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Research Article

Effectiveness of Three Different Smoking Cessation Interventions among Patients Visiting a Dental Institute in Bengaluru: A Randomised Trial

Anagha Reji[1]*, R Murali[2], Shamala A[3] and Mansi Yalamali[3]

[1]Assistant Professor, Department of Public Health Dentistry, Krishnadevaraya College of Dental Science and Hospital, Bengaluru, Karnataka, India

[2]Professor, Department of Public Health Dentistry, Krishnadevaraya College of Dental Science and Hospital, Bengaluru, Karnataka, India

[3]Associate Professor, Department of Public Health Dentistry, Krishnadevaraya College of Dental Science and Hospital, Bengaluru, Karnataka, India

***Corresponding Author:** Anagha Reji, Assistant Professor, Department of Public Health Dentistry, Krishnadevaraya College of Dental Science and Hospital, Bengaluru, Karnataka, India.

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Abstract

Background and Aim: Cigarette smoking is the cause of mortality in approximately five million people annually worldwide. The prevalence of tobacco consumption can be effectively reduced through an approach called tobacco cessation intervention. The present study was undertaken to assess the effectiveness of tobacco cessation strategies using three different interventions among smokers visiting a dental institute in Bengaluru, Karnataka, India.

Materials and Methods: A randomized clinical trial was conducted among smokers aged 18 - 50 years using smoking forms of tobacco products at the Tobacco Cessation Cell in a dental institute in Bangalore. A questionnaire developed based on the National Tobacco Control Program, Government of India; the Ministry of Health and Family Welfare; and the Fagerström questionnaire was used to collect information regarding demographics and tobacco use. Participants were randomly allocated into three intervention groups [Group 1: Motivational Interviewing (MI), Group 2: Nicotine Replacement Therapy (NRT; nicotine gum 4 mg), Group 3: MI + NRT (nicotine gum 4 mg)]. Exhaled carbon monoxide (CO) levels were recorded at baseline and at 6 consecutive follow-up visits over 3 months. Statistical analyses were performed using Kruskal-Wallis, Friedman, and Tukey's HSD post hoc tests.

Results: The study included 105 smokers (n = 35 in each group). There was a significant reduction in CO levels from baseline to 3 months in all three groups ($p < 0.001$). At the end of 3 months, a significant reduction in CO levels was seen in group 3 (i.e. MI + NRT) compared to the other two groups (MI alone and NRT alone) ($p < 0.001$).

Conclusion: With the given data and observations of the present study and other recent studies, it may be concluded that the combination of two different successful cessation methods i.e. MI and NRT provides synergistic effects with intense and greater success rates than those seen with either cessation method alone.

Keywords: *Smoking; Smoking Cessation; Nicotine; Nicotine Replacement Products; Motivational Interviewing*

Key Messages

What is already known on this topic

Smoking, a major contributor to preventable diseases and deaths, is characterized by high relapse rates due to nicotine addiction. While Nicotine Replacement Therapy (NRT) and Motivational Interviewing (MI) are individually recognized for enhancing cessation success, there is a need to investigate their combined effect in the Indian context.

What this study adds

This study demonstrates that combining MI with NRT is more effective for tobacco cessation than either strategy alone. It adds to the existing knowledge by showing that this combined approach leads to a greater reduction in smoking habits, as indicated by decreased exhaled carbon monoxide levels among participants.

How this study might affect research, practice, or policy

The findings suggest that integrating MI and NRT could be a highly effective strategy for tobacco cessation, particularly in high-nicotine-dependency cases. This approach could influence future research and guide cessation programs by advocating for the adoption of combined behavioral and pharmacological interventions, especially in settings like India, where tobacco use is prevalent.

Introduction

Tobacco smoking contributes to a range of preventable diseases and premature deaths, posing a significant public health concern [1]. Tobacco smoking has been associated with several chronic diseases, including cancer, cardiovascular and respiratory diseases, and multiple adverse reproductive outcomes [2]. In addition to its negative effects on health, the consequences of smoking extend to a significant economic burden on society through increased healthcare costs and lost productivity [3]. As per a 2019 estimate, there were more than 1 billion smokers worldwide.

Regular smoking behavior can be explained as a means to maintain nicotine levels and avoid withdrawal symptoms [4]. Studies show that nicotine replacement therapy (NRT) increases the chances of successfully quitting smoking [5]. The goal of NRT is to provide a temporary replacement of nicotine, thereby reducing the urge to smoke.

