STUDY PROTOCOL

The Effectiveness of Nutrition and Physical Activity Intervention on Psychosocial Well-Being of Mothers with Preterm Infants in Selangor

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1. Introduction:

1.1 Objectives: To determine the effectiveness of nutrition and physical activity intervention on psychosocial well-being of postpartum mothers with preterm infants.

1.2 Hypothesis: Nutrition and physical activity intervention are effective on improving psychosocial well-being of postpartum mothers with preterm infants.

2. Methodology

2.1 Sample size:

Sample size was calculated based on formula adapted from 'Medical Statistics Online Help', https://www.ouh.nhs.uk/researchers/planning/is-it-research/documents/medical-statistics-online-help.pdf :

$$n = \frac{2 \times \left[Z_{\left(1-\frac{\alpha}{2}\right)} + Z_{(1-\beta)} \right]^2}{\Delta^2}$$

Where,

Power of 80%, $Z_{(1-\beta)}$ = 0.8416 (at 5% significance level)

$Z_{\left(1-\frac{\alpha}{2}\right)}$ = 1.96

$\Delta = \frac{\text{Mean difference}}{\text{Standard deviation (sd.)}}$

Previous study by Daley et al., (2015), had conducted physical activity intervention to improve symptoms of PPD among postpartum mothers. The study has shown a significant reduction of depression score (EPDS) after implementation of 6 months of physical activity intervention. The mean difference of EPDS score between baseline and post-intervention is 4.79, with the standard deviation of 4.23. Therefore, the sample size of this study was calculated based on the following calculation:

$$n = \frac{2 \times [\, 1.96 + 0.8416 \,]^2}{(4.79/4.23)^2}$$

$$= 12$$

30 % of drop out rate = 12 + 4

$$= 16$$

With the inclusion of 30% of drop out rate, each arm (control and intervention group) will need the sample size of 16 participants. Therefore, this study needs at least 32 participants to involved in the phase II intervention study to detect statistically significant importance of the intervention's effect. In addition, Julious (2005) had recommended that with a minimum sample size of 12 for each arm was sufficient to form a pilot study of RCT, which is based on rational about feasibility, precision about the mean and variance, and regulatory considerations.

2.2 Location of the participant's detail:

Participant recruitment is expected to be conducted on 16th of May 2022. They are recruited from the Neonatal Intensive Care Unit of the government hospitals in Selangor's district. Below are the location selected to recruit the participants:

1. Hospital Shah Alam
2. Hospital Selayang
3. Hospital Serdang
4. Hospital Tengku Ampuan Rahimah
5. Hospital Ampang

However, the intervention will be conducted soon as the mother and infant discharged from the hospital.

2.3 Arm group information:

Intervention group: Nutrition and Physical Activity Intervention

This intervention involving behaviour modification, incorporates nutrition and physical activity modification. The intervention encourages participants to consume a healthy diet and active lifestyle during postpartum period. The participant will be provided an educational module entitled "Mommies can Eat and Exercise with No Stress" (MomEENS), in which the module will be delivered through a booklet and video. The MomEENS module consist of five key recommendations: 1. Eat healthy foods ;2. Eat foods rich in iron and folic acid; 3. Eat foods rich in omega-3 fatty acids; 4. Increase steps in a day and; 5. Increase body flexibility and strength. All the key recommendations will be explained in the booklet, while the video will provide full guidance on how to exercise during postpartum at home, explaining key recommendations 4 and 5. Face-to-face consultation with the participants will be held during baseline and 4th week to enhance the participation. Besides, Whatsapp and Facebook page group is developed as a step to enhance the compliance of participants. All the participants will be contacted once for every two weeks, lasting for about 5 to 10 minutes for each call to monitor the participant's progress.

