Tobacco Control Interventions during Last Decade in India: A Narrative Review

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ABSTRACT

Background: Various national level surveys, Global Adult Tobacco Survey (GATS) and Global Youth Tobacco Survey (GYTS) in different age groups have shown that tobacco addiction is prevalent across age, sex and geospatial distribution. In 2007-08, Government of India piloted a National Tobacco Control program which has suggested monitoring of tobacco control laws along with local IEC activities and school program for tobacco control.

Purpose of review: Objective of the current review was to identify these tobacco control interventions whose efficacies have been recently proved among Indian population.

Findings: The review paper is based on the synthesis of the results of 24 studies describing interventions. Review has showed that there is a lack of standardized and robust tool to measure efficacy of the tobacco use, prevention and intervention. Interventions have used social cognition theory, extensively. Studies focused on cessation of tobacco, generally lack any theoretical framework. These studies have used self reported tobacco quit rates rather than established sophisticated tools.

Conclusion: Review suggested that intervention package for community based trial should use more standardized tools to measure their outcome and can be benefitted from the use of more diverse theoretical framework for formulation of interventions.

Keyword: Tobacco control, Intervention, India, Prevention, Cessation

INTRODUCTION

Tobacco addiction is a very common form of addictions observed in India, 35% adults use tobacco products in India.[1] Various national level surveys, Global Adult Tobacco Survey (GATS) and Global Youth Tobacco Survey (GYTS) in different age groups have shown that tobacco addiction is prevalent across age, sex and geospatial distribution, as 48% male and 20% females use tobacco in some form and 38% adults and 25% adults use tobacco in rural and urban India respectively.[1,2] Almost 275 million adults consume tobacco products in India. Every year, tobacco consumption is associated with one million deaths in India. If trend continues till 2020, tobacco will cause almost 13% of all deaths.[3,4] Survey conducted by national agencies have shown that in spite of years of tobacco control efforts by Governmental and non governmental agencies, tobacco use prevalence did not show any significant reduction. In 2007-8 Government of India piloted National Tobacco Control program under the legislative tool which has been prominent since 1975 along with the monitoring of tobacco control laws, local IEC activities and some school programs for tobacco control were suggested along with the setting up of tobacco cessation facilities.[5] There were many studies conducted in the past to test various tobacco control intervention models at community level.

To understand which kind of intervention package worked under which circumstance and it's very important to review the intervention whose efficacy has been recently proved among Indian population. Present review is conducted to identify these tobacco control intervention studies in India. Present review will answer what kind of interventions were conducted in India during the past decade, among which population and what kind of different tools have been used to implement these interventions and how their efficacies have been determined and by using which outcome variables. Information collected from this review can be useful in identifying the gaps in current efforts of researchers in development of community based tobacco control interventions and it will also help in designing more robust feasible and contextual community based interventions of tobacco control for Indian population.

METHODOLOGY

Framing review under different themes:-

In last decades there were various studies conducted in India which primarily focussed on tobacco control. Various studies were conducted in different population according to age, sex and occupation and which also focussed on different aspects of tobacco control. Current paper reviews the paper published from last decade (2005-2015) and focuses on development and efficacy of tobacco control interventions. Unpublished papers thesis and literature available in gray area is not included in the review in order to keep the quality of the review intact. Also studies which are solely focussed on tobacco control interventions are included in the study where smoking cessation or prevention is a minor part of some major intervention programs like examples of prevention of non communicable diseases. Such studies were not included in the review for same purpose. Using this literature, the present review tries to identify the methodologies used to prove the efficacy of the intervention and critically analyze the theories used in development of these interventions and the outcomes used to check their efficacies.. As far as framing of this review under different themes is concernes, author has divided it in such a manner that it will able to answer the above mentioned questions.

This review is divided into four main themes. After interpretation of the reviewed papers under these themes, the review follows with the discussion about these themes and ends with the conclusion. Table 1 explains how review is framed under different themes and subthemes.

