

Facilitating exercise adherence among Kuala Selangor, Malaysia antenatal women: a study protocol

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ABSTRACT

Antenatal exercise is recommended for antenatal women for its numerous benefits. Despite knowing the advantages of exercise, most antenatal women are less active during pregnancy. It is vital to address women's knowledge, attitudes, and barriers facilitated by a behavioural theory while developing an intervention. This study's objective is to assess the effectiveness of antenatal exercise intervention based on behavioural theory in facilitating exercise adherence among antenatal women in Kuala Selangor, Malaysia. This study enrolled 220 pregnant women from six primary health clinics in the sub-urban district in a two-arm, cluster randomised controlled trial. Data will be collected in three phases: before the intervention, immediately and one-month post-intervention. The primary outcome measure is antenatal women's adherence to exercise, which will be assessed via a self-reported Exercise Adherence Rating Scale questionnaire. The intervention in this protocol is designed based on the information, motivation and behavioral (IMB) model to facilitate antenatal women's adherence to antenatal exercise, promoting an active lifestyle and reducing maternal complications. The findings may contribute to developing a future intervention that will promote more active lifestyles during pregnancy, which would increase overall health-related quality of life.

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1. INTRODUCTION

Pregnancy is a stage when hormonal, emotional, and social changes occur. During this period, it is necessary to introduce lifestyle changes that are beneficial for mothers and their unborn children's health. The opportunity to change their health practices that would benefit them and the child is considered an "educational time" in a woman's life [1]. Physical activity (PA) in pregnancy has optimized maternal and fetal health for better outcomes [2]. In response to this, regular physical activity has been recommended by the American College of Obstetrics and Gynecology (ACOG) to encourage antenatal women (ANW) to be active [3].

Today, most ANWs are less active during pregnancy [4], [5]. This means that the current recommended physical activity guidelines of 150 minutes of moderate-intensity PA per week still need to be met by most ANWs [6]. Around 60% of women in the United States did not engage in exercise during pregnancy [5]. A similar pattern is seen among 52.4% of ANW in the United Kingdom (UK), 78.5% in Ireland

and 16.4% in Saudi Arabia [7]. Less than 35% of Australian ANW fulfilled the recommended exercise [8]. Likewise, a study revealed that Asian women's PA during their pregnancy was significantly lower than before they became pregnant [9]. A recent study among ANW in Seremban, Malaysia supported this finding whereby 64.5% were reported as physically inactive [10]. This may contribute to an increase in the number of non-communicable diseases such as obesity, diabetes and hypertension, which might also increase government costs in future. One of the ways to improve maternal health would be to ensure antenatal exercise (ANE) during pregnancy.

Exercise during pregnancy is beneficial to lower the risk of maternal complications such as gestational diabetes mellitus (GDM), pre-eclampsia, low back pain and control of maternal weight gain; and reduces the need for obstetric intervention or caesarean sections during labour and delivery [11]. Besides, participation in physical activities and good social support are associated with high health-related quality of life (HRQoL) [12], [13]. However, ANW may not exercise due to their need for adjustment of significant physical and emotional changes at pregnancy which can result in discomfort, tiredness or absence of time that will make exercising difficult [14]–[16].

Awareness of benefits and contraindications is important to promote physical activity to reduce the risk of maternal complications. Further, the issue in practising exercise is adherence to perform the exercise on regular basis as recommended. In order to attain the benefits of exercising, adherence is a crucial component. It is important to create a module that can ease and guide pregnant women in practicing ANE appropriately and on time in order to facilitate good adherence.

The health belief model (HBM) has been used as an intervention to promote PA for pregnant women. Previous studies showed educational intervention using HBM and theory of planned behavior (TPB) was significantly increase health behaviour towards physical activity and intention to exercise regularly [17]. However, there is limited studies to promote a healthy lifestyle in pregnancy based on the information, motivation and behavioral skills (IMB) model.

