A QUASI EXPERIMENTAL STUDY ON HEALTH EDUCATION INTERVENTION IN MANAGING PREGNANT WOMEN WITH ANAEMIA IN SEPANG, MALAYSIA: A STUDY PROTOCOL

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ABSTRACT

Background: Anaemia is a common health problem among pregnant women in Malaysia and has a significant health consequence to mother and their infants. The provision of iron supplements and an array of health educational strategies to pregnant women are the most widely practice in Malaysia public health measures. In Malaysia currently, the implementation of health education methods and materials on anaemia in pregnancy given to the antenatal mothers differ throughout the country. The aim of this study is to develop, implement and evaluate the effects of a theory-based health educational intervention on the haemoglobin level among anaemic pregnant women.

Materials and Methods: This study uses a quasi-experimental study design and conceptualized based on the Health Belief Model (HBM). It will involve two groups of antenatal mothers (control and intervention) from two health clinics in the district of Sepang, Selangor. There will be 81 pregnant women with anaemia per group that met the inclusion and exclusion criteria. Data will be collected using self-administered questionnaire. The primary outcome variable is differences in haemoglobin levels between the intervention and control groups in the third trimester. Secondary outcome include knowledge regarding anaemia, HBM constructs, dietary iron intake and level of compliance towards iron supplementation. Both groups will be receiving routine antenatal care and practice. Additionally, the intervention groups will be given a validated theory-based health education intervention on anaemia in pregnancy. Univariate, bivariate and multivariate analysis will be performed. All hypotheses tests were two-sided and level of significance was set at 0.05.

Discussion: If the theory based health education intervention is effective in improving the outcome for pregnant women with anaemia, this approach could be taken into consideration to improve the anaemia in pregnancy after further research.

Keywords: Anaemia, Pregnancy, Health Belief Model, Health education Intervention
1.0 Introduction

Anaemia in pregnancy is a serious global public health issue and poses a significant health problem among pregnant women in Malaysia (Millman, 2015). Anaemia is defined by the World Health Organization (WHO) as haemoglobin levels of less than 11 g/dl for all trimester (WHO, 2001). Nutritional anaemia in pregnancy is found to be the most prevalent in Malaysia (Foo et al., 2004). About 27% of pregnant women in Malaysia have anaemia in 2011 and therefore still constitutes as a significantly moderate public health problem (WHO, 2011). The goals of anaemia management are to restore the normal level of red blood cells and haemoglobin and to replenish iron stores. The basic approaches use to prevent and control anaemia are: supplement with iron tablet and provide health education to the mothers (Millman, 2015). In Malaysia, all pregnant women were given health education on anaemia in pregnancy during their antenatal follow up. These health education which include education to increase intake of iron rich food by health care practitioners during pregnancy and empowering women with the knowledge and side effects of anaemia and important of taking and comply with iron supplementation (MOH, 2013). However, despite of these measures, there are still a high prevalence of anaemia among pregnant women. It is also noted that absence in a standardised protocol lead to the wide variation of health education methods and material being provided to the antenatal mother in Malaysia (Noraini et al., 2011).

As a public health measure, iron supplementation was recommended as a strategy for alleviating anaemia in pregnant women. Unfortunately, this strategy has been less effective than expected because of poor compliance towards iron supplementation or inadequate dose of iron supplement. A research by Thirukkanesh and Zahara in 2010 showed that, the compliance to daily vitamin and/or mineral supplements among pregnant women in Malaysia is only 49%. Apart from that, one of the contributing factors to the high proportion of anaemia among pregnant women in Malaysia is misperception towards iron supplement, which can be corrected with adequate education and knowledge (Noraini et al., 2011).

It is a known fact that inadequate dietary iron intake is one of the common factors for iron deficiency anaemia (Foo et al., 2004). Malaysians in general has a low mean dietary iron intake around 10mg/day, being markedly below the recommended intake of 27mg/day as reported by the Ministry of Health (MOH, 2005). While extra iron is required during pregnancy for expansion of red cell mass in the second trimester while more iron is needed for the developing fetus and placenta in the third trimester (Barret et al., 1994), inadequate dietary iron intake among pregnant mothers further depreciate their iron storage and led to the development of anaemia in pregnancy.

Empowering women with health education plays an important role in strengthening the health promoting behaviours. One of the ways is by having regular health education program to prevent illness and adverse outcome. The Health Belief Model (HBM) includes components of perceived susceptibility, perceived severity, perceived benefits and perceived barriers, cues to action and self-efficacy is one of the models that can be used aiming to changing individual’s behaviour. Based on this model, when people understand the level of risk that an unhealthy behaviour poses, and their susceptibility to the adverse consequences of their feelings, as well as understanding their behaviours, they become interested in methods to reduce their risks. By using learning methods to reduce existing barriers they are able to
mitigate these adverse effects, moreover, they can change their attitudes and the range of positive behaviours will increase (Khoramabadi et al., 2016).

