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Prevalence and risk factors of postpartum depression, general depressive symptoms, anxiety and stress (PODSAS) among mothers during their 4-week postnatal follow-up in five public health clinics in Perak: A study protocol for a cross-sectional study

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ABSTRACT

Introduction Postpartum depression, general depressive symptoms, anxiety and stress (PODSAS) are often overlooked, and may cause morbidity to new mothers, their babies and families. This study aims to determine the point prevalence of depression (post partum and general), anxiety and stress among mothers in five public health clinics in Perak at 4 weeks postdelivery and identify their associated risk factors. Findings from this study will be used to identify the needs for early screening and detection, encourage development of interventions to reduce its occurrence and support mothers with PODSAS.

Methods and analysis This cross-sectional study will recruit 459 postpartum mothers during their 4-week postnatal follow-up in five selected public health clinics in Perak from September 2019 to May 2020. Participants will be mothers aged 18 years and above at 4 weeks postdelivery who are able to understand the English and Malay languages. Non-Malaysians and mothers with known diagnosis of psychotic disorders will be excluded from the study. Sociodemographic information and possible risk factors of the participants will be captured via a set of validated questionnaires, postpartum depression (PPD) will be measured using the Edinburgh Postpartum Depression Scale questionnaire and general depressive symptoms, anxiety and stress will be measured using the 21-item Depression, Anxiety and Stress Scale. Data analysis will be conducted using SPSS V.25.0 (IBM). Besides descriptive statistics, multivariable regression analyses will be done to identify possible risk factors and their independent associations with depression (PPD and general depressive symptoms, combined and separately), anxiety and stress.

Ethics and dissemination The study protocol was reviewed and approved by the Medical Research Ethics Committee, Ministry of Health Malaysia on 7 August 2019. Results of this study will be reported and shared with the local health stakeholders and disseminated through conference proceedings and journal publications.

Registration number This study is registered in the Malaysian National Medical Research Register with the ID: NMRR-19-868-47647

Strengths and limitations of this study

- This study will examine the point prevalence of depression (postpartum depression and general depressive symptoms, combined and separately) and other psychological well-being (anxiety and stress) at 4-week post partum that have not been studied in depth before.
- Five public health clinics in urban and suburban areas of Perak may not be representative enough as to attribute the findings to the nationwide population.
- Self-administration of the questionnaire is encouraged and facilitated to improve data quality.
- Respondents will not reflect the incidence or prevalence rate of depression, anxiety and stress at other time points, or prevalence of these conditions during the first few weeks after delivery or months later in the postpartum period.

INTRODUCTION

After childbirth, a woman undergoes multiple changes associated with physical and emotional domains.[1] Some common physical changes experienced during pregnancy are weight gain, hair growth and stretch marks, while after pregnancy, the most common changes are weight loss, hair loss and sagging

breasts.[1] Mothers with a new or additional baby also experience emotional changes related to breast feeding demands, childcare stress and problems relating to maternal dissonance and difficult infant temperament.[2] In addition, there are also social demands that may contribute to the general depressive symptoms and stress such as compliance to the traditional postpartum care practices, financial strain related to low socioeconomic status, and social and sexual relationship with the partner or caretaker of the child.[2 3] Other emotionally draining aspects are biological, obstetric, clinical, psychological, social and infant factors which may also contribute to the prevalence of postpartum depression (PPD), general depression and stress.[2 3] Some of the risk factors for PPD such as history of physical abuse, mode of delivery and sex of the baby[2] differ between developing and developed countries. A systematic review by Villegas *et al*[4] reported that an increased risk of PPD in developing countries is related to some unique risk factors associated with poor relationship with the partner or in-laws, having an unemployed and uneducated husband, husband's psychopathology, years of marriage, having more than five children, having two or more children under the age of 7 and gender of the infant. Although the risk factors for PPD are considered multifactorial, studies have consistently identified the significant role of social support. Studies in both developed and developing countries have shown that lack of social support is an independent predictor of PPD.[3 5] Asian culture that dictates Asians to follow certain traditional rituals after delivery to protect the mother and child is one example of the stressors specific to the Asians, while poor marital relationship, stressful life events, child care stress, negative attitude towards pregnancy and learned helplessness are common and important psychological stressors predisposing to PPD.[3]

