

RANDOMISED CONTROL TRIAL TO ESTABLISH THE SMOKE-FREE HOME - A STUDY PROTOCOL

Lim K.H.^{1*}, Sumarni Mohd Ghazali¹, Jia Hui Lim²,
Chee Cheong Kee³, Hui Li Lim⁴

¹Institute for Medical Research, Jalan Pahang, 50588, Kuala Lumpur.

²Monash University Malaysia, Bandar Sunway, Selangor

³National Institute of Health, Bandar Setia Alam, Shah Alam, Selangor

⁴Hospital Sultan Ismail, Bandar Mount Austin, Johor Bahru, Johor

Corresponding author: Lim Kuang Hock, Institute for Medical Research, Jalan Pahang, 50588, Kuala Lumpur. Email: limkh@imr.gov.my/keelimkota@yahoo.com

<https://doi.org/10.32827/ijphcs.7.3.90>

ABSTRACT

Background: A multitude of studies revealed that SHS exposure had increased the risk of diseases and mortality. However, there are studies reported that a substantial proportion of Malaysian adults and youth were still exposed to SHS at home. Therefore, the reduction on the SHS at home is paramount essential to reduce the risk of morbidity and mortality among Malaysian. This study aims to investigate the effectiveness of randomised control intervention to establish smoke-free home and proportion of quit smoking rate among the intervention groups.

Materials and Methods: This study use open-label, parallel, randomised control trial and involve households from selected villages in the state of Selangor. A total of 70 households will be recruited into the study based on an expected reduction of 25% between baseline and week 12 in log-transformed mean home air quality (PM_{2.5}) between the control and intervention groups. The outcome variable is the incidence rate of smoke-free home initiation. Both intervention and control groups will receive health-related education materials on smoking, but for the intervention group, behavioural, personalised indoor air quality feedback, and other markers of SHS exposure will be introduced. Two-way repeated measure ANOVA, correlation and repeated proportion analysis will be employed in the analysis.

Expected outcome: This study will be able to determine the effectiveness of the randomised controlled trial intervention to establish a smoke-free home, which can then be expanded and integrated with other interventional programmes in reducing the SHS exposure to SHS at home among the Malaysian populations.

Keywords: Smoke-free home, randomised control trial, behavioural, indoor air quality feedback, SHS marker.

1.0 Introduction

Second-hand smoke (SHS) is defined as a mixture of exhaled mainstream smoke and sidestream smoke released from a smouldering cigarette or other smoking devices (WHO, 2004). Exposure to SHS contributes to various health problems, such as the increased risk of lung cancer, heart disease, and respiratory conditions among adults (Samet et al., 2009; Oono et al., 2011). In addition, 600,000 premature deaths annually were resulted from non-smokers being exposed to SHS. It is estimated to account for 0.7% of the total global burden of disease, and Oberg et al. (2011) estimated 10% of the total tobacco-related economic cost is attributable to second-hand tobacco smoke exposure (WHO, 2015). Furthermore, there is no safe level of exposure (USDHHS, 2006, WHO 2015). Therefore, efforts in reducing the SHS exposure among non-smokers and vulnerable groups are paramount importance to lessen the SHS related diseases.

The Malaysian government, through the Ministry of Health (MOH), have taken proactive measures to reduce SHS exposure among the public. These include the introduction of a law to restrict smoking in several public places, such as health facilities and public transport vehicles, through the Control of Tobacco Products Regulation 1993 (Government of Malaysia (GOV), 1993). The smoke-free public areas were expanded through several amendments. As of the year 2017, 38 public areas and workplaces have been gazetted under the regulation (GOV 2015; GOV 2017) to protect non-smokers from SHS exposure and to create environments that deter smokers from smoking. Increasing numbers of jurisdictions had reduced non-smokers SHS exposure in Malaysia (Lim et al., 2018). In addition to the prohibition of smoking in public areas legislation, MOH has also included the health promotion campaign to establish a smoke-free home in the community intervention programme (Lim et al., 2014).

