

**EFFECTIVENESS OF VERY BRIEF TELEPHONIC COUNSELLING
ON BEHAVIOURAL CHANGE IN QUITTING TOBACCO – A
PARALLEL DESIGN RANDOMIZED CONTROLLED TRIAL**

By

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Sri Devaraj Urs Academy of Higher Education and
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Under the guidance of

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DEPARTMENT OF COMMUNITY MEDICINE

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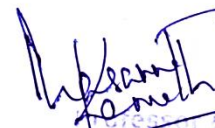
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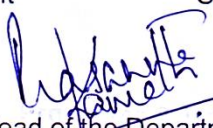


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LIST OF ABBREVIATIONS

BPL -Below Poverty Line

CI -Confidence Interval

CTRI -Clinical Trials Registry-India

FC -Face-to-Face Counselling

FCF -Face-to-Face Counselling plus Follow-up

FTND -Fagerstrom Test for Nicotine Dependence

FTND-ST - Fagerstrom Test for Nicotine Dependence-Smokeless tobacco

GATS -Global Adult Tobacco Survey

ICD -International Classification of Disorders

IEC -Institutional ethical committee

IIT -Intention-To-Treat analysis

MDR -Multi Drug Resistant

NRT -Nicotine Replacement Therapy

OR -Odds Ratio

PUC -Pre-University College RCT -Randomized control trail

RR -Relative risk

RLJHRC - R L Jalappa hospital and research center

SD -Standard deviation

SDUMC - Sri Devaraj Urs medical college

SOC -Stages of Change Model

SPSS -Statistical Package for the Social Sciences

STATA -Software for Statistics and Data Science

TB -Tuberculosis

USA -United States of America

WHO -World Health Organization

ABSTRACT

Introduction: Tobacco use is the leading single preventable cause of deaths globally. Every year around 7 million deaths are due to tobacco use. Almost half of the tobacco users are dying prematurely due to tobacco related causes every year. In India, tobacco related mortality is estimated to be 1.3 million. Smoking is contributing in increasing burden of non-communicable diseases a major way. If this trend continues deaths due tobacco use will account for 13% of all deaths in India by 2020.

In India according to Global Adult Tobacco Survey 2 (GATS 2) survey, the prevalence of current tobacco use was 28.6% among those aged 15 years and above and nearly 38.5% of smokers made an attempt to quit smoking using various methods of quitting for the past 12 months. But few are successful in the quitting. To support such attempts at quitting the efforts need to be expanded.

Brief or very brief interventions/counselling can be delivered in various modes, the most commonly used one being face-to-face counselling. This cannot be used to address large numbers, for which telephonic counselling is a better tool. The Cochrane review in 2013 has showed telephonic counselling to improve quitting by around 27%. There was a mixed result in terms of dose response i.e., number of calls needed to make the intervention more effective.

Telephone counselling may be a cost-effective way of providing individual counselling. Telephone contact can be timed such that it could maximize the level of support around a planned quit date, and counselling can be scheduled in response to the needs of the participant. There is no study from India which has assessed the effectiveness of telephonic counselling in improving the change in behaviour to quit tobacco. This study is intended to test the same in settings of low and middle-income country like India and also generate evidence to scalability under relevant national programs.

Objectives:

Among patients seeking care at screening out-patient department (OPD) who are tobacco users at R L Jalappa Hospital and Research Centre (RLJH&RC), Kolar.

Primary objective:

To assess the effectiveness of monthly individualized very brief telephonic counselling in changing the behaviour to quit tobacco according to the trans-theoretical model.

Secondary objectives:

1. To determine the proportion of individuals who are dependent on tobacco by using Fagerstrom Test for Nicotine Dependence (FTND) questionnaire.

2. To assess the level of motivation to quit tobacco among those who are willing to quit by using Richmond test for motivation.

Materials and methods: A facility based–open label parallel design Randomized Controlled Trial conducted during the months of May 2019 and June 2020. A total of 248 current tobacco users were recruited as per systematic random sampling. They were randomised into two equal parts after giving baseline face-to-face counselling to quit tobacco to all the participants. For intervention group monthly individualized very brief telephonic counseling was given for three consecutive months. The outcome (change in behaviour to quit tobacco) was assessed after six months from the date of recruitment for both intervention and control group.

Results: At baseline, about 41%, 39.1% and 19% of the study participants were in the pre-contemplation, contemplation, and preparation stage respectively.

Around 36 percent of the smokers were very high nicotine dependent and 36% of smokeless tobacco users were high dependent on nicotine. About 52% of the study subjects were having low level of motivation to quit tobacco.

About half of the study subjects were in low level of motivation to quit tobacco. Around 34% and 13.3% were in medium and high level of motivation to quit tobacco.

According to the intention-to-treat analysis for change in behaviour to quit

tobacco, about 50% in intervention group and 33% control had positive change in behaviour which was statistically significant {RR , CI : 1.5, (1.11 2.05) (p=0.008)}.

According to per protocol analysis for change in behaviour to quit tobacco about 72% in intervention group and 48.23% in control group had positive change in behavior and the difference was statistically significant { RR, (CI): 1.49, (1.15 1.93) (p=0.002)}.

Conclusion: The current study shows that very brief telephonic counselling was effective in changing the behaviour to quit tobacco among the current tobacco users and is feasible and acceptable to the tobacco users.

Key words: Change in behaviour to quit tobacco, Telephonic counselling, Nicotine dependency level, motivation to quit tobacco

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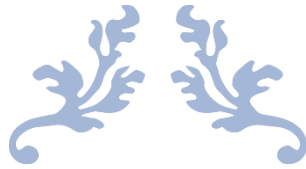
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INTRODUCTION



1. INTRODUCTION

Tobacco use is the leading single preventable cause of deaths globally. According to the World Health Organization(WHO), every year around 7 million deaths are attributed to the use of tobacco.⁽¹⁾ Almost half of the tobacco users are dying prematurely due to tobacco related causes every year.⁽²⁾ Around 80% of the world's 1.1 billion smokers live in low and middle income countries.⁽¹⁾

India is the third largest tobacco producing nation and second largest consumer of tobacco world-wide. Death due to tobacco in India is estimated to be 1.3 million.^(3,4) Of these 1 million deaths are due to tobacco smoking and the rest are due to use of smokeless tobacco.

Smoking is contributing to increasing burden of non-communicable diseases in a major way. If this trend continues deaths due tobacco use will account for 13% of all deaths in India by 2020.⁽⁵⁾

One feature of tobacco related morbidity in India is the high incidence of oral cancer, exceeding even that of lung cancer and accounting for almost half of all oral cancers in the world.⁽⁶⁾ India has the highest burden of both tuberculosis (TB) and Multi-Drug Resistant (MDR) TB based on estimates reported in Global TB Report 2016.⁽⁷⁾ Smoking increases the risk of TB by more than two-and-a-half times.⁽⁸⁾

According to Global Adult Tobacco Survey 2 (GATS 2) survey in India, the prevalence of current tobacco use among those aged 15 years and above is found to be 28.6% and among men it is 42.4 % and among women is 14.2%. Nearly 38.5% of smokers and 33.2% of smokeless tobacco users have made an attempt to quit tobacco

using various methods of quitting in the past 12 months. But few are successful in the quitting. But few are successful in the quitting.⁽⁹⁾

According to GATS 2, in Karnataka, about 22.8% of adults aged 15 and above are current tobacco users, of which 19.6% are current daily users and 3.2% are occasional users of tobacco. The prevalence of current tobacco use among men is 35.2% and among women is 10.3%. The mean age of tobacco use initiation was 19.8 years and around 51.5% of smokers and 44.6% of smokeless tobacco users have made quit attempt.⁽⁹⁾ To support such attempts at quitting the efforts need to be expanded.

At any age, quitting tobacco is beneficial for health; tobacco cessation is one of the best ways to add years to a tobacco user's life.⁽¹⁰⁾ Tobacco cessation is a complex process involving many unsuccessful attempts of quitting before attaining successful long-term abstinence.⁽¹¹⁾ In the framework of tobacco control interventions, the Transtheoretical Model (or the 'Stages of Change' model) proposed by Prochaska and DiClemente is the most widely accepted one.⁽¹²⁾ Transtheoretical Model proposes that tobacco users move linearly through distinct stages before they can quit successfully; and may relapse to earlier stages before achieving complete abstinence. These stages are Precontemplation, Contemplation, Preparation, Action and Maintenance.⁽¹³⁾ According to this model, tobacco cessation interventions should be matched according to the tobacco user's stage of readiness to quit and this may increase the prospect of positive behavioural change.⁽¹⁴⁾

Apart from readiness to quit, nicotine dependency also has an important role in determining the success of tobacco quit attempt. Tobacco users who want to quit after becoming aware of the adverse effects of tobacco on health are unable to do so because of the addictive nature of nicotine (WHO). Since the majority of smokers

smoke for most of their life alternating between periods of remission and relapse, nicotine dependence is recognized as a chronic and relapsing disease.⁽¹⁵⁾ Withdrawal symptoms commonly found among tobacco dependent individuals are strongly associated with relapse. Tobacco dependent people, despite having high motivation, made unsuccessful quit attempts.⁽¹⁶⁾ They are also at higher risk of poor quality of life, functional impairment and mental disorders like major depression and anxiety.

Motivation to quit tobacco use is also found to be a predictor of cessation. Whether a tobacco user succeeds in quitting depends on the balance between that individual's motivation to quit (i.e., expected benefits of tobacco cessation) and the degree of nicotine dependence.⁽¹⁷⁾ According to the trans-theoretical model, tobacco users who prepare their attempts to stop well in advance increase their chance of success. Thus, in an assisted tobacco-cessation program the motivation to quit should be the prerequisite to engage in a cessation attempt.⁽¹⁵⁾

In developing countries like India, most tobacco users are unaware of the harmful-effects of sustained tobacco use.⁽¹⁸⁾ The tobacco cessation approaches for tobacco users who are aware of ill-effects of tobacco vary from those who are unaware. Hence, tobacco cessation strategies need to be tailor-made based on the individual's tobacco-use behaviour.⁽¹⁹⁾ However, limited literature is available on stages of behavioural change among tobacco users from India. The stages of behavioural change among tobacco users will help the attending physician to individualize the tobacco treatment strategies using combination of behavioural counselling and pharmacotherapy.

Brief or very brief interventions/counselling can be delivered in various modes, the most commonly used one being face-to-face counselling. This cannot be used to

address large numbers, for which telephonic counselling is a better tool. The Cochrane review in 2013 has shown telephonic counselling to improve quitting by around 27%. There was a mixed result in terms of dose response i.e., number of calls needed to make the intervention more effective.⁽²⁰⁾

Telephonic counselling may be a cost-effective way of providing individual counselling. The telephonic contact can be timed such that it could maximize the level of support around a planned quit date, and counselling can be scheduled in response to the needs of the participant. There is no study from India which has independently assessed the effectiveness of telephonic counselling in improving the behavioural change in quitting tobacco. This study was conducted to test the same in settings of low and middle-income country like India and to generate evidence to scalability under relevant national programs.



OBJECTIVES OF STUDY



2. OBJECTIVES

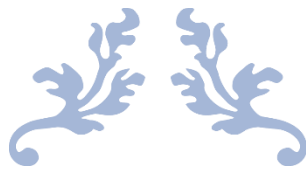
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REVIEW OF LITERATURE



3. REVIEW OF LITERATURE

3.1 Tobacco usage

Tobacco are the products which are completely or partially made of the tobacco leaf as raw material which are manufactured to be used for smoking, sucking, chewing, or snuffing. The type of tobacco use by the individual is dependent on many factors. Khaini -a tobacco, lime mixture was the highest used tobacco product in India, and this was used by 11.2% of adults. The next most used tobacco product was bidi and was smoked by 7.7 percent of adult Indians. Gutka - a tobacco, lime, areca nut mixture- ranks the third (6.8%) and betel quid with tobacco ranks the fourth (5.8%). The most commonly used tobacco products by men were khaini (17.9%) and bidi (14.0%) whereas among women, the three smokeless tobacco products i.e., betel quid with tobacco (4.5%), khaini (4.2%) and oral application products (4.3%) such as mishri, gul, gudakhu are almost equally used products.⁽⁹⁾

3.2 Ill-effects of tobacco use

Tobacco contains over 4000 chemical compounds which includes tar, carbon monoxide, hydrogen cyanide, nicotine, naphthalene, acetone, ammonia, arsenic, phenol, cadmium and polyvinyl chloride. Many of these agents are toxic and can cause at least 43 types of cancers. Examples of these are nitrosamines and benzopyrines. Smokeless tobacco is major concern in India and known to cause oral cancer. There are evidence that it causes some other cancer as well.⁽²¹⁾

Smoking also causes lung diseases such as chronic bronchitis and emphysema, and it will also exacerbate asthma symptoms in adults and children. Cigarette smoking is the most significant risk factor for chronic obstructive pulmonary disease. Smoking

increases the risk of heart disease, it includes stroke, heart attack, vascular disease, and aneurysm.⁽²²⁾

Secondhand and thirdhand smoking are also a significant public health concern. Exposure to secondhand tobacco smoke in the home is a risk factor for asthma in children. Thirdhand smoke: the chemical residue of smoking on surfaces where smoking has occurred can persist long after the smoke, it is a potential danger, especially to children, who not only inhale fumes released by these residues but also ingest the residues that get on their hands after crawling on floors or touching walls and furniture.⁽²³⁾

3.3 Nicotine dependence among tobacco users

Tobacco dependence is defined as “a cluster of behavioural, cognitive and physiological phenomena that develop after repeated tobacco use and that typically include a strong desire to use tobacco, difficulties in controlling its use, persistence in tobacco use despite harmful consequences, a higher priority given to tobacco use than other activities and obligations, increased tolerance and sometimes a physical withdrawal state”.⁽²⁴⁾

Nicotine is the main addictive chemical in tobacco which makes tobacco use a powerful addiction. Nicotine produces temporarily pleasing physical and mood-altering effects in the brain which alter the mesolimbic pathway; these effects reinforce continual use of tobacco and nicotine dependence.⁽²⁵⁾ Although as per the International Classifications of Disorders (ICD) and the ‘USA Diagnostic and Statistical Manual’, nicotine dependence is a disorder; these systems determine dependence only in a qualitative way. A metabolite in nicotine i.e., cotinine is measured in serum or saliva to know the level of nicotine dependence in an

individual. But as the test is cumbersome, different questionnaires were developed to find nicotine dependence.⁽²⁶⁾ For clinical practice, there is a need for quantifying dependence since it is a strong predictor of quitting tobacco. Therefore, the ‘Fagerstrom Tolerance Questionnaire’ or the ‘Fagerstrom Test for Nicotine Dependence’ (FTND) for smokers and ‘Modified Fagerstrom Test for Nicotine Dependence’ for smokeless tobacco was developed which is widely used to estimate the degree of the tobacco users’ dependence on nicotine.⁽²⁷⁾ For an individual, who wants to quit tobacco, the level of dependence will help to determine the suitable counselling for tobacco cessation.

