RESEARCH ARTICLE

Smoking Cessation Intervention in Rural Kerala, India: Findings of a Randomised Controlled Trial

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Abstract

Background: Prevalence of tobacco use is higher in the rural than urban areas of India. Unlike tobacco cessation clinics located in urban areas, community-based smoking cessation intervention has the potential to reach a wider section of the community to assist in smoking cessation in the rural setting. The present study aimed to assess the effectiveness of a cessation intervention in rural Kerala state, India. Materials and Methods: Current daily smoking resident males in the age group 18-60 years from four community development blocks in rural Kerala were randomly allocated to intervention and control groups. The intervention group received multiple approaches in which priority was given to face-to-face interviews and telephone counselling. Initially educational materials on tobacco hazards were distributed. Further, four rounds of counselling 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. Self-reported smoking status was assessed after 6 and 12 months. Factors associated with tobacco cessation were estimated using binomial regression method. Results: Overall prevalence of smoking abstinence was 14.7% in the intervention and 6.8% in the control group (Relative risk: 1.85, 95% CI: 1.05, 3.25). A total of 41.3% subjects in the intervention area and 13.6% in the control area had reduced smoking by 50% or more at the end of 12 months. Lower number of cigarettes/ bidi used, low nicotine dependence and consultation with a doctor for a medical ailment were the statistically significant predictors for smoking cessation. Conclusions: Rigorous approaches for smoking cessation programmes can enhance quit rates in smoking in rural areas of India.

Keywords: Community approach - intervention - smoking cessation - rural Kerala - India

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Introduction

It has been estimated that, approximately 180 million tobacco related deaths can be avoided, if tobacco consumption among adults can be reduced to 50% by the year 2020 (Mackay and Eriksen, 2002). Tobacco smoking is considered as the single largest contributor for over a dozen types of cancers and its associated premature deaths worldwide. Smoking is the most important risk factor for cancers of the lung, esophagus, nasopharynx, larynx, mouth, throat, kidney, bladder, pancreas, stomach and uterine cervix (IARC, 2004; Thun et al., 2010). Lung cancer leads the table of common cancers in the world with an estimated 1.61 million cases representing 12.7% of all new cancers (Ferlay et al., 2010). Smoking accounts for 80% of lung cancer cases in men (Mackay et al., 2006). It is also an established fact that 55% of total lung cancer deaths are reported from developing countries annually (Ferlay et al., 2010).

India, the second largest producer and consumer of tobacco products in the world, has more than one third of adults using tobacco in one form or the other. Annually in India, 800,000 deaths are attributed to tobacco use (International Institute for Population Sciences, 2010). The two most common cancers occurring among men are lung and oral cancers. More than 63,000 lung cancer cases are reported in the country every year (Noronha et al., 2012). In India, the mortality due to cancer is expected to rise because of the easy availability of smoking products, ranging from locally made bidis (made by wrapping coarse tobacco in dried temburni leaf) to branded cigarettes, the diverse culture and the noticeable difference in the urban-rural life style of the country (Jha, 2009).

The efforts to control tobacco have not seen a remarkable change as expected in India. Promotion of smoking cessation programmes has to be an integral part of a comprehensive tobacco control strategy and is the best possible method to avert mortality due to smoking. Community based intervention programmes were found to be successful for smoking cessation and the coverage of such programmes were high (Murthy and Saadicha, 2010). In a country like India, where majority of the population

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are residing in rural areas, high smoking prevalence and minimal accessibility to health systems network, it seems imminent to introduce smoking cessation programmes in the rural community so that a wider audience can be reached.

Currently there is scarcity of information on the effectiveness of community based smoking cessation intervention in rural India. Very few studies were reported from India to understand the effectiveness of community based tobacco cessation (Kumar et al., 2012) and no study has been reported to understand the efficacy of community based intervention programmes targeting individuals for smoking cessation. In this background, an attempt was made to introduce community based individual targeted intervention programmes for smoking cessation in the southern state of Kerala which is being widely acclaimed for its high literacy and good health indicators. The present study aims to assess self-reported short-term point prevalence smoking abstinence (no smoking in the past seven days) and harm reduction (reduction of smoking by more than 50% from the baseline survey) at 12 months after the baseline study.

