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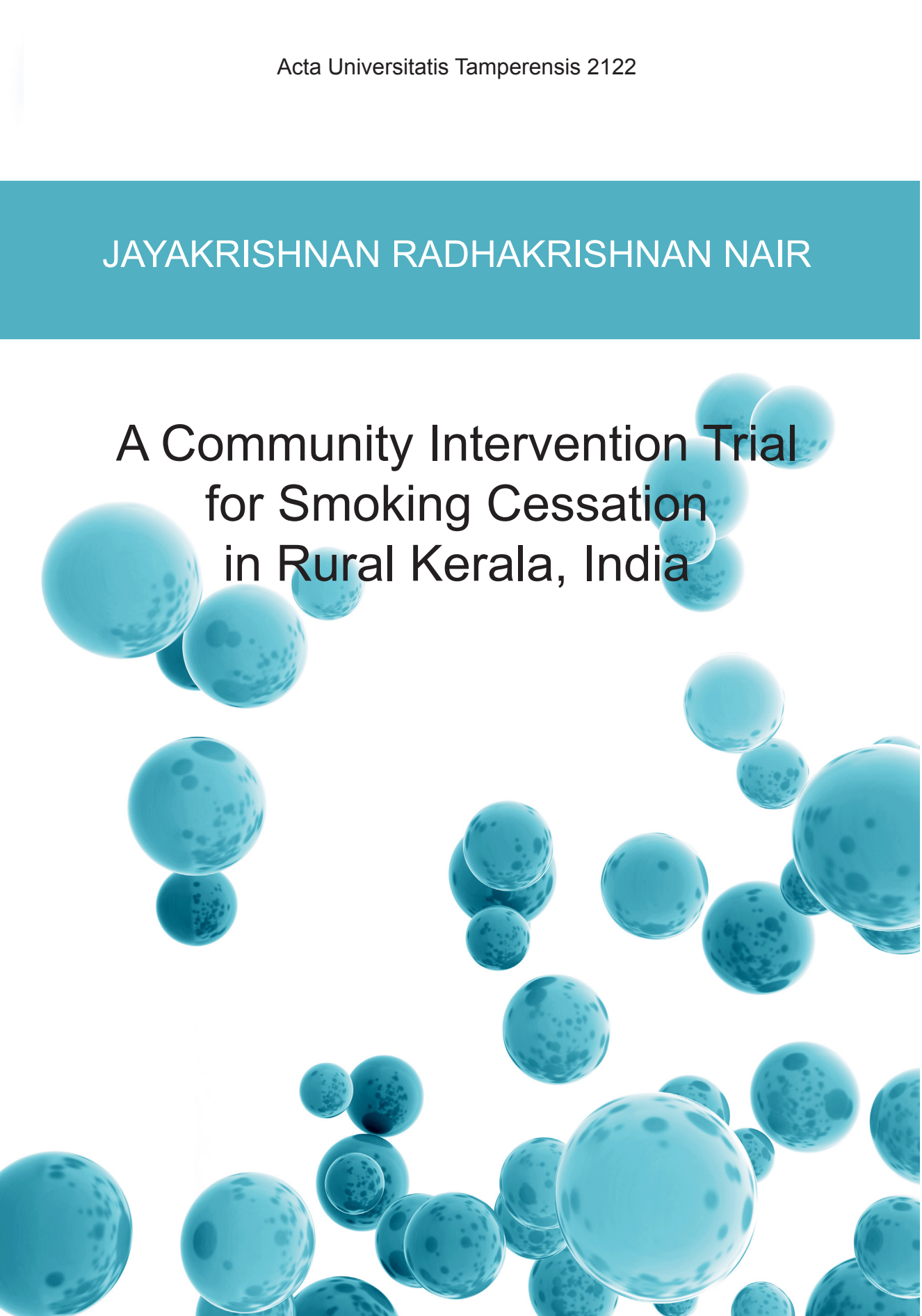
# A Community Intervention Trial for Smoking Cessation in Rural Kerala, India

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# ABSTRACT

Tobacco-related diseases have emerged as a major public health problem in India. Other than strengthening legislation, one of the priority areas envisaged under the tobacco control programme of the Government of India is tobacco cessation, which is aimed at assisting tobacco users to quit the habit. In a country where the majority of tobacco users live in rural areas, there is an imminent need to develop intervention programmes for tobacco cessation in the rural community. This thesis explores the effectiveness of a proactive community-based smoking cessation programme in the southern state of Kerala in India and also the predictors of smoking cessation. Furthermore, the thesis also attempts to illustrate the tobacco prevalence, the nicotine dependence status of smokers and the multiple approaches that have been adopted for intervention programmes in the community.

Men aged 18–60 years from four randomly allocated Community Development Blocks (2 intervention & control groups) of rural Thiruvananthapuram district were interviewed by Trained Accredited Social Health Activist workers. 'Current daily smokers' were thus identified for the study. Smokers in both groups were given antitobacco leaflets during the baseline survey. Nicotine dependence was assessed using the Fagerstrom Test for Nicotine Dependence scale.

In the intervention area, smokers further received four rounds of counseling (at 2–4 weeks, 4–6 weeks, 3 months and 6 months after the baseline survey) from trained medical social workers for which priority was given to face-to-face interview followed by telephone counseling. In the first round of intervention, a medical camp and group counseling was conducted in all the intervention clusters. Motivational counseling was conducted in the $2^{nd}$ and $4^{th}$ sessions. Self-reported smoking status was assessed at 12 months after completion of the baseline survey. Factors associated with smoking cessation after one year was estimated using binomial regression method.

In the intervention area, 97.4% of the eligible subjects were contacted at least once, either through face-to-face approach or using mobile phone, to provide cessation counseling.

Among the 3304 subjects interviewed, the overall prevalence of smoking was 28% (n=928) (mean age of smokers = 44.4 years, SD=9.2 years). Among the 928 smokers, 474 subjects were in the intervention area (mean age = 44.6 years, SD = 9.7 years) and 454 in the control area (mean age = 44.5 years, SD = 10.3 years). Majority of the smokers in the intervention and control areas were from the 'upper-lower' socioeconomic group (64.1% and 57.2%). The intervention and control groups were comparable in terms of age (p=0.89), SES (p=0.11) and nicotine dependence score (p=0.83).

The overall FTND score among study subjects was 5.06 (SD: 5.05). FTND scores in the control and intervention areas were 4.75 (SD: 2.57) and 5.33 (SD: 6.6) respectively. The FTND scores increased with age and decreased with higher socioeconomic status. The average FTND score was high among smokers using both bidi and cigarettes (mean 6.10, SD 2.17).

The self reported 7 day point prevalence rates of smoking abstinence without biochemical verification was 14.7% in the intervention and 6.8% in the control group (RR: 1.85, 95% CI: 1.05, 3.25). At the end of 12 months, 41.3% subjects in the intervention area and 13.6% in the control area had reduced smoking by 50% or more. Lower number of cigarettes/bidis, low nicotine dependence score and doctor consultation were the statistically significant predictors for cessation. In this study 4 sessions of counseling were given, which included a onetime group counseling session as well. The study demonstrated that proactive smoking cessation intervention utilizing multiple methods could enhance quit rates in smoking in rural areas of India.

# LIST OF ORIGINAL PUBLICATIONS

The present monograph is based on the following four publications reprinted here with the permission of the publisher

I       Jayakrishnan R, Mathew A, Uutela A and Finne P (2011). A community based smoking cessation intervention trial for rural Kerala, India. **Asian Pac J Cancer Prev** 12(12): 3191-3195.

II      Jayakrishnan R, Mathew A, Lekshmi K, Sebastian P, Finne P and Uutela A (2012). Assessment of nicotine dependence among smokers in a selected rural population in Kerala, India. **Asian Pac J Cancer Prev** 13(6): 2663-2667.

III     Jayakrishnan R, Mathew A, Uutela A, Auvinen A and Sebastian P (2013). Multiple approaches and participation rate for a community based smoking cessation intervention trial in rural Kerala, India. **Asian Pac J Cancer Prev** 14 (5): 2891-2896.

IV      Jayakrishnan R, Uutela A, Mathew A, Auvinen A, George PS and Sebastian P (2013). Smoking cessation intervention in rural Kerala, India – findings of a randomised controlled trial. **Asian Pac J Cancer Prev** 14 (11): 6797-6802.

# ABBREVIATIONS

| | |
|---|---|
| ASHA | Accredited Social Health Activists |
| CDB | Community Development Block |
| CI | Confidence Interval |
| COPD | Chronic Obstructive Pulmonary Disease |
| COTPA | Cigarettes and Other Tobacco Products Act |
| COMMIT | Community Intervention Trial |
| DALY | Disability Adjusted Life Years |
| DSM | Diagnostic and Statistical Manual of Mental Disorders |
| FCTC | Framework Convention on Tobacco Control |
| FTND | Fagerstrom Test for Nicotine Dependence |
| FTF | Face To Face |
| GATS | Global Adult Tobacco Survey |
| HBCR | Hospital Based Cancer Registry |
| IARC | International Agency for Research on Cancer |
| ICC | Intra Class Correlation |
| ICD | International Classification of Diseases |
| IEC | Information, Education, Communication |
| IIPS | International Institute for Population Sciences |
| ITT | Intention to Treat |
| IUTLD | International Union of Tuberculosis and Lung Diseases |
| MOHFW | Ministry of Health and Family Welfare |
| MPOWER | Monitor, Protect, Offer, Warn, Enforce, Raise |
| NFHS | National Family Health Survey |
| NHSDAA | National Household Survey of Drug and Alcohol Abuse |
| NTCP | National Tobacco Control Programme |
| PROC GENMOD | The procedure to fit generalised linear model |
| RCT | Randomised Controlled Trial |
| RCC | Regional Cancer Centre |
| RR | Risk Ratio |

| | |
|---|---|
| SAS | Statistical Analysis System Software |
| SES | Socio Economic Status |
| SD | Standard Deviation |
| TTM | Trans Theoretical Model |
| USD | United States Dollar |
| USPH | United States Public Health |
| WHO | World Health Organisation |
| 5 A's | Ask, Advise, Assess, Assist, Arrange |
| 5 R's | Relevance, Risks, Rewards, Roadblocks, Repetition |

# 1  INTRODUCTION

It has been suggested that tobacco consumption may emerge as one of the greatest challenges to public health globally by the end of the 21st century, with an estimated 1 billion deaths, if the smoking trend continues in the current pattern (Eriksen et al., 2015). The rise in population growth concomitant with the increase in tobacco use will result in more than 80% of tobacco attributed mortality in low and middle income countries by the year 2030 (Mathers and Loncar, 2006). The rise in mortality from smoking at middle age (30–69 years) is nearly three times higher when compared to non-smokers in the age group thus resulting in a reduction in life span among smokers by nearly 10 years (Jha, 2014). Despite the tremendous advances in public health campaigns and tobacco control laws, India is the second largest consumer of tobacco products in the world. The prevalence of tobacco use among men in India is 48% as against 20% among women (IIPS, 2010). In India, wide variation exists in tobacco prevalence among different states of the country. The prevalence of tobacco use ranges from 67% in the State of Mizoram to 9% in the State of Goa (IIPS, 2010). The health impact of smoking is enormous considering the wide spectrum of diseases associated with it. Nearly 900,000 people die every year in India due to diseases attributed to tobacco. If left unchecked, this number may rise above 1.5 million annually by the year 2020 (Murray and Lopez, 1997). Nearly a quarter of deaths among middle aged men in India are linked to smoking (Gajalakshmi et al., 2003). In India, the economic impact of cancer, coronary artery disease and chronic obstructive lung disease attributed to tobacco for the year 2002-2003 was so high that it exceeded the combined revenue and capital expenditure on medical and public health, water supply and sanitation (Gajalakshmi et al., 2003).

Nearly 3000 chemical constituents in smokeless tobacco and about 4000 chemicals in tobacco smoke have been identified of which many are known carcinogens. Nearly half of all cancers among males and one fourth among females in India are tobacco related (IIPS 2010). A large

proportion of cancer deaths in India particularly in the age group of 30-69 years were tobacco related (Dikshit et al., 2012). Quitting smoking is the best possible measure to avert mortality due to lung cancer. It has been reported that the risk of lung cancer can be reduced by 90% if the person quits the habit at 30 years of age (Peto et al., 2000).

With mounting evidence on the hazardous effects of tobacco in India, the Government of India has enacted various measures to counter the tobacco epidemic. The Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act (COTPA) was enacted in the year 2003. The WHO Framework Convention on Tobacco Control (WHO FCTC), which ensures key strategies aimed at reduction in demand and supply of tobacco, was ratified by the Government of India in the year 2004 (Kaur and Jain 2011).

Within the broader spectrum of tobacco control, tobacco dependence gains importance in view of the fact that it is a major obstacle that smokers have to overcome while involved in the process of quitting the habit. The addictive property of the alkaloid 'nicotine' found in tobacco makes addicts out of tobacco users and this property of nicotine is considered similar to that of cocaine (Government of India 2005). Smoking cessation virtually benefits every smoker regardless of age, sex, disease state or years of smoking. The risk of dying due to tobacco can be reduced by 50% among quitters as against those who continue smoking for the next 15 years, if the person is able to do so below 50 years of age (Murthy and Saddichha 2010). The effectiveness of individual smoking cessation has been reported elsewhere (Lancaster and Stead 2005). In India, smoking cessation has not been given much importance. The reason could be attributed to the fact that majority of the population reside in rural areas where accessibility to health systems is poor, which acts as a barrier to the implementation of tobacco cessation programmes. On the other hand, tobacco cessation centres have been emerging in the urban areas of India (Murthy and Saddichha 2010), which will be of more benefit to the urban educated community. It seems impending to introduce smoking cessation programmes in the rural community so that a wider population can be reached. Deeply embedded cultural habits concomitant with lack of knowledge on the risks associated with tobacco

are considered as major hurdles for tobacco control in rural areas (Murthy and Saddichha 2010).

Lessons learned from tobacco cessation clinics in India point to the fact that loss to follow up is a major concern. It is important to educate the community on the need for smoking cessation and its significance on health before undertaking such an intervention programme. This approach will be useful to retain subjects in tobacco cessation programmes (Varghese et al., 2012). Unlike tobacco cessation clinics where subjects volunteer to attend clinics, it is expected that a proactive intervention approach in the community will fill the void of loss to follow up. In this context, a community intervention programme using multiple approaches to deliver health education messages and counseling for smoking cessation gains considerable significance.

With this background, a smoking cessation intervention programme was implemented in a rural community in the state of Kerala located in the south west corner of India. Kerala represents 3% of the total population of the country and despite a poor per capita income, is known for better health indicator values than other states in India (Sauvaget et al., 2011). The literacy rate in the state particularly female literacy is the highest in the country. However relatively high tobacco prevalence has emerged as a major public health problem in the state. In Kerala, 35.4% of males in the age group of 15 years and above are 'current tobacco users'. Smoking is the predominant habit among adult males in Kerala where nearly a quarter of men smoke (22.4%) while the corresponding figure for smokeless tobacco use was 10% (IIPS 2010). Recently tobacco control measures have been intensified by a complete ban on the manufacture, storage and sale of panmasala containing tobacco (a smokeless tobacco product). This ban was enforced on the basis of the Food Safety and Standards Regulations 2011 of the Government of Kerala State (Office of the Commissioner of Food Safety, Kerala 2012). However the enforcement of smoking restriction in public places has not gathered much momentum in the state.

In this scenario, a community intervention trial was initiated among males in a rural area in Thiruvananthapuram district, Kerala with the objective of evaluating the effectiveness of an intensive community-based smoking cessation intervention in comparison with a control population. Before initiating the cessation programme, an attempt was made to

estimate tobacco prevalence among males in the age group of 18-60 years in the study population. A baseline survey was used to identify the current daily smokers to be included in the study. Additionally, the nicotine dependence status of smokers in the intervention and control areas was also assessed using the FTND scale.

# 2 REVIEW OF LITERATURE

The public health consequences of tobacco use are enormous in developing countries where two-thirds of the world population live. The magnitude of the problem is nothing short of massive, and the morbidity and mortality associated with tobacco consumption is catastrophic for a developing country like India. This review explores a wide range of issues related to tobacco from a broader international perspective. It also undertakes a detailed evaluation of the tobacco prevalence, health and socio-economic consequences and control measures that have been adopted in India. The review falls under eight major heads: the tobacco epidemic, tobacco addiction, health consequences, tobacco control measures, smoking cessation, methods, studies conducted on smoking cessation and predictors of smoking cessation.

## 2.1 The tobacco epidemic

### Global scenario

It is estimated that there are more than 1 billion current smokers in the world, of whom 80% live in low and middle income countries (Del Ciampo and Del Ciampo 2014, World Health Organisation 2008). Based on the current tobacco consumption pattern, approximately 450 million adults will lose their lives due to smoking between the years 2000 and 2050 of which 50% deaths will occur between 30-69 years of age (Jha 2009). It is also projected that nearly 180 million tobacco related deaths can be evaded, if tobacco consumption among adults could be reduced to 50% by the year 2020 (Shafey et al., 2009). Globally, 29% of the population aged 15 years and above, smoke daily (Jha et al., 2002). The severity of the global tobacco epidemic can be illustrated by the fact that it is going to kill 50% more people in the year 2015 than HIV/AIDS and is likely to be accountable for 10% of all deaths in the world (Mathers and

Loncar 2006). In the United States of America around 20 million people died of smoking alone since the year 1964 and 2.5 million non-smokers died of exposure to second hand smoke (U.S Department of Health and Human Services 2014).

Smoking prevalence continues to increase though it is more skewed towards low and middle income countries while high income countries show a decreasing trend, especially among men (Molarius et al., 2001, Nichter et al., 2010). In the past 2–3 decades, smoking consumption per adult per day had decreased by over 50% in the United States, the United Kingdom, Canada, France and other high-income countries (Forey et al., 2009). On the other hand, the prevalence of smoking among males has shown a steady increase in developing countries such as China and Indonesia. The WHO report on the global tobacco epidemic had pointed out that nearly two thirds of world's smokers live in 10 countries: China, India, Indonesia, Russia, United States of America, Japan, Brazil, Bangladesh, Germany and Turkey. It is also estimated that out of these 10 countries, 40% of smokers live in China and India (World Health Organisation 2008). In China, the adult tobacco prevalence estimates show that nearly 53% males and 2.4% females are 'current smokers' (Qiang et al., 2011). The tobacco epidemic will cause dangers in view of the increasing population, less resources to treat tobacco- attributed diseases, social and economic factors and the marketing strategy of the tobacco companies particularly targeting the vulnerable groups in these countries.

The irony of tobacco consumption is that, being considered as a legal consumer product, tobacco can cause harm to anyone exposed to it and kill half of those who use it (World Health Organisation 2008). One in ten deaths worldwide is attributed to tobacco, which accounts to more than 5 million deaths every year (Mathers and Loncar 2006). Without effective tobacco control strategies, it is expected that the mortality associated with tobacco will rise to one billion globally in the course of this century (World Health Organization 2008).

Tobacco has been estimated to cause 2–3% of Disability-Adjusted Life Years (DALY) throughout the world. Substantial increase in tobacco consumption worldwide will increase the tobacco related mortality from 3 million deaths reported two decades ago to more than 8 million deaths in 2020. DALYs due to tobacco will increase from 40 million (2.6% of all

DALYs in 1990) to 120 million (9% of all DALYs in 2020) which will make tobacco the most important public health problem (Murray and Lopez 1997). This rise is due to accumulated hazards in developing countries (Ezzati et al., 2002). Projections of global mortality and burden of disease from 2002 to 2030 have evaluated the future trend in tobacco attributed mortality based on socio-economic development and its observed relationships with cause-specific mortality rates. While a decline in deaths due to tobacco is projected for developed countries, the mortality is expected to double in low and middle income countries where 6.8 million deaths can occur due to tobacco use by the year 2030 (Figure 1).
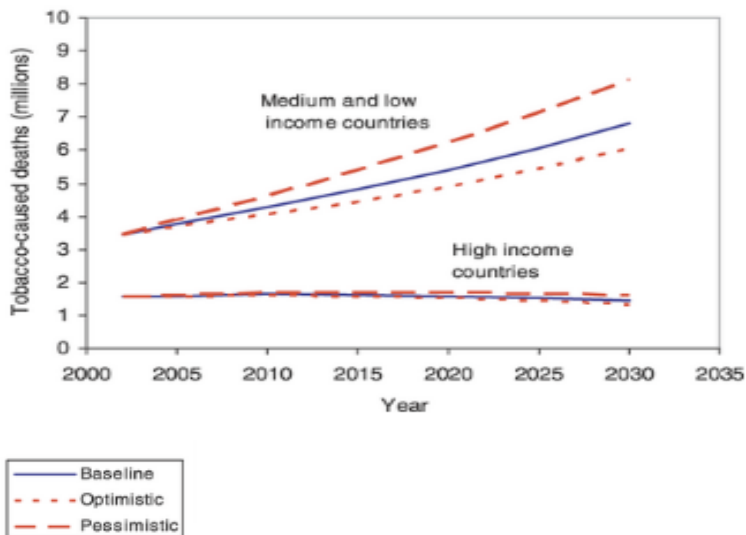


**Figure 1.**   Projections on tobacco-caused deaths for the world and for high-Income and middle- plus low-income countries, three Scenarios, 2002–2030 (Mathers and Loncar 2006).

## Tobacco use in the Indian scenario

A wide range of tobacco consumption practices exists in India. Around 1600 AD, the Portuguese brought tobacco, the pipe and cigar to the colony of Goa (Currently the state of Goa) in India for trade. Commercial production of cigarettes was introduced by the British 200 years later and

tobacco production was established in a large scale (Chaly 2007). India is currently the second largest consumer of tobacco products in the world while in global production it occupies the third place. Tobacco cultivation in India accounts for 9% of the total global production. Problems related to tobacco in India are very complex because of the relationship between huge burden of tobacco related diseases, deaths and economic interests (Sunley 2008). The beginning of the new millennium saw 81,820 million Indian rupees, which is equivalent to around 1387 million US Dollars (USD), as revenue from tobacco to the Indian economy which constituted 12% of the total excise tax. Foreign exchange earnings were 930 million Indian rupees (16 million USD), which represented 4% of India's total agricultural exports (Reddy and Gupta 2004). In India, around 800,000–900,000 deaths occur every year due to tobacco use (IIPS 2010). It is estimated that in the age group 30–69 years, 5 % of all deaths in women and nearly a quarter of all deaths in men are attributed to tobacco use (Rao and Chaturvedi 2010). While considering the economic burden of tobacco use, the total cost of tobacco use was estimated at 1.7 billion USD for the year 2004 and the direct health care costs due to tobacco use touched 1.2 billion USD, which was 4.7% of the country's total national healthcare expenditure. In the year 2004, nearly 411 million USD was lost in income due to tobacco-related non-attendance from work (John et al., 2009). In 2011, the total economic cost attributed to tobacco use from all diseases steeply increased to 22.4 billion USD in the country. This estimated cost was 1.16% of the Gross Domestic Product and was 12% more than the combined State and Central Government expenditures on health in the year 2011–2012 (Public Health Foundation of India 2014).

Tobacco is used in a wide variety of ways in India. Apart from the conventional smoking habit which is more prevalent in other parts of the globe, it is used in the smokeless form mainly to chew and further as application, sucking, gargling etc. A wide range of tobacco products are available for each type of tobacco use. While cigarettes and bidis (locally made by casing coarse tobacco in dried temburni leaf) are the most common smoking forms of tobacco, the smokeless form includes betel quid chewing and dry tobacco-arecanut preparations like panmasala, gutkha, mawa etc. Many of these products are widely used by females (IIPS 2010).

Among the manufactured tobacco products in India, bidi is the most dominant form which accounts for 31% of all manufactured tobacco production (Reddy and Gupta 2004). There are 46.4 million adult cigarette smokers and 73.3 million adult bidi smokers in India. Smoking in any form is higher in rural areas partly, due to the high prevalence of smoking (IIPS 2010). Bidi, the 'poor man's cigarette' alone comprised 48% of the tobacco market, with chewing tobacco and cigarettes comprising 38% and 14% respectively. Bidi accounts for nearly 85% of the total smoked in India and claims an estimated 600,000 lives per year (Voluntary Health Association of India 2010). Studies from Indian settings have reported significantly higher risk of all-cause mortality among bidi smokers which reinstates the fact that bidi smoking is equally hazardous or more compared to cigarette smoking (Gajalakshmi et al., 2003, Gupta et al., 2005).

Though most of these products are manufactured industrially on a large scale, some are made locally on a small scale, while few others are prepared by tobacco vendors right away for the awaiting customer and some others by the users themselves. Pattern of tobacco use among adults, 15 years of age and above, was reported by four national level surveys in addition to population based surveys in limited areas. The National Family Health Survey (NFHS round 2) conducted in the year 1998-1999 showed a tobacco prevalence of 46.5% among men and 13.8% among women aged 15 years and above. The survey found that prevalence of smoking and chewing among men were 29% and 28% while the corresponding figures for women were 2.5% and 12% (IIPS and Orc 2001). The National Household Survey of Drug and Alcohol Abuse (NHSDAA) conducted among males in the year 2002 in 25 states of India reported an overall tobacco prevalence of 58% (Reddy and Gupta, 2004). The follow-up National Family Health Survey (NFHS 3) conducted in 2005–2006 found that the prevalence of smoking and smokeless tobacco among men between 15–54 years had increased considerably (33.8% and 38%) while a declining trend was noticed among women in the 15–49 year age group (1.6% and 9.9%) (IIPS and Macro International 2007).

The Global Adult Tobacco Survey (GATS) conducted in India in the year 2009-10 reported that more than one third of adults use (15 years and above) tobacco in some form or the other. The overall prevalence of

tobacco use among men was 48% as compared to 20% among females (IIPS 2010).

## The Kerala scenario

Kerala is a small state at the southern tip of India which accounts for 3.3% of the total population of the country. In terms of human development Indicators, Kerala ranks at the top and its model for social development is often held up as a stellar example not only to other states in India, but also to many countries in the third world (Bhandari and Kala 2007). However there are problems for Kerala in other spheres of public health. Rise in tobacco use and diseases associated with tobacco have emerged as a major public health problem in the state. The total economic costs attributed to tobacco use in Kerala amounted to 170,000 USD in the year 2011, of which 52% was direct medical cost (Public Health Foundation of India 2014). In Kerala, smoking is predominantly a male habit while chewing is more or less similar in both groups. Current smoking prevalence among men in Kerala (27.9%) was higher than the reported prevalence of 24.3% for the whole of India (Thankappan et al., 2013). Cigarette smoking was found more common among people in the higher socioeconomic class when compared to bidi use which is more prevalent in the lower socioeconomic group.

One of the earliest studies that reported the tobacco prevalence of Kerala was conducted by the Kerala Shastra Sahitya Parishad (KSSP) in the year 1987. The KSSP study reported a smoking prevalence of 43 % among men aged 15 years and above (Kannan et al., 1991). A study conducted by the National Family Health Survey (NFHS round 2) in the year 1998-99 reported a smoking prevalence of 28% and 0.4% among men and women respectively. However the smokeless tobacco prevalence among men and women did not vary substantially representing 9.5% and 10.5% respectively (Thankappan and Thresia 2007).

The GATS conducted in the year 2009–2010 reported that 21.4% adults in Kerala use tobacco in one form or the other. Tobacco prevalence among males aged 15 years and above points to the fact that current tobacco users constituted 35.5% of them. Based on the type of current tobacco use among males aged 15 years and above, the GATS reported

that 27.9% of Kerala's adult male population were smokers (which include smokers alone and those who used both smoking and smokeless forms) while 7.6% used only smokeless tobacco. The findings were based on a household survey conducted on 1825 respondents from Kerala which included both males and females (IIPS 2010). Details of the GATS Kerala fact sheet are given in Table 1. From rural Kerala, a cohort study reported the incidence of tobacco use among subjects in the 15–64 year age group. The study found that 21.1% of younger individuals in the 15–24 year age group became smokers during the follow up period while 22% of older individuals (55–64 years) took up the habit of smokeless tobacco use. Among women, tobacco chewing was reported by 9.7% of subjects in the age group 55–64 years (Sathish et al., 2013). The factors linked to tobacco consumption are associated with age, sex and socioeconomic status. There is limited information on the influence of socio-cultural factors on tobacco use. The likelihood of developing a habit of using tobacco products by boys in school was two times higher, if their father is a current smoker. The chances of developing a habit of using tobacco products by boys is nearly 3 times higher if their friend is a current tobacco user (Pradeepkumar et al., 2005). Reports of tobacco use among school children, in the age group 12–19 years, point to the fact that 11% of students consumed tobacco in one form or the other, while students who experimented with any form of tobacco use was 35% (Thankappan and Thresia 2007).

