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Original Article

Community Section

Effectiveness of Tobacco Cessation Intervention in Tobacco Cessation Clinics, India: A Systematic Review

SODADASI DEEVENA HADASSAH[1], L VAMSI KRISHNA REDDY[2], P SIVA KUMAR[3], POTTEM NAGARJUNA[4], PICHIKA SWATHI[5]

ABSTRACT

Introduction: Tobacco use presents a formidable public health challenge globally, and India is no exception, bearing a significant proportion of the worldwide disease burden attributable to tobacco consumption. Recognising this critical health crisis, Tobacco Cessation Clinics (TCC) have been established across India to provide specialised support for individuals aiming to quit.

Aim: The present systematic review was aimed to explore the effectiveness of tobacco cessation intervention in TCCs in India.

Materials and Methods: A search for relevant studies was conducted using the keywords 'tobacco cessation India,' 'smoking cessation clinics India,' 'tobacco use cessation intervention India,' and 'pharmacotherapy smoking cessation India'. The search yielded 330 studies in PubMed, Google Scholar, Embase, and SCOPUS between 2004 and 2024. After duplicates were removed 52 full-text articles were retrieved and assessed for eligibility. Eligibility criteria included Randomised Controlled Trials (RCT) or quasi-experimental studies or cohort studies of any smoking cessation intervention with no age or gender limitation. The risk of bias was assessed using similar criteria for RCT and non-randomised studies guided by the Cochrane Handbook for Systematic Reviews.

Results: A total of 10 studies (1613 Indian tobacco users) with mean age of the participants ranged from 34 years to 50 years were included. The current systematic review identified different cessation methods, with some employing both behavioural change and pharmacological methods, and some utilising only one method. The most commonly used interventions were cognitive behaviour education (n=23), motivational interviewing (n=19), and pharmacotherapy (n=3). Among them, counselling and behavioural support can improve smoking cessation rates along with pharmacotherapy, but the effect varies depending on the characteristics of the support provided.

Conclusion: There were numerous tobacco cessation interventions for tobacco users in India, but the most effective intervention to change tobacco consumption behaviour is the combination of pharmacological and behavioural interventions. However, longer follow-up periods indicated reduced effectiveness.

Keywords: Smoking cessation, Smoking reduction, Smokeless Tobacco , Respiratory disease risk

INTRODUCTION

The tobacco epidemic is one of the biggest public health threats, killing more than eight million people a year around the world [1-3]. Globally, tobacco use (both smoked and smokeless) is associated with high mortality and morbidity including cancers, and respiratory and cardiovascular diseases [4]. In 2015, smoking was ranked among the five leading risk factors by Disability Adjusted Life Years (DALYs) and responsible for 11.5% of global deaths (6.4 million), of which 52% were in four countries (China, India, United States, and Russia) [5]. In 2017, 2.5 million DALYs and 90 791 lives were lost across the globe due to cancers attributed to Smokeless Tobacco (SLT), and six million DALYs and 2,58,006 lives were lost from ischemic heart disease attributed to SLT [6]. The overall burden of "smoking only," "smokeless only," and "dual use" of tobacco in India is 7.2%, 17.9%, and 3.4%, respectively, with the prevalence in males being greater than in females [7]. According to Global Adult Tobacco Survey (GATS-2) data, India had the second-lowest quit rate among GATS-2 countries, despite a high prevalence of knowledge aboutthe health consequences of smoking and/or chewing tobacco.Only 55.4% of smokers and 50.4% of SLT users have ever considered or intended to quit tobacco use [8]. Tobacco cessation is the only way to save the current tobacco users from tobacco related mortality and morbidity in the short run [9]. Recognising the importance of tobacco cessation, 13 TCCs were started in 2002 by the Ministry of Health and Family Welfare, Government of India, with the support of the World Health Organisation (WHO) India Country office. Later, they were increased subsequently to 19 to provide tobacco cessation intervention [9,10]. The Tobacco Cessation Clinic Resource Center (TCCRC), which is functioning in the National Institute of Mental Health and Neurosciences, (NIMHANS), Bangalore, is the national coordinating center for all the TCCs [11]. The objectives of these clinics were to evolve cessation strategies for smokers and SLT users, to generate experience in tobacco cessation interventions and find out the feasibility of scaling up these intervention strategies [12].

Although there are studies [13-15] to assess the most effective intervention among the non-pharmacological methods but there are no reviews which examined the effectiveness of both pharmacological and non-pharmacological interventions in tobacco cessation that are being delivered to the Indian people in the Indian settings of TCCs established by the Ministry of Health and Family Welfare, Government of India. The present systematic review was aimed to assess the effectiveness of tobacco cessation interventions includes pharmacological, non-pharmacological and e-health interventions which are delivered in the TCCs in India.

MATERIALS AND METHODS

The present systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines for systematic reviews. "PRISMA" [15] extension statement for reporting systematic reviews" was utilised for performing the current study. The present systematic

review was registered with International Prospective Register of Systematic Reviews (PROSPERO). The registration number was CRD42024614652 on 18 November 2024.

