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The Incidence and Risk Factors of Postpartum Depression, General Depressive Symptoms, Anxiety and Stress (PODSAS) among Mothers at First Follow-up Postnatally 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 are often overlooked, and they can cause a considerable amount of morbidity to new mothers, their babies and families. The aim of this study is to determine the incidence of depression (postpartum and general), anxiety and stress among postpartum mothers in five public health clinics in Perak, and to identify their associated risk factors. Findings from this study may inform the needs for early screening, detection and encourage development of interventions to reduce its occurrence and to support mothers with postpartum depression, general depressive symptoms, anxiety and stress.

Methods and Analysis: This cross-sectional study will recruit 459 postpartum mothers consecutively during their first-month postnatal follow-up in five selected public health clinics in Perak from September 2019 to February 2020. Mothers aged 18 years and above with all modes of deliveries, within six weeks post-delivery, and able to understand the English and Malay language will be invited to participate. Non-Malaysians and mothers with known diagnosis of psychotic disorders will be excluded from the study. A set of validated questionnaires will capture sociodemographic and possible risk factors, postpartum depression will be measured with the Edinburgh Postpartum Depression Scale questionnaire, and general depressive symptoms, anxiety and stress will be measured with the 21-item Depression, Stress and Anxiety Scale. Data analysis will be conducted using SPSS version 25.0 (IBM, Chicago, IL). Besides descriptive statistics, possible risk factors will be identified, and their independent associations with postpartum depression, general depressive symptoms, anxiety and stress will be estimated with multivariable regressions analyses.

Ethics and Dissemination The study protocol has been reviewed and approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia on 7th August 2019.

All results from this study will be reported and shared with the local health stakeholders, and disseminated through conferences proceedings as well as publication in journals.

Article Summary

Strengths and Limitations of This Study

- This study compares postpartum depression with general depression and other psychological well-being that have not been well studied before.
- Five public health clinics in urban and sub-urban areas of Perak may have limitation in representativeness of the participants to the nationwide population.
- Self-administration of the questionnaires is encouraged and facilitated to improve data quality.
- Respondents will be postpartum mothers at one-month post-partum, will not reflect the incidence of depression, anxiety and stress during the first few weeks after delivery, and months later in the postpartum period.

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INTRODUCTION

After a childbirth, a woman undergoes multiple changes that is associated with physical and emotional domains.[1] Some of the common physical changes experienced during pregnancy includes weight gain, hair growth, and stretch marks; after pregnancy, weight loss, hair loss, and sagging breasts are the most common changes.[1] Mothers with a new or additional baby also experience emotional changes related to the demands of breastfeeding, childcare stress, maternal neuroticism and difficult infant temperament.[2] There are also social demands that may contribute to general depressive symptoms and stress such as compliance to the traditional postpartum care practices, financial strain related to low socioeconomic status, social and sexual relationship with the partner and caretaker of the child.[3,4] Other emotionally draining aspects include biological, obstetric, clinical, psychological, social, and infant factors may also contribute to the incidence of postpartum depression, general depression and stress.[2,3] Risk factors for postpartum depression (PPD) are different between developing and developed countries. Klianin et al reported that PPD among Asian countries such as Pakistan and Malaysia ranged between 3.4% to 63.9%,[3] compared to that in Europe between 4.4% to 48%.[4] Many studies have described the association between socio-demographic factors and PPD, but few have explored the association between other stressors in women's lives after having a baby and a more general psychological morbidity.[3]

PPD is a significant health issue that can impact the health of the mother, her marital relationship, and interaction with the newborn as well as infant growth.[4] Although rates of depression do not appear to be higher in women in the period after childbirth compared to age-matched control women which are between 10-15%, but the rates of first onset and severe general depression are elevated by at least three-fold.[5] Depression at this critical period of life carries special meanings and risks to the woman and her family.[5] It is possible to identify

women with increased risk factors for PPD but the unacceptably low positive predictive values of many currently available antenatal screening tools make it difficult to recommend them for routine care.[6]

Depression is the most common psychological disorder during pregnancy and postpartum period. The first symptoms usually appear between the fourth and sixth week postpartum,[7] and the symptoms can range from mild to severe.[8] According to WHO, PPD begins with symptoms of depressed mood, anhedonia and low energy within a few days of delivery, most commonly on day 3 or day 4, also termed as postpartum blues.[5] It can persist up to several months, and untreated postpartum depression may lead to subsequent emotional, behavioral and cognitive problems of the child.[9] Despite these concerns, PPD remains under-diagnosed and under-treated in clinical practices in Malaysia.[10-12] This might be due to the social taboo that is associated with diseases that are related to psychiatry.[13] Other factors that contribute to the low detection rate includes low screening rate for PPD, and reduced awareness of the illness amongst mothers and caretakers.[10] In Malaysia, few studies reported that PPD ranged between 3.9% to 20.7%.[2,11,12] A study in 2002 noted that the incidence of PPD amongst Malay women in Bachok, Kelantan was 9.8%.[12] Another study in 2005 showed that the prevalence of PPD in Hospital University Sains Malaysia was 20.7%.[2] 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.[14] Another study in Thailand reported that a history of lifetime major depression, and depression during pregnancy were the most important risk factors for PPD.[15] For Malaysian women, depressive symptoms during late pregnancy, an emergency delivery, application of traditional postpartum practices, marital problems, as well as low income were associated with an increased risk of developing PPD.[5,16,17] A recent

systematic review supported the association between preterm birth and PPD.[18] In contrary, a local study suggested that a planned pregnancy may prevent the risk of PPD.[11]

The *Diagnostic and Statistical Manual of Mental Disorders,* 5th ed (DSM-5) categorizes general depression based on symptoms such as depressed mood or loss of interest for a duration of 2 weeks, while categorizing PPD based on symptoms such as sadness, anxiety or worry after the birth of a child.[19] General depressive symptoms during postpartum period includes 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. Psychosocial predictors of a general depression in a postpartum women includes lower occupational status, prenatal depression level, more distal stressors and personal psychiatric history, which reflected past and present experiences, showed an indirect effect.[20] While symptoms of major depressive disorder include excessive worry, feeling nervous or on edge, not being able to stop or control worrying, trouble relaxing, easily irritable or annoyed and feeling awful as if something bad is going to happen. Based on the Depression Anxiety Stress Scale (DASS) screening questionnaire, general depressive symptoms include not feeling positive, no initiative to do daily things, nothing to look forward to, feeling down-hearted and blue, not enthusiastic, absence of self-worth, and a feeling that life is meaningless. The DSM-5 does not distinguish between postpartum major depression and major depressive disorder, but does provide a postpartum onset specifier for major depressive disorder, defined as onset within four weeks of delivery.[21] Care for women who suffered from mild to moderate depressive symptoms may be overlooked, resulting in a late diagnosis and increased chances of aggravating PPD, which in turn raises the burden of healthcare costs, and negatively impacting the family relationships.[1]

In Malaysia, far less is known about postpartum anxiety. Anxiety disorders are more common in postpartum women than in the general population, with estimates of its incidence during the first 6 months of postpartum ranging from 6.1% to 27.9%,[22,23] with the prevalence of 4.4% to 8.2% at 6 to 8 weeks postpartum.[24] Characteristics of anxiety includes excessive worry that last is accompanied by restlessness, fatigue, poor concentration, muscle tension and sleep disturbance.[19] 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.[25] Excessive anxiety may have long-term effects on the mothers and their infants. Some of the experiences identified in relation to postpartum anxiety disorders were feeling of loss, frustration and guilt, accompanied by physical symptom of tension.[8] Postpartum anxiety is associated with disrupted mother–infant attachment, postpartum depression, reduced likelihood of breastfeeding, increased risk of infant abuse, delayed cognitive and social development in infants, and an increased likelihood of anxiety in children.[24] Some studies pointed to the importance of distinguishing anxiety from depression in order to provide appropriate treatments that target the symptoms and etiology of anxiety.[23]

Symptoms of stress during the postpartum period includes difficulty to wind down, over-reacting to situations, nervousness, agitation, difficult to relax, and very sensitive to changes. Prevalence rate of stress varied between 20% to 40%.[25] A study done in Taiwan, identified three most common factors that contributes to postpartum stress which includes maternity role attainment, lack of social support, and body changes.[26] The study also concluded that the level of postpartum stress varied based on the duration of postpartum.[26] Women who underwent caesarean delivery had higher antenatal stress, besides anxiety and depression levels, compared to women who did not undergo the procedure.[27] In contrary, a study in Lebanon showed that an intervention with a postpartum film that addresses common stressors during the postpartum

period and making available a 24-hour telephone hotline service, reduces stress in the postpartum period.[28] In Malaysia, however, no studies have been done to study the prevalence of stress during the postpartum period.

Many studies have been looking into the psychological well-being of mothers using only a brief unidimensional instrument such as the Edinburgh Postnatal Depression Scale (EPDS), without looking at the other aspects of the psychological well-being of postpartum mothers and its associated risk factors.[22,25,28] Furthermore, studies in Malaysia were conducted in Kelantan,[12] Negeri Sembilan[10] and Sabah[10] which have limited external validity to our population in Perak in terms of ethnicity and socioeconomic profiles. For example, the study done in Kelantan only studies the Malay ethnicity. Meanwhile, in Sabah, the cultural and sociodemographic background differs from that of the population in peninsular Malaysia. Risk factors such as confinement with in-laws, observing cultural taboos during confinement, lack of sleep, postpartum wound pain and other somatic symptoms are not well studied or established in the Malaysian context.[29] Additionally, studies restricted to women admitted to the hospital could be misleading.[16]

Accordingly, this study aims to determine the incidence and risk factors of postpartum depression, general depressive symptoms, anxiety and stress among mothers at one-month follow-up at public health clinics in Perak.

METHODS AND ANALYSIS

Study design

This will be a cross-sectional study over a period of six months from September 2019 to February 2020.

