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The association between premenstrual syndrome before pregnancy and antenatal depression: A cross-sectional study with prerecorded information

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Abstract

Aim: Some studies have examined the relationship between premenstrual syndrome (PMS) and antenatal depression. However, retrospective designs were used to obtain the PMS experiences. Different from such earlier research, this study aims to investigate the association between PMS before pregnancy and antenatal depression with a prospective design.

Method: This is a secondary analysis of a randomized controlled trial (RCT) conducted among pregnant women. Premenstrual symptoms before pregnancy of the participants were obtained prospectively via a period tracking app. At the baseline of the RCT, 5073 women participated. Of those, 3004 had one or more symptom records related to menstruation 1 year before pregnancy. The outcome, antenatal depression, was assessed using the Edinburgh Postnatal Depression Scale (EPDS) at the RCT baseline, and the cut-off value was set at 11. For covariates, age, education, planned pregnancy, and the number of children were also measured at the same time. Multiple logistic regression analyses were employed to estimate the odds ratio (OR) of having antenatal depression, adjusting for the covariates.

Results: A total of 366 individuals who had three or more cycles of menstrual-related symptom records were included in the analyses, and of those 52 were applicable to PMS before pregnancy. There was no significant association between PMS and antenatal depression (adjusted OR = 1.28, $P = 0.61$).

Conclusion: The present study was the first study to utilize a prospective design to obtain premenstrual symptoms. Future research should consider using a validated and objective measure of PMS diagnosis and a larger sample.

KEYWORDS
antenatal depression, pregnancy, premenstrual syndrome, prenatal depression

INTRODUCTION

Antenatal depression is one of the most significant public health issues because of its severe adverse impacts on both mothers' and infants' health.[1,2] A recent systematic review has reported that across the world approximately 20% of pregnant women suffer from antenatal depression.[3] Considering that the number of pregnancies per year in the world is around 200 million,[4] the population at risk is very broad. Antenatal depression is associated with inadequate diet, the use of tobacco, alcohol, and other harmful substances, reduced breastfeeding, postnatal depression, and the risk of suicide.[5–8] Moreover, antenatal depression can also result in poor infant physical health, such as preterm birth, low birth weight, and increased risk of infant hospitalization.[9–11] Therefore, preventing antenatal depression is of utmost importance, and it is essential to identify early on women who are at risk of antenatal depression.

Premenstrual syndrome (PMS) has been recently recognized as a potential risk factor of antenatal depression.[12–15] PMS is diagnosed when a woman has symptoms such as depression, irritability, breast tenderness, and pain in the 5 days before her period. The symptoms should disappear in 4 days after the period and continue to be observed for at least three menstrual cycles in a row.[16] Although the frequency of premenstrual symptoms is quite high (80%–90%),[17] only a small percentage get pharmacological management. Thus, if PMS is a potential risk of antenatal depression, controlling the symptoms even before pregnancy may work preventively.

The results of the studies above are consistent in indicating that there is a significant association between having PMS before pregnancy and antenatal depression.[12–15] The explanation is that PMS symptoms appear when a woman is very sensitive to changes in the amount of sex hormones (estrogen and progesterone).[18] Pregnancy brings hormone changes as well, and those women would react to such changes and present depressive symptoms, thus we consider whether there is a positive association between PMS before pregnancy and antenatal depression. However, all the previous studies were conducted with pregnant women, and the history of premenstrual symptoms was measured retrospectively, rather than prospectively. Therefore, there is a limitation in that the association might be overestimated due to the study design. To investigate the association between PMS and antenatal depression, we believe that a prospective study before pregnancy is essential. To date, there is no research using data recorded before pregnancy. In recent years, using health tracking apps has become more common among women. Datasets from such apps have a critical advantage in providing the start of each menstrual cycle and prospective information.[19] Thus, it is useful to use datasets from a period in the tracking app to conduct a prospective study.