While several intervention studies have been conducted in this area, only a small proportion has used established theories or model to guide the intervention. These studies have proven that theory-based interventions were able to improve the haemoglobin level among anaemic pregnant women (Mariam et al., 2010; Norontha et al., 2013; Khorambadi et al., 2016; Baharzadeh et al., 2016). Hence, this study will use Health Belief Model to guide the intervention.

There are many literatures that look into the efficacy of the iron supplementation in reducing anaemia. However, limited data is available on the effects of educational interventions on the efficacy of iron supplementation and reducing anaemia. Literature reviewed also showed many gaps in terms of the effectiveness of anaemia treatment, whereby, despite iron supplementation, anaemia among pregnant women still persists.

This study will determine whether the theory-based health education intervention on anaemia in pregnancy would change the compliance towards iron supplement, increase consumption of iron rich food of the mothers and finally will changes the level of haemoglobin.

1.1 Objectives

1.1.1 General objective

To develop, implement and evaluate the effects of a theory-based health educational intervention on the haemoglobin level among anaemic pregnant women in Sepang district, Malaysia.

1.1.2 Specific objective

i. To develop a theory based health education intervention on haemoglobin level among anaemic pregnant women in Sepang.

ii. To determine the mean level of knowledge related to anaemia, the HBM constructs (perceived susceptibility, severity, benefit and perceived barrier), the behavioural factors (compliance towards iron supplementation and dietary practice) and haemoglobin level of respondents in the intervention and control group at baseline.

iii. To implement and evaluate the effect of health education intervention on changing the mean level of knowledge related to anaemia, the HBM Constructs, the behavioural factor (the compliance towards iron supplementation and the dietary practice) and the haemoglobin level of the respondents within and between the intervention and control group at baseline and three months post intervention.

iv. To compare the effects of the intervention on the mean level of knowledge related to anaemia, the HBM constructs the compliance towards iron supplementation and the
dietary iron practice and haemoglobin level of respondent between the intervention and control groups at three months post intervention after adjusting the covariates.

2.0 Materials and Methods

2.1 Setting

The study will be carried out in two health clinics in Sepang District. Salak and Dengkil Health clinic will be selected as the study location. These two clinics are chosen because of similar population and type of health facilities that provide treatment to the respondents. The district of Sepang is the youngest district for the state of Selangor Darul Ehsan. It is situated in the southern parts of Selangor Darul Ehsan, bordering on the Hulu Langat, Kuala Langat and Petaling districts with total population of 262,600 people in 2010 (Department of Statistics, 2010). Sepang district has four health clinics which are Salak, Dengkil, Sungai Pelek and Sepang Health Clinic. The total number of births in Sepang for 2015 was 4663 and the total number of outpatients was 219,478 (MOH, 2015).

2.2 Study design

This study will use a quasi-experimental study design, measuring outcomes of the intervention at individual levels of the included pregnant women with anaemia. Individual outcomes within and between intervention and control group will be compared. It will involve pre-post intervention with control study involving two groups of the antenatal mothers (control and intervention) from two health clinics in Sepang district. Pregnant women in Salak Health clinic will be recruited as the control and those at Dengkil Health clinic will be recruited as the interventional subject. Both groups will be receiving routine antenatal care which includes iron supplementation from their respective clinics. Additionally, the intervention group will be given a theory-based health education intervention on anaemia in pregnancy. The study is conceptualized based on the Health Belief Model (HBM).

2.3 Study population

The sampling population is pregnant women in Salak and Dengkil Health Clinics diagnosed as having anaemia in pregnancy with haemoglobin (Hb) level of less than 11.0 g/dl and meet all the inclusion criteria. The inclusion criteria for the pregnant women with anaemia in the intervention and control groups are: pregnant women with a Hb of less than 11 g/dl booked before 24 weeks of pregnancy and want to continue their antenatal check-up at these clinics. Known case of anaemia secondary to medical or haematological disorders, severe anaemia (Hb < 7g/dl) and women with multiple pregnancies will be excluded from the study. The sampling methods are all eligible women who attended antenatal clinic during recruitment process was invited to participate in the study. All participants will be required to sign a consent form to agree to participate in the study after detailed information on the study is provided to them.
2.4 Sample size estimation