**Table 1.** Global Adult Tobacco Survey- Kerala Fact Sheet

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**Tobacco Use**
• In Kerala, 21.4% use tobacco in some form or the other
• 35.5 % males and 8.5 % females use tobacco in some form or the other
• Average age at daily initiation of tobacco is 18.3 years
• 58.6 % of daily users consume tobacco within half an hour of waking up

**Secondhand smoke**
• 41.8 % of adults were exposed to second hand smoke at home
• 18.7 % were exposed to second hand smoke at public places

**Media**
• 71.6 % of adults noticed anti-tobacco information on radio or television
• 38 % of smokers thought about quitting because of the warning label

**Awareness on health hazards**
• 95 % of adults believed that smoking can cause serious illness
• 91.9 % believed that smokeless tobacco causes illness

Source: IIPS 2010.

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## 2.2 Nicotine Addiction

### Biology of nicotine addiction

Nicotine absorbed from chewing tobacco passes through the liver first where it is partly metabolized into inactive substances and then reaches the blood stream. It is generally less active and less harmful than the nicotine present in cigarette smoke which is absorbed through the lungs. The latter passes directly to the blood stream without being first inactivated in the liver. Biologically nicotine is an extremely active substance and has a wide variety of effects. It resembles the important neurotransmitter acetylcholine in distribution of electrical charges within the molecule. Nicotine can combine with a major fraction of acetylcholine receptors (nicotinic cholinergic receptors) in the body, mainly the $\alpha 4\beta 2$ receptor (Rose et al., 2000). These cholinergic receptors are ligand–gated ion channels which permit the passage of positively charged cations. The binding of nicotine at the interface between two sub units of the receptor opens the channel, thereby allowing the entry of sodium (Na+) and calcium (Ca 2+). When more calcium enters the neuron, it will result in

the release of neurotransmitters (Benowitz 2010). The release of dopamine from the brain's reward centre, the nucleus acumbens, gives a pleasurable experience and perceived calm, positive reinforcement, tolerance and addiction. The half-life of nicotine is nearly 2 hours. Therefore, dopamine levels in the reward centre gradually decline after smoking, producing symptoms of withdrawal such as irritability, restlessness, feeling of misery and difficulty in concentration (Jarvis 2004).

The biological effects of nicotine are largely due to its resemblance to the acetylcholine neurotransmitter. When exposed to nicotine repeatedly, tolerance to nicotine develops which will eventually result in an increase in the binding sites on the nicotinic cholinergic receptors. Desensitization or unresponsiveness of the $\alpha 4\beta 2$ receptor occurs when it is exposed to a stimulus for a prolonged period. This could play a major role in tolerance and dependence. Withdrawal symptoms and cravings begin when the unresponsive receptors become responsive in the absence of nicotine particularly during night-time sleep (Dani and Harris 2005). Smoking alleviates craving and withdrawal symptoms due to the rapid delivery of nicotine as a result of which up-regulation and binding of nicotinic acetylcholine receptors happen. This enables the smoker to maintain the desensitized state by achieving the desired pharmacological effect and further rewarding effects from conditioned reinforcements and also facilitates the development of addiction (Balfour 2004, Hukkanen et al., 2005). Most smokers suffer from withdrawal symptoms mainly irritability, anxiety, adjusting with friends and relatives, lack of concentration, increased appetite and cravings upon smoking cessation (Rose et al., 2003). In low doses, nicotine acts as a stimulating agent like acetylcholine, allowing impulses to pass through the nerves. In large doses, it combines with and floods all receptors, blocking the passage of impulses. Nicotine can act as a stimulant or as a depressant depending on the dosage. Nicotine overdose (60 mg or more) causes a complete arrest of respiration (Sivaramakrishnan 2001).

The role of genetics in nicotine addiction has been a topic of interest among scientists in recent years. The biological pathways which regulate the intake and metabolism of nicotine are known, though not fully understood. The Genome Wide Association Study (GWAS), a large meta-analysis, revealed that the genetic contribution to smoking related traits were strongest, when there was a variation in the nicotinic acetyl choline

receptor (nACHR) subunit genes. The most prominent genetic evidence was found in the chromosome 15q25.1 locus, where at least two distinct loci were identified as contributing to heaviness of smoking (Loukola et al., 2014, Thorgeirsson et al., 2008).

In order to quit smoking, smokers must overcome both physical and psychological dependence. The person adapts to nicotine when the smoking pattern increases which in turn develops tolerance which further increases the smoking behavior (American Cancer Society 2014). Experiencing pleasurable sensations from smoking are the result of psychological factors due to tobacco dependence, while increased dopamine levels in the brain point to physiological factors (Chaney and Sheriff 2012). Social/behavioral factors are related to environmental factors which include forming a daily habit of smoking while drinking a cup of coffee or alcohol, establishing friendships and social gathering. Repetition of these factors, in course of time, leads to behavioral dependence on smoke. Years of smoking lead to a conditioning effect which stimulates the user to smoke a cigarette. Hence the success of a smoking cessation programme is also associated with managing conditioned behaviors.

## Measurement of nicotine dependence

Measurement of nicotine dependence is vital for clinical research while studying the tobacco use patterns, behaviour and addiction of various populations. The level of addiction can be measured by clinical and biochemical means. Estimation of concentration of nicotine or cotinine in blood, saliva and urine are useful biochemical methods. The two common methods used in clinics to determine the nicotine dependence are the Fagerstrom Test for Nicotine Dependence scale and the Heaviness of Smoking Index (HSI) score.

## Fagerstrom Test for Nicotine Dependence (FTND)

The FTND, a 6 item questionnaire, has gained considerable significance since 1978 when the scale was first introduced. To compensate for inaccuracies a revised FTND scale was introduced in the year 1991 which has gained wide popularity ever since. The FTND is considered as a self

reported tool that conceptualizes nicotine dependence based on physiological and behavioral factors (Table 2). The six items of FTND scale are given below. Based on the total score, the level of addiction can be low (score less than 4), medium (score 4–6) or high (score greater than 6) (Perez-Rios et al., 2009, Wu et al., 2011). The duration of smoking had a linear effect on nicotine dependence while an inverse relation was found for high literacy and occupation. One of the key barriers for smoking cessation is higher nicotine dependence. The nicotine dependence of a habitué was highly associated with mood, anxiety, personality and exposure to substance abuse (Goodwin et al., 2011). Since the physical characteristics of tobacco products differ from one another and considering that the FTND questionnaire was mostly related to smoking behavior, renaming the FTND to Fagerstrom Test for Cigarette Dependence (FTCD) was also considered (Fagerstrom 2012).

**Table 2.**    Fagerstrom Test for Nicotine Dependence for smokers

| Questions | | Points | | | |
|---|---|---|---|---|---|
| | | 0 | 1 | 2 | 3 |
| 1 | How soon after you wake up do you smoke your first cigarette? | After 60m* | Between 31–60 m* | Between 6–30 m* | Within 5 m* |
| 2 | How many cigarettes do you smoke? | 1-10 | 11-20 | 21-30 | >30 |
| 3 | Which cigarette would you hate most to give up? | All others | First one in the morning | | |
| 4 | Do you find it difficult to refrain from smoking in places where it is forbidden? | No | Yes | | |
| 5 | Do you smoke more during the first hours after waking than during the rest of the day? | No | Yes | | |
| 6 | Do you smoke even when you are ill enough to be in bed most of the day? | No | Yes | | |

* minutes; (Source: Heatherton, et al. 1991)

## Heaviness of Smoking Index (HSI)

A shorter version of the FTND is the HSI which takes into account two items of the FTND- the time to light the first cigarette of the day and the number of daily cigarettes. When compared to high nicotine dependence, its effectiveness to assess low nicotine dependence in large population based surveys was not established completely (Pérez-Ríos et al., 2009). Though the FTND was the older scale, which is being used globally for its easiness and ability to predict major outcomes, a few scales such as the Nicotine Dependence Syndrome Scale described below, introduced later have gained considerable significance in the recent years.

## Nicotine Dependence Syndrome Scale (NDSS)

The NDSS is a 19 item questionnaire which is a relatively new measure developed to capture complex psychometric properties of nicotine dependence. This multidimensional scale yields a total score for nicotine dependence as well as 5 independent scores for the 5 sub factors. This include *Drive-* understanding the sense of compulsion to smoke, craving and withdrawal factors, *Priority*, based on the preference to smoke in front of other driving forces, *Tolerance* to smoking, *Continuity* of smoking and *Stereotypy*, which is the rigidity and tendency to smoke uniformly under any circumstance (Shiffman et al., 2004).

## The Wisconsin Inventory of Smoking Dependence Motives (WISDM)

The WISDM is a scale of 68 items derived from theories pertaining to substance use. The goal of WISDM is to ascertain the performance of each item in the scale based on the established dependence criteria. The scale also looks into measures like weight control and social interactions which will be useful for understanding new dimensions in nicotine dependence (Shenassa et al., 2009).

## Hooked on Nicotine Check List (HONC)

The HONC questionnaire is a 10 item self assessment questionnaire which is considered as the most sensitive tool to measure low nicotine dependence. Due to its excellent psychometric properties, it is widely used in educational institutions and also in health care settings (Wellman et al., 2005).

## DSM-V for Substance Use Disorders

The DSM developed by the American Psychiatrists Association is the standard classification for mental disorders used for clinical, research and policy purposes. The DSM-IV because of its less predictive validity to assess nicotine dependence has not been widely used in nicotine dependence research. The DSM-IV followed dependence and abuse disorders as two separate diagnoses. Hence, the DSM-V was proposed to increase the validity of the generic criteria specified in DSM-IV. The DSM-V combined dependence and abuse as a single disorder. A major change involved in DSM-V is the inclusion of craving for nicotine, an important predictor of smoking cessation and severity dimension ratings based on the fact that dependence is a continuous process developed by frequent repetitions (Hasin et al., 2013).

## ICD-10 codes for Tobacco/Nicotine dependence and second hand smoke exposure

The ICD-10 came as a modification of ICD - 9 in various aspects. While the ICD 9 used single code for tobacco use disorder, it was replaced in ICD 10 in which focus was based on six broad criteria. The items and the ICD codes are as follows. 1. Nicotine dependence (F 17) 2. Maternal tobacco use and exposure (O99.3 P04.2, P96.81), 3. Toxic effect of tobacco and nicotine (T65.2), 4. Environmental tobacco smoke exposure (Z57.31, Z77.22) 5. Counseling and medical services not elsewhere classified

(Z71.6, Z72.0) and 6. History of nicotine dependence (Z 87.8) (University of Wisconsin 2015).

## 2.3    Health Consequences of tobacco smoking

### The global health consequence

The health consequences of tobacco use have been reported extensively from many parts of the world. Broadly, the common health hazards of tobacco involving morbidity and mortality can be categorized under three groups namely, chronic obstructive pulmonary diseases (COPD), cardiovascular diseases and cancer. In addition to this, tobacco use will have adverse affects on the reproductive health, digestive process, vision, dental hygiene etc virtually affecting every organ of the body (Rao and Chaturvedi 2010).

A meta-analysis of observational studies on smoking and cancer from 1961 to 2003 revealed a nine-fold risk of lung cancer among smokers as compared to non-smokers followed by laryngeal cancer (RR 6.98, 95% CI 3.14–15.52), pharyngeal cancer (RR 6.76, 95% CI 2.86–15.98) and oral cancer (RR 3.43 95% CI 2.37–4.94) (Gandini et al., 2008).

The evidence of smoking related cardiovascular disease was found even in the lowest levels of exposure (Erhardt 2009). The global multi sites study conducted in 52 countries reported a nearly three-fold increased risk of Coronary Heart Disease (CHD) in smokers when compared to non-smokers (Yusuf et al., 2004, Iodice et al., 2008). A cohort study conducted in 52 countries titled the INTERHEART study, estimated a risk of 2.95 (95% CI: 2.77–3.14) for a smoker to develop heart disease (Teo et al., 2006).

The association between smoking and diseases like COPD (Forey et al., 2011), diabetes (Willi et al., 2007, Eliasson 2003, Yeh et al., 2010), atherosclerotic disease (Cheng et al., 2013) and TB were also well established (Dye and Williams 2010, Yen et al., 2014).

In India, the mortality associated with cigarette and bidi smoking were 36% and 68% (Gupta et al., 2005). Although the health impact of bidi smoking has not been fully evaluated, the association between bidi

smoking and cancers of various sites were reported. A cohort study conducted in Mumbai, India, reported an increase in all course mortality among bidi smokers particularly oral and pharyngeal neoplasm in the age group of 35 years and above (Gupta et al., 2005). Tobacco related cancers account for 42% of all male cancer deaths and 18% of cancer deaths among women (Dikshit et al., 2012). Other than cancer, smoking associated COPD is a major public health problem in India. The effects of environmental tobacco smoke on COPD were assessed by a multicentric study which concluded that non-smoking males exposed to environmental tobacco smoke had 1.4 times higher risk of COPD (OR 1.4, 95% CI 1.21–1.61) than those who were not exposed to it (Jindal et al., 2006). One of the reasons for increase in coronary artery diseases in India is attributed to smoking (Patil et al., 2004). A two-fold increase in mortality from cardiovascular disease due to bidi smoking was reported from Chennai in South India (Gajalekshmi et al., 2003).

In the state of Kerala, approximately 24,000 deaths annually were attributed to tobacco use (Thankappan and Thresia 2007). The hospital based cancer registry report of Regional Cancer Centre (RCC), Thiruvananthapuram observed that nearly 43% of cancers among men and 12% of cancers among women were tobacco related (Regional Cancer Centre 2012). The oral cancer screening trial conducted in Kerala had shown that other than smokeless tobacco, bidi and cigarette smoking were also associated with oral cancer occurrence (Sankaranarayanan et al., 2000). The relative risk for gingival cancer and lung cancer among subjects who smoked bidi alone was 2.6 and 4 respectively when compared to non-users in any form (Jayalekshmi et al., 2011).

One of the reasons for an increase in hypertension among the rural population of the state of Kerala was attributed to smoking. A cohort study conducted in rural Kerala that followed subjects in the age group of 15–64, who were initially free of the disease, found that 'current smokers' had a twofold risk of acquiring hypertension when compared to nonsmokers (Sathish et al., 2012).

## 2.4    Tobacco control measures

### Tobacco control measures in the international arena

Recognizing the fact that tobacco epidemic is a global challenge, many developed countries have started implementing tobacco control measures of their own since the 20th century. One single measure cannot be an absolute solution for the problem. Tobacco control requires a multipronged strategy, which includes both demand and supply reduction measures (World Health Organization 2004). The WHO has introduced policies, which could contain the scourge of tobacco and thus prevent millions of premature deaths worldwide (World Health Organization 2008). Tax increase, advertisement bans, smoking restrictions, warning label display, public education, product regulation and availability of cessation facilities are demand reduction measures, whereas control of smuggling, restriction of access to minors and crops substitution are the supply reduction measures, which have been found effective in reducing tobacco use (Jha and Chaloupka 1999).

   The Framework Convention on Tobacco Control (FCTC) was unanimously adopted by the World Health Assembly after a series of discussions and meetings on 21st May, 2003. The FCTC came into force on 27 February 2005. The FCTC aims to protect the current and future generations from the hazards of tobacco use including health, social, environmental and economic hazards through activities that aim at preventing initiation of tobacco use, promoting quitting and protecting non-smokers from second-hand smoke (Munzer 2013).

### Tobacco Control Legislation in India: past and present

Tobacco control legislation in India started long before the FCTC came into existence. In 1975, the Government of India enacted the Cigarettes (Regulation of Production, Supply and Distribution) Act (The Cigarettes Act, 1975) that made it compulsory to display a statutory health warning on all packages and advertisements of cigarettes. During the 1980's and 1990's the Centre and many State Governments imposed further

restrictions on tobacco trade, and efforts were initiated to bring forward a comprehensive legislation for tobacco control. The year 2003 was a landmark year for the Indian tobacco control programme when the Indian parliament passed the Cigarettes and Other Tobacco Products (COTPA, 2003) bill in April 2003 and later became an act in May 2003 (Government of India 2003). The provisions of the law include prohibition of advertisements, prohibition of sponsorship of sports and cultural events by tobacco industries, pictorial depiction of specified health warnings, prohibition of smoking in public places, prohibition of sale to minors, ban on sale of cigarettes and tobacco products within a radius of 100 yards of educational institutions and tobacco content regulation in all Indian tobacco products (Kaur and Jain 2011).

The state of Kerala had also taken up a leadership role in an initiative to ban smoking in public places in the year 1999 through a landmark judgment in the Kerala High Court, before the Supreme Court (the highest judicial forum and final court of appeal) of India passed the judgment to ban smoking in public places all over the country in the year 2001 (Kaur and Jain 2011). In the year 2012, Kerala became the second state in India after Madhya Pradesh to ban the manufacture and sale of gutkha containing panmasala (a type of smokeless tobacco) based on the Food Safety and Standards Act 2006 (Office of the Commissioner of Food Safety, Kerala, 2012).

## 2.5    Smoking cessation

Smoking cessation has emerged as one of the most important strategies to substantially reduce tobacco related morbidity and mortality. Current smokers have to quit the habit in order to reduce smoking related deaths and diseases. Smoking cessation benefits every smoker irrespective of age, disease status and duration of smoking. It has been estimated that 180 million deaths could be avoided if adult smoking were to decrease by 50% or more by the year 2020 (Mackay and Eriksen 2002). If adequate steps are not taken for smoking cessation programmes worldwide, it is estimated that 450 million deaths would occur by the year 2050 (Jha 2009). There is substantial evidence to show that smoking cessation in smokers who fall under the 25-34 years of age category could gain about

10 years of life than smokers in the category who continue to smoke. Quitting smoking at the age of 45–54 years and 55–64 years could help a person gain 6 and 4 years of life, respectively (Jha et al., 2013). The updated quick reference guide for clinicians by the US Department for Health and Human Services had stressed on the importance of tobacco to be considered as a chronic disease and the details of tobacco use to be noted and addressed during clinical settings. Further it also stressed on adopting combination strategies rather than a single strategy to counter it (The Clinical Practice Guideline Treating Tobacco Use and Dependence 2008). A notable concern is the lack of consistently applied operational definition of what constitutes cessation. Smoking cessation constitutes a dynamic process in a smoker's life, which is often characterized by repeated failures before attaining long term smoking abstinence (Zhou et al., 2009). While smoking cessation among adults is termed as volitional efforts by the individual towards permanently stopping the behavior (Ockene et al., 2000), a sustained abstinence from tobacco products for at least six months but preferably for a year is also considered as an indicator for smoking cessation (Campbell 2003). When compared to high income countries, tobacco cessation strategies were found not successful in the low and middle income countries because the services offered were meagre (Nichter et al., 2010). Unlike developing countries, the prevalence of ex-smokers has increased in developed countries over the past three decades. In the United Kingdom, the prevalence of smoking among adult males above 30 years has fallen from 70% in 1950 to 30% in a span of five decades. Currently more than 30% of UK male population comprises of ex-smokers. But in developing countries like India, Vietnam and China the prevalence of ex-smokers among men were 5%, 10% and 2% respectively (Jha et al., 2006). These low figures reported could be falsely elevated because of the inclusion of people who had quit the habit due to the severity of illness, which prompted them to quit, or they might have had early symptoms of illness due to tobacco use (Martinson et al., 2003). Tobacco cessation assumes great significance in a country like India where all forms of tobacco use are increasing particularly in the 15–24 year age group (Thankappan and Mini 2008). However cessation intervention programmes are yet to gain momentum in India.

## Health benefits of smoking cessation

It was reported that regardless of the diseases affected with smoking at the time when a person stops smoking, the health benefits are enormous for ex-smokers, which include both short term and long term benefits. Mortality reduction is the most significant aspect of smoking cessation due to the fact that smokers die a decade or more earlier than non-smokers (Centre for Disease Control and Prevention 2005). Smoking cessation markedly reduces the risk of lung cancer, coronary heart disease and COPD among smokers (Murthy and Saddichha 2010). The risk of cardiovascular mortality among patients who had prior myocardial infarction could be lowered by 36% after two years if the person abstains from smoking (Critchley and Capewell 2003). Another study conducted among patients who had undergone percutaneous coronary intervention reported 2.1 life years gained after smoking cessation (deboer et al., 2013). The impact of smoking cessation is so high in view of the fact that 90% of lung cancer mortality could be avoided if a person stops smoking before reaching the middle age and also reduces the risk of death from other diseases (Jha 2009). Peto et al reported that ex-smokers who had quit the habit at various stages of life had shown a declining trend to acquire lung cancer. The cumulative risk of lung cancer at age 75 for men when they quit the habit at ages 60, 50, 40 and 30 years were 10%, 6%, 3% and 2% respectively (Peto et al., 2000).

The effects of smoking cessation is not adherent to ex-smokers alone, rather it also minimizes the risk of passive smoking induced illness particularly among children, which include pneumonia, middle ear infections, bronchitis and exacerbation of bronchial asthma (U.S Department of Health and Human Services 2006).

## 2.6    Smoking cessation methods

Smoking cessation interventions can be broadly grouped as behavioral, drug based and intervention using alternate methods (hypnotherapy, acupuncture, alternative and natural remedies) (Shearer 2006). Due to the addictive nature of tobacco products, support is essential for many tobacco users in quitting the habit. For smoking cessation, the term

'support' implies to a variety of techniques, which involve advice, motivation, guidance and counseling given as part of behavioral intervention or together with appropriate pharmacological treatment with the intention to assist smokers to quit the habit and to prevent the consequence of relapse. Hence both pharmacologic and behavioral intervention methods contribute to tobacco cessation (Aveyard and Raw 2012). Therefore the use of these intervention methods in an appropriate manner as part of the broader comprehensive tobacco control strategy has to be envisaged in order to attain success in tobacco cessation intervention programmes.

## Pharmacotherapy for smoking cessation

Pharmacotherapy is the use of medications to alleviate the effects of withdrawal symptoms of patients addicted to tobacco and thereby make quitting easier. Nicotine replacement therapy (NRT), which contains purified nicotine was the first type of its kind that gained considerable significance for smoking cessation and is still being used globally. This was followed by Bupropion, an antidepressant drug, also considered as the first non-nicotine drug for smoking cessation. It acts by inhibiting dopamine reuptake into the neuro synaptic vesicles (Wilkes 2008). It also acts by relieving some withdrawal symptoms including depression. The effectiveness can be increased by combining it with nicotine medications or behavioral therapy.

Varenicline, a partial agonist of nicotine receptor $\alpha_4\beta_2$, acts by releasing dopamine and creating similar reinforcing effects and thus maintaining a moderate dopamine level but not to the full extent that nicotine does because of its partial binding to the receptor (Crooks et al., 2014, Jiloha 2010). If a patient smokes while using varenicline, the drug will block the ability of nicotine to bind to $\alpha_4\beta_2$ nicotinic receptor and therefore block the nicotine induced dopamine release and its subsequent rewarding/reinforcement effects (Rollema et al., 2007). Recent studies indicate that Varenicline can also interact with $\alpha6\beta_2$ receptor, which also regulate dopamine release and hence aid in smoking cessation (Bordia et al., 2013). Clonidine and nortryptyline are other drugs but their use is limited due to less effectiveness and more side effects.

## Behavioural interventions for smoking cessation

Simple advise from the part of the health care provider, which might last only for a couple of minutes results in 1 among 40 tobacco habitués deciding to quit tobacco use. Brief advice conveyed by a health professional or a paramedical staff including a message to quit smoking and a follow-up of the person is the most basic intervention (Fiore 2000). In smoking cessation intervention, the term 'advice' can range from simple verbal instructions to quit smoking to the extent of providing information on the harmful effects of smoking in detail. The chance of quitting could be increased if more time is spent on advice and discussion and further to review progress in follow up visits (Coleman 2004). Intervention from health professionals has shown to increase the percentage of tobacco quitters as much as by an additional 4–7% and a tendency to remain abstinent for 6 months or more.

In smoking cessation, the commonly used behavioural interventions range from minimal intervention given in clinical settings to more rigorous interventions like face to face individual counseling, group counseling and telephone counseling. The effectiveness of these intervention modalities have been comprehensively investigated in randomized controlled trials (RCTs) and outcomes have been assessed (Mottillo et al., 2009).

Behavioural support and guidance has got a prominent role to improve the chances of smokers to quit smoking. Behavioural programmes focus on three key objectives. These include maintaining or motivating the individual to have a smoke free life, support to avoid or minimize motivation to smoke and further encouraging them to convert it into action (West 2000). The Cochrane review of behaviour therapy programmes, acting as an adjunct to pharmacotherapy for smoking cessation, observed that behaviour support increased the success of quit chance from 10–25% (Stead and Lancaster 2012).

Behavioural therapy is based on the concept that a behavior is a process, which is learnt from the environment and the symptoms of faulty learning (abnormal behavior) are acquired through conditioning. Behavioural therapy aims to help people achieve specific aims or goals, by focusing on the current situation rather than the past (Association for Behavioural and Cognitive Therapies 2008). This is possible by

## Physician advice in clinical settings

Brief intervention offered by physicians was reported to produce 5–10% quit rate among tobacco users every year (Government of India 2005)

## Non Doctor Health Professional (NDHP) advice

Face to face individual counseling customised for the individual.

Group counselling – where a group leader, mostly a health professional, addresses a group of smokers about the problem, discusses the problem, gives messages and explains the techniques to quit smoking and motivates participants to interact and support each other to solve their problems. The potential advantages of group counseling includes collecting feedback from the group members and learning from their experience, increasing members' supportive social networks and reducing the costs (Hiscock et al., 2013).

Telephone counselling – a programme that can be provided as a component of an existing smoking cessation regime or separately, which can cover a larger segment of the population. Telephone counseling, particularly multiple sessions of counseling, was found to be effective (Stead et al., 2006).

## Self-help behavioral support

Behavioral support can also be offered through self help materials. This helps in reaching out to a much wider area of the target group. Information, education and communication materials in printed formats act as a source of advice, guidance and support for tobacco habitués. It was reported that printed materials could be useful in quitting the habit compared to a situation in which there was no intervention at all, though the success rates were small. However, the effect of self help materials on smoking cessation when combined with intervention methods, like doctor advice and nicotine replacement therapy, did not show any extra benefits (Lancaster and Stead 2005). Recently, the focus of attention has shifted from the 'conventional' approach of distributing materials, that adopted the principle of repeating the same message to all smokers, to

'customized' printed materials based on the individual's need. When compared to standard printed materials, tailor made materials, if prepared in a culturally appropriate way, were found to be much useful in enhancing quit rates in smoking cessation (Hartmann-Boyce et al., 2014).

## Approach to behavioural intervention

The U.S. Public Health Service Clinical Practice Guide line: Treating tobacco use and dependence, has provided recommendations for treating tobacco dependence based on over 6000 research studies. The 5 A's is a brief intervention method/approach in counselling (Ask, Advise, Assess, Assist and Arrange) used to guide the health professional in smoking cessation counseling. Brief intervention refers to a variety of treatment strategies involving opportunistic advice, discussion, motivation and counselling with or without drug supplementation. This brief intervention can be used with numerous types of behaviour change, which can reinforce the person to foster a decision and commitment to change. Typically a brief intervention takes 5-15 minutes (Fiore 2000).

Patients entering a health care setting should be **asked** about their tobacco use status as part of taking a routine case history, which has to be documented. All tobacco users should be **advised** to quit, and their willingness to attempt to quit has to be **assessed**. Patients who are prepared to make a quit attempt should be **assisted** in their efforts. A tobacco habitué after receiving brief counselling will be assisted by the clinician to set a quit date and will be further encouraged to get support of friends, family and colleagues. The findings of the United States Public Health Service (USPHS) Clinical Practice Guideline indicate that a strong dose-response relation exists between the duration of each person-to-person contact session and successful treatment outcomes. It was also indicated that intensive interventions are more effective than minimal interventions and should be used wherever deemed to be appropriate (Hurt et al., 2009).

An intervention programme cannot be successful until the necessary changes in the lifestyle of a patient are made. An intervention may not be successful if the patient is educated repeatedly on a problem and its outcomes, which can at times become annoying for the medical

professional and the patient. Furthermore, an assurance in terms of improved outcome for patients does not guarantee their motivation for long-term change (Zimmerman et al., 2000). Thus apart from the treatment aspect, a physician has to assist patients in making the necessary changes in the patient behaviour for health improvement. Experience from smoking and alcohol cessation strategies shows that a patient passes through various stages of change where physicians have to choose the mode of intervention and not the regular approach of 'one size doesn't fit all' (Prochaska et al., 1992, Miller 1993). The emergence of stage of change model and motivational interviewing strategies were two developments that demonstrated widespread utility (Prochaska et al., 1992).

The Trans Theoretical Model (TTM) has been widely used in smoking cessation strategies, which helps to identify the different stages through which a smoker passes through during the process of quitting. The health care provider could identify those stages and suitable strategies could be utilized for smoking cessation. Five stages of change have been recognized in TTM (Prochaska and Velicer 1997). In the pre-contemplation stage, people do not consider quitting smoking in the near future. However in the contemplation stage, people consider a change with an intent to quit within the next 6 months, while those in the preparation stage will make a serious attempt to quit the habit within the next 4 weeks. The action and maintenance stages refer to ex-smokers who have already quit the habit in the last 6 months or more (Prochaska and Velicer 1997, Schumann et al., 2006).