Materials and Methods

Settings and participants

The study was conducted in 4 randomly allocated Community Development Blocks (CDB's) in rural Thiruvananthapuram district of Kerala state in South India between November 2010 and February 2012. Each CDB represents 5-7 panchayaths (lower level of administrative system) and each panchayath is further divided into wards. A total of 11 wards representing 11 clusters (5 from intervention and 6 from control area) were selected from the CDBs using random sampling method (Figure 1). Men in the age group of 18-60 years who were 'current daily smokers' were considered eligible for the study. Details regarding the recruitment of subjects in the study were published by Jayakrishnan et al. (2011). The human ethics committee of the Regional Cancer Centre, Thiruvananthapuram had accepted the study protocol prior to the commencement of the study. The rationale for conducting the study was explained to the study participants and a written informed consent was obtained. The participation to the study was purely voluntary.

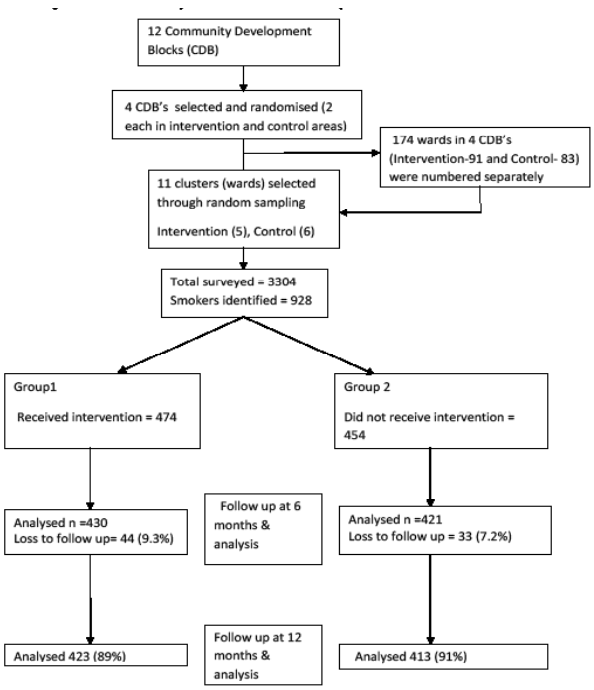

Figure 1. Participant Enrolment to the Study

Sample size

Sample size was estimated a priori using 5% alpha error and 80% power with a design effect of 1.5 to account for cluster effect. The assumption was a quit rate of 10% in the intervention group and 5% in the control group. The required number of participants in each group was 450.

Data collection

Trained female community health workers were utilised to collect the baseline data. The baseline data was collected using a pre-tested structured questionnaire that included details of socio-demographic characteristics, personal habit details, particularly smoking status mainly the type and duration of smoking and nicotine dependency status using revised Fagerstrom scale of nicotine dependence (FTND). Internal consistency, validity and test-retest reliability of FTND were also assessed for the study and published in Jayakrishnan et al. (2012). For assessment of socioeconomic status (SES), the scores of education, occupation and family income of each participant were combined. The details of assessment of SES were given elsewhere (Jayakrishnan et al., 2011).

Intervention methods

Smokers in the intervention and control areas were given awareness on tobacco hazards in general along with multicoloured anti-tobacco leaflets in 'Malayalam' (the local language). The content of the leaflets were designed to give an overview of tobacco and its ingredients, smoking induced health hazards in general, second hand smoke and related hazards for women and children and importance of smoking cessation. The leaflets contained the importance of 'role modelling' against tobacco use in the community.

In addition to anti-tobacco leaflets, a quick reference guide for tobacco cessation titled "How to quit tobacco?" [Developed by the Tobacco Cessation Clinic, Regional Cancer Centre (RCC), Thiruvananthapuram in the local language, (Malayalam)] was also distributed in the intervention area. The book contents are information on tobacco hazards, photographs of oral pre-cancer and cancer, advantages of quitting, barriers for quitting, different stages of behaviour change, methods for quitting and relapse prevention strategies.