According to D’Souza et al in a study conducted in 2012 among 189 attendees of a tobacco cessation clinic in Bangalore, about two-thirds of the smokers were reported to have high levels of nicotine dependence (Fagerstrom score greater than or equal to 6/10). The overall mean (SD) dependence score was 5.8 (2.5). Pre-contemplators and contemplators had higher nicotine dependence scores compared to those in the preparation/action stage among all types of tobacco users (exclusive smokers, exclusive chewers and those who used both forms).⁽²⁸⁾

According to Islam et al in a community-based cross-sectional study conducted in 2014 on 128 adult tobacco users in West Bengal, 63.4% of the study participants had intention to quit tobacco and 80.9% were highly dependent on nicotine. Mean (SD) FTND score was higher among those who did not intend to quit {7.76(1.90), $p < 0.001$ } compared to those who intended to quit {4.65 (2.41)}. Majority of those who were highly dependent on nicotine (n=49/60, 82%) had never made a previous quit attempt.⁽²⁹⁾

Smokers with higher nicotine dependence had more serious withdrawal symptoms than smokers with low nicotine dependence.⁽³⁰⁾ Hence, smokers with low nicotine dependence can quit more easily compared with smokers with high nicotine dependence.⁽³¹⁾

3.4 Health benefits of quitting tobacco

There are immediate and long-term health benefits. People start to reap the health benefits within hours or even minutes of quitting tobacco use. One day of quitting tobacco helps to reduce a person's heart rate and blood pressure, and blood carbon monoxide levels can be expected to return to normal. The circulation and lung function of a quitter improves within 3 months of quitting smoking. Coughing and shortness of breath will generally decrease within 1–9 months of quitting smoking. The risk of death due to tobacco use also begins to decrease soon after quitting. Current evidence suggests that the risk of death due to ischemic heart disease is halved within 5 years of quitting, and the risk of stroke returns to that of a never smoker within 5–15 years. Even the risk of death due to lung cancer will be reduced by 30–50% within 10 years of quitting smoking.⁽³²⁾

3.5 Tobacco cessation interventions

Tobacco cessation support plays a significant role in reducing the prevalence of tobacco use by improving the quit rate among tobacco users and should be made readily accessible.

Without assistance only 4% of attempts to quit tobacco will succeed.⁽³³⁾ Proven cessation medication and professional support to a tobacco user can double his chance of successfully quitting the tobacco.⁽³⁴⁾ Various approaches have been

developed to help people stop using tobacco. These range in terms of intensity, cost and effectiveness. It is broadly categorized into Behavioural and pharmacological interventions.

3.5.1 Behavioural intervention: Behavioural intervention for tobacco cessation are generally low cost and can be very effective. Brief advice from health professionals to a tobacco user as a part of their routine consultations or interactions helps motivating people who might not otherwise seek tobacco cessation support and encouraging them to quit.⁽³⁵⁾

Toll-free quit lines are a convenient way for tobacco users who are ready to quit and can access brief and potentially intensive behavioural counselling. Those that use quit lines increase their absolute quit rate by 4 percentage points, which is doubling of success compared to those who attempt to quit without assistance.⁽³⁴⁾ This quit rate can be further increased if the quit line is “proactive” and counsellors make follow-up calls to potential tobacco quitters. With the advent and spread of mobile phone technologies, people who want to quit can now be accessed not only through telephone calls but also via text messages. A major development in recent years has been the mobile phone-based interventions for cessation which have been shown to be very promising. Text message interventions can increase the absolute quit rate by 4%.⁽²⁰⁾

3.5.2 Pharmacological interventions: It include nicotine replacement therapies (NRTs) and medications which do not contain nicotine but reduce tobacco withdrawal symptoms. Both forms of therapy are effective aids to help people to quit tobacco use. Efficacy of pharmacotherapies is generally high and compared to people who do not use an intervention, absolute quit rate increases can range from 6% for a

single type of NRT to almost 15% for varenicline. Combining more than one NRT (patches and a faster-acting form) can also increase the effectiveness of NRTs. Both behavioural cessation support and pharmacotherapies are effective in helping people to quit tobacco use. Combining both behavioural and pharmacotherapy interventions, however, is more effective and can double the chances of successfully quitting.⁽³⁶⁾

Table 1. Types of tobacco cessation interventions.⁽³⁵⁾

Behavioural interventions	Population level approaches	Brief advice	A few minutes of advice given to all tobacco users to stop using tobacco and is given during routine consultation with a physician or Health care worker
		Quit lines	A telephone counselling service is provided through a national toll-free quit line and it involves both proactive and reactive counselling. A reactive quit line only responds to incoming calls and provides an immediate response to a call made by the tobacco user, whereas in proactive quit line, it provides ongoing support by scheduling a follow-up calls to tobacco users.
		mTobacco cessation	Personalized tobacco cessation support is given to a tobacco user via mobile phone text messaging

	Individual specialist approaches	Intensive Behavioural support	It refers to individual or group counselling to help people stop their tobacco use. It includes all cessation assistance that imparts knowledge about tobacco use and quitting and provide support for changing behaviour
		Cessation Clinics	Tobacco cessation clinics offer intensive behavioural support, and provide appropriate medications or advice delivered by specially trained practitioners.
Pharmacological intervention	Nicotine replacement therapies (NRTs)		NRTs are available in several forms including gum, lozenges, patches, inhalers, and nasal spray. These NRTs reduce craving and withdrawal symptoms by providing a low, controlled dose of nicotine without the toxins found in cigarettes. The doses of NRT are gradually reduced over time to help the tobacco user wean off nicotine by getting used to less and less stimulation.
	Non-nicotine pharmacotherapies		These include medications such as bupropion, varenicline and cytisine. These pharmacotherapies reduce cravings and withdrawal symptoms and decrease the

		pleasurable effects of cigarettes and other tobacco products.
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3.6 The trans-theoretical model for tobacco cessation

Tobacco cessation has now been understood as a process than a mere outcome of ‘quitting tobacco’. The ‘trans-theoretical model’ or the ‘stages of change model (SOC)’ proposed by Prochaska and DiClemente examines this process through a succession of ‘stages’ of behavioural change.⁽³⁷⁾

The trans-theoretical model interprets change as a process involving progress through five stages. The different stages of behavioural change are – Pre-contemplation, Contemplation, Preparation, Action and Maintenance.⁽³⁸⁾

Pre-contemplation stage is defined as the stage where “individuals are not intending to change in the near future, i.e. in the impending six months.” They may be ignorant or under informed about the consequence of their behaviour. Conversely, they may have made several quit attempts (in the context of tobacco use) unsuccessfully and now question their ability to successfully quit.

Contemplation is defined as the stage where “individuals intend to change in the coming six months.” They are aware of the pros as well as the cons of changing their behaviour. Because of this equilibrium between the pros and cons, they may develop an unsureness which cause them to be stuck in this stage for long periods of time.

Preparation is defined as the stage where “individuals intend to act in the immediate future, i.e. in the next thirty days”. They have usually taken some noteworthy action

like successfully having quit for 24 hours in the last year. Individuals in this stage have an action plan; for example, consulting their physicians, reducing the number of beedis or cigarettes smoked, setting a quit date etc.

Action is defined as the stage where “individuals have made a definite evident modification in their routine in the past six months”. Reduction in the number of cigarettes smoked or substituting with low-tar varieties do not count as action, only complete abstinence counts.

Maintenance is defined as the stage “where individuals have maintained the overt specific modification for a period longer than six months and are working to avert relapse”.

3.7 Stages of change of readiness to quit tobacco

The **Global Adult Tobacco survey (2016-17)** is a nationally representative household survey of individuals aged 15 years and above. As per the survey, in India among current smokers 8.4% were planning to quit within the next month (Preparation); 13.1% were thinking about quitting within next 12 months, 33.9% wanted to quit sometime in the future but not within the next 12 months(47% Contemplation);42% were not interested in quitting smoking. Thus, 44.6% of smokers were in the precontemplation stage. The proportion of the contemplators and preparators decreased with increase in age and increased with increase in education attainment. The distribution of smokers across stages did not differ with different occupational groups.⁽⁹⁾

Among smokeless tobacco users, 7.8% of current users planned to quit within the next month (Preparation); 11.7% within the next year but not in the next month and

30.2% wished to quit sometime in the future but not in the next 12 months (41.7% Contemplation). 47.8% of current smokeless tobacco users were not interested in quitting. About 50.3% of smokeless tobacco users were in precontemplation stage. The differentials in these proportions across age and education were similar to those of smoking.⁽⁹⁾

In Karnataka, about 7.4% of current smokers and 7.9% of smokeless tobacco users were planning to quit in next month; 17.3% of smokers and 13.2% of smokeless tobacco users were thinking of quitting with in next 12 months; 41.2% current smokers and 27.1% of smokeless tobacco users were willing to quit someday but not in the next 12 months; 30.6% of smokers and 47.3% of smokeless tobacco users were not interested in quitting; 2.6% of current smokers and 4.5 % of smokeless tobacco users did not know about quitting tobacco.⁽⁹⁾

According to **D'souza** et al a descriptive study conducted among 189 attendees in the tobacco cessation clinic of a tertiary hospital in Bangalore, the patients' baseline motivational stage was as follows: 14% were in Pre-contemplation (With no intention to quit tobacco), 48% in Contemplation(Awareness that smoking is a problem but with ambivalence about the perspective of changing and hence no quit date planned), 37% in Preparation/Action (6-month intention to quit/Has quit in the last 1-month or 1-month intention to quit) and 1% in Maintenance (Has quit for more than 1 month). There was an inverse relationship between nicotine dependence and motivational stages across all types of tobacco users – smokers, smokeless tobacco users and those who used both forms.⁽²⁸⁾

A cross-sectional study done by **Daoud et al** in 2015 among a random sample of 735 Arab minority men in Israel who were current smokers, 61.8% were in the precontemplation stage, 23.8% were in the contemplation stage and 14.4% were in the preparation stage. The factors significantly associated with 'SOC' of readiness to quit smoking were marital status, educational level, and presence of a chronic disease. Majority of the participants in the pre-contemplation stage were unmarried (65.8%, $p=0.039$), were educated up to high school (63.7%, $p=0.023$) and had a lower probability of having a chronic disease (66.3%, $p<0.001$). Age and employment status were not found to be associated with the 'stages of change'. The smoking-related factors significantly associated with SOC were duration of smoking, previous attempts to quit smoking and knowledge of ill effects of smoking. Pre-contemplators had long term (≥ 21 years, 67.8%) or short term (≤ 5 years, 67.8%) duration of smoking ($p=0.025$), didn't attempt quitting earlier (71.9%, $p<0.001$) and had low scores on knowledge about ill-effects of tobacco. Age of initiation of smoking, the quantity of cigarettes smoked per day and nicotine dependence scores were not significantly associated with SOC. After multivariate analysis, presence of a chronic disease, shorter duration of smoking, higher number of quit attempts and a higher score on knowledge about ill-effects of tobacco were significantly associated with the probability of being in an advanced stage of readiness to quit smoking whereas number of years of schooling and marital status were not significantly associated.⁽³⁹⁾

According to a cross sectional analysis done by **Mbulo et al** in 2015 on data from the Global Adult Tobacco Survey 2009-2013 from 21 countries, most smokers were found to be in the pre-contemplation stage after which was contemplation stage and then preparation stage across all countries. Three fourths i.e. 74.8% of smokers were

categorized into pre-contemplation stage; this ranged from 61.4% in Qatar to 89.5% in Indonesia. Smokers in the contemplation stage ranged from 7.1% in Indonesia to 31.2% in Qatar. The preparation stage had the lowest proportion of smokers with an average of 6.7%, ranging from less than 3% in China, Greece, Russia and Thailand to 12.9% in Nigeria.⁽⁴⁰⁾

In a descriptive study conducted by **Sharifirad et al** in 2012 among conveniently selected 578 students of six Iranian universities aged between 18-49 years, 55.5% were reported to be in pre-contemplation stage, 18.9% in contemplation stage, 17.1% in preparation stage, 4.7% in action and 3.8% in maintenance stages. The mean (SD) age of initiation was 18.4 (3.2) years.⁽⁴¹⁾

Table 2. Studies on Stages of Change (SOC) in tobacco use have used different definitions for the stages as shown below:

Stage	Description and references
Pre-contemplation	1. Currently smoking and not seriously considering quitting within the next 6 months.(37,42,43) 2. No or never intending to quit.(28,39,44) 3. Did not make a quit attempt in the past 12 months and do not consider quitting in the next 12 months.⁽⁴⁰⁾
Contemplation	1. Currently smoking and seriously considering quitting in the next six months but not in the next

	30 days; had not made a 24 quit attempt in the past one year or both.⁽³⁷⁾ 2. Thinking to quit in the next 6 months.^(39,43) 3. Considering quitting within the next 12 months.⁽⁴⁰⁾ 4. Awareness that smoking is a problem but with ambivalence about changing, hence no quit date planned.⁽²⁸⁾
Preparation	1. Planning to quit within next 30 days; have made a 24-hour quit attempt in the past year.^(37,40,43,45) 2. Thinking to quit within next month.^(42,43) 3. 6-month intention to quit.⁽²⁸⁾
Action	1. Quit smoking for 6 months.⁽⁴³⁾ 2. When a daily smoker has achieved 24 hours abstinence lasting up to 6 months of cessation 3. Former smoker.⁽⁴⁴⁾ 4. Has quit in the last one month or one-month intention to quit .⁽²⁸⁾
Maintenance	1. Abstinent for 6 months to 5 years.⁽³⁹⁾ 2. Changed overt behaviour for more than 6 months.⁽⁴²⁾ 3. Has quit for more than one month.⁽²⁸⁾

3.8 Level of motivation to quit tobacco among current users who wish to quit

Motivation refers to “a fundamental mechanism or pattern of mechanisms that lie at the heart of why and how people change addictive and health behaviours”. Being motivated to change a behaviour is vital to an individual’s performance and whether or not a successful outcome is accomplished.⁽⁴⁶⁾ The Richmond test is one of the scales among different questionnaires available to assess a tobacco user’s level of motivation to quit.

Table 3. Balance between the level of motivation and the degree of nicotine dependence⁽¹⁷⁾

		Motivation	
		High	Low
Dependence	High	• Unlikely to stop but could do so without help • Primary intervention goal is to increase motivation	• Likely to stop with minimal help • Primary intervention goal is to trigger a quit attempt
	Low	• Unlikely to stop • Primary intervention goal is to increase motivation to make smoker receptive to treatment for dependence	• Unlikely to stop without help but would benefit from treatment • Primary intervention goal is to engage smoker in treatment

Whether a tobacco user makes a successful quit attempt depends on the balance between their motivation to stop tobacco use and their degree of dependence on

tobacco.⁽¹⁷⁾ Those who are highly motivated to quit but also are highly dependent on nicotine should be focused on in engaging in a cessation clinic.