According to a 2021 report by the International Commission to Reignite Fight Against Smoking (ICRFAS), India has the second highest number of smoking individuals in the age group of 16 - 64 years [6]. Such statistics underscore the urgency of the need for effective smoking cessation interventions in the country. To address the issue of tobacco use in India, the Government of India launched the National Tobacco Control Programme (NTCP) in 2007 - 2008. As part of this program, tobacco cessation clinics were established at the national, state, and district levels in collaboration with the World Health Organization (WHO) to provide necessary services [7,8]. The coverage and effectiveness of such services are yet to be ascertained. Despite such efforts by the government, the smoking rates remain high in several states, highlighting the need for improving their coverage and access in India [1,9].

The ICRFAS report (2021) indicates that the rate of smoking cessation in India is also among the lowest worldwide (< 20%) [6]. Although interventions, such as NRT, potentially ease the transition from smoking to complete abstinence, the addictive properties of high doses of nicotine as delivered by cigarette smoking, pose significant challenges for individuals aiming to quit smoking, even among those with a sincere desire to quit [10]. Among those who attempt to quit on their own, 80% of individuals resume smoking within the first month [10].

The lack of proven cessation tools often subverts the efforts of many tobacco users with the desire to quit [6]. Additional factors, such as readiness to change, indecisions regarding quitting, and establishing the motivation for cessation, may also play a role [11]. Resolving the hesitancy about behavioral change and bolstering intrinsic motivation can be effective means for smoking cessation [12]. Motivational interviewing (MI) is an evidence-based method that aims to help overcome the ambivalence that hinders people from making desired changes in their lives [12]. This approach has also been extended in the context of smoking cessation to address concerns about behavior change among persons who smoke and to establish internal motivations [13].

Addiction is driven by physical, psychological, and behavioral (habit) factors. Identifying the most dominant driver among these in an individual can aid the choice of personalized tools and resources to deal with the process of withdrawal and tailor interventions

accordingly [14]. In addition to the availability of cessation services, the method of cessation support, involvement of healthcare providers, and pharmacotherapy have been reported to play a critical role in determining the success of attempts to quit smoking [9]. Implementing evidence-based strategies, such as NRT and MI, can effectively support individuals in their quit attempts [15]. Augmenting NRT, which helps maintain the level of nicotine in the blood, with MI can help overcome motivation barriers that may interfere with the smoking cessation efforts [10,16,17].

Aim of the Study

This study aimed to assess and compare three different tobacco cessation interventions among smokers in Indian setting.

Methods

Study design

This parallel-arm randomized controlled trial was conducted between December 2021 and November 2022 at the Department of Public Health Dentistry and Tobacco Cessation Cell, Krishnadevaraya College of Dental Sciences and Hospital, Bengaluru to compare the effectiveness of MI, NRT, and a combination of MI and NRT among individuals who smoke. The study protocol was approved by the institutional ethical review committee. Study participants were explained the nature of the study, and written informed consent was obtained from all participants. Participants were free to withdraw from the study at any point during the study. The CONSORT (Consolidated Standards of Reporting Trials) 2010 checklist was used to ensure a standardized and transparent reporting of the trial. The completed checklist can be found in the Supplementary Information.

Study sample

The estimated sample size for this study was 35 in each group, aiming for a power of 80% and a confidence level of 95%. Simple random sampling was used for screening individuals for tobacco smoking from those reporting at the study site. The selected individuals were referred to the tobacco cessation cell for assessment of the severity of tobacco dependence using the Fagerström scale [18]. The inclusion criteria for this study encompassed individuals aged 18 years and older with a smoking habit, regardless of gender. Only participants with a Fagerström score > 6 and expressing the willingness to quit tobacco were selected. Exclusion criteria were individuals with a medical or terminal illness, pregnancy, current psychiatric care, a history of alcohol or drug abuse, hypersensitivity to nicotine or menthol, temporomandibular joint (TMJ) dysfunction, or those wearing dentures. Those using smokeless tobacco or not willing to quit smoking were also excluded. Individuals who were scored as highly dependent on smoking (Fagerström score > 6) were randomly allocated to the study groups (MI, NRT, and MI + NRT) until the required sample size was achieved.

Study interventions

MI

An MI session encompasses various communication techniques, such as open-ended questions, affirmations, and reflective listening to convey empathy, highlight discrepancies, manage resistance, and reinforce self-belief in the ability to change [13,19,20]. During the counseling sessions, the following aspects were discussed:

1. Reasons behind the smoking habit.
2. The specifics of the smoking habit, including timing, location, activities, situations, feelings, and triggers.
3. The potential consequences of the habit.
4. Setting a definitive date to quit.
5. Selecting a cessation strategy.

