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A randomised controlled trial to evaluate the effectiveness of a culture and disease-specific, patient-centric multi-component tobacco cessation intervention package for the patients attending non-communicable disease clinics in Punjab, India

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ABSTRACT

Background: Developing an infrastructure to support tobacco cessation through existing systems and resources is crucial for ensuring the greatest possible access to cessation services. The present study aims to evaluate the effectiveness of a newly developed multi-component cessation among tobacco users in Non-Communicable Disease (NCD) clinics, functioning under the National Programme for Prevention & Control of Cancer, Diabetes, Cardiovascular Diseases, & Stroke (NPCDCS) of the Government of India.

Methods: The intervention package consisting of culture- and disease-specific four face-to-face counselling sessions, pamphlets, and short text messages (bilingual) with follow-ups at 3rd, 6th, and 9th months with an endline assessment at 12th months was delivered to the intervention arm of the two-arm- parallel group randomised controlled trial at two selected NCD clinics. Self-reported seven-day abstinence, frequency of use, expenditure in seven days at each follow-up, FTND score, stage of change and plasma cotinine

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values were assessed at baseline, follow-ups, and endline (using Liquid Chromatography –Mass Spectrometry), as applicable.
Results: The intervention arm reported a significantly more reduction in self-reported frequency of tobacco use at 6 months (mean: 13.6, 95% CI (7.8–19.4)), 9 months (mean: 20.3, 95% CI (12.2–28.4)) and 12 months (mean: 18.7, 95% CI (8.7–28.7)). The plasma cotinine concentration at endline in the intervention arm was statistically significantly lower than the baseline concentration.
Conclusion: Strengthening existing health systems is crucial for offering cessation support in the resource-restraint setting of LMICs to assist in quitting sustainably.

Background

Non-communicable diseases (NCDs) account for approximately 5.87 million (60%) of all deaths in India (World Health Organization, 2014a). Besides, there are 268 million (28.6%) adult tobacco users, 99.5 million (10.7%) current smokers and 199.4 million (21.4%) current smokeless tobacco (SLT) users in India (Global Adult Tobacco Survey, 2016–17). The literature available globally highlights the certainty between tobacco use and its linkage with NCDs. A European survey (EUROASPIRE) or multicentric setting reported that 21% of CHD patients continue to smoke even after being diagnosed with the disease (Scholte Op Reimer et al., 2006). The prevalence was 26 in patients with COPD (Garcia-Aymerich et al., 2000) while a global review estimated tobacco use among diabetes patients to be 20.81% (Roderick et al., 2019). A study conducted at an outpatient NCD clinic in Ballabhgarh, India reported a 20.8% prevalence of tobacco use (Kumar et al., 2021). Continued smoking with long-term disease conditions adds to excess death rate and morbidities by hastening disease progression, unfavourable outcomes, excessive complication rates, and poor treatment compliance (Gerber et al., 2009).

The body of evidence on the health benefits (both generic and disease-specific) of tobacco cessation continues to grow and evolve (United States Public Health Service Office of the Surgeon General; National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking & Health, 2020a, 2020b). Along with many 'teachable moments' during their care, patients with chronic illnesses are usually more amenable to messages related to tobacco cessation (Hansen & Nelson, 2011). Likewise, patients with diabetes, hypertension, and coronary heart disease are more motivated for tobacco cessation. They also feel the need to receive continuous support than what general populace seeks (Wilkes & Evans, 1999). The evidence from developed nations has demonstrated the effectiveness of cessation interventions (counselling, healthcare worker-delivered cessation advice, telephone and individual counselling, disease-specific messages, culturally tailored, etc.) among NCD patients, resulting in higher abstinence rates and better health outcomes in comparison to usual care (Canga et al., 2000; Epstein et al., 2017; Kaiser et al., 2018; Patel et al., 2016; Persson & Hjalmarson, 2006; Thabane & Group, 2012). In India, where the burden of SLT is the largest, as well as preceded by smoking, it is crucial to provide support to all types of tobacco users. Under the National Programme for Prevention and Control of

Cancers, Diabetes, Cardiovascular Diseases, and Stroke (NPCDCS), 'NCD Clinics' were introduced by the Government of India in the years 2010–2011 for the prevention of NCDs. The service offers a comprehensive examination, diagnosis, and management of subjects suffering from these diseases in conjunction with diet counselling as well as lifestyle management (Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India, 2010).

