

# Evaluation of smoking cessation intervention in patients with chronic diseases in smoking cessation clinics

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## Abstract

This study aimed to evaluate the effects of psychological intervention and psychological plus drug intervention on smoking cessation among male smokers with single chronic diseases.

A total of 509 male smokers were divided into psychological group (n=290) and psychological plus drugs (n=219) groups according to their will. The physicians provided free individual counseling and follow-up interviews with brief counseling for all the subjects. In addition to mental intervention, patients in psychological plus drug group also received bupropion hydrochloride or varenicline tartrate to quit smoking. Outcomes were self-reported, regarding the 7-day point prevalence on abstinence rate and continuous abstinence rates at 1-, 3-, and 6-month follow-up period. Data analyses were performed using intention-to-treat analysis and per protocol analysis.

With regards to the 3 follow-up time points, 7-day point-prevalence abstinence rate in psychological plus drugs group was all higher than that in the psychological intervention group. Additionally, the 3-month continuous abstinence rate (21.4%) of the 6-month follow-up in the psychological group was not significantly higher than that (26.9%) in the psychological plus drugs group ( $P > .05$  for all). Fagerström test score, stage of quitting smoking, perceived confidence or difficulty in quitting, and chronic disease types were independently correlated with 3-month continuous abstinence in the 6-month follow up ( $P < .05$  for all). The results were similar between intentional analysis and protocol analysis.

The psychological intervention and psychological plus drugs intervention exerted good effects on smoking cessation in a short time (1 month). Nevertheless, the advantages did not appear during long-time (6 months) follow-up.

**Abbreviations:** 5A = ask, advise, assess, assist and arrange, 5R = relevance, risks, rewards, roadblocks and repetition, CI = confidence interval, ITT = intention-to-treat analysis, OR = odds ratio, PLA = people's liberation army, PP = per protocol analysis, SD = standard deviation.

**Keywords:** psychological intervention, psychological plus drug intervention, smoking cessation

## 1. Introduction

Tobacco dependence is a critical public hygiene problem around the world. The number of smokers in China accounts for one-

third of the global smoking population,<sup>[1]</sup> which brings about tremendous health hazard along with social economical burden. In recent 3 decades, the male smoking rate has always been high in China. The global tobacco survey (only China) indicates that Chinese male smoking rates were 57.4% and 52.9%, respectively in 2002 and 2010, that was to say, it decreased by <5% during the 8 years.<sup>[2,3]</sup> As a chronic addictive disease, tobacco dependence is so hard to quit that merely few smokers manage to quit smoking for the first time, nevertheless, majority of smokers experience relapse after smoking cessation.<sup>[4]</sup> The survey in some developed western countries like England and America demonstrates that doctors' professional smoking cessation guidance and treatment could effectively improve the success rate of smoking cessation. Particularly, the use of smoking cessation drugs during the intervention could obviously relieve cessation symptoms, additionally, it significantly improves the success rate of smoking cessation.<sup>[5-7]</sup>

In October 2008, China PLA General Hospital established the first smoking cessation clinic to provide correlated services regularly. This study aimed to evaluate the effects of psychological intervention and psychological plus drugs intervention on smoking cessation by assaying the characteristics of smokers with tobacco-related chronic diseases that visited our smoking cessation clinic voluntarily. The gender differences on smoking cessation remained unclear,<sup>[8]</sup> thus only the male smokers were collected in this study to reduce the potential confusing factors. It

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also offered relevant fundamental data in order to enhance the success rate of smoking cessation and implement tobacco intervention together with service modes specialized in treating smokers with chronic diseases.

## 2. Materials and methods

### 2.1. Subjects

The subjects of this study were required to satisfy the following criteria: male patients spontaneously visited the smoking cessation clinic in China PLA General Hospital from October 2008 to August 2013; they were with tobacco-related chronic diseases and willingness to accept follow-up investigations; all of them were diagnosed with single chronic disease; the written informed consent was signed by each case. During the study period, a total of 509 eligible cases visited our hospital who were recruited in our investigations. The study was approved by the Ethic Committee of China PLA General Hospital.

