

Effectiveness of a brief intervention for smoking cessation using the 5A model with self-help materials and using self-help materials alone: A randomised controlled trial

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Abstract

Introduction: The ‘5A’ model for smoking cessation was introduced in 2000 by the US Department of Health and Services. This brief intervention was recommended worldwide for smoking cessation. However, little is known about its effectiveness for smoking cessation in a primary care setting in Malaysia.

Objective: To determine the effectiveness of a brief intervention for smoking cessation using the ‘5A’ model with self-help materials compared to using self-help materials alone.

Methods: This randomised controlled trial was conducted at the Primary Care Clinic at the University Malaya Medical Centre (UMMC) between June and October 2009. Subjects were all current smokers aged 18 years and above. A total of 208 subjects were recruited and randomised into two groups. Subjects in the intervention group were given a brief intervention based on the ‘5A’ model with self-help materials, while the control group received self-help materials alone. Subjects were later followed up at one and four months via telephone calls. The outcome measure was a self-reported attempt to quit smoking.

Results: At one-month follow-up, 15/77 (19.5%) of the participants in the intervention group had attempted to quit smoking compared to 8/80 (10.0%) in the control group. There was no significant difference between the two groups ($p=0.09$). At the four-month follow-up, 13/58 (22.4%) participants in the intervention group had attempted to quit smoking compared to 9/57 (15.8%) in the control group. Once more, there was no significant difference between the two groups ($p=0.37$).

Conclusion: This study showed that there was no significant difference between a brief intervention using the ‘5A’ model with self-help materials and using self-help materials alone for smoking cessation in a Malaysian primary care setting. However, these results do need to be treated with caution when taking into consideration the high dropout rate and bias in the study design.

Introduction

Tobacco smoking remains the biggest preventable cause of morbidity and mortality.¹ It is a well-known risk factor for developing cardiovascular diseases, chronic obstructive pulmonary disorders, and cancers of the lung, oral cavity, larynx, oesophagus, stomach, pancreas, colorectum, bladder, and kidney.^{1,2} Mackay reported in 2001 that one in three adults worldwide (1.1 billion people) were smokers.³ In 2009, the Tobacco Atlas highlighted the loss of a staggering 500 billion US dollars annually due to tobacco use.⁴ These economic costs come as a result of lost productivity, misused resources, missed opportunities for taxation, and premature death. In Malaysia, the overall prevalence of current smokers aged 15 years old and above was 22.8% in 2015, with 43.0% of males being smokers and 1.4% of females.⁵

There is clear evidence that simple advice from a physician has little effect on cessation rates.⁶ Assuming an unassisted rate for quitting smoking of 2 to 3%, an intervention in the form of brief advice can increase the rate by a further 1 to 3%. Additional components appear to have only a small effect, although there is a small additional benefit of more intensive interventions over very brief interventions. Standard self-help materials may increase rates of quitting over no intervention, but the effect is likely to be small.^{7,8} Alternative therapies, such as hypnosis, acupuncture, acupressure, laser therapy, and electrostimulation, have no scientifically proven effects.^{9,10} A systematic review by Lemmens et al. found evidence of effectiveness for the following strategies (in decreasing order of effectiveness): group behavioural therapy

(odds ratio (OR): 2.17, confidence interval (CI): 1.37-3.45), bupropion (OR: 2.06, CI: 1.77-2.40), intensive advice from a physician (OR: 2.04, CI: 1.71-2.43), nicotine replacement therapy (OR: 1.77, CI: 1.66-1.88), individual counselling (OR: 1.56, CI: 1.32-1.77), telephone counselling (OR: 1.56, CI: 1.38-1.77), nursing intervention (OR: 1.47, CI: 1.29-1.67), and tailored self-help interventions (OR: 1.42, CI: 1.26-1.61).¹¹ In Malaysia, Wee et al. found that older age and longer durations of prior attempts to quit smoking were predictors of successful smoking cessation.¹²

A study in Chile using a brief intervention based on the '5A' model showed that 15.2% of women reported quitting smoking for at least 1 month in the intervention clinic versus 7.8% in one of the control clinics.¹³ When using the '5A' model, health care providers should follow a 5-step process: (i) *Ask* every patient about tobacco use, (ii) *Advise* smokers to quit, (iii) *Assess* smokers' willingness to attempt to quit, (iv) *Assist* smokers who are willing to make an attempt to quit, and (v) *Arrange* for follow-up contact to prevent relapse.¹⁴⁻¹⁷