WHO recommends to 'develop an infrastructure to support tobacco cessation and treatment of tobacco dependence by existing systems and resources to ensure the greatest possible access to services' (World Health Organization, 2019). The Global Adult Tobacco Survey-2 (GATS) findings reported that about 55.4% of current smokers and 49.6% of current SLT users planned or thought of quitting (Global Adult Tobacco Survey, 2016–17) presenting an important opportunity to provide help to quit. Cessation support can more than increase the chance of successful tobacco cessation (Global Adult Tobacco Survey, 2016–17). However, till now, the effectiveness of NCD clinics in providing tobacco cessation assistance remains unexplored. The trials undertaken on these disease-specific groups have focused on one or two chronic conditions. Contrastingly, the evidence suggests that an established NCD clinic in the health system has the potential to engage more patients from various NCDs with constant infrastructure and human resources (Bhatt & Goel, 2018). Besides, identification of stage of change could help in developing tailored interventions to support tobacco users in quitting at different stage of change (Mbulo et al., 2017). Also, particular culture-sensitive cessation interventions have been shown to decrease risky health behaviours, address cultural barriers to change, and improve acceptability. Evidence also suggests that involving the family in the tobacco cessation process and leveraging their role and influence leads to better outcomes (Bhatt et al., 2021). An intervention study by Thankappan et al among diabetic smokers in diabetes clinics of Kerala, India found that the value addition of culturally sensitive diabetic-specific cessation counselling sessions delivered by non-doctor health professionals led many patients to quit or significantly reduce their smoking habit thereby preventing complications from diabetes (Thankappan et al., 2013). Apart from increasing scientific rigour and validity, biochemical confirmation of cessation is critical in studies where socio-cultural beliefs, norms, and individual attributes affect the reporting of tobacco use status (Benowitz et al., 2020).

The present study aims to evaluate the effectiveness of a newly developed multi-component culture and disease-specific, patient-centric, cessation intervention (using the TTM framework) among tobacco users compared to usual care in NCD clinics in Punjab, functioning under NPCDCS program of the Government of India.

Methods

Study area and settings

Punjab is home to a population of 27.7 million (Census, 2011) and is divided into twenty-two districts (Department of Planning Government of Punjab, 2011). Majority of the population practices the Sikh religion. Punjabi is the official language of the state and is also spoken by the majority of natives (Government of Punjab, India, n.d.). At the time of GATS-2 in Punjab (2016), 13.4% of all adults (25.3% of men,

0.5% of women) either smoke and/or use SLT. Also, 47.5% of current smokers and 49.7% of SLT users planned to or were thinking about quitting (Tata Institute of Social Sciences, Mumbai and Ministry of Health and Family Welfare, Government of India, 2018). Based on this background, two NCD clinics running at the district level of Punjab were selected for the pilot study where the intervention was 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 the program, the 'NCD clinics' initiative was launched at Community Health Centre (CHC) level and district hospitals for comprehensive diagnosis and management of subjects suffering from major NCDs. 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 equipped with a team containing a medical officer, counsellor, nurse, and a data entry operator and provide screening, diagnosis, management, and counselling services for NCDs focusing primarily on lifestyle and dietary modifications (Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India, 2010).

Study design and participant eligibility

It was a parallel group randomised controlled trial (RCT) including two arms with an allocation ratio of 1:1. The patient (participant) was the unit of randomisation. The study had a recruitment period of six months (October 2018–March 2019). The intervention period of three months and follow-ups were carried out at third, sixth, and ninth months. Endline assessment to measure the effect of the intervention was conducted at 12th month. The participants comprised NCD patients who were tobacco users and were seeking treatment from the NCD clinic. The eligible patients were screened based on the inclusion & exclusion criteria. Those meeting the eligibility criteria were enrolled in the study after obtaining their informed consent. The enrolled patients were randomly assigned into either the control arm (routine care) or the intervention arm following block randomisation using a computer-generated random sequence using a block size of four.

Inclusion criteria

These included the patients suffering from NCDs (Diabetes, Hypertension and other CVDs, Stroke, Cancer, Chronic Respiratory Diseases such as COPD and asthma) visiting the NCD clinics aged 30, and using any tobacco products (smoked/smokeless). As required to comprehend the information given in the intervention package, the participants should be able to read simple texts in the local language as well as have access to a mobile phone. Patients following the mentioned inclusion criteria and willing to give informed consent to be a part of the study and involve their family members in the process were included in the study.

Exclusion criteria

Patients already on Nicotine Replacement Therapy (NRT) or at the end stage of cancer, on renal dialysis, psychiatric illness, multi-morbidities, etc. (with poor prognosis of advanced stage NCD) were not included.

