Evaluating the impact of culturally specific patient-centric behavioral intervention package versus usual care for tobacco cessation among patients attending noncommunicable disease clinics in North India: A single-blind trial pilot study protocol

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ABSTRACT

BACKGROUND: In a low and middle-income country (LMIC) like India, non—communicable diseases (NCDs) contribute a major proportion (61.8%) of all causes of death. Out of this, 48% of cardiovascular diseases , 23% of Chronic Respiratory Diseases , and 10% of Cancer deaths are attributable to tobacco use. Tobacco use is a major risk factor for NCDs and thus, the tobacco cessation approach is a high priority intervention to combat complications and death among NCD patients. While several interventions are available for tobacco cessation, in resource constraint countries like India, the effectiveness of low-cost, culturally specific patient-centric tobacco cessation behavioral intervention holds a potential that needs to be evaluated. A newly developed evidence-based tobacco cessation intervention package will be compared with the existing/usual care provided under the National Programme for Prevention and Control of Cancers, Diabetes, Cardiovascular Diseases, and Stroke (NPCDCS) at NCD clinics.

METHODS AND DESIGN: 2 arm, parallel-group randomized controlled trial.

PARTICIPANTS: Patients aged ≥30 years suffering from NCD, currently using tobacco, and attending NCD clinics in 2 districts of Punjab, India.

SAMPLE SIZE: A total of 200 participants meeting the selection criteria will be recruited. They will be allocated either to the intervention arm or control (usual care) arm (100 each) using block randomization.

INTERVENTION: For the participants, there will be 4 face-to-face disease-specific cessation counseling sessions, disease-specific pamphlets, short text messages in vernacular language, that is, Punjabi. Follow-ups will be done at the third, sixth, ninth, and 12th months.

PRIMARY OUTCOME: Seven-day abstinence, biochemically verified by plasma cotinine levels.

SECONDARY OUTCOME: Quit attempts, number of sticks/number of times of smokeless tobacco usage in a day, and stage of behavior change in tobacco users.

DISCUSSION: This multicomponent culturally specific-patient-centric behavioral intervention package for tobacco cessation at NCD clinic settings focusing on the individual, family, and social environment could increase the outreach of cessation services using existing resources, thereby strengthening health systems and enhancing the quality of life of NCD patients.

TRIAL REGISTRATION: The protocol for the study has been registered with the Clinical Trials Registry in India under the registration number CTRI/2018/01/011643.

KEYWORDS: cessation, cotinine, high-pressure liquid chromatography, noncommunicable disease clinic, randomized controlled trial

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Background

Tobacco use is a global epidemic that kills more than 8 million people annually.[1] Worldwide, the Disability Adjusted Life Years (DALY's) attributable to tobacco smoking and smokeless tobacco (SLT) was 148.6 million[2] and 6 million,[3] respectively. Almost one-fifth of the world's population resides in India,[4] where 28.6% (266.8 million) of the adults aged 15 years and above use tobacco in any form.[5] The number of years lived with disability (YLDs) among NCD patients increased by 61.1% between 1990 and 2017, according to the Global Burden of Disease study.[6] World Health Organization (WHO) has projected that if adequate measures are not taken to control NCDs, then the annual toll of deaths due to NCDs shall rise to 55 million by 2030.[7] In India, the contribution of NCDs to total deaths has increased from 37.9% (in 1990) to 61.8% (in 2016).[4]

The consumption of tobacco in either form, smoked or smokeless, among patients suffering from NCDs has many deleterious consequences. Tobacco smoking among patients with diabetes mellitus leads to an increase in glycosylated hemoglobin (HbA1c),[8] which results in higher morbidity and premature death due to the development of macrovascular complications.[9] The prognosis among smokers with heart failure is poorer than nonsmokers with heart failure.[10] Tobacco use also poses a risk for secondary/recurrent stroke among stroke survivors[11] and predisposes patients with Chronic Obstructive Pulmonary Disease (COPD), poor health outcomes with further deterioration in primary lung disease.[12] Continued use of tobacco among patients diagnosed with tobacco-related cancers leads to reduced treatment efficacy with a higher rate of complications.[13] Further, smokeless tobacco (SLT) use has also been implicated as an established risk factor for causing various cancers,[14] and type 2 diabetes emllitus,[15] adverse cardiovascular events, reducing the likelihood of survival after a myocardial infarction (MI) or stroke.[16]

The WHO identifies tobacco as a modifiable behavioral risk factor for NCDs.[17] Tobacco use is a learned behavior, and nicotine addiction is a very complex process involving biological, behavioral, psychological, and cultural factors. The interplay between these factors results in the continued use of tobacco products among the users.[18] There is plenty of evidence that has incorporated the health belief model in motivating tobacco users to quit and educating them about the impact of tobacco use and passive exposure to tobacco smoke.[19,20] However, there are certain limitations of this model that suggest considerable factors that are not related to health but do impact health behavior and are not predicted by HBM. This is seen in tobacco smoking as HBM does not consider habitual behavior, and health beliefs may not have an intervening outcome among seeking health care information and intending to quit.[21,22] Interventions involving the Social Cognitive Theory (SCT) process raise resistance and self-efficacy, increasing the likelihood of successful quitting.[23] However, there is also evidence that emotional factors, higher anxiety levels affect self-efficacy making the quitters more vulnerable to relapse after cessation.[24] Moreover, behavior arises from complex interactions, and the SCT ability to explain human behavior is unreal and weakens its usefulness in practical settings.[25]

In this paper, we propose a cessation intervention for the tobacco users of Punjab based on the Transtheoretical Model (TTM), also called as Stages of Change model. This model has been widely used in the development of cessation interventions.[26] TTM has evolved through studies examining smokers' experiences who quit, thus understanding their habitual behaviors in various stages of readiness and assisting physicians in administering a customized plan of action for quitting tobacco use.

