Smoking Cessation Intervention Program in Primary Health Centers in Palakkad district, Kerala

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Thesis submitted to

Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram

in partial fulfillment of the requirements for the degree of Doctor of Philosophy

Achutha Menon Centre For Health Science Studies (AMCHSS)

Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST)

Thiruvananthapuram, Kerala, India

February 2009

SMOKING CESSATION INTERVENTION PROGRAM IN PRIMARY HEALTH CENTERS IN PALAKKAD DISTRICT, KERALA

A thesis presented by

A S Pradeep Kumar

for the degree of **Doctor of Philosophy (PhD)**

of

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, THIRUVANANTHAPURAM

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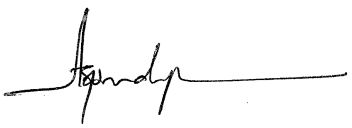
DECLARATION

I, A. S. Pradeep Kumar, hereby declare that the thesis titled "**Smoking cessation intervention program in primary health centers in Palakkad district, Kerala**" submitted to Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram is an original research work undertaken by me under the guidance of Dr K. R. Thankappan, Professor and Head of the Department, Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology and has not been submitted in full or in part for award of any degree in any other institution or university.



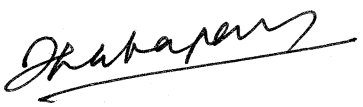
A. S. PRADEEP KUMAR

Thiruvananthapuram
February, 2009

CERTIFICATE

This is to certify that A.S.Pradeep Kumar has fulfilled the requirements of the regulations relating to the nature and prescribed period of research for the Ph.D. degree of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram. The thesis entitled **"Smoking cessation intervention program in primary health centers in Palakkad district, Kerala"** is an original work carried out under my guidance and supervision.

Supervisor



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February, 2009

ACKNOWLEDGEMENT

There are many people whose help, support, guidance and effort have contributed significantly to this research work. I wish to place on record my gratitude to all of them.

I express my heartfelt thanks to **Dr K. R. THANKAPPAN**, Professor, AMCHSS, SCTIMST my research supervisor for his valuable and insightful guidance and advice which helped shape this thesis into its present form. He helped me in his various capacities, as guide, academician, principal investigator of the project and head of the department.

My **doctoral advisory committee members** were Dr T K Sundari Ravindran, Dr Aleyamma Mathew, Prof. Mark Nichter and Prof. Harry A Lando. I gratefully acknowledge the crucial contributions that they have made in improving this thesis.

DR. T. K. SUNDARI RAVINDRAN, Honorary Professor, AMCHSS, for her insightful comments, constructive criticisms and critical evaluation at different stages of the research.

DR. ALEYAMMA MATHEW, Associate Professor, Regional Cancer Center, Thiruvananthapuram , for her inputs and suggestions during the research process.

Prof. MARK NICHTER, Regent Professor, University of Arizona, USA, for sparking off and maintaining my interest in the study of tobacco. Despite a busy schedule of teaching and research activities, he was always there to help me with the reading and improvisation of my thesis. I am indebted to him for the inspiration, innovative ideas and careful reviewing of the manuscript without which this thesis would never have happened.

Prof. HARRY A. LANDO, Professor, University of Minnesota, USA, for his warmth, conscientiousness and constructive review of the manuscript. Being a tobacco researcher for more than three decades, his immense and in-depth knowledge proved to be irreplaceable and was a source of reference.

I also wish to thank the **Fogarty International center of the National Institutes of Health**, USA for grant RO1 TW005969-04 that gave an opportunity to become a Ph D scholar through providing employment.

I am also indebted to

Prof. K. Mohandas, Director, SCTIMST, Thiruvananthapuram who, due to his keen interest in public health, provided constant support and inspiration.

Dr.T.K.Kuttamani, Former Director, Kerala State Health Services Department for providing official sanction to conduct this research project and for his encouragement.

Dr. Manju R. Nair, Scientist C, AMCHSS, for taking pains to help me during the manuscript preparation and also for her critical inputs at every stage of the research.

Dr. P. S. Sarma, Additional Professor, AMCHSS, for patiently helping me out with the intricacies of statistical analysis.

Dr. A K Radhakrishnan, former District Medical Officer, Palakkad, and **Dr. P. R. Karunakaran**, District Medical Officer, Palakkad, for their valuable help in conducting the research by facilitating the data collection process in Palakkad.

Mr. E. Ayyappan, District Education Media Officer, Palakkad, for mobilizing the various research teams and organizing the research training programs.

Ms. Jasmine T. George, District Public Health Nurse, Palakkad for supervising the field work and **Ms. Miji Miriam** for monitoring the field activities and data entry.

Godwin S K, Arun B and **Edwin Sam**, research scholars at AMCHSS for their friendship and support.

The participants and the primary health centre teams at Palakkad without whose support this research would have never materialized

I am thankful to Mrs. Deepa Prasad for her gracious help with language editing.

And above all, to my wife, **Leela** and sons, **Vishnu** and **Hari** for their unrelenting support in all my efforts.

A.S. Pradeep Kumar

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Abstract

Background: Tobacco use is one of the major public health problems in Kerala. Tobacco cessation is essential to save current users from premature deaths due to their tobacco use. Smoking cessation clinical practice guidelines for primary care clinicians mostly exist in developed countries. Drug therapy, a key component of those guidelines, is not practical in developing countries including India due to issues of availability and affordability. Behavioral interventions have been found to be useful in such contexts. Studies on the effectiveness of smoking cessation interventions are limited in India

Objectives: To assess the effectiveness of brief advice of a doctor combined with counseling by a non-doctor health professional compared to brief advice of a doctor alone in smoking cessation in primary care settings.

Methodology: A total of 875 male current smokers (mean age 44 years) were recruited from seven primary health centres of Palakkad district for an intervention study. Using a computer generated table 444 smokers were recruited in the intervention group and 431 in the control group. Smokers in the intervention group were provided doctor's advice and counseling by a non-doctor health professional whereas the control group received only doctors' advice. Both groups of smokers were followed up for 12 weeks. Quitters at 12 weeks were followed up till 26 weeks.

Results: Continuous smoking abstinence for week three through six months was 10.1% among participants who received counseling compared to 6.0% among participants in the non counseled group (OR 1.8; 95% CI: 1.1–3.0). At week three, six and 12, weekly smoking abstinence rates were 1.8 (95% CI: 1.2–2.7), 1.5 (95% CI: 1.0–2.1) and 1.4 (95% CI: 1.0–2.0) times higher respectively among those who received counseling compared to those who did not. Quit attempts were 3.9 times and harm reduction (cutting down smoking more than 50%) was 1.7 times higher among those who received counseling than those who did not. Quantity of smoking, intention to quit and presence of past quit attempts were the strongest predictors of both continuous smoking abstinence and weekly smoking abstinence.

Conclusion: In this randomized control trial of male current smokers, counselling by non doctor health professionals resulted in significantly higher smoking abstinence rates.

Chapter 1
Literature Review

1.1. Introduction

There is no public health problem of greater importance today than tobacco control. The public health consequences of tobacco use are enormous and the economic burden of tobacco related mortality and morbidity on both the households and the health services of developing countries are catastrophic. Tobacco use sickens and kills many people who are at the height of their productivity, depriving families of their breadwinners. For this reason, the public health impact of tobacco is greater than the number of people whose health has been negatively affected by their tobacco use. Their ill health affects all those who depend on them, the well-being of their wives, children and elders. Their ill health affects the work force of the nation, and is a huge drain on the health care system, given that most people who die from tobacco related diseases do so slowly, requiring significant expenditure on medical care. Tobacco use also exacerbates poverty. When impoverished dependant users of tobacco are compelled to spend their scarce household resources on tobacco products, even children may suffer for basic needs like food, education, clothing and health care. Meeting the demand for tobacco also has several negative outcomes. Tobacco farming, for example, is associated with environmental degradation and reduces the land available for food crops. As Nichter has noted, tobacco leads to three inter-related forms of dependency: dependency of the physical body due to the addictive nature of nicotine; dependency of the land on pesticides and chemical fertilizers due to the demands of this cash crop; and dependency of the state on tax revenue, which makes it difficult to ban this harmful and addictive drug.[1]

This is a report of research on tobacco cessation. The introductory chapter on literature review is organized into the following five sections: tobacco use: prevalence and patterns of consumption, tobacco addiction, tobacco-related mortality and morbidity, tobacco control and tobacco cessation.

1.2. Tobacco use: prevalence and patterns of consumption

1.2.1. The Global scenario

In the late 1990s there were 1.3 Billion smokers in the world.[2] Among them more than one Billion were men and 0.25 Billion were women. Smoking was higher among men above 14 years in developing countries (50%) than developed countries (35%) while lower among women of the same age in developing countries (9%) than developed countries (22%). A worldwide report on smoking among men and women, based on estimates available for 2005, found that more than half of the one billion male smokers were from three countries (300 million from China, 160 million from India and 60 million from Indonesia).[3] This report revealed more significant gender difference in smoking in developing countries than in developed countries. The prevalence of smoking among men was highest in China (63%) and Japan (54%) where as the prevalence of smoking among women was only 3.8% and 14% respectively. By comparison, the gender difference in the United Kingdom and the United States was only 4% with male smoking prevalence of 28% and 26% respectively. Youth smoking was highest in the central and eastern European Union and in some parts of India. The total cigarette consumption in the whole world was 5.5 trillion per year in 2000, which would be about 1000 cigarettes for every man, woman and child per year (i.e., 3 cig/day/human being). The top five countries that had the highest consumption of cigarettes were China (1,800 billion), USA (402 billion), Russia (363 billion), Japan (312 billion) and Indonesia (173 billion).

In 1996, Peto et al. had estimated that 30-40% of the 2.3 Billion children and teenagers in the world would become smokers in early adult life, and about 250 million of these future smokers would be killed by smoking. [4] At present nearly 40% of children worldwide are exposed to passive smoking. [3] The country with the highest proportion of children exposed to second hand smoke at home was Indonesia (63%). Second hand smoke exposure was also quite high in China (53%) and India (34%).

1.2.2. The Indian scenario

Tobacco was introduced in India 400 years ago by the Portuguese. The British introduced commercially produced cigarettes 200 years later, and also established tobacco production in the country. [5] In the next two centuries tobacco consumption grew at the rate of two to three percent per annum, and now, India is the second largest producer and the third largest consumer of tobacco in the world.[2] The pattern of tobacco use in India is different from other countries. Smoking *bidi* and the use of some forms of smokeless tobacco are peculiar to India. *Bidi*, a hand-rolled, filter-less tobacco cigarette, is a common alternative to the traditional cigarette and accounts for the largest portion of tobacco consumption. Among tobacco users, nearly 40% use *bidi*, 20% use cigarettes and 40% use various other forms of tobacco like hookah (a traditional water pipe for smoking), chewing pan (sliced arecanut, catechu and spices wrapped in betel leaf smeared with lime, for chewing), *khaini* (a mixture of tobacco flakes and lime to dip behind the lip or beneath the tongue), pan masala or *guthka* (a mixture of tobacco and areca nut for chewing), *mishri* (a powdered tobacco rubbed on the gums as toothpaste), nasal snuff etc. A population based, cross- sectional, house-to-house survey of nearly 100,000 people aged 35 years and above in the city of Bombay during 1992-94, found that about two-thirds of male and all of female tobacco users were using smokeless tobacco, and half of the male smokers were using *bidi* for smoking.[6] National Family Health Survey 2 (NFHS 2), a national level survey conducted in 1998-99 found that the prevalence of smoking and chewing tobacco or pan masala among men was 29% and 28% respectively, and among women was 2.5% and 12% respectively.[7] An estimation based on this survey assessed that about 194 million people (47% of men or 150 million and 14% of women or 44 million) above 14 years of age consumed some form of tobacco.[8] The follow-up national survey (NFHS 3) in 2005 – 06, among men between 15 and 54 years and women between 15 and 49 years found that the prevalence of both smoking and smokeless tobacco use had increased among men (33.3% and 38% respectively) and had decreased among women (1.6% and 9.9% respectively).[9] Both NFHS 2 and 3 showed a significant gender difference in tobacco use with more harm to men.

1.2.3. The Kerala scenario

In Kerala, the earliest reliable prevalence study on tobacco use covering the entire rural area of the state was conducted in 1987.[10] National Sample Survey (NSS) conducted in 1988 and 1993 – 94 also collected data on tobacco use in Kerala.[11] But these studies were not comparable with newer studies because of definitional problems and difference in methodology. The two comparable data sets were NFHS 2 and 3. The prevalence of current smoking among men and women found by NFHS 2, a cross sectional, population based household survey done in 1998-99 among a sample of 2834 households, was 28% and 0.4% and that of smokeless tobacco or pan masala was 9.5% and 10.5% respectively.[12] The follow up national survey (NFHS 3) in 2005-06, among men between 15 and 54 years and women between 15 and 49 years found an increase in the prevalence of current smoking among men (35.8%) and a decrease among women (0.1%) over the last seven years.[9] Prevalence of any tobacco use among this population was 43.5% among men and 1.8% among women. This study revealed a higher prevalence of current smoking among males in Kerala than in India as a whole. NFHS 2 and 3 found significantly higher prevalence of current smoking among men compared to women.

1.3. Tobacco addiction

Addiction is the loss of control of drug use and when a user would like to stop or reduce the level of consumption of an addictive drug, like nicotine, he would find it difficult to do so. Nicotine, the cause of tobacco addiction, is considered to be a highly addictive substance and is the most widely used substance of abuse.[13,14]

1.3.1. Tobacco toxins

Cigarette smoke is a dangerous cocktail of about 4,000 chemicals and more than 50 of them are cancer causing agents.[13] Secondhand smoke also contains hundreds of chemicals known to be toxic or carcinogenic.[15] The amount of tar, nicotine, and carbon monoxide present in the different brands of cigarettes, and in the same brand available in different geographical areas may differ. An analysis, using a standardized smoking machine method, of smoke deliveries of 77 cigarette brands purchased from 35 countries showed a variation of 6.8 to 21.6 mg of tar per cigarette, 0.5 to 1.6 mg of nicotine per cigarette, and 5.9 to 17.4 mg of carbon monoxide per cigarette.[16] This study also found that the brands of cigarettes from the Eastern Mediterranean, Southeast Asia, and Western Pacific WHO regions had higher tar, nicotine, and CO than the same brands from the European, American, or African WHO regions. The concentration of some chemicals in cigarettes and *bidi* were also different. *Bidi* is more addictive than cigarettes since nicotine concentration in the tobacco of *bidi* (21.2 mg/g) is significantly greater than the tobacco from the commercial filtered (16.3 mg/g) and unfiltered (13.5 mg/g) cigarettes.[17] Smokeless tobacco also contains nicotine, various nitrosamines and alkaloids. Chewing of betal quid can result in exposure to tobacco specific nitrosamines and arecanut specific nitrosamines.[18]

1.3.2. Mechanism of addiction

Smoking is associated with physical or physiological dependence, psychological dependence and behavioral or social dependence. Physical or physiological dependence is associated with direct and indirect effects of nicotine on brain neurotransmitters that are directly related to the behaviors associated with addiction and withdrawal. Nicotine from cigarette smoke is rapidly absorbed from the

lungs and quickly delivered to the brain where nicotine exerts its actions by binding to nicotinic cholinergic receptors (nAChRs) mainly the α4β2 receptor.[19] Nicotine stimulates the release of neurotransmitters to give a pleasurable experience, positive reinforcement, tolerance, and addiction. Hence most smokers suffer from withdrawal symptoms of irritability, restlessness, anxiety, problems getting along with friends and family, difficulties in concentrating, increased hunger and eating, and cravings for tobacco upon stopping smoking.[20] Further studies have found that the stimulation of nicotinic receptors in the respiratory tract plays a role in mediating the immediate subjective effects of cigarette smoking.[21] Therefore, controlled deep breathing was found to be useful in relieving symptoms of smoking withdrawal symptoms and craving during smoking cessation attempts.[22]

Psychological dependence is the influence on specific moods and "cues," like finger movement, lip movement, etc. When such cues are not satisfied the smokers will have irritation, anger, feeling of something lost, etc. Behavioral dependence is related to environmental factors associated with pleasurable or rewarding effects of nicotine. This is known as conditioning and is a powerful contributor to addiction in smoking. Thus, smoking becomes a specific behavior in association with drinking a cup of coffee or alcohol, friendship making and social gathering. Repetition of these coexisting behaviors over time leads to the behavioral dependence on smoke. Behaviors can be conditioned to either the positive or negative reinforcing effects of nicotine. The smoker can associate smoking with relieving other negative feelings, such as stress, since smoking becomes associated with relieving the negative affects of nicotine withdrawal. Managing conditioned behaviors is often an important factor in the success of nicotine cessation.

An extensive review on this subject by Rose in 2006 suggested that the substitutes for the sensory effects of smoking may be effective in relieving the craving for cigarettes and in facilitating smoking cessation.[23] He added that the techniques for devaluing smoking-related cues like de-nicotinized cigarettes and the use of nicotinic agonist and/or antagonist treatment during a quit attempt may decrease craving and enhance subsequent abstinence.

1.3.3. Measurement of addiction

Clinical and biochemical methods are available to measure the level of addiction. Estimation of concentration of nicotine or cotinine in blood, saliva and urine are useful biochemical methods. Two common clinical methods are the Heavy Smoking Index (HSI) score and the Fagerstrom Test on Nicotine Dependence (FTND) scale. An HSI score is based on two items: the time to the first cigarette of the day and the number of daily cigarettes. The FTND scale is based on six items as given below in Box 1. 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).

Box 1. Fagerstrom Test on Nicotine Dependence (FTND) scale

	Score			
	0	1	2	3
Time interval between first puff and waking up in the morning	After 60 m*	Between 31–60 m*	Between 6–30 m*	With in 5 m*
Quantity of smoking	1 - 10	11 - 20	21 - 30	> 30
Smoking is most hated to give up	No	Yes		
Difficult to avoid smoking in prohibited places	No	Yes		
Smoking more in the morning than the rest of the day	No	Yes		
Smoking while ill	No	Yes		

* minutes

1.4. Tobacco related mortality and morbidity

"An hour a day in a room with a smoker is about more than 100 times more likely to cause lung cancer in a non-smoker than one who spends 20 years in a building with asbestos" (Sir Richard Doll in 1985)[3]

1.4.1. Diseases due to direct effect

Tobacco harms every organ of the body.[24] Smoking can cause cancer that affects lips, mouth, throat, larynx, lungs, esophagus, stomach, pancreas, cervix, kidney, and bladder. The risk of cancer increases with the number of cigarettes smoked and the number of years of smoking. Smokers have about 20 times more risk of developing lung cancer than non-smokers. Smoking is responsible for 90% of lung cancers in men and 80% in women. Smoking also causes hypertension, stroke, heart disease, and other cardiovascular problems. The INTERHEART study, a cohort study conducted in 52 countries, estimated a risk of 2.95 (95% CI: 2.77-3.14) for a smoker to develop heart disease.[25] The International Studies of Infarct Survival (ISIS) collaboration study, with 14,000 cases and 32,000 controls revealed that 80% of heart diseases between 30 to 49 years, 67% between 50 to 59 years, and 50% between 60 to 79 years were associated with smoking, and the risk ratio for myocardial infarction (MI) was about five, three and two in the respective age groups.[26] The WHO MONICA study found that 50% of heart disease in males and females below 50 years of age was due to smoking.[27] One Indian case control study with about 1,000 participants revealed that the relative risk of MI among current smokers in urban areas was 4.7, and *bidis* were found to be equally dangerous as cigarettes in causing MI.[28]

Smoking is also a major cause of respiratory diseases, including obstructive lung diseases, influenza, pneumonia, tuberculosis (TB), and others. Several studies have shown an association between smoking and TB-related infection, disease and mortality. Smokers were found to have twice the risk of TB infection[29] and five times the risk of death due to TB.[30] Light smokers and heavy smokers were found to have two and four times the risk of contracting active TB disease respectively.[8] TB patients who continued to smoke after completing therapy had three times the risk of TB

relapse compared to those who did not smoke after therapy.[31] The risk of deaths from respiratory diseases (RR 2.12, 95% CI 1.57–2.87), tuberculosis (RR 2.30, 95% CI 1.68–3.15), and neoplasm (RR 2.60, 95% CI 1.78–3.80) was significantly higher in male smokers than never tobacco users.[32] Smoking causes menstrual problems and pregnancy complications in women, and infertility and impotence in both men and women.[33]

Gupta et al. reported that *bidi*s are not less hazardous than cigarettes, and that smokeless tobacco is also associated with higher mortality. An analysis of 52,568 participants in a cohort study followed up for five to six years revealed that the relative risk of all cause mortality among tobacco users was 1.39 for male cigarette smokers, 1.78 for male *bidi* smokers, and 1.35 for female smokeless tobacco users when compared to non users.[34] Later, an analysis of a larger sample (97,244 subjects) who were followed up for 5.5 years found that the adjusted relative risk of all cause mortality was 1.37 (95% CI 1.23–1.53) and 1.64 (95% CI 1.47–1.81) for male cigarette and *bidi* smokers respectively, with a significant dose response relationship for each cigarette or *bidi* smoked and 1.25 (95% CI 1.15–1.35) for female smokeless tobacco users.[32]

Smokeless tobacco is an important causative factor in cancers of the mouth, lip, tongue and pharynx. Arecanut chewing is the cause of Oral Submucous Fibrosis (OSF). Even smokeless tobacco can lead to heart and blood vessel disease.[28] The INTERHEART study found an odds ratio of 2.23 (95 CI: 1.41 – 3.52) for developing heart disease among those who chew tobacco.[25] Smokeless tobacco use during pregnancy was shown to have increased the chance of delivering a low birth weight baby by 40 to 90%, reduced the birth weight by 105 gm (95% CI: 30 – 181) and reduced the gestational age by 6.2 (95% CI: 3.0 – 9.4) days.[36]

1.4.2. Diseases due to indirect effect

The EPIC prospective study[36], the "5 B's" review[37] and a study by Lam et al. in Hong Kong[38] gathered evidence for association between secondhand smoke and lung diseases. Scientific evidence further indicates that there is no risk-free level of

exposure to secondhand smoke.[15] Exposure of adults to secondhand smoke has immediate adverse effects on the cardiovascular system and causes coronary heart disease. Even brief exposure can trigger respiratory symptoms, including cough, phlegm, wheezing, and breathlessness. Children exposed to secondhand smoke are at an increased risk of sudden infant death syndrome (SIDS), acute respiratory infections, ear problems, and severe asthma. Exposure to secondhand smoke during pregnancy caused poor birth outcomes such as pre-maturity, low birth weight and respiratory problems in the newborn. Nonsmokers who are exposed to secondhand smoke had increased risk of heart disease[25] of 25-30% and increased lung cancer of 20 – 30%.[16] A meta-analysis of 18 studies assessed a 25% excess risk of heart disease for those exposed to secondhand smoke.[39]

1.4.3. Disease burden due to Tobacco Use

1.4.3.1. The Global scenario

Globally, tobacco is the second major cause of death and fourth commonest cause of the global burden of disease (GBD).[40] In 2000, tobacco contributed 10% of deaths — 4.83 million deaths (2.41million in developing countries and 2.43 million in developed countries) and 4.1% of GBD.[41] The leading causes of death from smoking were cardiovascular diseases (1.69 million deaths), chronic obstructive pulmonary disease (0.97 million deaths), and lung cancer (0.85 million deaths). Peto estimates that tobacco use was responsible for over 100 million deaths in the last century and will be responsible for 1,000 million deaths in the present century.[42] Unless urgent steps are taken, about 650 million users (half the people that smoke today) will eventually be killed by tobacco.[43]

Tobacco will cause about 10 million deaths each year by 2020 and about 450 million deaths worldwide in the next 50 years if the current smoking patterns continue without any change. There are three different estimates about the number of lives that can be saved by reducing smoking at different levels. Peto calculates that 20-30 million premature deaths can be averted in the first quarter of the century and about 150 million deaths in the second quarter, if current smoking can be reduced by 50%; i.e., a 50% reduction in tobacco prevalence will save 200 million lives in the next 50 years. Mackay concludes that we may be able to avert more than 300 million tobacco-

related deaths in the next 50 years, if adult cigarette smoking can be reduced by 50%.[3] Frieden declares that more than 100 million deaths can be averted by 2020 if global adult smoking prevalence can be reduced by five percent.[44]

1.4.3.2. The Indian scenario

In India, tobacco related diseases are on the rise and in 2000 accounted for one million deaths annually.[45] Tobacco accounted for 13% of all deaths, 50% of cancers among men, and 20% of cancers among women in 1999.[46] About 90% of oral cancer and 60% of heart disease before 40 years of age were attributed to tobacco use. About 154,000 cancers, 4.2 million cases of heart diseases and 3.7 million cases of lung diseases in 1996 were ascribed to tobacco and the total cost due to these three diseases in 1999 was estimated as 277.6 billion rupees. Among urban males, tobacco use was estimated to be the cause of 53% of heart attacks.[28] Based on a retrospective study of 43,000 adult male deaths and 35,000 controls in rural Tamil Nadu, Gajalakshmy et al. predicted an annual national death toll of 700,000 people (660,000 males and 40,000 females) due to smoking alone.[47] Of these 550,000 deaths among men were in the age group of 25-69 years and one quarter of all deaths among middle aged men was attributed to smoking.