The proportion of non-smokers living in smoke-free homes (SFHs), defined as a home where no one is allowed to smoke anywhere inside the house, is increasing in many countries. Many studies have shown that SHS exposure could be substantially reduced when smoking in the home is restricted entirely (Pizacani et al., 2004; Hughes et al., 2009). However, The Global Adult Tobacco Survey in Malaysia revealed there is only 17.8% of Malaysian households have “Implemented” the smoke-free home (Institute of Public Health (IPH), 2012) and one-third of Malaysia population (33.9%) was exposed to SHS at home. In addition, 37.8% of school-going adolescents have reported SHS exposure at home for at least once during the last seven days (IPH, 2016). Therefore, it is time to increase the proportion of smoke-free home in Malaysia to reduce the prevalence of SHS exposure at home, primarily to protect the vulnerable groups (i.e. children and elderly) in Malaysia.

General objective:

To determine the effectiveness of behavioural, personalised indoor air quality feedback, and other markers of SHS exposure (e.g., saliva cotinine) with the adoption of smoke-free home.

Specific objectives:

1. To determine the change in air quality in the home, measured as average 16-24 hours levels of particulate matter of <2.5 (PM_{2.5}), between baseline and 12 weeks.
2. To determine changes in maximum PM_{2.5}, the proportion of time PM_{2.5} exceeded the WHO recommended levels of maximum exposure of $25 \mu\text{g}/\text{mg}^3$.
3. To measure the child salivary cotinine and caregivers' cigarette consumption.
4. To determine quit attempts and quitting altogether during the intervention among smokers.
5. To determine the proportion of smoke-free home adoption between control and intervention groups.

2.0 Materials and Methods**2.1 Study design**

Open-label, parallel, randomised control trial.

2.2 Sample size determination

The sample size of an interventional study with the ratio 1:1, with the power of study of 80%, type one error (alpha) of 5%, and the expected reduction of 25% (based on experts opinion) between baseline and week 12 in log-transformed mean home air quality (PM_{2.5}) in the intervention group compared with the control group. Fifty-eight households from experimental and 58 controls will be selected. To cater for non-response rate of 20%, 70 households will be ultimately invited to participate in the study.

2.3 Locality

Ten villages located in Selangor state will be selected randomly, five will be randomly assigned to intervention groups, while the remaining will be grouped into the control group. All the respondents that fulfilled the inclusion criteria will be invited to participate in the study. In both treatment groups, data were collected during home visits at baseline, 7, 12 and 24 weeks, carried out by a trained researcher. Participants will complete the questionnaires on socioeconomic status, their health, family and household composition, current smoking behaviour and beliefs relating to home smoking with children.

2.3.1 Inclusion criteria

- (a) Malaysian citizen;
- (b) At least 18 years old;
- (c) Were the caregiver of a child aged under 5 years living in their households with more than one child under 5 years;
- (d) They are smoking tobacco inside their home.

2.3.2 Exclusion criteria

- (a) Non-Malaysian;
- (b) Trying to quit smoking or had attempted to do so in the 3 months preceding recruitment;
- (c) As were pregnant smokers, those planning a pregnancy or breastfeeding during the intervention period;
- (d) Those with health-based contraindications to nicotine replacement therapy (NRT) use;
- (e) Those are living in hostels or institutions.

2.4 Intervention

The intervention comprised of feedbacks on the air quality measured in the home, salivary cotinine concentration, and behavioural support on how to create a Safe Free House (SFH) delivered by a trained research team member; and advice for temporary abstinence or for cutting down tobacco smoking in the home, provided at baseline, 7 and 12 weeks.

2.4.1 Measurement of indoor air quality

Indoor air will be sampled for up to 24 hours using a Sidepak Aerosol Monitor AM510 (TSI Instruments Ltd, High Wycombe, UK). The instrument will be positioned in the main living area. The number of sampling point will be based on the total floor areas of the house (Department of occupational, safety and Health, 2010). Monitors were set with the calibration factor of 0.30 by the manufacturer to measure particle sizes of second-hand smoke (PM_{2.5}). Using Trackpro software installed on the air monitors, the research team will convert the data collected during the three periods of air quality measurement (i.e. baseline, week 7 and week 12) into a graphical format that could be easily explained to the participant immediately after each measurement period, relating the information to the WHO recommended 24 hours of PM_{2.5} concentrations below 25 µg/m³ per 24-hour period (WHO, 2005). Participants will be shown with the graphs with attention drawn to periods that showed particularly high or low SHS exposure in the home, supported by the discussion on reasons for high or low values as well as strategies to reduce exposure both in general and during periods when the levels were particularly high. Data collected at weeks 7 and 12 will be superimposed on the baseline graph to enable the comparison of PM_{2.5} levels over the intervention period.

