

# Designing a Spouse-based Educational Intervention Module to Reduce Second-hand Smoke in Pregnant Women: A Study Protocol

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## ABSTRACT

**Introduction:** Secondhand smoke (SHS) exposure affects not only the maternal wellbeing but also unborn baby. This study aims to develop a spouse-based educational intervention to reduce SHS exposure by examining the understanding and perception of both pregnant women and their smoking spouses.

**Methods:** Using a sequential exploratory mixed-method research design, this study will be conducted through four phases. In the first phase, a qualitative study will be conducted to examine the understanding and perception of pregnant women and their smoking spouses regarding secondhand smoke exposure. In the second phase, the content of the educational intervention will be designed based on the outcomes of the first phase and from the literature review. Validation of the designed intervention will be conducted by experts to assess the accuracy of the contents in phase 3. After the validation, a pilot study will be conducted to measure the comprehensiveness of the module. The feasibility and effectiveness of the intervention will be measured in phase four by a pre-test and post-test study design.

**Expected outcome and conclusion:** The designed educational intervention module of SHS exposure can be used as a breakthrough point to empower non-smoking pregnant women to protect themselves from secondhand smoke exposure, and also to facilitate the smoking spouse to change their smoking behavior, and thus promote the smoke-free home.

**Keywords:** Educational intervention, Second-hand smoke, Pregnant women, Smoking spouse

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## INTRODUCTION

Smoking causes significant harm to the smokers themselves and those around them, known as second-hand smoke (SHS).<sup>1</sup> Annually, 600 000 deaths from SHS exposure have been reported globally due to exposure to SHS.<sup>2</sup> There is no safe level of SHS, and its adverse effects still occur even at a lower level.<sup>3</sup> A recent study found that the more people are exposed to SHS, the higher their risk of health problems that they are exposed to<sup>1</sup>. In adults, SHS exposure causes lung cancer, cardiovascular diseases, and chronic obstructive pulmonary diseases (COPD).<sup>4</sup> SHS exposure in children increases the risk of sudden infant death syndrome, lower respiratory tract infections, asthma, respiratory illness, meningitis, and middle ear disease.<sup>5</sup>

While SHS exposure is harmful to the general population, high-risk groups such as pregnant women should be given priority. Pregnant women require special care and attention as exposure to SHS not only affects the wellbeing of the mother but also their unborn baby. It is estimated that more than a third (35%) of non-smoking women worldwide are exposed (even during pregnancy to SHS).<sup>6</sup> The negative effects of maternal smoking are widely debated and these include the increased risk of premature birth, low birth weight, fetal abnormalities, and fetal mortality.<sup>5</sup> Similar effects have been reported for pregnant women exposed to SHS but at a lower level of relative risk and dependent on the amount, type, and timing of exposure.<sup>7</sup> Toxic substances from SHS exposure cross the placenta and directly affect the fetus thus increasing the risk of neonatal and perinatal morbidity and mortality such as stillbirth and congenital malformation and low birth weight<sup>8-10</sup>. However, a few health promotion measures implemented in Malaysia to promote comprehensive smoke-free policies and to protect people from exposure to SHS especially towards pregnant women<sup>11</sup> as compared to developed countries which preventing people from SHS exposure has become their top priority<sup>12</sup>. These highlights the necessity of SHS prevention intervention to educate the public on the harmful effects of SHS exposure toward pregnant women and their unborn babies, particularly to smoking spouses as the main source of SHS exposure at home<sup>10,13-</sup>

<sup>14</sup>

The content of the intervention should emphasize both pregnant women and their smoking spouse since most of the interventions do not directly target that husband who smokes but provide the intervention to non-smoking pregnant women on ways to help their smoking husband to quit thus the real outcome of the intervention are inconclusive<sup>15</sup>. In addition, the involvement of smoking spouses in ensuring the health of their pregnant wives is important to increase awareness of the dangers of smoking and increase sensitivity to the need to prevent SHS exposure at home<sup>16</sup>. Pregnancy can be a motivating factor for changing the behavior of a smoking spouse<sup>14</sup>. However, to overcome the phenomenon of quitting during pregnancy as temporary abstinence among smoking spouses, the intervention must also focus on understanding factors that contribute to their continuing to smoke<sup>17</sup> and any potential barrier and facilitator to achieve smoking cessation<sup>18</sup>.