The total economic cost of tobacco use in India for the year 2004 was $ 1.7 billion (77% for smoking and 23% for smokeless tobacco use) and was 16% higher than the total excise tax revenue collected from all tobacco products in India during the financial year 2003 – 04.[48] This cost was much more than the expenditure of government of India for tobacco control activities in 2006 ($ 551876).

1.4.3.3. The Kerala scenario

In Kerala, available mortality and morbidity statistics attributable to tobacco are mostly on cancers. According to the population based cancer registry in the Thiruvananthapuram district, the age adjusted incidence of oral cancer had increased from 11.8 to 14.1 per 100,000 males between 2000 and 2002.[49] NFHS 3 has shown that two of the major tobacco related chronic diseases, namely diabetes and asthma, are higher in Kerala than in many other Indian states.

1.5. Tobacco control

Tobacco control measures are necessary to save millions of lives and to prevent immense economic loss. In order to achieve the Millennium Development Goals (MDGs) by 2015, the World Health Organization (WHO) urged all nations to include tobacco control as an ingredient of every aspect of policy.[50]

1.5.1. Evolution of tobacco control policies

Many countries in the world started implementing tobacco control measures of their own in the latter half of the 20th century.[51] The earliest and best examples are from New Zealand[52] and Thailand, [53] both of which achieved reduction in smoking prevalence by tax increases, advertising bans and strong warning labels. In the USA, a revolution in tobacco control occurred after 1996 when nicotine derivatives were made available over the counter along with other tobacco control measures.[51]

Any single measure is not an absolute solution to the problem. A comprehensive mix of policies and strategies that include both demand reduction measures and supply reduction measures are needed for effective tobacco control.[54] Tax increases, advertisement bans, smoking restrictions, warning labels display, public education, product regulation, and availability of cessation facilities are demand reduction measures. Control of smuggling, restriction of access to minors, and crop substitution are the supply reduction measures found useful to reduce the use of tobacco products.[55] The best practices for establishing comprehensive, sustainable and accountable tobacco control programs should include statewide programs, community programs, school programs, clinic programs and networking programs.[56]

1.5.2. Framework Convention on Tobacco Control (FCTC)

In the late 1990s, many developed countries started facing challenges and losing momentum for tobacco control activities. The tobacco industry penetrated markets across the world with an annual turnover of almost US$400 billion in 2000, using a wide range of methods to buy influence and power.[57] The industry was strong enough to topple even governments. The global community found a need for a united movement of countries against the threats of the tobacco industry. Thus WHO thought of a Global Tobacco Control Program in 1993.[58] After a series of discussions and

meetings, the World Health Assembly for WHO unanimously adopted the Global Tobacco Control Treaty on 21 May 2003, namely the Framework Convention on Tobacco Control (FCTC).[59] The FCTC entered into force on 27 February 2005 and as of March 2008, 168 countries have signed and 152 countries have ratified the treaty. The FCTC is a delicately balanced package considering the views of all three parties: the Government, the people and the industry. The FCTC (details given in annexure 1) aims to protect present and future generations from the consequences of tobacco use including health, social, environmental, and economic hazards through activities for preventing initiation of tobacco use, promoting quitting of tobacco use, and protecting non-smokers from environmental tobacco smoke (ETS).[59]

1.5.3. The tobacco industry's strategies against tobacco control

As the global movement to reduce tobacco use is gaining momentum, the tobacco industry has been adopting newer strategies towards countries unprepared to deal with its deadly products and deceptive marketing techniques. Cigarette manufacturers have used two complementary strategies to deal with the public relations problems resulting from the massive evidence that their products are highly addictive and fatal to their customers. The two strategies are defensive and offensive. The defensive strategy is aggressive lobbying by projecting weak or false scientific evidence (eg; tobacco prevents Alzheimer's disease) developed in favor of tobacco industry. The offensive strategy is to keep good public relationships by designing the products to appear safe. Filter cigarettes, cigarettes with low levels of tar or nicotine, and reduced ignition potential cigarettes (RIP cigarettes) are some examples. These products were often marketed with overt health claims. Although people could understand some false claims, they continued using them as they were addicted to tobacco. In addition, there is good evidence that those who smoke the so called low tar cigarettes believed that they were safer.

1.5.4. Effectiveness of Policy Measures

1.5.4.1. Impact of price measure

A study on cigarette prices in 80 countries for the years 1990 to 2001 showed that cigarette prices were higher in developed countries and lower in developing countries.[60] The cigarette had become more expensive in developed countries and less expensive in developing countries over the years. In India, the cigarette prices were higher earlier but have become less costly over the years and hence there is enough room for a price hike in India. Increasing price was found to be the single most effective measure to reduce short-term consumption and a useful measure to reduce long-term consumption.[61] The effect of change in price on change in consumption is measured in terms of price elasticity (P.E)[†]. The World Bank in 1999 and Chaloupka et al. in 2002 showed that P.E for developing countries was 0.8 and for developed countries was 0.4. P.E in South East Asia Region (SEAR) countries was found as 0.74 for short run and 1.21 for long run. Analysis of data from all 52 countries in the European Union revealed a P.E of 0.46 for local cigarettes and 0.74 for foreign cigarettes.[62] P.E in different countries varied from 0.4 to 1.6, but that for Russia and China was negligible due to low price and high levels of addiction.[63] Prevalence did not fall in California state of the United States between 1996 and 1999 even when there was a decrease in consumption with price hike due to the presence of hardcore smokers and occasional smokers.[64] The Community Intervention Trial for Smoking Cessation (COMMIT) survey from 1988 to 1993 found that P.E in US and Canada was 0.24 but there was no reduction in prevalence since[65] smokers adjusted by switching to lower priced brands with higher tar and nicotine when there was a price rise.[66] A two-year follow-up interview survey in Taiwan (2000-02) revealed that 72% did not reduce the number of cigarettes they smoked but 18% switched to lower priced brand and 28% reduced the number but 8% switched to a brand with high tar and nicotine.[67] Studies proved that the tobacco industry adjusted the tax hike by reducing the price,[68] giving a subsidy to teenagers,[69] smuggling, tax evasion and tax avoidance.[70, 71]

[†] It is the measure of inverse variation between consumption and price. It is also the percentage reduction in tobacco consumption for 10% increase in price.

1.5.4.2. Impact of non price measures

Global experiences of various non price measures are given below in Box 2.

Box 2. Global experiences of various non price measures

Measures	Global Experiences
Advertise-ment ban	Consumption decreased up to 9% in five countries (Norway, Finland, Canada, New Zealand and France),[72] by six percent in 22 high-income countries,[55] and seven percent in European Union. Smoking scenes in films increased after 1990 in many countries[73] including India.[74] (Such scenes promoted smoking habits among teens.[75, 76])
Smoking restrictions	Consumption decreased in public places by four to 10%,[55] in work places by 2.8 to 4.7%,[77] and in schools by 5 to 11%.[78] Cigarette consumption decreased in work places by 29% and smoking prevalence reduced by 4% (26 studies from US, Australia, Canada and Germany).[77] Restrictions in work places may be useful to reduce the consumption but its effectiveness in bringing down prevalence is doubtful (Cochrane meta analysis).[79]
Public education	Smoking prevalence decreased by 4% in Massachusetts and more than 1% in comparison states of US.[80] Quit rate and quit attempts increased a little but reported doubtful reliability due to the presence of concurrent events in the community (Cochrane review).[81] Health warnings on cigarette packages were a prominent source of health information and useful only to promote quitting among those who were thinking of quitting by other measures.[82]
Cessation programs	Community interventions increased knowledge of health risks, changed attitudes to smoking and increased quit attempts but this rarely led to higher quit rates (Cochrane meta analysis).[83] Contact with a health professional increased cessation and the effectiveness of professionals decreased from doctors to multi provider teams, dentists, and nurses in that order (meta analysis).[84]

Price raise was an effective measure to reduce consumption but cigarette consumption decreased only when the price rise made cigarette unaffordable. When the price exceeded the affordable level hard core smokers adjusted by brand switching, either to low priced brands to avoid reduction in number or to brands with high levels of nicotine and tar to get the required levels of chemicals with fewer cigarettes. In India, since products with wide range in price and quality are available, hard core smokers, occasional smokers, and price insensitive smokers have enough options to adjust to a price hike by switching the brands of cigarettes or switching from cigarettes to *bidi* or smokeless tobacco. Advertisement bans and smoking restrictions were useful to augment the impact of price measures in forcing tobacco users to quit. Warning labels, social attitudes, legislation and public health measures served as important sources of motivation to quit smoking and many smokers could give up smoking without any individual intervention. But many others could not quit on their own and needed assistance to achieve successful quitting. It is also vital to encourage and support smokers to quit as early as possible. Hence cessation programs should be a compulsory component of all evidence-based best practices of tobacco control programs in every country in order to achieve mortality reduction within the next few decades.

1.5.5. Legislation in India

In India, legislation against tobacco started in 1975 with the "*The Cigarette Act 1975,*" which made publishing of warning labels in cigarette packets and cigarette advertisements mandatory, but there was no specification about the size or wordings.[85] Thus, the industry started using the phrase, *"smoking is injurious to health"* in cigarette packets, but in very small letters so that it is neither easily visible nor readable. Then another law was enacted, the Tobacco Board Act 1975, which imposed certain restrictions on farming tobacco. In 1991, WHO and the Government of India jointly organized the Conference on Tobacco or Health in Delhi. The Government of India accepted all recommendations and enacted several rules during 1991 to 2002. The Indian Railways banned sale and use of cigarettes initially, and *gutka* and pan-masala later, on platforms and in railway compartments.

In 2003, the Government enacted the comprehensive Tobacco Control Rule namely "The cigarettes and other tobacco products (prohibition of advertisement and regulation of trade and commerce, production, supply and distribution) bill, 2003".[86] The provisions of these laws are given in the Box 3. In 2005, the government imposed some restrictions even in the display of boards at the point of sale and banned tobacco scenes in films but allowed displaying smoking scenes of historic characters as such if they were smokers, as well as tobacco scenes present in live telecast and scenes present in the foreign films.[87] As per the new rule viz Prohibition of smoking in public places rules, 2008, which came into effect on 2, October 2008, the owner, proprietor, manager, supervisor or officer in charge of the affairs of public place was made responsible for ensuring the place is smoke free.[88] This rule permits smoking areas in air ports, hotels with 30 or more rooms, and restaurant with 30 or more seats but with stringent conditions. In addition to police officers, a large number of other personnel were also authorized to impose and collect fines against violations of this rule. The government announced descriptive rules regarding packaging and labeling of tobacco products that it planned to implement beginning on 30, November 2008.[89, 90]

Box 3. Cigarettes and Other Tobacco Products Act, 2003

- Total ban on direct and indirect advertisements of all tobacco products
- Prohibition on sponsorship of sports and cultural events
- Ban on smoking in public places
- Ban on sale of tobacco products to minors
- Pictorial depiction of specified health warnings
- Restrict nicotine and tar contents and depict the levels in packages in future
- Ban on sale of cigarettes and tobacco products within a radius of 100 yards of educational institutions

1.6. Tobacco cessation

"Knowing is not enough; we must apply.
Willing is not enough; we must do." (Goethe)[91]

Campbell defines smoking cessation as validated sustained abstinence from cigarettes and/or other tobacco products for at least six months, but preferably for a year.[92]

"To cease smoking is the easiest thing I ever did. I ought to know because I've done it a thousand times." This popular quotation, attributed to Mark Twain reveals the difficulties of long-term quitting.[91]

Substance dependence is determined by psychosocial, cultural, environmental, biological and genetic factors that may or may not be cured but can be treated effectively, much like a neurological or psychiatric disorder.[14] Tobacco dependence is to be considered as a treatable chronic disease like diabetes, hypertension and hyperlipidemia.[93] Like any other chronic disease repeated relapses are common in tobacco dependence and need to be treated.

1.6.1. Health benefits of cessation

The potential health benefits of smoking cessation are substantial. Smoking cessation benefits virtually every smoker regardless of age, sex, disease state, or years of smoking.[94] The quit rate and extent of harm reduction by smokers varies with diseases.[95,96] After smoking cessation, the risk for lung cancer decreased over 10 years to about 30–50% that of continuing smokers, but the risk remained high even after 20 years of abstinence compared to non- smokers.[97] Success in quitting yielded an increase in life expectancy of up to 10 years. Cessation not only reduced the risk of tobacco related diseases and retarded the progression of established tobacco related diseases but also increased the life expectancy even when smokers quit smoking after the age of 65 years or after the development of tobacco related disease.[98] The excess risk of death from smoking falls soon after cessation but continues for at least 10-15 years. Irrespective of the age of quitting, former smokers lived longer than smokers

who continued, though the benefit was greater with quitting at younger ages. Survival of smokers who stopped before 35 years is about the same as that for non-smokers.

The risk of heart disease decreased much more quickly after quitting smoking and the excess mortality due to smoking decreased by 35% with in two to four years. In a meta-analysis by Wilson and colleagues in 2000, the odds ratio for death for smokers who stopped smoking after myocardial infarction was 0.54, against an odds ratio of more than 0.75 for the control group of smokers who got conventional standard treatments following myocardial infarction.[99] Smoking cessation also reduced the risk of death after a stroke and episodes of pneumonia and influenza. Cessation resulted in a small increase in lung function and reversed the effect of smoking on subsequent rate of decline in lung function.[100]

1.6.2. Interventions for cessation

The U.S. Department of Health and Human Services (USDHHS) has published the first comprehensive guideline for the treatment of tobacco use and dependence.[101] Subsequently some national governments (Canada, Australia, New Zealand, UK) have come out with their own guidelines with some modifications for implementation in their own countries.[102-105] Several journals have published articles based on the USDHHS guideline[93, 106-109] All these guidelines and hundreds of research reports, all from abroad, clearly reveal that effective tobacco dependence treatments are a reality now. According to these guidelines, smoking cessation methods can be behavioral, drug, and alternate methods (Box 4).

1.6.2.1. Behavioral interventions

Theories and models of human behavior can explain the reasons for indulging in tobacco use, and guide the development and refinement of health promotion and education efforts. There are several psychological models to explain human behavior such as the Health belief model,[110] Theory of Reasoned action, Social cognitive theory or Social learning theory, the Trans-theoretical model or the Stages of change model,[111] and the Pressure system model.[112]

Box 4. Methods for smoking cessation

Behavioral Interventions	• Doctor's Advice • Health Professional (HP) Intervention ▪ Individual / Group / Telephone counseling • Self Help Materials supply
Drug Interventions	• First line drugs ▪ Nicotine Replacement therapy ▪ Lozenges, Gum, Tablets, Patch, Inhaler, Nasal spray ▪ Non Nicotine drugs ▪ Bupropion, Varenicline • Second line drugs ▪ Nortryptyline, Clonidine • Less used drugs ▪ Anxiolytics, Mecamylamine, Lobeline, Opioid agonists, Silver Acetate, Placebo • Nicotine Vaccine
Alternative Interventions	• Acupuncture, Hypnosis, Aversive Therapy, Exercise

The Behavioral approach for smoking cessation is largely based on the trans-theoretical model (TTM) and includes stage-based interventions. This model separates individuals into five different stages:

- pre-contemplation (not thought of quitting smoking within the next 6 months),
- contemplation (thought of quitting smoking),
- preparation (preparing to quit smoking and waiting for a trigger point like disease),
- action (stopped smoking)
- maintenance (sustaining smoking cessation more than 6 months).

Usually progression through the stages is sequential although relapse to an earlier stage can occur. Interventions derived from stage theories of behavior change usually

incorporate several key elements. It is necessary to accurately identify an individual's stage of change (or readiness to change) so that an intervention based on stage specific processes of change can be applied. Stage of change needs to be reassessed frequently, and the intervention should reflect changes in the individual's readiness to change. These elements of the intervention are repeated until the individual achieves and maintains the change in behavior. In this way, stage based interventions evolve and adapt in response to the individual's movement through the stages of change. Many studies agree with the stages of change theory except one, which questioned the validity of the stages of change algorithm since more than half the pre-contemplators in his study were contemplating cessation and most contemplators were not merely contemplating cessation but were trying to quit.[113]

Behavioral interventions in tobacco use: Behavioral therapy provides help to avoid stimuli that trigger smoking (such as alcohol use, first morning coffee or tea, stress, and smoking friends). It attempts to alter routine smoking, anticipate cravings, and address the consequences of nicotine withdrawal (such as oral needs, weight gain, cough and cravings). This is possible by

- doctor's advice of varying session length and frequency,
- Non-Doctor Health Professional (NDHP) advice in the form of individual counseling (a face to face program tailored for the individual),
- group counseling (a program to address a group of smokers by one health professional to give common messages and techniques so that participants can help each other later to solve their problems and to support each other),
- telephone counseling (a program to provide necessary information through interactive sessions through a telephone quit line) etc.

The effectiveness of different cessation approaches vary by the type of adviser, duration of advice, number of sessions, type of counseling and characteristics of the beneficiary.

Self-help materials: Another means of behavioral approach is supply of self help materials. There are several dozen quit-smoking pamphlets, books, and guides available from developed countries offering tips on how to quit smoking. These

materials can be culturally adapted to help smokers in identifying smoking triggers, handling smoking situations, relaxation exercises, and controlling weight. There are videotapes, quit-by-mail programs, telephone hotlines and even computer programs available abroad to assist the smoker to quit.

1.6.2.2. Drug interventions

Drug therapy has been increasingly relied upon in developed countries to assist smoking cessation. Nicotine medications attenuate the symptoms of abstinence and satisfy craving by substituting nicotine through safer means. This is the rationale of nicotine replacement therapy.[114] Nicotine medications sustain existing nicotine-mediated neuro-pharmacologic effects through three main mechanisms: reduce withdrawal symptoms (all or prominent ones) and enable people to function while they learn to live without cigarettes; reduce the reinforcing effects of tobacco-delivered nicotine; and provide some effects for which the patient previously relied on cigarettes, such as sustaining desirable mood and attention states.[115] It thus makes it easier to handle stressful or boring situations, and to manage hunger and body weight gain. Nicotine patches are applied once daily while other therapies are self administered more than once a day on need basis. Nasal sprays provide the fastest delivery and the highest levels of nicotine.

Nicotine replacement therapies should generally be avoided or used with caution in special populations, including pregnant women, patients with cardiovascular disease, adolescents, and people who smoke fewer than 10 cigarettes per day.[101, 116, 117] The choice of product is typically based on a patient's preference, his or her medical history and potential contraindications or precautions. One randomized trial with 504 patients who were followed up for 12 weeks to compare four different nicotine medications (gum, patch, inhaler and nasal spray) revealed that the products did not differ in their effects on withdrawal discomfort, urges to smoke or abstinence rates. But treatment compliance was high for the patch, low for gum and very low for spray and inhaler.[118]

Bupropion, an anti-depressant drug, acts by relieving some withdrawal symptoms including depression. It is ineffective in preventing craving, anxiety, restlessness or hunger. The effectiveness can be increased by combining with nicotine

medications or behavioral therapy. Varenicline, a partial agonist of nicotine receptor α4β2, acts by (1) releasing dopamine and creating similar reinforcing effects but not to the full extent that nicotine does because of its partial binding of the receptor and (2) binding to the nicotine receptor (like a physical antagonist) and blocking the effects of nicotine or a nicotine replacement agent. If a patient smokes while using varenicline, the drug will block the ability of nicotine to bind to the receptor and, therefore, block the dopamine-induced behavioral reinforcement. The drug can simulate the pleasure and reward effects of dopamine release to reduce withdrawal symptoms and cravings. Clonidine and nortryptyline are other possible drugs but their use is limited due to less effectiveness and more side effects.