The largest number of TTM-related intervention studies have focused primarily on smoking cessation[27-29] and very few on smokeless tobacco among disease-specific groups, especially in India, where the burden of SLT use remains relatively high.[30] In addition, tailoring interventions incorporating modified theoretical concepts of TTM is much required to cater to different tobacco users across varying stages of behavior change.[27,31] Further, there is evidence that TTM supports the cultural relevance of thematic constructs for various public health interventions such as physical activity, weight control, unhealthy alcohol use, etc.[32-34] Moreover, harnessing the power of TTM of change in adapting multiculturalism has also been documented in various domains.[35] Besides, the model considers an individual level of motivation and readiness to change when setting goals in contrast to other behavior change models. The development of culture-specific cessation interventions has been reported to effectively reduce risky health behaviors and address the cultural roadblocks to change.[34,36]

The state of Punjab lies in the northern part of India, and the majority of residents practice Sikhism as the primary religion. The Sikh Code of Conduct strictly prohibits tobacco use for its followers and is categorized as a tabooed practice.[37,38] Due to this, many users do not disclose their tobacco use status and therefore do not seek help to quit.[39] Further, the state has rich cultural diversity wherein the residents from neighboring states of the country migrate in search of better work opportunities.[40] The risk health behavior such as tobacco use of individuals from such diverse backgrounds could be addressed through a patient-

centric approach. This patient-centric approach has also been demonstrated to increase the acceptability among users besides managing their craving and cutting down on tobacco use.

Moreover, the lives of most Indians are centered on the institution of the family. Therefore, the involvement of family members in developing a quit plan is centric to this approach as well. Evidence also suggests that the involvement of the family in the cessation process by harnessing their influence yields better outcomes.[41]

Biochemical verification of quit status is vital in trials where social norms and personal characteristics influence reporting of tobacco use status apart from increasing the scientific rigor and validity.[42] The present study also proposes to undertake biochemical verification of tobacco use by analyzing plasma cotinine levels (long half-life, greater sensitivity, and specificity),[43] using high-pressure liquid chromatography.[44] Assessment of cotinine in blood samples produces uniform matrix measurement and does not require adjustment for hydration levels among users.[43] Moreover, literature also reports a relationship between plasma cotinine levels and nicotine dependence score.[45] Majority of the studies have reported salivary and urine cotinine levels.[46,47] However, assessment of plasma cotinine among the NCD population has not been widely reported.

The existing literature from developed countries aptly demonstrates the effectiveness of tobacco cessation services among these patients at the clinics. However, the majority of these trials have been conducted among tobacco smokers and not SLT users. In an LMIC like India, where the burden of SLT remains the highest, followed by smoking, it is necessary to offer support to SLT users and smokers at every available opportunity. Nonetheless, given the growing burden of NCDs in India, the utilization of NCD clinics for delivering "opportunistic cessation support" can be enchased. These NCD clinics are established under the National Programme for Prevention and Control of Cancers, Diabetes, Cardiovascular Diseases, and Stroke (NPCDCS) launched by the Government of India in 2010–2011.[48] The feasibility and effectiveness of NCD clinics in delivering tobacco cessation package has not been evaluated. Most of the trials conducted on such disease-specific populations cater to 1 or 2 diseases, whereas an established NCD clinic of the health system would favor engaging more patients of different NCDs with infrastructure and human resources being constant.

Thus, we aim to assess the effectiveness of a patient-centric culture-specific intervention using the TTM framework among smoked and smokeless tobacco users in NCD clinics running under the NPCDCS program of the Government of India. Box-1 List of operational definitions used in study[49]

Methods

Study design and period

It will be a randomized controlled trial (RCT) comparing 2 parallel groups with an allocation ratio of 1:1. The patient (participant) is the unit of randomization. The study will comprise 6 month recruitment period with intervention at the routine visits during the 1-year follow-up (at third, sixth, ninth month and a final assessment at 12th month) (Figure 1).

Study area and settings

Punjab is one of the wealthier states situated in northwest India. With a population of 27.7 million (Census, 2011), the state is divided into 22 districts. Each district is further divided into 3–4 Community Development Blocks, the rural area administratively designated for planning and development.[50] Sikhism is the most widely practiced religion, and Punjabi is the widely spoken language in the state.[51] Global Adult Tobacco Survey−2 (GATS-2, 2016–2017) reports current tobacco use prevalence in the state to be 13.4%.[5] The NCDs contribute to 66% of the total disease burden in Punjab.[4] The state-wide STEPS survey reported an overall prevalence of diabetes mellitus and hypertension as 8.3% and 40.1%, respectively, which are higher than the national average.[52,53] 2 NCD clinics running at the district level of Punjab will be selected for the pilot study where the intervention will be delivered.

Specific program settings

During 2010–2011, the Government of India initiated a National Programme for Prevention and Control of Cancers, Diabetes, Cardiovascular Diseases, and Stroke (NPCDCS) under which "NCD clinics" were established at Community Health Centre (CHC) level and district hospitals for comprehensive diagnosis and management of subjects suffering from Cancer, Diabetes, Hypertension, Cardiovascular Diseases, and Stroke in conjunction with dietary counseling and lifestyle management. The Punjab State has been a forerunner in implementing the NPCDCS. The State Cells for NCD Control under the Director of Health Services, Punjab, runs District NCD Control Cells in all 22 districts. These NCD clinics are staffed by a medical officer, counselor, nurse, and a data entry operator and provide screening, diagnosis, management, and counseling services for NCD's focusing primarily upon lifestyle and dietary modifications.[48]

Study participants

The participants will comprise tobacco-using patients visiting the NCD clinic to seek management of their NCD ailment.