## 3. Methods

### 3.1. Grouping

A total of 509 patients were included in our study. According to the patients' will, they were divided into 2 groups: psychological intervention group and psychological + drugs intervention group. After smoking cessation, physicians treated each patient with psychological intervention, physicians advised those patients failing to quit smoking for many times to take smoking cessation drugs in order to assist stopping smoking, and patients can make voluntary decision. On the basis of drugs' utility stated by patients themselves when receiving telephone follow-up, we divided patients into the psychological plus drugs intervention group and the pure psychological intervention group. Physicians prescribed medicine in the first diagnosis for patients, but as for patients declining to take drugs ultimately, they belonged to the psychological intervention group.

### 3.2. Psychological intervention group

In terms of the psychological intervention group, the physicians in smoking cessation clinics needed to receive professional smoking control training then attended specific tests. When going on the first smoking cessation diagnosis, those physicians who passed the examination treated patients with mental guidance including 5A, 5R, and intervention. 5A referred to asking (to understand whether patients were smoking or not), advice (to strengthen patients' awareness to quit smoking), assessment (to confirm patients' willingness to cease smoking), assistance (to assist patients to give up smoking) as well as arrangement (to arrange follow-up after the first diagnosis for patients then continue to go on tobacco cessation intervention).<sup>[9]</sup> At the same time, smoking cessation physicians were required to give answers to those questions raised by patients who intended to cease smoking, explain conscious misunderstandings, supply individual smoking cessation suggestions to patients, and assist patients intending to stop smoking to conquer psychological as well as psychological tobacco dependence.

After the first diagnosis, telephone visitors who had received professional smoking control training were demanded to launch 3 times follow-up including 1-, 3-, and 6-month follow-up. Telephone interviewers needed to give calls to patients and fill in the elaborate follow-up questionnaires by inquiring patients; in addition, they supervised smokers to quit smoking, answered

questions, and provided patients with mental support as well as assistance. Missing follow-up was defined as at least 7 times failure to contact patients by telephone at each time point. More importantly, some persons were arranged to inspect the quality of telephone follow-up. Five percent of questionnaires were taken out per month in order to verify their authenticity and accuracy.

### 3.3. Psychological + drug intervention group

Patients in the psychological + drug intervention group took either bupropion hydrochloride or varenicline tartrate to give up smoking. Those with previous known psychiatric disease or epilepsy would be excluded from the study. The patients were informed the possible side effects of each drug, and they could choose the drugs willingly. Bupropion hydrochloride (sustained release) 150 mg once a day was the standard treatment for smoking cessation. Varenicline tartrate was administrated a dose of 5 mg (2 times daily). The side effects caused by drugs were estimated by a question.

As regards psychological together with the drug intervention group, the mental intervention of first diagnosis and follow-up in the psychological plus drug intervention group was the same with that in the psychological intervention group. In 1-, 3-, and 6-month follow-up, 7-day point-smoking cessation<sup>[10]</sup> was defined as self-statement at least 7-day smoking cessation during of 1-, 3-, and 6-month follow-up. In 3- and 6-month follow-up, 1-month continuous abstinence<sup>[10]</sup> was considered as self-statement of at least 1 month smoking cessation during 3- and 6-month follow-up. In the 6-month follow-up, 3-month continuous abstinence was regarded as self-statement of at least 3 months smoking cessation during of the 6-month follow-up. MicroCO (PARI GmbH, Germany) was used to test carbon monoxide and MicroCO would demonstrate figures, moreover we should test the carbon monoxide content of subjects quantitatively. F score was obtained in accordance with nicotine dependence,<sup>[10]</sup> additionally, 0–3 point indicated low nicotine dependence, 4–5 point was on behalf of moderate dependence of nicotine, and 6–10 point represented high dependence of nicotine.

### 3.4. Statistical analysis

The database was established by Epidata software and 2 technical clerks inputted data to the software system. The system would check automatically and correct comparatively. SPSS 19.0 software was applied for statistical analysis. The continuous data were presented as mean  $\pm$  standard deviation (SD), and compared with the Student's *t* test. The  $\chi^2$  test was performed for the categorical data. The crude odd ratio (OR) with corresponding 95% confidence interval (CI) was calculated using  $\chi^2$  test, while adjusted OR was calculated by logistic regression analysis after adjusting to the demographic characteristics and tobacco-related factors. Excel software was utilized to draw quit rate graph. The abstinence rate analysis was conducted using 2 methods intention-to-treat analysis (ITT, missing interviewees were regarded as smokers) and per protocol analysis (PP, 6-months missing interviewees were eliminated).  $P < .05$  was considered statistically significant.

