

Addition of one session with a specialist counselor did not increase efficacy of a family physician-led smoking cessation program

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Abstract

Objective: Higher-intensity counseling sessions increase the smoking abstinence rate. However, counselors are limited in Taiwan. This study was performed to determine whether the addition of one session with a specialist counselor increases the efficacy of a family physician-led smoking cessation program.

Methods: Participants opted to either visit a family physician for brief counseling and pharmacotherapy (Po) or visit a specialist counselor for an initial session followed by a family physician for brief counseling sessions with pharmacotherapy (P+). The 7-day point prevalence (PP) rate was evaluated at weeks 12 and 24.

Results: In total, 356 patients were enrolled. In the intention-to-treat analysis, the PP rate at week 12 was higher in the Po than P+ group, but there was no significant difference at week 24. In the per-protocol analysis, the PP rates at weeks 12 and 24 were not significantly different between the Po and P+ groups. The adjusted odds ratios also revealed no significant differences in either the intention-to-treat analysis or the per-protocol analysis between the two groups.

Conclusion: The addition of one session with a specialist counselor had no benefit over the provision of counseling through a family physician at either 12 or 24 weeks of follow-up.

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Keywords

Smoking cessation, physician's brief counseling, specialist counseling, family physician, prospective study, intention-to-treat analysis, per-protocol analysis

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Introduction

Smoking is associated with an increased risk of multiple cancers, heart disease, stroke, pregnancy complications, chronic obstructive pulmonary disease, and several other diseases.¹ In many countries, tobacco-related diseases are the leading cause of preventable death and account for an estimated one in every five deaths.² Aside from primary prevention, smoking cessation is the most effective intervention to reduce the risk of premature death and disability among people who smoke. The guidelines set by the United States Public Health Service (USPHS) recommend the combination of counseling and medication as a more effective approach than medication alone.³

Although direct interaction between physicians and patients is limited, the provision of brief advice from a physician is known to be effective; however, it may be suboptimal.⁴ Several articles have shown that who provides support might influence differences in quitting rates; additionally, the occupations of people undergoing smoking cessation might affect smoking abstinence.⁵⁻¹⁰ Research from the UK also suggested that specialist advisors are superior to practitioners who provide counseling alongside other roles in both short- and long-term follow-up.⁵⁻⁸ Face-to-face contact with a professional counselor is thought to be effective in enhancing smokers' behavioral changes.¹¹ Professional counseling for smoking cessation has therefore been integrated into the health care

system.¹² However, the most common and available intervention for smoking cessation in Taiwan is counseling with a physician. Most patients in Taiwan only receive behavioral counseling during a physician's visit with concurrent pharmacotherapy because of limited resources for multiple counseling sessions with a counselor.

The Taiwanese government began to fund smoking cessation services in 2002. Patients who wanted to quit smoking could receive medication and counseling assistance from a certified doctor. This counseling is more intensive than the typical advice provided by a physician because the physicians who provide this counseling are required to attend a government-sponsored 7-hour program that provides training for conducting these sessions. The training reviews smoking risks, smoking cessation benefits, 5As guidelines (ask, advise, assess, assist, arrange), counseling skills, pharmacotherapy, social support, and relapse prevention. Because behavioral support from a specialist counselor is less available in Taiwan, we propose the following strategy: a specialist counselor provides counseling for about 30 minutes at the first visit, and then a well-trained family physician continues with subsequent follow-up counseling sessions of about 10 minutes every visit in combination with pharmacotherapy. We investigated whether this strategy is more effective than sole counseling sessions with a family physician. If the efficacy was superior, one additional session with a specialist counselor might be necessary. To the best of our knowledge,

no other studies have compared these two models of counseling when combined with pharmacotherapy.

Methods

Study design

This was a prospective observational study conducted in an outpatient clinic.

Participants and inclusion and exclusion criteria

We enrolled all participants from among those who visited family physicians in the special smoking cessation outpatient department of National Taiwan University Hospital from 1 October 2012 to 30 September 2014. All participants had visited the family physicians by themselves without referral. Each participant provided written informed consent prior to enrollment in this study. The inclusion criteria were an age of ≥ 18 years and either a smoking habit of at least 10 cigarettes per day or a Fagerström score¹³ of ≥ 4 points. Each participant agreed to receive pharmacotherapy in addition to behavioral counseling. The exclusion criteria were pregnant or breastfeeding women and declining to receive follow-up telephone calls.

