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Effects of family functions on antenatal depression symptoms among women in the third trimester of pregnancy: Self-efficacy as a partially mediator

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Abstract

Objective: To explore the prevalence of depressive symptoms among pregnant women during their third trimester, and completely evaluate the relationship between family functions and the antenatal depressive symptoms.

Design: Community-based, cross-sectional study was conducted among women during the third trimester of pregnancy.

Setting: This study was conducted among pregnant women registered at community health service centers of urban Hengyang City, Hunan Province, China from July to October, 2019.

Participants: A population-based sample of 813 people aged between 17 and 54 years was selected in 14 randomized communities by multi-staged cluster random sampling method.

Main outcome measures: The Family Adaptation Partnership Growth Affection and Resolve Index （APGAR）, the General Self-efficacy Scale (GSES) and Patient Health Questionnaire（PHQ-9）were used to access family functions, self-efficacy and depression symptoms, respectively.

Results: The prevalence of antenatal depression symptoms is 9.2%. Self-efficacy level partially mediated the relationship between family functions and depressive symptoms(β=-0.05, 95%CI: -0.07to -0.03, $p < 0.05$), and the mediating effect accounted for 17.09% of the total effect.

Conclusions: The mediating effect of self-efficacy on the relationship of family functions and antenatal depression symptoms among women in the third trimester of pregnancy was found in this study.

Keywords：antenatal depression symptoms；self-efficacy；family functions；China

Strengths and limitations of this study

- Antenatal depression symptoms would directly affect the health of the pregnant women, which also indirectly led to adverse pregnancy outcomes and did harm to the health of the next generation. Most of the studies focused on postnatal depression and there is less data available on antenatal depression among women in the third trimester of pregnancy.
- This study aimed to assess the prevalence of antenatal depressive symptoms among women in the third trimester of pregnancy, and completely evaluate the effect of self-efficacy correction between family functions and the antenatal depressive symptoms. This study provides evidence and support for identifying high-risk pregnant women with emotional problems in order to take early intervention measures.
- The cross-sectional study limited the ability to make causal inferences. Also, the finding might be

affected by inevitable reporting bias.

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Instruction

Antenatal mental health has become a global public health issue[1]. Depression was the most common mood disorders in the general population, the prevalence ranged from 5% to 10%, which of women was about twice as high as that of men, and childbearing age was the peak of the disease[2]. Depression was one of the most common complications during pregnancy[3]. The meta-analyses of perinatal depression reported the prevalence was 6–13%[4]. The prevalence of antenatal depression was significantly higher than that at any other time, which was about 5-17%[5]. Furthermore, some studies estimated that the prevalence of depression during pregnancy vary from 7-15% in developed countries[6 ,7], and 19-25% in less developed countries[6 ,8]. Also, there is a study indicates that the third trimester of pregnancy was a high-incidence period of depression[9]. Depression not only directly affected the physical and mental health of the pregnant women[10], but also indirectly did harm to the health of the next generation[11]. Depression during pregnancy have been associated with maternal self-harm, suicidal-ideation, placental abruption, preterm delivery, it also might lead to low birth weight, low Apgar score, maladaptive emotional and behavioral development of offsprings[12 ,13]. However, most of the studies on maternal depression mainly focused on postnatal depression and there is less data available on antenatal depression.

Family is an important emotional support sources, family functions play an important role in human life and social development. Family functions refer to the effectiveness of family members' emotional connection, family rules, family communication and coping with external events in the family system[14]. Previous study have showed that good family functions were potential predictors of psychological wellbeing of family members[15]. Similarly, a randomized controlled trial in China intervened with the families of women who had experienced miscarriage, finding that women with a higher level of subjective family-support had a lower incidence of emotional problems[16]. On the contrary, family can also be a source of conflict and stress, we have reason to doubt that family dysfunction is a potential risk factor for antenatal depression in pregnant women.

Self-efficacy was put forward in 1986 by the famous American psychologist Albert Bandura in his book *Social Foundations of Thought and Action: A Social Cognitive Theory*. Bandura defined it as the conviction that one can successfully execute behaviors required to produce a desired outcome in a specific situation[17]. Bandura et al pointed out that self-efficacy affected or determined people's thinking mode, emotional response mode and then affected people's choice of behavior, this effects might be self-aiding or self-hindering [18]. People's self-efficacy might also affect the depression symptoms they suffer from in threatening situation. A study on the emotional problems of women after abortion showed participants with high self-efficacy exhibited significantly lower levels of depression than that with low self-efficacy[19]. A study suggested that individual well-being and the perception of success were directly dependent on the strength of our respective families of origin[20]. Based on the above theory, this study assumes that self-efficacy is considered a buffer in this predictive relationship between family functions and antenatal depression symptoms.

In summary, this study aims to explore the prevalence of antenatal depressive symptoms among pregnant women during their third trimester, and completely evaluate the relationship between family functions and the occurrence of antenatal depressive symptoms, as well as the effect of self-efficacy on this potential relationship, in hopes of providing medical personnel with some useful information that can aid early mental interventions on high-risk pregnant women.

Methods

Participants and procedure

This cross-sectional study was conducted in urban communities of Hengyang City, Hunan Province, China， from July to October, 2019. A total of 813 eligible individuals from 14 communities were involved by multi-staged cluster random sampling metord. The specific sampling steps are as follows: there were five districts in urban Hengyang, each street was numbered, randomly selected a street from each district (Zhengxiang Street, Qingshan Street, Baishazhou Street, Guangdonglu Street, Zhurong Street). Then, proportional sampling was carried out at a proportion of 1/3, 14 communities were included (four communities in Zhengxiang Street， three communities in Qingshan Street ， three communities Baishazhou Street ， two communities in Guangdonglu Street ， two communities in Zhurong Street) . All pregnant women who were registered in community health service centers and meeting the inclusion criteria were potential subjects in this study(n=819). The inclusion criteria for the study were as follows: 1. women in the third trimester of pregnancy; 2, pregnant women over 16 years old ;3. pregnant women who had local household registration, or migrant people who lived in urban of Hengyang City for more than 6 months. The exclusion criterion: 1. pregnant women with cognitive disorders, severe mental illnesses or other serious diseases cannot fill out the questionnaire by themselves; 2. pregnant women who refused to participate in the study. Although we strongly encouraged all potential recruiters to participate in our research, there were still six people were excluded, because of refusals to respond and failure to contact. The response rate of questionnaires was 99.3% (813/819).