PPD is a significant health issue that can impact the health of the mother, her marital relationship, interaction with the newborn as well as infant growth.[5] Although the prevalence of PPD and general depression is between 10% and 15% in the first 3 months of post partum, an increasing trend in prevalence was observed after 3 months until 12 months of post partum and no difference in prevalence was observed through self-reports or clinical interviews.[6] Hence, depression at this critical period of life carries special meanings and consequences to the mother and her relationship with her baby.[6] It is possible to identify mothers with an increased risk for PPD and general depression in the postpartum period using appropriate and validated tools which are acceptable and can be more efficient than clinical interviews.[6 7]

Depression is the most common psychological disorder during the postpartum period. The first symptom usually appears within 4 weeks of delivery,[8] which can range from mild to severe.[8] According to WHO, symptoms of PPD, also termed as postpartum blues, begin with a depressed mood, anhedonia and low energy within a few days of delivery, most commonly on day 3 or day 4.[6] The *Diagnostic and Statistical Manual of Mental Disorders,* 5th ed. (DSM-5) categorises PPD as a major depressive episode 'with peripartum onset if onset of mood symptoms occurs during pregnancy or within 4 weeks following delivery'.[9] Symptoms can persist up to several months, and if left untreated, PPD may lead to subsequent emotional, behavioural and cognitive problems of the child.[6 10] Despite these concerns, PPD remains underdiagnosed and undertreated in clinical practices in Malaysia.[11–13] This might be due to social taboos associated with psychiatric diseases.[14] Other factors that contribute to the low detection rate include low screening rate for PPD and lack of awareness of the illnesses among mothers and caretakers.[11] Studies showed that between 1990 and 2002, the prevalence of PPD ranged between 10% and 15% within 12 months post partum in western societies compared with the more varied prevalence rates of between 3.4% and 63.9% among Asian countries within the similar postpartum period and timeframe.[3 6] In Malaysia, studies reported that the incidence and prevalence of PPD were 9.8% and 20.7%, respectively.[12 13]

A systematic review suggested that a history of general depression, stressful life events, low social support, antenatal anxiety, unplanned pregnancy, preference of infant's gender and low income were risk factors leading to PPD in Asian countries such as India and Bangladesh.[15] A study in Thailand reported that a history of lifetime major depression and depressive symptoms during pregnancy were the most important risk factors for PPD.[16] For Malaysian women, depressive symptoms during late pregnancy, an emergency delivery, preterm birth, application of traditional postpartum practices, marital problems, as well as low income were likely to be associated with an increased risk of developing PPD.[6 17–19] On the other hand, a local study suggested that a planned pregnancy may prevent the risk of PPD.[12]

With regards to general depression in the postpartum period, the general depressive symptoms during the postpartum period include experiencing continuous low mood or sadness, feeling hopeless and helpless, having low self-esteem and feeling tearful that the mother is unable to take care of the child.[9] Psychosocial predictors of a general depression in postpartum women which include lower occupational status, prenatal depression level, more distal stressors and personal psychiatric history reflecting past and present experiences, showed an indirect effect.[20 21] Based on the Depression Anxiety Stress Scale (DASS) screening questionnaire, the general depressive symptoms include not feeling positive, not having the initiative to do daily activities, having nothing to look forward to, feeling down-hearted and blue, not feeling enthusiastic, lacking self-worth and having the feeling that life is meaningless.[21] Care for women who suffer from mild to moderate depressive symptoms may be overlooked, resulting in late diagnosis and increased chances of aggravating PPD and other psychological disorders, which in turn, increase the burden of healthcare costs and impact family relationships negatively.[1]

