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Evaluating Smoking Cessation Counseling Bundle Behavioral Intervention for Mongolian Adults Who Use Nicotine Patches

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Objectives: The objective of this study is to evaluate the effectiveness of a behavioral intervention based on the World Health Organization (WHO) 5A and 5R guidelines in Mongolia who use the Nicotine Replacement Therapy (NRT) patch. The study aims to assess the impact of the intervention on smoking cessation rate. The finding of this study will contribute to the existing literature on smoking cessation interventions and provide valuable insights into the effectiveness of a behavioral approach in a Mongolian population.

Methods: In the intervention study, out of total of 806 people interested in the part of this study. The study team excluded their eligibility criteria of the study participant. A sample of 625 people who fulfilled study inclusion criteria received advice about the negative consequences of tobacco. After that, 479 people decided to quit smoking and 41 people were excluded due to health contraindications, and the final sample 454 people began nicotine replacement therapy to quit smoking. Participants in the treatment group received nicotine replacement patches for 28 days, while those in the counseling group received four sessions of behavioral change counseling (5A, 5R).

Results: 454 were found to be eligible to take part in the study and were subsequently assigned to one of two groups, with 230 and 224 participants assigned to each group, respectively. In the second month of follow-up, 90 (39.1%) of participants who received NRT patches quit smoking. The group that received NRT + Behavioral intervention was 1.02 times as successful, or 0.7% more effective, than the group that did not receive behavioral intervention (P=0.872).

Conclusion: WHO 5A, 5R brief counselling were more effective than group without behavioral intervention for smoking cessation, but difference was insignificant.

Keywords: Tobacco, Smoking cessation, Tobacco use cessation devices, Directive counseling, Behavior therapy

Introduction

Tobacco use kills 7.7 million people annually, with one in every five male deaths worldwide attributed to it. In 2019, there were 1.14 billion active smokers worldwide, smoking 7.41 trillion cigarettes equivalents. Tobacco use caused 7.69 million deaths and 200 million disability-adjusted life-years, with 86% of deaths occurring among current smokers [1]. In 2010, a survey of 3450 people aged 15 to 64 in Mongolia found that 46.3% of males and 6.8% of females smoked [2]. The DSM-5 categorizes tobacco dependence as a type of substance use disorder along with other addictions. Clinical criteria for these disorders include experiencing cravings, withdrawal symptoms, difficulty controlling substance use, and continued use despite being aware of negative health consequences [3]. Literature Review on this topic discusses the effectiveness of interventions based on theory or theoretical constructs, specifically focusing on motivational interviewing (MI) as a successful counseling technique for bringing about positive behavioral changes in patients. MI has been evaluated for a wide range of behavior modification goals and has shown to be successful in both lowering maladaptive behaviors and fostering adaptive health behavior change. Additionally, the MI appears to be more effective when combined with other active therapy techniques and is a potential clinical tool that can be incorporated with other evidence-based treatments. A systematic review reveals that approximately three out of four studies found MI to have a significant and clinically relevant effect, with an equal effect on physiological and psychological diseases[4-7].

The 5As approach, originally developed for smoking cessation, has also been adapted for weight loss intervention. It consists of five brief interventions (Ask, Advise, Assess, Assist, and Arrange) that primary care physicians can use to assist tobacco users in quitting. Randomized controlled trials have shown that medical intervention using the 5As approach increases the proportion of smokers who quit for at least six months, and it is a cost-effective intervention. However, routine delivery of the 5As approach remains low in some regions[8-10]. Although brief smoking cessation interventions that follow the 5As algorithm can trigger smokers to quit, routine delivery remains low in Europe and China [11, 12]. Nicotine replacement therapy (NRT) can increase the success rate of smoking cessation by reducing withdrawal symptoms through the substitution of nicotine. NRT is available in different forms such as skin patches, chewing gum, nasal sprays, inhalators, and lozenges. A systematic review of 136 trials with 64,640 participants showed that NRT can increase the likelihood of quitting smoking by 50-60%, and it can be effective with or without additional counseling. Adherence to NRT is important, as it doubles the success rate of smoking cessation. However, NRT may cause skin irritation or irritation of the mouth [13, 14]. In summary, combining behavioral support and pharmacotherapies, such as NRT, has been shown to be effective in helping people quit smoking. Many guidelines recommend this approach, and studies have demonstrated that it leads to higher long-term abstinence rates compared to behavioral therapy alone or no intervention [15]. While previous studies have examined smoking prevalence and the effectiveness of interventions such as motivational interviewing and nicotine replacement therapy, this current study specifically aims to evaluate the effectiveness of behavioral interventions using the WHO 5A and 5R guidelines in the context of nicotine behavior therapy. The study aims to determine if the implementation of the 5A and 5R guidelines results in increased smoking cessation rates among participants. Additionally, this study focuses on the specific population of smokers in Mongolia, which has not been extensively studied in relation to smoking cessation interventions. Therefore, the current study aims to fill a gap in the literature by evaluating the effectiveness of a specific intervention approach in a unique population.