The initial data collection was followed by despatch of personal invitation letter to each participant in the intervention group to attend a group counselling cum medical examination camp fixed at a specific date in each cluster. The letter also mentioned about the importance of participating in a general medical camp and guidance offered to quit smoking in the camp and in succeeding house visits. The local administrative heads, health

workers and medical doctor's of the respective health centres of each cluster were also informed about the programme and requested their support for the success of the programme. The group counselling session and medical camp were conducted within 2 weeks after completion of the baseline data collection in each cluster.

For succeeding interventions, two medical social workers, trained at the Tobacco Cessation Clinic of RCC, conducted house to house visit at 2-4 weeks, 4-6 weeks, 3 months and 6 months time period for counselling against tobacco use. The outcome of the study was assessed after 12 months. During each visit, permission was taken from the smoker prior to counselling. Each counselling took around 15 minutes which stressed on developing coping skills, harm reduction strategies, stress reduction methods and develop social support for quitting. Illustrations of hazards of smoking in general along with photographs of lung cancer and oral cancer patients who were treated at the RCC, Thiruvananthapuram were used by the counsellors in the initial two visits. Informed consent was obtained from patients to show their photographs along with their messages in the local language. In the absence of meeting a participant in the first house visit, a second attempt was made to contact the person in the next 2-3 days or the person was given counselling via mobile phone. Subjects who were unable to contact after all those attempts were considered as 'lost to follow up'. Thus a combined approach was adopted which included mobile phone counselling and face to face interview for succeeding intervention. Priority was given for face to face interview in follow-up visits on the assumption that it will be useful to develop a rapport between the subject and the interviewer (Jayakrishnan et al., 2013).

Statistical analysis

The baseline characteristics of the intervention and control group were compared to look for statistical significance. The mean and percentage values were compared using independent sample t-test and Chi-square test, respectively. A p-value of less than 0.05 was considered to be statistically significant. The outcome measures were analyzed using intention-to treat (ITT) analysis. The participants for whom no endpoint data were available due to refusal to participate or loss to follow up were counted as failures (i.e. there was no reduction in smoking status). In all other cases the missing data were replaced by the last observed status.

The risk ratio along with 95% confidence interval for quit status at different time points were estimated using binomial regression method after adjusting for age, education, occupation, types, duration and frequency of smoking, consultation with doctor and nicotine dependency score. PROC GENMOD procedure using the software SAS (version 8.1) was used for the estimation of risk ratio.

Results

Subject characteristics

We recruited 928 'current daily smokers' who were identified from the selected community through house to house interview (Figure 1). Of these, 474 (mean age: 44.56 years, SD: 9.66 years) were from the intervention area and 454 in the control area (mean age: 44.47 years, SD: 10.30 years). The overall FTND score among current daily smokers was 5.04 (SD: 5.05) and this score in the control and intervention groups were 4.75 (SD: 2.57) and 4.92 (SD: 2.51) respectively.

Follow up of subjects

Four hundred and sixty two (97.5%) subjects in the intervention and 424 (93.3%) subjects in the control area were contacted at least once during the follow-up period of 12 months after completing the baseline survey. The two arms were homogenous with reference to age group, socioeconomic status score and revised FTND score (Table 1). Cigarette smoking was the most common habit among both groups representing 62.5% in the control and 53.8% in the intervention areas.