In a cross-sectional study conducted in 2013 among 111 smokers in Lebanon by Bou et al, the mean (SD) score of Richmond test measuring the level of motivation of smokers to quit smoking was 4.41 (2.61); this corresponded to a weak motivation of the participants to quit smoking. Most of the participants were men (59.46%), had a mean (SD) age of 44.9 (16.01) years and were educated (68.47%).⁽⁴⁷⁾

3.9 Effectiveness of telephonic counselling following face-to-face counselling in improving quit rate among tobacco users

According to Jayakrishna et al, a community-based study done to assess the effectiveness of a smoking cessation intervention in rural Kerala state, India. Multiple approaches have been tried for the intervention group where the priority was given to face to face interview and telephonic counselling and control group receiving general awareness training and anti-tobacco leaflets. Self-reported smoking status was assessed after 6 and 12 months. The results showed overall prevalence of smoking abstinence was 14.7% in the intervention group and 6.8% in the control group (Relative risk: 1.85, 95% CI: 1.05, 3.25). A total of 41.3% subjects in the intervention area and 13.6% in the control area had reduced smoking by 50% or more at the end of 12 months.⁽⁴⁸⁾

A facility based; non-randomized controlled study was done in Beijing by **Lei et al** in 2016 on effectiveness of additional telephone counselling in cessation of smoking. This study was conducted among Chinese male smokers who sought treatment in a part-time regular smoking cessation clinic of a large general hospital in Beijing and

they have compared the quit rates of one group which received face-to-face counseling (FC) alone (one session of 40 min) to another group which received the same face-to-face counseling plus four follow-up sessions of brief telephone counseling (15–20 min each) at 1 week, 1, 3 and 6 month follow-up (FCF) and no smoking cessation medication was provided. The study was done on eligible male smokers with total sample size of 547 (N = 547) and were divided into two groups: FC (n = 149) and FCF (n = 398). Analysis by intention to treat, at 12-month follow-up, the 7-day point prevalence and 6-month continuous quit rates of FC and FCF were 14.8 % and 26.4 %, and 10.7 % and 19.6 % respectively. The adjusted odds ratios (95 % confidence intervals) of quitting in FCF compared to FC was 2.34 (1.34–4.10) (P = 0.003) and 2.41 (1.28–4.52) (P = 0.006), respectively. ⁽³¹⁾

A facility based, longitudinal, non-randomized controlled study was conducted by **Lei et al** on additional follow-up telephone counselling and initial smoking relapse in Beijing. The smokers were non-randomized and divided into 2 groups: individual face-to-face counselling group, and individual face-to-face counselling plus follow-up telephone counselling group (FCF group). Initial smoking relapse timing was compared between the groups. Of 547 participants, 457 smokers (117 in FC group and 340 in FCF group) had achieved at least 24-hour abstinence. Most of the smoking relapse had occurred in the first 2 weeks after the quit date. Smokers in the FC group tended to relapse smoking earlier than FCF group and the log-rank test was statistically significant with $p=0.003$. ⁽³⁰⁾

According to **Blebil et al**, a study was conducted at 2 major hospitals in Penang, Malaysia in 2014. Participants were randomly allocated into two groups, one group had received the usual care that followed in the clinics (control) and the other group had received usual care plus telephonic counselling during the first month of quit

attempt (intervention). At the end of three months, control group was less likely to quit smoking, 36.9% and 46.7% had quit smoking in control group and intervention group respectively but was not statistically significant {OR (95% CI) 0.669 (0.395-1.133), $p = 0.86$)}. However, at six months, 48.6% of the control group were quit smoking successfully compared to 71.7% of the intervention group and was statistically significant ($p < 0.001$).⁽⁴⁹⁾

The varied difference in the nature of quitting tobacco across various regions calls for identifying country or region-specific interventions that would be accepted by the community and can be practiced easily with the existing human resource and allocated health budget.



MATERIALS AND METHODS



4. MATERIALS AND METHODS

4.1 Topography of Kolar district

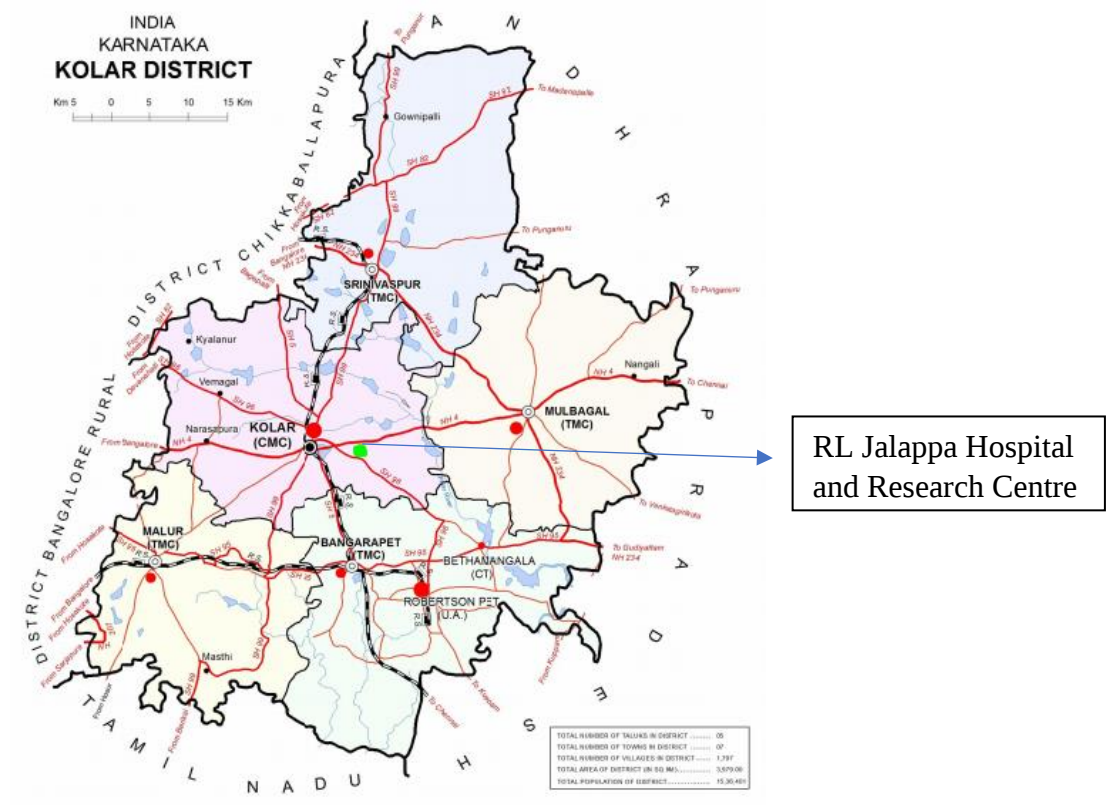


Figure 1. Map of Kolar district.⁽⁵⁰⁾

Kolar district is in the state of Karnataka, India. It consists of 6 taluks: Kolar, Mulbagal, Malur, Bangarpet, Srinivaspur and Kolar Gold Fields. According to 2011 census the total population of Kolar is 15,36,401 with 7,76,396 males and 7,60,005 females.⁽⁵⁰⁾

4.2 Study design

This is a Facility based – open label parallel design randomized controlled trial.

4.3 Study setting

RL Jalappa Hospital and Research Centre (RLJH & RC), a tertiary health care centre in Kolar.

4.4 Study duration

The study was conducted between May 14th, 2019 and June 30th, 2020.

4.5 Study population

All patients from Kolar who are currently tobacco user (who have used any form of tobacco at least once in the last one month) for any duration, seeking care at screening OPD of RLJH&RC, Kolar.

4.6 Sample size calculation

Assuming 20% change from pre-contemplation phase to contemplation phase and above with baseline pre-contemplation phase of 50% among tobacco users, confidence interval of 95%, power of 80% and dropout rate of 30%, with a 1:1 allocation ratio between two groups the minimum required sample size was calculated to be 124 in each of the two groups i.e., a total of 248 tobacco users (calculated using OpenEpi Version 3.01).

$$n_1 = \frac{[Z_{\alpha/2} + Z_{1-\beta}]^2 \bar{p}\bar{q}(r+1)}{r(p_1 - p_2)^2}$$

and

$$n_2 = n_1$$

where

- n_1 = number exposed

- n_2 = number unexposed
- $z_{\alpha/2}$ = standard normal deviate for 2 tailed test based on alpha level (relates to the confidence interval level)
- z_{β} = standard normal deviate for one tailed test based on beta level (relates to the confidence power level)
- r = ratio of unexposed to exposed
- p_1 = proportion of exposed with disease and $q_1 = 1 - p_1$
- p_2 = proportion of unexposed with disease and $q_2 = 1 - p_2$

$$\bar{p} = \frac{p_1 + p_2}{r + 1} \text{ and } \bar{q} = 1 - \bar{p}$$

Inclusion criteria:

All current tobacco users willing to participate (who have used any form of tobacco at least once in the last one month) aged 18 years and above, residing in Kolar district for at least last six months and having mobile/telephone at household (at least one member in the family who dines with the participant at least once a day) attending the screening OPD at R L Jalappa Hospital and Research Centre (RLJH&RC), Kolar.

4.7 Exclusion criteria:

Patients with history of any cancer and/or mental illness.

4.8 Sampling procedure

Systematic random sampling method was used to recruit the participants. Baseline data collection and recruitment was done over a period of six and half months from 14th May 2019 to 10th December 2019. Assuming the daily adult OPD attendance to be around at least 100, and 12% of them will be tobacco users; there will be around 12 tobacco users attending the screening OPD every day. After screening for eligibility criteria, every 3rd current tobacco user was included in the study and data

was collected from 4 patients per day for 10 days in a month (any 2 Monday, 2 Tuesday, 2 Wednesday, 2 Thursday and 2 Friday) for six and half months. Everyday lottery method was used to choose the first number randomly (from 1 to 3) and then took every third tobacco user until four tobacco users were recruited for the day. The recruitment was done from 9 am to 4 pm at the Screening OPD with a break from 1.30 pm to 2.30 pm.

4.9 Randomization details

Randomization was done by an expert from the department of Community Medicine, SDUMC and was not a part of the study. Randomization software was used to generate random allocation sequence to allocate participants to either Group A (intervention) or Group B (control group) with the ratio 1:1. Randomization sequence was generated using block randomization with unequal block size and the allocation sequence was concealed using sequentially numbered sealed opaque envelopes. The envelopes were opened by investigator after finishing the baseline data collection/recruitment for the day and allocated the respective participants into two groups.

4.10 Study tool

A semi-structured questionnaire was developed based on the objectives of the study. The questionnaire was translated into local language and back translated to English. It was validated by pre-testing it among a subset of the sample population and modifications were done accordingly

The study variables were sectioned into five domains: socio-demographic characteristics, tobacco use behaviour, stages of readiness to quit, nicotine dependence and motivation to quit tobacco.

1. Socio-demographic characteristics: details on sex, age, education, occupation, number of family members and monthly income.
2. Tobacco-use behaviour: details collected in this domain includes the age of initiation of tobacco product, the type of tobacco product (smoke/smokeless/both), the frequency of use (daily, few days in a week, occasionally), history of a previous quit attempt, the purchasing and storing patterns.
3. **Stage of readiness to quit** questions were modelled on **Prochaska and DiClemente 's trans-theoretical model**. These included patients' knowledge of harmful effects of tobacco, their willingness to quit, setting of a future quit date and the actions taken to quit tobacco.⁽³⁸⁾
4. Nicotine dependence: was assessed by **Fagerstrom Addiction Scale** for Smokers and **Modified Fagerstrom Questionnaire** for Smokeless Tobacco Users.

The Fagerstrom Addiction Scale for Smokers had a set of 8 questions having a maximum score of 11, which categorises smokers into various grades of dependence.

The Modified Fagerstrom Questionnaire for Smokeless Tobacco user had 9 questions with a highest possible score of 16. It categorises Smokeless Tobacco Users into various grades of dependence.⁽³⁸⁾

5. The motivational level in participants who were thinking of quitting tobacco: was assessed using the **Richmond test for motivation**. It is a four-item scale that evaluates tobacco users' motivation for tobacco cessation by assessing the

readiness to quit if it were easily done. The Richmond test has a maximum score of 10.⁽⁵¹⁾

4.12 Pilot study

A pilot study was conducted among five current tobacco users attending screening OPD of RLJH before the start of the study. Modifications to the questionnaire where necessary were made based on the responses. These participants were excluded from the study.

4.13 Approval for the study

The study protocol was approved by the Institutional Ethical review Committee (IEC). CTRI registration was done before the starting the study with registration number CTRI/2019/05/019088.

4.14 Study variables

a. Independent variables: Socio-demographic variables including:

1. Age: Age was considered in completed years at the time of interview
2. Gender: Male and Female
3. Socio- economic status - modified B.G Prasad scale (May 2019) was used to classify socio-economic status of study participants

Table 4. Modified B G Prasad socioeconomic status classification, 2019.⁽⁵²⁾

Monthly per capita income in Rupees (May 2019)	Socio-economic class
Rs 7008 and above	Upper class
Rs 3504-7007	Upper middle class
Rs 2102-3503	Middle class
Rs 1051-2101	Lower middle class
Below Rs 1050	Lower class

4. Occupation –The engagement in a particular income earning activity for the major part of the day was categorized as main occupation.

Table 5. Classification of individuals according to their occupation.⁽⁵³⁾

Professional	Doctor, Engineer, Principal, Lawyer, Military officer, Senior executive, Business Proprietor, Writer, Scientist, Large employer, Director, University Professor, Police officer, Others (Horse rider)
Semi Professional	Teacher, Pharmacist, Social worker, Owner of small business and manager, Farmer, others (Computer programmer, constructor, Govt employee, Nurse)
Skilled worker	Artisans, clerk, Supervisor, Carpenter, Tailor, Mechanic, Electrician, Railway guard, Painter, Modelor, Smiths, Baker, Driver, Shop assistant, Petty trader, constable, soldier, potter, barber, linesman, others (tinkering, welder, gardener, cook, mason, postman, plumber)
Semi-skilled	Factory operator, Agricultural labour, shoemaker, security guard, shop helper
Unskilled	Labourer, Domestic servants, peon, sweeper, washerman, others.

5. Education: Number of years of education was considered.
6. Marital status: unmarried, married, widow/widower/separated/divorcee
7. Presence of co-morbidity

Tobacco use related variables including:

9. Age at initiation of tobacco use in years
10. Type of tobacco product - smoke/smokeless/both
11. Type of smoke form tobacco includes beedi/cigarette/cheroot/beedi & cigarette
12. Type of smokeless form tobacco includes betel quid/hans or pan parag/snuff
14. Frequency of use – occasionally/few days in a week/daily
15. Tobacco purchasing behaviour - single unit/many units at a time/ in packets
16. Number of cigarettes smoked per day
17. Number of beedis smoked per day
18. Storing tobacco products at home/workplace for use in spare time – yes/no
19. Knowledge of ill-effects of tobacco - yes/no
20. Previous attempt to quit – yes/no

b. Outcome variables

1. Stage of readiness to change categorized into pre-contemplation, contemplation, preparation and action. Proportion of study participants in precontemplation, contemplation, preparation and action stages.
2. Nicotine dependence level: Proportion of individuals with low, medium and high dependence.
 - Fagerstrom Addiction Scale for Smokers score:
Score 0-2 = very low
Score 3-5 = medium dependence
Score 6-7 = high dependence
Score 8-11 = very high dependence
 - Modified Fagerstrom Questionnaire for Smokeless Tobacco Users:
Score 0-4 = low dependence
Score 5 -8= medium dependence
Score 9-12= high dependence
Score 13-16 =very high dependence
3. Motivation level – Proportion of individuals with low, medium, and high level of motivation.

Richmond score 0 to 6 classified as “low motivation”, 7 to 9 as “medium motivation” and = 10 as “high motivation”

4.15 Study procedure

4.15.1 Eligibility screening

The tobacco users were screened as per the systematic random sampling. Those fulfilling the inclusion criteria were requested to participate in the study; all those who gave informed written consent were included in the study.

4.15.2 Baseline assessment/recruitment

All the participants after obtaining informed written consent were interviewed using the semi-structured questionnaire. After administering the questionnaire, a face-to-face counselling was done by the investigator for not more than 5 minutes. This face-to-face counselling was based on the 5 A's strategy of World Health Organization {**ask** (identify smoking status), **advise** patients to quit smoking, **assess** readiness to quit, **assist** with making a quit attempt, and **arrange** follow-up}.(54) This did not exceed five minutes (brief advice). The phone number of the investigator was given at the end and was informed about the monthly follow up call they will be receiving for next three months if they are in intervention group and all will be called at after six months from the date of enrolment to know about their status of quitting.