Inclusion criteria and exclusion criteria

This shall include the patients visiting the NCD clinic who are

- Age 30 years and above

- Diagnosed with 1 or more NCDs (Diabetes, Hypertension and other CVDs, Stroke, Cancer, Chronic Respiratory Diseases such as COPD and asthma)

- Using any tobacco product (smoked/smokeless)

- Able to read simple texts in local language

- Access to a mobile phone

- Willingness to give informed consent to be a part of the study and involve their family members in the process.

Exclusion criteria

- Patients already on Nicotine Replacement Therapy (NRT)

- Patients in the event of the end stage of cancer, on renal dialysis, psychiatric illness, multimorbidities, etc.

Intervention

Description. In addition to the routine clinical services at NCD clinics, the Health Care Providers (HCP's) comprehensively assess the patient for tobacco use status, disease condition (any complication/improvement), along with providing brief advice for adherence to prescribed treatment and benefits of quitting. At the end of the consultation, the doctor will instruct the patient to meet the counselor. The designated counselor will provide face-to-face counseling (15 to 20 minutes) using the 5 A's and 5 R's[54] approaches. After that, the nurse will assist in the patient's documentation, collect blood samples, and encourage
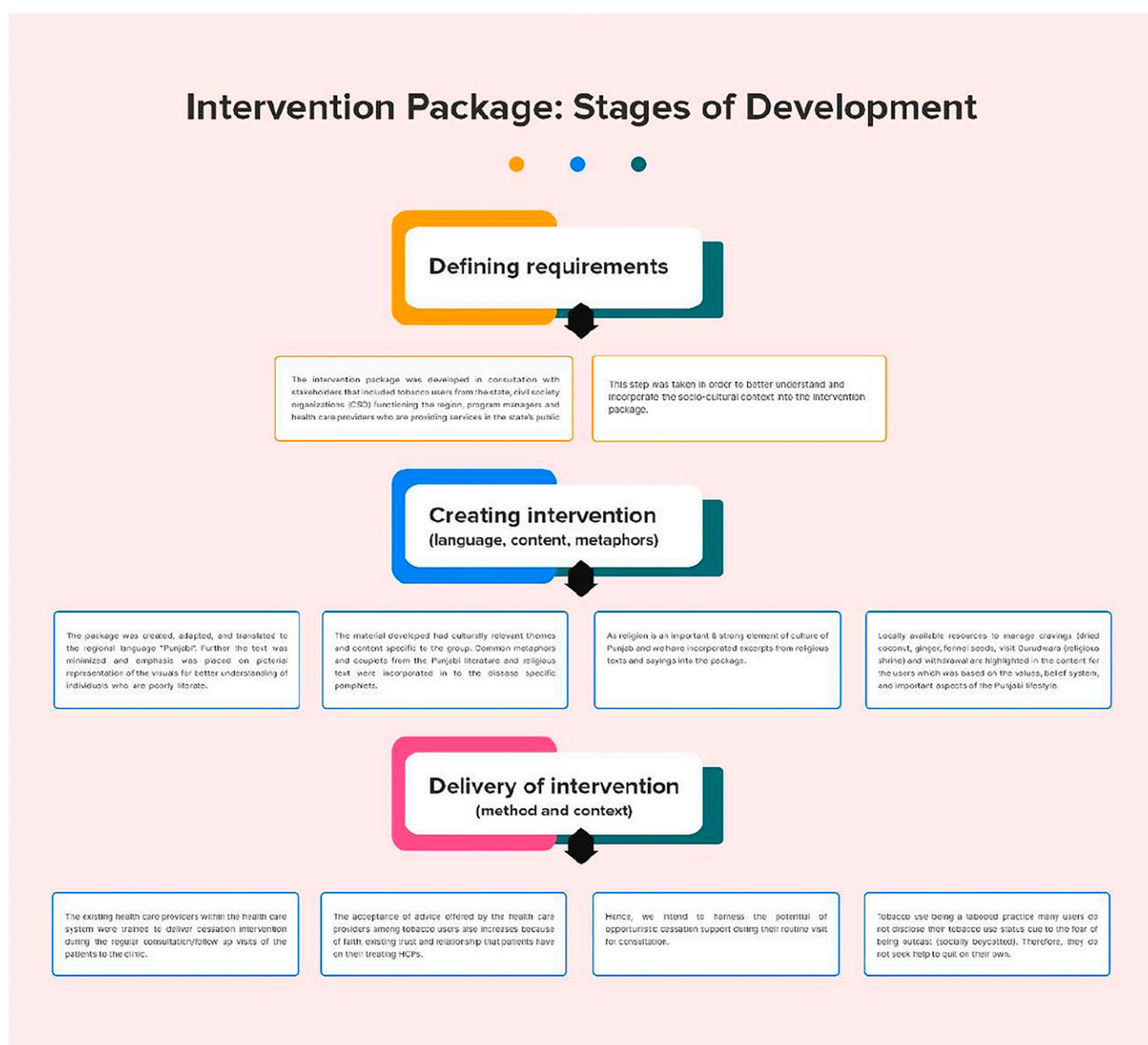

Figure 1. Stages of package development

the patient to conform to the treatment and abstain from tobacco use (reinforcement). The researcher who shall give the follow-up dates to the participants for subsequent sessions will supervise the whole cycle. They will also be provided tobacco cessation-specific cards to record their sessions, follow-up visits, and stage of behavior change. The participant's family will be actively roped in during the counseling sessions and seek inputs assisting the user in the development of a quit plan. The accompanying family member would be sent a short text message informing about the user's stage of change. The detailed roles and responsibilities of each are provided in Table 1.

