Effect of Midwife-led Breastfeeding Counseling based on Bandura's Model on Self-efficacy and Breastfeeding Performance: An Educational Trial Study

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Abstract:
Aim: Breastfeeding Counseling in order to increase Breastfeeding Performance.

Background: Exclusive breastfeeding (EBF) is a policy for increasing children's survival and decreasing the illnesses of children all over the world.

Objectives: The present study investigated the effect of Midwife-led Breastfeeding Counseling based on Bandura's Model on Self-efficacy and Breastfeeding Performance.

Methods: The present study was an educational trial with a pretest-posttest design and a control group. 60 women in the intervention group received 4 session group counseling program based on Bandura's theoretical structures during pregnancy. After that, the second stage of the study was conducted between 1-3 days and 10-15 days after childbirth using the face-to-face method to meet the needs and concerns of mothers about breastfeeding. The control group received no counseling program and only received routine health care.

Results: showed that the awareness means in the intervention group was 25.6 and in the control group, it was 21.1, which showed a significant increase in the intervention group. In addition, it was indicated that the mothers' self-efficacy increased by 18 units in the intervention group and decreased by 1 unit in the control group after the intervention. Findings showed that the attitudes of the intervention group increased by 11 units, and 4 units in the control group after the intervention. 54 mothers in the intervention group and 17 mothers in the control group only used breastfeeding for their babies.

Conclusion: Breastfeeding self-efficacy is an appropriate theoretical model to perform interventions and should be considered to prolong breastfeeding and better performance.

Keywords: Breastfeeding, Self-efficacy, Prenatal care, Reproductive health, Midwife, Counseling.

1. INTRODUCTION

Exclusive breastfeeding (EBF) as a policy for increasing children's survival and decreasing the illnesses of children all over the world has been recommended by the World Health Organization (WHO) and is one of the 3rd Millennium Development goals. All countries have been recommended to promote and develop the exclusive breastfeeding program for children up to 6 months after birth [1]. Globally, about 40% of babies are exclusively breastfed; this rate is expected to increase to 50% by 2025. Despite the increasing rate of EBF over the last two decades, it is far from fully reaching the goal designed by UNICEF [2]. Not only can breastfeeding prevent different infections (gastrointestinal, respiratory, and skin) by improving the immune system, but also it is associated with physical and mental development in infancy [3]. Moreover,
EBF can decrease mothers' weight [4], the risk of ovarian cancer [5], and postpartum depression [6]. In a systematic review study in Iran, exclusive breastfeeding was estimated at 53% on 63071 mothers between the years 2014 to 2018 [7]. Although education and correcting the false beliefs about breastfeeding have been effective, the support of family and health personnel, including midwives, has had an important effect on its continuation [8 - 10].

Studies have indicated that, in Iran, 70% of mothers breastfeed their babies after delivery, but less than 50% of them continue it [11]. Different factors such as mother's low literacy, being employed, lack of family support, insufficient knowledge about breastfeeding, type of delivery, gender of the baby, lack of mother's self-efficacy, as well as cultural barriers and lack of health personnel support can be effective [12, 13]. Studies have indicated that breastfeeding can be continued months after delivery if the health personnel can start education during pregnancy and follow it after delivery [8, 14]. In addition, scientific and theoretical methods of training and education can improve mothers' self-efficacy and performance in breastfeeding [9, 15]. One of the theories used to change behavior is Bandura's social cognitive theory (SCT). Introducing the predicting factors and the effective principles in forming a behavior, this theory introduces the knowledge structures, expectations of consequences, values of consequences, self-efficacy, social support, self-regulation, and situational understanding as the most important determinants and guides in designing interventions. According to this theory, only observing others' behavior is insufficient for learning, but mental and motivational processes play an important role in learning. Unlike traditional behaviorists, Bandura believed that external motivations are not the only source of individual motivation. He regarded internal motivations such as pride, satisfaction, and perfection as internal rewards for the individual to learn [16, 17]. The concept of self-efficacy developed by Bandura refers to one's reassurance to successfully perform a task and achieve the goal. Bandura argued that self-efficacy is a constructive ability by which cognitive, social, emotional, and behavioral skills are effectively managed to achieve different goals. According to Bandura, individuals' previous knowledge, skills, and successes are not good predictors of their future performance, but beliefs about their abilities affect their performance [17]. In this regard, the social cognitive theory assumes that behaviors, including breastfeeding-related behaviors, are influenced by individual factors such as attitudes, beliefs, self-efficacy, and behavioral factors such as breastfeeding patterns, as well as social-environmental or interpersonal factors such as verbal support and encouragement [18].