Nicotine vaccine: Nicotine-specific vaccine is a novel approach to treat nicotine dependence and is in the developmental stage only.[119] This vaccine will stimulate the formation of antibodies (Nic-IgG) that have a high affinity and specificity for nicotine.[120] These antibodies neutralize nicotine in the blood and thereby prevent its entry into the brain and block the nicotine-induced release of dopamine in the nucleus acumens of the brain.[121] Thus it blocks the rewarding effects of nicotine, and also prevents nicotine from relieving the symptoms of withdrawal, thereby helping in quitting and reducing relapse.

1.6.2.3. Alternative interventions

Acupuncture and related techniques are promoted by some people as a treatment for smoking cessation believing that they may reduce nicotine withdrawal symptoms. Hypnotherapy is also promoted as a method for aiding smoking cessation in some parts of the world. It is supposed to act on the underlying impulses to weaken the desire to smoke or strengthen the will power to stop. Regular exercise may help people give up smoking by moderating nicotine withdrawal symptoms and cravings.

Another type of behavioral therapy associated with superior outcome is aversive smoking. This involves sessions of guided smoking where the patient smokes intensively, often to the point of discomfort, malaise, nausea, and/or vomiting. This may extinguish the urge to smoke. Some aversive smoking techniques, such as rapid smoking, may constitute a health risk and should be conducted only with appropriate

medical screening and supervision. Aversive smoking interventions are infrequently used today. Aversive smoking interventions (rapid smoking, rapid puffing, other aversive smoking techniques) increase abstinence rates and may be used with smokers who desire such treatment or who have been unsuccessful using other interventions.

1.6.2.4. Global evidences of effectiveness

An extensive Medline search was done in September 2006, before the beginning of this research study, with search words (1) smoking cessation methods and (2) treatment of nicotine dependence, to get free access review articles with meta-analysis and guidelines in English to find the effectiveness of smoking cessation methods. Four guidelines and 84 reviews including one review from India were obtained. The United States Department of Health and Human Services (USDHHS) Clinical Practice Guideline,[101] Cochrane reviews and studies published by Gorin et al[84] and Watts et al[122] had their own meta-analyses reports. All other reviews have quoted Cochrane reviews or USDHHS guideline as their sources of evidence.

USDHHS first published the Clinical Practice Guideline (CPG) for Treating tobacco use and dependence in 1996 and updated it in June 2000. The guideline is based on two systematic reviews of all available scientific literature until then. The first review, conducted in 1995, included 3000 articles identified from studies between 1974 and 1994. The second one, conducted in 1999, reviewed another 3000 articles identified from studies between 1995 and 1999. Both reviews were combined to get a database of 6000 articles which were published from 1 January, 1974 to 1 January, 1999. The database was screened to get articles based on randomized controlled trials that were followed up to at least five months after quit date and published in peer-reviewed journals. Among the above mentioned 6000 articles, 180 articles were from meta-analysis and 500 other general articles. In addition, the USDHSS also conducted 50 meta-analyses to get evidence for different interventions.

Cochrane reviews[123-133] provide combined results of the world's best medical research studies and are recognized as the gold standard in evidence-based healthcare. Cochrane published the initial reviews on tobacco cessation in 2004. The review was based on meta-analyses of high quality data registered with the Cochrane

library through March 2004. Only studies that assessed the abstinence rate at least six months after first advice were considered for analysis. Analyses were based on 39 trials conducted between 1972 and 2003 that studied more than 31,000 smokers. Most participants in these trials were from unselected populations and the most common setting was primary care. This review was further updated in 2006.

Gorin and colleagues conducted meta analysis of 37 articles published between 1990 and 2004 on evidence of brief intervention by various health professionals. Watts and colleagues reviewed literature on evidence of pharmacotherapy published from January 1999 to January 2001 and conducted meta-analyses.

These studies show that the chance of quitting smoking with behavioral intervention commonly varies from 1.1 to 2.5 and with drug therapy ranges from 1.5 to 2.8 compared to control groups. The usual effect size of quitting achieved with behavioral intervention varied from 8.6 to 12.8 but that of drug therapy varied from 13.2 to 16.6. Thus, the effectiveness of behavioral intervention and drug interventions are comparable, although the comparisons of success rates between trials are difficult to interpret because of methodological differences.

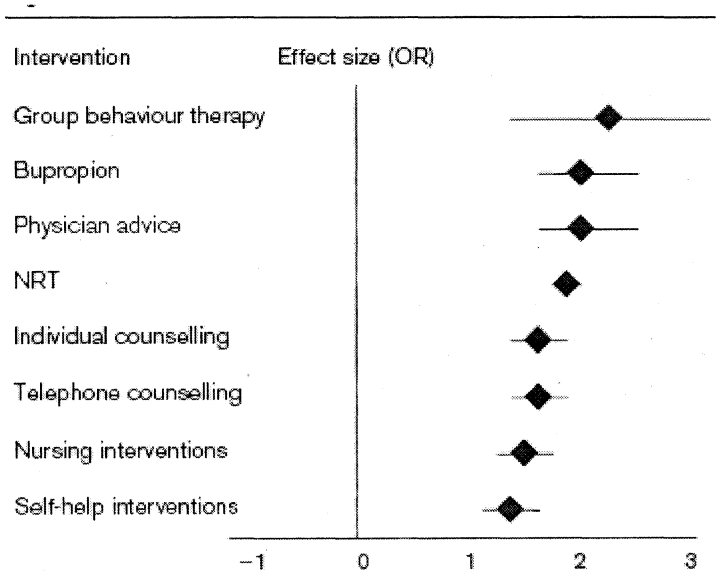
Important results selected from the above studies are given in Table 1. Detailed results are included as annexure 2.

Table 1. Results from meta-analysis studies

Intervention	Agency	Number of trials	Effect Size %	OR (95% CI)
Doctor Advice				
Brief advice vs. no advice	Cochrane Library, 2006	17	2.5	1.74 (1.48 – 2.05)
	USDHHS, 2000	7	2.3	1.3 (1.1 – 1.6)
Brief advice vs. minimal advice	Gorin et al, 2004	13	-	6.01 (2.46 – 13.29)
NDHP* advice				
Brief advice vs. no advice	Cochrane Library, 2006	20	1.2	1.47 (1.29 – 1.68)
	USDHHS, 2000	29	5.6	1.7 (1.3 – 2.1)
Individual counseling vs. no counseling	Cochrane Library, 2006	18	4.0	1.56 (1.32 – 1.84)
	USDHHS	58	6.0	1.7 (1.4 – 2.0)
Self Help Materials				
Provide materials vs. No materials	Cochrane Library, 2005	11	slight	1.24 (1.07 – 1.45)
	USDHHS, 2000	29	0.7	1.1 (0.9 – 1.3)
Multiple Interventions				
2 types intervention vs. no intervention	Cochrane Library, 2006	-	-	-
	USDHHS, 2000	54	7.7	1.9 (1.6 – 2.2)
NRT† vs. no drug or placebo[129]				
Any form of NRT vs. no drug or placebo	Cochrane Library, 2006	96	7.0	1.77 (1.66 – 1.88)
	USDHHS, 2000	-	-	-
GUM (NRT) vs. no drug or placebo	Cochrane Library, 2006	51	8.0	1.66 (1.52 – 1.81)
	USDHHS, 2000	13	6.6	1.5 (1.3 – 1.8)
Buproprion vs. no drug or Placebo	Cochrane Library, 2006	19	10.0	2.06 (1.77 – 2.40)
	USDHHS, 2000	2	13.2	2.1 (1.5 - 3.0)
Nortiptyline vs. Placebo	Cochrane Library, 2006	4	12	2.79(1.70 - 4.59)
	USDHHS, 2000	5	11.7	2.1 (1.4 – 3.2)

*Non Doctor Health Professional; †Nicotine Replacement Therapy

In 2008, Fiore et al. updated the USDHHS Guideline[134] reflecting the distillation of a literature base of more than 8,700 research articles published from 1975 to 2007 and Valery et al. developed a pictogram to show the effectiveness of various smoking cessation interventions as shown below in Figure 1.[135]



Graphic overview of effect sizes of interventions for smoking cessation. NRT, nicotine replacement therapy; OR, odds ratio.

Fig 1. Effect size of various interventions cited from Valery et al.[135]

1.6.2.5. Predictors of outcome

Smoking behavior and smoking cessation behavior are complex. Literature describes four stages of quitting smoking:

1. intention to quit (stage of contemplation to quit at some point in the smoking career),
2. quit attempt (stage when smoking cessation lasts more than 24 hours),
3. initial quit success (stage when abstinence period lasts for days or weeks) and
4. long term quit success (stage when abstinence period indefinitely continues for months and years).

In general practice, promoting lifestyle changes is difficult since health-related habits are influenced by deeply rooted demographic, socioeconomic and cultural factors.[136] Many of these characteristics can be modified so as to increase the chance of success. The role of possible predictors of successful stopping smoking has not been consistently and unequivocally identified even after several studies. Despite this, different studies have demonstrated the effectiveness of interventions to influence an individual's chances of success in stopping smoking. Assessment of patients' individual characteristics would allow doctors to target their efforts both on patients for whom stopping smoking is likely to be particularly difficult and on patients most likely to succeed. The predictors of success may be grouped as patient factors, provider factors and societal factors.

Patient factors: Patient factors include demographic profile (age, sex, and socioeconomic status), individual beliefs and attitudes, disease profile, level of addiction, self-efficacy, quit experiences and coping skills. A Medline search in 2006 revealed that the last comprehensive review on the subject was in 1992 by Lennox, based on 87 articles and reports published before 1991.[137]

Demography: Lennox found that age and socioeconomic status had no influence on the outcome of cessation attempts and that females had a lower success rate. He also found that the chances of success in any one quit attempt decreased with increase of age. The proportion of ex-smokers to smokers was higher at a higher age owing to an

increase in the total number of attempts with age and increased mortality of smokers of a higher age. But several studies conducted later differed from his findings and showed more quit attempts in younger ages and better quit success with older ages. Male sex, white race and higher socioeconomic status were found to be positively associated with both quit attempts and quit success.[138-143] The association of quit success with higher age and higher socioeconomic status was further strengthened by a 10 year longitudinal study of 2554 Danish adults.[144] A European multi-centric trial (CEASE) also found an association of higher age, male sex and good housing with quit success but no association of education and employment with quit success.[145] Another one year follow up study conducted in the United Kingdom in 1996 failed to find association between demographic characteristics and both quit attempt and quit success.[146] Then the four country study conducted in the United States, Canada, United Kingdom and Australia between 2002 and 2003 with a nationally representative sample of 6682 current smokers ruled out association of age, sex and socioeconomic status with both quit attempt and quit success.[147] A six year longitudinal study of 454 smokers residing in 83 areas of Netherlands revealed that the odds of both quit attempts and quit success among smokers living in deprived area was low, irrespective of the demographic profile.[148] In deprived areas prevalence of smoking may be high. Hence peer influence to continue smoking will be high and social pressure to quit will be low. Therefore factors like peer influence, social pressure, health concerns, etc may be more crucial determinants than demographic factors for quit attempts and quit success.

Individual beliefs and attitudes: Perceived beliefs and attitudes regarding health and disease determine behaviors including smoking. Knowledge and perceptions are the basis of beliefs and attitudes. Perceived beliefs and attitudes regarding the health consequences of smoking and health benefits of giving up smoking showed an association with intention to quit.[149, 150]

Health concerns: In a comprehensive review of the literature spanning five decades, McCaul and colleagues found that the primary factor motivating smokers to quit was health concern.[151] This finding was robust across retrospective studies of former smokers and cross-sectional studies of current smokers. Health concerns were also

reported as a primary motivating factor among smokers in the COMMIT survey, a cohort study that monitored smokers for 13 years. Smokers who had made one serious attempt to quit in the period from 1988 to 2001 reported that the most common reasons for quitting were concerns for current and future health (92 percent), expense (59 percent), concern for effects on others (56 percent), and setting a good example for children (52 percent).[139] These results were similar to those found in an earlier COMMIT survey (1988 to 1993).[140] Attempts of smoking cessation before the onset of heart disease had shown very low rates of success[152] and after the onset of disease had shown variable success rates of up to 71%.[153] Stress was shown to be adversely associated with both short term and long term cessation. Stress factors like anxiety, depression, higher frequency of life events and lower personal security were found to be associated with less long term success in stopping smoking. Lower stress levels usually predicted long term abstinence but not quit attempts.

Nicotine dependence: There is conclusive evidence that a higher level of nicotine addiction is associated with difficulty in quitting. This relationship was found to be true even when other variables were controlled. Fewer cigarettes a day had the strongest association with quit attempts[147, 154] and quit success.[137, 138, 146, 147, 154] Studies analyzing the relationship of quitting with the time of first cigarette of the day, FTND score and HSI score revealed varying results. Several studies demonstrated low success in any one cessation attempt when the duration of smoking career was long.

Past quit attempts: Repeated quit attempts, longer duration of quit period and fewer withdrawal symptoms were other favorable predictors of quit attempt and quit success. [137, 140, 146, 147] Withdrawal symptoms were seldom recognized as the immediate precipitant of a relapse. Ex-smokers who relapsed within one week of stopping smoking were more likely than those who relapsed later to attribute their relapse to withdrawal symptoms. The people who relapsed early after giving up smoking were more likely to be heavy smokers' who experienced frequent cravings.

Self efficacy: Lennox found from various studies that the role of coping skills was large in preventing relapse. The use of multiple coping skills was associated with long term abstinence and doubled the chances of surviving a crisis. Indicators of self efficacy like various measures of strength of desire or motivation to stop smoking,

readiness to quit smoking and confidence to quit smoking were shown to correlate positively with quit success.[146]

In an intervention program, if the participant is in the stage of pre-contemplation the counselor has to motivate the smoker to intensify the desire so that it creates the intention to quit. This is possible by creating awareness on the harms of tobacco and changing beliefs through health education and advice. If the participant has intention to quit, they should be encouraged to attempt a quit and helped to develop multiple coping skills. Simple increase in the number of quit attempts itself increases the chance of quit success. As long as the socio economic characteristics of a particular participant remain constant, the relevant factors that can be changed are the level of daily smoking, self-efficacy and coping skills. When a smoker is not addicted to nicotine and not using more than ten cigarettes per day behavioral intervention is the best way to build up self-efficacy and coping skills. We may be seeing more addiction among those who smoke fewer than 10 cigarettes per day. In a number of countries, smokers have cut back due to increased price and smoking restrictions. There are other smokers who have cut back in an attempt to reduce their risk and yet still are very much nicotine dependent. Medications may be indicated in these cases.

Provider factors: Provider factors include attitude, knowledge, skills, and time availability of providers and type of intervention used. Training health professionals to provide smoking cessation interventions has a measurable effect on professional performance. The Cochrane review in 2000 found that the training program had increased the chances of asking and advising but not increased the quit rates.[155]

Societal factors: Several studies have shown that the support of non-smoking friends and family members enhances the outcome. Better outcome was found in subjects whose partners participated in a reinforcing or encouraging, rather than a policing or nagging role. The USDHHS guideline reported a three to five percent increase in quit rates when there was social support along with other components for smoking cessation. Meta analyses conducted by two agencies failed to find an increase in quit rate in programs designed to increase social support. [155-157] Both reports suspected that the social support component might not really have supported the smoker. West and

colleagues found that the objection of a partner had an association with quit attempt and no association with quit success.[146] He could not attribute a significant association of quitting smoking with the presence of children in the family. But qualitative studies in Kerala found that a male smoker did not respect the objection of his wife but tried to comply with the objection of children.[158]

Table 2. Predictors of intention to quit attempt and quit success

	Quit intention	Quit attempt	Quit success
Desire to quit smoking	✓		✓
Awareness of harms of smoking	✓		
Motivation, health beliefs and concerns	✓		
Past quit attempts		✓	✓
Fewer daily cigarettes		✓	✓
Age		✓	✓
Males			✓
Fewer withdrawal symptoms and cravings		✓	✓
Presence of multiple coping skills		✓	✓
Self Efficacy			✓

✓ Represents positive association

An adverse relationship exists between outcome and the number of smokers in the environment. Alcohol consumption is a common cause for relapse. Studies have found that over 20% of all relapses occurred while subjects were drinking alcohol. Family crises, such as an argument with the spouse, or work-related crises, such as pressure to meet a deadline were other causes for relapse.

1.6.3. Tobacco cessation in primary care

Health promotion and prevention are important in primary care. Primary care workers are engaged in many preventive activities including immunization and health education as well as disease control activities including early detection and treatment of high blood pressure, diabetes, smoking and other lifestyle risk factors. Primary care workers are in a unique position to identify and intervene with patients whose

substance use is hazardous or harmful to their health and wellbeing. Patients view primary care as a credible source of advice about health risks.

Globally, most smokers are addicted to nicotine and fail repeatedly in their attempts to quit. Smokers who attempt to quit smoking with the use of some assistance succeed better than self-quitters. However, many smokers do not know about effective cessation methods.[159] Several studies have shown that tobacco cessation advice provided by health professionals including doctors, nurses, dentists, and dental hygienists enhanced the quit rate among their patients. The code of practice on tobacco control agreed upon by WHO and health professional organizations encourages health care professionals to routinely ask patients about tobacco consumption and exposure to tobacco smoke, to give advice patients on how to quit smoking and to ensure appropriate follow-up of their cessation goals.[160] Researches have shown that smokers prefer to get advice and programs through their doctor or other health professionals.[84, 101, 106] Intervention in health system should be brief intervention or intensive intervention depending on the length and duration of intervention sessions, type and number of providers, nature of settings for intervention, etc. Every tobacco user should be offered at least a minimal intervention. Minimal interventions lasting less than three minutes have increased overall tobacco abstinence rates.

1.6.3.1. Brief Intervention

The term brief intervention refers to a variety of treatment strategies involving opportunistic advice, discussion, negotiation or encouragement and/or counseling with or without drug supplementation. An important primary impact of brief intervention is motivation. The effect is to trigger a decision and commitment to change. A high percentage of pre-contemplators and early contemplators can be detected by screening procedures and can challenge them to foster a decision and commitment to change. Once this motivational decision has been made, the individual can proceed to apply their own natural skills to accomplish change.

Brief interventions typically take 5 to 10 minutes, but even interventions as brief as three minutes are effective in promoting quitting smoking. The intervention package will depend on a number of factors like an individual's willingness to quit, acceptability of intervention offered and previous ways they have tried to quit etc. The

basic package should include (1) simple opportunistic advice to stop (2) an assessment of the patient's commitment to quit and (3) an offer of behavioral support that includes a provision of self-help material and a referral to more intensive support if required. The popular approach for smoking cessation is the 5 A's model for all hospital clinics. The steps in this model are

(1) **Ask** and identify the smoker at every opportunity. Implement a systematic plan in the clinic to screen all patients to identify and document all tobacco users.

(2) **Advise** all smokers to quit. Urge all tobacco users to quit tobacco use by giving a strong, clear, and highly personalized message.

(3) **Assess** smokers' willingness to quit. Find out whether the smoker is in pre-contemplation, contemplation, preparation, action or maintenance phase.

(4) **Assist** smokers to stop. Provide necessary guidance and support depending on the stage of willingness to quit.

(5) **Arrange** follow up contacts. Take steps to follow up during next visits or through telephone or home visits.

A patient-specific approach should be used for patients contemplating or actively involved in quitting. Different counseling styles should be used for a motivated patient attempting to quit and an unmotivated patient who may just be considering quitting. For patients who are not motivated to quit use the Five R's (Box 5) and for patients who are ready to quit provide assistance by counseling and advice (Box 6).

This model is from developed countries. In developing countries also public health intervention for smoking cessation is urgently needed[162] and a suitable model has to be developed through a series of baseline studies. [163]

Box 5. Five R's for motivational intervention

Five R's

1. Encourage the patients about the **relevance** of quitting smoking in the presence of his health problems or family situations.
2. Discuss the **risks** associated with continued smoking, including acute risks (like breathlessness, decrease in performances, infertility), long-term health effects (like heart attacks, stroke, cancer), and family risks (like diseases to spouse, children, adaptation of smoking behavior by children).
3. Emphasize the **rewards** and benefits of quitting, such as improved health, cost savings, and good family relations.
4. Address **roadblocks** or barriers that are specific concerns, such as withdrawal symptoms, cravings, fear of relapse in the past, or lack of social support.
5. **Repetition** of asking and educating patients at every visit reinforces the importance of quitting.

Box 6. Assistance for Quitting

Help in the preparation of quitting	• Set a quit date within two weeks • Inform family members and friends as appropriate • Anticipate challenges • Remove tobacco products from surroundings
Provide practical counseling to solve problems	• Coping methods to tide over withdrawal discomfort and cravings • Methods to avoid triggers, abstain from alcohol • Techniques to escape from or acquaint with smoking friends
Provide i/t† social support	• Offer support from health system when needed
Provide e/t‡ social support	• Help them to seek and gain support from family members and friends
Drug therapy	• Prescribe suitable drugs if needed
Provide materials	• Supply materials for self learning

†intra-treatment; ‡extra-treatment

Chapter 2
Rationale and Objectives

Based on the literature review, evidence for tobacco cessation is very strong. In order to reduce tobacco-related mortality over the next 30 to 50 years, smoking cessation must be promoted and adult smokers should be encouraged to quit. Preventing young people from starting smoking would cut the number of deaths related to tobacco, but not substantially until after 2050. Quitting by current smokers is therefore the only way in which tobacco related mortality can be reduced in the medium term.[42] Cessation will also have an indirect effect on tobacco prevention and control.

Another important consideration is the cost-effectiveness of smoking cessation treatments. Such treatments not only enhance a smoker's likelihood of achieving long-term abstinence to more than double, but are highly cost-effective also.[4] **Error! Bookmark not defined.** Effective counseling and medications for smoking cessation are found to be one of the most cost-effective healthcare practices in terms of life-years saved per dollar of expenditure. In fact, tobacco dependence treatment is far superior to that of many other potentially life-saving interventions and more cost-effective than the treatment of hypertension, diabetes and hyperlipidemia and there is a distinct economic advantage in encouraging patients to quit.

