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The Effect of Educational Intervention with Mobile Health Technology on COVID-19 Induced Stress among Pregnant Women: A Randomized Controlled Trial

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ABSTRACT

Background & aim: The spread of COVID-19 has increased the stress level in pregnant women. The present study was performed to determine the effect of a mobile-based health educational intervention on the stress induced by the COVID-19 pandemic among pregnant women.

Methods: This randomized controlled trial study was carried out on 80 pregnant women (40 sample intervention and 40 control) referred to Gonabad Comprehensive Urban Health Service Centers from October to December 2021 who were selected using stratified random sampling. Data collection tools included demographic questionnaire (12 questions) and the valid and reliable questionnaire of the Corona Stress Scale (CSS-18). The questionnaires were filled out through self-administered method svia the Porsline platform in three stages: before, immediately after, and one month after the intervention. The intervention group received five 30-minute education sessions as twice a week based on the latest Ministry of Health maternity and neonatal health guidelines. The control group received educational content in PDF format. Data were analyzed by Wilcoxon, Benferroni, Mann-Whitney, and independent t-tests using SPSS (version 16).

Results: The mean COVID-19 stress score before the intervention was not statistically significant in the two groups (P= 0.92). After the intervention, the mean stress score of COVID-19 in the intervention group was estimated 48.12 ±12.24, which was significantly lower than the control group (57.02 ± 15.99) (P<0.001).

Conclusion: Mobile-based education intervention reduces COVID-19 stress in pregnant women. It is suggested that this approach be implemented for the provision of healthcare to pregnant women during the COVID-19 pandemic.

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Introduction

Pregnancy is associated with significant physiological and psychological changes. It is a joyful and enjoyable period for pregnant women; however, it is often regarded as a stressful experience (1). The degree of stress exposure increases during this period (2), and it appears to be the most obvious sign of pregnant women's healthy behaviors. Women's sensitivity to stressful situations is higher than men's, and this sensitivity becomes more prominent during pregnancy (3). Approximately 30% of pregnant women experience some type of stress in their daily lives (4). Preterm birth, intrauterine growth retardation, preeclampsia, birth weight loss, and abortion are all related to stress (3). In addition, it affects the neural development of the fetus and the ratio of male to female births, and male births decrease in cases

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of maternal stress (5). Stress leads to a decrease in blood supply to the uterus and thus to the placenta and also leads to attention deficit disorder and autism in children (6).

The COVID-19 disease is a new respiratory disease characterized by symptoms ranging from a common cold to severe respiratory symptoms (7). It spread rapidly throughout the world, causing public health emergencies, particularly among vulnerable populations. Pregnant mothers are also among the high-risk and vulnerable groups (8). The study performed in 2020 on 166 pregnant women in Turkey to determine the effect of the COVID-19 pandemic on perceived sleep quality, stress, and social support found that 88 percent of women had decreased sleep quality, which was significantly associated with perceived stress levels (9).

Another study was conducted in Kashan to evaluate the perceived anxiety and stress of pregnant women during the COVID-19 pandemic and related factors; the results showed that the perceived stress score was 24.57 ± 7.00, which indicates the high level of stress of pregnant women during the COVID-19 pandemic (10). The research conducted in Poland showed that the stress level of pregnant women was moderate to severe during the COVID-19 pandemic (11).

During the COVID-19 pandemic, many pregnant women avoided referring to the doctor regularly due to the fear of contracting the coronavirus. They are also concerned about the fetus and infant, breastfeeding, infant care, screening, and vaccination in these pandemic conditions (10). As a result, it is necessary to maintain mental health and make psychological changes to improve mental health in high-risk groups (12). One of the psychological and social interventions to control stress is education, increasing awareness, and giving useful information to the person (13). There are various educational methods to increase people's awareness. One of these methods is the use of mobile health technology. Mobile health, or mHealth, refers to the use of mobile phones or portable digital devices in healthcare services to improve people's health. It has been proposed since 2003 and is considered one of the sub-branches of electronic health. Mobile health is a term used for medical and public health applications supported by mobile communication devices. Due to the mobile phone's easy portability and internet connection, it is possible for patients to access medical services in any place (14). Mobile health has led to a big transformation in the traditional way of providing health services and can improve health through access to health services due to the pervasiveness of mobile phone technology in different locations all over the world (15). According to the recommendations of the American College of Obstetricians and Gynecologists (ACOG) and the Royal Australian and New Zealand College of Obstetricians and Gynecologists (RANZCOG), the use of telehealth applications is suggested to maintain the prenatal and postnatal care of pregnant women (16,17). In this regard, mobile-based research was conducted in Turkey during COVID-19, and the results showed that the use of mobile phone programs can affect the level of anxiety in pregnant women by increasing access to health services (18). Another study in the Netherlands also confirmed the effectiveness of companion health tools in monitoring blood pressure in pregnant women (19).