Control group:

The participants in the control group will be received advice on the standardised Malaysian food pyramid and be instructed to follow their usual standard care as suggested by their healthcare provider. Postpartum women in Malaysia typically attend postpartum healthcare visits with an exam on day 30 after childbirth but receive no other routine care following this appointment unless a specific health problem has been identified. Participants in the control group performed the same evaluations. They received the same incentives as those in the intervention group, but they did not receive any educational module and contact from the investigator during the 8 weeks follow-up.

2.4 Period of overall study:

This intervention will be delivered for 8 weeks. During 0 week, the researcher will collect baseline data. Subsequently, the outcome measurement will be taken at 4th week and 8th week.

2.5 Eligibility criteria for participants

Inclusion criteria:

1. Participants with EPDS score ≥ 12
2. Mothers with an infant nearly graduated from NICU due to prematurity with minimum stays of 7 days (Gestational age: < 37 weeks).
3. Postpartum mothers (within 4th to 8th weeks after childbirth).
4. Aged between 19 until 40 years old.
5. Mothers were from Malaysian citizen.
6. Mothers who only reside in Selangor, Klang Valley or Negeri Sembilan during their postpartum confinement.
7. Only Malay mothers will be selected (due to the small number population of Chinese and Indian, following from Phase 1)
8. Mothers who undergo vaginal delivery for the current child.

Exclusion criteria:

1. Mothers that are clinically diagnosed with mental illness or other known psychiatric disorders
2. Mothers who illiterate either in Malay or English
3. Mothers who are currently pregnant
4. Mothers whose infant has genetic or congenital anomaly or severe cardiorespiratory instability
5. Mothers who have chronic or terminal disease (such as cancer, renal failure, hypothyroid, exercised-induced asthma and uncontrolled hypertension and diabetes) or diseases that would limit to exercise.
6. Mothers who have any condition that would make exercise unsafe or unwise.

2.6 Randomisation:

The investigator had used a computer-generated randomisation list for allocation of the participants (http://www.jerrydallal.com/random/random_block_size_r.htm). This study will employ block randomization, with the block size of 8, and equal randomization ratio (1:1) between intervention and control groups. The allocation sequence was concealed from the investigator enrolling and assessing participants in sequentially numbered, opaque, sealed and stapled envelopes. Corresponding envelopes were opened only after the enrolled participants completed all baseline assessments and it was time to allocate the intervention. Investigator with no clinical involvement in the trial had conduct the block

randomisation via computer generated random number list to allocate the participants. Research investigator will recruit the participants based on their eligible criteria. After the participants had completed the baseline and give the consent to participate, the research investigator will assign the participants to their respective groups based on the sealed envelopes. Researcher and participants are not possible to be blinded due to nature of intervention.

2.7 Procedures for participant recruitment

After being informed about the study and potential risks, the participants will be screened according to their eligibility criteria. The participants who are eligible to participate in the study will be contacted again and asked for consent to join the study. After obtaining the consent, the participant will undergo a baseline assessment, and subsequently, the investigator will assign the participant to their respective groups, the intervention and control groups. All of the health assessments will be conducted at baseline, 4th week and 8th week.

The intervention group participant will receive confinement module, and exercise recorded video as part of the intervention's instrument. Introduction of the intervention will be given by the research investigator, during baseline recruitment. The intervention's participants will receive detailed instructions regarding the frequency and duration of exercise and dietary modification in addition to behavioural and motivational strategies to improve psychosocial behaviour. The briefing of intervention process (face-to-face consultation) will be held at participant's house as the infants have already been discharged from the NICU. At 4th week and 8th week of intervention, research investigator will come back to the participant's house to do the outcome measurement and communicate with the participant if any enquiries occur during the intervention period. Below are the summary of timeline and content of interventions:

Arm	Month	Schedule	Content
Intervention	1 & 2	Monthly	Face-to-face consultation : Overview of MomEENS intervention - Benefits of exercise and sufficient diet intake during postpartum period - Goal setting and making time for physical activity
	1 & 2	Weekly	Exercise through recorded video: at least three times per week
	1 & 2	Daily	Increase walking steps up until 5000 steps per day, follow the diet as per recommendation
	1 & 2	Twice weekly	Follow-up telephone calls/ messages: To monitor the compliance of intervention throughout the intervention period.