Outcome at 6 and 12 months after the baseline survey

Self-reported point prevalence abstinence at 12-month follow up in the intervention and control areas was 14.7% and 6.8% respectively. The rate of quitting tobacco smoking at 12-months was 1.8 times more in the intervention group compared to the control group [adjusted Risk Ratio (RR): 1.85, 95%CI: 1.05, 3.25]. The quit status reported at 6 months interim period was higher in the intervention area (16%) compared to control area (5.7%) (p=0.0001). (Table 3)

A statistically significant association was found between number of 'sticks' used and the quit rate which was found to be higher among those who smoked less cigarettes/bidis (Table 2). Nicotine dependency was another predictor for smoking cessation. Higher smoking abstinence was observed among subjects with less nicotine dependence scores (RR: 1.15, 95%CI: 1.01-1.34). A positive correlation was found between smoking abstinence and doctor consultation for a medical ailment/ medical advice (RR: 2.42, 95%CI: 1.50, 3.87). This

Table 1. General Characteristics of the Study Subjects (ITT Analysis)

Factors		Control (n=454) (%)	Intervention (n=474) (%)	p value*
Age group	≤25	13 (2.8)	13 (2.7)	0.132
	26-35	98 (21.5)	79 (16.6)	
	36-45	127 (28)	158 (33.3)	
	46-55	135 (29.7)	154 (32.5)	
	>55	81 (17.8)	70 (14.7)	
Socio economic status score**				
Lower & Upper lower (≤10)		262 (57.7)	304 (64.1)	0.114
Lower Middle (11-15)		157 (34.6)	148 (31.2)	
Upper Middle (16-25)		33 (4.4)	21 (4.4)	
Upper Income (26-29)		2 (0.4)	1 (0.2)	
Forms of smoke use	Bidi	57 (12.5)	73 (15.4)	0.05*
	Cigarette	284 (62.5)	255 (53.8)	
	Both	113 (24.8)	146 (30.8)	
Baseline nicotine dependence score				
0-2 (Very low)		89 (19.6)	90 (18.9)	
3-5 (Low-moderate)		180 (39.6)	183 (38.6)	0.83
6-10 (High-very high)		185 (40.7)	201 (42.4)	

*Chi-square test was used to find p-value; significant at 5%level; **scores obtained by combining scores of education, occupation and family income

Table 2. Tobacco Quit Status- at 12 Months (ITT analysis)

Quit Status		Intervention(474)	%	Control (454)	%	Risk ratio
		70	14.7	31	6.8	1.85 (1.05-3.25)*
Age group	<35	17/92	18.5	9/112	8	
	36-45	23/158	14.6	6/127	4.7	
	46-55	17/154	11	10/135	7.4	0.88 (0.91-1.91)
	>55	13/70	18.6	6/81	7.4	
Chew tobacco	0	56/363	15.4	21/294	7.1	
	1	9/75	12	8/118	6.8	0.97 (0.68-1.4)
	2	5/35	14.3	2/34	5.9	
Alcohol Habit	0	26/154	16.9	11/145	7.6	
	1	23/213	10.8	11/205	5.4	0.91 (0.70-1.19)
	2	18/95	18.9	7/93	7.5	
	3	3/12	25	2/11	18.2	
Smoke Type	Bidi	4/73	5.4	6/57	10.5	
	Cigarette	50/255	19.6	22/284	7.7	0.92 (0.62-1.36)
	Both	16/146	10.9	3/113	2.6	
Number of Cigarette used	Nil	4/73	5.4	6/57	10.2	
	≤5	45/199	22.6	18/205	8.8	1.1 (1.01-1.20)*
	6-15	18/160	11.2	6/163	3.7	
	>15	3/42	7.1	1/29	3.4	
Number of Bidi used	Nil	50/255	19.6	22/284	7.7	
	≤5	8/44	18.2	3/42	7.1	1.1 (1.02-1.18)*
	6-15	10/121	8.3	6/110	5.4	
	>15	2/54	3.6	0/18	0	
Baseline nicotine dependence score	0-2 (Very low)	31/88	35.2	11/89	12.4	1.15 (1.01-1.34)*
	3-4 (Low)	16/97	16.5	13/119	10.9	
	5 (Moderate)	11/86	12.8	1/61	1.6	
	6-7 (High)	10/130	7.7	6/113	5.3	
	8-10 (Very High)	2/71	2.8	0/72	0	
Doctors Visit	At least one visit	46/291	15.8	20/187	10.7	2.42 (1.50-3.87)*

