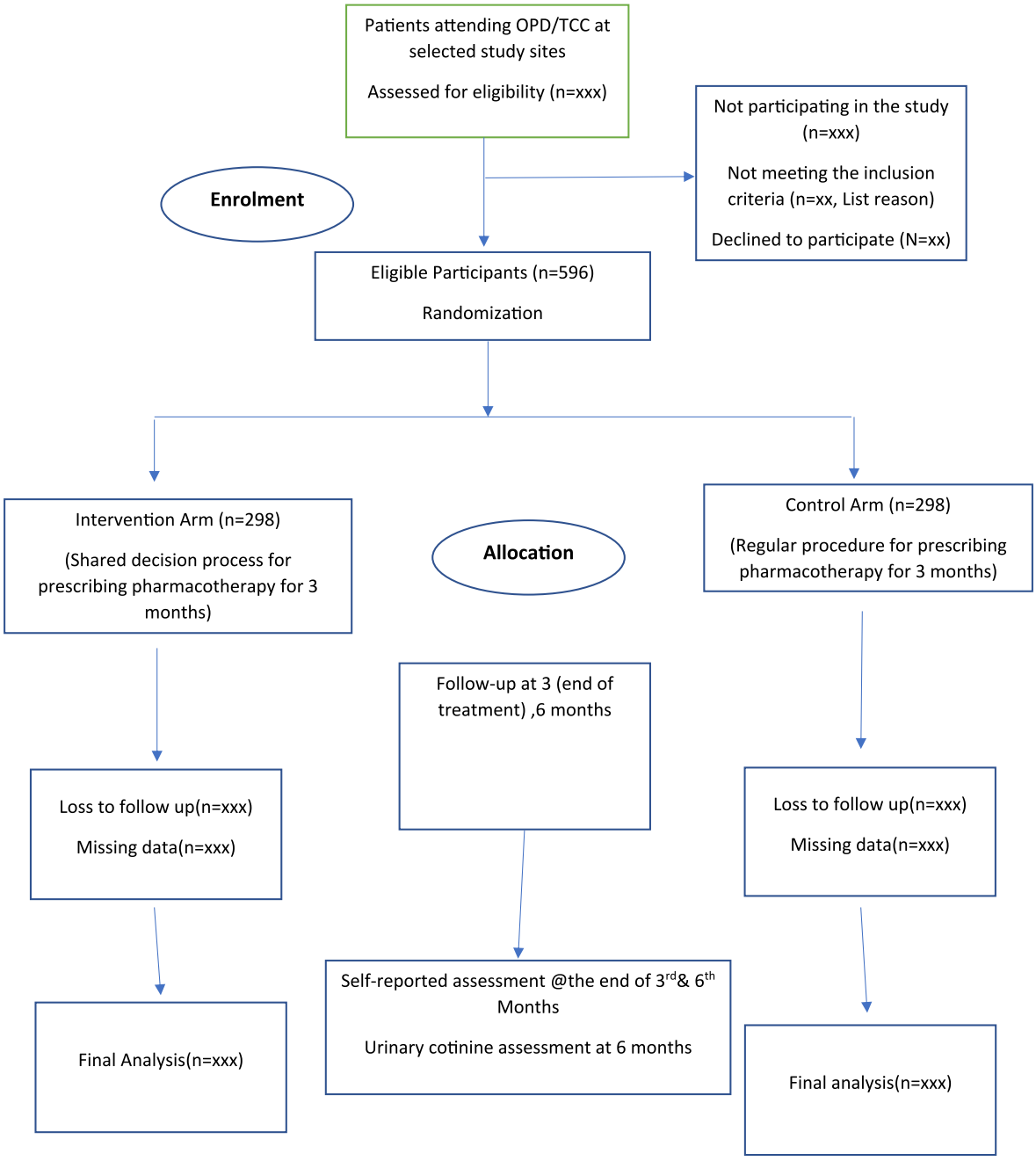

Fig. 1. Consort flow chart for enrolment and follow-up plan for randomized controlled trial therapy.

per the inclusion and exclusion criteria, and they will be given a brief explanation of the study and asked about their willingness to take part in it. If the patient is willing, their informed consent will be obtained, and a patient information sheet will also be provided. The participants will subsequently be assigned at random to either the intervention arm or the control arm (Fig. 1).