Since breastfeeding and success in this important task depend on various factors, identifying the influential factors will help adopt strategies to prevent early termination of exclusive breastfeeding. This study's aim is to investigate the effect of Midwife-centered Breastfeeding Counseling based on Bandura's Model on Self-efficacy and Breastfeeding Performance.

2. MATERIALS AND METHODS

The present study was an educational trial with a pretest-posttest design with a control group. First, sampling was performed using the multistage method. 3 clusters of health centers (out of 7) were randomly selected. 40 women from each center were selected using the convenience sampling method. The inclusion criteria were Iranian nationality, living in the city of Kermanshah, having a health record in health centers understudy, willingness to participate in the study, normal pregnancy, and gestation age of 32 weeks. The exclusion criteria were emigration during the intervention, infant death, medical prohibition of breastfeeding, and unwillingness to continue participating in the study. Then, the samples were invited to one of the centers and divided into two groups of intervention and control using the 4-block randomization method. 6 blocks were formed, and the letters were placed inside the envelopes with the created sequence, and the samples were assigned to one of the groups based on the opened envelopes they chose.

This study is ethically and scientifically approved under the code IR.ARAKMU.REC.1398.225 in Arak University of Medical Sciences. Using the following formula and assuming α=0.05, a confidence level of 95%, 𝜇=0.2, a study power of 80%, and a standard deviation of 1.56 (39), the sample size was determined to be 60 women in each group. Written informed consent forms was obtained from each woman. The sampling duration was 2 months (from late November to mid-February). The sampling was performed by one of the researchers, who was a midwife-counselor. Counseling during pregnancy was performed in groups, and after delivery, it was performed face-to-face. First, the samples were provided with demographic, awareness, attitude, and breastfeeding self-efficacy questionnaires. Then, the intervention group received a group counseling program based on Bandura's theoretical structures in week 32 of pregnancy. The group meetings were held in 4 groups of 15 for 4 sessions up to 36 weeks. In the first and second sessions, the principle of self-regulation, in the third session, the principle of reciprocal determinism (counseling and training self-efficacy performance), and in the fourth session, the principle of modeling (vicarious experience) was used. After receiving 4 sessions of counseling during pregnancy, the researchers asked mothers for their telephone numbers to make an appointment with them after childbirth. The second stage of the study was conducted between 1-3 days and 10-15 days after childbirth using the face-to-face method and based on the last principle of Bandura's theory (the principle of performance) to meet the needs and concerns of mothers in the intervention groups about breastfeeding (removing obstacles based on the principle of social cognitive theory) in their houses. In counseling sessions, the mothers discussed the subject (the method of group discussion) and the researcher corrected their opinions if necessary, and finally, the conclusion was made and the mothers' questions were answered. The researcher's telephone number was given to the mothers so that they could receive advice in case of problems or concerns. The checklist of breastfeeding performance was completed 8 weeks after delivery. During this period, the control group received no counseling program and only received routine health care. Table 1 presents the contents of...
The tools used in this study were demographic and midwifery questionnaires. Awareness, attitude, self-efficacy and performance were assessed as the main outcomes. The MacMillan et al. questionnaire was used to assess breastfeeding awareness [19]. This questionnaire was used by Mahboobi Ghaza’ani et al. in Iran and its validity and reliability were calculated as 0.89 and 0.85, respectively [20]. 26 items assessed awareness and the correct answers were scored with 1 point and incorrect answers with 0. The total score of the questionnaire is between 0 and 26. The attitude was assessed by the questionnaire of Shaker et al., which consists of 16 items. It was scored based on a 4-point Likert scale (agree, no idea, disagree). The total score is between 16 and 48 [21]. This questionnaire has been used in Iran [22]. Another questionnaire used in this study was Denis’s self-efficacy questionnaire [23]. It has been translated into Persian. It consists of 13 items. All items start with “I always can…” and the options are scored on a 4-point Likert scale (strongly agree, agree, no idea, disagree) [24, 25]. Another tool was the performance checklist consisting of 10 items (4 items were related to the way of breastfeeding and 6 items assess mothers’ performance). Mahboobi Ghaza’ani et al calculated the validity and reliability of the checklist in 2014 (the reliability of performance items was calculated as 90% using the kappa coefficient of agreement). The questions were asked as yes/no questions about exclusive breastfeeding; the higher score indicates better performance (1 point was given to each correct performance and 0 for each incorrect one) [20]. The data were analyzed using Stata 14.