4.15.3 Intervention details

For the intervention group three phone calls were made one month apart in the first three months. The telephonic counselling for less than 90 seconds (very brief advice) was done, and the counselling was based on the individual's baseline level of nicotine dependence and their level of motivation to quit. The telephonic calls were made at the time convenient to the participant. Those who did not respond to the call, one more telephonic call after one hour was made to contact the participant on that particular day allotted for the participant and the procedure was repeated for the next two days until the telephone call is answered and those not answered were considered as 'not receiving the intervention' for that month. Effort was made to make three telephonic calls within the first three months with four weeks gap between successful calls and in those who missed intervention, extension was done so as to they finish three telephonic counselling within six months of recruitment. Those who have not received the intervention calls for two successive months were considered as 'loss to follow up' and were removed from per protocol analysis but were included in the intention to treat analysis. Figure 2 shows the flowchart of telephonic counselling followed and it is based on the 5 A's strategy of World Health Organization (ask (identify smoking status), advise patients to quit smoking, assess readiness to quit, assist with making a quit attempt, and arrange follow-up).⁽⁵⁴⁾

Figure 2. Flow chart of telephonic counselling followed.(24)

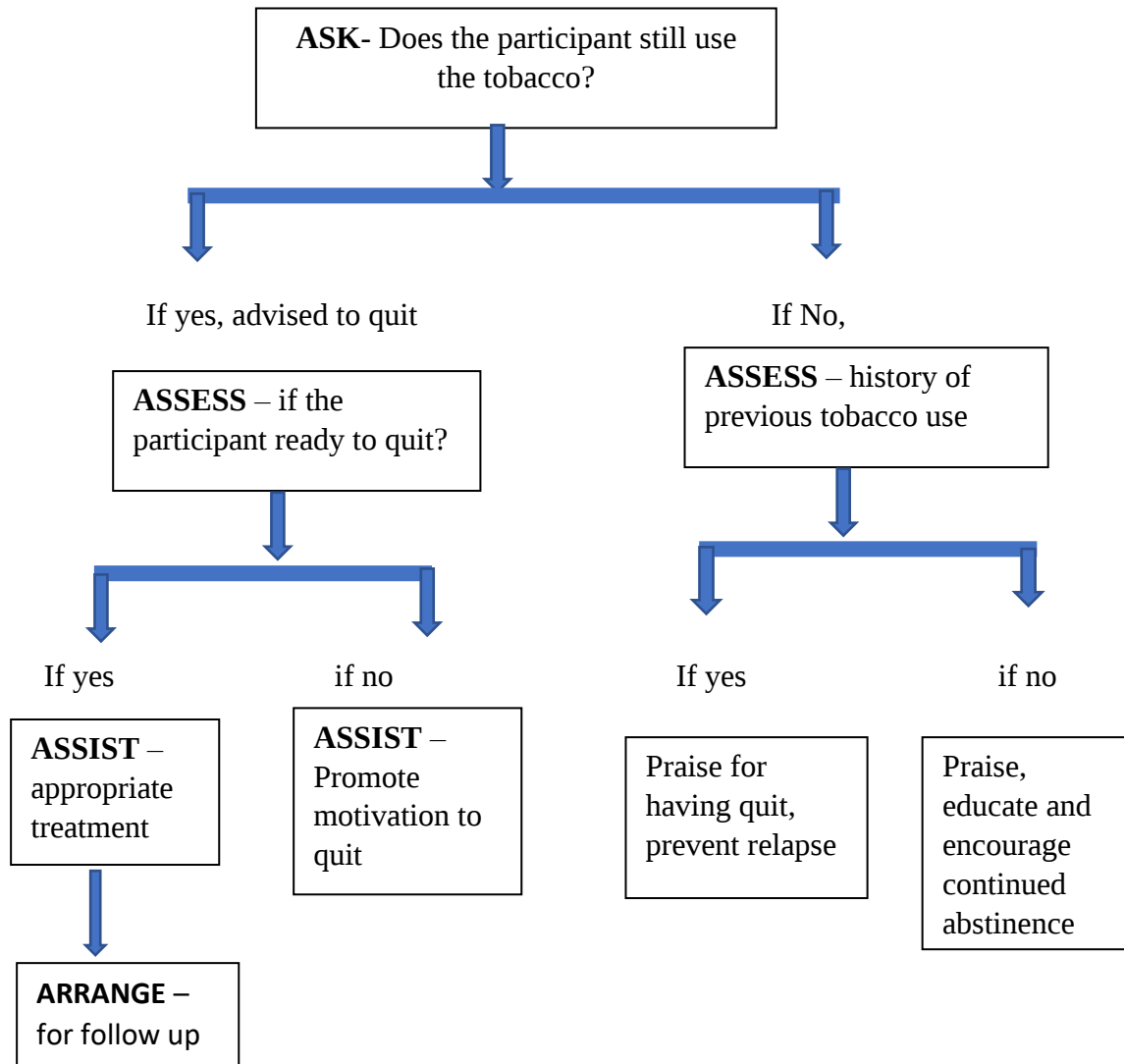


Table 6. Examples for very brief telephonic counselling

Scenario	Very brief telephonic counselling (less than 90 seconds)
If the participant is in pre-contemplation stage (who is not ready to quit tobacco)	Advise: “quitting tobacco is important for you now and Cutting down when you are ill is not enough and it is the most important thing you can do for your health and your family’s health.” “I can surely help you in this matter.” Illness related to tobacco use, its social and economic cost, the impact of tobacco use on children and others in the household was told. Benefits of quitting tobacco was told. Assessed if they are willing to quit.
Contemplation (planning to quit within 6 months)	Advice: health effects of tobacco use were told and encouraged them by telling “quitting is possible with will power and support from the family, friends, peer group and health professionals.” Motivated them to quit and suggested them to use nicotine gums (available at tobacco cessation centre, at district hospital, Kolar)
Preparation stage (planning to quit within 1 month)	Advised them to set a quit date and to tell their family, friends and relatives about their plan of quitting tobacco & to seek their help. Also told them to remove tobacco products in the

	surrounds and at work place. Also explained how treatment (NRT) helps in quitting
Action stage (quit tobacco in last 1 month)	Praised them and encouraged them to continue abstinent. Also told about some common withdrawal symptoms and coping strategies.

4.15.4 End assessment

After six months of recruitment telephonic calls were made to all the participants (both the groups) and tobacco use questionnaire was administered to see the behaviour change in the intention to quit tobacco. Those who have not responded, one more telephonic call after one hour was made to contact the participant on the particular day allotted for that participant and the procedure was repeated for the next two days until the telephone call is answered. Those who did not answer the end assessment call was considered as ‘loss to follow up’.

4.16 Operational definitions

Current tobacco user – an individual who has used any form of tobacco at least once in the last 30 days.

Pre-contemplation stage – This is a stage during which a tobacco user has not considered quitting.

Contemplation – This is a stage during which individuals are using tobacco and are considering quitting in the next six months.

Preparation – This is a stage during which a tobacco user is preparing (experimenting with different ways) to quit in the next thirty days.

Action – A stage during which a tobacco user has quit using tobacco somewhere in the last one-month period. The individual has used tobacco in the last one month but has quit at the time of data collection.

Nicotine Dependence: Fagerstrom Test score ≥ 6 was considered as high dependence on tobacco for smoke forms and ≥ 9 for smokeless forms of tobacco.

Motivation to quit tobacco: Richmond score = 10 was considered as high level of motivation to quit tobacco.

Measurement of outcome variable:

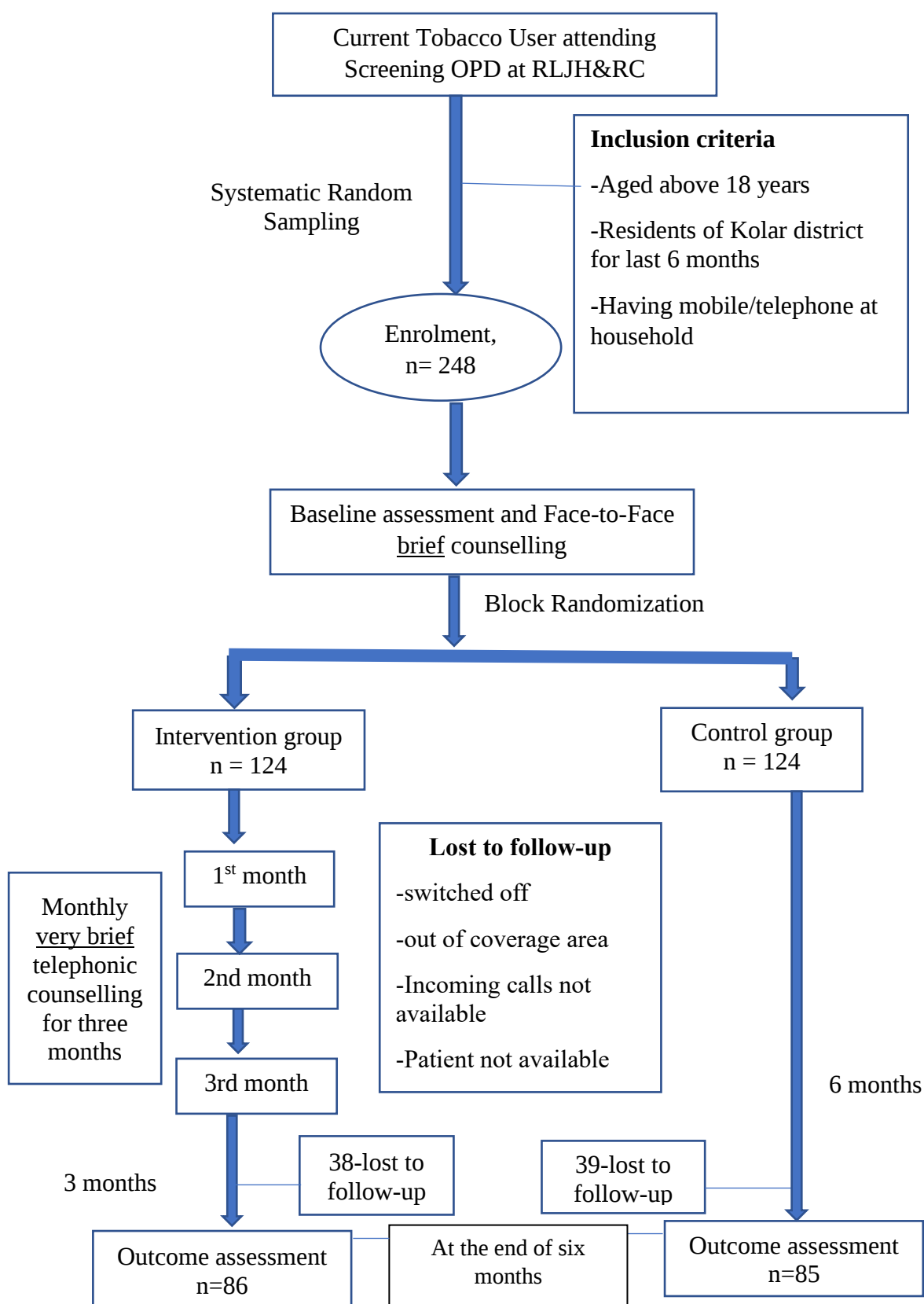
1. Stage of readiness to change categorized into pre-contemplation, contemplation, preparation and action. Proportion of study participants in pre-contemplation, contemplation, preparation and action stages will be described.
2. Nicotine dependence level: Proportion of individuals with low, medium and high dependence will be described.

Fagerstrom Addiction Scale for Smokers score: 0-2 very low, 3-5 medium dependence, 6-7 high dependence, 8-11 very high dependence

3. Modified Fagerstrom Questionnaire for Smokeless Tobacco Users score 0-4 low dependence, 5-8 medium dependence, 9-12 high dependence, 13-16 very high dependence.

4. Motivation level – Proportion of individuals with low, medium, and high level of motivation were described.
5. Richmond score 0 to 6 classified as “low motivation”, 7 to 9 as “medium motivation” and =10 as “high motivation”.

Figure 3. Flowchart depicting the participant's recruitment and study procedure



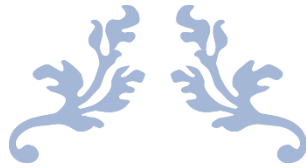
4.17 Statistical analysis

Data entry was done using EpiData Entry Client v3.1 and were analysed using IBM SPSS Statistics 22 and STATA v12.

Continuous data like age, age at tobacco initiation, number of cigarettes smoked per day, number of beedis smoked per day were summarized as Mean and Standard deviation (SD)

Categorical variables like gender, socio-economic status, education, occupation, presence of co-morbidity, type of tobacco product, type of smoke form, type of smokeless form, frequency of use, tobacco purchasing behaviour, storing tobacco products, knowledge of ill-effects of tobacco, previous quit attempt, nicotine dependence level, stage of change, and motivational level were summarized as proportions.

Differences in socio-demographics and tobacco-use behaviour across the groups were assessed using the Chi-square test for categorical variable and t test for continuous variable. A p- value of < 0.05 was accepted as statistically significant. Relative risk was calculated to assess the effectiveness of intervention with 95% confidence interval. Both Intention-To-Treat (ITT) analysis and Per-Protocol-analysis were done and reported separately. A $p < 0.05$ was accepted as statistically significant.



RESULTS



5.RESULTS

The study was conducted among 248 patients seeking care at screening out-patient department (OPD) who are tobacco users at R L Jalappa Hospital and Research Centre (RLJH&RC), Kolar.

Comparison of sociodemographic characteristics across two groups

The baseline socio-demographic characteristics of the adult tobacco users across two groups are depicted in Table 7. The mean (SD) age in years in intervention group was 46.8 (12.7) years and in control group was 46.4 (13.9) years. More number of study participants were males, 62.10% and 59.7% in intervention group and control group respectively. Education status across the groups were almost similar in both the groups.

Distribution of occupation across the groups were almost similar and more than half of the participants were unskilled workers. The distribution by marital status across two groups were almost similar. Majority of them were married at the time of the data collection in both the groups (more than 90%). The study participants who belongs to lower middle class (social class IV) were 29.8% in group A and 28.2% in group B, the distribution across the groups were almost similar. In about 12.9% in group A and 11.3% in control group were having chronic morbidity.