6. Quitting and dealing with cravings.
7. Coping with withdrawal symptoms.
8. Life after smoking.

All MI sessions were personally conducted by the principal investigator to ensure consistency and standardization of the study protocol. Depending on the participants' preference, the sessions were conducted in Kannada, Hindi, or English. Each session lasted for 15 to 20 minutes.

NRT

Participants were provided with 4 mg Nicotex® nicotine gums as an NRT modality. They were instructed to employ a 'chew-and-park' method, which involved intermittently chewing the gum and parking it until a tingling sensation was experienced. It was recommended to retain the gum in the mouth for about 30 minutes to facilitate nicotine release, adjusting as required based on individual needs. Five of the study participants experienced mild acidity attributable to using the nicotine gums. This was addressed by prescribing antacid lozenges to relieve their symptoms.

MI + NRT

In this group, the participants received a combination of MI and Nicotex® nicotine gum (4 mg).

Study visits and outcome measures

The study interventions were administered by the principal investigator over a period of 3 months involving baseline assessment and six visits. During the first visit (baseline), the questionnaire developed by the National Tobacco Control Programme, Government of India, Ministry of Health and Welfare was used to collect demographic information of the participants, the source of participant referral, tobacco usage history, quit status history, level of nicotine dependence, associated substance use, and history (family history, medical history, physical examination, oral history, and clinical examinations). The participants were asked to choose a quit date within 2 weeks of the baseline visit. Baseline measurements were conducted using the Fagerström test for assessment of physical nicotine dependence and PiCO™ Smokerlyzer® for monitoring exhaled air carbon monoxide (CO) levels. The Fagerström test for nicotine dependence is conducted using a questionnaire that consists of six questions. Questions pertain to an individual's smoking habits and compulsion to use tobacco. Each question is scored, and a total final score is determined. The total score indicates the level of nicotine dependence (0 - 2: very low dependence; 3 - 4: low dependence; 5: moderate dependence; 6 - 7: high dependence; and 8 - 10: very high dependence). The PiCO™ Smokerlyzer measures the amount of CO in exhaled breath. Higher CO readings are indicative of higher smoking intensity. These readings are expressed in parts per million (ppm), which is the amount of CO in a million parts of air. The ppm reading can also report the level of CO in the blood (the carboxyhaemoglobin [COHb] reading); %COHb reflects the percentage of red blood cells carrying CO instead of oxygen. For smoking abstinence outcomes, a self-report measure (point prevalence abstinence) was used that was validated using the CO status considered as a biochemical validation of cessation. The remaining six visits were equally spaced at 2-week intervals starting 2 weeks after the quit date. During the visits, participants received the assigned study intervention, and smoking status was assessed.

Statistical analysis

Data were compiled and tabulated using Microsoft Office Excel and subjected to analysis using Statistical Package for the Social Sciences (SPSS) version 26.0. The continuous variables were summarized using means and standard deviations. For categorical variables, frequencies and percentages were calculated. The reported p-values were obtained using two-sided tests with a 5% level of significance. The normality of data was assessed using the Shapiro-Wilk test. A comparison of Fagerstrom scores across groups was performed using one-way ANOVA. Friedman test was used to evaluate the difference in exhaled CO levels between the seven time points. The Kruskal-

Wallis test was used for the comparison of exhaled CO levels across different time points in the three treatment groups. Tukey's Honestly Significant Difference (HSD) *post hoc* test was used for pairwise comparisons of mean differences in exhaled CO levels across different time points and among the treatment groups.