A change in the behaviour of habitués is needed. Health care providers should counsel tobacco habitués who are not ready to make a quit attempt. Those who are unwilling to make a quit attempt may lack information about the hazards of tobacco, may have apprehensions about quitting or could already be discouraged because of relapse. Motivational intervention plays a major role in such individuals where the provider, as a credible expert, will get an opportunity to educate, reassure, and motivate the persons, a process, which is predominantly built around the '5R's approach (Relevance, Risks, Rewards, Roadblocks, and Repetition). Motivational interventions are most likely to be successful when the health care provider is empathetic, promotes freedom to patients to express their concerns, avoids arguments, and supports the person's self-

efficacy. The importance of motivational counselling was substantiated by the guidelines recommended by USPHS in the backdrop of those who are not ready to set a target quit date (Fiore et al., 2009).

## 2.7    Tobacco cessation studies conducted in India

Most of the tobacco cessation programmes conducted in the early 1980's and 1990's were carried out as part of community interventions for cancer control. In the state of Karnataka, the efficacy of an antitobacco community education programme, based on screening of films, exhibits and personal contact, revealed a reduction of tobacco use among males by 10.2% and 16.3% among females while the corresponding quit rates were 26.5% and 36.7% respectively (Anantha et al., 1995). In the state of Bihar, a study was conducted using community volunteers for tobacco cessation. The study showed a quit rate of 4% and a dose reduction rate of 3% using minimal sustained cessation programmes (Sinha and Dobe 2004). The effectiveness of group counselling was evaluated in the state of Tamil Nadu where a trained physician offered two rounds of intervention along with self help materials on tobacco cessation in the intervention area. The study showed a point prevalence abstinence of 12.5% in the intervention area compared to 6% in the control area after two months (Kumar et al., 2012). A school based intervention programme targeting teachers conducted in the state of Bihar had also demonstrated a 50% quit rate in the intervention area immediately after intervention while the corresponding figures for the control area was 15%. Post intervention survey done in 9 months time period showed a quit rate of 19% in the intervention area and 7% in the control area (Sorensen et al., 2013).

### Tobacco Cessation Studies conducted in Kerala

Very few studies have been reported from Kerala on tobacco cessation. A randomized control trial conducted at primary health care settings in Kerala reported continuous smoking abstinence of 10.1% in the intervention group at 6-month follow up that received counseling from a physician and paramedical professional compared with the control group

that received only a brief intervention from the physician (Pradeepkumar 2009).

In a pilot study conducted at government hospital clinical settings in Kerala to understand the impact of smoking among diabetic patients, it was reported that 45% of ever users of tobacco had completely quit the habit while 55% continued using tobacco despite physician's advice. The study reported that specific advice from the part of the physician could have resulted in higher quit rates if the physicians were trained for doing cessation programmes (Thresia et al., 2009). While analyzing the efforts taken by doctors of the public sector hospitals for tobacco cessation among their patients, it was understood that one third of doctors asked about the tobacco use status while three fourths of them advised patients to quit tobacco use. However, information on how to quit tobacco was offered by only one tenth of the doctors (Thankappan et al., 2009). A smoking cessation programme for diabetic patients conducted at two diabetic specialty clinics located at two peri-urban cities in Kerala has come up with promising results. The study reported that the odds of quitting was 8.4 times more among those who were given diabetic specific cessation counseling sessions as compared to the minimal intervention group (Thankappan et al., 2013).

## 2.8    Predictors of smoking cessation

Health-related habits are mostly influenced by deep rooted socio-demographic and cultural factors (Ashenden et al., 1997). The determinants of successful quitting have not been consistently identified even after several studies because the methodological approach varied from one study context to another. In spite of this, studies have demonstrated the effectiveness of interventions on influencing the individual's chances of success in stopping smoking (Osch et al., 2009, Lu et al., 2001, Vahidi et al., 2013). Various psychosocial and demographic variables have been found to be useful indicators of smoking cessation (Walker and Loprinzi 2014). Though majority of the studies examined the basic intrinsic predictors of cessation, very few studies utilised nationally representative samples of smokers where both help-seeking and non-help-seeking populations were included (Hyland et al., 2006). In the

literature search, the common predictors identified were grouped mainly into five domains. This include socio-demographic factors, smoking related factors, psychological and mood related factors, cognitive factors and other health related behaviours.

A description of these domains are given below.


## Socio-demographic

A strong socio-demographic gradient for smoking cessation was reported in long term studies that monitored cessation of smoking. Within the broad spectrum of socio-demographic characteristics, poor standards of living concomitant with low educational standards were inversely associated with smoking cessation (Graham and Der 1999), while increase in age, having a spouse/living partner and higher education resulted in successful quitters (Lee and Kahende 2007). The long term predictors of smoking cessation were assessed in a Polish study where a representative sample of 7840 individuals based on the Global Adult Tobacco Survey data was analyzed. The study results observed that increase in age, higher education and better awareness on health hazards were significantly associated with long term smoking cessation (Kaleta et al., 2012). A Danish cohort study that successfully followed 2554 subjects for a period of 10 years also observed similar findings. The study observed that along with motivation to quit and spouse/co-habitant's smoking behavior, increase in age and social status influenced cessation of smoking (Osler and Prescott 1998).

In one of the largest community intervention trials conducted for smoking cessation, the Community Intervention Trial (COMMIT) study followed a cohort of 13415 non-clinic based smokers over a period of time (1988–1993). The study found that multiple factors were associated with smoking cessation which included a combination of psychological, physiological and social processes (Hymowitz et al., 1997)

## Smoking related factors

*Nicotine dependence and associated factors*

There is conclusive evidence to show that high level of nicotine dependence is associated with difficulty in quitting. A cohort study conducted among 6603 residents of 20 US communities involved in the COMMIT reported that the major factor predicting long term cessation among smokers was dependence on nicotine (Hyland et al., 2004). The longitudinal data from the International Tobacco Control four country survey (ITC-4) also reported nicotine dependence to be the most consistent variable associated with both initiation and maintenance of smoking cessation (Hyland et al., 2006). A telephone based 5 year follow up study, conducted by Hymowitz et al, among 13,415 smokers observed that nicotine dependence was the most important predictor for cessation of smoking. Out of the six items in the FTND scale, two items (time to take up the first cigarette in the morning and number of cigarettes smoked) assumed great significance because those variables had the largest relative risk for cessation of the habit (Hymowitz et al., 1997). Those study results were almost in par with clinic based interventions (Lichtenstein et al., 1997). In general, relapse rate was found more among smokers with high FTND score (FTND≥7) because of intense withdrawal symptoms they might have experienced in the process of quitting.

*Age at smoking initiation*

Initiating smoking at an early stage could result in high nicotine dependence, which may trigger a smoking cessation relapse (Lando et al., 1999, Khuder et al., 1999). It was also reported that males who start smoking before 16 years of age had less chance of quitting compared to those who initiate smoking at a later age (Caponnetto and Polosa 2008).

*Previous quit attempts*

Previous quit attempts are considered to be a positive sign of future successful cessation attempt (Srivastava et al., 2013). The likelihood of cessation is more when there is repeated quit attempts and longer

duration of quit period. Hence information on previous quit attempts should be utilized to enhance motivation to quit. The basis of this notion was that a smoker who managed to quit in the past at least for a short period has more likelihood to be successful in future smoking cessation attempt (Caponnetto and Polosa 2008). Longer the smoking abstinence, the more a person is likely to succeed on a succeeding attempt. Positive reinforcement from the health care provider will play a major role in this situation. It is also important to elicit reasons for previous relapses, which will assist in identifying methods to prevent future relapse (Murray et al., 2000, Borrelli 2002).

## Psychological factors

*Motivation to quit and self efficacy*

Most smokers believe that motivation to quit is essential for cessation of the habit (Balmford and Borland 2008). According to the trans-theoretical model, smokers who had made attempts to stop smoking had higher chances of success. Hence for smoking cessation intervention to succeed, motivation to quit could be considered as an important prerequisite for smokers to make an attempt to quit (Cosci et al., 2011). If a smoker is in the stage of pre-contemplation where the person has no intention to quit in recent times, the intervention has to take this aspect into consideration and streamline the programme to motivate the smoker to develop an intention to quit. Indicators of self efficacy, like measures of strength of desire or motivation to quit, readiness for cessation and confidence to quit smoking, have shown positive correlation with successful quit outcomes (Yu et al., 2004). It is also argued that motivation to quit is an important predictor for quit attempts; however its role in quit maintenance is not fully justified (Borland et al., 2010).

*Mood related factors*

Smoking was reported to be 2–3 times more commonly found among persons with bipolar disorders when compared to those without any disorders (Diaz et al., 2009). When compared with non-nicotine

dependent smokers, anxiety associated disorders were found high among high nicotine dependent individuals (Caponnetto and Polosa 2008). However there is limited evidence to show that smoking cessation outcomes worsens the existing mood related disorders in the long run (Heffnera et al., 2012).

## Influence of alcohol and related factors

Combined use of tobacco and alcohol will have more damaging effect than the use of one of them. In persons with multiple habits like smoking and alcoholism, the benefits of smoking cessation intervention will be useful not only to counter the smoking habit, but also to reduce alcohol consumption (Friend and Pagano 2005). Clinical studies related to the treatment of alcohol related disorders, where smoking cessation was also targeted, noted that abstinence from smoking does not trigger alcohol relapse (Sullivan and Covey 2002). A study conducted by Cooney et al found that nicotine dependent habitués responded to alcohol cues with increased craving for alcohol and smoking, while nicotine deprived alcoholics responded to alcohol cues without the urge to drink but to smoke (Cooney et al., 2003).

Addiction to nicotine is the most important reason for repeated failure among a smoker's attempt to quit the habit. Smokers who attempt to quit by getting some assistance succeed more than self-attempted quitters. However, many smokers are unaware of appropriate cessation methods. In smoking cessation, behavioral intervention plays a major role in assisting smokers to quit the habit. Ranging from the commonly adopted minimal clinical intervention, which includes brief advice from a healthcare provider to more rigorous interventions like individual counselling, group counselling, and telephone counselling, several intervention strategies have been extensively investigated in RCT's, and have shown widely varying quit rates (Mottillo et al., 2009). However majority of the studies were reported from developed countries.

In a developing country like India, smoking cessation programmes assume greater significance considering the high smoking prevalence, particularly in rural areas, and disproportionate infrastructure facilities for the treatment of smoking associated diseases. In this scenario, the need

for effective, feasible and financially viable non-drug intervention programmes for smoking cessation have to be looked upon to counter the tobacco menace. The current study was undertaken in the state of Kerala where the prevalence of smoking is high. Currently the focus of attention in the state is more on generating an awareness on tobacco hazards among the public, with the aim of preventing the initiation of the habit of tobacco use, rather than persuading smokers to quit the habit. It is in this back drop that the study was initiated, with an intention to come up with practical suggestions to persuade and guide the community towards smoking cessation in rural Kerala.

# 3    THEORETICAL FRAMEWORK OF THE STUDY

A theoretical framework helps to organise the study in a systematic way and provides a background for interpreting the study findings. Such a framework is the Behaviour Change Wheel enunciated by Susan Michie with colleagues (Michie et al., 2011). The wheel was based on 19 previous frame works to help to characterise and design behaviour change interventions. The Behaviour Change Wheel model was developed to encompass three criteria of usefulness. These include a comprehensive coverage, coherence and links to overarching model of behaviour. The three layers of the framework include sources of behaviour, intervention functions and policy categories.

## Behaviour Change Wheel (BCW) (Michie et al., 2011)

The sources of behaviour change include capability, motivation and opportunities. Capability includes psychological and physical capability to engage in an activity, which also includes having the knowledge and skills. Motivation which is partly reflective includes the process that rejuvenates and directs behaviour along with systematic conscious decision making while automatic motivation include impulses, urges, drives and emotions. Opportunity includes both physical and social aspects. Opportunity is defined as all factors that make the behaviour possible or which prompt it.

The intervention functions are found to play key roles in behaviour change. The intervention functions include education (enhance knowledge or understanding about the outcome), persuasion (use communication to induce positive or negative feelings or stimulate action), incentivisation (create expectation of reward), coercion (create expectation of punishment or cost), training (impart skills), restriction (use rules to reduce the opportunity to engage in target behaviour or to increase the target behaviour by reducing the opportunity to engage in

competing behaviour), environmental restructuring (change the physical or social context), modelling (provide examples for people to aspire to or imitate), and enablement(increase means or reduce barriers to increase capability beyond education or opportunity beyond environmental restructuring.

The policy measures in this model are divided into 7 categories. They are communication/marketing (use print, electronic, telephonic or broadcast media), guidelines (create documents that recommend or mandate practice), fiscal (utilising the tax system to reduce or increase the financial cost), regulation (establish rules or principles of behaviour or practice), legislation (make or change laws), environmental/social planning (design or control the physical/ social environment) and service provision (delivering a service).

## Framework for the study (Figure 2)

The Behaviour Change Wheel model was integrated into the present study to identify the sources of behaviour for smoking cessation, which reveal the pathway to appropriate intervention functions and further to develop appropriate policy measures.

## 1. Sources of behaviour

The sources of behaviour form the hub of the wheel including capability, motivation and opportunity.

  a. Motivation: The current study focused on capability and motivation to enhance cessation of smoking in an individual. A person's motivation to smoking cessation is a conscious decision making process, which was evaluated by using the interview schedule based on the individual's intention to quit the habit within 6 months and by assessing his ability as a role model for his family.

  b. Capability: In this study, the interview schedule was used to assess the extent of an individual's capacity to accept smoking cessation intervention. For this, the smoking status of the individual during the baseline survey was compared with his smoking behavior during the past 6 months.

## 2. Intervention functions

A package of services is essential to motivate smoking cessation in the rural community where there is high smoking prevalence and minimal access to the health system network. The current study focused on 4 intervention functions out of the nine intervention functions envisaged in the BCW. These include education, environmental restructuring, modeling and enablement.

   a. Education: There were five different types of intervention for smoking cessation provided to the subjects in the present study. These include (1) distribution of multi coloured leaflets (2) a quick reference guide in the local language (3) communication letter by the Principal Investigator (4) health education session in medical camps and (5) documentary film in the local language.

   b. Environmental restructuring for smoking cessation: In this section the focus of attention was to sensitize the health care providers (doctors and health workers of the local government hospitals), community volunteers and local political leaders about the magnitude of the tobacco menace in the community. Health care providers were further sensitised about the intervention programme and were prompted to ask about smoking behaviour during their routine service. The support of community volunteers and local political leaders were also sought-after for implementing intervention programmes in their respective localities.

   c. Modelling: To provide an example for people to initiate the intervention, documentary films with messages of celebrities (a local film actor and a noted scholar) were screened at all the medical camps conducted in the intervention clusters. The local film actor and the noted scholar shared their views on tobacco hazards and stressed the need for tobacco cessation in the documentary film.

   d. Enablement: To increase the capability of the person to perform the action, behaviour support was offered in the form of group counselling as well as individual counselling through trained volunteers at definite time periods. In addition to this, doctors provided brief advice for subjects who participated in the medical camps conducted in all the intervention clusters.

## 3. Policy category

Among the seven policy categories envisaged in the BCW, the current study interventions were centered on service provision category. This study aims to deliver a service in the rural community where smoking

cessation services were not given due importance. In the service provision category, two sub groups were identified. These include education and enablement. In the education category, the study utilised self help materials on tobacco control, health education in medical camps and documentary films as tools for intervention in the rural settings. For enablement, service delivery was explored in the form of medical camps, group counselling and individual counseling (face to face counseling and telephone counselling).
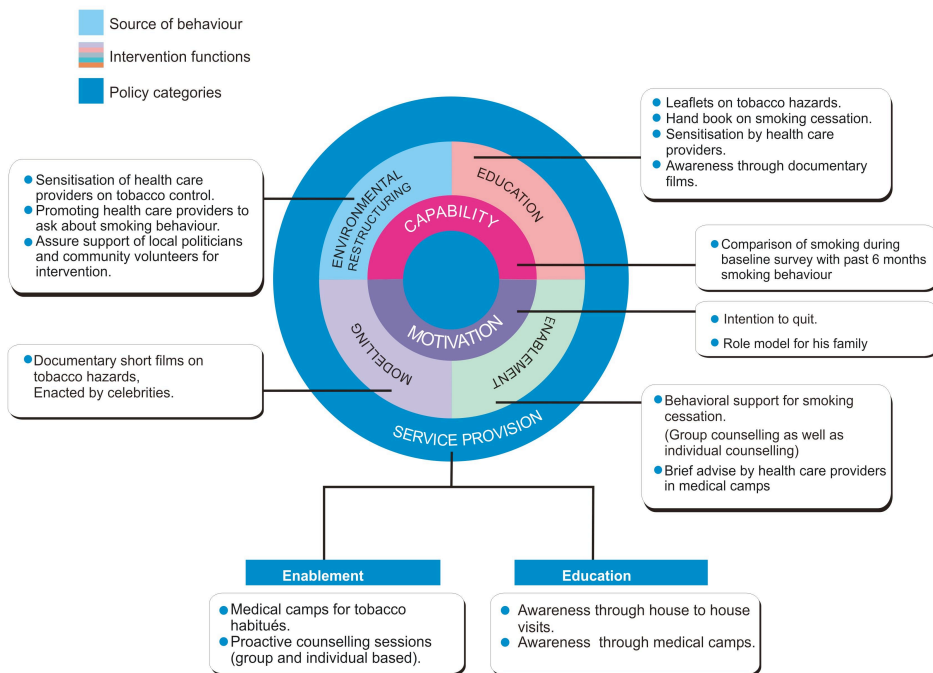


**Figure 2.** Framework of the study (Based on the BCW model)

# 4   AIMS AND OBJECTIVES

The aim of this thesis was to assess the implementation and effectiveness of conducting a proactive community intervention programme for smoking cessation in rural Kerala, India. In the initial phase, to understand the magnitude of tobacco prevalence in the community where the study was planned, it was decided to study the prevalence and correlates of tobacco use in the community. Additionally, it was essential to identify smokers in the intervention and control areas and to compare the groups in terms of their smoking status, nicotine dependency and socio-demographic characteristics. The study also attempted to assess the participation rate of subjects in various intervention programmes. Considering the fact that smoking is a major public health problem in Kerala, assessing quit rates at the end of one year provides insights into developing suitable models for smoking prevention strategies in the community.

The specific objectives of the study are the following:

1   To determine the prevalence of tobacco use and further to compare the socio-economic characteristics of subjects in the intervention and control groups for a community based smoking cessation trial in rural Thiruvananthapuram, Kerala (Paper 1).

2   To assess the internal consistency, validity, test-retest reliability of the FTND scale and the overall FTND scores of subjects in the study area (Paper 2).

3   To assess the implementation, feasibility and participation rates of the intervention (Paper 3)

4   To evaluate the effectiveness of an intensive community based smoking cessation intervention programme on smoking quit outcomes based on an annual follow-up in rural Kerala, India (Papers 3 and 4).

# 5   MATERIALS AND METHODS

## 5.1    The study design (Paper 1)

The study was conducted in rural Thiruvananthapuram district, which is the southernmost district in the state of Kerala. In the initial phase of the study, 4 Community Developmental Blocks (CDB's) were identified from 12 CDB's in Thiruvananthapuram district through a multistage sampling technique.

Randomised Controlled Study Design was adopted to allocate intervention and control groups (2 CDB's each in intervention and control areas) for the study.

Random sampling method was chosen to identify 11 clusters from 4 Community Developmental Blocks (5 from intervention and 6 from control areas)

Census method of data collection was adopted to identify "current daily smokers" from 11 clusters, for recruitment into the study.

## 5.2    The study context

In India, based on the 'panchayat raj' system, decentralization of power at the local level exists where the grama-panchayaths form the basic units of administration. The panchayath raj works on a 3 tier system, which includes grama-panchayath, community development block (CDB) panchayath and the district panchayath. The Thiruvananthapuram district panchayat has 12 CDBs with a population ranging from 140,000 to 214,000 per CDB. Each CDB is formed of 5–7 grama-panchayaths and are further divided into wards. The lowest level of administrative system in a panchayath is called a ward, where the population ranges from 1500 to 2000. In the initial stage, the socio-demographic characteristics of 12 CD blocks were looked upon for inclusion in the study. 4 blocks were excluded in the initial phase due to the fact that the demographic

characteristics, particularly the socio-economic characteristics of the population differ widely from the remaining 8 CDBs. From the remaining 8 blocks, 4 more blocks were excluded due to the prevalent mixed socio-demographic pattern in those areas. Moreover, the feasibility of doing the study in those areas was also considered, since access to these areas was limited. After selection of the CDB's, all wards in the selected CDBs of intervention and control arms (91 and 83) were numbered separately and 11 wards were selected using random sampling method (5 wards for intervention and 6 wards for control areas). Each ward represents a cluster and thus 11 cluster units were identified for the study. Location of intervention and control area is given in Figure 3.
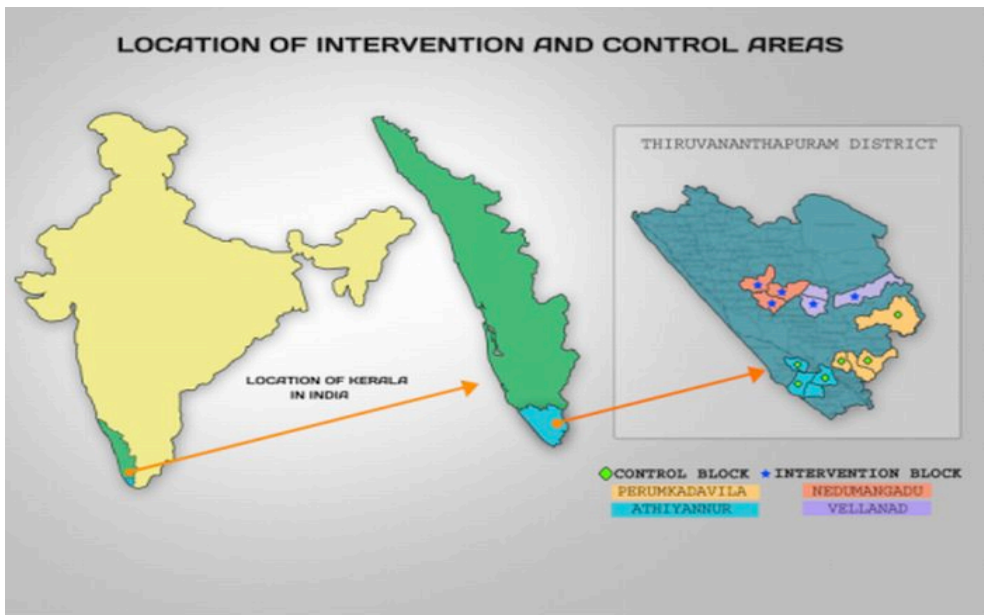


**Figure 3.** Map of the study area

## 5.3　The Study Protocol (Paper 1 and Paper 3)

### Defining the problem

In a diverse country like India, tobacco prevalence is high, particularly in the rural areas of the country as compared to urban areas (Chockalingam et al., 2013). In the state of Kerala, smoking prevalence among males was reported to be 27.9%, which was higher than the Indian national average of 24.3% (Thankappan et al., 2013). Considering the huge adverse impact of smoking on the health status of a smoker and also on passive smokers, tobacco control measures have to be intensified in the community. While tobacco use is a major public health issue particularly in the lower socio-economic strata, rural areas are the most affected, which requires urgent attention. In Kerala, tobacco cessation activities are minimal and among them the focus is more in the urban areas, while the rural communities are deprived of such facilities. With high smoking prevalence and minimal access to health systems network, a package of services to motivate smoking cessation in the rural community is essential. On the flip side, cultural habits, which are deeply embedded along with the lack of knowledge on the hazards of tobacco are considered as major hurdles for tobacco control in rural areas (Murthy and Saddichha 2010). In this circumstance, it was assumed that, proactive smoking cessation counselling, if given in an organised manner, would be effective in the rural community, through which a wide audience could be covered. In the current study, a baseline survey was conducted initially, to understand the prevalence of tobacco consumption and smoking dependence in the community, which helped assess the magnitude of the problem.

### Process evaluation

A clear description of the intervention was finalized based on a series of discussions with local stakeholders, which included ward counselors,

local community volunteers, health workers and doctors of government health centres in the study area. To effectively implement smoking cessation intervention, the feasibility of using multiple approaches to deliver health education messages and counselling against smoking cessation were discussed. The study plan was finalized based on the protocol developed during these sessions.

## Inclusion and exclusion criteria of the study (Paper 1)

Males in the age group of 18–60 years who had reported using at least one cigarette/bidi daily during the study period were identified through baseline survey and considered eligible for the study. Females were excluded from the study due to the fact that smoking among females was reported to be nil in Kerala (IIPS 2010). Subjects who could not speak, mentally disabled and terminally ill patients were also excluded from the study.

## Data collection for base line survey (Paper 1)

Trained women volunteers conducted house to house visits in the study clusters and the rationale for conducting the study was explained to the study participants. The participation to the study was purely voluntary. Informed consent was obtained from each participant that stated their willingness to participate in the study. During the initial house visits by women volunteers, the participants in the intervention group were informed about the details of intervention and the follow up visits.

## Training to the data collectors (Paper 1)

Accredited Social Health Activists (ASHA workers) were utilized to conduct the initial baseline survey. ASHA workers are selected from their respective villages for community health promotion under the National Rural Health Mission programme of the Government of India. Two ASHA workers were identified for each cluster, thus representing 22 volunteers for 11 clusters (10 for intervention and 12 for control areas). A one day

training programme was organised for the ASHA workers of the intervention area at the RCC, Thiruvananthapuram. The topics covered in the training programme included tobacco hazards, importance of tobacco control in the community and the need for community based tobacco cessation. The training was given to the ASHA volunteers by the principal researcher and a psychologist from the RCC, Thiruvananthapuram. The training programme gave emphasis on awareness of tobacco hazards, assessment of nicotine dependence and conduct of household survey using lectures, slide presentations and mock interviews. A pictorial guide on hazards of tobacco was given to each ASHA volunteer in the intervention arm as a ready reckoner, to help them make the people understand the harmful effects of tobacco, while drawing the baseline data.

ASHA workers in the control group were given half day training by the Psychologist in data collection and also the training to assess the nicotine dependence status of smokers. The training was conducted in one of the clusters in the control area.

## Follow up survey and counselling sessions (Paper 3)

Follow up survey and counselling sessions were conducted by trained counsellors in the intervention area at definite time periods. The ASHA workers accompanied the medical social workers during each visit.

## Training for counsellors to undertake follow-up counselling sessions (Paper 3)

Two medical social workers, who had expressed willingness, were selected to conduct counselling in the intervention area. The researcher explained the objectives of the study and the study procedure to the medical social workers. They were trained at the tobacco cessation clinic of the RCC, Thiruvananthapuram, to undertake follow-up counselling sessions in the intervention area. The training was of a duration of three days. On the first day, theory sessions were conducted. Practical sessions were conducted on the remaining two days, in order to get the experience of conducting counselling among tobacco habitués. They were trained to understand the different stages of change based on the

Prochaska and Diclemente model (Prochaska et al., 1992). The popular approach for smoking cessation used in hospital clinics termed as the 5 A's model (Ask, Advise, Assess, Assist, Arrange) was discussed in detail with the councilors. The steps in this model include:

**Ask** about tobacco use status, type, quantity and history

**Advise** those people who use tobacco to stop the habit. Advise should be clear, strong, personalized, supportive and non confrontational

**Assess** to determine stages of readiness to change, determine self efficacy to carry out and succeed in quitting and elicit response on the pros and cons of tobacco use

**Assist** those who are willing to change by reinforcing commitment to change, provide necessary guidance and support depending on the stage of willingness to quit

**Arrange** for follow-up by discussing the time period of next follow-up through home visit or telephone

In addition to counselling tips, counsellors were introduced to motivational counselling based on the 5 R's approach (**relevance** of quitting, **risks** associated with continued smoking, **rewards** of quitting, **roadblocks** to quit, and **repetition** for educating subjects). Motivational counselling was intended for those subjects who are not motivated to quit the habit. Practical sessions for social workers were conducted in the tobacco cessation clinic of RCC.

## Tools for data collection (Paper 1)

### *Baseline study questionnaire*

A pretested two staged questionnaire in the local language (Malayalam) was used for data collection. The first part of the questionnaire was used for baseline survey in the community to identify subjects for the study groups. The first part included questions that sought information on the locality of residence, age and socio-demographic characteristics. Information on tobacco use, which included smoking and smokeless tobacco and details of alcohol consumption, were also collected. With reference to the smoking status, detailed information from the individual

was collected, particularly the smoking status, which included the type of smoking, duration and initiating factors for smoking, previous quit attempts, attitude towards quitting and the motivation to quit. To assess the nicotine dependence status of the study subjects, the six item modified FTND scale was used. Each eligible subject was then assigned a unique number for future follow-up.