Table 7. Baseline socio-demographic characteristics of adult tobacco users across two groups (N=248)

Variable	Classes	Intervention group(n=124) n (%)	Control group(n=124) n (%)	p value [^]
Mean age in years (SD)	-	46.8 (12.7)	46.4 (13.9)	0.841 ^{\$}
Gender	Male	77 (62.1%)	74 (59.7%)	0.696
	Female	47 (37.9%)	50 (40.3%)	
Educational status	Illiterate	63 (50.8%)	61(49.2%)	0.983
	Primary school	7 (5.6%)	6 (4.8%)	
	Middle school	12 (9.7%)	19 (15.3%)	
	High school	26 (21%)	22 (17.7%)	
	PUC and above	16 (12.9%)	16 (12.9%)	
Occupation	Skilled [#]	14 (11.3%)	18 (14.5%)	0.300
	Semi-skilled	35 (28.2%)	44 (35.5%)	
	Unskilled	58 (46.8%)	52 (41.9%)	
	Unemployed	17 (13.7%)	10 (8.1%)	
Marital Status	Married	109 (87.9%)	108 (87.1%)	0.848
	Others [@]	15 (12.1%)	16 (12.9%)	
Socio-Economic Status [*]	Social class I	7 (5.6%)	11 (8.9%)	0.612
	Social class II	25 (20.2%)	26 (21.0%)	
	Social class III	26 (21.0%)	31 (25%)	
	Social class IV	37 (29.8%)	35 (28.2%)	
	Social class V	29 (23.4%)	21 (16.9%)	
Chronic morbidity	No	108 (87.1%)	110 (88.7%)	0.697
	Yes	16 (12.9%)	14 (11.3%)	

[^] Chi-square test, ^{\$} t test, [#] includes Professional, semi-professional and skilled,

[@] Includes Unmarried, widow, widower, divorcee, separated,

^{*}According to modified B G Prasad classification 2019

Table 8. Baseline tobacco use behaviour of adult tobacco users across 2 groups (N=248)

Variable	Classes	Intervention group(n=124) n(%)	Control group(n=124) n(%)	p value [^]
Type of tobacco product	Smoke	43 (34.7)	42 (33.9)	0.940
	Smokeless	77 (62.1)	77 (62.1)	
	Both	4 (3.2)	4 (4.0%)	
Frequency of use	Occasionally	5 (4.0%)	6 (4.8%)	0.778
	Few days in a week	13 (10.5%)	10 (8.1%)	
	Daily	106 (85.5%)	108 (87.1%)	
Purchasing pattern	Single unit	29 (23.4%)	29 (23.4%)	0.507
	Many units at a time	56 (45.2%)	48 (38.7%)	
	In packets	39 (31.4%)	47 (37.9%)	
Keeping tobacco products at home or workplace	No	67 (54.0%)	63 (50.8%)	0.611
	Yes	57 (46.0%)	61 (49.2%)	
Knowledge of harmful effects of tobacco	No	49 (39.5%)	63 (50.8%)	0.074
	Yes	75 (60.5%)	61 (49.2%)	
Ever thought of quitting tobacco	No	49 (39.5%)	47 (37.9%)	0.794
	Yes	75 (60.5%)	77 (62.1%)	
Plan to quit tobacco	No	45 (36.3%)	35 (28.2%)	0.174
	Yes	79 (63.7%)	89 (71.8%)	
Time frame to quit tobacco	No	43 (34.7%)	33 (26.6%)	0.168
	Yes	81 (65.3%)	91 (73.4%)	
Previous quit attempt	No	95 (76.6%)	93 (75%)	0.767
	Yes	29 (23.4%)	31 (25%)	
Mean age of initiation of tobacco (SD) in years	-	21.9 (8.9)	21.1 (9.0)	0.498 ^{\$}

[^] Chi square test

^{\$} t Test

The baseline distribution of tobacco use behaviour among adult tobacco users across the groups are shown in Table 8. Most of the participants in the study were smokeless (62%) tobacco users. About 34% and 4% of the study participants were smokers, and both (smoking & smokeless) tobacco users respectively; the type of tobacco use was similar across the groups.

Mean (SD) age of initiation of tobacco use in years was 21.9 (8.9) and 21.1 (9.0) in group A and group B respectively. Majority of current tobacco users were daily users about 85.5% in group A and 87% in group B. Tobacco purchasing pattern and keeping those products at home/workplace were almost similar in the two groups.

The knowledge of harmful effects of tobacco use was more among the intervention group (60.5%) compared to 49.2% in control group ($p=0.074$).

More number of the participants in both the groups had thought of quitting tobacco in the past, 60.5% and 62.1% in intervention and control group respectively. About 63.7% in intervention group and 71.8% in control group were planning to quit in the future. More number of participants in both the groups had a time frame to quit tobacco and was almost similar across the groups. About 23.4% in intervention group and around 25% in control group had made a quit attempt in the past.

Figure 4. Baseline Stages of quitting tobacco among adult tobacco users (N=248)

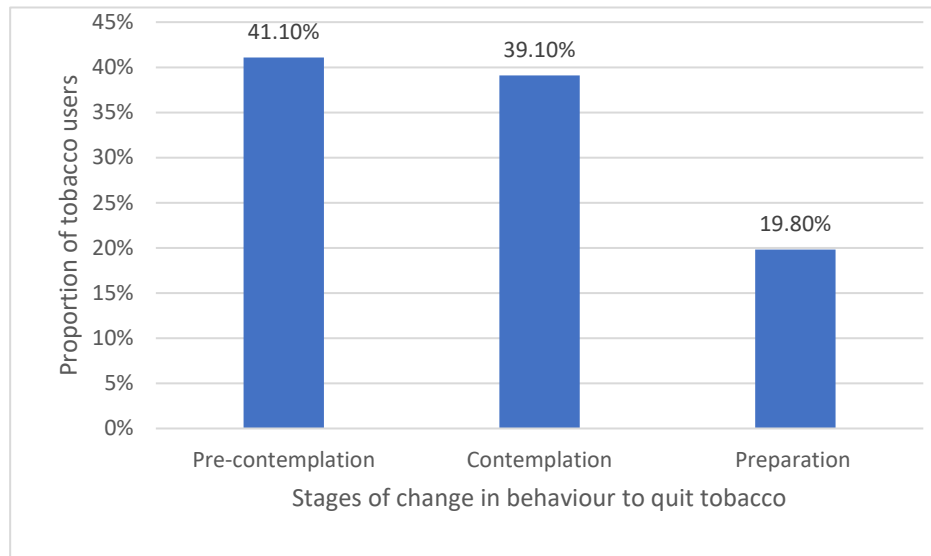


Figure 4 shows the stages of quitting tobacco at the baseline. Among study participants (N=248) more participants were in pre-contemplation stage (41.1%). About 39.1% and 19.8% were in contemplation and preparation stages respectively.

Figure 5. Baseline distribution of Nicotine Dependence among smoker's according to Fagerstrom Test for Nicotine Dependance (FTND)

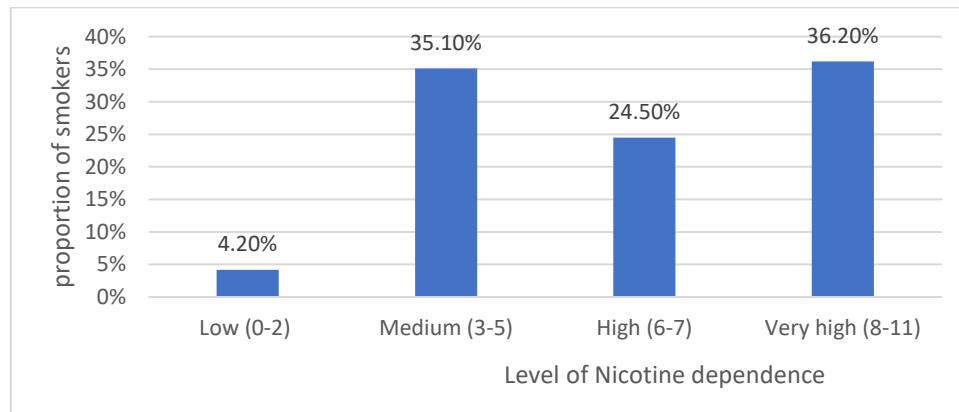


Figure 5 shows the baseline nicotine dependence among smokers (n=94). The mean (SD) nicotine dependence score was 6.3 (2.5). More number of smokers were medium (35.1%) and very high (36.2%) dependent on nicotine. About 4.4% and 24.5% were low and high dependent on nicotine, respectively.

Table 9. Baseline distribution of Nicotine Dependence among smokeless tobacco users according to Modified Fagerstrom Test for Nicotine dependence

Nicotine dependence among smokeless tobacco users*	Frequency n= 163	Percentage
Mean score (SD)	7.9 (2.9)	
Low (0-4)	21	12.9%
Medium (5-8)	82	50.3%
High (>9)	60	36.8%

Table 9 shows the nicotine dependence among smokeless tobacco users (n=163), the mean (SD) score was 7.9 (2.9). About half of the smokeless tobacco users had medium level of nicotine dependence. About 12.9% and 36.8% were low and high dependent on nicotine respectively

Table 10. Distribution of Level of motivation to quit tobacco among tobacco users (N=248)

Level of motivation to quit*	Frequency (N=248)	Percentage
Mean score (SD)	6.4 (2.3)	
Low (0-6)	129	52.0%
Medium (7-9)	86	34.7%
High (=10)	33	13.3%

*Richmond test score

Table 10 shows the level of motivation to quit tobacco among study participants (N=248). About half of them were having low level motivation to quit tobacco. About 34% and 13.3% were having medium level and high level of motivation respectively.

Table 11. Stages of Change in behaviour to quit tobacco among tobacco users according to intention-to-treat

	Change in behaviour to quit tobacco – Intention-to-treat			
	Total	Yes n (%)	RR ^{\$} (95% CI) [@]	p value [^]
Intervention group	124	62 (50%)	1.51 (1.11 2.05)	0.008*
Control group	124	41 (33.0%)		

\$ Relative risk, @ 95% confidence interval, *p < 0.05 is significant

Table 11 shows the intention-to-treat analysis for the change in behaviour to quit tobacco. All the study participants (N=248) who were recruited initially were included in the analysis by keeping no change in behaviour for those who were lost to follow-up. In intervention group about 50% had positive change in behaviour compared to 33% in control group. Among intervention group there is 1.5 times (1.11 2.05) higher chance of positive change in behaviour in quitting tobacco compared to control group and is statistically significant with p=0.008.

Table 12. At 6 month per protocol analysis of stages of change in behaviour to quit tobacco among tobacco users

	Change in behaviour to quit tobacco – per protocol			
	Total	Yes n (%)	RR ^{\$} (95% CI) [@]	p value [^]
Intervention group	86	62 (72%)	1.49 (1.15 1.93)	0.002*
Control group	85	41 (48.23%)		

\$ Relative risk, @ 95% confidence interval, *p < 0.05 is significant

Table 12 shows the per protocol analysis of change in behaviour to quit tobacco. In intervention group out of 124 study participants 38 were lost to follow up (30% drop-out rate) and remaining 86 were included in the analysis. Among them about 72% had positive change in behaviour in quitting tobacco. In control group, out of 124 participants 39 were lost to follow-up (31% drop-out rate) and remaining 85 were included in the analysis. About 48.23% of them had positive change in behaviour in quitting tobacco. Among intervention group there is 1.49 times (1.15 1.93) higher chance of change in behaviour to quit tobacco compared to control group and is statistically significant with p=0.002.

Table 13. Tobacco quit rate across the groups (N=248)

Tobacco quit status	Group A (n=124) n (%)	Group B (n=124) n (%)	Total	p value [@]
Yes	32 (25.8%)	30 (24.19%)	62 (25%)	0.086
No	54 (43.5%)	55 (44.3%)	109 (43.9%)	
Lost to follow-up	38 (30.6%)	39 (31.4%)	77 (31.1%)	

@ chi square test.

Table 13 showing the one month quit rate among the study participants (N=248). In the intervention group 25.8% of study participants had quit the tobacco and in control group 24.19% had quit the tobacco use but the difference across the groups were not statistically significant.



DISCUSSION



6 .DISCUSSION:

6.1 Tobacco use behaviour of the study participants

In the present study about 34% of the study participants smoked tobacco; smokeless tobacco use was found in about 62% of the study participants and 3.63% used both smoke and smokeless forms of tobacco. According to the GATS India Survey 2016-17,⁽⁹⁾ among the 28% of adults currently using tobacco in India, 10% are smokers, 21% use smokeless tobacco whereas 7% use both forms. The tobacco use pattern in current study is comparable to the distribution of tobacco consumption in Karnataka according to the GATS 2 Survey wherein among the 22.8% of current tobacco users, around 6.5% are smokers, 14% are smokeless tobacco users and 2.3% use both forms. However, the distribution of smokers is less when compared to a study by D'Souza et al among participants attending a tobacco cessation clinic in Bangalore where most of the participants (98%) were smokers.⁽²⁸⁾

In the present study about 86% of the tobacco users were current daily users. This is comparable to the distribution of daily v/s occasional use of tobacco in another region (D'Souza et al in Bangalore, Girgis et al in Australia).^(28,55) It is seen that most of the current tobacco users are daily users; 89% in India according to the GATS 2 Survey.⁽⁹⁾

In the present study about 54% of the participants reported knowledge of the harmful effects of tobacco. This was less when compared to the findings of Safa et al in a study among TB patients in Iran where 81% of the participants were aware of the hazardous effects of smoking on the lungs.⁽⁴³⁾ This maybe because about 50% of our study participants were illiterate. Also, according to the GATS Survey, it was

found that perceptions of harmful effects of tobacco use lessen with increasing age and more than 50% of our study participants were > 45 years old.⁽⁹⁾ This could be an implication for media strategies for circulating information on hazardous effects of tobacco focusing on target groups like persons in older age group and with low literacy levels.

The mean age of initiation of tobacco use this study was 21.5 years. This is comparable to the findings of D'Souza et al (22 years).⁽²⁸⁾ But this is higher in comparison with GATS 2 survey where it is 18.7 years in India and 19.8 years in Karnataka.⁽⁹⁾ However, the age of initiation of tobacco use in the present study is higher when compared to other countries where tobacco users initiate at a much younger age.

6.2 Stages of change of readiness to quit tobacco

In the present study, around 41.1% of the participants were in the pre-contemplation stage to quit tobacco, while 39.1% were in the contemplation stage. We could find only very few studies from India reporting the tobacco users' stages of readiness to quit. According to GATS 2 Survey which reported that about 75% of the tobacco users in India were in pre-contemplation stage and 13% were in contemplation stage.⁽⁹⁾ However, in a study by D'Souza et al, the same were reported to be pre-contemplation (14%) and contemplation (48%).⁽²⁸⁾ This difference in the stages from our study could be due to the said study was conducted among patients attending a tobacco cessation clinic who therefore are inherently different from other patients attending outpatient clinics.

In our study, more people were thinking of quitting tobacco when compared to the participants in other studies by Daoud et al, Dotinga et al, Wewers et al where more than 55% of the participants were in the pre-contemplation phase.^(39,44,56) This may be because these studies were done in community settings, unlike the present study where all the participants presented to the hospital would have been advised by their physicians to quit tobacco. It may also be due to the social desirability bias.

In the present study, only 19.7% of the tobacco users were in the preparation stage. Preparation was reported to be 8.4% in the GATS 2 Survey and according to D'souza et al, 37% were in the preparation/action stage.^(9,28) Increased access to cessation therapies is needed to facilitate the movement of tobacco users across the stages, i.e. from pre-contemplation stage to advanced SOC.

6.3 Nicotine dependence among the tobacco users

In the present study, among smokers (n=94) the mean (SD) dependence score was 6.31 (2.45). This was higher in compared to the mean dependence score as reported by other studies {Daoud et al 4.2 (2.6), D'Souza et al 5.8 (2.5)}.^(28,39)

In our study, about 36% of the smokers had high nicotine dependence. This was comparable to the Girgis et al study among Arabic speakers in Australia where 36% reported high nicotine dependence.⁽⁵⁵⁾ However, according to Islam et al, in a study conducted in West Bengal, about 80% of the tobacco users had high dependence on nicotine.⁽²⁹⁾ This may be because they have reported dependence as a single proportion despite 44.5% of their study population being exclusive smokeless tobacco users.

In the present study, among smokeless tobacco (n=163) users the mean (SD) dependence score was 7.87 (2.89). This was lower than the mean score reported by D'Souza et al among exclusive tobacco chewers which was 10.8 (3.3).⁽²⁸⁾ This maybe because they have used the FTND-ST scale (total score=10) for measuring dependence whereas we have used the Modified Fagerstrom Questionnaire for Smokeless Tobacco Users (total score=16) as recommended by the Government of India in the Manual for Tobacco Cessation. There is a difference in the score based on variables like the length of the dipping day, the amount of time a fresh dip is kept in the amount and craving for tobacco if not used for two hours. Hence, our scores are much lower accounting for the lower dependence level. Further studies are needed to explore the nicotine dependence level among smokeless tobacco users using standardized tools.

In our study, only 36% of smokeless tobacco users had high nicotine dependence. According to Shanti et al, in a study among 90 tobacco chewers in Bhopal all the participants were reported to have high dependence on nicotine.⁽²⁸⁾ This could be because their definition of high dependence included only two constructs from the Fagerstrom scale; i.e., use within 30 minutes of waking up and more than 25 dips per day. This could also be because all their participants were in the pre-contemplation stage of readiness to quit.