In Malaysia, much less is known about postpartum anxiety. Anxiety disorders are more common in postpartum women than in the general population, and based on studies done in the USA,[22] its incidence usually occurs during the first 6 months of post partum, ranging from 6.1% to 27.9%,[23 24] with the prevalence rate of 4.4%–8.2% at 6–8 weeks post partum.[22] A study in Croatia reported 17% prevalence of high anxiety occurring immediately after childbirth, 20% at 6weeks post partum and the comorbidity of anxiety and PPD was 75%.[25] Characteristics of anxiety include excessive worry that lasts, accompanied by restlessness, fatigue, poor concentration, muscle tension and sleep disturbance.[9] Other symptoms include excessive worry, feeling nervous or on the edge, inability to stop or control worrying, having troubles relaxing, feeling easily irritable or annoyed and feeling awful as if something bad is going to happen. While a certain degree of anxiety in response to becoming a new mother is normal and even adaptive, some mothers can experience anxieties that are excessive and debilitating.[26 27] Examples of postpartum panic disorders include personality problem exhibited by being over vigilance and excess checking on baby's breathing.[26] Excessive anxiety may have long-term effects on mothers and their infants. Some of the experiences identified in relation to postpartum anxiety disorders are feeling of loss, frustration and guilt, accompanied by physical symptoms of tension.[8] Postpartum anxiety is associated with disrupted mother–infant attachment, PPD, reduced likelihood of breast feeding, increased risk of infant abuse, delayed cognitive and social development in infants and an increased likelihood of anxiety in children.[22] Some studies pointed to the importance of distinguishing anxiety from depression in order to provide appropriate treatments that target the symptoms and aetiology of anxiety.[24]

Symptoms of stress during the postpartum period at the first 6 weeks postdelivery include difficulty to wind down, over-reacting to situations, nervousness, agitation, difficulty to relax and becoming very sensitive to changes. The prevalence rate of stress varied between 20% and 40%.[26] A study done in Taiwan identified the three most common factors that contribute to postpartum stress that is, maternity role attainment, lack of social support and body changes.[28] The study also concluded that the level of postpartum stress varied based on the duration of post partum.[28] Women who underwent caesarean delivery had higher antenatal stress and anxiety and depression levels compared with women who did not undergo the procedure.[29] In contrast, an Islamic lifestyle has been shown to be protective against pregnancy-specific stress.[30] A study in Lebanon showed that an intervention with a postpartum film that addresses common stressors during the postpartum period and availability of a 24hours telephone hotline service reduce stress during the postpartum period.[31] In Malaysia,; however, no studies have been carried out on the prevalence of stress during the postpartum period.

Many studies have looked into the psychological well-being of mothers using only a brief unidimensional instrument such as the Edinburgh Postnatal Depression Scale (EPDS) without looking at other aspects of the psychological well-being of postpartum mothers and their associated risk factors.[23 26 31] Furthermore, studies conducted in Malaysia were done in Kelantan,[13] Negeri Sembilan[11] and Sabah[11] which have limited external validity in terms of ethnicity and socioeconomic profiles in comparison to the population in Perak. For example, the study carried out in Kelantan only focused on the Malay ethnicity while in Sabah, the cultural and sociodemographic background differs from that of the population in peninsular Malaysia. As such, risk factors such as confinement with in-laws, observing cultural taboos during confinement, lack of sleep, postpartum wound pain and other somatic symptoms have not been well studied or established in the Malaysian context.[32] Additionally, these studies were restricted to women admitted to hospitals; thus, data which were collected solely through interviews could be misleading as a result of the Hawthorne effect and socially pleasing answers.[17]

Accordingly, this study aims to determine the point prevalence and risk factors of postpartum depression, general depressive symptoms, anxiety and stress (PODSAS) among mothers at 4-week follow-up at public health clinics in Perak. It will look into the overall depression based on the combined EPDS and DASS general depression subscale measures. It will also explore the relationship of these two established measures for any possible contextual differences as few studies, if any, have examined this.

METHODS AND ANALYSIS

Study design

This will be a cross-sectional study over a period of 9months beginning from September 2019 to May 2020.

Setting

The study will be conducted among postpartum mothers who have postnatal follow-up in five public health clinics in Perak: four in the district of Kinta (urban) and one in the district of Kerian (suburban). The four clinics in Kinta district will be Pasir Pinji Health Clinic, Gunung Rapat Health Clinic, Buntong Health Clinic and Greentown Health Clinic. The fifth clinic is Bagan Serai Health Clinic which is located in the Kerian district. These clinics are selected as these are the clinics where the researchers will be practicing at the time of the study. These clinics provide antenatal care starting from the booking and continuing postnatally after the mothers have delivered in hospitals. Postnatally, the health of the mothers and babies will be examined within days and weeks during follow-up home visits by nurses from these clinics. The mothers and babies will also be inspected by medical officers at the health clinics at 4weeks after delivery for general health checks, counselling on contraception and review of the baby including immunisation.

