Comparing Motivational Interviewing-Based Treatment and its combination with Nicotine Replacement Therapy on smoking cessation in prisoners: a randomized controlled clinical trial

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Abstract

Background: The prevalence of smoking is much higher in prisoners than it is in the general population. Prisoners who smoke cause many health problems for themselves and other prisoners. Therefore, we should help them stop smoking.

Objective: To compare the effects of motivational interviewing-based (MI-based) treatment and its combination with nicotine replacement therapy (NRT) on smoking cessation in prisoners at Mashhad Central Prison.

Methods: The study was designed as a double-blind, randomized, controlled clinical trial, and it began in February 2013 and ended in February 2014. Two hundred and thirteen prisoners met the inclusion criteria and were enrolled in the study. They were divided randomly into three groups, i.e., MI-based treatment, MI with NRT, and the control group, which didn't receive any therapy. The outcome measures were reported after intervention and at a 90-day follow-up, and changes in the CO levels in expired air and nicotine dependency were measured.

Results: The average age of the subjects was 37.59 ± 8.76, and their mean duration of imprisonment was 3.3 ± 1.90 years. They smoked an average of 21.84 ± 8.72 cigarettes per day. Analysis of the concentration of CO in expired air in the pre-test, post-test, and at the follow-up for the three groups showed that the variations in the mean CO concentrations in the MI group and the MI with NRT group at the pre-test and at the post-test were statistically significant ($p < 0.001$), but no significant changes occurred between the post-test and the follow-up ($p > 0.050$). In addition, the results indicated that CO concentration in expired air in the MI with NRT group was statistically significant, with better efficacy of smoking cessation, compared with control group and the MI group after the follow-up ($p = 0.02$).

Conclusions: Motivational interviewing combined with NRT for smoking cessation is more effective than MI alone, and it resulted in a significant decrease in the CO concentration in expired air at the 90-day follow-up.

Trial registration: The trial is registered at the Thai Clinical Trial Registry with the TCR identification number TCTR20150724001

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Keywords: motivational interviewing, nicotine replacement therapy, smoking cessation, prisoners

1. Introduction

Cigarette smoking is a global health issue, and evaluations indicate that it causes the deaths of approximately five million people worldwide every year. Since the danger of smoking extends beyond the actual users (for instance, the

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problems it causes second-hand smokers), many more people are affected adversely (1). Considering the current smoking patterns, it is estimated that it will cause approximately 10 million deaths per year by 2020 (2). The prevalence of smoking is much higher in prisoners than in the general population (3, 4), perhaps because many prisoners have backgrounds that encouraged smoking, such as substance abuse, psychiatric disorders, and poor socio-economic conditions (5). Smoking has long been considered as part of the prison culture around the world (6, 7). The large numbers of tobacco users who spend their time indoors in a crowded population for long hours comprise an environment in which there are likely to be exposures to high levels of smoke for smokers and non-smokers alike. In an experiment regarding nicotine concentrations, air samples from a prison with no indoor limits on smoking indicated that the concentration of nicotine in the living area was more than 12 times greater than the average nicotine concentration in a random selection of smokers' houses (8). In spite of the high prevalence of smoking in correctional facilities, there have been few efforts to describe the details of the smoking behaviors of prisoners (9, 10). The prevalence of smoking among people whose ages range from 15 to 65 is 20% in the Iranian population (11), but no detailed data are available about the percentage of prisoners who smoke in Iranian prisons. The purpose of a smoking policy in prison is to protect the health of non-smokers and to protect the health of the smokers (12). The high percentage of smokers in prisons and the many prisoners who were willing to quit smoking led to the establishment of a permanent smoking-cessation clinic at Mashhad Central Prison.