Search strategy: To be included in the present review, the search executed in various databases such as EMBASE ("Excerpta Medica Database"), Scopus, PubMed Central, Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE ("Medical Literature Analysis and Retrieval System Online"), search engines such as Google Scholar, ScienceDirect and EMBASE. The authors have combined the Medical Subject Headings (MeSH) along with free-text headings for executing the search strategy. The authors executed the search strategy utilising the suitable Boolean operators ("AND" and "OR" and "NOT") in between the pre-defined search terms. Study authors were contacted to identify additional studies. Index terms and keywords used for search strategy was ("tobacco use cessation"[MeSH Terms] OR ("tobacco"[All Fields] AND "cessation"[All Fields]) OR "tobacco use cessation"[All Fields] OR "tobacco cessation"[All Fields]) AND ("ambulatory care facilities"[MeSH Terms] OR ("ambulatory"[All Fields] AND "care"[All Fields] AND "facilities"[All Fields]) OR "ambulatory care facilities"[All Fields] OR "clinic"[All Fields])) AND (("tobacco use cessation"[MeSH Terms] OR ("tobacco"[All Fields] AND "cessation"[All Fields]) OR "tobacco use cessation"[All Fields] OR "tobacco cessation"[All Fields]) AND ("methods"[MeSH Terms] OR "methods"[All Fields] OR "intervention"[All Fields]))) AND effectiveness[All Fields]) AND ("India"[MeSH Terms] OR "India"[All Fields])

Inclusion criteria:

- Interventional studies evaluating the effectiveness of tobacco cessation intervention among tobacco users in TCCs in India.
- Articles searched were restricted to articles in English published as full text, from the year Jan 2004 to March 2024.
- Studies including RCTs or quasi-experimental studies or cohort studies with no age or gender limitation.

Exclusion criteria:

- Abstracts, case report, pilot studies, reviews, letters to editor were excluded.
- Articles published in other languages are excluded.
- Publications lacking primary data or quantitative results, incomplete studies or abstracts were excluded along with the unpublished literature.

Study Procedure

Studies done among the tobacco users in India irrespective of their age, gender, comorbidities, and type of tobacco use (smoking or smokeless or both) were included.

Intervention type: Interventions eligible for this review were: non-pharmacological interventions including-Individual face to-face intervention (behavioural counselling or motivational interviewing), group intervention (group counselling or health talk), e-Health intervention (m-Health or internet-based), self-help or printed intervention, brief advice (not adopting any counselling strategy) and Pharmacological interventions {Nicotine Replacement Therapy (NRT) or non-Nicotine Replacement Therapy (NRT)}, First-line pharmacotherapies are nicotine replacement therapies (NRT), bupropion and varenicline. Some national guidelines recommend nortriptyline or clonidine. A combination of behavioural intervention and pharmacotherapy is also recommended. Studies comparing these interventions either with one another or against standard care were eligible for inclusion in the analysis.

Comparison: Comprehensively to include Standard Care/Minimal Intervention and Active Comparators. Standard Care represents the control or baseline treatment, typically encompassing Brief Advice, Usual Care (routine clinic practice, often limited to generic self-help materials), or a No Intervention/Waiting List approach, serving as the benchmark to evaluate the additional benefit of a new intervention. Concurrently, the comparison also includes Active Comparators, which are head-to-head trials where one eligible intervention (e.g., Varenicline) is compared against another (e.g., NRT or a specific behavioural counseling technique), allowing for an assessment of relative efficacy among evidence-based treatments. This dual definition ensures the review captures all relevant effectiveness data, whether against the status quo or against a competing treatment option.

Study outcome: Studies reporting the outcome as tobacco cessation rate or quit rate or continuous abstinence rate or point prevalence abstinence were eligible. Along with them Fagerström Test for Nicotine Dependence (FTND) and behavioural change regarding tobacco consumption were also taken into consideration.

Study selection: Two independent investigators (1 and 2) did the first step in study selection process by screening the title, keywords, and abstract. Each of the two investigators retrieved the full-text studies and shortlisted them for the second stage of screening based on the eligibility criteria. At the second step, the retrieved full-texts were screened by the same two investigators (1 and 2) and those matching the eligibility criteria were finally included and further analysis was done based on these studies. Discrepancy/disagreement during the selection process was resolved and the studies were finalised by the third investigator (3). The third investigator (3) was also responsible for monitoring and ensuring the quality of screening.

Quality assessment and data extraction: Following the search, all identified citations were collated and uploaded into bibliographic software, and duplicates were removed. After finalising the full-text articles that are eligible for inclusion and analysis in the review, both the investigators were involved in the manual data extraction process using predefined semi-structured data collection form that was defined at the stage of protocol itself. The form collected the following set of information:

General details included: Author, journal, publication year, country and methodological part included.

Study design, study setting (community/ workplace/ facility/ school), participant details, study duration, sample size in both groups.

Intervention details: Intervention type (pharmacological or non-pharmacological), mode of delivery (physician/nurse/community health worker or peer administered intervention), duration of intervention, and frequency of intervention.

Outcome measure: Tobacco cessation rate in terms of quit or abstinence, timepoint of outcome measurement. Data were recorded by the first author and the recording of entry was verified again by the second author for the correctness of data. The quality of included studies was assessed using the Cochrane quality of study and risk of bias assessment tool [16].