Sample size, randomisation, allocation concealment and blinding

To calculate sample size, estimated abstinence of (0.9%) in the usual care group and (14.4%) (Lou et al., 2013) in the intervention group were considered based on the existing literature. Keeping the margin of type I error as 5%, a power of 90% at 95% of the confidence interval, the sample size was calculated with an additional 20% of the calculated sample to compensate for the loss to follow-up. STATA version 22 was used to calculate sample size, using power analysis for two sample proportions (Pearson's chi-squared test). A sample size of 160 was obtained and multiplied with an adjustment factor for a 20% follow-up loss, resulting in 200 (i.e. 100 in each group) participants being recruited in the study. The participants were randomised into intervention and control (routine care) groups using block randomisation to prevent anticipation of the allocation and reduce the researcher's bias. An independent faculty who was not involved in the study generated a random sequence using a computer. Participants were enrolled based on the pre-generated random sequence and were assigned to the intervention or control group. The trial was single-blinded, i.e. only the study participants were unaware of their allocation. Both these groups were actively followed up for 12 months (Figure 1).

Components of the package for the intervention group and implemented framework

The idea of this study was to develop and test an intervention by utilising existing resources at the level of the selected health facility. The routine clinical services at NCD clinics include consultation by the doctor for the patient's current NCD, brief advice to quit; diet and lifestyle counselling by the counsellor; guidance by the nurse on treatment, medication, and encouragement to the patient to conform to the treatment and abstain from tobacco use. The intervention package, based on the Trans-Theoretical Model (TTM) to understand behaviour change, included the following additional components:

Disease-specific counselling

The basic component of the intervention care package was the delivery of four disease-specific-based disease counselling sessions for the patients of the intervention arm at an interval of 15 days, spread over three months. These were completed before the first personal follow-up visit scheduled at the end of third month. These sessions were synchronised with the participant's existing plan of visits to the NCD clinic (consultation or reviewing of reports).

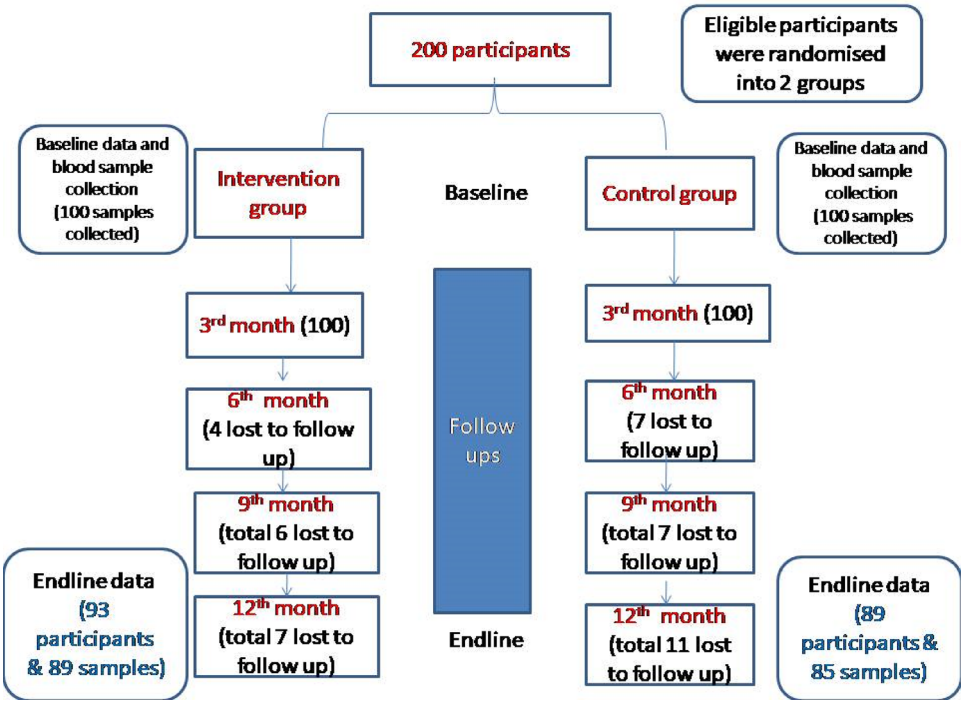

Figure 1. CONSORT flow diagram for enrolment and follow-up plan of study participants.

Disease-specific pamphlets

The second component of the intervention care package included the development and distribution of the disease-specific pamphlet. These were given to participants in the intervention arm containing information on the following: tobacco-specific NCD mechanism, tips to managing craving in specified NCD, case vignette, space for entering follow-up details, and contact information. These disease-specific pamphlets were developed bilingual (Hindi/Punjabi) and were given in the desired language of the participant.