Ethics approval was provided by the Ethics Committee of Xiangya School of Public Health, Central South University (XYGW-2019-056). 813 participants were given written information about the purpose of this study and signed a written informed consent. Participants were expected to filled out structured questionnaires by themselves. In addition, the trained research assistants from Xiangya School of Public Health, Central South University would always available to provide assistance and ensure independent responding. Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Measures

The questionnaire included four sections: demographic characteristics, the revised Chinese version of Family Adaptation Partnership Growth Affection and Resolve Index（APGAR）, the General Self-efficacy Scale (GSES) and Patient Health Questionnaire（PHQ-9）. Demographic characteristics included ethnicity (the Han ethnicity, minority), marital status (stable, unstable), occupation (employed, unemployed), education level (senior school and below, college / university degree and above), and so on. In this study, being married was defined as being in a stable marriage. Unstable marriage including unmarried, divorce, widowhood, and so on.

Assessment tools for family functions

Family Adaptation Partnership Growth Affection and Resolve Index（APGAR）was originally developed by Smilkstein (1978) [21], which was a simple self-assessment tool for evaluating the subjective satisfaction of family functions. Five items were used to evaluate five different aspects of family function: family adaptation, family partnership, family growth, family affection and family resolve. Family APGAR index was answered on a 3-point Likert scale from "often" (two points) to "rarely" (zero point). The total score was zero to ten points, good family function has a high family APGAR index between seven and ten, family dysfunction has a moderate family APGAR index between four and six, and severe family dysfunction has a low family APGAR index less than three. Family APGAR index has been widely used and has good reliability and validity[22]. The Cronbach's α is 0.876.

Assessment tools for self-efficacy

The General Self-efficacy Scale (GSES) was publicized in 1981 by Ralf Schwarzer[23] and translated into Chinese by Zhang in 1995[24], which was used to evaluate the self-efficacy level of pregnant women. There are ten items, which were measured using a 4-point Likert scale from "absolutely wrong" (one point) to "absolutely right" (four points). According to the norm of using the GSES, the method of calculating the final self-efficacy score was to divide the total score by ten. The final score ranged from one to four, based on partition criterion for scale, self-efficacy level could be divided into three levels: high (3.1-4), medium (2.1-3), and low (1–2)[25]. The Chinese version of GSES has good reliability and validity which has been validated by et al[24].The Cronbach' α of this scale was 0.898.

Assessment tools for antenatal depression symptoms

Patient Health Questionnaire（PHQ-9）were used to assess the subjective depressive symptoms of pregnant women during the last two weeks. PHQ-9 was revised according to the diagnostic criteria of DSM-IV [26], which was widely known as simple self-management tools and used in clinical and investigation research[27]. PHQ-9 consisted of nine items, each item described a symptom of depression: 1. loss of pleasure; 2. be down in spirits or hopelessness; 3. sleep disorder; 4. lack of energy; 5. diet disorder; 6. self-deprecation; 7. trouble concentrating; 8. changes in physical behavior; 9. thoughts of self-harm. Of this scale, subjects rated the frequency of each symptom using a scale of descriptors: not at all, sometimes, more than half the days, nearly every day (scored from zero to three). The total score is 27 points, usually ten points were used as the positive critical value[28]. The Chinese version of the PHQ-9 has been validated by Yu et al[29].The Cronbach' α of this scale was 0.773.

Statistical analysis

The method of double input with *EpiData 3.1* was adopted. *SPSS 19.0* software were used for statistical analysis. Quantitative variables were described as the *mean± SD*. Categorical variables were expressed as *n (%)*. The *T*-test was applied for comparisons of each scale scores of the participants with different demographic characteristics, the variable of $p < 0.05$ was used as the adjustment variable. Pearson's correlation analysis was conducted to examine the relationships between family functions, self-efficacy level and antenatal depression symptoms. A structural equation model was established by *AMOS 24.0*. Based on the assumption in this study, family APGAR index as predictors, self-efficacy as mediator, and antenatal depression symptoms as outcome. The total effect (weight c) of family functions on antenatal depression symptoms was composed of a direct effect (weight c') of the family functions on the antenatal depression symptoms and an indirect effect (weight a*b) of family functions on antenatal depression symptoms through a proposed mediator. Bootstrapping is a non-parametric resampling method that generates an empirical approximation of the sampling distribution of a statistic from the available data and constructs confidence intervals for the indirect effect[30]. Bootstrap method was used to examine the effect of self-efficacy in explaining the relationship among family functions and antenatal depression symptomss[31].The confidence interval was set at 95%. Statistical significance level was accepted as $p < 0.05$. All statistical tests were 2-sided.

Result

Prevalence of depressive symptoms and the distribution of scores in each scale

According to the standard of division, taking ten points as the positive critical value of PHQ-9, 75 (9.2%) participants reported antenatal depressive symptoms within two weeks. The mean family APGAR index was 7.26±2.57, more than half （60.4%）of the participants reported better family functions, 31.5%（n=256）were moderate family dysfunction, 8.1%（*n*=66）participants were severe family dysfunction. The mean self-efficacy score was 2.55±0.55, 134（16.5%）and 495（60.9%）participants reported high and middle level of self-efficacy, respectively. At the same time, more than one fifth of participants reported that they had a low level of self-efficacy (n=184, 22.6%). (**Table 1, Table 2**)

Table 1. Frequencies and percentages of antenatal depression symptoms, different level of family functions and self-efficacy.

Variables		N（%）
Family functions	Severe family dysfunction（0-3）	66 （8.1）
	Moderate family dysfunction（4-6）	256（31.5）
	Better family functions（7-10）	491（60.4）
Self-efficacy	Low level（1-2）	184（22.6）
	Middle level（2.1-3）	495（60.9）
	High level（3.1-4）	134（16.5）
Antenatal depression symptomss	Yes（≥10）	75（9.2）
	No	738（90.8）

Table 2. Comparison of each scale scores of the participants with different demographic characteristics.