The present study aimed to examine the association between PMS and antenatal depression using prerecorded premenstrual data before pregnancy among participants in a randomized controlled trial (RCT). As a strength of this study, a period tracking app was used to obtain the PMS data.

METHODS

Study design and settings

This study is a cross-sectional study with prerecorded information among expecting women who participated in an RCT[20] (trial registration number UMIN000038190). Participant recruitment and a survey were conducted via an app (Luna Luna Baby, run by MTI Ltd). According to gestational weeks, this app provides users with information on fetus growth, and mental and physical states. Users register the date of the last menstruation in the app to detect the number of weeks of pregnancy. Users who met the eligibility criteria as described below received a notification to participate in the RCT. Those who agreed to participate answered an online self-report questionnaire developed by the authors (November 2019–March 2020). The app Luna Luna Baby has a sister app called Luna Luna, also run by MTI Ltd. Luna Luna is an ovulation and period tracking app where users prospectively register their period date and related symptoms (e.g., headache, breast tightness, or sleepiness). Most of the RCT participants used to be users of Luna Luna, so the PMS data for the year before pregnancy of the participants was obtained via Luna Luna. This study protocol received ethical approval from the Graduate School of Medicine and Faculty of Medicine research ethics committee of the University of Tokyo (No. 2019150NI). We obtained informed consent from all participants via questionnaire instructions on the app. The instructions assured the protection of personal information and explained that the data would be anonymized when provided to the researchers. Any identifying information (participants' names and other identifiers that could lead to the identification of a participant) was removed when we received the data through MTI Ltd. Our study has been reported according to Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[21]

Participants

At the RCT baseline, a total of 5073 pregnant women were recruited and completed the survey in order of arrival. Participant eligible criteria were (a) over 20 years old and (b) at 16–20 weeks gestation. MTI Ltd sent notifications with an invitation to participate in the RCT through the app to those who met criteria (a) and (b). If the eligible pregnant woman agreed to the online survey terms and conditions, they could access the self-report questionnaire. Participating pregnant women were awarded 500 Yen as a reward for participation in the RCT at the end of the intervention. Among the RCT participants, those who had more than three cycle records related to menstruation before pregnancy were extracted from this current study.

The intervention provided in the RCT was Internet-based cognitive behavioral therapy, which was composed of six modules. The participants learned one module in 1 week and they were requested to complete all modules until 32 weeks gestation.

Considering the time to finish the program, those who were at 16–20 weeks gestation were recruited.

Variables and measurements

All data were obtained via the two apps (Luna Luna Baby and Luna Luna). PMS symptom records for 1 year before pregnancy were obtained from Luna Luna. Antenatal depression and participants' demographic data were measured using the authors' online self-report questionnaire at the RCT baseline. Since we used the online survey, there were no missing values in the antenatal depression scale and demographic data.

Depressive symptoms

Antenatal depression

Antenatal depression was measured at the baseline survey of the RCT on Luna Luna Baby using the Edinburgh Postnatal Depression Scale (EPDS).[22] EPDS consists of 10 items assessing any symptoms of depression in the previous 7 days. All items were rated on a three-point Likert scale, with a higher score indicating severe depression. EPDS has been translated into Japanese and has good reliability and validity.[23] A previous systematic review has suggested that a cut-off value of 11 or higher of EPDS maximizes combined sensitivity and specificity for antenatal depression, thus we employed this value for our study.[24] Cronbach's α coefficient for EPDS in this study sample was 0.81.

