นิพนธ์ต้นฉบับ

Effectiveness of Smoking Cessation Programme Based on Integrative Modern and Thai Traditional Medical Concepts in Patients with Non-Communicable Diseases: A Single-Blinded Randomized Controlled Trial

Witsanu Aninlabon*, Jatuporn Tripattarakitgoson, Khumwong Ongart

Pak Nam Lang Suan Hospital, Pak Nam Sub-District, Lang Suan District, Chumphon 86150, Thailand

***Corresponding author:** uiseiwporh@gmail.com*

Abstract

Effects of smoking cessation on patients with non-communicable diseases (NCDs) were assessed. A smoking cessation programme was implemented based on the concept of behavior change in NCD patients using modern and Thai traditional medicinal principles by taking care of the body using the principles of natural foot reflexology and herbal medicines including *ma-waeng* lozenges, *ya-dokkhao* (white flower) herbal tea and *rangjued* capsules. In the control group were NCD patients with conventional treatment who did not follow this programme. The study was approved by the Ethics Committee of Human Research, Surat Thani Hospital. A total of 88 NCD patients in Pak Nam Lang Suan Hospital were randomly assigned to two groups: 44 in the experimental group and the other 44 in the control group. The research instruments comprised a questionnaire and the smoking cessation programme. The model of behavior change was applied to stop smoking by integrating modern and Thai traditional medicine. Results indicated that most participants were male and had suffered from hypertension, dyslipidemia and diabetes. Among all participants, 46.30% in the experimental group could stop smoking while 41.70% in the control group could also do so. No significant difference in the effect of smoking cessation was shown between the two groups after the six-month study period ($p = 0.68$), but 34 patients (44.16%) could successfully quit smoking. The findings showed that the smoking cessation programme, based on the concept of the behavior change model using integrative modern and Thai traditional medical principles, could induce smoking cessation in NCD patients.

Key words: smoking cessation, tobacco, non-communicable diseases

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ประสิทธิภาพของโปรแกรมการเลิกบุหรี่ที่มีการบูรณาการร่วมกันของการแพทย์แผนปัจจุบันและการแพทย์แผนไทยในผู้ป่วยโรคไม่ติดต่อเรื้อรัง : การศึกษาเชิงทดลอง