To develop effective prevention intervention toward SHS exposure it is relevant that we know their knowledge, attitude, and avoidance behavior toward SHS exposure<sup>13</sup> and the barrier that influences their avoidance behavior<sup>19</sup>. There is a current study that looked into the prevalence, knowledge, attitudes, and avoidance behavior of pregnant women in Malaysia toward SHS exposure<sup>13</sup>, however, the knowledge on the exploration of qualitative findings of their perception or understanding form toward SHS exposure, especially among non-smoking pregnant women and their smoking spouse is limited. Therefore, the purpose of the study was to design spouse-based educational intervention to reduce SHS exposure through exploring the understanding and perception of both pregnant women and their smoking spouses.

## METHODS

### Research design

This study will use a sequential exploratory mixed-method research design. It is a design in which the researcher first begins by exploring with qualitative data and analysis, then develop the content of the education module based on these result and subsequently use these tools in the quantitative phase of the study. The intervention mapping (IM) protocol by Bartholomew<sup>20</sup> will be used as a planning tool for developing this systematic

intervention. This study consists of four phases: (1) formative research (need assessment), (2) development of the intervention, (3) formative evaluation (experts review and pilot study), and (4) process evaluation (intervention study). Completing all four phases serves as a blueprint for designing, implementing, and evaluating an intervention based on a foundation of theoretical, empirical, and practical information<sup>21</sup>.

### **Research hypothesis**

Referring to the main purpose of the study, the hypothesis will be measured based on the view of educational intervention. The mean score for knowledge, attitude, and avoidance behavior toward SHS exposure of pregnant women will be significant differences in the intervention group as compared to the control group. The mean score of motivation to quit, readiness to quit and knowledge of the smoking spouse's also will be significantly different in the intervention group compared with the control group.

#### ***Phase one: Formative research (Need Assessment)***

A qualitative study using in-depth face-to-face interviews will be conducted to explore their understanding and perception of SHS exposure. Two groups of participants will be recruited which include pregnant women and smoking spouses. Inclusion criteria for pregnant women are: women at reproductive age (18 to 45 years of age), non-smoking but living with a smoking spouse, and had SHS exposure at most minuscule six cigarettes per week or more within two months before or since pregnancy and carbon monoxide (CO) score level more than six ppm to indicate SHS exposure<sup>22</sup>. Pregnant women who had a medical problem and mental disability either before or during pregnancy and did not understand English or Malay will be excluded.

Eligible criteria of a smoking spouse are: smoke at least one cigarette stick per day with a six ppm or more CO score to indicate smoking status, living with a non-smoking pregnant wife, and did not participate in any clinical trial simultaneously (i.e joining smoking cessation clinic). Potential participants who met the sampling criteria will be invited to participate in this study. An information package

consisting of an information sheet and a consent form will be given before the interview. The interview will be arranged according to participants' preferences. Only one face-to-face interview session will be conducted for each participant. The phone call follow-up interview will be conducted if the researcher requires additional data. The interview schedule will be conducted separately between pregnant women and their smoking spouses to minimize information bias. The interview will be transcribed and analyzed verbatim using thematic analysis. The findings will be presented through themes such as the barriers in creating a smoke-free home and strategies to reduce SHS exposure and this will be used to develop the intervention in phase 2. The estimated duration for this phase to be complete will be around 6 months including the interview and data analysis of the finding.

#### ***Phase two: Development of the intervention***

The objective for phase two is to establish the content of the intervention module. The module's content of the intervention will be integrated from the finding of phase one and a review of the literature. The content will be focused on pregnant women and their smoking spouses which may include the briefing on SHS information, communication skills, and smoking cessation. The educational method may include sharing the experience of pregnant women with smoking spouses and ex-smokers' experiences through digital stories (i.e video, written descriptions, and voice notes). In addition, there is an educational pamphlet for take-home messages to reinforce health education information. Subsequent follow-up phone calls will also be conducted after one month and three months of the intervention to discuss with the pregnant women and their smoking spouse if any difficulties encounter to create a smoke-free environment at their home and reinforce negotiation skills.