*Follow up study questionnaire*

Follow up questionnaire was used to collect information regarding current smoking, tobacco chewing, alcohol consumption, medical consultation for any ailment, doctor's advice to quit tobacco, reasons to quit tobacco, mode of quitting (abrupt/gradual), challenges faced while quitting the habit, status of other tobacco habits and alcohol (if any). The follow up questionnaire was used at a time period of 2-4 weeks, 4-6 weeks, 3 months, 6 months and 12 months.

## Intervention methods used in the study (Paper 3)

*Invitation letters for medical camp cum counselling*

After the baseline survey, invitation letters were sent to the study subjects and communication was initiated over phone to key personnel in the locality for attending medical camp cum group counselling. Postal communication messages were sent by the health care provider (RJ) to smokers of their respective clusters in the intervention area to attend a group counselling session cum medical examination on a specific date. The letter provided information about the hazards of tobacco and invited them to attend a general medical camp cum group counselling. In addition to this, local administrative heads of each cluster, health workers and the medical doctor in the government health centre nearest to each study area were also sensitized on the programme.

*Conduct of medical camps and group counselling sessions*

Health education session and medical camps were conducted in each cluster at a time period of 2–4 weeks after completion of the base line survey. The health education session included a twenty minute documentary film on tobacco and cancer in the vernacular language (Malayalam). The group counselling session for participants stressed on the benefits of quitting tobacco, plan for quitting tobacco, common withdrawal symptoms and measures to overcome them, coping and relapse prevention strategies. A health professional and a medical social worker conducted the group counselling session. This was followed by a medical camp for smokers in each cluster.

*Individual counselling at 4–6 weeks, 3 months and outcome assessment at 6 and 12 months (Figure 4)*

Following the group counselling session in each cluster, individual counselling sessions were conducted by 2 medical social workers trained at the Tobacco Cessation Clinic of RCC at a time period of 4–6 weeks, 3 months and 6 months after the completion of the baseline survey. Those who were unable to attend the group counselling were contacted at 2-4 weeks, either through a face-to-face approach or by telephone counselling. The final survey to assess the outcome of intervention was conducted at 12 months. Each counselling stressed on developing coping skills, harm reduction strategies and stress reduction methods for quitting.

Face-to-Face interview and counselling was conducted at a time period of 2–4 weeks. If unable to contact the subject during the first house visit, a second attempt was made 2–3 days after the first attempt and if found unsuccessful, the subject was given counselling via mobile phone. If the person could not be contacted after these three attempts, he was considered as 'loss to follow-up'. In this session, the above mentioned strategies for counselling and tips for quitting the habit as well as setting up a quit date were provided. On an average, FTF took 10 minutes. In the subsequent follow-up session (at 4–6 weeks), motivational intervention based on the 5 R's approach (*relevance* of quitting, *risks* associated with continued smoking, *rewards* of quitting, *roadblocks* to quit, and *repetition* for educating subjects) was given for those who were unable to quit on the target date. The subject was also requested to identify a new quit date. On

an average, FTF in the second session took 15 minutes. In the third session (follow-up at 3 months), mobile phone based counselling was provided to the subjects. The smoking status and barriers for quitting the habit among those who still could not quit were analyzed and tips for quitting were delivered.

In the fourth session (follow-up at 6 months), motivational intervention based on the 5 R's approach was given to those who were unable to quit the habit. During this time period, all subjects in the control group also were contacted through house visits or by mobile phone to obtain their smoking status. The final smoking status assessment was conducted 12 months after the baseline survey.

## Tools for smoking cessation (Papers 3 and 4)

*Quick reference guide for tobacco cessation in the local language*

In the intervention area, ASHA volunteers distributed a quick reference guide for tobacco cessation titled 'How to quit tobacco?' The reference guide was developed by the Tobacco Cessation Clinic of the RCC, Thiruvananthapuram in the local language (Malayalam). It contained information about the advantages of quitting, barriers to quitting, different methods for quitting and relapse prevention strategies.

*Distribution of Information, Education and Communication materials to subjects in the intervention and control areas*

Smokers in the intervention and control group were given multi-coloured anti-tobacco leaflets in the local language. Each leaflet provided information on the ingredients in tobacco, health hazards of active and passive smoking and the need for smoking cessation. (Appendix).
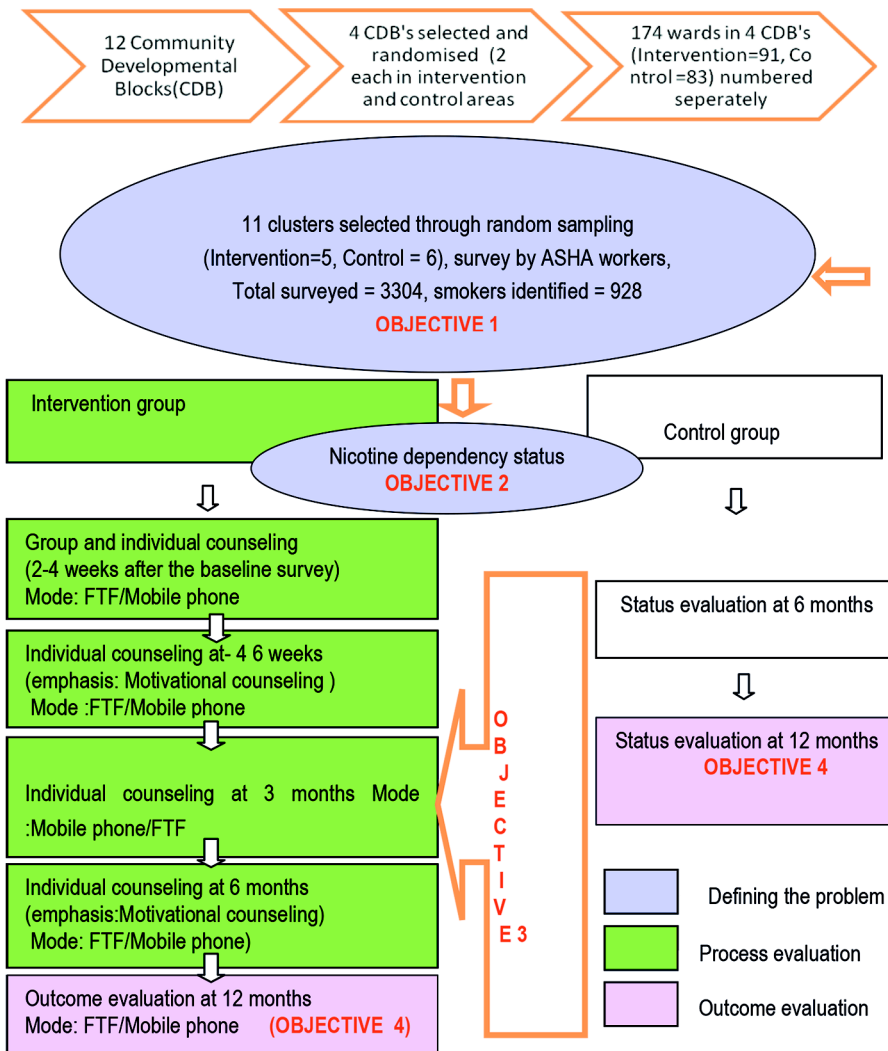
**Figure 4.** Flowchart of the study design and protocol

## 5.4 Sample size and study approval (Paper 1 and Paper 4)

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 estimated number of participants in each group was 450.

The study protocol was approved by the institutional review board of the Regional Cancer Centre (RCC), Thiruvananthapuram and Ethical clearance was acquired from the institutional ethics committee of the RCC, Thiruvananthapuram prior to the commencement of the study.

## 5.5 Assessment of age and socio-demographic characteristics
(Paper 1)

Based on the sample characteristics, age was classified into five groups to ensure homogeneity within each group. Socioeconomic status (SES) was determined by categorizing the study subjects into upper, upper-middle, lower-middle, upper-lower and lower income groups. Categorization of SES was done by combining the subject's education, occupation and family income. The scores used for education were 1, 2, 3, 4, 5, 6, 7 which correspond to illiterates and holders of primary school certificate, middle school certificate, high school certificate, intermediate/post high school diploma, graduate or post graduate and profession or honours respectively.

Occupation was classified into student, unemployed, unskilled, semi-skilled, skilled, clerical/shop-owner/farmer, semi-profession and profession respectively. An 'unskilled' worker was defined as those who require low skill and not specially trained in any particular job, whereas 'skilled' worker was the term used for those who were trained in a particular job. Participants categorized as 'unskilled' in this study were mainly manual labourers, cleaners, sweepers and hotel food suppliers, while those in the 'skilled' category included electricians, mechanics, plumbing workers, carpenters, etc. A 'semi-skilled' person was described as a person who required less training and experience when compared to a skilled worker. Other than those who assisted skilled workers, drivers, masons, painters, sales men etc. were classified as 'semi-skilled' in this study. A 'semi-professional' was described as those who required fewer years of education and training when compared to a professional. This group mainly included office assistants, computer/telephone operators, parallel college teachers, etc. For occupation, scores of 1, 2, 3, 4, 5, 6, 10 were given for those who belonged to the groups unemployed, unskilled-

work, semi-skilled work, skilled-work, clerical/shop-owner/farmer, semi-professional and professional respectively.

The monthly family income assessment was based on the total income generated by all the family members living in the same household. Due to steady inflation and consequent fall in the currency value, the income scale had to be updated periodically. The income classification was based on the updated Kuppuswamy socio-economic status scale for the year 2007 (Kumar et al., 2007). For family income, scores of 1, 2, 3, 4, 6, 10 and 12 were given for subjects whose family income per month in the Indian currency 'Rupee' was $\leq$ 979, 980–2935, 2936–4893, 4894–7322, 7323–9787, 9788–19574 and $\geq$ 19575 respectively. Similar to the Kuppuswamy socio-economic status scale, a person's SES score in this study came under the following categories. A score of 26–29 denoted upper SES group, 16–25 upper middle, 11–15 lower middle, 5–10 upper lower and <5 lower SES group. Age groups were classified as 18.0–25.9, 26.0–35.9, 36.0–45.9, 46.0–55.9 and 55.0–60.9 years.

## 5.6    Quit attempts and motivation to quit among study subjects

Quit attempts of subjects in the intervention and control area were assessed in the study. Quit attempts of subjects within 6 months prior to the baseline survey were taken. In this study, a 'quit attempt' was defined as an attempt by the subject to quit smoking, which lasted at least 24 hours continuously at a time.

Motivation to quit among study subjects, with reference to whether they had thought of quitting in the course of the 6 months prior to the baseline survey, was also considered. Those who had not thought of quitting were included in the pre-contemplation stage, while subjects who had thought of quitting during that time period were included in the contemplation stage.

## 5.7 Assessment of nicotine dependence among study subjects
(Paper 2)

Current daily smokers who used at least one cigarette or bidi were included in the study. Age at the commencement of smoking was calculated by subtracting the current age in years from the duration of smoking in years. Pack years was calculated as number of cigarettes/bidis per day * number of years smoked/10 (In India, usually a pack has 10 cigarettes/ bidis).

Information on nicotine dependence of study subjects was also collected by the ASHA volunteers using the FTND scale. The scale consisted of 6 items and had a total score of 10. The items included in the scale were, (1) How soon after you wake up do you smoke the first cigarette/bidi? (2) Do you find it difficult to refrain from smoking in places where it is forbidden (3) Which cigarette/bidi do you hate most to give up? (4) How many cigarettes/bidis per day do you smoke (5) Do you smoke more frequently during the first hours after waking than during the rest of the day? (6)Do you smoke if you are so ill that you are in bed most of the day? The scale was used to identify nicotine dependence among smokers and further to classify the type of intervention needed for smoking cessation. Apart from counselling alone, the FTND scores were also helpful in understanding the percentage of smokers who were in need of pharmacological therapy as well.

The items under FTND were first translated into Malayalam (the local language) and then back before using them. Two investigators independently translated the English version into the local language and checked for major discrepancies, if any. ASHA volunteers were trained to use the local version of FTND before it was used in the community.

## 5.8 Outcome measures (Paper 4)

Smoking quit rates and harm reduction rates at a time period of 6 months and 12 months, after the baseline survey, were considered as outcome measures. Self reported smoking abstinence without biochemical verification during the last seven days or more before the day of conducting the interview at the 6 month and 12 month time period were

considered as the criteria to assess smoking abstinence. Harm reduction rate was defined as the proportion of participants who reduced the quantity of smoking by 50% or more during this time period.

## 5.9    Supervision and monitoring of the study

Cross-checking and supervision were done to find out whether guidelines were followed by the enumerators in the field. Initially data enumerators of the intervention and control areas had to undertake a pilot study for three days in their respective areas after the training. After completing the pilot survey, discussions were held with the enumerators individually and their problems and doubts were cleared. At a few instances, the researcher accompanied the enumerators who had difficulty in asking certain questions to the participants, assessed the interview procedure and cleared their doubts. The baseline data of a few participants were randomly taken and cross checked by the researcher.

## 5.10    Statistical methods applied for the study (Papers 1-4)

To assess the homogeneity of the selected population, initially, the following three comparisons were made. To assess the factors associated with smoking, age and socio-demographic characteristics between smokers and non-smokers were compared using t-test for continuous variables and Chi square test for categorical variables. Subsequently, only smokers were selected for the trial and for comparisons of their age, socio-demographic characteristics, intensity, reasons for smoking, FTND score, quit attempts and motivation to quit between the intervention and control area, t-test and chi-square test were used for continuous and categorical variables.

The outcome measures were analyzed using intention-to treat (ITT) analysis. ITT analysis is based on the principle that all subjects continue to be considered in the group to which they were originally assigned. The ITT approach is used in randomised controlled trials to analyse results that consider all subjects who were randomised and assigned to the particular group when the trial started, regardless of whether they

completed the intervention given to their group (Olivio et al., 2009). In this study all the 'current daily smokers', identified in the baseline survey, were included in the ITT analysis. For subjects who were unable to be contacted during the follow up time period were counted as failures (no reduction in smoking status). In all other cases the missing data were replaced by the last observed status. The multivariate log-binomial regression analysis was done to examine the independent effects of variables, while adjusting for possible confounding effects and risk ratio was obtained. In the analysis where log-binomial regression fails to converge, Poisson regression with robust error variance was used an alternative.

Generalised estimation analysis using PROC GENMOD, was used for cluster adjustment and to assess the quit rates. The data were analyzed using the SAS statistical software (version 8.1). A p-value of 0.05 was considered to be statistically significant.

In the study, the internal consistency of FTND scale was computed using Cronbach's alpha coefficient, which denotes how closely related were a set of items with the same ability or trait in the scale when considered as a group. Spearman's correlation was used to assess criterion validity of FTND scale in correlation with smoking initiation and number of years smoked since the measures were in ordinal scale. For test-retest reliability of FTND, Wilcoxon signed-rank test was used to understand whether the mean ranks differ.

# 6  RESULTS

Initially, a general description of the study population along with background characteristics is provided. Intervention and control groups with reference to predictor variables like age, socioeconomic status, type, duration and frequency of smoking, quit attempts before intervention and nicotine dependence status are compared. Further, validation of nicotine dependence scale, assessment of nicotine dependence based on predictor variables, smoking cessation intervention strategies and participation rates at different follow-up time, and finally overall quit rate and associated factors are presented.

## 6.1  Baseline survey characteristics (Paper 1)

### Participation rate: intervention vs control area

A total of 3304 subjects were interviewed through a house to house survey conducted in eleven clusters (ward) of the intervention (n=5) and control arms (n=6). Wards 1, 2, 3, 6 and 10 were in the intervention group and 4, 5, 7, 8 and 9 were in the control group. A total of 1525 subjects in the intervention area were interviewed on their tobacco habits through a house to house survey, while in the control area the corresponding number of subjects were 1779. The participants in each ward varied from 215 (cluster number 7) to 363 (cluster number 5). The highest proportion of subjects was in the 26–35 age group (26.5%), while the 55–60 year age group had the lowest proportion (10.1%). Age-wise distribution of subjects in each cluster of the intervention and control areas is given in table 3.

**Table 3.** Age distribution of subjects in the study arms: intervention vs control area

| Age group distribution of subjects | | | | | | | |
|---|---|---|---|---|---|---|---|
| Study areas | Ward | 18–25 (n=521) | 26–35 (n=877) | 36–45 (n=855) | 46–55 (n=717) | 55–60 (n=334) | Total N=3304 |
| Intervention | 1 | 44(14.4) | 83(27.2) | 73(23.9) | 66(21.6) | 39(12.8) | 305 |
| Intervention | 2 | 49(15.7) | 82(26.3) | 91(29.2) | 72(23.1) | 18(5.8) | 312 |
| Intervention | 3 | 51(15.9) | 86(26.9) | 95(29.7) | 68(21.3) | 20(6.3) | 320 |
| Control | 4 | 68(19.8) | 82(23.9) | 82(23.9) | 74(21.6) | 37(10.8) | 343 |
| Control | 5 | 61(16.8) | 109(30) | 84(23.1) | 87(24.0) | 22(6.1) | 363 |
| Intervention | 6 | 43(13.2) | 57(17.5) | 117(36.0) | 71(21.8) | 37(11.4) | 325 |
| Control | 7 | 20(9.3) | 57(26.5) | 57(26.5) | 49(22.8) | 32(14.9) | 215 |
| Control | 8 | 35(13.9) | 80(31.7) | 51(20.2) | 62(24.6) | 24(9.5) | 252 |
| Control | 9 | 59(17.2) | 88(25.7) | 72(21.0) | 67(19.5) | 57(16.6) | 343 |
| Intervention | 10 | 39(14.8) | 72(27.4) | 70(26.6) | 55(20.9) | 27(10.3) | 263 |
| Control | 11 | 52(19.8) | 81(30.8) | 63(24.0) | 46(17.5) | 21(8.0) | 263 |
| Total | | 521(15.8) | 877(26.5) | 855(25.9) | 717(21.7) | 334(10.1) | 3304 |

*Figures in parenthesis are row percentages

## Prevalence of tobacco and alcohol habits: intervention vs control areas

Information on tobacco and alcohol habits was collected from both the study groups. The overall prevalence of 'current users' of smoking and smokeless tobacco (daily and non-daily users) were 29.1% and 13.7% respectively. The overall prevalence of 'current daily smoking' was 28.1%. Over a quarter of subjects in the control area (26%) and 31% of subjects in the intervention area were current daily smokers. A total of 928 participants (474 subjects in the intervention and 454 subjects in control areas) were enrolled in the study, which included only 'current daily smokers'. No significant difference was observed between the two groups with reference to 'current daily smokers' (p= 0.92). However 'current daily smokeless tobacco' users were found to be more in the control area (11.3%) than in the intervention area (8.9%) (p<0.01). It was noted that the prevalence of 'current alcohol consumption' was higher among study subjects (30.3%) of which 20% of subjects in the intervention area and 17% in the control area were daily alcohol users (p=0.92) (Table 4).

**Table 4.** Prevalence of tobacco and alcohol habits by study arm

| Type of habit | Total<br>N= 3304 | Intervention<br>n = 1525 | Control<br>n = 1779 | p value |
|---|---|---|---|---|
| **Smoking**<br>Daily users<br>Occasional users | <br>928 (28.1%)<br>34 (1.00%) | <br>474(31.08%)<br>16 (1%) | <br>454 (26%)<br>18 (1%) | <br>0.92<br> |
| **Smokeless tobacco**<br>Daily users<br>Occasional users | <br>323 (9.8%)<br>129 (3.9%) | <br>121 (8.9%)<br>54 (3.5%) | <br>202 (11.3%)<br>75 (4.2%) | <br><0.01<br> |
| **Alcohol**<br>Daily users<br>Occasional users | <br>598 (18.1%)<br>403 (12.2%) | <br>301 (20%)<br>234 (15.3%) | <br>297 (17%)<br>169 (9.4%) | <br>0.92<br> |

## Age distribution of smokers and non-smokers in the study areas

Distribution of age and demographic characteristics among smokers and non-smokers are given below. The mean age of smokers and non-smokers were 45 years (SD: 10 years) and 37 years (SD: 12 years) respectively. The mean age of current daily smokers in the 18–60 year age group was 44.4 years (SD: 9.2 years). The proportion of daily smokers increased with age, which was more in the 36–55 year age group (62%) ($p < 0.01$). Compared to older age groups, the lowest smoking prevalence (3%) was reported in the 18–25 year age group (Figure 5).
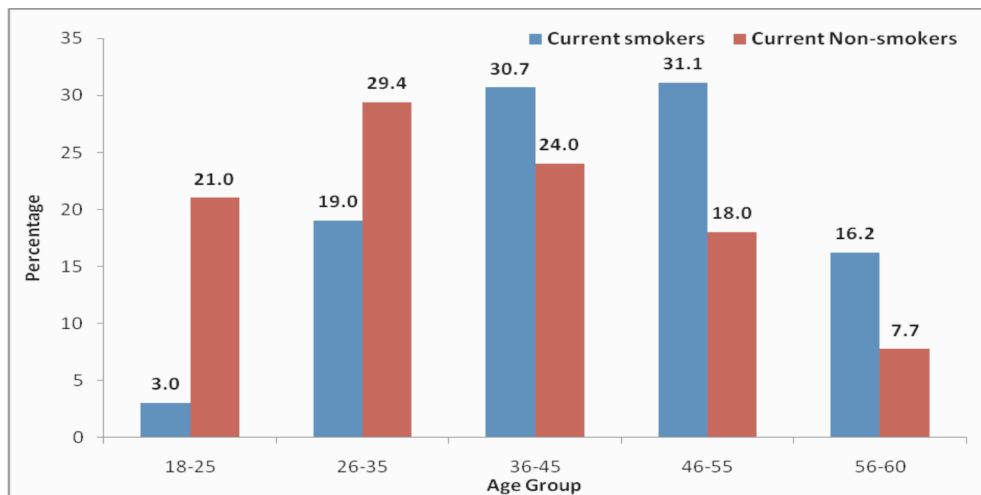


**Figure 5.** Age distribution: current smokers vs non smokers

## Smoking characteristics: intervention vs control group

Cigarette smoking was the most common smoking habit noticed among both groups, representing more than half of the smokers (58.08%). This was followed by users of both bidi and cigarette, who represented over a quarter of the smokers (28%), and bidi users alone who represented around 14%. Cigarette users constituted 53.8% and 62.5% in the intervention and control areas respectively. Among bidi users, 15.4% belonged to the intervention group, while 12.5% formed the control group. However, subjects who took both forms constituted 31% in the intervention and 25% in the control area (Paper1)

## Age and socio-demographic characteristics of smokers in the intervention and control groups

Among the 928 smokers identified, 474 subjects resided in the intervention area (mean age 44.56 years, SD 9.66 years) and 454 in the control area (mean age: 44.47 years, SD: 10.3 years). In both the study groups, smoking was lower in the 18–25 year age group, while the highest smoking prevalence was reported in the 36–55 year age group. The smoking status of participants based on the distribution of education, occupation and family income were more or less comparable in both study groups. It was reflected in the overall mean socioeconomic status score taken separately for intervention and control groups (10.5 and 10.2). Majority of smokers in the intervention and control areas were from the 'upper-lower' socioeconomic score group (64.1% and 57. 7%). There was no significant difference between the two groups with reference to age (p=0.13) and socioeconomic score (p= 0.11) (Table 5).

**Table 5.** Age and socio-demographic characteristics of smokers: intervention vs control group

| Factors | Control-area n=454 (%) | Intervention area n=474 (%) | Total N=928 (%) | p value |
|---|---|---|---|---|
| **Age Group** | | | | |
| <=25 years | 13 (2.86) | 13 (2.74) | 26 (2.80) | |
| 26–35 years | 98 (21.59) | 79 (16.67) | 177 (19.07) | |
| 36–45 years | 127 (27.97) | 158 (33.33) | 285 (30.71) | 0.13 |
| 46–55 years | 135 (29.74) | 154 (32.49) | 289 (31.14) | |
| > 55 years | 81 (17.84) | 70 (14.77) | 151 (16.27) | |
| **Socio-Economic Score** | | | | |
| Lower and Upper lower (<=10) | 262 (57.7) | 304 (64.1) | 566 (61) | |
| Lower Middle (11–15) | 157 (34.6) | 148 (31.2) | 305 (33) | |
| Upper Middle (16–25) | 33 (4.4) | 21 (4.4) | 54 (5.5) | 0.11 |
| Upper Income (26–29) | 2 (0.4) | 1 (0.2) | 3 (0.5) | |
| Mean (SD) | 10.53 (3.48) | 10.20 (2.65) | 10.36 (3.09) | |

Figures in parenthesis are column percentages

## Quit attempts and plan to quit within 6 months after intervention

When enquired about smoking quit attempts that lasted for at least 24 hours, 17% of the participants in the control area and 22% in the intervention area reported successful quit attempts within 6 months prior to the base line survey (table 6). No significant difference was observed in quit attempts between the two groups (p= 0.08). Among those who had attempted to quit, more than one third of participants attempted it without any reason. Social pressure and medical complications were the other two common reasons for quit attempts in both the groups, while awareness on health hazards was reported by 12.8% subjects in the control area and 14.5% in the intervention area. When asked about their plans to quit smoking within 6 months after the baseline survey, no significant difference was noted between the two groups. More than half of the smokers had not thought about quitting the habit within 6 months after the baseline survey. 58% of participants in the control area and 53.5% in the intervention area belonged to this group (p = 0.16)

**Table 6.** Previous quit attempts and plan to quit within 6 months

| Success in previous quit attempts | Control ) | Intervention | p-value for difference between groups |
|---|---|---|---|
| | N = 454 | N = 474 | |
| Successful quit attempts<br>Not successful quit attempts | 78 (17.1)<br>376 (82.8) | 103 (21.7)<br>371 (78.2) | 0.08 |
| **Plan to quit within 6 months** | N = 454 | N = 474 | |
| Plans to quit within 6 months<br>No plans to quit within 6 months | 190 (41.8)<br>264 (58) | 220 (46.4)<br>254 (53.5) | 0.16 |

* Figures in parenthesis are column percentages

## 6.2 Nicotine dependence of subjects (paper 2)

### FTND score and socio-demographic characteristics

The overall FTND score among current daily smokers was 5.06 (SD: 5.05). FTND scores in the control and intervention areas were 4.75 (SD: 2.57) and 5.33 (SD 6.6) respectively. The FTND score among current daily smokers (5.06) can be termed as moderate dependence (Paper 2). A linear relation was found between FTND score and age. Participants in the 56–60 year age group reported the highest FTND score (mean 5.32, SD 2.39), while the lowest score (mean 2.54, SD 2.30) was reported by participants in the 18–25 year age group. While correlating FTND scores with employment of the study subjects, the scores were found to be relatively similar among unemployed (mean 5.11, SD 2.78), unskilled (mean 5.11, SD 2.52), and semiskilled workers (mean 5.41, SD 2.38). In terms of education, an inverse relation was found between FTND score and increase in education. The scores were highest among illiterates (mean 6.41, SD 1.91) and primary school certificate holders (mean 5.87, SD 2.52), while graduates or those with higher degrees reported the lowest FTND score (Mean 2.92, SD 2.23). The average FTND score was highest among combined users (mean 6.10, SD 2.17) followed by bidi

alone (mean: 5.39, SD: 2.36) and cigarette alone (mean: 4.10, SD: 2.50). The mean FTND score was marginally higher among married men (mean 4.90, SD 2.52) than unmarried men (mean 4.12, SD 2.65).

Further analysis of the FTND scores in the control and intervention areas revealed that the scores were relatively similar in both the groups (Control area 4.75 (SD: 2.57) and Intervention area 5.33 (SD: 6.6)) respectively. Moderate to high nicotine dependence score (in the range of 5–7) was reported by 26.7% of subjects in the control area and 46% of subjects in the intervention area, where as around 15% of subjects in both the groups reported very high FTND scores ranging from 8–10. There was no significant difference in the baseline FTND scores between the intervention and the control groups (p= 0.83) (Table 7).