Setting

The study will be conducted among postpartum mothers who are followed-up postnatally in five public health clinics in Perak, four from Kinta District (urban) and one from Kerian District (sub-urban). The four clinics from Kinta District will be Health Clinic Pasir Pinji, Health Clinic Gunung Rapat, Health Clinic Buntong and Health Clinic Greentown. Whereas the other clinic, Health Clinic Bagan Serai is in Kerian district. These clinics are where the researchers will be practising at the time of this study. These clinics provide antenatal care starting from booking, until postnatal after the mothers have delivered in hospitals. Postnatally, the health of the mothers and babies will be examined during follow-up home visits by nurses from these clinics within days and weeks. The mothers and babies will also be seen by medical officers at the health clinics one month after delivery for general health checks, counselling on contraception and review of the baby including immunization.

Participants

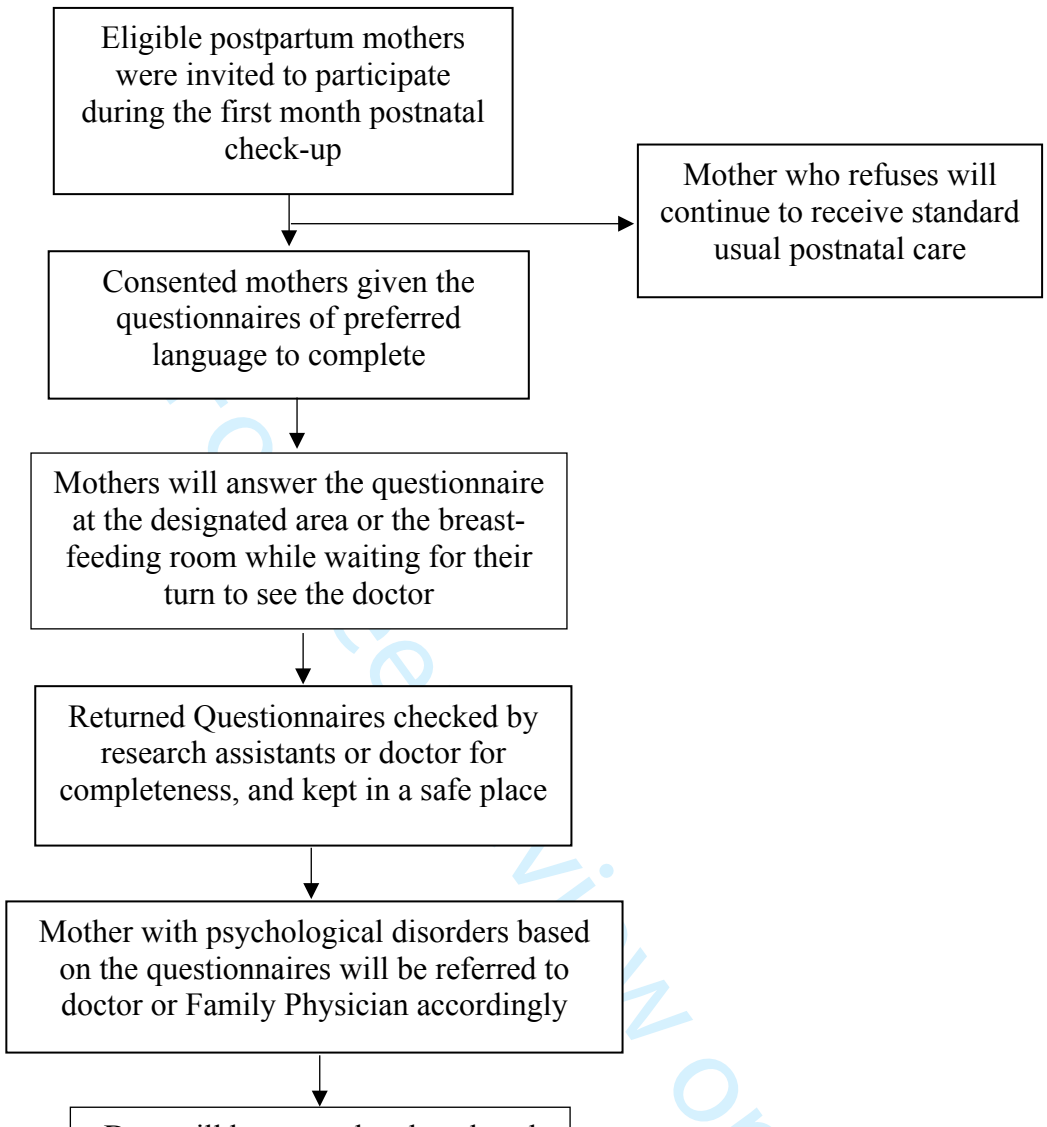
Postnatal mothers who are followed-up at the participating public health clinics during their first month scheduled postnatal visit. These postpartum mothers are those aged 18 years and above, within six weeks post-delivery irrespective of mode of delivery. They must be able to read and understand the Malay or English language, and give written consent. Mothers with a known diagnosis of psychotic disorders such as bipolar mood disorder and schizophrenia as documented in the antenatal book or by self-report from family members are excluded because they may not be able to respond appropriately to the questionnaire. At the same time, non-Malaysian mothers are excluded because of differences in psychosocial background and they are very few in numbers.

Sampling

All eligible postnatal mothers attending the one-month postnatal check-up will be invited to participate. The eligibility will be screened a day earlier based on the clinic copy of the antenatal medical records. For those who fulfil the eligibility criteria, the questionnaires and consent form will be attached to the clinic copy of the antenatal medical records. When the mothers present to the postnatal clinic's registration counter, their eligibility will further be confirmed, followed by an explanation regarding the study, and those who agree to participate will sign the consent form before given the study questionnaires. They will self-administer the questionnaires at a designated waiting area for their turn to the medical consultation. After returning the completed questionnaires, every participant will be given a token of appreciation, which includes a fact sheet on postpartum depression, 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 postpartum depression 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 for further management. Patients with mild or moderate score psychological disorders based on the questionnaires will be given appropriate counselling and follow-up care in the health clinics. Confidentiality of the participants will be guarded throughout the study.

Figure 1: Flow of the participants during the data collection



Research Tools

The research tools used in this study include the following three parts and the estimated time required to complete the whole questionnaire is about 30 minutes. Part 1 covers questions on the subject's sociodemographic characteristics and Part 2 covers questions which explores the risk factors according to the variables used. Part 1 and 2 questions were created based on the literature review. The variables used in the questionnaire and their definitions are available in

the Supplementary Material Table S1. Face and content validity of Part 1 and 2 will be further tested in a pilot study with 50 postnatal mothers (10 each in the five health clinics) with the same eligibility (see further below).

Part 3 consists of the validated English or Malay version of the Edinburgh Postpartum Depression Scale questionnaire (EPDS) and the Depression Anxiety and Stress Scales (DASS-21).[30-35] EPDS was originally in the English language and developed in 1987 by Cox, Holden and Saqovsky.[17] The available Malay language version of the EPDS was developed by Azidah et al in 2004 and was validated on a sample of postpartum Malaysian women in Kelantan, North East of Peninsular Malaysia.[30] The questionnaire has 10 questions with the total scores ranging from 0 to 30. Items scores range from zero to three on a 4-point Likert scale and scores are summed to get an overall score, with some items reversed scored.[31] The study findings suggested an EPDS cut-off score value of 11.5 for depression with the sensitivity of 72.7% and specificity of 92.6%.[30] The Malay version of the EPDS was also shown to have good internal consistency (Cronbach's alpha = 0.86) and good split-half reliability (Spearman split half coefficient = 0.83). Based on the study conducted by Wan Mahmud and Mohamed, the instrument also showed satisfactory discriminant and concurrent validity. The cut-off point of 11 were considered optimal for screening a population of Malay-speaking women at 4 to 12 weeks postpartum.[32]

The DASS-21 scale will be used to determine the incidence of other psychological disorders (general depression, anxiety and stress) among the participants.[33] 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).[34,35] 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 summed. DASS is suitable to be used in many different clinical settings.[36,37] The score ranges from 0-21 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 excludes stress, score 8-13 indicates moderate stress and scores 13 and above shows major stress.[33] The Malay version DASS-21 had a Cronbach's alpha values of 0.75, 0.74, and 0.79 for depression, anxiety and stress subscales, respectively.[35] A systematic review of the measurement properties of DASS-21 showed significant association with other similar constructs such as with 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).[38] The overall construct validity was rated as high in the hypotheses testing.[39]

By using both EPDS and DASS-21, we will also be able to determine the incidence of postpartum depression and other psychological well-beings among the postpartum mothers at the same setting.

Pilot study

We have pilot tested the data collection process in August 2019 at each participating health clinic until 10 eligible participants completed the questionnaires. Improvement on the questionnaires and process were carried out based on the findings from this testing. The 50 samples from this pilot study will not be included in the actual study.

Sample size calculation

Based on the various study done in Malaysia, the incidence of postpartum depression and psychological disorders range from 3.9 to 28.8%. There was no past study with a population that is the same to our study. We take the approach of best estimation of the incidence rate for postpartum depression and psychological disorders to be at 10%. Using logistic regression in the GPower 3.1.2 and with estimated proportion of postpartum depression and psychological disorders as 10%, with the smallest odd ratio of 2.5 of the potential risk factor[40] 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 patient's medical record and questionnaires returned, the sample size needed becomes 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 standardized 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 variables. Imputed variables will be set within a pre-defined clinically possible range. Data cleaning will be done using SPSS to check that each data point is entered within plausible ranges or else verification from the original data source will be conducted. Data analysis will be done using SPSS version 25.0 (IBM, Chicago, IL).

Descriptive statistics will be used to summarize the sociodemographic data. We will report 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 (standard deviation) or median (interquartile range) based on the normality of their distribution. Categorical data will be presented as frequency (percentage). 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 never been schooling; occupation into unemployed/ routine and manual occupation/ intermediate occupation/ higher managerial, administrative and professional occupations; household income into less than RM1000, RM1000 – RM5000, RM5000 – RM 10,000 and more than RM 10,000; with whom mother observed postnatal care into with parents, parents-in-law, husband, confinement lady 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 male or female, baby weight, number of babies whether one or more than one, term or preterm, admission during postpartum period, any medical complication. Correlation between the total scores for postpartum depression, general depressive symptoms, anxiety and stress will be done using the Pearson's or the Spearman's according to the distribution of the total scores, normally or non-normally distributed, respectively.