Considering the relationship between pregnancy stress and some complications of pregnancy, as well as the significant financial burden of pregnancy stress on the economies of the family (20) and nations, and given that most studies of COVID-19 focused on the physical effects and the possibility of vertical transmission of COVID-19, there are few studies on the effects of the COVID-19 pandemic on pregnant women's mental health (10,11,18); therefore, the present study was conducted to determine the effect of educational intervention with mobile health technology on stress induced by the COVID-19 pandemic in pregnant women.

Materials and Methods

This study was a two-group (control and intervention) randomized controlled trial with the ethics code of IR.GMU.REC.1400.055. The clinical trial registration code is IRCT2021080105204.

The population of this study consisted of pregnant women referred to Gonabad urban health centers from October to December 2021 (three months). Among them, 80 eligible pregnant women were included in the study by

stratified random sampling (n=40 in each group). By visiting urban community health centers, a list of pregnant women was compiled, and they were contacted to participate in the study. Informed consent was obtained from all participants.

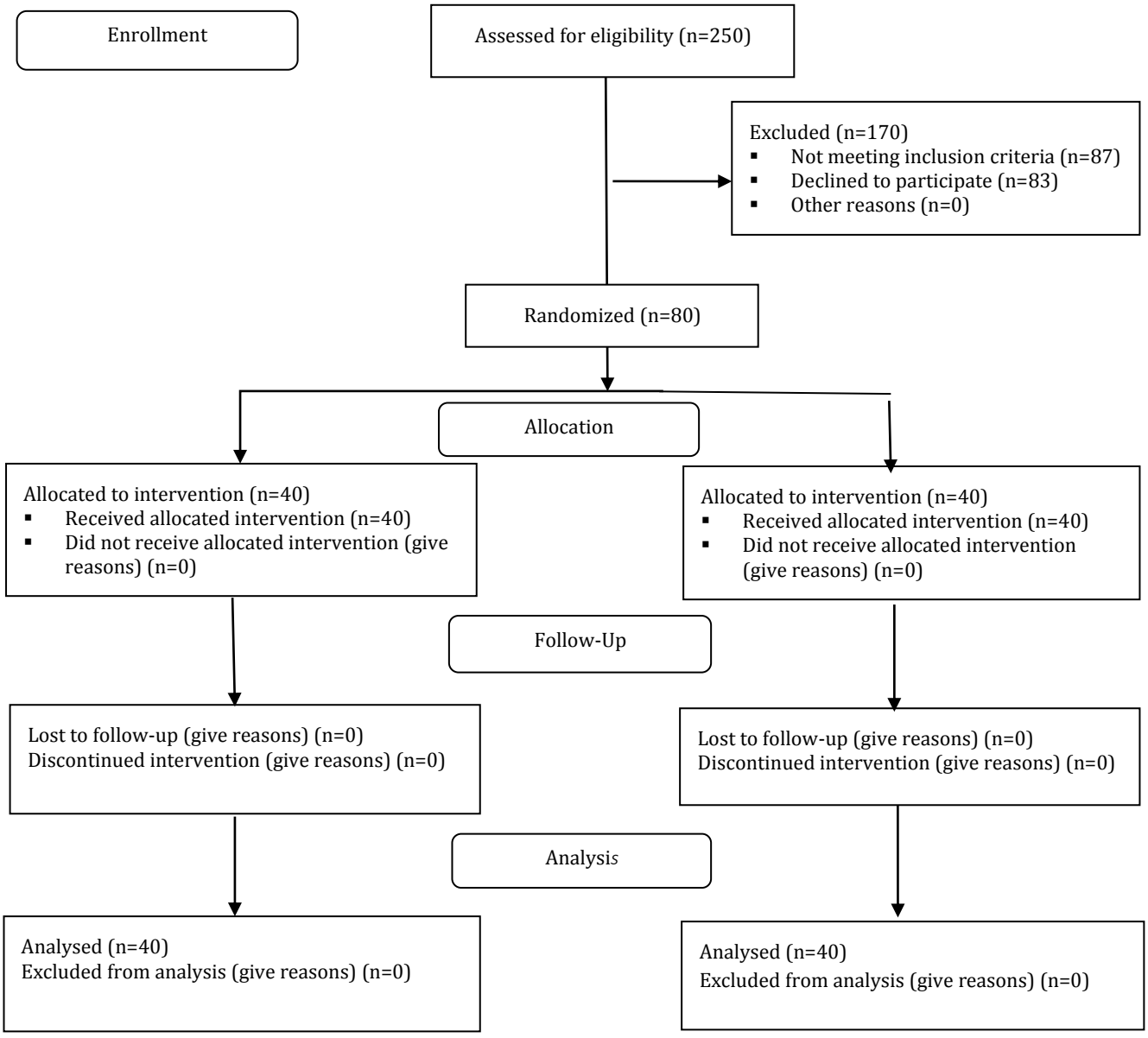

Figure 1. The CONSORT flow diagram of intervention in the two groups

Inclusion criteria were maternal age of 15-45 years, gestational age > 12 weeks, having

reading and writing literacy, no pregnancy complications or diseases such as preeclampsia, eclampsia, gestational diabetes, and amniotic fluid volume disorders, no stressful event other than COVID-19 disease in the previous six months, no mental or physical illness, no history of infertility, having WhatsApp Messenger or the ability to install it on the phone and consent to participate in the study. Exclusion criteria were acute mental and physical illness, the occurrence of a stressful event for the sample during the study, premature rupture of fetal membranes and preterm delivery, diagnosis of abnormal fetal presentation during the study, the occurrence of a traumatic event, infection of the pregnant women with COVID-19 during the study, and failure of sample participants to complete the questionnaires or view educational materials three times during the study period.