Generation of an unpredictable randomized allocation sequence: We will employ stratified block randomization with a 1:1 allocation to ensure that participants are allocated to the intervention and control groups in similar proportions based on their smoking intensity. Prior to randomization, participants will be categorized into heavy smokers and light/moderate smokers using established criteria (e.g., the number of cigarettes smoked per day). The size of the randomly permuted blocks will be 10. A simulation tool will be used to create a blocked randomization list.

Allocation concealment & Blinding: Sequentially numbered, opaque, sealed envelopes (SNOSE) will be used. After writing the participant's name and other details on the envelope, the envelopes will be numbered and opened sequentially. One of the study members other than the researcher will create the intervention group allocation sequence in opaque envelopes, which the medical officer will open for participant enrollment. The study groups will be unknown to participants and investigators in this double-blind trial.

Intervention Package: There are two intervention packages.

Intervention Group: SDM in Tobacco Cessation (3 months): For better results in quitting, shared decision-making must be integrated into tobacco dependency therapy. **The three-talk model** of SDM will be used for tobacco cessation (see Fig. 2).

Team talks, **option talk**, and **decision talk** are the three steps of SDM (Fig. 3 [26]):

1. Team talks: Assuring patients that they will not be left alone to make difficult choices and that the clinician will support and even lead if requested.
2. Option talk: provision of more detailed information regarding the various available options.
3. Decision talk: supporting patients to consider preferences and make decisions.

A decision aid in the form of a flip chart will be used to aid the SDM process, containing information about willingness to quit tobacco, rewards of quitting tobacco on health, side effects of tobacco consumption, information about previous efforts to quit tobacco, withdrawal symptoms of quitting tobacco, coping strategies, therapies available for quitting tobacco and their advantages, side effects, directions of use, contraindications, and finally asking the patients their choice of drug,