Short text messages (SMS) service

The next component of the intervention package included the delivery of bilingual SMSs. On enrolment, a welcome text was sent to the participant on mobile phone, followed by an introductory text which highlighted the need of quitting and a few generic tips. Text messages were sent every 15 days. The motivational messages were customised as per the disease status and stage of behaviour change. Subsequently, the participants were sent a reminder call for the next follow-up. To engage the family in the participants' journey towards tobacco cessation, SMS at regular intervals were sent to the participant's family mentioning the participant's progress and seeking family support by the researcher.

Delivery of intervention

At the end of the consultation, the doctor instructed the patient to meet the counsellor. The designated counsellor provided face-to-face patient-specific

(status of NCD control and stage of change of patient towards tobacco cessation) counselling (15 to 20 min) using the 5 A's & 5 R's (World Health Organization, 2014b) and TTM strategy (Mbulo et al., 2017). The participants were asked to draw a decision matrix for themselves, listing out the benefits and harms of continuing and discontinuing tobacco use. They were encouraged at this stage to set a quit date for them. Thereafter, the nurse assisted in blood sample collection and encouraged the patient to follow a medication regime and abstain from tobacco use. The blood sample was collected at baseline and endline and was analysed to assess the level of plasma cotinine before and after administration of intervention (an indicator of exposure to one or the other forms of tobacco). They were also issued disease-specific pamphlets. The researcher gave the follow-up dates to the participants for upcoming sessions and supervised the entire cycle. The patient was encouraged to bring a family member along on the subsequent follow-ups. The family member was actively roped in during the counselling sessions to seek input assisting the patient in the development of a quit plan and encouraged to provide a supportive environment. The family member was sent a short text message informing about the user's progress and stage of change.

Service provision in the control group

The 'usual care' or 'routine care' was administered in the control arm, which included services that are being provided by the government under the NPCDCS (Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India, 2010). It included a thorough examination, diagnosis, disease management by the doctor, and brief advice on giving up tobacco use. The nurse assisted in the examination of the patient, provided health education about NCD risk factors to patients and attendants, and assisted in follow-up care. While the dietary and lifestyle management counselling, as was provided by the NCD counsellor.

Training of health care providers

Before rolling out the intervention package, the health care providers (HCPs) were trained on the tobacco cessation intervention package. The one-day training workshop was carried out in collaboration with the Department of Health and Family Welfare, Punjab. The HCPs were provided training by the subject experts. The curriculum of the training workshop included tobacco use, risk, the impact of continued tobacco use on NCDs, benefits, and challenges of quitting, use of the 5 A's ('Ask, Advise, Assess, Assist, Arrange'), and 5 R's ('Relevance, Risks, Rewards, Roadblocks, and Repetition') (World Health Organization, 2014b) approach and various stages of change. The training sessions for nurses were carried out at respective pilot districts. Besides, the researcher observed them while they delivered the package in real-world settings and provided feedback. The trainings were carried out in March 2019.

Experimental method validation

Experimental

To estimate plasma cotinine levels among the study participants, the first step was standardisation of liquid chromatography–tandem mass spectrometry (LC–MS/MS) method (Please refer to figures 2 and 3 in supplementary file). This was carried out by following the method validated by Abdallah et al. (2016) The details of the methods are given in the supplementary file.

Data collection

The baseline information of the study participants for both groups included socio-demographic information, NCD type and duration, type of tobacco used, age of initiation, frequency of use, duration of use, and expenditure using a pretested questionnaire. Besides, FTND score (Ebbert et al., 2006; Heatherton et al., 1991) and stage of change were also assessed (Heather & Rollnick, 1993). At each follow-up (3rd, 6th, 9th, 12th months) the participant was asked whether he had used tobacco (smoked/SLT) even once during the last seven days, frequency of use, the average amount spent on tobacco products, quit attempt in last seven days (if any), FTND score and stage of change. Participants who didn't turn up for follow-up were contacted by three phone calls at an interval of 15 days, after which they were counted as 'lost to follow-up'.

Blood samples were collected from participants of both groups at baseline and endline to assess the plasma cotinine levels. After obtaining 2 ml of the sample *via* vein puncture from the participant, it was transferred to an EDTA vial and labelled. The samples were transported from the district-level facility to the laboratory at PGIMER in a cold box. The samples were centrifuged for 3 min and transferred into storage tubes; labelled and stored in −80 °C in cryoboxes until analysis.

Study outcomes

Each study participant was followed up for 12 months following enrolment. The primary outcome of the study was self-reported seven-day abstinence from tobacco use at each follow-up. The secondary outcome included a change in frequency of tobacco use (number of sticks/number of times SLT used per day), the average amount spent on tobacco products, and quit attempt (tobacco use abstinence for 24 h) in the last seven days. The Fagerstrom Nicotine Dependence Score (FTND) (Ebbert et al., 2006; Heatherton et al., 1991), stage of behaviour change (Heather & Rollnick, 1993), was also assessed. We also analysed plasma samples for cotinine level estimation among both intervention and control groups at baseline and endline.