Scale		Family APGAR	GSES	PHQ-9
Ethnicity	The Han ethnicity	7.26±2.56	2.55±0.55	4.86±3.47

	Minority	7.20±3.10	2.51±0.67	5.27±2.74
	t	0.094	0.238	-0.45
Marital status	Stable	7.37±2.52	2.56±0.55	4.81±3.36
	Unstable	6.35±2.79	2.40±0.54	5.39±4.21
	t	3.47*	2.60*	-1.47
Occupation	Employed	7.37±2.61	2.59±0.57	4.78±3.56
	Unemployed	6.96±2.44	2.43±0.50	5.12±3.17
	t	-2.02*	-3.70*	1.25
Education	Senior school and below	6.57±2.63	2.44±0.54	5.05±3.44
	College / university degree and above	7.76±2.40	2.62±0.55	4.74±3.47
	t	-6.75*	-4.61*	1.26

$^{*}p < 0.05$

Each scale score of participants with different demographic characteristics

There were 813 participants included in this study, mean age was 28.98±4.52. The participants with stable marital status(t=3.47, p < 0.05), occupation(t=-2.02, p < 0.05) and higher level of education (t=-6.75,p < 0.05)tend to had higher family APGAR index, the participants with stable marital status(t=2.60, p < 0.05), occupation(t=-3.70, p < 0.05) and higher level of education (t=-4.61, p < 0.05)tend to had higher self-efficacy level, the differences were statistically significant. Marital status, occupation, education level will be adjusted in the structural equation model. There was no significant difference in the scores of other demographic variables in the three scales (**Table 2**).

Pearson's correlation analysis of self-efficacy, family functions, depressive symptoms

There was a significant correlation between family functions, depressive symptoms and self-efficacy in pregnant women. Pearson's correlation analysis results showed family functions had positive correlation with self-efficacy (r = 0.31, p<0.05). Self-efficacy level negatively and significantly associated with antenatal depression symptoms (r=-0.23, p<0.05). The negative correlation between family functions and antenatal depression symptoms was statistically significant (r=-0.28, p<0.05) (**Table 3**).

Table 3. Means, standard deviations（*SD*）, and correlations among family functions, self-efficacy, antenatal depression symptoms. (*n*=813)

Variables	Mean	*SD*	1	2	3
1.Family functions	7.26	2.57	1.00	-	-
2.Self-efficacy	2.55	0.55	0.31*	1.00	-
3.Antenatal depression symptoms	4.87	3.46	-0.28*	-0.23*	1.00

$^{*}p < 0.05$

Mediating effect of self-efficacy level between family functions and depressive symptoms

The mediation model showed that the correlation between family functions and self-efficacy level was statistically significant(β=0.30, 95%CI: 0.24 to 0.37, $p < 0.00$), the correlation between self-efficacy level and antenatal depression symptoms was statistically significant (β=-0.15, 95%CI: -0.22 to -0.08, $p < 0.00$), the direct effect on the relationship between family functions and antenatal depression symptoms was statistically significant(β=-0.24, 95%CI: -0.31 to -0.16, $p < 0.00$), the effect of self-efficacy on the relationship between family functions and antenatal depression symptoms was statistically significant (β=-0.05, 95%CI: -0.07 to -0.03, $p < 0.00$) (**Table 4**). Self-efficacy level partially mediated the relationship between family functions and depressive symptoms, and the mediating effect accounted for 17.09% of the total effect. The mediation model of the relationship between family functions and antenatal depression symptoms by self-efficacy is shown in **Figure 1**.

Table 4. Mediation role of self-efficacy in the relationship between family functions and antenatal depression symptoms (*n*=816, Bootstrap=5000)

Effect	**Paths**	**β**	***SE***	**BCa 95%CI Lower**	**Upper**	***p***
Direct effects	Family functions→Self-efficacy	0.30	0.03	0.24	0.37	0.00
	Family functions→Antenatal depression symptoms	-0.24	0.04	-0.31	-0.16	0.00
	Self-efficacy→Antenatal depression symptoms	-0.15	0.04	-0.23	-0.08	0.00
Indirect effect	Family functions→Self-efficacy→Antenatal depression symptoms	-0.05	0.01	-0.07	-0.03	0.00

β, *SE* and 95%CI were the standardized regression effect value, standard error and 95% confidence interval of the direct and indirect effect estimated by the percentile bootstrap method. BCa = Biased-Corrected and Accelerated 5000 bootstrapping; adjusted variables: marital status, occupation, education level.

Discussion

In this study, the prevalence of antenatal depression symptoms is 9.2%, which was similar to the findings of previous studies[32,33]. Besides, the findings showed that family functions were negatively associated with antenatal depression symptoms among women in the third trimester of pregnancy, in line with the study by Jin et al in China[34]. A study which carried out in Taiwan, China also reported that pregnant women with antenatal depression symptoms tended to have lower family APGAR scores[35]. The Chinese people attach great importance to the family clan relations, they regard the family and its members as one of the most important sources of social support and spiritual sustenance. Pregnancy is viewed as a stressor, with the increasing of sensitivity and vulnerability of women in pregnancy, they are more likely to be influenced by the negative external environment and life events, which may lead to depression and other harmful emotional problems. Families with well-functioning can help pregnant women coping with stress and crisis, and provide spiritual and material help at critical times. However, family dysfunction reflect that pregnant women can't acquire enough attention, love and assistance from families, even family may be the source of mental pressure, so that depressive symptoms starts or aggravates.

Furthermore, a significant indirect effect of family functions on antenatal depression symptoms through self-efficacy was found in this study. Self-efficacy varies from person to person, and often changes within the individual over time and in response to specific experiences and environment. First of all, the quality of family functions was closely related to the level of self-efficacy, which is similar to the finding which focus on the relationship between family supports and maternal self-efficacy by Puspasari et al[36]. The possible reason is that a harmonious family atmosphere and positive family functions would contribute to the increasing of the effective handling of stressors, the perceptions of individual self-worth and success[15]. In addition, the level of self-efficacy could predicted the mental activity and attitude in the face of difficulties and stressors, which would lead to different emotional response outcome[37]. People with high self-efficacy are able to control self-abandoned thoughts, tend to handle situations rationally, are willing to accept the challenges of emergency. On the contrary, people with low self-efficacy are prone to faltering, deal with problems emotionally, are helpless in the face of stress, and easily are distracted by fear, panic, and shyness, which are more likely to have depressive symptoms. This may be a pathway for self-efficacy to play an intermediary role in the relationship between stressors and stress outcomes, which in line with the model of Pearlin et al [38].

In addition, the mediation effect value is 17.09%, indicates partial mediation. The finding reflected that there were other mediators in the relationship between family functions and antenatal depression symptoms. Some other potential mediators have been proposed in previous studies among pregnant women. A study by Waqas et al in Pakistan showed that social support was a mediator of the relationship of total number of children, gender of children and antenatal depression[39]. Relational resilience as a potential mediator between adverse childhood experiences and prenatal depression was found by Howell et al[40]. However, the mediating effect of these variables has not been demonstrated in the relationship between family functions and antenatal depressive symptoms, which is worth exploring in future studies.