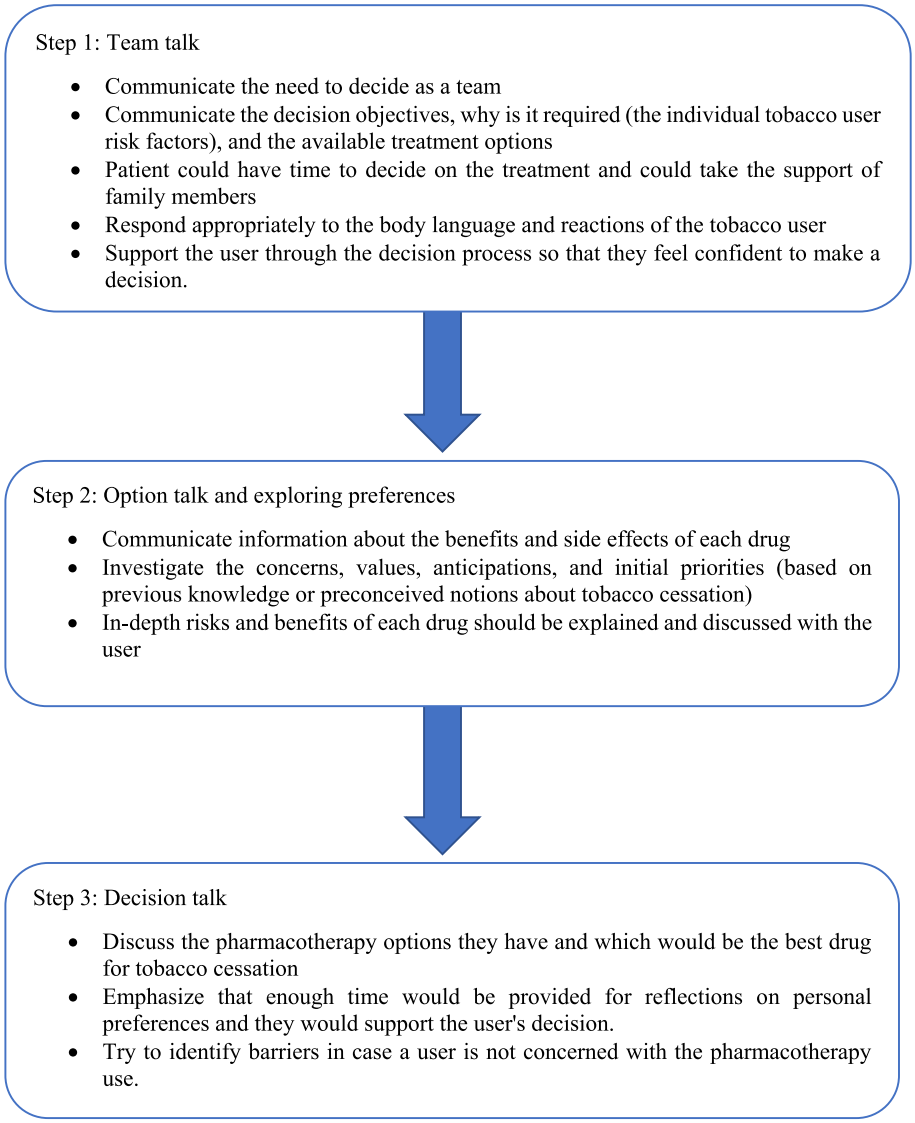

Fig. 2. Overview of the SDM process of tobacco cessation session in the intervention arm.