STATISTICAL ANALYSIS

Due to the observed heterogeneity across the included studies concerning intervention delivery, comparator groups (Standard Care vs. Active Comparator), and variations in outcome definitions and follow-up periods, a quantitative pooling of data (meta-analysis) was not performed. Instead, a structured narrative synthesis was utilised to integrate the findings. Data extraction focused on key study characteristics, including design, population demographics, the specific components of the Intervention and Comparison groups, and the primary outcome of tobacco cessation rate (reported as quit rate, continuous abstinence, or point prevalence abstinence). The findings were presented in summary tables to facilitate comparison and were subsequently grouped and discussed based on crucial factors, such as the type of intervention (e.g., pharmacological vs. behavioural) and the duration of follow-up. The synthesis aims to identify and discuss the patterns of effectiveness of tobacco cessation interventions across different Indian clinic settings, acknowledging the potential influence of methodological and contextual factors on the reported outcomes.

RESULTS

The electronic search retrieved 3325 titles in the initial search stage (PubMed=645, Google scholar=2680). The titles of the studies were screened and almost 2995 records were excluded. After the duplicates were removed were left with 330 articles among these abstracts were screened and at last 52 full-text articles were retrieved and assessed for eligibility. Then, A total of 40 articles were excluded after reading the full-text articles. The primary reasons for exclusion included: non-eligible study design (e.g., cross-sectional or qualitative studies), non-eligible outcome measures (e.g., not reporting abstinence rates), non-eligible participant population (e.g., studies outside of India or non-clinic settings), and intervention misalignment (e.g., focus on prevention rather than cessation). Following this, 12 articles met the initial inclusion criteria and were retained for critical appraisal and data quality assessment. During this critical appraisal process, two articles were subsequently excluded due to major methodological incongruity with the review (e.g., high risk of bias stemming from non-random allocation or excessive attrition). Finally, 10 articles were included in the systematic review for data synthesis [Table/Fig-1] [17-26].

The search results were reported in the final systematic review is presented in the PRISMA flow diagram [Table/Fig-2].

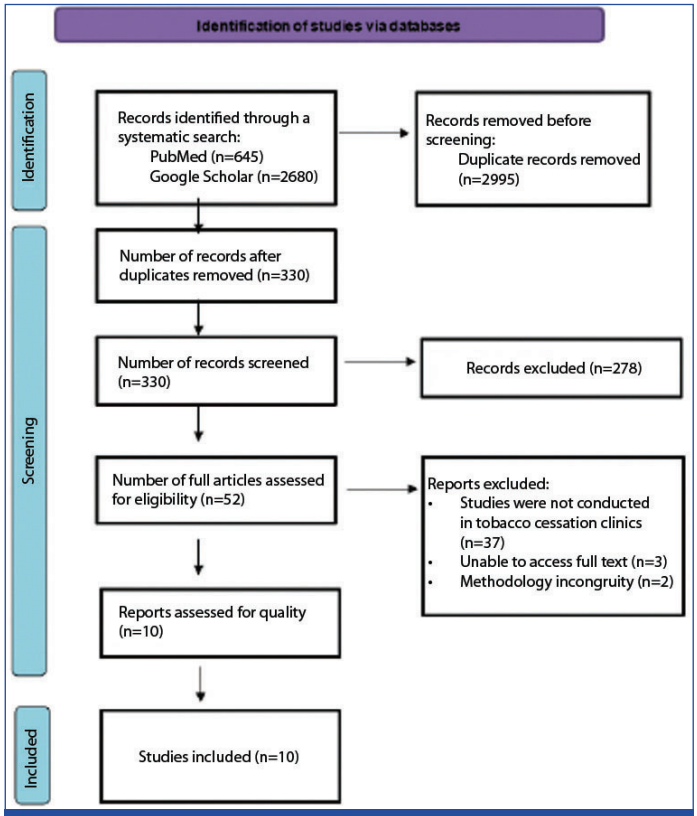
Data from included studies involved specific details about the setting, sample size, population characteristics, methodology, interventions, outcome measurements, and descriptions of main results.

The studies included a total of 1613 Indian participants. Mean age of the participants ranged from 34 years to 50 years. There were six RCT, two non-RCT and 2 cohort studies. All studies reported changes in quitting tobacco use of quit durations ranging from four weeks to two years. Intervention types were grouped into two categories: Pharmacological and non-pharmacological. Pharmacological interventions along with behavioural approach based on the dependence, consisted of three studies [17-19]. Non-pharmacological intervention consisted of seven studies [20-26]. Most studies were conducted in states such as Maharashtra, Karnataka, Gujarat, Kerala, and Tamil Nadu.