Hence, this study will address the knowledge gap by conducting a theory-based intervention approach to facilitate behavior change, particularly in exercise adherence. This study aimed to assess the effectiveness of antenatal exercise intervention based on behavioural theory in facilitating exercise adherence among antenatal women. The uniqueness of the intervention in this study is its accessibility, as the module will be delivered through an online approach. The intervention delivery strategies will be developed based on up-to-date approaches via social media such as Tiktok and Telegram.

The three constructs of the IMB model interplay to influence a behavioral change in which both information and motivation initiate the behavioral skills. The conceptual framework of this study is displayed in Figure 1. For studies of behavioural intervention in various aspects of health, the IMB models have been used as a theoretical basis [18] related to chronic diseases such as diabetes mellitus [19], [20] and adherence to medication and PA [21]. For instance, a lifestyle intervention using IMB model to prevent GDM in early pregnancy reported a significant difference on the mean glucose level [22].

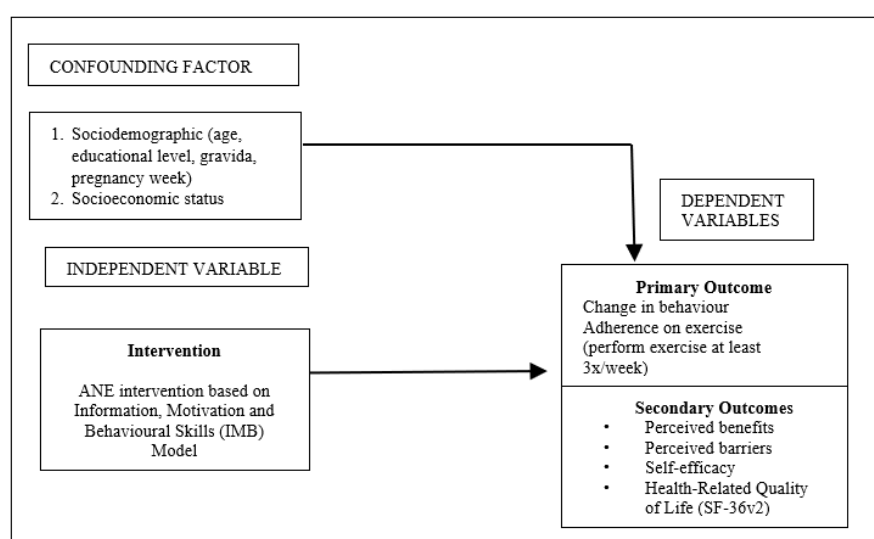


Figure 1. Conceptual framework using information, motivation and behavioural skills model on antenatal exercise adherence

2. METHOD

2.1. Study design and sampling

This study is a two-armed, parallel, single-blinded, cluster-randomized trial. The cluster in this study is a primary health clinic. There are two groups: the intervention group and the control group. The participants is blinded for the study. The intervention group will receive a 12-week ANE intervention in addition to standard antenatal care (ANC), while the control group will only receive standard ANC. Kuala Selangor's district situated in the state of Selangor, at the western coast of Malaysia. It is a sub-urban and developing district with an increasing number of populations of child-bearing age and has the potential for higher birth rates (Household income and basic amenities survey in Selangor) [23].

Six primary health clinics in the Kuala Selangor district have been selected for this study. First, those clinics were chosen based on the top six clinics with the highest number of antenatal women who come for an antenatal visit. The clinics are ranked based on number of antenatal visits in a year using the statistics record from Health District Office. Based on the rank, Kuala Selangor, Ijok, Bukit Cherakah, Tanjong Karang, Jeram and Bestari Jaya health clinic were included in this study.

Then, using a simple randomisation method, these clinics are divided into intervention and control groups performed as; numbers will be assigned to the clinics and written on paper, folded and mixed up; the numbers will then be picked randomly. Finally, first three clinics will be assigned as intervention clinics, and the other three clinics will be assigned as control clinics. The process of random allocation will be carried out by research assistant who is not involved in this study. Subsequently, stratified randomization based on their parity will be performed among the participants from each clinic to minimize the unequal number of nulliparous and multiparous in the intervention and control groups.