## 4. Results

### 4.1. General information of subjects

Among the 509 patients, 31.2% of smokers were with cardio cerebral vascular disease, 23.9% with respiratory disease, and

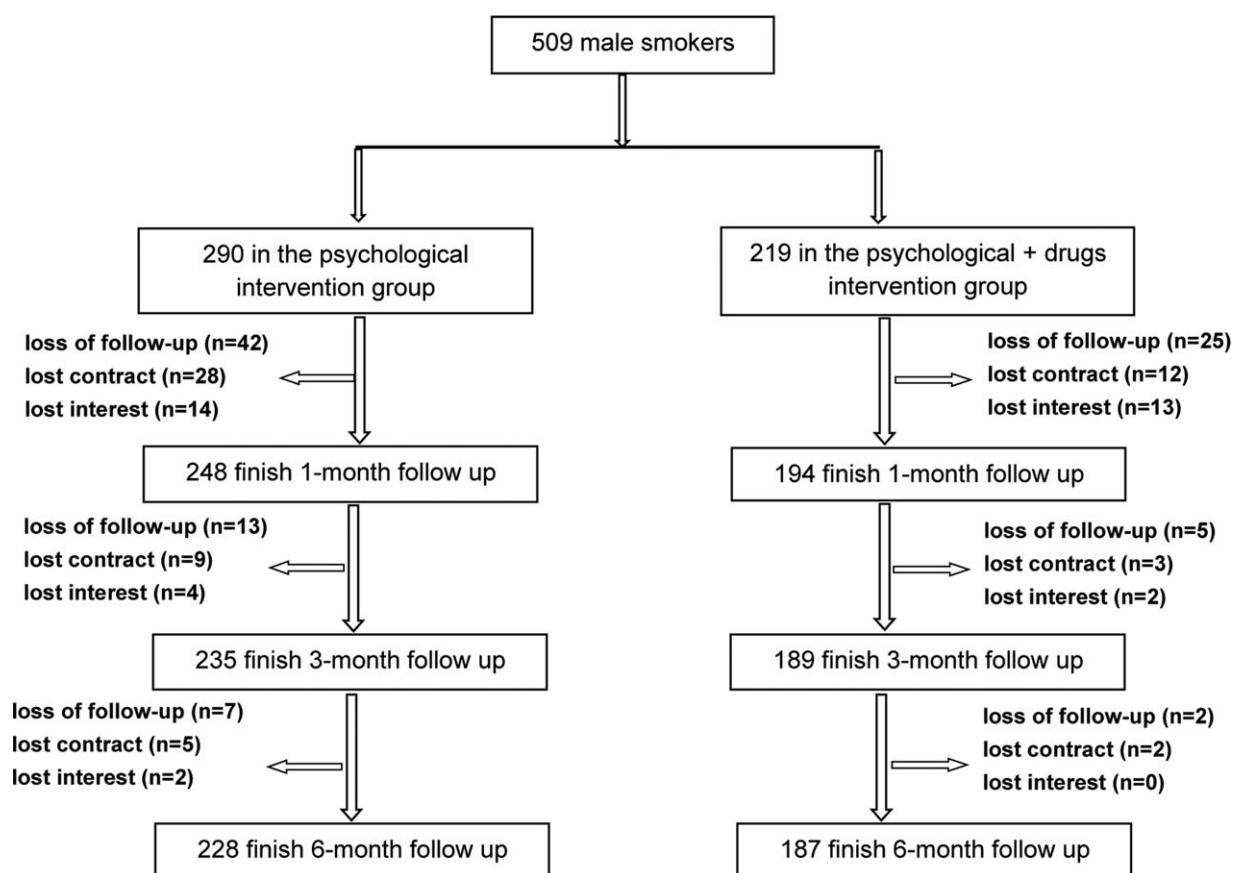


Figure 1. The flowchart of smoking cessation intervention grouping and follow-up.

remaining smokers suffered from other chronic diseases like diabetes and chronic diseases of digestive system. Besides, 290 cases were included in the psychological intervention group and 219 cases in the psychological + drugs intervention group. In the meanwhile, there were 63 smokers (28.8%) in the psychological plus drugs intervention group taking bupropion hydrochloride to quit smoking, while 156 cases (71.2%) took varenicline tartrate. There were 94 patients in the 2 groups failing to accomplish the follow-up, the rate of which reached 18.7%, including 62 patients in the psychological intervention group and 32 patients in the psychological plus drugs intervention group (Fig. 1). By statistical analyses, we found that each demographic characteristics as well as tobacco-related factors between missing interviewees and successful interviewees had statistical significance.