PMS symptoms

PMS has multiple definitions from various organizations. For example, the American College of Obstetricians and Gynecologists (ACOG) definition is that a woman's symptoms must (a) be present in the 5 days before her period for at least three menstrual cycles in a row, (b) end within 4 days after her period starts, and (c) interfere with some of her normal activities.[16] The common emotional symptoms are depression, irritability, increased nap-taking or anxiety, and physical symptoms such as breast tenderness, headache, aches and pains, and skin problems. Differently, the National Institute for Health and Care Excellence (NICE) in the United Kingdom defines a vast array of psychological symptoms such as depression, anxiety, irritability, loss of confidence, mood swings, or physical symptoms, such as abdominal distension or breast tightness. Those symptoms should be recorded prospectively over two cycles using a symptom diary.[25] Also, to distinguish PMS from typical physiological menstrual symptoms, it must be demonstrated that symptoms cause significant impairment to the individual during the luteal phase of the menstrual cycle.[25]

Based on the diagnostic criteria of PMS by ACOG, we defined having more than one of the following symptoms from 5 days before until the start of menstruation and for three or more coming cycles as PMS: sleepiness (sleepy, somewhat sleepy), physical condition (very bad, bad), fatigue (tired), mood (bad), back pain (strong, medium, somewhat), abdominal pain (strong, medium, somewhat), joint pain (strong, medium, somewhat), headache (strong, medium, somewhat), breast tightness (strong, medium, somewhat), and acne (a lot). Symptoms not continuously recorded were also included, and having applicable symptoms at first, second, and fourth cycles was also defined as PMS. For sensitivity analysis, we also determined status using another definition of PMS. Since the continuity of the cycles with symptoms was not included in the primary definition, having at least one symptom for two continuous cycles was recognized as the second PMS definition. We obtained symptom records for 1 year before a participant's pregnancy from Luna Luna, and all the symptoms were recorded prospectively.

Covariates and demographic variables

As confounders, we measured age, education (university or more/less), planned pregnancy (yes/no), and the number of children (none/one or more).

Sample size calculation

This study is a secondary analysis using the baseline data from an RCT, and as such a prior sample size calculation was not conducted. A post hoc sample size calculation was employed to estimate statistical power ($1 - \beta$) for the primary analysis, using G*power.[26,27] Because there are no studies that have investigated the prevalence of antenatal depression among pregnant women with PMS experiences, we used the prevalence among general pregnant women as a probability. A systematic review[28] reported that the period prevalence of antenatal depression in Japan is 14.0%. The Cox–Snell R^2 score calculated among the covariates in the analysis was 0.07. The proportion of women with PMS in this sample was almost 15%. Eventually, when the α error was 0.05, the total sample size was 366 and the odds ratio (OR) was 1.3, thus the estimated statistical power was 11.3%.

Analyses

The proportions of participants who had antenatal depression were compared in the two groups that were classified based on having PMS or not. Multiple logistic regression was employed to estimate the OR of having antenatal depression both in bivariate analysis and multivariate analysis and was simultaneously adjusted for demographic covariates (age, education history, planned pregnancy, or the number of children). Statistical significance was conducted as two-tailed, with $P < 0.05$ as a level of statistical significance. A variance inflation factor exceeding 10 is regarded as indicating serious multicollinearity and values >4.0 may cause concern.[29] For sensitivity analysis, we employed the same

statistical method with the second PMS definition, and we also used EPDS cut-off value 13 with the first PMS definition. To assess the goodness-of-fit of the two models, the Hosmer–Lemeshow test was conducted. All statistical analyses were performed using IBM SPSS Statistics for Windows, version 27 (IBM Corp.).

RESULTS

Participant flow

The RCT recruited 5073 pregnant women, of whom 3004 individuals (rate 59.2%) had some symptom records 1 year before their pregnancy. A total of 2638 individuals were excluded because they had no records for more than two cycles. The symptoms included were sleepiness, physical condition, fatigue, mood, back pain, abdominal pain, joint pain, headache, breast tightness, and acne. Those who listed a positive state (i.e., not sleepy or good physical condition) were recognized as having sufficient data. Finally, 366 individuals (rate 7.2%) had adequate records and were included in this study and the analysis. The participant flowchart is shown in Figure 1.