In Pbert et al.'s study,¹⁸ the '5A' model recommended by the US Public Health Service Clinical Practice Guideline was used on adolescents aged 13 to 17 years. It showed that the adolescents who received the provider- and peer-delivered intervention were more likely to report having quit smoking at the six-month, but not the 12-month, follow-up. Further, Pbert et al., in another study, concluded that a four-session smoking cessation intervention based on the '5A' model could feasibly be delivered by school nurses and increase self-reported short-term abstinence rates among the students interested in quitting smoking.¹⁹ However, in comparison, Unrod et al. found that a computer-based, tailored intervention built on the '5A' model demonstrated that intervention patients were more likely than controls to be abstinent, but the difference did not reach statistical significance at six months post-intervention.²⁰

The aim of this study was to determine the effectiveness of this intervention in an urban population at the primary care level in Malaysia. The findings from this study should help to provide evidence as to whether the '5A' model could be used as an effective smoking cessation programme in the Malaysian primary care setting.

Methods

This study used a randomised controlled trial. The enrolment period was from 1 June 2009 till 30 June 2009. The subjects were recruited from the Primary Care Clinic at the University Malaya Medical Centre, which provides outpatient care to the public from the cities of Kuala Lumpur and Petaling Jaya and the surrounding urban areas. The inclusion criteria for the study were that the subjects were aged 18 years and above and current smokers. The exclusion criteria were smokers presently receiving pharmacological treatment for smoking cessation at the time of the study, those with psychiatric illnesses, and those who were pregnant. Subjects who fulfilled the inclusion criteria were approached by the principal investigator as they registered at the clinic, and those who agreed to participate in the study were randomly allocated to one of two groups via a random number table.²¹ Following the number sequence, subjects who received odd numbers were put into the control group, while those received even numbers were assigned to the intervention group. After this random allocation, each subject completed a questionnaire and then had a face-to-face interview with the principal investigator based on the questionnaire. The questionnaire included socio-demographic data, smoking cessation behaviour, and the six-item Fagerström test of nicotine dependence (FTND) scale.^{22, 23}

Subjects in the intervention group were given a brief intervention based on the '5A' model and self-help materials by the same investigator. This brief intervention included the following:

5A	Providing a Brief Smoking Cessation Intervention	Time
Ask	Ask about duration of tobacco use, amount and type of tobacco use.	1 min.
Advice	Advise all smokers to quit in a clear, strong, and personalized manner. Clear: <i>"I think it is important for you to quit smoking now and I can help you."</i> <i>"Cutting down while you are ill is not enough"</i> Strong: <i>"As your doctor, I need you to know that quitting smoking is the most important thing you can do to protect your health now and in the future. The clinic staff and I will help you."</i> Personalised: <i>Tie tobacco smoking to current health/illness and/or its social and economic costs, motivational level/readiness to quit, and/or the impact of tobacco smoking on children and others in the household.</i>	30 sec.
Assess	Assess the subject's willingness to quit smoking using the Prochaska Stages of Change model. ²¹ Pre-contemplation: Provide motivational intervention or discontinue. Contemplation: Provide motivational intervention and information. Preparation: Provide assistance. Action & Maintenance: Congratulate and encourage the subject	30 sec.
Assist	Assist the subject with a plan for quitting and set a quit date. Tell family, friends, and co-workers about quitting and request understanding and support. Provide self-help materials and explain (tips to quit smoking, list of clinics for quitting smoking, problem-solving strategies).	3-5 min.
Arrange	Arrange follow-up in one month after the quit date either in person or via telephone. Subsequent follow-up in four months. If the subject has quit smoking, congratulate him/her on his/her success. If tobacco smoking has occurred, review circumstances and elicit recommitment to total abstinence. Remind smoker that a lapse can be used as a learning experience. Identify problems already encountered and anticipate challenges in the immediate future. Consider using more intensive treatment; if not available, referral is indicated.	5 min.

Adapted from the Malaysian Clinical Practice Guideline on Treatment of Tobacco Smoking and Dependence (2016)¹⁵ and Quit smoking. You too can help! A guide for dental practitioners (2008).¹⁶

The control group was given self-help materials only without explanation. The self-help materials included information on such topics as the harmfulness of smoking, benefits of quitting smoking, tips on quitting smoking, and a contact telephone number for clinics for quitting smoking under the Ministry of Health in Malaysia. These self-help materials were used as the control because the principal investigator thought that this method would help to facilitate the recruitment of the subjects into this study.

Subjects were followed up at one and four months from the time of enrolment via telephone calls and were asked about their attempt to quit smoking. Those who did not answer the telephone during three consecutive attempts (all 1 hour apart) to reach them on the same day were considered drop-outs.