Results

Participant characteristics

A total of 105 participants were included in this study. All participants were males and their ages ranged between 19 and 50 years. Out of 105, 42 (40%), 21 (20%), and 42 (40%) participants were in the 19 - 30 years, 31 - 40 years, and 41 - 50 years age groups, respectively. The socioeconomic status of most of the participants (95.2%) fell under the upper-middle, lower-middle, or upper-lower classes (modified Kuppuswamy socioeconomic scale [21]). Most (81%) participants smoked cigarettes, followed by beedi (17.1%). A total of 40.0% reported consuming 11-20 cigarettes/beedis daily. Those smoking 1 - 10 and 21 - 30 units daily were 34.3% and 25.7%, respectively. Over half of the participants (53.3%) had been smoking for a duration spanning 11 - 20 years, while those with a shorter smoking history of 1 - 5 years and 6 - 10 years were 20.0% and 26.7%, respectively. Peer pressure emerged as the primary motivator for 50.5% of the sample. This was followed by craving at 28.6% and stress and tension at 21.0%. As for the purchase patterns, a clear majority, 72.4%, made daily purchases, whereas 16.2% bought when needed, and 11.4% opted for bulk purchases. Most of the participants (60.0%) acknowledged previous attempts to quit smoking, leaving 40.0% who had never tried quitting. Table 1 summarizes the characteristics of the study participants. The severity of tobacco dependence was assessed using the Fagerström scale (Figure 1). There was no significant difference among treatment groups for the severity of tobacco dependence ($p = 0.28$).

Characteristic	Type	N (%)
Age (years)	19 - 30	42 (40.0)
	31 - 40	21 (20.0)
	41 - 50	42 (40.0)
Sex	Male	105 (100.0)
Socioeconomic status	Upper	4 (3.8)
	Upper-middle	30 (28.6)
	Lower-middle	41 (39.0)
	Upper-lower	29 (27.6)
	Lower	1 (1.0)
Form of smoking	Cigarette	85 (81.0)
	Beedi	18 (17.1)
	Cigarette + beedi	2 (1.9)
Number of cigarettes/beedi per day	1 - 10	36 (34.3)
	11 - 20	42 (40.0)
	21 - 30	27 (25.7)
Duration of habit (years)	1 - 5	21 (20.0)
	6 - 10	28 (26.7)
	11 - 20	56 (53.3)
Reason for smoking	Peer pressure	53 (50.5)
	Stress and tension	22 (21.0)
	Craving	30 (28.6)
Purchase	Daily purchase	76 (72.4)
	When needed	17 (16.2)
	Bulk	12 (11.4)

Previous attempts at quitting	Yes	63 (60.0)
	No	42 (40.0)
Fagerström score (mean ± SD)	MI	7.05 ± 0.22
	NRT	7.23 ± 0.72
	MI + NRT	7.05 ± 0.23
MI: Motivational Interviewing; NRT: Nicotine Replacement Therapy; SD: Standard Deviation.		

Table 1: *Participant characteristics.*

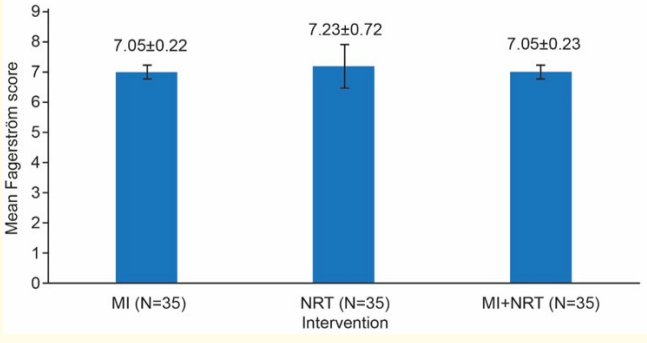

Figure 1: *Comparison of mean Fagerström score across the intervention groups.*

MI: Motivational Interviewing; NRT: Nicotine Replacement Therapy.

Comparison of mean exhaled CO levels between the groups

At baseline, the mean exhaled CO levels for the MI, NRT, and combined MI + NRT groups were 17.11 ± 3.92 ppm, 15.58 ± 3.07 ppm, and 17.45 ± 4.97 ppm, respectively. No significant difference was observed among these groups at baseline (p = 0.31) and week 2 (p = 0.19). However, by week 4, a significant overall difference began to emerge (p = 0.03), with the MI + NRT group showing a greater reduction when compared to the MI group (p = 0.01). This trend became increasingly evident in subsequent visits. By week 6, the MI + NRT group's mean exhaled CO level was significantly reduced compared to both MI (p = 0.004) and NRT (p = 0.04) groups. Similarly, weeks 8, 10, and 12 recorded significantly lower exhaled CO levels for the combined MI + NRT group compared to MI and NRT alone. The comparisons of mean exhaled CO levels across groups at different time points are presented in table 2 and figure 2.