Statistical analysis

Data analysis was done using Statistical Package for Social Sciences (SPSS IBM Corp, Released 2013, IBM SPSS Statistics for Windows, version 22.0). Kolmogorov Smirnov

test for normality of continuous data was applied. Data that were not normally distributed were represented by median and inter-quartile range (IQR). Frequencies were reported for the categorical variables. Bivariate analysis was done using the chi-square test (for categorical variables) and independent samples median test as well as t-test (for skewed and continuous variables, respectively). Per protocol analysis and intention to treat analysis (ITT) was done. Follow-up variables with missing data were set to their baseline values (tobacco users). The primary and secondary outcomes measures were compared between both groups at baseline, follows ups (third, sixth, ninth) and endline, as applicable. The comparison was represented as odds ratios (ORs) at 95% confidence interval (CI) with statistical significance at two-tailed $p < .05$.

Results

Table 1 describes the pattern of tobacco use among the study participants. The mean age of initiation reported was 21.7 ± 5.1 years. The majority were smokeless tobacco users (50.0) with a daily frequency of use (98.0%) and used a single form of tobacco (95.5%). No significant difference between the tobacco use patterns of both the intervention and control groups was observed (Table 1).

The difference in the proportion of tobacco use among study participants in past week at six, nine month follow-up and endline was statistically significantly lesser in the intervention group. There was a significant difference in expenditure on tobacco purchase between intervention and control group participants at endline with less expenditure reported among intervention group participants (Table 2).

Supplementary Table 2 presents the biochemical analysis results to measure plasma cotinine levels among study participants at the end of the intervention. The Plasma Cotinine concentration in endline in the intervention arm was statistically significantly lower than the baseline concentration. In the control arm as well, a similar trend was found, however, the reduction at endline was not statistically significant.

Table 1. Comparison of pattern of tobacco use between intervention and control groups.

		Group						
Characteristic	Category	Intervention arm ($n = 100$)		Control arm ($n = 100$)		Total ($N = 200$)		p Value (Chi-square)
Age of initiation of tobacco use (years)	Mean ± SD	21.1 ± 4.14		22.3 ± 6.01		21.7 ± 5.1		**.887**[a]
	Median (IQR)	20 (18.2–23.0)		20(18.2–25.0)		20 (18.2–24)		
Duration of use	Mean ± SD	30.1 ± 9.2		29.9 ± 10.5		30.3 ± 9.9		**1.000**[a]
	Median (IQR)	31 (23.0–38.0)		30 (21.2–38.7)		31 (22–38)		
		n	%	n	%	n	%	
Type of tobacco used	Smoked	47	47.0	46	46.0	93	46.5	.908
	Smokeless	49	49.0	51	51.0	100	50.0	
	Dual	4	4.0	3	3.0	7	3.5	
Frequency of use	Daily	98	98.0	98	98.0	196	98.0	1.000
	Less than daily	2	2.0	2	2.0	4	2.0	
Number of types of tobacco used	Single form	94	94.0	97	97.0	191	95.5	.498
	More than one types	6	6.0	3	3.0	9	4.5	

[a]Independent samples medians test.

Table 2. Comparison of outcome measures between intervention and control group at 3rd, 6th, 9th and 12th months follow ups, by per protocol analysis.*

Outcome measures		Intervention group ($n=100$)		Control group ($n=100$)		OR (95% CI)	p Value
Self-reported seven-day abstinence							
Follow up		n	(%)	n	(%)		
3 months	Yes	97	97	97	97	1.0(0.19–5.0)	1.000
	No	3	3	3	3		
6 months	Yes	67	69.8	88	93.6	6.88 (2.52–18.81)	<.01
	No	29	30.2	6	6.4		
9 months	Yes	66	70.2	88	94.6	8.50 (2.83–25.53)	<.01
	No	28	29.8	5	5.4		
12 months	Yes	66	71.0	84	93.3	5.72 (2.23–14.6)	<.01
	No	27	29.0	6	6.7		
Change in the self-reported frequency of use (% change)^#							
						Mean difference (95% CI)	
At 3 months (mean ± SD)		−17.63 ± 21.5		−4.00 ± 19.9		13.6 (7.8–19.4)	<.01
At 6 months (mean ± SD) ($n=170$)		2.4 ± 55.1		−12.6 ± 35.8		−15.0 (−28.7 to −1.2)	.034
At 9 months (mean ± SD) ($n=168$)		−9.1 ± 29.0		−16.3 ± 34.4		−7.2 (−17.1 to 2.8)	.155
At 12 months (mean ± SD) ($n=163$)		−10.0 ± 28.7		−13.7 ± 45.0		−3.7 (−15.8 to 8.5)	.551
Self-reported expenditure on tobacco products in last seven days (% change) INR							
At baseline ($n=200$)		40.0 (30.0–60.0)		40.0 (30.0–60.0)		40.0 (30.0–60.0)	.289
3 months ($n=200$)		40.0 (30.0–60.0)		40.0 (35.0–60.0)		40.0 (30.0–60.0)	.938
6 months ($n=186$)		30.0 (0.0–50.0)		40.0 (30.0–60.0)		40.0 (20.0–50.0)	.064
9 months ($n=184$)		30.0 (0.0–50.0)		40.0 (30.0–58.75)		40.0 (20.0–50.0)	.057
12 months ($n=179$)		25.0 (0.0–40.0)		40.0 (30.0–60.0)		40.0 (20.0–50.0)	.020