**Table 7.** Baseline nicotine dependence score: intervention vs control groups

| Baseline nicotine dependence score | Control group | Intervention group | p value |
|---|---|---|---|
| 0–2 (Very low) | 89 (18.8%) | 88 (18.6%) | |
| 3–4 (Low) | 119 (25.1%) | 97 (20.5%) | |
| 5 (Moderate) | 61 (2.9%) | 86 (18.1%) | 0.83 |
| 6–7 (High) | 113(23.8%) | 132(27.8%) | |
| 8–10 (Very High) | 72 (15.2%) | 71(15.0%) | |
| Total | 454 | 474 | |

## Time to smoke the first cigarette / bidi before and after intervention

The time to smoke the first cigarette/bidi after waking up in the morning is considered an important predictor for harm reduction and smoking cessation (Baker et al., 2007). At the beginning of the study, 44 subjects (9.3%) had smoked after 60 minutes of waking up in the intervention area while the corresponding figure was 50 (11%) in the non-intervention area. Post intervention assessment at the end of 12 months revealed that, more than a quarter of subjects (27.6%) in the intervention area delayed the habit by 60 minutes or more when compared to 15.4% in the control area. Pre and post intervention assessment of those who smoked within 5 minutes of waking up was 42.8% and 7.2% in the intervention group,

while the corresponding figures in the non-intervention group were 37.7% and 12.6% respectively. This points to the fact that within the group, the proportion of smokers decreased by 35.6% units in the intervention group and 25.1% in the control group. On the other hand, when the two groups were compared at the end of 12 months, the proportion of smokers who smoked within 5 minutes of waking up was relatively similar (7.2% in the intervention group and 12.6% in the control group) (table 8).

**Table 8.** Time to smoke the first cigarette/bidi before and after intervention

| Time | Control group | | Intervention group | |
|---|---|---|---|---|
| | At the baseline survey | After 12 months | At the baseline survey | After intervention |
| After 60 minutes | 50 (11) | 42 (9.2) | 44 (9.3) | 88 (18.6) |
| 31-60 minutes | 51(11.2) | 122(27) | 62(13.1) | 137 (28.9) |
| 6-30 minutes | 182 (40.1) | 163(35.9) | 163(34.4) | 119 (25.1) |
| Within 5 minutes | 171 (37.7) | 57(12.6) | 203 (42.8) | 34 (7.2) |
| Missing values | 0 | 70(15.4) | 2 (0.4) | 111 (23.3) |
| Total | 454 | | 474 | |

*Figures in parenthesis are column percentages

## Reliability and validity of FTND scale

To analyze the internal consistency of FTND scale, evaluation was conducted on 150 participants. Internal consistency of 0.70 was observed, which can be termed as moderate (Paper 2).

Test-retest reliability, which was assessed two months after conducting the baseline survey revealed an intra-class correlation coefficient (ICC) of 0.77 (95% CI: 0.67 to 0.84, p<0.001) for the FTND scale. There was no significant difference in scores for the two administrations of the FTND (p=0.59) (Paper 2). There was little association of the FTND score with age at start of smoking (rho = 0.187, p = 0.02). The association of the scale was strongest, with number of pack-years smoked (rho = 0.677, p < 0.01).

## 6.3     Participation rate of counselling at different time periods
### (Paper 3)

In the baseline survey, a total of 474 and 454 subjects in the intervention and control groups were contacted and their smoking status was obtained. All these subjects were given information, education and communication materials. A total of 5 camps were conducted at a time period of 2–4 weeks in 5 clusters. 75 subjects (16%) attended medical camp and received group counselling. As part of the further attempts to provide individual counselling to the remaining subjects (n=399) in the intervention area, 351 (88%) were contacted through face to face interview and 34 (8.5%) through mobile phone. Thus a total of 460 (97%) subjects received either group or individual counselling at a time period of 2–4 weeks. The total number of subjects contacted at various time periods in each cluster and the mode of communication are given in figure 6.
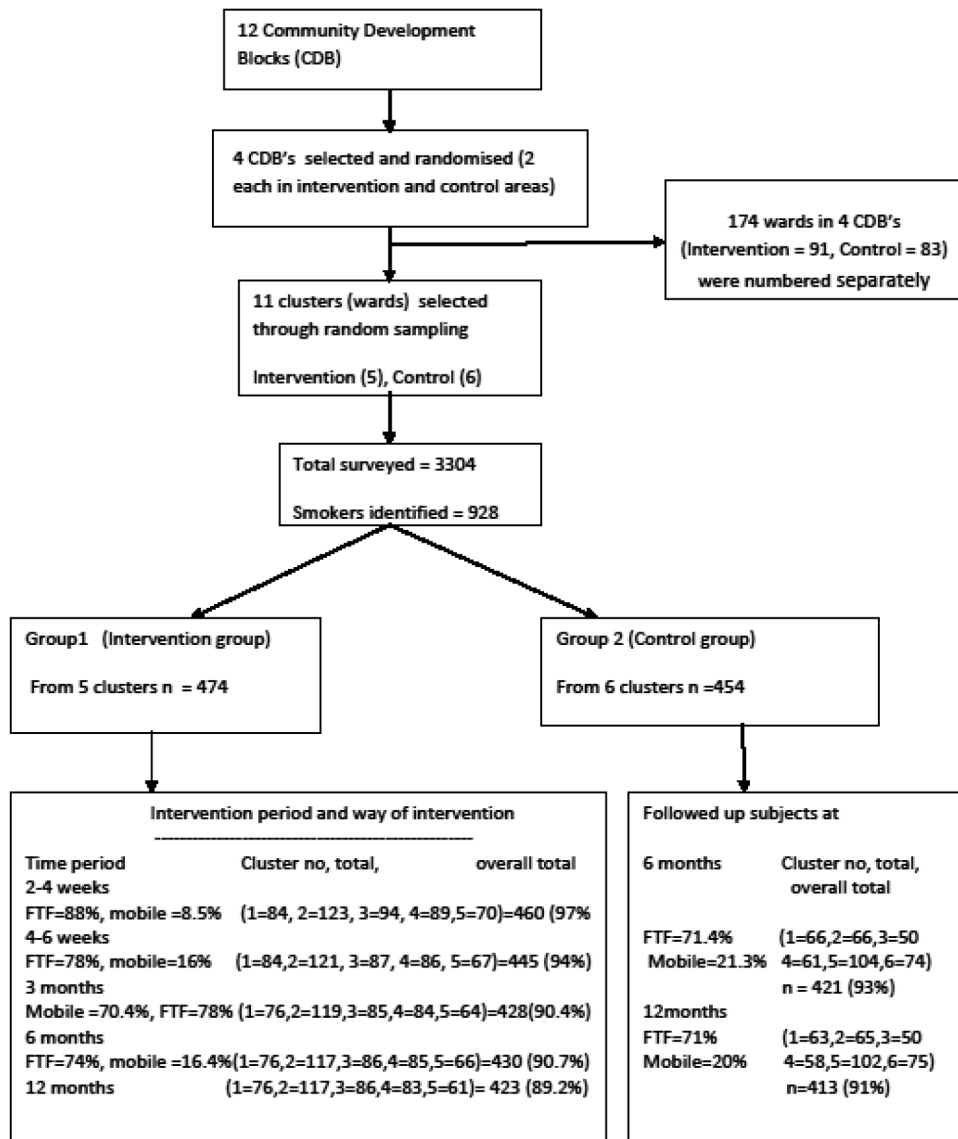
**Figure 6.** Participant enrolment to the study

## 6.4    Smoking quit rate at 12 months (paper 4)

### Quit outcomes at 6 and 12 months after the baseline survey

The outcome variables considered were quit rates and harm reduction rates at a time period of 6 months and 12 months. For adjustment of possible interactions and confounding factors, binomial regression analysis was performed to arrive at the final model. Independent variables considered were age, type of smoking, alcohol, smokeless tobacco use, doctor consultation for medical ailment/advice, quit attempts, plan to quit, number of sticks smoked daily and baseline nicotine dependence score. Self-reported point prevalence abstinence at 12-month follow up in the intervention and control areas were 14.7% and 6.6% respectively. The rate of quitting tobacco smoking at 12-months was nearly two fold 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 also higher in the intervention area (16%) as compared to control area (5.7%) (p =0.0001). At a time period of 6 months, the intervention group reported 2.6 times more quit rates when compared to the control group (RR 2.64, 95% CI: 1.45, 4.80).

### Quit rate and baseline nicotine dependence score

Nicotine dependence score was found to be an important predictor for smoking cessation. Table 9 describes the quit rate at month 12 with reference to the baseline nicotine dependence score of the study participants. A statistically significant association between very low nicotine dependence and smoking cessation was observed (p<0.01). The association between moderate level nicotine dependence and smoking cessation also showed significant results (p =0.01). However quit rates declined with high and very high nicotine dependence.

**Table 9.** Baseline nicotine dependence score and quit rate at 12 months

| Baseline nicotine dependence score | Quit | Group | | | |
|---|---|---|---|---|---|
| | | Control | Intervention | Total | P_value |
| 0–2 (Very low) | No<br>Yes<br>Total | 78 (87.8)<br>11(12.2)<br>89 (100) | 57 (64.2)<br>31(35.7)<br>88 (100) | 130 (75.2)<br>43(24.8)<br>173 (100) | 0.01 |
| 3–4 (Low) | No<br>Yes<br>Total | 106 (89.1)<br>13 (10.9)<br>119 (1000 | 81 (83.5)<br>16 (16.5)<br>97 (100) | 174 (85.7)<br>29(14.3)<br>203(100) | 0.32 |
| 5 (Moderate) | No<br>Yes<br>Total | 60 (98.3)<br>1 (1.7)<br>61 (100) | 75 (87.2)<br>11 (12.8)<br>86 (100) | 127(92)<br>11(8)<br>138(100) | 0.05 |
| 6–7 (High) | No<br>Yes<br>Total | 107 (94.6)<br>6 (5.4)<br>113 (100) | 120 (92.3)<br>10 (7.6)<br>130 (100) | 218(93.6)<br>16 (6.8)<br>234(100) | 0.60 |
| 8–10 (Very High) | No<br>Yes<br>Total | 72(100)<br>0<br>72 (100) | 69 (97.2)<br>2 (2.8)<br>71 (100) | 136 (98.6)<br>2 (1.4)<br>138(100) | 0.49 |

## Smoking cessation and influence of medical consultation

Medical consultation with/medical advice from a doctor was found to have a profound impact on the quit rate among subjects at a time period of 12 months. Among those who were contacted at least once during the 12 month follow up period, 63% of subjects in the intervention area and 44% of subjects in the control area had contacted a doctor for medical consultation. The findings revealed that among quitters in the intervention area, 65.7% had consulted a doctor during the study period. A similar quit rate was observed among study subjects in the control area also (64.5%) ($p = 0.02$). A positive correlation was found between smoking abstinence and doctor consultation for a medical ailment/medical advice (adjusted RR: 2.42, 95% CI: 1.50, 3.87) (paper 4). This reiterates the fact that higher chance of quitting was found among subjects who sought medical consultation from a doctor (Table 10).

**Table 10.** Doctor consultation for any ailment and quit rate at 12 months

| Doctor consultation | Intervention | Total quit in intervention area | Control | Total quit in control area | p value |
|---|---|---|---|---|---|
| Consulted<br>Not consulted | 291 (63)<br>171 (37) | 46 (65.7)<br>24 (34.3) | 187 (44.1)<br>237 (55.9) | 20 (64.5)<br>11 (35.5) | 0.02 |
| Total | *462 | 70 | * 424 | 31 | |

*Subjects in the intervention and control areas who were contacted at least once during the 12 month follow up period; Figures in parenthesis are column percentages.

## 6.5    Predictors of smoking cessation (Paper 4)

At 6 months after completing the base line survey, the quit outcome was 16% in the intervention area and 5.7% in the control area. It was observed that those who received behavioral intervention had nearly three fold chance of quitting when compared to the non intervention group (RR 2.64, 95% CI 1.45, 4.80). Significant predictors of smoking cessation were lesser number of cigarettes, smokeless tobacco, alcohol use and low nicotine dependence.

At 12 months, the significant predictors of a greater likelihood of short term quit included lower number of cigarettes, lower number of bidis, lower nicotine dependence score and medical consultation with a doctor (Paper 4). A significant association was found between the number of cigarettes/bidis used and the quit rate. It was shown that quit outcomes were more in the 'less than 6 cigarettes/bidis' group. Nicotine dependence 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). However, the strongest predictor for smoking cessation was consultation with a doctor for medical ailment/advice (RR. 2.42 (1.50–3.87) (Paper 4).

### Factors associated with quitting

The major factor that influenced subjects in the intervention and control groups to quit the habit was self interest (intervention area 28.5% and control area 24.2%). In the intervention area, medical problem was the second common factor to quit (24.2%) while advice from a doctor

influenced more subjects in the control area to quit smoking (22.5%). With reference to challenges to quit, craving and drowsiness were reported to be major challenges in quitting the habit. Over a third of the respondents in the intervention area reported 'craving' as the biggest challenge to quit (34.8%) followed by drowsiness (30.4%), while drowsiness was reported as the major factor in the control area (40%) followed by craving (23.3%). Among those who quit the habit, the mode of quitting was also assessed. More than 60% of subjects in the intervention and control areas reported quitting as a gradual process, while over a third of the respondents reported abrupt quitting (table 11).

**Table 11.** Factors associated with quitting: intervention vs control groups

| Factors associated with quitting | Intervention n=70 (%) | Control group n=31 (%) | Total (N=101) |
|---|---|---|---|
| Influencing factors to quit | | | |
| Self Interest | 20 (28.5) | 12 (38.7) | 32 (31.6) |
| Medical problems | 17 (24.2) | 5 (16.1) | 22 (21.7) |
| Advice from health worker | 15 (21.4) | 2 (6.4) | 17 (16.8) |
| Pressure within family | 10 (14.2) | 5 (16.1) | 15 (14.8) |
| Doctor advice | 8 (11.4) | 7 (22.5) | 15 (14.8) |
| Challenges to quit | | | |
| Craving | 24 (34.8) | 7 (23.3) | 31 (30.6) |
| Drowsiness | 21 (30.4) | 12 (40) | 33 (32.6) |
| Constipation | 13 (18.8) | 5 (16.7) | 18 (17.8) |
| Others | 11 (15.9) | 6 (20) | 17 (16.8) |
| Mode of quit | | | |
| Gradual | 48 (68.5) | 19 (61.3) | 67 (66.6) |
| Abrupt | 22 (31.5) | 12 (38.7) | 34 (33.6) |

## 6.6    Harm reduction status at 6 and 12 months follow-up period

Reduction of smoking by 50% or more when compared to the baseline survey was considered as a method for harm reduction adopted by the study subjects. At 6-month time period, more than three-fold reduction in smoking was observed in the intervention group when compared to the control group (RR 3.78, 95% CI 2.60, 5.50). At 12 month time-period, the corresponding reduction was two-fold in the intervention group (RR 2, 95% CI 1.72, 2.33) when compared to the non-intervention group (p value <0.0001).

## 6.7　Predictors of harm reduction at 6 and 12 months follow-up

The two common predictors of harm reduction at a time period of 6 months and 12 months were total socioeconomic score and the number of sticks used. At a time period of 12 months, in addition to this, time to smoke the first cigarette/bidi after 5 minutes of waking up (6–30 minutes and after 30 minutes) and occasional alcohol users were also found to be significant predictors of harm reduction. It was observed that the more a person delayed the habit of smoking after waking up, greater was the chance for him to reduce the habit by 50% or more. In the current study, more than two fold greater chances of harm reduction were found for a person who started smoking at 6–30 minutes or more when compared to those who smoked early (table 12).

**Table 12.** Predictors of harm reduction at 6 and 12 months

| At 6- month follow-up | | |
|---|---|---|
| **Predictors** | **Risk ratio** | **95% CI** |
| Total socio-economic score | 1.03 | 1.002, 1.07 |
| Number of sticks used | 1.01 | 1.003, 1.03 |
| **At 12-month follow-up** | | |
| **Variable** | **Risk ratio** | **95% CI** |
| total socio-economic score | 1.10 | 1.05, 1.15 |
| Occasional alcohol users | 1.33 | 1.09, 1.6 |
| Number of sticks used | 1.03 | 1.01, 1.04 |
| **Time to smoke the first stick** | | |
| 6–30 minutes | 2.01 | 1.01, 3.27 |
| 31–60 minutes | 2.34 | 1.13, 4.14 |

# adjusted for age, smoking duration and frequency, alcohol use, smokeless tobacco use, total socio-economic score, baseline nicotine dependency score and doctor consultation for medical ailment/advice.

# 7    DISCUSSION

The present thesis provided the results of a community based smoking cessation intervention trial for the rural population in Kerala (Papers III and 1V). The intervention trial was conducted in a span of one year after conducting the base line survey. Initially the study explored the prevalence of tobacco smoking in Thiruvananthapuram District, which was reported to be 28% and further compared the smoking status of subjects, in the intervention and control groups, based on age, socioeconomic status and nicotine dependence. To assess the nicotine dependence of smokers, the FTND scale was utilized. The overall nicotine dependence score was reported to be 5.04 (SD 5.05), which was considered to be moderate. When tested for its internal consistency, the FTND scale had moderate internal consistency (Cronbach's alpha coefficient 0.70) and the test-retest reliability was 0.77 (0.77 (95% CI: 0.67, 0.84). After completing the baseline survey, multiple intervention approaches were adopted in the intervention area for smoking cessation. The outcome evaluation to assess the effectiveness of the intervention was done 12 months after completing the baseline survey. When compared to the control areas, nearly two fold increase in quit outcomes was reported in the intervention areas (RR 1.85, 95% CI (1.05, 3.25). In this section, the study results are discussed in relation to existing literature from India, and also from other countries under the following sub-heads.

## 7.1    Problem identification

### Comparison of baseline characteristics (Intervention vs Control area)

In the initial phase of the study, 3304 subjects were interviewed through a house to house survey conducted in eleven clusters of the intervention (n=5) and control arms (n=6). The population size of the randomly

selected clusters was not uniform in the intervention and control areas. Cluster size was also not uniform in two clusters of the control area. Hence an additional cluster was chosen through random selection in the control area representing 6 clusters. Due to the variation in cluster and population size, significant difference was noted in the socioeconomic characteristics of the general population between the two groups. However, when homogeneity of smokers in the two groups were compared it was found that smokers in the two groups were comparable in terms of age, socioeconomic score, quit attempts, duration of smoking and nicotine dependence score.

## Prevalence of smoking among men in the 18–60 year age group

In the present study, the overall prevalence of 'current smokers' was 28.1% and the corresponding prevalence in the intervention and the control groups were 31% and 26% respectively (Paper 1). The GATS India (2010) reported 24.1% prevalence of daily use of tobacco among men in Kerala. The National Family Health Survey (NFHS 3), a population based household survey reported 35.8% prevalence of smoking among men in Kerala in 2005–2006 (IIPS and Macro International 2007). The prevalence of smoking in the current study was higher than the GAT study report but lower when compared to NFHS 3 report. The sample selection and the study areas selected might have affected the results. Since this study was conducted exclusively in the rural settings, it can be expected that the smoking prevalence would be more in the rural population. However it is possible that a lower smoking prevalence mentioned in the GATS India report was based on surveys conducted among mixed population (urban and rural).

The study reported low smoking prevalence in the younger age group when compared to the older age groups. A possible reason could be the improved awareness on tobacco hazards among youngsters through print, electronic and social media, while on the other hand, a house to house survey could result in under-reporting of smoking habits particularly among youngsters. A nationally representative cross sectional house-hold survey conducted in India also noted that the difference in the degree of agreement between individual self reports and house-hold informant

reports for tobacco use in the form of under reporting was higher for the younger age groups (Rani et al., 2003). However, the possibility of non-smokers taking up the smoking habit in the later stages has to be considered, which was a finding in the current study. A national survey on smoking behavior in Canada conducted in 2003, reported that one fifth of smokers initiated the habit after 18 years, where as an increase in the proportion and intensity of smoking was observed among those who had already started the habit (Hammond 2005).

## Smoking characteristics of study participants: a comparison of intervention vs control groups

Cigarette smoking was the most common smoking habit noticed in both groups, representing more than half of the smokers (58.08%), followed by users of both bidi and cigarette (28%) and bidi users alone (14%). In the current study, nearly three-fourth of the bidi smokers were in the lowest socio-economic category. A review article by Thankappan and Thresia (2007), also reported high bidi smoking among people from the lower socioeconomic strata in Kerala. In the present study, a major proportion of smokers in both the intervention and control groups were cigarette users, which is comparable with the findings of other studies (Ray and Gupta 2008), which also reported an increase in cigarette smoking in Kerala, Delhi and the North Eastern states of India.

The validated Kuppuswamy SES scale, which is being increasingly used for assessing the socioeconomic conditions in the Indian communities, was used for assessing the SES status in this study as well (Kumar et al., 2007). Though the scale is widely used for assessment of SES in the urban population, the scale was used in this study conducted in Kerala state due to the reason that the settlement pattern and occupational diversity are relatively homogenous in the urban and rural populations in Kerala, which is often referred to as a urban-rural continuum (Parayil 1996, Mridul 1999). While considering the overall socioeconomic pattern, majority of smokers belonged to the 'upper-lower SES group', while non-smokers were mostly from the 'upper-middle SES group'. The reasons for the high prevalence of smoking among the socially disadvantaged groups could be attributed to the lack of knowledge on tobacco hazards due to low

education, lack of social support for quitting, addiction and low motivation to quit as well as non-cooperation to behavioural and pharmacological therapy (Sansone et al., 2012, Hiscock et al., 2012).

When the socio-demographic characteristics of smokers in the two groups were compared, the overall socioeconomic score of the two groups were comparable without significant difference (p=0.11). Though the education pattern of the two groups were comparable, significant difference was found in the household income and occupation category (p<0.05). This difference also could have reflected in the smoking frequency of subjects in the two groups with a significant difference found in minimum (<10 sticks) and maximum number of cigarettes/bidis (>30) smoked. It is possible that social disparities of subjects in terms of wage pattern and occupation, coupled with managing stressful conditions, could have a bearing on the subjects, persuading them to smoke in moderation or more. The tendency of the low SES groups to adopt unhealthy practices like smoking despite the monetary and health care costs that are incurred, points to the difference in the social circumstance in which they live (Pampel et al., 2010).

## Nicotine dependence score among study participants

The overall FTND score among current daily smokers in the study was 5.04 (SD: 5.05), which could be termed as moderate dependence. No significant difference was observed between the two groups when FTND score was compared (p=0.83). The findings revealed that the FTND score increased with age and the results were found to be statistically significant (p<0.01) (paper 2). Similar to the study findings, a study conducted in a rural setting in India observed that the FTND score was directly proportional to age, with high scores among subjects above 40 years of age (Jadhav and Singh 2013). This positive association is an indication that the duration of habit and nicotine dependence are positively correlated. For smokers, the possibility of coping with stressful conditions will be more difficult as a result of ageing that could have resulted in an increased nicotine dependence when compared to the younger age groups. In the present study, higher literacy and occupation were inversely related to nicotine dependence. It was observed that a strong

socioeconomic gradient is associated with tobacco use, which had its reflection on the nicotine dependency status. Similar to the present study finding, the results of a study conducted among psychiatric patients in South India also reported higher nicotine dependence among older and less educated patients, whereas no association was found between nicotine dependence and the specific disease studied (Chandra et al., 2005).

The FTND score was comparatively lower in the present study even though the age group selected for the study ranged from 18 to 60 years. Another study conducted among the tribal population of Kerala in the district of Palakkad also reported a moderate FTND score of 5 (Jayakrishnan et al., 2005). Change in attitude towards smoking within the family and society, along with improvement in personal knowledge on the health hazards of tobacco, could have influenced smokers to smoke in a way, which they might have perceived to be less harmful. The duration of smoking has a linear effect on smoking dependence which was reflected in high FTND score as ageing progressed. Similar findings were reported by Wu et al., (2011), in a study conducted among the migrant population in China.

In the present study, the FTND score was high for both forms of tobacco. When each smoking habit was analysed separately, the 'bidi alone' users had high FTND score in contrast to the moderate FTND score in cigarette users. The nicotine dependence potential of bidi could be due to the high nicotine content it has (37.70 milligrams of nicotine per gram) when compared to cigarettes, which has less than a half of it (16.54 milligrams per gram). This could probably be the reason for the wide use of bidi smoking in India (Pakhela and Maru 1998, Reddy et al., 2008).

The FTND score was found to have moderate internal consistency (Cronbach's alpha coefficient 0.70). Moderate internal consistency for FTND was reported by other studies as well (Yee et al., 2011, Wu et al., 2011). The psychometric qualities of FTND are satisfactory when compared to the earlier Fagerstrom Tolerance Questionnaire that might have resulted in the greater internal consistency of FTND.

The test-retest reliability of the scale was moderate with an intra-class correlation coefficient of 0.77. The test-retest reliability was assessed two months after completing the first version. Though it was reasonably good, higher test-retest reliability could have been achieved if the test was

repeated in a short interval after completing the first one. In the United States, few studies that assessed the test- retest reliability of FTND among subjects with Psychiatric disorders showed varying results between two evaluations. The study, which reapplied FTND after one week showed higher test-retest reliability (Buckley et al., 2005). On the other hand, another study when repeated FTND at three weeks interval showed satisfactory results. However, it did not present the correlation coefficient (Pomerleau et al., 1994). Hence it is possible that the time lag between evaluations could hinder comparisons of the results.

Within the 6 item FTND scale, a substantial inter-observer agreement was found for the items 'do you smoke smoke if ill' (Kappa statistic 0,752, SD 0.089) and 'morning smoking' (Kappa statistic 0.661, SD 0.079), while the remaining 4 items had moderate agreement. While the FTND questionnaire was translated to the local language, it was essential to suit the wordings in the local language for easy understanding among study subjects (Paper 2). Hence, all the items in the scale were rephrased to match the original version in English. All these factors could have led to the moderate results when test-retest reliability was analysed.


## 7.2    Process evaluation (Paper 3)

The process evaluation of the study was developed after discussions on the magnitude of the problem and the need for the development of appropriate strategies for intervention with the local stakeholders and community volunteers. The feasibility of using multiple approaches to deliver health education messages and counselling against smoking cessation were envisaged. To provide a context for the interpretation of the study findings, it is important to organize the programme in a contextual framework. An ideal framework to understand the change in behaviour would have the 'individual' at the hub of the framework, with a whole range of life style factors encircling it, which in turn is surrounded by the entire socio-economic and cultural factors of the community. The commonly used psychological models include the Health belief model (Kim et al., 2012), the Trans-theoretical model (Prochaska and Velicer 1997), Social Learning Theory (Grusec 1992) and the Behaviour Change Wheel model (Michie et al., 2011). The National Institute for Health and

Clinical Excellence (NICE) guidance for behaviour change at population, community and individual levels observed that the most effective measures for intervening in behaviour change is to intervene at many levels simultaneously and systematically (National Institute for Health and Clinical Excellence 2007).

The current study model was developed on the basis of the 'behaviour change wheel' model, which explored the psycho-social dynamics of behavior change at three levels namely the sources of behavior, intervention functions and policy categories (Michie et al., 2011). In order to recognize and enhance the person's ability to change the behavior for cessation of smoking, 'capability' and 'motivation' of the individual were assessed during the baseline survey. For assessing the 'capability' of a person to change his behaviour, the quit attempts of a person before 6 months of conducting the baseline survey were assessed. To judge the level of motivation of a person to change his behaviour, the intention to quit the habit within a period of 6 months after the baseline survey was evaluated. It was reported that the self-belief of a person coupled with one's ability to abstain from smoking was found to be effective in smoking cessation outcomes and also in preventing relapse (Ockene et al., 2000, Gwaltney et al., 2001).

## Multiple approaches at different time periods in the intervention areas

### The need for multiple approaches

A chronic condition like tobacco smoking needs intervention at regular intervals, which is also the case for a smoker who tries multiple quit attempts to quit the habit (Fiore et al., 2009). Hence, it is important to retain study subjects for a longer period, which eventually would help to understand the factors associated with continuing smoking and relapse. Studies had reported that intensive interventions work more than less, intensive ones leading to better outcomes (Nohlert et al., 2013, Murthy and Saddichha 2010). However the effectiveness of intensive intervention programmes and the extent to which subjects have to be retained for follow-up remains uncertain.

It was reported that combinations of interventions are far more effective than a single approach for persons who attempt to quit smoking (Galanti 2008). An important task in this smoking cessation trial was to increase the quit rate among study subjects in the intervention area. To fulfill this objective, 4 different approaches were planned for smoking cessation intervention. This included (a) distribution of IEC materials to study participants (b) personal invitation letters along with antitobacco message by the Principal Investigator (RJ) to the study subjects for attending medical camp cum group counseling and for sensitizing key personals in the locality about the intervention (c) conduct of medical camps cum counseling and (d) individual counseling at four time points, which include time periods of 2–4 weeks, 4–6 weeks, 3 months and 6 months. The study was planned to retain the subjects in the intervention area as much as possible so that the chances of making a change in the smoking pattern from the category of "no improvement" to "improvement" category could be envisaged.