The stratified random alocation was applied in such a way that each of the comprehensive centers for health services was considered a stratum. From the list of pregnant women at each center, proportionate to the sample size and the population of that center, the sample were randomly selected and contacted. Participants were then randomly assigned to either the intervention or control groups using quadruple permutation blocks. The six possible block modes (AABB, ABAB, BBAA, BABA, ABBA, and BAAB) were initially listed, and each block was assigned a number between one and six. A number was chosen from a table of random numbers, and individuals were thus randomly assigned to experimental (A) or control (B) groups. This process was repeated until the sample size was reached.

The sample size was calculated using G.Power version 3.9.2.1 software and a similar study (78). Also considering the confidence level and test power of 95%, the sample size was determined as 36 people for each group with a 10% chance of dropping out; 40 people were considered for each group, for a total of 80 people for the entire study (Figure1).

Both the intervention and control groups received educational content in the form of a PDF file. The educational intervention was conducted in the form of a video in five sessions of 30 minutes, two sessions per week, by the first researcher, and only in the intervention group (Table 1). Considering the current situation of the COVID-19 epidemic and the need to maintain social distancing, the sessions were held virtually using mobile health technology. A WhatsApp group was formed for both the control and intervention groups. In the control group, a PDF file of the educational content was provided, and the questionnaires were completed in three stages. The content of the training sessions was selected based on the latest guidelines of the maternal and newborn health department of the Ministry of Health. Data collection tools included demographic questionnaire and the standard questionnaire of Corona stress scale (CSS-18).

The standard questionnaire of the Corona stress scale was designed to check the level of stress based on the literature related to stress and had 18 questions. This scale has three sub-scales: mental states of stress (10 questions), physical states of stress (5 questions), and behaviors related to corona stress (3 questions). The total stress score of corona is obtained from the sum of all the questions and higher scores mean more stress. The scale is scored on the 5-point Likert scale of never (score 0), rarely (score 1), sometimes (score 2), often (score 3), and always (score 4).

