Original Article

Role of clinical pharmacist in smoking cessation: A prospective randomized trial

M. G. Rajanandh, C. Ramasamy, A. D. Nageswari[1], N. Ethirajan

Department of Pharmacy Practice and [1]Respiratory Medicine, SRM Medical College Hospital and Research Centre, SRM University, Kanchipuram District, Tamil Nadu, India

Address for correspondence:
Mr. M. G. Rajanandh,
Department of Pharmacy Practice,
SRM College of Pharmacy,
SRM University, Kattankulathur,
Kanchipuram District - 603 203,
Tamil Nadu, India.
E-mail: mgrpharm@gmail.com

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ABSTRACT

Objective: In accordance with the pharmacist oath, service to the community is the moral responsibility of a clinical pharmacist. Patient counseling is one among the service to public towards greater wellbeing. It is designed to help people to explore and resolve their incongruity about behavior change. It was developed as a treatment for alcohol abuse, but it may also help smokers to a make a successful attempt to quit. The present study is aimed to study the role of clinical pharmacist in smoking cessation in smokers. **Materials and Methods:** A prospective randomized usual led trial was carried out. The study was approved by human institutional ethical committee. The sample size was calculated using standardized formula. Participants (n=80) were recruited based upon inclusion and exclusion criteria and were allocated on random basis into two groups, namely usual care and intervention care using computerized randomization model. Participants in both groups were counseled based on their nicotine dependence level. **Results:** We found improvements between baseline and after intervention regarding the outcome. At the end of motivational enhancement counseling, participants in the interventional arm showed significant improvement in quitting smoking habit than the usual arm. **Conclusion:** Study has proved that motivational enhancement counseling do have a tremendous reach in male smokers. The better understanding of the reason behind every individual smoker is an important key in motivating them and in getting the positive results.

INTRODUCTION

Counseling is a short term, theory based, non-directive, nonjudgmental process. During this process, a person (client) who is basically, psychologically healthy and facing adjustment, developmental and/or situational concerns or problems is empowered to gain awareness of him/herself and of his/her situation and to make decisions through the support and assistance offered by another person (counselor) through their relationship. Peer counseling refers to the provision of such support and assistance by trained peers. It differs from professional counseling in that it is very brief, less formal and not provided by professional counselors. In this context, persons are said to be peers when they share a common identity or experience. The commonality may be age, gender, career, education, social orientation or any other self-defined common experience. Peer counseling helps to create an environment in which the client feels accepted, non-defensive and able to talk freely.

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Smoking is a well-known health hazard and it is a global health problem. Around 1.1 billion people smoke all around the world, which is anticipated to increase more than 1.6 billion by 2025. Many people are negligent to accept the danger and continue smoking. Although some smokers are in denial about the risks associated with smoking, the majority of smokers continue literally addicted to nicotine. Smoking a cigarette a day might

end up in having a risk of heart disease that is halfway between that of a smoker and a non-smoker. Smoking causes vascular stenosis,[1] lung cancer[2] and chronic obstructive pulmonary disease.[3] Smoking is a risk factor in Alzheimer's disease.[4] Medical experts have conducted certain studies which revealed the harmful effects of smoking which can result in death. It is believed that only very few smokers can successfully quit the habit of smoking in their very first attempt. Arresting the habit is not easy unless serious commitment and resolution is pertinent with the individual.

The reason why it is hard to quit smoking despite of known facts is not clearly understood. The answer to the question sounds irrational as getting addicted. Possibly, the reason behind is addiction why smokers find it hard to quit smoking. Psychological dependence caused by nicotine can hinder the commitment made to quit smoking. But this psychological dependence can be overcome by the will power of the individual.[5] Willingness can make a very big difference in terms of the results we get on attempting to quit smoking.