*per protocol analysis, included only those participants who adhered to the study protocol.
^Minus sign indicates the reduction in quantity of tobacco used (from the previous follow up).
#t-test used

Self-reported seven-day abstinence

The first-ever status of seven-day abstinence was recorded at the third-month follow-up. The proportion of participants who practiced seven-day abstinence in the intervention group and control groups was the same (3% in each group) (Table 3).

At six months, the proportion of participants who reported seven-day abstinence was 27% in the intervention group and 4% in the control group, this difference was statistically significant. Furthermore, at the nine-month follow-up, the endline difference in the proportion of participants reporting seven-day abstinence was statistically significant with a higher proportion of participants practicing abstinence in the intervention group (Table 3).

Self-reported frequency of tobacco use

The percent change in the quantity of tobacco use at the three-month follow-up was statistically significantly higher (greater reduction in tobacco use) among intervention group participants. A similar trend was seen at 9-month and 12-month (endline) follow-up with a higher percent reduction in self-reported frequency of tobacco use in intervention group participants.

The 50–100% reduction in cotinine level was higher in the intervention group in comparison to the control group after intervention delivery (Table 4).

Table 3. Outcome measures among study participants by Intention to treat analysis.*

Outcome measures		Intervention group (n = 100) n	(%)	Control group (n = 100) n	(%)	OR (95% CI)	p-value
Self-reported 7-day abstinence							
3-months	No	97	97.0	97	97.0	1.0(0.19-5.0)	1.000
	Yes	3	3.0	3	3.0		
6-months	No	73	73.0	96	96.0	8.8 (2.9-26.4)	<0.01
	Yes	27	27.0	4	4.0		
9-months	No	74	74.0	96	96.0	8.4 (2.8-25.2)	<0.01
	Yes	26	26.0	4	4.0		
12- months	No	73	73.0	94	94.0	5.7 (2.2-14.7)	<0.01
	Yes	27	27.0	6	6.0		
Change in the Self reported frequency of tobacco use (% change)^#							
						Mean difference (95% CI)	P-value
% change at 3-months (Mean ± SD)		−17.63 ± 21.5		−4.00 ± 19.9		13.6 (7.8-19.4)	<0.01
% change at 6-months (Mean ± SD)		−8.35 ± 57.8		−2.40 ± 27.9		5.9 (-6.7-18.6)	0.356
% change at 9-months (Mean ± SD)		−22.24 ± 37.7		−1.92 ± 16.1		20.3(12.2-28.4)	<0.01
% change at 12-months (Mean ± SD)		−21.33 ± 37.9		−2.59 ± 34.0		18.7(8.7-28.7)	<0.01
Self reported expenditure on tobacco products in last 7 days INR							
Baseline [median (IQR)]		50.0 (40.0-60.0)		40.0 (30.0-60.0)		40.0 (30.0-60.0)	0.119
3-months [median (IQR)]		40.0 (30.0-60.0)		40.0 (35.0-60.0)		40.0 (30.0-60.0)	0.887
6-months [median (IQR)]		40.0(25.0-60.0)		40.0(30.0-60.0)		40.0 (30.0-60.0)	0.469
9-months [median (IQR)]		40.0(20.0-60.0)		40.0 (30.0-58.8)		40.0 (30.0-60.0)	0.470
12- months[median (IQR)]		40.0(20.0-60.0)		40.0 (30.0-60.0)		40.0 (30.0-60.0)	0.383
Plasma cotinine level (ng/ml)							
at baseline Mean ± SD		206 ± 141.16		213.76 ± 145.72		7.5(-32.5-47.6)	0.710
at endline (12 months) Mean ± SD		137.79 ± 121.25		182.18 ± 124.96		44.3(9.9-78.8)	0.012

*intention-to-treat analysis, assumed all non-responders/dead/lost to follow up patients as current tobacco users, no quit attempt in last 7 days of follow up; and with same tobacco use frequency and expenditure as that of baseline.

