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Impact of health education and cognitive behavioural therapy intervention during tobacco cessation session for smokers: A comparative study in Eastern India.

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ABSTRACT

Background: Tobacco use remains the leading cause of death worldwide. Smoking cessation is the only way to fight the most feared disease in the world. Current evidence-based treatment approaches to smoking cessation include several behavioural treatments and health education-such as cognitive behavioural therapy, and individual and group counseling which tobacco cessation can help control global causes of preventable death. Health professionals play an important role in combating the tobacco epidemic.

Materials and methods: All the current smokers who had participated in this study submitted their self-reported case record forms. Baseline data was collected, tobacco history was obtained, the Fagerstrom nicotine dependency questionnaire was administrated and for the quitter, a standardized cotinine test was used. The total number of participants enrolled in this study is 240, but only 190 participants completed the entire program study. Tobacco users who met the inclusion criteria were randomly assigned to three intervention groups: the health education (HE) group, the cognitive behavioural therapy group (CBT), and the combination of health education with the cognitive behavioural therapy (HE+CBT) group. All the participants were visited five times within the six-month duration. Pearson's Chi-square test, paired and unpaired t-tests, Fagerstrom score scale, and Fisher's exact test were used to test the effectiveness of all interventions among the groups. SPSS 22.0, IBM, USA, was used for the analysis of all statistical events.

Results: Both groups showed no difference in attempts to quit and had no statistical significance. The reduction in Fagerstrom's score was greater in the HE+CBT group than in the individual CBT and HE groups. Among all the groups, the HE+CBT group shows more effectiveness in cessation therapy than those in the individual groups, which improves the possibility of smoking cessation.

Conclusion: In term of tobacco habit reduction, the combination of HE and CBT is more effective than individual therapy for smokers. Further, it can be studied that which kind of barriers are faced by the health professionals during the practice of HE and CBT intervention in their tobacco cessation practices in order to making the sessions clinically effective and educationally more impactful, as well as the heavy tobacco users are can be given immediate attention and prior opportunity for the treatment.

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Introduction

Tobacco is a deadly substance that brings darkness to life. For smokers, it is a pleasurable thing. Smokers are blind to seeing the toxic effect of smoking rather than enjoying it for a short moment with long-lasting health hazards. Smokers use a variety of forms of tobacco, but tobacco leaves are primarily used for smoking (cigarettes, hookahs, cigars, hookahs, pipes), and rechargeable and disposable e-cigarettes, e-cigarettes, e-pipes, and vaporizers are other forms of smoking materials.[1] More than 40,000 chemicals and 60 types of carcinogens are present in tobacco.[2] These carcinogens present in tobacco are specific aromatic amines, polycyclic aromatic hydrocarbons (PAHs), N-nitrosamines, volatile hydrocarbons, and nitro compounds phenols and aldehydes.[3]

Over 80% of the world's 1.3 billion tobacco users live in low- and middle-income countries. In 2020, 22.3% of the global population used tobacco, 36.7% of all men and 7.8% of the world's women. Tobacco kills more than 8 million people each year. More than 7 million of those deaths are the result of direct tobacco use while around 1.2 million are the result of non-smokers being exposed to second-hand smoke.[4] The WHO announced in 2008 that tobacco use is the world's largest preventable cause of death.[5]In the future, both the addiction rate and death rate can enormously about one billion people can die in this century if the consumption rate of tobacco globally remained at this level as per WHO.[3] According to data from the National Vital Statistics System recorded in 2016 it was found that 7.2% of women smoked cigarettes during pregnancy.[6]

Smoking causes sensitization of cells, causing hyper-responsiveness in the body, and inflammatory changes due to the constant entry of foreign toxins. Smoking leads to the destruction of respiratory epithelium, alters and weakens immunity, and increases the frequency and severity of getting infections, diabetes, increase risk of clot formation, slows down blood supply to ear lower limbs, fertility problems, and osteoporosis. Recently studies have shown that nicotine inhibits the expression of angiotensin-2 conversion enzyme in various organs (lungs, heart, brain) and cells.[7-9] Smoking induces Inflammation occurs as a combination of changes that include the activity of neutrophils, dendritic cells macrophages, basophils, and eosinophils. As the end of the consequence of constant inflammation, carcinogenicity becomes the outcome at the end.[10] Carcinogenic change due to smoking mostly leads to cancer of the lungs, pharynx, larynx, oral cavity, stomach, pancreas, esophagus, urinary bladder (kidney), and cervix as well as acute myeloid leukemia. In addition, smoking causes major respiratory symptoms, chronic obstructive pulmonary disease, stroke, coronary heart disease, abdominal aortic aneurysm, and subclinical atherosclerosis.[11]