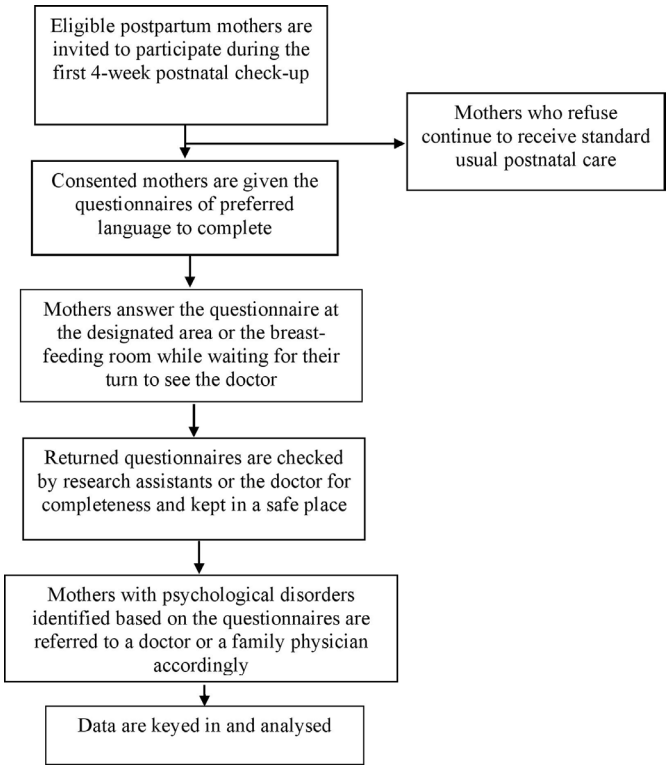

Figure 1 Flow of the participants during data collection.

Participants

The study will involve postnatal mothers who have follow-up at the participating public health clinics during their 4-week scheduled postnatal visit. They are 18 years and above and are at 4-week postdelivery irrespective of mode of delivery, able to read and understand the Malay or the English language and able to give a written consent. The study will exclude those who are illiterate. Also excluded are mothers with a known diagnosis of depression, neurosis or psychotic disorders such as bipolar mood disorder and schizophrenia as documented in the antenatal book or by self-report from family members as they may not be able to respond appropriately to the questionnaire. Mothers who are non-Malaysian are also excluded due to the differences in psychosocial background, in addition to being few in numbers.

Sampling

All eligible postnatal mothers attending the 4-week postnatal check-up will be invited to participate. The eligibility will be screened a day earlier based on the copy of their antenatal medical records available at the clinics. Those who fulfil the eligibility criteria will receive a copy of the questionnaire and a consent form which will be attached to the clinic copy of the antenatal medical records. When the mothers arrive at the registration counter of the postnatal clinic, their eligibility will be further confirmed, followed by an explanation regarding the study. Those who agree to participate will sign the consent form before they are given the study questionnaire. They will self-administer the questionnaire at a designated waiting area while waiting for their turn for medical consultation. After returning the completed questionnaire, every participant will be given a token of appreciation that is, a fact sheet on PPD, general depression, anxiety and stress for educational purposes.

All returned questionnaires will be checked for completeness by a research assistant or the doctors on duty at the postnatal clinics. Participants who are found to have PPD based on the EPDS questionnaire or severe psychological disorders based on the DASS-21 will be referred to the doctors or family physicians at the clinic within the same week of questionnaire completion for further management. Patients with mild or moderate score of psychological disorders based on the questionnaire will be given appropriate counselling and follow-up care in the health clinics within a month following the completion of the questionnaire. Confidentiality of the participants will be guarded throughout the study (figure 1).

Research tools

The research tool used in this study is a three-part questionnaire with an estimated time of about 30 min to complete the whole questionnaire. Part 1 covers questions on the subject's sociodemographic characteristics while part 2 contains questions which explore the risk factors according to the variables used. Questions in part 1 and part 2 were created based on the literature review. The variables used in the questionnaire and their definitions are available in online supplementary table S1. Face and content validity of part 1 and part 2 will be further tested in a pilot study involving 50 postnatal mothers (10 from each health clinic) with the same eligibility (see below).