The study protocol was approved by the institutional review board of National Taiwan University Hospital.

Interventions

Patients chose to either visit a family physician for brief counseling sessions every 2 to 4 weeks with concurrent pharmacotherapy (physician's brief counseling group, Po) during an 8-week treatment course or receive counseling from a specialist counselor for an initial visit and then follow up with a family physician for brief counseling sessions with concurrent pharmacotherapy

(add-on professional counseling group, P+). The session with the counselor was approximately 30 minutes. The subject matter of the counseling followed the USPHS guidelines and included discussing the damage that is caused by smoking and the benefits of smoking cessation, setting a quit date, managing withdrawal symptoms, identifying supportive resources, adopting an appropriate diet and exercise regimen, and preventing relapse. The specialist counselor was a certified specialist nurse whose main role was to provide smoking cessation support, had completed a 48-hour training program, and had received a certificate from the Health Promotion Administration (HPA) of the Taiwanese government. The whole program was performed by the same specialist counselor. The brief counseling sessions, which were provided by five male family physicians, lasted approximately 10 minutes per visit. The subject matter of the counseling was a condensed version of that with the specialist counselor. All physicians underwent a 7-hour training course and received certificates from the HPA of Taiwan.

Pharmacotherapy included nicotine replacement therapy and varenicline. The physicians explained the benefits and disadvantages of each medication to the patients, and the patients then chose the medication based on their preference. The standard treatment duration was 8 weeks; the prescriptions that were provided lasted for 2 weeks in principle but could be extended to 4 weeks upon patient request.

Outcome measures

A well-trained staff member at the National Taiwan University Hospital called the patients at weeks 12 and 24. If a patient reported no smoking during the previous 7 days, the smoker was considered to have quit. According to the USPHS guidelines, the 7-day point-prevalence (PP), rather

than continuous abstinence, was used as the chief outcome variable.³ The PP rates were calculated by intention-to-treat analysis (patients lost to follow-up were classified as smokers) and per-protocol analysis (patients lost to follow-up were excluded from the analysis).

Statistical analysis

We examined differences in categorical variables using the chi-square test, whereas continuous variables were analyzed by the independent Student's *t* test. An odds ratio (OR) of >1 denoted a favorable effect of the add-on professional counseling, and a 95% confidence interval (CI) not including a value of 1 was considered statistically significant. To adjust for possible confounding factors such as sex, body mass index (BMI), comorbidities, Fagerström score, duration of smoking, number of outpatient visits, and medications, we calculated adjusted ORs using multivariate logistic regression models. According to reports from the HPA, the abstinence rate in the physician counseling group was approximately 30%. We considered a 15% increase in the abstinence rate a clinically meaningful

difference. To detect this difference with a type I error of <0.05 and a type II error of <20%, the sample size required in this study was 352.

Results

In total, 453 patients were recruited during the study period. We excluded 95 patients because they declined pharmacotherapy and 2 patients because they had missing counseling data. Among the 356 included patients, 159 were in the Po group and 197 were in the P+ group (Figure 1); this sample size achieved the goal of the study design.

The patients' baseline characteristics are listed in Table 1. In the Po group, most of the patients were male (86.2%) and middle-aged (mean age, 48 years); the average BMI was 24.5 kg/m². A total of 64 (46%) patients had comorbidities, including diabetes, hypertension, heart disease, chronic kidney disease, chronic obstructive lung disease, cancer, and cardiovascular disease. With respect to the preferred pharmacotherapy, 76 (47.8%) patients chose nicotine replacement therapy. The mean duration of