In this study, we examined the efficacy of motivational interviewing-based (MI-based) treatment (MI-Only) and the combination of MI with nicotine replacement therapy (MI-NRT) on smoking cessation, and we compared the results with those of the control group among prisoners of Mashhad Central Prison in Mashhad, Iran. To our knowledge, our study is the first-ever randomized clinical trial of smoking cessation with a combination of MI and NRT in prisoners. Motivational interviewing (MI), a technique described by Miller in 1983 that initially was used to treat alcoholism (13), is useful for promoting change in addictive behavior and other health behaviors (14). MI uses a directional, supportive, and non-judgmental therapeutic style that emphasizes the personal responsibility of an individual to make decisions about the change, and it often incorporates personalized feedback that is designed to correct normative misperceptions and to increase awareness of the personally-relevant consequences of smoking (15). Nicotine replacement therapy (NRT) is highly effective in smoking cessation, and it is used widely (16).

2. Material and Methods
2.1. Trial design
The study was designed as a double-blind, randomized, controlled clinical trial, and it began in February 2013 and ended in February 2014. Two hundred and thirteen prisoners met the inclusion criteria and were enrolled in the study. They were divided randomly into three groups, i.e., the MI-based treatment group, the MI with NRT group, and the control group, which didn't receive any therapies. The outcome measures, i.e., changes in the CO concentrations in expired air and nicotine dependency, were reported after intervention and at the 90-day follow-up.

2.2. Participants
The study was conducted in a smoking cessation clinic at Mashhad Central Prison, which has one of the highest prison populations in Iran. The prison is located in northeast Iran. In some sections of the prison, a smoking ban has been implemented, and, in other sections, inmates can smoke only outdoors. All of the 213 participants in the study were prisoners.

2.3. Interventions
The participants completed a baseline assessment that consisted of demographic information, smoking history, nicotine dependency, and the concentration of CO in expired air measured by Bedfont Micro-Smokerlyzer (Bedfont Scientific, Ltd., UK). The degree of nicotine dependency was assessed by Fagerström's test (Fagerström & Schneider, 1989). According to the answers each smoker provided for the questions, a certain score was obtained that varied from 0 to 10 points. The extent of the dependency was considered to be low when the score was in the range of 0 to 3 points; moderate dependency was from 4 to 6 points; and high dependency was 7 or more points. The members of the control group were not instructed or advised to quit smoking or to reduce the frequency of smoking. All of the prisoners who were in the MI and MI-NRT groups received five, 30-minute, face-to-face counseling sessions every week that were designed to enhance their motivation to quit smoking and help them develop the skills required to do so. Each participant in the MI with NRT group received NRT doses based on their smoking level at the time. The participants used one 2-mg piece of gum for every cigarette they smoked during the day. They were encouraged to use NRT for five weeks to minimize their nicotine-withdrawal symptoms.

2.4. Outcomes

In order to verify whether the prisoners had quit smoking, we measure the CO concentrations in their expired air during each visit. The Bedfont Micro-Smokerlyzer was used for this purpose, and it was adjusted and calibrated by the manufacturer. Concentrations of >10 ppm of CO indicated that the participants were smokers; 6–10 ppm indicated sporadic smokers, and < 6 ppm indicated non-smokers (9). Smoking statuses were assessed when the intervention was completes and at the 90-day follow-up. The assessment consisted of determining the number of cigarettes smoked per day, the degree of nicotine dependency according to Fagerström's test, and the CO concentration in the expired air of the participants in the MI group, the MI-NRT group, and the control group.

2.5. Sample size

Over a one-year period, from February 2013 to February 2014, 347 male inmates voluntarily applied for service in this clinic, and 253 of them were eligible for the intervention based on the following criteria:
1) Imprisoned for more than six months
2) Smoke more than 10 cigarettes per day and express an intention or motivation to quit
3) Scheduled to be imprisoned for another six months to enable follow-up
4) No use of other drugs for mental or physical issues.

Personal meetings with prisoners, without the presence of a guard, were held in order to protect medical confidentiality and to develop a trust-based relationship. The data were collected by staff members of the smoking cessation clinic.

2.6. Randomization

The study was a double-blind, randomized, controlled clinical trial. Among the 253 eligible participants, 213 completed the entire period. The subjects were divided randomly into three groups, i.e., the MI group, the MI with NRT group, and the control group.