No one is born with an addiction, but during the course of life stress, anxiety, depression, pressure, social environment, family problems, and dealing with problems lead an individual to choose an addictive path to forget the problem for a few moments without actually facing it. Addiction starts with enjoyment, to get relief, and to feel good, but as time passes, it gets included as a habit and day-to-day maintenance. The mortality rate in smokers is three times higher and their life expectancy gets reduced and they die an average of 10 years earlier than those non-smokers.[12] The risk of developing stroke and head and neck cancer are two to four times higher and 10 times respectively, in smokers as compared to non-smokers.[13,14]

The solution to addiction is de-addiction. Cessation of habits and maintaining them without relapse are the main steps to increasing the quality of life and expanding life span. Tobacco cessation methods include Cognitive behavioural Therapy (CBT) includes methods such as self-help which can be provided by health professionals, health education, Intensive therapy provided at cessation centres, and pharmacological means including Nicotine Replacement Therapy (NRT) and the use of antidepressants like bupropion.[15]

According to Dr. Saul McLeod, 2019, CBT is based on the idea that how we think (cognition), how we feel (emotion) and how we act (behaviour) all interact together. And this theory if we apply to change someone's habit and change of behaviour of different triggering factors that influence to do habit in terms of tobacco addiction. Similarly, several theories support the practice of health education. When identifying a theory to guide health education or disease prevention programs, it is important to consider a range of factors, such as the specific health problem being addressed, like tobacco cessation comprehensive and active awareness of the population through health promotion strategies are the primary tools for smoking prevention and cessation.

The aim of this research was not to let the end of life of smokers on ashtray. This study aimed to find the effectiveness of Cognitive behavioural Therapy (CBT) and Health Education (HE) intervention and the combination of both therapies (HE+CBT) in 3 different groups of smokers in tobacco cessation. The researcher hypothesized that CBT's effects on tobacco cessation are stronger than HE's an intervention to reduce tobacco habits in smokers. Therefore, this study was conducted to evaluate the effectiveness of the intervention (Group-1, HE only; Group-2, CBT only; Group-3, HE with CBT) in three groups of smokers in the city of Bhubaneswar. In this study, participants were between 18 and 67 years old and all participants in the three groups were male.

Quitting smoking is one of the most difficult challenges in the life of smokers. One may reach the final goal of quitting after several attempts. If the patient again starts to get attached to cigarettes after completion of tobacco cessation, then the net outcome is zero. Relapse is quite common in smoking patients after cessation of the habit.[16,17] Three out of 10 ex-smokers were observed to relapse.[18] On average, 23.8% of patients experienced relapse following the completion of CBT.[19] Previous study shows that CBT is more effective than HE when 2 groups are compared to each other. In this study, the combination of HE and CBT has a stronger effect on tobacco cessation than either the individual HE or CBT uses a combination of therapy to increase the effectiveness of quitting.

High-intensity smoking cessation interventions in hospital settings can be effective for smoking cessation in smokers with high nicotine dependence.[20] So in our study, we put extra and more intense cessation sessions by combining both Cognitive behavioural therapy and Health Education. CBT is a type of psychotherapeutic treatment that makes individuals identify and change the destructive or disturbing patterns of thought which cause a negative influence on their emotions and behaviours.[21] We also know that CBT is a promising psychological intervention for people who want to quit smoking because changing and restructuring thought processes, combined with new learning behaviours, is essential for people who want to effectively quit smoking. The thought processes of each smoker are different from one another, so it is necessary to counsel the present mental state and then put positive energy to improve quitting capabilities. So, for the effective and efficient result of tobacco cessation, multiple management of therapy should be included to help the smoking individual to defeat the smoking habit and to live long and strong. At the same time, health education will help to make a positive mind-set by spreading active awareness to the individual through health promotion strategies as it is one of the basic tools for smoking prevention and cessation.[22] So, a combination of cessation therapy may lead to a positive impact on the reduction in the prevalence of smoking. This study compared three types of counselling to continue to be positive about problem elimination by breaking it down into smaller parts and meeting points on current issues rather than focusing on the past.

