A cluster randomised controlled trial on effectiveness of carbon monoxide measurement feedback among college smoker : A study protocol

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ABSTRACT

Introduction: For the last 30 years, tobacco smoking has continued to be the leading cause of premature deaths in Malaysia. Majority of the smokers in Malaysia are at the pre-contemplation and contemplation stages. Therefore, for the purpose of increasing smoking cessation among this group, the strategies that motivate them to quit smoking have to be reviewed.

Objective: This study aims to evaluate the effectiveness of carbon monoxide measurement feedback and the standard brief motivation adopted to encourage the smoker to quit.

Methods: A single-blind, cluster randomised controlled trial was conducted at ten tertiary colleges in Selangor. The study recruited young adult smokers at the pre-contemplation and contemplation stages. The subjects in the control group received a standard brief motivational strategy. On the other hand, the intervention group received additional carbon monoxide measurement and a motivational feedback module. A follow up was conducted at the first, third and sixth month to measure changes in smoking cessation stage. Subsequently, the secondary outcomes of a mean number of cigarette consumption and quit smoking attempt were analysed. A total of 160 subjects were required to detect the expected difference of 17% in primary outcomes between the groups. This study utilised Generalised Estimating Equations (GEE) to handle the clustering effects.

Conclusion: Biomedical risk assessment feedback mechanism by using carbon monoxide is a promising aid to motivate the smoker to quit. This mechanism is a relatively easy, quick and non-invasive technique. Thus, it can be utilised as a reinforcement relating to the harmful effect of smoking. Besides, it can also increase the smokers' self-efficacy and decisional balance to adopt behavioural changes.

KEY WORDS:
Smoking, cessation, motivation carbon monoxide, Transtheoretical Model

INTRODUCTION

For the last 30 years, tobacco smoking has continued to be the leading cause of premature deaths in Malaysia. The continuance of the current trend and pattern of smoking in Malaysia will impose a significant burden on future healthcare. Based on the latest National Health and Morbidity Survey 2015,[1] the prevalence of tobacco smoking in Malaysia was 22.8%. Nevertheless, in terms of age group, the prevalence of smoking is significantly lower among young adults i.e., 13.2% of the group aged 18 to 19 and 25.3% of the group aged 20 to 24. The trend among this age group was similar to result showed in the previous Global Adult Tobacco Survey 2011.[2] In fact, compared to other age groups, the current smokers in this age group had the highest prevalence of making a quit attempt in the past 12 months (55.7%) and being advised to quit smoking by a healthcare provider in the past 12 months (90.2%). Therefore, there is plenty of opportunities to reduce the prevalence of smoking by focusing on a cohort of this age group of young adults. Malaysia, as one of the ratifying parties in the Framework Convention on Tobacco Control (FCTC), has pledged to promote smoking cessation. The current management of smoking cessation in Malaysia includes delivering of a standard brief motivation at healthcare facilities[3] to motivate the smokers who have no attempt to quit.

Transtheoretical Model (TTM) has been widely used to describe smoking behaviour based on the behavioural theory by Prochaska.[4] There are five stages of change: namely (i) pre-contemplation, (ii) contemplation, (iii) preparation, (iv) action, and (v) maintenance. At the pre-contemplation stage, the smokers have no intention to change behaviour in the next six months. During the contemplation stage, they develop an intention. Subsequently, at the preparation stage, the smokers intend to change in the next few months. The smokers usually go to the quit smoking clinic in the last three stages. During the fourth stage, they have made specific changes within the last six months through maintenance. While attention has been provided regarding smoking cessation, the stage-based strategy is important to mobilise the smokers from the lower stages.[5] Based on the TTM Model for smoking cessation stages of change, 70% of the smokers in Malaysia were at the contemplation stage whereas 30% at

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the pre-contemplation stage.[5] Another study showed that among the younger smokers, 87.36% of them were at pre-contemplation and contemplation stages whereas only 12.62% of them were at the preparation stage.[6] A local study conducted in Johor discovered that almost 60% of the current young smokers had the intention to quit.[7]