Components. Four disease-specific counseling sessions will be given to the patient at an interval of 15 days, spread over 3 months. These will be completed before the first personal follow-up visit scheduled for third month. These sessions will be synchronized with their routine visits to the NCD clinic. During the personal visits, the patients shall be provided with disease-specific pamphlets containing information on the following: tobacco-specified NCD mechanism, tips to managing craving in specified NCD, case vignette, space for entering follow-up details, and contact information. Besides it, Short Text Messages (SMS) will be sent to the intervention group participants. On enrollment, a welcome text will be sent to the intervention participant on their mobile phone, followed by an introduction text informing them about the need and chronology of administration of the intervention package. After that, text messages will be sent at an interval of 15 days, consisting of messages according to disease and stage of behavior change, motivational content, and a reminder for the subsequent follow-up. SMS will also be sent to the participant's family mentioning the

participant's progress and seeking family support by the researcher. The contents of each counseling session are detailed in Table 2.

Features
  i. Culture-specific

The socio-cultural setting of Punjab is different from the neighboring states in north India. Punjab is a state which has a comparatively low prevalence of tobacco use. It exhibits a culture where tobacco use is ostracized. As a comparison, its neighboring states have a higher prevalence of tobacco use which is engrained in their cultural practice irrespective of gender. Thus, every culturally diverse group has distinct needs. This opens an opportunity to tailor our intervention that appropriately fits the needs and preferences of this particular cultural group. We have incorporated the strategies proposed by Kreuter and Wray, 2003[55] for culturally tailored interventions. These strategies emphasize the importance of cultural tailoring in making information more relevant and applicable to the targeted subgroup.[55] Besides, evidence identifies 5 elements/strengths of culturally tailored interventions. We have integrated these elements into the current intervention package: (1) culturally respectful and patient-centric care (Punjabi culture and PCC-based case vignettes); (2) healthy lifestyle promotion (quitting tobacco use); (3) increased family supports (encourage to bring a family member along during sessions); (4) use of technology (SMS to patients that are disease-specific and stage of change-based); and (5) increased knowledge of disease (disease-specific pamphlets that illustrate how continued tobacco use would impact their current disease).[56] The photographs from the community that will be used in the disease-specific pamphlets would be real-time

Table 1. Roles and responsibilities of health care providers during the study.

COMPONENT	WHO WILL DELIVER	WHEN TO DELIVER	WHO WILL RECEIVE	
			INTERVENTION ARM	CONTROL ARM
Disease-specific tobacco cessation counseling sessions	Counselor	In total of four disease-specific tobacco cessation counseling sessions will be provided by the counselor at NCD clinic using 5 A's and 5 R's approach at an interval of 15 days	√	X (Counseling on lifestyle management)
SMS to patients	Researcher	Depending upon the current disease/s, the patient is suffering from and his/her current stage of behavior change, messages will be sent at an interval of 15 days	√	X
SMS to family members	Researcher	SMS will be sent after enrollment and at each follow-up	√	X
Disease-specific tobacco cessation pamphlet	Counselor	This will be given at the time of enrollment and would brief the patient on how tobacco will exacerbate his/her NCD; general tips for its management along with tips for managing craving, short case vignette; a section to document follow-up visits with stage of behavior change of patient; and, contact details of researcher/s for any queries	√	X

and culturally relatable. Couplets and adages from local and religious contexts would be incorporated into the intervention package. The text messages and pamphlets will be translated into the vernacular language (Punjabi). The local role models would be highlighted for adopting a tobacco-free lifestyle. The tips for managing craving due to tobacco withdrawal would revolve around the available local cultural resources and real-time experiences of tobacco users from the community (Figure 2)

ii. Individualized and Patient-Centric

It is intended to use a client segmentation approach in the study. Since different stroke works for different people, the intervention shall be individualized based upon the disease profile of tobacco users and the stage of behavior change. The counselor will use various visual mediums depicting common complications of patient-specific NCDs exacerbated by tobacco

use. For example, for a hypertensive tobacco user, how continuing tobacco use would impact the patient's blood pressure, which could increase their risk of a cardiovascular event. The patient would be asked to draw a decision matrix for himself and list down the pros and cons of continuing and discontinuing tobacco use, and setting a quit date for them. The patient would be encouraged to bring along a family member during each visit. The accompanying family member would be motivated to provide a supportive environment and sit along with the counseling sessions.

iii. Trans Theoretical Model Based Strategy

All the events in the lives of people are culturally interpreted. Whatever behavior change is contemplated by the provider, and individuals view it with the prism of culture. Moreover, harnessing the power of TTM of change in adapting multiculturalism has also been documented in various domains. Stage-based model is

Table 2. Overview of the content of tobacco cessation counseling session in the intervention arm.

Session 1:
1. General rapport building
2. Asking and documenting the complete profile of patient's
3. Ask the brief history of the concerned NCD: diagnosis-duration-progress-complications (if any.)
4. Ask the brief history of tobacco use: initiation (when, reason, and duration), craving time, type, quantity and frequency of tobacco used, expenditure incurred and family history of tobacco use.
5. Assessing his stage of motivation regarding quitting tobacco use; in which stage the patient is currently in.
6. Strategy formulation which is culture-specific and patient-centric with inputs from family member.