2.7. Statistical methods

All data analyses were conducted using SPSS 15. The data were expressed as mean ± SD or as a proportion of the sample size. The data were checked for normality by the Kolmogorov–Smirnov (K-S) test. All sample measurements were reported by 95% confidence interval (CI), calculated by the maximum likelihood estimation method. Differences in proportions of quality variables were judged by the χ^2 test. Descriptive statistics and comparisons of the means (one sample t-test and paired sample t-test) also were used. A two-sided p-value of < 0.05 was considered statistically significant. Outcomes were evaluated among all participants who provided follow-up data. Repeated measures analysis of variance (rANOVA) was used as a statistical approach for repeated measure designs for the analysis of CO concentration in expired air during the pre-test, post-test, and at the follow-up. The Scheffe test was more conservative than the other post-hoc tests, meaning that a larger difference between the means was required for the results to be significant. Therefore, we used the Scheffe post-hoc test to determine which groups (MI, MI with NRT, or control groups) caused significant differences in the outcomes.

2.8. Research ethics

All of the prisoners in this study signed an informed consent form. In addition, the study was approved by the Ethics Committee at Educational and Research Centre, District XI of State Prisons, Mashhad, Iran.

3. Results

3.1. Sample

Three hundred and seventy-four male prisoners applied for smoking-cessation services. Among them, 253 (67%) were eligible to receive the intervention, and 213 (84%) of the prisoners who were eligible, completed the entire program. Each of the three groups had 71 participants.

3.2. Demographic and imprisonment information

The average age of the participants in this study was 37.59 ± 8.76. Out of the 213 prisoners who attended the smoking cessation clinic, more than half of them were married (57.2%) and had not finished secondary education (35.6%). A small percentage of the smokers (3.7%) were illiterate (unable to read/write). Table 1 provides the details of the demographic data of the participants. The mean duration of imprisonment of the prisoners who attended the clinic was 3.3 ± 1.90 years, and 38% of the prisoners were imprisoned for the first time.

Table 1. Demographic data and Imprisonment status of participants in the study

Characteristics		MI group n (%)	MI-NRTGroup n (%)	Control Group n (%)	Total n (%)
Marital status	Single	9 (12.7)	11 (15.5)	10 (14.1)	30 (14.0)
	Married	43 (60.6)	38 (53.5)	41 (57.7)	122 (57.2)
	Divorced	17 (23.9)	21 (29.6)	18 (25.4)	56 (26.2)
	Widowed	2 (2.8)	1 (1.4)	2 (2.8)	5 (2.3)
Education	Illiterate	3 (4.2)	2 (2.8)	3 (4.2)	8 (3.7)
	Primary school	25 (35.2)	24 (33.8)	19 (26.8)	68 (31.9)
	Junior high school	23 (32.4)	27 (38.0)	24 (33.8)	74 (34.7)
	Senior high school	18 (25.4)	16 (22.5)	21 (29.6)	55 (25.8)
	University	2 (2.8)	2 (2.8)	4 (5.6)	8 (3.7)
Detention	First-time offender	28 (39.4)	28 (39.4)	25 (35.2)	81 (38.0)
	Repeat offender	43 (60.6)	43 (60.6)	46 (64.8)	132 (62.0)
	Duration of imprisonment (year)	3.19 ± 2.14	3.02 ± 1.01	2.89 ± 1.90	3.3 ± 1.90
Age (mean ± SD)		38.70 ± 8.95	37.13 ± 9.17	36.96 ± 8.35	37.59 ± 8.76

3.3. Smoking history and reasons to quit smoking
The results showed that the prisoners who attended the clinic smoked an average of 21.84 ± 8.72 cigarettes per day. The mean length of time that had smoked tobacco was 15.58 ± 3.55 years. On average, they had made more than four attempts to quit smoking. The main reason that they wanted to quit smoking was health problems (35.6%). The other reasons they gave for wanting to quit were to improve their physical condition (30.0%) and financial problems (17.3%) (Table 2). At the beginning of study, the mean score on Fagerström's test was 5.31 ± 2.5. Basically, the three groups had essentially the same CO concentration in their expired air (Table 3).