Arm	Month	Schedule	Content
	1 & 2	Monthly	Outcome measurement is measured at baseline, 4th week and 8th week.
Control	1 & 2	Daily	No intervention regime is given, postpartum mothers in this group are following their normal routine postpartum care.

The participants in the control group will receive information regarding food pyramid Malaysia, and instructed to follow their usual standard of care as suggested by their health care provided. Participants in the control group will perform the same evaluations during baseline, 4th week and 8th week of follow up.

2.8 Outcome Measurement:

2.8.1 Primary Outcome Measurement

A. Edinburgh Postnatal Depression Scale

The presence of depressive symptoms will be assessed using the Edinburgh Postnatal Depression Scale (EPDS) (Cox, Holden, & Sagovsky 1987). The EPDS is a 10-item self-administered questionnaire designed specifically to measure PPD. All items will be rated on a 4-point Likert-type scale, with a total score ranging from 0-30. Categories of response are scored 0,1,2, and 3 based on increased symptom severity. EPDS can only be used for screening but not for the clinical diagnosis of depression (Arifin et al. 2014). The Malay version of the scale was validated in the local setting with the cut off 11/12 was used to determine a woman at risk of having depressive symptoms (Arifin et al., 2014; Mahmud et al., 2003). Score of ≥12 indicates the presence of postpartum depression whereas <12 indicates absence of postpartum depression .

B. Perceived Stress Scale (PSS)

The Perceived Stress Scale (PSS) was developed by Sheldon Cohen & Williamson (1988), designed to measure the degree to which circumstances of an individual are considered stressful via their feelings and thoughts in the past month. The item asked regarding the current levels of stress, unpredictable, uncontrollable, and overloaded events, unexpectedly occur during their lives. The PSS consist of 10 items, derived from 5-point Likert scale (0= never, 1= almost never, 2= sometimes, 3= fairly often, 4= very often). Four items that are positively stated (item 4,5,7, and 8) are scored reversely (0= very often, 1= fairy often, 2= sometimes, 3= almost never, 4= never). The total score is calculated from the sum of 10 items, whereas higher scores indicate higher levels of perceived stress. In this study, Malay version of PSS-10 is used to enable participants to understand the questions asked and to make the assessment more culturally appropriate (Sandhu et al., 2015).

C. Postpartum Sleep Quality Scale (PSQS)

The Postpartum Sleep Quality Scale (PSQS) consists of 14 item scale, designed to assess subjective sleep quality during postpartum periods (Yang et al., 2013). Two domains were developed from the PSQS: "Factor 1: Infant night care-related daytime dysfunction", and "Factor 2: Physical symptoms related sleep inefficiency". Factor 1 explained how having care of infants at night impacted the quality of postpartum woman's sleep and the ability to handle daytime activities. Factor 2 described the physiological factors underlying sleep and sleep inefficiency symptoms of a woman. The PSQS found to be a valid and reliable tool, as previous study had demonstrated PSQS have adequate internal consistency between the item (Cronbach's α= 0.88; Factor I α =0.89, Factor II α= 0.82) (Yang & Chen, 2018).

D. Positive Affect Balance Scale (PABS)

This scale consist of 10 item scales, which 5 items were developed for each positive and negative affect components, asking the psychological reactions of people respond to their daily lives, and individual's ability to cope with daily stresses. "Positive affect" questions are associate to social participation, satisfaction with social life, and engagement in activities. Three-point scale of "never", "sometimes", or "often" are answers made to the questions represents the past week's experiences. All calculations of positive affect score, a negative affect score and a total affect balance score can be made. The positive impact score (ranging from 5 to 15) with 15 being the highest (most positive result) will be used in this study. PABS has been proven to be a reliable tool for measuring psychosocial well-being, as reported by previous study (Moriwaki, 1974).