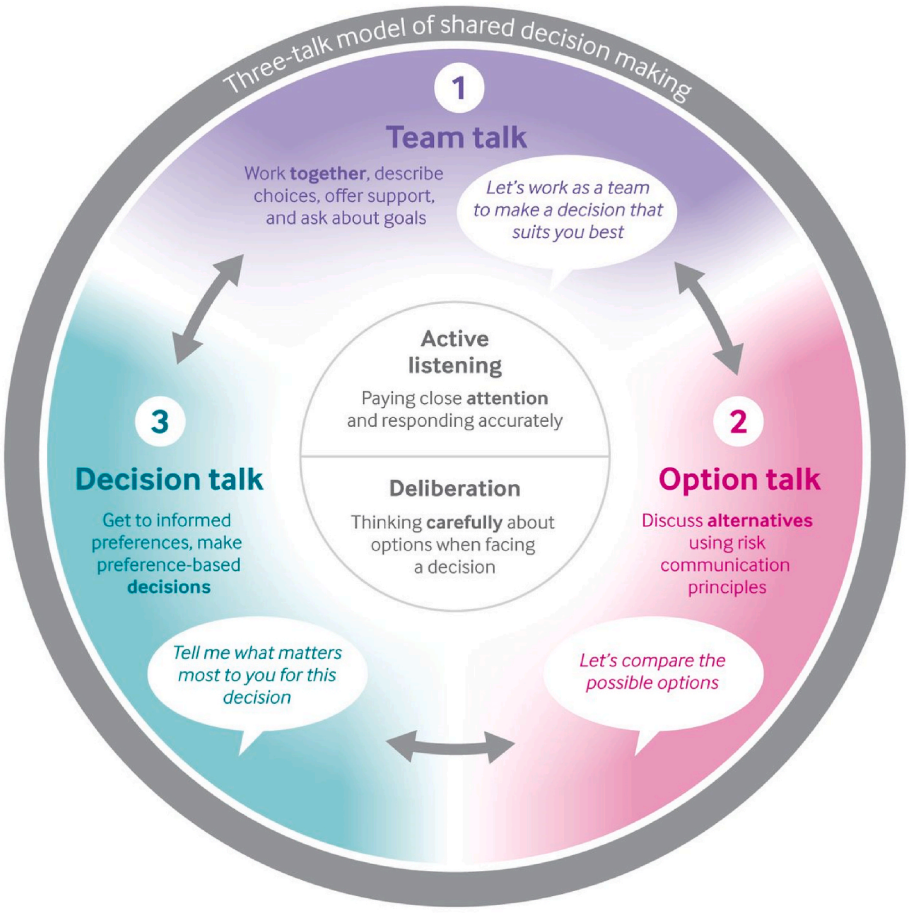

Fig. 3. Three-talk model of shared decision making, 2017.

which can be used by any health care physician. "**A Practical Guide for Health Professionals to** Support **the Implementation of Shared Decision-Making for Tobacco Cessation**" will be developed, which will cover topics such as the objective of the guide and for whom it is intended. Neurophysiology, Tobacco Cessation Therapies, and SDM Why is it Significant? Importance and Benefits, Knowledge, or Skills Required of Health Professionals to Conduct SDM, Patient Opinions on SDM, SDM in Tobacco Cessation, Case Studies.

3.2. Control group: standard of Care/Usual Care

Evidence-based behavioral and pharmacotherapy intervention strategies for tobacco users have been approved by the Government of India [11]. Tobacco cessation medications fall into two categories: 1. Nicotine Replacement Therapy (NRT) 2. Non NRT. It includes nicotine gum, patch, inhaler, and nasal spray. Nicotine inhaler and nasal spray are unavailable in India. Bupropion and Varenicline are India's first-line tobacco cessation drugs.

Implementation plan: Health care providers at TCC/OPD will ask patients about their tobacco use in addition to routine clinical services. If the patient is found to have a history of tobacco use, the medical officer will refer the patient to the counsellor or junior research fellow (JRF). They will further assess the patient as per the inclusion and exclusion criteria. The JRF **or** counsellor will explain the study to the patient and ask about their willingness to take part in the study. If the patient is willing, the counsellor or junior research fellow will get the patient to sign the informed consent form and patient information sheet. Administers the questionnaire to the patient, hands over the questionnaire to the patient, and refers him to the medical officer. The medical officer picks out the sealed envelope provided, opens it, and delivers the intervention as per the groups (a, b) mentioned in the envelope. The medical officer will hand over the questionnaire to the patient and refer him or her to the counsellor. The patient will hand over the questionnaire to the counsellor. The counsellor will counsel the patient and refer the patient to the pharmacist. The pharmacist dispenses the medications to the patient. Task Shifting: Where appropriate, Junior research fellows will explore the possibility of task-shifting some aspects of the SDM process to other trained healthcare personnel, such as counselors or nursing staff. JRF have already established a robust monitoring and evaluation framework to assess the fidelity of the SDM intervention across participating health facilities. This will include regular check-ins with MOs, patient feedback, and direct observation of consultations (with patient consent) to ensure the intervention is implemented as intended.

3.3. Outcome measures

3.3.1. Primary outcome

Urinary cotinine analysis for evaluating 7-day point prevalence abstinence of study participants (no tobacco used during the preceding 7 days) after six months to determine the tobacco use status. For confirmation of not using tobacco in any form in the past 7 days will be tested using immune-chromatographic test strip (Nic Alert) [27].

3.3.2. Secondary outcomes

- Cumulative days of tobacco abstinence within 6 months of follow-up.
- Self-reported number of quit attempts within 6 months.
- Self-reported temporary or complete relapse to tobacco use within 6 months.

- Rate of withdrawal from the intervention among the study participants within 6 months.
- Change in knowledge of tobacco users before and after intervention. Patient satisfaction with the intervention.