S. No.	Study	Study area	Title	Study design	Study population	Intervention
1.	Mony PK et al., [25] (2014)	Bangalore, India	Tobacco cessation outcomes in a cohort of patients attending a chest medicine outpatient clinic in Bangalore city, Southern India.	Cohort study	189 patients ≥18 years, attending the TCC in St John's Medical College Hospital, a tertiary-care, hospital	Counselling alone (41%), NRT with chewing gums (34%), medication alone (13%), and NRT+medication (12%)
2.	Sujatha S et al., [19] (2023)	Bangalore, India	Long-term follow-up of tobacco cessation intervention in a dental setting: A randomised trial	Randomised controlled trail	1206 subjects registered to the TCC in a dental Outpatient Department (OPD) in Bangalore.	Moderate 30-minutes of individual intervention - 3Es and 6As (3Es- Every patient at Every visit tobacco use documentation was Ensured and 6As was followed-Ask, Advise, Associate, Assess, Assist and Arrange) model, an adaptation of WHO 5A model consisting of behaviouralcounseling and pharmacologic therapy was provided for all patients
3.	Goyal J et al., [23] (2020)	India	Effectiveness of cognitive behavioural therapy and basic health education for tobacco cessation among adult tobacco users attending a private TCC	Randomised Controlled trial	100 individuals of age 41-60 years, attending the TCC of the Department of the Public Health Dentistry	Basic Health Education provided information on the harmful effects of tobacco use. Cognitive-behavioural cessation and relapse prevention strategies and these included discussions on barriers to cessation, quitting self-efficacy, previous quit attempts, risk perceptions, and pros and cons of quitting
4.	Mohanty DP et al., [26] (2023)	Eastern India	Impact of health education and cognitive behavioural therapy intervention during tobacco cessation session for smokers: A comparative study in Eastern India.	Randomised controlled trial	240 adult tobacco users ≥18-68 years were recruited attending a tertiary care hospital in Bhubaneswar, India.	Interventions for the study groups included Cognitive Behavioural Therapy and Basic Health Education.
5.	Leena SA et al., [24] (2016)	India	Effectiveness of cognitive behaviour therapy in tobacco cessation at a dental setting: A hospital-based randomised controlled trial	Randomised controlled trial.	194 patients ≥18 years met the inclusion criteria at a selected dental setting out of 519.	All the individuals received Health education therapy, and later 94 randomly selected individuals who were assigned to CBT received cognitive behaviour therapy
6.	Kumar V et al., [22] (2021)	Mumbai, India.	Effectiveness of Tobacco Cessation Counselling and Behavioural Changes Using Multi Theory Model (MTM): A Follow-Up Study.	Non-randomised uncontrolled trial.	100 tobacco users ≥18 years visiting dental college in Bangalore.	10-minute face-to-face intervention and doubt clearing sessions. Multi Theory Model (MTM) for behaviour change divides into initiation and sustenance.
7.	Piplani A et al., [17] (2022)	Haryana, India	Effectiveness of smoking cessation interventions in dental settings: a randomised controlled trial	Randomised controlled trail	132 participants of age 18-50 years, attending TCC of Postgraduate Institute of Dental Sciences (PGIDS), Rohtak (Haryana).	Pharmacotherapy along with Motivational Interviewing (MI) - MI+placebo (composed of starch and lactose) (Group-A), MI+bupropion (150 mg) (Group-B) and MI+bupropion+nicotine chewing gums(2mg) (Group-C)
8.	Mehta A et al., [18] (2020)	Delhi, India.	Evaluation of Cessation Services Provided at a TCC in a Teaching Dental Hospital.	Retrospective cohort study.	357 patients ≥18 years who received tobacco cessation intervention through a TCC in the Department of Public Health Dentistry of a government teaching dental hospital in Delhi, India (April 2016-March 2018).	The intervention follows the intensive 5As approach. Prescribed NRT in form of nicotine chewing gum depending upon quantity of tobacco consumed per day.
9.	Sehgal A et al., [21] (2023)	Loni, India	Effectiveness of brief counseling (5As): Antenatal tobacco cessation support programme among pregnant women availing Antenatal Care (ANC).	Quasi-randomised study design	271 subjects aged > 18 yrs attending ANC clinic and TRCC clinic of Pravara Rural Hospital, Loni	Intervention includes Brief Advice with the help of 5A's framework.

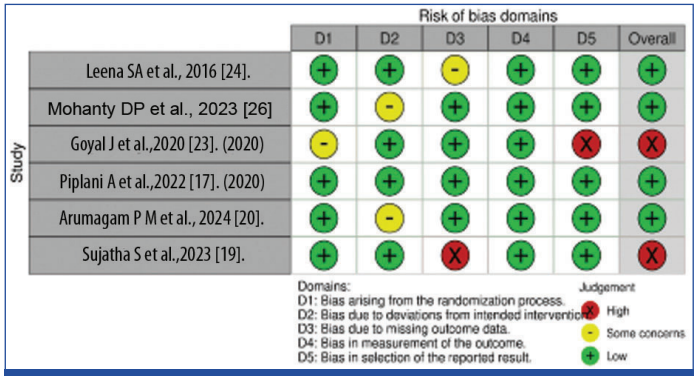
10.	Arumugam PM, et al., [20] (2024)	Bangalore, India	The effect of behavioural modification therapy on tobacco cessation among patients visiting a dental institution in Bangalore - a pragmatic study	Pragmatic randomised controlled trail	60 subjects ≥18-80 years among the individuals attending the TCC of the Department of the Public Health Dentistry, RajaRajeswari Dental College and Hospital, Bangalore.	Intervention includes Behavioural Modification Therapy (BMT) for 20 minutes aimed at changing tobacco cessation through monitoring of thought, skill building, interpersonal contact, and mood.

[Table/Fig-1]: Study population, study area, study design and intervention of included articles [17-26].



[Table/Fig-2]: PRISMA flow diagram for the systematic review which included searches of database.