Moreover, patients in the psychological intervention group and the psychological plus drugs intervention group were mainly middle-aged persons with 43 years of age averagely. Most of them were married, had stable jobs with high salary, and received higher education (at least junior college). It was so common that patients were with large amount of cigarettes (>20 cigs/day) and high dependence of nicotine. More than half of the patients had been smoking for >20 years; at the same time, they had made several prior attempts to quit smoking. Additionally, more than half of the patients were advised to cease smoking by other medical workers. The perceived importance, difficulty as well as confidence in abstinence from smoking were scored by smokers themselves: 86, 73, and 67 scores, respectively (Table 1). As for

the 2 groups, they had statistical significance in occupation, Fagerström test score, status of giving up smoking, self-evaluation of importance, and difficulty in quitting smoking.

#### 4.2. Results of intentional analysis

The quit rate of male patients with chronic diseases between the psychological intervention group and the psychological plus drugs intervention group in the smoking cessation clinics (intentional analysis) is shown in Table 2. As to 1-, 3-, and 6-month follow-up in the psychological intervention group, 7-day point-prevalence abstinence rate was 22.4%, 25.5%, and 26.6%, respectively, which was lower than that in the psychological plus drugs intervention group with 32.4%, 30.1%, and 30.1%, respectively. The crude and adjusted OR (95%CI) of all the factors illustrated that the 7-day point-prevalence abstinence rate of the 1-month follow-up in the psychological plus drugs intervention group was significantly higher than that in the psychological intervention group meanwhile OR (95%CI) was 1.66 (1.12–2.47) and 2.05 (1.31–3.21), respectively. The 1-month continuous abstinence rate of 3- and 6-month follow-up in the psychological intervention group was 20.0% and 25.2%, respectively, which was lower than that in psychological plus drugs intervention group with 28.3% and 28.8%, respectively; nevertheless, the statistical significance only existed in the 1-month continuous abstinence rate of the 3-month follow-up in the 2 groups. Additionally, the 3-month continuous abstinence rate (21.4%)

**Table 1****Demographic characteristics and tobacco-related factors of 509 male smokers in 2 groups.**

	Psychological intervention (N=290)	Psychological +drug intervention (N=219)	P value
Demographic characteristics			
Age, mean (SD), years	43.7 (11.5)	42.4 (9.5)	.160
Age, years, number, %	N (%)	N (%)	
<31	37 (12.8)	21 (9.6)	.105
31–40	77 (26.6)	73 (33.3)	
41–50	97 (33.4)	81 (37.0)	
>50	79 (27.2)	44 (20.1)	
Marital status			
Married	259 (89.3)	196 (89.5)	.946
Single or divorced	31 (10.7)	23 (10.5)	
Education			
College and above	167 (57.6)	127 (58.0)	.927
High school and below	123 (42.4)	92 (42.0)	
Occupation			
Currently employed	218 (75.2)	183 (83.6)	.022
Student/unemployed/retired/others	72 (24.8)	36 (16.4)	
Family income per month (Yuan, USD 1=6 Yuan)			
<3000	106 (36.6)	69 (31.5)	.389
3000–6000	78 (26.9)	58 (26.5)	
>6000	106 (36.6)	92 (42.0)	
Chronic diseases			.353
Cardio cerebral vascular disease	97 (33.4)	62 (28.3)	
Respiratory disease	64 (22.1)	58 (26.5)	
Other chronic diseases	129 (44.5)	99 (45.2)	
Tobacco related factors			
Cigarettes smoked on average daily, cig/day			
≥20	181 (62.4)	148 (67.6)	.293
10–19	77 (26.6)	55 (25.1)	
<10	32 (11.0)	16 (7.3)	
Smoking duration, years			
<20	103 (35.5)	72 (32.9)	.535
≥20	187 (64.5)	147 (67.1)	
Prior attempts to quit smoking			
0	66 (22.8)	36 (16.4)	.078
≥1	224 (77.2)	183 (83.6)	
Fagerström test score			
Severe (6–10)	139 (47.9)	134 (61.2)	.010
Moderate (4–5)	63 (21.7)	39 (17.8)	
Low (0–3)	88 (30.3)	46 (21.0)	
Stage of quitting smoking			
Contemplation	74 (25.5)	33 (15.1)	.014
Preparation	102 (35.2)	83 (37.9)	
Action	114 (39.3)	103 (47.0)	
Expenditure on cigarettes per day, Yuan (mean:20)			
<20	132 (45.5)	101 (46.1)	.893
≥20	158 (54.5)	118 (53.9)	
Perceived health status at the first visit			
Fair/poor/very poor	220 (75.9)	178 (81.3)	.143
Very good/good	70 (24.1)	41 (18.7)	
Number of other smokers in household			
0	239 (82.4)	179 (81.7)	.843
≥1	51 (17.6)	40 (18.3)	
Medical advice to quit	161 (55.5)	123 (56.2)	.884
Current drinkers	197 (67.9)	143 (65.3)	.532
Exhaled CO level at first visit (ppm)	11.4±7.5	12.7±8.6	.063
Perceived importance of quitting (score)	85.3±18.5	89.7±14.3	.004
Perceived difficulty in quitting (score)	72.5±23.8	81.7±18.8	<.001
Perceived confidence in quitting (score)	68.1±24.0	70.2±24.1	.333