Data Collection: Prior to full-scale implementation, we will conduct pilot testing of the SDM intervention in a small number of facilities to gather feedback from MOs regarding the feasibility of the process. For data collection, a pre-tested questionnaire in the local language (Hindi) will be utilized, with the first section serving as a baseline for data collection and the second section serving as a follow-up means at three and six months. Baseline data will include demographics, current illness, tobacco use pattern, Fagerstrom nicotine dependence scale score [28, 29], previous quit behavior, attitude towards quitting, preparedness to quit, and reasons to continue. Follow-up data will include tobacco use status, cumulative days abstinence, withdrawal symptoms, and coping mechanisms. Patient satisfaction questionnaire PSQ-18 [30] will be used for assessing the satisfaction of patients with the intervention at the end of intervention. Furthermore, a urine specimen will be obtained during the final follow-up assessment (after 6 months) for the biochemical verification of cotinine. Changes in knowledge will also be assessed during the final follow-up (Table 1). While the current study timeline may limit our ability to fully assess the long-term sustainability of smoking cessation, we will incorporate an additional follow-up assessment later point (e.g., 6 months post-intervention) if resources permit. If feasible, we will propose an optional follow-up study focusing specifically on the long-term sustainability of smoking cessation. Participants from the original study could be re-enrolled for extended follow-up, allowing us to gather additional data on the durability of the intervention's effects. Throughout the study, we will try to gather data on

Table 1
Data collection items and schedule at baseline and follow-up in the study.

	Enrollment	Randomization	Post Randomization	
Time Points		T0 (Baseline)	T1 (3rd Month Follow Up)	T2 (6th Month Follow Up)
ENROLLMENT	X			
Eligibility Assessment	X			
Informed Consent	X			
Assignment of intervention & Control Group	X			
INTERVENTION				
Shared Decision making		X———	———X	
Standard of Care/Usual Care		X———	———X	
ASSESMENTS				
1. Socio-demographic & Tobacco use history 2. Fagerstrom Tobacco Nicotine Dependence 3. Previous quit behaviour 4. Attitude towards quitting 5. Preparedness to quit tobacco use and 6. Reasons to continue		X	X	
1. Information regarding present tobacco use status. **2.** Cumulative days of abstinence **3.** Withdrawal symptoms **4.** Coping mechanisms			X	X
5. Change in knowledge				
Urine cotinine assessment				X
Patient satisfaction questionnaire PSQ-18				X

the time required for SDM consultations, patient and provider satisfaction, and any challenges encountered during implementation. This data will help us assess the feasibility of SDM in routine OPD settings and provide recommendations for scaling up if found effective.

Training of health care providers: We will conduct comprehensive training sessions for Medical Officers (MOs) to efficiently integrate the SDM process into their routine consultations. Healthcare professionals in TCC and OPD will receive shared decision-making intervention training. This training will be led by tobacco cessation experts and the Haryana Health Department. Training will be a one-day workshop. The proposed training workshop will cover the prevalence and effects of tobacco use, the pros and cons of quitting, SDM in tobacco cessation, and using decision aids to facilitate SDM. A guide for health professionals to implement SDM for tobacco cessation will be published. Additionally, the investigator will observe package administration in authentic settings and provide valuable insights and evaluations. To identify areas for improvement, TCC/OPD clinic healthcare providers, NTCP program administrators, and public health experts will provide qualitative feedback on the intervention package.