To analyze the association between the sociodemographic and clinical variables with PPD, general depressive symptoms, anxiety and stress, multiple or multinomial logistic regressions analyses will be used after categorization of these outcomes according to the recommended cut-offs. A cut-off points of 11 based on the EDPS will be considered as having PPD.[32] For general depression, scores 5 and below indicates no depressive sign, 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, score 5-8 indicate moderate anxiety symptoms and scores higher than 8 indicate major anxiety. For the stress category, scores 7 and below excludes stress, score 8-13 indicates moderate stress and scores 13 and above shows major stress.[33] The lowest scored category will be used as the referent group, and the PPD, general depressive symptoms, anxiety and stress will be represented by the two higher scored categories, respectively. We may run additional multinomial logistic regression analyses with the three categories and to compare the results if the sample size within each of the categories allow. Those sociodemographic and clinical factors with a *P* value < 0.20 from the simple logistics regression analyses (crude odds ratio) will be included in the final multiple logistics regression analyses (adjusted odds ratio). Multicollinearity between any independent variables will be checked according to the tolerance < 0.4 (VIF ≥ 2.5). In the present of multicollinearity, the more meaningful or important variable from clinical perspectives will be selected for use in the final regression analysis. Odds ratio (OR) will be presented with 95% confidence interval (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, 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 the incidences of postpartum depression, general depression, anxiety and stress among the postpartum mothers in public health clinics in Perak. The five public health clinics chosen for this study are likely to be representative of the Perak population from the aspects of ethnicity distribution. Although all ethnicities in Malaysia can read and understand the Malay language to some extent but without having the Chinese and Tamil versions of the questionnaires available, may impair responses from

mothers of these ethnicities with lower educational background. We will assess the representativeness of the participants to the population of postpartum mothers in Perak and nationwide from other socio-demographic aspects and clinical characteristics from the most recent report of the National Obstetrics Registry.[41]

All the five participating clinics have a separate service for Maternal and Child Health care with the estimated live birth ranging from 450 to 1500 babies per year in each clinic. Thus, we will be able to reach the target sample size. General depressive symptoms, anxiety and stress are novel variables that have been shown to be predictors of postpartum depression but have been rarely explored in the Malaysian setting. As these concepts are personal and sensitive, the study adopts self-administration approach and facilitated by a trained research assistant only to clarify difficult items faced by the respondents. Furthermore, a quiet designated area provided will hopefully help to improve quality responses.

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

Patient and Public Involvement

Based on feedbacks from the patients involved in the pilot study, improvement on the questionnaires and process were implemented.

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Author Contributions

All authors conceived the study from the beginning. TP assisted with development of the questionnaire and variables, VG and PS contributed to the study design, PNMAB assisted with the sample size calculation, PK and PNMAB will assist with the data analysis, SAMR drafted the initial manuscript, study design, and drafted 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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Competing Interest

None

ETHICS AND DISSEMINATION

Ethical consideration

This study is registered on the National Medical Research Register (NMRR-19-868-47647) and ethics approval has been obtained from the Medical Research and Ethics Committee (MREC) Ministry of Health Malaysia with the reference number of KKM/NIHSEC/P19-1129(11) on 07 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 computer that is protected. On completion of the study, data in the computer will be copied to CDs and data in the computer will be erased. CDs and any hardcopy 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 seven years after the completion of the study. The CDs and data will be destroyed after the period of storage. Subjects will not be allowed to view their personal data, as the data will be consolidated into a database. Subjects can write to the investigators to request access to the study findings 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 name and details of patients need to be disclosed, a written expressed consent will be obtained prior to presentation and publication.

Data sharing statement

Collected data will be made available upon request to the corresponding author. All requests are to provide a clear study protocol to the principal investigator. Deidentified and

anonymised participant data for all the outcomes will be shared once the results have been published. There is no time period or limit. Data use will be advised to refer to the published study protocol.

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Supplementary Table S1: Definitions of the variables

No.	Variables (Operational definition)	Description	Type of variable
1	Antenatal code	• White • Green • Yellow	Categorical
2	Age	Maternal age in completed years	Interval
3	Ethnicity -according to the paternal side	• Malay • Chinese • Indian • Others	Categorical
4	Religion	• Islam • Buddha • Hindu • Christian • Others	Categorical
5	Marital status	• Single • Married • Divorced/ • Widow	Categorical
6	Educational level - highest attained	• Primary education • Secondary education • Diploma/ Technical studies • Tertiary education • Never school	Categorical
7	Maternal Occupation	• Unemployed • Routine and manual occupations • Intermediate occupations • Higher managerial, administrative and professional occupations	Categorical
8	Duration of marriage	Duration of marriage in completed years	Interval
9	Husband occupation	• Unemployed • Routine and manual occupations • Intermediate occupations • Higher managerial, administrative and professional occupations	Categorical
10	Combined household income	• <RM1000 • RM1000-RM5000 • RM5000-RM10,000 • >RM10,000	Categorical
11	Smoking status -all types	• Yes, intensity – no of stick(s) • No • Ex-smoker	Categorical

12	Alcohol status -all types	• Yes • No • Currently stopped	Categorical
13	Husband practicing polygamy	• Yes • No	Categorical
14	If polygamy, wife no	• 1 • 2 • 3 • 4	Categorical
15	No of children	• 0 • 1 • 2 • 3 • 4 • >5	Ordinal
16	Pre pregnancy baby gender preference	• Male • Female • No preference	Categorical
17	Antenatal care	• Government • Private • None	Categorical
18	Planned pregnancy -Is the current pregnancy planned and not unexpected?	• Yes • No	Categorical
19	Satisfied with marriage -self-report	• Yes • No	Categorical
20	Marital problems -respondent's own perception of her marriage	• Yes • No	Categorical
21	Period of marital problems	• Before child delivery • After child delivery	Categorical
22	Stable relationship with husband - self-report	• Yes • No	Categorical
23	Domestic violence -Self-report of physical or emotional abuse at home during young before marriage	• Yes • No	Categorical
24	Domestic violence in this marriage and during pregnancy	• Yes • No	Categorical
25	Relationship with parents -respondent's own perception of the relationship between mother and her parents	• Yes • No	Categorical

26	Relationship with parent in law - respondent's own perception of the relationship with her in parent in law	• Yes • No	Categorical
27	Underlying medical illness before pregnancy -Any underlying diabetes, hypertension, asthma or any other chronic illnesses	• Yes • No	Categorical
28	Underlying medical illness during pregnancy -Hypertension, gestational diabetes etc	• Yes • No	Categorical
29	History of miscarriage -any history of abortion before 22 weeks in the previous pregnancy	• Yes • No	Categorical
30	Underlying mental illness -Diagnosed of having mental illness prior to pregnancy	• Yes • No	Categorical
31	History of mental illness during pregnancy -Diagnosed of having mental illness during her current pregnancy	• Yes • No	Categorical
32	History of mental illness during postpartum period -Diagnosed of having mental illness during her postpartum period	• Yes • No	Categorical
33	Family history of mental illness -Is there any parents of 1st degree relative being diagnosed of having mental illness?	• Yes • No	Categorical
34	Inadequate help from spouse during postpartum period - respondent's own perception of inadequate support during postpartum period	• Yes • No	Categorical
35	Inadequate help from other family members during postpartum period - respondent's own perception of inadequate support during postpartum period	• Yes • No	Categorical
36	Inadequate help from others during postpartum period - respondent's own perception of inadequate support during postpartum period	• Yes • No	Categorical

37	Inability to establish breast feeding -the inability to exclusively breast feed, requiring top up using formula milk	• Yes • No	Categorical
38	No confidence to care for the child -the inability of mother to care for the baby, thus being dependent on others	• Yes • No	Categorical
39	Undergone stressful life events -any recent events, occurred during antenatal and postpartum period, such as financial burden, passing of her loved ones or events that are perceived as stressful by respondent herself	• Yes • No	Categorical
40	Any cultural taboos observed during postnatal care that contributed to mother's stress	• Yes • No	Categorical
41	With whom respondent observed postnatal care during confinement	• Parents • Parents in law • Husband • Confinement lady/ centre • Alone	Categorical
42	Inadequate help to take care of newborn at night - self-report	• Yes • No	Categorical
43	Inadequate sleep/rest - respondent's own perception of inadequate sleep or rest during postpartum period	• Yes • No	Categorical
44	Dissatisfied with body weight and appearance post delivery - respondent's own perception on the satisfaction of her body weight and appearance post delivery	• Yes • No	Categorical
45	Intrapartum experience - respondent's own perception of having bad experiences during labour. E.g.: unbearable pain	• Yes • No	Categorical
46	Mode of delivery	• SVD • Instrumental delivery • Planned caesarean section • Emergency caesarean section	Categorical

47	Postnatal complication -experienced wound pain, wound breakdown, readmission to ward	• Yes • No •	Categorical
48	Type of complication	List complication.	Categorical
49	Readmission after discharge during postpartum period	• Yes • No	Categorical
50	Outcome of the baby	• Alive • Gender • Birth weight • Twins • Gestational weight • Admission to ward • Medical complication	Categorical
51	Edinburgh Postpartum Depression scale scoring (Less than 11 – no postpartum depression 11 or more – postpartum depression)	Total score (range 0 - 30) • Less than 11 – no postpartum depression • 11 or more – postpartum depression	Interval Categorical
52	Depression anxiety stress scale (DASS) scoring	Total scores (range 0-21) • Depression - Mild: 6-7 - Moderate: 8-10 - Severe: 11-14 - Very severe: 15 to 21 • Anxiety - Mild: 5-6 - Moderate: 7-8 - Severe: 9-10 - Vere severe: 11 to 21 • Stress - Mild: 8-9 - Moderate: 10-13 - Severe: 14-17 - Very severe: 18 to 21	Interval Ordinal Ordinal Ordinal

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-8
Objectives	3	State specific objectives, including any prespecified hypotheses	2
Methods			
Study design	4	Present key elements of study design early in the paper	8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	9-11
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	9-10
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	11-13, Supplementary Table S1
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	14-16
Bias	9	Describe any efforts to address potential sources of bias	16-17
Study size	10	Explain how the study size was arrived at	14
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	14-16
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	14-16
		(*b*) Describe any methods used to examine subgroups and interactions	14-16
		(*c*) Explain how missing data were addressed	14-16
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	14-16
		(*e*) Describe any sensitivity analyses	14-16

Results			NA
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	11
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	NA
		(b) Indicate number of participants with missing data for each variable of interest	NA
Outcome data	15*	Report numbers of outcome events or summary measures	NA
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	NA
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	NA
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	16-17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	NA
Generalisability	21	Discuss the generalisability (external validity) of the study results	NA
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	18

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

The Incidence and Risk Factors of Postpartum Depression, General Depressive Symptoms, Anxiety and Stress (PODSAS) among Mothers at First Follow-up Postnatally in Five Public Health Clinics in Perak: A Study Protocol for a Cross-sectional Study

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The Incidence and Risk Factors of Postpartum Depression, General Depressive Symptoms, Anxiety and Stress (PODSAS) among Mothers at First Follow-up Postnatally 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 are often overlooked, and they can cause a considerable amount of morbidity to new mothers, their babies and families. The aim of this study is to determine the incidence of depression (postpartum and general), anxiety and stress among postpartum mothers in five public health clinics in Perak, and to identify their associated risk factors. Findings from this study may inform the needs for early screening, detection and encourage development of interventions to reduce its occurrence and to support mothers with postpartum depression, general depressive symptoms, anxiety and stress.