^Minus sign indicates the reduction in quantity of tobacco used (from the previous follow up).

Table 4. Proportional distribution of percentage reduction in cotinine level in intervention and control group after intervention delivery.

		Group: Control (n = 99) n	%	Intervention (n = 100) n	%	Total n	%	p Value (chi-square)
Percent cotinine level change	50–100% reduction	24	24.2%	42	42.0%	66	33.2%	.004
	Less than 50% reduction	20	20.2%	25	25.0%	45	22.6%	
	No change or increase in cotinine level	55	55.6%	33	33.0%	88	44.2%	

Self-reported expenditure on tobacco products in the last seven days INR

The change in tobacco use among study participants was assessed based on the tobacco purchase expenditure at multiple follow-ups. It was found that the average expenditure on tobacco products was similar across both groups.

Plasma cotinine level (ng/ml)

The mean plasma cotinine level in the intervention group was significantly lower in the intervention group as compared to the control group.

The FTND was administered to those who were still using tobacco at the particular follow-up. Thus, this was analysed using a per-protocol approach. The proportion of participants with low dependence on tobacco use at sixth and ninth-month follow-up and baseline was higher in the intervention group as compared to the control group, indicating the reduction in dependence severity with the passage of time among those who were delivered the intervention. The findings were statistically significant (Supplementary Table 3).

Plasma cotinine concentration was assessed both for intervention and control arms at baseline and endline. The subgroup analysis was performed for each arm to assess the median change in plasma cotinine concentration from baseline to endline post-intervention period. It was found that the median plasma cotinine concentration at endline in the intervention group was lesser than the baseline group and the difference was statistically significant. However, the reduction in plasma cotinine level at endline in the control group was not statistically significant. This indicates the significant effectiveness of intervention among the participants in the intervention group whereas poor effectiveness of usual care in contribution to tobacco cessation. (Supplementary Table 4)

Discussion

The current assessed the effectiveness of a multi-component culturally specific, disease-specific, and patient-centric tobacco cessation intervention package among patients attending the district-level NCD clinics in Punjab, India. The intervention harnessed the potential of TTM based strategy to provide customised disease-specific counselling sessions and short text messages to the participants.

The current study found a significant impact of the intervention package on the intervention group at six months and afterward. The odds of the impact of the intervention package on self-reported seven-day abstinence among the intervention group was 8.8 times than the control group at 6 months which was reduced to 8.4 times at 9 months and 5.7 times at 12 months intervals. This concluded that the impact of the intervention was reduced over a period of time. The intervention group in the current study also reported a significantly more reduction in self-reported frequency of tobacco use at 3 months (mean: 13.6, 95% CI (7.8–19.4)), 9 months (mean: 20.3, 95% CI (12.2–28.4)) and 12 months (mean: 18.7, 95% CI (8.7–28.7)) but the mean difference in self-reported frequency at 12 months was less than at 9 months which can be attributed to the fading effect of the intervention package. The reduction in the impact of the intervention package can be attributed to the 'fading effect'. The fading effect is a psychological phenomenon where the intended effect of an intervention reduces longitudinally over a period of time. Although the risk of relapse is reported during an early period such as during the initial few days, and weeks of quit attempts, and the risk of relapse reduces over a period of time but even former smokers who have quit for months are found to have a relapse

(Agency for Healthcare Research and Quality, n.d.; Hawkins et al., 2010). A study carried out among African American smokers also reported higher biochemically verified quit rates in the culturally targeted group (63%) in comparison to the standard treatment group (36%) (Matthews et al., 2009). Contrastingly, a study on the effect of Facebook group-tailored interventions found significantly higher effects of the intervention at 3 months than at 6 months and at 12 months (Ramo et al., 2018). The change in tobacco use among study participants was assessed based on the tobacco purchase expenditure at multiple follow-ups. The current study found no significant difference in the self-reported expenditure of tobacco products in the last seven days at different intervals of time in both groups. One assumption can be that the study participants in the intervention group might have changed the type of tobacco product i.e. from cheaper to costlier, decreasing the frequency and increasing the abstinence period.

An intervention study by Thankappan et al among diabetic smokers in Kerala reported that the odds of quitting were 8.4 for the intervention-2 group as compared to the intervention-1 group at six months. Furthermore, the study concluded that culturally sensitive disease-specific cessation counselling leads many patients to quit or significantly reduce their smoking habit thereby preventing complications from diabetes (Thankappan et al., 2013). In the present study the OR of self-reported abstinence was 8.8 and 8.4 times higher in the intervention group at sixth and ninth months, respectively. This could be probably attributed to the acceptability of positive reinforcement strategies reflected through the intervention package.