วิษณุ อนิลบล*, จตุพร ไตรภัทรกิจโกศล, คุ้มวงศ์ องอาจ

โรงพยาบาลปากน้ำหลังสวน ตำบลปากน้ำ อำเภอหลังสวน จังหวัดชุมพร 86150

***ผู้รับผิดชอบบทความ**: uiseiwporh@gmail.com

บทคัดย่อ

การศึกษานี้มีวัตถุประสงค์เพื่อเปรียบเทียบผลของการเลิกบุหรี่ของผู้ป่วยโรคไม่ติดต่อเรื้อรังโรงพยาบาลปากน้ำหลังสวน ที่ได้รับโปรแกรมส่งเสริมการเลิกบุหรี่โดยประยุกต์จากแนวคิดของแบบจำลองขั้นตอนการเปลี่ยนแปลงพฤติกรรมต่อการเลิกบุหรี่ในผู้ป่วยโรคไม่ติดต่อเรื้อรังที่สูบบุหรี่โดยการบูรณาการร่วมกันของการแพทย์แผนปัจจุบันกับการแพทย์แผนไทย โดยการแนะนำการดูแลตัวเองด้วยหลักธรรมานามัย การนวดกดจุดสะท้อนเท้า การใช้สมุนไพรเพื่อช่วยเลิกบุหรี่ คือ ยาอมมะแว้ง ชาชงหญ้าดอกขาว รางจืดแบบแคปซูล เทียบกับในกลุ่มผู้ป่วยโรคไม่ติดต่อเรื้อรังที่ไม่ได้รับโปรแกรมประยุกต์หรือได้รับการรักษาแบบเดิม การวิจัยนี้เป็นการวิจัยเชิงทดลอง ศึกษาในกลุ่มตัวอย่างจากกลุ่มผู้ป่วยโรคไม่ติดต่อเรื้อรังโรงพยาบาลปากน้ำหลังสวน จำนวน 88 คน โดยวิธีจับฉลากรายชื่อแบบไม่ใส่คืน ได้กลุ่มตัวอย่าง ในกลุ่มทดลองจำนวน 44 คน และกลุ่มควบคุมจำนวน 44 คน ผ่านจริยธรรมการวิจัยในมนุษย์จากคณะกรรมการจริยธรรมการวิจัยในมนุษย์โรงพยาบาลสุราษฎร์ธานี เครื่องมือที่ใช้ในการวิจัย คือ แบบสอบถามและโปรแกรมส่งเสริมการเลิกบุหรี่โดยประยุกต์จากแนวคิดของแบบจำลองขั้นตอนการเปลี่ยนแปลงพฤติกรรมต่อการเลิกบุหรี่โดยการบูรณาการร่วมกันของการแพทย์แผนปัจจุบันและการแพทย์แผนไทย ผลการศึกษาพบว่า กลุ่มตัวอย่างที่สูบบุหรี่ส่วนใหญ่เป็นเพศชาย มีอายุอยู่ในช่วง 60-69 ปี มากที่สุด ส่วนใหญ่มีโรคประจำตัวเป็น ความดันโลหิตสูง ไขมันในโลหิตสูง และเบาหวาน กลุ่มตัวอย่างส่วนใหญ่มีระดับความพร้อมในการเลิกบุหรี่อยู่ในระยะชั่งใจ ร้อยละ 75.30 ผลการเลิกสูบบุหรี่ในกลุ่มทดลองและกลุ่มควบคุมหลังเข้าร่วมการวิจัยครบ 6 เดือน มีผู้เลิกบุหรี่ได้ทั้งหมด ร้อยละ 44.16 โดยกลุ่มทดลองเลิกบุหรี่ได้ร้อยละ 46.30 และกลุ่มควบคุมเลิกบุหรี่ได้ร้อยละ 41.70 ผลของการเลิกสูบบุหรี่ในกลุ่มทดลองและกลุ่มควบคุม ไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติ มีผู้ป่วยที่สามารถเลิกบุหรี่ได้ทั้งหมด ร้อยละ 44.16 ดังนั้น การประยุกต์โปรแกรมการเลิกบุหรี่โดยประยุกต์จากแนวคิดของแบบจำลองขั้นตอนการเปลี่ยนแปลงพฤติกรรมต่อการเลิกบุหรี่ในผู้ป่วยโรคไม่ติดต่อเรื้อรังที่สูบบุหรี่โดยการบูรณาการร่วมกันของการแพทย์แผนปัจจุบันและการแพทย์แผนไทย สามารถทำให้ผู้ป่วยเลิกสูบบุหรี่ได้

คำสำคัญ: การเลิกสูบบุหรี่, บุหรี่, โรคไม่ติดต่อเรื้อรัง

Introduction and Objective

In 2017, the World Health Organization cited smoking as one of the major health threats; accounting for deaths at more than seven million people every year. Among these, more than six million people are smokers and

another 0.89 million people die from second hand smoke. About 80% from 100 million of people around the world who smoke are in low- or middle- income countries[1]. Data from the Thailand Tobacco Consumption Survey Project in 2011, indicated that 13 million smokers (accounting for 24% of the population) were aged 15 and over. Among smokers, 46.6% were male while only 2.6% were female. This survey report stated that reducing the number of smokers was difficult. Current smokers who had previously considered quitting was about 54.0%, but those who have successfully stopped smoking was only 27.2%[2].

Non-communicable diseases (NCDs) are a major public health problem in many countries. They affect patients, families, societies and economies and their incidence is increasing. Patients with non-communicable diseases who cannot control their symptoms often develop severe complications leading to disability and death. Most patients cannot control non-communicable diseases. According to the Office of the Health Promotion Fund, in 2009, 14 million people suffered from chronic non-communicable diseases. Data from the Bureau of Non-Communicable Diseases, Department of Disease Control, Ministry of Public Health, Thailand[2] reported an increasing mortality rate per 100,000 population with chronic non-communicable diseases from 2003 to 2012; this included hypertension, diabetes, ischemic heart disease, stroke, chronic obstructive pulmonary disease and cancer. A study in Southeast and South Asia found that 55% of all deaths were caused by chronic non-communicable diseases. Smoking is one of the four major causes of chronic non-communicable diseases and especially affects oral and lung cancer, chronic respiratory failure and heart disease[3]. A smoking cessation study was conducted for patients with chronic non-communicable diseases in hospitals under the management of a multidisciplinary team of pharmacists in Pak Nam Chumphon Hospital[4]. Patients with chronic diseases, hypertension and diabetes, who were still smoking were selected. The total quitting rate was 30.7% after one year. Average number of cigarettes smoked per day and level of nicotine addiction (Fagerstrom score) were monitored at each stage of change and were found to be decreased significantly. However, a few existed studies suggested the use of traditional Thai medicine to ameliorate nicotine addiction. Few studies have urged to consider the use of herbs and Thai traditional medicine for smoking cessation.