Participant characteristics

Table 1 describes the demographic characteristics of the participants and includes stratification by having PMS or not. The PMS group included 52 individuals (14.2%) and the non-PMS group included 314 individuals (85.8%). The participants' average ages in the PMS group and non-PMS group were 30.92 and 30.60 years old, respectively. The average weeks of pregnancy in each group were 17.23 and 16.60, respectively. In both groups, almost all had partners, and more than half of them had a university or higher education. More than 80% of the PMS groups and more than 70% of the non-PMS group were having a first-child pregnancy. Almost 80% of each group planned the pregnancies. The average EPDS scores were 4.85 in the PMS group and 5.02 in the non-PMS group.

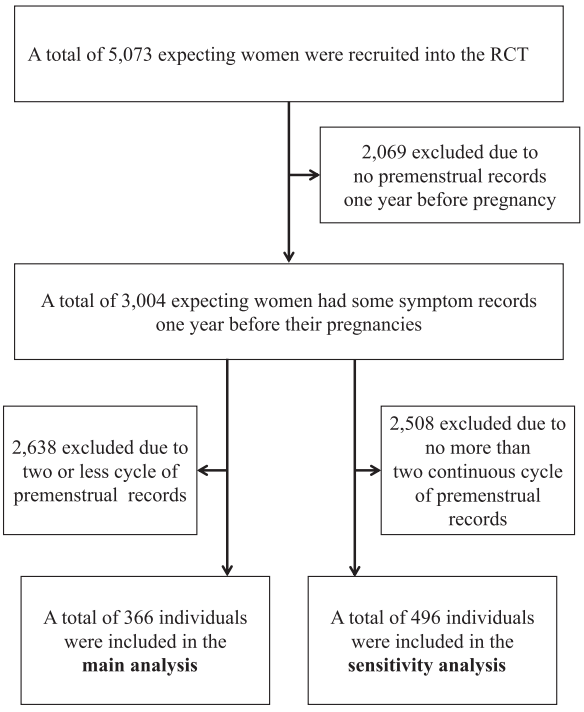

FIGURE 1 Participant flowchart of this study

PMS symptom records

Table 2 presents the total number of recorded symptoms over 5 days before the start of each menstrual cycle among the participants. The 52 PMS group and 314 non-PMS group participants could choose to report from 10 different types of symptoms if applicable. A total of 1055 and 1864 symptoms were recorded, respectively. Within the PMS group, frequently appearing symptoms were breast tightness (19.9%), abdominal pain (16.6%), and poor physical condition (12.7%). Within the non-PMS group, poor physical condition (15.3%) was the most frequent symptom. Subsequently, the next most prevalent symptoms were abdominal pain (15.2%) and breast tightness (15.0%). In both groups, increased acne was recorded least as a symptom (3.4% and 4.0%, respectively).

Association between PMS and antenatal depression

Table 3 shows the results from multiple logistic regression analyses (crude and adjusted). There was no significant association between PMS before pregnancy and antenatal depression in the crude model (OR = 1.01, 95% confidence interval [CI] 0.40–2.53, $P = 0.99$). After adjusting covariates, no significant association was seen between PMS antenatal depression (OR = 1.28, 95% CI 0.49–3.38, $P = 0.61$). Regarding covariates, the ORs of having university or more educational status (OR = 0.43, 95% CI 0.21–0.88, $P = 0.02$) and having a planned pregnancy at this time ($R = 0.33$, 95% CI 0.16–0.68, $P < 0.01$) had a significant association with antenatal depression.

Table 4 shows the results from sensitivity analyses (crude and adjusted). No significant associations were seen in the analyses (crude: OR = 1.29, 95% CI 0.64–2.60, $P = 0.48$; adjusted: OR = 1.29, 95% CI 0.62–2.69, $P = 0.61$). In both primary and sensitivity analyses, the *P*-values of the Hosmer–Lemeshow test were over 0.05.

We additionally used EPDS cut-off value 13 for sensitivity analysis and the results are shown in Table A1. No significant associations were seen in the analyses (crude: OR = 0.26, 95% CI 0.03–1.97, $P = 0.24$; adjusted: OR = 0.30, 95% CI 0.04–2.30, $P = 0.24$).