We need a total of 162 pregnant women with anaemia. The sample size (N) for this study will be calculated by comparing the means of two groups when end point is quantitative data; N = 2 S^2 (z(1-α/2) +z(1-β))/ (μ1-μ2)^2 with ; S = pooled standard deviation, Z1-α/2 = 1.96 (confidence level of 95%, α is 0.05), Z1-β= 0.84 (power of 80%, β is 0.2), μ1-μ2 = estimated mean difference of two groups. Total number is 58 subjects per group; with 20% attrition (58/0.8) gives 73 subjects in each group. Adjust the eligibility of respondent (73/0.9) gives 81 subjects in each group. Based on the above calculation, the sample size of 162 pregnant women with anaemia will consists of 81 pregnant women from intervention and other 81 pregnant women from control groups.

2.5 Intervention module

The intervention module is unique as it has been developed through the process of consultations with a group of experts, studying relevant literature and received opinions from the community being served. The content focuses on changing the haemoglobin blood level through changing their dietary iron intake, increasing their compliance towards iron supplementation, changing their perception and increasing their knowledge regarding anaemia. The module will be delivered to all participants in the intervention group. The goal of this health educational intervention is for behavioural change (dietary iron intake and compliance towards iron supplementation).

2.5.1 Theoretical framework of health education intervention module

The module development was guided by the Health Belief Model (HBM). The Health Belief Model is a model that illustrates the relationship between belief and health, and it is based on the hypothesis that preventive health behaviour consists of personal beliefs. Health Belief Model is widely used in intervention programs that aiming to changing behaviours, especially those related to dietary practices, knowledge and perception towards certain health problems (Glanz et al., 2008). The HBM addresses four major components for compliance with recommended health action: perceived barrier of recommended health action, perceived benefits of recommended health action, perceived susceptibility of the disease and perceived severity of the disease. In addition, self-efficacy and cues of action also may influence preventive health behaviours. The anaemia in pregnancy health education intervention module addresses several of the components in order to address major reason for non-compliance concerning recommendations for anaemia in pregnancy prevention.

2.5.2 Intervention strategies

This program will be implemented using three strategies: Pre and post intervention assessment and health education intervention. The pre-test assessment will be measured through standardised questionnaire given to the participating women before 24 weeks of gestation and followed by the health education intervention will be held within 12 weeks (3 month). There is a variety of learning activities during that period that include health talks, small group discussions, poster presentation and pamphlets. Post intervention evaluation will be measured between the 35th to 37th weeks of gestation in the third trimester.
2.6 Assessment

2.6.1 Baseline assessment

Prior to starting the intervention program, baseline or pre-test assessment need to be performed among the anaemic pregnant women at the selected health clinics to identify their baseline haemoglobin level, socio-demographic status, baseline status of their knowledge, perception towards anaemia in pregnancy, dietary iron status and level of compliance towards iron supplementation. A set of self-administrated pre-test questionnaire will be used to capture the baseline data. The questionnaires will be answered by all participants and their answers are made confidential. The questionnaires consist of four sections. All participants must give their consent prior to answering the questionnaires. The outcome of the activity is to determine a baseline level of knowledge, perception and anaemia preventive behaviour and haemoglobin level prior to health education program.

2.6.2 Post intervention assessment

After the completion of the twelve week intervention period, the impact and outcome evaluation of the intervention program will be carried out using a set of questionnaires. The same set of questionnaires that is used in the pre-intervention assessment, except their socio-demographic status, is distributed to the participants which consists of measurement of knowledge, HBM construct, dietary practices and compliance towards iron supplementation. The post intervention haemoglobin level will be taken from the participants’ antenatal book. The outcome of the activity is to determine a post-intervention level of knowledge, perception and anaemia preventive behaviour after health education program. The evaluations will be attained through comparing the result of pre and post the implementation of health education intervention program among and between both intervention and control groups. Evaluation of the health education process is also done to control, assure or improve the quality of the program.

2.6.3 Health education intervention

Health education interventions are implemented after a pre-intervention assessment has been conducted. The health education intervention periods will be held within 12 weeks. There is a variety of learning activities during that period. The methods and material of the theory based health intervention programme included health talk, small group discussion, poster presentation and pamphlets.

