



# The Effect of Mindfulness-integrated Cognitive Behavior Therapy on Depression and Anxiety among Pregnant Women: a Randomized Clinical Trial

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## ABSTRACT

**Introduction:** Pregnancy can be associated with different psychological problems such as depression and anxiety. These problems are often neglected and left untreated. This study aimed to examine the effect of mindfulness-integrated cognitive behavior therapy on depression and anxiety among pregnant women.

**Methods:** A convenient sample of 80 pregnant women were selected. Participants were randomly allocated to either the experimental or the control groups. Participants in the experimental group received mindfulness-integrated cognitive behavior therapy while women in the control group only received routine prenatal care services. A demographic questionnaire, the Edinburgh Postnatal Depression Scale, and the Beck Anxiety Inventory were used for data collection. Descriptive statistics measures such as frequency, mean, and standard deviation as well as the repeated-measures analysis of variance test were used for data analysis.

**Results:** After the study intervention, the mean scores of anxiety and depression in the experimental group were significantly lower than the control group.

**Conclusion:** Mindfulness-integrated cognitive behavior therapy can significantly alleviate pregnant women's depression and anxiety. So implementation of this method alongside with other prenatal care services is recommended.

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## Introduction

Pregnancy is among the most stressful events in women's life. Therefore, prevalence of depression, anxiety, phobia, and obsessive disorders are increased during pregnancy.<sup>1</sup>

About 18% of pregnant women are depressed during pregnancy while 14% of them experience depression for the first time during pregnancy.<sup>2</sup> Anxiety is also other common disorder during pregnancy with a prevalence of around 18%.<sup>3</sup>

Depression and anxiety are often comorbid with each other. Evidence shows that these two disorders cannot be differentiated from each other.<sup>4</sup> The results of an interview-based study revealed that more than one third of pregnant women had comorbid symptoms of depression and anxiety.<sup>5</sup>

Untreated gestational depression and anxiety can affect mothers' relationships with their infants and other family members<sup>6</sup> and may lead to different negative consequences for both mother and fetus. For instance, they are associated with intrauterine growth retardation,<sup>7</sup> infant's depressive behaviors,<sup>8</sup> depression during adolescence,<sup>9</sup> low birth weight,<sup>10</sup> premature delivery,<sup>11</sup> mothers' postnatal depression,<sup>12</sup> and lower accountability to infants.<sup>13</sup> Anxiety can also predispose children to behavioral, emotional, and cognitive disorders later in their life.<sup>14</sup> Given their high prevalence and negative consequences, effective and timely management of depression and anxiety during pregnancy is of paramount importance.

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However, studies have shown that neither pregnant women nor psychiatrists pay attention to the management of depression and anxiety.<sup>6,15</sup> Chan *et al.*, reported that pregnant women consider inattentiveness as a right option for management of depression.<sup>15</sup> Currently, psychological problems are treated mainly by using psychotherapy and drug therapy. Given their unique conditions and their concerns over the negative effects of medications on fetus, most pregnant women prefer psychotherapy over drug therapy.<sup>16</sup>

Two effective psychotherapeutic interventions which have been used for pregnant women are cognitive behavior therapy (CBT)<sup>17</sup> and interpersonal therapy.<sup>18</sup> However, these interventions have not been developed for managing comorbid psychological problems such as depression and anxiety.

In recent years, mindfulness-based interventions were developed and used for managing psychological problems among pregnant women. One of these interventions is mindfulness-integrated cognitive behavior therapy (MiCBT) which integrates mindfulness-based techniques with cognitive behavior therapy. MiCBT aims at managing comorbid psychological problems such as depression and anxiety. It is a structured treatment strategy which trains clients to internalize their attention in order to regulate their emotions and attention and then externalize and use their regulated emotions and attention for managing their problems.<sup>19</sup>

Previous studies have shown the effectiveness of MiCBT in alleviating depression and hyperglycemia among patients with type II diabetes mellitus,<sup>20</sup> reducing students' procrastination, perfectionism, and worry.<sup>21</sup> However, to our knowledge, the effects of MiCBT have not yet been evaluated among pregnant women. The aim of present study was to examine the effect of mindfulness-integrated cognitive behavior therapy on depression and anxiety among pregnant women.