Session 2:
1. Recap of previous session
2. Plan the session according to the motivational stage of the particular patient. For example, for a patient in pre contemplation, contemplation or relapse stage, follow the 5R's technique, or else if a patient is in preparation, Action or maintenance stage, assist him in his own attempt to quit.
3. Ask the patient to identify potential relevance of quitting, risks involved in continuing tobacco use and the benefits/rewards that he/she would experience once he/she quits.
4. Ask the patient to draw a matric of benefits vs harmful effects of tobacco use in his life, with a special emphasis of any such ill effects that he has suffered as compared to others in family/social circle who are suffering from any chronic disease but do not use tobacco.
Discuss about awareness of the patient in regard to the role of tobacco in aggravating complications of his NCD tobacco on progression of the disease that he/she is suffering from.
6. Asking about any past attempts of quitting tobacco and difficulty faced while making such attempts
7. Helping the patient to find triggers for tobacco use—guiding in dealing with such triggers, resolve hurdles without bulging in.

Session 3:
1. Assessing his current tobacco use: whether the previous sessions have made any difference in his tobacco use pattern. In case he has curtained the use or stopped, appreciate him for the efforts that he has put in.
2. In case tobacco use is continuing or has minimally decreased, try to find specific reasons (roadblocks) for that such as fear of withdrawl symptoms, inability to deal with triggers/the desire to take and address these specifically.
3. In case the person still does not sounds motivated enough for the change, keep on repeating the protocol of advising and assisting him.
4. On the other hand, if the patient is motivated enough, assist him in all possible ways by dealing with his apprehensions.
5. Arrange for follow-up in the tune his follow-up in NCD Clinic

Session 4:
1. A recap of all the previous sessions.
2. Review of his/her current symptoms and medications, which are currently going on for his/her NCD.
3. Assist the patient by addressing any problems that currently he/she is facing both due to NCD as well as tobacco use.
4. Assessing his current motivational stage, and even arranging for further follow-ups for continuing motivation enhancement till the change is brought about.
5. Assessing the primary reason that he/she feels is important for him to change his tobacco use pattern.
6. Making him ware that a relapse can happen in future and help to be in such cases.

very relevant because all people are not a single entity and not in the same phase of behavior change. There is evidence that TTM supports the cultural relevance of thematic constructs for various public health interventions such as physical activity, weight control, unhealthy alcohol use, etc. A TTM-based strategy would be adapted to motivate tobacco users depending upon their stage of behavior change and present morbidity. This strategy would be incorporated into counseling sessions and short text messages, which will be sent on the mobile phone. For example:

Stage of Change—Precontemplation

Action intended (e.g.,: diabetic tobacco users)

Session: Since in this stage, the tobacco users are not thinking about quitting tobacco products, do not/cannot see its need, and have no intention of quitting. Therefore, they shall be informed about the benefits of quitting their tobacco use and the reduced risk of associated complications. Family member's co-attending the session will be apprised of the same too. The attempt will be to shift them to the next stage by generating interest and emotional perspective would be highlighted.

SMS

**Hello!!

A sensible person will quit tobacco use for himself, his family, and his kids. Start thinking about quitting tobacco at the earliest. Quitting tobacco will keep your sugar levels/ Diabetes under control and eliminate/minimize its complications—heart attack, asthma, and other respiratory diseases, cancer, blindness, kidney disease, etc. will also be reduced.

"Choose life not tobacco"!! SPH-PGI, Chandigarh

** Hello would be addressed as *"Sat Shri Akal"* (in Punjabi) and *"Namastey/Namaskar"* (in Hindi) in translated text messages. The complete text of messages would be translated to vernacular language "Punjabi" and "Hindi". Depending upon the language preference of the user, text messages in the preferred language would be sent to the participant.

iv.   Multimodal Behavioral Intervention Package

The current package encompasses modalities including individualized patient-centric face-to-face counseling, delivery of culture and disease-specific messages, active involvement of family during the intervention, and customized mobile SMS to the stage of behavior change of tobacco users.
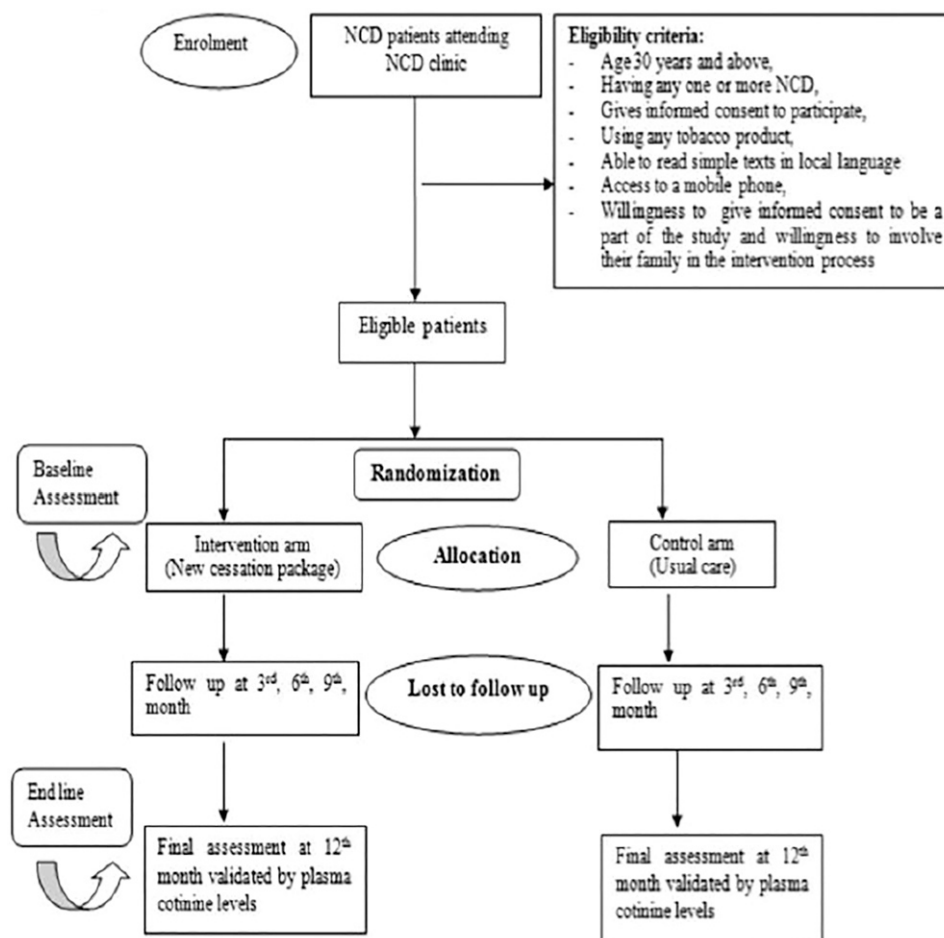