Table 1: Themes and subthemes in the review

Themes	Subthemes
Objective of tobacco control	a) Prevention b) Cessation c) both
Method to prove efficacy of an intervention	a) Cluster RCT b) RCT c) Quasi community based non/ or randomized
Intervention content and format	a) Intervention tools b) Used of theory in the intervention
Outcome of the intervention	Outcome variables

Databases for search:-

a) Published peer-reviewed papers were selected using the following databases PubMed, Medline and Google scholars were used to find out research articles and interventions.

b)Research papers were searched on these databases using terms:- Tobacco use; Tobacco control, prevention of tobacco use, cessation of tobacco use, smoking, smokeless tobacco use, randomized control trial, community based trial, community based intervention; these phrases were used separately and in combination. All collected research material have been reviewed for relevance of the topic. Irrelevant and repeated materials were deleted from the study.

Literature review strategy:-

Stage 1:- Exclude the study based on the Population of interest and exclusion criteria.
Stage 2:- Exclude based on the Abstract

Stag 3:- Exclude study based on the full text and methodology
Stage 4:- Finalized which approach should be used according to objectives of literature review
Stage 5:- Write main body of literature review information
Stage 6:- Write conclusion about literature used in review

RESULTS

In last decade 23 studies and 1 protocol were published in the peer review literature whose primary aim was checking efficacy of tobacco control intervention. Table 2 have listed all the twenty-three studies and their relevant details along with author and date.

Objective of tobacco control intervention (Prevention and cessation):- Total 23 studies were found and published in India mentioning Tobacco

Table 2:- Details of studies included in the review

First Author/ Reference no/ Year	Sample size and Characteristics	Prevention/ Cessation	Study design	Intervention design	Theory used	Output variables
Saraf D. S. / 19/ 2015	2348 children studying in 6th and 7th grade	Cessation	Cluster randomized controlled trial.	The intervention consisted of a school component (policies),a classroom component (activities) and a family component [Information Education & Communication (IEC) material].	Not mention	Knowledge about physical activity, diet and tobacco and current use of tobacco
Naik S./ 14/2014	1600 convicted prisoners for survey and 300 for intervention and 300 control	Cessation	A randomized controlled trial	Motivational intervention for the study group.	Not mention	Tobacco use and Fagerstrom test was done by using Fagerstrom questionnaire and carbon monoxide grade was estimated by using smokerlyzer.
Verma A./20/2015	720 adolescents aged 15-16 years	Both	Quasi non randomised non control pre post trial	Educational interventions were imparted to all study subjects in a phased manner	Not mention	knowledge, attitudes, intentions and behaviors, use and prevention
Mishra G.A./16/2014	304 women	Both	Community based intervention	Three interventions conducted at three months interval, comprised of health education, games and counseling sessions and a post intervention follow-up.	Not mention	Quitting tobacco use
Dable R.A./15/2014	53 male students	Both	Quasi non randomized non control pre post trial	Four session	Not mention	Health awareness and perception of students who use tobacco
Raja M./ 13/2014	40 n1:- 20; n2:-20	Cessation	Randomized trial	Cognitive behavioral therapy (CBT) group (study group) and Basic health education (BHE) group (control group).	-	Fagerstrom's test for Nicotine Dependence (FTND) was used to assess subjects' nicotine addiction levels.
Pati S./ 21/2014	149 1st year medical and dental students	Both	Quasi non randomized non control pre post trial	Two skill-building workshops were held with approximately 15 participants in each workshop and four staff facilitating each workshop.	No theory but several key principles are mention in the full text	Attitudes regarding physicians' roles, to promote behavior change and the self-confidence to apply knowledge and implement motivational interviewing skills.
Sarkar B.K./6/2014	Total of 32 clusters, total of 992 participants.	Cessation	Cluster randomised trial (Protocol)	brief advice including training in craving control using simple yogic breathing exercises (BA-YBA) and the control arm is very brief advice (VBA).	Not theory	Russell Standard: self-report of sustained abstinence for at least 6 months following the intervention confirmed at the final follow-up by salivary cotinine.