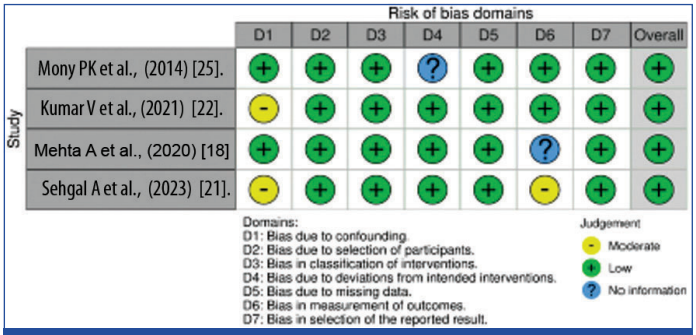
Risk of bias within studies: The risk of bias was assessed using similar criteria for RCT and non-randomised studies guided by the Cochrane Handbook for Systematic Reviews of intervention [27]. Four RCT have provided adequate information on all the domains [17,20,23,24]. Only four RCT studies reported sufficient information on randomisation [22-24,26] and two provided adequate information on allocation concealment [17,23]. One study had some concerns in completely elaborating the outcome results and statistical analysis [23]. None of the studies provided information on blinding of participants or investigators or blinding of outcome assessors. One study used intention to treat analysis [18] where all randomised patients were included in their originally assigned groups and missing data was recorded as non-abstinence. Two studies had a high-risk [18,19] of reporting fewer outcomes than expected or not reporting the use of a protocol. Other four studies showed low-risk among all the given domains [17,18,23,24,26] as shown in [Table/Fig-3,4]. Among non-RCT two studies did not elaborate on confounding



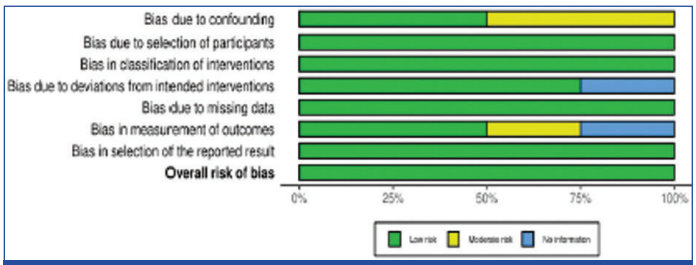
[Table/Fig-3]: Traffic light plot showing risk of bias among randomised controlled trials according to the robvis tool [17,19,20,23,24,26].

[Table/Fig-4]: Summary plot for risk of bias according to Risk-of-bias Visualisation (Robvis) tool.

factors [21,22], one provided no information on deviations from intended interventions [25] and two study was did not provide any sound information on the bias in measurement of outcomes [18,25] as shown in [Table/Fig-5,6].



[Table/Fig-5]: Traffic light plot showing risk of bias among non-randomised controlled trials according to the Robvis tool [18,21,22,25].



[Table/Fig-6]: Summary plot for risk of bias according to Robvis tool.

Interventions

Setting: TCCs established in the dental institutions of India.

Recruitment method: One study reported recruitment methods, including the information about the tobacco cessation intervention programme through newspaper pamphlets, smoking cessation camps, and radio talk [14]. In another study patients were contacted through phone and recalled to TCC [15]. Remaining eight studies, the recruitment method included were the patients attending the TCC in the respective dental colleges [19,20,22-26]. Overall, in all the ten studies recruited participants who have an intention to quit smoking.

Smoking outcome measures: One study reported only continuous abstinence at 12 months [19]. Five studies measured Point prevalence abstinence [17,18,20,24,25]; three at six months, one at 24 weeks and at one month. Three studies measured the reduction in FTND scores at four weeks and six months [20,23,24]. One study has assessed the behaviour abstinence at 12 weeks [22]. Another study assessed the motivational levels using the transtheoretical model along with Fagerstrom's Addiction Scale for Smokers at 12 weeks [23]. Seven studies have assessed the quit rate based on the continuous abstinence or PPA or self-assessment.

Intervention characteristics: The studies used a variety of different staff members to deliver the interventions, including investigator, health instructor, faculty members and postgraduate students of the department. The main intervention categories included counseling only; counseling and NRT [17,18]; NRT only includes nicotine gums, bupropion and varenicline [19]; Basic Health Education (BHE) only [23]; Cognitive Behavioural Treatment (CBT) only [24]; 5A's approach only; CBT and NRT [25]; Motivational interviewing [24]; One approach, used in three of the intervention Multi Theory Model (MTM) [22] for behaviour change.

Effectiveness of smoking cessation interventions [Table/Fig-7] [17-25]: Out of ten, eight studies reported significant effects at four weeks or 12 weeks or six months or 12-month follow-up. One study showedthe overall continuous abstinence rate at 6 months as 18.9% [17]. The other after an intensive 5As approach given along with the nicotine gums based on their tobacco dependency showed that the odds of quitting were higher in participants with low tobacco dependence (OR 3.03, CI 0.98,9.35) and those who were satisfied with counselling method at TCC (OR 8.8, CI 2.05, 38.35) [18]. The effect of Moderate intervention - 3Es and 6As model, an adaptation of WHO 5A model consisting of behaviouralcounselling and pharmacologic therapy was provided for all patients were analysed at the end of 12 months the tobacco quit rate was 180 (18%), tobacco reduction >50% was 342 (34.2%), no change 415 (41.5%) and relapse 62 (6.2%) [19]. Comparison between the Cognitive Behavioural Therapy (CBT) and BHE among which CBT group had significantly reduced mean Fagerstrom's addiction scores at baseline (4.8±7.3), (3.8±3.1) at the 1st follow-up and at the 2nd follow-up (3.5±8.9) (p<0.001) showing a great impact [23].

That effectiveness of the MTM as intervention for behaviour change delivered for 12 months, reinforced during 2nd and 6th week, showed a significantly increase in mean MTM behaviour change score from baseline (32.78±4.8) to two weeks (52.37±5.27), six weeks (49.81±4.34) and 12 weeks (48.7±3.50) (p<0.001) [22].