Figure 2. Flow diagram for enrollment and follow-up plan of RCT.

Control arm

The "usual care" will be administered in the control arm. The "usual care" includes services that are being provided by the government under the National Programme for Prevention and Control of Cancers, Diabetes, Cardiovascular Diseases, and Stroke (NPCDCS). This will comprise a comprehensive examination, diagnosis, management of the disease by the doctor, and brief advice on quitting tobacco use. The nurse will assist in patient's examination, imparting education about risk factors of NCDs to the patients and attendants with assistance in follow-up care. The counselor shall provide diet and lifestyle management counseling as well as assistance with follow-up care.

The researcher shall actively monitor both these groups for 12 months.

Outcome indicators

The primary outcome would be 7-day abstinence from tobacco use.

The secondary outcome would include a quit attempt, the number of sticks/pouches of SLT used expenditure on tobacco products, switching to any other tobacco products (if any).

Sample size

For calculating sample size, estimated abstinence of (.9%) in the usual care group and (14.4%)[47] in the intervention group with type I error 5%, power of 90% at 95% of the confidence interval will be taken along with additional 20% of the calculated sample to compensate for the loss to follow-up. STATA version 13SE was used to calculate sample size, using power analysis for 2 sample proportions (Pearson's chi-squared test). We arrived at a sample size of 160 for the study and multiplied with an adjustment factor for a 20% follow-up loss, resulting in 200 (.ie.,, 100 in each group).

Enrollment, randomization, and generation of random sequence

NCD patients will be screened using a screening tool based upon standardized tools (WHO-STEPS survey and GATS questionnaire),[5,57] which will comprise questions on basic socio-demographics, disease history, and duration, along with the history of tobacco use. They will then be screened based upon the inclusion and exclusion criteria. Those who meet the eligibility requirements will be invited to participate during their routine visit to the NCD clinic (Figure 3). Their informed consent will be obtained and then shall be randomly assigned into either the control arm (usual care) or the intervention arm via block randomization using a computer-generated random sequence using a block size of 4.

Concealment of allocation and blinding

Block randomization method would be used to prevent anticipation of the allocation and reduce the researcher's bias. An independent faculty not involved in the study will generate a random sequence using a computer. The researchers will enroll participants based upon the random sequence and assign them to the intervention or control arm. Participants will be unaware of their allocation; however, the researcher will be aware of the patient's (participant's) allocation at the time of enrollment and follow-up to allow appropriate intervention and follow-up questionnaires can be administered.

Data collection

Baseline information. Baseline information from the enrolled patients will be collected by using a pretested questionnaire which will include their basic socio-demographic information, tobacco use history (age of initiation, years of use, type of tobacco product used, quantity and frequency, expenses on tobacco products, any previous quit attempts, etc.), history of NCD (the type of NCD, first diagnosis, number of years, and medication) in both arms. Further, each participant will be administered the Fagerstrom nicotine dependence scale[58,59] to assess nicotine dependence and the Readiness to Change questionnaire to determine the stage of behavior change.[60]

Follow-up

Follow-up of the enrolled participants will be done at an interval of third, sixth, ninth months with a final assessment at 12th months following their recruitment. Data will be collected on 7-day abstinence from tobacco, quit attempts made, the number of
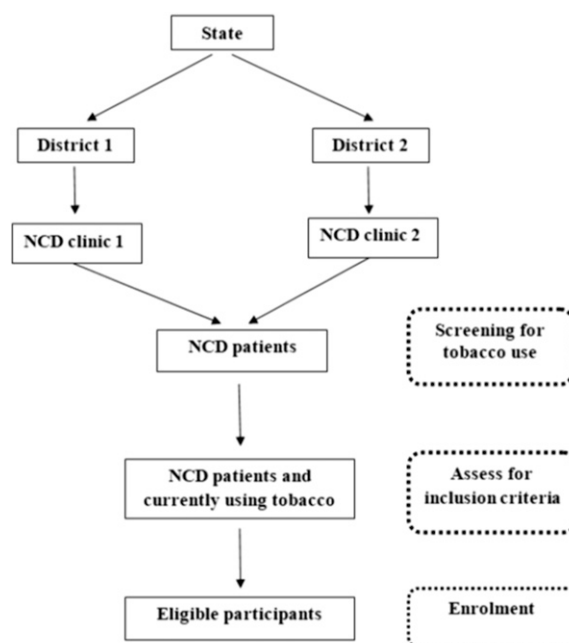

Figure 3. Participant selection and enrollment.

