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Original Research Article

Efficacy of providing free nicotine replacement chewing gum to induce quit attempts in tobacco users- A prospective observational study

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ABSTRACT

Background: To assess the effectiveness of providing free NRT to tobacco users in increasing quit attempts and to assess the perception of adherence, side effects and safety issues related to the usage in increasing quit attempt.

Materials and Methods: A observational study was conducted to motivate tobacco users to have a quit attempt with a nicotine replacement sample among patients visiting out-patient department of a dental college. Baseline evaluation (demographic), Modified Fagerstrom test for Nicotine Dependence (MFTND) to assess nicotine addiction level, "breath analyzer" for the quantitative detection of levels of carbon monoxide were assessed. A free NRT sample was given. Telephonic follow up was done at an interval of 2 weeks, 1 month to assess the reduction in the mean MFTND score and to assess the perception of using NRT sample. All data was entered and analysed in SPSS for Windows version 22.

Results: Among the 40 subjects 80% were in the age group of 30-50 years and were males. The levels of carbon monoxide using breath analyser showed 80% of the subjects as heavy and chain smokers. Out of 40 subjects, 29 (72.5%) subjects were having high dependence calculated using MFTND which reduced to 2(5%) after using nicotine chewing gum. The mean and standard deviation of pre MFTND was 7.97±2.35 and for post MFTND it was 5.57±2.14 and the difference was highly significant ($p< 0.005$).

Conclusions: The results of this study confirm the efficacy of providing free nicotine replacement sample a novel strategy in motivating tobacco users to induce quit attempt.

1. Introduction

Tobacco is a well-acknowledged social and health evil. The history of tobacco use traces back to the dawn of human civilization and has deeply entrenched into the human society since time immemorial. The social, economic, and health impact of tobacco has been a subject of intense debate over the recent decades.[1] It is the greatest disease-producing product, with its prevalent addictive habit influencing the behaviour of human beings for more than four centuries.[2] It is consumed orally in a variety of forms such as smoking and chewable forms.[2] According to WHO (2009) consumption of tobacco has been growing at the rate of 2% to 5% per annum.[1]

India has played a leadership role in global tobacco control. With the growing evidence of harmful and hazardous effects of tobacco, the Government of India enacted various legislations and comprehensive tobacco control measures.[3] These include advertising bans, package labelling, prohibition of smoking at public places and

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raising taxes. Such policies encourage the social norm of non-smoking and increase the demand for cessation services.[4]

Nicotine is highly addictive and many smokers are unable to quit successfully due to withdrawal symptoms. Nicotine replacement therapy (NRT) is a safe and effective pharmacotherapy to reduce these symptoms during early abstinence and to increase the quit rate in the longer term.[5,6] The low prevalence of using NRT in India may be due to the higher price of NRT. Very few smokers therefore use NRT for their quit attempts, especially those who do not prefer to obtain free NRT from the smoking cessation clinics.

One promising approach to encourage cessation among less motivated smokers is Motivation by giving free NRT sample, a treatment approach that emerged from the alcohol and drug treatment literature that focuses on fostering motivation for, and commitment to behaviour change.[7] Motivation has been defined as a collaborative, person centred form of guiding to elicit and strengthen motivation for change.[8] Principles of motivation include using a collaborative style, eliciting individuals' reasons for change rather than persuading, and supporting autonomy so that individuals do not feel pressured to change and can feel autonomously or "internally" motivated. These strategies are thought to be more effective than questioning, persuading, or giving advice. Motivation mediates cessation outcomes and may be more effective for low motivated smokers. Providing free NRT sample might also be beneficial for tobacco users who have just developed the motivation to quit and will act soon. With this background the present study is proposed to assess the effectiveness of providing free NRT samples to tobacco users in increasing motivation to quit and also to assess the perception of use and adherence to NRT in increasing quit attempts.

2. Aims and Objectives

The study aims to motivate tobacco users using proactive approach to induce quit attempt by providing a free NRT sample

3. Materials and Methods

3.1. Study design

A observational study was conducted to motivate tobacco users to have a quit attempt with a nicotine replacement sample.

3.2. Study setting

The study was conducted at an out-patient department of a dental college in Bangalore.

3.3. Source population

Patients aged 20-60years visiting out-patient department of a dental college in Bangalore.

3.4. Study population

The study was conducted among tobacco users aged 20-60years visiting out-patient department of a dental college in Bangalore.

3.5. Study period

For a period of two weeks from 1st August 2018 to 14 August 2018.

Sample size and sampling technique: a total of 60 subjects were included based on convenience sampling technique for the feasibility of the study.