#### ***Phase three: Formative evaluation (experts review and pilot study)***

The validation process of the module content is the final part of the development before implementing and evaluating the intervention's effectiveness. This validation process will be conducted among experts in the field. In doing so, at least three smoking experts will be selected based on inclusion criteria

which have at least more than five years of experience in smoking prevention fields including counsellors, consultants, and pharmacists to assess the module contents in terms of coverage of the topic, the accuracy of the contents, relevance to the target population, and appropriateness of the strategies. The experts are asked to make any recommendations and suggestions on the module content. Then, a pilot study will be conducted to ensure that the module content is acceptable and at a basic level for comprehension as it was delivered in its final form. The participants of non-smoking pregnant women with the criteria aged between 18 to 45 years old, first pregnancy and first trimester, and their smoking spouse from the selected Maternal Child Health (MCH) will be asked to join this validation process. A set of questionnaires will be given to them to evaluate the content of the module. Finally, the module content will be revised according to the feedback given by the end-user (target population) and experts during the validation process.

**Phase four: Process evaluation (intervention study)**

Upon validation, a prospective single-group study design with pre-test and post-test will be conducted to evaluate the effectiveness of the designed module. The study population will be non-smoking pregnant women and their smoking spouses from six selected MCH clinics in Kuantan, Pahang. Both pregnant women and smoking spouses will be randomly recruited based on inclusion and exclusion criteria. At this phase, the pregnant women will be assessed in terms of their knowledge, attitude, and avoidance behavior toward SHS exposure, while their smoking spouses will be assessed in terms of their knowledge on SHS exposure and their readiness, and motivation to quit smoking at 3-months and 6-month post-intervention. The participants from phase one will not include in this phase.

<b>Pregnant women</b>	<b>Smoking spouse</b>
<ul style="list-style-type: none"> <li>• 18 to 45 years old (reproductive age)</li> <li>• Non-smoking</li> <li>• First trimester (12-week gestation or less based on last menstrual period)</li> <li>• Having and living with a smoking spouse</li> <li>• Had history of SHS exposure by their smoking spouse (at least six cigarettes per week or more within 2 months before or since pregnancy)</li> <li>• Breath CO level more than 6 ppm (indicate SHS exposure)</li> </ul>	<ul style="list-style-type: none"> <li>• Smoke at least one cigarette per day</li> <li>• Has a non-smoking wife</li> <li>• Not participate in any clinical trial at the same time (e.g. smoking cessation clinic)</li> <li>• Breath CO level more than 6 ppm (indicate smoker)</li> </ul>

**Table I.** Inclusion criteria for phase 4

<b>Pregnant women</b>	<b>Smoking spouse</b>
<ul style="list-style-type: none"> <li>• Have a medical problem and mental disability either before or during pregnancy.</li> <li>• Do not understand Malay or English</li> </ul>	<ul style="list-style-type: none"> <li>• Not staying with their pregnant wife for more than one week</li> <li>• Do not understand Malay or English</li> </ul>

**Table II.** Exclusion criteria for phase 4

The selection of participants will be based on convenience sampling. The sampling method will be a simple random technique.

### Sample size

The sample size was determined using PS Software (1990)

Type of study: t-test

Designed: paired

P0	= 0.56,	P1	= 0.22
$\alpha$	= 0.05,	Power	= 0.80
m	= 1		
n	= 74		

Based on the calculation, the required sample size is 74 participants. It was recommended to add 10-20% for dropouts. In conclusion, a total number of 81 to 88 were acceptable