CI=confidence interval, CO=carbon monoxide, OR=odds ratio, SD=standard deviation.

of the 6-month follow-up in the psychological intervention group was not higher than that (26.9%) in the psychological plus drugs intervention group; however, the difference between the 2 groups had no statistical significance.

Intentionally analysis of 1-, 3-, 6-month-follow-up continuous abstinence rate is demonstrated in Fig. 2. With regards to the 3 follow-up time points, the 7-day point-prevalence abstinence rate in the psychological plus drugs intervention group was all higher

**Table 2**

**By intention-to-treat, quit rates of 2 groups at 1-, 3-, and 6-month follow-up in 509 male smokers.**

	Psychological intervention (N=290)	Psychological +drug intervention (N=219)	Crude OR (95%CI)	P value	Adjusted OR (95%CI)	P value
1-month follow-up						
7-day point-prevalence abstinence rate	65 (22.4)	71 (32.4)	1.66 (1.12–2.47)	.012	2.05 (1.31–3.21)	.002
3-month follow-up						
7-day point-prevalence abstinence rate	74 (25.5)	66 (30.1)	1.26 (0.85–1.86)	.248	1.08 (0.80–1.46)	.628
1-month continuous abstinence	58 (20.0)	62 (28.3)	1.58 (1.05–2.38)	.029	0.95 (0.69–1.30)	.744
6-month follow-up						
7-day point-prevalence abstinence rate	77 (26.6)	66 (30.1)	1.19 (0.81–1.76)	.373	1.18 (0.87–1.59)	.294
1-month continuous abstinence	73 (25.2)	63 (28.8)	1.20 (0.81–1.78)	.364	1.21 (0.89–1.65)	.225
3-month continuous abstinence	62 (21.4)	59 (26.9)	1.36 (0.90–2.04)	.145	1.19 (0.86–1.63)	.291

Adjusted OR: adjusted to the demographic characteristics and tobacco-related factors summarized in Table 1. CI=confidence interval, OR=odds ratio.

than that in the psychological intervention group. The abstinence from smoking rate of the psychological plus drugs intervention group decreased a bit during the 3-month follow-up, but the rate maintained at about 30%. The time point-prevalence abstinence rate of the psychological intervention group increased a bit, varying from 22.4% in the 1-month follow-up to 25.5% in the 3-month follow-up and 26.6% in the 6-month follow-up (Fig. 2). Besides, the multivariate analysis was performed to analyze the influence factor that affects the 3-month continuous abstinence in the 6-month follow-up among the study population. The results showed high Fagerström test score (OR=2.17, 95%CI=1.63–3.12, P=.006) and perceived difficulty in quitting (OR=1.78, 95%CI=1.23–2.65, P=.008). Compared with patients with the contemplation stage of quitting smoking, the patients with preparation (OR=0.71, 95%CI=0.32–0.92, P=.020) and action stages (OR=0.53, 95%CI=0.21–0.91, P=.012) were more likely to quit smoking. In addition, the smoking cessation was high among patients with perceived confidence in quitting (OR=0.52, 95%CI=0.32–0.88, P=.007), cardiocerebral vascular disease (OR=0.62, 95%CI=0.12–0.88, P=.026), and respiratory disease (OR=0.89, 95%CI=0.21–0.96, P=.035) (Table 3).

