



Evaluation of Effectiveness of Chronic Care Model on Smokeless Tobacco Cessation by Measuring Urinary Cotinine Level among the Patient Attended in the Selected Dental College & Hospital, India -An Experimental Study

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Background: Smokeless tobacco is one of the most common causes of preventable death. It is a big social and health issue. Smokeless tobacco utilization is a significant cause of morbidity and mortality in India, with more than 20% of the world's tobacco-related mortality occurring in India. The Chronic Care Model is a guide for the principal care management of higher-quality chronic diseases. The Chronic Care Model gives a structure that redirects health care resources to better meet the demands and issues of individual with chronic illness.

Objectives: To explore the effectiveness of chronic care model for smokeless tobacco cessation in patients reporting to Sharad Pawar Dental College and Hospital.

Methodology: The study will be conducted among patients reporting to Out Patient Department of

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Sharad Pawar Dental College and Hospital who are chronic smokeless tobacco users. This study will be conducted between two groups, in one of the groups chronic Care Model will be used and behavioural counselling will be given and in other group only behavioural counselling will be given. Urinary cotinine level test will be performed on both groups of patients consuming smokeless tobacco.

Results: The chronic care model would be advantageous for the smokeless tobacco cessation. In India, there appears to be an immediate need for the promotion of awareness and informing people about the health problems associated with the use of smokeless tobacco through the model of chronic care.

Conclusion: The utilization of Chronic Care Model (CCM) helps patient realize that not only it is a habit to use smokeless tobacco, but a chronic condition that requires long-term treatment to cure it.

Keywords: Cotinine; smokeless tobacco; tobacco cessation.

1. INTRODUCTION

Several health issues are associated because of tobacco consumption. Smokeless tobacco usage has been linked to an increased risk of oral cancer, nicotine dependency, as well as systemic disorders [1]. In India, smokeless tobacco usage is a leading cause of disease and mortality. Tobacco use is thought to be responsible for more than 7 million fatalities per year. Today around 3,50,000 of worldwide tobacco related mortality occurs in India. In 140 countries nearly 356 million people consume smokeless tobacco from which 82% of which lies in Southeast Asia. Because of the consumption of smokeless tobacco more than 0.65 million people die every year [2].

There are regional variances in the usage of smokeless tobacco in different regions of the world. The abrasive quality, tobacco content, chemical component, and manufacturing method of smokeless tobacco may all contribute to these variances. So far, about 3000 chemicals have been discovered in the tobacco plant. Tobacco has several effects mostly because of alkaloids. In tobacco, nicotine is the most important alkaloid. Nicotine's major metabolite is cotinine, which is transformed to cotinine via C-oxidation in roughly 70% of exposed nicotine. Cotinine levels in biologic fluids including blood, urine, and saliva have long been used to determine whether or not a person consumes tobacco [3].

Main metabolite of nicotine is cotinine and its amount in the urinary excretion is a suitable marker since it is less affected by urine flow and pH. It has a lengthy half-life, decreased plasma protein interaction (2.6 percent), and dose-independent distribution mechanisms in bodily fluids. Cotinine is an effective indicator for assessing tobacco usage because of these features. Cotinine is probably the most accurate

indicator for instances when precision is critical [3].

For the care of the higher quality long term sickness, CCM is a guide for it within primary care. CCM estimates that its six interconnected components will improve, resulting in system change in which engaged individuals interface with proactive, planned practices. The six interrelated components are-Health system-organization of care, clinical information systems, delivery system design, decision support, self-management support, community resources [4]. These are the following components:

Health system-organization of care includes programme arranging that achieve quantifiable objectives for enhanced patient care. For example-Visible support, guidance and scope of improvement will be provided by teaching faculty of institution and the healthcare workers for tobacco cessation [5]. The next component is self-management support which deals with patient should take responsibility of his own health by utilizing education provided by health care resources. For example- Healthcare education material regarding smokeless tobacco in the form of flyers, pamphlets provided to patient by institution will aid them in the management of their own health [6]. The subsequent component is decision support which explains about Incorporation of evidence-based guidelines into routine clinical practice is the need of the hour. For example-Educating patients about adverse effects of consuming smokeless tobacco and helping them in reaching to a correct decision [7]. The fourth component is delivery system design and here the emphasis is on teamwork and broadened spectrum of experience for chronic care team members would make a difference. For example- For constant care of patient, team from institution will deliver counselling for tobacco cessation and

detail of the patient and also specific detail regarding smokeless tobacco usage and cessation advice given will be entered and unique ID number will be provided for tracking [8]. In this chronic care model the next important component is Clinical information systems which includes creating data framework depending on patient population in order to give pertinent patient information should be worked upon. For example- Cotinine test will be performed by the researcher, acts as a surveillance system to keep check on patients which is a necessary step in follow up [9]. Community Resources focuses on creating an organisation which involves community organisations, that supports and meets the needs of patients, is an integral component of the model. For example- All the facility of the institution will be utilized for help which will affect whole community for its betterment.