First Author/ Reference no/ Year	Sample size and Characteristics	Preven-tionCes-sation	Study design	Intervention design	Theory used	Output variables
Mini G./8/2014	Randomized 224 male diabetes patients into intervention groups 1 and 2.	Cessation	A randomized controlled trial	Both groups received a standard diabetic-specific smoking cessation message from a doctor. Intervention group 2 additionally received counseling	"5 As" (Ask, Advise, Assess, Assist, Arrange). Readiness to quit, "5 R"s (Relevance, Risks, Rewards, Roadblocks, Repetition)	Change in knowledge and the quit rates between the two groups at 6 months.
Jayakrishnan R./12/2013	454 non intervention group	Cessation	A randomized controlled trial	Face-to-face interviews and telephone counseling. Educational materials on tobacco hazards were distributed. Four rounds of counseling sessions were conducted which included a group counselling with a medical camp as well as individual counselling by trained medical social workers. The control group received general awareness training on tobacco hazards along with an anti-tobacco leaflet.	Importance of 'role modelling' against tobacco use in the community. And developing coping skills, harm reduction strategies, stress reduction methods and develop social support for quitting.	Self-reported smoking status was assessed after 6 and 12 months.
Sorensen G./17/2013	2833;randomly selected 72 government schools with grades 8 to 10 from 10 school districts .	Cessation	Cluster randomized	Intervention activities and materials aimed to emphasize teachers as role models, increase understanding of the risks related to tobacco, increase motivation to quit, build skills for quitting, cope with withdrawal, and promote skills for maintenance.	Social contextual model for health behavior change	Tobacco use cessation
Jayakrishnan R./12.2013	454 control;474 intervention	Cessation	Community based RCT	Distribution of education materials on tobacco hazards during, sending invitation letters to the study subjects for attending medical camp cum group counseling. Conduct of medical camp cum counselling and Individual counselling at four time points	-	Smoking status ,type and duration of smoking and nicotine dependency status using revised Fagerstrom scale of Nicotine Dependence (FTND)
Savant S.C./7/2013	150 industrial workers stratified randomly into three groups (control, individual and group counseling groups)	Cessation	Randomised control	-	The protocol followed was of 5 As (Ask, Advice, Assess, Assist and Arrange for follow up) and 5 Rs (Relevance, Risks, Rewards, Roadblocks and Relapse)	Urine cotinine level and tobacco quit rate
Thankappan K.R./21/2013	224 adult diabetes patients aged 18 years or older who smoked	Cessation	parallel-group randomized controlled trial,	Advised to quit smoking by a doctor and distributed diabetes specific education materials. The intervention-2 group received an additional diabetes specific 30 minutes counseling session using the 5As (Ask, Advise, Assess, Assist and Arrange), and 5 Rs (Relevance, Risks, Rewards, Roadblocks and Repetition) from a non-doctor health professional.	-	Tobacco quit