Thus, in our study, nicotine dependence was almost equal among smokers (36.1%) and in tobacco chewers (36.8%). Most of the evidence on nicotine dependence comes from studies where the majority of the tobacco users are smokers. In India, since almost a quarter (26%) of the adult population uses smokeless tobacco, a stratified analysis may be required to comment on the differences in nicotine dependence

among smoke and smokeless tobacco users and therefore in quitting behaviour.

6.4 Motivation level to quit tobacco

There are many studies which describe the tobacco user's level of motivation to quit tobacco; however, we have limited our discussion to only those studies which have used the Richmond test to measure the individual's motivation to quit.

In the present study, a greater number of study participants who were thinking of quitting tobacco reported low or medium motivation (52% and 35% respectively). Only 13% had a high motivation to quit. This is in contrast to another study done by Pawlina et al among smokers seeking treatment for smoking cessation in Brazil where motivation level was as high as 51% among smokers.⁽⁵⁷⁾ This could be due to lack of support (tobacco social environment: friends/colleagues /family members who also use tobacco) and poor access to cessation services in our setting. The National Tobacco Control Program has been launched by the Ministry of Health and Family Welfare in India in 2008 to reduce the tobacco burden in the country by creating a supportive tobacco-free environment, however it is in its infancy stage.⁽⁵⁸⁾

In this study, the mean (SD) score using the Richmond test for motivation was 6.36 (± 2.33) which corresponded to a low motivation to quit. The mean Richmond score in our study was higher than those reported by Khalil et al and Cordoba et al (4.4 and 4.8 respectively).^(47,59)

6.5 Very brief telephonic counselling in improving behavioural stage in quitting tobacco

In the current study among the current tobacco users showed positive change in behaviour in both intervention and control group. By intention to treat analysis, at six

months the positive change in behaviour was more in intervention group (50%) compared to control group (33%) and the difference was statistically significant {RR, 95% confidence interval were 1.51, (1.11 2.05) respectively}. This was the first study done on stages of change in behaviour to quit tobacco. There are no studies with the similar outcome to compare.

According to per-protocol analysis, at 6 months the positive change in behaviour was more in the intervention group (72%) compared to the control group and the difference was statistically significant {RR, 95% confidence interval were 1.49, (1.15 1.93) respectively}. There are no studies with the outcome as stages of change in behaviour to quit tobacco to compare.

At six months, the one month quit rate among intervention group was 25.8% and among control group it was 24.1%, the difference was not statistically significant between the groups. In a study by Wu et al, seven day quit rate at 6 month among smokers in control group (only baseline face-to-face counselling) it was 16.1% and in intervention group (face-to-face counselling plus 1, 3, 6 monthly telephonic brief counselling) it was 25.9% in control group.⁽³¹⁾ This difference might be because the study by Wu et al was done in a smoking cessation centre where people will be highly motivated to quit tobacco. It was a non-randomized controlled trial done only on smokers and they have considered 7-day abstinence rate. In our study we have not calculated sample size for the quit rate (not our study objective) and we have included both smokers and smokeless tobacco users. According to Radhakrishna et al a community based study, the smoking abstinence rate among intervention group (face-to-face counselling plus telephonic follow up) was 14.7% and 6.8% in the control group (receiving general awareness training and anti-tobacco leaflets).⁽⁴⁸⁾ The

difference could be because of the study setting, as our study was a hospital based study, the proportion of elderly, women and those with any chronic morbidity in the study population may not be representative of the tobacco users in the community.



SUMMARY & CONCLUSION



7. SUMMARY AND CONCLUSION

A facility based–open label parallel design Randomized Controlled Trial was done to assess the effectiveness of monthly individualized very brief telephonic counselling in changing the behaviour to quit tobacco as per the trans-theoretical model among the current tobacco users attending the screening OPD of RLJH&RC, Kolar during the months of May 2019 and June 2020.

A total of 248 participants were recruited and randomized into two equal groups. For intervention group monthly individualized very brief telephonic counselling was given for three consecutive months following baseline face-to-face counseling for all the study participants. The outcome (change in behaviour) was assessed after six months from the date of recruitment for both the groups.

At baseline, about 41%, 39.1% and 19% of the participants in the study were in pre-contemplation, contemplation, and preparation stage respectively.

By intention-to-treat analysis, about 50% had positive change in behaviour in intervention group compared to 33% in control group and was statistically significant {RR (95% CI): 1.5 (1.11 2.05) (p=0.008)}.

According to per protocol analysis 72% had positive change in behaviour in intervention group compared to 48.23% in control group and was statistically significant {RR (95% CI):1.49 (1.15 1.93) (p=0.002)}.

The study shows that the very brief telephonic counselling was effective in positively changing the behaviour to quit tobacco among the current tobacco users and it is a feasible and acceptable by the tobacco users.



RECOMMENDATIONS



8. RECOMMENDATIONS

Monthly individualized very brief telephonic counseling was effective in changing the behaviour to quit tobacco. The doctors play a significant role in changing the behaviour of tobacco use among the patients attending the hospital. We, therefore, recommend all the doctors to take an active and continual role in motivating them to quit tobacco. Hence, considering the time constrain very brief telephonic counseling by the doctor will improve the positive change in behaviour as it is found effective in the study.



LIMITATIONS



9. LIMITATIONS

1. There is the possibility of social desirability bias in the study.
2. The individuals' tobacco use behaviour was self-reported and the study participants were not supervised by the investigator nor from the other family members who could have been the supervisor.
3. The intervention group received more attention from the counselling and is might have been more inclined to falsely report abstinence. The biochemical verification of abstinence could have been done (exhaled carbon monoxide test).
4. This is a hospital-based study where the patients will be motivated and more receptive to counseling, so the results may not be generalized to the tobacco users in the community.



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ANNEXURES



Annexure I

Proforma for data collection

Section A:

Form

No.:

1. Name:

2. Address:

3. Socio-demographic details

Age	
Gender	
Education	
Occupation	
Marital status	
Total monthly family income	
Number of family members	
Number of children in the house	
Type of ration card	
Presence of chronic disease	

Section B:

1. Do you currently smoke or chew tobacco products? Yes/No if yes,
proceed further

2. What type of tobacco products do you use? Smoke
Smokeless.....Both.....

3. At what age did you start using tobacco products? smoke.....
smokeless.....

4. How frequently do you use tobacco products? Occasionally/few days in a week/every day

5. How do you purchase tobacco products? Single unit / Many units at a time / In packets

6. Do you keep any tobacco products at home or work place to use during spare time? Yes/No

7. Do you know the harmful effects / diseases as a result of tobacco use? Yes/No

If yes,
enumerate.....

8. Have you ever thought of quitting smoking? Yes / No if yes, proceed further

9. Have you discussed with someone that you want to quit tobacco? Yes/No

If yes, with whom.....

10. Do you have a plan to quit tobacco use? Yes / No

11. Have you set any time frame to quit tobacco use? Yes / No

If yes, when: Within a month/Within next 2-3 months/within next 6 months / beyond

12. How you are planning to cut down the use of tobacco products?

13. Have you taken any steps to cut down your tobacco use? Yes / No

If yes, enumerate.....

14. Have you ever attempted quitting tobacco use? Yes / No

If yes,

Reasons for failed quit attempt.....

Reasons for quit attempt.....

Annexure II

PROFORMA: Fagerstrom Tobacco Addiction Scale for smokers to know the Nicotine Dependency among smokers.

1. How soon after you awake do you smoke your first cigarette?

0. After 30 minutes 1. Within 30 minutes

2. Do you find it difficult to refrain from smoking in places where it is forbidden, such as the library, theatre, or doctors' office?

0. No 1. Yes

3. Which of all the cigarettes you smoke in a day is the most satisfying?

0. Any other than the first one in the morning

1. The first one in the morning

4. How many cigarettes a day do you smoke?

0. 1-15

1. 16-25

2. More than 26

5. Do you smoke more during the morning than during the rest of the day?

0. No

1. Yes

6. Do you smoke when you are so ill that you are in bed most of the day?

0. No

1. Yes

7. Does the brand you smoke have a low, medium, or high nicotine content?

0. Low

1. Medium

2. High

8. How often do you inhale the smoke from your cigarette?

0. Never

1. Sometimes

2. Always

Annexure III

PROFORMA: Modified Fagerstrom Tobacco Addiction Scale to know the Nicotine Dependency among smokeless tobacco users.

1. After a normal sleeping period, do you use smokeless tobacco within 30 minutes of waking?
 - a) Yes
 - b) No
2. Do you use smokeless tobacco when you are sick or have mouth sores?
 - a) Yes
 - b) No
3. How many times do you use tobacco per week?
 - a) Less than 2 times
 - b) More than 2 times
 - c) More than 4 times
4. Do you intentionally swallow your tobacco juices rather than spit?
 - a) Never
 - b) Sometimes
 - c) Always
5. Do you keep a dip or chew in your mouth almost all the time?
 - a) Yes
 - b) No
6. Do you experience strong cravings for a dip or chew when you go for more than two hours without one?
 - a) Yes
 - b) No
7. On average, how many minutes do you keep a fresh dip or chew in your mouth?
 - a) 10-19 minutes
 - b) 20-30 minutes
 - c) More than 30 minutes
8. What is the length of your dipping day (total hours from first dip/chew in a.m. to last dip/chew in p.m.)?

- a) Less than 14.5 hours
- b) More than 14.5 hours
- c) More than 15 hours

9. On average, how many dips/chews do you take each day?

- a) 1-9 times
- b) 10-15 times
- c) > 15 times

ANNEXURE IV

PROFORMA: Richmond Test for motivation (Among those who are thinking of quitting) to know the level of motivation to quit tobacco

1. Would you like to quit tobacco if you could do it easily?

No - 0 points

Yes - 1 point

2. How interested are you to quit tobacco?

Not at all - 0 points

A little - 1 point

A lot - 2 points

Very interested - 3 points

3. Will you try to stop using tobacco in the following two weeks?

Definitely not - 0 points

Perhaps - 1 point

Yes - 2 points

Definitely yes - 3 points

4. How likely are you to be a non-tobacco user in the following 6 months?

Definitely not - 0 points

Perhaps - 1 point

Yes - 2 points

Definitely yes - 3 points

ANNEXURE V

PROFORMA: Tobacco Cessation Follow - Up Survey

Follow - Up Period:

Follow-up	Date	Seconds of counselling
First		
Second		
Third		

1. Have you quit tobacco? Yes / No
2. Do you have a plan to quit tobacco use? Yes / No
3. Have you set any time frame to quit tobacco use? Yes / No

If yes, when:

- a) Within a month
- b) Within next 2-3 months
- c) Within next 6 months
- d) Beyond

ANNEXURE VI

Institutional Ethical Committee Certificate

 SDUAHER	SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION & RESEARCH SRI DEVARAJ URS MEDICAL COLLEGE Tamaka, Kolar INSTITUTIONAL ETHICS COMMITTEE	
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Members

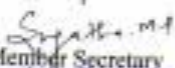
1. Dr. D.E.Gangadhar Rao,
(Chairman) Prof. & HOD of
Zoology, Govt. Women's
College, Kolar,
2. Dr. Sujatha.M.P.,
(Member Secretary), Assoc.
Prof. of Anesthesia, SDUMC,
3. Dr. C.S.Babu Rajendra Prasad,
Prof. of Pathology,
SDUMC
4. Dr. Srinivas Reddy.P.,
Prof. & HoD of
Forensic Medicine, SDUMC
5. Dr. Prasad.K.C.,
Professor of ENT, SDUMC
6. Dr. Sumathi.M.E
Prof. & HoD of Biochemistry,
SDUMC.
7. Dr. Bhuvana.K.,
Prof. & HoD of Pharmacology,
SDUMC
8. Dr. H.Mohan Kumar,
Professor of Ophthalmology,
SDUMC
9. Dr. Hariprasad, Assoc. Prof
Department of Orthopedics,
SDUMC
10. Dr. Pavan.K.,
Asst. Prof. of Surgery, SDUMC
11. Dr. Talasila Sruthi,
Assoc. Prof. of OBG, SDUMC
12. Dr. Mahendra.M.,
Asst. Prof. of Community
Medicine, SDUMC
13. Dr. Mamata Kale,
Asst. Professor of
Microbiology, SDUMC

No. SDUMC/KLR/IEC/125/2018-19

Date:29-11-2018

PRIOR PERMISSION TO START OF STUDY

The Institutional Ethics Committee of Sri Devaraj Urs Medical College, Tamaka, Kolar has examined and unanimously approved the Synopsis entitled "**Effectiveness of very brief telephonic counselling on behavioural change in quitting tobacco - A parallel design randomized controlled trial**" being investigated by **Dr.Sushma A & Dr.Prasanna Kamath B T** in the Department of Community Medicine at Sri Devaraj Urs Medical College, Tamaka, Kolar. **Permission is granted by the Ethics Committee to start the study.** However, final report has to be submitted to the Ethics Committee after completion of the study for presentation in conference or for publication.


Member Secretary
 Institutional Ethics Committee
 Sri Devaraj Urs Medical College
 Tamaka, Kolar.


Chairman
CHAIRMAN
 Institutional Ethics Committee
 Sri Devaraj Urs Medical College
 Tamaka, Kolar

ANNEXURE VIII

Modified B G Prasad Classification

Socio-Economic status: Modified B.G. Prasad classification was used for socio-economic status for rural and urban families according to per capita income 2019

Modified BG Prasad classification according to 2019.(52)

Socio-economic classification	Social class	Per capita monthly income	
		In 1961	2019
Upper class	I	≥ 100	≥ 7008
Upper middle class	II	50-99	3504-7007
Middle class	III	30-49	2102-3503
Lower middle class	IV	15-29	1051-2101
Lower class	V	<15	1050 and below

ANNEXURE VIII a

ಪ್ರಶ್ನಾವಳಿ

ಮಾಹಿತಿ ಸಂಗ್ರಹ ನಮೂನೆ

ವಿಭಾಗ A:

ಫಾರ್ಮ್ ಸಂಖ್ಯೆ:

1. ಹೆಸರು:
2. ವಿಳಾಸ:
3. ಸಾಮಾಜಿಕ-ಜನಸಂಖ್ಯಾ ವಿವರಗಳು

ವಯಸ್ಸು	
ಲಿಂಗ	
ಶಿಕ್ಷಣ	
ಉದ್ಯೋಗ	
ವೈವಾಹಿಕ ಸ್ಥಿತಿ	
ಒಟ್ಟು ಮಾಸಿಕ ಕುಟುಂಬ ಆದಾಯ	
ಕುಟುಂಬದ ಸದಸ್ಯರ ಸಂಖ್ಯೆ	
ಮನೆಯಲ್ಲಿರುವ ಮಕ್ಕಳ ಸಂಖ್ಯೆ	
ರೇಷನ್ ಕಾರ್ಡ್ ಪ್ರಕಾರ	
ದೀರ್ಘಕಾಲದ ಕಾಯಿಲೆ ಇರುವಿಕೆ	

ವಿಭಾಗ ಬಿ:

1. ನೀವು ಪ್ರಸ್ತುತ ಧೂಮಪಾನ ಉತ್ಪನ್ನಗಳನ್ನು ಧೂಮಪಾನ ಮಾಡುತ್ತೀರಾ ಅಥವಾ ಅಗಿಯುತ್ತಿದ್ದೀರಾ? ಹೌದು / ಇಲ್ಲ ಹೌದಾದರೂ, ಮುಂದುವರಿಯಿರಿ
2. ನೀವು ಯಾವ ವಿಧದ ತಂಬಾಕು ಉತ್ಪನ್ನಗಳನ್ನು ಬಳಸುತ್ತೀರಿ? ಧೂಮಪಾನ ಹೊಗೆರೆಹಿತ..... ಎರಡೂ.....
3. ಯಾವ ವಯಸ್ಸಿನಲ್ಲಿ ನೀವು ತಂಬಾಕು ಉತ್ಪನ್ನಗಳನ್ನು ಬಳಸಲು ಪ್ರಾರಂಭಿಸಿದ್ದೀರಿ? ಧೂಮಪಾನ..... ಹೊಗೆರೆಹಿತ.....
4. ನೀವು ಎಷ್ಟು ಬಾರಿ ತಂಬಾಕು ಉತ್ಪನ್ನಗಳನ್ನು ಬಳಸುತ್ತೀರಿ? ಕೆಲವೊಮ್ಮೆ / ವಾರದಲ್ಲಿ ಕೆಲವು ದಿನಗಳು/ ಪ್ರತಿ ದಿನ

5. ನೀವು ತಂಬಾಕು ಉತ್ಪನ್ನಗಳನ್ನು ಹೇಗೆ ಖರೀದಿಸುತ್ತೀರಿ? ಏಕ ಘಟಕ / ಒಂದು ಸಮಯದಲ್ಲಿ ಅನೇಕ ಘಟಕಗಳು / ಪ್ಯಾಕೆಟ್‌ಗಳಲ್ಲಿ

6. ನೀವು ಯಾವುದೇ ತಂಬಾಕು ಉತ್ಪನ್ನಗಳನ್ನು ಮನೆಯಲ್ಲಿ ಅಥವಾ ಕೆಲಸ ಮಾಡುವ ಸ್ಥಳದಲ್ಲಿ

ಇಟ್ಟು ಅದನ್ನು ಬಿಡುವಿನ ವೇಳೆಯಲ್ಲಿ ಬಳಸುತ್ತೀರಾ? ಹೌದು / ಇಲ್ಲ

7. ತಂಬಾಕು ಬಳಕೆಯಿಂದಾಗುವ ಹಾನಿಕಾರಕ ಪರಿಣಾಮಗಳು / ರೋಗಗಳು ನಿಮಗೆ ತಿಳಿದಿದೆಯೇ? ಹೌದು / ಇಲ್ಲ

ಹೌದಾದರೆ, ವಿವರಿಸಿ.....