The samples of this study were selected from pregnant women enrolled in community health service centers, with low no response rate. Compared with the study with hospital samples, the samples were more representative of the real situation of ordinary pregnant women. Women in the third trimester of pregnancy were selected to evaluate their antenatal depression symptoms for nearly two weeks, with less recall bias. There are some limitations in this study. First, it was a cross-sectional study, for which a causal relationship could not be inferred. Second, it cannot be denied that the results of this study may be influenced by some confounding factors that have not been considered. Third, because of the self-filled questionnaire, there was an inevitable reporting bias in this study. Future studies should investigate the causal relationships among family functions, self-efficacy and antenatal depression symptoms with longitudinal designs.

Conclusion

In summary, the prevalence of antenatal depression symptoms is 9.2% among women in the third trimester of pregnancy. Last but not least, this study also contributes to the literature by exploring self-efficacy as a mediator to explain the relationship between family functions and antenatal depression symptoms. Based on this finding, we can take measures to aid early mental interventions on high-risk pregnant women, and then reduce the pain and financial burden of the depression on the pregnant women and the family.

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Competing interests None.

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Patient consent Obtained.

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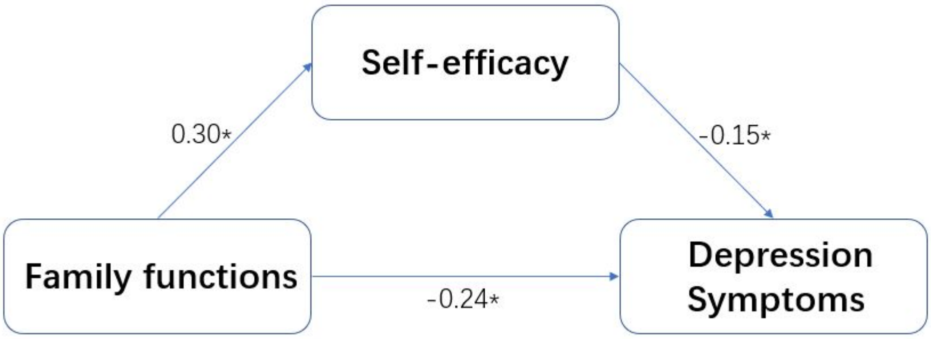
Self-efficacy
0.30*
-0.15*
Family functions
-0.24*
Depression Symptoms

Figure 1. Structural equation model testing self-efficacy as a mediator in the relationship between family functions and depressive symptoms. (a) The model has been adjusted for marital status, occupation, education level. The above values have been standardized. (b) *$p<0.05$

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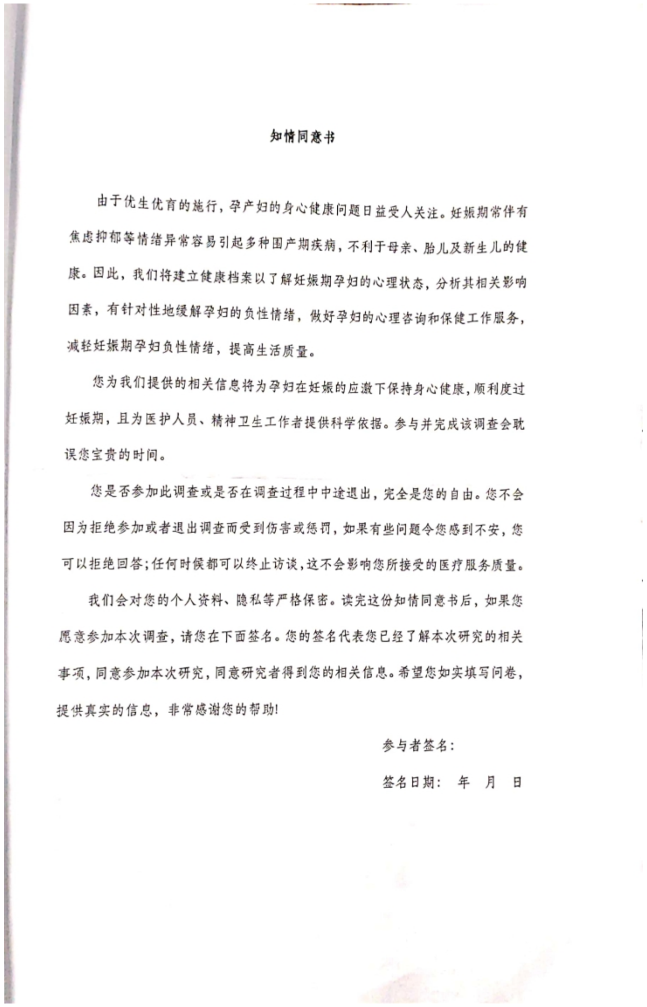

知情同意书

由于优生优育的施行，孕产妇的身心健康问题日益受人关注。妊娠期常伴有焦虑抑郁等情绪异常容易引起多种围产期疾病，不利于母亲、胎儿及新生儿的健康。因此，我们将建立健康档案以了解妊娠期孕妇的心理状态，分析其相关影响因素，有针对性地缓解孕妇的负性情绪，做好孕妇的心理咨询和保健工作服务，减轻妊娠期孕妇负性情绪，提高生活质量。

您为我们提供的相关信息将为孕妇在妊娠的应激下保持身心健康，顺利度过妊娠期，且为医护人员、精神卫生工作者提供科学依据。参与并完成该调查会耽误您宝贵的时间。

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参与者签名：

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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	P1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	P1
Introduction			**P2**
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	P2
Objectives	3	State specific objectives, including any prespecified hypotheses	P2
Methods			**P2**
Study design	4	Present key elements of study design early in the paper	P3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	P3
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	P3
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	P3
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	P3-4
Bias	9	Describe any efforts to address potential sources of bias	P3
Study size	10	Explain how the study size was arrived at	P3
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	P3
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	P4
		(*b*) Describe any methods used to examine subgroups and interactions	P3
		(*c*) Explain how missing data were addressed	P3
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	P3
		(*e*) Describe any sensitivity analyses	No
Results			P4

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	P3-4
		(b) Give reasons for non-participation at each stage	P3
		(c) Consider use of a flow diagram	No
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	P4-5
		(b) Indicate number of participants with missing data for each variable of interest	No
Outcome data	15*	Report numbers of outcome events or summary measures	P5
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	P4-6
		(*b*) Report category boundaries when continuous variables were categorized	P5
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	P5-6
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	P5-6
Discussion			P6
Key results	18	Summarise key results with reference to study objectives	P6-7
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	P7
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	P7
Generalisability	21	Discuss the generalisability (external validity) of the study results	P7
Other information			P8
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	P8

*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.