Table 2. Reasons to quit smoking

Reasons for the intention to quit smoking	MI n (%)	MI with NRT n (%)	Control n (%)	Total n (%)
Health problems (e.g., respiratory symptoms)	24 (33.8)	27 (38.0)	25 (35.2)	76 (35.6)
Improved physical condition	24 (33.8)	18 (25.4)	22 (31.0)	64 (30.0)
Financial problems	11 (15.5)	12 (16.9)	14 (19.7)	37 (17.3)
Other reasons	12 (16.9)	14 (19.7)	10 (14.1)	36 (16.9)

Table 3. Smoking history and baseline smoking status

Characteristics	MI Mean ± SD	MI-NRT Mean ± SD	Control Mean ± SD	Total Mean ± SD
Mean age first smoked tobacco (years)	19.94 ± 5.19	21.31 ± 5.92	21.35 ± 6.71	20.86 ± 5.94
Mean length of time smoked tobacco (years)	15.83 ± 3.94	14.86 ± 3.83	16.05 ± 2.88	15.58 ± 3.55
Mean times ever attempted to quit smoking	3.97 ± 1.30	4.45 ± 1.16	4.34 ± 1.09	4.25 ± 1.18
Number of cigarettes smoked per day	19.89 ± 8.16	22.32 ± 9.01	23.32 ± 9.02	21.84 ± 8.72
Mean Fagerström's test score	5.21 ± 1.71	4.84 ± 2.12	5.01 ± 1.91	5.02 ± 1.92
Mean CO-oximetry in expired air	18.01 ± 4.32	17.67 ± 4.57	18.21 ± 3.98	17.96 ± 4.29

3.4. Post-intervention and follow-up outcomes
Analyses of the CO concentrations in the expired air in the pre-test (before intervention), the post-test (after intervention), and at the follow-up in the three groups are presented in Table 4. This table shows that changes in the mean CO concentrations in the two groups that were studied, i.e., the MI group and the MI-NRT group, were statistically significant at two different times, i.e., 1) at the pre-test and at the post-test and 2) at the pre-test and at the follow-up. No significant changes occurred between the post-test and the follow-up ($p > 0.050$). In addition, the mean difference of CO concentration between the control group and the other two groups was significant ($p < 0.001$). However, the results of the Scheffe post-hoc test showed that the reductions of the CO concentrations in the expired air of the MI-NRT were statistically significant and better than in the control and MI groups ($p = 0.02$).The differences between the numbers of cigarettes smoked daily and Fagerström's test score for the MI group and the MI-NRT group between the pre-test and the post-test and between the pre-test and the follow-up were statistically significant, and the differences were stull observed between the post-test and the follow-up (Table 4).

Table 4. Results of CO concentration from expired air, number of cigarettes smoked per day, and Fagerström's test score in pre-test, post-test, and at follow-up

		MI Mean ± SD	p	MI-NRT Mean ± SD	p	Control Mean ± SD	p
Mean CO-oximetry	Pre-test and Post test	7.80 ± 4.34	0.001	10.87 ± 4.53	0.001	0.36 ± 2.36	0.19
	Pre-test and Follow-up	7.81 ± 4.80	0.001	11.24 ± 3.82	0.001	0.37 ± 1.74	0.07
	Post-Test and Follow-up	0.01 ± 2.95	0.96	0.37 ± 2.24	0.16	0.01 ± 2.29	0.95
cigarettes smoked per day (number)	Pre-test and Post-test	9.38 ± 8.34	0.001	9.81 ± 5.36	0.001	0.40 ± 4.49	0.44
	Pre-test and Follow-up	5.90 ± 9.57	0.001	10.15 ± 3.27	0.001	0.09 ± 3.33	0.80
	Post-Test and Follow-up	3.47 ± 3.29	0.413	0.33 ± 5.68	0.618	-0.31 ± 4.07	0.52
Fagerström's test score	Pre-test and Post-test	2.88 ± 2.47	0.001	6.50 ± 2.41	0.001	0.21 ± 2.09	0.39
	Pre-test and Follow-up	3.62 ± 2.97	0.001	7.81 ± 2.60	0.001	-0.70 ± 1.61	0.43
	Post-Test and Follow-up	0.73 ± 1.51	0.113	1.31 ± 1.27	0.068	-0.91 ± 2.51	0.25