8. ನೀವು ಎಂದಾದರೂ ಧೂಮಪಾನವನ್ನು ತೊರೆಯಲು ಯೋಚಿಸಿದ್ದೀರಾ? ಹೌದು / ಇಲ್ಲ ಹೌದು, ಮುಂದುವರಿಯಿರಿ

9. ನೀವು ತಂಬಾಕು ಸೇವನೆಯಿಂದ ಹೊರಬರಲು ಬೇರೆಯವರೊಂದಿಗೆ ಚರ್ಚಿಸಿದ್ದೀರಾ? ಹೌದು / ಇಲ್ಲ

ಹೌದಾದರೆ, ಯಾರೊಂದಿಗೆ

10. ನೀವು ತಂಬಾಕು ಸೇವನೆಯನ್ನು ತೊರೆಯುವ ಯೋಜನೆಯನ್ನು ಹೊಂದಿದ್ದೀರಾ? ಹೌದು / ಇಲ್ಲ

11. ತಂಬಾಕು ಬಳಕೆಯಿಂದ ಹೊರಬರಲು ನೀವು ಯಾವುದೇ ಸಮಯ ಚೌಕಟ್ಟನ್ನು ಹೊಂದಿದ್ದೀರಾ? ಹೌದು / ಇಲ್ಲ

ಹೌದಾದರೆ, ಯಾವಾಗ: ಒಂದು ತಿಂಗಳೊಳಗೆ / ಮುಂದಿನ 2-3 ತಿಂಗಳುಗಳಲ್ಲಿ

/ ಮುಂದಿನ 6 ತಿಂಗಳೊಳಗೆ / ಅದಕ್ಕಿಂತ ಆಚೆ

12. ನೀವು ತಂಬಾಕು ಉತ್ಪನ್ನಗಳ ಬಳಕೆಯನ್ನು ಕಡಿತಗೊಳಿಸಲು ಹೇಗೆ ಯೋಚಿಸುತ್ತಿದ್ದೀರಿ?

13. ತಂಬಾಕು ಸೇವನೆಯನ್ನು ಕಡಿತಗೊಳಿಸಲು ನೀವು ಯಾವುದಾದರೂ ಕ್ರಮಗಳನ್ನು ತೆಗೆದುಕೊಂಡಿದ್ದೀರಾ? ಹೌದು/ ಇಲ್ಲ

ಹೌದಾದರೆ, ವಿವರಿಸಿ.....

14. ನೀವು ಎಂದಾದರೂ ತಂಬಾಕು ಸೇವನೆಯನ್ನು ತೊರೆಯಲು ಪ್ರಯತ್ನಿಸಿದ್ದೀರಾ? ಹೌದು / ಇಲ್ಲ

ಹೌದಾದರೆ,

ನಿಮ್ಮ ಪ್ರಯತ್ನ ವಿಫಲವಾಗಲು ಕಾರಣಗಳು.....

ನೀವು ತಂಬಾಕು ತೊರೆಯಲು ಕಾರಣಗಳು .-----

ANNEXURE VIII b

ಧೂಮಪಾನಿಗಳಿಗೆ ಫೇಜಿಸ್ಟ್ರಾನ್ ತಂಬಾಕು ಅಡಿಕ್ಷನ್ ಸ್ಕೇಲ್

1. ನೀವು ಮುಂಜಾನೆ ಎಚ್ಚರವಾದ ಎಷ್ಟುಸಮಯದ ನಂತರ ಮೊದಲ

ಧೂಮಪಾನವನ್ನು ಮಾಡುತ್ತೀರಾ?

30 ನಿಮಿಷಗಳ ನಂತರ/ 30 ನಿಮಿಷಗಳಲ್ಲಿ

2. ಲೈಬ್ರರಿ, ಥಿಯೇಟರ್, ಅಥವಾ ವೈದ್ಯರ ಕಚೇರಿ ಮುಂತಾದ ನಿಷೇಧಿಸಿರುವ ಸ್ಥಳಗಳಲ್ಲಿ ಧೂಮಪಾನವನ್ನು ತಡೆಯುವುದು ಕಷ್ಟ ಎಂದು ನೀವು ಕಂಡುಕೊಳ್ಳುತ್ತೀರಾ??

0. ಇಲ್ಲ

1. ಹೌದು

3. ನೀವು ದಿನದ ಯಾವ ಸಮಯದಲ್ಲಿ ಧೂಮಪಾನ ಮಾಡಿದರೆ ಹೆಚ್ಚು

ತೃಪ್ತಿಕರವಾಗಿರುತ್ತದೆ?

0. ಬೆಳಿಗ್ಗೆ ಮೊದಲನೆಯದನ್ನು ಬಿಟ್ಟು ಬೇರೆ ಸಮಯದ್ದು

1. ಬೆಳಿಗ್ಗೆ ಮೊದಲನೆಯದು

4. ದಿನಕ್ಕೆ ಎಷ್ಟು ಸಿಗರೇಟುಗಳ ಧೂಮಪಾನ ಮಾಡುತ್ತೀರಾ?

0. 1-15

1. 16-25

2. 26 ಕ್ಕೂ ಹೆಚ್ಚು

5. ದಿನದ ಉಳಿದ ದಿನಗಳಿಗಿಂತ ಹೆಚ್ಚು ಬೆಳಿಗ್ಗೆ ನೀವು ಧೂಮಪಾನ ಮಾಡುತ್ತೀರಾ?

0. ಇಲ್ಲ

1. ಹೌದು

6. ನೀವು ಅನಾರೋಗ್ಯದಿಂದ ಬಳಲುತ್ತಿದ್ದು ಹೆಚ್ಚಿನ ಸಮಯ ಹಾಸಿಗೆಯ

ಮೇಲಿರುವಾಗಲೂ ಧೂಮಪಾನ ಮಾಡುತ್ತೀರಾ?

0. ಇಲ್ಲ

1. ಹೌದು

7. ನೀವು ಧೂಮಪಾನ ಮಾಡುವ ಬ್ರಾಂಡ್ ಕಡಿಮೆ, ಮಧ್ಯಮ ಅಥವಾ ಹೆಚ್ಚಿನ ನಿಕೋಟಿನ್ ಅಂಶವನ್ನು ಹೊಂದಿರುತ್ತದೆಯೇ??

0. ಕಡಿಮೆ

1 ಮಧ್ಯಮ

2. ಹೆಚ್ಚು

8. ನೀವು ಧೂಮಪಾನ ಮಾಡುವಾಗ ಹೊಗೆಯನ್ನು ಎಷ್ಟು ಬಾರಿ ಸೇವಿಸುತ್ತೀರಿ?

0. ಎಂದಿಗೂ ಇಲ್ಲ

1. ಕೆಲವೊಮ್ಮೆ

2. ಯಾವಾಗಲೂ

ANNEXURE VIII c

ಪ್ರಶ್ನಾವಳಿ

ಹೊಗೆರಹಿತ ತಂಬಾಕು ಬಳಕೆದಾರರಿಗೆ ಮಾರ್ಪಡಿಸಿದ

ಫೇಜ್‌ಸರ್ವೆಮ್

1. ನೀವು ಮುಂಜಾನೆ ಎದ್ದ ನಂತರ 30 ನಿಮಿಷದೊಳಗೆ ಹೊಗೆರಹಿತ ತಂಬಾಕನ್ನು ಸೇವಿಸುತ್ತೀರಾ?

a. ಇಲ್ಲ

b. ಹೌದು

2. ನೀವು ಅನಾರೋಗ್ಯ ಅಥವಾ ಬಾಯಿ ಹುಣ್ಣು ಹೊಂದಿರುವಾಗ ಹೊಗೆರಹಿತ ತಂಬಾಕನ್ನು ಸೇವಿಸುತ್ತೀರಾ?

a. ಇಲ್ಲ

b. ಹೌದು

3. ನೀವು ವಾರದಲ್ಲಿ ಎಷ್ಟು ಬಾರಿ ಹೊಗೆರಹಿತ ತಂಬಾಕನ್ನು ಸೇವಿಸುತ್ತೀರಿ?

a) 2 ಕ್ಕಿಂತ ಕಡಿಮೆ

b) 2 ಕ್ಕೂ ಹೆಚ್ಚು ಬಾರಿ

c) 4 ಕ್ಕೂ ಹೆಚ್ಚು ಬಾರಿ

4. ನೀವು ತಂಬಾಕಿನ ರಸವನ್ನು ಉಗುಳುವ ಬದಲು

ಉದ್ದೇಶಪೂರ್ವಕವಾಗಿ ನುಂಗಿದೀರಾ?

a) ಎಂದಿಗೂ ಇಲ್ಲ

b) ಕೆಲವೊಮ್ಮೆ

c) ಯಾವಾಗಲೂ

5. ನೀವು ಬಹುತೇಕವಾಗಿ ನಿಮ್ಮ ಬಾಯಿಯಲ್ಲಿ ತಂಬಾಕನ್ನು ಅಗಿಯುತ್ತೀರಾ?

a. ಇಲ್ಲ

b. ಹೌದು

6. ನೀವು ಎರಡುಕ್ಕಿಂತ ಹೆಚ್ಚಿನ ಘಂಟೆಗಳ ಕಾಲ ಹೋದಾಗ ತಂಬಾಕನ್ನು ಸೇವಿಸದಿದ್ದಾಗ ಸೇವನೆ ಮಾಡಲು ಬಲವಾದ ಬಯಕೆಯಾಗಿರುವ ಅನುಭವ ಉಂಟೆ? ಒಂದು ಗಂಟೆ ಇಲ್ಲದೆ?

a. ಹೌದು

b. ಇಲ್ಲ

7. ನೀವು ಸರಾಸರಿಯಾಗಿ, ನಿಮ್ಮ ಬಾಯಿಯಲ್ಲಿ ಎಷ್ಟು ನಿಮಿಷಗಳವರೆಗೆ ತಂಬಾಕನ್ನು ಅಗಿಯುವಿರಿ?

a) 10-19 ನಿಮಿಷಗಳು

b) 20-30 ನಿಮಿಷಗಳು

c) 30 ನಿಮಿಷಗಳಿಗಿಂತ ಹೆಚ್ಚು

8. ದಿನದಲ್ಲಿ ಎಷ್ಟು ಸಮಯ ತಂಬಾಕನ್ನು ಅಗಿಯುವಿರಿ (ಮೊದಲು ಅಗಿಯುವುದರಿಂದ ರಾತ್ರಿ ಅಗಿಯುವವರೆಗೆ ಒಟ್ಟು ಗಂಟೆಗಳು ಅಗಿಯುವಿರಿ)

a) 14.5 ಗಂಟೆಗಳಿಗಿಂತ ಕಡಿಮೆ

b) 14.5 ಕ್ಕೂ ಹೆಚ್ಚು ಗಂಟೆಗಳು

c) 15 ಗಂಟೆಗಳಿಗೂ ಹೆಚ್ಚು

9. ಸರಾಸರಿ, ನೀವು ದಿನಗಳಲ್ಲಿ ಎಷ್ಟು ತಂಬಾಕನ್ನು ಅಗಿಯುವಿರಿ?

a) 1-9 ಬಾರಿ

b) 10-15 ಬಾರಿ

c) > 15 ಬಾರಿ

ANNEXURE VIII d

ಪ್ರೇರಣೆಗಾಗಿ ರಿಚ್‌ಂಡ್ ಟೆಸ್ಟ್

1. ನೀವು ಸುಲಭವಾಗಿ ತಂಬಾಕಿನಿಂದ ಹೊರಬರಲು ಸಾಧ್ಯವಾದರೆ
ಹೊರಬರಲು ಬಯಸುವಿರಾ?

ಇಲ್ಲ	-	0 ಅಂಕ
ಹೌದು	-	1 ಅಂಕ

2. ನೀವು ತಂಬಾಕು ತೊರೆಯಲು ಎಷ್ಟು ಆಸಕ್ತಿ ಹೊಂದಿದ್ದೀರಿ?

ಇಲ್ಲವೇ ಇಲ್ಲ	-	0 ಅಂಕ
ಸ್ವಲ್ಪ	-	1 ಅಂಕ
ಬಹಳ	-	2 ಅಂಕಗಳು
ಬಹಳ ಆಸಕ್ತಿ	-	3 ಅಂಕಗಳು

3. ಮುಂದಿನ ಎರಡು ವಾರಗಳಲ್ಲಿ ನೀವು ತಂಬಾಕು ಬಳಸುವುದನ್ನು ತೊರೆಯಲು
ಪ್ರಯತ್ನಿಸುತ್ತೀರಾ??

ಖಂಡಿತವಾಗಿಯೂ ಇಲ್ಲ	-	0 ಅಂಕ
ಬಹುಶಃ	-	1 ಅಂಕ
ಹೌದು	-	2 ಅಂಕಗಳು
ಖಂಡಿತ ಹೌದು	-	3 ಅಂಕಗಳು

4. 6 ತಿಂಗಳುಗಳಲ್ಲಿ ನೀವು ತಂಬಾಕು ಅಲ್ಲದ ಬಳಕೆದಾರರಾಗಲು ಎಷ್ಟು
ಸಾಧ್ಯತೆಗಳಿವೆ?