Material and methods

Research design

This is a one-arm, randomized, single-blind trial. The questionnaire was collected at the clinic on the first, fourteenth, one month, and two months. The following questions were asked regarding smoking usage (age started, duration, age they started daily, per day, per week) and questions about trying to quit smoking (how many times, when was the last time, how long did you quit, why did you decide to quit). The FTND (Fagerstrom Test for Nicotine Dependence) [16] was also performed. Data collectors in the experiment were not blindfolded. Throughout the entire period, health care personnel were reportedly gathering adverse reaction reports and responding to them. The subjects who enrolled in

the trial each received a trial registration number, which was then utilized for randomization. Randomization was performed by creating a number based on the number of people who had received treatment, and then it was planned according to a 28-day course of daily NRT patches that were distributed to subjects who had enrolled twice. On the day that they went to the clinic, they received their first distribution. The next appointment was scheduled for in two weeks. The final clinical visit after a period of 28 weeks to have a checkup on one's health. Parallel to the therapeutic session, the behavioral intervention (5A, 5R brief intervention counseling) [9] was carried out on three separate occasions.

Table 1. The source and sample populations (by district)

Districts	Total population (18-65 aged)	The first visit	Treatment started	Finished
Bayanzurkh	230,125	134	98	81
Songinokhairkhan	202,652	108	101	68
Bayangol	130,160	113	70	54
Khan-Uul	121,296	110	72	68
Chingeltei	85,313	84	58	50
Sukhbaatar	86,353	76	55	45
Total	**855,899**	**625**	**454**	**366**

The intervention study ran from February 1 to June 30, 2022. The results were calculated for a total of 454 people, 230 in the NRT+ behavioral advice group and 224 in the control group (NRT+ no behavioral advice) (Table 1). The sample size for this study was determined using the G power analysis [17] and we used following formula; To calculate the sample size required for a study that aims to detect a difference in the smoking cessation rate between an intervention group and a control group, we can use the following formula:

$$n = (Z\alpha/2 + Z\beta)^2 * (p1(1-p1) + p2(1-p2)) / (p1 - p2)^2$$

Where:

n: sample size per group

$Z\alpha/2$: the Z-value for the chosen level of significance (e.g., 1.96 for 95% confidence level)

$Z\beta$: the Z-value for the chosen level of power (e.g., 0.84 for 80% power)

p1: the expected proportion of smokers who will quit in the intervention group (e.g., 0.48 or 48%)

p2: the expected proportion of smokers who will quit in the control group (e.g., 0.32 or 32%)

Assuming a 95% confidence level and 80% power, and using the proportions provided (p1 = 0.48 and p2 = 0.32), the sample size per group is:

$$n = (1.96 + 0.84)^2 * ((0.48 * 0.52) + (0.32 * 0.68)) / (0.48 - 0.32)^2 \; n = 104.8$$

Therefore, a minimum sample size of 105 participants per group would be required to detect a significant difference in smoking cessation rates between the intervention and control groups.

Dosing and Dispensing of NRT

In the study, if a person smokes less than 19 cigarettes per day, the first dose of NRT will be distributed by 28 mg over the first two weeks. In addition, 10mg NRT will be administered every two weeks to one month. If a person smokes more than 20 cigarettes per day, 42mg will be distributed in the first week, 28mg for 8-14 days, and 10mg for 15-28 days. A designated study physician performed the initial screening at each of the six district hospitals that took part in the Trial training.