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The association between family functions and antenatal depression symptoms : a cross-sectional study among pregnant women in urban communities of Hengyang City, China

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The association between family functions and antenatal depression symptoms：a cross-sectional study among pregnant women in urban communities of Hengyang City, China

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Abstract

Objective: To explore the prevalence of depressive symptoms among women in late pregnancy, and assess mediating effect of self-efficacy in the association between family functions and the antenatal depressive symptoms.

Design: Community-based, cross-sectional study was conducted among women during the third trimester of pregnancy.

Setting: This study was conducted among pregnant women registered at community health service centers of urban Hengyang City, China from July to October, 2019.

Participants: 813 people were selected from 14 communities by multi-staged cluster random sampling method.

Main outcome measures: The Family Adaptation Partnership Growth Affection and Resolve Index （APGAR）, the General Self-efficacy Scale (GSES) and Patient Health Questionnaire（PHQ-9）were used to access family functions, self-efficacy and antenatal depression symptoms, respectively.

Results: In this study, 9.2% pregnant women reported the symptoms of antenatal depression (95CI%: 7.2% to 11.2%). After adjustment, the results showed that severe family dysfunction (AOR: 3.67; 95% CI: 1.88 to 7.14) and low level of self-efficacy (AOR: 3.16; 95% CI: 1.37 to 7.27) were associated with antenatal depressive symptoms($p < 0.05$). Furthermore, self-efficacy level partially mediated the association between family functions and antenatal depressive symptoms(β=-0.05, 95%CI: -0.07 to -0.03, $p < 0.05$), and the mediating effect accounted for 17.09% of the total effect.

Conclusions: This study reported 9.2% positive rates of antenatal depression symptoms among women in the third trimester of pregnancy in Hengyang City, China. The mediating effect of self-efficacy on the association between family functions and antenatal depression symptoms among women in the third trimester of pregnancy was found in this study, which provide a theoretical basis to maternal and child health personnel to identify high-risk pregnant women and take targeted intervention for them.

Keywords：antenatal depression symptoms；self-efficacy；family functions；China

Strengths and limitations of this study

- This study aimed to assess the prevalence of antenatal depressive symptoms among women in the third trimester of pregnancy, and completely evaluate the effect of self-efficacy correction between family functions and the antenatal depressive symptoms. This study provides evidence and support for identifying high-risk pregnant women with emotional problems in order to take early intervention measures.
- In this study, the selection of sample is representative, pregnant women were enrolled from community health service centers, with low no-response rate and recall bias.
- The cross-sectional study limited the ability to make causal inferences. Future studies should investigate the causal relationships among family functions, self-efficacy and antenatal depression symptoms with longitudinal designs.

Word count: 3296

Instruction

Depression was the most common mood disorders in the general population, the prevalence ranged from 5% to 10%, which of women was about twice as high as that of men, and childbearing age was the peak of the disease[1]. Furthermore, depression was one of the most common complications during pregnancy[2]. The meta-analyses of perinatal depression reported the prevalence was 6% to 13%[3]. The prevalence of antenatal depression was significantly higher than any other time[4], especially in the third trimester of pregnancy [5]. Also note that, the prevalence of depression in less developed countries is higher than that in developed countries, vary from 19% to 25% during pregnancy [6-8]. Depression not only directly affected the physical and mental health of the pregnant women[9], but also indirectly did harm to the health of the next generation[10]. During pregnancy, depression symptoms have been associated with self-harm, suicidal-ideation, placental abruption, preterm delivery, they also might lead to low birth weight, low Apgar score, maladaptive emotional and behavioral development of offsprings[11 ,12]. From what has been discussed above, antenatal depression has become a global public health issue[13], particular attention needs to be paid to antenatal depression among women in late pregnancy in developing countries. However, many studies on maternal depression mainly focused on postnatal depression and there is less data available on antenatal depression in China.

Family is an important emotional support sources, family functions play an important role in human life and social development. For pregnant women, family functions refer to the effectiveness of family members' emotional connection, family rules, family communication and coping with external events in the family system during pregnancy[14], including family adaptation, family partnership, family growth, family affection, family resolve. Generally speaking, in well-functioning families, pregnant women can get support and guidance from other members when they encounter difficulties and crises, and obtain material and emotional satisfaction. On the contrary, family can also be a source of conflict and stress, a study proposed family members' expectations on the newborn were usually manifested through excessive attention and care to pregnant women, which might increase negative effects and stress to the pregnant women[15]. It is not clear whether there is a factor that influences the association between family functions and antenatal depression symptoms, leading two these two different effects. Self-efficacy is one of the possible factors of this contradictory result. A study suggested self-efficacy was negatively correlated with depression, anxiety and other adverse emotional problems[16]. For pregnant women, self-efficacy can be expressed as the conviction that women can successfully execute behaviors required to produce a desired outcome during pregnancy[17]. Self-efficacy may affect or determine pregnant women’s thinking mode, emotional response mode and the choice of behavior, which might be self-aiding or self-hindering [18]. The mediating effect of self-efficacy in the association between family functions and depressive symptoms has not been proven during pregnancy. Based on the above theory, .this study aims to explore the prevalence of antenatal depressive symptoms among pregnant women during their third trimester, and completely assess the association between family functions, self-efficacy and antenatal depressive symptoms, in hopes of providing medical personnel with some useful information that can aid early mental interventions on high-risk pregnant women.

Methods

Participants and procedure

This cross-sectional study was conducted in urban communities of Hengyang City, Hunan Province, China， from July to October, 2019. A total of 813 eligible individuals from 14 communities were involved by multi-staged cluster random sampling method. The specific sampling steps are as follows: there were five districts in urban Hengyang, each street was numbered, randomly selected a street from each district. Then, proportional sampling was carried out at a proportion of 1/3, 14 communities were included. The sample size calculation formula for cross-sectional studies was used to calculate the minimum theoretical sample size for this study. According to the prevalence of antenatal depression symptoms, which have been reported in a previous study[19], d=0.1, α=0.05. Finally, 812 people were required in order for the participants to represent the population. All pregnant women who were registered in community health service centers and meeting the inclusion criteria were potential subjects in this study(n=819). The inclusion criteria for the study were as follows: 1. women in the third trimester of pregnancy; 2, pregnant women over 16 years old ;3. pregnant women who had local household registration, or migrant people who lived in urban of Hengyang City for more than 6 months. The exclusion criterion: 1. pregnant women with cognitive disorders, severe mental illnesses or other serious diseases cannot fill out the questionnaire by themselves; 2. pregnant women who refused to participate in the study. Through the information provided by the community maternal management system, we contacted each potential recruiter and made an appointment for the interview time. Accompanied by the community maternal and child health personnel, trained investigators handed out questionnaires by calling at the house and collected them on the spot. 813 participants were given written information about the purpose of this study and signed a written informed consent. Participants were expected to filled out structured questionnaires by themselves. In addition, the trained research assistants from Xiangya School of Public Health, Central South University would always available to provide assistance and ensure independent responding. Although we strongly encouraged all potential recruiters to participate in our research, there were still six people were excluded, because of refusals to respond and failure to contact. The response rate of questionnaires was 99.3% (813/819). Ethics approval was provided by the Ethics Committee of Xiangya School of Public Health, Central South University (XYGW-2019-056).