DISCUSSION

This study investigated the association between PMS before pregnancy and antenatal depression among pregnant women who participated in a large RCT. This study demonstrated no significant

TABLE 1 Demographic characteristics in expecting women with and without PMS (*N* = 366)

	PMS (*N* = 52)		Non-PMS (*N* = 314)		
	N (%)	Mean (SD)	*N* (%)	Mean (SD)	*P*
Age		30.92 (4.51)		30.60 (4.30)	0.62
20–29	20 (38.5)		136 (43.3)		
30–39	30 (57.7)		172 (54.8)		
40–49	2 (3.8)		6 (1.9)		
Week of pregnancy		17.23 (1.45)		16.60 (1.12)	**<0.01**
16	25 (48.1)		226 (72.0)		
17	9 (17.3)		32 (10.2)		
18	4 (7.7)		26 (8.3)		
19	9 (17.3)		16 (5.1)		
20	5 (9.6)		14 (4.5)		
Having partner					0.86
Yes	51 (98.1)		309 (98.4)		
No	1 (1.9)		5 (1.6)		
Education					0.12
University or more	33 (63.5)		163 (51.9)		
Less	19 (36.5)		151 (48.1)		
Number of children					0.11
None	44 (84.6)		233 (74.2)		
One or more	8 (15.4)		81 (25.8)		
Planned pregnancy					0.64
Yes	43 (82.7)		251 (79.9)		
No	9 (17.3)		63 (20.1)		
Recorded cycles	5.56 (1.96)		4.21 (1.67)		**<0.01**
EPDS[a] score		4.85 (3.82)		5.20 (4.21)	0.57
11 or more	6 (11.5)		36 (11.5)		
13 or more	1 (1.9)		22 (7.0)		

Note: Bold numbers mean that the significance level is $P < 0.05$.

Abbreviation: PMS, premenstrual syndrome.

[a]Edinburgh Postnatal Depression Scale.

association between PMS and antenatal depression in the crude or adjusted model. The sensitivity analyses showed the same results.

Prior studies have suggested a positive association between PMS and antenatal depression.[12–15] Jeong et al. speculated that PMS and pregnancy are in common as both have a condition that induces abrupt hormonal changes, which may cause antennal depression.[13] Contrary to our hypothesis, this study found no significant associations, which is inconsistent with earlier studies. However, our data for the prospective symptom records to identify PMS were following diagnosis guidelines for the first time, and thus this study design difference may have given different results. Although this study's nonsignificant results may be due to a lack of statistical power, the ORs were still quite different from previous studies (OR 2.73–8.69). This difference may be explained by the PMS symptoms that were measured prospectively, unlike earlier studies, which were subject to recall bias. Additionally, an earlier study investigating racial differences in PMS sensitivities suggests that Asians tend to report less severity than Hispanics and whites.[30] Also, Takeda et al. considered the possibility that Japanese women avoid verbal expression of PMS to maintain social harmony under Confucian ethics.[31] Thus, it may be possible that the Japanese women in this study actually had PMS symptoms but did not count them in their self-reported symptoms, or reported lower severity and were not recognized as having PMS, which may have weakened the association between PMS and antenatal depression.

PMS pathology has yet to be completely established. Some studies have suggested that PMS is elicited by the drop in progesterone concentrations in the late luteal phase and this is linked to CNS neurotransmitter changes.[32,33] Conversely, some have proposed that PMS is triggered by the preovulatory peak in estradiol, or by the postovulatory increase in progesterone, or both.[34,35] In common, patients with PMS are considered as very sensitive to hormone fluctuations.[18] Throughout pregnancy, estradiol and progesterone continue to rise dramatically and do not decrease, which might have different effects on people with PMS compared to when they were not pregnant. In addition, women do not have the symptoms attributable to menstrual cycles while pregnant, so it may be possible to that their mental burden due to the symptoms becomes lighter, and thus they may not have antenatal depression. Systematic reviews have suggested a significant positive association between PMS before pregnancy and postpartum depression.[36,37] After delivery, the sex steroid hormones rapidly decrease, and as mentioned above, women with PMS are considered as being highly sensitive to hormone fluctuations, and this rapid change could trigger postpartum depression. As such, it may be speculated that PMS before pregnancy is not associated with antenatal depression, but rather may be associated with postpartum depression.