2.1. Rationale of the study

The success of any smoking cessation intervention depends on the individual's motivation to quit and level of nicotine dependence.[164] Henningfield and colleagues wrote, quoting many articles published in the past, that all reinforcing effects of smoking were not solely attributable to nicotine alone.[121] Nicotine replacement medications could substantially reduce most physiological and cognitive withdrawal symptoms while tobacco cravings will persist. Various sensory stimuli like auditory and visual cues accompanying cigarettes and cigarette smoking were effective in triggering and relieving such cravings. Thus nicotine replacement medications should not be viewed as stand-alone medications that make people stop smoking.

Reassurance and guidance from health professionals can be critical for many smokers to achieve and sustain abstinence.

In India, the drugs available for smoking cessation are nicotine gum and bupropione. The cost of the daily requirement of each drug is more than the cost of cigarettes required per day. In addition, drugs are not free from adverse effects. A study with 33,247 patients showed that the use of NRT is not associated with any increase in the risk of myocardial infarction, stroke, or death,[165] but nicotine drugs are generally unsafe for use in the presence of heart disease.[120] Nicotine gum is contraindicated in patients with gastric ulcers and is unsuitable for denture users. Nicotine nasal spray is unsuitable for use in patients with asthma, allergies, nasal polyps, sinus problems, rhinitis, and recurrent epistaxis. Approximately 5% to 20% of users can become addicted to nicotine gum and acute nicotine withdrawal may occur on abrupt discontinuation. One meta-analysis of 21 randomized controlled studies involving 6644 NRT users and 2766 placebo controls revealed that the risk of relapse was higher after stopping NRT than after stopping placebo.[166]

There are drawbacks to the vaccine approach as well.[167] Vaccines may be useful to prevent the onset of smoking. In current smokers, a high dose of vaccine is needed since they will have very high levels of nicotine in their blood. Again, vaccine will not address nicotine withdrawal or cravings and so counseling or medications are needed to get the best results. Motivation and counseling are important prerequisites for using vaccine in current smokers because they can circumvent the effect of the vaccine by simply increasing the number of cigarettes.

Hence the value of behavioral intervention should not be underestimated and can be considered as the first line management option for smoking cessation in India. This is consonant with the concluding remarks of Tim Coleman in BMJ 2004, where he states that non-pharmacological interventions need to be recognized as equal contributors to the overall success of smoking cessation interventions, which can achieve up to 20% success with any quit attempt, and that they cannot be discarded as inferior or irrelevant alternatives to drug treatment.[168] He also mentions that the provision of non-pharmacological interventions, ranging from simple advice to

intensive behavioral support, needs to become a routine component of healthcare delivery to smokers. Certainly non-pharmacological interventions can be used in contexts where medications are not available or are too expensive.

In Kerala, doctors are busy clinicians and may not have sufficient time to advice the smoker successfully. An NDHP may be able to find some time to complement doctor's advice. As the effect size and odds of quitting with an NDHP alone was found to be low, a doctor's advice is mandatory. A doctor's time can be minimized to about one minute, concentrating in giving a strong, personalized and short message, since an NDHP can spend about five to 10 minutes in motivating and counseling. Educational materials may be used to enhance the effectiveness of doctor's advice further in changing smoking behavior. A randomized controlled trial with three months follow up of 915 patients conducted by Kreuter and colleagues proved the effectiveness of a similar intervention.[169] A doctor gives a brief strong personalized message, then an NDHP provides brief counseling and a health worker frequently follows up–this may be a good model for implementation in Kerala.

In Kerala, smoking prevalence among the general population in 2006 was 35.8%[9] and in 2004 any tobacco use among patients attending government hospitals was 57.3%.[170] A regional survey found that among male smokers 83% wanted to quit and 51% tried to quit unsuccessfully.[171] Current smoking among male tuberculosis (TB) patients at the time of diagnosis was 71.2% and one third of smokers who had quit at the time of diagnosis failed to sustain no-smoking status later.[172] A study in Kerala by the Quit Tobacco International group in 2003 revealed that only one-third of doctors always asked patients about tobacco use and three-fourths advised patients routinely to quit smoking but only one-eighth offered useful information on how to quit.[173] A cross sectional survey conducted just before this intervention program among patients attending Primary Health Centers (PHCs) in the study district showed that 66.6% of male patients were smokers, 45% were interested in quitting, 24% tried quitting, and only about one third got advice from the doctor.[174] It is expected that the unmet need will increase enormously with the strict implementation of the Tobacco Products Act, which prevents smoking in public places. When smokers who are unable to quit are forced to quit, they will frantically look for help in quitting.

Personal interviews with doctors in busy clinics revealed that they had little time for counseling and did not get any training in delivering brief smoking cessation intervention. The Government of India, in collaboration with WHO, has started 16 Tobacco Cessation Clinics (TCCs) in connection with specialist hospitals in various parts of the country and was the only major effort in cessation activity in this country. Provision for drug therapy is also available in these centers. The proportion to which this service is available is negligible when compared with the needy population. Except for a few studies from these centers, the studies available from India that have investigated the effectiveness of brief cessation interventions are scarce. Therefore there is a need to find out an effective, feasible and financially viable non-drug intervention for smoking cessation to be integrated with the clinical set up in PHCs.

The following hypotheses and objectives guided this study.

2.2. Hypotheses

1. Brief advice from a doctor combined with counseling by an NDHP is more effective than brief advice from a doctor alone in the promotion of smoking cessation in clinical settings.
2. Age, economic status, chronic disease, number of sticks smoked daily, time to first cigarettes/bidi in the morning, intention to quit, readiness to quit, confidence to quit, presence of past quit history of quit and type of intervention are the expected predictors.

2.3. Objectives

- To assess whether the brief advice from a doctor combined with counseling by an NDHP is more effective than brief advice from a doctor alone in the promotion of smoking cessation in clinical settings.

- To find out the predictors of smoking cessation.

Chapter 3

Methodology

3.1. Study area

The district of Palakkad in Kerala was selected for the study because of feasibility. The researcher had worked in this district for four years in the capacity of district program manager under the reproductive and child health project supported by the World Bank. He has an in-depth knowledge of the district and a good rapport with the district health administration. The district had a human development index score of 0.761 compared to 0.773 of Kerala as a whole and ranked 10^{th} among 14 districts.

In Kerala, the health care system follows a pyramidal structure. At the apex there is a headquarters, with a team of health managers. The district medical officer is their chief. Under the head quarters there are peripheral units, namely Community Health Centres (CHCs) and PHCs. CHCs are larger in size and better in facilities and staffing. In each centre, there will be one or more doctors, nurses, pharmacists and health workers. The doctors are usually busy with consultation, and may not have enough time to spend on patient counseling. The nurses and pharmacists can do patient counseling in addition to their routine work. The health workers normally do field work by visiting families and providing both general and specific health education to communities.

There were 94 Primary Health Care units, of which 82 were designated as PHCs and 12 as block PHCs or CHCs. In 61 PHCs there was only one doctor, and in others, more than one. The six PHCs in tribal areas and four in remote areas were excluded from the study since the patients attending these institutions were different from the general population. The PHCs without a full time doctor in position were also excluded from the study. Thus 64 PHCs and 80 doctors (60% females) working in these centers were considered for selection.

3.2. Intervention Program Development

An Awareness Generation Training Program (AGT) for doctors was organized with the help of district health managers (District Medical Officer, District Reproductive Child Health (RCH) officer and District Media Education Officer) in two batches: on 11th and 12th December 2006. The duration of the training program was one day and half of the doctors were invited for each day. This program aimed (1) to develop suitable, effective and culturally specific doctor's messages to promote quitting smoking and (2) to discuss a draft intervention plan for smoking cessation program suitable for PHCs. Doctors were requested to use these messages to advise their patients who smoke, to quit smoking. The modified intervention plan was used for the intervention study. The AGT program sensitized the doctors about tobacco harms and health professional's roles in tobacco control.

3.2.1. Awareness Generation Training program

All the 80 doctors working in 64 PHCs were invited to attend the AGT but only 55 doctors from 31 institutions participated: 28 on first day and 27 on second day. Two thirds of them were females. The training contents included the global disease burden of non-communicable diseases (NCD), the share of tobacco in the NCD problem, the FCTC, tobacco harms, tobacco control methods, prevalence of tobacco use in Kerala, smoking cessation programs, role of medical profession in tobacco control etc. Then participants were divided into four groups on each day with six to seven participants in each group and the groups either engaged in discussions to develop suitable doctor's messages useful to promote quitting smoking or discussed the draft intervention plan. Two groups discussed the first topic mentioned above and then the other two groups discussed the second topic. After group discussions, each group presented their ideas and opinions in the common forum for open discussion. The district health managers, doctors, investigator and experts from Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Thiruvananthapuram participated in these discussions.

3.2.2. Development of doctor's messages

After sensitization, the four groups engaged in discussions to develop effective and culturally appropriate doctor's messages. They presented the messages and doctor's attitudes towards health education to patients. The doctors revealed that they were busy in their clinics and were unable to devote time for counseling against any disease. The usual time spent with each patient was not even sufficient to enquire about the diseases and to examine the patient in detail. But within the limited time they would give short messages against diseases pertinent to the particular patient. The doctors also informed the investigator that one message was not sufficient to address all types of patients. There should be different messages suitable to address patients in different age groups with different diseases and different attitudes towards quitting. They developed several different messages so that the doctor can select the most appropriate message for each situation. The messages were short and related to the specific disease condition of the patient. The forum identified eight messages most suitable in four different situations from the list after discussion, modification, deletion and selection. These are given in Box 7.

Later these messages were field tested among a group of smoking patients who were assessed their opinion. Their suggestions and modifications were incorporated and coined into the four most suitable messages in four different situations. The messages developed are given in Box 8. These messages were used by the doctors to promote quitting smoking during the intervention study.

3.2.3. Development of Intervention Protocol

After sensitization, four groups engaged in discussions on a draft intervention plan presented their ideas and opinions in the common forum for open discussion. The doctors were interested in devoting the time for maximum benefit. They said that they should ask about the smoking habit to identify the smoker, advise smokers with short messages and entrust a nurse or pharmacist to provide counseling. The nurse or pharmacist who provides counseling would assess the quantity of smoking and willingness to quit before giving counseling.

Box 7. List of messages developed in AGT program to promote quitting smoking

Sl. No.	Situation	Message
1	A patient (smoker) with any chronic disease like asthma, heart disease, hypertension, diabetes, cancer, TB, etc.	Drugs alone are not sufficient to cure your disease. You should quit smoking for life.
		If you continue smoking, there is no benefit of treatment. You may either smoke or treat; don't continue both.
2	A patient (smoker) with some minor ailments like gas in the stomach, numbness of limbs, mouth lesions, chest pain, recurrent or prolonged cough, wheeze, etc.	Smoking is the cause of your disease. Now it is mild. If you don't quit smoking (and other tobacco products) now, you will become a victim of serious incurable disease. Then treatment will be unaffordable.
3	Any suspected smoker attending the clinic.	Do you smoke? Smoking is not good for your disease. Better to quit now.
		Smoking may decrease the effect of drugs. So quit smoking to get the maximum benefit of medicines.
		Any way you are suffering. Don't put your children in trouble. So quit smoking now.
4	A father (smoker) bringing a child with chest infection or wheeze.	Drugs alone are not enough to cure the disease. If you don't quit smoking your child will get frequent disease / wheeze.
		You are causing disease to your child. So you should quit smoking for the betterment of your child.

The doctors suggested that they could add 'Smoking cessation counseling' as the first item in the prescription list which will serve as the tag to identify the smoker. When the prescription reaches the pharmacy, the pharmacist can identify and can invite them for counseling. After counseling, pharmacists can also reinforce cessation by giving a message.

Box 8. List of messages selected and modified by the patients

Sl. No.	Situation	Message
1	A patient (smoker) with any chronic disease like asthma, heart disease, high blood pressure, diabetes, cancer, etc.	If you continue smoking, it will destroy your organs and will kill you. Drugs alone are not sufficient to cure your disease. Better to quit for early relief.
2	A patient (smoker) with some minor symptoms like gas in the stomach, numbness of limbs, mouth lesions, chest pain, recurrent or prolonged cough, wheeze, etc.	Your smoking is the cause of your disease. If you don't quit smoking (and other tobacco products) now, this mild disease may become cancer / heart attack / asthma / TB / stroke (name appropriate one). It will be incurable and expensive.
3	A father (smoker) bringing a child with chest infection or wheeze.	Drugs alone are not sufficient to cure the disease. Your smoking is the cause of your child's disease. Better to quit for the health of your child.
4	Any suspected smoker attending the clinic.	If you continue smoking, medicines may be less effective, need more time for cure and may relapse. Better to quit and avert deadly complications.

3.3. Intervention Program

3.3.1. Study design, Study sites, Study sample

Study design: A randomized controlled trial with two groups in the ratio 1:1 was conducted in PHCs in Palakkad district from January 2007 to February 2008. The study compared the effectiveness of minimal intervention (doctor advice alone) to augmented intervention (AI: doctor advice coupled with non-doctor health professional counseling) at week three, six and 12 after intervention. Those who had quit within 12 weeks were also followed up at 26 weeks to find out their smoking status at this time point.

Study sites: All doctors who attended an awareness generation program on tobacco lessons were invited to participate in the study and to conduct the study in their clinics. According to the final intervention plan, four health professionals (one doctor, one nurse, one pharmacist and one health worker) were needed in each PHC to conduct the study. Initially 14 doctors representing 14 clinics expressed willingness to take up the study. Later three doctors withdrew since they could not ensure the support of other team members in their PHCs. The remaining 11 doctors who volunteered were selected to conduct the study and the corresponding 11 PHCs were identified as the study sites.

In eight study sites there were only one nurse and one pharmacist per center and in the other three sites there were two to five nurses and two pharmacists per center. In one site there was only one health worker and in all other sites there were several health workers. When there was only one personnel in a particular category (nurse or pharmacist or health worker) (s)he was inducted as the team member in that category and when there were more than one, the doctor identified the most suitable person from past experience and inducted him/her as the team member. Willingness was obtained from all before incorporating as the member of the study team.

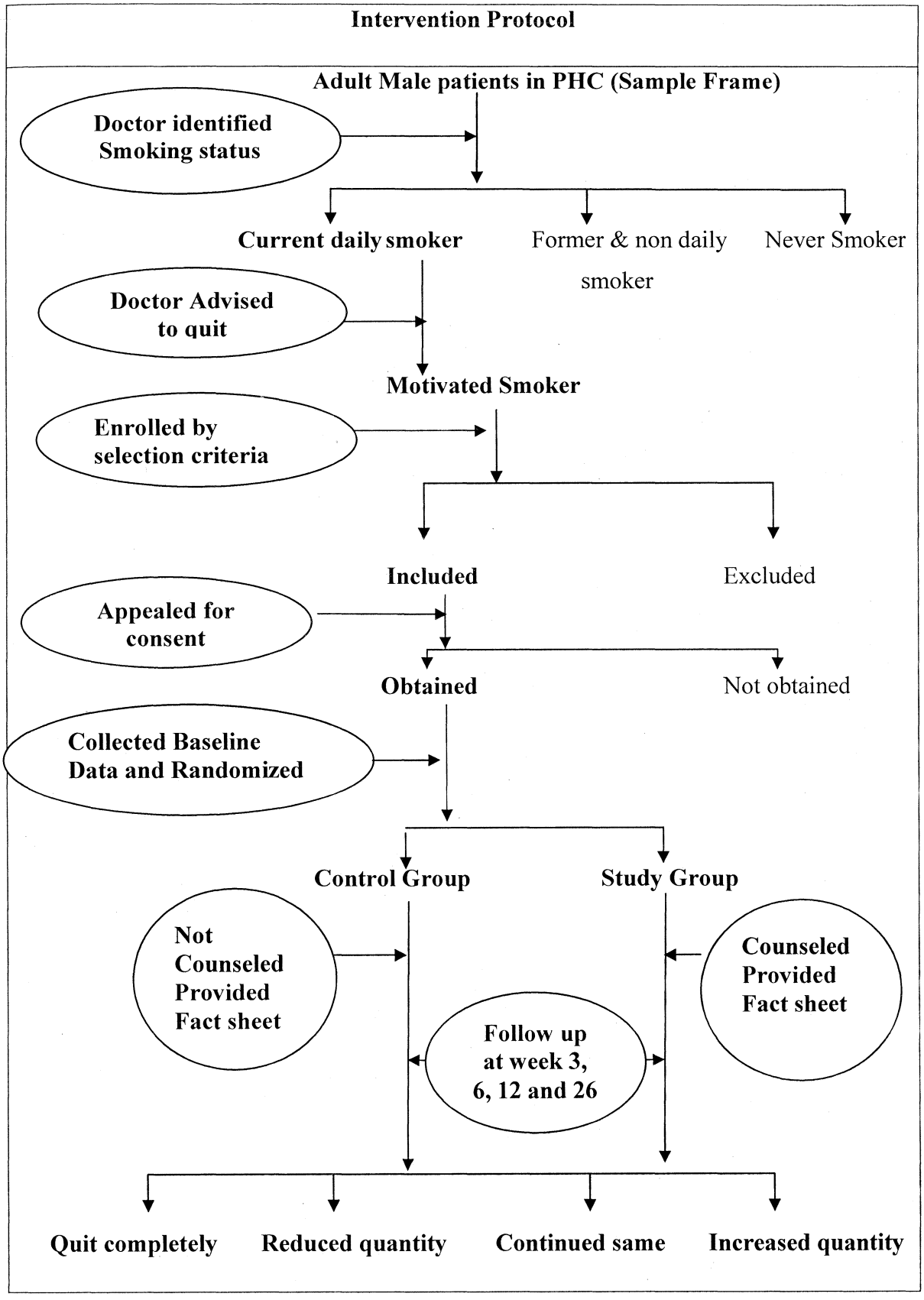
Study sample: Studies conducted in other countries revealed a 3% to 10% quit rate with no intervention, a 6% to 13% quit rate with doctor's advice of one to three minutes and a 6% to 19% quit rate with non doctor health professional counseling. Therefore, assumptions of quit rate to calculate the sample size were 10% for doctor's advice of about one minute and 18% with combined intervention. Sample size

calculated by statcalc in Epi Info with 8% effect size, 0.05 Type I error (alpha) and 80% Power was 618 (1:1 ratio). Considering the non response rate, sample size was increased by 20% which provided the sample size of 740 (1:1 ratio). Even though 11 sites could be identified, all sites were not expected to comply fully with the protocol. The sample size for each PHC was calculated in such a way to get sufficient total sample even if only half the selected sites could conduct the study properly. Thus the required sample size calculated for each PHC was 120 ± 30.

3.3.2. Study protocol and procedure

The study was conducted based on the protocol developed during the awareness generation program. Details of the intervention protocol are given in Figure 2. The doctor asked the smoking status of male patients attending the out-patient clinic to identify current smokers and assessed the quantity of smoking to recruit those who smoked at least one cigarette / *bidi* per day in the last 30 days. Then the doctor advised all current smokers to quit smoking by giving a strong, specific, personalized, short message in less than one minute. Along with the list of prescribed drugs, the doctor added smoking cessation counseling (SCC) as the first item in the list. When this patient reached the pharmacy to collect medicines, they directed him to the counselor. The pharmacist or nurse who was on duty on that day served as the counselor. The counselor screened the participant with eligibility criteria and collected baseline data from those who satisfied the selection criteria after getting their written consent. Then the counselor randomized the participant into a minimal intervention group or an augmented intervention group, using a computer generated random table. The counselor gave the fact sheet on tobacco harms to the minimal intervention group participants, reinforced doctor's quit message and sent them away with out counseling. But the counselor gave the fact sheet on tobacco harms to AI group participants, reinforced the doctor's quit message and counseled using health education materials on tobacco harms and a quit guide book developed by QTI project. All participants in both groups were strongly advised to quit smoking within the next two weeks.

Figure 2.Final Intervention protocol used in this study



The pharmacists also gave the message when the smokers returned to the pharmacy to collect drugs. All the patients in the intervention and the control group were instructed to come for follow up on a particular day. If they did not come on that day or within one week health workers visited them at their homes or workplaces. Both groups were followed up at three weeks, six weeks and 12 weeks to assess their smoking status. During the follow-up, the health workers advised participants of both groups to quit. Those who had quit within 12 weeks were also followed up at 26 weeks to find out their smoking status at this time point. Those who had not quit within 12 weeks were considered as persistent smokers.

3.3.3. Screening and eligibility criteria

The male patients who attended the out patient clinics of PHCs were the study population. Patients who attended the out patient clinic of age 18 years and above, had smoked at least one cigarette / *bidi* daily during the last one or more years, lived within the PHC area, and were able to read Malayalam were included in the study. Non daily smokers and current daily smokers who had not smoked in the last 24 hours and had a smoking abstinence period of more than one week during the last one year were excluded.

3.3.4. Randomization

A predefined computer generated randomization sequence in boxes of 30 was used for randomization. Questionnaires for the minimal intervention group and augmented intervention group were sequentially arranged and serially numbered before delivery to the study team since the team members were not familiar with the randomization process. When a patient was recruited the questionnaire with the lowest serial number was used to collect the data and as per the instructions in the questionnaire (see below) he was automatically enrolled in the MI group or AI group.