### Instruments

The main instrument for this phase 4 is the pre-intervention and post-intervention (three month and six months) questionnaires. There will be two questionnaires used in this study; for pregnant women and smoking spouses. The questionnaire for pregnant women was adapted and modified from previous studies by Siti Munira et al.<sup>13</sup> and Suriani et al.<sup>23</sup> It consists of four parts: socio-demographic characteristics and pregnancy history, knowledge, attitude, and avoidance behavior toward SHS exposure. The knowledge toward SHS will be assessed using ten questions, and for each correct response, 1 point will be awarded. The attitude toward SHS exposure will be assessed using eight questions with 5 points Likert response scale. The scale is 'strongly agree' = 5, 'agree' = 4, 'not sure' = 3, 'disagree' = 2 and 'strongly disagree' = 1. The avoidance behavior toward SHS exposure part will be assessed using ten questions with 4 points Likert response scale (1= all the time; 2= always; 3= sometimes; 4 = never). The questionnaire for smoking spouses gathered socio-demographic characteristics, smoking history, readiness and motivation to quit, and knowledge toward SHS exposure. Smoking spouse readiness to quit part will be assessed using Transtheoretical Model. The translated version of the questionnaire adopted from the Health Education Unit, National Cancer Institute which was originally from the URICA

DELTA, Project Reduced Drinking Version 2004<sup>24</sup> will be used. This questionnaire consists of four subscales including Pre-contemplation, Contemplation, Action, and Maintenance, with two questions in each subscale. Responses to each of the 12 items were given on a scale of 1-3, with 1 for 'disagree', 2 for 'undecided', and 3 for 'agree'. The score will be calculated based on the means for all the subscales separately and subtracting the mean of the pre-contemplation from the summation of the other three subscales means. In the motivation to quit part questionnaire<sup>25</sup> the question is a single item, self-rated questionnaire on how strong the smokers' motivation level is with five responses on a scale of 1-5, 1 for 'not sure', 2 for 'not strong at all', 3 for 'not very strong', 4 for 'quite strong', and 5 for 'very strong'. Meanwhile, the questionnaire for knowledge of smoking spouse will use the same questions in pregnant women questionnaire.

In addition, the participants will be screened for exhaled breath CO level using a standard handheld CO analyzer (piCO Smokerlyzer, Bedford Scientific Ltd, England) to confirm their exposure to SHS (pregnant women) and smoking status (smoker). The eligible participants include those who exhaled carbon monoxide levels with six ppm and more.

### Data collection method

The potential participants who met the sampling criteria are invited to participate in this study. An information package that consists of an information sheet and consent form will be sought before conducting the study. Each participant will complete a baseline questionnaire, and exhale CO level will be measured. Then, the participant will be received spouse-based educational interventions. Three months and six months following the intervention, participants will complete a follow-up questionnaire, and exhale CO level will be reassessed.

### Data analysis

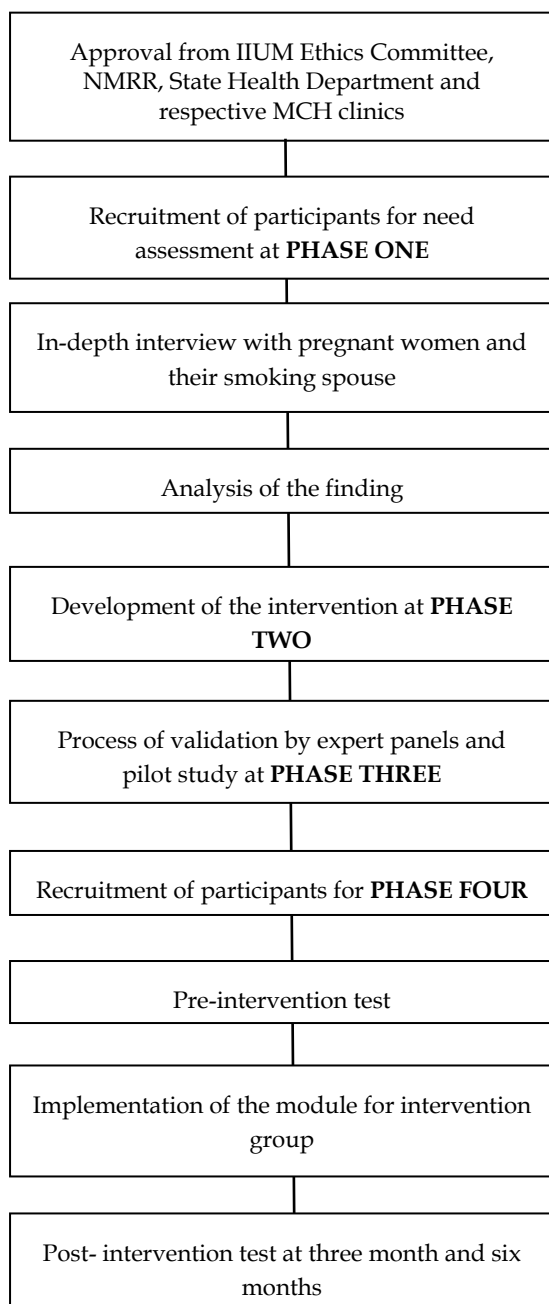
The data of the study will be statistically analyzed with the Statistical Package for Social Sciences (SPSS) computer software program. Descriptive statistics of frequencies, percentages, and means will be used to describe the demographic profile of the participants. The differences between the pre-intervention