## Materials and methods

This was a single blind randomized controlled trial. We used the cluster random sampling method to select three healthcare centers from all healthcare centers which had the necessary facilities for conducting the study and were located in Kashan, Iran. Study population included of all pregnant women referring to Akramian, Taleghani, and Ketabchi health centers. We referred to the study setting and compiled a list of all pregnant women with a gestational age of one to six months. As all pregnant women had already referred to the health centers since the fifth week of their pregnancy to receive prenatal care services, the lowest gestational age was six weeks. On the other side, the length of our intervention was eight weeks with a one-month follow-up and thus, the highest gestational age was considered to be six months. Pregnant women with higher gestational ages were excluded due to the likelihood of going into labor before the end of the follow-up period and the probable confounding effects of labor on their mental status. Accordingly, we only selected the pregnant women who had a gestational age of one to six months.

Then, midwives working in the study setting were asked to inform pregnant women about the study. Pregnant women who had agreed to participate were included in the study.

The inclusion criteria consisted of pregnant women in the one to six months of gestational age, had at least a high school degree, acquired a score of greater than 13 in the Edinburgh Depression Scale and a score of greater than 16 in the Beck Anxiety Inventory, and had no history of psychological disorders or chronic physical problems, have not received psychotherapy or drug therapy during the last six months preceding the study, and women whose depression and anxiety were not secondary to certain known causes such as grief, marital conflict, divorce, or unwanted pregnancy.

The exclusion criteria were having no desire for continuing participation in the study,

having two or more absences from the study intervention sessions, and having a premature delivery. With an alpha of 0.05, a beta of 0.1, and an effect size of 0.8 (25), the Cohen's formula for sample size calculation revealed that 33 participants were necessary for each study group. However, by considering an attrition rate of 10%, we recruited 40 participants to each group. Participants were randomly allocated into experimental and control groups using block randomization method, by using units of 4 blocks.

The study primary outcomes were depression and anxiety which were measured three times: before the intervention (T1), immediately after (T2), and one month after intervention (T3). The measurement tools were a demographic questionnaire, the Edinburgh Postnatal Depression Scale, and the Beck Anxiety Inventory. The Edinburgh Postnatal Depression Scale (EPDS) had been previously used for measuring pre- and postnatal depression among women.<sup>22</sup> It consists of ten four-point items. Items 1, 2, and 4 are scored from 0 to 3 while the other items are scored reversely. The total score of the EPDS is 0–30. Scores of greater than 13 were considered as having depression. The Cronbach's alpha of the Persian EPDS has been reported to be 0.92.<sup>23</sup> We also assessed the reliability of the EPDS which yielded a Cronbach's alpha of 0.82 (n= 100).

The Beck Anxiety Inventory (BAI) is a 21-item questionnaire for measuring anxiety severity. Each BAI item represents one of the common manifestations of anxiety. On each item, a respondent can choose one of the four points of 'Not at all', 'Mildly', 'Moderately', and 'Severely' which are scored 0–3, respectively. Thus, the total BAI score is 0–63. The cutoff scores of the BAI are as follows: 0–7: no or minimal anxiety; 8–15: mild anxiety; 16–25: moderate anxiety; and 26–63: severe anxiety. The validity and the reliability of the Persian BAI have been confirmed with a Cronbach's alpha of 0.92.<sup>24</sup> We also found that the Cronbach's alpha of the inventory was 0.78 (n= 1513).

The study intervention was a MiCBT program which was implemented in eight 90-minute sessions. The contents of each session were as follows:

Session 1. An overview of MiCBT, the flow of the program, and the contents of the next sessions;

Session 2. The basic principles of mindfulness, the components of CBT, and mindful breathing;

Session 3. Mindful breathing (continued), step-by-step body scanning exercises, and awareness of visceral sensations;

Session 4. Body scanning exercises (continued), behavior therapy techniques (such as problem solving), and the relationship of mindfulness with CBT;

Session 5. Body scanning exercises (continued);

Session 6. Interpersonal skills, assertiveness, and role play;

Session 7. Acceptance and management of suffering in daily life;

Session 8. Review and evaluation.<sup>19</sup>

The intervention was performed by a MSc in clinical psychology (first author) who had received specialized training in this area under the supervision of a PhD in clinical psychology. Intervention sessions were held at Akramian health center.

Participants in the experimental group received MiCBT while participants in the control group received only routine prenatal care services such as weight control, blood pressure monitoring, and delivery-related educations. At the end of the study participants in control group received training manual of intervention sessions.