3. RESULTS

The results of the Demographic and obstetric variables in the control and Intervention groups are shown in Table 2. The mean age in group control and intervention was 29.4±6.3 and 29.1±5.3, respectively. 23 (38.3%) in control and 24(40.6%) in intervention group had diploma level. There was no significant difference between demographic and obstetrics in the two groups (Table 2). Also, Table 3 showed that the awareness means in the intervention group was 25.6, and in the control group, it was 21.1, which showed a significant increase in the intervention group. In addition, it was indicated that the mothers’ self-efficacy increased by 18 units in the intervention group, and decreased by 1 unit in the control group after the intervention (Table 3). The other findings are brought out in Table 3.

54 mothers in the intervention group and 17 mothers in the control group only used breastfeeding for their babies (Table 4). The other findings about breastfeeding behaviors brought out in Table 4.

### Table 1. Contents of counseling sessions.

| Sessions 1: Self-regulation structure (awareness and attitude)- gestation age of 32 weeks. | • Introduction and familiarity of the members together.  
| • Explaining the group goals and rules.  
| • The counseling sessions aimed to increase mothers’ awareness through making conversations about the importance of exclusive breastfeeding and its effect on their attitudes (making empathy and common sense among the group members). |
| Session 2: The used structure: the principle of self-regulation learning (mental attitudes and norms), gestation age of 34 weeks. | • Improving mothers and others’ beliefs and norms about the importance of exclusive breastfeeding, asking mothers and the individuals affecting breastfeeding behavior about their feelings, failures, and successes in breastfeeding, and helping them to express their feelings and abilities (understanding the tuitions and guidelines, making empathy and common sense about exclusive breastfeeding in mothers) and accepting it as a value. |
| Session 3: The used structure: the principle of reciprocal determinism (counseling about the performance training, self-efficacy), gestation age of 36 weeks. | • Training the correct way of breastfeeding to mothers by using role-play, mollag, and shows (doing group work with the aim of practical experience and increasing the mothers' self-esteem) to increase self-awareness and self-communication (recognizing and understanding feelings, understanding others' feelings, identifying needs and finding a way to meet them). |
| Session 4: The used structure: modeling (vicarious experience), gestation age of 38 weeks. | • The mothers' empowerment and adaptation through providing a model with successes in exclusive breastfeeding, using role-play with the aim of practical experience of breastfeeding, and decreasing negative stressful feelings through increasing positive feelings of communicating with others.  
| Sessions 5, 6, and 7 (after childbirth): The used structure: the principle of performance (achieving desired performance, resolving problems). | • Helping the mothers to express their positive feelings, discussing the barriers of exclusive breastfeeding and trying to identify them, and finding problem-solving solutions. |

### Table 2. Demographic and obstetric variables in control and Intervention groups.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control Group</th>
<th>Intervention Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean±SD age</td>
<td>6±29.4</td>
<td>29.1±5.3</td>
</tr>
<tr>
<td>Education level of women</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Less than diploma</td>
<td>14 (23.3)</td>
<td>18 (30.5)</td>
</tr>
<tr>
<td>Diploma</td>
<td>23 (38.3)</td>
<td>24 (40.6)</td>
</tr>
<tr>
<td>College education</td>
<td>23 (38.3)</td>
<td>17 (28.8)</td>
</tr>
</tbody>
</table>
### Table 3. Comparison of knowledge, attitude, self-efficacy and behavior of breastfeeding control and Intervention groups.