*significant at 5% level

Table 3. Outcome at 6 Month Follow-up

Reduction in smoking	Control n=454	%	Intervention n=474	%	Total (928)
No attempt	298	65.6	58	12.2	356
Tried but could not reduce	62	13.7	50	10.5	112
Reduced but could not reduce by 50%	22	4.8	107	22.6	129
Reduced by 50%	35	7.7	112	23.6	147
Reduced more than 50%	11	2.4	71	15	82
Quit the habit	26	5.7	76	16	102

*p<0.0001

Table 4. Harm Reduction at 12 Month Follow-up

Reduction in smoking	Control n=454	%	Intervention n=474	%	Total (928)
No attempt	232	51.1	49	10.3	281
Tried but could not reduce	96	21.1	52	11	148
Reduced but could not reduce by 50%	33	7.3	106	22.4	139
Reduced by 50%	45	9.9	112	23.6	157
Reduced more than 50%	17	3.7	84	17.7	101

*p<0.0001

reiterates the fact that higher chance of quitting was found among subjects who sought medical consultation from a doctor (Table 2).

Overall, 17.7% of study subjects in the intervention area had reduced smoking by more than 50% at the end of 12 months (Table 4). In terms of reducing smoking to any level, it was observed that nearly a quarter of subjects in the intervention area (21.3%) and three-fourths of subjects in the control area (72.2%) were unable to change their smoking status compared to the baseline survey (Table 4).

Discussion

In the present study, overall prevalence in smoking abstinence was 14.7% in the intervention and 6.8% in the control group, with a 2-fold risk ratio of quitting tobacco smoking among theintervention group. The quit rates achieved in this study were comparatively high when compared to a study conducted in Bihar state of India where identified volunteers were trained to give community cessation activities resulting in 4% quit rate and 2% dose reduction rate (Sinha and Dobe, 2004). A possible reason for high quit rates could be the rigorous approaches used in smoking cessation interventions. The other reasons could be the augmentation of anti-tobacco campaigns by various organizations (governmental and non-governmental), media campaigns against tobacco and the implementation of Indian legislation against tobacco viz. the Cigarettes and Other Tobacco Products Act, 2003 with its subsequent amendments (Cigarettes and Other Tobacco Products Act, 2003). These reasons could have had a complimentary effect to the study hypothesis.

The Cochraine review on individual behavioural counselling for smoking cessation had revealed the fact that interventions given outside routine clinical settings by smoking cessation counsellors or health educators were

useful for smokers to quit (Lancaster and Stead, 2005). The impact of individual level intervention for smoking cessation was reported by meta-analysis conducted in 58 trials which differed in treatment format viz. self help, group counselling, person-to-person contact, pro-active telephone counselling etc. Similar to the present study, an estimated odds ratio of 1.7 for successful cessation was observed with individual intervention compared to no intervention (Fiore et al., 2008). Similar results were observed in a study conducted in Tamil Nadu where group counselling sessions were given by a medical professional in the community. The self reported abstinence was 12.5% in the intervention area, 2 months after intervention (Kumar et al., 2012). A worksite intervention programme conducted in Mumbai, India with a multi component tobacco cessation intervention that included general awareness, individual and group counselling reported 17% quit rate after three rounds of intervention (Pimple et al., 2012).

In the present study, it was observed that lesser the dependency to nicotine more is the chance of quitting which was found to be statistically significant. This fact has been substantiated by evidence from other studies as well which had also shown high quit rates (Hymowitz et al., 1997; Ferguson et al., 2003; Hyland et al., 2004).