This questionnaire was designed and validated in Iran by Salimi and colleagues in 2019. Cronbach's alpha was 0.99 for the entire questionnaire, and the construct validity was used to confirm the validity of the questionnaire, and indicators such as RMSEA (Root Mean Square Error of Approximation), SRMR (Standardized Root Mean Square Residual), GFI (Goodness of fit index), AGFI (Adjusted goodness of fit index) were confirmed in the factor analysis, which indicates the good fit of the scale (21). The questionnaires were self-administered, and they took about 10 minutes to complete.

The demographic questionnaire includes two sections: personal information (mother's age, spouse's age, place of residence, mother's education, spouse's education, economic status, employment status of mother and her husband), and pregnancy-related data (number of deliveries, type of delivery, gestational age and history of chronic diseases,). The demographic

questionnaire was completed before the intervention, and the Corona stress scale was completed before, immediately after, and one month after the intervention by the sample participants on the porcelain platform. Data were analyzed by SPSS (version 16) using Wilcoxon, Benferroni, Mann-Whitney, Kolmogorov-smirnov, and independent t-tests.

Results

The mean gestational age at the time of enrolment in the intervention group was 26.25±7.36 weeks, and in the control group, was 24.65±7.67 weeks (P= 0.34).

Table 1. Educational session content based on the Ministry of Health Department of Maternal and Neonatal Health instructions via mobile

Session	Title	Goals
First session	COVID-19 disease explanation, personal hygiene, and transmission modes	At the end of the session, the pregnant mother will be able to: 1- Explain the modes of transmission and prevention of COVID-19 disease. 2- Understand the advantages of personal hygiene in the prevention of COVID-19 disease. 3- Understand the risks of poor personal hygiene and the prevention of COVID-19 disease. 4- Decide to observe personal hygiene under any circumstances. 5- Correctly apply personal hygiene principles and methods.
Second session	COVID-19 in pregnancy and childbirth	At the end of the session, the pregnant mother will be able to: 1- Describe the risks of coronavirus infection during pregnancy. 2- 2. Describe the early signs of Coronavirus disease in pregnant women. 3- Understand the nutritional recommendations in the context of the COVID-19 epidemic. 4- Compare the advantages and disadvantages of receiving a coronavirus vaccine. 5- Believe that not adhering to COVID-19 disease prevention tips is dangerous to her and her baby. 6- Consider it dangerous for her and the fetus to participate in the gatherings. 7- Understand the significance of care and separation at home. 8- Understand the doctor's or midwife's advice on the safety of COVID-19 vaccines. 9- Observe the doctor's or midwife's recommendations for COVID-19 disease prevention. 10- Confirm that not receiving prenatal care is dangerous to her and her fetus. 11- Despite the risk of coronavirus, decide to go to the hospital when necessary. 12- Stay at home in quarantine if she becomes ill and follow the safety precautions. 13- Receive the vaccine if deemed necessary by the doctor's diagnosis.
Third session	COVID-19 and breastfeeding	At the end of the session, the pregnant mother will be able to: 1- Describe methods for transmitting the Coronavirus from an infected mother to an infant while breastfeeding. 2- Know the necessary healthcare measures to take while breastfeeding her baby, in the event of a Coronavirus infection. 3- Understand the possible ways for virus transmission from an infected mother to an infant. 4- Know the benefits of breastfeeding an infant. 5- Follow the doctor and midwife's advice regarding breastfeeding her baby during the COVID-19 epidemic. 6- Understand the risks of not breastfeeding her infant 7- Decide to breastfeed her infant despite the difficulty of breastfeeding in the case of Coronavirus disease infection. 8- Breastfeed her baby while following hygienic guidelines.