First Author/ Reference no/ Year	Sample size and Characteristics	Prevention/Cessation	Study design	Intervention design	Theory used	Output variables
Pai A/22/2012	45 patients attending the outpatient department at the Dental College,	Cessation	A randomized controlled trial	Behavioral therapy (counseling), nicotine replacement therapy or placebo irrespective of their level of dependence		Cessation
Pimple S./9/2012	Tobacco users identified, 224	Cessation	Case studies	Individual and group behavior therapy was implemented in three stages at a worksite	Supportive Psychotherapy, Cognitive Behavior Therapy and Psychodrama.	Fagerström score, for both smoking and smokeless forms of tobacco Tobacco quit rates
Sorensen G./23/2012	1851: survey and Total number enrolled in trial students = 800.	Both	Quasi-experimental design,	Activities focused on building awareness about the hazards of tobacco, developing life skills, and advocacy development.		self-reported tobacco use in the last 30 days.
Kumar M.S./10/2012	400 men (20-40 years) currently using any form of tobacco	cessation	A Cluster randomized trial.	A physician offered two sessions of health education 5 weeks apart along with self-help material on tobacco cessation to the intervention group. The control group received only self-help material.		Self-reported point prevalence abstinence
Stigler M.H./11/2011	14,085 students who completed 1 or more of the 3 surveys: 6365	Prevention	group-randomized, controlled intervention trial	Intervention strategies included classroom activities, school posters, parent postcards, and peer-led health activism.	Social influences model (USDHHS, 1994) and Social Cognitive Theory,	Tobacco use behaviors and tobacco use intentions.
Jayakrishnan R/12/2011	Males in the age group of 18.0 to 60.0 years; Among the 928 smokers	cessation	Community based smoking cessation intervention trial	Smokers in the intervention arm were given multicoloured anti-tobacco leaflets in Malayalam with descriptions of tobacco induced health hazards.	Not mention	Personal habits particularly smoking status viz; type of smoking, duration and initiating factors for smoking
Mishra G.A./24/2010	4-arm cluster randomized trial of 18 months duration among 646 BPO employees,	cessation	a cluster randomized trial.	Arm 1: (Control Group): Distribution of pamphlets (information on hazards of tobacco) to all employees. Arm 2 :Active Health Education (HE) sessions followed by focus group discussion (FGD)Arm 3 : Active HE sessions followed by FGD and Behavioral Therapy (BT) in the form of one-to-one counseling. Arm 4 : Active HE sessions were followed by FGD, BT, and Pharmacotherapy (PT).	Not mention	tobacco cessation.
Arora M./25./2010	6,023	Both	A group-randomized intervention trial.	The four intervention strategies include (a) training workshops b) community-based interactive activities and outreach programmes: (c)community-based cessation clinics/services (d) enforcement provisions of Tobacco Control Act in India	Not mention	Ever use tobacco , past six months use and current use of multiple forms of tobacco
Perry C.L./26/2009	6th- and 8th-grade students in 2004; 14,063 students	Prevention	Group-randomized trial	Intervention consisted of behavioral classroom curricula, school posters, a parental involvement component, and peer-led activism.	Social cognitive theory	Self-reported use of cigarettes, bidis and chewing tobacco and future intentions to smoke or use chewing tobacco.

control intervention as their chief objective. Out of twenty-three, six studies focussed on both tobacco use prevention and control. Most of them focussed on adolescent students and one study specifically was conducted on women. 14 studies were focussed on tobacco use cessation and 3 studies focussed on prevention of tobacco use. From these studies it has become very clear that tobacco control interventions are mostly centered on tobacco cessation part and focusses on people who are already using tobacco rather than preventing part where all the potential at risk non users are focus of an intervention like Adolescents and people working in certain industry. Among these articles one protocol focussing on tobacco cessation intervention using cluster randomized trial design was published by Sarkar et al., 2014.[6]

Method used to prove efficacy of an intervention:- Various research designs were used by the researchers. Most common method was group randomized controlled trial in the community or school based sample frame, followed by quasi non randomized non control trial, where single group is given intervention and efficacy was measured by the change in pre and post assessment intervention in the same group. A complicated research design like cluster randomized trial was used in only four studies and one study used case series design. Along with the sample frame, sample size among these studies depends on the study design itself. Cluster randomized trials and group randomized trials contain large numbers of participants as compared to quasi non randomized non control studies. Most of the studies which focus on both the prevention and control part of the intervention prefer quasi experimental designs while the studies which focus on cessation of tobacco use prefer more sophisticated designs like cluster randomized or group randomized trial.

Intervention content and format :-

Theoretical basis for intervention:- Out of 24 studies 11 studies did not mention any model or theory as base for designing tobacco control intervention, 5 A's (Ask, Advice, Assess, Assist and Arrange for follow-up) and 5 R's (Relevance, Risks, Rewards, Roadblocks and Relapse) principle were used in two studies, both studies were focussed on tobacco cessation and showed significant increase rate in tobacco quit rate among intervention group. Both the studies were conducted on adult population.[7,8] As far as other models or theories are concerned, social cognitive theory is commonly used for intervention in the group and community based intervention. Social cognitive theory was used for interventions which focussed on tobacco use prevention rather than cessation. Cessation studies used role modeling social contextualization and when indi-

vidual one to one therapy was concerned, cognitive behavioral therapy was used. Study conducted by Pimple and their colleagues among factory workers in Mumbai during 2012 used very innovative and unique approach. They used individual and group therapy for their cessation study and along with Cognitive behavior therapy, psychodrama was also included in their intervention package.[9] Most of the studies which did not mention any theory as based for their intervention were conducted for tobacco used cessation purpose.