<table>
<thead>
<tr>
<th></th>
<th>Control Group</th>
<th>Intervention Group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean±SD</td>
<td>Mean±SD</td>
<td></td>
</tr>
<tr>
<td>Knowledge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-intervention</td>
<td>16.4±5.2</td>
<td>12.7±5.7</td>
<td>0.001</td>
</tr>
<tr>
<td>Post intervention</td>
<td>21.1±1.4</td>
<td>25.6±0.66</td>
<td></td>
</tr>
<tr>
<td>Attitude</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-intervention</td>
<td>35.4±5.2</td>
<td>35.8±4.4</td>
<td>0.001</td>
</tr>
<tr>
<td>Post intervention</td>
<td>39.5±7.37</td>
<td>47.5±1.89</td>
<td></td>
</tr>
<tr>
<td>Self-efficacy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-intervention</td>
<td>33.7±11.1</td>
<td>31.7±7.8</td>
<td>0.001</td>
</tr>
<tr>
<td>Post intervention</td>
<td>32.4±14.5</td>
<td>49.9±4.70</td>
<td></td>
</tr>
<tr>
<td>Behavior of breastfeeding</td>
<td>8 weeks later</td>
<td>Mean difference (4.05 -)</td>
<td>Mean difference (11.6 -)</td>
</tr>
<tr>
<td></td>
<td>5.71±3.40</td>
<td>9.37±1.62</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5.43±2.92</td>
<td>9.62±0.84</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6 months</td>
<td>Mean difference (0.283 -)</td>
<td>Mean difference (0.254-)</td>
</tr>
</tbody>
</table>

### Table 4. Comparison of breastfeeding behavior 8 weeks after delivery in 2 intervention and control groups.

<table>
<thead>
<tr>
<th>Breastfeeding Performance Checklist</th>
<th>-</th>
<th>Control Group Number (%)</th>
<th>Test Group Number (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hugging the infant correctly during breastfeeding</td>
<td>Yes</td>
<td>50 (83.3)</td>
<td>59 (100)</td>
<td>p=0.001</td>
</tr>
<tr>
<td>Holding the breast correctly to put it in the infant's mouth</td>
<td>Yes</td>
<td>48 (80)</td>
<td>59 (100)</td>
<td>p=0.001</td>
</tr>
<tr>
<td>Taking the entire areola in the infant's mouth</td>
<td>Yes</td>
<td>50 (30)</td>
<td>58 (98.3)</td>
<td>p=0.001</td>
</tr>
<tr>
<td>The Correct sucking of the breast by the infant</td>
<td>Yes</td>
<td>50 (30)</td>
<td>59 (100)</td>
<td>p=0.001</td>
</tr>
<tr>
<td>Using breast milk only</td>
<td>Yes</td>
<td>17 (28.3)</td>
<td>54 (91.5)</td>
<td>p=0.001</td>
</tr>
<tr>
<td>Using formula together with breast milk for infants</td>
<td>Yes</td>
<td>40 (66.6)</td>
<td>6 (10.1)</td>
<td>p=0.001</td>
</tr>
<tr>
<td>Using sugar water during colic for infants</td>
<td>Yes</td>
<td>35 (58.3)</td>
<td>2 (3.39)</td>
<td>p=0.001</td>
</tr>
<tr>
<td>Using mangosteen or clay milk in case of jaundice infants</td>
<td>Yes</td>
<td>13 (21.6)</td>
<td>0</td>
<td>p=0.001</td>
</tr>
</tbody>
</table>
4. DISCUSSION

The results of the present study aiming to investigate the effect of breastfeeding counseling based on Bandura's theory on knowledge, attitude, self-efficacy, and duration of exclusive breastfeeding showed a significant increase in the mothers' knowledge score. In line with the results of this study, a systematic study showed that educational interventions in both prenatal and postnatal periods increased exclusive breastfeeding for 6 months [26]. A systematic study based on Bandura's social cognitive model on 1660 mothers indicated that the self-efficacy scores were significantly higher in the intervention group compared to the control group. In addition, interventions using verbal persuasion (52%) are the most common and effective interventions [27].