A striking influence between doctor consultation and quit rates were observed in this study. It is assumed that the presence of a medical problem and a medical remedy/ advice from a consulting doctor along with general advice to quit smoking might have increased quitting rates. A study conducted in clinical settings in Kerala had found that physician advice combined with non-medical health provider counselling reported 21.4% of tobacco abstinence at 6 weeks time period (Kumar and Thankappan, personal communication). In an another smoking cessation study conducted among diabetic patients in clinical settings in Kerala reported 52% smoking abstinence after 6 months follow-up for those who were given counselling by a non-doctor health provider and brief intervention by a doctor (Thankappan et al., 2013). It is possible that strong and personalised advice offered on medical grounds by the physician could have influenced subjects to quit tobacco. Though interventions in clinical settings are effective in increasing the quit rate, the question that may arise is that whether smokers really need to acquire a disease to visit clinics and initiate smoking cessation. Most often it was observed that smokers in the younger age may not acquire smoking related diseases and it is expected that older patients would turn to clinics more frequently. The most important aim of a smoking intervention programme is to improve health and to prevent or minimise ill health as a consequence of smoking (Aveyard and Raw, 2012). Hence, community cessation could be given more priority to clinic based programmes so that quitters will benefit from a life with minimal disease or free from diseases due to smoking.

In the present study, 41.3% of study subjects in the intervention area and 13.6% in the control area had reduced smoking by 50% or more at the end of 12 months. 18% of subjects in the intervention area had reduced smoking by more than 50% which is also comparable to a study conducted in the southern state of Tamilnadu, India where 22% harm reduction was reported (Kumar et al., 2012). It is difficult to assess harm reduction because of the difficulty in quantifying the response of the person. In the present study, harm reduction was assessed by comparing the average number of cigarettes a person smoked at the beginning of the study and later at the end of the study. It is possible that the response given by a subject to how many cigarettes/bidis a person smoked per day could be subjective in nature which could also be related to the nature of the person during the time of interview. Though harm reduction rate was high in this study, it is possible that apart from person-to-person counselling provided by trained volunteer, subjects in the intervention area could have had got additional advice from the medical doctor when the subject might have gone for consultation on medical grounds. This view could be substantiated by the fact that more than 50% of subjects in the intervention arm had consulted a doctor at least once during the study period. This included subjects who had attended the group counselling session cum medical camp conducted in the intervention area after completion of the baseline survey. Moreover, medical professionals of the respective health centres of each cluster was sensitised on the study and its intentions that could have complimented the effect.

Unlike quit rates which was found to be higher among subjects who smoked lesser number of cigarettes/bidis and a lower nicotine dependence score, harm reduction by more than 50% could be difficult particularly among those whose nicotine dependence score varies from moderate to severe. The association between smoking reduction and reduced levels of nicotine dependence had been reported earlier (Mooney et al, 2011).

The important barriers for quitting in the present study were craving (42%) and drowsiness (17.3%). Though it is difficult to convey the exact meaning of craving, we used this term to those who had an intense urge to smoking. Hence craving is an indicator of nicotine dependence which was reported in other studies as well (Richter et al., 2002). Another highlighting factor of the study was that more than three-fourths of the study subjects in the intervention area had made an attempt to change their habit while less than a quarter of subjects were able to do so in the control area.

Trained social workers were utilised in the present study for behavioural intervention and was found to be successful to enhance the quit rate. It is possible that their social acceptance might have been acquired through a one-to-one interaction approach that ultimately resulted in developing a good rapport with the person to understand the barriers for smoking cessation and to give quitting tips.

A major limitation of the study was the absence of biochemical validation to assess the smoking status due to resource constraints. The counsellors who assessed the outcomes were not blinded to intervention and control groups while collecting the follow-up status. However, this study was done with multiple intervention methods which also included 4 rounds of person to person counselling at different time periods in a span of one year. Hence it is expected that, multiple approaches could have a profound implication in altering the smoking status of an individual

when compared to a single method resulting in better outcomes.

In conclusion, for a developing country like India, where majority of tobacco cessation clinics are confined to urban areas, priority has to be given to extent tobacco cessation services to rural areas, where majority of tobacco users are residing. Community intervention programmes fills the gap between anti-tobacco awareness generation and cessation clinic services. This intervention did not increase quit rates of heavy smokers for which pharmacological therapy along with behavioural counselling has to be considered. However, this study would be an ideal platform for researchers to take up suitable models for community specific tobacco cessation intervention programmes particularly in the rural areas.

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