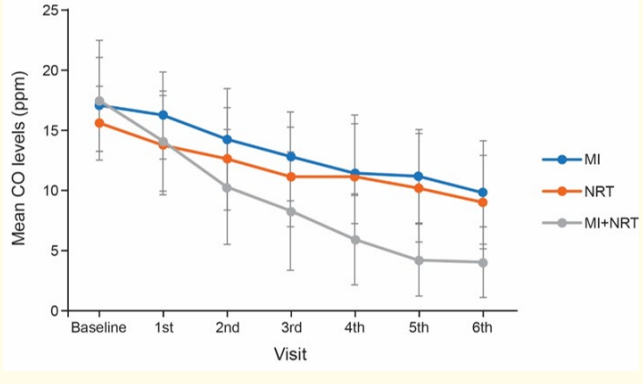

Figure 2: *Trends of mean exhaled CO levels for intervention groups at different visits.*

CO: Carbon Monoxide; MI: Motivational Interviewing; NRT: Nicotine Replacement Therapy; ppm: Parts Per Million.

Comparison of mean exhaled CO levels at different time points

The mean exhaled CO levels showed significant reductions from baseline to the 3-month period for all three groups (MI, NRT, and MI + NRT). For the MI group, a significant decrease in exhaled CO levels was observed from the baseline to week 6, week 2 to weeks 8, 10, and 12, and week 4 to week 12. No other time points exhibited significant differences in exhaled CO levels for the MI group. For the NRT group, a significant decline in exhaled CO levels was observed between the baseline and week 6, week 2 and week 12, and week 4 and week 12. Other comparisons within this group did not reveal any significant changes in exhaled CO levels for the NRT group. The MI + NRT combination group showed multiple significant reductions, including from the baseline to weeks 4 and 6, week 2 to weeks 4, 6, 8, 10, and 12, week 4 to weeks 8, 10, and 12, and week 6 to weeks 8, 10, and 12. The time to the first significant reduction in CO levels was by week 4 for the MI + NRT group, while for the MI and NRT groups, a statistically significant decrease was first observed by week 6. Results from pairwise comparison of CO levels at different visits are presented in table 3.

Comparison	MI	NRT	MI + NRT
Baseline vs. week 2	0.91	0.49	0.20
Baseline vs. week 4	0.19	0.40	0.003*
Baseline vs. week 6	0.04*	0.04*	0.002*
Week 2 vs. week 4	0.40	0.81	0.005*
Week 2 vs. week 6	0.20	0.48	0.001*
Week 2 vs. week 8	0.04*	0.48	0.001*
Week 2 vs. week 10	0.01*	0.25	0.001*
Week 2 vs. week 12	0.005*	0.03*	0.001*
Week 4 vs. week 6	0.83	0.98	0.22
Week 4 vs. week 8	0.78	0.98	0.003*
Week 4 vs. week 10	0.78	0.80	0.001*
Week 4 vs. week 12	0.04*	0.03*	0.001*
Week 6 vs. week 8	0.94	0.99	0.03*
Week 6 vs. week 10	0.94	0.85	0.03*
Week 6 vs. week 12	0.40	0.51	0.01*
Week 8 vs. week 10	0.99	0.98	0.47
Week 8 vs. week 12	0.43	0.78	0.41
Week 10 vs. week 12	0.82	0.89	0.91
*Statistically significant.			

Table 3: *The p-values from pairwise comparison of mean CO levels at different time points using Tukey's HSD post hoc test.*

Discussion

This study was conducted to evaluate the comparative effectiveness of MI, NRT, and NRT in combination with MI in the cessation of tobacco smoking among individuals visiting the Department of Oral Medicine and Radiology and Tobacco Cessation Cell, Krishnadevaraya College of Dental Sciences and Hospital, Bangalore. The outcomes from this study reflect that NRT when used in combination with clinician-guided MI can result in greater success rates compared to the interventions alone.

The risk of diseases is known to diminish rapidly with quitting and permanent abstinence from smoking [2,22,23]. However, once established, the addiction to smoking can be challenging to address [10]. The pharmacologic effects of nicotine are known to play a

role in the establishment of addiction, making a case for consideration of pharmacotherapy to improve the rates of cessation success [24]. Addressing behavioral impediments, such as readiness to change, indecision, and motivation, have also been pointed out as critical variables contributing toward the success of quit attempts [19]. Factoring such issues alongside mainstream NRT has the potential to further enhance the outcomes.