Part 3 consists of the validated English or Malay version of the EPDS questionnaire and the DASS-21.[33–38] EPDS which was developed by Cox *et al* [18] was originally written in the English language.[17] The Malay language version of the EPDS was developed by Kadir *et al*, and it was validated based on the sample of postpartum Malaysian women in Kelantan, North East of Peninsular Malaysia.[33] The questionnaire contains 10 questions assessing the mothers' feelings in the past 7 days. Item score ranges from 0–3 on a 4-point Likert scale, and the scores are summed up to get an overall score ranging from 0 to 30, with some reversed scored items.[35] The findings of the study suggested an EPDS cut-off score value of 11.5 for depression with a sensitivity of 72.7% and specificity of 92.6%.[34] The Malay version of the EPDS was also shown to have good internal consistency (Cronbach's α=0.86) and good split-half reliability (Spearman split half coefficient=0.83). Based on a study conducted by Wan Mahmud and Mohamed, the instrument also showed satisfactory discriminant and concurrent validity.[35] The cut-off point of 11 was considered optimal for screening a population of Malay-speaking women during 4–12 weeks post partum.[35]

The DASS-21 scale will be used to determine the incidence of other psychological disorders (general depression, anxiety and stress) among the participants.[37] The

DASS-21 consists of seven self-report items for the three different subscales of general depression (DASS-21-D), anxiety (DASS-21-A) and stress (DASS-21-S).[38 39] Each item is scored on a 4-point Likert scale ranging from 0 ('did not apply to me at all') to 3 ('applied to me very much'). The scores for the total DASS-21 and for each subscale are then summed up. DASS is suitable to be used in many different clinical settings to assess emotional states over the past 1 week.[40 41] The score ranges from 0 to 21 for each of the subscales with a separate scoring each.

For general depression, scores 5 and below indicate no depression; scores 6–10 indicate moderate depression and scores higher than 10 indicate major depressive symptoms. For the anxiety subscale, scores 4 and below indicate no anxiety; scores 5–8 indicate moderate anxiety symptoms and scores higher than 8 indicate major anxiety. For the stress category, scores 7 and below exclude stress; scores 8–13 indicate moderate stress and scores higher than 13 indicate major stress.[37] The Malay version of DASS-21 had a Cronbach's α values of 0.75, 0.74 and 0.79 for depression, anxiety and stress subscales, respectively.[38] A systematic review of the measurement properties of DASS-21 showed a significant association with other similar constructs such as the Hospital Anxiety and Depression Scale (pooled r=0.69 for depression and pooled r=0.66 for anxiety), the Beck Depression Inventory (pooled r=0.73), Beck Anxiety Inventory (pooled r=0.75) and Positive and Negative Affect Schedule (pooled r=0.56).[41] The overall construct validity was rated as high in the hypotheses testing.

Using both the EPDS and DASS-21 will enable the point prevalence of PPD and other psychological well-beings among the postpartum mothers in the same setting to be determined.

Pilot study

A pilot test was conducted on the data collection process in August 2019 at each participating health clinic, and 10 eligible participants completed the questionnaires. Improvements on the questionnaire and process were then carried out based on the findings of the pilot test. The 50 samples from this pilot study will not be included in the actual study.

Sample size calculation

Based on the various studies done in Malaysia, the prevalence of PPD and psychological disorders ranges from 3.9% to 28.8%.[2 5 42] There was no previous study done with a population similar to this study. This study takes the approach of best estimation of the prevalence for PPD and psychological disorders to be at 10%. Using logistic regression in the GPower V.3.1.2 and with estimated proportion of PPD and psychological disorders as 10%, with the smallest OR of 2.5 of the potential risk factor[42] with 0.80 power and significance at two-sided α of 0.05, the estimated sample size is 321. Taking into consideration of about 30% of non-response rate and incomplete or missing data in patients' medical records and questionnaires returned, the sample size needed is 459.