3.3.5. Study instruments

a. Tools for data collection

A pre-tested two-part questionnaire in the local language (Malayalam) was used for data collection, with an initial part to collect baseline data and a second part to collect follow up information. The information regarding demographics, present

illness, tobacco use pattern, variables to assess FTND score, previous quit behavior, attitude towards quitting, preparedness to quit smoking and reasons to continue smoking were collected as baseline data (Annexure 2). Preparedness to quit smoking of participants was assessed by grading their intention, readiness, motivation and confidence levels of quit on a *likert* scale[175] of four points and the participants in grade four were considered to have prepared to quit. The information regarding present smoking status, quit / relapse date, withdrawal symptoms and coping mechanisms were collected as follow-up data. Socio-economic status and smoking status were assessed by noting self declaration. History of past quit attempts was accounted only if the quit attempt lasted for more than 24 hours. The participant was contacted at week three, six, 12 and 24 but noted the smoking status of previous weeks also by enquiring.

b. Tools for intervention

A fact sheet, picture book, question-answer book and quit guideline book were used for intervention. The fact sheet was an abstract of tobacco harms in text form and the picture book was an illustration of organs affected by tobacco-related diseases with short notes. Frequently asked questions about tobacco harms/cessation and their answers were given in the question-answer book. The quit guideline book contained lessons to achieve quitting smoking, options to avoid withdrawal symptoms and instructions to avoid smoking during persuading social situations. These are the tools developed and field tested by the QTI team.[176] A copy of the fact sheet was given to all participants. The fact sheet and picture book were used to explain tobacco harms and the question-answer book was used to answer the queries raised by the participants during counseling. The quit guideline book was used as an aid to give counseling uniformly to all counseled group participants in all clinics.

3.3.6. Training of the team

A one-day training workshop was arranged one week before the beginning of the intervention. All team members were invited with the help of district health managers. In the workshop 43 members out of 44 from 11 teams attended. The research program was explained to the doctors, nurses, pharmacists and health workers. They were given a copy of health education materials on tobacco harms (fact

sheet, picture book and question-answer book) and quit guideline book. A copy of the study procedure, doctor's messages and screening criteria were also given to all of them. One subject expert talked about tobacco harms, tobacco control methods, prevalence of tobacco use among doctors in Kerala, smoking cessation programs, the role of medical profession in tobacco control etc. The researcher explained the actual study procedure, protocol, screening criteria, randomization and tools for intervention. During this session doubts were cleared. Role playing was also organized in which the participants played their own roles and other people's roles in the study so as to make the procedure clear to all. Later the interview schedule for baseline data collection was discussed in detail, question by question, and mock interviews were conducted with the participants. Finally the quit book was read, the counseling procedure was explained, doubts were cleared and a counseling exercise conducted to make everything uniform. All agreed to co-operate with the study and were enthusiastic in participating in a novel attempt, for the first time in their career. All teams were asked to conduct a pilot study in their PHCs for one week from the next day of the training. After one week, the researcher visited each study site and discussed the problems, cleared the doubts they had and asked them to start the study. A second meeting of all members of the study team was conducted in March 2007. In addition to the assessment of the progress and monitoring of activities, follow-up procedure and the data collection schedule were also discussed in detail in this meeting.

3.3.7. Study period

The study was conducted between January 2007 and February 2008. The enrolment of participants took place between March and June 2007. The continuous follow up was done up to October 2007 and the final follow up was done in January and February 2008.

3.3.8. Supervision and monitoring of study

Possible steps such as constant supervision, cross checking etc were taken to prevent contamination between the non-counseled (minimal intervention group) and the counseled group (augmented intervention group) and to pursue the guidelines. All teams were asked to conduct a pilot study in their PHCs for one week starting the day

after the training. After one week, the researcher visited each study site and discussed problems, cleared doubts they had and permitted the study to start. The research assistant telephoned each team every week in the initial phase and less frequently later to enquire about the progress and to clear up doubts. The researcher visited all sites regularly, watched the procedure and interviewed the counselor and a few participants to ensure that the procedure was followed in each site and compared with the standard procedure of the study. The researcher also cross checked the baseline data of some participants. The District Public Health Nurse, who was a senior faculty in the Nursing School, also supervised and cross checked the data during her routine visits to the study sites.

3.3.9. Compliance at various study sites

A few of the participants (five) in the counseled group were busy and could not listen to counseling even though they co-operated with all other aspects of the study. They did not get counseling and were moved to the non-counseled group. Conversely, a few of the participants (two) in the non-counseled group were enthusiastic to get some counseling to quit smoking. They were given counseling and were moved to the counseled group. This was done to satisfy ethical considerations. This might not have influenced the statistical significance since the numbers were too small.

At the end of the recruitment it was found that two teams, site two and site eight could recruit only fewer than 45 participants. In addition, the site two team had deviated from intervention protocol also– the doctor did not give the proper message and after some time the doctor who got training handed over the responsibility to an another doctor who did not get the training. These two teams, i.e., the team that could not recruit the minimum required number and the team that deviated from the protocol were excluded from the analysis. In site three, the trained doctor became sick immediately after the onset of the study and the responsibility was handed over to the next doctor who happened to be trained. In site six, the trained doctor was busy with clinical activities and hence he handed over the responsibility to the next doctor who was not trained. Here the pharmacist was also absent in the team. Actually the health worker in this site was young and enthusiastic and he himself had given counseling to

the majority of participants and made follow up visits. Although 118 participants were recruited and followed up here, this site was also excluded from analysis since the site had many deviations from the protocol. Those who could not be followed up at each time point were also excluded from analysis for that time point. Thus only participants from seven sites were included for analysis.

3.3.10. Definitions

Communicable diseases (CD): All infectious diseases

Non communicable diseases (NCD): Asthma, cancer, heart diseases, diabetes, and hypertension (high blood pressure)

Ever smoker: one who reported smoking a cigarette or *bidi* any time in the past **Current smoker:** one who reported smoking a cigarette or *bidi* any time during the last 30 days

Quantity of smoking: the number of sticks smoked in a day. This was calculated by adding the number of cigarettes and number of *bidis* smoked daily.

Time of first cigarette: the time elapsed after waking up in the morning until he takes the first puff in the morning

Level of addiction was calculated by the Fagerstrom Test on Nicotine Dependence (FTND) scale (explained in page 8)

Quit attempts: Self reported earnest efforts to quit smoking which resulted in temporary or permanent longer intervals of smoke free periods than usual

3.4. Outcome measures

Quit Attempt Rate within three weeks; Harm Reduction Rate at 12 weeks; Weekly Point Prevalence of Smoking Abstinence up to 12 weeks; Continuous Smoking Abstinence Rate at three weeks, six weeks, 12 weeks, and 26 weeks, and Relapse Rate at three weeks, six weeks and 12 weeks were calculated as outcome measures. Self report of no smoking and no use of any smokeless tobacco product during the last seven days or more was considered as the criteria to assess **smoking abstinence** at all points of contact.

- **Quit Attempt Rate** was defined as the proportion of participants who attempted to quit smoking within three weeks after counseling.
- **Harm Reduction Rate** was defined as the proportion of participants who reduced the quantity of smoking to less than 50% of the precounseling level by 12 weeks after counseling.
- Continuous Smoking Abstinence was used when the participant had quit smoking with in two weeks after counseling and kept smoking abstinence continuously through weeks three, six, 12 and 26. **Continuous Smoking Abstinence Rates** at three weeks, six weeks, 12 weeks, and 26 weeks were defined as the proportion of participants remained quit continuously from quit date through three weeks, from quit date through six weeks, from quit date through 12 weeks, and 26 weeks respectively.
- **Weekly Point Prevalence of Smoking Abstinence** at three weeks, six weeks and 12 weeks were defined as the proportion of participants who reported smoking abstinence for the previous seven days of each visit.
- **Relapse Rate** at six weeks, 12 weeks and 26 weeks were defined as the proportion of participants who restarted smoking after an initial quit lasted for seven days or more.

3.5. Ethical consideration

This study was done as a part of the QTI project which got ethical clearance from the Government of India and the Institutional Review Boards (IRBs) of US Institutional partners and the Sree Chitra Tirunal institute for Medical Sciences and Technology, Trivandrum. The Director of Health Services in the state of Kerala gave approval to conduct the study. Prior to administering the survey, the investigators explained the purpose of the study to all participants in both phases of study. The voluntary nature of participation and the anonymous and confidential nature of the questionnaire were strongly emphasized. Informed written consent was obtained from all the participants. In phase two, all the participants got a fact sheet and doctor's advice to quit smoking, which can be considered as the standard care. More over those who were interested in getting counseling in the non counseled group were also given counseling and moved to the counseled group.

3.6. Statistical Analysis

The completed questionnaires were scrutinized, edited, and coded by the investigator and entered by the research assistant concurrently. The software package used for data entry and analysis was SPSS version 11.5. The analysis was done using appropriate statistical tests to find out the mean, proportions, standard deviation, p value, regression coefficients etc. Overall group differences of the baseline characteristics of participants were examined using an analysis of variance for continuous variables and the χ^2 test of association for categorical variables. Group comparisons of non smoking rates were done by using the χ^2 test of association. All significant tests were two tailed using a significance level of $p < 0.05$.

Chapter 4

Results

In this section the main findings of the study are presented. The data generated from the intervention program were analyzed and presented in five sections to find out the effectiveness of doctor advice enriched with counseling over doctor advice alone. A brief description of the enrollment and flow of participants through the study according to site and follow up is presented first, followed by background characteristics of participants, outcome of intervention, outcome indicators and predictors of smoking cessation behavior.

4.1. Enrollment and follow up

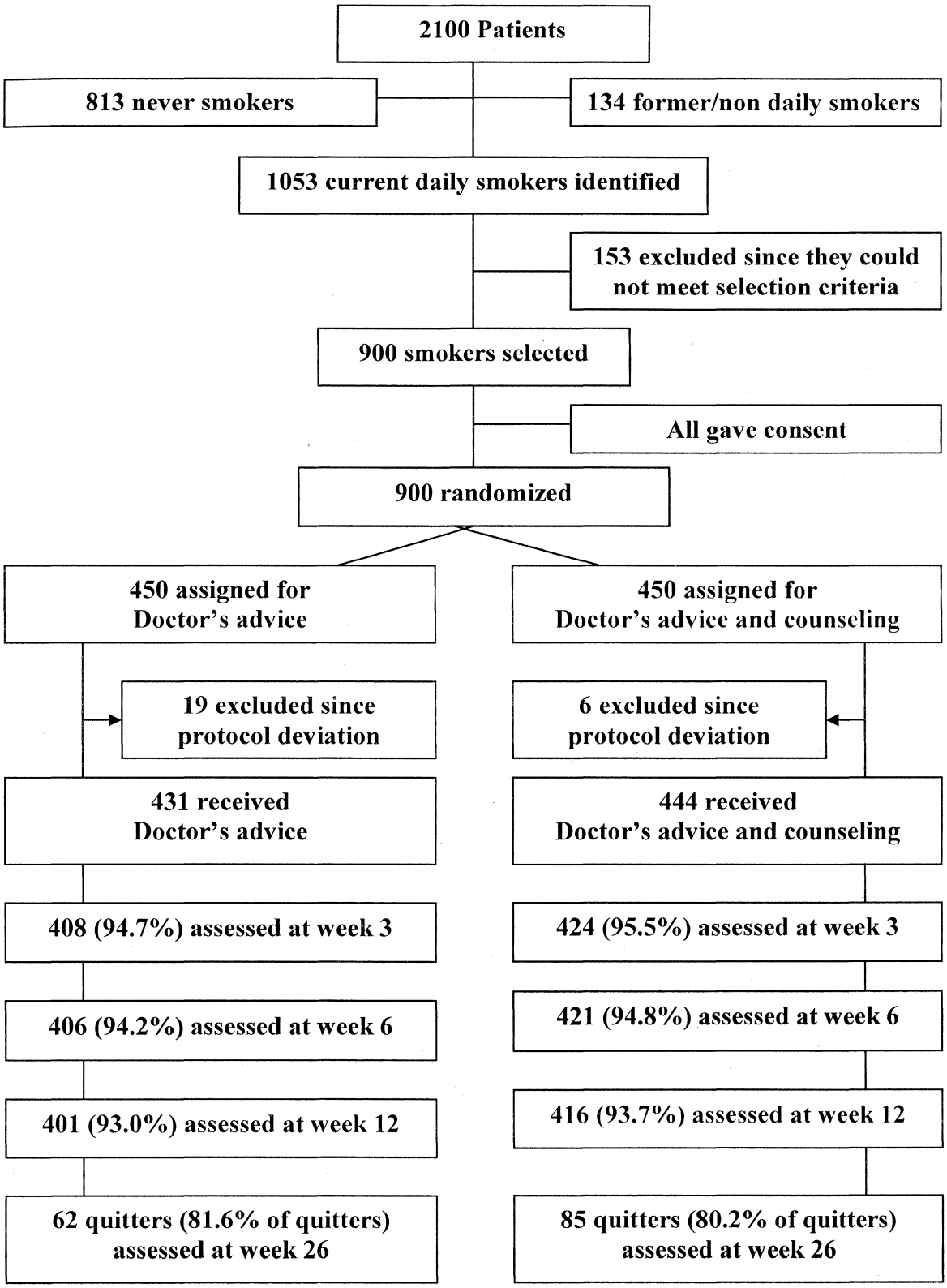
Study sites and participants

A total of 2100 male patients attended seven PHCs were screened and 1053 current daily smokers were identified excluding 134 former/non daily smokers and 813 never smokers. By applying selection criteria, 900 participants were enrolled in the study and 25 were excluded from analysis due to deviation from protocol. The study sites with number of participants are described in Table 3 and flow of participants through the study is given in Figure3.

Table 3. Study sites and participants

Sl. No	Health Institution	Number enrolled	Number included for analysis		
			Non-counseled	Counseled	Total
1	Ozhalappathy	120	58	62	120
2	Elappully	120	60	60	120
3	Koduvayur	150	72	73	145
4	Kizhakkencherry	150	65	65	130
5	Nagallasserry	120	59	61	120
6	Elambulasserry	120	62	58	120
7	Kalladikkodu	120	60	60	120
	Total (%)	**900**	**431 (49.3)**	**444 (50.7)**	**875 (100)**

Fig 3. Participants enrolled and followed up



The numbers of participants who were followed up at the third, sixth, 12th and 26th weeks are given in Table 4. About 80% of 182 participants who quit smoking within 12 weeks after intervention were followed up in the 26th week.

Table 4. Number (%) of participants followed up at different time points

	Non counseled N = 431 No (%)	Counseled N = 444 No (%)	Total N = 875 No (%)
Week 3	408 (94.7)	424 (95.5)	832 (95.1)
Week 6	406 (94.2)	421 (94.8)	827 (94.5)
Week 12	401 (93.0)	416 (93.7)	817 (93.4)
Week 26	61 (14.2)	85 (19.1)	146 (16.7)±

± 80.2% of 182 participants who quit smoking within 12 weeks after intervention

4.2. Background characteristics of participants

Demographic profile

All participants were males. Table 5 gives mean age, mean years of education and economic status of participants in two groups. There was no significant difference in mean age and mean years of education but the economic status was significantly different for the two groups, with a significantly higher number of participants belonging to the low economic status in the counseled group compared to non-counseled group.

Table 5. Age, education and economic status of participants

	Non counseled N = 431 No (%)	Counseled N = 444 No (%)	Total N = 875 No (%)
Mean age (SD)	43.9 (12.5)	44.2 (12.2)	44.0 (12.3)
Mean years of education (SD)	5.6 (3.6)	5.5 (3.7)	5.5 (3.6)
Economic Status ($P < 0.05$)			
Low	307 (71.2)	347 (78.2)	654 (74.7)
Medium	124 (28.8)	97 (21.8)	221(25.3)
Total	431 (100)	444 (100)	875 (100)

Demographic characteristics of participants are given in table 6. There was no significant difference between the control and study groups.

Table 6. Demographic characteristics of participants

	Non-counseled N = 431 No (%)	Counseled N = 444 No (%)	Total N = 875 No (%)
Age in years			
18 – 24	27 (6.3)	31 (7.0)	58 (6.6)
25 – 44	192 (44.5)	188 (42.3)	380 (43.4)
45 – 64	197 (45.7)	204 (45.9)	401 (45.8)
More than 64	15 (3.5)	21 (4.7)	36 (4.1)
Education in years of schooling			
Illiterate	66 (15.3)	73 (16.4)	139 (15.9)
1 - 5	169 (39.2)	164 (36.9)	333 (38.1)
6 - 10	177 (41.1)	187 (42.1)	364 (41.6)
More than 10	19 (4.4)	20 (4.5)	39 (4.5)
Marital Status			
Currently Married	381 (88.4)	394 (88.7)	775 (88.6)
Never Married	50 (11.6)	48 (10.8)	98 (11.2)
Widow/Widower	0 (0)	2 (0.5)	2 (0.2)
Total	431 (100)	444 (100)	875 (100)
Employment Status			
Unemployed	31 (7.2)	38 (8.6)	69 (7.9)
Laborers and Farmers	291 (67.5)	316 (71.2)	607 (69.4)
Skilled and business	78 (18.1)	76 (17.1)	154 (17.6)
Others	31(7.2)	14 (3.2)	45 (5.1)

Morbidity profile

The morbidity profile of the study population is given in table 7. The total does not add to 100% because many individuals reported more than one illness. Other illnesses include arthritis, backache, headache and some minor illnesses that were not diagnosed as communicable disease or non-communicable disease. The proportion of those who reported non-communicable diseases was significantly higher among the non-counseled group when compared to the counseled group. However, those in the counseled group reported a significantly higher proportion of communicable diseases than those among the non-counseled group.

Table 7. Disease profile of participants

	Non-counseled N = 431 No (%)	**Counseled N = 444 No (%)**	**Total N = 875 No (%)**
Presence of NCD†	114 (26.5)	91 (20.5)	205 (23.4)*
Presence of CD‡	225 (52.2)	271 (61.0)	496 (56.7)*
Presence of injury	40 (9.3)	44 (9.9)	84 (9.6)
Presence of other disease	255 (59.2)	213 (48.0)	468 (53.5)*

* $P < 0.05$; † Non-communicable Disease; ‡ Communicable Disease

Table 8. NCD profile of participants

	Non-counseled N = 114 No (%)	**Counseled N = 91 No (%)**	**Total N = 205 No (%)**
Presence of Asthma	74 (64.9)	67 (73.6)	141 (68.8)
Presence of Heart disease	6 (5.3)	11 (12.1)	17 (8.3)
Presence of Cancer	2 (1.8)	1 (1.1)	3 (1.5)
Presence of Diabetes	26 (22.8)	8 (8.8)	34 (16.6) *
Presence of Hypertension	19 (16.7)	14 (15.4)	33 (16.1)

* $P < 0.05$

Table 8 provides information on individual non-communicable diseases in both groups. Some individuals reported more than one NCD. Thus the number does not add up to 114 in the non counseled group or 91 in the counseled group. The different non-communicable diseases did not significantly differ between the two study groups except in the case of diabetes mellitus.

Tobacco habits

Tobacco habits were enquired about in detail and information on both tobacco smoking and chewing were collected. This information is given in Table 9. All the participants in both the groups were daily smokers. There was no significant difference in tobacco habits between the two groups.

Table 9. Tobacco habits of participants

	Non-counseled N = 431 No (%)	Counseled N = 444 No (%)	Total N = 875 No (%)
Any tobacco use	431 (100)	444 (100)	875 (100)
Daily smoking	431 (100)	444 (100)	875 (100)
Any smokeless tobacco used	35 (8.1)	33 (7.4)	68 (7.8)
Products used for smoking			
Cigarette	128 (29.7)	122 (27.5)	250 (28.6)
Bidi	201 (46.6)	217 (48.9)	418 (47.8)
Cigarette and Bidi	102 (23.7)	105 (23.6)	207 (23.7)
Smokeless tobacco product used			
Betal quid chewing	19 (4.4)	24 (5.4)	43 (4.9)
Gutka / khaini use	12 (2.8)	6 (1.4)	18 (2.1)
Snuff use	10 (2.3)	5 (1.1)	15 (1.7)

Smoking characteristics

FTND components of smoking characteristics are presented in Table 10.

Table 10. Tobacco smoking characteristics of participants

		Non-counseled N = 431 No (%)	Counseled N = 444 No (%)	Total N = 875 No (%)
Number of sticks smoked daily				
	1- 10	223 (51.7)	186 (41.9)	409 (46.7)
	11 - 20	120 (27.8)	140 (31.5)	260 (29.7)
	21 - 30	69 (16.0)	64 (14.4)	133 (15.2)
	> 30	19 (4.4)	54 (12.2)	73 (8.3)
	Total	431 (100)	444 (100)	875 (100)*
Time to first puff in the morning after waking up				
	More than 60 minutes	110 (25.5)	146 (32.9)	256 (29.3)
	31- 60 minutes	21 (4.9)	61 (13.7)	82 (9.4)
	6-30 minutes	105 (24.4)	113 (25.5)	218 (24.9)
	Less than 5 minutes	195 (45.2)	124 (27.9)	319 (36.5)
	Total	431 (100)	444 (100)	875 (100)
Smoked more in the morning than the rest of the day		110 (25.5)	101 (22.7)	211 (24.1)
Had difficulty in refraining from smoking in prohibited places		51 (16.8)	53 (11.9)	104 (11.9)
Believed to smoke even when suffer from some illness in future		62 (14.4)	42 (9.5)	104 (11.9)*
Smoking was the most hated thing to quit in life		73 (16.9)	82 (18.5)	155 (17.7)

* $P < 0.05$

The quantity of smoking was significantly lower among the non-counseled group (13.3) than the counseled group (17.0). The other characteristics of smoking

indicative of tobacco dependence, including time to first cigarette after waking up, smoking in the morning hours and difficulty in refraining from smoking in a prohibited place, did not significantly differ between the two groups. However, a significantly higher proportion of the participants in the non-counseled group answered in the affirmative when asked whether they would smoke even when they are ill. Important smoking characteristics of both groups of participants are summarized in Table 11. There was no significant difference between the two groups with regard to the age of initiation, duration of smoking and FTND score of smoking addiction.

Table 11. Important smoking characteristics of participants

	Non-counseled N = 431 No (SD)	**Counseled N = 444 No (SD)**	**Total N = 875 No (SD)**
Mean age of initiation (SD) in years	19.3 (6.9)	19.2 (6.8)	19.8 (6.3)
Mean duration (SD) in years	24.6 (14.1)	25.0 (13.2)	24.8 (13.7)
Mean quantity of smoking (SD)	13.3 (10.5)	17.0 (15.0)	15.2 (13.1)*
Mean FTND score (SD)	3.3 (2.3)	3.1 (2.3)	3.2 (2.3)

* $P < 0.05$

Tobacco addiction

Addiction levels among participants in the two groups are given in Table 12.