3.6. Inclusion criteria

Adults aged 20-60 years

1. Participants with history of tobacco from past 5 years
2. Participants who had earlier tried to quit
3. Participants who had given consent

3.7. Exclusion criteria

Participants who had not used NRT for the past 3 months

Participants who have no severe angina and serious cardiac arrhythmias and have not suffered an acute myocardial event in the past 4 weeks;

1. Participants who could not comprehend the questions
2. Participants who were wearing removable prosthesis

3.8. Procedure A

The data was collected using a proforma which consists of four parts.

Part A: Sociodemographic data of the participants and biochemical validation of smoking using a bedfont monitor smokerlyzer or breathanalyser to check the CO levels.

Part B: Modified Fagerstorm test for nicotine dependence. (MFTND)

It contains six items that evaluate the quantity of tobacco consumption the compulsion to use and dependence on nicotine.

Part C: CPI INDEX (WHO 2013) To assess periodontal status based on gingival bleeding and pocket scores of the individual.

Part D: Willingness to quit assessed using three questions like time since last attempt to quit, highest number of quitting days and tobacco had any adverse effect on your health.[9]

All the participants were male and a total sample of 50 was selected based on inclusion criteria. A Proactive

approach was carried out in the study. In this approach Face-to-face conversation with the subjects using a pro-forma to record baseline information was done during the pre-intervention. Free NRT sample with a education leaflet containing instructions on its usage and side effects was given to the subjects. Telephonic 'cold calling' during the follow up periods at the interval of 2 weeks and 1 month and whenever required by the participant was done.

3.9. Ethics, consent and permission

Permission was obtained from the ethical committee of the institution before undertaking the study and informed consent was obtained from the participants.

3.10. Procedure B

The principal investigator helped the subjects in deciding which type of NRT flavour (mint, pan, cinnamon) he can use and advise him on how to use the NRT based on his habit and daily tobacco consumption. He will also be provided with an education card about NRT. The choice of NRT (flavour) will be made according to the subject's preference and the investigator will provide medication counselling. Later, the subjects will receive a free pack of 1-week of Nicotex chewing gum dosage 2mg & 4mg depending on the levels of MFTND score and CO levels. Subjects were blinded about the company of chewing gum. If the subject is willing to continue the counselling at recruitment, the investigator introduced the NRT's side effects, adherence and effectiveness. Otherwise, the investigator contacted the participants to provide such details and enquire about his usage of NRT by telephone within 2 days. Subjects were motivated to use NRT and were repeatedly told about the process of chewing NRT and were helped with side effects if had any during telephonic cold calling. They were called at the intervals of 2 weeks and 1 month.

3.11. Follow up

After one month Subjects were requested to spend 5-10mins of their time to share their experience of using NRT. Perception of subjects for adherence to NRT its usage and side effects were assessed using treatment experience questionnaire[10] during telephonic follow up. Treatment experience questionnaire used to record the perception of participant consisted of three main scales. They are 1) treatment appraisal -4 items 2) perceived required co-operation-3 items 3) perceived required somatosensory intensity 3-items. The response of the participants were recorded using a 5 point Likert scale varying from strongly agree, agree versus dis-agree and strongly disagree.

3.12. Statistical analysis

All data was entered and analysed in SPSS for Windows version 22. Descriptive statistics were performed for socio-demographic data, CPI scores, CO levels, willingness to quit questionnaire, pre and post MFTND scores and treatment experience questionnaire. Inferential statistics were done for comparison of The Mean Fagerstorm test for nicotine dependence scores between pre and post intervention using Paired t –test. coGuide version V.1.0 was used for statistical analysis.[11]

4. Results

The final analysis consisted of 40 subjects as 6 subjects lost to follow up and 4 subjects discontinued intervention.

Among the 40 subjects 80% were in the age group of 30-50 years and were males. The socio-economic status was calculated using kuppuswamy scale modified 2016. A majority of study subjects 33(82.5%) belong to upper middle class. Out of 40 subjects 36 (90%) subjects were having both gingival bleeding and periodontal pockets and only 4(10%) were free from the disease. The levels of carbon monoxide using breath analyser showed 80% of the subjects as heavy and chain smokers. Out of 40 study subjects 29(72.5%) subjects were having dependence calculated using MFTND which reduced to 2(5%) after using nicotine chewing gum (Table 1).

The mean and standard deviation of pre MFTND was 7.97±2.35 and for post MFTND it was 5.57±2.14. When both were compared using t- test p value was 0.005 which was highly significant which means there was reduction in dependence level using nicotine replacement therapy. (Table 2)

Twelve (30%) out of 40 of the subjects have attempted to quit more than a year before and 40% had quit less than a week and 30(75%) subjects said that they did not any adverse effect on health (Figures 1 and 2).

Figure 3 They are 1) treatment appraisal -4 items 2) perceived required co-operation-3 items 3) perceived required somatosensory intensity 3-items. The response of the participants were recorded using a 5 point Likert scale varying from strongly agree, agree versus dis-agree and strongly disagree and all the subjects agreed to the questions in all three domains.