In the adjusted model of multiple logistic regression analyses, the ORs of antenatal depression of the group having an education (university or more) and planned pregnancy were significant and lower compared to the other groups. When it comes to education, generally speaking, there is a clear relationship between low socioeconomic status and depression.[38] Socioeconomic status is often measured as a combination of education, income, and

TABLE 2 The total number of recorded symptoms in the 5 days before the start of each menstrual cycle in PMS and non-PMS groups (*N* = 366)

Symptoms	PMS (*N* = 52) *N* (%)	Non-PMS (*N* = 314) *N* (%)
Total symptoms	1055 records	1846 records
Sleepiness	90 (8.5%)	181 (9.8%)
Physical condition	134 (12.7%)	282 (15.3%)
Fatigue	50 (4.7%)	103 (5.6%)
Mood	77 (7.3%)	142 (7.7%)
Back pain	128 (12.1%)	210 (11.4%)
Abdominal pain	175 (16.6%)	281 (15.2%)
Joint pain	45 (4.3%)	102 (5.5%)
Headache	110 (10.4%)	195 (10.6%)
Breast tightness	210 (19.9%)	276 (15.0%)
Acne	36 (3.4%)	74 (4.0%)

Abbreviation: PMS, premenstrual syndrome.

TABLE 3 The association between PMS and antenatal depression (EPDS score 11 or more) among pregnant women in Japan (*N* = 366): multiple logistic regression adjusting demographic factors

PMS and covariates	Crude Odds ratio (95% CI)	*P*-value	Fully adjusted[a] Odds ratio (95% CI)	*P*-value
PMS				
Yes	1.01 (0.40–2.53)	0.99	1.28 (0.49–3.38)	0.61
No	1.00 (reference)		1.00 (reference)	
Age				
20–29	–		1.00 (reference)	
30–39	–		0.60 (0.30–1.23)	0.16
40–49	–		0.59 (0.06–5.64)	0.65
Education history				
Less	–		1.00 (reference)	
University or more	–		0.43 (0.21–0.88)*	0.02
Number of children				
None	–		1.00 (reference)	
One or more	–		1.96 (0.94–4.07)	0.07
Planned pregnancy				
Yes	–		0.33 (0.16–0.68)**	<0.01
No	–		1.00 (reference)	

Abbreviations: CI, confidence interval; EPDS, Edinburgh Postnatal Depression Scale; OR, odds ratio; PMS, premenstrual syndrome.

[a]Adjusted by age, education, number of children, and planned pregnancy.

*$P < 0.05$; **$P < 0.01$.

TABLE 4 The association between PMS and antenatal depression (EPDS score 11 or more) among pregnant women in Japan ($N = 496$): a sensitivity analysis of multiple logistic regression by another definition of PMS

	Crude		Fully adjusted[a]	
PMS and covariates	Odds ratio (95% CI)	*P*-value	Odds ratio (95% CI)	*P*-value
PMS				
Yes	1.29 (0.64–2.60)	0.48	1.29 (0.62–2.69)	0.61
No	1.00 (reference)		1.00 (reference)	
Age				
20–29	–		1.00 (reference)	
30–39	–		0.46 (0.26–0.82)*	0.01
40–49	–		1.09 (0.21–5.82)	0.92
Education history				
Less	–		1.00 (reference)	
University or more	–		0.45 (0.25–0.79)*	0.01
Number of children				
None	–		1.00 (reference)	
One or more	–		1.65 (0.89–3.06)	0.12
Planned pregnancy				
Yes	–		0.51 (0.28–0.92)*	0.03
No	–		1.00 (reference)	

Abbreviations: CI, confidence interval; EPDS, Edinburgh Postnatal Depression Scale; OR, odds ratio; PMS, premenstrual syndrome.