Table 12. Level of addiction of participants to smoking

Addiction level	Non-counseled No. (%)	Counseled No. (%)	Total No. (%)
Low	242 (56.1)	264 (59.5)	506 (57.8)
Medium	147 (34.1)	142 (32.0)	289 (33.0)
High	42 (9.7)	38 (8.6)	80 (9.1)
Total	431 (100)	444 (100)	875 (100)

There was no significant difference in the level of addiction between the two groups, although there was a significant difference in the quantity of smoking between the two groups.

Attitude towards smoking and Quit behavior

Details about attitude towards smoking and quit behavior are given in Table 13. About half of the non-counseled group participants and three fourths of the counseled group participants thought that smoking even one stick of cigarette/*bidi* per day was harmful. However the proportion of participants who considered smoking even one cigarette or bidi harmful was significantly higher among the counseled group than the non counseled group. More than 40 percent of the participants in both the groups had made one or more attempts to quit smoking in the last year. On an average the number of quit attempts was 2.6 and the number did not differ significantly between two groups.

Table 13. Attitude and quit smoking behavior of participants

	Non counseled N = 431 No (%)	**Counseled N = 444 No (%)**	**Total N = 875 No (%)**
Smoking even one cigarette is harmful	54.4%	76.2%	65.8%*
Smoking even one bidi is harmful	52.2%	74.6%	63.9%*
Attempted to quit smoking in the past one year	189 (43.9)	186 (41.9)	375 (42.9)
Mean number of quit attempts made in the past one year (SD)	2.5 (2.7)	2.8 (3.2)	2.6 (2.9)

* $P < 0.05$

Preparedness to quit smoking

Intention, motivation, readiness and confidence to quit smoking were considered as the variables for preparedness to quit smoking. The levels of these variables when graded on a likert scale of four points are given in Table 14.

Table 14. Intention and motivation of participants to quit smoking

	Non-counseled No. (%)	Counseled No. (%)	Total No. (%)
Intention to quit			
No intention	14 (3.2)	3 (0.7)	17 (1.9)
Mild intention	33 (7.7)	50 (11.3)	83 (9.5)
Moderate intension	268 (62.2)	309 (69.6)	577 (65.9)
Strong intention	116 (26.9)	82 (18.5)	198 (22.6)
Total (p = 0.001)	431 (100)	444 (100)	875 (100)*
Motivation to quit			
No motivation	21 (4.9)	12 (2.7)	33 (3.8)
Mild motivation	40 (9.3)	53 (11.9)	93 (10.6)
Moderate motivation	209 (48.5)	267 (60.1)	476 (54.4)
Strong motivation	161 (37.4)	112 (25.2)	273 (31.2)
Total (p = 0.001)	431 (100)	444 (100)	875 (100)*
Readiness to quit			
Not ready	14 (3.2)	4 (0.9)	18 (2.1)
Slightly ready	43 (10.0)	49 (11.0)	92 (10.5)
Moderately ready	246 (57.1)	316 (71.2)	562 (64.2)
Obviously ready	128 (29.7)	75 (16.9)	203 (23.2)
Total (p = 0.001)	431 (100)	444 (100)	875 (100)*
Confidence to quit			
No confidence	24 (5.6)	17 (3.8)	41 (4.7)
Slight confidence	49 (11.4)	65 (14.6)	114 (13.0)
Moderate confidence	230 (53.4)	278 (62.6)	508 (58.1)
Good confidence	128 (29.7)	84 (18.9)	212 (24.2)
Total (p = 0.001)	431 (100)	444 (100)	875 (100)*

* $P < 0.05$

More than 80 percent of the participants expressed moderate to strong levels of intention, readiness, motivation and confidence to quit smoking. Participants who had intention, readiness, motivation and confidence levels of grade four in the likert scale were considered to have prepared to quit. The details are summarized in Table 15 a significantly higher proportion of the participants in the non-counseled group had strong levels of intention, motivation, readiness and confidence to quit smoking than the counseled group.

Table 15. Preparedness of participants to quit smoking

	Non-counseled N = 431 No (%)	**Counseled N = 444 No (%)**	**Total N = 875 No (%)**
Strong intention to quit	116 (26.9)	82 (18.5)	198 (22.6)*
Strong motivation to quit	161 (37.4)	112 (25.2)	273 (31.2)*
Obviously ready to quit	128 (29.7)	75 (16.9)	203 (23.2)*
Good confidence to quit	128 (29.7)	84 (18.9)	212 (24.2)*

* $P < 0.05$

Perceived benefits of quitting smoking

Table 16. Participants' perceived benefit of quitting smoking

	Non-counseled N = 408 N (%)	**Counseled N = 393 N (%)**	**Total N = 801 N (%)**
Better health	122 (29.9)	151 (38.4)	273 (34.1)
Economic benefit	123 (30.1)	102 (26.0)	225 (28.1)
Prevention of diseases	127 (31.1)	102 (26.0)	229 (28.6)
Speedy recovery of diseases	17 (4.2)	23 (5.9)	40 (5.0)
Others	19 (4.7)	15 (3.8)	34 (4.2)

The major benefits of quitting smoking as mentioned by the participants are presented in Table 16. While there was no significant difference in terms of their perceptions between the non-counseled and counseled groups, it was interesting to note that about three fourths of the participants considered health related benefits (including prevention and recovery from diseases) as compared to economic benefit.

Future plans of participants at the time of baseline data collection

Future plan of mode of quit and preparation time needed to quit are presented in Table 17.

Table 17. Participants plans to quit smoking at the time of baseline data collection

		Non-counseled No. (%)	Counseled No. (%)	Total No. (%)
Feasible mode of quitting smoking				
	Gradual	327 (80.5)	348 (80.7)	675 (80.6)
	Abrupt	79 (19.5)	83 (19.3)	162 (19.4)
	Total	406 (100)	431 (100)	837 (100)
Preparation time needed to quit				
	Less than 3 days	59 (23.0)	69 (25.6)	128 (24.3)
	3 days to < 2 weeks	95 (37.1)	62 (23.0)	157 (29.8)
	2 weeks to 1month	55 (21.5)	49 (18.1)	104 (19.8)
	More than 1 month	47 (18.4)	90 (33.3)	137 (26.0)
	Total	256 (100)	270 (100)	526 (100)*

* $P < 0.05$

About 80 percent of the participants felt gradual quitting was more feasible than abruptly quitting. More than half said that they would be able to quit within the next two weeks whereas about a quarter of the participants needed more than a month.

4.3. Outcome of intervention

Smoking status of participants at different points of time

The results of smoking status and quantity of smoking of the participants in both the groups assessed at different points of time are detailed in Table 18.

Table 18. Smoking status of participants at different points of time

	Non-counseled N = 431 N (%)	Counseled N = 444 N (%)	Total N = 875 N (%)
Week 3			
Smoking continued at the same level	176 (43.1)	112 (26.4)	288 (34.6)
Smoking reduced up to 25%	85 (20.8)	77 (18.2)	162 (19.5)
Smoking reduced up to 50%	57 (14.0)	84 (19.8)	141 (16.9)
Smoking reduced by more than 50%	45 (11.0)	73 (17.2)	118 (14.2)*
Successfully quit	45 (11.0)	78 (18.4)	123 (14.8)*
Week 6			
Smoking continued at the same level	93 (22.9)	78 (18.5)	171 (20.7)
Smoking reduced up to 25%	89 (21.9)	56 (13.3)	145 (17.5)
Smoking reduced up to 50%	102 (25.1)	82 (19.5)	184 (22.2)
Smoking reduced by more than 50%	58 (14.3)	115 (27.3)	173 (20.9)*
Successfully quit	64 (15.8)	90 (21.4)	154 (18.6)*
Week 12			
Smoking continued at the same level	69 (17.2)	68 (16.3)	137 (16.8)
Smoking reduced up to 25%	60 (15.0)	39 (9.4)	99 (12.1)
Smoking reduced up to 50%	106 (26.4)	79 (19.0)	185 (22.6)
Smoking reduced by more than 50%	90 (22.4)	124 (29.8)	214 (26.2)*
Successfully quit	76 (19.0)	106 (25.5)	182 (22.3)*

* $P < 0.05$

Around one fourth of both the groups had either successfully quit or reduced by more than half by the third week. The proportion of those who had reduced smoking by more than half and those who had successfully quit at the third week were significantly higher among the counseled group than the non-counseled group. These proportions were found to be significantly higher in the counseled group in the sixth and 12th weeks also.

Smoking status of early quitters at week 26

At week 12 after intervention, 182 participants had successfully quit and nearly 80% of these early quitters (147) were followed up at week 26 to assess their then smoking status. The results are presented in Table 19. Almost two thirds of the early quitters had continued to be quit at week 26 whereas about one third had relapsed. About seven percent had reverted to their original level of smoking. The smoking status of the early quitters was not significantly different between the two groups at week 26.

Table 19. Smoking status of early quitters at week 26

	Non-counseled No. (%)	Counseled No. (%)	Total No. (%)
Week 26			
Abstinence continued	44 (71.0%)	52 (61.2%)	96 (65.3%)
Relapsed and reduced the quantity to less than 26% of pre-intervention level	4 (6.5%)	12 (14.1%)	16 (10.9%)
Relapsed and reduced the quantity to more than 26% of pre-intervention level	11 (17.7%)	14 (16.5%)	25 (17.0%)
Relapsed and reverted to the quantity of the pre-intervention level	3 (4.8%)	7 (8.2%)	10 (6.8%)
Total	62 (100%)	85 (100%)	147 (100%)

* $P < 0.05$

On further analysis it was found that 51 out of the 52 participants in the counseled group, who had quit at 26 weeks, had actually done so in the first three

weeks itself. In contrast, only 27 out of 44 (61%) early quitters in the non counseled group did so in the first three weeks.

Mode of quit used by successful quitters

Mode of quit used by successful quitters at different points of time are given in Table 20. Nearly half of those who quit within the first three weeks after intervention quit gradually whereas the other half quit abruptly. However, all those who quit after three weeks quit gradually only.

Table 20. Mode of quit used by successful quitters at different points of time

	Non-counseled No. (%)	Counseled No. (%)	Total No. (%)
Quit at week 3			
Gradual	23 (51.1)	30 (38.5)	53 (43.1)
Abrupt	22 (48.9)	48 (61.5)	70 (56.9)
Total	45 (100)	77 (100)	122 (100)
Quit at week 6			
Gradual	21 (100)	20 (100)	41 (100)
Abrupt	0	0	0
Total	21 (100)	20 (100)	41 (100)
Quit at week 12			
Gradual	15 (100)	19 (100)	34 (100)
Abrupt	0	0	0
Total	15 (100)	19 (100)	34 (100)

Withdrawal Symptoms on quitting

Major withdrawal symptoms experienced by those who quit at different time points are given in Table 21. Craving and drowsiness were the main symptoms mentioned. The proportion of quitters who experienced other withdrawal symptoms like constipation, indigestion, anxiety, tension, stress, etc. was negligible. There was

no difference in the experience of withdrawal symptoms of quitters in the two study groups.

Table 21. Withdrawal Symptoms experienced by quitters at different points of time

	Non-counseled No. (%)	Counseled No. (%)	Total No. (%)
Quit at week 3			
Craving	14 (31.1%)	14 (18.2%)	28 (23.0%)
No withdrawal symptoms	24 (53.3%)	56 (72.7%)	80 (65.6%)
Drowsiness	9 (20.0%)	7 (9.1%)	16 (13.1%)
Quit at week 6			
Craving	9 (42.9%)	8 (40.0%)	17 (41.5%)
No withdrawal symptoms	11 (52.4%)	10 (50.0%)	21 (51.2%)
Drowsiness	3 (14.3%)	3 (15.0%)	6 (14.6%)
Quit at week 12			
Craving	7 (46.7%)	8 (47.1%)	15 (46.9%)
No withdrawal symptoms	6 (40.0%)	9 (52.9%)	15 (46.9%)
Drowsiness	15 (100%)	17 (100%)	32 (100%)

More than two thirds who quit smoking at different points of time did not use any substitutes. Very few mentioned the use of cumin seed, candy, water, tea, pepper, clove and cardamom.

Reasons for not quitting

The important reasons as stated by the participants for not quitting are listed in Table 22. Craving and habituation were cited as the most common reasons and the reasons were not significantly different among the two groups.

Table 22. Reasons for not quitting smoking at different points of time

	Non-counseled	Counseled	Total
Not quit at week 3, No (%)	**363**	**346**	**709**
Craving	121 (33.3%)	173 (50.0%)	294 (41.5%)
Habituation	85 (23.4%)	76 (21.9%)	161 (22.7%)
No specific reason	53 (14.6%)	10 (2.9%)	63 (8.9%)
Not quit at week 6, No (%)	**340**	**324**	**664**
Craving	107 (31.5%)	164 (50.6%)	271 (40.8%)
Habituation	77 (22.6%)	71 (21.9%)	148 (22.3%)
No specific reason	7 (2.1%)	5 (1.5%)	12 (1.8%)
Not quit at week 12, No (%)	**320**	**302**	**622**
Craving	116 (36.3%)	163 (54.0%)	270 (44.8%)
Habituation	76 (23.7%)	59 (19.6%)	135 (21.7%)
No specific reason	5 (1.6%)	4 (1.3%)	9 (1.4%)

Factors that helped to quit

Factors reported to have helped to quit are presented in table 23. Self control and the advice of a doctor were the most common factors mentioned by the participants that helped them to quit. It was not different among the two groups. However, the overall findings suggest that advice of doctor may be a very important motivating factor.

Table 23. Factors that helped to quit

	Non-counseled N = 62 N (%)	Counseled N = 85 N (%)	Total N = 147 N (%)
Self control	35 (56.5%)	47 (57.3%)	82 (56.9%)
Help and cooperation of friends	6 (9.7%)	13 (15.9%)	19 (13.2%)
Help and cooperation of family	20 (32.3%)	36 (43.9%)	56 (38.9%)
Advice of doctor	54 (87.1%)	68 (82.9%)	122 (84.7%)
Use of substitutes	6 (9.7%)	10 (12.2%)	16 (11.1%)

The most important factor that helped to quit

The most important factors reported to have helped to quit are presented in table 24. The only significantly different factor was advice of doctor.

Table 24. The most important factor that helped in quitting

	Non-counseled N = 62 N (%)	Counseled N = 85 N (%)	Total N = 147 N (%)
Self control	22 (36.1%)	24 (30.4%)	46 (32.9%)
Help and cooperation of friends	1 (1.6%)	2 (2.5%)	3 (2.1%)
Help and cooperation of family	11 (17.7%)	8 (10.1%)	19 (13.5%)
Advice of doctor	22 (35.5%)	42 (53.2%)	64 (45.4%)*
Use of substitutes	0 (0%)	2 (2.5%)	2 (1.4%)
Others	6 (9.6%)	4 (5.0%)	10 (7.0%)

* $P < 0.05$

4.4. Outcome indicators

Quit attempt rate

Quit attempt rate within three weeks after intervention in the non-counseled group and counseled group are given in Table 25.

Table 25. Quit attempt rate with in 3 weeks after intervention

	Non-counseled N (%)	Counseled N (%)	Total N (%)	OR (95% CI)
Attempted	320 (78.4)	396 (93.4)	716 (86.1)	3.9 (2.4 – 6.1)†
Not attempted	88 (21.6)	28 (6.6)	116 (13.9)	
Total	408 (100)	424 (100)	832 (100)	

† P < 0.001

Harm Reduction rate

Harm Reduction rate (reduced smoking quantity > 50%) among the two groups at 12 weeks is indicated in Table 26.

Table 26. Harm Reduction rate at 12 weeks

	Non-counseled N (%)	Counseled N (%)	Total N (%)	OR (95% CI)
More than 50% reduction in smoking	90 (27.7)	124 (40.0)	214 (33.7)	1.7 (1.2 – 2.4)*
All others except successful quitters	235 (72.3)	186 (40.0)	421 (66.3)	
Total	325 (100)	310 (100)	625 (100)	

* P value < 0.05

Quit rate at different points of time

Weekly point prevalence of smoking abstinence and Continuous smoking abstinence rates were calculated.

Weekly Point Prevalence of smoking abstinence

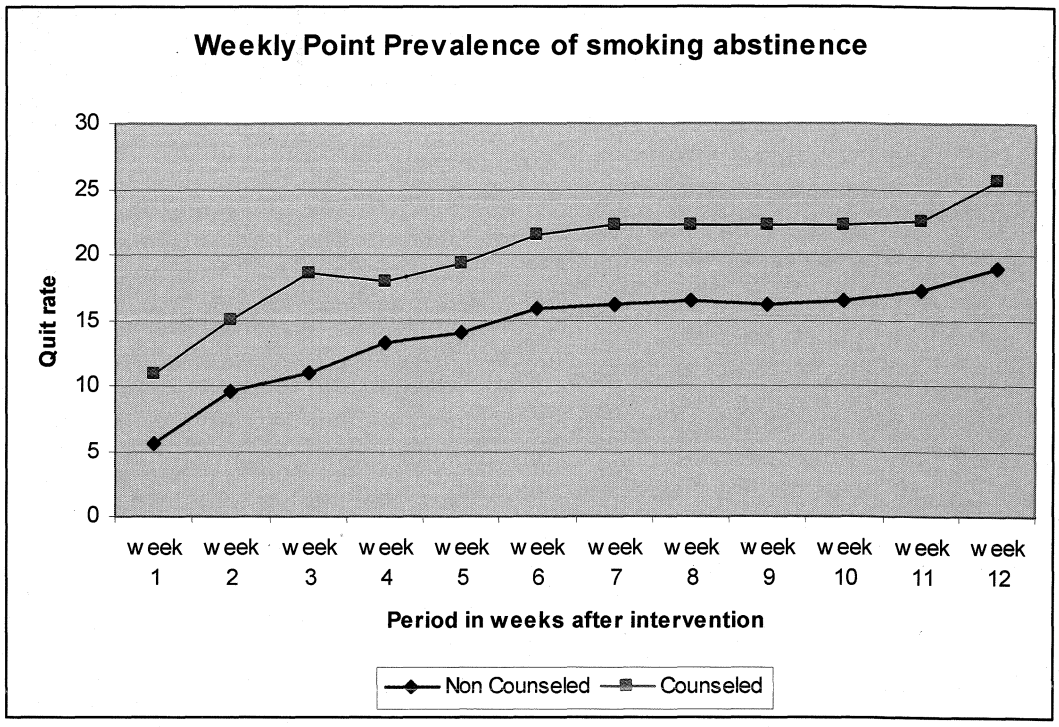
Weekly point prevalence of smoking abstinence at different weeks is shown in Table 27. The quit rates at every week from the first to the twelfth weeks except week four and 11 were significantly higher among those in the counseled group compared to the non-counseled group.

Table 27. Weekly Point Prevalence of smoking abstinence

	Non-counseled N = 431 N (%)	Counseled N = 444 N (%)	Total N = 875 N (%)	OR (95% CI)
Week 1	23 (5.6)	46 (10.8)	69 (8.3)	2.0 (1.2 - 3.4)**
Week 2	39 (9.6)	63 (14.9)	102 (12.3)	1.7 (1.1 - 2.5)*
Week 3	45 (11.0)	78 (18.5)	123 (14.8)	1.8 (1.2 - 2.7)**
Week 4	54 (13.3)	75 (17.8)	129 (15.6)	1.4 (1.0 - 2.1)
Week 5	57 (14.0)	81 (19.2)	138 (16.7)	1.5 (1.0 - 2.1)*
Week 6	64 (15.8)	90 (21.4)	154 (18.6)	1.5 (1.0 - 2.1)*
Week 7	65 (16.2)	92 (22.1)	157 (19.2)	1.5 (1.0 - 2.1)*
Week 8	66 (16.5)	92 (22.1)	158 (19.3)	1.4 (1.0 - 2.0)*
Week 9	65 (16.2)	92 (22.1)	157 (19.2)	1.5 (1.0 - 2.1)*
Week 10	66 (16.5)	92 (22.1)	158 (19.3)	1.4 (1.0 - 2.0)*
Week 11	69 (17.2)	93 (22.4)	162 (19.8)	1.4 (1.0 - 2.0)
Week 12	76 (19.0)	106 (25.5)	182 (22.3)	1.4 (1.0 - 2.0)*

* P value < 0.05; ** P value < 0.005

Graph 1. Weekly Point Prevalence of smoking abstinence



Continuous Smoking Abstinence rates

Continuous Smoking Abstinence rates from week three to week 12 among the non-counseled group (10%) and counseled group (16%) are given in Table 28. The rates at all time points were significantly different. Almost all who quit within three weeks after intervention continued their quit status at weeks six, nine and 12.