This study was approved by the University Malaya Medical Centre (UMMC) Medical Ethics Committee (Reference Number 709.5).

Statistical analysis

For the sample size calculation with 95% confidence, a simple formula for calculating the sample size is given by $\text{Size per group} = c \times \frac{\pi_1(1 - \pi_1) + \pi_2(1 - \pi_2)}{(\pi_1 - \pi_2)^2}$, where $c = 7.9$ for 80% power (used in this study) and 10.5 for 90% power, and π_1 and π_2 are the proportion estimates.²⁴

For this study, $\pi_1 = 0.078$ (7.8%) and $\pi_2 = 0.228$ (22.8%), so $\text{Size} = 7.9 \times \frac{(0.078(1-0.078) + 0.228(1-0.228))}{(0.078-0.228)^2} = 87$ (each group) $\times 20\% + 87 = 104$ (each group)

Data entry and analyses were done using the Statistical Package for the Social Sciences (SPSS) Version 15.0 for Windows. Results were presented in a frequency table with means and standard deviations for numerical data and absolute numbers and percentages for categorical data. The student t-test was used to compare the means (control and intervention) of numerical variables, such as age, the

number of cigarettes smoked per day and number of years smoking. While cross tabulation using the Chi-square test was used to test for relationships between the categorical variables, such as sex, ethnic group, marital status, education level, income level, age started smoking, types of cigarettes smoked, and attempts to quit smoking at the one- and four-month follow-ups. Per protocol, the last two tests were used to provide an estimate of the true efficacy of the intervention. The level of significance for all tests was set at 0.05.

Results

A total of 208 subjects were recruited for this study. One-hundred and four subjects were randomised into each of the intervention and control groups (Figure 1).