TTM is also widely used for smoking intervention. Specific intervention to the lower stage of pre-contemplation and contemplation groups can increase uptake at quit smoking clinic as it is predictive of making a quit attempt and smoking relapse.[8] Thus, stage-based intervention by using TTM on the young adults has a promising result. A systematic review of smoking cessation intervention among the young adults discovered three studies, targeting at the stages of change of individual participants by using TTM.[9]

The result of these studies indicated the intervention of brief clinical message, motivational counselling and booster sessions by utilising TTM-based computer expert system had a risk ratio of 1.56 (95%CI 1.21 - 2.01) for cessation outcome at 1 year compared to standard care.[9] Further review on stage-based tobacco intervention discovered a significant difference in the progress of the stages, intention to quit and smoking cessation outcome. A randomised clinical trial in Turkey by using TTM-based counselling discovered that the rates of smoking cessation and progress are significant compared to control.[10]

Furthermore, apart from the five stages of change, the model indicated ten processes of change which explained how cognition, emotion and behaviour changes take place. The intervention should apply the specific process of change, such as consciousness-raising at the early stage.[11] The conscious awareness also requires internal cues and external cues. The intervention on external cues, such as pictorial warning on cigarette packages, has proved to be successful.[12] On the other hand, the intervention on internal cues, such as depression and anxiety, also has shown to be effective. Nevertheless, these two cues act independently and not synergistically.[13] Moreover, utilising carbon monoxide feedback forms of the biomedical risk assessment feedback to motivate the smokers in quitting. Biomedical risk assessment, includes spirometer, atherosclerotic plaque imaging, genetic testing or carbon monoxide analyser, uses the external cues to demonstrate the effect and severity of smoking to the smokers.

Nevertheless, it is relatively easy, quick and less technicality to use carbon monoxide analyser. One of the first trials by Jamrozik et al. in 1984 was conducted in general practice in London and Oxford.[14] The four-arm trial comprised of control with brief advice, exhaled carbon monoxide feedback and health visitor showed no significant difference in attempts to stop smoking but the significant difference on quit smoking. The exhaled carbon monoxide group had a significant 13.9% of quit rate compared to 8.5% of the control group adjusted for a social group class. It indicated that the added impact of carbon monoxide measurement.[14] Several other studies showed the promising results in increasing the level of motivation to quit.[15,16] A study conducted by Choi et al. in Korea compared the CO measurement feedback with self-help material. The study discovered a significant increase in motivation after four weeks but with wide confidence intervals due to small sample size.[15] In 2011, a randomised clinical trial conducted in the UK discovered that adding carbon monoxide measurement to standard quit advice significantly increased the motivation to quit. Nevertheless, it did not significantly differ in quit attempts or abstinence16 Thus, it can be concluded that carbon monoxide measurement feedback immediately increases the cognitive effect. Nonetheless, the effect does not last long transforming into a quit attempt or abstinence. It raises the threat appraisal that can be exploited among the unmotivated smokers. Nevertheless, the strategies to provide the smokers with biofeedback has not been explored in Malaysia. Carbon monoxide analyser (CO analyser) is usually used to confirm smoking status at the last three stages instead of being used as a biofeedback mechanism at the initial stage to develop a smoker's intention to quit. The measurement of carbon monoxide is a relatively non-invasive and easy technique. Thus, it can be employed easily. This study aims to explore its effect on the smoker's motivation to quit compared to the current standard brief motivational strategy. Furthermore, the purpose of the study is to research the effectiveness of CO analyser as biofeedback compared to the standard brief motivation on the lower scale of stages by measuring: (i) motivational stage as the primary outcomes; and (ii) behaviour (mean number of cigarettes smoked per day) and number of quit attempts as the secondary outcomes.

MATERIALS AND METHODS

Design and settings

A single-blind, cluster randomised controlled trial was conducted in all community colleges in Selangor. There are 10-community colleges in Selangor and they were randomised to be either a control group or intervention group. The healthcare professionals provided a standard brief motivational intervention to the subjects in the control group, whereas the intervention group received an additional carbon-monoxide measurement feedback. Figure 1 shows the CONSORT diagram for the study.