The mean plasma cotinine level in intervention group was significantly lower in the intervention group as compared to control group (mean: 44.3, 95% CI (9.9–78.8)) at 12 months. The cotinine levels are suggestive of effect of intervention package in the intervention group. A study found a significant decrease in urinary cotinine levels in the intervention arm as compared to the control arm when brief interventions to preteens and adolescents to create smoke-free homes were given in the form of the toolkit for creating the smoke-free home CD, coaching calls, photo story, newsletter and success stories portraying families and their reasons for having smoke free homes (Yilmaz et al., 2013).

Tobacco cessation is a challenging behaviour change to achieve, demanding the user's commitment as well as psychological, and social support to overcome challenging times of withdrawal effects (Hartmann-Boyce et al., 2013). Culturally relevant interventions have the potential to significantly decrease healthcare disparities and enhance the quality of life for the population subgroups. A recent scoping review also highlighted five major strengths of culturally tailored interventions for ethnic minority groups. These included increased knowledge of the disease, promotion of a healthy lifestyle, increased family support, technology use, and culturally respectful and patient-centric care (Joo & Liu, 2021). The newly developed intervention package that was assessed in this study has incorporated all the aforementioned elements. Besides, the study contributes to the existing evidence by focusing on both smoked and smokeless tobacco users, leveraging the existing manpower and infrastructure of the NCD clinics to offer cessation assistance and biochemical verification using LC-MS/MS method. Since the intervention package was co-produced with all relevant stakeholders including healthcare providers and

program managers, it gave an edge during implementation. Furthermore, the findings from the study could provide a base to assist healthcare policymakers to roll out culture and disease-specific cessation projects at a larger scale for diversified socio-cultural populations in similar settings. In addition, syncing of sessions & follow-up visits of participants with their routine NCD consultation visits ensured good attendance and less attrition.

However, there are certain limitations of the study as well. A smaller sample size could not make the findings generalisable. The social desirability bias associated with tobacco use in Punjab might have contributed to the under-reporting of tobacco use status among the participants. Furthermore, due to its limited usage among illiterates, the study had to exclude such participants. The lack of any pharmacotherapy support or NRT support in the package was another limitation that could have probably supported users with higher dependence. Also, the use of LC-MS/MS for biochemical verification at a large scale could be difficult to implement due to the high operational cost. The findings may be limited to male users as there were no female participants in the study.

We also make the following recommendations. In order to increase the access and outreach of cessation services, the package could be expanded to similar other settings of other national health programs. Besides, the inclusion of health facilities that are running in a private setup offering all levels of healthcare at different tiers would expand the avenues of offering cessation support to the NCD cohort. Going a step ahead in offering personalised treatment, understanding the influence and role of gene-genes, and gene-environment interactions could be harboured for developing an advanced personalised treatment for tobacco users (Lessov-Schlaggar et al., 2008). In addition, recognising the diverse socio-cultural landscape of India, introducing and streamlining the concept of 'social prescription' for tobacco addiction by engaging community forces, civil society, and local bodies could strengthen the cessation efforts at grass root levels.

Conclusion

WHO suggests that to address NCDs and risk factors an integrated approach is required for low-resource contexts to efficiently utilise limited resources by adapting and implementing various models in local settings (World Health Organization, 2020). Since, decreasing tobacco use is one of the best buys for preventing NCDs (Thakur et al., 2011) it's crucial to strengthen the existing health systems by training human capital, using each opportunity to offer cessation support to increase access to cessation resources (World Health Organization, 2005), especially for high-risk individuals (Alwan, 2011). Hence, a culturally relevant patient-centric intervention package focusing on behaviour change has the potential to be scaled up in the resource-restraint setting of LMICs to assist in quitting sustainably.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Ethics approval

The ethical approval for the study was obtained from the Institute Ethics Committee, Post Graduate Institute of Medical Education and Research, Chandigarh, India. (IEC no.INT/IEC/2017/1361). Prior permissions were obtained from the State Tobacco Control Cell and State NCD Control Cell, Department of Health and Family Welfare, Punjab, India to carry out the study in selected districts. The study was also registered with the Clinical Trials Registry; India [registration number CTRI/2018/01/011643]. The participants were enrolled in the study after obtaining informed consent in their native language. A Participant Information Sheet (PIS) was shared with each eligible participant to share details of study.

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Data availability statement

The data supporting the study findings are available upon request from the corresponding author.

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