Data analysis

The investigators have the overall responsibility for compilation, maintenance and management of the study questionnaires and database. The database is stored on a password-protected computer in a locked office. In making sure that data entry is of good quality, all research assistants will be trained to facilitate in the administration of the questionnaires in a standardised manner and to check on the completeness of the returned questionnaires. Data will be entered and checked for accuracy by two separate persons from two different clinics before analysis. Multiple imputation (with 10 runs) may be used to replace missing data in the variables. Imputed variables will be set within a predefined clinically possible range. Data cleaning will be done using SPSS to check that each data point is entered within plausible ranges; otherwise, verification from the original data source will be conducted. Data analysis will be done using SPSS V.25.0 (IBM).

Descriptive statistics will be used to summarise sociodemographic data. A report will be prepared on the sociodemographic and clinical characteristics (age, ethnicity, education level, parity and mode of delivery) of the non-participants and refusals to compare to that of the participants. Numerical data will be presented as mean (SD) or median (IQR) based on the normality of their distribution. Categorical data will be presented as frequency (percentage). Point prevalence of depression (PPD and general depressive symptoms, combined and separately), anxiety and stress will be reported based on the recommended cut-offs. A cut-off point of 11 based on the EPDS will be considered as having PPD.[35] For general depression, DASS-21-D scores of ≤ 5 indicate no depressive sign; scores 6–10 indicate moderate depression and scores ≥ 11 indicate major depressive symptoms. The EPDS ≥11 and DASS-21-D ≥6 will be combined to indicate an overall depression. For the anxiety subscale, DASS-21-A scores ≤ 4 indicate no anxiety; score 5–8 indicate moderate anxiety symptoms and scores ≥ 9 indicate major anxiety. For the stress category, DASS-21-S scores ≤ 7 exclude stress; scores 8–13 indicate moderate stress and scores ≥ 14 show major stress.[36] Some categorical variables will be further merged: marital status into married/not married and divorced or widowed; educational levels into primary/secondary/diploma or technical studies/tertiary education and have never been to school; occupation into unemployed/routine and manual occupation/intermediate occupation/higher level: managerial, administrative and professional occupations; household income into less than RM1000, RM1000–RM5000, RM5000–RM10 000 and more than RM10 000; who supported the mother with postnatal care—parents, parents-in-law, husband, confinement woman or confinement centre, alone and others; mode of delivery into normal vaginal delivery/instrumental delivery/planned caesarean section and

emergency caesarean section. Outcomes of the baby include alive or not, gender as male or female, baby weight, number of babies whether one or more than one, term or preterm, admission during postpartum period and any medical complication. Correlation between the total scores for PODSAS will be done using the Pearson's or the Spearman's correlations according to the distribution of the total scores, normally or non-normally distributed, respectively.

To analyse the association between sociodemographic and clinical variables with PPD, general depressive symptoms, anxiety and stress, multiple or multinomial logistic regressions analyses will be used after the categorisation of these outcomes according to the recommended cut-offs (see above). The lowest score category will be used as the referent group, and the PPD, general depressive symptoms, anxiety and stress will be represented by the two higher score categories, respectively. Additional multinomial logistic regression analyses might be run with the three cut-offs categories and the results compared if the sample size within each of the categories allows it. These sociodemographic and clinical factors with a p value <0.20 from the simple logistics regression analyses (crude OR) will be included in the final multiple logistics regression analyses (adjusted OR). Multicollinearity between any independent variables will be checked according to the tolerance <0.4 (Variance Inflation Factor ≥2.5). In the present of multicollinearity, the more meaningful or important variable from the clinical perspectives will be selected for use in the final regression analysis. OR will be presented with 95% CI. P value of <0.05 is considered statistically significant. In all the final models, Q–Q plots will be checked for normality of residuals, and the residual plots will be checked for linearity and homogeneity assumptions to ensure statistical assumptions are acceptably met.