WHO-5A, 5R group counseling package

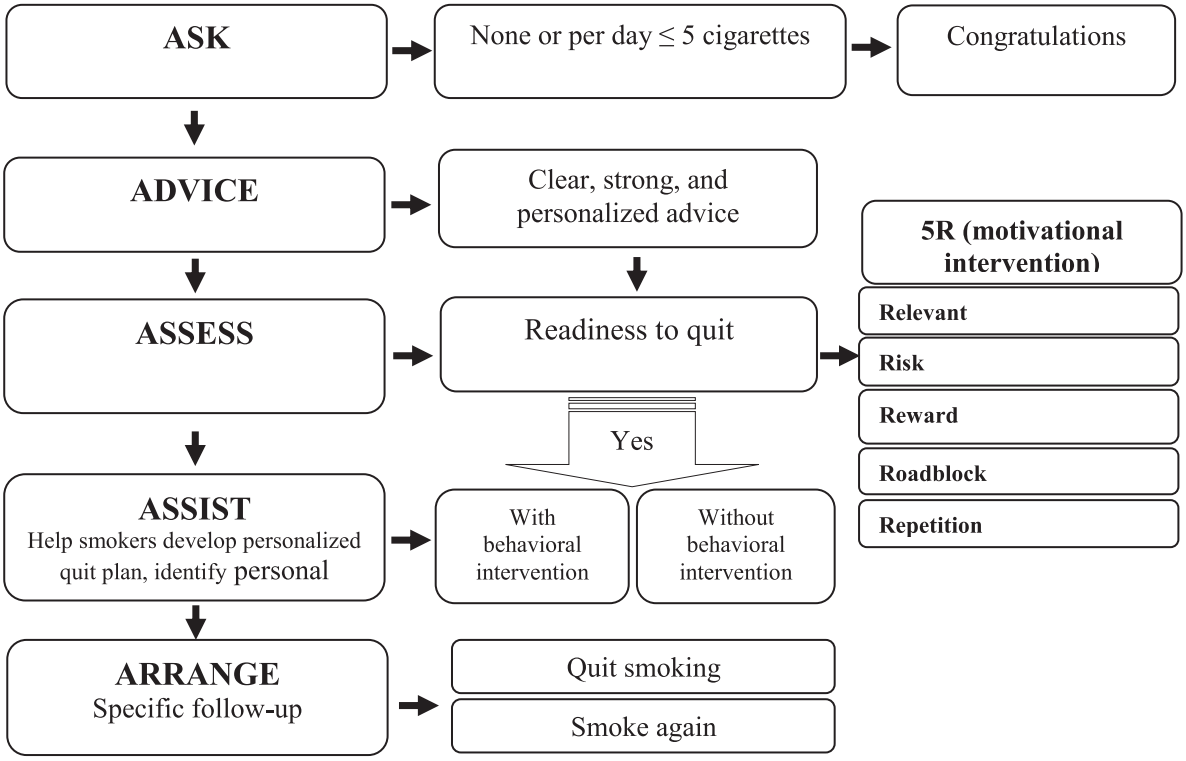

Figure 1. 5A, 5R Model

During the ASK phase, participants' tobacco use was assessed, and participants were included in the study if they smoked 5 cigarettes per day. 2. During the ADVICE-consulting phase, basic advice on the harmful effects of tobacco on human health, the economy, and social life was provided. 3. During the ASSESS phase, the readiness to quit smoking was evaluated. If a participant was not ready to quit smoking, the readiness assessment was repeated, along with additional counseling using the 5R approach. 4. If the participant was ready, treatment was initiated during the ASSIST phase, and participants in the advice-only group were given behavioral change advice (5A, 5R). 5. Tobacco use was assessed using self-assessment during the ARRANGE stage as shown in (Figure 1).

Setting

The trial's central coordination was handled by the Mongolian University of Medical Sciences (MNUMS). Participants were recruited, screened, consented to, enrolled, and in person at six district hospitals that serve six of Ulaanbaatar's nine municipal districts (Bayangol, Songinokhairkhan, Chingeltei, Khan-Uul, Sukhbaatar, Bayanzurkh).

Inclusion Criteria

This trial participant must meet the following inclusion criteria:

- You must be a current daily smoker at least five times a day
- Must be between the ages of 18 and 65.
- Be willing to try to quit smoking using a Nicotine Replacement Therapy and to take part in clinical counseling sessions with health social worker and psychiatric doctors
- Be prepared to provide informed consent both verbally and in writing.

- Consistent phone access and the ability to conduct follow-up phone interviews are required.
- Resides or works for at least the next two months in one of the six district hospital study districts.
- A Mongolian citizen who has enrolled in the government's health-care system.

Participants recruitment

There are 1.5 million people living in the urban zone of Mongolia known as Ulaanbaatar. There are nine different districts in Ulaanbaatar. We recruited cigarette smokers who had official residential registration and temporary residents who had been living in Ulaanbaatar for less than six months in each of the nine districts that are served by the six district hospitals that are serving as study sites for this trial: (Bayanzurkh District Health Center, Sukhbaatar District Health Center, Songinokhairkhan District Hospital, Bayngol District Health Center, Chingeltei District Health Center and Khan-Uul District Health Center) (Figure 2)