2.2. Sampling method and recruitment

The six clinics chosen were randomly assigned with 1:1 allocation into the intervention and control groups. The procedures involved in the recruitment of subjects in this study follow the consort statement for cluster randomized trial as shown in Figure 2. In each clinic, the participant's name is list as a code number by the researcher. Only the researcher has access to the participant's name and code, with full responsibility for all record protection and confidentiality to ensure blinding. In order to avoid participant duplication, the list of those codes will be stored together with an individual's last four digits national identification card. To prevent communication among intervention and control groups as well as to minimise contamination, it will be necessary to recruit participants based on the clinics they are representing. For example, if clinic A is allocated in the intervention group and clinic B is allocated in the control group, the ANW in clinic A will receive the intervention and standard ANC while ANW in clinic B will only receive standard ANC only.

2.3. Sample size estimation

The sample size for this study was determined by comparing the means of cluster randomization design using a formula by Donner & Klar [24] with 80% test power, 5% Type I error and 0.02 intra-cluster correlation coefficient (ICC), $n = (Z_{1-\alpha/2} + Z_{1-\beta})^2 (2\sigma^2) [1 + (m-1)\rho] / (\mu_1 - \mu_2)^2$. The calculation is based on previous study of physical behaviour among pregnant women [19]. The estimated standard deviation (σ) and mean difference of intervention and control group ($\mu_1 - \mu_2$), cluster size (m) are: $\sigma = 10.2$, $\mu_1 - \mu_2 = 6.18$, $m = 59$ [25] and $p = 0.02$ (ICC), $n = 184$, after adjusting for 20% attrition rate, $n + 20\% = 220$ final sample size for both intervention and control group.

ANW with the following characteristics: i) Malaysian citizen, aged 18-49 years; ii) at 12-20 weeks of gestation; iii) able to read and understand Malay language; iv) who did not actively exercise or attend any ANE class on current pregnancy; v) who will continue their ANC visit in the same clinic until delivery are eligible for participation. ANW who presented and/or diagnosed with medical or obstetric complications, high risk pregnancy (e.g. placenta previa; persistent bleeding), non-singleton pregnancy and high-risk for preterm delivery will be excluded. Nevertheless, ANW having gestational diabetes mellitus on diet control or having hypertension without medication will be included.

2.4. Data collection method

Ethical Approval has been obtained from the Institutional Review with the reference number of NMRR-21-1518-60816 and Institutional Review Board of the Universiti Putra Malaysia. The study has been registered under India Clinical Trial on March 10, 2022 (CTRI/2022/03/040973), overall status of the study in recruiting phase and will be completed by August 2023.

An advertisement about this study with a quick response (QR) code will be accessible at the respective clinics. Participants in both arms will be recruited in small batches based on weekly recruitment. In every alternate week, data collectors will recruit participant from intervention and control arm. The ANW in the

respective clinics will receive study procedure protocol and will be asked to answer screening questions for the inclusion and exclusion criteria.

To ensure common and clear understanding of the relevant details of the study, briefing session will be provided. Participant informed consent will be sought for each participant and will sign consent once agree to participate. Subsequently, selected participant will complete baseline assessment (t0). Researcher and data collectors will collect participant's phone number and add participant into respective telegram group according the recruitment week.