## Response from healthcare providers and community volunteers to the medical camps

20 key personnel including community workers, primary care health workers, medical doctor and a local politician (ward member) of each cluster were invited to the camps in the intervention area and were explained the importance of the camp and group counselling. Primary care health workers formed the first level of contact between the community and health services facilities in the locality. Primary care health workers attached to health centres are engaged mainly in primary prevention activities where thrust was given for disseminating health education on risk factors of communicable and non-communicable diseases. Hence, health workers in the primary care settings are in a position to identify and intervene with patients as well as healthy individuals, to give advice on health risk behaviours, while the community workers are mainly from the community itself who can also influence people in the community and can advocate for community rights. On the other hand, the chance for interaction for doctors is more in clinical settings alone. Simple advice on the part of a medical professional

had the potential to increase the quit rate up to 3% (Stead et al., 2013). Out of the 20 invited, 15 responded by participating in the camps.

## Compliance to camps and group counseling sessions by subjects in the intervention area

Repeated interventions are required for successful tobacco abstinence due to the fact that tobacco dependence is a chronic condition (Anderson et al., 2002). When compared to unassisted simple advice, brief advice in the form of minimal intervention is expected to produce successful quit rates with some more benefits reported on even more intensive interventions (Stead et al., 2013).

The group counselling cum medical camps were conducted in all the 5 clusters of the intervention area. In addition to this, a documentary film was also displayed, which included messages from two celebrities and confessions of two patients affected with tobacco related cancers, who were treated at the RCC. However, the response was poor for group counseling, which constituted only 16% of the total subjects in the intervention area. Change in social attitudes towards smoking, due to enhanced knowledge on tobacco hazards, strengthening of tobacco control policies and the belief that smoking is no longer an acceptable practice in the society, might have resulted in the poor acceptance to group counselling (Graham 2012, Stuber et al., 2008)**.** Disparities in health seeking behaviour are generally high among the lower SES group, which could be another reason for the lower participation in group counselling sessions. Excluding 3% of the study subjects, the rest of the subjects in the intervention area were provided individual counselling through FTF and mobile phones within a period 2–4 weeks after the baseline survey.

## Approaches and responses for individual counselling methods

In the subsequent sessions, a proactive approach was adopted and the subjects were interviewed through FTF or by mobile phone. In all the follow-up sessions, majority of the subjects (90%) were contacted through FTF or mobile phone. Medical social workers, who were trained on tobacco cessation programme conducted FTF and mobile phone

counselling and thus they could deliver the message on tobacco hazards and offer quitting tips. The technical expertise on the subject and experience in counselling added to the credibility of social workers to conduct follow up counselling in the intervention area. This study has revealed that non-doctor health professionals like medical social workers could be utilised effectively for smoking cessation. A study conducted by Thankappan et al among diabetic patients in Kerala had also found that non-doctor health professionals would be useful to assist patients understand the benefits of quitting, asses the road blocks of quitting and plan the quitting process of patients accordingly (Thankappan et al., 2013).

Proactive counselling using multiple modes like FTF and mobile phone were found to be effective in increasing the participation rate in this study. The current study being conducted in a rural community setting looked upon the possibility of using mobile phones during follow-up sessions, either as an alternative to FTF in case of loss of follow up during house visits or as the prime mode for counselling during the 3 months-time period. Mobile phone services were utilised for patient's follow-up in tobacco cessation clinics (Kumar et al., 2007), To our knowledge, the current study is the first of its kind in India to utilize mobile phone as a mode for delivering proactive counselling for smoking cessation in the community. A meta analysis of 51 randomised or quazi randomised controlled trials reported that proactive counselling increased quit outcomes in intervention group as compared to the control group where a dose response relationship between number of telephone calls and quitting was observed (Stead et al., 2013). Overall 97.4% subjects in the intervention group were contacted at least once during the follow-up period through FTF or mobile phone while in the control area 93.3% subjects were contacted in the same manner during the follow-up period of 6 and 12 months.

In the control group, assessment of smoking status was done at a time period of 6 months and 12 months, like in the intervention area. The purpose was to correlate the smoking status in the both the groups during the interim phase of the study and to understand how it would reflect when the results were analysed after 12 months.

## 7.3    Outcome evaluation

### Smoking abstinence at 12 months

The overall prevalence in smoking abstinence at 12 months after the baseline survey was 14.7% in the intervention and 6.8% in the control group, with a 2-fold risk ratio of quitting the habit in the intervention group. The study results were analysed based on the ITT approach for which the final analysis has to be done for all the subjects recruited in the study. In the current study, though all the participants recruited for the study were not followed up till the end of the study, the drop outs in both intervention and control groups were minimal. During the study period, 97.4% of subjects in the intervention group and 93.3% in the control group were contacted at least once after completing the baseline survey. During the final outcome evaluation at 12 months, around 90% of subjects in both groups were contacted. It has been reported that when the drop outs in the study exceeded 30% and more the power of the study would be affected and can lead to biased estimates (Wright and Sim 2003). However, in the current study the drop out in both the groups were nearly 10%, which ensured an unbiased estimate. The results indicate that multipronged strategies for smoking cessation were more likely to result in better quit outcomes. Rigorous approaches used for smoking cessation intervention could be a factor for reasonable quit rates in the present study. It was reported that the success rate of self initiated quitting after one year ranges between 3% to 5%, while behavioural intervention could increase quit outcomes in the range of 7% to 16% and further up to 24% when combined with medical support (Laniado-Laborín 2010). The one-to-one interaction between the study participants and medical social workers, complimented with interaction between health workers who live in the same locality and the study participants, might have contributed positively to the smoking abstinence. In addition to this, spearheading of anti-tobacco campaigns by various organisations (governmental and non-governmental) in Kerala and strengthening of COTPA 2003 with its

subsequent amendments also could have had an additional effect on the study hypothesis.

The effectiveness of individual behavioural counselling for smoking cessation given outside routine clinical settings by counsellors or health educators was already reported in the Cochrane review (Lancaster and Stead 2005). The guideline panel on treatment of tobacco use and dependence by the U.S Department of Health and Human Services reported that the intensity of counselling was one of the key factors related to smoking abstinence (Fiore et al., 2000). Group counselling along with 4 rounds of counselling sessions on a one-to-one basis might have resulted in better quit rates in the current study. Moreover, motivational counselling was done for subjects in the second and fourth rounds using the 5 R's approach. All these factors could have contributed positively for better quit outcomes in the intervention area. From the Indian context, studies conducted in Tamil Nadu and Mumbai also reported quit outcomes, which are comparable to the present study results. While in Tamil Nadu, group counselling sessions conducted by a medical professional reported 12.5% smoking abstinence in the intervention group, 2 months after intervention, in Mumbai, a worksite intervention programme with multiple approaches for tobacco cessation reported 17% quit outcomes after three rounds of intervention (Kumar et al., 2012, Pimple et al., 2012).

A school based intervention programme targeting teachers conducted in the state of Bihar had also demonstrated the impact of intervention in tobacco cessation programmes. The study observed a 50% quit rate in the intervention area immediately after intervention, while the corresponding figures for the control area was 15%. Post intervention survey done at a time period of 9 months showed a quit rate of 19% in the intervention area and 7% in the control area (Sorensen et al., 2013). In the current study, smoking abstinence rate at a time period of 6 months was also higher in the intervention area (16%) compared to control area (5.7%) (p<0.01).

## 7.4    Predictors of smoking cessation (Paper 4)

In the present study the predictors of smoking cessation at a time period of 12 months were lower nicotine dependence score, lesser number of cigarettes/bidis used and medical consultation with a doctor.

It was observed that the chance of quitting was more among those who had less dependence to nicotine. This relationship was found to be true even when other variables were controlled. In the intervention group, over a third of the subjects in the "very low" nicotine dependent category had quit the habit while in the control group it was 12.4%. In both the groups, the proportion of quitters was more in this category. There is conclusive evidence that higher level of nicotine addiction is associated with difficulty in quitting. Enhancing strategies for readiness to change would have increased the self efficacy of smokers (Warnecke et al., 2001) particularly among the less nicotine dependent group for smoking cessation. For smokers with low nicotine dependence, who were unable to quit the habit, enhancing self efficacy along with social support could have motivated smokers to quit the habit. For smokers who did not intend to quit (FTND score >4), behavior intervention alone cannot achieve the desired results but requires a combined approach including pharmacotherapy. Higher FTND score indicates an individual's intense dependence to nicotine, which necessitates a multipronged strategy that combines both pharmacological and non-pharmacological interventions for overcoming dependence to nicotine (Jhanjee et al., 2009). Similar to our study findings, a study conducted in West Bengal in India also reported that subjects with high FTND scores were 1.83 times more unintended to quit the habit compared to their counterparts with low FTND scores (Islam et al., 2014). High smoking abstinence among subjects with less nicotine dependence was also reported by other studies (Hymowitz et al., 1997, Ferguson et al., 2003, Hyland et al., 2004).

It has been documented that smoking abstinence was better achieved without medication when a person smokes <=10 cigarettes a day. The results of the present study showed that the chance of quitting was significantly higher among those who smoked 10 sticks or less per day

compared to those who smoked more. Counselling increased the chance of quitting among those who smoked up to 10 cigarette/bidi daily, which was 1.1 times (95% CI: 1.01–1.20) more than those who did not receive counseling.

In the present study, the quit rates were high among smokers with very low nicotine dependence. However, for heavy smokers who were highly dependent on nicotine (score >5) behavior intervention alone cannot achieve the desired results but requires a combine approach including pharmacological therapy. The Community Intervention Trial for smoking cessation (COMMIT) demonstrated high odds of quitting among light smokers (<25 cigarettes/day) in the intervention area compared to the control area (OR 1.7, p<0.05). The reason for high abstinence in these studies also reflect on other factors implemented in the community such as aggressive programmes for tobacco control including media campaigns, increased taxes on tobacco products and a strengthened legislation (Hyland et al., 2006). This also reiterates the fact that a multidimensional approach to tobacco control can increase quit rates from smoking. However, efforts to strengthen these approaches have not become fully functional in a developing country like India and hence cannot achieve better results.

An equally interesting observation in our study was that better quit rates could be achieved when a doctor advised his/her patients to quit the habit. It was assumed that though subjects might be aware of the general health hazards of smoking, an awareness regarding the extent to which these hazards could impact their lives may not be found among study subjects in general. Hence, a simple advice from the doctor to quit the habit, supplemented with further explanations from the medical social worker could positively influence quit behavior. It could also be possible that the subjects in the intervention area were motivated to seek additional support from the doctor based on counseling and quitting tips they received from the medical social workers. The physician's advice could be more influential in a context where smokers have not heard the message to quit on numerous occasions. This study reiterates the fact that conscious efforts by doctors and other health professionals to encourage quitting during each patient visit could be useful in accomplishing better smoking abstinence rates. Few studies on tobacco cessation were conducted in clinical settings in Kerala. Combined intervention measures

like physician advice and non-medical health provider counseling reported nearly a quarter of tobacco abstinence at a time period of 6 weeks in a study conducted in the northern district of Palakkad in Kerala (Pradeepkumar 2009). Another study conducted among diabetic patients reported more than 50% smoking abstinence after 6 months follow-up for combined intervention offered by a non-doctor health provider and a doctor (Thankappan et al., 2013). On medical grounds, it is possible that strong and personalized advice offered by the physician could have influenced subjects to quit tobacco. Familiarity with the physician and the value attached to their advice by the rural community could also be reasons, which ensured such high quit rates. However an argument that can arise in this context is if smokers really need to acquire a disease to visit clinics and thereby initiate smoking cessation. Most often it was observed that older smokers would turn to clinics more frequently than their younger counterparts due to the fact that smoking related disease burden is more common among the former group. However, it is argued that a smoking intervention programme should improve health and prevent or minimize ill health as a consequence of smoking (Aveyard and Raw, 2012). In this scenario, priority should be given to community cessation programmes so that quitters will benefit from a life with minimal disease or free from smoking induced diseases.

The analysis explored the association between SES and quit rates. In the bivariate analysis, high quit rates were achieved among subjects in the lower and 'upper-lower' category, whereas no significant association was found with participants with higher socioeconomic status. However in the regression analysis, this association was not found to be statistically significant. Socio-demographic characteristics, a combination of education, occupation and income, may have a greater impact on smoking cessation program in the general population. Higher education, higher income and better jobs were found to be the successful predictors of quitting smoking in the published literature (Loon et al., 2005, Fernandez et al., 2001). Lack of sufficient representation in higher categories of education, economic status and less number of participants with better jobs may be the reasons for the absence of predictive power of these variables in the present study.

## 7.5    Harm reduction status at 12 months follow up

At 12 months after completing the baseline survey, a two-fold reduction in smoking was observed in the intervention group when compared to the control group. While it was observed that less number of cigarettes/bidis was associated with more quit outcomes, harm reduction strategies were found more successful for those who reported smoking heavily (more than or equal to10 cigarettes) during the time of baseline survey as compared to 'less smokers'. It is possible that those who smoked less might have perceived that smoking fewer sticks may not pose a health hazard for them. While on the other hand, heavy smokers who received intervention might have observed that smoking hazards could be reduced if reduction in the frequency of smoking is attained, if at all they could not completely quit the habit. Even though a person was unable to quit the habit but was in a position to reduce the frequency of smoking, it could have a positive impact on the person's health. Studies have shown that reduction in smoking by 50% or more could decrease the mortality associated with smoking. In addition to this, the perception that smoking is harmful could facilitate subsequent thinking on smoking cessation though they were unable to quit smoking at present (Hughes 2000). At a time period of 12 months, the predictors of harm reduction were total socio-economic score, number of sticks used, occasional alcohol users and time to smoke the first stick after waking up. The important predictive factor was the time to smoke the first stick (within 6-30 minutes and more than 30 minutes). Delaying the habit to the maximum possible extent is a strategy, which cannot be easily carried out by smokers with moderate to high nicotine dependence. In the present study, intervention was effective in delaying the habit among those who reported smoking within 6 to 30 minutes and more after waking up. Intervention programmes for smoking cessation even at the cost of less quit outcomes could be successful if it can increase harm reduction rates by lowering the nicotine dependence of individuals. Reports have shown that the predictive validity of the first item of FTND scale (time to smoke the first cigarette in the morning) is higher than the other items in the scale and is

considered as an effective item to assess the nicotine dependence (Giovino et al., 2007).

The socioeconomic status of the individual also played a major role in reducing smoking at a level of 50% or more, in the present study. Significant harm reduction was observed among subjects with high total socioeconomic score. It is possible that quit attempt could occur more among those with better education, occupation and income, which were reflected in a person's overall total socioeconomic score. Low intention to quit was reported from studies conducted in the Indian and South Asian context where smokers in the lower socioeconomic strata had less or no intention to quit the habit (Panda et al., 2014, Yong et al., 2005, Li et al., 2010)

Another interesting finding in this study was occasional alcohol consumption emerging as a predictor for harm reduction. Smoking cessation was reported among persons with remission in alcohol dependence and other substance abuse (Kalman et al., 2010). While studying alcohol related outcomes, it was reported that continuing smoking may trigger a relapse of the alcohol habit. However in the treatment of alcohol use disorders, smoking cessation may enhance alcohol abstinence if smoking cessation was also included as part of the treatment regime (Friend and Pagano 2005). In the present study, occasional alcohol users had not increased their alcohol consumption, which possibly could be attributed to smoking cessation intervention being partially effective in controlling triggers from alcohol consumption.

For interpretation of harm reduction in the present study, the average number of cigarettes/bidis a person smoked at the beginning of the study and later at the end of the study were compared. It is difficult to quantify the response of the subjects on how many cigarettes/bidis they had reduced, given the possibility that it might be subjective since it is mainly related to a person's attitude during the time of interview. In the present study multiple modes of intervention might have influenced the study subjects in reducing the number of cigarettes/bidis. Apart from this, medical professionals of the respective health centres in each cluster were sensitised on the study intentions, which also could have played a major role.

## Limitations of the study

The clusters selected for the study were few in number, which might have limited the balancing effect of random allocation. The population size of the randomly selected clusters was not uniform in the intervention and control areas. Two clusters of the control area had less population when compared to other clusters. Hence an additional cluster was chosen through random selection in the control area, thus representing a total of 6 clusters. This has resulted in a difference in the socioeconomic structure of the selected general population.

The study was restricted to male smokers due to the reason that smoking was a predominant problem among the males in Kerala. While females were excluded from the study because smokeless tobacco was the only form of tobacco use among them in Kerala (IIPS 2010), which needs to be studied as a separate entity altogether.

Another 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.

Measurements of self-efficacy of the subjects were not done during follow-up sessions, which could have been useful to increase the quit rates.

In this study, the tobacco dependence was measured only in terms of the physiological domain, i.e. nicotine dependence. However, though tobacco dependence is a multifactoral phenomenon, this study has not focussed on the other domains of tobacco dependence such as social and psychological domains, which could have been of great use in understanding the psycho-social dynamics of tobacco dependence.

The health care providers working in the government health sector of the respective intervention areas were sensitised of the study motives and intervention. However, the study did not collect relevant details from subjects on whether they received advice from the concerned doctor, which could have been useful to understand the doctor's response to the study initiatives.

# 8   SUMMARY AND CONCLUSION

The prevalence of smoking among males in Kerala, India, is reported to be higher than the national average and this has led to an increased burden of tobacco associated diseases. In an attempt to curb this burden, there has been an augmentation of tobacco control activities in the state. However, most of these activities are confined to the urban areas of the state. Hence there is an urgent need to strengthen tobacco control in the rural areas of the state where tobacco consumption is high. Therefore this study was carried out to address the magnitude of smoking in the rural community of Kerala and also to draw conclusions on the effectiveness of community based smoking cessation intervention based on a proactive approach.

The study observed that the prevalence of smoking in the rural areas of the state was high, particularly among the lower socioeconomic community. The overall nicotine dependence status was found to be moderate, which denoted that multiple approaches were required to strengthen tobacco control in the rural community. The study utilised proactive community based intervention, which was found to be useful to retain subjects in the study for follow up and intervention.

The major objective of the study was to determine the effectiveness of smoking cessation intervention programme. The study outcome revealed that smoking cessation intervention utilizing multiple methods can enhance quit rates in smoking in the rural areas. The study demonstrated that proactive intervention programmes utilising trained health workers filled the gap between anti-tobacco awareness generation and cessation clinic services in a community. Moreover, the study has provided an ideal platform for researchers to take up suitable models for implementation in the rural areas of other states in the country.

## Recommendations

This study conducted in a rural community in the state of Kerala has important public health implications. Very few studies have been conducted in India that have attempted to determine the effectiveness of a multi component proactive smoking cessation intervention programme on a rural community setting. The study results were encouraging and have revealed that smoking cessation programmes can be successfully implemented in the community using multiple approaches. While a wide network of health programmes are being conducted in the rural areas of India, particularly under the National Health Mission of the Government of India and non-governmental organisations, the findings of the study evoke wide possibility for integration of tobacco cessation activities into the health programs.

Although the study was done in the Thiruvananthapuram district of Kerala, it was assumed that a wide variation in tobacco use patterns do not exist in other districts of the state. The state of Kerala has a well-knit primary health institution network in the rural settings, which are mostly utilized by the poorer sections of the society. Training of medical officers and paramedical health workers in tobacco cessation intervention and encouraging them to conduct smoking cessation intervention programmes will be useful to counter the tobacco menace in the rural community.

Counselling in the form of doctor advice and non-doctor counselling can be effectively utilised for smoking cessation activities. The study design was made in such a way that door to door counselling was given preference. However, the framework of the primary health system encompasses field work activities for health workers of the primary health care centres that necessitate them to visit every household in the primary health centre jurisdiction at least once in two months. While the health workers conduct house visits, smoking status assessment of the household coupled with simple advice would be helpful to encourage tobacco habitués to quit their habit. Since tobacco use prevalence is more among the poorer sections of the society, training of health workers on tobacco cessation and further training of community volunteers by these health

workers in their respective communities can also be considered for tobacco cessation.

Hence integrating tobacco cessation activities into the already existing public health programmes will not only be cost effective but the follow up of these activities could be efficiently conducted without additional human resources as well.

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# 11 APPENDIX



**Figure 7.** Leaflet distributed in the study areas for smoking cessation

Source: Regional Cancer Centre, Thiruvananthapuram

**Figure 8.** Tobacco cessation booklet in Malayalam language distributed in the intervention area

Source: Regional Cancer Centre, Thiruvananthapuram

Cancers Of The Oral Cavity

Cancer of the Cheek in a Panmasala user

Tongue Cancer due to Smoking and Alcohol Consumption



Oral precancers - Leukoplakia, Erythroplakia
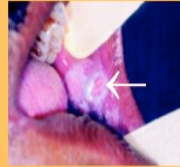
Stage before Cancer Formation

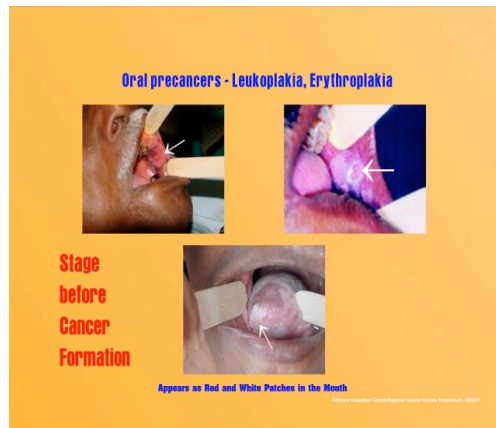Appears as Red and White Patches in the Mouth

**Figure 9.** Information, Education and Communication Materials used for smoking cessation

Source: Regional Cancer Centre, Thiruvananthapuram

# 12 Original publications

# RESEARCH COMMUNICATION

# A Community Based Smoking Cessation Intervention Trial for Rural Kerala, India

## R Jayakrishnan[1*], Aleyamma Mathew[1], Antti Uutela[2], Patrik Finne[3]

## Abstract

    **Objectives**: An attempt was made to compare tobacco prevalence and socioeconomic factors of two groups (intervention and control) from a selected rural community in Thiruvananthapuram, Kerala, India. **Methods**: Data were collected from resident males in the age group of 18.0 to 60.0 years from 4 randomly allocated Community Development Blocks of rural Thiruvananthapuram district (2 intervention & control groups). Trained Accredited Social Health Activists workers were utilised to collect data from both the groups through a face to face interview. **Results**: Among 3304 subjects were interviewed, the overall prevalence of smokers was 28% (n=928) (mean age=44.4 years, SD=9.2 years). Socio-economic status (SES) score points indicated that majority of smokers belonged to the upper lower SES category (61%) (mean SES score =10, SD= 3) and among non-smokers, the participants mainly belonged to the lower middle SES score (45%) (mean SES score =12, SD= 3) (p-value=0.0001). Among the 928 smokers, 474 subjects were in the intervention area (mean age =44.56 years, SD =9.66 years) and 454 in the control area (mean age= 44.47 years, SD =10.30 years). No significant difference was found between the intervention and control groups according to age (p=0.89) and SES (p=0.11). Majority of smokers in the intervention and control areas were from the upper lower SES group (64.14% and 57.17%). **Conclusion**: Smoking continues to be a predominant public health problem among males in rural Kerala particularly among lower socio-economic population. Apart from strengthening legislation, multiple cost effective intervention approaches are required to reduce tobacco consumption in the community.

**Keywords**: Prevalence - smoking - socioeconomic status - rural - Kerala

## Introduction

India is the second largest consumer of tobacco products in the world in spite of the advances in public health campaigns complemented with tobacco control laws. Nearly 900, 000 people die every year in India due to diseases attributed to tobacco. According to the Global Adult Tobacco Survey (GATS), the prevalence of tobacco use among males in India is 48% compared with 20% among females (GATS: India, 2010). Reports from the World Health Organisation predicts that deaths in India due to tobacco may exceed 1.5 million annually by 2020 (Murray and Lopez, 1996). The state of Kerala located in the south west corner of India representing 3% of its total population is known for better health indicator values than other states of India. However there are problems for Kerala in other spheres of public health. 'Tobacco control' is one area where the state is on par with other states in India. In Kerala, 35.4% of males aged 15 years and above are "current tobacco users" and the prevalence of current smokers alone is reported to be 22.4% (GATS: India, 2010).

Health professionals have got a major role in tobacco cessation. Studies have shown that tobacco cessation advice from health professionals has enhanced the quit rate among patients (Lancaster et al., 2000). Tobacco cessation centres are emerging in urban areas of India whereas rural areas with high prevalence of tobacco use are deprived of such facilities. Deeply embedded cultural habits concomitant with lack of knowledge on the risks associated with tobacco are considered as major hurdles for tobacco control in rural areas (Murty and Saadicha, 2010). Moreover, there is paucity of information related to the effectiveness of community based tobacco cessation intervention from rural areas. In this scenario, a study was initiated with the objective of evaluating the effectiveness of a community based smoking cessation intervention in comparison with a control population among males in a rural area in Thiruvananthapuram district, Kerala. Before initiating this study, an attempt was made to estimate tobacco prevalence among males in the age groups of 18-25, 26-35, 36-45, 46-55 and 56-60 years in the above same study population. Further, the socio-economic characteristics of the intervention and control groups

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were compared. In the present paper, tobacco prevalence and socio-economic characteristics of the two groups are presented.

## Materials and Methods

Thiruvananthapuram district has 12 Community Development Blocks (CDBs) with a population ranging from 140,000 to 214,000 per CDB. Each CDB consists of 5-7 panchayaths and each panchayath is further divided into wards. The ward forms the lowest level of administrative system which has a population of approximately 1500-2000. Among the 12 CDBs in the district, 4 CDBs, whose socio-economic status are relatively similar, were selected and randomised into 2 intervention and 2 control groups. All wards of the panchayaths (91 in intervention area and 83 in control area) within the selected CDBs were numbered separately, and 11 wards (5 from intervention and 6 from control area) were selected from them using random sampling method. Each ward represents a cluster and thus 11 cluster units were identified for the study.

The study protocol was approved by the institutional ethics committee of the Regional Cancer Centre, Thiruvananthapuram and informed consent was obtained from each participant. Smoking prevalence was assessed using a pre-tested semi structured questionnaire. All men in the age group of 18.0-60.9 years were included in the house-to-house survey. Bedridden subjects, subjects who cannot speak and those who are mentally retarded were excluded prior to entry into the study.

Accredited social health activists (ASHA) of the respective clusters were identified for potential study aids. An ASHA is a trained female community health activist selected from the village itself under the National Rural Health Mission programme of Government of India. They are trained to work as an interface between the community and the public health system. Their main work is to create awareness on health and its social determinants and initiate the community towards increased utilisation and accountability of existing health services (Ray, 2005). Those ASHAs who were willing to take part in the study were then trained for the field work and they were instructed about the study protocol.

ASHA volunteers collected details on smoking and distributed multicoloured anti-tobacco leaflets in the community through house to house survey. The study protocol was explained to all eligible subjects. Information on the ward/cluster, house number, name of the participant, address, type of house (based on roof and floor of the house), facilities in the household (availability of refrigerator, television, washing machine, computer and vehicles), and household income were collected. Furthermore, age, education, occupation, marital status, parity, personal habits particularly smoking status viz; type of smoking, duration and initiating factors for smoking were collected. Smokers in the intervention arm were given multicoloured anti-tobacco leaflets in Malayalam (the local language) with descriptions of tobacco induced health hazards. The leaflets also spoke for the importance of 'role modelling' against tobacco use in the community. Each eligible subject was then assigned a unique number

**Table 1. Smoking, Smokeless Tobacco and Alcohol Consumption by Age**

| Type of habits | Age – group | Never users | Ever users | Total |
|---|---|---|---|---|
| Smoking | <=25 | 484(92.9) | 37(7.1) | 521 |
| | 26-35 | 681(77.7) | 196(22.3) | 877 |
| | 36-45 | 549(64.2) | 306(35.8) | 855 |
| | 46-55 | 405(56.5) | 312(43.5) | 717 |
| | 56-60 | 166(49.7) | 168 (50.3) | 334 |
| | Total | 2285(69.2) | 1019(30.8) | 3304 |
| | <=25 | 470(90.2) | 51(9.8) | 521 |
| Smokeless | 26-35 | 756(86.2) | 121(13.8) | 877 |
| tobacco | 36-45 | 740(86.5) | 115(13.5) | 855 |
| | 46-55 | 598(83.4) | 119 (16.6) | 717 |
| | 56-60 | 258(77.2) | 76(22.8) | 334 |
| | Total | 2822(85.4) | 482(14.6) | 3304 |
| | <=25 | 471(90.4) | 50(9.6) | 521 |
| Alcohol | 26-35 | 601(68.5) | 276(31.5) | 877 |
| | 36-45 | 542(63.4) | 313(36.6) | 855 |
| | 46-55 | 423 (59) | 294(41) | 717 |
| | 56-60 | 206(61.7) | 128(38.3) | 334 |
| | Total | 2243(67.9) | 1061(32.1) | 3304 |

Figures in parenthesis are row percentages

for future follow up.