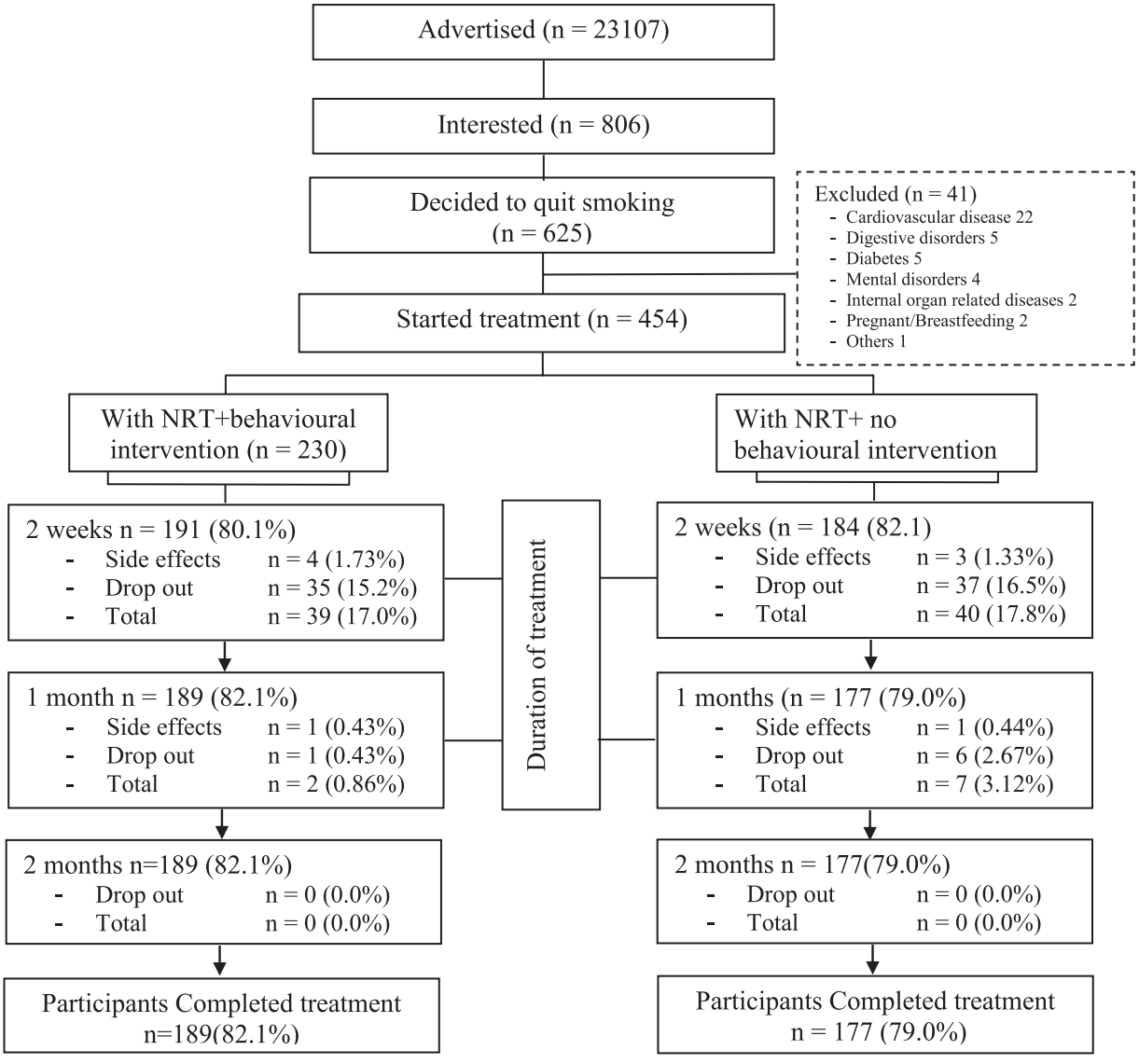

Figure 2. Participant recruiting flow chart

Procedures

According to Table 1, promotional content shared on Facebook and broadcasted on television. Volunteers who are interested in helping will be joining the six district hospitals. Participants who satisfied the fundamental inclusion criteria were extended an invitation to conduct an in-person clinical screening with a study physician at their district hospital of residence to determine their eligibility for the study. At this point in the process, participants in the study were provided with generic information on the health, economic, and social effects of smoking. It was a simple task that just required fifteen minutes of our time. If they consent to take part in the experiment, a treatment date for tobacco treatment will be arranged. On the appointed day, the participant will fill out a self-reported questionnaire on their personal health, then psychiatric doctor will check to see if it is possible for them to be qualified for the study.

Outcome measurement

The outcomes were measured by tobacco consumption. It included 1) self-reported continuous abstinence at 14 days, 1month and 2 months 2) self-reported 7-day point prevalence at 14 days, 1 month, and 2 months, and 3) self-reported cigarette consumption at 14 days, 1 month, and 2 months.

- Health and Behavior outcomes (14 days, 1 month, and 2 months):
  - Symptoms of withdrawal symptoms (cardiovascular, digestive, metabolism, respiratory, psychologically and others)
  - Survey measures of intention to quit and self-related chances of quitting
- Substance Use Smoking Cessation Pharmacotherapy Outcomes (14 days, 1 month, and 2 months)
  - Compliance with randomized treatment regimen (daily NRT patch consumption).

Statistical Analysis

Statistical analysis of trial data was conducted with SPSS 25.0 software. In the nicotine replacement therapy group, compliance was defined as using nicotine replacement therapy two weeks and two months safter the quit date. Participants with missing data were assumed to have disregarded the study protocol. In addition, a comprehensive case study was conducted, and quit rates, relative risk, risk difference, and the required number of patients were computed., Fisher's exact test was utilized given that the cell size in the provided tables was less than 5. The change from baseline in symptoms of tobacco withdrawal (for abstainers), nicotine dependence score, and number of cigarettes smoked per day over time was evaluated. Using Kaplan–Meier curves, the log rank test, Cox Proportional Hazard was used the time to first lapse from quit date was determined (return to daily smoking).

Ethics

The Research Ethics Control Committee of Mongolian National University of Medical Sciences organized its meeting. The research project was granted ethical clearance during the conference that took place on the 20th December 2019 (2019/3-13). It was also coordinated by the Research Ethics Control Committee of the Ministry of Health. The research proposal was awarded ethical approval during the conference held on November 15, 2019. (07). The ultimate ethical clearance from the MNUMS ethical approval board was received on January 20, 2023, with the identifier number (2023/01).