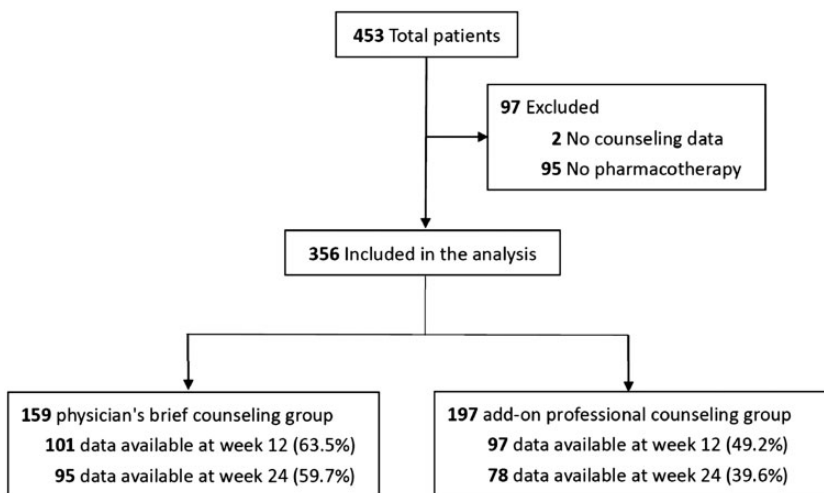


Figure 1. Flow diagram of study participants.

Table 1. Baseline characteristics of participants in the two study groups

	Physician's brief counseling N = 159	Add-on professional counseling N = 197	P value
Age, years	48.0 ± 13.0	48.8 ± 12.2	0.53
Male sex	137 (86.2%)	167 (85.6%)	0.89
Body mass index, kg/m ²	24.5 ± 4.4	25.0 ± 4.1	0.42
Comorbidity	64 (46.0%)	61 (31.1%)	0.005
Duration of smoking, years	25.8 ± 12.4	27.0 ± 12.5	0.40
Medications			0.84
Nicotine replacement therapy	76 (47.8%)	92 (46.7%)	
Varenicline	83 (52.2%)	105 (53.3%)	
Fagerström score	6.3 ± 2.2	6.2 ± 2.3	0.52
Number of outpatient visits	2.7 ± 1.7	2.1 ± 1.2	0.001

Data are presented as mean ± standard deviation or n (%).

smoking was 25.8 years, the mean Fagerström score was 6.3, and the mean number of outpatient visits was 2.7. The baseline characteristics of the patients in the P+ group were similar to those of the patients in the Po group, and there were no significant differences except for a lower comorbidity rate (31.1% vs. 46.0%, *P* = 0.005) and fewer outpatient visits (2.1 vs. 2.7, *P* = 0.001) in the P+ group.

In the intention-to-treat analysis, the 7-day PP rate at week 12 was higher in the Po than P+ group (24.5% vs. 15.2%, respectively; OR, 0.55; 95% CI, 0.33–0.99). However, the difference in the 7-day PP rate at week 24 was not statistically significant (21.4% vs. 14.2%, respectively; OR, 0.61; 95% CI, 0.35–1.06). After adjusting for age, sex, BMI, comorbidities, Fagerström score, duration of smoking, number of outpatient visits, and medications, there was no statistically significant difference between the two study groups (week 12: adjusted OR, 0.56; 95% CI, 0.25–1.29; week 24: adjusted OR, 0.61; 95% CI, 0.24–1.54) (Table 2).

In the per-protocol analysis, there was no statistically significant difference in the 7-day PP rate at week 12 between the Po and P+ groups (38.6% vs. 30.9%,

respectively; OR, 0.71; 95% CI, 0.40–1.28), and a similar finding was observed at week 24 (35.8% vs. 35.9%, respectively; OR, 1.00; 95% CI, 0.54–1.88). After adjusting for the same variables described in the intention-to-treat analysis, there was still no statistically significant difference between the two groups (week 12: adjusted OR, 0.72; 95% CI, 0.29–1.76; week 24: adjusted OR, 0.91; 95% CI, 0.33–2.51) (Table 2).

Discussion

To the best of our knowledge, this is the first study to compare one session with a specialist counselor followed by brief counseling sessions with a family physician versus sole counseling with a family physician in patients administered pharmacotherapy. We found no statistically significant differences in the abstinence rates between the two study groups at either the 12-week or 24-week follow-up. The sample size achieved the goal of the study design but may not have been large enough to detect small differences between the study groups.