Table 3. Data collection overview in both arms.

DATA COLLECTION MEASURES	BASELINE	3RD MONTH FOLLOW-UP	6TH MONTH FOLLOW-UP	9TH MONTH FOLLOW-UP	12TH MONTH FOLLOW-UP
Questionnaire administration	X	X	X	X	X
Fagerstorm Nictine Dependence Scale	X	X	X	X	X
Readiness to Change questionnaire	X	X	X	X	X
Plasma continine assessment	X				X

tobacco products used (number of sticks/pouches consumed), the expenditure made on tobacco products, switch to any other tobacco product (if any). Thereafter, Fagerstorm Scale for Nicotine Dependence will be administered, and the stage of behavior change will also be assessed at each follow-up visit. The plasma cotinine level of tobacco users will be done at baseline and last, follow-up (12th month by the researcher) using the high-pressure liquid chromatography (HPLC) technique. The follow-up visits will be synced with their routine visits regarding management for NCD ailment, which might reduce the dropout rate in the study. SMS will be sent to the family of the patient after each follow-up. Participants who do not turn up for follow-up will be tried to retrieve by 3 phone calls at an interval of 15 days, after which they will be counted as "lost to follow-up (Table 3)."

Training of health care providers

The health care providers of NCD clinics shall be trained on tobacco cessation intervention package by experts in tobacco cessation in collaboration with the Department of Health and Family Welfare, Punjab, through a 1-day workshop. The training workshop curriculum will broadly cover topics like tobacco use as a major risk factor for NCDs and its impact, benefits, and challenges of quitting 5 A's and 5 R's algorithm.[61] Further, the researcher will observe them while administering the package in real settings and provide valuable inputs and feedback. Also, qualitative feedback will be sought from health care providers at the NCD clinic, administrative authorities of both programs (NTCP and NPCDCS), and public health experts for improvement in the intervention package.

Data management and analysis

Each study participant will be assigned a unique identification number, and their information and blood samples collected will be stored using that unique identity number. Double data entry will be done, errors will be checked, and data will be analyzed using IBM SPSS version 22. Descriptive analysis will be undertaken for baseline and follow-up variables as appropriate. Chi-square test of the association will be used to compare socio-demographic and tobacco use characteristics between groups at baseline. Logistic regression will be used to undertake between-group comparisons on the primary and secondary outcomes at third, sixth, ninth, and 12th-month follow-up (95% confidence intervals). Multivariate models using multiple logistic regression analysis will be used to identify the correlates of quit attempts. Statistical significance will be set at two-tailed $P < .05$. Mann–Whitney test will be carried out to compare secondary outcomes (such as the number of quit attempts and number of sticks/SLT pouches used per day). Intention to treat analysis will be done while comparing the outcome in participants in the intervention arm with those in the control arm. To assess the difference in cessation between types of tobacco use, we would compare the overall quit rate between intervention and control groups followed by subgroup analysis among the type of tobacco users.

Discussion

A lack of intervention protocol was cited as a barrier to culturally tailored intervention research in many studies.[56] Culturally tailored intervention has immense potential to reduce health care disparities and improvise the quality of life for specific subgroups. Adopting these strategies will help us in achieving Sustainable Development Goals. This study focuses on smoked as well as smokeless tobacco users, and there is meager evidence in the country where a culture-specific patient-centric intervention package is evaluated among smokeless tobacco users. It undertakes capacity building of existing human resources, further strengthening and increasing the outreach of cessation services, with a potential to ensure suitability within the system for the long term. Further, the study proposes utilizing and encash existing NCD clinics to deliver "opportunistic cessation support." Development and implementation of culturally tailored patient-centric cessation interventions could retain study participants and decrease dropouts. The application of mobile technology to deliver culturally, linguistically, and stage of change appropriate short text messages could prove to be an efficient method of staying connected and intervention delivery. Further assessment of implementer experiences concerning this intervention could elicit the strengths and areas of improvisation to practice and upscale interventions for culturally diverse groups. In addition, the findings could support health care

Box-1 List of operational definitions used in study[61]

Current tobacco smoker: An individual who is currently smoking any tobacco product, either daily or occasionally.
Current SLT user: An individual who is currently using any smokeless tobacco product, either daily or occasionally.
Health Care Provider (HCP): Includes health professionals involved in health care delivery to patients such as medical doctors, nurses, etc.
Quit attempt: Tobacco use abstinence by the current tobacco user for at least 24 hours since last follow up.
Point prevalence abstinence (PPA): Measure of cessation outcome at a particular point in time. In this trial, 7- day point prevalence abstinence will be used.
Biochemical verification: Presence of nicotine/ cotinine/ other chemicals in blood, urine or exhaled air assessed biochemically. It is done for verifying the self-reported status for a successful quit by a smoker or SLT user. In this trial, blood samples will be used.
Nicotine Replacement Therapy (NRT): Treatment administered to substitute the nicotine obtained from tobacco by pharmaceutical nicotine for a limited period (usually for 6-8 weeks). It helps reduce the withdrawal symptoms, predominantly craving, (witnessed during initial phase of abstinence; about 2-4 weeks) when users are attempting to stay quit. The NRT can be administered by mouth using gum, through skin using patches or as lozenges.
Relapse: Resuming tobacco use after a successful quit, i.e. after an absolute abstinence for a month or more.
Harm Reduction: It implies to the methods used to reduce harm led by continued tobacco use. In this study cutting down on number of sticks smoked per day/ number of pouches of SLT chewed per day will be used.

policymakers to initiate large-scale projects to deliver culturally tailored patient-centric care and enhance health care among diverse socio-cultural groups.