Intervention tools:- Most of the community based tobacco use cessation study were relied on information leaflets and similar format for passing health education messages to the participants, followed by the multiple individual counselling sessions with participants along with health behavior education. Study conducted in Tamilnadu by Kumar and colleagues (2012) consisted of one to one, two counselling sessions five weeks apart and few studies like study conducted in Pune by Savant and colleagues in 2013 and by Pimple and colleagues in Mumbai (2012) asses the efficacy of the group counselling for cessation of tobacco use .[7,9,10] Studies conducted for preventive purpose used more direct approach for health education tools like posters, audio visual presentation, peer led activities and studies in school also involve parents at least for one activity like parent post card or interactive sessions with parents etc. Leaflets containing information about health hazards of tobacco use were also included along with these tools but they were not chief component of intervention. Studies focus on both aspects of tobacco control, delivering intervention in more than one session. Interactive education sessions, group workshops were prominently used. Life skill development was prominently included in these studies and along with it, study conducted under project ACTIVITY also provided community based clinic and cessation services.[11]

Outcome of the intervention :- *Outcome variables* :- Most of the tobacco cessation studies use self reported tobacco use or tobacco quit rate or self reported tobacco use cessation as a major outcome indicator to measure efficacy of the intervention design. Four studies used Fagerstrom scale of nicotine dependence (FTND) to asses efficacy of intervention along with tobacco quit rate.[9,12,13,14] Self report of sustain abstinence was used in few studies as major outcome variable, along with cessation of tobacco use, change in knowledge about health hazards of tobacco use was also common in cessation studies. Only one study conducted in the Pune used biological indicator like urine Cotinine level to measure tobacco quit rate instead of relying on the self reported tobacco use prevalence.[7]

Tobacco use prevention studies used current tobacco use behavior Tobacco use intention was major outcome variable used in these studies. Apparently there is no consistency in the outcome variables used by the studies focusing on both prevention and cessation aspects of tobacco control. Most of the studies used tobacco use rate, knowledge and attitude regarding to hazards of tobacco use, but study conducted by Dable and colleagues used perception of tobacco use along with awareness as major outcome indicator to measure efficacy of tobacco control intervention.[15] Literature review of the cessation studies have shown that, whenever study design had control group there has been significant decrease in the smoking, and increase in tobacco quitting or decrease in prevalence of the tobacco use were observed in intervention group compared to the control group. Few studies have compared multiple control groups like study conducted by Raja and colleagues (2014) have shown that any intervention whether it is cognitive behavior therapy or Basis health education, helps tobacco users to quit tobacco.[13] Another study where multiple interventions were compared was study conducted among BPO employees where along with control groups which received pamphlet about health hazards of tobacco use, there were other three interventions like Active health education session, Behavior therapy and last arm receiving active session behavior therapy and pharmacological intervention.[16] This have shown that group which received pharmacotherapy showed significantly higher reduction of tobacco consumption compared to the three other groups.

Almost all studies focussing on prevention purpose including studies that focus on both the aspects of tobacco use showed significant increase in knowledge regarding health hazard of tobacco use in intervention group. Study conducted by Stigler et al., (2011) has shown that there is significant increase in perception of tobacco use among intervention group.[11] Increase in health awareness and increase in quit rate observed among most of the interventions, focussed on both prevention and cessation of tobacco use. Overall most of the interventions showed significant changes in the targeted outcome variables which means most of these interventions were found to be efficient in tobacco control and can be used in the comprehensive tobacco control intervention at international level.

DISCUSSION

This review has showed that in last decade in India there were various studies conducted to prove efficacy of intervention for tobacco control. Tobacco control interventions were roughly divided into three different categories for purpose of this review. Studies focussed on tobacco use cessation, tobacco use prevention and third type focussed on both aspects of tobacco prevention and intervention.