Socioeconomic status (SES) was determined by categorizing the study subjects into upper, upper middle, lower middle, upper lower and lower income groups. Categorisation of SES was done by combining the subject's education, occupation and family income. For education, scores of 1, 2, 3, 4, 5, 6, 7 were given for illiterates and holders of primary school certificate, middle school certificate, high school certificate, intermediate/post high school diploma, graduate or post graduate and profession or honours respectively. For occupation, scores of 1, 2, 3, 4, 5, 6, 10 were given for those who belonged to the groups unemployed, unskilled-work, semi-skilled work, skilled-work, clerical/shop-owner/farmer, semi-profession and profession respectively. Similarly for family income, scores of 1, 2, 3, 4, 6, 10 and 12 were given for subjects whose family income per month in the Indian currency 'rupee' was <979, 980-2935, 2936-4893, 4894-7322, 7323-9787, 9788-19574 and >19575 respectively. A person's SES score therefore comes in the following categories. A score of 26-29 denotes upper SES group, 16-25 upper middle, 11-15 lower middle, 5-10 upper lower and <5 lower SES group. Age groups were classified as 18.0-25.9, 26.0-35.9, 36.0-45.9, 46.0-55.9 and 55.0-60.9 years.

Current daily smoker who use atleast one cigarette or bidi (locally made by wrapping coarse tobacco in dried temburni leaf) and with or without smokeless-tobacco chewing habits were included for the intervention study. Comparisons of intervention and control groups as well as comparison of smokers and non-smokers according to age and SES were carried out. Two sample t tests and chi-square tests were employed to compare the groups' characteristics.

## Results

A total of 3304 subjects were interviewed in the house to house survey. The participation rate of eligible

**Table 2. Smoking Status by Demographic and Socio-Economic Characteristics**

| Current smokers | Current | Non-smokers | Total |
|---|---|---|---|
| Number of subjects | 928 (28.1%) | 2376 | 3304 |
| Age in years | | | |
| Mean (SD) | 44.5(9.9) | 36.8(11.6) | 38.9(11.72) |
| Median | 45.0(18-60) | 35.0(18-60) | 38.9(18-60) |
| p-Value[a] | | | <0.0001 |
| Age Group | | | |
| 18-25 years | 26(3%) | 495(21%) | 521 |
| 26-35 years | 177(19%) | 700(29.4%) | 877 |
| 36-45 years | 285 (30.7%) | 570(24%) | 855 |
| 46-55 years | 289 (31.1%) | 428(18%) | 717 |
| 56-60 years | 151 (16.2%) | 183 (7.7%) | 334 |
| Total socioeconomic score | | | |
| P – Value[b] | | | 0.0001 |
| <5 (lower) | 0 (0%) | 2 (0.08%) | 2 |
| 5 – 10 (Upper lower) | 566 (61%) | 966(40.6%) | 1532 |
| 11 – 15 (Lower middle) | 305 (32.8%) | 1064 (44.7%) | 1369 |
| 16 – 25 (Upper middle) | 54 (6%) | 335 (14%) | 389 |
| 26 – 29 (Upper) | 3 (0.3%) | 9 (0.3%) | 12 |

[a]P-Value calculated using two sample t test; [b]p-Value calculated using chi-square test; Figures in parenthesis are column percentages

**Table 3. Summary of Smoking Status**

| | Control area | Intervention area | Total |
|---|---|---|---|
| Number of Smokers | 454 | 474 | 928 |
| Type of Smoking | | | |
| Beedi | 57 (12.56%) | 73 (15.40%) | 130 (14.01%) |
| Cigarette | 284 (62.56%) | 255 (53.80%) | 539 (58.08%) |
| Both | 113 (24.89%) | 146 (30.80%) | 259 (27.91%) |
| Years Since Smoking | | | |
| N | 454 | 474 | 928 |
| Mean (SD) | 15.05 (8.28) | 15.78 (9.09) | 15.42 (8.71) |
| Median (Min – Max) | 15.0 (1.00 - 40.0) | 15.0(1.00 - 45.0) | 15.0(1.0 - 45.0) |
| Total Cigarette & Beedi/ Day | | | |
| N | 454 | 474 | 928 |
| Mean (SD) | 10.90 (6.81) | 13.19 (8.94) | 12.07 (8.05) |
| Median (Min – Max) | 10.0(1.00 - 40.0) | 12.0 (2.00 - 52.0) | 10.0 (1.0 - 52.0) |
| Reasons for Smoking | | | |
| Craving | 159 (35.02%) | 164 (34.60%) | 323 (34.81%) |
| Refreshment | 114 (25.11%) | 127 (26.79%) | 241 (25.97%) |
| Work Relief | 82 (18.06%) | 43 (9.07%) | 125 (13.47%) |
| Halitosis | 14 (3.08%) | 12 (2.53%) | 26 (2.80%) |
| Fun | 20 (4.41%) | 56 (11.81%) | 76 (8.19%) |
| Toilet Rituals | 65 (14.3%) | 72 (15.19%) | 137 (14.76%) |
| No. of Cigarettes & Beedis /Day | | | |
| <10 | 234 (51.5%) | 192 (40.51%) | 426 (45.91%) |
| 10-20 | 159 (35.0%) | 185 (39.03%) | 344 (37.07%) |
| 21-30 | 47 (10.4%) | 64 (13.50%) | 111 (11.96%) |
| 31 or more | 14 (3.08%) | 31 (6.54%) | 45 (4.85%) |

Figures in parenthesis are column percentages

individuals interviewed for the baseline survey was 82% and 85% in the intervention and control groups, respectively. The participants in each ward varied from 215 to 363. In both intervention and control groups, the maximum number of participants belonged to 26-45 year age group (Table 1).

The overall prevalence of current daily smokers in the 18-60 year age group was 28.1% (mean age=44.4 years, SD=9.2 years) whereas the prevalence of current daily smokeless tobacco users and alcohol habitués were 9.8% and 18.1% respectively. Irrespective of the type of habits such as smoking, smokeless tobacco and alcohol use, consumption elevated with increased age (Table 1). Smoking (7.1%) and smokeless tobacco use (9.8%) were the lowest among the 18-25 year age group and the highest consumption was reported in 56-60 year age group (50.3%, 22.8%). Alcohol consumption was lowest among the 18-25 year age group (9.6%) and highest in the 46-55 year age group (41%).

The proportion of daily smokers was more in the 36-55 year age group (62%), than among non-smokers in the corresponding age group (p<0.0001) (Table 2). SES score points indicated that majority of smokers belonged to the upper lower SES group (61%) (mean SES score =10, SD = 3) and among non-smokers, the participants mainly belonged to the lower middle SES group (45%) (mean SES score =12, SD= 3) (p-value= 0.0001).

Among the 928 smokers identified, 474 subjects were in the intervention area (mean age =44.56 years, SD =9.66 years) and 454 in the control area (mean age= 44.47 years, SD =10.30 years). No significant difference was found between the intervention and control groups with reference to age (p=0.89) and SES (p=0.11). Majority of

smokers in the intervention and control areas were from the upper lower SES group (64.1% and 57.27%) (Table 4). Among smokers, more than 50% smoked cigarette alone (58.08%) and 14% smoked bidi, while over a quarter of the smokers had the habit of consuming both bidi and cigarettes (28%). Cigarette users constituted 53.8% and 62.5% in the intervention and control areas. Proportion of bidi users in the intervention group was 15.4%, while it was 12.5% in the control group. However, subjects who took both forms constituted 31% in the intervention and 25% in the control areas. 'Craving' was the major reason given for continuing smoking (34.6 % in intervention and 35.0% in control areas). Other reasons included refreshment, fun, work relief and toilet rituals (Table 3). It was observed that among subjects in the 55+ age group, 60% and subjects in the 46-55 age group, 41% initiated smoking habit after the age of 33 years.

## Discussion

The present paper provides results of a house-to-house survey for identifying smokers for initiating a cluster-randomized behavioural intervention study. The overall prevalence of 'current smoking' (28.1%; in the intervention group 31% and the control group 26%) among the study population was slightly higher than in other recent studies in Kerala. The Global Adult Tobacco Survey (GATS) India (2010) reported 22.4% prevalence of smoking among men in Kerala. The National Family Health Survey (NFHS 2), a population based household survey done in 1998-99 (NFHS 2, 2001) reported almost similar tobacco prevalence and NFHS 3 a continuation

of NFHS 2 done in 2005-2006 (NFHS 3, 2007) reported a higher prevalence of tobacco smoking among men in Kerala and which were 28% and 35.8% respectively. Tobacco use prevalence in India is usually higher in the rural population. The present study was conducted exclusively among the rural population and the result thus are in line with what can be expected. It was observed that smoking was clearly lower in the younger age group compared to older age groups. A possible contributing factor to this result could be that the youngsters might have underreported their smoking habits, since the data collection was done through house to house survey or they might have enhanced their knowledge on smoking hazards through education or print and electronic media. Though smoking is predominantly among males, tobacco chewing has increased recently among men owing to the smoking ban in public places and tobacco industries targeting smokeless tobacco products (Thankapan and Thresia, 2007). This reason could have influenced younger generation in shifting their habit pattern from smoking to smokeless tobacco use. In the present study, it was observed that subjects in the older age groups initiated their habit at later ages. This could be one of the reasons for lower proportion of smokers in the younger age groups. It is expected that non-smokers may also turn to smoking at a later age and the study results highlights the importance of initiating tobacco controlled programmes in the community.

Variation in smoking prevalence might be due to the difference in the socio-economic characteristics as well. In the present study, similar scores as provided in the Kuppuswamy's SES scale are used as it is a validated scale (Kumar et al., 2007). The Kuppuswamy scale is primarily meant for urban population and has been used in the Indian scenario for public health research (Khandekar et al., 2006; Prasad et al., 2009). The present study is conducted among rural population. However, unlike other states in India, the urban-rural differentials in terms of the settlement pattern and occupational diversity are minimal in Kerala which is often represented as an urban-rural continuum (Parayil, 1996; Mridul, 1999) and thus the results in the present study using the same Kuppuswami's scoring system may not be much differed. A difference in socioeconomic background was observed between smokers and non-smokers on the present study. The mean SES score varied among smokers and non-smokers (10 and 12; p <0.0001). Though the difference was not too high, the findings revealed that majority of smokers belonged to the 'upper lower SES group' when compared to non-smokers who were mostly from the 'upper middle SES group'. This clearly refers to education, occupation and income as three major factors that can influence the initiation and continuation of smoking habit. The observation of smoking as a widely prevalent habit among people with lower standards of living in the present study was supported by evidences from other studies reported from India (Rani et al., 2003; Subramaniam et al., 2004; Sorensen et al., 2005). Though bidi smoking is predominantly common in rural areas in many parts of India, in the present study, a major proportion of smokers in both the intervention and control groups were

cigarette users, followed by a combination of cigarette and bidi users and bidi users alone. Studies have shown an increase in cigarette smoking in Kerala, Delhi and the North Eastern states of India (Gupta and Samira, 2008). This may be attributed to the availability of cheaper variety of cigarettes or replacement of bidi by branded smokeless tobacco products available at an affordable price in the market.

Studies have reported that female health volunteers within the community can be effectively utilised for tobacco control activities because of their accessibility and acceptability to the community (Sreedharan et al., 2010). In the present study also more co-operation and acceptability was obtained since trained female ASHA volunteers within the community had conducted the base line survey to identify tobacco habitués. General information on tobacco hazards to both the groups and specific information in the intervention areas was also delivered by them. However, the time and cost factors associated with succeeding visits of ASHA volunteers to the residence of subjects who were not covered in the initial visit are limitation of the study. Despite these limitations, this study reports the recent smoking status of the population in rural Kerala which could be generalised to other rural areas of Kerala state.

In conclusion, though legislation against smoking and other tobacco products has been intensified in India recently, smoking continues to be a predominant public health problem among males in rural Kerala particularly among lower socio-economic population. Considering the high priority given to tackle the tobacco menace, there is a need to develop multiple approaches where measures to strengthen existing regulations against tobacco combined with cost effective interventions for tobacco cessation particularly in rural areas has to be initiated and sustained.

## Acknowledgements

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# RESEARCH COMMUNICATION

# Assessment of Nicotine Dependence among Smokers in a Selected Rural Population in Kerala, India

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## Abstract

**Objectives**: An attempt was made to understand the nicotine dependence of smokers selected for an ongoing smoking cessation intervention programme in rural Kerala, India. **Methods**: Data were collected from resident males in the age group of 18 to 60 years from 4 randomly allocated community development blocks of rural Thiruvananthapuram district (2 intervention and 2 control groups). Trained accredited social health activist workers were utilised to collect data from all groups through face to face interview. Nicotine dependence among participants was assessed by means of the six-item Fagerström Test for Nicotine Dependence (FTND) translated into the local language. The internal consistency of FTND was computed using Cronbach's alpha coefficient. Criterion validity (concurrent) was assessed by correlations of nicotine dependence scores with age at initiation of smoking and cumulative smoking volume in pack-years. **Results**: Among the 928 smokers identified, 474 subjects were in the intervention area (mean age =44.6 years, SD =9.66 years) and 454 in the control area (mean age= 44.5 years, SD =10.30 years). The overall FTND score among current daily smokers was 5.04 (SD: 5.05). FTND scores in the control and intervention areas were 4.75 (SD: 2.57) and 4.92 (SD: 2.51) respectively. The FTND scores increased with age and decreased with higher literacy and socioeconomic status. The average FTND score was high among smokers using both bidi and cigarettes (mean 6.10, SD 2.17). Internal consistency analysis yielded a Cronbach's alpha coefficient of 0.70 in a subsample of 150 subjects, a moderate result. The association of the scale was strongest, with the number of pack-years smoked (rho = 0.677, p < 0.001). **Conclusion**: A moderate level of nicotine dependence was observed among smokers in the current study. Tobacco cessation strategies could be made more cost effective and productive if a baseline assessment of nicotine dependence is completed before any intervention.

**Keywords**: Smoking - rural India - Fagerstrom test for nicotine dependence - tobacco cessation strategies

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## Introduction

The public health impact of tobacco use is enormous, given its effect in the bio-physical, psychological and social spheres of life. The World Health Organisation estimated that more than 5 million deaths occur every year worldwide due to tobacco use (MPOWER package, 2008). While the prevalence of smoking has come down in developed countries, the focus of attention has shifted to low and moderate income countries, where the increase in population and rapid rise in smoking constitutes a major public health problem (Abdullah and Husten, 2004). India being the second largest consumer and the third largest producer of tobacco products in the world, it is estimated that nearly 900,000 people die annually in India due to tobacco attributable diseases (Reddy and Gupta 2004). Smoking is the predominant habit among males in India constituting more than 50% of the tobacco users. The addictive property of the alkaloid 'nicotine' found in tobacco makes addicts out of tobacco users and this property of nicotine is considered similar to those

of cocaine (Banegal, 2005). Dependency on nicotine is the major obstacle that smokers have to overcome while in the process of quitting the habit. Though tobacco consumption, in general, is considered as a major public health problem in India, nicotine dependency is one area which has not been given much importance. Assessment of nicotine dependence has emerged as an important area of research while studying the tobacco use patterns, behaviour and addiction in various populations.

Measurement of nicotine dependency in smoking research has gained significant importance since 1978 when the Fagerstrom Tolerance Questionnaire was developed (Fagerstrom,1978). To compensate for inaccuracies in the psychometric properties of the older scale, the Fagerstrom Test for Nicotine Dependence (FTND), a 6 item questionnaire, was introduced and has gained wide popularity since 1991. The FTND is considered as easy to obtain self-reporting tool that conceptualise dependence through physiological and behavioural symptoms (Pérez-Ríos et al.,2009). Studies conducted in different contexts had shown high test-retest

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reliability and moderate internal consistency for the FTND scale (Weinberger et al., 2007; Wu et al.,2011).

The state of Kerala located in the south west corner of India has been recognised for its high literacy rate and good level of health indicators. However, tobacco control is one area where the state is only on par with many other states in India. In Kerala, the prevalence of "current tobacco users" among males above 15 years of age was reported to be 35.4% and the prevalence of "current smokers alone" is estimated to be 22.4% (GATS: India, 2010).

There is paucity of information on the effectiveness of community based smoking cessation intervention in rural India. In this backdrop, a smoking cessation intervention programme is being implemented in rural Thiruvananthapuram district of Kerala, India (Jayakrishnan et al., 2011). One of the key domains which we intended to look upon is the nicotine dependency of smokers in the study areas. In the present article, the internal consistency, validity, test-retest reliability of the FTND and the overall FTND scores of subjects in the study area are assessed.

## Materials and Methods

The study design is a community based randomised intervention trial in 4 Community Development Blocks (CDB's) in Thiruvananthapuram district. Ward is the lowest level of administrative system of CDBs. A total of 11 wards (5 from intervention and 6 from control area) were selected from the above 4 selected CDBs using random sampling method. Each ward represents a cluster and thus 11 cluster units were identified for the study. Men in the age group 18-60 years who is a smoker, i.e., reports using at least one cigarette/bidi (locally made by wrapping coarse tobacco in dried temburni leaf) daily were included for the study.

Nicotine dependency status information of study subjects were collected by trained Accredited Social Health Activists (ASHA). An ASHA is a female community health activist working under the National Rural Health Mission programme (NRHM), a programme of the Government of India primarily to improve the health standards of people residing in the rural areas. They were trained to interview eligible subjects to collect and record information on socioeconomic characteristics, tobacco and alcohol habits and nicotine dependency status of smokers. One day training was given by a dentist and a psychologist from the Regional Cancer Centre, Thiruvananthapuram. The training programme gave emphasis on awareness of tobacco hazards, assessment of nicotine dependency and conduct of household survey using lectures, slide presentations and mock interviews.

Nicotine dependency was assessed using the Fagerstrom Test for Nicotine Dependency scale (FTND). The FTND scale consists of 6 items and has a total score of 10. Other than cigarette smoking, the FTND was also utilised to assess the nicotine dependency of bidi smokers in the current study. The 6 items include, (1) time to take up the first cigarette/bidi after awakening in the morning (2) difficulty in refraining from smoking in places where it

is forbidden (3) unwillingness to give up the first cigarette in the morning (4) number of cigarettes/bidis smoked per day (5) intensity of smoking during the morning hours and (6) smoking even when bedridden due to illness. A score of 5 or more indicates a significant dependence while a score of 4 or less presents a low to moderate dependence (Heatherton et al., 1991).

The items under FTND were first translated into Malayalam (the local language) and then back before using them. Two investigators (a dentist and a psychologist) independently translated the English version into the local language. The investigators came into a consensus on the translation of questionnaire which was again back translated to the original version for comparison. Since no major discrepancy was noted, the translated version was used for the study. ASHA volunteers were trained on the use of local version of the FTND conducting mock surveys and further the queries aroused were clarified by the investigators. The volunteers later completed the questionnaire through house to house survey and were checked by the investigators for its completeness. Retest was assessed after two months of completing the initial FTND questionnaire among a subsample of 91 subjects. The internal consistency of the FTND was computed using Cronbach's alpha coefficient. Internal consistency measures the extent of inter-correlation amongst a set of measurement items with the same ability or trait in the scale (Kaplan and Saccuzzo, 2005). Criterion (concurrent) validity was assessed by correlations of nicotine dependence scores with age at initiation of smoking and cumulative smoking volume in pack-years. The age at start of smoking was calculated by subtracting the current age in years from the duration of smoking in years. To measure the amount smoked by a person over a period of time, pack years was calculated as number of cigarettes/ bidis per day * number of years smoked/10. A finding of higher correlations would support criterion validity. Since the measures were scored on ordinal scales, we used Spearman's rank correlations in the analysis. Wilcoxon signed- rank test was used to assess whether mean ranks differ when the FTND scale was repeated.

Test–retest reliability of item specific and aggregate scale were determined by intra-class correlation coefficient, using a two-way mixed effect model with absolute agreement definition and weighted kappa statistic using linear weighting respectively.

## Results

The overall prevalence of current daily smokers in the 18-60 year age group was 28.1% (mean age: 44.4 years, SD: 9.2 years). Among the 3304 males in the intervention and control arm, a total of 928 'current daily smokers' were identified from house to house survey. Of the 928 smokers, 474 subjects were in the intervention area (mean age: 44.56 years, SD: 9.66 years) and 454 in the control area (mean age: 44.47 years, SD: 10.30 years). The average number of cigarettes and bidis consumed per day corresponds to 13.19 (SD: 8.4) in the intervention and 10.90 (SD: 6.8) in the control groups. Cigarette smoking was the most common habit among both groups representing 62.5% in

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the control and 53.8% in the intervention areas. The mean duration of smoking was 15.05 years in the control area (SD: 8.28) and 15.78 years (SD: 9.09) in the intervention area (Table 1).

The overall FTND score among current daily smokers was 5.04 (SD: 5.05). FTND scores in the control and intervention areas were 4.75 (SD: 2.57) and 4.92 (SD: 2.51) respectively. The FTND scores increased with age and decreased with higher literacy and socioeconomic status. The average FTND score was found to be higher among those who had the habit of smoking both bidi and cigarette (mean 6.10, SD 2.17) followed by bidi alone (mean: 5.39, SD: 2.36) and cigarette alone (mean: 4.10, SD: 2.50) (Table 2).

Internal consistency analysis for FTND scale was conducted among 150 daily smokers in the survey. Internal consistency evaluation yielded a Cronbach's alpha coefficient of 0.70 suggesting moderate internal consistency.

Intra-class correlation coefficient (ICC) for test–retest was 0.77 (95% CI: 0.67 to 0.84, p<0.001) for the FTND scale. There was no significant difference in scores for the two administrations of the FTND with mean difference -0.10 (p=0.59) (Table 3). There was little association of the FTND score with age at start of smoking (rho = 0.187, p = 0.022). The association of the scale was strongest, with
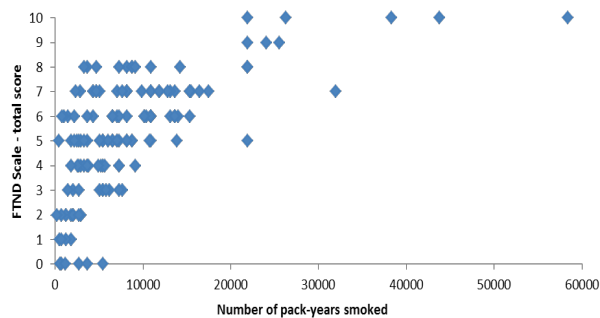


**Figure 1. Correlation between FTND Scale and Number of Pack-Years Smoked**

**Table 1. Summary of Smoking Status**

|  | Control group | Intervention group | Total |
|---|---|---|---|
| Number of Subjects | 454 | 474 | 928 |
| Smoking Status |  |  |  |
| Number | 454 (100%) | 474 (100%) | 928 (100%) |
| Type of Smoking |  |  |  |
| Beedi | 57 (12.56%) | 73 (15.40%) | 130 (14.01%) |
| Cigarette | 284 (62.56%) | 255 (53.80%) | 539 (58.08%) |
| Both | 113 (24.89%) | 146 (30.80%) | 259 (27.91%) |
| Years Since Smoking |  |  |  |
| N | 454 | 474 | 928 |
| Mean (SD) | 15.05 (8.28) | 15.78 (9.09) | 15.42 (8.71) |
| Median | 15 | 15.00 | 15 |
| (Min-Max) | (1.00 - 40.00) | (1.00 - 45.00) | (1.00 - 45.00) |
| Total Number of Cigarette and Beedi per Day |  |  |  |
| N | 454 | 474 | 928 |
| Mean (SD) | 10.90 (6.81) | 13.19 (8.94) | 12.07 (8.05) |
| Median | 10 | 12.00 | 10 |
| (Min-Max) | (1.00 - 40.00) | (2.00 - 52.00) | (1.00 - 52.00) |
| Total Dependency Score |  |  |  |
| N | 454 | 472 | 926 |
| Mean (SD) | 4.75 (2.57) | 4.92 (2.51) | 4.84 (2.54) |
| Median | 5 | 5 | 5 |
| (Min-Max) | (0.00 - 10.00) | (0.00 - 10.00) | (0.00 - 10.00) |

**Table 2. Distribution of FTND Total Score for Current Daily Smokers Based on the Background Characteristics**

| Variables |  | N | Mean | Std. Dev | Med | Min-Max |
|---|---|---|---|---|---|---|
| Group | Control group | 454 | 4.75 | 2.58 | 5 | 0-10 |
|  | Intervention group | 472 | 4.92 | 2.51 | 5 | 0-10 |
| Age | <25 | 26 | 2.54 | 2.30 | 2 | 0-7 |
|  | 26-35 | 177 | 4.34 | 2.49 | 4 | 0-10 |
|  | 36-45 | 285 | 4.67 | 2.60 | 5 | 0-10 |
|  | 46-55 | 289 | 5.27 | 2.43 | 6 | 0-10 |
|  | >55 | 149 | 5.32 | 2.39 | 5 | 0-10 |
| Job |  |  |  |  |  |  |
| Student |  | 3 | 2.00 | 3.46 | 0 | 0-6 |
| Unemployed |  | 18 | 5.11 | 2.78 | 5.5 | 0-9 |
| unskilled worker |  | 408 | 5.11 | 2.52 | 5 | 0-10 |
| semiskilled worker |  | 162 | 5.41 | 2.38 | 5 | 0-10 |
| skilled worker |  | 180 | 4.29 | 2.58 | 4 | 0-10 |
| clerical, shop owner, farmer |  | 105 | 4.34 | 2.48 | 4 | 0-10 |
| semi profession |  | 47 | 3.77 | 2.28 | 4 | 0-9 |
| Profession |  | 3 | 5.67 | 1.53 | 6 | 4-7 |
| Education |  |  |  |  |  |  |
| Illiterate |  | 17 | 6.41 | 1.91 | 6 | 3-9 |
| primary school certificate |  | 80 | 5.87 | 2.52 | 6 | 0-10 |
| middle school certificate |  | 247 | 5.36 | 2.40 | 6 | 0-10 |
| high school certificate |  | 470 | 4.58 | 2.48 | 5 | 0-10 |
| Inter. |  | 71 | 4.27 | 2.75 | 4 | 0-10 |
| graduate |  | 39 | 2.92 | 2.23 | 3 | 0-8 |
| profession |  | 2 | 4.00 | 2.83 | 4 | 2-6 |
| Type of Smoking | Bidi | 128 | 5.39 | 2.26 | 6 | 0-10 |
|  | Cigarette | 539 | 4.10 | 2.50 | 4 | 0-10 |
|  | Both | 259 | 6.10 | 2.17 | 6 | 0-10 |
| Marriage | No | 72 | 4.12 | 2.65 | 4 | 0-10 |
|  | Yes | 854 | 4.90 | 2.52 | 5 | 0-0 |

*2 cases were excluded because of missing FTND score

**Table 3. FTND scale specific test-retest reliability (n=91)**

| Items | Kappa statistic (SE) | P-value |
|---|---|---|
| Time to 1st Cigarette | 0.598 (0.069) | <0.001 |
| Forbidden cigarettes | 0.593 (0.094) | <0.001 |
| Most hate to give up | 0.487 (0.098) | <0.001 |
| Cigarettes/ day | 0.604 (0.066) | <0.001 |
| Morning smoking | 0.661 (0.079) | <0.001 |
| Smoke if ill | 0.752 (0.089) | <0.001 |

*SE-standard error

number of pack-years smoked (rho = 0.677, p < 0.001) (Figure 1).

## Discussion

The present study tried to explore the nicotine dependency status of smokers residing in rural areas of Kerala state, India. In this study, the FTND scores of intervention and control groups were 4.92 and 4.75 respectively which can be classified as low to moderate level dependence. The FTND score was found to have moderate internal consistency (Cronbach's alpha coefficient 0.70). The test-retest reliability of the scale was found to be moderate with an intra-class correlation coefficient of 0.77.

Evaluation of nicotine dependency is an important

step before planning any treatment for smoking addiction. However, a good understanding of nicotine dependency estimation is lax among physicians which are bound to failures while choosing treatment strategies. In a country like India with diverse cultural, ethnic and demographic back ground, where smoking prevalence is high, a better understanding of nicotine dependency will add-on to more possibilities in the treatment of nicotine dependence. Though a few studies were conducted in India to estimate the nicotine dependency status of selected sub-groups (Chandra et al.,2005; Jhanjee and Sethi, 2010), this study was conducted exclusively in a rural population. Though studies from rural areas have not been reported, a study conducted among 500 male students representing 5 universities in Ranchi district of India reported a FTND score of 6.7±2.22 (Sahoo and Jayant., 2010). The FTND score was comparatively lower in the present study even though the age group selected for the study ranged from 18 to 60 years. A better understanding of the attitude change in society and family towards smoking concomitant with personal awareness on its adverse effects could have influenced smokers to smoke in a much more responsible way as perceived by them. Our finding that the FTND score increased with age is an indication that duration of smoking has a linear effect on smoking dependence while higher literacy and occupation were inversely related. Wu et al., (2011), in a study conducted among migrant population in China also reported similar findings. A possible reason is that coping with stressful conditions could become difficult among smokers with age resulting in an increased smoking dependency when compared to younger age groups. Our finding also points to the fact that a strong socioeconomic gradient is associated with tobacco use which had its reflection on the nicotine dependency status. A study conducted among psychiatric patients who had attended a major hospital in South India also reported of higher dependence among older and less educated patients, whereas no association was found between nicotine dependence and the specific psychiatric diagnosis represented in the study (Chandra et al., 2005).