The effectiveness of herbal white dahlia seeds in smoking cessation was examined. Dried powder of white grass was packed in capsules for 12 weeks of oral administration. Patients treated with white grass capsules were more likely to quit smoking, compared

to the control group. In addition, the result of studies have shown that for patients with chronic non-communicable disease, indigenous knowledge that is consistent with the social context can be utilised to promote Thai traditional medicine programmes to help quit smoking[5]. Activities associated with the principles of nature, herbal steam, massage, reflexology and detoxification could be use to help quit smoking. Thus, quitting smoking by using Thai traditional medicine programme could resulted in a significantly higher success.

Many types of services are offered in current Thai smoking cessation clinics. These are based on cooperation between smokers, relatives, society and service providers. Use of the transtheoretical or stage of change model to regulate behavior change in smokers can be very successful[6-9]. In 2017, non-communicable chronic diseases, diabetes, stroke, heart disease, chronic obstructive pulmonary disease, cancer and hypertension accounted for 12% of all diseases in Pak Nam Lang Suan Hospital. Only 7.3% of the patients were admitted to the smoking cessation clinic and only 2% were able to quit for more than six months.

According to this data, the research team was interested in testing the effectiveness of a designed Smoking Cessation Programme which integrating the concepts of modern medicine and Thai traditional medicine on patients with chronic non-communicable diseases.

Methodology

Materials

This study was approved by the Ethics Committee of Human Research, Surat Thani Hospital Institutional Review Board (IRB). Written consent was obtained from all participants and a full and detailed explanation of the proposed research was provided.

Subjects

Patients with chronic non-communicable diseases who were smokers were enrolled at Pak Nam Lang Suan Hospital, Chumphon Province, Thailand.

Inclusion criteria:

- age over 18
- currently smoking or having quit smoking for no more than six months
- no serious physical or mental health problems (can read and write)
- no hearing problems affecting participation in activities.

Exclusion criteria:

- unable to continue the activities for assessment at the end of six months.

Methods

Study design

This research was a single-blinded randomized controlled trial with a pre-posttest.

The effects of smoking cessation in patients with chronic non-communicable diseases were studied at Pak Nam Lang Suan Hospital. The experimental group received a smoking cessation programme based on the concept of the behavior change model with integration of modern medicine and Thai traditional medicine. The control group received only conventional treatment. Total study population was 384 and patients were evaluated between July and December 2018 (six months).

Sample size was calculated using the formula for experimental research for qualitative variables. A recent study found that the experimental group (smokers who participated in Smoking Cessation Programme) achieved success in stopping smoking at 34.3%, while the success rate of control group was only 15.2%. The study aim was to induce 50% of smokers quit smoking with 90% confidence and 80% test power ($p = 0.094$)[4]. Therefore, approximately 20 participants were needed in each group. In this study, 88 participants were enrolled using simple random sampling without replacement. There were 44 patients in the experimental group and 44 patients in the control group. Intervention was applied to each group by blinding (Figure 1).

Research tools

The instruments used in this research consisted of two parts as 1) the smoking cessation programme adapted from the theory of self-efficacy and the behavior change theory and 2) a questionnaire classified into five parts.