Materials and methods

A randomized controlled study was conducted to understand the effectiveness of CBT, HE, and a combination of both from December 2019 and May 2020 for 6 months among smokers attending a tertiary care hospital in Bhubaneswar, India. Ethical clearance was obtained by the Institutional Ethics Committee (DMR / IMSSH / SOA / 180338).

A Randomised control study was done with a sample size of 240. The sample size of two hundred and forty participants was analyzed using the G Power software with a statistical power of 90% with a 95% confidence interval and an effect size (d) of 0.89 calculated. All the participants are current tobacco users attending the tobacco cessation centre of the selected tertiary referral centre. All information regarding the cessation process was explained and written informed consent was obtained from all participants. A pretested customized questionnaire was administered to assess their knowledge of addiction in participants. The participants were blindly assigned into three groups based on the intervention used which is group 1 health education (HE), group 2 and Cognitive behavioural therapy only, and a combination of both HE and CBT. The examiner was competent enough to constructively provide HE and CBT to all participants in the Tobacco Cessation Centre.

The quit attempt was assessed after a week and a cotinine test and Nicotine dependency were performed to validate quitting. The sample is organized by considering the current tobacco users who have defined themselves as continuous users of smoking tobacco from the first day of recruitment in the study. 240 participants were able to fulfil the inclusion criteria which include males between ages 18-68 years, and patients with smoking habits. Various exclusion criteria were added to the study which contains patients undergoing treatment for severe psychiatric problems, alcohol users, and patients on nicotine replacement therapy (NRT), with hearing difficulty, patients > 68 years old were excluded from the study. Almost all participants belonged to a low socio-economic status with marginal educational and income levels. All the participants in enrolled group 80 and participant are randomly selected individuals (computer-generated randomization) and were assigned to Group-1 (HE), Group-2 (CBT), and Group-3 (HE+CBT) interventions. Some participants dropped out of the study after the 1st visit and they lost to follow-up after 1st visit. After dropping out of each group, the total number of participants was 62 for the HE, 67 for CBT, and 61 for the HE+CBT group. All the individuals in group 1 receiving HE counselling, who was assigned to CBT received Cognitive behavioural therapy, and group 3 participant receive both therapy of HE and CBT. All the participants were visited five times (1st Visit, follow up by 2nd, 6th , 12th and 24th weeks) within the six-month duration.

At the 1st visit, baseline data were collected. The self-structure case record form was preparedto know the patient's detailed history; the participant must have all the information available for which a self-assessment could be completed. The case record form includes various contains like age, gender, occupation, marital status, living arrangement, and details about tobacco history (types of smoking, age of onset, socio-economic status, details of smoking history, no of year of regular use, past quit attempt tobacco addiction, alcohol history, family history of tobacco and motivational level of tobacco cessation), Fagerstrom's questionnaire form was used to know nicotine dependency. All the data are collected and translated into MS excel sheets of Microsoft office.

At the 2nd visit, the patient who was previously enrolled blindly in group 1 received health education intervention. Health education is provided through custom-made posters and videos developed in the local language (Odia, Hindi, English) which will clarify tobacco-related deaths, the chemical constituent of nicotine, various forms of tobacco use, its deadly effects on health, the benefits of quitting the habit, and the instructions of how to quit. A pamphlet was provided consisting of various for using cigarettes and written instructions on quitting process were handed over to all group 1 participants receiving. The intervention in CBT were provided through (a) provision of cognition (by self-identification of the reason for the initiation of habit, identification of the daily routines conditions, and learning to reduce and cope with the negative situation or urge associated with the withdrawal of nicotine, (b) provision of counselling to change the behaviour towards addiction(by breaking the daily urge or habit of same routine, managing the temptation and resisting it , and the various day-to-day tension or stress that provoke the usage, (c) interviewing

to motivate patient to make them understand and accept the real environment which all the normal individual are facing and accepting (through various series of questions, insight was provided to make them understand the need to quit the smoking tobacco), and (d) the patient again starts to get attached toward cigarettes after completion of tobacco cessation, then the net outcome is zero so at last the relapse prevention strategies were introduced and asked them to follow it.