Study population

The study population consisted of college students who are smokers, aged from 18 to 24 years old. Inclusion criteria were smokers at the pre-contemplation and contemplation stages. The "smoker" is defined based on the Centers for Disease Control and Prevention (CDC) criteria as "someone who has smoked at least 100 cigarettes in their lifetime, including every day and someday smokers".[17] Those who currently on any smoking cessation programme or self-quit attempt were excluded as they were already at the action and maintenance stages. Those who have any lung or heart diseases as being declared in their entrance health examination form were also excluded. The college entrance health examination included chest radiograph examination and medical check-up by medical practitioner.

Subjects recruitments

The first phase of recruitment was the screening for eligible smokers at all campuses. Such screening was conducted through a preliminary questionnaire. A single stage sampling was only conducted within college level. Further, a simple random sampling was conducted to get the required participants in each college after getting their informed consent. The second phase of recruitment involved random allocations of each college to either intervention or control

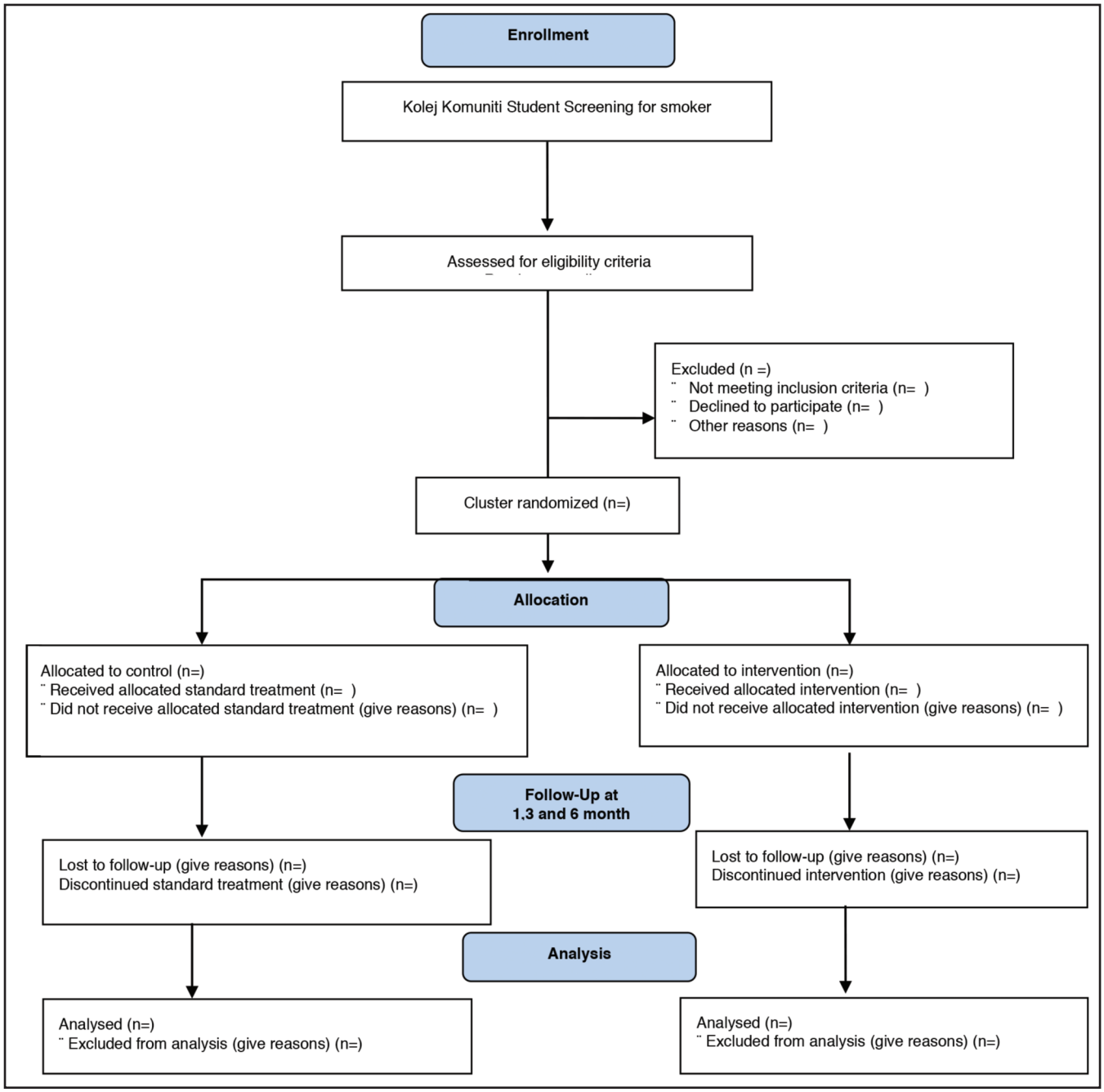

Fig. 1: CONSORT Diagram

group by using the restricted block randomisation. The colleges received either control or intervention arm, i.e., five colleges in each arm. During the baseline and the follow-up period, those who intended to quit were referred to the nearest quit smoking clinics in government health facilities. This is to ensure they received appropriate treatment.

Sample size

Under individual randomisation, the sample size was calculated based on Lwanga and Lemeshow formula,[18] with an alpha level of 0.05 and power of 0.8, and an estimated attrition rate of 10%. Thus, 67 subjects were required in each group to detect a difference equal to or more than 14% in smoking cessation phase. On the other hand, the cluster sample size was based on the formula for the fixed number of cluster.[19] Based on Suen et al., 2016, with the intra-cluster correlation (ICC) of 0.005, a total of 16 subjects per cluster was required to detect such differences.[20]

Intervention

The control group received a standard brief motivational strategy based on the national Clinical Practise Guidelines (CPG) that was provided to the smokers attending government healthcare facilities. The brief motivation

consists of relevance, risks, rewards, roadblocks and repetition themes. The purpose of the brief motivation is to support the patient's self-efficacy. The counsellors at both colleges were provided with a standard training of delivering the brief motivation. On the other hand, in addition to the 5R brief motivation, the intervention group received a biofeedback module by using a CO analyser. The CO level was measured by using ICO Smokelyzer (Bedfont Scientific Ltd., Rochester, UK) where the CO analyser test was