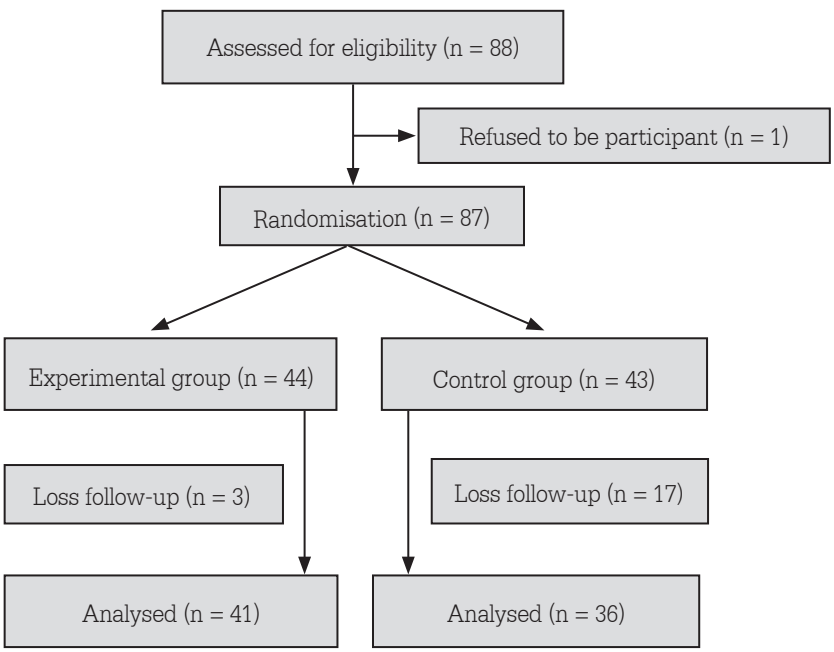

Figure 1 Protocol flow chart showing the number of subjects in each group (Consort diagram).

These included sociodemographic and health-related characteristics, smoking behavior, the nicotine addiction evaluation scale using the Fagerstrom test for nicotine dependence (FTND)[5], the perception of self-efficacy in quitting smoking[6] as a visual analogue scale with a score of 0 to 10 and information on determining the date to quit smoking.

The questionnaire was quality checked for content validity and reliability. Content validity was evaluated by three experts to determine the consistency index between the questions and calculate the IOC value of all items equal to 1 following their recommendations. After consideration by a specialist, the questionnaire was improved for clarity of content and language suitability before use. Content validity was assessed by a sample of 25 patients and the Cronbach's alpha coefficient was calculated. The reliability of the questionnaire was determined at 0.7 which was within the acceptable parameters.

Interventions

Both the experimental group and the control group received different treatments during the six months of the course. The control group received advice from nurses and general practitioners to stop smoking. Modern medicine was used to help patients to stop smoking including mouthwash and vitamin C. The experimental group received advice from nurses and general practitioners to stop smoking. They also receive medication with integration of Thai traditional medicine that suggested taking care of the body using the principles of natural foot reflexology, use of herbs to help stop smoking, lozenges, herbal tea and white flowers capsule ride. The treatment was motivated by public health volunteers.

Evaluation

Knowledge concerning cigarette smoking behavior, nicotine addiction, assessment of self-efficacy of stopping smoking and social support provided by the questionnaire was collected by the researchers and research assistants. Smoking behavior changes among the participants after six months of the programme, results of smoking cessation (no cigarettes used) and carbon monoxide breath levels were evaluated.

Statistical analysis

Data were analyzed by descriptive statistics such as mean, percentage, frequency and standard deviation (SD.), while inferential statistics such as the Kruskal-Wallis test and Pearson's chi-squared test were used to compare statistical significance between the two groups at the 0.05 level.

Results

Most of the respondents were male in both the experimental group and the control group at 95.50% and 97.70% respectively and

60-69 years of age with average age of 59.41 years (SD. = 12.38). In the experimental group, average age was 58.64 years (SD. = 12.21) and 62.26 years (SD. = 12.04) in the control group. Most of the patients suffered from hypertension, dyslipidemia and diabetes in both groups (Table 1).

The average smoking rate was 10.59 cigarettes per day (SD. = 7.85). In the experimental group, the average smoking rate was 11.84 cigarettes per day (SD. = 6.89) and in the control group, the average smoking rate was 9.31 cigarettes per day (SD. = 8.61). In the experimental group, patients had smoked for an average duration of 34.66 years (SD. = 14.75), while in the control group patients had smoked for an average duration of 36.81 years (SD. = 14.16). Most patients in the experimental group and control group had a stage of contemplation for smoking cessation (83.70% and 66.70% respectively) (Table 2).

An average score for nicotine addiction is 2.96 (SD. = 2.48) for nicotine addiction in both groups, 3.60 (SD. = 2.31) in the experimental

Table 1 Demographic and clinical characteristics of the subjects.