Results

General characteristics of the study participants

Table 2. The study general characteristics by intervention groups

	Total		With NRT+ behavioral intervention‡		NRT+Without behavioral intervention	
	N	(%)	N	(%)	N	(%)
Gender						
Male	342	75.3	174	50.9	168	49.1
Female	112	24.7	56	50.0	56	50.0

Age group						
Until 29	55	12.1	28	50.9	27	49.1
30 - 39	116	25.6	56	48.3	60	51.7
40 - 49	132	29.1	76	57.6	56	42.4
50 - 59	96	21.1	44	45.8	52	54.2
60 - 65	55	12.1	26	47.3	29	52.7
Ethnicity						
Khalkh	402	88.5	206	51.2%	196	48.8
Kazakh	5	1.1	3	60.0%	2	40.0
Durvud	16	3.5	8	50.0%	8	50.0
Buriad	8	1.8	3	37.5%	5	62.5
Others	23	5.1	10	43.5%	13	56.5
Marital status						
Single	58	12.8	33	56.9%	25	43.1
Married	327	72	163	49.8%	164	50.2
Relationship	40	8.8	18	45.0	22	55.0
Living separately	7	1.5	4	57.1	3	42.9
Divorced	16	3.5	7	43.8	9	56.3
Widowed	6	1.3	5	83.3	1	16.7
Number of family members						
1-2	107	23.6	52	48.6	55	51.4
3-4	217	47.8	109	50.2	108	49.8
+5	130	28.6	69	53.1	61	46.9
Living condition						
Ger§	42	9.3	19	45.2	23	54.8
Ger brick house	144	31.7	74	51.4	70	48.6
House	262	57.7	134	51.1	128	48.9
Apartment	4	0.9	3	75.0	1	25.0
Other	2	0.4	0	0.0	2	100.0
Education						
No education	4	0.9	2	50.0	2	50.0
Low	5	1.1	2	40.0	3	60.0
Low+	56	12.3	29	51.8	27	48.2
Middle	130	28.6	69	53.1	61	46.9
Technical and professional	40	8.8	17	42.5	23	57.5
Upper	199	43.8	98	49.2	101	50.8
Post graduate education	20	4.4	13	65.0	7	35.0
Occupation						
State organization	124	27.3	55	44.4	69	55.6
Non-state organization	31	6.8	17	54.8	14	45.2
Private organization	188	41.4	102	54.3	86	45.7
Regular unpaid work	9	2	4	44.4	5	55.6
Retired	52	11.4	26	50.0	26	50.0

University or school student	4	0.9	3	75.0	1	25.0
Unemployed (no disability)	30	6.6	14	46.7	16	53.3
Unemployed (with disability)	8	1.8	4	50.0	4	50.0
Other	8	1.8	5	62.5	3	37.5
Income						
Until 500'000₮	114	25.1	62	55.4	50	44.6
500'001-1'000'000₮	126	27.7	58	46.0	68	54.0
1'00'001-1'500'000₮	62	13.7	32	51.6	30	48.4
1'500'001-2'000'000₮	90	19.8	45	50.0	45	50.0
2'000'000₮ over	62	13.7	32	51.6	30	48.4

§ Ger-Traditional Mongolian house where raw or improved coal is burned. NRT- denotes Nicotine-Substitute Therapy.
‡ Behavioral intervention was based on the WHO brief counseling package (5A 5R)

Table 2 shows the socio-demographic factors among NRT+behavioral intervention and without NRT and behavioral intervention group. 454 were found to be eligible to take part in the study and were subsequently assigned to one of two groups, with 230 and 224 participants assigned to each group, respectively. After two months, twenty percent of patients in each group were no longer able to be followed up with (Figure 1). Similarities existed between the treatment groups' baseline characteristics (Table 2).In the study, half of the study participants equally distributed among NRT+behavioral intervention and without behavioral intervention. Gender was only significant between two groups than other variables (Table 2).

Table 3. Whether or not NRT are utilized in the recommended manner (self-reported)

NRT users	**Total**		**With NRT§+ behavioral intervention‡**		**NRT+Without behavioral intervention**	
	N	**%**	**N**	**%**	**N**	**%**
NRT treatment helped						
Yes	360	96.0	182	95.3	178	96.7
No	15	4.0	9	4.7	6	3.3
Study participants followed recommended NRT patch						
Always	318	84.8	168	88.0	150	81.5
Sometimes	51	13.6	19	9.9	32	17.4
None	6	1.6	4	2.1	2	1.1

§ NRT denotes nicotine-replacement therapy
‡ Behavioral intervention was based on the WHO brief counseling package (5A 5R)
N (%) means number (percentage)

Table 3 described that the NRT treatment was judged as effective by 360 (96.0%) of the respondents, while only 15 (4.0%) of them rated it as ineffective. However, 318 of them (84.8%) answered in a way that was consistent with the instructions, 51 (13.6%) responded occasionally, and 6 (1.6%) did not respond at all. When asked to specify the reasons for not using the product according to the directions, 41 people (71.9% of total responses) said that they forgot, 6 people (10.5% of total responses) said that they did not feel confidence to quit smoking, and 2 people (3.5%) said that they detected negative effects (Table 3).

Table 4. Tobacco related questions between two intervention groups.