This review highlights the fact that the focus of most of the studies conducted during last decade in India was on tobacco use cessation than prevention. Community based randomized trial were used most of the times to prove efficacy of cessation intervention. Most of the studies were solely focussed on specific interest group like industrial and BPO workers and various groups of patients attending clinic for different ailments. For these sample frames group based randomized design were used. Intervention for cessation were designed by using different tools but most common method of communication used by the researchers were distributing leaflets and conducting group counselling sessions. Few innovative ideas were also tested in last decade like the study conducted by Sarkar et al. (2014) used Yogic breathing technique as part of intervention package to control craving for tobacco use, followed by few studies that focus on enhancing life skills by conducting workshop but workshop methods were restricted to the specific groups or studies where large number of participants were not involved.[6,17,18] Noticeable thing is that, majority of these interventions for cessation of tobacco use, did not use any theory from social, psychological, anthropological and behavioral sciences for development of their intervention. Psychotherapies like cognitive behavior therapy is used only in one study where intervention were based on one to one counselling with physician in multiple sessions. Most important thing is that, these studies have used large sample sizes and complex study designs like Cluster randomized trial to prove the efficacy of their interventions.

Review have shown that researchers still rely on self reported tobacco use as outcome variable or non biological tests like Fagerstrom Nicotine Dependence test (FNDT) to measure the efficacy of their intervention, Biological indicators like urine continine level have been rarely used in last decade, almost never in the community based trial. Collecting and analyzing biological samples may not be very practical in community based studies with large sample sizes , especially when other non invasive method of assessing nicotine dependency, like FNDT is available to the researchers. Same reason applies for the studies which do not use cognitive behavior therapies (CBT) in the community based studies because practical feasibility of CBT at community level is very questionable.

As far as tobacco use prevention is concerned, most of the studies have their primary focus on the adolescents of age 13 years to 16 years, most of the studies use school as sample frame. In this aspect, there is more uniformity seen amongst the participant's demographic characteristics in preventive studies. In cessation studies sampling frames varied a lot and did not show any consistency. Tobacco prevention interventions mostly used leaflets interactive sessions and audio visual presentation along with peer led activities. Few school based studies also involved parents of the participants in the intervention to gain maximum efficacy from intervention. Surprisingly, preventive interventions were based on social cognitive theories. This particular theory is most commonly used theory in the creation of tobacco use prevention intervention during last decade in India. This is very contradictory to the findings from cessation studies, where most of the interventions were not directly based or derived from any theoretical framework. Most of the studies used current tobacco use rate as outcome variable for measuring efficacy of their intervention. Along with that other variables like intention to use tobacco, knowledge, attitude and awareness about the hazardous effects of tobacco use were regularly used to measure efficacy of intervention, but none of the standardized tools to measure those variables were used, because there is no psychometrically valid tool standardized available for Indian population which can measure these variable uniformly. Reviews have shown that as far as measuring efficacy of tobacco use prevention intervention is concerned, there is a need of robust, standardized tool to measure its efficacy accurately.

Review has already mentioned that there were few studies that focused on both prevention and cessation aspect of tobacco control, these studies most of the times were community based randomized studies devoid of any similarity in the demographic characteristics of their participants across studies and contain very heterogeneous population derived from diverse sample frame. Interventions of these studies were not based of any theoretical framework like cessation studies and most of the study used more than one intervention session to deliver interventions. So passive health education tools like leaflets and brochure distribution were part of the intervention but not entirely focussed on them. In one study, community based clinical service were also made available. Outcome variables used by these studies were also very diverse but in majority of cases, tobacco quit rate or prevalence of current tobacco use were used.

The review of literature noted following observations

1. There is lack of a standardized and robust tool to measure efficacy of the tobacco use prevention intervention as variables used by the researchers were not standardized and not comparable with each other.

2. As far as formulation of intervention package for tobacco use cessation is concerned, use of some theoretical framework will be more helpful to create more appropriate intervention.

3. Most of the cessation studies rely on the self reported tobacco quit rate or use prevalence as an outcome variable instead of using standardized tool like FNDT.

4. Tobacco use prevention intervention is mostly derived from social cognition theory. Other theoretical frameworks like Health belief models can be useful to formulate tobacco use prevention intervention.

Review has showed that there is a need of more robust and contextual tool to measure efficacy of prevention intervention, to increase standardized outcome variables like FNDT and urine cotinine level for tobacco use cessation intervention and finally there is also need to use different theoretical frameworks other than social cognition in the formulation of tobacco use prevention intervention.

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