The process of **data management and analysis** will involve assigning a unique identifier to each subject participating in the study. This identifier will be used to archive both their data and urine specimens. The double data entry procedure will be executed, subsequently followed by error verification, and ultimately, data analysis will be conducted using IBM SPSS version 23. In the case of quantitative data, the estimation of the mean and standard deviation will be conducted. The calculation of the median and interquartile range will be performed for nominal and ordinal data. The outcomes will be compared between the intervention and the comparator groups as well as change outcomes pre and post in both the groups to evaluate the impact of a specific intervention on behavioral outcomes, specifically tobacco cessation. The study participants' descriptive statistics will be reported in terms of proportions for categorical variables and as mean values accompanied by their corresponding standard deviation (SD) for continuous variables. The chi-square test will be employed to assess disparities between proportions, while the *t*-test will be utilized to evaluate disparities between means when comparing two groups. In all analyses, the conventional significance level of 0.05 will be employed to reject the null hypothesis, which posits no difference between groups. The main focus of the study will involve examining the extent of tobacco abstinence after a period of 6 months, which will be assessed using a 7-day point prevalence measure. The analysis will be performed utilizing an intention-to-treat analysis. If needed Mixed-Model Regression Analysis will be used based on the treatment effect across the 3 health centers. Missing completely at random (MCAR) framework will be used for handling missing data in the analysis.

4. Discussion

Tobacco use remains a significant public health concern, and there is a growing interest in exploring innovative approaches to enhance cessation efforts. In many healthcare contexts, shared decision making—active patient participation in treatment decisions—has shown potential. SDM programs improved knowledge, set more realistic expectations, reduced decisional conflict, increased decision-making participation, decreased indecision, and increased value-choice agreement compared to regular care or basic information pamphlet. SDM has been described as "a way of making decisions in which clinicians and patients share the best available evidence and patients are helped to think about their options so that they can make informed choices." Hence, we propose a model of SDM for tobacco cessation based on the most used and most cited three-talk model, i.e., choice talk, option talk, and decision talk, given by Elwyn et al. [13], incorporated in conjunction with a decision aid in the form of a flip chart.

As far as our current understanding goes, there has been no research conducted in an Indian context that has examined the impact of SDM on a specific group of patients for tobacco cessation within a healthcare facility. Therefore, the research will generate empirical data regarding the efficacy of interventions in those environments and endorse a customized intervention approach. Given the absence of documented information pertaining to the relative efficacy of SDM compared to standard treatment in the context of smoke cessation within the Indian healthcare system, the outcomes of the current research will provide robust evidence to support the replication of the proposed protocol in similar healthcare settings globally.

This research has few policy and programmatic consequences. The SDM package with tobacco cessation decision assistance was designed via formative research, thus evidence will guide its acceptability and practicality across several centers and nations. This research will help policymakers, implementers, and educators implement the intervention with limited health system resources including healthcare professionals and space. Since tobacco cessation research is in its infancy in LMIC and MICs, this will motivate researchers to develop fresh evidence in real-time practice. Our study focuses on three health centers in Haryana: two district hospitals and one Community Health Centre (CHC). We have acknowledged the limitations related to the external validity of focusing on only three health centers. Based on the study's outcomes, we will provide recommendations for scaling up the intervention and adapting it to other health centers with similar or different characteristics.

5. Conclusion

The incorporation of SDM into the management of tobacco dependency holds significant significance. Enhanced treatment outcomes are most likely to be achieved with the active participation of both the patient and the physician, who possess expertise in their respective domains. The objective of this study is to evaluate the efficacy of shared decision making in the management of tobacco dependency. This entails collaborative efforts between physicians and patients to establish medical decisions that are grounded in empirical data and congruent with the patient's own values.

CRediT author statement

Dr Kshtriya Pranav S: Writing – original draft, review & editing, Dr. Sonu Goel: Writing – review & editing, Dr. Abhishek Ghosh: Writing – review & editing.

Ethics approval

Ethical approval for the study was sought from the Institute Ethics Committee, Post Graduate Institute of Medical Education and Research, Chandigarh, India. (PGI/IEC/2020/001629). Permissions are also obtained from State Department of Health and Family Welfare, Haryana India for carrying out the study.

Funding

This work is supported by the Science and Engineering Research Board, Government funding agency of India, 3rd & 4th Floor, Block II Technology Bhavan, New Mehrauli Road New Delhi-110016 (File No: CRG/2021/008371). (Sanction order no. & date SERB/F/2494/22-23.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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