Motivational counseling has been used primarily for the behavioral management of disorders.[6] Motivational counseling interventions are those services provided by the health care professionals in order to adopt and change the behaviors of patients which end up in positive outcomes. It denotes a cooperative work demanding active participation from both patient and healthcare professionals that aims to facilitate the patient's independent initiative to positive health behaviors.[7] Systematic reviews have shown motivational interviewing to be effective for alcohol, weight usual, diet and exercise but few attempts were made to determine the evidence of motivational interviewing applied specifically to smoking cessation.[8-10] The guiding principles are expressing empathy, developing discrepancy, rolling with resistance and supporting self-efficacy, which have been detailed to precede motivational interviewing.[11] Effective interventions may be delivered by a variety of primary care clinicians. Research shows that providing pharmacists with specialized tobacco cessation counseling training results in increasing counseling activities. Dr. Karen Hudmon's recent survey of more than 1,100 Northern California pharmacists indicated that less than 1 in 10 have formal training in tobacco cessation counseling. However, 87% indicated interest in receiving formal training, 70% believe that training would increase the number of patients they counsel, and 94% believe that it would increase the quality of the assistance that they provide to the patients.[12] The present study has been done to prove the active role of pharmacist in motivating and counseling the smokers to quit smoking. An attempt has been made to find the effectiveness of the brief motivational enhancement counseling in smokers.

MATERIALS AND METHODS

A prospective randomized usual led trial was carried out in SRM Medical College Hospital and Research Center. The questionnaire and material used for the study were evaluated and approved by the institutional review board of SRM Medical College hospital and Research Center. Ethics clearance number: 142/IEC/2011. The participants were followed up for 3 consecutive months to motivate and educate.

Sample size calculation

Considering α error at 0.05 and 80% power (1-β=0.8) of study with the standard deviation (σ) of 0.05 using 1:1 ratio of paired sample *t*-test, 40 patients must complete the study in each group. Considering 20% dropout, 48 patients should be included in each group.

Participants and randomization

We approached the people who had come for the consultation in the departments of respiratory and general medicine at SRM Medical College Hospital and Research center and briefly explained who we were (that is provided information about the university, department, investigators and aims of the study) and asked whether they were smokers. If they signposted they were smokers, we continued with the study protocol. The equality between the usual and intervention care was justified by recruiting participants having FEV_1 value 50-80% (Mild as per the COPD classification on PFT basis) using the PFT digital apparatus. Out of 117 participants recruited with criteria satisfied, 82 participants completed the study period and they were randomly allocated into usual care (40) and interventional care (40). Remaining participants were excluded from the study due to lost to follow-up. Randomization was performed by random allocation software version 1.0.

Inclusion/exclusion criteria

Inclusion criteria listed, men from 18 to 65 years of age, participant with FEV_1 value from (50-80)%. Exclusion criteria listed, women, participants with chronic illness, mentally challenged. All the smokers were requested to fill the questionnaire. The questionnaire filled describes the individual's demographic details, smoking history and baseline

evaluation. Fragerstom nicotine check form [13,14] is also used to determine the dependence level towards nicotine. After the randomization, motivational interviewing was performed to all the participants in the interventional arm. Motivational interviewing helped us to understand every individual's different perception over smoking. The counseling was given thrice, each month. We counseled participants about beneficial outcomes of smoking cessation and harmful effects of smoking using smoking related materials, significant pictorials and booklets pertaining to smoking hazards.

Outcome measures

The study measured the effects of behavioral counseling. Participants in interventional care group were given with motivation enhancement counseling. They were explained about the effects of smoking for ten minutes using the study materials. The readiness to change was the base evaluation for further intervention and if the participant was not sure or not motivated to stop smoking, strategies derived from motivational interviewing. Also apart from the behavioral counseling, we called each participant by telephone at the end of every month. Data was collected and analyzed statistically. Number of days without smoking and number of cigarettes smoked per day were used to compare the abstinence rates.