During each follow-up after the intervention, a follow-up timeline was set on a calendar which was used to assess the self-reported outcome variables. At every follow-up visit, participants are screened for all parameters such as reduced consumption, point prevalence abstinence, attempted abstinence, continuous abstinence, relapse, and participant turnover rate. Fagerstrom's nicotine dependency scale and nicotine kit test have been performed in the 6th, 12th and 24th week follow-up. A standardized cotinine test was used to validate the self-reported quit rates, the cotinine test was done by Nicotine test kit with the help of a urine sample the rapid kit include 2 types of result (cotinine "positive" / "Negative"), if the patient use any form of nicotine before 5 to 7 days. The instruction for the cotinine test has been explained back side of the test kit. If the sample is wrongly placed may be the result invalid so the researcher helps the patient how to test it.

Participants in this study had five follow-up visits, including the first, (1st Visit, follow up by 2nd, 6th , 12th and 24th weeks) which was completed within six months of the study period. Fagerstrom's Test for Nicotine Dependence is a standard instrument for assessing the intensity of physical addiction to nicotine. It contains six items that evaluate the quantity of cigarette consumption, the compulsion to use, and dependence. In scoring the Fagerstrom's Test for Nicotine Dependence, yes/no items are scored from 0 to 1 and multiple choice items are scored from 0 to 3. The items are summed to yield a total score of 0-10. The higher the total Fagerstrom's score, the more intense the patient's physical dependence on nicotine. This questionnaire was used at the start of the study and follow-up examinations. The distribution of the mean Fagerstrom's addiction scale for smokers was assessed [Table-5]. Participants were followed up for 6 months (a total of five sessions at 1st, 2nd, 6th, 12th, and 24th weeks from the 1st visit), and follow-up reminder was done online by sending them reminder message. Pearson's Chi-square test [Table-1], Paired and unpaired t-tests, and Fisher's exact test were used to test the effectiveness of all interventions within the groups. SPSS 22.0, IBM, USA was used for the analysis of all statistical events.

Results

One hundred and ninety patients were included in this study and divided into three groups. The groups consisted of participants between the ages of 18 to 68 years. The mean age of the three groups in this study was: Group 1 of HE 37.6±2.8 years, Group 2 of CBT 39.2±2.48, while in the HE with CBT group 40.8±3.48 years. 80% of the population were in a lower-upper class of socioeconomic status. 87% of participants are using the smoking form (Bidi, cigarette, Huka) than the smokeless form(pan, gutka and khaini) of tobacco or rest are both forms of tobacco usage. Forty-four percent of the tobacco users were alcoholics with 39% of them reporting a family history of tobacco usage, and 85% of smokers are more than 10yr of regular smoking history. 95% of the sample was in the contemplation stage of motivation at recruitment. Knowledge of the participants at the baseline was poor with a mean score of 8.63 that means Out of all groups the knowledge score average between the group is 8.63 (maximum score = 21). Age, sex, types of smoking, age of onset, socio-economic status, details of smoking history, no of the year of regular use, past quit attempt tobacco addiction, alcohol history, family history of tobacco, and the stage of motivation were compared between the groups at baseline using Pearson's Chi-square and no significant difference was found. Intention to treat analysis was done, and the dropouts in the follow-up sessions were considered to continue tobacco usage (Figure 1).