Two studies found evidence that NRT is of benefit not alone but combined with motivational interviewing or behavioural counselling [17,24]. The intervention comprised of 30-40 minutes individual sessions delivered for three months. Pharmacotherapy was given based on the nicotine dependence levels. Heavy smokers with moderate-to-high dependence were randomised to one of the three intervention groups: A: MI+Placebo, B: MI+bupropion, and C: MI+NRT+bupropion. The continuous abstinence rates were 12.2%, 22.2%, and 23.4% in Group-A, B, and C, respectively [17]. One study found evidence that a behavioural support is of benefit [17]. Based on the Behavioural Modification Therapy (BMT) delivered for 20 minutes, there was a significant reduction in addiction and CO levels from the baseline to six months of follow-up [20].

S. No.	Study	Outcome measures	Statistical tests used	Results	Conclusion/recommendations
1.	Mony PK et al., [25] (2014)	self-reported point prevalence abstinence rates at 2 years, FTND score or Heaviness of Smoking Index (HSI) score	Chi-square test, multivariate logistic regression analysis, SPSS-PC (version 13.0 (Chicago: SPSS Inc; USA), significance was set at a p<0.05.	Self-reported point prevalence abstinence was 5 per cent by 'intent-to-treat' analysis and 10 per cent by 'responder' analysis. Two clinical parameters – high level of nicotine dependence (estimated by the HSI) and the absence of vascular or other chronic disease were found to be associated with successful quitting; these were however, not significant on multivariate analysis	The current study has identified low quit-rates in a cohort of patients attending a hospital-based TCC. In the absence of clear-cut predictors of cessation with low quit-rates, there should be continued efforts to improve cessation outcomes and identify predictors for action.
2.	Sujatha S et al., [19] (2023)	Fagerström Test for Nicotine Dependence (FTND)/ FTND-ST and salivary cotinine levels.	SPSS PC, version 13.0. (IBM), Descriptive statistics with inferential testing using Chi square test. significance was set at a p<0.05.	At the end of 12 months the tobacco quit rate was180 (18%), tobacco reduction >50% was 342 (34.2%), no change 415 (41.5%) and relapse 62 (6.2%).	The current study has identified adequate long-term abstinence rates in a cohort of dental patients attending a hospital-based TCC. Providing brief–moderate interventions and NRT holds plenty of promise and this intervention is relatively cost-effective because it is part of the existing health-care services which are used by the majority of tobacco users.
3.	Goyal J et al., [23] (2020)	Impact of community based tobacco cessation intervention in tobacco abstienece.	Paired and unpaired "t" tests, SPSS, version 20. P values of <0.05 were considered to be statistically significant.	The reduction in mean FTND score was found in both Group A and B on follow-up. But when both groups were compared, reductions in mean FTND scores were found to be more in CBT group than in BHE group at all time intervals.	Individuals in both the group have quit the tobacco use by both the interventions followed by proper schematic follow up.
4.	Mohanty DP et al., [26] (2023)	Assessment of Fagerstrom's Addiction Scale/ Fagerstrom's Test for Nicotine Dependencefor Smokers was assessed.	Pearson's Chi-square test, Paired and unpaired t-tests, and Fisher's-exact test. Statistical Package for Social Sciences (SPSS 22.0, IBM, Armonk, NY, USA). Statistical significance was considered at p<0.05.	Continuous abstinence was significantly high in group HE+CBT (92.4%) compared to group CBT (78.4%) and group HE (42.6%).The percentage of lapse in group HE (62%) was significantly higher than in group CBT (51.5%) and group HE+CBT (34.5%).	The effectiveness of combined therapy (HE+CBT) is more effective in reducing tobacco habits than function of individual therapy among smokers.
5.	Leena SA et al., [24] (2016)	Quit rates, Cotinine levels.	Mann-Whitney U-test, Pearson's Chi-square and Kendall's tau-b tests intention-to-treat analysis, IBM SPSS Inc. Released 2009. PASW Statistics for Windows, Version 18.0. Chicago: SPSS Inc.	Continuous abstinence was significantly high in CBT (HE: 30%, CBT: 68.1%) (p=0.000). Percentage of lapse was significantly higher in HE (HE: 49%, CBT: 35%, p=0.035). Reduced use and point prevalence abstinence were significantly higher in HE. Quit attempt in both the groups was equal showing no statistical significance. Attrition was significantly higher in HE compared to CBT.	CBT plays a vital role in achieving continuous abstinence, overcoming social factors, and reducing lapse among the tobacco users.
6.	Kumar V et al., [22] (2021)	Fagerstrom score, assessment of their tobacco habit and change in behaviour.	Dropout analysis with hot-deck imputation of data, Repeated measure ANOVA, Independent t test, Statistical software (SPSS version 22.0; SPSS, Chicago, IL, USA) with a p-value of <0.05 was considered statistically significant.	A total of 64 participants completed the 12 week follow-up. The mean age was 44.3±10.1 years and 75.8% were males. There was significantly increase in mean MTM behaviour change score from baseline (32.78±4.8) to 2 weeks (52.37±5.27), 6 weeks (49.81±4.34) and 12 weeks (48.7±3.50) (p<0.001).	There was increase in MTM model scores in subsequent follow up suggesting behavioural changes and overall effectiveness of the TCC among tobacco users.