There are only few cases about that have focused on information and convictions about smokeless tobacco usage in India. Smokeless tobacco is most commonly use in India and leads to well established adverse health effects mainly oral cancers. As there is inadequate knowledge of harmful sequels among smokeless tobacco users the application of chronic care model for smokeless tobacco cessation would be beneficial. Hence the study is first of its kind to explore the same. The aim of the study is to explore the effective usage of chronic care model for smokeless tobacco cessation in Indian scenario as compared to behavioural counselling.

2. METHODOLOGY

This randomized controlled trial design will be implemented on patients for its utilization. The present study will be done among amongst 32 patients, who will visit Sharad Pawar Dental College, Sawangi (Meghe) District Wardha. The patients fulfilling the inclusion criteria will participate in the study. It is a double blinded study as the investigator and the participants will be blinded. A randomized controlled trial will be conducted between two groups. Chronic Care Model and behavioural counselling will be used in Group A patients and only behavioural counselling will be given in Group B patients.

2.1 Sampling Procedure

The study sample consist of patients reporting to Out Patient Department of Sharad Pawar Dental College and Hospital.

2.2 First Study Sitting

On the first visit, demographic details of the sample patients will be taken for better tracking. Urinary cotinine level test will be performed on both groups of patients who are dependent on smokeless tobacco which is based on classification of level of dependence which is given below. Group A patients will be intervened with the use of Chronic Care Model (CCM) and behavioural counselling for the smokeless tobacco cessation and Group B will be given behavioural counselling. CCM is a strategy to caring for patient with long term illness that is organised. In the CCM, a constructive interaction between an informed, interested patient and a well-prepared, proactive clinical practise team of doctors and health professionals leads to improved practical and clinical outcomes for disease management.

2.3 Second Study Sitting

Both groups of patients will be recalled after 10 days to test the urinary cotinine level. The previous urinary cotinine level will be compared with the current urinary cotinine level. This procedure is performed to examine the impact of chronic care model use for smokeless tobacco cessation.

2.4 Third Study Sitting

Both groups of patients will be recalled after 21 days to test the urinary cotinine level. Participant timeline: Patients will be recalled after 10 days and 21 days.

2.5 Inclusion Criteria

- Patients aged between 18 to 60 years
- Patients should be a smokeless tobacco consumer for at least more than a year
- Patients should only consume smokeless tobacco

2.6 Exclusion Criteria

- Patients below 18 years and above 60 years
- Patients with any major systemic conditions
- Patients consuming other tobacco products along with smokeless tobacco

Table 1. Level of dependence and its description

Level of dependence	Description
High	Individuals who use smokeless tobacco within 30 minutes of waking up or who use it 25 or more times per day
Moderate	Individuals who use smokeless tobacco more than 30 minutes after waking up or less than 25 times per day
Low	Those who neither use smokeless tobacco 30 minutes of waking up nor use it more than 25 times a day

Sample Size: Sample size is determined using the following formula

$$n = \frac{z\alpha/2^2 \times \sigma^2}{E^2}$$

where,

σ = previous expected values=17

E =desired Margin of error = 5

$Z_{\alpha/2}$, confidence interval of 90%, $z = 1.65$

n = sample size

Substituting the values in the formula:

$$\text{Sample size } n = \frac{(1.65)^2 \times (17)^2}{(5)^2} = 31.46$$

With above mentioned calculation, sample size determination is 32 in number and considering drop outs, the sample size is determined to be 32. The total minimum sample size with 90% of confidence interval is 16 for each group. The study is divided into two groups which will include 16 in each group. The sample size was calculated taking care of the dropouts of the patients included in the study.

Data collection, management, and analysis methods: Data collection methods: The data will be collected by measuring the urinary cotinine level by using cotinine strips from smokeless tobacco users.

Data management: All the demographic details and measurement of urinary cotinine levels and the responses of the participants to the questionnaire will be collected in excel sheet.

Statistical methods: Statistical analysis will be done by SPSS software version 22. Descriptive analysis and frequency distribution will be done for demographic details and the type of smokeless tobacco habit. Paired t-test will be done for evaluating the difference between the cotinine levels pre and post intervention. The effectiveness of chronic care model will be measured by chi square statistics and spearman correlation. Any Significant difference will be

calculated at p value<0.05. Auditing will be done by primary investigator throughout the study.

3. EXPECTED OUTCOMES/RESULTS

These data suggest that chronic care model would be advantageous for the smokeless tobacco cessation. There is a crucial requirement to raise consciousness and alert communities to the health risk of smokeless tobacco use in India. This study uses Chronic Care Model which will help the patients to understand that consuming smokeless tobacco is not just a habit but a chronic disease that requires long term treatment for its cure. The Chronic Care Model provides a structure that redirects health care resources to better meet the requirements and concern of people with long term diseases.

4. DISCUSSION

Nicotine addiction and dependency are caused by the use of smokeless tobacco. Smokeless tobacco use, according to IARC publications and other research, is one of the risk factors for oral malignancies, periodontal and dental disorders, and genetic harm in users.