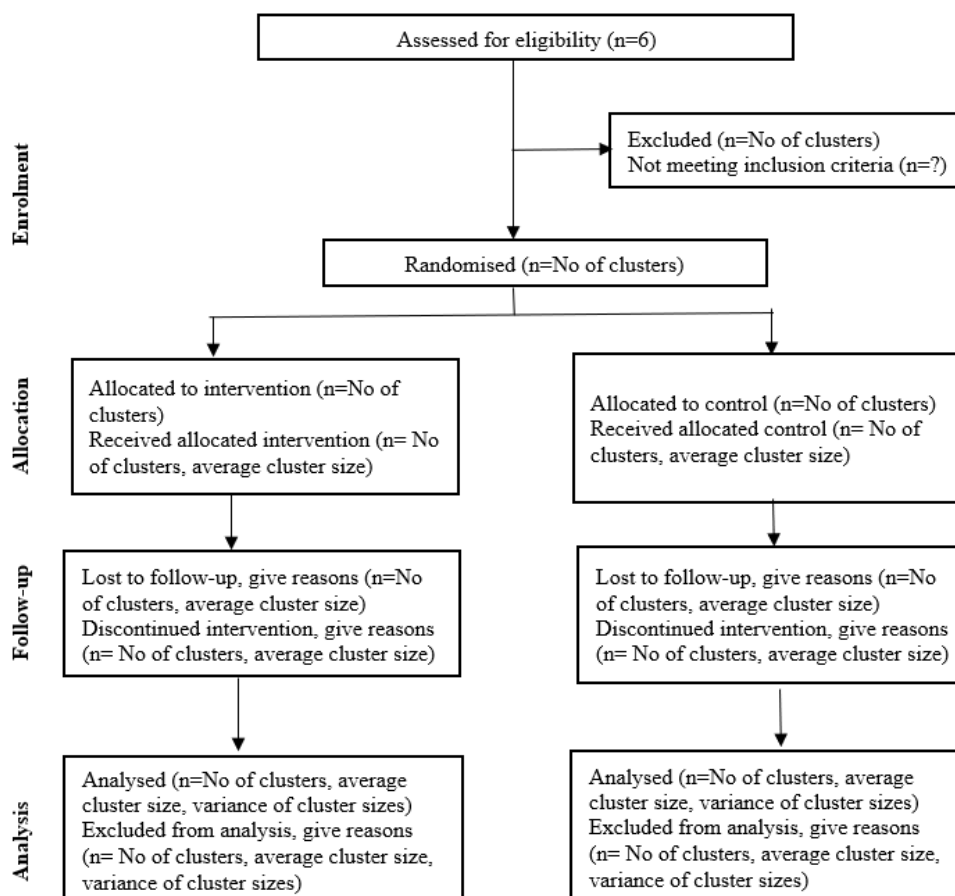


Figure 2. Consort extensions of cluster randomized trial [26]

Data will be collected in three stages: (t0), at baseline - before the intervention; (t1), immediately post intervention; and (t2), one-month post intervention. Baseline assessment will be conducted at clinic, both post intervention assessment will be conducted online via google form, the link will be shared in respective telegram group and individual WhatsApp.

A reminder for post intervention assessment (t1) and (t2) will be shared via respective Telegram group and individual Whatsapp before the actual date. Participant will answer the questionnaire using same ID code. Once completed the intervention, participant in intervention arm will share their recorded exercise diary via WhatsApp.

2.5. Intervention

The intervention arm will receive standard ANC and ANE intervention. Due to the ease of respondents better understanding, the ANE intervention based on IMB model is developed and delivered in Malay language named as #mamisihat, as shown in Table 1. The intervention consists of: i) Information (#mamisihat informasi) - 5 series of 5 minutes Tiktok video called as “kapsul senaman 1-5” will be shared every 2 weeks. The video consisting of ANE introduction and benefits of ANE, aiming to improve participant knowledge hence enable to practice and facilitate exercise adherence. Each series of “kapsul senaman” explaining in details of benefits of antenatal exercise for mother and baby with subtitle and graphic. ii) Motivation (#mamisihat motivasi)-12

series of animated short messaging video will be shared weekly to boost motivation to perform exercise self-confidently. iii) Behavioural skills (#mamisihat tingkahlaku)- guided ANE video will be shared at first week participant join telegram group, aiming to allow ANW to practice exercise independently later facilitate exercise adherence.

Once participant in intervention arm joined Telegram group, 1st information video series, 1st motivation video and guided exercise video will be accessed. The following information and motivation video series will be uploaded in telegram according to the schedule. Participant will receive exercise diary along with ID code. The feature of the scenes #mamisihat informasi 1st series and 2nd series as shown in Figures 3(a) and (b). Figure 4(a) illustrated animated video of 1st #mamisihat motivasi and Figure 4(b) illustrated home screen of #mamisihat tingkahlaku.