2.4.2 Saliva cotinine measurement

The saliva samples used to measure cotinine, a major proximate metabolite of nicotine and a biological marker for SHS exposure, were taken from the household members during the home visit by a member of the research team in the presence of the caregiver. The saliva samples will be collected using the Salimetrics test kits ([Salimetrics, 2009](#)), which contained a piece of chewable cotton stick in a sterile tube. Stimulated saliva samples will be collected by asking the subject to chew the cotton stick for two minutes and then place the cotton back in a sterile tube. Samples will be transported to the laboratory within 10 hours of collection. Before sample collection, respondents will be advised to avoid acidity, high-sugar food nicotine, and prescription/over-the-counter medications within the prior 12 hours. In addition, they will be advised not to brush teeth or eat a major meal within 60 minutes of sample

collection, not to rinse the mouth with water to remove food residue and have to wait for at least 10 minutes before saliva collection.

The saliva cotinine result will be delivered to the participant after the result for each measurement was obtained; the research team member will discuss the result with the participants.

2.4.3 Behavioural support

Behavioural support for the intervention group will be comprised of face-to-face home visits by a specialist SFHA offered on four occasions (i.e. 1-2 days after baseline measurements, at 3, 7 and 12 weeks) and lasting for up to 1 hour. The trained research team member and participants will be discussing on the current smoking behaviours in and around the home using a 'Smokefree Home Factsheet', and explore personalised strategies to avoid smoking indoors in the context of individual circumstances. In addition, participants will receive a minimum of three proactive phone calls (e.g. during the first week, fourth and after eight weeks of follow-up) and they will be offered to contact the trained research team member via phone or text message on an ad hoc basis for support during the intervention period during office hours if it is necessary. Adult smokers living in the same household were eligible to receive the same behavioural support.

2.5 Control group

Participants randomised to the control group will be provided with a 'Smoke-Free Homes resource pack', The pack contains a fact sheet, booklet, door hangers, magnets, stickers, information on constituents of tobacco smoke and how to keep the family members from exposure to SHS.

The concentration of air PM2.5, salivary cotinine and behavioural on smoking will be measured in all intervention and control groups, after 24 weeks to determine the sustainability of the intervention effect of 12 weeks.

2.6 Data analysis

An intention-to-treat analysis was performed using all randomised participants. Two-way repeated measure ANOVA analysis will be utilised to determine the PM2.5 airborne concentration within and between intervention and control group, while correlation analysis will be used to determine the relationship between the child salivary cotinine and caregivers' cigarette consumption. All above-mentioned statistical analysis will be run using the SPSS statistical software version 20. STATA statistical software will be used to determine the proportion of time that PM2.5 has exceeded the WHO recommended levels of maximum exposure of 25 µg/mg³, and quit attempts and quitting altogether during the intervention among the smokers in intervention and control groups. All statistical analysis will be tested at a 95% confidence interval.

3.0 Expected Outcome

The study will enable the effectiveness of the air quality measured in the home, salivary cotinine concentration, and behavioural support on how to create a Safe Free House in established the smoke-free home among smoker(s) who smoked in the home. The successful of the intervention will enable the replication of similar methods in other localities in the country, to address the SHS exposure at home among Malaysian population.

Acknowledgement

We would like to thank the Director-General of Health, Malaysia, for his permission to publish this paper.

Declaration

No conflict of interest declared.

Authors contribution

Author 1: Literature review and written the final version of manuscript.

Author 2: contributed to the idea for the study, and revised the manuscript.

Author 3: Design the study and revised the manuscript.

Author 4: Literature review, and revised the manuscript.

Author 5: Study design, statistical analysis and revised the manuscript.

References

Department of occupational safety and Health (2010). Industry Code of Practice. Malaysia: Ministry of Human Resource.

Government of Malaysia (2005). Food act 1993: Control of tobacco product regulations. 2004. Retrieved from <http://www.tobaccocontrollaws.org/files/live/Malaysia/Malaysia%20-%20TC%20Regs%202004.pdf>.