[a]Adjusted by age, education, number of children, and planned pregnancy.

*$P < 0.05$; **$P < 0.01$.

occupation, therefore low education could be one reason for depression. This relationship may explain the low OR of antenatal depression in the higher education group. Regarding the effect of unplanned pregnancy, in an earlier study conducted among reproductive-aged women who had an experience of pregnancy within 1 year, there was a significant association between unplanned pregnancy and current depression.[39] This study did not measure antenatal depression, but unplanned pregnancy could negatively affect an expecting woman's mental health.

To the best of our knowledge, this is the first study to investigate the association between PMS before pregnancy and antenatal depression using prospective individual symptom records. The results in our study were inconsistent with prior studies utilizing a retrospective design. As an implication of this research, we have added new information on women's mental health, especially pregnant women. Studies that use objective and validated PMS measures, such as doctor's diagnosis, would be required for future studies.

LIMITATIONS

This study has several limitations. First, the low statistical power. Unfortunately, no data were available for those who did not voluntarily record premenstrual symptoms, and we could not reach a sufficient sample size. Low statistical power because of the small sample size may cause a failure to detect important associations. Further study with a sufficient sample size to improve the accuracy of analyses is needed. Second, all variables were measured by a self-reported survey, and thus there is a possibility that the participants answered the questionnaire to be socially desirable, which may cause reporting bias. Third, the PMS diagnosis we employed in this study could only partially follow international guidelines, such that the PMS diagnosis lacks objectivity. The definition of PMS in the study was broader than that of ACOG, in that we defined PMS if there were 3 months of symptoms, even if they were not continuous. Although there is an earlier study that did not use the definition of 3 consecutive months,[40] those who did not meet strict PMS criteria might be identified as PMS in this study. In addition, other definitions of PMS by other measures, such as data on PMS awareness or history of PMS diagnosis by physicians, were not collected. Therefore, it was not possible to compare the findings in the study to the results using definitions of PMS based on other than the used indicators. Lack of knowledge and awareness of PMS may lead to reporting bias by not recording PMS symptoms even if they are present, and people who may originally have PMS may not be included in the PMS group or in this survey. For future research, prospective detailed symptom records and a specialized medical doctor's diagnosis should be obtained. Fourth, the depressive state before pregnancy or the family history of depression were not adjusted in this study. This may cause an overestimate of the results. Fifth, data on pregnancy

complications such as high blood pressure and anemia were not collected and those were not adjusted in the analysis. There might be a possibility that the complaints may delay their participation in this study. Sixth, the proportion of those included in this study from the RCT participants was deficient because many were excluded due to inadequate symptom records. There is a possibility that the women who had some PMS symptoms were only recorded on the app, and this may cause selection bias. Moreover, due to the study design of the original RCT, it is a limitation that the participants were only 16–20 gestation week pregnant women. However, it is reported that the prevalence rates of antenatal depression in the second and third trimesters are similar,[41] thus we speculated that using depressive symptoms at later gestation weeks as an outcome would not change the results. Finally, all the participants were recruited among the app users, thus this study's generalizability is limited.

CONCLUSION

The present study found no significant associations between PMS before pregnancy and antenatal depression. Future research should consider using a validated and objective measure of PMS diagnosis and a larger sample.

DISCLOSURE

The authors paid the necessary expenses to MTI Inc., and MTI Inc. provided the authors with the opportunity to recruit study participants and collect information from study participants electronically. The study's sponsor had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The authors had access to the data in the study and the final responsibility of submitting the paper.

AUTHOR CONTRIBUTIONS

Yui Hidaka, Norito Kawakami, Kazuhiro Watanabe, and Daisuke Nishi made substantial contributions to the conception, the design of the work, and the acquisition, analysis and interpretation of the data. The authors drafted and revised the work, and approved the version to be published. The authors also agree to be accountable for all aspects of the work.