Patient and public involvement

We did not involve patients or the public in our work. Each participant received a report describing the results of our study.

Measures

The questionnaire included four sections: demographic characteristics, the revised Chinese version of Family Adaptation Partnership Growth Affection and Resolve Index（APGAR）, the General Self-efficacy Scale (GSES) and Patient Health Questionnaire（PHQ-9）. Demographic characteristics included marital status (stable, unstable), occupation (employed, unemployed), education level (senior school and below, college / university degree and above). In this study, being married was defined as being in a stable marriage. Unstable marriage including unmarried, divorce, widowhood.

Assessment tools for family functions

Family Adaptation Partnership Growth Affection and Resolve Index（APGAR）was originally developed by Smilkstein (1978) [20], which was a simple self-assessment tool for evaluating the subjective satisfaction of family functions. Five items were used to evaluate five different aspects of family function: family adaptation, family partnership, family growth, family affection and family resolve. Family APGAR index was answered on a 3-point Likert scale from “often” (two points) to “rarely” (zero point). The total score was zero to ten points, good family function has a high family APGAR index between seven and ten, family dysfunction has a moderate family APGAR index between four and six, and severe family dysfunction has a low family APGAR index less than three. Family APGAR index has been widely used and has good reliability and validity[21]. In this study, the Cronbach's α is 0.876.

Assessment tools for self-efficacy

The General Self-efficacy Scale (GSES) was publicized in 1981 by Ralf Schwarzer and translated into Chinese by Zhang in 1995[22,23], which was used to evaluate the self-efficacy level of pregnant women. There are ten items, which were measured using a 4-point Likert scale from “absolutely wrong” (one point) to “absolutely right” (four points). According to the norm of using the GSES, the method of calculating the final self-efficacy score was to divide the total score by ten. The final score ranged from one to four, based on partition criterion for scale, self-efficacy level could be divided into three levels: high (3.1-4), medium (2.1-3), and low (1–2)[24]. The Chinese version of GSES has good reliability and validity which has been validated by et al[23].The Cronbach' α of this scale was 0.898 in this study.

Assessment tools for antenatal depression symptoms

Patient Health Questionnaire（PHQ-9）were used to assess the subjective depressive symptoms of pregnant women during the last two weeks in this study. PHQ-9 was revised according to the diagnostic criteria of DSM-Ⅳ[25], which was widely known as simple self-management tools and used in clinical and investigation research[26]. PHQ-9 consisted of nine items, each item described a symptom of depression: 1. loss of pleasure; 2. be down in spirits or hopelessness; 3. sleep disorder; 4. lack of energy; 5. diet disorder; 6. self-deprecation; 7. trouble concentrating; 8. changes in physical behavior; 9. thoughts of self-harm. Of this scale, subjects rated the frequency of each symptom using a scale of descriptors: not at all, sometimes, more than half the days, nearly every day (scored from zero to three). The total score is 27 points, usually ten points were used as the positive critical value[27]. The Chinese version of the PHQ-9 has been validated by Yu et al[28].The Cronbach' α of this scale was 0.773 in the study.

Statistical analysis

The method of double input with *EpiData 3.1* was adopted. *SPSS 19.0* software were used for statistical analysis. Categorical variables are expressed as *n (%)*, the χ2 test was applied for comparing the different characteristics between participants in two groups (depressive symptoms vs no depressive symptoms). The crude odds ratio (COR), adjusted odds ratio (AOR) and 95% confidence interval (95% CI) were reported by multivariate binary logistic regression models. The adjusted variables including marital status, occupation and education. A structural equation model was established by *AMOS 24.0*. Based on the assumption in this study, family APGAR index as predictors, self-efficacy as mediator, and antenatal depression symptoms as outcome. The total effect (weight c) of family functions on antenatal depression symptoms was composed of a direct effect (weight c') of the family functions on the antenatal depression symptoms and an indirect effect (weight a*b) of family functions on antenatal depression symptoms through a proposed mediator. Bootstrapping is a non-parametric resampling method that generates an empirical approximation of the sampling distribution of a statistic from the available data and constructs confidence intervals for the indirect effect[29]. Bootstrap method was used to examine the effect of self-efficacy in explaining the relationship among family functions and antenatal depression symptomss[30].The confidence interval was set at 95%. Statistical significance level was accepted as $p < 0.05$. All statistical tests were 2-sided.

Result

Characteristics of participants and the prevalence of antenatal depressive symptoms

In the study, the majority of participants were in a stable marriage (89.5%) and were employed (73.7%). More than half of them have college/university degree and above (58.1%). 60.4% of them have better family functions, 31.5% and 8.1% have moderate and severe family dysfunction, respectively. 60.9% of them have medium levels of self-efficacy, 22.6% and 16.5% have low and high level, respectively (**Table1**). According to the standard of division, taking ten points as the positive critical value of PHQ-9, 75 (9.2%) participants reported antenatal depressive symptoms within two weeks (95CI%: 7.2% to 11.2%).

The results of Chi-square tests and multivariate binary logistic regression analysis

According to the results of Chi-square tests shown in **Table 1**, the differences in family functions and self-efficacy between the two groups were statistically significant ($p < 0.05$). Besides, the results of multivariate binary logistic regression showed that severe family dysfunction (AOR: 3.67; 95% CI: 1.88 to 7.14) and low level of self-efficacy (AOR: 3.16; 95% CI: 1.37 to 7.27) were the risk factors for antenatal depressive symptoms, after adjusted for occupation, marital status and education. (**Table2**)

Table 1. The characteristics of the two groups of participants were compared (depressive symptoms vs no depressive symptoms).