Session	Title	Goals
Fourth session	COVID-19 and infants	At the end of the session, the pregnant mother will be able to: 1- Recognize possible coronavirus symptoms in an infant. 2- Know the necessary steps when the baby's test is positive. 3- Understand the health tips during home quarantine. 4- Pay attention to the doctor's and midwife's advice on the importance of mother-infant contact. 5- Decide to observe kangaroo mother care in the context of the COVID-19 outbreak. 6- Perform neonatal screening for COVID-19 pandemic. 7- Provide the necessary care for infants and toddlers during the Corona disease pandemic.
Fifth session	Clarifying ambiguities	**Question and answer** **Mothers' questions and ambiguities are answered**

Table 2. Demographic characteristics of the participants in the intervention and control groups

Variable	Intervention N (%)	Control N (%)	Total N (%)	P value
Place of residence				
City	35(87.**5**)	33(82.5)	68(85.0)	
Village	5(12.5)	7(17.5)	12(15.0)	0.53
Total	40(100)	40 (100)	80(100)	
Mother's education				
University	40	16(40)	40	
Diploma	23	12(30.0)	23	0.10
High school	17	12(30.0)	17	
Total	80(100)	40(100)	80(100)	
Spouse education				
University	18(45.0)	19(47.5)	37(46.3)	
Diploma	17(42.5)	13(32.5)	30(37.5)	0.53
Highschool	5(12.5)	8(20.0)	13(16.3)	
Total	40 (100)	40(100)	80(100)	
Mother's occupation				
Housewife	32(80.0)	33(82.5)	85(81.3)	
Employed	8(20.0)	7(17.5)	15(18)	0.77
Total	40(100)	40(100)	80(100)	
Spouse's occupation				
Freelance	27(67.5)	29(72.5)	56(70.0)	
Employee	13(32.5)	11(27.5)	24(30.0)	0.62
Total	40(100)	40(100)	80(100)	
Economic status				
Low	6(15.0)	9(22.5)	15(18.8)	
Average	34(85.0)	31(77.5)	65(81.3)	0.39
Total	40(100)	40(100)	80(100)	
Types of previous deliveries				
Cesarean section	10(25.0)	9(22.5)	19(23.8)	
Natural birth	14(35.5)	12(30.0)	26(32.5)	0.79
Non	16(40.0)	19(147.5)	35(43.8)	
Total	40(100)	40(100)	80(100)	
Number of pregnancies				
one	14(35.0)	17(42.5)	31(38.8)	
Two	18(45.0)	11(47.5)	29(36.3)	0.24
Three and more	8(20.0)	12(30.0)	20(25.0)	
Total	40(100)	40(100)	80(100)	

The mean age in the intervention group was 29.23±5.04 years, and in the control group was 28.10±8.36 years (p=0.46). Other demographic and obstetric characteristics of the participants were presented in Table 2.

The results showed that at the start of the study, no statistically significant differences were found between the two groups in terms of demographic and obstetric characteristics. After identifying the normality of the data (Kolmogorov-Smirnov), the Mann-Whitney test was applied to compare the groups. The results showed that the mean score of Corona Stress Scale score in the intervention group before, immediately after, and one month after the intervention in the experimental and control groups was significantly different. Also, the mean score of Corona Stress Scale in the intervention group was statistically significant compared to the control group.

Table 3. Mean scores of Corona Stress Scale (CSS-18) before, immediately after, and one month after educational intervention in intervention and control groups

Variable	Intervention		Control		Mann-Whitney test result
	SD ± Mean	median (inter quartile range)	SD ± Mean	median (inter quartile range)	
Corona- related stress					
Before intervention	59.97±9.90	64.00 (15.75)	60.42±11.42	62.00 (14.50)	P=0.92 Z=-0.01
Immediately after the intervention	53.10±11.35	55.00 (19.50)	59.45±9.06	63.00 (12.75)	P<0.001 Z=-0.53
One month after the intervention	48.12±12.24	49.00 (18.50)	57.02±15.99	63.00 (18.25)	P<0.001 Z=-0.62
Friedman test result	P<0.001		P=0.44		