ಖಂಡಿತವಾಗಿಯೂ ಇಲ್ಲ	-	0 ಅಂಕ
ಬಹುಶಃ	-	1 ಅಂಕ

ANNEXURE VIII e

ತಂಬಾಕು ನಿಲುಗಡೆ ಅನುಸರಣಾ ಸಮೀಕ್ಷೆ

ಅನುಸರಣೆ - ಅವಧಿ: ದೂರವಾಣಿ ಸಮಾಲೋಚನೆ

ಅನುಸರಣೆ	ದಿನಾಂಕ	ಸಮಯ
ಮೊದಲನೇ		
ಎರಡನೇ		
ಮೂರನೇ		

1. ನೀವು ತಂಬಾಕು ಸೇವನೆಯನ್ನು ತೊರೆದಿದ್ದೀರಾ? ಹೌದು / ಇಲ್ಲ
2. ನೀವು ತಂಬಾಕು ಸೇವನೆಯನ್ನು ತೊರೆಯುವ ಯೋಜನೆಯನ್ನು ಹೊಂದಿದ್ದೀರಾ? ಹೌದು / ಇಲ್ಲ
3. ತಂಬಾಕು ಬಳಕೆಯಿಂದ ಹೊರಬರಲು ನೀವು ಯಾವುದೇ ಸಮಯ ಚೌಕಟ್ಟನ್ನು ಹೊಂದಿದ್ದೀರಾ? ಹೌದು/ ಇಲ್ಲ

ಹೌದಾದರೆ, ಯಾವಾಗ:

- a) ಒಂದು ತಿಂಗಳೊಳಗೆ
- b) ಮುಂದಿನ 2-3 ತಿಂಗಳುಗಳಲ್ಲಿ
- c) ಮುಂದಿನ 6 ತಿಂಗಳೊಳಗೆ
- d) ಅದಕ್ಕಿಂತ ಆಚೆ

ANNEXURE IX

Information sheet

Title: Effectiveness of Very Brief Telephonic Counselling on Behavioural Change in Quitting Tobacco – A Parallel Design Randomized Controlled Trial

My name is Dr. Sushma. A, Postgraduate in the department of Community Medicine, Sri Devaraj Urs Medical College, Kolar. I am carrying out a study on quitting tobacco usage by face to face and telephonic counselling on behavioral change. The study has been reviewed by the local ethical review board and has been started only after their formal approval.

Tobacco is a leading preventable cause of death; millions of deaths are occurring due to its use and also increases the burden of non-communicable diseases. In this regard I will help you to quit tobacco usage by giving face to face and telephonic counselling to bring in behavioral change. You need not have to answer any questions that you do not want to answer, and you may end this interview at any time you want to. However, your honest answer to these questions will help us to understand the health status. We would greatly appreciate your help in responding to the questionnaire. The interview will take about half an hour.

Participation in this study doesn't involve any cost for you. This study is not only beneficial to you but also to the community at large. The results gathered from this study will be beneficial in estimating the effectiveness of counselling on behavioral change in quitting tobacco

All the information collected from you will be strictly confidential and will not be disclosed to any outsider unless compelled by law. This information

collected will be used only for research.

There is no compulsion to participate in this study. You will be no way affected if you don't wish to participate in this study. You are required to sign only if you voluntarily agree to participate in this study. Further, you are at a liberty to withdraw from the study at any time if you wish to do so. Be assured that your withdrawal will not affect your treatment by the concerned physician in any way. It is up to you to decide whether to participate. This document will be stored in the safe locker in the department of Community Medicine in the college and a copy is given to you for information.

For any further clarification you are free to contact the principal investigator,

Dr. Sushma. A Mobile No: 88925816125

ANNEXURE X

ಮಾಹಿತಿ ಪತ್ರ

ಪರಿಚಯ: ನನ್ನ ಹೆಸರು ಡಾ|| ಸುಷ್ಮ. ನಾನು ಶ್ರೀ ದೇವರಾಜ್ ಅರಸ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜಿನ ಸಮುದಾಯ ವೈದ್ಯಶಾಸ್ತ್ರ ವಿಭಾಗದಲ್ಲಿ ಉನ್ನತ ವಿದ್ಯಾಭ್ಯಾಸ ಮಾಡುತ್ತಿರುವ ವಿದ್ಯಾರ್ಥಿನಿ.

ನಾನು “ತಂಬಾಕು ತೊರೆಯುವುದರಲ್ಲಿ ವರ್ತನೆಯ ಬದಲಾವಣೆಯ ಬಗ್ಗೆ ಬಹಳ ಸಂಕ್ಷಿಪ್ತ ದೂರವಾಣಿ ಸಮಾಲೋಚನೆಯ ಪರಿಣಾಮಕಾರಿತ್ವ”ದ ಬಗ್ಗೆ ಅಧ್ಯಯನ ಮಾಡುತ್ತಿದ್ದೇನೆ. ಈ ಅಧ್ಯಯನಕ್ಕೆ ಕಾಲೇಜಿನ ನೈತಿಕ ಸಮಿತಿಯ ವತಿಯಿಂದ ಮನ್ನಣೆ ದೊರೆತಿರುತ್ತದೆ.

ಸಂಶೋಧನೆಯ ಕುರಿತಾದ ಮಾಹಿತಿ: ತಂಬಾಕು ಸೇವನೆಯಿಂದ ಅನೇಕ ಹಾನಿಕಾರಕ ಪರಿಣಾಮಗಳು ಉಂಟಾಗುತ್ತವೆ. ತಂಬಾಕು ತೊರೆಯುವುದರಿಂದ ಈ ಹಾನಿಕಾರಕ ಪರಿಣಾಮಗಳನ್ನು ಬಹುತೇಕ ತಡೆಗಟ್ಟಬಹುದು. ತಂಬಾಕು ತೊರೆಯುವುದರಲ್ಲಿ ಸಂಕ್ಷಿಪ್ತ ದೂರವಾಣಿ ಸಮಾಲೋಚನೆ ಉಪಯೋಗಕಾರಿಯಾಗಬಹುದು. ಆದ್ದರಿಂದ ಈ ಸಂಶೋಧನೆ ಸಂಕ್ಷಿಪ್ತ ದೂರವಾಣಿ ಸಮಾಲೋಚನೆಯ ಪರಿಣಾಮಕಾರಿತ್ವದ ಕುರಿತು ಆಗಿದ್ದು, ಈ ವಿಷಯವಾಗಿ ನಾನು ನಿಮ್ಮನ್ನು ಕೆಲವು ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳುತ್ತೇನೆ.

ನಿಮಗೆ ಈ ಅಧ್ಯಯನದಿಂದ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಹೊರಗುಳಿಯುವ ಅವಕಾಶವಿರುತ್ತದೆ. ನಿಮ್ಮ ಪ್ರಾಮಾಣಿಕ ಉತ್ತರವು ನಮ್ಮ ಅಧ್ಯಯನಕ್ಕೆ ಬಹು ಉಪಯುಕ್ತವಾಗಿರುತ್ತದೆ. ನಮ್ಮ ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯನ್ನು ನಾವು ಶ್ಲಾಘಿಸುತ್ತೇವೆ. ಅರ್ಧಘಂಟೆಯ ಕಾಲ ಈ ಅಧ್ಯಯನಕ್ಕಾಗಿ ನೀವು ನಮ್ಮೊಡನೆ ಕಳೆಯಬೇಕಾಗಬಹುದು. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನಿಮಗೆ ಭಾಗವಹಿಸಲು ಯಾವುದೇ ರೀತಿಯ ಖರ್ಚು ಇರುವುದಿಲ್ಲ. ನಿಮಗೆ ಮಾತ್ರವಲ್ಲದೆ ನಮ್ಮ ಸಮಾಜಕ್ಕೂ ಸಹ

ಉಪಯುಕ್ತವಾಗಿರುತ್ತದೆ. ನಿಮ್ಮಿಂದ ಪಡೆಯಲಾದ ಎಲ್ಲಾ ಮಾಹಿತಿಗಳನ್ನು ಗೌಪ್ಯವಾಗಿ ಇಡಲಾಗುವುದು. ಕಾನೂನಿನ ಚೌಕಟ್ಟಿನ ಹೊರಗೆ ಯಾವುದೇ ಕಾರಣಕ್ಕೂ ನೀವು ಕೊಡುವ ಮಾಹಿತಿಯನ್ನು ಬಹಿರಂಗ ಪಡಿಸುವುದಿಲ್ಲ. ನಿಮ್ಮಿಂದ ಪಡೆದಿರುವ ಮಾಹಿತಿಯನ್ನು ಕೇವಲ ಅಧ್ಯಯನಕ್ಕಾಗಿ ಮಾತ್ರ ಉಪಯೋಗಿಸಿಕೊಳ್ಳಲಾಗುವುದು.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ತಮ್ಮ ಹಾಗೂ ತಮ್ಮ ಕುಟುಂಬದ ಸಾಮಾಜಿಕ ಮಾಹಿತಿಯನ್ನು ಪಡೆಯಲಾಗುವುದು ಮತ್ತು ದೈಹಿಕ ಪರೀಕ್ಷೆ ಮಾಡಲಾಗುವುದು.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲೇಬೇಕೆಂಬ ಕಡ್ಡಾಯವೇನಿಲ್ಲ, ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸದೇ ಇದ್ದರೂ ನಿಮಗೇನು ತೊಂದರೆಯಾಗುವುದಿಲ್ಲ. ನೀವು ಸ್ವಇಚ್ಛೆಯಿಂದ ಭಾಗವಹಿಸಿದರೆ ಮಾತ್ರ ನಿಮ್ಮ ಸಹಿಯನ್ನು ಈ ಸಮ್ಮತಿ ಪತ್ರದಲ್ಲಿ ತೆಗೆದುಕೊಳ್ಳಲಾಗುವುದು. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಯಾವುದೇ ಹಂತದಲ್ಲಿ ಹೊರಗುಳಿಯುವ ಅಧಿಕಾರ ನಿಮಗಿರುತ್ತದೆ. ನೀವು ಅಧ್ಯಯನದಿಂದ ಹೊರಗುಳಿದರೂ ಸಹ ನಿಮ್ಮ ಚಿಕಿತ್ಸೆಗೆ ಯಾವುದೇ ರೀತಿಯ ದುಷ್ಪರಿಣಾಮಗಳಾಗುವುದಿಲ್ಲವೆಂದು ಈ ಮೂಲಕ ಧೃಢೀಕರಿಸುತ್ತೇನೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವ ನಿರ್ಧಾರ ತಮಗೆ ಬಿಟ್ಟದ್ದು. ಈ ಮಾಹಿತಿಯು ಕಾಲೇಜಿನ ಸಮುದಾಯ ವೈದ್ಯ ಶಾಸ್ತ್ರ ವಿಭಾಗದ ಸುರಕ್ಷಿತ ಲಾಕರ್‌ನಲ್ಲಿ ಇಡಲಾಗುವುದು ಹಾಗೂ ಒಂದು ಪ್ರತಿಯನ್ನು ತಮಗೆ ನೀಡಲಾಗುವುದು.

ಹೆಚ್ಚಿನ ಮಾಹಿತಿಗಾಗಿ ಮುಖ್ಯ ಅಧ್ಯಯನಗಾರರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ಡಾ|| ಸುಷ್ಮ. ಎ

ದೂರವಾಣಿ ಸಂಖ್ಯೆ: 8892581625

ANNEXURE XI

INFORMED CONSENT

Sl. no:

TITLE OF THE STUDY: Effectiveness of Very Brief Telephonic
Counselling on Behavioural Change in Quitting Tobacco – A Parallel
Design Randomized Controlled Trial

I, the undersigned, agree to participate in this study and to undergo
counselling and disclosure of my personal information and as outlined in this
consent form.

I have been read out/ explained in my local language i.e. in _____
and understand the purpose of this study and the confidential nature of the
information that will be collected and disclosed during the study. I have had
the opportunity to ask questions regarding the various aspects of this study
and my questions have been answered to my full satisfaction. The
information collected will be used only for research.

I understand that I remain free to withdraw from this study at any time.
Participation in this study is under my sole discretion and does not involve
any cost to me.

Subject's name and signature /thumb impression

Name and signature of witness

1. Date:

2. Date:

Name and signature of interviewer:

Date:

Name and signature of Principal Investigator: Dr. Sushma. A

Contact No: 8892581625

Date:

ANNEXURE XII

ಒಪ್ಪಿಗೆ ಪತ್ರ

ಕ್ರಮ ಸಂ.

ಶೀರ್ಷಿಕೆ: “ತಂಬಾಕು ತೊರೆಯುವುದರಲ್ಲಿ ವರ್ತನೆಯ ಬದಲಾವಣೆಯ ಬಗ್ಗೆ ಬಹಳ

ಸಂಕ್ಷಿಪ್ತ ದೂರವಾಣಿ ಸಮಾಲೋಚನೆಯ ಪರಿಣಾಮಕಾರಿತ್ವ” ಬಗ್ಗೆ ಸಂಶೋಧನೆ.

ಈ ಕೆಳಗೆ ಸಹಿ ಮಾಡಿರುವ ನಾನು ಈ ಸಮೀಕ್ಷೆಯಲ್ಲಿ ಬಾಗವಹಿಸಿ, ವೈದ್ಯಕೀಯ

ಪರೀಕ್ಷೆಗೆ ಒಳಪಡಲು ನನ್ನ ಸಂಪೂರ್ಣ ಸಮ್ಮತಿಯನ್ನು ನೀಡುತ್ತಿದ್ದೇನೆ.

ನನಗೆ ಈ ಸಂಶೋಧನೆಯ ಉದ್ದೇಶ ಹಾಗೂ ಇನ್ನಿತರ ಮಾಹಿತಿಗಳನ್ನು ಸ್ಪಷ್ಟವಾಗಿ

ನನಗೆ ಅರ್ಥವಾಗುವ ಭಾಷೆಯಲ್ಲಿ ತಿಳಿಸಿರುತ್ತಾರೆ ಹಾಗೂ ನನಗೆ ಈ ಬಗ್ಗೆ

ಯಾವುದೇ ಸಂದೇಹಗಳಿರುವುದಿಲ್ಲ. ಇದರಲ್ಲಿ ಬಾಗವಹಿಸಲು ಬಲವಂತವಿಲ್ಲ ಮತ್ತು

ಯಾವುದೇ ಸಮಯದಲ್ಲಾದರೂ ನಾನು ಇದರಿಂದ ಹೊರಉಳಿಯಲು ಬಯಸಿದಲ್ಲಿ

ನನಗೆ ಸಂಪೂರ್ಣ ಸ್ವಾತಂತ್ರ್ಯವಿರುತ್ತದೆಂದು ತಿಳಿದಿದ್ದೇನೆ.

ಈ ಸಮೀಕ್ಷೆಯಲ್ಲಿ ಬಾಗವಹಿಸುವುದು ನನ್ನ ಸ್ವಯಂಪ್ರೇರಿತ ನಿರ್ಣಯವಾಗಿದ್ದು

ಇದರಲ್ಲಿ ಬಾಗವಹಿಸಲು ನನಗೆ ಯಾವುದೇ ಖರ್ಚು ತಗುಲುವುದಿಲ್ಲ ಎಂದು

ತಿಳಿದಿದ್ದೇನೆ.

ಹೆಸರು: _____

ಸಹಿ: _____

ದಿನಾಂಕ: _____

ANNEXURE XIII

Data acquisition images



Investigator preparing chits for concealing the randomization sequence in brown opaque envelop after randomization



Investigator giving baseline face-to-face counselling for the study participants.

ANNEXURE XIV

GANTT CHART

STEP	ACTIVITY	TIME PERIOD														
		2018				2019						2020				
		Aug	Sept	Nov	Dec	Jan	Feb to Mar	April	May	June to July	Sep to Nov	Dec	Jan to June	July to Aug	Aug to Sep	Sep to Oct
1	Topic search and selection															
2	Synopsis submission															
3	Approval by IEC															
4	Proforma Preparation and validation															
5	Pilot project															
6	Review of literature															
7	CTRI Registration															
8	Data collection															
9	Follow Up															
10	Data analysis															
11	Dissertation writing															
12	Submission of dissertation															