5. Discussion

Nicotine replacement therapy (NRT) is the most commonly used intervention for tobacco cessation introduced almost 20 years back. It was designed to replace blood nicotine levels, minimising withdrawal symptoms like depression, anxiety, weight gain, insomnia, irritability etc.[12,13] It is considered safe as it is devoid of all the carcinogens and harmful chemicals contained in a cigarette or beedi[14] Previous studies strongly supported that NRT is a safe and

Table 1: Distribution of study population according to age, socio-economic status, CPI scores, Pre and post FTND scores

Variables	Frequency (n=40)	Percentage
Age		
20-30	8	20%
30-40	15	37.5%
40-50	17	42.5%
Socio-economic status		
Upper middle	33	82.5%
Lower middle	5	12.5%
Upper lower	2	5%
CPI-scores		
Absent	4	10%
Present	36	90%
Pre-MFTND		
Low dependence	2	5%
Low to moderate dependence	3	7.5%
Moderate dependence	6	15%
High dependence	29	72.5%
Post-MFTND		
Low dependence	6	15%
Low to moderate dependence	12	30%
Moderate dependence	20	50%
High dependence	2	5%

Table 2: Comparison of pre and post MFTND scores using t-test

Variable	Mean and SD	P Value
Pre –MFTND	7.97±2.35	0.005
Post - MFTND	5.57±2.14	

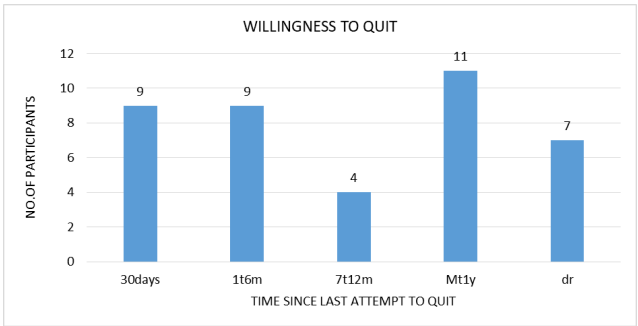

Fig. 1: Distribution of study population according to time since last attempt to quit

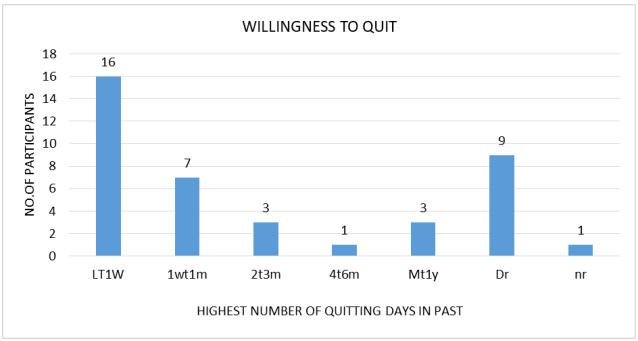

Fig. 2: Distribution of study population according to highest number of quitting days in past

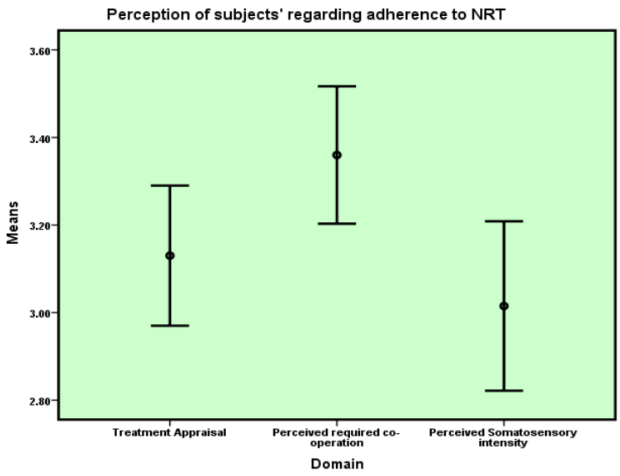

Fig. 3: Perception of subjects regarding adherence to NRT

effective tobacco cessation aid,[5,15,16] but the low literacy reduces the using prevalence. Despite the widespread promotion of tobacco cessation messages, an increase in the proportion of hard-core tobacco users and a reduction in the quit rate support that more effective methods for promoting cessation aids are needed.[9] The present RCT assessed whether providing a free NRT sample is an effective health promotion strategy to enhance more quit attempts and increase abstinence. The present study is the first to extend this approach by directly initiating a face-to-face conversation with the tobacco users and then providing medication samples.

To the best of our knowledge this is the first study of its kind in India where a free NRT sample was given to tobacco users for motivating them to have a quit attempt. There were no direct studies so for the purpose of discussion we have compared with other studies where NRT was used.