RESULTS AND DISCUSSION

Pre-intervention level on counseling in intervention group and usual care group

Intervention care group

The analysis portrays that in intervention group, 23 (60 %) of them are less frequent level of smokers; 13 (33.3 %) of them are more frequent level of smokers and 4 (6.7 %) are most frequent level of smokers. That is in the usual group, 22 (56.7 %) of them are less frequent level of smokers; 15 (40 %) of them are more frequent level of smokers and 3 (3.3 %) smoker is most frequent level of smoker [Table 1].

Usual care group

Table 2 represents frequency and percentage of post intervention level of smoking in usual and intervention group. The analysis portrays that in the usual group, 29 (80 %) of them are less frequent level of smokers; 7 (16.7 %) of them are more frequent level of smokers and 4 (3.3 %) is most frequent level of smoker. That is in the intervention group, 23 (60 %) of them are less frequent level of smokers; 14 (36.7 %) of them are more frequent level of smokers and 3 (3.3 %) smoker is most frequent level of smokers.

Post intervention level on smoking cessation in intervention and usual group

Intervention care group

The analysis portrays [Tables 3 and 4] that the mean value 330 with SD 212 of pretest and mean value 245 with SD 158 of posttest projects't' value as 5.87 which is statistically significant and mean value of 311 with SD 204 of pretest and mean value of 309 with SD 204 of posttest projects't' value as 0.812 which is statistically not significant.

Smoking cessation study might enhance the effectiveness of the pharmacological treatment in various diseased conditions. The present study has done with the motivation to prove the motivational enhancement counseling over smoking cessation. It

Table 1: Frequency and percentage distribution of pre intervention level of smoking cessation between intervention and usual care groups

Level of smoking	Intervention group (*n*=40)		Usual group (*n*=40)	
	Frequency	% of smokers	Frequency	% of smokers
Less frequent	18	60	17	56.7
More frequent	10	33.3	12	40
Most frequent	2	6.7	1	3.3

Table 2: Frequency and percentage distribution of post intervention level of smoking cessation between intervention and usual care groups

Level of smoking	Intervention care group (*n*=40)		Usual care group (*n*=40)	
	Frequency	% of smokers	Frequency	% of smokers
Less frequent	24	80	18	60
More frequent	5	16.7	11	36.7
Most frequent	1	3.3	1	3.3

Table 3: Comparison between pre and post test mean levels of smoking in intervention care group

Test	Mean (*n*=40)	SD (*n*=40)	Paired *t* test (*n*=40)
Pre test	330	212	T=5.87
Post test	245	158	Significant

Table 4: Comparison between pre and post test mean levels of smoking in usual care group

Test	Mean (*n*=40)	SD (*n*=40)	Paired *t* test (*n*=40)
Pre test	311	204	T=0.812
Post test	309	204	NS

is also true that smoking cessation might help people of low and medium classed economic status to save money. In the present study, it was found that people spend upto two thousand rupees (Indian currency) a month over the habit. And it was also sorted out that people from middle income group smokes more comparing the low and high income group. Married men smoke in higher percentage than the single. Most smokers stated that relaxation is the outcome what they are looking for and also other reasons like habituation and fantasy. Most beginners reported that they smoke for fun and fantasy. As they grow, fantasy transforms to habituation and addiction. Nowadays, the number of people who smoke beedi (Indian cigar) is less comparing the cigarette smokers. The present study has also proved the same.

Almost everyone knows the injurious effects of smoking. However, there are few existing and short lasting advantages of smoking which tends them not to give up the habit smoking. Smoking is a well-known addictive habit which is very hard to get rid of. Nicotine stimulates the dopaminergic pathways in the brain, an area that is involved in reinforcement for other drugs of abuse; eventually develops addiction.[13] Even though smoking is proven a harmful habit, there are still so many people who smoke to the extreme.