Variables	Depressive symptoms （n=75）	No depressive symptoms （n=738）	Total （n=813）	χ^2 value	*p* value
Marital status				0.21	0.65
Stable	66(88.0)	662(89.7)	728(89.5)		
Unstable	9 (12.0)	76 (10.3)	85(10.5)		
Occupation				0.04	0.84
Employed	56(74.7)	543(73.6)	599(73.7)		

Unemployed	19(25.3)	195(26.4)	214(26.3)		
Education				0.39	0.53
Senior school and below	34(45.3)	307(41.6)	341(41.9)		
College / university degree and above	41(54.7)	431(58.4)	472(58.1)		
Family functions				23.77	0.00
Severe family dysfunction（0-3）	17(22.7)	49 (6.6)	66 (8.1)		
Moderate family dysfunction（4-6）	22(29.3)	234(31.7)	256(31.5)		
Better family functions（7-10）	36(48.0)	455(61.7)	491(60.4)		
Self-efficacy				21.65	0.00
Low level（1-2）	33(44.0)	151(20.5)	184(22.6)		
Middle level（2.1-3）	34(45.3)	461(62.5)	495(60.9)		
High level（3.1-4）	8 (10.7)	126(17.1)	134(16.5)		

Data are presented as n (%).

Table 2

Multivariate binary logistic regression analysis of family functions and self-efficacy associated with antenatal depression symptoms.

Variables	COR* (95% CI)	AOR** (95% CI)
Family functions		
Severe family dysfunction	**3.67(1.88,7.14)**	**3.67(1.88,7.14)**
Moderate family dysfunction	0.99(0.56,1.74)	0.99(0.56,1.74)
Better family functions	**1.00**	**1.00**
Self-efficacy		
Low level	**3.16(1.37,7.27)**	**3.16(1.37,7.27)**
Middle level	1.14(0.51,2.55)	1.14(0.51,2.55)
High level	**1.00**	**1.00**

Abbreviations: COR, crude odds ratio; AOR, adjusted odds ratio.

* Multivariate binary logistic regression model.

**Some general characteristics were adjusted (marital status, occupation and education).

Characters in bold indicate statistical significance, *p* < 0.05.

Mediating effect of self-efficacy level between family functions and depressive symptoms

There was a significant correlation between family functions, antenatal depressive symptoms and self-efficacy in pregnant women. In indirect effects, family functions showed a positive correlation with self-efficacy(β=0.30, 95%CI: 0.24 to 0.37, $p < 0.05$), and self-efficacy showed a negative correlation with antenatal depression symptoms(β=-0.15, 95%CI: -0.22 to -0.08, $p < 0.05$). In direct effect, family functions showed a negative correlation with antenatal depression symptoms(β=-0.24, 95%CI: -0.31 to -0.16, $p < 0.05$)(**Table 3**).

Self-efficacy level partially mediated the association between family functions and depressive symptoms, and the mediating effect accounted for 17.09% of the total effect. The mediation model of the association between family functions and antenatal depression symptoms by self-efficacy is shown in **Figure 1**.

Table 3. Mediation role of self-efficacy in the association between family functions and antenatal depression symptoms (*n*=813, Bootstrap=5000)

Paths	β	*SE*	BCa 95%CI		*p*
			Lower	Upper	
Direct effects					
Family functions→Self-efficacy	0.30	0.03	0.24	0.37	0.00
Family functions→Antenatal depression symptoms	-0.24	0.04	-0.31	-0.16	0.00
Self-efficacy→Antenatal depression symptoms	-0.15	0.04	-0.23	-0.08	0.00
Indirect effect					
Family functions→Self-efficacy→Antenatal depression symptoms	-0.05	0.01	-0.07	-0.03	0.00

β, *SE* and 95%CI were the standardized regression effect value, standard error and 95% confidence interval of the direct and indirect effect estimated by the percentile bootstrap method. BCa = Biased-Corrected and Accelerated 5000 bootstrapping; adjusted variables: marital status, occupation, education level.

Discussion

In this study, the prevalence of antenatal depression symptoms is 9.2%(95CI%: 7.2% to 11.2%), which was similar to the findings of previous studies[31 ,32]. Besides, the findings showed that the risk of depression symptoms in participants who had family dysfunction was 3.67 times as much as that in the reference group(better functions group), family functions were directly and negatively associated with antenatal depression symptoms among women in the third trimester of pregnancy, the finding was in line with the study by Jin et al. in China[33]. A study which carried out in Taiwan, China also reported that pregnant women with antenatal depression symptoms tended to have lower family APGAR scores[34]. Probably because Chinese people attach great importance to the family clan relations, they regard the family and its members as one of the most important sources of social support and spiritual sustenance. Pregnancy is viewed as a stressor, with the increasing of sensitivity and vulnerability of women in pregnancy, they are more likely to be influenced by the negative external environment and life events, which may lead to depression and other harmful emotional problems. In a well-functioning family, family members can detect the physical and psychological changes of women during pregnancy, and provide timely and effective spiritual and material help when pregnant women cope with stressor and crisis, so as to enhance their sense of family belonging, identity[35]. However, family dysfunction reflects that pregnant women can't acquire enough attention, love, identity and assistance from families, even family may be the source of mental pressure, so that depressive symptoms starts or aggravates. In this study, no significant association was found between high level of family functions and depressive symptoms among women in their third trimester of pregnancy.

Furthermore, this study found that self-efficacy had a significant mediating effect on the association between family functions and antenatal depression symptoms, which was also recognized by Faure et al[36]. Self-efficacy varies from person to person, and often changes within the individual over time and in response to specific experiences and environment. The level of self-efficacy could predict the mental activity and attitude in the face of difficulties and stressors, which would lead to different emotional response outcome[37]. People with high self-efficacy are able to control self-abandoned thoughts, tend to handle situations rationally, are willing to accept the challenges of emergency. In other words, when a pregnant woman receives insufficient support, everyday life care, spiritual comfort and sympathy from her families, good self-efficacy can alleviate her negative emotions and depressive symptoms. On the contrary, people with low self-efficacy are prone to faltering, deal with problems emotionally, are helpless in the face of stress, and easily are distracted by fear, panic, and shyness, which are more likely to have depressive symptoms. Even in a family with good family functions, pregnant women with low self-efficacy could not make full use of family support and turn it into the motivation to improve their negative emotions[38]. This may be a pathway for self-efficacy to play an intermediary role in the association between stressors and stress outcomes, which also in line with the model of Pearlin et al [39]. In addition, the mediation effect value is 17.09%, indicated partial mediation. The finding reflected that there were other mediators in the association between family functions and antenatal depression symptoms. Some other potential mediators have been proposed in previous studies among pregnant women. A study by Waqas et al. in Pakistan showed that social support was mediated the association between total number of children, gender of children and antenatal depression[40]. As a potential mediator, relational resilience affected the association between adverse childhood experiences and prenatal depressionl[41]. However, the mediating effect of these variables has not been demonstrated in the relationship between family functions and antenatal depressive symptoms, which is worth exploring in future study.