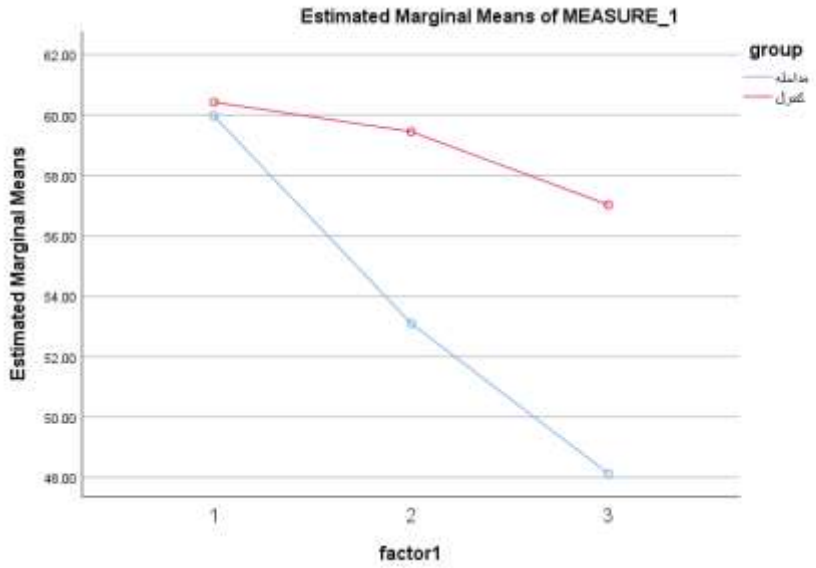

Figure 2. Comparison of corona stress scale scores before, immediately after, and one month after the educational intervention in the intervention and control groups

Furthermore, Friedman test results revealed that the corona stress score in three time periods (before, immediately after, and one month after the intervention) was statistically significant in the intervention group ($P < 0.001$) but not in the control group ($P = 0.44$) (Table3).

The Wilcoxon test with Bonferroni correction result revealed that in the intervention group, there was a statistically significant difference between the Corona stress score before and immediately after the intervention ($P< 0.001$).

Also, the Corona stress score was statistically significant before and one month after the intervention ($P<0.001$). This test revealed a statistically significant difference in the intervention group immediately after the intervention and one month later ($P < 0.001$) (Figure2).

Discussion

The present study was conducted to determine the effect of educational intervention with mobile health technology on stress induced by the COVID-19 pandemic in pregnant women. According to the findings of the present study, educational intervention with mobile health technology can reduce COVID-19-related stress levels in pregnant women. Also, the mean score of COVID-19-related stress decreased significantly before and immediately after the educational intervention in the intervention group. Furthermore, the changes in the mean score of COVID-19-related stress in pregnant women before and one month after the educational intervention had a significant decrease in the intervention group, but this decrease was not significant in the control group. Several studies have found that the COVID-19 pandemic increases stress in pregnant women (22-24).

Mikolajkow et al. (2020) conducted a study aimed at investigating stress levels and the general psychological state of Polish pregnant women during the COVID-19 pandemic. The results showed that 17% had a high level of stress, 11% had a high level of internal psychological stress, and 13% had a high level of external stress. Both "fear of lack of social support" and "fear of infection" affected stress levels (23). Therefore, while continuing care and counselling, it is crucial to protect this group from pregnancy distress and the risks of the COVID-19 pandemic (25). Mobile health applications, which can be easily obtained through virtual application markets, can meet this need (26).

In the study by Hashemzahi et al. (2021), which determined the effect of self-care training for COVID-19 through telemedicine on the perceived stress and anxiety of coronavirus disease in pregnant women, the results showed that self-care training through telemedicine is effective in reducing the perceived stress and anxiety of pregnant women during the coronavirus epidemic (27). The educational content in the present study was based on the standard guidelines of the Ministry of Health, and one of the special points of this research was determining the goals of each session before the intervention. In the aforementioned study, Cohen's Perceived Stress Questionnaire was used to measure stress during the COVID-19 pandemic, but in the present study, the Corona Stress Scale was used, which is a more appropriate tool for measuring stress related to Corona.

Aslani et al. (2015) conducted a study to investigate the effect of group stress management training with a solution-oriented approach on pregnancy stress in 60 pregnant women with a gestational age of 17-20 weeks. Educational intervention with a solution-oriented approach can reduce the stress of pregnant women (28). Although the education model of the mentioned study was different from the present study, both confirmed the effective role of education in reducing the stress level of pregnant women.