connected to the readily available mobile phone application. The measurement was repeated twice with one week apart to reflect the changes in CO level. A brief explanation regarding the test was explained to the subjects. Subsequently, the application displayed the result to the subjects with an interpretation of the results. After that, a feedback consisted of 20 minutes of slideshow incorporating four themes, i.e. the harmful effect of tobacco smoking, the effect of CO, the measurement of CO and benefit of smoking cessation. The contents of the result and the slideshow were emailed to the subjects for reinforcement. The purpose of the CO test is to enhance self-efficacy and the awareness of the smokers regarding the risk of smoking. The counsellor at the college would spend 20 minutes for each session to complete the brief motivational strategy. For the intervention group, each session of brief motivational strategy and biofeedback module would take one hour.

Outcome assessment

The outcome assessment was conducted on the first, third and sixth-month post-intervention via questionnaire. The primary outcome was the proportion of changes relating to the stages of smoking cessation based on the TTM in the third and sixth-month. The outcome was recorded as either increase in stages (0), or maintain or decrease in stages (1). The secondary outcome of the study referred to the behaviour changes regarding a mean number of cigarettes smoked per day and quit attempt at first, third and sixth month. The outcome measurement was conducted as a follow-up by the counsellors at first, third and sixth month to conduct the assessment of the smoking cessation stages.

Variable measurement

At a starting position, a questionnaire was used to collect the following information: (a) sociodemographic characteristics; (b) smoking characteristics; (c) Fagerstrom Test for Nicotine Dependence (FTND); (d) peer pressure inventory; and (e) environmental tobacco smoke (ETS) exposure. The sociodemographic characteristics of the subjects include age, gender, ethnicity, religion and family per capita income. Besides, the smoking characteristics include a mean number of cigarette smoker per day, the age of smoking initiation, a method of acquiring first cigarette, type of smoking, previous quit attempts, and average money spent for smoking per month. On the other hand, the physical dependence on nicotine was measured by utilising a modified version of the FTND that has been translated and validated in the local language. The Peer Pressure Inventory was used to assess the direction and intensity of peer pressure from three domains only i.e. peer conformity, peer involvement and misconduct.[21] The ETS questionnaire was employed to measure the exposure at the institution, home and social settings which was categorised into high or low exposure. In the third and sixth month, the outcome was measured by employing a similar questionnaire to assess the stage of smoking cessation, date of smoking cessation, and mean number of cigarette smoke per day.