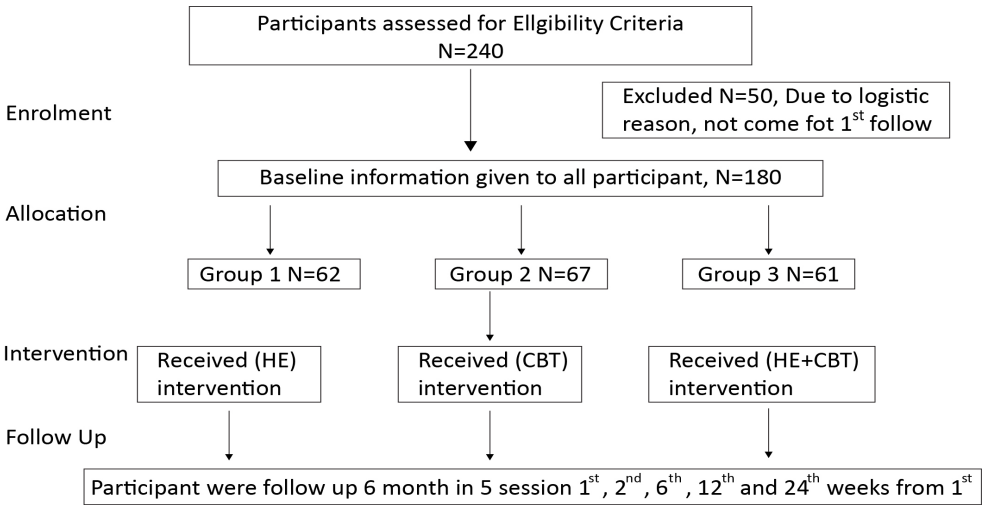

Figure 1 *Study design.*

The baseline addiction and knowledge scores were assessed using Mann–Whitney U test and were found to be similar between the intervention groups (Table 1).

Table 1 Mann-Whitney U Test: Baseline assessment of addiction and knowledge score.

	Health education		Cognitive behaviour therapy		Z	*p*
	Mean	SD	Mean	SD		
Addiction scores	-	-	-	-	-	-
Smoking form	4.26	2.021	4.58	2.128	0.441	0.651
Smokeless form	6.02	2.123	6.78	2.325	0.958	0.327
Knowledge score	7.21	3.132	7.36	3.234	0.002	0.889

A reduction in the use of all groups was calculated and found that group HE+CBT (93%) was significantly higher as compared to others Group HE (71.3%) and Group CBT (82%) statistical differences in significance. (p=0.004). The rate of quit attempt are similar in the initial phase of the study, but later on, the quit attempt rate is slightly high in the HE+CBT group with no statistical differences in significance. Point prevalence abstinence was significantly higher in group HE (87.5%), followed by group CBT (79%) and group HE+CBT (80.6%). Continuous abstinence was significantly high in group HE+CBT (92.4%) compared to group CBT (78.4%) and group HE (42.6%).The percentage of lapse in group HE (62%) was significantly higher than in group CBT (51.5%) and group HE+CBT (34.5%). The relapse rate (3.4%) was comparatively lower than in all three groups and there is no significant difference was found. The rate of attrition was high (92%) with reasons to change of address, and change of phone number (Table 2).

Table 2 Evaluation of the effectiveness of total 3 groups using Pearson's Chi-square test.

Outcome Variables	HE, n 62 (%)	CBT, n 67 (%)	HE+CBT, n 61 (%)	χ2	p
Reduced use	44(71.3%)	54(82%)	57(93%)	9.112	0.004$
Quit attempt	47(76.4%)	59(88.6%)	58(95.3%)	8.328	0.063
Point prevalence	54(87.5%)	53(79%)	49(80.6%)	0.067	0.768
Continuous abstinence	26(42.6%)	52(78.4%)	56(92.4%)	33.139	0.000*
Lapse	38(62%)	35(51.5%)	21(34.5%)	4.462	0.029
Relapse	6(10.2%)	5(8.5%)	2(3.4%)	0.051	0.642
Attrition	57(92%)	55(81.4%)	44(72%)	2.987	0.061

*Note: *Highly significant, $: Significant, χ2: Pearson's Chi-square test, HE: health education, CBT: cognitive behavioural therapy.*