**4.3. Results of PP analysis**

PP analysis referring to quit rate of male patients with chronic diseases between psychological intervention group and psychological plus drugs intervention group in the smoking cessation clinics is explained in Tables 4 and 5 and Fig. 3. We could draw

the conclusion that the results of PP analysis were similar with that of ITT analysis.

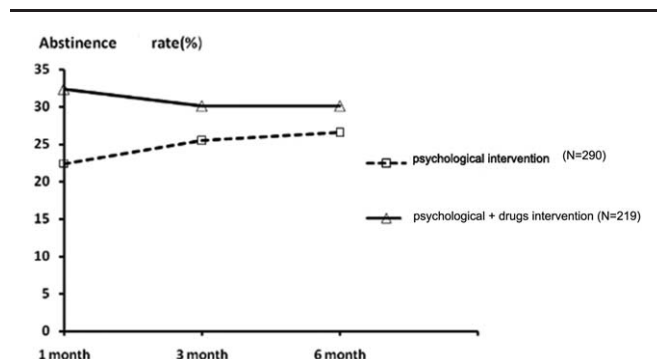
**4.4. Adverse effect of drugs**

During the whole observation period, using the auxiliary smoking cessation drugs (bupropion and varenicline) was safe and well tolerated. In 17.8% (39/219) adverse reaction occurred, the most common including gastrointestinal disorders (12.2%), nervous system disorders (2.3%), mental disorders (2.3%), and cardiovascular system disorders (1%).

**5. Discussion**

Our study was the first domestic research based on the reality and facts. It assessed the effects of psychological intervention and psychological + drugs intervention on smoking cessation among male smokers with chronic diseases.<sup>[11–17]</sup> It was characterized by standard intervention as well as appropriate intervention time; what’s more, the number of samples in this study was much larger than that in other domestic studies.<sup>[18–20]</sup> Compared with other overseas smoking cessation clinics, there were more middle-aged persons in our clinic and score of nicotine dependence was much higher.<sup>[21,22]</sup> Our study also reflected that more and more patients with chronic diseases were willing to visit smoking cessation clinics to focus on their health due to their elder age and influences of chronic diseases.

The psychological + drugs intervention was adopted in our study, fortunately it exerted good effects on smoking cessation in



**Figure 2.** It showed quit rates of 2 groups at 1-, 3-, and 6-month follow-up by intention-to-treat analysis.

**Table 3**

**Multivariate analysis of factors to 3-month continuous abstinence in the 6-month follow-up (ITT).**

Factors	OR (95%CI)	P value
Fagerström test score	2.17 (1.65–3.12)	.006
Stage of quitting smoking (compared with contemplation)	–	–
Action	0.53 (0.21–0.91)	.012
Preparation	0.71 (0.32–0.92)	.020
Perceived confidence in quitting	0.52 (0.32–0.88)	.007
Perceived difficulty in quitting	1.78 (1.23–2.65)	.008
Chronic disease (compared with other disease)	–	–
Cardio cerebral vascular disease	0.62 (0.12–0.88)	.026
respiratory disease	0.89 (0.21–0.96)	.035

CI=confidence interval, ITT=intention-to-treat analysis; OR=odds ratio.



**Table 4**

By per protocol analysis, quit rates of 2 groups at 1-, 3-, and 6-month follow-up in 415 male smokers.

	Psychological intervention (N=228)	Psychological +drug intervention (N=187)	Crude OR (95%CI)	P value	Adjusted OR (95%CI)	P value
1-month follow-up						
7-day point-prevalence abstinence rate	65 (28.5)	71 (38.0)	1.54 (1.02–2.32)	.042	1.85 (1.15–2.98)	.011
3-month follow-up						
7-day point-prevalence abstinence rate	74 (32.5)	66 (35.3)	1.14 (0.76–1.71)	.543	1.32 (0.83–2.11)	.237
1-month continuous abstinence	58 (25.4)	62 (33.2)	1.45 (0.95–2.23)	.085	1.73 (1.06–2.82)	.028
6-month follow-up						
7-day point-prevalence abstinence rate	77 (33.8)	66 (35.3)	1.07 (0.71–1.61)	.745	1.26 (0.79–2.01)	.331
1-month continuous abstinence	73 (32.0)	63 (33.7)	1.08 (0.72–1.63)	.718	1.25 (0.78–2.00)	.359
3-month continuous abstinence	62 (27.2)	59 (31.6)	1.23 (0.81–1.89)	.331	1.36 (0.83–2.21)	.220