Cok I et al studied the urinary cotinine levels of smokeless tobacco (Maras powder) users. The objective of this study is to determine the cotinine level of maras powder users and to compare the result with cigarette smokers and passive smokers. Urinary cotinine level of subjects was calculated using capillary gas chromatography with FID detection. A substantial difference has been reported between the cotinine levels of maras powder users and cigarette smokers, which three times higher in maras powder users ($p < 0.001$). The present study indicates that smokeless tobacco poses a danger to public health and should not be seen as a convenient alternative to cigarettes [10].

Barr V et al studied the expanded Chronic Care Model: An integration of concept and strategies from population health promotion and the chronic

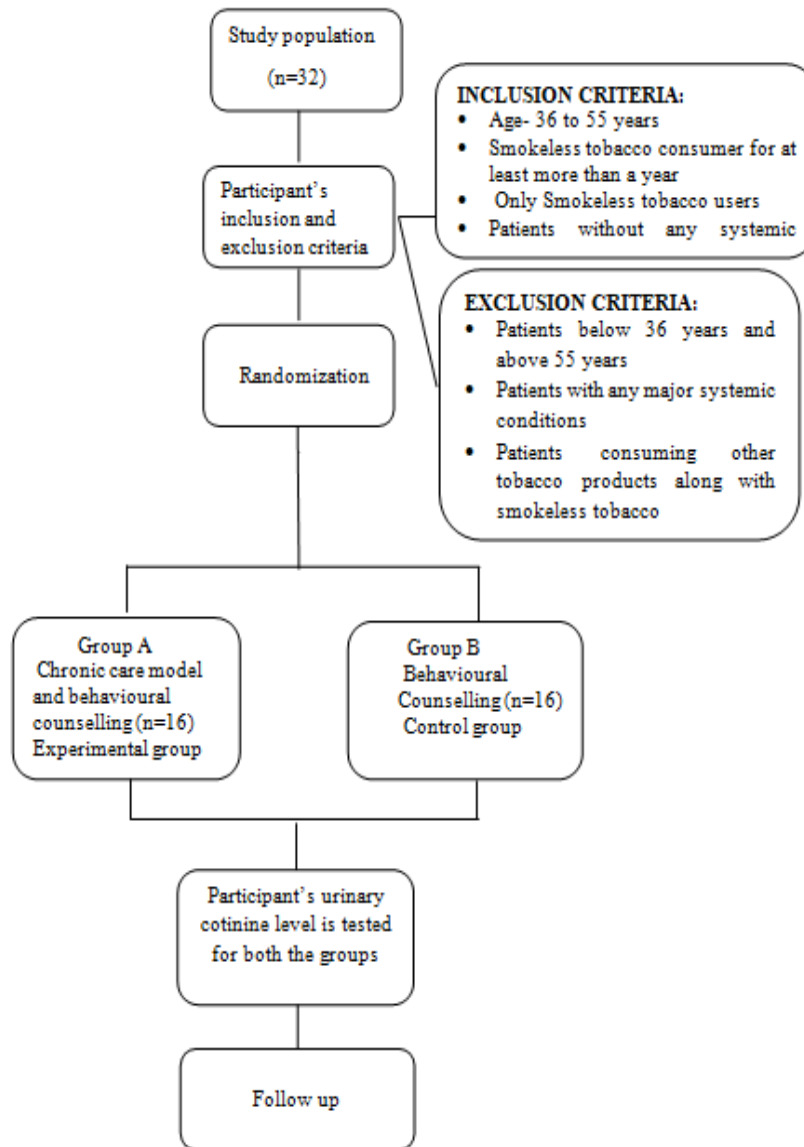


Fig 1. Trial design

care model. The use of chronic care model has enable health care teams to illustrate successful an appropriate solution to this growing challenges. However the new chronic care model is oriented to clinically-oriented system and is difficult to use for prevention and health promotion professional. In order to further incorporate prevention and health promotion element into chronic care model, and update version for the Expanded Chronic Care Model adopted. This new model includes elements in the field of population health promotion in such a way that broad- based preventive initiative is made [5].

Smokeless tobacco poses a hazard to public health. There is an urgent necessity to educate people and to warn about the health dangers of smokeless tobacco consumption to communities.

5. CONCLUSION

These data suggest that chronic care model would be advantageous for the smokeless tobacco cessation. This study uses Chronic Care Model which will help the patients to understand that consuming smokeless tobacco is not just a habit but a chronic disease that requires long term treatment for its cure. The Chronic Care

Model provides a structure that redirects health care resources to better meet the requirements and concerns of people with long term diseases.

ETHICAL APPROVAL

Research ethics approval: Institutional Review Board has approved for further research.

Protocol amendments: The ethical committee considered protocol revisions, and the IRB board **completed a review.** The Ethical Committee has reviewed and approved all of the changes.

CONSENT

Informed consent will be obtained from the participants.

Additional consent for urine samples will be obtained from the participants.

Confidentiality: The data of the participants will be kept confidential.

DECLARATION

We declared no conflict of interest because all of the authors contributed equally to the start of the research and have not highlighted any conflicts of interest regarding their responsibilities.

Data availability: Data will be accessed by the primary investigators.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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