There are many smokers who see the positive side of smoking. Most smokers say that they find nothing more enjoyable and relaxing as smoking. They say that smoking clears their head and eliminates any negative thoughts. Most smokers are unaware of the fact that with every puff, they inhale around 7000 various toxins including tar, carbon monoxide, arsenic, benzene, cadmium, formaldehyde, ammonia and hydrogen cyanide etc., which causes various forms of cancer and other diseases.[14] Surely, it cannot be a pleasurable experience when one knows that with every puff, he is becoming more prone to many diseases.[15]

Most smokers take the pleasure of analgesic activity of nicotine. As such, the analgesic effect of nicotine has been proven in feline visceral pain models and replicated in numerous animal and human studies.[16] Smokers are very prone to develop back pain and associated chronic pain disorders, which have been justified clinically.[17] Furthermore, when comparing smokers and non-smokers with chronic pain disorders, it was came to know that smokers have higher pain intensity scores that have greater impact on occupational and social function.[18]

People who smoke assumes that smoking helps them in maintaining ideal weight and it is true when it does the same.[19] Various clinical studies performed in humans determined that the body weight and BMI are significantly lower in smokers when compared to nonsmokers.[20] The intensity of smoking rather than duration has a predominant impact on weight loss in humans. Hyperphagia and weight gain are the common events which follows smoking cessation observed more frequently in women.[21] There is no difference in hunger sensation on administration of nicotine to both smokers and non-smokers. Some studies suggest that smoking does increase the metabolic rate and suppresses the appetite of a person. This might end up in minor weight loss or no loss. However, smoking also results in wrinkles, dull complexion, bad breath, chapped lips among various other things. If beauty is a concern, then smoking is the last thing one should do.

Smoking cessation include 9 pharmacotherapies and 3 types of counseling (intra and extra treatment social support, skills building) conducted with 3 types of modalities (individual, group, and telephone).[22] Smokers are being opportunistic in making decision to quit smoking. Every smoker from the age group 30 to 40 are having greater plan to quit smoking at one point in their life time. Most smokers are planning to quit after marriage. There are very few reasons staying behind their smoking habit like fantasy, stress, drinking alcohol, work nature and loneliness. Most beginners do have the reason called fantasy. This is because of the atmosphere they are in and this is being the primary level, which may transform to the further level. Most experts recommend more research that most current smokers cannot or will not quit completely.[23] Smokers beyond 50 years of old were not really interested to quit unless they have chronic diseases, which really intrudes their daily life.

Work nature is also the very big reason to be concerned. Smokers do think that smoking is the cheapest habit to manage the stress and pain. It is really not easy to motivate them to quit smoking unless they have a strong desire to quit the habit. Motivational along with change in atmosphere will help them a very lot. Smokers indulged in profession with major physical activity are facing a very big problem since their chances to quit smoking is very least comparing others.

Many smokers who wish to quit the habit of smoking cannot be succeeding in their mission due to various reasons. Nicotine withdrawal literally defines the

effects experienced by an individual who is nicotine dependent and stops smoking suddenly or reduces his/her nicotine intake substantially. The common withdrawal syndrome is characterized by physical and psychological effects like irritability, poor concentration, frustration or anger, restlessness, insomnia, depression, anxiety, problems getting along with friends and family, increased appetite, and craving for smoking.[24,25]When smokers quit smoking suddenly, they often get strong cravings, especially when they are being in smoking associated minds (e.g. meeting a friend, on a coffee break, etc). At times, people can experience nicotine withdrawal symptoms cutting down the number of cigarettes smoked. Ex-smokers have to overcome the fact that nicotine is an appetite suppressant. A study conducted on 1991 reported that the mean weight gain due to smoking cessation was 2.8 kg (6.2 lb) for men and 3.8 kg (8.4 lb) for women who concluded that weight gain is not likely to nullify the health benefits of smoking cessation, but its cosmetic effects may interfere with attempts to quit.[24] Depression is another factor. The habit is having a substantial relationship with depression and anxiety. The risk of not usual ling stress and of developing anxiety and irritability were the leading barriers to smoking cessation.