A randomized and controlled clinical trial was conducted on 108 pregnant women with unsuccessful breastfeeding in health centers of Tabriz in 2017. The participants were randomly assigned to two groups, intervention and control. The intervention group received four prenatal counseling sessions, and the control group only received routine care. Then, the mothers who gave birth to their babies received one counseling session up to 4 months after delivery. Both groups completed the breastfeeding self-efficacy questionnaire on day 15, 2nd month, and 4th month after delivery. Self-efficacy mean scores in the intervention group were 119.3±1.05, 128.3±8.3, and 133.8±10.3 and in the control group, 105.3±16.1, 105.7±19.7, and 109.4±24.7, respectively, which indicated a significant difference [28]. A systematic study showed that about 96.2% of mothers have heard about exclusive breastfeeding, and 49.2% knew that EBF duration is only the first six months after delivery. Moreover, 42.1% of mothers disagreed and 24% of them strongly disagreed that breastfeeding immediately within one hour after the birth of the baby is important, and 47.9% of mothers agreed that the baby should have colostrum. While 42% of mothers preferred exclusive breastfeeding for the first 6 months. In contrast, 55.9% did exclusive breastfeeding for at least 6 months [29]. A cross-sectional study on 334 women showed that the ratio of women with sufficient knowledge about exclusive breastfeeding and those who intended to do it was 60.2% to 38.6%, while only 34.4% had received exclusive breastfeeding counseling. In this study, having a positive attitude predicted sufficient knowledge about exclusive breastfeeding [30]. In this study, after providing counseling sessions, the breastfeeding skill of the mothers in the intervention group increased, and they learned strategies to resolve problems. Further, since they identified their strengths, and the support sources were encouraged by the researcher, these mothers felt that they can successfully breastfeed by solving breastfeeding problems such as the baby's refusal to breastfeed, low milk supply during breastfeeding, and early cessation of breastfeeding. The presence of a counselor in the mothers' living environment helped them consider their needs and differences in prioritizing service and counseling needs; therefore, it can be said that breastfeeding counseling led to improved breastfeeding performance in the mothers of the intervention group. There was a follow-up process after delivery so that the mothers' breastfeeding was evaluated and the mothers' concerns in this regard were considered. Studies have indicated that postnatal training can be effective in mothers' successful breastfeeding.

Baghersad et al. (2020) conducted a study to investigate the effect of postpartum care at home on mothers' health. The mothers in the intervention group received 2 sessions postpartum care program. The results showed that counseling can affect exclusive breastfeeding; therefore, the presence of healthcare workers at home and counseling with mothers and family members can play an important role in the breastfeeding counseling process. Postpartum services at home are the best way to meet families' educational and support needs because, during the first days after delivery, it has been hard for families to move, and they prefer to have the related services and care at home [31]. Panahi et al. performed an educational intervention on 38 couples, which consisted of two 46-minute sessions in one week on 3-5 days and one week after delivery. They showed that the percentage scores of awareness, attitudes, and performance of the mothers in the intervention group after three measurements significantly increased [32]. A 3-week intervention program based on the self-efficacy theory was performed on 104 women. 93 women completed the questionnaires (50 in the intervention group and 43 in the control group). The intervention group received the breastfeeding program, and the control group received routine care. The data of the two groups were compared regarding the scores of breastfeeding self-efficacy, infant feeding attitude, and breastfeeding performance, which were measured by the breastfeeding self-efficacy scale-short form (BSES-SF), the Iowa infant feeding attitudes scale (IIFAS), and structured questionnaire of breastfeeding performance, respectively. The gathering data were performed at the onset of study, 36 weeks of pregnancy, and 1 week, 1 month, 3 months, and 6 months after delivery. The results showed that the mean difference in breastfeeding self-efficacy at 36 weeks of pregnancy, 1 week after delivery, 1 month after delivery, and 3 months after delivery was 7.3 (P<0.001), 6.7 (P<0.001), 7.9, and 8.1, respectively. The breastfeeding attitudes of mothers in the intervention group from 36 weeks of pregnancy to 6 months after delivery significantly improved (the mean difference changed from 3.5 to 4.7 (P<0.005). The exclusive breastfeeding level in the intervention group compared to the control group in 1 week after delivery (98% vs. 86%), 1 month after delivery (100% vs. 90.7%), and 3 months after delivery (94% vs. 76.7%) was significantly higher [33]. The researcher of the present study concluded that mothers' self-efficacy is a significant predictor of breastfeeding duration, and the strategies to increase collective self-efficacy can improve the