Table 28. Continuous Smoking Abstinence rates at different points of time

	Non-counseled N = 431 N (%)	Counseled N = 444 N (%)	Total N = 875 N (%)	OR (95% CI)
Week 3 to 6	43 (10.6)	70 (16.6)	113 (13.7)	1.7 (1.1 - 2.5)*
Week 3 to 9	43 (10.6)	70 (16.6)	113 (13.7)	1.7 (1.1 - 2.5)*
Week 3 to 12	42 (10.3)	68 (16.2)	110 (13.3)	1.7 (1.1 - 2.5)*
Week 3 to 26	24 (6.0)	42 (10.1)	66 (8.1)	1.8 (1.1 - 3.0)*

* P value < 0.05

Graph 1. Weekly Point Prevalence of smoking abstinence

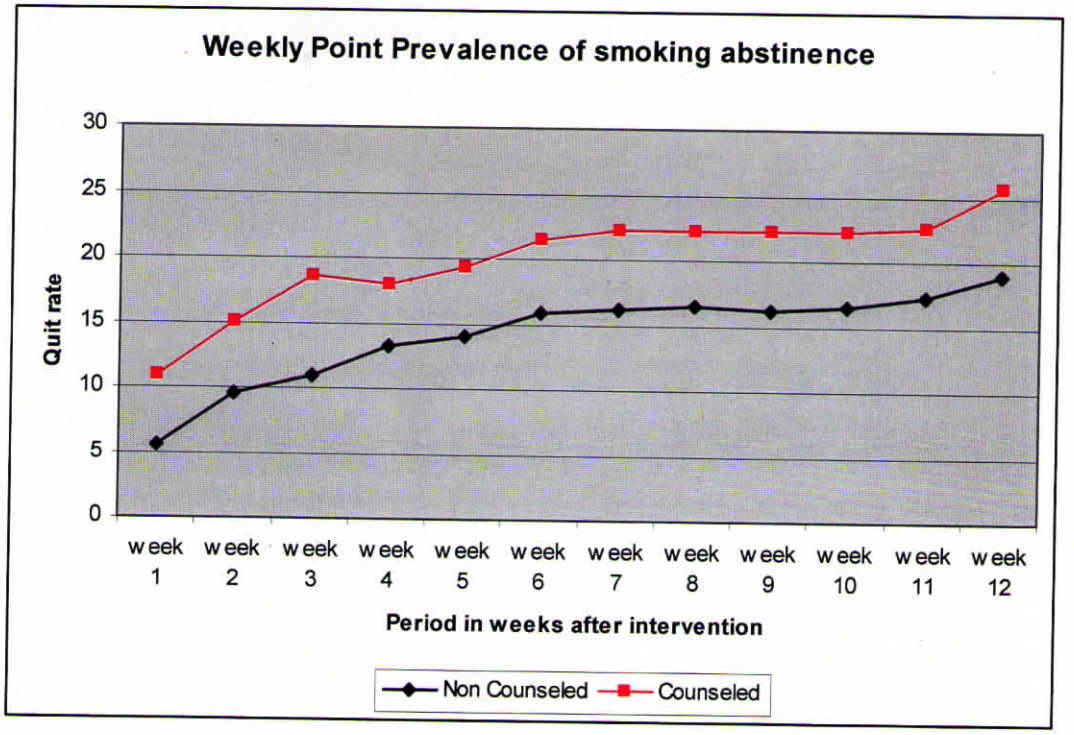


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Table 28. Continuous Smoking Abstinence rates at different points of time

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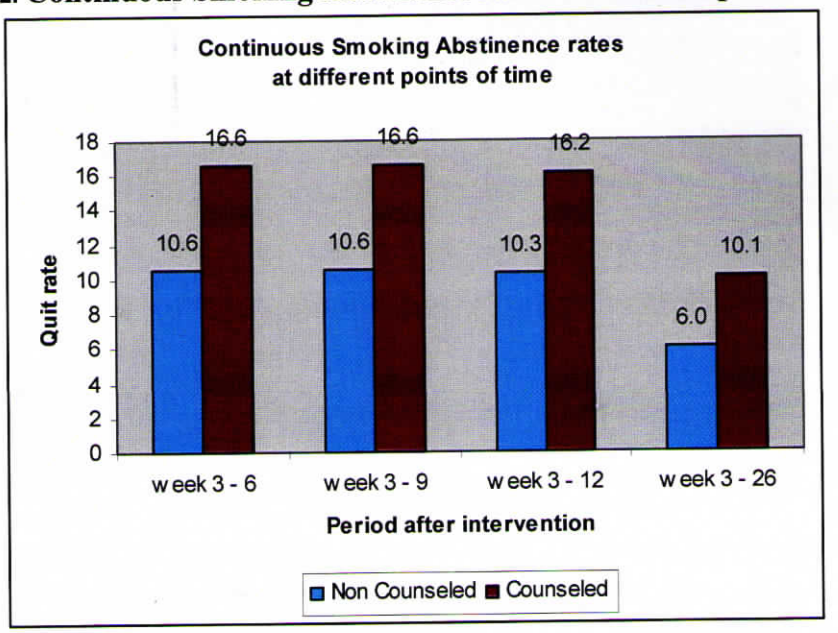
Week 3 to 6	43 (10.6)	70 (16.6)	113 (13.7)	1.7 (1.1 - 2.5)*
Week 3 to 9	43 (10.6)	70 (16.6)	113 (13.7)	1.7 (1.1 - 2.5)*
Week 3 to 12	42 (10.3)	68 (16.2)	110 (13.3)	1.7 (1.1 - 2.5)*
Week 3 to 26	24 (6.0)	42 (10.1)	66 (8.1)	1.8 (1.1 - 3.0)*

* P value < 0.05

Graph 2. **Continuous Smoking Abstinence rates at different points of time**



Relapse rate

At 12 weeks 182 participants had successfully quit smoking however, during this period 16 other participants also quit temporarily but relapsed soon. About 35%, out of 147 participants who had quit smoking at 12 weeks were found to have relapsed at week 26 and the relapse rate was not different between the two groups.

4.5. Predictors of smoking cessation behavior

Predictors of quit attempt

Logistic regression was undertaken to measure the influence of factors such as intervention, economic status, number of sticks smoked daily, time to first cigarette/bidi in the morning and intention to quit that were significantly associated with quit attempt in bivariate analysis. All these factors were found significantly associated with quit attempt. The details are shown in Table 29. Counseling intervention, low economic status, a higher number of cigarette/*bidi* daily, less than 30 minutes to the first puff in the morning and strong intention to quit were the statistically significant independent predictors of a greater likelihood of quit attempt.

Table 29. Results of logistic regression analysis showing the predictors of quit attempt

Characteristics		Quit attempt (%)	Adjusted OR (95% CI)
Intervention	Doctor advice	78.4	Reference
	Doctor advice and counseling	93.4	3.3 (2.1 – 5.3)
Economic Status	Medium	80.8	Reference
	Low	87.9	1.6 (1.1 – 2.5)
Number of sticks smoked daily	1 to 10	84.1	Reference
	> 10	87.7	1.5 (1.0 – 2.3)
Time to first cigarette/ *bidi* in the morning	< 31 minutes	93.6	Reference
	> 30 minutes	81.4	0.4 (0.2 – 0.6)
Intention to quit	Low	84.3	Reference
	Strong	92.0	2.1 (1.2 – 3.9)

Predictors of short term quit success

Independent variables considered for logistic regression to measure the influence on short term quit success were intervention, age, chronic disease, number of sticks smoked daily, time to first cigarettes/bidi in the morning, intention to quit, readiness to quit, confidence to quit and presence of past quit history. Variables which showed significant association in bivariate analysis were included in logistic regression and the strength of association with quit success are given in Table 30. Statistically significant predictors of a greater likelihood of short term quit success included counseling intervention, younger age, lower number of cigarette/bidi daily, more than 30 minutes to first puff in the morning, presence of past quit history and strong intention to quit.

Table 30. Results of logistic regression analysis showing the predictors of short term quit success

Characteristics		Quit rate (%)	Adjusted OR (95% CI)
Intervention	Doctor advice	19.2	Reference
	Doctor advice and counseling	25.5	1.6 (1.1 – 2.3)
Age	> 24 years	20.2	Reference
	18 – 24 years	54.7	3.0 (1.6 – 5.6)
Number of sticks smoked daily	> 10	10.1	Reference
	1 to 10	36.5	4.2 (2.8 – 6.3)
Time to first cigarette/ *bidi* in the morning	> 30 minutes	14.7	Reference
	< 31 minutes	35.0	2.0 (1.4 – 3.0)
Intention to quit	Low	19.9	Reference
	Strong	31.0	2.5 (1.2 – 5.0)
Presence of past quit history	No	16.7	Reference
	Yes	30.1	1.9 (1.3 – 2.8)

Predictors of long term quit success

Logistic regression was undertaken to measure the influence of factors such as age, economic status, number of sticks smoked daily, time to first cigarette/bidi in the morning, intention to quit, readiness to quit and presence of past quit history that were significantly associated with long term quit success in bivariate analysis. The three factors that were identified in the multivariate analysis as significant predictors of long term quitting success included a lower number of cigarettes/*bidi* daily, presence of quit history in the past and a strong intention to quit. More are given in Table 31.

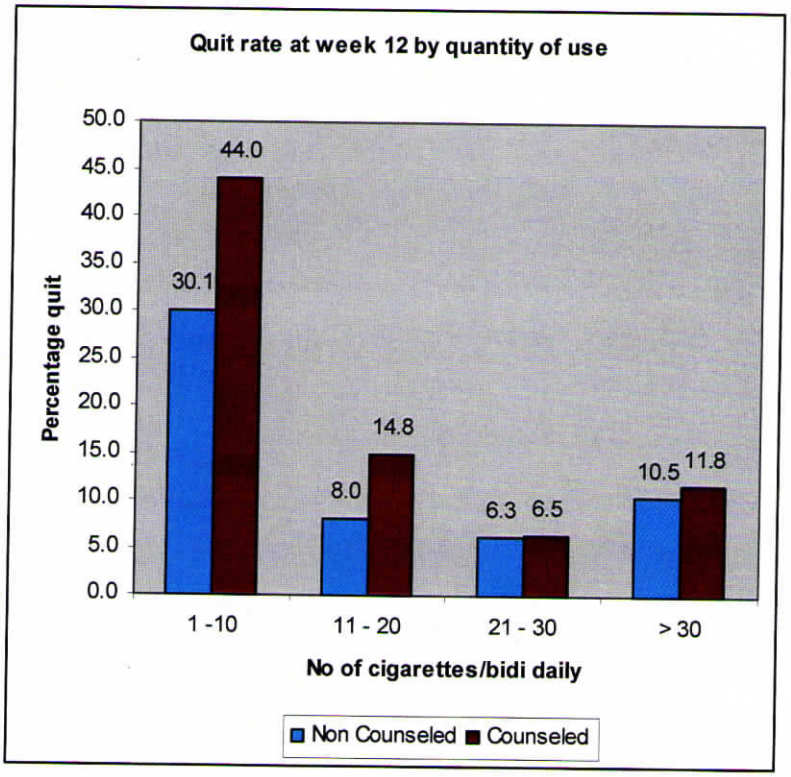
Table 31. Results of logistic regression analysis showing the predictors of long term quit success

Characteristics		Cumulative Quit rate (%)	Adjusted OR (95% CI)
Number of sticks smoked daily	> 10	2.4	Reference
	1 to 10	14.4	4.2 (2.5 – 7.2)
Intention to quit	Low	6.5	Reference
	Strong	13.7	2.2 (1.0 – 5.0)
Presence of past quit history	No	4.7	Reference
	Yes	12.8	1.7 (1.1 – 2.7)

Quantity of smoking among quitters

Quit rates at week 12 were higher among the counseled group than the non-counseled group who smoked up to 20 cigarettes/*bidis* daily. This was significantly different when the quantity was up to 10 cigarettes/*bidis* daily.

Graph 3. Quit rate at week 12 by quantity of use



Chapter 5

Discussion

Although tobacco use is extremely high in India with 194 million tobacco users, research on tobacco cessation using randomized controlled trials in India has not been reported so far. This randomized controlled trial involving 875 patients in seven primary health centres of Palakkad district of Kerala is the first of its kind from India.

5.1. Continuous Smoking abstinence rate

At six months the continuous abstinence rates among those in the intervention group was 1.8 times (95% CI: 1.1–3.0) higher compared to those who received doctor advice alone. This was a very crucial finding in terms of practical tobacco cessation practices. The participants who had quit smoking within three weeks of intervention showed a higher chance of continuous smoking abstinence even at week 26. There were more early quitters among the counseled group than the non-counseled group indicating that focused and multi-pronged strategies of tobacco cessation were more likely to result in early quitting and prolonged abstinence. Hence tobacco cessation intervention using counseling in addition to doctor's advice will be a more effective and feasible method for early and sustained smoking abstinence in primary health care settings in the district. In the present study this was accomplished with the service of nurses and pharmacists. Field workers of primary health centers could also achieve this if they can provide counseling services to smoking patients after they are advised by the doctors to quit smoking. This could be tried in the primary health care settings of Kerala. Although the qualifications of field workers are comparatively less than that of nurses and pharmacists they could be given some training in counseling and effectively used for this purpose in the future.

5.2. Weekly point prevalence of smoking abstinence

The weekly point prevalence of smoking abstinence was found to be significantly higher among those who received counseling. The quit rates at the third, sixth, and the twelfth week showed this difference. Counseling had doubled the odds of quitting at week one but the chance of quitting declined to 1.4 times at week four. The highest odds at week one could be due to the immediate effect of counseling. However a major reason for the fall in difference between the two groups in the succeeding weeks might have been due to the fact that the process of follow up by the health workers at the home or work place of the participants would have served like counseling for those who did not receive counseling from nurses and pharmacists.

The weekly point prevalence of smoking abstinence in this study showed a steady increase in both groups as the weeks progressed. Intervention studies with drug and non-drug methods have reported progressive decline in weekly point prevalence of smoking abstinence.[177] The high initial quit rates and subsequent decline may be due to the effect of the drug and its subsequent withdrawal. In contrast to this, in this study each contact with the health worker in the form of follow up would have acted as a reinforcement of the tobacco cessation message and might have served like repeated counseling. The social network and interaction between the health workers and the study participants who live in the same locality and familiarity with them may have contributed positively to the continued smoking abstinence. This perhaps could be a good model for dissemination.

The levels of intention, motivation, readiness and confidence to quit smoking, the indicators used to measure the preparedness to quit, were significantly lower in the counseled group. However the risk perception regarding smoking was significantly higher among participants who got counseling than the comparison group. The mean number of 17 cigarettes/bidi smoked by the participants in the counseled group was significantly higher compared to the mean number of 13 in the non counseled participants. This higher quantity of use by the counseled group could be one of the reasons for their low preparedness for quitting. Nearly 30 percent in the non counseled group had strong intention, good confidence and greater readiness to quit smoking as compact against less than 20 percent in the counseled group. This difference with regard to increased quantity of smoking and lower preparedness to

quit among smokers in the counseled group could be one of the reasons for the lower odds ratio for quitting in the present study. In addition doctor's advice in developing country situations such as Kerala has a strong value compared to non-doctors advice. The intervention group had a significantly higher proportion of participants belonging to low socio economic status and this would have also reduced the overall quit rates in this group. Many studies had consistently reported the negative relationship between socio economic status and quit rates.

It has been documented that smoking abstinence is better achieved without drugs when a person smokes up to 10 cigarette/*bidi* per day. In the present study nearly half of the participants smoked up to 10 cigarettes daily. The results of the present study showed that the chance of quitting was significantly higher among those who smoked up to 10 cigarettes/*bidi* daily compared to participants who smoked more than 10 cigarette/*bidi* per day. Counseling further increased the chance of quitting among those who smoked up to 10 cigarette/*bidi* daily; which was 1.8 times (95% CI:1.2–2.8) more than those who did not receive counseling.

With respect to non-doctor counseling as a strategy, previous studies have compared effectiveness of non-doctor counseling against routine care or no advice. The odds ratio in a meta-analysis of previous individual behavior counseling was 1.56 (95% CI: 1.32–1.84)[125] compared to 1.4 (1.0–2.0) in this study. Meta-analysis results as reported in the USDHHS guideline indicate that low intensity counseling of three to 10 minutes was 1.6 times more effective than no intervention. Bala and Lesniak showed that non-pharmacological smoking cessation methods available in Poland, namely simple advice by a doctor and individual and group counseling, increased the probability of smoking cessation and smoking abstinence for 12 months by 1.5 to two times.[178] Review of studies registered in the Cochrane data base up to February 2005 and other studies published up to March 2004 found that the individual counseling provided by a nurse (OR 1.43, 95% CI: 1.24–1.64) and other health care providers (OR 1.62, 95% CI: 1.35–1.94) was more effective in comparison with the control group who were devoid of similar therapy.[179]

Physical dependence including craving and withdrawal symptoms are cited as the major barriers to quitting. However in the present study craving at three, six and 12 weeks was not significantly different between those who quit in the counseled and

non counseled group. Craving is an indicator of dependence and therefore related to the mean number of cigarette/*bidi* smoked per day. The reason for a lack of difference between the two groups in terms of craving may be because of the mean number of cigarette/*bidi* is low in this study. Similarly in contrast to the withdrawal symptom rates reported by studies, about two thirds of the quitters did not report any withdrawal symptoms except drowsiness. This was also not different between the two groups and could also be due to the lower mean number of cigarette/*bidi*. This area warrants more explorative research.

Regarding the nature of quit behavior it was interesting to note that more than one third (35 percent) of those who attempted to quit reported abrupt quitting. In terms of relapse, however, there was no difference between those who had quit abruptly and gradually in congruence with evidence from literature.

The quit rate found in the study with doctor advice alone (19.0 percent) appears to be greater than the quit rate found in the USDHHS Guideline (10.2%; 95% CI: 8.5–12.0).[101] Similarly, the quit rate with doctor advice augmented with counseling (25.5 percent) also seems to be greater than that of low intensive counseling in the USDHHS Guideline (16.0%; 95% CI: 12.8–19.2). The results of the USDHHS Guideline and Cochrane studies are the outcome at six months or later but that of the present study was at 12 weeks. Almost one third reduction in the quit rate could be expected in the present study at six months since one third of the quitters at week 12 had relapsed at six months.

But a question to be looked into is why this study yielded better outcome than expected in a place where neither tobacco control is a priority nor quitting smoking is a regular practice. Might there be a novelty effect? Doctor's advice could be more powerful in a context where smokers have not already heard the message to quit on numerous occasions.

The characteristics of the study setting itself could be one of the reasons for such a high quit rate. A primary health centre setting in a comparatively rural backdrop is not exactly comparable with the clinical settings that have been reported by the other studies. Familiarity with the doctor and the health workers and the importance of the health workers and the value attached by a rural community to the advice given by government doctors could also be reasons that ensured such high quit

rates. Palakkad district, in addition, is still a predominantly rural and agrarian district of Kerala where urbanization has not yet crept in to a large extent. This is reflected in the demographic profile of the study participants also. Since the patients who attended PHCs were generally unaware of the serious implications of smoking on health a simple advice from a doctor and further explanations from other health professionals could have positively influenced quit behavior.

However there are studies that reported higher quit rates compared to the present study. The effectiveness of counseling in this study was lower than that of a recent Chinese study, which reported an adjusted odds ratio of 6.42 at the six-month follow up with a smoking cessation program.[177] Quit rate after six months in the intervention group in the above study was 40.5 percent (47/116) and in the control group was 5.0 percent (5/101). The continuous abstinence rate at six months was 28.4 percent (33/116) in the intervention group and 3.0 percent (3/101) in the control group. The participants in the intervention group received a course on smoking cessation based on social cognitive theory which could be a reason for better results. Results from the smoking cessation program in primary care settings in Spain also showed that the intervention group was 5.2 times (95% CI: 1.63–17.13) more likely to quit than the comparison group who got antismoking advice (quit rate was 18.4 percent compared to 3.4 percent).[180] The higher abstinence rate in the Spanish study might be due to motivational intervention delivered by therapists and the use of Bupropione when nicotine dependency was high (Fagerstrom score >7). The intensity of the intervention (e.g., total contact time) may be an another factor. In general more intense interventions produce higher abstinence rates than do brief interventions.

Quit rate in the present study was lower than that of hospital settings in other studies. Trials of smoking cessation interventions in hospitalized patients have also resulted in increased cessation rates, especially in specific populations such as those with acute myocardial infarction or, to a lesser extent, those undergoing elective surgery. Whether these results may be generalized to patients hospitalized in a tertiary care center remains uncertain. This could be due to the difference in the profile of illnesses for which the client sought care from the primary health centre. Participants in this study attended the primary care clinic either for mild disease or for routine follow up care of chronic diseases instead of serious diseases like myocardial

infarction, cancer, severe asthma, surgical procedures etc in hospital settings which may be the reason for the lower outcome.

5.3. Harm reduction rate

Harm reduction or reduction of tobacco use by more than 50 percent is another important outcome measure of any tobacco cessation intervention. About one third of participants, who continued to smoke, reduced their tobacco consumption by more than fifty percent and the proportion of those who achieved harm reduction was significantly higher among the counseled group at the third, sixth and 12th weeks. Those in the counseled group were 1.7 times (95% CI: 1.2–2.4) more likely to reduce harm by more than fifty percent compared to the group that received doctors' advice only. The harm reduction rate of this present study was comparable with that of some interventions with NRT. The meta-analysis by Wang et al. found the superiority of NRT over placebo by 2.06 times (95% CI: 1.34–3.15) in achieving harm reduction.[181] Harm reduction could deliver substantial reductions in the morbidity and mortality currently caused by tobacco consumption. In the light of the arguments for using nicotine substitutes or smokeless tobacco products for accomplishing harm reduction of tobacco smoking by Britton and Edwards in the Lancet 2007, attaining similar levels of harm reduction by a non-drug method assumes greater significance.[182] Moreover in the Indian situation smokeless tobacco use has been reported to cause several types of cancers.[34] Therefore it cannot be recommended as a substitute for smoking.

5.4. Quit attempt rate

Quit attempt rate has been considered as an important outcome measure of tobacco cessation. The quit attempt rate within three weeks after intervention in the counseled group was four times higher compared to the group that did not get counseling. Results of a similar study from Spain in 1996 in the primary health care setting reported that quit attempts were 1.5 times (95% CI: 1.2–2.0) higher among the group of patients who received doctor's advice compared to those who did not and 10.9 times (95% CI: 6.4–18.6) higher if the doctor's advice was followed up with visits by non doctor health professionals compared to their counterparts. The mean addiction score and quantity of smoking were also comparable with the present

study.[183] The odds of quit attempts in our study was comparatively less than this Spanish study probably because in our study both groups received doctor's advice and follow-up visits. However the quit attempts were high in both the groups in our study: 93.4% in the counseled group and 78.4% in the non-counseled group. In the light of international evidence that repeated quit attempts result in more quit success, this finding assumes great significance.

5.5. Relapse rate

Relapse rate during the first 12 weeks of study was negligible among both counseled and non-counseled group. At six months one third of all quitters had relapsed and the relapse rates in the two groups were not significantly different. Lack of follow up for three months after 12 weeks might be the reason for relapse. Further studies are needed to know how such relapses can be prevented.

5.6. Predictors of quit behavior

The findings indicate that for both short term (at week 12) and long term (at week 26) quit success the strongest predictors were measures of nicotine dependence, intention to quit and presence of past quit attempt. The finding that those who had smoked more were more dependent on smoking was consistent with previous findings.[139, 140, 183] The magnitude of association of dependence indicator was larger in the present study than some of the studies in which even NRT was used. On the contrary the measures of readiness to quit, confidence to quit and disease profile were not associated with short term or long term quit success.