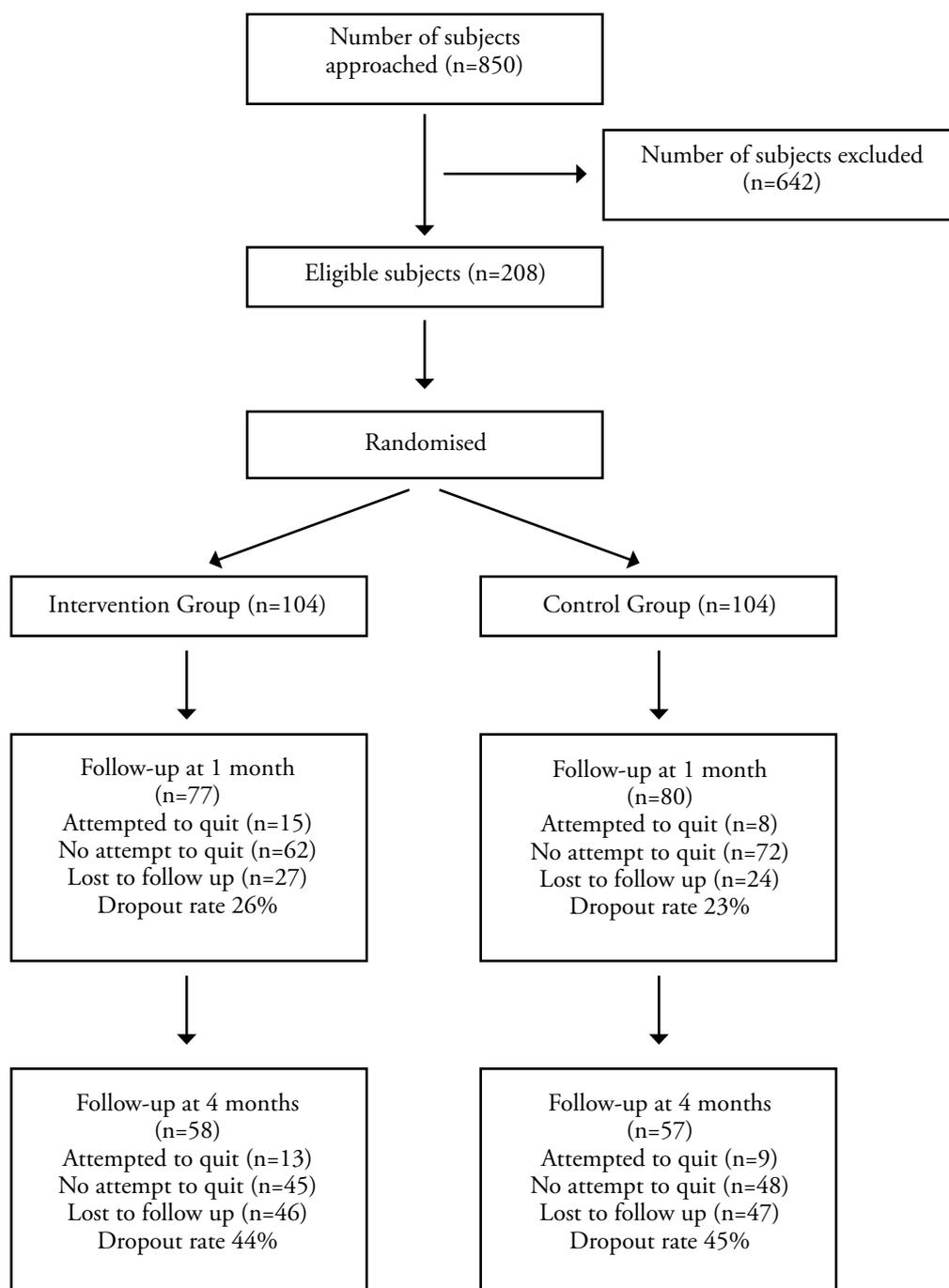


Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram of the progress of the participants through the study.

A comparison of the socio-demographic characteristics of the intervention and control groups is shown in Table 1.

Table 1. Socio-demographic characteristics of the subjects by group (n=208)

	Intervention Group (n=104)	Control Group (n=104)	p value
Age (years), mean \pm SD	40.09 \pm 14.28	39.94 \pm 14.14	0.94
<i>Sex, n (%)</i>			
Male	97(93.3)	97(93.3)	1.00
Female	7(6.7)	7(6.7)	
<i>Ethnic Group, n (%)</i>			
Malay	53(51.0)	58(55.8)	0.12
Chinese	12(11.5)	15(14.4)	
Indian	29(27.9)	29(27.9)	
Other	10(9.6)	2(1.9)	
<i>Marital Status, n (%)</i>			
Single	35(33.7)	35(33.7)	0.25
Married	68(65.4)	64(61.5)	
Other	1(1.0)	5(4.8)	
<i>Education Level, n (%)</i>			
Primary	13(12.5)	13(12.5)	0.95
Secondary	65(62.5)	63(60.6)	
Tertiary	26(25.0)	28(26.9)	
<i>Income Level, n (%)</i>			
<RM 500	14(13.5)	11(10.6)	0.71
500-999	18(17.3)	18(17.3)	
1000-1999	39(37.5)	31(29.8)	
2000-2999	21(20.2)	27(26.0)	
3000-3999	6(5.8)	9(8.7)	
4000-4999	2(1.9)	1(1.0)	
>5000	4(3.8)	7(6.7)	

Comparison of the smoking characteristics of the subjects showed no significant differences between the intervention and control groups, and this information is summarised in Table 2.

Table 2. Smoking Characteristics by Group (n=208)

	Intervention Group (n=104)	Control Group (n=104)	p value
No. of cigarette smoked per day, mean \pm SD	12.53 \pm 7.06	12.43 \pm 7.52	0.92
No. of years smoking, mean \pm SD	20.92 \pm 13.10	19.48 \pm 12.51	0.42
<i>Age started smoking, n (%)</i>			
4-12yr	6(5.8)	6(5.8)	0.32
13-17	32(30.8)	38(36.5)	
18-25	52(50.0)	39(37.5)	
26-35	13(12.5)	17(16.3)	
36-46	1(1.0)	4(3.8)	
<i>Types of cigarettes, n (%) #</i>			
Filtered	102(93.6)	100(90.1)	0.41
Non-filtered	2(1.8)	4(3.6)	0.41
Cigar	1(0.9)	0(0)	0.32
Tobacco leaf	4(3.7)	7(6.3)	0.40

Multiple responses per individual possible. The intervention group had 109 responses, and the control group had 111 responses.

The attempts to quit smoking recorded at the one- and four-month follow-ups are shown in Table 3.

Of the subjects available for follow-up at one month, 19.5% (n=15) in the intervention group had attempted to quit smoking, while 10.0% (n=8) had attempted to quit smoking in the control group (p= 0.09).

At the four-month follow-up, 22.4% (n=13) had attempted to quit smoking in the intervention group, while 15.8% (n=9) had attempted to quit smoking in the control group (p= 0.37).