The samples of this study were selected from pregnant women who were enrolled from community health service centers, with low no-response rate. Compared with the study with hospital samples, the samples were more representative of the truth of ordinary pregnant women. Women in the third trimester of pregnancy were selected to evaluate their antenatal depression symptoms for nearly two weeks, with less recall bias. There are some limitations in this study. First, this study was a cross-sectional study, although this study proved the association between family functions, self-efficacy and antenatal depression symptoms based on the established structural equation model, the validity of the theory still needs to be further followed up or tested through intervention experiments. Second, in this study self-filled questionnaires were used, there was an inevitable reporting bias in this study, which might lead to the underestimation of positive reporting rate of depressive symptoms.

Conclusion

In summary, in this study the prevalence of antenatal depression symptoms is 9.2% among women in the third trimester of pregnancy. In this study, the findings suggested that pregnant women's self-efficacy mediated the association between family functions and antenatal depression symptoms. On the one hand, family functions can negatively predict antenatal depression symptoms; on the other hand, self-efficacy can indirectly and negatively predict antenatal depression symptoms. Based on this finding, maternal and child health personnel can provide some early mental interventions to high-risk pregnant women, including family counseling courses for pregnant women's families to improving family functions and peer education courses for pregnant women to increase their sense of self-identity and self-worth according to the actual needs. Reducing the pain and economic burdens of depression both by pregnant women themselves and their families.

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Patient consent Obtained.

Ethics approval Study protocol was approved by the Ethics Committee of Xiangya School of Public Health, Central South University (XYGW-2019-056).

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Figure 1. Structural equation model testing self-efficacy as a mediator in the association between family functions and depressive symptoms. (a) The model has been adjusted for marital status, occupation, education level. The above values have been standardized. (b) *$p < 0.05$

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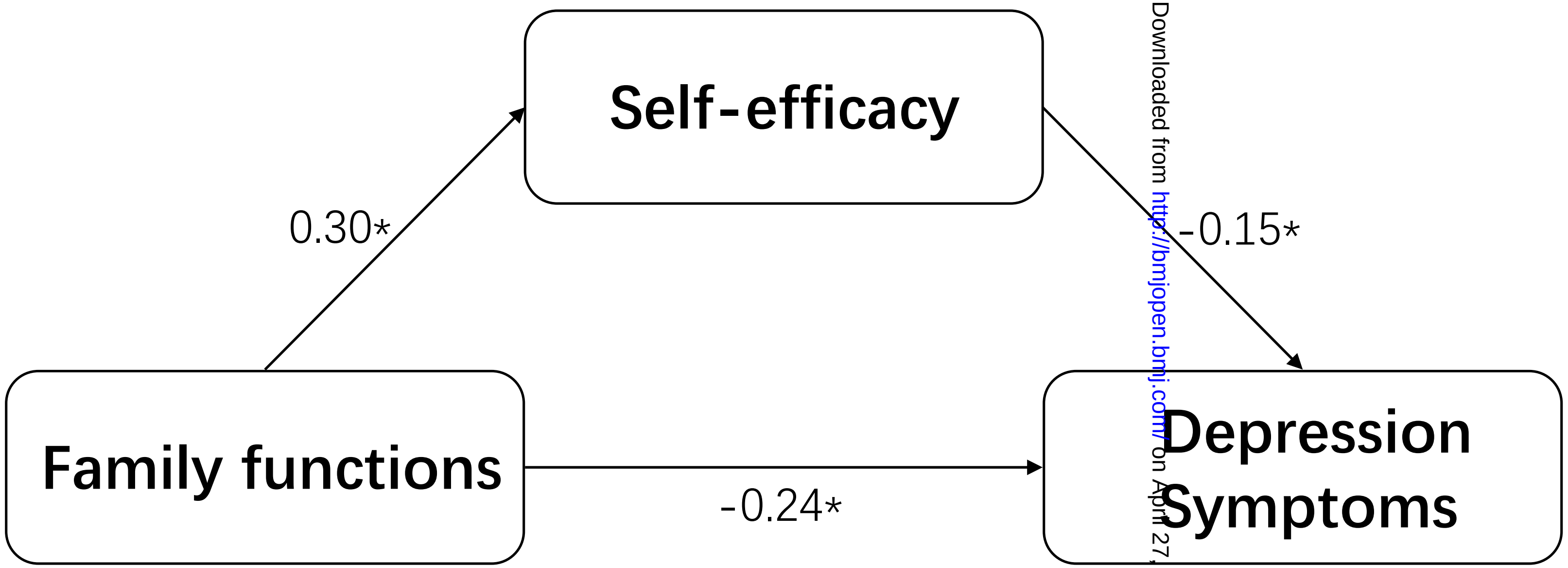
Self-efficacy
0.30*
-0.15*
Family functions
-0.24*
Depression
Symptoms

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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	P1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	P1
Introduction			**P2**
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	P2
Objectives	3	State specific objectives, including any prespecified hypotheses	P2
Methods			**P2**
Study design	4	Present key elements of study design early in the paper	P3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	P3
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	P3
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	P3
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	P3-4
Bias	9	Describe any efforts to address potential sources of bias	P3
Study size	10	Explain how the study size was arrived at	P3
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	P4
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	P4
		(*b*) Describe any methods used to examine subgroups and interactions	P4
		(*c*) Explain how missing data were addressed	P4
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	P4
		(*e*) Describe any sensitivity analyses	No
Results			P5

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	P5
		(b) Give reasons for non-participation at each stage	P3
		(c) Consider use of a flow diagram	No
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	P4-5
		(b) Indicate number of participants with missing data for each variable of interest	No
Outcome data	15*	Report numbers of outcome events or summary measures	P5
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	P5
		(*b*) Report category boundaries when continuous variables were categorized	P5
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	P6
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	P6
Discussion			P6
Key results	18	Summarise key results with reference to study objectives	P6-7
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	P7
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	P7
Generalisability	21	Discuss the generalisability (external validity) of the study results	P7
Other information			P8
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	P8

*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.

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