Characteristics	Experimental group (n = 44) n (%)	Control group (n = 43) n (%)	*p*-value
Gender			
Male	42 (95.50)	42 (97.70)	1.0000
Female	2 (4.50)	1 (2.30)	0.5637
Age (years)			
< 40	6 (13.6)	1 (2.30)	0.0588
40 –49	4 (9.10)	6 (14.00)	0.5271
50 – 59	12 (27.30)	11 (25.60)	0.8348
60 – 69	17 (38.60)	13 (30.20)	0.4652
> 70	5 (11.40)	12 (27.90)	0.0896
± SD	58.64 ± 12.21	62.26 ± 12.04	
Underlying diseases			
Diabetes	14 (31.80)	14 (32.60)	1.0000
Hypertension	26 (59.10)	34 (79.10)	0.3017
Dyslipidemia	28 (63.60)	26 (60.50)	0.7855
COPD/asthma	3 (6.80)	4 (9.30)	0.7055
Cerebrovascular disease	1 (2.30)	0 (0.00)	0.3173
Chronic heart disease	3 (6.80)	0 (0.00)	0.0833
Chronic kidney disease	1 (2.30)	1 (2.30)	1.0000
Thyroid disease	2 (4.50)	0 (0.00)	0.1573

Table 2 Smoking behavior.

Smoking behavior	Experimental group (n = 43) n (%)	Control group (n = 42) n (%)	*p*-value
Number of cigarettes smoked (per day)			
0-10	27 (62.80)	34 (85.00)	0.3701
11-20	15 (34.90)	5 (11.90)	0.0253
> 20	1 (2.30)	3 (7.10)	0.3173
± SD	11.84 ± 6.89	9.31 ± 8.61	
Years of smoking	(n = 36)	(n = 38)	
< 10	1 (2.63)	2 (5.60)	0.5637
11-20	10 (26.30)	5 (13.90)	0.1967
21-30	7 (18.40)	6 (16.70)	0.7815
> 30	20 (50.00)	23 (63.90)	0.6473
± SD	34.66 ± 14.75	36.81 ± 14.16	
History of smoking cessation			
Current smoking	42 (87.70)	42 (100)	1.0000
Quit (< six months)	1 (2.30)	0 (0.00)	0.3173
Stage of change			
Pre-contemplation	0 (0.00)	3 (7.10)	0.0832
Contemplation	36 (83.70)	28 (66.70)	0.3173
Preparation	4 (9.30)	9 (21.40)	0.1655
Action	3 (7.00)	2 (4.80)	0.6547
Maintenance	0 (0.00)	0 (0.00)	-

group and 2.29 (SD. = 2.50) in the control group during the six month research period for all the participants before joining the research project. After participating in the project, average carbon monoxide level in the breath of the samples decreased (Table 3).

Before and after the intervention, carbon monoxide concentration in the exhaled breath was detected by a handheld breath analyser. Before intervention, median carbon monoxide concentration in exhaled breath of all patients was 6 ppm and ranged at 1-22 ppm (Figure 2). Carbon monoxide concentration in the breath decreased at three and six months after intervention in both groups (Figures 2).

The median value of the number of cigarettes smoked per day before intervention was 10 and the range was 1-30. After the intervention, the median of the number of cigarettes smoked per day decreased at one and six months after treatment and the range was 0-20 (Table 4).

Results of smoking cessation in the experimental group and the control group

Table 3 Addiction levels for nicotine dependence before the intervention (Fagerstrom test)

Nicotine addiction score (total score = 10)	Experimental group (n = 43) n (%)	Control group (n = 41) n (%)
0	3 (6.80)	13 (31.70)
1	7 (15.90)	8 (19.50)
2	4 (9.10)	6 (14.60)
3	5 (11.40)	2 (4.90)
4	11 (25.00)	3 (7.30)
5	8 (18.20)	3 (7.30)
6	0 (0.00)	4 (9.80)
7	1 (2.30)	1 (2.40)
8	2 (4.50)	0 (0.00)
9	2 (4.50)	0 (0.00)
10	0 (0.00)	1 (2.40)
	$\overline{x}$ = 3.60, S.D. = 2.31	$\overline{x}$ = 2.29, S.D. = 2.50