Data analysis

Data was entered and analysed in R Studio version 1.0.153 by using Generalised Estimating Equations (GEE) package. In descriptive statistics, the categorical data results were described as a percentage (%) while continuous data as either mean and standard deviation or median and interquartile range. Multiple imputations were also used for the missing data and sensitivity analysis was conducted. Significant level was taken at alpha (α) of 0.05, whereas all P values reported for two-sided. Baseline comparison was analysed by using chi-square test and independent t-test. The outcome variables were compared at the beginning and the effects of the intervention after the first, third and sixth month using GEE. The young adult smoking intervention study usually considers the nesting of intact social groups within each group. Therefore, analysis of the intervention effect has to be analysed at the cluster level and taking into account the intra-class correlation among observation within each cluster. This study adopted a binary GEE model to test the difference between groups after adjusting for potential confounder and multiple imputations for those failed to follow-up. Subgroups analyses were conducted to measure the interaction between time factors x group interaction. To correct for multiple testing, Bonferroni correction will be used to adjust probability values. This study carried out an intention to treat analysis (ITT). Plots were produced to describe the time relationship between outcome and interaction with the group.

RESULTS

The proportion of changes in stage of change was expected to be higher in the intervention group compared to the control group. Apart from that, it was expected to sustain in the first, third and sixth month. Such proportion of changes was to be translated into a mean number of cigarette smoked per day and number of a quit attempt.

DISCUSSION

Smoking is one of the leading modifiable risk factors for non-communicable worldwide disease. As shown by the survival curve, the majority of the smoker relapse at the initial attempt and subsequently manage to quit successfully after several attempts. Therefore, the interventions to mobilize the smokers in making initial quit attempt is equally important. Despite brief advice has proved to be cost effective,[22] adding the biomedical risk assessment may increase the overall results. The figures indicated that improvement can be still made by the current management that promotes smoking cessation. There are a group of smokers who never quit. It is unlikely for the young adults to undertake pharmacotherapy or behavioural treatments.[23] Nevertheless, the young adults have the highest prevalence of smokers whom the healthcare workers had advised to quit smoking. Thus, the intervention aims to resolve this issue, particularly among the young smoker cohort. This group of smokers requires an intervention that provides external cues to raise their awareness of smoking cessation intention. The progression in

the stage of change requires some changes in perception of smoking.[24] The pictorial warning on cigarette packs affect the smoking frequency of the young smokers and forms the incremental effects on their quitting thought.[25] Similarly, the information provided by the CO analyser is able to convey the negative health belief about smoking to the smokers and thus changes the smokers' decisional balance. Ultimately, the smokers will make the intention to quit.

Nevertheless, there are some limitations to this study. The emailed CO result and interpretation were assumed to be received by the smokers and thus reinforced the risk of smoking on them. Another potential limitation of the study is regarding the privacy and confidentiality of the health informatics. There is a rising concern on the privacy of sensitive health-related data, particularly with health mobile apps.[26] Nevertheless, it is beyond the resources of this study to develop security and privacy protection in addition to what has been supplied by the device provider.

The results of this study can provide an insight on whether biomedical risk assessment can be utilised as an additional motivational tool for the young smokers to quit smoking. It is expected that the CO measurement can be used to increase smokers' motivation to change their behaviour and quit smoking.

CONCLUSION

Carbon monoxide measurement is a relatively simple, quick and non-invasive method which can be adopted as an additional method to motivate the smokers in quitting. Nevertheless, the future study should expand into other subgroup populations of smokers and other issues such as cost-effectiveness study.

ETHICS

This study has been granted an ethical approval from the Universiti Putra Malaysia's ethics committee (FPSK-P074 (2017) and has been registered at Australia New Zealand Clinical Trial Registry (ANZCTR) with trial id ACTRN12618000291280. The individual informed consent forms consisted of the information sheet and the consent form were collected from the participants before the study. The principal investigator had informed and explained to the participants regarding the data use and the purpose of research.

COMPETING INTERESTS

The authors declare that they have no competing interests.

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