The evaluation in the 2nd session showed a significantly low reduction in consumption in group HE and significantly high abstinence attempts and point prevalence abstinence in group CBT and HE. The proportion of smokers with a frequency of more than ten cigarettes/day decreased (p=0.16) by the second follow-up (p=0.07) in group HE+CBT compared to groups CBT and HE. At the end of the 2nd follow-up, the majority of participants in both groups HE and CBT were in the contemplation phase passed while other participants in group CBT+HE had reached the preparation phase of cessation as compared to group HE. In the third session (6 weeks after the intervention), the attempt to quit, the point prevalence abstinence, and lapse were significantly higher in group HE and CBT but Group (HE+CBT) had significantly higher continuous abstinence. Relapse was more common in group-HE and Group CBT but in Group HE+CBT there is no relapse. During the 4th session (12 weeks after the intervention) abstinence attempts and withdrawals were more in group HE, while point prevalence abstinence and continuous abstinence were more in group CBT+HE. During the 5th session (24 weeks after the intervention), the continuous abstinence in group HE+CBT is highly significant than in the other two groups (Table 3). The cotinine test validated for a real quitter. The true quitters were significantly higher in HE+CBT (p=0.006) (Tables 4). The mean reduction in the Fagerstrom's score in the three groups was significantly higher in the combination group (CBT+HE) (2.1 3.2), followed by the CBT group (3.1 6.5) and then the HE-Group (3.4 4.4), and the difference was considered that nicotine dependency is less from baseline to 24th follow up (Table 5).

Table 3 Percentage of outcome during follow up (follow up week 2nd, 6th, 12th and 24th).

Outcome Variables	HE, n 62 (%)	CBT, n 67 (%)	HE+CBT, 61 (%)	χ2	*p*
	Follow up: 2nd week after intervention				
Reduced use	35 (56.6%)	40 (60.6%)	40 (66.7%)	11.108	0.000
Quit attempt	38 (61.5%)	48 (72%)	49 (81%)	21.189	0.002
Point prevalence	20 (32%)	30 (45.4%)	40 (60.5%)	8.879	0.000
Continuous abstinence	0	0	0	-	-
Lapse	15 (24%)	13 (19%)	8 (12.7%)	0.987	0.032
Relapse	0	0	0	-	-

Table 3 Percentage of outcome during follow up (follow up week 2nd, 6th, 12th and 24th). (continued)

Outcome Variables	HE, n 62 (%)	CBT, n 67 (%)	HE+CBT, 61 (%)	χ2	*p*
	Follow up: 6th week after intervention				
Reduced use	0	0	1 (2.1%)	2.150	0.143
Quit attempt	20 (32%)	12 (18.6%)	5 (9.5%)	8.567	0.003
Point prevalence	40 (65%)	18 (26.6)	7 (11.7%)	24.569	0.000*
Continuous abstinence	22 (36%)	33 (48.6%)	41 (68.7%)	54.879	0.000*
Lapse	28 (45%)	15 (22.6%)	9 (15.3%)	3.678	0.015
Relapse	4 (7%)	2 (3%)	0	2.870	0.03
Attrition	23 (38%)	14 (21%)	7 (12%)	3.982	0.053
	Follow up: 12th week after intervention				
Reduced use	0	0	0	-	-
Quit attempt	7 (12%)	6 (8.4%)	3 (5%)	0.213	0.761
Point prevalence	5 (7.5%)	6 (9%)	7 (11.7%)	0.426	0.567
Continuous abstinence	14 (23%)	16 (24%)	16 (27%)	0.433	0.651
Lapse	5 (8%)	4 (6.3%)	5 (8.4%)	0.180	0.672
Relapse	0	0	0	-	-
Attrition	39 (63%)	37 (56.5%)	29 (48.6%)	1.573	0.554
	Follow up: 24th week after intervention				
Reduced use	0	0	0	-	-
Quit attempt	4 (6%)	1 (2%)	1 (1.6%)	0.431	0.543
Point prevalence	0	5 (8%)	3 (6.4%)	0.321	0.078
Continuous abstinence	14 (23%)	27 (40.7%)	40 (66.5%)	8.021	0.046$
Lapse	10 (16%)	7 (11%)	5 (9.7%)	1.678	0.382
Relapse	2 (4%)	2 (3%)	0	0.056	0.387
Attrition	55 (88%)	51 (76.3%)	40 (66%)	3.987	0.058

*Note: *Highly significant, $: significant. χ2: Pearson's Chi-square test, HE: health education, CBT: cognitive behavioural therapy.*

Table 4 Cotinine test validation by Nicotine test kit after 6 months (based on continuous abstinence).