Young smokers (less than 25 years) were more likely to succeed in short term smoking abstinence, rather than long term. This is in contradiction to earlier studies that found that quit smoking success was greater with older age.[139, 140] One reason for this may be that many of them were using a very low number of cigarettes and hence addiction levels might have been low. Another reason could be that young smokers are more likely to quit and restart smoking frequently or would not be smoking consistently on all days in a week. So any intervention can influence them for a while, but not for a long term. In previous studies, many of the participants in the older age

group suffered from serious illnesses, and might have already been persuaded to quit, whereas in the present study there were not many seriously diseased participants.[145]

Socio-demographic characteristics, a combination of education, occupation, income, may have a greater impact on smoking cessation programs in the general population. Higher education, higher income and better jobs were found to be successful predictors of quitting smoking in the published literature. Lack of sufficient representation in higher categories of education and economic status and a lower number of participants with better jobs may be the reasons for the absence of predictive power of these variables in the present study. This has happened since the subjects who participated in this study were selected from those who sought care at Primary Health Centers which is used more by those from lower socio-economic groups, for reasons of affordability.

Neither non-communicable diseases nor communicable diseases were predictors of quit behavior. The Collaborative European Anti Smoking Evaluation (CEASE) trial conducted in 17 European countries also failed to establish an association of quit behavior with diseases other than cardiac and respiratory.[145] People with low nicotine dependence might have quit shortly after the first appearance of symptoms, thereby not allowing the disease to progress to chronic stages, which may be reason for non association.

The counseled group could initiate but could not sustain long term quit success. Counseling was a less predictive factor for long term quit success, although it was a stronger predictive factor for short term quit success. A slow decline in the effect of counseling, inability to resist the craving and habituation, and non-use of coping substitutes could have toppled early success. This could have been avoided if they had utilized the support of family, friends and health-workers.

FTND score has been reported a less powerful predictor of nicotine dependence in India.[184] Low predictive power of a dependence questionnaire was cited as a possible reason for the lack of association between quit behavior and variables other than quantity of smoking in the FTND scale. Although the present study did not use FTND score specifically, the mean number of cigarettes/*bidi* smoked per day was taken as a proxy indicator of addiction level and a similar association with quit rates was found.

The predictor that was consistent in all three stages of quit behavior was the intention to quit. Positive association with stronger levels of intention to quit is very much encouraging since Hyland et al.[139] had recorded abstinence of more than 13 years among those who expressed a lot of desire to quit. About 98 percent of participants in this study had some degree of intention, but only less than one-fourth had very strong intention. For building up strong levels of intention, intervention through doctor advice is a pre-requisite for quit success. This was reflected in the participants' response about the factors that helped them to quit. More than 80 percent thought doctor advice and self efficacy were the crucial determinants in quitting. Reinforcing doctor advice during counseling will yield better results. Various counseling approaches can be utilized for improving self efficacy. Although perception regarding harm due to smoking was greater among the counseled group at baseline, this did not significantly affect their quit behavior. This could indicate the fact that effective tobacco message and counseling by health professionals can change smoking behavior irrespective of their perceptions. Conscious efforts by doctors, nurses, health workers and pharmacists to encourage quitting at each contact point could be useful to accomplish better permanent smoking abstinence rates.

5.7. Strengths and limitations of the study

Conduction of the study in different sites with different investigators may be considered as the strength of the study since the health system includes different types of people with different levels of knowledge, attitude and practice. Large sample size and high follow up rate were two other important strengths of this study. In contrast to the usual intervention studies of a similar nature nearly 90percent of the participants could be followed up at week 12 and 80 percent of all quitters even at week 26. The method of follow up in this study was by visiting clients at their home or work site. The fact that each primary health centre has a geographically described area for provision of its services and that the clients of a primary health centre generally hail from that area must have aided such high follow up rate. More importantly the routine field work that the health workers are required to carry out as part of their job responsibility gave them the additional advantage of knowing the exact location and situation of most of the clients.

A major limitation of the study was the absence of biochemical validation of smoking status due to lack of resources and facilities. Another important limitation was the delivery of doctor advice. The tailored personalized messages used by different investigators and the art of counseling in different sites might had been different. This could have influenced the study results in each site but it might have influenced both groups in a similar manner. But utmost care was taken to make everything uniform in all sites by giving uniform training, supplying printed guiding materials for advice and counseling, and monitoring the activities. Other limitations regarded baseline data collection and baseline characteristics of the participants. Baseline data collection itself might have enhanced motivation and quit rate among the control group. But the study revealed that motivation was not a significant factor predicting quit behavior. The participants were selected from the patients who attended the PHCs. They were generally poor, less educated, rural and agrarian. Hence some caution is warranted in generalizing the findings. This program did not include smokeless tobacco cessation program due to limitation of time and resources.

5.8. Implications of the study for tobacco cessation

This study has important public health implications. To the best of my knowledge this is the first study from India to report the outcomes of a smoking cessation programme within clinical settings. In the presence of a wide network of primary health care institutions in the country with organised field-based activities and of medical officers and other trained non-doctor health professionals, this study presents a huge potential in terms of tobacco cessation within clinical settings and especially primary health care. Although the study can be generalized only to Palakkad district of Kerala the other districts in the state are likely to be similar with regard to tobacco use pattern. Primary health centres in the entire state of Kerala are utilized more by the poorer sections of the society. Since tobacco use prevalence is greater in the poorer sections of society primary health centres can be effectively used in the entire state of Kerala for tobacco cessation.

The network of primary health care institutions in Kerala with medical officers and trained paramedical health workers is highly conducive for tobacco cessation strategies that involve doctor advice and non-doctor counselling. The very design of the field work that is part of the duties of health workers of the primary health care centres requires them to visit a household at least once in two months. Mere assessment of smoking during their interaction with the households/smokers on such occasions could act as repeated counselling and reinforcement of tobacco cessation messages. Quit rates being higher even among the non-intervention group in the study is a good example of this.

In addition it is also worth noting that the smoking abstinence at three weeks among the non counseled group was 11%. Although this was significantly lower than the counseled group it indicates the difference that doctor advice can make in tobacco cessation among patients attending health care facilities. Therefore training of medical officers and co-opting them into tobacco cessation strategies is crucial from a policy perspective.

Tobacco use in South Asia is distinct from the rest of the world in terms of relatively high use of smokeless forms of tobacco. In the present study nearly eight percent of the smokers also used smokeless tobacco products. Any intervention in tobacco cessation in India and Kerala therefore should also address smokeless tobacco use. There is a high likelihood that smokers who quit smoking as a result of smoking cessation programs in this region might substitute smoking with smokeless forms of tobacco and may be overlooked when tobacco cessation messages are developed and impact assessments on quit rates are assessed during interventions.

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Annexure 1

Framework Convention on Tobacco Control – Guidance

- Article 1 to 5: definitions, legal measures and guiding principles
- Article 6: Price raise through tax rise
- Article 7: advises the government to recognize and implement effective non-price measures necessary to reduce the demand for tobacco
- Article 8: Adopt effective measures to protect citizens from exposure to tobacco smoke in workplaces, indoor public places and public transport
- Article 9: Regulate the content and emissions of tobacco products (tar, nicotine, carbon monoxide), enforce disclosure of contents and establish quality testing laboratories
- Article 10: Regulate the packaging and labeling of tobacco products to prevent the use of misleading and deceptive terms like "low tar", "light", "ultra-light", or "mild or safe"
- Article 11: Regulate the packaging and labeling of tobacco products to depict large, clear, visible and legible warning labels covering 30 to 50% or more of the principal display areas. Avoid the use of terms like "low tar", "light", "ultra-light", or "mild or safe" on the cigarette packages since these words may provoke some subpopulation to think that this brand is more suitable for them. Use text or graphics
- Article 12: Promote and strengthen public awareness of tobacco control issues and propagate health risks of tobacco and exposure to tobacco smoke
- Article 13: Enact laws for comprehensive ban on tobacco advertising, promotion and sponsorship
- Article 14: Adopt and develop suitable tobacco cessation programs
- Article 15: Eliminate smuggling and illicit trade
- Article 16: Prohibit the sale of tobacco products to and by minors
- Article 17: Change policies to support economically viable alternative sources of income for tobacco workers and growers
- Article 18: Protect environment
- Article 19 to 35: Liability, research information exchange, finance and administration, and organization and dispute settlements

Results of meta-analyses studies mentioned in section 1.6.2.4.

Intervention	Agency	Number of trials	Effect Size %	OR (95% CI)
Doctor Advice				
Brief advice vs. no advice	Cochrane Library	17	2.5	1.74 (1.48 – 2.05)
	USDHHS	7	2.3	1.3 (1.1 – 1.6)
Brief advice vs. Minimal advice	Gorin et al	13	-	6.01 (2.46 - 13.29)
Intensive advice vs. brief advice	Cochrane Library	15	slight	1.44 (1.24 – 1.67)
	USDHHS	43	2.6	1.6 (1.2 – 2.0)
Single session vs. 2 to 3 sessions	Cochrane Library	-	-	-
	USDHHS	45	3.9	1.4 (1.1 – 1.7)
Single session vs. 4 to 8 sessions	Cochrane Library	-	-	-
	USDHHS	45	8.5	1.9 (1.6 – 2.2)
NPHP advice*				
Brief advice vs. no advice	Cochrane Library	20	1.2	1.47 (1.29 – 1.68)
	USDHHS	29	5.6	1.7 (1.3 – 2.1)
Brief advice vs. Minimal advice	Gorin et al	19	-	Not significant
Individual counseling vs. no counseling	Cochrane Library	18	4.0	1.56 (1.32 – 1.84)
	USDHHS	58	6.0	1.7 (1.4 – 2.0)
Group counseling vs. no counseling	Cochrane Library	7	10.0	2.17 (1.37 – 3.45)
	USDHHS	58	3.1	1.3 (1.1 – 1.6)
Group counseling vs. Individual counseling	Cochrane Library	-	-	-
	USDHHS	58	2.9	-
Telephone counseling vs. no counseling	Cochrane Library	8	2.0	1.41 (1.27 – 1.57)
	USDHHS	58	2.3	1.2 (1.1 – 1.4)

Results of meta-analyses studies mentioned in section 1.6.2.4. (contd)

Intervention	Agency	Number of trials	Effect Size %	OR (95% CI)
HP advice				
Single HP advice vs. No advice	Cochrane Library			
	USDHHS	37	7.5	1.8 (1.5 – 2.2)
2 types HP advice vs. No advice	Cochrane Library			
	USDHHS	37	12.8	2.5 (1.9 – 3.4)
Doctor's intervention vs. Nurse intervention	Gorin et al	Meta regression 13 vs. 19	-	4.13 (1.30 – 6.96)
Self Help Materials				
Provide materials vs. No materials	Cochrane Library	11	slight	1.24 (1.07 – 1.45)
	USDHHS	29	0.7	1.1 (0.9 – 1.3)
Multiple Interventions				
Single type intervention vs. no intervention	Cochrane Library	-	-	-
	USDHHS	54	4.3	1.5 (1.2 – 1.8)
2 types intervention vs. no intervention	Cochrane Library	-	-	-
	USDHHS	54	7.7	1.9 (1.6 – 2.2)
3 or 4 interventions vs. no intervention	Cochrane Library	-	-	-
	USDHHS	54	12.4	2.5 (2.1 – 3.0)
Team intervention vs. Minimal intervention	Gorin et al	13	-	0.79 (-0.19-3.71) (significant)

***Non Doctor Health Professional**

Results of meta-analyses studies mentioned in section 1.6.2.4. (contd)

Intervention	Agency	Number of trials	Effect Size %	OR (95% CI)
Drug Intervention				
NRT vs. no drug or placebo				
Any form of NRT vs. no drug or placebo	Cochrane Library	96	7.0	1.77 (1.66 – 1.88)
	USDHHS	-	-	-
GUM (NRT) vs. no drug or placebo	Cochrane Library	51	8.0	1.66 (1.52 – 1.81)
	USDHHS	13	6.6	1.5 (1.3 – 1.8)
	Watts et al			
Patch (NRT) vs. no drug or placebo	Cochrane Library	34	6.0	1.81 (1.63 - 2.02)
	USDHHS	27	7.7	1.9 (1.7 – 2.2)
Nasal spray (NRT) vs. no drug or placebo	Cochrane Library	4	12.0	2.35 (1.63 – 3.38)
	USDHHS	3	16.6	2.7 (1.8 -4.1)
Inhaler (NRT) vs. no drug or placebo	Cochrane Library	4	8.0	2.14 (1.44 - 3.18)
	USDHHS	4	12.3	2.5 (1.7 – 3.6)
Lozenges(NRT) vs. no drug or placebo	Cochrane Library	-	-	2.05 (1.62 – 2.59)
	USDHHS	-	-	-
Multiple Forms (NRT) vs. no drug or placebo	Cochrane Library	5	weak	-
	USDHHS	3	11.2	1.9 (1.3 – 2.6)

Results of meta-analyses studies mentioned in section 1.6.2.4. (contd)

Intervention	Agency	Number of trials	Effect Size %	OR (95% CI)
Non - NRT vs. no drug or placebo				
Buproprion vs. no drug or Placebo	Cochrane Library	19	10.0	2.06 (1.77 – 2.40)
	USDHHS	2	13.2	2.1 (1.5 - 3.0)
Nortiptyline vs. Placebo	Cochrane Library	4	12	2.79(1.70 - 4.59)
	USDHHS	5	11.7	2.1 (1.4 – 3.2)
Clonidine vs. Placebo	Cochrane Library	6	11	1.89 (1.30 – 2.74)
	USDHHS	5	11.7	2.1 (1.4 – 3.2)
Varenicline vs. Placebo	Cochrane Library	3		
	USDHHS			
Alternate Interventions				
Acupuncture vs. Placebo	Cochrane Library	24	No effect	-
	USDHHS	5	0.6	1.1 (0.7 - 1.6)
Aversive smoking vs. No therapy	Cochrane Library	25	Insufficient evidence	–
	USDHHS	62	6.5	1.7 (1.04 – 2.80)
Hypnosis vs. Placebo	Cochrane Library	9	No effect	–
	USDHHS	No study met the criteria	No analysis	–
Exercise vs. Placebo	Cochrane Library	11	Inconclusive	–
	USDHHS		Not mentioned	

***Non Doctor Health Professional; †Nicotine Replacement Therapy**

Annexure 3

Sree Chitra Tirunal Institute for Medical Sciences and Technology

Achutha Menon Centre for Health Science Studies, Thiruvananthapuram

Questionnaire for An intervention program for smoking cessation

Consent

We would like to know some of your personal details, your tobacco habit and your opinion regarding tobacco cessation. We shall keep the findings confidentially and will use only for research purpose. Apart from asking some personal questions, there will not be any harm to your health. We expect your cooperation. Please sign if you agree to participate in this study.

I have read/heard reading the above mentioned information regarding the study. I have understood about the study and my participation in the study as well. I know that I have the freedom to opt out of the study at any point. I am willing to participate in this study and giving my consent.

Signature :_

Id. No.	Health institution: PHC/CHC		Date
Name and Address	Phone:		
Age	Education: 1. Not gone to school 2. Studied upto ..... class		Occupation
Marital status	1. Married 2. Unmarried	3. Widower 4. Others	
SES	1. Lower class	2. Middle class	3. Upper class
Present illness	1. Lung disease 2. Stomach disease 3. Urinary disease	4. Arthritis, Joint pain 5. Fracture, injury ..... 6. Viral fever	7. Others
Any other disease	1. Cancer 2. Heart disease	3. Diabetes 4. TB (Tuberculosis)	5. Hypertension 6. breathlessness
Tobacco products using now (During last one week)		1. Cigarette 2. Bidi 3. Chewing pan	4. Pan masala 5. Nasal snuff
Age at which smoking started			
Number of cigarette/bidi using daily (during last one week)		.....cigarette	.....bidi
Time interval between waking up in the morning and first puff		1. with in 5 minutes 2. 6-30 minutes	3. 31-60 minutes 4. more than 1 hour
Do you smoke more in the first hour after waking up than the rest of the hours			1. Yes 2. No
Do you find it difficult to avoid smoking in places where smoking is banned?			1. Yes 2. No
Do you smoke if you are in bed due to illness?			1. Yes 2. No
Is anybody else smoke in the house?			1. Yes 2. No
Is it common to smoke in your work place?			1. Yes 2. No
In your opinion, without harming the health	How many cigarettes can be smoked daily?		
	How many bidis can be smoked daily?		
During the last one year, have you ever stopped smoking for more than 24 hours?			1. Yes 2. No

If yes	How many times?		
	Why did you stop smoking?	1. Knew about health hazards 2. Suffering from illness 3. Due to financial constraints 4.	
	What were the difficulties faced when stopped smoking?	1. Nothing 2. Constipation 3. Indigestion 4. Craving to smoke	5. Drowsiness 6. Headache 7. Others

When you tried to stop smoking, which one was more difficult to stop	1. First in the morning 2. Rest of the time
Which one do you hate most?	1. Quitting smoking 2. Anything else
How important is to quit smoking to keep you healthy?	1. Not important 2. A little important 3. Important 4. Very important
Do you like to quit smoking now?	1. Do not like 2. Like a little 3. Like 4. Like very much
Are you ready to quit smoking now?	1. Not ready 2. Some what ready 3. Ready 4. Definitely ready
If yes, how much is your motivation to quit smoking?	1. No motivation 2. Some motivation 3. Motivation 4. Strong motivation
How much is your confidence to quit smoking?	1. No confidence 2. Some confidence 3. Confidence 4. Good confidence

Facts for providing counseling

Mention 3 reasons for not quitting smoking	1. 2. 3.
Mention 3 important occasions of smoking in a day. (Also mention the provoking reasons)	1. 2. 3.
Mention 3 important benefits, if you quit smoking? (Those who like to quit only need to answer)	1. 2. 3.
When can you quit smoking?	
How do you like to quit smoking?	1. Gradual 2. Abrupt

Provide counseling if intervention group; Do not provide counseling if control group ----------. Give Fact sheet

Name of Counselor

Follow-up at 3 weeks

Tobacco products using now (During last one week)	1. Cigarette 2. Bidi 3. Chewing pan	4. Pan masala 5. Nasal snuf 6. Nothing
If quit smoking already		
Date of quit		
Mode of quit	1. Gradual	2. Abrupt
If continuing smoking		
Number of cigarette/bidi using daily (during last one week)	..... cigarette	..... bidi
Have you ever tried to quit smoking?	1. No 2. Tried, but could not reduce 3. Reduced up to 50%	4. Reduced more than 50% 5. Anything else
If not, why did not try?		
If tried, why you could not quit smoking?		
Do you like to quit smoking now?		1. Yes 2. No
Those who quit smoking and tried to quit smoking		
What were the difficulties faced when stopped smoking?	1. Nothing 2. Constipation 3. Indigestion 4. Craving to smoke	5. Drowsiness 6. Headache 7. Others
What do you did to overcome these difficulties?		

If continuing smoking, advise to quit smoking.

Date Name of Counselor

Follow-up at 6 weeks

Tobacco products using now (During last one week)	1. Cigarette 2. Bidi 3. Chewing pan	4. Pan masala 5. Nasal snuf 6. Nothing
If those who quit has relapsed smoking		
Number of cigarette/bidi using daily (during last one week)	..... cigarette	..... bidi
What made you to restart smoking?		
Do you like to quit smoking now?		1. Yes 2. No
If those who were smoking last time, quit smoking now		
Date of quit		
Mode of quit	1. Gradual	2. Abrupt
If those who were smoking last time, still smoking now		
Number of cigarette/bidi using daily (during last one week)	..... cigarette	..... bidi
Have you ever tried to quit smoking?	1. No 2. Tried, but could not reduce 3. Reduced up to 50%	4. Reduced more than 50% 5. Anything else
If not, why did not try?		
If tried, why you could not quit smoking?		
Do you like to quit smoking now?		1. Yes 2. No
Those who quit smoking and tried to quit smoking		
What were the difficulties faced when stopped smoking?	1. Nothing 2. Constipation 3. Indigestion 4. Craving to smoke	5. Drowsiness 6. Headache 7. Others
What do you did to overcome these difficulties?		

If continuing smoking, advise to quit smoking.

Date Name of Counselor

Follow-up at 12 weeks

Tobacco products using now (During last one week)	1. Cigarette 2. Bidi 3. Chewing pan	4. Pan masala 5. Nasal snuf 6. Nothing
If those who quit has relapsed smoking		
Number of cigarette/bidi using daily (during last one week)	..... cigarette	..... bidi
What made you to restart smoking?		
Do you like to quit smoking now?		1. Yes 2. No
If those who were smoking last time, quit smoking now		
Date of quit		
Mode of quit	1. Gradual	2. Abrupt
If those who were smoking last time, still smoking now		
Number of cigarette/bidi using daily (during last one week)	..... cigarette	..... bidi
Have you ever tried to quit smoking?	1. No 2. Tried, but could not reduce 3. Reduced up to 50%	4. Reduced more than 50% 5. Anything else
If not, why did not try?		
If tried, why you could not quit smoking?		
Do you like to quit smoking now?		1. Yes 2. No
Those who quit smoking and tried to quit smoking		
What were the difficulties faced when stopped smoking?	1. Nothing 2. Constipation 3. Indigestion 4. Craving to smoke	5. Drowsiness 6. Headache 7. Others
What do you did to overcome these difficulties?		

If continuing smoking, advise to quit smoking.

Date Name of Counselor

Follow-up at 26 weeks

Tobacco products using now (During last one week)	1. Cigarette 2. Bidi 3. Chewing pan	4. Pan masala 5. Nasal snuf 6. Nothing
If those who quit has relapsed smoking		
Number of cigarette/bidi using daily (during last one week)	..... cigarette	..... bidi
What made you to restart smoking?		
Do you like to quit smoking now?		1. Yes 2. No
If those who were smoking last time, quit smoking now		
Date of quit		
Mode of quit	1. Gradual	2. Abrupt
If those who were smoking last time, still smoking now		
Number of cigarette/bidi using daily (during last one week)	..... cigarette	..... bidi
Have you ever tried to quit smoking?	1. No 2. Tried, but could not reduce 3. Reduced up to 50%	4. Reduced more than 50% 5. Anything else
If not, why did not try?		
If tried, why you could not quit smoking?		
Do you like to quit smoking now?		1. Yes 2. No
Those who quit smoking and tried to quit smoking		
What were the difficulties faced when stopped smoking?	1. Nothing 2. Constipation 3. Indigestion 4. Craving to smoke	5. Drowsiness 6. Headache 7. Others
What do you did to overcome these difficulties?		

If continuing smoking, advise to quit smoking.

Date

Name of Counselor