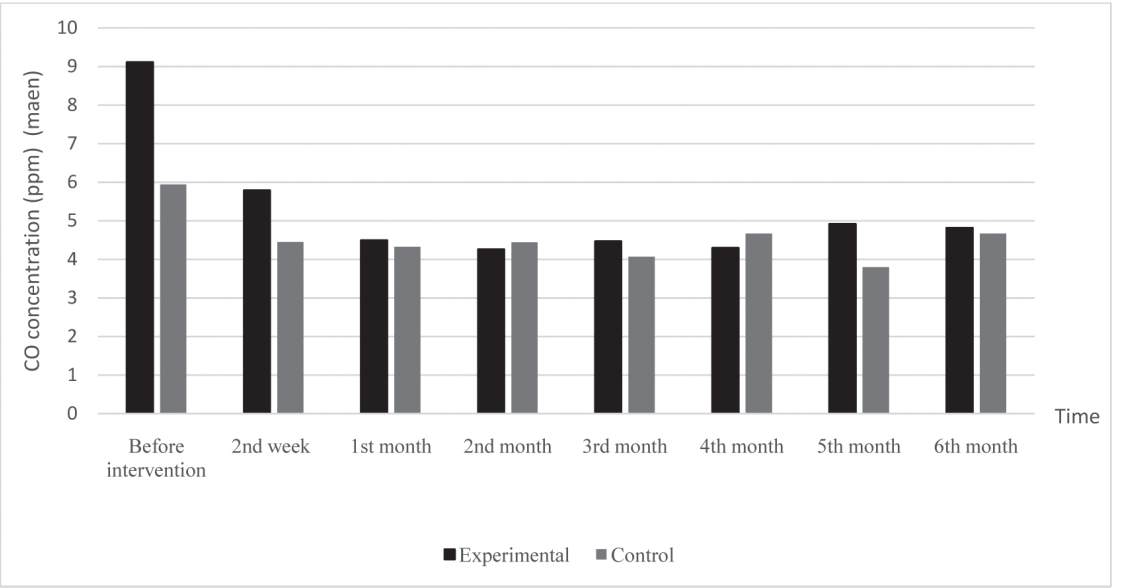

Figure 2 Carbon monoxide breath concentration before and after intervention at six months.

after six months of research show that in the experimental group (41 patients), 19 patients quit smoking (46.30%). In the control group (36 patients), 15 patients in the control group quit smoking (41.70%). Statistical analysis using Pearson's chi-squared test = 0.17 (p-value = 0.68) revealed no statistically significant differences between these two groups (Table 5).

Table 4 Number of cigarettes smoked per day before and after intervention in both groups.

	Number of cigarettes smoked							
	Before intervention (n = 87)	After intervention						
		2nd wk (n = 84)	1st month (n = 84)	2nd month (n = 84)	3rd month (n = 83)	4th month (n = 83)	5th month (n = 81)	6th month (n = 81)
Median	10.00	3.00	3.00	3.00	2.00	2.00	1.00	1.00
Mean	10.18	4.93	4.30	3.88	3.65	3.05	2.57	2.46
SD	7.204	5.178	4.708	4.278	4.087	3.912	3.755	3.768
Minimum	1	0	0	0	0	0	0	0
Maximum	30	20	20	20	20	20	20	20

Table 5 Results of smoking cessation at six months after intervention (n = 77).

Smoking behavior	Experimental group (n = 41) n (%)	Control group (n = 36) n (%)	*p*-value
Quit	19 (46.30)	15 (41.70)	0.68
Current smoking	22 (45.71)	21 (58.30)	

*Pearson's chi-squared test; $\alpha < 0.05$

Discussion

Smoking is a cause of non-communicable diseases, especially cancer of lung and respiratory organs, cardiovascular disease such as stroke and ischemic heart disease or the lung disease, chronic obstructive pulmonary disease. Smoking is a preventable health risk behavior that can use medications or the consultations to modify this habit. The medications that can use to stop smoking including the modern medication and Thai medication or Thai herbs. The Thai medicine that have been proposed such as lozenges, herbal tea, white flowers ride or natural foot reflexology. However, the methods that can use for smoking cessation may also use many medication or the many methods together. This study is a single-blinded randomized controlled trial to compare the effects of smoking cessation among non-communicable disease patients at Pak Nam Lang Suan Hospital. The programme applied was based on the concept of a behavioral change by integrating modern medicine and Thai traditional medicine com-

pare to the used of modern medicine only. The experimental group received medication with integration of Thai traditional medicine that has been suggested for taking care of health i.e. natural foot reflexology, use of herbs to help stop smoking, lozenges, herbal tea and white flowers capsule ride. Many previous studies showed that some herbs can help the smoker to stop smoking such Thripopskul W (2011) (4) showed the efficacy of Vernonia cinerea in smoking cessation.