Tobacco related questions	Total	NRT+Behavioral intervention	NRT+No Behavioral intervention	P Value*
	Mean (SD)	Mean (SD)	Mean (SD)	
The age started use tobacco	19.2 (6.5)	19.4 (6.3)	18.6 (6.6)	0.157
Years of tobacco use	23.2 (11.6)	22.7 (11.4)	23.6 (11.8)	0.438
The age when daily smoking began	20.7(7.2)	21(6.9)	20.5 (7.4)	0.419
Cigarette consumption per day	15.4(7.2)	15.6 (7.6)	15.2 (6.8)	0.600
Intention to quit smoking				
Attempts to give up smoking	241(80.1)	164 (71.3)	177 (79)	0.057
Number of tries of quit smoking (average)	2.4 (1.5)	2.37 (1.52)	2.42 (1.5)	0.776
The last time tried quitting (by year)	3.5 (5.8)	3.86 (6.48)	3.19 (5.14)	0.298
Time for endurance (by month)	8 (20.2)	6.98 (15.2)	8.99 (23.4)	0.377

*P value was calculated with independent t-test; no significant differences were observed between groups

Table 4 shows the participants in the study began smoking at an average of 19.2 years. The mean duration of smoking was 23.2 and there was no significant difference between NRT and behavioral intervention groups. The average daily cigarette consumption was 15.4. Among NRT and behavioral intervention, cigarette consumption was similar between groups (15.6 and 15.2 respectively). 241 (80.0%) of the study participants had attempted to quit smoking in the past, with a mean of 2.4 smoking quitting attempts. The average duration of smoking cessation was 8 months (Table 4).

Behavioral intervention results

Table 5. Analysis of the beginning and ending of treatment according to intervention group

Variables	With NRT§+ behavioral intervention‡	NRT+Without behavioral intervention	RR*	Risk difference	P value
	n=230	n=224	95% CI		
Quit rate: Quit smoking + continued to smoke, but at lower rate than before†					
14 days	187 (81.3)	176 (78.6)	1.035 (0.944 - 1.135)	2.70	0.467
1 month	181 (78.7)	170 (75.9)	1.037 (0.938 - 1.146)	2.80	0.476
2 months	176 (76.5)	155 (69.2)	1.106 (0.988 - 1.238)	7.30	0.079
Quit rate: Quit smoking†					
14 days	108 (47.0)	96 (42.9)	1.096 (0.893 - 1.344)	4.1	0.380
1 month	117 (50.9)	101 (45.1)	1.128 (0.931 - 1.368)	5.8	0.218
2 months	90 (39.1)	86 (38.4)	1.019 (0.809 - 1.284)	0.70	0.872
Quit rate: Quit smoking + continued to smoke, but at lower rate than before‡					
14 days	185 (97.9)	169 (95.5)	1.025 (0.987 - 1.065)	2.40	0.197
1 month	181 (95.8)	170 (96.0)	0.997 (0.956 - 1.040)	-0.20	0.893
2 months	176 (93.1)	155 (97.6)	0.063 (0.994 - 1.138)	5.50	0.071
Quit rate: Quit smoking‡					
14 days	106 (56.1)	93 (52.5)	1.067 (0.884 - 1.289)	3.60	0.497

1 month	117 (61.9)	101 (57.1)	1.085 (0.915 - 1.286)	4.80	0.045
2 months	90 (47.6)	86 (48.6)	0.098 (0.792 - 1.213)	-1.00	0.853

† It was anticipated that a total of 454 cases or absentees were still smoking as they had been before.
§ The total number of instances, or patients who received treatment and were cured, was 336.

* RR (Relative Risk) was calculated with Chi-Square test

§ NRT denotes nicotine-replacement therapy

‡ Behavioral intervention was based on the WHO brief counseling package (5A 5R)

Table 5 describes that on the fourteenth day of treatment, 204 (44.93%) of the 454 participants (100%) who had begun treatment had quit smoking. On the first month, 218 (48.01%) of the participants had quit smoking, and on the second month, 176 (38.76%) had quit smoking. When compared to the counseling group, 108 (47.0%) quit smoking on day 14, 117 (50.9%) quit smoking during the first month, and 90 (39.1%) quit smoking during the second month. In the counseling group, 96 (42.9%) quit smoking on day 14, and 96 (42.9%) quit smoking during the first month. In the second month, 101 (45.1%) and 86 (38.4%) quit smoking respectively. When compared to the group that did not receive counseling, the counseling group had a success rate that was 1.135 times higher or 2.7 percent higher after the 14th day of treatment (p=0.467), 1.146 times higher or 2.8 percent higher after the first month (p=0.476), and 1.238 times higher or 7.3 percent higher after the second month of follow-up (p=0.079). There was no statistically significant difference between these results (Table 5).

Comparing only never-smokers in the groups that received and did not receive counseling, among the 366 participants who finished treatment, 185 (97.9%) in the counseling group at day 14, 181 (95.8%) at month 1, and 176 (95.8%) at month 2 93.1%), in the group that did not receive counseling, 169 (95.5%) quit smoking on the 14th day, 170 (96.0%) on the 1st month, and 155 (87.6%) on the In comparison to the non-advised group, the advised group had an effectiveness that was 1.025 times higher or 2.4 percent higher at the 14th day of treatment (p=0.197), 0.987 times higher or 2.04 percent higher at the first month (p=0.893), and 1.063 times lower or 5.5 percent lower (p=0.071) at the second month of follow-up (Table 5).