Methods and Analysis: This cross-sectional study will recruit 459 postpartum mothers consecutively during their first-month postnatal follow-up in five selected public health clinics in Perak from September 2019 to February 2020. Mothers aged 18 years and above with all modes of deliveries, at one month post-delivery, and able to understand the English and Malay language will be invited to participate. Non-Malaysians and mothers with known diagnosis of psychotic disorders will be excluded from the study. A set of validated questionnaires will capture sociodemographic and possible risk factors, postpartum depression will be measured with the Edinburgh Postpartum Depression Scale questionnaire, and general depressive symptoms, anxiety and stress will be measured with the 21-item Depression, Stress and Anxiety Scale. Data analysis will be conducted using SPSS version 25.0 (IBM, Chicago, IL). Besides descriptive statistics, possible risk factors will be identified, and their independent associations with depression (postpartum depression and general depressive symptoms combined and separately), anxiety and stress will be estimated with multivariable regressions analyses.

Ethics and Dissemination The study protocol has been reviewed and approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia on 7th August 2019.

All results from this study will be reported and shared with the local health stakeholders, and disseminated through conferences proceedings as well as publication in journals.

Article Summary

Strengths and Limitations of This Study

- This study will examine the incidence proportion of depression (postpartum depression and general depressive symptoms combined and separately), and other psychological well-being (anxiety and stress) that have not been well studied before at one month postpartum.
- Five public health clinics in urban and sub-urban areas of Perak may have limitation in representativeness of the participants to the nationwide population.
- Self-administration of the questionnaires is encouraged and facilitated to improve data quality.
- Respondents will not reflect the incidence 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.

Word count: 4793 (Main text until Expect Outcome, excluding title page, abstract, acknowledgement, references, figures and tables).

INTRODUCTION

After a childbirth, a woman undergoes multiple changes that is associated with physical and emotional domains.[1] Some of the common physical changes experienced during pregnancy includes weight gain, hair growth, and stretch marks; after pregnancy, weight loss, hair loss, and sagging breasts are the most common changes.[1] Mothers with a new or additional baby also experience emotional changes related to the demands of breastfeeding, childcare stress, maternal neuroticism and difficult infant temperament. In addition, there are also social demands that may contribute to general depressive symptoms and stress such as compliance to the traditional postpartum care practices, financial strain related to low socioeconomic status, social and sexual relationship with the partner and caretaker of the child.[3,4] Other emotionally draining aspects including biological, obstetric, clinical, psychological, social, and infant factors may also contribute to the incidence of postpartum depression, general depression and stress.[2,3] Some of the risk factors for postpartum depression (PPD) are different between developing and developed countries such as history of physical abuse, mode of delivery and sex of baby.[3] In a research done by Villengas et al entitled *Postpartum Depression Among Rural Women From Developed and Developing Countries: A Systematic Review* The increased risk of PPD in developing countries are related to some unique risk factors which are associated with poor relationship with partner or in laws, having an unemployed and uneducated husband, husband's psychopathology, years of marriage, having more than 5 children, having 2 or more children under the age of 7, infants gender and infants gender. 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 show that the lack of social support is an independent predictor of PPD.[3,4] Example of other stressors is that Asian cultures dictates that they follow certain traditional rituals after delivery to protect the mother and child and the more general

psychological morbidity refers to cognitive, behavioural, learned helplessness, and self-control.[3]

PPD is a significant health issue that can impact the health of the mother, her marital relationship, and interaction with the newborn as well as infant growth.[4] Although the incidence rates of depression do not appear to be higher in women in the period after childbirth compared to age-matched control women which are between 10-15%, but the rates of first onset and severe general depression are elevated by at least three-fold.[5] Depression at this critical period of life carries special meanings and risks to the woman and her family.[5] It is possible to identify women with increased risk factors for PPD but the unacceptably low positive predictive values of many currently available antenatal screening tools make it difficult to recommend them for routine care.[6]

Depression is the most common psychological disorder during the postpartum period. The first symptoms usually appear within 4 weeks of delivery,[7] and the symptoms can range from mild to severe.[8] According to WHO, PPD begins with symptoms of depressed mood, anhedonia and low energy within a few days of delivery, most commonly on day 3 or day 4, also termed as postpartum blues.[5] It can persist up to several months, and untreated postpartum depression may lead to subsequent emotional, behavioural and cognitive problems of the child.[9] Despite these concerns, PPD remains under-diagnosed and under-treated in clinical practices in Malaysia.[10-12] This might be due to the social taboo that is associated with diseases that are related to psychiatry.[13] Other factors that contribute to the low detection rate includes low screening rate for PPD, and reduced awareness of the illness amongst mothers and caretakers.[10] Studies show that the prevalence of PPD ranged between 10 to 15% within 12 months postpartum in the Western societies between 1990 to 2002, and

the prevalence were 3.4% to 63.9% within 12 months postpartum among the Asian countries between 1998 and 2008.[3,5] In Malaysia, few studies reported that PPD ranged between 3.9% to 20.7%.[2,11,12] A study in 2002 noted that the incidence of PPD amongst Malay women in Bachok, Kelantan was 9.8%.[12] Another study in 2005 showed that the incidence rate of PPD at 4-6 weeks postpartum in Hospital University Science Malaysia was 20.7%.[2] 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.[14] Another study in Thailand reported that a history of lifetime major depression, and depression during pregnancy were the most important risk factors for PPD.[15] For Malaysian women, depressive symptoms during late pregnancy, an emergency delivery, application of traditional postpartum practices, marital problems, as well as low income were associated with an increased risk of developing PPD.[5,16,17] A recent systematic review supported the association between preterm birth and PPD.[18] In contrary, a local study suggested that a planned pregnancy may prevent the risk of PPD.[11]

The *Diagnostic and Statistical Manual of Mental Disorders,* 5th ed (DSM-5) categorizes general depression based on symptoms such as depressed mood or loss of interest for a duration of 2 weeks, while categorizing PPD based on symptoms such as sadness, anxiety or worry after the birth of a child.[19] General depressive symptoms during postpartum period includes 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. Psychosocial predictors of a general depression in a postpartum women includes lower occupational status, prenatal depression level, more distal stressors and personal psychiatric history, which reflected past and present experiences, showed an indirect effect.[20] Based on the Depression

Anxiety Stress Scale (DASS) screening questionnaire, general depressive symptoms include not feeling positive, no initiative to do daily things, nothing to look forward to, feeling down-hearted and blue, not enthusiastic, absence of self-worth, and a feeling that life is meaningless. The DSM-5 does not distinguish between postpartum major depression and major depressive disorder, but does provide a postpartum onset specifier for major depressive disorder, defined as onset within four weeks of delivery.[21] Care for women who suffered from mild to moderate depressive symptoms may be overlooked, resulting in a late diagnosis and increased chances of aggravating PPD, which in turn raises the burden of healthcare costs, and negatively impacting the family relationships.[1]

In Malaysia, far less is known about postpartum anxiety. Anxiety disorders are more common in postpartum women than in the general population, with estimates of its incidence based on studies done in the United States[22] during the first 6 months of postpartum ranging from 6.1% to 27.9%,[23,24] with the prevalence of 4.4% to 8.2% at 6 to 8 weeks postpartum.[22] A study in Croatia reported 17% prevalence of high anxiety immediately after childbirth, 20% six weeks postpartum, and the comorbidity of anxiety and PPD was 75%.[25] Characteristics of anxiety includes excessive worry that lasts and is accompanied by restlessness, fatigue, poor concentration, muscle tension and sleep disturbance.[19] Other symptoms include excessive worry, feeling nervous or on edge, not being able to stop or control worrying, trouble relaxing, 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 “maternal neurosis’ which centrally presents as overvigilance and excess checking on baby’s breathing.[26] Excessive anxiety may have long-term effects on the mothers and their infants. Some of the experiences identified in

relation to postpartum anxiety disorders were feeling of loss, frustration and guilt, accompanied by physical symptom of tension.[8] Postpartum anxiety is associated with disrupted mother–infant attachment, postpartum depression, reduced likelihood of breastfeeding, 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 which is the first 6 weeks post-delivery include difficulty to wind down, over-reacting to situations, nervousness, agitation, difficult to relax, and very sensitive to changes. Prevalence rate of stress varied between 20% to 40%.[26] A study done in Taiwan, identified three most common factors that contributes to postpartum stress which includes 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 postpartum.[28] Women who underwent caesarean delivery had higher antenatal stress, besides anxiety and depression levels, compared to 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 making available a 24-hour telephone hotline service, reduces stress in the postpartum period.[31] In Malaysia, however, no studies have been done to study the prevalence of stress during the postpartum period.