In one study, the long-term quit rate of smokers who quit by themselves was approximately 3%,⁶ which is particularly lower than the rate in both groups of our

Table 2. Seven-day point prevalence rates of the two study groups

Time of follow-up	Physician's brief counseling	Add-on professional counseling	OR (95% CI)	Adjusted OR ^a (95% CI)
Intention-to-treat analysis				
12 weeks	(N = 159) 39 (24.5%)	(N = 197) 30 (15.2%)	0.55 (0.33–0.99)	0.56 (0.25–1.29)
24 weeks	(N = 159) 34 (21.4%)	(N = 197) 28 (14.2%)	0.61 (0.35–1.06)	0.61 (0.24–1.54)
Per-protocol analysis				
12 weeks	(N = 101) 39 (38.6%)	(N = 97) 30 (30.9%)	0.71 (0.40–1.28)	0.72 (0.29–1.76)
24 weeks	(N = 95) 34 (35.8%)	(N = 78) 28 (35.9%)	1.00 (0.54–1.88)	0.91 (0.33–2.51)

Data are presented as n (%) of patients with characteristic unless otherwise indicated.

^aAdjusted for age, sex, body mass index, comorbidity, Fagerström score, duration of smoking, number of outpatient visits, and medications.

OR, odds ratio; CI, confidence interval.

study. Intervention consisting of brief advice increases the smoking abstinence rate and should be offered to all smokers who wish to quit.¹⁴ A specialist counselor provides more intensive behavioral change techniques to patients, such as motivational interviewing.³ Therefore, smokers may achieve better results if referred to specialist counselors who promote abstinence. However, most patients in Taiwan do not have access to multiple professional counseling. Our study reveals that the addition of just one session with a specialist counselor might not achieve a more effective result. Therefore, whether more intensive professional counseling improves the smoking cessation rate in Taiwan should be further investigated.

The baseline characteristics of our two study groups were similar except for a lower comorbidity rate and fewer outpatient visits in the P+ group. The presence of a comorbidity is a favorable factor for smoking cessation. A retrospective cohort study showed that compared with matched participants who did not receive a diagnosis of myocardial infarction, stroke, diabetes mellitus, or cancer, the relative cessation

rates in the year of disease occurrence were 11.2, 7.2, 2.5, and 4.8, respectively.¹⁵ A study among Japanese patients also revealed an OR of 1.21 (95% CI, 1.08–1.36)¹⁶ for smoking cessation with a comorbid disease compared with healthy people. The comorbidity may have influenced the compliance with smoking cessation.^{15,16} In addition, the USPHS guidelines suggest that there is a dose-dependent relationship between the number of counseling sessions and the treatment effects.³ The lower comorbidity rate and fewer outpatient visits in the P+ group could have resulted in a worse outcome. Because differences in the baseline characteristics might have biased our results, we used multivariate logistic regression models to adjust for possible confounding factors. The adjusted ORs revealed no statistically significant differences in the abstinence rates between the two study groups at either week 12 or week 24 in the intention-to-treat analysis and per-protocol analysis.

The 7-day PP rate at week 12 in the intention-to-treat analysis was significantly higher in the Po than P+ group. The 7-day PP rate at week 24 was also higher in this

group, but the difference was not statistically significant. This result was largely attributable to the fact that more patients were lost to follow-up and were considered to be smokers in the P+ than P₀ group. Furthermore, there were no significant differences in the per-protocol analysis in which the patients lost to follow-up were excluded. Because of the high percentage of missing data, we considered that the intention-to-treat analysis might not have been accurate.

The USPHS guidelines suggest that higher-intensity and longer counseling sessions increase the abstinence rate.³ A meta-analysis published in 2017 provided moderate-quality evidence for a small benefit of more intensive counseling compared with brief counseling (relative risk, 1.29; 95% CI, 1.09–1.53; 11 studies, 2920 participants; $I^2 = 48\%$).¹⁷ However, this is not consistent across studies.^{18–20} In a Cochrane review published in 2013 that evaluated the effects of a physician's advice, more intensive interventions had greater effects, but no significant difference was found between the intensive and minimal intervention subgroups.¹⁸ In a Cochrane review published in 2015, intensive interventions combined with pharmacotherapy revealed a relative risk of 1.15 (95% CI, 1.06–1.24) compared with brief interventions, but this study showed little evidence of a dose response. In the 47 included studies, 15 had point estimates of <1; that is, they reported higher quit rates in the less intensive interventions.¹⁹ A Cochrane review published by Stead and Lancaster²⁰ also revealed favorable effects of combining pharmacotherapy with behavioral interventions compared with usual care, brief advice, or less intensive behavioral support. However, there was no clear evidence that increasing the duration of personal contact increased the effect. Because of the variations in the content and intensity of behavioral counseling,

our finding that no benefit was obtained from the addition of one session with a specialist counselor to brief counseling with a family physician does not contradict previous studies. If either more or longer sessions had been provided, the results might be different. It is also possible that the well-trained family physicians provided counseling of sufficient quality to eliminate differences between the intervening groups.