Self-report	Cotinine test	HE, n (%)	CBT, n (%)	HE+CBT	χ2	*p*
Quit	Positive	10 (38.4)	6 (11.5%)	3 (5.3%)	11.345	0.006
	Negative	3 (11.53)	22 (42.3%)	56 (96.4%)		

*Note: *Significant. χ2: Pearson's Chi-square test, HE: health education, CBT: cognitive behavioural therapy.*

Table 5 Fagerstrom's Nicotine dependency scale for smokers at baseline and follow ups (6th, 12th and 24th).

Fagerstrom's addiction scale	HE Group, n (%) (N=62)				CBT group, n (%) (N=67)				HE+CBT group, n (%) (N=61)			
	Baseline	6th follow up	12th follow up	24th follow up	Baseline	6th follow up	12th follow up	24th follow up	Baseline	6th follow up	12th follow up	24th follow up
<=8 score	56 (90.32)	57 (91.93)	58 (93.54)	59 (95.1)	63 (94.02)	64 (95.52)	65 (97.01)	66 (98.5)	54 (88.52)	57 (93.44)	60 (98.36)	60 (98.36)
>8 score	6 (9.67)	5 (8.06)	4 (6.45)	3 (4.8)	4 (5.97)	3 (4.47)	2 (2.98)	1 (1.4)	7 (11.47)	4 (6.55)	1 (1.63)	1 (1.63)
Total	62 (100)	62 (100)	62 (100)	62 (100)	67 (100)	67 (100)	67 (100)	67 (100)	61 (100)	61 (100)	61 (100)	61 (100)
Mean	4.2±5.6	3.8±7.2	3.4±4.4	3.5±4.7	5.9±4.4	3.7±7.3	3.1±6.5	3.3± 6.9	4.3±5.4	3.1±4.5	2.1±3.2	2.1±3.2

Note: Mean scores between baseline, Fagerstrom's Nicotine dependency 1st follow up on 6th week and 2nd follow up on 12th week + 3rd follow up on 24th week; (p<0.001), CBT: cognitive behavioural therapy; HE: health education.

Discussion

The best way to stop the global smoking epidemic is to have good tobacco control programs via counselling. It is important to keep in mind that addiction to the use of tobacco should be treated as a chronic persistent disorder. Treatment for removing smoke in the lives of tobacco users requires persistent efforts to assist tobacco users by changing their behavioural and making them to attempts quitting it.[23]

Unhealthy behaviour is one of the main causes of human disease and behaviour management is the possible way in life smokers to make them quit. Changing unhealthy behaviour often seems very easy but in short term, the most difficult is to sustain it.[23,24] It is proven that the likelihood of achieving success in tobacco cessation can be through effective counselling. Through counselling programs, various information and resources are provided to tobacco users for developing a quit plan and addressing specific barriers to quitting and managing different withdrawal symptoms.[25] the methods and intensity of counselling vary as it varies from individual to individual based on the amount and type of support they needed.[26]