Many studies have been looking into the psychological well-being of mothers using only a brief unidimensional instrument such as the Edinburgh Postnatal Depression Scale (EPDS),

without looking at the other aspects of the psychological well-being of postpartum mothers and its associated risk factors.[23,26,31] Furthermore, studies in Malaysia were conducted in Kelantan,[12] Negeri Sembilan[10] and Sabah[10] which have limited external validity to our population in Perak in terms of ethnicity and socioeconomic profiles. For example, the study done in Kelantan only studies the Malay ethnicity. Meanwhile, in Sabah, the cultural and sociodemographic background differs from that of the population in peninsular Malaysia. Risk factors such as confinement with in-laws, observing cultural taboos during confinement, lack of sleep, postpartum wound pain and other somatic symptoms are not well studied or established in the Malaysian context.[32] Additionally, studies restricted to women admitted to the hospital and data collected solely through interviewing could be misleading as a result of Hawthorne effect and socially pleasing answers.[16]

Accordingly, this study aims to determine the incidence proportions and risk factors of postpartum depression, general depressive symptoms, anxiety and stress among mothers at one month follow-up at public health clinics in Perak. It will look into an overall depression from 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 because few studies if any have examined this.

METHODS AND ANALYSIS

Study design

This will be a cross-sectional study over a period of six months from September 2019 to February 2020. It will measure incidence proportions instead of prevalence because the study is designed to measure the number of new PPD over the number at risk after a specified period of time (one month postpartum).

Setting

The study will be conducted among postpartum mothers who are followed-up postnatally in five public health clinics in Perak, four from Kinta District (urban) and one from Kerian District (sub-urban). The four clinics from Kinta District will be Health Clinic Pasir Pinji, Health Clinic Gunung Rapat, Health Clinic Buntong and Health Clinic Greentown. Whereas the other clinic, Health Clinic Bagan Serai is in Kerian district. These clinics are where the researchers will be practising at the time of this study. These clinics provide antenatal care starting from booking, until postnatal after the mothers have delivered in hospitals. Postnatally, the health of the mothers and babies will be examined during follow-up home visits by nurses from these clinics within days and weeks. The mothers and babies will also be seen by medical officers at the health clinics one month after delivery for general health checks, counselling on contraception and review of the baby including immunization.

Participants

Postnatal mothers who are followed-up at the participating public health clinics during their first month scheduled postnatal visit. These postpartum mothers are those aged 18 years and above, at one month post-delivery irrespective of mode of delivery, are able to read and understand the Malay or English language, and able to give a written consent. Those who are illiterate will not be included in the study. 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 are excluded because they may not be able to respond appropriately to the questionnaire. At the same time, non-Malaysian mothers are excluded because of differences in psychosocial background and they are very few in numbers.

Sampling

All eligible postnatal mothers attending the one month postnatal check-up will be invited to participate. The eligibility will be screened a day earlier based on the clinic copy of the antenatal medical records. For those who fulfil the eligibility criteria, the questionnaires and consent form will be attached to the clinic copy of the antenatal medical records. When the mothers present to the postnatal clinic's registration counter, their eligibility will further be confirmed, followed by an explanation regarding the study, and those who agree to participate will sign the consent form before being given the study questionnaires. They will self-administer the questionnaires at a designated waiting area while waiting for their turn to the medical consultation. After returning the completed questionnaires, every participant will be given a token of appreciation, which includes a fact sheet on postpartum depression, 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 postpartum depression 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 psychological disorders based on the questionnaires will be given appropriate counselling and follow-up care in the health clinics within a month of questionnaire completion. Confidentiality of the participants will be guarded throughout the study (Figure 1).

Research Tools

The research tools used in this study include the following three parts and the estimated time required to complete the whole questionnaire is about 30 minutes. Part 1 covers questions on the subject's sociodemographic characteristics and Part 2 covers questions which explores the risk factors according to the variables used. Part 1 and 2 questions were created based on the literature review. The variables used in the questionnaire and their definitions are available in the Supplementary Material Table S1. Face and content validity of Part 1 and 2 will be further tested in a pilot study with 50 postnatal mothers (10 each in the five health clinics) with the same eligibility (see further below).

Part 3 consists of the validated English or Malay version of the Edinburgh Postpartum Depression Scale questionnaire (EPDS) and the Depression Anxiety and Stress Scales (DASS-21).[33-38] EPDS was originally in the English language and developed in 1987 by Cox, Holden and Saqovsky.[17] The available Malay language version of the EPDS was developed by Azidah et al in 2004 and was validated on a sample of postpartum Malaysian women in Kelantan, North East of Peninsular Malaysia.[33] The questionnaire has 10 questions assessing feelings in the past seven days. Items scores range from zero to three on a 4-point Likert scale and scores are summed to get an overall score ranging from 0 to 30, with some items reversed scored.[34] The study findings suggested an EPDS cut-off score value of 11.5 for depression with the sensitivity of 72.7% and specificity of 92.6%.[33] The Malay version of the EPDS was also shown to have good internal consistency (Cronbach's alpha = 0.86) and good split-half reliability (Spearman split half coefficient = 0.83). Based on the study conducted by Wan Mahmud and Mohamed, the instrument also showed satisfactory discriminant and concurrent validity. The cut-off point of 11 were considered optimal for screening a population of Malay-speaking women at 4 to 12 weeks postpartum.[35]

The DASS-21 scale will be used to determine the incidence of other psychological disorders (general depression, anxiety and stress) among the participants.[36] 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).[37,38] 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 summed. DASS is suitable to be used in many different clinical settings assessing emotional states over the past one week.[39,40] The score ranges from 0-21 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 excludes stress, score 8-13 indicates moderate stress and scores 13 and above shows major stress.[36] The Malay version DASS-21 had a Cronbach's alpha 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 significant association with other similar constructs such as with 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.

By using both EPDS and DASS-21, we will also be able to determine the incidence of postpartum depression and other psychological well-beings among the postpartum mothers at the same setting.

Pilot study

We have pilot tested the data collection process in August 2019 at each participating health clinic until 10 eligible participants completed the questionnaires. Improvement on the questionnaires and process were carried out based on the findings from this testing. The 50 samples from this pilot study will not be included in the actual study.

Sample size calculation

Based on the various study done in Malaysia, the incidence of postpartum depression and psychological disorders range from 3.9 to 28.8%.[3,4,42] There was no past study with a population that is the same for our study. We take the approach of best estimation of the incidence rate for postpartum depression and psychological disorders to be at 10%. Using logistic regression in the GPower 3.1.2 and with estimated proportion of postpartum depression and psychological disorders as 10%, with the smallest odd ratio 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 patient's medical record and questionnaires returned, the sample size needed becomes 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 standardized 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 variables. Imputed variables will be set within a pre-defined clinically possible range. Data cleaning will be done using SPSS to check that each data point is entered within plausible ranges or else verification from the original data source will be conducted. Data analysis will be done using SPSS version 25.0 (IBM, Chicago, IL).

Descriptive statistics will be used to summarize the sociodemographic data. We will report 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 (standard deviation) or median (interquartile range) based on the normality of their distribution. Categorical data will be presented as frequency (percentage). Incidence proportion or risk of the occurrence of depression (postpartum depression and general depressive symptoms combined and separately), anxiety and stress will reported based on the recommended cut-offs. A cut-off points of 11 based on the EDPS will be considered as having PPD.[35] For general depression, DASS-21-D scores 5 and below indicates no depressive sign, scores 6-10 indicate moderate depression and scores higher than 10 indicate major depressive symptoms. The EDPS $\geq$ 11 and DASS-21-D $\geq$ 6 will be combined to indicate an overall depression. For the anxiety subscale, DASS-21-A scores 4 and below indicate no anxiety, score 5-8 indicate moderate anxiety symptoms and scores higher than 8 indicate major anxiety. For the stress category, DASS-21-S scores 7 and below excludes stress, score 8-13 indicates moderate stress and scores 13 and above shows 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 never been schooling; occupation into unemployed/

routine and manual occupation/ intermediate occupation/ higher managerial, administrative and professional occupations; household income into less than RM1000, RM1000 – RM5000, RM5000 – RM 10,000 and more than RM 10,000; who supported the mother with postnatal care - parents, parents-in-law, husband, confinement lady 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 male or female, baby weight, number of babies whether one or more than one, term or preterm, admission during postpartum period, any medical complication. Correlation between the total scores for postpartum depression, general depressive symptoms, anxiety and stress will be done using the Pearson's or the Spearman's according to the distribution of the total scores, normally or non-normally distributed, respectively.

To analyse the association between the sociodemographic and clinical variables with PPD, general depressive symptoms, anxiety and stress, multiple or multinomial logistic regressions analyses will be used after categorization of these outcomes according to the recommended cut-offs (see above). The lowest scored category will be used as the referent group, and the PPD, general depressive symptoms, anxiety and stress will be represented by the two higher scored categories, respectively. We may run additional multinomial logistic regression analyses with the three cut-offs categories and to compare the results if the sample size within each of the categories allow. Those sociodemographic and clinical factors with a P value < 0.20 from the simple logistics regression analyses (crude odds ratio) will be included in the final multiple logistics regression analyses (adjusted odds ratio). Multicollinearity between any independent variables will be checked according to the tolerance < 0.4 (VIF ≥ 2.5). In the present of multicollinearity, the more meaningful or important variable from clinical perspectives will be selected for use in the final regression analysis. Odds ratio (OR) will be

presented with 95% confidence interval (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, 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 the incidence proportions of postpartum depression, general depression, anxiety and stress among the postpartum mothers in public health clinics in Perak. We propose to measure an incidence instead of a prevalence or prevalence rate because the study designed to measure the number of new conditions (PPD, general depressive symptoms, anxiety and stress) over the number of women at risk and free from the psychological conditions at immediate postpartum, after a specified period of time (one month postpartum). Therefore, it is an incidence proportion or risk of the occurrence of the conditions. It is not an incidence rate because the study is cross-sectional in its sampling method and does not follow-up the participants. A prevalence would be the effect estimate if the study proposes to study the conditions in a defined population such as all women within the first month postpartum. We recognise that the distinction between incidence proportion and prevalence rate for depression, anxiety and stress is slim when the condition-free status at the immediate postpartum is based on self-report without objective measures. However, based on the study designs the effect estimate is closer to an incidence proportion than prevalence rate.[43] For a study to determine the prevalence rate of PPD within one month postpartum, it will need a cross-sectional survey among representative women at 1-week, 2-week, 3-week and 4-week postpartum using the EPDS.