Adjusted OR: adjusted to the demographic characteristics and tobacco-related factors summarized in Table 1. CI=confidence interval, OR=odds ratio.

**Table 5**

Multivariate analysis of factors to 3 month continuous abstinence in the 6-month follow-up (PP).

Factors	OR (95%CI)	P value
Fagerström test score	2.35 (2.48–3.55)	.008
Stage of quitting smoking (compared with contemplation)	–	–
Action	0.60 (0.18–0.87)	.015
Preparation	0.78 (0.26–0.94)	.031
Perceived confidence in quitting	0.55 (0.24–0.91)	.010
Perceived difficulty in quitting	1.85 (1.38–2.73)	.009
Chronic disease (compared with other diseases)	–	–
Cardio cerebral vascular disease	0.71 (0.25–0.89)	.018
respiratory disease	0.91 (0.48–0.99)	.041

CI=confidence interval, OR=odds ratio, PP=per protocol analysis.

short time (1 month). Nevertheless, by long time (6 months) follow-up, we found that although abstinence rate of the psychological + drugs intervention group was significantly higher than that in the psychological intervention group, the discrepancy between the 2 groups had no statistical significance. We also found that 47.6% of patients reported that they took smoking cessation drugs for <4 weeks and 40.2% of patients just for 4–8 weeks, which possibly resulted from drug compliance together with side effects. Consequently, quit smoking rates were not able to sustain for long time because patients could not take smoking

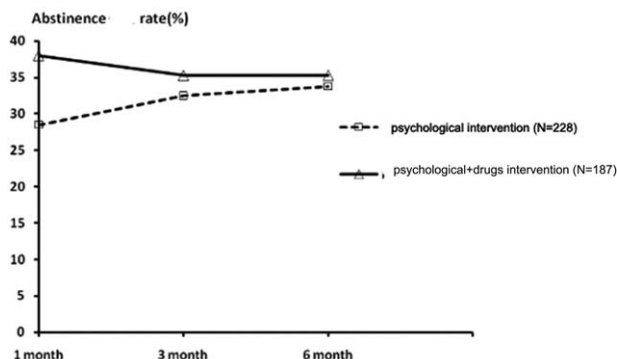
cessation drugs with a full treatment course. In addition, patients in the psychological group had stronger motivation on smoking quitting and have better adherence. From the results summarized in Table 1, we found that the score for the perceived difficulty in quitting was significantly higher in psychological + drugs groups. Multivariate analysis demonstrated that the score for perceived difficulty in quitting was an independent biomarker for 3-month continuous abstinence during the 6-month follow up. Thus, the unreasonable grouping might introduce the bias to the final results.

In addition, there were several limitations in our study. First of all, the rate of missing interviewees was a bit high (18.7%), however, compared with similar studies domestically and abroad, 18.7% was in the normal scale. The difference of demographic characteristics and tobacco-related factors between lost interviewees and successful interviewees with the 6-month follow-up, which indicated that lost follow-up had few impacts on results of analysis. Secondly, we applied telephone follow-up in statistical analysis, therefore, measurement bias would exist to some extent when patients stated quit smoking rate themselves. Finally, two-thirds of the patients in our clinic were not local residents so merely 30 cases were treated with carbon monoxide blowing test as well as salivary cotinine test, the results of which demonstrated that only 1 smoker failed to abstain from smoking.

In conclusion, our results showed that the drugs combined psychological intervention is better than pure psychological intervention in smoking cessation in a short time. Thus, in clinical smoking cessation should provide appropriate intervention method and auxiliary drugs according to patients' actual demand. Our study may provide related basic data for a scientific and effective clinical smoking cessation study, but further research is needed to confirm our results.

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**Figure 3.** Quit rates of 2 groups at 1-, 3-, and 6-month follow-up, by complete case (per protocol) analysis.

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