2.8.2 Secondary outcome:

A. Anthropometry measurement:

The anthropometry measurement is consisted of measurement of participant's body weight, height, waist circumference and blood pressure. Body weight is measured to the nearest 0.1 kilogram (kg) with a portable standard scale using Seca 813 Electronic Flat (Birmingham, United Kingdom) weighing scale. Height of the participant is measured to the nearest 0.1cm using Seca 217 Height Measure (Birmingham, United Kingdom). Waist circumference is measured to the nearest 0.1cm using Seca 201 Ergonomic circumference measuring tape (Birmingham, United Kingdom). The resting blood pressure is measured using automated non-invasive blood pressure monitor device with cuff, Omron Blood Pressure Monitor HEM 7120 (Kyoto, Japan). During the assessment, neither the participants nor the observer should talk while using the electronic devices.

B. Multiple Pass 24-Hour Diet Recall

A multiple pass 24-hour diet recall will be performed to assess the dietary intake of the mother. Multiple pass 24-hour diet recall found to maximise recall accuracy for quantitation (Tran et al. 2000), with the used of the following algorithm: The first pass encourages the respondent to freely report all

food and drink consumption for the previous 24 hours without any interruption. In second pass, the researcher probes for greater details on the exact time, type and quantity of food and drink consumed, and in the final pass, the researcher reviews all food reported in order, prompting for omissions and clarifying the ambiguities (Nightingale et al., 2016). Nutrient analysis software, the Nutritionist Pro Diet Analysis, will be used to calculate the average nutrients intake, which is based on the Nutrient Composition of Malaysian Foods database and the U.S. Department of Agriculture (USDA) Foods database.

C. International Physical Activity Questionnaire- Short Form

This is a sel-report questionnaire that assesses the types of intensity of physical activity and sitting time that people do as part of their daily lives. are considered to estimate total physical activity in MET-min/week and time spent sitting. There are 7 items asking for the number of days a week they participated in the activities and the average time for each session on each activity (hours and minutes) they spent during the past 7 days. The intensity score is then calculated based on the MET classification levels (low, moderate, high).

D. Breastfeeding Self-Efficacy -Short Form (BSES-SF)

The Breastfeeding Self-Efficacy Scale- Short Form (BSES-SF) is a self-report instrument developed to measure breastfeeding confidence (Dennis, 2003). BSES-SF consist of 14 items, with each item is followed by the phrase "I can always". The answer option is assisted with a 5-point Likert-type scale where 1 indicates not at all confident and 5 indicates always confident. The sum of all item will be in the range of 14 for the minimum score, and 70 is the maximum score, which indicates the data as continuous (Husin et al., 2017). BSES-SF is a very excellent measure of breastfeeding efficacy as it has shown a high reliability (with Chronbach's Alpha value is 0.97) and validity score (BSES-SF is significantly correlated ($p< 0.05$) with other theoretically related concepts (self-esteem, postpartum depression and perceived stress)) (Dennis, 2003).

3. Statistical Data Analysis

Descriptive statistics are present for the baseline demographic and psychosocial variables. All analyses will use the intention-to-treat principle, whereby participants are analysed in the group to which they were randomized. Continuous variables will be presented using means and standard deviations and categorical variables will be summarized using percentages. Data is analysed using repeated measures ANOVA to determine the effectiveness of intervention. All statistical analysis will be carried out using *Statistical Package for Social Science (SPSS)* version 22.0 (SPSS Incorporation, Chicago, IL, USA).

4. Ethical considerations

This study was approved by the UiTM Research Ethics Committee (REC/06/2021 (MR/431)). Participant information sheet is used to inform the mothers about the study, apart from the researcher's

direct discussion. As well as the written consent obtained, all the participants were recruited voluntarily. It was told that the participation was purely voluntary and that they could refuse to answer any questions at any point or withdraw without consequence. The confidentiality of data from the research is ensured.