The five public health clinics chosen for this study are likely to be representative of the Perak population from the aspects of ethnicity distribution. Although all ethnicities in Malaysia can read and understand the Malay language to some extent but without having the Chinese and Tamil versions of the questionnaires available, may impair responses from mothers of these ethnicities with lower educational background. We will assess the representativeness of the participants to the population of postpartum mothers in Perak and nationwide from other socio-demographic aspects and clinical characteristics from the most recent report of the National Obstetrics Registry.[44] All the five participating clinics have a separate service for Maternal and Child Health care with the estimated live birth ranging from 450 to 1500 babies per year in each clinic. Thus, we will be able to reach the target sample size. General depressive symptoms, anxiety and stress are novel variables that have been shown to be predictors of postpartum depression but have been rarely explored in the Malaysian setting. As these concepts are personal and sensitive, the study adopts self-administration approach and facilitated by a trained research assistant only to clarify difficult items faced by the respondents. Furthermore, a quiet designated area provided will hopefully help to improve quality responses.

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

Patient and Public Involvement

Based on feedbacks from the patients involved in the pilot study, improvement on the questionnaires and process were implemented.

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Author Contributions

All authors conceived the study from the beginning. TP assisted with development of the questionnaire and variables, VG and PS contributed to the study design, PNMAB assisted with the sample size calculation, PK and PNMAB will assist with the data analysis, SAMR drafted the initial manuscript, study design, and drafted 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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Competing Interest

None

ETHICS AND DISSEMINATION

Ethical consideration

This study is registered on the National Medical Research Register (NMRR-19-868-47647) and ethics approval has been obtained from the Medical Research and Ethics Committee (MREC) Ministry of Health Malaysia with the reference number of KKM/NIHSEC/P19-1129(11) on 07 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 computer that is protected. On completion of the study, data in the computer will be copied to CDs and data in the computer will be erased. CDs and any hardcopy 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 seven years after the completion of the study. The CDs and data will be destroyed after the period of storage. Subjects will not be allowed to view their personal data, as the data will be consolidated into a database. Subjects can write to the investigators to request access to the study findings 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 name and details of patients need to be disclosed, a written expressed consent will be obtained prior to presentation and publication.

Data sharing statement

Collected data will be made available upon request to the corresponding author. All requests are to provide a clear study protocol to the principal investigator. Deidentified and anonymised participant data for all the outcomes will be shared once the results have been published. There is no time period or limit. Data use will be advised to refer to the published study protocol.

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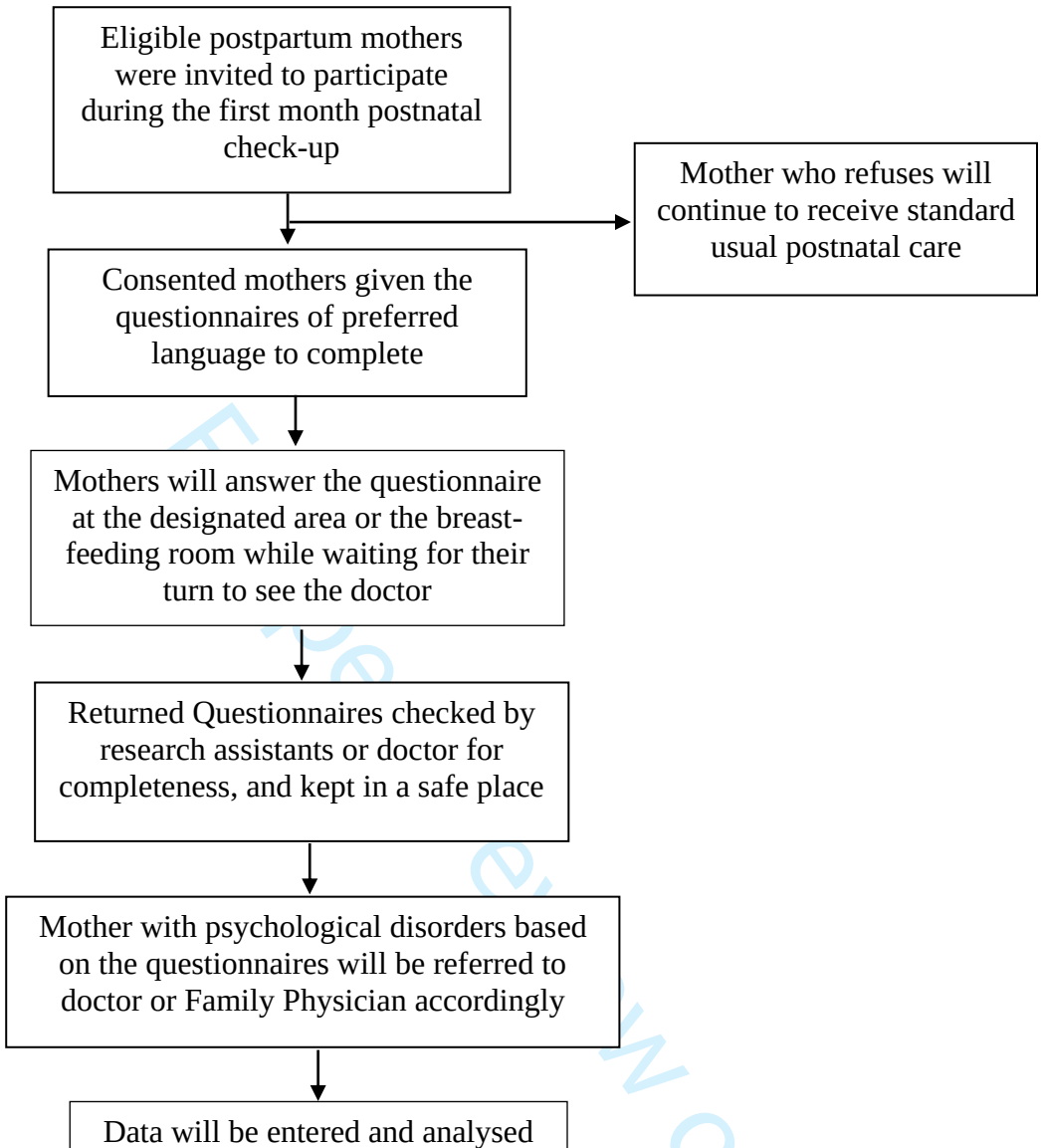
Figure 1: Flow of the participants during the data collection



Supplementary Table S1: Definitions of the variables

No.	Variables (Operational definition)	Description	Type of variable
1	Antenatal code	• White • Green • Yellow	Categorical
2	Age	Maternal age in completed years	Interval
3	Ethnicity -according to the paternal side	• Malay • Chinese • Indian • Others	Categorical
4	Religion	• Islam • Buddha • Hindu • Christian • Others	Categorical
5	Marital status	• Single • Married • Divorced/ • Widow	Categorical
6	Educational level - highest attained	• Primary education • Secondary education • Diploma/ Technical studies • Tertiary education • Never school	Categorical
7	Maternal Occupation	• Unemployed • Routine and manual occupations • Intermediate occupations • Higher managerial, administrative and professional occupations	Categorical
8	Duration of marriage	Duration of marriage in completed years	Interval
9	Husband occupation	• Unemployed • Routine and manual occupations • Intermediate occupations • Higher managerial, administrative and professional occupations	Categorical
10	Combined household income	• <RM1000 • RM1000-RM5000 • RM5000-RM10,000 • >RM10,000	Categorical
11	Smoking status -all types	• Yes, intensity – no of stick(s) • No • Ex-smoker	Categorical

12	Alcohol status -all types	• Yes • No • Currently stopped	Categorical
13	Husband practicing polygamy	• Yes • No	Categorical
14	If polygamy, wife no	• 1 • 2 • 3 • 4	Categorical
15	No of children	• 0 • 1 • 2 • 3 • 4 • >5	Ordinal
16	Pre pregnancy baby gender preference	• Male • Female • No preference	Categorical
17	Antenatal care	• Government • Private • None	Categorical
18	Planned pregnancy -Is the current pregnancy planned and not unexpected?	• Yes • No	Categorical
19	Satisfied with marriage -self-report	• Yes • No	Categorical
20	Marital problems -respondent's own perception of her marriage	• Yes • No	Categorical
21	Period of marital problems	• Before child delivery • After child delivery	Categorical
22	Stable relationship with husband - self-report	• Yes • No	Categorical
23	Domestic violence -Self-report of physical or emotional abuse at home during young before marriage	• Yes • No	Categorical
24	Domestic violence in this marriage and during pregnancy	• Yes • No	Categorical
25	Relationship with parents -respondent's own perception of the relationship between mother and her parents	• Yes • No	Categorical

26	Relationship with parent in law - respondent's own perception of the relationship with her in parent in law	• Yes • No	Categorical
27	Underlying medical illness before pregnancy -Any underlying diabetes, hypertension, asthma or any other chronic illnesses	• Yes • No	Categorical
28	Underlying medical illness during pregnancy -Hypertension, gestational diabetes etc	• Yes • No	Categorical
29	History of miscarriage -any history of abortion before 22 weeks in the previous pregnancy	• Yes • No	Categorical
30	Underlying mental illness -Diagnosed of having mental illness prior to pregnancy	• Yes • No	Categorical
31	History of mental illness during pregnancy -Diagnosed of having mental illness during her current pregnancy	• Yes • No	Categorical
32	History of mental illness during postpartum period -Diagnosed of having mental illness during her postpartum period	• Yes • No	Categorical
33	Family history of mental illness -Is there any parents of 1st degree relative being diagnosed of having mental illness?	• Yes • No	Categorical
34	Inadequate help from spouse during postpartum period - respondent's own perception of inadequate support during postpartum period	• Yes • No	Categorical
35	Inadequate help from other family members during postpartum period - respondent's own perception of inadequate support during postpartum period	• Yes • No	Categorical
36	Inadequate help from others during postpartum period - respondent's own perception of inadequate support during postpartum period	• Yes • No	Categorical