Adverse events

Table 6. Self-reported adverse events who receive NRT patch

Adverse symptoms	14 days (n=375)	1 month (n=366)	2 months (n=366)	P value
Cardiovascular system				
Changes in blood pressure	28 (7.7)	40 (10.9)	30(8.9)	0.049
Increased heart rate	30 (8.2)	34 (9.3)	19 (5.2)	0.095
Digestive system				
Dry mouth and gingivitis	53 (14.5)	39 (10.7)	28 (7.7)	0.012
Nausea	53 (14.5)	31 (8.5)	22 (6.0)	0.000
Heartburn	43 (11.7)	25 (6.8)	19 (5.2)	0.003
Change in the sense of smell and taste	32 (8.7)	21 (5.7)	16 (4.4)	0.045
Metabolism				
Increased appetite	129 (35.2)	116 (31.7)	70 (19.1)	0.000
Gain weight	63 (17.2)	80 (21.9)	58 (15.8)	0.088
Changes in the menstrual cycle	10 (2.7)	5 (1.4)	3 (0.8)	0.110
Respiratory system				
Coughing	60 (16.4)	30 (8.2)	36 (9.8)	0.001
Shortness of breath, chest rumbling	33 (9.0)	50 (5.5)	15 (4.1)	0.017
Psychiatric symptoms				

Desire to smoke	96 (26.2)	63 (17.2)	43 (11.7)	0.000
Changes in sleep pattern	63 (17.2)	52 (14.2)	25 (6.8)	0.000
Getting angry	58 (15.8)	49 (13.4)	39 (10.7)	0.118
Others				
Weakness and sweating	33 (9.0)	29 (7.9)	13 (3.6)	0.08
Blurred vision	26 (7.1)	20 (5.5)	9 (2.5)	0.014

Table 6 shows the 14th day and 1st month of treatment, increased cardiovascular pressure, increased heart rate, dry mouth, heartburn, nausea, and gastrointestinal disturbances; changes in the sense of taste; increased appetite from the metabolic side; weight gain; changes in the menstrual cycle in women; coughing, shortness of breath; chest tightness; and psychological side effects were observed among the study participants. On the other hand, smoking cravings, alterations in sleep patterns, angry outbursts, weakness, and perspiration were common symptoms, which tended to diminish after the second month of follow-up (Table 6).

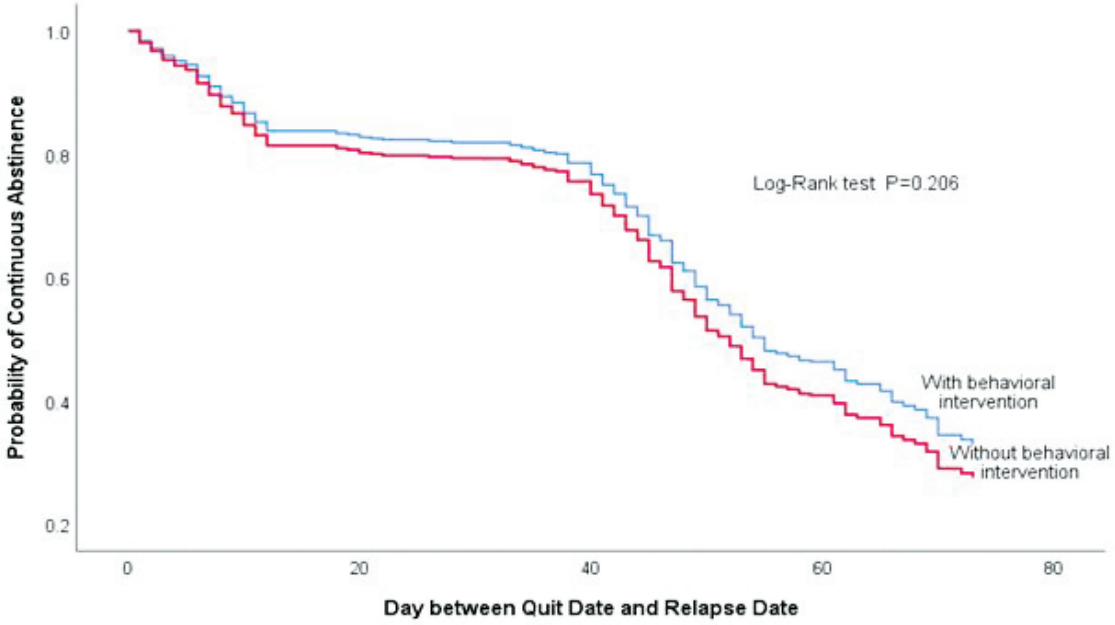

Figure 3. Kaplan-Meier Curve for Time to Relapse

Figure 2 shows that practically none of the participants in the study who were assigned to the NRT group quit on the quit date (Day 0). The number of days it takes to go back to smoking cigarettes on a regular basis (daily) was used as a measure of "time to relapse".