As a precautionary measure, basic exercise measures such as an indicator to stop the exercise if present of: any leakage of amniotic fluid, vaginal bleeding, excessive shortness of breath, chest pain or dizziness will be provided in the video. The talk test and rated perceived exertion (RPE) scale will be explained in the video at the beginning session to enable participants to monitor exercise intensity and exertion on their own. The moderate intensity of the exercise is self-monitored using a talk test. Borg's scale for perceived exertion, which is recommended in pregnancy will be taught by researcher [27].

Participant will be advised to achieve moderate intensity with self-perceived exertion was set at 12-14 (somewhat hard). Participants will be trained to record exercise weekly (frequency, intensity and duration of exercise) in exercise diary. Weekly reminder message will be shared in Telegram group by researcher. To account for a lower response, a reminder call and feedback survey will be conducted in a Telegram group in every two weeks to monitor participant compliance.

Table 1. Summary of ANE intervention strategy

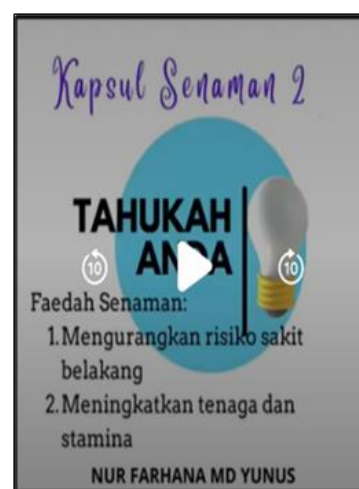
Model Construct	Content	Frequency	Intervention strategy
Information (#mamisihat informasi)	- Introduction on ANE - Indication, contraindication and precautions of ANE - Warning sign to discontinue exercise - Benefits of ANE in details	- Every 2 weeks (week 1-9)	Short lecture (tiktok video)
Motivation (#mamisihat motivasi)	- Short motivation messages	- Weekly (week 1-12)	Animated video
Behavioural skills (#mamisihat tingkahlaku)	- Guided ANE consists of stretching, mobilising, strengthening, pelvic floor exercise, aerobic and breathing exercise	- Once (week 1)	Guided exercise video

2.6. Control

Participants in the control group will receive standard ANC only. Once participant in control arm joined Telegram group, participant will receive information about the study and date for post intervention assessment (t1) and (t2). Participant will be received reminder to answer post intervention assessment in the respective Telegram group and individual Whatsapp before the actual date.



(a)



(b)

Figure 3. Feature of the scenes #mamisihat informasi (a) 1st series (b) 2nd series

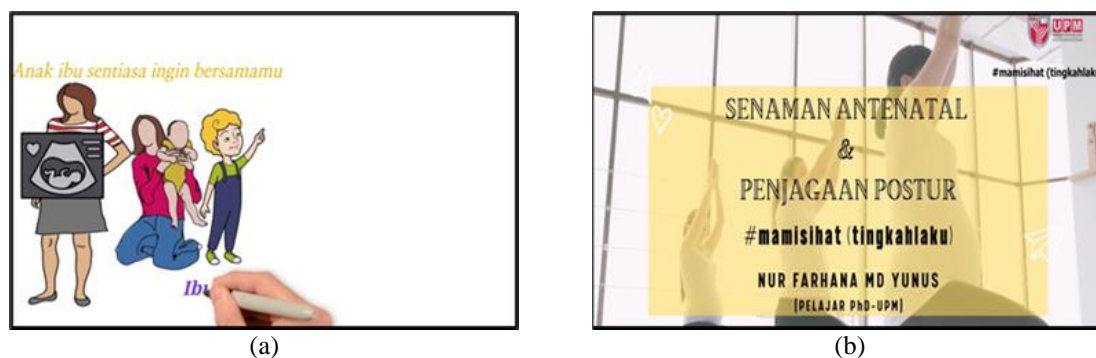


Figure 4. Feature of the animated video (a) scene of 1st series of #mamisihat motivasi (b) home screen of #mamisihat tingkahlaku

2.7. Study measures

Exercise Adherence Rating Scale (EARS) questionnaire will be used to assess the primary outcome-exercise adherence [28]. EARS has six items with 5-point Likert scale from completely agree to completely disagree. The total scores ranging 0-24 with higher score indicate greater adherence and cut-off score of 17/24 as an acceptable adherence.