37	Inability to establish breast feeding -the inability to exclusively breast feed, requiring top up using formula milk	• Yes • No	Categorical
38	No confidence to care for the child -the inability of mother to care for the baby, thus being dependent on others	• Yes • No	Categorical
39	Undergone stressful life events -any recent events, occurred during antenatal and postpartum period, such as financial burden, passing of her loved ones or events that are perceived as stressful by respondent herself	• Yes • No	Categorical
40	Any cultural taboos observed during postnatal care that contributed to mother's stress	• Yes • No	Categorical
41	With whom respondent observed postnatal care during confinement	• Parents • Parents in law • Husband • Confinement lady/ centre • Alone	Categorical
42	Inadequate help to take care of newborn at night - self-report	• Yes • No	Categorical
43	Inadequate sleep/rest - respondent's own perception of inadequate sleep or rest during postpartum period	• Yes • No	Categorical
44	Dissatisfied with body weight and appearance post delivery - respondent's own perception on the satisfaction of her body weight and appearance post delivery	• Yes • No	Categorical
45	Intrapartum experience - respondent's own perception of having bad experiences during labour. E.g.: unbearable pain	• Yes • No	Categorical
46	Mode of delivery	• SVD • Instrumental delivery • Planned caesarean section • Emergency caesarean section	Categorical

47	Postnatal complication -experienced wound pain, wound breakdown, readmission to ward	• Yes • No •	Categorical
48	Type of complication	List complication.	Categorical
49	Readmission after discharge during postpartum period	• Yes • No	Categorical
50	Outcome of the baby	• Alive • Gender • Birth weight • Twins • Gestational weight • Admission to ward • Medical complication	Categorical
51	Edinburgh Postpartum Depression scale scoring (Less than 11 – no postpartum depression 11 or more – postpartum depression)	Total score (range 0 - 30) • Less than 11 – no postpartum depression • 11 or more – postpartum depression	Interval Categorical
52	Depression anxiety stress scale (DASS) scoring	Total scores (range 0-21) • Depression - Mild: 6-7 - Moderate: 8-10 - Severe: 11-14 - Very severe: 15 to 21 • Anxiety - Mild: 5-6 - Moderate: 7-8 - Severe: 9-10 - Vere severe: 11 to 21 • Stress - Mild: 8-9 - Moderate: 10-13 - Severe: 14-17 - Very severe: 18 to 21	Interval Ordinal Ordinal Ordinal

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-8
Objectives	3	State specific objectives, including any prespecified hypotheses	2
Methods			
Study design	4	Present key elements of study design early in the paper	8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	9-11
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	9-10
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	11-13, Supplementary Table S1
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	14-16
Bias	9	Describe any efforts to address potential sources of bias	16-17
Study size	10	Explain how the study size was arrived at	14
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	14-16
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	14-16
		(*b*) Describe any methods used to examine subgroups and interactions	14-16
		(*c*) Explain how missing data were addressed	14-16
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	14-16
		(*e*) Describe any sensitivity analyses	14-16

Results			NA
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	11
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	NA
		(b) Indicate number of participants with missing data for each variable of interest	NA
Outcome data	15*	Report numbers of outcome events or summary measures	NA
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	NA
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	NA
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	16-17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	NA
Generalisability	21	Discuss the generalisability (external validity) of the study results	NA
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	18

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

The Prevalence and Risk Factors of Postpartum Depression, General Depressive Symptoms, Anxiety, and Stress (PODSAS) among Mothers at First Follow-up at 4-Week Postnatally in Five Public Health Clinics in Perak: A Study Protocol for a Cross-sectional Study

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The Prevalence and Risk Factors of Postpartum Depression, General Depressive Symptoms, Anxiety, and Stress (PODSAS) among Mothers at First Follow-up at 4-Week Postnatally 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 are often overlooked, and may cause morbidity to new mothers, their babies and families. This study aims to determine the point prevalence of depression (postpartum and general), anxiety and stress among mothers in five public health clinics in Perak at four weeks post-delivery 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 postpartum depression, general depressive symptoms, anxiety, and stress.

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 post-delivery 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 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 version 25.0 (IBM, Chicago, IL). Besides descriptive statistics, multivariable regression analyses will be done to identify possible risk factors and their independent associations with depression (postpartum depression 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 7th August 2019. Results of this

study will be reported and shared with the local health stakeholders and disseminated through conference proceedings and journal publications.

Article Summary

Strengths and Limitations of the 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 postpartum that have not been studied in depth before.
- Five public health clinics in urban and sub-urban 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 breastfeeding 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, general depression, and stress.[2,3] Some of the risk factors for postpartum depression (PPD) such as history of physical abuse, mode of delivery, and sex of the baby[3] differ between developing and developed countries. A systematic review by Villengas 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 seven, 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.[2,5] 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.[2]

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 three months of postpartum, an increasing trend in prevalence was observed after three months until 12

months of postpartum, 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) categorizes 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, behavioral and cognitive problems of the child.[6,10] Despite these concerns, PPD remains under-diagnosed and under-treated 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 amongst mothers and caretakers.[11] Studies showed that between 1990 and 2002, the prevalence of PPD ranged between 10 and 15% within 12 months postpartum in Western societies compared to the more varied prevalence rates of between 3.4% and 63.9% among Asian countries within the similar postpartum period and timeframe.[2,6] 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 United States[22,] its incidence usually occurs during the first 6 months of postpartum, ranging from 6.1% to 27.9%,[23,24] with the prevalence rate of 4.4% to 8.2% at 6 to 8 weeks postpartum.[22] A study in Croatia reported 17% prevalence of high anxiety occurring immediately after childbirth, 20% at six weeks postpartum, 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, postpartum depression, reduced likelihood of breastfeeding, 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 etiology of anxiety.[24]

Symptoms of stress during the postpartum period at the first 6 weeks post-delivery 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 i.e. 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 postpartum.[28] Women who underwent caesarean delivery had higher antenatal stress and anxiety and depression levels compared to 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 24-hour 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 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 nine months 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 (sub-urban). 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 4-week after delivery for general health checks, counselling on contraception, and review of the baby including immunization.

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 post delivery 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 i.e. a fact sheet on postpartum depression, 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 postpartum depression 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 3-part questionnaire with an estimated time of about 30 minutes 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 the Supplementary Material 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 Edinburgh Postpartum Depression Scale questionnaire (EPDS) and the Depression Anxiety and Stress Scales (DASS-21).[33-38] EPDS which was developed in 1987 by Cox, Holden, and Saqovsky was originally written in the English language.[17] The Malay language version of the EPDS was developed by Azidah et al. in 2004, and it was validated based on the sample of postpartum Malaysian women in Kelantan, North East of Peninsular Malaysia.[34] The questionnaire contains 10 questions assessing the mothers' feelings in the past seven days. Item score ranges from zero to three 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 alpha = 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. The cut-off point of 11 was considered optimal for screening a population of Malay-speaking women during 4 to 12 weeks postpartum.[37]

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 one week.[40,41] The score ranges from 0-21 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 alpha values of 0.75, 0.74, and 0.79 for depression, anxiety, and stress subscales, respectively.[40] 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).[42] 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 postpartum depression 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 postpartum depression and psychological disorders ranges from 3.9 to 28.8%.[3,4,42] 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 postpartum depression and psychological disorders to be at 10%. Using logistic regression in the GPower 3.1.2 and with estimated proportion of postpartum depression and psychological disorders as 10%, with the smallest odd ratio 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 standardized 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 pre-defined 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 version 25.0 (IBM, Chicago, IL).

Descriptive statistics will be used to summarize 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 (standard deviation) or median (interquartile range) based on the normality of their distribution. Categorical data will be presented as frequency (percentage). Point prevalence of depression (postpartum depression 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 and below indicate no depressive sign; scores 6-10 indicate moderate depression; and scores higher than 10 indicate major depressive symptoms. The EPDS $\geq$ 11 and DASS-21-D $\geq$ 6 will be combined to indicate an overall depression. For the anxiety subscale, DASS-21-A scores 4 and below indicate no anxiety; score 5-8 indicate moderate anxiety symptoms; and scores higher than 8 indicate major anxiety. For the stress category, DASS-21-S scores 7 and below exclude stress; scores 8-13 indicate moderate stress; and scores 13 and above 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 – RM 10,000 and more than RM 10,000; who supported the mother with postnatal care - parents, parents-in-law, husband, confinement lady 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 postpartum depression, general depressive symptoms, anxiety, and stress 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 analyze 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 categorization 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 odds ratio) will be included in the final multiple logistics regression analyses (adjusted odds ratio). Multicollinearity between any independent variables will be checked according to the tolerance < 0.4 (VIF ≥ 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. Odds ratio (OR) will be presented with 95% confidence interval (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 postpartum depression, 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 four weeks postpartum 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 four weeks of postpartum. 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 postpartum 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 socio-demographic 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 health care 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 postpartum depression, 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 programs 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 postpartum depression, 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.

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 07 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. Upon 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 seven 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.

Data sharing statement

Collected data will be made available upon request to the corresponding author. All requests are to provide a clear study protocol to the principal investigator. Deidentified and anonymized participant data for all the outcomes will be shared once the results have been published. No time period or limit has been set. Data use will be advised to refer to the published study protocol.