Table 7. Cox proportional hazard model regression results

Groups	Hazard ratio	95% CI		p value
		Lower	Upper	
With NRT+ behavioral intervention	0.861	0.68	1.089	0.212
NRT+Without behavioral intervention	1			

According to the log-rank test, individuals who received NRT+behavioral intervention had a longer median time before experiencing relapse compared to those who did not get behavioral intervention (P=0.206) (Figure 3), (Table 7). According to the results of the survival analysis, a higher level of adherence to the combination of NRT and behavioral intervention is more likely to aid in the process of quitting smoking than the group that did not receive behavioral intervention (HR 0.861).

Discussion

This study confirmed that the systematic review included 136 trials of NRT involving 64,640 people who wanted to quit smoking. According to this study, hospital patients who receive NRT are 1.4 times more likely than placebo groups to quit smoking. All kinds of NRT increased the likelihood that an individual's attempt to quit smoking would be successful. The likelihood of quitting increased by 50 to 60 percent. NRT is more effective with extra behavioral intervention [13]. Our intervention lasted four weeks for the NRT plus behavioral intervention, with a two-month follow-up. A 2006 meta-analysis of tobacco cessation interventions in adolescents concluded that pharmacotherapy trials were ineffective for maintaining abstinence after 6 months and advocated for more studies with a minimum duration of 6 months [18]. In our study, 360 (96.0%) of the respondents rated NRT treatment as effective, and 318 (84.8%) answered in accordance with the instructions. A total of 7521 adult participants aged 18 and up from 16 studies discovered that being adherent to NRT doubles the rate of successful quitting (OR = 2.17, 95% CI, 1.34-3.51), with a p-value of 0.001[14]. Significant effort was put into developing behavioral treatment techniques, testing these techniques with smokers in a variety of settings (group and individual sessions), and analyzing the effects of different treatment intensities before the advent of pharmacological interventions for smoking cessation [19].It appears that multi-pronged treatments (such as smoking bans in tandem with individual counseling) are more beneficial than single-pronged ones, and similar results have been seen when combining pharmacotherapy and nonpharmacologic intervention [20]. In our study's behavioral intervention group, when compared to the control group, the behavioral intervention group had a success rate that was 1.135 times higher (2.7 percent) after the 14th day of treatment (p=0.467), 1.146 times higher (2.8 percent) after the first month (p=0.476), and 1.238 times higher (7.3 percent) after the second month of follow-up (p=0.079). These results had no statistically significant difference. This was also consistent with the study, which found no significant difference in smoking rates between the intervention and control groups in a three-month study of the effectiveness of a WHO-5A-based comprehensive tobacco control program in workplaces with migrant workers [12]. When medication was not made available, there was strong evidence that individual counselling was more successful than a minimal contact control (short advise, routine care, or supply of self-help materials) [21]. In this study also found that gender was significantly different among NRT+behavioral intervention and without behavioral intervention. It is given that men and women use tobacco in different ways, it's crucial to think about how a person's sex can influence their ability to self-administer intravenous nicotine. Human research and national surveys of smoking behavior reveal sex differences are complex and may significantly affect susceptibility to initiate tobacco product use, development to dependence, and difficulties in successful cessation, despite the fact that men are more likely to smoke than women [22]. The study's advantage is that we used randomization provided by a random number generator developed by the project's statistical team. This study was representative of Ulaanbaatar's central six districts. Professional health social workers and psychiatric doctors from the district were on the ground collecting data. The study's limitations include (1) the fact that all participants in both groups received NRT treatment while those in the behavioral intervention groups were only assigned to one group, (2) the absence of urine and salivary analysis to confirm nicotine levels, and (3) the use of self-reported questionnaires to record all responses related to smoking cessation. (4) Since it was not possible to directly compare the pharmacological groups, a single-blind, single-arm study design was utilized. The last limitation of this study is the sample size. The sample size was relatively small, which may limit the generalizability of the findings to the broader population. A larger sample size would have allowed for more robust statistical analyses and may have provided more accurate and reliable results. Furthermore, a larger sample size would have allowed for the examination of subgroups within the population, which may be important for identifying potential differences in the relationships between variables.

Future research direction

Previous research has shown that individualized treatment plans that are tailored to an individual's specific needs and preferences may be more effective in promoting smoking cessation compared to one-size-fits-all interventions. Another potential direction for future research is to explore the use of technology-based interventions for nicotine behavior therapy. Recent advances in technology have created new opportunities for delivering smoking cessation interventions remotely, such as through smartphone apps, text messaging, and telehealth services. These interventions may be particularly useful for individuals who have difficulty accessing traditional in-person smoking cessation programs, such as those who live in rural areas or have mobility limitations. Finally, future studies could investigate the use of combination therapies for nicotine addiction, such as combining nicotine replacement therapy with behavioral interventions or pharmacotherapy. These combination therapies may be more effective in promoting long-term smoking cessation compared to single-mode interventions alone.

Conclusion

In conclusion, our study evaluated the effectiveness of WHO 5A and 5R brief counseling interventions for smoking cessation in adults in Mongolia who use the NRT patch. While the intervention group receiving the counseling showed a higher smoking cessation rate compared to the control group without the intervention, the difference was found to be statistically not significant.

Conflict of Interest

Pfizer USA has provided funding for this publication, and to our knowledge no conflicts of interest exist. As the designated corresponding author, I attest that all other authors have seen and agreed to the submission.

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