This pilot study protocol outlines the design of a single-blind randomized controlled trial that compares a novel tobacco cessation intervention package with the existing usual care within the NCD clinics running under the NPCDCS Programme. The proposed intervention package shall increase the outreach of cessation services to the population using available resources, thereby strengthening health systems. It is a documented fact that HCPs are uniquely positioned to make a significant difference in the lives of tobacco-using patients suffering from any noncommunicable disease through minimal intervention because of their established relationship and trust with the patient. Further, there are amply documented pieces of evidence that tobacco users benefit in terms of quit rate more in case of disease-specific advice rather than generic advice. To the best of our knowledge, this RCT is the first to assess the effectiveness of utilizing NCD clinics for tobacco cessation services in India. The results of this pilot study could be pertinent to improve the quality of life of patients suffering from NCDs by supplementing efforts in their disease management through behavioral counseling and providing a base for larger-scale trials.

This intervention shall provide an opportunity to intervene when the patient's receptivity to the advice offered is optimal and mutually benefit both the programmes (National Tobacco Control Programme and NPCDCS) resulting in reduced prevalence of NCDs and tobacco use. Thus, this pilot study shall also guide the policymakers and implementers in adopting this framework for tobacco cessation intervention in other similar settings. The intervention proposed in this study will be developed on the TTM model, which could offer cessation support to the user according to its stage of change. The intervention will be culturally specific and thus more adaptable and applicable in the given context. The involvement of a tobacco user and his family make the intervention patient-centric, where they can collectively develop an individualized quit plan and the user can also garner support from family members during the process.

The strengths of the study are its highly rigorous RCT design, where patients are blinded to intervention to prevent contamination; use of biochemical verification of quit status; intensive behavioral counseling package involving tobacco user and his/her family; use of multimodal behavioral intervention package (face-to-face counseling sessions, pamphlets, and short text messages) which is specific to disease and stage of behavior change of tobacco users. The consideration of tobacco users' socio-cultural and patient-centric approach in developing intervention makes it robust and adaptable in similar settings. The proposed intervention also emphasizes empowering patients to develop their quit plan, building on their needs and concerns. Through this intervention package, we also attempt to harness the power of TTM of change in adapting multiculturalism in tobacco cessation.

However, the social desirability bias attached to tobacco use in Punjab might lead to the underreporting of tobacco use status among the patients attending the NCD clinic. Further, as multispecialty and tertiary care hospitals exist within the study area, patients with cancer, stroke, and cardiovascular diseases may seek consultation and treatment in these health facilities instead of routine NCD clinics. Besides, the longer follow-up period (up to 12 months) may lead to substantial dropouts. Also, the proposed study may fall short of proposing any specific solutions for illiterates due to its limited application among them.

Conclusion

Tobacco use is a major risk factor for developing NCDs and exaggerating its complications. For LMICs and MIC's wherein financing is a critical issue for sustaining any health programme, the accessibility and affordability of pharmacotherapy becomes a significant bottleneck in the effective delivery of tobacco cessation services. Hence, a culturally specific patient-centric intervention package focusing on behavior change appears to be a sustainable way to help NCD patients quit successfully.

Appendix

List of Abbreviations

DALY	Disability Adjusted Life Years
SLT	Smokeless tobacco
NFHS	National Family Health Survey
NCD	Non Communicable Disease
LMIC	Low and Middle-Income Countries
CVD	Cardiovascular Diseases
WHO	World Health Organization
COPD	Chronic Obstructive Pulmonary Disease
MPOWER	Monitoring tobacco use, Protecting people from second-hand smoke, Offer help to quit tobacco, Warn against harms of tobacco, Enforce laws and Raise taxes on tobacco products
FCTC	Framework Convention on Tobacco Control
RR	Relative Risk
RCT	Randomized Controlled Trial
AOR	Adjusted Odds Ratio
CBT	Cognitive Behavioral Therapy
GoI	Government of India
TCC	Tobacco Cessation Clinics
NTCP	National Tobacco Control Program
MoHFW	Ministry of Health and Family Welfare
NPCDCS	National Programme for Prevention and Control of Cancers, Diabetes, Cardiovascular Diseases, and Stroke
CHC	Community Health Centre
GATS	Global Adult Tobacco Survey
COTPA	Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply, and Distribution) Act
DTCC	District Tobacco Control Cell
NRT	Nicotine Replacement Therapy
5A	Ask, Advice, Assess, Assist, and Arrange
5R	Relevance, Risks, Rewards, Roadblocks, and Repetition
SMS	Short Text Messages
HCP	Health Care Providers
CTRI	Clinical Trials Registry, India
TTM	Trans Theoretical Model
SCT-	Social Cognitive Theory
HBM-	Health Belief Model

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Authors' contributions

SG conceptualized the idea. GB did a review of the literature. SG, RG, SG, and BM designed the study. GB drafted the paper. The draft was critically revised for important intellectual content by all authors and thereafter approved the final version. All authors have read and approved the manuscript. SG is the guarantor for all aspects of the study ensuring those questions related to the accuracy or integrity of any part of the work that is investigated.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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