Physicians in Taiwan are expected to provide more intensive counseling than the traditional brief advice because all undergo training in a 7-hour smoking cessation program. According to a study published by Guo et al.,²¹ the training program is satisfactory and effective. Because all of the physicians in our study received this training, the results of our study might not be reproducible for physicians who do not have comparable counseling skills. Additionally, to help smokers quit, family physicians are well positioned in the roles of motivators and counselors because they are more aware of their patients' lifestyles and health conditions and may be better at motivating their patients to quit than a specialist counselor who speaks to a new patient for one session. Good rapport exists between family physicians and their patients, which contributes to the physicians' roles as effective counselors.²² A study in northwestern Ontario revealed that most family physicians (>91%) were confident in providing smoking cessation interventions and believed that they could help patients quit.²³ People also might be more likely to take advice from a high-status physician than a low-status nurse. One study showed that patients who saw nurses were generally less likely to quit than patients who were treated by other advisor types,⁷ although the nurse in our study was a certified specialist counselor. Furthermore, male doctors were associated with better quit rates.¹⁰ In this program, all family physicians were male. Our study

revealed that only one professional counseling by a specialist nurse did not providing a higher abstinence rate compared with family physician counseling. This finding might be unique to family physicians and not generalizable to other specialties. In addition, the drop-out rate from week 12 to 24 was significantly lower in the Po than P+ group (3.8% vs. 9.6%, respectively). This difference is surprising because the nature of the intervention was similar by that point in the study. This is probably because the patients in the physician-treated Po group had more visits and comorbidities.

Our study has several strengths. The real-world nature of this study might offer better estimates of abstinence rates. Both the specialist counselor and the family physicians received specific training; therefore, the variations in the quality of the services were small. The 24-week follow-up was sufficient to justify the results; previous research has indicated that a high percentage of those who ultimately return to smoking will do so after 24 weeks of abstinence.²⁴⁻²⁷ A meta-analysis in 2008 suggested that the 24-week follow-up time point had a result similar to that yielded by the use of longer follow-up time point,³ although a longer follow-up time could be more informative. The results were robust in the different analysis methods, including the intention-to-treat analysis, the per-protocol analysis, and the crude and adjusted ORs. The only exception was the crude OR in the intention-to-treat analysis at week 12, which showed a favorable effect of brief counseling with a physician; therefore, the conclusion was not changed.

Our study also has several limitations. The fact that smokers could choose between the two interventions might have introduced selection bias. The baseline characteristics of the two study groups were different. The P+ group had a lower rate of comorbidities and lower number of

visits. Although the adjusted ORs revealed no significant differences, the abstinence rates might have been biased. A high percentage of patients in both groups were lost to follow-up, and the treatment effects might not have been precisely evaluated. The smoking status data were self-reported, but there was no biological verification of the outcomes; thus, the abstinence rates might not have been reliable. Because the allocation of participants to the treatment groups was not randomized and the patients chose the medications based on their preference, selection bias was inevitable. Furthermore, an 8-week treatment period is relatively short; longer treatment durations might be necessary to detect significant differences between the study groups. Only one study site in Taiwan was used, and our conclusions might not be generalizable to other populations. Although the sample size was reasonable according to our study design, the participants might have been too few in number to detect significant differences under the assumption that a 15% increase in the abstinence rate was a clinically meaningful difference. The conclusions of our study require validation with a larger cohort.

Given that one session with a specialist counselor in our study had no significant effect, more intensive professional counseling should be considered to increase the abstinence rate and should be further investigated. It is also reasonable to extend the option of offering smoking cessation services from other specialties to determine whether the results of this study are only applicable to family physicians.

Conclusions

In this prospective observational study, the addition of one session with a specialist counselor had no benefit over a family physician's brief counseling when combined with pharmacotherapy at either a 12- or

24-week follow-up. Larger randomized controlled trials are required to verify these results.

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