In our study, Almost all subjects were male. Most of them smoked more than female, which is in concord with the results of many previous studies on smoking behavior in Thailand[7,10-13]. Almost all subjects have a stage of contemplation to stop smoking before participating in this interventions; but, they felt that they are not ready to quit smoking. Thus, this is a challenging reason for researchers to have an effective to encourage participants to stop smoking. As a result, activities must be organized to suit each individual with different of the readiness to quit smoking.

From this study, smoking addiction results were evaluated by the number of cigarettes smoked per day, nicotine addiction levels and carbon monoxide concentration in exhaled breath. The average number of cigarettes smoked per day was 10.59, This results is consistent with the study of Kuwalairat P, *et. al* (2015)[7], Kleebpratoom P, *et. al* (2016)[11] and Intarakumhang Na Rachasima S, *et. al* (2012)[13] noted that the average number of cigarettes smoked per day was more than ten. After the study, the average number of cigarettes smoked per day deceased in both the experimental and control groups. These result indicated that this program can decrease the number of cigarettes smoked per day and leading to stop smoking in some individual..

Nicotine addiction levels that used to measure the severity of smoking addiction, were evaluated by the Fagerstrom test. Before the study, the median of nicotine addiction score was three. Nicotine from smoking a cigarette rapidly reaches the brain in as little as seven seconds after inhalation. The elimination half-life of nicotine is two to three hours, meaning that the level of nicotine in the blood decreases by 50% after a smoker stops smoking for that length of time[14-15]. The study of Kuwalairat P, *et. al* (2015)[7] and Chaijandee P, *et. al* (2016)[16] demonstrated that the nicotine level can decrease after the intervention of smoking cessation program or by consuming some medication.

Breath concentrations of carbon monoxide greater than 4-6 ppm. were assessed for the risk of carbon monoxide poisoning or recent exposure to carbon monoxide and used to differentiate smokers from nonsmokers[17-18]. This value decreased after our intervention at three and six months in both groups. Previ-

ous research results also reported that carbon monoxide concentrations in exhaled breath decreased after intervention of smoking cessation program (Kuwalairat P (2015)[7] and Kleebpratoom P (2016)[11].

As seen from the result, the intervention of this study showed no statistically significant differences between the experimental and control groups for inducing smoking cessation. However this program helped patients to stop smoking at 44.16%. In contrast, without any formal treatment intervention, numbers of people who successfully quit smoking are estimated each year at less than 1%[19]. The result obtained was with accord to the result of Kuwalairat P, *et. al* (2015). They found that the outcomes of smoking cessation among non-communicable disease patients at community hospitals under the supervision of clinical pharmacist helped patients to stop smoking at 30.70%[7], Raya P, *et al*.(2015) reported that the effects of smoking cessation program which applying the Transtheoretical model helped patients to stop smoking at 37.50%[10] and Chaijandee P, *et al.* (2016) presented that the clinical outcome of pharmaceutical care for smoking cessation helped patients to stop smoking at 43.06%[16]. All the mentioned study results revealed that the application of pharmaceutical care in addition to medication could lead to a good clinical outcome for the smoking cessation; the same as was found in this study.

Conclusions

Our result indicated that patients with non-communicable diseases who followed the intervention programme of Thai traditional medicine were more likely to successfully stop smoking (46.30%) than those in the control group (41.70%) who only administered modern medicine and followed the standard advice from general practitioners and nurses. However, there was no statistically significant difference in the effect of smoking cessation behavior between the two groups after six months of treatment.

This model integrating modern medicine and Thai traditional medicine offers an opportunity to increase smoking cessation by health care services. However, more experiments are needed to demonstrate the benefit of this integration programme.

Research limitations

This research only studied a specific group of patients with non-communicable diseases. The intervention programmed was adapted from previous programmed used for patients suffering from other diseases in the contexts of different hospitals or health care providers.

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