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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Author Contributions

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; and 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; and 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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Competing Interest

None declared

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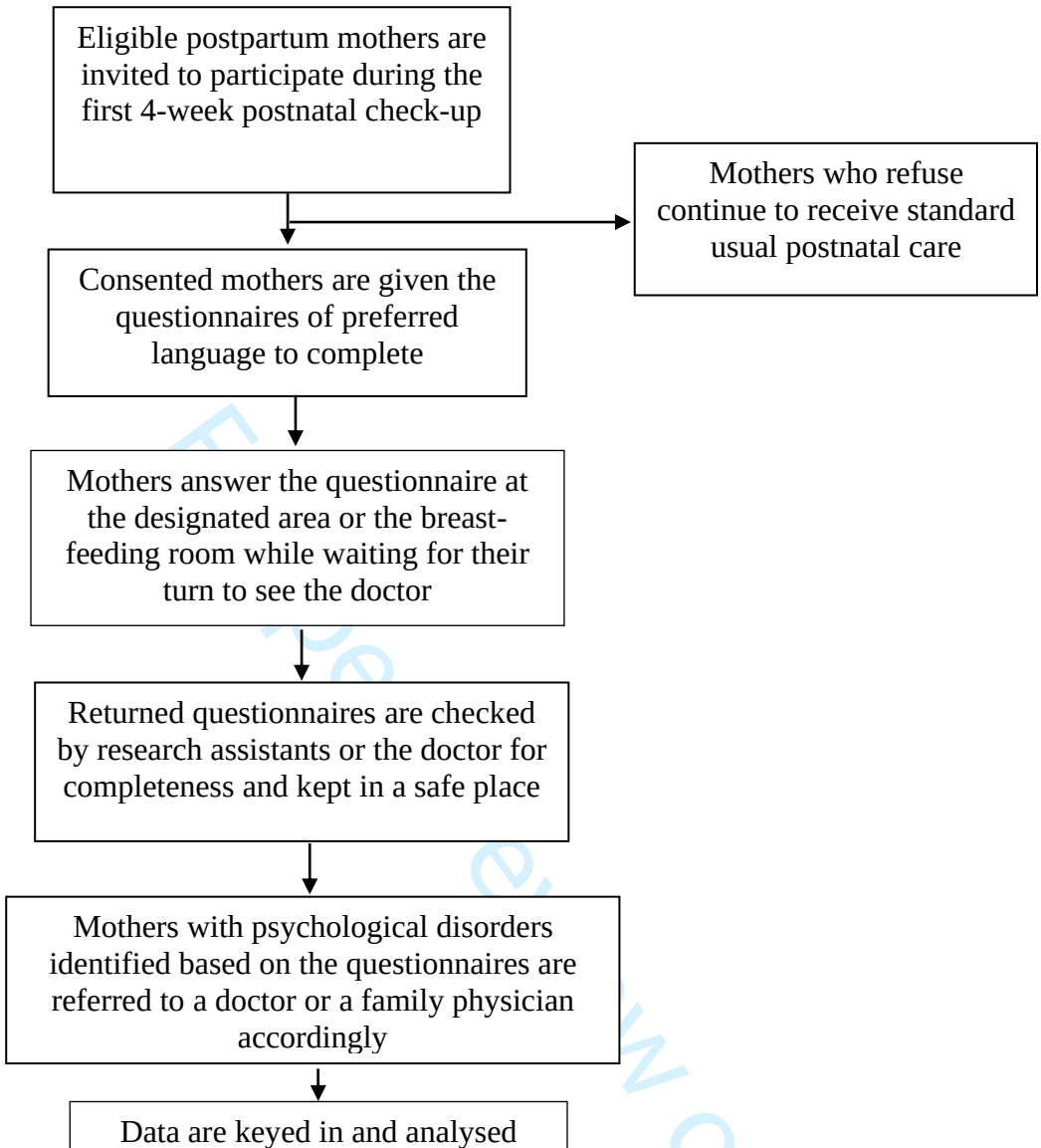
Figure 1: Flow of the participants during data collection



Supplementary Table S1: Definitions of the variables

No.	Variables (Operational definition)	Description	Type of variable
1	Antenatal code	• White • Green • Yellow • Red	Categorical
2	Age	Maternal age in completed years	Interval
3	Ethnicity -according to paternal side	• Malay • Chinese • Indian • Others	Categorical
4	Religion	• Islam • Buddha • Hindu • Christian • Others	Categorical
5	Marital status	• Single • Married • Divorced • Widow	Categorical
6	Education level - highest attained	• Primary education • Secondary education • Diploma/ Technical studies • Tertiary education • Never been to school /No schooling	Categorical
7	Occupation	• Unemployed • Routine and manual occupations • Intermediate occupations • Higher level: managerial, administrative or professional	Categorical
8	Duration of marriage	Duration of marriage in completed years	Interval
9	Husband occupation	• Unemployed • Routine and manual occupations • Intermediate occupations • Higher level: managerial, administrative or professional occupations	Categorical
10	Combined household income	• <RM1000 • RM1000-RM5000 • RM5000-RM10,000 • >RM10,000	Categorical

11	Smoking status -all types	• Yes, intensity – no of stick(s) • No • Ex-smoker	Categorical
12	Alcohol status -all types	• Yes • No • Currently stopped	Categorical
13	Husband practicing polygamy	• Yes • No	Categorical
14	If polygamy, wife no	• 1 • 2 • 3 • 4	Categorical
15	No of children	• 0 • 1 • 2 • 3 • 4 • >5	Ordinal
16	Pre-pregnancy baby gender preference	• Male • Female • No preference	Categorical
17	Antenatal care	• Government • Private • None	Categorical
18	Planned pregnancy -Is the current pregnancy planned and not unexpected?	• Yes • No	Categorical
19	Satisfied with marriage -self-report	• Yes • No	Categorical
20	Marital problems -respondent's own perception of her marriage	• Yes • No	Categorical
21	Period of marital problems	• Before child delivery • After child delivery	Categorical
22	Stable relationship with husband - self-report	• Yes • No	Categorical
23	Domestic violence -Self-report of physical or emotional abuse at home before marriage	• Yes • No	Categorical
24	Domestic violence in this marriage and during pregnancy	• Yes • No	Categorical

25	Relationship with parents -respondent's own perception of the relationship between the mother and her parents	• Yes • No	Categorical
26	Relationship with parent in law - respondent's own perception of the relationship between her and her parent-in-law	• Yes • No	Categorical
27	Underlying medical illness before pregnancy -Any underlying diabetes, hypertension, asthma or any other chronic illnesses	• Yes • No	Categorical
28	Underlying medical illness during pregnancy -Hypertension, gestational diabetes etc.	• Yes • No	Categorical
29	History of miscarriage -any history of abortion before 22 weeks in previous pregnancy	• Yes • No	Categorical
30	Underlying mental illness -Diagnosed of having mental illness prior to pregnancy	• Yes • No	Categorical
31	History of mental illness during pregnancy -Diagnosed of having mental illness during her current pregnancy	• Yes • No	Categorical
32	History of mental illness during postpartum period -Diagnosed of having mental illness during her postpartum period	• Yes • No	Categorical
33	Family history of mental illness -Is there any parents of 1st degree relative being diagnosed of having mental illness?	• Yes • No	Categorical
34	Inadequate help from spouse during postpartum period - respondent's own perception of inadequate support during postpartum period	• Yes • No	Categorical
35	Inadequate help from other family members during postpartum period - respondent's own perception of inadequate support during postpartum period	• Yes • No	Categorical
36	Inadequate help from others during postpartum period	• Yes	Categorical

	- respondent's own perception of inadequate support during postpartum period	• No	
37	Inability to establish breast feeding -the inability to exclusively breast feed, requiring top up using formula milk	• Yes • No	Categorical
38	No confidence to care for the child -the inability of the mother to care for the baby, thus being dependent on others	• Yes • No	Categorical
39	Experienced stressful life events -any recent events, occurred during antenatal and postpartum period such as financial burden, passing of loved ones or events that are perceived as stressful by respondent	• Yes • No	Categorical
40	Any cultural taboos observed during postnatal care that contribute to mother's stress	• Yes • No	Categorical
41	With whom respondent observed postnatal care during confinement	• Parents • Parents in law • Husband • Confinement lady/ centre • Alone	Categorical
42	Inadequate help to take care of new born at night - self-report	• Yes • No	Categorical
43	Inadequate sleep/rest - respondent's own perception of inadequate sleep or rest during postpartum period	• Yes • No	Categorical
44	Dissatisfied with body weight and appearance post delivery - respondent's own perception on the satisfaction of her body weight and appearance post delivery	• Yes • No	Categorical
45	Intrapartum experience - respondent's own perception of having bad experiences during labour. E.g.: unbearable pain	• Yes • No	Categorical
46	Mode of delivery	• SVD	Categorical

		• Instrumental delivery • Planned caesarean section • Emergency caesarean section	
47	Postnatal complication -experienced wound pain, wound breakdown, readmission to ward	• Yes • No •	Categorical
48	Type of complication	List complication	Categorical
49	Readmission after discharge during postpartum period	• Yes • No	Categorical
50	Outcome of the baby	• Alive • Gender • Birth weight • Twins • Gestational weight • Admission to ward • Medical complication	Categorical
51	Edinburgh Postpartum Depression scale scoring (Less than 11 – no postpartum depression 11 or more – postpartum depression)	Total score (range 0 - 30) • Less than 11 – no postpartum depression • 11 or more – postpartum depression	Interval Categorical
52	Depression anxiety stress scale (DASS) scoring	Total scores (range 0-21) • Depression - Mild: 6-7 - Moderate: 8-10 - Severe: 11-14 - Very severe: 15 to 21 • Anxiety - Mild: 5-6 - Moderate: 7-8 - Severe: 9-10 - Vere severe: 11 to 21 • Stress - Mild: 8-9 - Moderate: 10-13 - Severe: 14-17 - Very severe: 18 to 21	Interval Ordinal Ordinal Ordinal

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-9
Objectives	3	State specific objectives, including any prespecified hypotheses	9
Methods			
Study design	4	Present key elements of study design early in the paper	9
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	9-13
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	10-11
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	16-18, Supplementary Table S1
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	14-16
Bias	9	Describe any efforts to address potential sources of bias	16-17
Study size	10	Explain how the study size was arrived at	13-14
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	14-16
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	14-16
		(*b*) Describe any methods used to examine subgroups and interactions	14-16
		(*c*) Explain how missing data were addressed	14-16
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	14-16
		(*e*) Describe any sensitivity analyses	14-16

Results			NA
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	11
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	NA
		(b) Indicate number of participants with missing data for each variable of interest	NA
Outcome data	15*	Report numbers of outcome events or summary measures	NA
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	NA
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	NA
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	3, 16-18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	NA
Generalisability	21	Discuss the generalisability (external validity) of the study results	NA
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	18

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.