Government of Malaysia. (2015). Declaration of non-smoking area. 2015. Retrieved from [http://www.federalgazette.agc.gov.my/output/pub_20150709_P.U.%20\(B\)%20273%](http://www.federalgazette.agc.gov.my/output/pub_20150709_P.U.%20(B)%20273%)

20%20Perisytiharan%20Kawasan%20Larangan%20Merokok%202015.pdf

- Government of Malaysia (2017). Declaration of non-smoking area. Retrieved from [http://www.federalgazette.agc.gov.my/output/pub_20170414_P.U.%20\(%20B\)%20195%202017.pdf](http://www.federalgazette.agc.gov.my/output/pub_20170414_P.U.%20(%20B)%20195%202017.pdf)
- Hughes, S.C., Corcos, I.A., Hofstetter, C.R., Hovell, M.F., Irvin, V.L., et al. (2009). Home smoking restriction among Korean in Seoul. *Asia Pacific Journal of Public Health*, 21(1), 63-70.
- Institute for Public Health. (2012). *Report of the Global Adult Tobacco Survey (GATS). Malaysia 2011*. Malaysia: Ministry of Health.
- Institute for Public Health. (2016). *Tobacco & E-Cigarette Survey Among Malaysian Adolescents (TECMA) 2016*. Malaysia: Ministry of Health.
- Kegler, M.C., & Malcoe, L.H. (2002). Smoking restrictions in the home and car among rural native American and white families with young children. *Preventive Medicine*, 35(4): 334-342.
- Lim, K.H., M Fadhli, M.Y., Omar, M., Rosnah, R., M, Nazaruddin, B., Sumarni, M.G. et al. (2014). *Technical Report. Evaluation of effectiveness of implementation of "Komuniti Sihat Perkasa Negara" (KOSPEN) Programme in Malaysia - Phase I*. Malaysia: Institute of Public Health.
- Lim, K.H., Teh, C.H., M Haniki, N.M., Sayan, P., Ling, M.Y., M Fadhli, M.Y., et al. (2018). Exposure to tobacco second-hand smoke and its associated factors among non-smoking adults in smoking-restricted and non-restricted areas: findings from a nationwide study in Malaysia. *BMJ Open*, 8, e017203.
- Oberg, M., Jaakkola, M.S., Woodward, A., Peruga, A., & Pruss-Ustun, A. (2011). Worldwide burden of disease from exposure to second-hand smoke: a retrospective analysis of data from 192 countries. *Lancet*, 377, 139-146.
- Oono, I.P., Mackay, D.F., & Pell, J.P. (2011). Meta-analysis of the association between second hand smoke exposure and stroke. *Journal of Public Health*. 33, 496-502. doi:10.1093/pubmed/fdr025
- Pizacani, B. A., Martin, D. P., Stark, M. J., Koepsell, T. D., Thompson, B., & Diehr, P. (2004). A prospective study of household smoking bans and subsequent cessation related behaviour: the role of stage of change. *Tobacco control*, 13(1), 23-28. <https://doi.org/10.1136/tc.2003.003038>
- Salimetric (2009). [Guidelines for Interpreting Cotinine Levels: United States](https://salimetrics.com/guidelines-for-interpreting-cotinine-levels-united-states/). Retrieved from <https://salimetrics.com/guidelines-for-interpreting-cotinine-levels-united-states/>

- Samet, J. M., Avila-Tang, E., Boffetta, P., Hannan, L. M., Olivo-Marston, S., Thun, M. J., & Rudin, C. M. (2009). Lung cancer in never smokers: clinical epidemiology and environmental risk factors. *Clinical cancer research : an official journal of the American Association for Cancer Research*, 15(18), 5626–5645. <https://doi.org/10.1158/1078-0432.CCR-09-0376>
- Shaw A, Ritchie D, Semple S, Turner S, O'Donnell R, Amos A, Millo L, Wilson J.(2012).. Reducing children's exposure to second hand smoke in the home: a literature review. A report by ASH Scotland.
- U.S. Department of Health and Human Services (2006). *The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General*. Atlanta (GA): Centers for Disease Control and Prevention (US).
- World Health Organization (2004). *Tobacco smoke and involuntary smoking: summary of data reported and evaluation*. Geneva: World Health Organization.
- World Health Organization (2005). *WHO Air quality guidelines, for particulate matter, ozone, nitrogen dioxide and sulfur dioxide, Global Update 2005*. Geneva: World Health Organization.
- WHO 2015, WHO Smoke free initiative (2015). *Protect people from exposure to second-hand tobacco smoke*, Retrieved from. <https://www.who.int/tobacco/mpower/protect/en/index1.html>