7.	Piplani A et al., [17] (2022)	Self-reported continuous abstinence rates at 6 months	Mann-Whitney U test, Kruskal-Wallis test, Wilcoxon signed-rank test, and Pearson's Chi-square test with p-value fixed at 0.05.	The overall continuous abstinence rate at 6 months was 18.9%. The continuous abstinence rates were 12.2%, 22.2%, and 23.4% in Group A, B, and C, respectively (p=0.318). There was no significant difference in 7-day point prevalence abstinence from smoking at the end of 3 months in between the three groups (p=0.06).	MI plays a significant role in smoking cessation and offers benefits comparable to pharmacotherapies and hence can be used as an integral part of smoking cessation interventions.
8.	Mehta A et al., [18] (2020)	7 days of point-prevalence abstinence (7PPA), Urine cotinine levels.	Intention-To-Treat (ITT) analysis, Kolmogorov-Smirnov normality test, Mann-Whitney U test/Chi-square with an odds ratio (OR) and 95% Confidence Interval (CI), Friedman'stest, A p-value of <0.05 was considered statistically significant.	At 6 months, there was a significant difference (p<0.001) in 7 days point-prevalence abstinence (28% vs 10.8%), reduction of tobacco by at least 50% (62.4% vs 40.9%) with an attrition rate of 15.3% vs 30.5% in intervention and control group respectively. 16.5% of participants expressed interest in pharmacotherapy for tobacco cessation, 3.5% were referred to a specialised tobacco cessation centre, two control group participants were hospitalised for drug default, and withdrawal symptoms reported were mild.	Implementing a tobacco cessation intervention based on the stage of motivation aids in abstinence and reduction of tobacco use in Persons who Smoke (PwS).
9.	Sehgal A et al., [21] (2023)	Behavioural change regarding tobacco consumption.	No statistical tests were mentioned.	It was observed that post-counseling, 52 out of these 60 women, making 86% of the study subjects were still consuming tobacco. The method of brief counseling made an impact on the cessation of tobacco consumption in 13.37% of the study subjects.	Concluded that the use of brief counseling and motivational interviewing is feasible in most settings without inhibiting the other important aspects of ANC or disrupting the patient flow.
10.	Arumugam P M et al., [20] (2024)	Fagerstroms Test for Nicotine Dependence (FTND)]	Inferential Statistics like Student paired t-tests, Repeated measures of ANOVA followed by Bonferroni's post hoc analysis, Independent Student t. Statistical Software version 20.110 (MedCalc Software Ltd., Ostend, Belgium.	Participant's average addiction level on the Fagerstrom scale was 3.7 (CI=(2.6 to 4.7) for smokers at baseline, which was reduced to 2.2, CI=(1.3 to 3.1) at the end of treatment (p<0.0001) and 5.4 CI=(4.5 to 6.2) for participants using Smokeless Tobacco (SLT) at baseline, which was reduced to 2.4, CI=(1.8 to 3.1) at the end of treatment (p<.0001). Based on BMT there was a significant reduction in addiction and Carbon Monoxide (CO) levels from the baseline to 6 months of follow-up.	By using BMT and well-planned follow-up, people in both groups were able to minimise their tobacco use, and the majority of participants had a favourable attitude towards the tobacco cessation programme.

[Table/Fig-7]: Outcome measures, statistical tests, results, conclusion of included articles [17-26].
SPSS: Statistical package for social sciences; PASW: Predictive analytics software statistics; ANOVA: Analysis of variance

Two studies where NRT was given along with behavioural counselling showed not significant results. The effectiveness of behavioural counselling along with pharmacologic therapy delivered to the participants categorised into one of five 'stages of readiness to change'. Self-reported point prevalence abstinence was five per cent by 'intent-to-treat' analysis and 10% by 'responder' analysis [25]. In another one the multinomial regression analysis where intensive 5a's approach was delivered, showed that the participants with low dependence on tobacco (OR 3.03, CI 0.98, 9.3) and those who found counselling helpful (OR 8.87, CI 2.05, 38.3) had higher odds of quitting tobacco, although the differences between the concurrent groups were not statistically significant [18].

Two studies showed that continuous abstinence was significantly high in CBT supporting that CBT has a successful positive impact for tobacco cessation [24]. Among CBT group, the mean Fagerstrom's addiction score at baseline (4.8±7.3) significantly reduced (3.8±3.1) at the 1st follow-up and at the 2nd follow-up (3.5±8.9) (p<0.001) [23]. Another supporting the method of brief counselling which made an impact on cessation of tobacco consumption in 13.37% of the study subjects [21].

DISCUSSION

The purpose of this review was to evaluate the efficacy of recommended individual, group or community-level smoking cessation interventions in India. The present study is important, because the current evidence supporting the effectiveness of smoking cessation interventions emanate from decades of research conducted in India including both pharmacological and non-pharmacological interventions. Differences in smoking behaviour, cultural contexts, health-care access and health-care systems may influence the translation of these interventions to Indian population where smoking prevalence is rising. Because of these concerns, smoking cessation research has been recognised as a priority in India [28].

The present systematic review investigated the effectiveness of interventions on tobacco cessation among tobacco users attending the TCCs in India. Ten studies met the inclusion criteria and their data extracted and analysed. This article provides evidence from 10 interventional studies conducted among Indian population.