The health talk is given by the researcher on topics such as introduction to anaemia in pregnancy, predisposing factor of anaemia in pregnancy, sign and symptoms of anaemia in pregnancy, complication of anaemia in pregnancy, prevention of anaemia in pregnancy, benefit of taking iron supplementation, knowledge on wrong perception of anaemia and iron supplementation and knowledge on the various sources of food that contain high iron. It is later followed by question and answer session or activity. In this activity, participants are able to ask anything regarding anaemia in pregnancy and all questions will be answered with the simple way and easier for them to understand. The time required to complete health talk session is within 60 minutes. The outcome of the health talk would enable participants to gain...
knowledge on the facts of anaemia in pregnancy, complication of untreated anaemia and management of anaemia in pregnancy (iron supplementation and dietary iron intake) and its importance.

The second activity of the health education intervention programme is small group discussion. A session on small group discussion will be conducted and facilitated by the researcher between two to four weeks after the health talk. The participants are divided into nine small groups with eight to ten participants in one group. Each group will encounter one session during the intervention period based on timing of the participants. This activity deals with the issues to enhance the compliance towards iron supplementation and to increase the dietary iron intake by identifying their barriers towards anaemia preventive behaviours. The outcome of the discussion would enable participants to understand the severity of anaemia in pregnancy, understand the susceptibility of anaemia in pregnancy, identify and overcome the barrier of not comply with iron supplement and dietary iron intake and identify the benefit of taking iron supplement and dietary iron intake. The participant also will be provided with the checklist on compliance for iron supplementation. The time required to complete group discussion session is within 60 minutes.

The materials used in the health education intervention programme are poster and pamphlets. Poster and pamphlets will be designed to make teaching interesting and receptive. Two posters will be used in this activity. A large poster (A1 size) will be placed in the health clinic at all time during the intervention period. It will include information regarding the complication of anaemia and importance of taking iron supplementation and consumption of iron rich food. In addition, the participants will be given a small poster (A4 size) to bring home as their continuous learning material after the small group discussion session. The small poster will provide guidelines of various iron rich food. A checklist on compliance towards iron supplementation will be pasted in the maternal health record. Apart from that, a pamphlet also will be distributed to the participant as a self-learning tool and continuous material that aimed at enriching their information about anaemia after the health talk or small group discussion. It also helps to deliver take home messages to the participants about anaemia in pregnancy. It will cover the information regarding the definition, causes, complications and prevention of anaemia in pregnancy and examples of food rich of iron. These materials are also aiming to maintain adherence towards anaemia preventive behaviour.

2.7 Data collection

2.7.1 Characteristics of pregnant women

The study researcher will collect the data of patient’s individual characteristics (such as: sociodemographic, knowledge on anaemia, perception, level of compliance and consumption of iron rich food).

2.8 Outcome measures

The primary outcome of the study is a haemoglobin level. The secondary outcome of the study is compliance towards iron supplementation, dietary iron intake, knowledge related to anaemia and HBM construct (perceived susceptibility, perceived severity, perceived benefit,
and perceived barrier). The Hb level will be measured before the twentieths four week of gestation (T0) and between week 35 and 37 of gestation in the third trimester (T1). The difference between T0 and T1 in the intervention group will be compared with the difference in the control group. All primary and secondary outcomes of the intervention group will be compared to those in the control group.

2.9 Data analysis

Data will be analysed using IBM Statistical Package for Social Science (SPSS) version 22.0. All hypotheses tests were two-sided and level of significance α was set at 0.05. Both descriptive as well as inferential analyses will be analyses. An outcome variable is compared at the baseline and the effects of intervention on changes in outcome measures will be determined within three month after intervention period. Descriptive statistics analysis will be performed by using frequencies, percentage, means and standard deviations. Bivariate analysis such as paired t test and independent t test will be utilized where appropriate. Confidence interval is set at 95% for the estimation of mean. Multivariate analysis such as generalized estimating equations (GEE) will be conducted to determine the effect of intervention on the primary and secondary outcome after adjusting for the covariates.

3.0 Discussion

The high prevalence of anaemia in pregnancy required good compliance and perception to anaemia to prevent the adverse effects of anaemia in the perinatal period. Learning from the experiences of other low income countries in handling similar conditions, a systematic and theory based approached are needed to empower women with knowledge and good perception of anaemia and important of comply with iron supplementation given.

The primary objective is to evaluate the effect of theory based health education intervention in managing pregnant women with anaemia, indicated by a difference in haemoglobin level in pregnancy, it is expected that this approach will be effective in managing anaemia in pregnancy in order to prevent perinatal morbidity and mortality. If the module is effective in improving the outcome of pregnant women with anaemia, this approach could be taken into consideration to improve the outcome for anaemia in pregnancy after further research.

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Declaration

No conflict of interest is declared

Authors contribution

Author 1: Literature search and writing the manuscript
Author 2: Review the manuscript
Author 3: Review the manuscript

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