The study included only adult participants according to the Indian tobacco consumption regulations. All participants were males, possibly reflecting societal reservations resulting in a reluctance of females to reveal their smoking habit [25]. The evaluation of tobacco usage patterns revealed an inclination toward cigarettes; however, beedi has been reported as the most commonly smoked tobacco product in India [26]. Such difference may be a result of the urban location of the study. Cigarettes are most common in urban areas, and the use of beedi is more common in rural areas [27]. The influence of friends or peer pressure is reported to be the main reason for the initiation of smoking habit [28]. Such observation supports the need for measures to address the socio-cultural determinants of tobacco use in tailoring preventive measures. Most study participants (60%) had previously attempted to quit smoking, underscoring the known challenges associated with smoking cessation. Notably, baseline assessments of the Fagerstörm score showed no significant differences among the study groups, mitigating the concerns of sampling bias. While the primary focus of this study was on nicotine dependence, several other predictors of smoking cessation have been identified. Aspects such as sex, age, age at smoking initiation, history of previous quit attempts, depression, anxiety, alcoholism, motivation, living as a couple, and presence of smokers in the household or workplace can potentially affect the outcomes [29].

While all three interventions resulted in a decrease in exhaled CO levels over time, reflecting reduced tobacco smoking, the combination of MI and NRT exhibited the most pronounced effect. Such results can be understood by the dual nature of the approach that this combined strategy offers MI to address the behavioral aspect of addiction, whereas NRT alleviates the physical withdrawal symptoms associated with nicotine dependence. The NRT used in this study was 4 mg nicotine gum, recognizing that those highly dependent on smoking derive greater benefit from this concentration (compared to 2 mg), as was the case for this study population [30]. Although there are differences in participant characteristics, the results corroborate previous reports emphasizing the benefits of combining behavioral and pharmacological interventions for smoking cessation [16,31]. The manual for tobacco cessation by the Ministry of Health and Family Welfare (Government of India) states that pharmacological interventions, when used with behavioral strategies, can result in about 25% - 30% quit rates [14]. Although the results from this study showed a reduction in smoking status with MI alone, a systematic review of existing evidence suggests insufficient evidence to assess whether MI alone can promote smoking cessation compared to no intervention [13]. A prospective study among male students from Haryana, India monitoring the motivation, readiness to change, nicotine dependence, and smoking status for 6 months reported less promising results with MI alone [32]. However, the possibility of MI supporting the effect of other interventions has been put forth [13,32]. Additionally, with the intensity of MI being defined based on a combination of number of sessions and their duration, the benefits of higher-intensity MI compared to lower-intensity MI in increasing smoking cessation rates have been indicated.

The findings suggest that the simultaneous use of MI and NRT can be particularly beneficial for individuals with a high level of nicotine dependence (Fagerström score > 6) in Indian settings. Given the high number of individuals smoking tobacco in India, scalable interventions that combine behavioral counseling with pharmacotherapy could significantly reduce tobacco-related morbidity and mortality. However, challenges such as a lack of personnel with expertise in behavioral counseling and compliance can function as barriers to implementation.

This study had certain limitations that need to be taken into consideration while interpreting the results. Being conducted in a dental hospital setting, the study population seeking dental care might have different motivations, perceptions, or health behaviors, thus limiting the broad applicability of the results. Owing to all-male participants, the outcomes may not be fully representative of the general population, particularly females. Data concerning personal details and tobacco usage were primarily collected through self-reported

questionnaires. Such an interview method inherently poses the risk of biases (such as recall bias, social desirability bias, and interviewer bias) related to the validity of the data. Although this study compiled data over 3 months, the potential for relapse exists. Therefore, a longer-term follow-up is necessary to better understand the sustained impact of the interventions. The NRT intervention assessed in this study was nicotine gum; therefore, the differences in effectiveness among other formulations used in NRT, such as patches, lozenges, mouth sprays, and inhalators, cannot be evaluated. The influence of the clinician's involvement on the outcomes cannot be overlooked. It is possible that the observed benefits were partly due to the consistent support and presence of the principal investigator, making it challenging to separate the effects of the interventions from the clinician's influence as differences in clinician training and experience as well as individual perceptions could also play a vital role.

Conclusion

The combined use of MI and NRT offers a promising approach for enhancing smoking cessation outcomes in India, as reflected by significant reductions in exhaled CO levels. While both interventions have independent merit, their concurrent application provides a comprehensive approach that addresses both behavioral motivations and physical withdrawal symptoms. Healthcare professionals aiming to assist individuals in their quit attempts should consider such a combined strategy for improving smoking cessation outcomes.

Author Contributions

All authors have contributed equally to the concept, design, drafting, review and finalization of the manuscript.

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Competing Interests

None.

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