4. Discussion

The psychosocial factors in a community of prisoners differ from other social groups, such as the level of education, substance abuse, attitudes towards health, and lifestyle (17). Smoking is highly popular among prison populations. The issue of tobacco smoking in this population has been neglected by the public health sector, and the health and economic benefits of smoking cessation in this community have not been estimated. We believe that this is the first study to assess the feasibility of multiple interventions, consisting of MI therapy, NRT with MI therapy, and controlled situations, to promote smoking cessation among prison inmates. Richmond and colleagues (18) assessed a multi-component intervention. Lacking a control group, they used a cognitive behavioral therapy instead of MI, and conducted the experiment on a small population of prisoners.

According to the results of previous studies, adherence to counseling and NRT predicts successful cessation (19). In our study, the participants were assigned into three groups, i.e., the MI group, the MI-NRT group, and the control group. Our analyses demonstrated that the MI-NRT group had better efficacy than the MI group. We compared the groups over a longer follow-up period than previous studies, and we evaluated cigarette smoking by CO concentration in the participants' expired air and by self-reports. Similar to our study, Harris et al. (20) conducted a randomized controlled trial to examine the efficacy of individually-delivered MI-counseling sessions in smoking cessation. Their subjects were college students, and their results were compared with those of a control-matched group. They found that MI therapy was effective in increasing cessation attempts and in the short-term reduction of smoking days. Also, they noted that there were no significant differences in 30-day cessation during the treatment, at the end of the treatment, or at the follow-up. The results of our study demonstrated that MI has a significant impact on individuals compared with the control group who didn't receive any therapies after the 120-day follow-up. The results from our MI trials were different from those reported in previous studies (21, 22) in which it was found that MI had a modest impact on self-reported smoking rates among adolescent smokers, with almost no impact on biochemically-confirmed cessation. However, our results were in good agreement with the results of another study (23) that indicated that MI was more effective than giving brief advice on smoking cessation. Richmond et al. (18) found that any smoking-cessation intervention requires researchers to deal with prison-specific issues, such as exhaustion, stress, transfers to other prisons, court conditions, and isolation from family and friends. It is possible that differences in the results of the studies can be attributed to different study conditions, variations in the content and quality of MI, or, especially, the population sample that was studied. Also, the measurements of cigarette-smoking cessation and MI efficacy were not conducted the same way in all of the studies, i.e., some used questionnaires and self-reports, while others used CO-oximetry, as was the case in our study. Also, there is no formal analysis to monitor the content of the interventions or to assess the practitioners' level of competence. Miller et al. (24) concluded that workshop sessions are not sufficient for MI practice and that detailed, individual supervision is needed. Other studies have focused on how the effects of MI training should be studied, and they have suggested the need form audio-recorded evaluation of post-workshop results using the MI Skills Code (25). In our study, the overall findings suggest that MI for smoking cessation has positive effects on attempts to quit. In addition, we found that MI-NRT for smoking cessation is more effective than MI alone, as evidenced by increasing abstinence and significantly decreased CO concentrations in the participants' expired air at the 120-day follow-up.

5. Conclusions

We concluded that MI-NRT is an effective method for smoking cessation among prisoners and that it should be offered as a routine therapy to all imprisoned smokers who indicate a desire to stop smoking. The authors hope to confirm the findings in a larger sample size, in a more rigorously-designed trial, and a longer follow-up period. Also, we acknowledge the limitations of the study, the possibility of recruiting subjects from other prisons, giving them interventions, and encouraging prison inmates to quit smoking voluntarily.

Conflict of Interest:
There is no conflict of interest to be declared.

Authors' contributions:
All authors contributed to this project and article equally. All authors read and approved the final manuscript.

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