<table>
<thead>
<tr>
<th>Breastfeeding Performance Checklist</th>
<th>Control Group Number (%)</th>
<th>Test Group Number (%)</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Using of other milks for infants</td>
<td>Yes</td>
<td>9 (15)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>51 (85)</td>
<td>p=0.001</td>
</tr>
<tr>
<td>Using of bottle and pacifier</td>
<td>Yes</td>
<td>52 (86.6)</td>
<td>8 (13.5)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>8 (13.4)</td>
<td>51 (86.4)</td>
</tr>
</tbody>
</table>
quality and continuation of exclusive breastfeeding. Factors such as ease of access to a counselor, continuation of services, and efficiency seem to be effective on the dimensions of quality and mothers’ satisfaction. Considering the role of breastfeeding counseling in increasing self-efficacy and continuation of breastfeeding in nursing mothers through reinforcing their ability to express their positive feelings, coping with exclusive breastfeeding problems, trying to identify the problems, as well as studying the problem-solving styles and advantages of exclusive breastfeeding for mother and the baby, it is suggested to use this type of counseling and follow-up processes in visits after delivery by trained midwives. Akso conducted a study entitled “effect of breastfeeding counseling on the continuation of exclusive breastfeeding” on 60 women hospitalized in Aydin maternity hospital. Counseling was performed 3 days after delivery at the mother’s home and face-to-face. Telephone interviews were performed 1 week and 4 months after delivery to evaluate the breastfeeding method. The results showed that the mothers with higher self-efficacy continued exclusive breastfeeding up to six months after delivery. The present study showed that the mothers’ self-efficacy can be a significant predictor of breastfeeding duration and that the strategies to increase collective self-efficacy can improve the quality and continuation of exclusive breastfeeding [34].

Breastfeeding self-efficacy is an appropriate theoretical model to perform interventions and should be considered to prolong breastfeeding and level. It is also a valid tool for identifying the mothers who are at risk of breastfeeding cessation.

CONCLUSION
Counseling at home after delivery improves the breastfeeding process and mothers' satisfaction. Factors such as ease of access to a counselor, continuation of services, and efficiency can affect dimensions and quality, and mothers’ satisfaction.

Considering the role of breastfeeding counseling in increasing breastfeeding continuation and self-efficacy in nursing mothers through reinforcing the ability to express positive feelings, mothers’ familiarity with problems and barriers of breastfeeding and trying to identify problems, studying problem-solving styles, as well as the advantages of exclusive breastfeeding for mother and the baby, it is suggested the trained midwives use this counseling method and follow-up processes in visits after delivery. Like other studies in this field, the present study had limitations, such as a limited follow-up process (up to 6 weeks after delivery) due to time limitations. It is suggested to conduct further studies with larger sample size and more follow-up processes.

ABBREVIATION

EBF = Exclusive Breastfeeding

ETHICS APPROVAL AND CONSENT TO PARTICIPATE
The thesis was approved under the ethical code in the ethics committee of the Arak University of Medical Sciences.no. IR.ARAKMU.REC.1398.225. Moreover, women had the right to participate in or leave the study.

HUMAN AND ANIMAL RIGHTS
No animals were used for studies that are the basis of this research. All the humans were used in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013 (http://ethics.iit.edu/ecodes/node/3931).

CONSENT FOR PUBLICATION
The participants in this study signed the written informed consent forms.

STANDARDS OF REPORTING
STROBE guidelines were followed.

AVAILABILITY OF DATA AND MATERIALS
The data that support the findings of this study are available from Arak University of Medical Sciences, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are, however available from the authors upon reasonable request and with permission of Arak University of Medical Sciences.

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CONFLICT OF INTERESTS
The authors have no competing interests to declare.

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