This study compares two types of counselling methods used such as counselling and CBT to continue to be positive about problem elimination and meeting points on current issues rather than focusing on the past. In the previous studies and literature searches, the age group that was included in the study was 14 to 65 years and the mean age for the CBT group was found to be 19-48.32 years.[27-32] In this present study, participants were in the age group of 18-68 years and the mean age group was found to be 37.6 years, 39.2 years and 40.8 years respectively in HE, CBT and HE+CBT groups. Gilpin *et al*. reported that smoking is believed to reduce anger and sadness in men.[33] In one previous research, only patients had been considered for the study.[34] In this study patients receiving treatment for tobacco cessation are male patients. The prevalence of tobacco consumption is largely related to the level of education and the socio-economic condition of the population. The lack of social and emotional security affects tobacco use from the lower working class and large family groups.[35] The level of Education and degree of awareness of the individuals mostly matter in controlling tobacco habits.[36] In this study age, sex, socioeconomic status, types of tobacco usage, alcohol usage, and the stage of motivation are not playing any significant role in tobacco cessation. In the current study, overall 44% of the tobacco users consumed alcohol but in the study conducted by Kumar *et al*, overall 69.5% of the study subjects gave a history of alcohol consumption and in another clinical trial done by Reddy *et al*., 43.6% shows the history of alcohol consumption.[37,38] In this study, half of the participants in the three groups started smoking in early adolescence 15-19 years, while other studies showed a little early age onset of 14.7-15.7 years.[30,31] Primarily the use of Tobacco begins during adolescence. It was found that nine out of ten individuals start smoking at the age of 18 years.[39] There is an important role of duration in quitting as it is very difficult for most smokers. Smokers often attempt to quit before successfully quitting, with some relapsing even after prolonged abstinence.[39] In the current three-group study, the majority of participants smoked for more than ten years. The average smoking duration was found to be (7.3±3.1 years) for the HE group, 7.7±3.9 years for CBT, and (7.9±2.8) for the HE+CBT group. The present study contrasts with previous studies, according to which three-quarters of the participants smoked <10 cigarettes per day as their group of participants also included smokeless tobacco.[40] The overweight of the study participants accounted for 5 years or more cigarette years in which fewer participants (12%) smoked <10 cigarettes per day. In the present study, the majority of participants smoked up to 250-285 cigarettes in one month. In the follow-up, the counselling was effective in three groups and the smokers reduced their cigarette smoking. In the three groups, the most effective advice on smoking cessation is the HE+CBT group. The mean number decreased in all three groups from baseline to subsequent follow-up. However, the difference was statistically significant in the combination of both therapies of HE & CBT.

In our study, the Fagerström's Test for Nicotine Dependence score at baseline was (4.2±5.6) in the HE, (4.7±5.9) in the CBT group, and (4.3±5.4) in the HE+CBT group. Fagerstrom's addiction score was found to be significant in two groups (CBT and HE + CBT) taking into account their initial value with the 3rd and 6th follow-up examinations (p<0.001), but in a previous study significant reduction in groups of CBT and groups of HE was found. 26 Fagerstrom's score reduction was greater in the HE+CBT group than in the CBT and HE groups. It was interesting to note that the reduction took place despite the interventions with equal contacts. This gives authenticity to the instruments adopted and used by the groups studied and indicates the differences in the interventions adopted. The main aim of the study is to motivate patients to give up smoking. Various studies show that CBT is more effective than HE [27,28,41-44,34] only one study shows that CET (Cognitive Enhancement Therapy) is more effective than CBT therapy.[29] Any intervention which was given to tobacco users from either HE or CBT groups was helpful to the patients in quitting the habit of tobacco. But if we add both therapies interventions HE+CBT it helps Tobacco users become aware of inaccurate or negative thinking so they can view challenging situations more clearly and respond to them more effectively. Basically, it is a matter of motivation and change of habit and behaviour towards tobacco use. The present study agrees that HE+CBT combined therapy is more effective at nicotine addiction and smoking cessation compared to the other two groups.

Conclusion

We concluded from the study that the effectiveness of combined therapy (HE+CBT) is more effective in reducing tobacco habits than function of individual therapy among smokers. Health professionals should use a combination of HE and CBT interventions for tobacco users, especially smokers, for their quitting and heavy tobacco users are getting immediate attention for the tobacco cessation treatment. In the future, we can carry on the study with

the barriers that impact health professionals during the use of HE and CBT intervention in their tobacco cessation practices for making the sessions clinically effective and educationally more impactful.

Limitations

There were three main factors to consider for limitations of this study; only males were included, only smokers were included, followed-up, and shorter study duration. This research also tried to establish some relationship between tobacco use cessation with appropriate education and the socioeconomic status of the participants. These findings also could not justify the general population. Finally, they used questionnaires that might be considered prepossession because the participants came to the hospital for their treatment. Multiple studies are required to test the effectiveness of CBT in this community and should run for long-term follow-up assessments with different gender distributions.

Ethical approval

The study is approved by the Institutional Ethics Committee (DMR / IMSSH / SOA / 180338).

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Conflict of interest

There are no conflicts of interest.

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