Five studies reported significant effects on smoking cessation, providing evidence of effectiveness of CBT, motivational interviewing, NRT, and combinations of the two [17,20,24-26]. The result for combination is more favourable as it involves motivation and treatment as well. One study included a MTM for behavioural change which deals with initiation and sustenance of tobacco cessation also showed a significant behavioural change in the tobacco users [22]. A cohort study has shown a low quit rate due to absence of clear-cut predictors of cessation [25]. An interventional study by Sujatha S et al., (2023) has given 3Es and 6As (3Es- Every patient at every visit tobacco use documentation was ensured and 6As was followed-Ask, Advise, Associate, Assess, Assist and Arrange) model, an adaptation of WHO 5A model consisting of behavioural counselling and pharmacologic therapy as intervention concluding adequate long-term abstinence rates [19]. An interventional study done by Piplani A et al., (2022) showed the overall continuous abstinence rate at six months as 18.9% supporting that Motivational interviewing plays a significant role in smoking cessation and offers benefits comparable to pharmacotherapies and hence can be used as an integral part of smoking cessation interventions [17]. Sarkar BK et al., (2017) has proved that a brief community intervention in the low-income communities has a significantly higher abstinence rates in the intervention group than the control group, 12.4% and 6.1%, respectively [29].

The majority of these reviews complement the conclusions of the present study, which show that among non-pharmacological therapies, CBT, e-Health interventions such as text messaging, telephone counselling and individual and group counselling are the most effective means of helping people quit smoking. The results of our study have confirmed and reinforced the body of research showing that these non-pharmacological therapies are, in fact, highly beneficial in helping the nation's tobacco users quit [30]. Behavioural counselling was the most commonly investigated

intervention. All identified studies reported that behavioural counselling was more effective than minimal contact control (brief advice, usual care or provision of self-help materials) [28]. A recent cochrane meta-analysis of 12 studies that evaluated m-Health interventions for smoking cessation reported greater quit rates in the intervention group [28]. These interventions can be delivered in the primary care setting or can be referred to community settings with feedback to the primary care clinician. Physician advice, nurse advice, individual counselling with a cessation specialist, group behavioural interventions, telephone counselling, and mobile phone-based interventions have all been found to be effective to increase cessation of cigarette smoking.

To the best of the authors knowledge, the present systematic review is the first of its kind to investigate the effectiveness of TC interventions in Indian settings and this makes it particularly useful for the decision-makers. Moreover, the review addresses the effectiveness of TC interventions for both smoking and smokeless form of tobacco, both sexes and across different age groups. The majority of research conducted on this topic in India was in the form of RCTs, non-randomised and cohort studies which are ranked highest in the hierarchy of evidence. Cohort studies are distinguished by their ability to measure the outcome of interest and the ease with which large samples can be obtained. Likewise, RCTs are known for their ability to minimise the risk of confounding and provide the most reliable research design.

Limitation(s)

The present systematic review has certain limitations. Given the limited number of studies involving e-Health intervention and pharmacological interventions in India, it is better to conduct more large-scale RCTs utilising some form of e-Health intervention and pharmacological intervention to find out whether giving them individually benefits them rather than a combination therapy. Also, none of the studies provided information on blinding of participants or investigators, in addition, variability between the studies in terms of methodological parameters such as frequency, duration, and mode of delivery of intervention, outcome definition, and participant characteristics such as age, gender, and comorbidities remain. It is difficult to adjust for such variation given the wide variation across each of these characteristics, resulting in minimal number of studies under each of these characteristics. Hence, performing individual patient data (to adjust for variation in participant characteristics) or performing network meta-analysis using original dataset might be the best form of investigation for future studies.

CONCLUSION(S)

The present systematic review aids in exploring different types of Tobacco Cessation interventions that contribute to the effectiveness of TC programmes implemented in the India. The most effective intervention to change tobacco consumption behaviour is the combination of pharmacological and behavioural interventions. Among non-pharmacological interventions the group intervention was the best intervention followed by individual face-to-face counselling and e-Health intervention for tobacco cessation in India. Self-help or brief advice as intervention did not yield significant results for tobacco cessation. Nonetheless, more high-quality large-scale RCTs either individual or by combining the e-Health, individual or group counselling interventions are required to provide conclusive evidence and subsequent adoption into the national health programmes in India Tobacco users are always worried about the withdrawal symptoms.

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PARTICULARS OF CONTRIBUTORS:
1. Postgraduate Student, Department of Public Health Dentistry, Anil Neerukonda Institute of Dental Sciences, Visakhapatnam, Andhra Pradesh, India.
2. Principal and Head, Department of Public Health Dentistry, Anil Neerukonda Institute of Dental Sciences, Visakhapatnam, Andhra Pradesh, India.
3. Professor, Department of Public Health Dentistry, Anil Neerukonda Institute of Dental Sciences, Visakhapatnam, Andhra Pradesh, India.
4. Associate Professor, Department of Public Health Dentistry, Anil Neerukonda Institute of Dental Sciences, Visakhapatnam, Andhra Pradesh, India.
5. Associate Professor, Department of Public Health Dentistry, Anil Neerukonda Institute of Dental Sciences, Visakhapatnam, Andhra Pradesh, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Sodadasi Deevena Hadassah,
Room No. 5, Department of Public Health Dentistry, Sangivalsa,
Visakhapatnam-531162, Andhra Pradesh, India.
E-mail: shafaremaria@gmail.com

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