Basharpour et al. (2016) investigated the effectiveness of mindfulness-based stress reduction training (MBSR) on the quality of life and well-being of pregnant women in Ilam, west of Iran. Educational intervention based on mindfulness can lead to the improvement of the mental state of pregnant women (29). Also, Karbalai et al. (2019) showed that self-care training was effective in reducing perceived stress, health literacy, and self-care behaviors in women with gestational diabetes. Self-care significantly reduces perceived stress and increases self-care behaviors in women with gestational diabetes (30). In another study, Shirazi et al. (2016) used mindfulness

techniques to teach stress management to pregnant women. The results confirmed the role of education in managing and reducing the stress of pregnant women (31). Similar to the results of the present study, these studies showed that education can reduce stress. In the study of Shirazi et al. (2016), educational CDs were available to the subjects during the study. Continuity in education and the availability of materials without time and place restrictions can have a positive role in the results of this research. Moulaei et al. (2021), in their study, evaluated a mobile phone-based application to provide self-care for pregnant women during COVID-19. The results suggest that mobile health-based applications can increase self-care among pregnant women during the COVID-19 pandemic. Also, the use of mobile health technology had a positive effect on the prevention of COVID-19, and in the case of COVID-19 infection, the disease was well managed (32). Their results were similar to the results of the present study. Ozkan and colleagues (2020) examined the impact of the COVID-19 pandemic on pregnancy distress and the use of mobile health applications by pregnant women during the pandemic. The results showed that during the COVID-19 epidemic, the number of pregnant women receiving health services decreased, which led to an increase in the level of distress in pregnant women. The use of mobile health applications to provide health services reduced the level of distress in pregnant women (18). Guo and colleagues (2019) showed that mobile health intervention for the management of gestational diabetes mellitus improves patients' compliance, controls blood glucose, and reduces weight gain; therefore, it decreases the rates of complications in both pregnant women and fetuses (33).

Ammar et al. (2020), in their study, discovered that educational intervention based on the theory of planned behavior could reduce COVID-19 stress levels in dental academics. Behavior changes in the sample led to reduced anxiety and stress, as well as reduced COVID-19 mortality (34). Their study has been done with appropriate methodology and sample size. The educational intervention has been able to reduce the level of stress in the participants. Nosratabadi and colleagues (2022) carried out a study to investigate the impact of virtual education on the fear that COVID-19 causes in pregnant women. The results showed that virtual education reduces the fear of pregnant women caused by the COVID-19 pandemic, and the results were consistent with our study (35). Some studies reported findings that were similar to the current study's findings (36-38). Although the variables and statistical population are different from the present study, the positive role of education was confirmed.

Most studies reported similar results to the present study, except the study of Asadi et al. (2012), where the educational intervention could not have an effect on the sample when choosing the mode of delivery (39). The sample size in their study was different from the present study, and their participants were only 24-28-week pregnant women, while in the present study, pregnant women with gestational ages of >12 weeks constituted the research sample. The number of training sessions in the mentioned study was less than in the present study, which can be one of the reasons for the difference in the results. Also, the purpose of the study and the methodology of their study were different. Choosing the method of delivery can be influenced by the opinions and beliefs of those around the pregnant women; perhaps it is necessary to influence the subjective norms of the participants in a more appropriate way.

One of the strengths of the present study was that, due to the COVID-19 epidemic and the need to maintain social distancing, mobile health technology was used, which allowed pregnant women to benefit from educational content. In addition, the sample were randomly selected, and using this method, the results of the study could be more generalizable to the community. Additionally, we conducted the intervention using the educational materials that the maternal and newborn health department at the Ministry of Health has approved. One of the limitations of the present study was that since the training was provided virtually, sample may not have paid enough attention to it. The use of a self-administered method to complete the questionnaires was another limitation. We attempted to overcome this limitation by adhering to the instructions and urging the

sample to follow the guidelines. Considering the importance of mental health for pregnant women and the effects of stress on pregnant women, it is possible to consider educational intervention using mobile health technology as a cost-effective method with no time or place constraints to improve their mental health status.

Conclusion

Based on the findings of this study, education with mobile health technology can lead to a significant reduction in the level of stress related to COVID-19 in pregnant women. Since educational interventions designed to reduce pregnancy stress are critical and can minimize adverse outcomes for women and infants during the epidemic, it is suggested that this strategy be used in the care of pregnant women and stress management.

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Conflicts of interest

The authors declared no conflicts of interest.

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