Table 3. Quit smoking attempts at the one- and four-month follow ups

	Intervention Group	Control Group	p value
<i>Attempt to quit smoking at 1 month, n (%)</i>			
Yes	15(19.5)	8(10.0)	0.09
No	62(80.5)	72(90.0)	
<i>Attempt to quit smoking at 4 months, n(%)</i>			
Yes	13(22.4)	9(15.8)	0.37
No	45(77.6)	48(84.2)	

Discussion

Some of the socio-demographic characteristics of the subjects in this study were comparable to the findings in previous local studies.^{5,12,25} In particular, almost all subjects were male, and there were fewer Chinese than smokers from other major races. More than 85% of subjects had at least a secondary or tertiary education. The subjects started smoking predominantly in their teens and young-adult years, and the number of cigarettes smoked per day was, on average, 12.5.

The objective of this study was to determine the effectiveness of a brief intervention based on the '5A' model and providing self-help material compared with providing self-help material alone for smoking cessation at a primary care clinic. This study showed that there was no significant difference between the intervention group and the control group for smoking cessation at the one- and four-month follow-ups (**Table 3**). Although there was no statistically significant difference in the rate for quitting smoking between the two groups, there were a substantial number of smokers who had attempted to quit smoking by the one-month and four-month follow-ups in the intervention group.

Wee et al.'s review of smoking research in Malaysia has drawn attention to the limited number of local studies on intervention strategies to curb smoking and, in particular, non-pharmacological intervention strategies.²⁵ Therefore, there is a need for more local clinical trials in this area.

The 2014 Cochrane Database of Systematic Reviews found that standard, print-based self-help materials increased rates of quitting compared to no intervention, but the effect is likely to be small.²⁶ The authors failed to find evidence that the self-help materials provided an additional benefit when used alongside other interventions, such as advice from health care professionals or nicotine-replacement therapy. However, there was evidence that materials that are tailored to individual smokers are more effective than non-tailored materials, although the absolute size of the effect is still small. The findings from this study were consistent with the conclusion from the Cochrane Database Systematic Review with regard to the lack of additional benefits when self-help materials are used alongside other interventions, such as brief advice using the '5A' model.

There are some limitations to this study. The first limitation concerns investigator bias in view of the fact that study was not blinded. A second limitation emerges from the use of even or odd numbers for randomization since selection bias could be present if the subjects happened to enter the clinic in a particular pattern. In this study, however, this limitation was trivial because there was no particular pattern of entry into the study. This point is further enforced by the heterogeneous distributions of the different characteristics of the study subjects. The third limitation is the response bias in self-reporting attempts to quit smoking. This bias could be reduced by using exhaled carbon monoxide measurements or urinary cotinine levels. However, neither method was used in this study due to non-availability of such facilities in which

to conduct these measurements at the time the study was conducted. The fourth limitation is that there were many subjects who were lost to follow-up at the one-month and four-month follow-up intervals in this study. The dropout rate was high in the follow-up period and nearly identical for both groups, as indicated by the 26% drop-out rate for the intervention group and the 23% drop-out rate for the control group at the one-month follow-up, and then 44% and 45% drop-out rates for the respective groups at the four-month follow-up session. The results do need to be treated with caution by taking into account the high dropout rates and the bias in the study design. The majority of the subjects cited stress and peer pressure (64.5 % in the intervention group, and 62.8% in the control group) as the two main reasons for relapse, while one-fifth cited reasons for relapse related to withdrawal symptoms, such as craving (23.6% in the intervention group, and 21.7% in the control group). One suggestion for improving the study design for the future is to have another control group without any intervention, which is the usual case for comparison, to be absolutely sure that the effect on quitting smoking was due to the '5A' model using self-help materials or self-help materials alone and not purely by chance. Although some reasons for the high dropout rate in both groups in this study were provided, it might be worth exploring this issue further in a future qualitative study to gain additional insights into the challenges faced by smokers in quitting smoking.

This study showed that a brief intervention based on the '5A' model and providing self-help

material was not more effective than using self-help material alone for smoking cessation in the primary care clinic. One implication from this study for clinical practice is that clinicians can use either of these methods to help people to quit smoking, as no one method is superior to the other. The choice of which method to use will depend on the time available providing help because the brief intervention based on '5A' model is much more time consuming (10 to 12 minutes) compared to just providing the self-help materials to smokers who want to quit.

Conclusion

This study showed that there was no significant difference between a brief intervention based on the '5A' model and providing self-help materials and using self-help materials alone for smoking cessation in a primary care setting. However, these results do need to be treated with caution when considering the high dropout rates and bias in the study design.

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Conflict of interest

None

How does this paper make a difference to general practice?

- Clinicians can use a brief intervention based on the '5A' model and providing self-help materials or using self-help materials alone to help people to quit smoking, as no one method is superior to the other.
- The choice of method will depend on the time available because the brief intervention based on the '5A' model takes more time (10 to 12 minutes) compared to just providing the self-help materials to smokers who want to quit.

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