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CONFLICT OF INTEREST

Daisuke Nishi has received personal fees from Startia Inc., en-power Inc., MD.net, and Mitsubishi Heavy Industries Kobe Shipyard outside the submitted work. Norito Kawakami is currently receiving grants from Fujitsu Ltd, Fujitsu Software Technologies Ltd, SB At Work Corp., personal fees from Occupational Health Foundation, Japan Dental Association, Sekisui Chemicals, Junpukai Health Care Center, Osaka Chamber of Commerce and Industry, and nonfinancial support from Japan Productivity Center as relevant financial activities outside the submitted work. Additionally, MTI Ltd has been involved in this study as mentioned in the manuscript. Yui Hidaka and Kazuhiro Watanabe declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS APPROVAL STATEMENT

This work was approved by the research ethics committee of the Graduate School of Medicine and Faculty of Medicine, The University of Tokyo, Japan (No. 2019150NI).

PATIENT CONSENT STATEMENT

We obtained informed consent from all the participants via the Internet survey.

CLINICAL TRIAL REGISTRATION

This is a secondary analysis of a randomized controlled trial (RCT). The trial number of the original RCT is UMIN000038190.

CONSENT FOR PUBLICATION

This manuscript is not currently being considered by another publication, is not in press in any other format, and has not been published previously. We will comply with all the copyright and proprietary regulations as stipulated by *Psychiatric and Clinical Neurosciences Reports*.

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APPENDIX A

See Tables A1 and A2.

TABLE A1 The association between PMS and antenatal depression (EPDS score 13 or more) among pregnant women in Japan ($N = 366$): a sensitivity analysis of multiple logistic regression with another EPDS cut-off value

	Crude		Fully adjusted[a]	
PMS and covariates	Odds ratio (95% CI)	*P*-value	Odds ratio (95% CI)	*P*-value
PMS				
Yes	0.26 (0.03–1.97)	0.24	0.30 (0.04–2.30)	0.24
No	1.00 (reference)		1.00 (reference)	
Age				
20–29	–		1.00 (reference)	
30–39	–		0.66 (0.26–1.70)	0.38
40–49	–		1.48 (0.15–15.05)	0.74
Education history				
Less	–		1.00 (reference)	
University or more	–		0.61 (0.24–1.53)	0.29
Number of children				
None	–		1.00 (reference)	
One or more	–		1.29 (0.49–3.41)	0.61
Planned pregnancy				
Yes	–		0.29 (0.12–0.71)**	<0.01
No	–		1.00 (reference)	

Note: *$P < 0.05$, **$P < 0.01$.

[a]Adjusted by age, education, number of children, and planned pregnancy.

TABLE A2 Association between PMS and antenatal depression (EPDS score: 10 or more) among pregnant women in Japan (*N* = 366): multiple logistic regression adjusting demographic factors.

	Crude		Fully adjusted[†]	
PMS and covariates	**Odds ratio (95% CI)**	***P* value**	**Odds ratio (95% CI)**	***P* value**
PMS				
Yes	0.67 (0.27–1.66)	0.39	0.81 (0.32–2.06)	0.65
No	1.00 (reference)		1.00 (reference)	
Age				
20–29	–		1.00 (reference)	
30–39	–		0.86 (0.47–1.60)	0.64
40–49	–		0.53 (0.06–5.03)	0.58
Education history				
Less	–		1.00 (reference)	
University or more	–		0.36 (0.19–0.67)**	<0.01
Number of children				
None	–		1.00 (reference)	
1 or more	–		1.32 (0.68–2.57)	0.41
Planned pregnancy				
Yes	–		0.36 (0.19–0.70)**	<0.01
No	–		1.00 (reference)	

[†]Adjusted by age, education, number of children and planned pregnancy.

*$P < 0.05$; **$P < 0.01$.