The secondary outcomes are based on the IMB constructs: information (perceived benefits and perceived barriers using Exercise Benefits/Barriers Scale (EBBS) questionnaire [29], motivation and behavioural (exercise self-efficacy using Pregnancy Exercise Self Efficacy Scale (P-ESES) [30]. Health related quality of life (HRQoL) using SF-36v2. Perceived benefit has 18 items score based on 4-point Likert scale ranging from strongly disagree (1), disagree (2), agree (3), strongly agree (4), total scores ranging from 18 to 72 marks and scores higher than mean/median scores indicate higher perceived benefits of exercise, perceived barrier has nine items scored on a 4-point Likert scale ranging from strongly disagree (1), disagree (2), agree (3), strongly agree (4) total score ranging from 9 to 36 marks and scores higher than mean/median scores indicate higher perceived barriers of physical activity. SF-36v2 is divided into eight categories with 36 subitems, all items are scored and a higher score gives more favourable health status.

2.8. Quality control

For questionnaire validity, three experts from public health and three experts from the physiotherapy field to confirm its appropriateness, relevance, and clarity, taking into account the learning skills to meet the needs of the participants. The content validity ratio shall be calculated, each with a minimum value of 0.5. Face validity will be conducted among twenty ANW from clinic which not involved in the intervention study. Further amendments were done based on their feedback. In order to ensure reliability, the questionnaire has been pretested.

In term of intervention module validity, twenty ANWs from a clinic not involved in the intervention study will be subject to content and validity tests. The criteria for inclusion will be the participant who is literate in Malay. The target participant will be focused only on video illustrations, sufficiently specific and understandable content, legibility and quality information, indicating "yes" or "no". The validation process will be carried out by the experts (public health doctor and physiotherapist) and ANW until there are no further recommendations for changes. The items in the content are either edited, removed, or remain unchanged after extensive discussion among the researchers.

One BSc physiotherapy as data collector participated in the data collection process The data collector was provided with a two day training on the data collection process. During the actual data collection process, close supervision has been carried out.

2.9. Statistical analysis

The intention-to-treat (ITT) analysis will be used for data analysis. Primary analyses consist of descriptive data on demographic and socioeconomic characteristics of the participants. Prior to the inferential statistical test, a normality test will be performed. The Chi-square test will be used for categorical data, while for continuous data, independent and paired T-test or Mann-Whitney U and Kruskal Wallis test will be used.

Generalized estimating equation (GEE) will be used to compare the variations in results between and within intervention groups over time when adjusting for covariates. The significance level is set at 0.05, and a 95% confidence interval (CI) will be used to get a significant result. Data analysis will be performed using the SPSS version 27.

3. CONCLUSION

The expected outcomes can be used for future researchers and public health practices. The current body of evidence does not provide sufficient guidance on the effectiveness of ANE interventions on exercise adherence among ANW women. If the ANE intervention module using the IMB model is shown to be effective in enhancing exercise adherence, it can be a good strategy to improve the physical activity among ANW, which can be adopted into practice in various antenatal settings. In order to obtain feedback, develop the material, and examine whether ANE's intervention module is feasible, the qualitative analysis should be part of any subsequent studies. This may incorporate mobile apps to maximize the potential benefit. ANE intervention can also be a cost-effective intervention, as facilitated ANW to engage in exercise would promote a healthy lifestyle, reduce maternal complications, improve HRQoL and at the same time may improve pregnancy outcomes for both mother and fetus.





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


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


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