In our study, the FTND score was highest for both forms of tobacco. However for 'bidi alone users', it showed a high dependency score than 'cigarettes alone' which had a moderate dependence. Though 'bidi alone users' constituted nearly one fourth of the study subjects when compared to 'cigarette alone users', the fact that high dependency among 'bidi alone users' could be attributed to the high nicotine content in bidi. Studies conducted to analyse the levels of nicotine and other alkaloids in Indian tobacco products reported high nicotine content in sun cured tobacco used for making bidis (37.70 milligrams of nicotine per gram) when compared to conventional cigarettes which has 16.54 milligram per gram (Pakhele and Maru 1998; Pakhele et al., 1997). Moreover, bidi smoking is more common among the lower socioeconomic group where awareness on tobacco hazards could be reasonably low.

In our study the FTND score was found to have moderate internal consistency. A study conducted among poly drug abuse users in India reported low reliability (Jhanjee and Sethi, 2010). However, moderate internal consistency for FTND was also reported by few other studies (Vink et al., 2005; Weinberger et al.,2007; Wu et al., 2011). While translating the questionnaire, emphasis was given to translate the following items of the original questionnaire to suit the wordings in the local language for easy understanding among study subjects. Item 1 (How soon after waking do you smoke your first cigarette?) was rephrased in the following manner to match the original version in English (After you wake up, how soon you will smoke the first cigarette/bidi?). Item 2 (Do you find it difficult to refrain from smoking in public places where it is forbidden?) The term 'public place' has to be rephrased, since the authors were of the belief that it could be perceived as a vague term among public and hence could not comprehend properly. The Cigarettes and Other Tobacco Products Act, 2003 of the Government of India has defined the term 'public place' as a place where the public have access, whether as of right or not, and includes auditorium, hospital buildings, railway waiting room, amusement centers, restaurants, public offices, court buildings, educational institutions, libraries, public conveyances and the like which are visited by general public.(COTPA, 2003). With this definition as the background the item 2 was revised to "do you smoke in places where the public have access". In item 3 ("Which cigarette would you hate most to give up?) the depiction of "hate the most to give up" was modified to "you think the most difficult to avoid" which was believed to have equal meaning as in the original question in English.

The test-retest reliability of the FTND scale was found to be reasonably good in this study. Studies had reported high test-retest reliabilities of FTND among non-psychiatric patients (Pomerleau et al., 1994; Hudmon et al., 2005; Vink et al., 2005) and in patients with schizophrenia (Yang et al., 2003). The test-retest reliability was assessed after two months of completing the first version. Though it was reasonably good, higher test-retest reliability could have been achieved if the test was repeated in a short interval after completing the first one.

In conclusion, the study reported moderate level of nicotine dependence in the rural population in Thiruvananthapuram, Kerala. Tobacco cessation strategies, either clinic or community oriented, and group intervention programmes could be made more cost effective and productive if a baseline assessment of nicotine dependency could be completed before intervention.

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# RESEARCH ARTICLE

# Multiple Approaches and Participation Rate for a Community Based Smoking Cessation Intervention Trial in Rural Kerala, India

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## Abstract

<u>Background</u>: To illustrate multiple approaches and to assess participation rates adopted for a community based smoking cessation intervention programme in rural Kerala. <u>Materials and Methods</u>: Resident males in the age group 18-60 years who were 'current daily smokers' from 4 randomly allocated community development blocks of rural Thiruvananthapuram district, Kerala (2 intervention and 2 control groups) were selected. Smoking status was assessed through house-to-house survey using trained volunteers. Multiple approaches included awareness on tobacco hazards during baseline survey and distribution of multicolour anti-tobacco leaflets for intervention and control groups. Further, the intervention group received a tobacco cessation booklet and four sessions of counselling which included a one-time group counselling cum medical camp, followed by proactive counselling through face-to-face (FTF) interview and mobile phone. In the second and fourth session, motivational counselling was conducted. <u>Results</u>: Among 928 smokers identified, smokers in intervention and control groups numbered 474 (mean age: 44.6 years, SD: 9.66 years) and 454 respectively (44.5 years, SD: 10.30 years). Among the 474 subjects, 75 (16%) had attended the group counselling cum medical camp after completion of baseline survey in the intervention group, Among the remaining subjects (n=399), 88% were contacted through FTF and mobile phone (8.5%). In the second session (4-6 weeks time period), the response rate for individual counselling was 94% (78% through FTF and 16% through mobile phone). At 3 months, 70.4% were contacted by their mobile phone and further, 19.6% through FTF (total 90%) while at 6 months (fourth session), the response rate was 74% and 16.4% for FTF and mobile phone respectively, covering 90.4% of the total subjects. Overall, in the intervention group, 97.4% of subjects were being contacted at least once and individual counselling given. <u>Conclusion</u>: Proactive community centred intervention programmes using multiple approaches were found to be successful to increase the participation rate for intervention.

**Keywords:** Face-to-Face (FTF) - counselling - smoking - cessation

## Introduction

The rise in population growth concomitant with the increase in tobacco use will result in more than 80% of tobacco related deaths in low and middle income countries by the year 2030 (Mathers and Loncar, 2006). India, the second largest consumer of tobacco products in the world, has more than one third of adults using tobacco in one form or the other (GATS: India, 2010). In a nationally represented case control study of smoking and death in India, it was reported that the annual death rate due to tobacco use in India is around 1 million of which 70% deaths will occur among the 30-69 age group (Jha et al., 2008). The tobacco use prevalence was found to be significantly higher in the rural areas and among the poorer

social class when compared to urban and high socio-economic groups (Rani et al., 2003). The health impact of smoking is enormous considering the wide spectrum of diseases associated with it. In India, the economic impact of three most common tobacco related diseases namely cancer, coronary artery disease and chronic obstructive lung disease for the year 2002-2003 exceeded the combined revenue and capital expenditure at the national and state level on medical and public health, water supply and sanitation (Gajalakshmi et al., 2003). Nearly half of all cancers among males and one fourths of cancers among females are tobacco related (GATS: India, 2010). A large proportion of cancer deaths in India particularly in the age group of 30-69 years were tobacco related (Dikshit et al., 2012). Smoking contributes to more than 80% of

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lung cancers (Mackay et al., 2006). Quitting smoking is the best possible measure to avert mortality due to lung cancer. It has been reported that quitting the habit at age 30 avoids 90% of the subsequent risk of death from lung cancer (Peto et al., 2000).

Smoking cessation virtually benefits every smoker regardless of age, sex, disease state or years of smoking. The benefits of smoking cessation was reported to be so high that the risk of dying due to tobacco can be reduced by 50% among quitters when compared to continuing smokers in the next 15 years, if the person is able to do so below 50 years of age (Murthy and Sadichha, 2010). The effectiveness of individual smoking cessation has been reported elsewhere (Lancaster and Stead, 2005).

In a country like India, where majority of the population 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 as to reach a wider audience. The importance of initiating community based cessation programmes in India has to be looked-after, since clinic based initiative is confined predominantly to urban and educated users (Murthy and Sadichha, 2010). Loss to follow up was also a major concern in tobacco cessation clinics. It was reported that educating the community on the importance of tobacco cessation is essential to retain them in tobacco cessation programmes (Cherian et al., 2012). Considering the fact that loss to follow-up will be a barrier for community based smoking cessation strategies, proactive approaches are required to counter the problem. Hence the feasibility of using multiple approaches to deliver health education messages and counselling against smoking cessation needs to be assessed. Currently there is scarcity of information on the effectiveness of community based smoking cessation intervention in rural India. With this background, a community based smoking cessation intervention programme was conducted using multiple intervention approaches in a rural population in Kerala, India. The present paper mainly illustrates these multiple approaches and assessed its participation rate of the programme.

## Materials and Methods

### Settings and participants

Of the 12 Community Development Blocks (CDB's) in rural Thiruvananthapuram district of Kerala state, 4 CDB's whose socioeconomic status are relatively similar was selected for the study and randomised to 2 intervention and 2 control groups. CDB's are lower level of administrative systems in the state. A total of 11 wards (5 from intervention and 6 from control area) were selected from the selected CDBs. Briefly, each ward represents a cluster thus forming 11 clusters for the study. Details regarding the sample selection procedure were published in Jayakrishnan et al. (2011). Males in the age group 18-60 years who had reported of using at least one cigarette/bidi (bidi is locally made by wrapping coarse tobacco in dried temburni leaf) daily during the study period was considered as eligible for the study. Subjects who could not speak, mentally disabled and terminally ill patients were excluded for the study. Ethical clearance was acquired from the institutional ethics committee of the Regional Cancer Centre (RCC), Thiruvananthapuram 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. Estimated sample size in each group was 450.

### Initial survey

Initial data collection to identify smokers was taken by trained female Accredited Social Health Activists (ASHA). An ASHA is a trained female community health worker selected from the respective villages under the National Rural Health Mission programme of Government of India. Other than socio-demographic factors, details of personal habits particularly smoking status viz; type and duration of smoking and nicotine dependency status using revised Fagerstrom scale of Nicotine Dependence (FTND) were also collected. Details regarding internal consistency, validity and test-retest reliability of FTND were published (Jayakrishnan et al., 2012).

### Multiple Intervention approaches

A total of four different approaches such as i) distribution of education materials on tobacco hazards during baseline survey, ii) sending invitation letters to the study subjects and communication over phone to key personnel in the locality for attending medical camp cum group counselling, iii) conduct of medical camp cum counselling and iv) individual counselling at four time points (2-4 weeks after the base line survey (if the person was not contacted through group counselling), 4-6 weeks, 3 months and 6 months). Tobacco status from both intervention and control groups were assessed at 12 months.

Distribution of Information, Education and Communication (IEC) materials on tobacco hazards: Smokers in the intervention and control group were given multi-coloured anti-tobacco leaflets in 'Malayalam' (the local language). Each leaflet provided information about the descriptions of ingredients in tobacco, smoking induced health hazards, passive smoking hazards for women and children and thereby the importance of smoking cessation. The leaflets also showed the importance of 'role modelling' against tobacco use in the community. In the intervention group, other than the multi-coloured anti-tobacco leaflets, ASHA volunteers distributed a quick reference guide for tobacco cessation titled "How to quit tobacco?" The reference guide was developed by the Tobacco Cessation Clinic of RCC, Thiruvananthapuram in vernacular language (Malayalam), which contains information about the advantages of quitting, barriers for quitting, different methods for quitting and relapse prevention strategies.

Invitation letter to study subjects, invitation over the phone to local administrative heads and health care providers to attend a medical campaign cum group counselling: After completion of initial data collection

from each cluster, communication messages were sent by the health care provider (RJ) via post to smokers of the respective clusters in the intervention arm to attend a group counselling session cum medical examination at a specific date. The letter provided information about the hazards of tobacco and to attend a general medical camp cum group counselling. Telephonic communications were sent to the local administrative heads of each cluster, health workers and the medical doctor in the government health centre nearest to each study area requesting their support for successfully conducting the programme. Key community volunteers of each cluster were also sensitised to assure their support for the intervention programme.

Conduct of medical camps and group counselling sessions: For each cluster, health education session and medical camps were conducted on different days to get maximum participation. Each session was conducted at 2-4 weeks time period after completion of the base line survey in each cluster. Each health education session was carefully planned so as to incorporate topics related to hazards of tobacco, benefits of quitting, barriers to quitting and plan to quit. The session had three components (1) a twenty minute documentary film in the vernacular language (Malayalam) on tobacco and cancer which was produced by the RCC, Thiruvananthapuram. The documentary film gave emphasis on common tobacco related cancers occurring in Kerala, social and economic consequences of tobacco in the community and family, perceptions of local people to tobacco use, confession of a lung cancer patient and an oral cancer patient about their smoking and smokeless tobacco habits and its consequences. This was followed by messages of a noted Malayalam actor and a Malayalam litterateur against substance abuse and its implications in the society. Secondly, a group intervention session for participants was conducted that stressed on the benefits of quitting tobacco, plan for quitting tobacco, common withdrawal symptoms and measures to overcome them, coping and relapse prevention strategies were also discussed. A health professional and a medical social worker conducted the group counselling session. Thirdly, a general medical camp was conducted after completing the above sessions.

Individual counselling through multiple approaches: After completing the health education session and medical camp in each intervention area, 2 medical social workers, trained at the Tobacco Cessation Clinic of RCC, conducted individual counselling sessions. Individual counselling was conducted at 2-4 weeks among those who did not attend group counselling. Subsequently all the subjects were followed up at 4-6 weeks, 3 months and 6 months time period after the completion of baseline survey. The final survey to assess the outcome of intervention was conducted at 12 months. During each visit, permission was taken from the subject prior to counselling. Each counselling stressed on developing coping skills, harm reduction strategies and stress reduction methods for quitting. Flip charts were used by the counsellor in the initial two visits to show the hazards of smoking in general and pre-post treatment photographs of oral cancer patients

who were treated at the RCC, Thiruvananthapuram. Informed consent was obtained from the patients to show their photographs along with their messages in the local language.

Individual counselling at 2-4 weeks, was provided through Face-to-Face (FTF) interview. In the absence of a participant in the first house visit, an attempt was made to contact the person in the next 2-3 days or the person was given counselling via mobile phone. If the person could not be contacted after these two attempts, he was considered as "loss to follow up". In this session, the above mentioned strategies for counselling and tips for quitting the habit as well as setting up a quit date was provided. In the subsequent follow-up session (at 4-6 weeks), FTF and mobile phones were used for contacting the subject. In this session, if the person was unable to quit on the target date, a revised plan which included a motivational intervention based on the 5 R's approach (relevance of quitting, risks associated with continued smoking, rewards of quitting, roadblocks to quit, and repetition for educating subjects) was given. The subject was also requested to set up a new quit date. On an average FTF took 15 minutes. In the third session (follow-up at 3 months), the subjects were contacted to their mobile phones as they were already acclimatized with the interviewer. If the person was unable to contact over mobile phone, an attempt was made to contact through house visit. The interviewer enquired about the smoking status and assessed the barriers for qutting the habit among those who still continued the habit. Quitting tips were given over phone among those who were unable to quit the habit. For each individual, telephone counselling took 5-10 minutes

In the fourth session (follow-up at 6 months), FTF and those who were unable to contact through FTF, mobile phones were used for contacting the subject in the intervention group. In this session also, a motivational intervention based on the 5 R's approach was given, if the person was unable to quit the habit. At this time point all subjects in the control group were contacted through house visit and mobile phone for those who were not able to contact through house visit in order to obtain their smoking status. In the final survey at 12 months-time, smoking status of both the groups were obtained through house visit followed by mobile if not able to contact through house visit.

## Results

A total of 928 'current daily smokers' (28.2%) were identified from 3304 subjects interviewed through a house to house survey and were included in the study. Mean age of 474 subjects in the intervention group was 44.56 years (SD: 9.66 years) and the mean age of 454 subjects in the control group was 44.47 years (SD: 10.30 years). The smoking prevalence in the intervention and control areas was 31% and 26% respectively. Among smokers, more than 50% smoked cigarette alone (58.08%) and 14% smoked bidi; while over a quarter of the smokers had the habit of consuming both bidis and cigarettes (28%). Cigarette users were 53.8% and 62.5% in the intervention and control areas respectively. Average

number of cigarettes and/or bidis consumed per day was 13.19 (SD: 8.4) in the intervention and 10.90 (SD: 6.8) in the control groups. Average age at which the habit started was 15 years (SD: 8.28 years) in the intervention and 15.8 years (SD: 9.1 years) in the control group (Table 1).

In the intervention area, a total of 5 camps were conducted at 2-4 weeks time period after completion of baseline survey in 5 clusters and only 75 subjects (16%) attended medical camp and received group counselling. An attempt was made to provide individual counselling to the remaining subjects (n=399) in the intervention area. Among these subjects 351 (88%) were contacted through FTF and 34 (8.5%) through mobile phone. Thus a total of 460 (97%) subjects received either group or individual counselling at 2-4 weeks time period.

In the second session at 4-6 weeks time period, 78% of subjects were contacted through FTF and further 16% through phone (total 94%). In the third session, at 3 months, 70.4% were contacted to their mobile phone

## Table 1. Summary of Smoking and Socio-economic Status

| Smoking & socio-economic status | Control group | | Intervention group | | Total | |
|---|---|---|---|---|---|---|
| Number of Subjects | 454 | | 474 | | 928 | |
| Smoking Status | | | | | | |
| No. of Smokers | 454 | (100%) | 474 | (100%) | 928 | (100%) |
| Type of Smoking | | | | | | |
| Bidi | 57 | (12.56%) | 73 | (15.40%) | 130 | (14.01%) |
| Cigarette | 284 | (62.56%) | 255 | (53.80%) | 539 | (58.08%) |
| Both | 113 | (24.89%) | 146 | (30.80%) | 259 | (27.91%) |
| Years Since Smoking | | | | | | |
| Mean (SD) | 15.05 (8.28) | | 15.78 (9.09) | | 15.42 (8.71) | |
| Median (Min-Max) | 15.00 (1-40) | | 15.00 (1-45) | | 15.00 (1-45) | |
| Number of Cigarette and Bidi per Day | | | | | | |
| Mean (SD) | 10.90 (6.81) | | 13.19 (8.94) | | 12.07 (8.05) | |
| Median (Min-Max) | 10.00 (1-40) | | 12.00 (2-52) | | 10.00 (1-52) | |
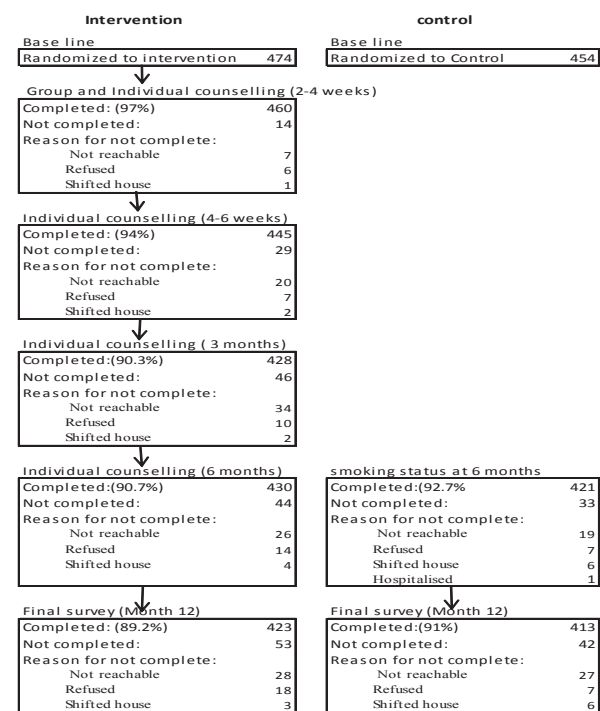
and further, 19.6% through FTF (total 90%). In the fourth session, at 6 months in the intervention group, 74% through FTF and 16.4% through mobile phone (90.4%) and in the control group 71.4% through FTF and 21.3% though mobile phone (92.7%). In the final survey, 89.2% of the intervention and 91% of the control groups were contacted. Overall, 97.4% of the subjects were being contacted at least once in the intervention group and individual counselling given. Number of subjects participated in each visit is given in the Figure 1. In all the sessions, the major reason for those not being attended the counselling was "unable to contact" (Figure 1).

## Discussion

The present paper illustrated multiple approaches and assessed its participation rate for a community based smoking cessation programme in rural Kerala. The main objective of this cessation programme was to participate all the selected subjects in the group counselling and among the failures, individual counselling through FTF and mobile phones within a period of 2-4 weeks after the baseline survey. In the baseline survey, it was observed that the overall tobacco smoking prevalence was 28% which was marginally higher than the prevalence reported among adult males (22.4%) in the Global Adult Tobacco Survey Report, 2010. The possibility of higher smoking rates in rural areas could justify the prevalence rate mentioned in the present study.

In the present study, the group counselling included a session with the display of a documentary film on tobacco hazards and also donations of a lung and an oral cancer patient treated at Hospital. However, the response to attend group counselling was poor. The poor acceptance to group counselling intervention in terms of low participation rate need not be due to the fact that social aspects to smoking rather than in general and the awareness on smoking as a public health problem is widely understood than others (2). Further, the chance of stigmatization of subjects involved at the session might have resulted in less participation. Another possible factor in lower participation could be underestimation of the personal risk of tobacco related illness (Weinstein, 2002). In the present study, the rest of all the subjects except 3% could be provided individual counselling through FTF and mobile phones within a period 2-4 weeks after the baseline survey. Medical social workers, who were trained on tobacco cessation programme, conducted FTF and mobile phone counselling and thus they could deliver the message on tobacco hazards and quitting tips.

In order to obtain good support from the community, other than the study subjects, communication messages were given over phone to 20 key personnel which included community workers, medical doctor and a local politician (ward member) of each cluster about the importance of this camp cum group counselling and further invited them to attend the medical camp cum group counselling programme. 15 of them responded by participating in the camp. Community workers such as primary care health workers attached to health centres



**Figure 1. Participant Flow to Intervention at Different Time Periods**

Intervention

Base line
Randomized to intervention    474

Group and Individual counselling (2-4 weeks)
Completed: (97%)    460
Not completed:    14
Reason for not complete:
Not reachable    7
Refused    6
Shifted house    1

Individual counselling (4-6 weeks)
Completed: (94%)    445
Not completed:    29
Reason for not complete:
Not reachable    20
Refused    7
Shifted house    2

Individual counselling (3 months)
Completed:(90.3%)    428
Not completed:    46
Reason for not complete:
Not reachable    34
Refused    10
Shifted house    2

Individual counselling (6 months)
Completed:(90.7%)    430
Not completed:    44
Reason for not complete:
Not reachable    26
Refused    14
Shifted house    4

Final survey (Month 12)
Completed: (89.2%)    423
Not completed:    53
Reason for not complete:
Not reachable    28
Refused    18
Shifted house    3

control

Base line
Randomized to Control    454

smoking status at 6 months
Completed:(92.7%)    421
Not completed:    33
Reason for not complete:
Not reachable    19
Refused    7
Shifted house    6
Hospitalised    1

Final survey (Month 12)
Completed:(91%)    413
Not completed:    42
Reason for not complete:
Not reachable    27
Refused    7
Shifted house    6

are engaged in preventive activities like immunisation and health education on risk factors on communicable and non communicable diseases. Hence, in community settings they are in a position to identify and intervene with patients as well as healthy individuals to give advice on health risk behaviours. A doctor has a greater chance for interaction with patients in clinical settings. It was also reported that simple advice on the part of a medical professional has the potential to increase the quit rate by 2-3% (Stead et al., 2008). Political leader at the decentralised level of the administrative system was invited to inaugurate the programme at each cluster and to seek his/her assistance for implementation of succeeding intervention programmes.

In the present study, follow-up sessions were also conducted by the social workers before the final survey. The technical 'know-how' on the subject influenced the social workers for conducting follow-up counselling. It was assumed that if subjects could be retained for a longer period in the intervention area, greater was the chance of making a change in the smoking pattern from the category of "no improvement" to "improvement" category. Considering the fact that tobacco dependence is a chronic condition also necessitates repeated interventions to succeed in quitting the habit (Anderson et al., 2002). Moreover retaining smokers for a longer period would help to understand the factors associated with abstinence from smoking and relapse. Reduction in tobacco use was reported among patients attending cessation clinics when they were retained in follow-up group for a longer period (Murthy and Saadicha, 2010).

In all the follow-up sessions, around 90% subjects were contacted through FTF or mobile phone. Our study was effective in increasing the participation rate due to the main reason that proactive counselling was done using multiple modes mainly FTF and mobile phone. Though mobile phone services were utilised for patient's follow-up in tobacco cessation clinics (Kumar et al., 2007), the current study being conducted in community settings explored the possibility of using mobile phones in all the follow-up sessions as either an alternative to FTF or at 3 months time point where it was used as the prime mode of counselling.

In the present study, behavioural counselling was given by FTF and mobile phone counselling on an individual basis. However priority was given for FTF on the assumption that it will be useful to develop a good rapport between the subject and the interviewer. Another factor for using FTF was to elicit information by communicating questions with greater care to get the best possible response which were useful for succeeding interventions for comparison. In the first two sessions of individual counselling, we used pictorial representation to illustrate the hazards of smoking particularly tobacco associated oral and lung cancers. The effective utilisation of pictures of smoking associated illness were reported by other studies as well (Pai and Prasad, 2012; Kumar et al., 2012). The wider acceptance of using the 5 A's approach in clinic settings to assess various smoking associated factors viz ask about the habit, advice to quit, assess willingness to quit, assist to quit and arrange follow up in

clinical settings and the 5 R's approach (relevance to quit, risks of habit, rewards of quitting, road blocks in quitting, repetition of motivation) were demonstrated by other studies (Cornuz et al., 2007; Fiore et al., 2009; Thankappan et al., 2013). Reports of increased quit rate through face to face counselling had already been reported (Lancaster and Stead, 2006, King et al., 2008). The Cochrane review of behaviour therapy programs acting as an adjunct to pharmacotherapy for smoking cessation observed that behaviour support increased the success of quit chance from 10-25% (Stead and Lancaster, 2012).

In the present study, at 3 months follow-up time, the primary mode of contact used was mobile phone counselling for which a response rate of more than 70% was observed. The method was used to understand the smoking status of the individual at that time period and to provide a brief advice based on the status. To our knowledge, no study was reported from India to establish the effectiveness of telephone counselling. Though FTF was given priority as a whole in this study, proactive telephone counselling was found to be useful to increase the coverage. Telephone counselling was commonly used in western countries because of its wide reach and cost effectiveness. Quit lines were found to increase smoking abstinence rates (Perera and Lancaster, 2006). Though the response to telephone counselling was high in the present study when compared to FTF, it was observed that the enthusiasm to seek advice through telephone counselling was not encouraging. In all other sessions FTF was given priority to telephone counselling, while telephone counselling was used when the person was lost to follow up in FTF.

Motivational counselling was conducted in second and fourth sessions of this study. The importance of motivational counselling was substantiated by the guide lines recommended by United States Public Health Service (USPHS) in the backdrop of those who are not ready to set a target quit date (Fiore et al., 2008).

In the control group, smoking status assessment was done at 6 months and 12 months time point like in the intervention area. The intention was to explore whether any change in behaviour pattern was seen in their smoking status in the interim phase and to know how it would reflect when the pattern is assessed after 12 months.

Notwithstanding the limitations of this study particularly the time and manpower involved, the socio-demographic profile of Kerala with its high literacy compared to the rest of the country, complemented to increased participation to this intervention.

In conclusion, proactive community centred intervention programmes using multiple methods were found to be successful to increase the coverage for intervention. Community specific suitable methods for tobacco intervention strategies may be adopted in a country like India where diverse socio-demographic and political systems prevails.

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# RESEARCH ARTICLE

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

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## Abstract

<u>Background</u>: 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. <u>Materials and Methods</u>: 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. <u>Results</u>: 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. <u>Conclusions</u>: 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

## 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



**Figure 1. Participant Enrolment to the Study**

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.

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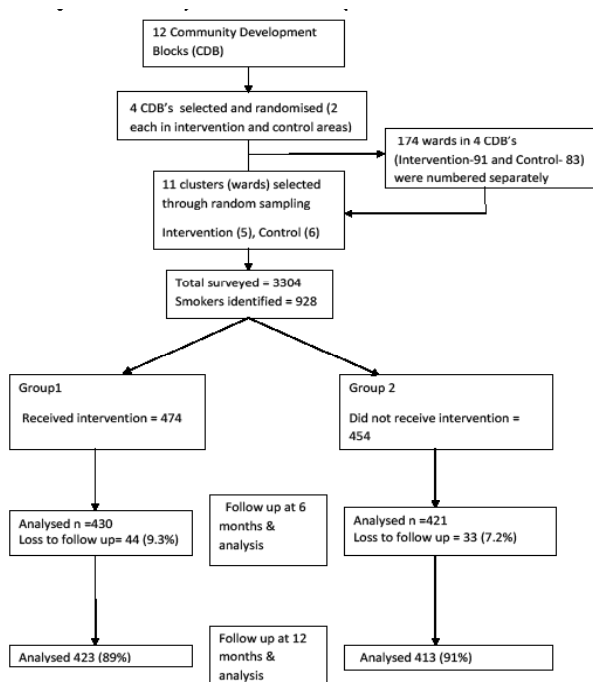
workers and medical doctor's of the respective health centres of each cluster were also informed about the programme and requested their support for the success of the programme. The group counselling session and medical camp were conducted within 2 weeks after completion of the baseline data collection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

## Acknowledgements

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