The subjects were in the age group of 20-50 which was in contrast to the study conducted in Finland[13,17] where middle aged population was the sample, though our study also consisted of 80% of population in the age group of

30-50. All the study subjects were males. This finding was in comparison to study conducted by Mithali raj et al.[17] in Lucknow and in contrast to the study conducted by Gaurav[18] in Bangalore where both males and females were considered. The study subjects were patients visiting out –patient department of a dental college in Bangalore. This finding was in contrast to both the studies conducted by Mithali[17] and where Gaurav[18] factory workers of Lucknow and PGs and interns of all dental colleges of Bangalore were considered. 82.5% of the study subjects belonged to upper middle class calculated using Kuppuswamy scale modified 2016. This finding is in comparison to mithali et al.[17] where maximum of the subjects were not much educated. The nicotine dependence was tested using Fagerstorm scale where 72.5% of them were having high dependence before intervention which changed to 60% having moderate dependence and the finding was highly significant after using NRT. This was similar to the findings of mithali et al.[17] were FTND was used. The present study also used Smokerlyzer or Breath analyser to check the levels of CO in the subjects. This finding was in contrast to the study conducted by Mithali et al.[17] used Nano-check rapid nicotine test which checks cotinine in urine. 48% of the subjects were chain smokers according to the levels of breath analyser. The two major strengths of the study were using FTND and Breath analyser and the subjects were also examined for their periodontal status using CPI index. The results of the index showed that 90% of the subjects were having gingival bleeding and pockets. This finding was in comparison to study conducted in Finland[19] where smoking was associated with tooth loss. The results of willingness to quit questions showed that majority of the subjects were not motivated to have a quit attempt. This was similar to study conducted by Mathew et al.[8] in south Carolina were subjects were unmotivated to quit and also study by Cornuz et al.[20] showed that smokers who do not intend to quit smoking, physicians should inform and sensitise them about tobacco use and cessation. The results of treatment experience questionnaire on the three domains of treatment appraisal, perceived co-operation and perceived somatosensory intensity showed that using NRT was beneficial, required skills and co-operation and the effects were felt if practised correctly. Because unmotivated tobacco users comprise a large proportion In India the present study will increase understanding on how to help these unmotivated people to quit. The results of this study are also relevant to other health care workers who recommend nicotine replacement therapy. Examination of quit attempts rather than cessation conserves resources but will provide a strong preliminary indication of the potential efficacy of Motivational interviewing for tobacco treatment in Indian population. In addition, unlike previous studies on smoking cessation and tooth loss, we carried out more thorough analyses by utilising both self-reported and clinically assessing oral health to study associations of tobacco on behaviour and oral health status.

6. Limitations

A limitation of this study is that we used the self-reported perceptions of patients, which may be subject to social desirability bias or recall bias. The sample size used was small which could affect the external validity of the study. Another limitation was that the study was based only on patients attending a out-patient department of one college in one city. No sample was included from public university clinic, from private dental offices, dentistry schools or different socioeconomic groups of society, which may increase the likelihood of patients reporting positive attitudes toward dental cessation counselling. All the study subjects were males which can lead to gender bias and generalizability of the results to other groups. Based on this research, it appears that using more than one assessment measure (FTND) of dependence can provide a more complete assessment of multiple dimensions of tobacco dependence. In follow up CO levels were not checked to see if the levels decreased or not. Oral hygiene habits and other dietary habits were not considered which could act as confounding variables.

7. Conclusion

The results of this study confirm and support the efficacy of the tested nicotine replacement gum and recommended in a ‘real world’ active tobacco cessation program which produces a statistically significant change in the dependence levels. Considering the stagnant incidence of quit attempts in the present study this novel and easy-to-use cessation induction strategy holds promise for translation and should be established through appropriate settings at different levels of the health system, including options to ensure its coverage under the national health insurance system to motivate smokers quit the habit. Additional research is necessary to replicate the current findings and effectiveness of the motivational programme in promoting patients’ behavioural change and quit efforts.

8. Author Contributions

Rohini Sharma have conceptualized the study and played primary role in compiling, analysis and interpretation of the data. All the drafts were prepared, reviewed and final draft was approved by Umashankar G. k, Shuhaib Rahman, Somanath Patil.

Rohini Sharma, Umashankar G. k, have contributed in fine tuning of the proposal, contributed in data collection and entry. Rohini Sharma, Umashankar G. K, Shuhaib Rahman, Somanath Patil reviewed the results and contributed to preparation and review of drafts. All the authors have read and approved final version of the

manuscript. All the authors take complete responsibility for the content of the manuscript.

9. Conflict of Interests

The authors declare no conflicts of interest.

10. Source of Funding

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