Some do have problem in eliminating the signals which tends them to continue the habit. So many signals that they get is from the working atmosphere which cannot be ruled out. The change in atmosphere is not that possible nowadays. Smoking harms nearly every organ of the body and diminishes a person's overall health. Millions of Americans have health problems caused by smoking. Smoking causes disease relating heart, cancers of the mouth and larynx, stroke and ischemic heart diseases (IHD) and chronic obstructive pulmonary disease, tuberculosis.[24] Aronson *et al.*, in a prospective study of young adults presenting with acute respiratory illness, found that compared with nonsmokers, smokers had lower respiratory tract illnesses, a longer duration of cough, and more abnormalities heard by chest auscultation. Men who smoke are at greater risk of erectile dysfunction.[25]

CONCLUSION

Intervention was taken up to provide counseling to all the smokers. However, the response was on the same scale. The present study showed the different perspectives of smokers over the habit of smoking. Pictorial information had the highest reach and good response. Smokers evidenced greatest interest when they were interacted with pictorials defining the effects of smoking. Most smokers had not responded well in the beginning and they were also reluctant to follow-up. The level of involvement gradually hiked. Diseased participants were more conscious and the commitment to quit the habit was higher with them. This certainly indicates that pharmacist's counseling on smoking can be of greater help in reducing the habit. Clinical pharmacist counseling on smoking cessation can reduce smoking related diseases and death.

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Questionnaire Form

Department of Pharmacy Practice

SRM Medical College Hospital and Research Centre,
Kattankulathur, Potheri, Chennai – 603 203
Reference: (Global Youth Tobacco Survey 2008)

Name: _____ Date: _____

Ip/Op No: _____

Age: _____

Adress: _____

_____

Sex: ○ Male ○ Female

Occupation: _____

Socio-Economic Status: ○ Low ○ Medium ○ High

Contact No: _____

Questionnaire:

1. How old were you when you first tried a cigarette?
   _____
2. How did you start smoking?
   _____
3. Why do you smoke?
   _____
4. During the past 30 days, on how many days did you smoke cigarettes?
   _____
5. During the past 30 days, how many cigarettes you smoke (average)?
   _____
6. Where do you usually smoke?
   _____
7. Do you ever have a cigarette or feel like having a cigarette first thing in the morning?
   No, I don't feel like having a cigarette first thing in the morning. ○ Yes ○ No
   Yes, I sometimes feel like having a cigarette first thing in the morning. ○ Yes ○ No
   Yes, I always feel like having a cigarette first thing in the morning. ○ Yes ○ No
8. Does smoking cigarettes help people feel more or less comfortable at celebrations, parties, or in other social gatherings?
   ○ Yes ○ No
9. Do you have any other substances use or psychiatric illness?
   ○ Yes ○ No
10. Do your first degree relatives smoke?
    ○ Yes ○ No
11. Do you think you will continue smoking after 12 months?
    ○ Yes ○ No
12. Do you think that smoking cigarettes makes you gain or lose weight?
    ○ Yes, Gain ○ No, lose
13. Do you think cigarette smoking is harmful to your health?
    ○ Yes ○ No
14. Has anyone in your family discussed the harmful effects of smoking with you?
    ○ Yes ○ No
15. Once someone has started smoking, do you think it would be difficult to quit?
    ○ Yes ○ No
16. How many attempts you made so far to quit smoking?
    _____
17. What is the longest period you stay out of smoking?
    _____
18. Have you ever received help or advice to help you stop smoking?
    Yes, from a program or professional ○ Yes ○ No
    Yes, from a friend ○ Yes ○ No
    Yes, from a family member ○ Yes ○ No
19. Do you think you would be able to stop smoking if you wanted to?
    ○ Yes ○ No
20. What was the main reason you decided to stop smoking?
    To improve my health ○ Yes ○ No
    To save money ○ Yes ○ No
    Because my family does not like it ○ Yes ○ No