and post-intervention scores are established using paired t-test.

**Ethical consideration**

This study will seek approval from Kulliyah of Nursing, International Islamic University Malaysia (IIUM), and the National Research Registry of Malaysia (NMRR). The key ethical issues of this study are concerning (1) recruitment, (2) confidentiality, (3) consent, and (4) safe storage, access, and disposal of data. This study will be guided by the guidelines and protocol given by the Research Ethics of IIUM.

**Figure 1:** The summary of the flow of the study



**Expected Outcomes and Benefits of the study**

Various studies were conducted to reduce exposure to SHS among pregnant women by overcoming the barriers to pregnant women establishing smoke-free homes<sup>26</sup>. These include enhancing their self-efficacy<sup>26-27</sup>, increasing awareness by providing knowledge<sup>26-28</sup>, changing attitude<sup>28</sup>, and developing negotiation skills.<sup>26,29</sup> To date, most of the intervention studies focused either on pregnant women’s avoidance behaviors or changing smoking spouse behaviors as outcomes.<sup>26-27,29</sup> However, the most effective intervention to reduce SHS exposure should focus on both pregnant women and their smoking spouses<sup>15</sup>. In addition, the evidence of specific strategies is limited because self-reported exposure during pregnancy is maybe unreliable and must be duplicated with the biochemically-validated outcome. Reduction of the information bias might be made through precise objective measures during the screening of potential participants in addition to self-report<sup>30</sup>.

First-ever guidelines for the prevention and management of tobacco use and SHS exposure during pregnancy was recommended that healthcare providers ask all pregnant women about exposure to SHS as early as possible in the pregnancy, and at every antenatal care visit<sup>31</sup>. The content of the educational intervention should emphasize information about the risks of SHS exposure to pregnant women from SHS exposure, and wherever possible, to provide cessation support to their smoking spouses. Therefore, additional studies are needed to design the most effective intervention based on guidelines<sup>31</sup> as an effort to reduce SHS exposure during pregnancy, including ones that might promote creating smoke-free homes<sup>19</sup>.

This present study provides vital information by exploring the understanding and perception of non-smoking pregnant women and their smoking spouse toward SHS exposure and the limitations they had in creating a smoke-free home. This knowledge is required to ensure that the intervention developed can be tailored to individuals’ specific characteristics thus optimizing healthcare resources<sup>19</sup>. This designed module can be used as a breakthrough point to educate and empower non-smoking pregnant women to protect themselves from exposure, help the smoking

spouse change their smoking pattern, and quit smoking. In addition, it might lead to better health in the family; the father, the mother, and their unborn baby. Ultimately, the prevalence of neonatal and perinatal morbidity and mortality related to SHS exposure can be reduced. We suppose that this educational intervention has the potential to be integrated into clinical recommendation guidelines thus improving the women's health from risk of SHS exposure, particularly during pregnancy.

## CONCLUSION

In the future, this intervention can be integrated into routine antenatal care in a health care setting to reduce SHS exposure, especially toward pregnant women and their unborn children, and indirectly promote smoking cessation toward smoking spouses.

## CONFLICT OF INTEREST

There were no conflicts of interest.

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