Expected outcomes

This study aims to obtain accurate estimates of point prevalence of PPD, general depression, anxiety and stress among postpartum mothers in public health clinics in Perak. It is proposed that point prevalence is measured instead of prevalence rate or incidence as the study is designed to measure the number of new conditions (PPD, general depressive symptoms, anxiety and stress) over the number of women at risk at 4 weeks post partum due to the lack of proper assessment of the women's psychological conditions between the period after delivery and the time of participation in the study. It is not incidence rate as the study is cross-sectional in its sampling method and does not follow-up on the participants. A prevalence rate would be the effect estimate if the study proposes to study the conditions in a defined population such as all women throughout the first 4 weeks of post partum. It is noted that the distinction between point prevalence, prevalence rate and incidence proportion for depression, anxiety and stress is slim when the condition-free status at the immediate post partum is based on self-report without objective measures. However, based on the study design, the effect estimate is closer to a point prevalence than it is to prevalence rate or incidence proportion.[43]

The five public health clinics chosen for this study are likely to be representative of Perak population in terms of ethnicity distribution. Most ethnicities in Malaysia can read and understand the Malay language to some extent; however, without the Chinese or Tamil version of the questionnaires, this might impair the responses received from mothers of these ethnicities, particularly those with lower educational background. The study will assess the representativeness of the participants to the population of postpartum mothers in Perak and nationwide from other sociodemographic aspects and clinical characteristics from the most recent report of the National Obstetrics Registry.[44] All the five participating clinics have separate services for maternal and child healthcare and have an estimated live births ranging from 450 to 1500 babies per year in each clinic. Thus, it is possible to reach the target sample size. General depressive symptoms, anxiety and stress are novel variables that have been shown to be predictors of PPD, but they are rarely explored in the Malaysian setting. As these concepts are personal and sensitive, the study adopts the self-administration approach facilitated by a trained research assistant whose responsibility is only to clarify difficult items faced by the respondents. Furthermore, a quiet designated area will be provided to help improve the quality of responses.

By identifying the demographic and clinical risk factors associated with depression, anxiety and stress in postpartum mothers, effective counselling and awareness programmes can be designed for high-risk pregnant mothers. The findings of this study will provide information to the public and create better awareness on psychological well-being during the postpartum period. This may further help in reducing incidences of PPD, anxiety and stress in mothers with a newborn.

Patient and public involvement

Based on the feedback received from patients who participated in the pilot study, several changes were made to the questionnaire, and the data collection process was refined. In the patient section, the categorical list for patient's occupation was taken out. Instead, respondents are given the option to write down their occupation. This was done following a confusion caused by the options given for occupation. The questionnaire was also formatted to improve its readability and reduce the number of pages to encourage self-administration by patients.

Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

ETHICS AND DISSEMINATION

Ethical consideration

This study is registered in the National Medical Research Register (NMRR-19-868-47647), and ethics approval

was obtained from the Medical Research and Ethics Committee (MREC) Ministry of Health Malaysia with reference number KKM/NIHSEC/P19-1129(11) on 7 August 2019. All collected data and responses obtained from the observation will be kept strictly confidential, and no unique identifier(s) will be present on the questionnaire package. Results and data presented will not identify individual mothers. Participation in this study will not bring any risk or harm to the current treatment of postnatal mothers.

Privacy and confidentiality

Participant's name will be linked to the study identification number for this research only on the Consent Form. The study identification number instead of patient identifiers will be used on the data sheet. All data will be entered into a protected computer. On the completion of the study, data in the computer will be copied to CDs, and the data in the computer will be erased. CDs and any hardcopy of data will be safeguarded in a locked cabinet in the Sister's room in the designated public health clinics of the investigators and maintained for a minimum of 7 years after the completion of the study. The CDs and data will be destroyed after the storage period. Subjects will not be allowed to view their personal data as the data will be consolidated into a database. However, subjects may write to the investigators to request access to the findings of the study if the need arises.

Publication policy

No personal information will be disclosed, and participants will not be identified when the findings of the research are published. If the names and details of the patients need to be disclosed, a written expressed consent will be obtained prior to presentation and publication.

Dissemination plan

All results from this study will be reported and shared with the local health stakeholders and disseminated through conference proceedings as well as journal publications.

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Contributors All authors conceived the study from the beginning. TP assisted with the development of the questionnaire and variables. VG and PS contributed to the study design. PNMAB assisted with the sample size calculation. PK, TP and PNMAB will assist data analysis. SAMR drafted the initial manuscript, study design and the final study protocol. LZM, SA and VP provided local guidance and general administrative support for the study at the clinic level. BHC supervised and contributed to all aspects of the study. All authors critically revised the study protocol and approved the final manuscript for publication. BHC is the guarantor of the study.

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