Descriptive statistics measures such as frequency, mean, and standard deviation as well as statistical tests such as repeated-measures analysis of variance (ANOVA) were used for data analysis by using SPSS (version 11.5) software.

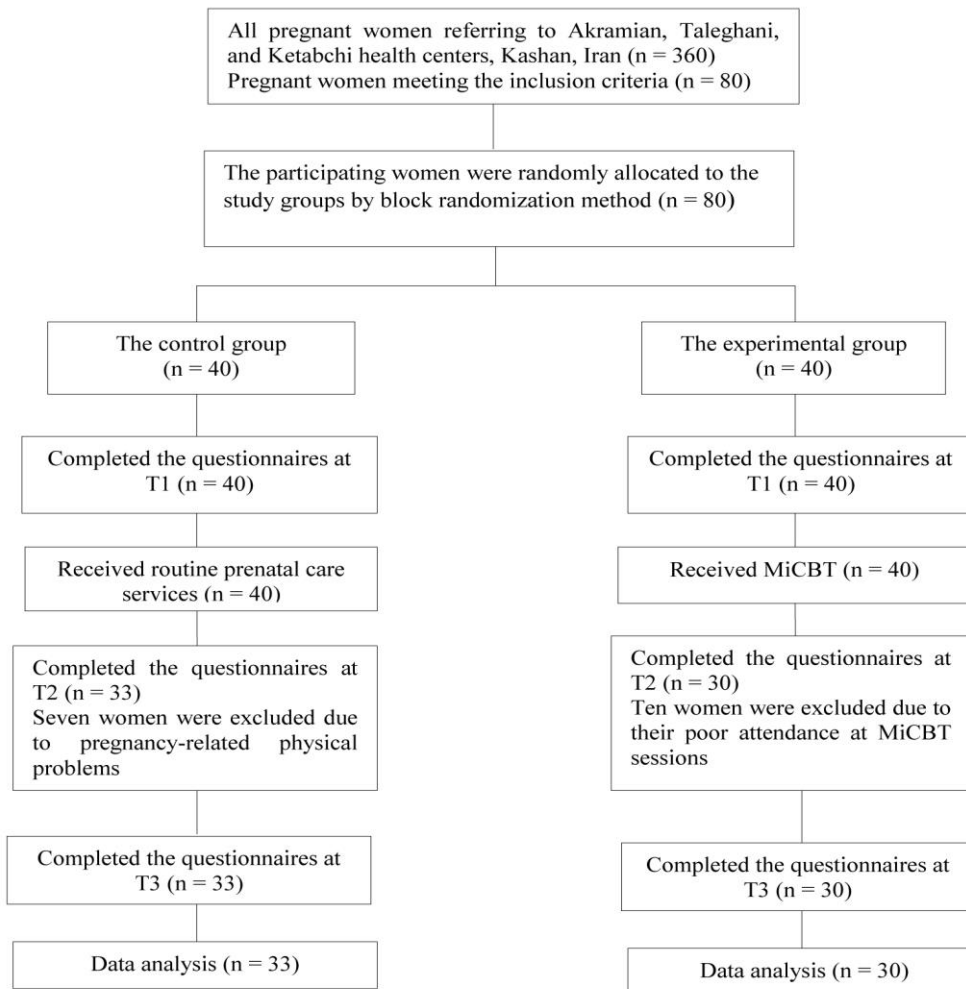
This study was approved by the ethics committee of Kashan University of Medical Sciences, Kashan, Iran, with an approval code of P/13/0/3/4005, December 17, 2014 and is

registered in the Iranian Registry of Clinical Trials with the IRCT2015012920869N1 code. Before implementing the intervention, participants were asked to fill out and sign the informed consent form of the study.

## Results

Eighty pregnant women participated in this study (40 person for each group). Ten participants from the experimental were excluded due to their poor attendance at MiCBT sessions. Moreover, seven participants from the control were also excluded because of developing pregnancy-related physical problems or their failure to complete the study questionnaires at either T2 or T3. Finally, data analysis was performed on the data retrieved from 63 participants (30 women in the experimental and 33 women in the control

group) (Figure 1). Demographic characteristics of participants are shown in Table 1. Chi-square and independent-samples t-test were used for demographic variables (Age, body mass index and gestational age were analyzed using the t-test, and educational level, previous childbirth and job were analyzed using the chi-square test). The of participants' mean age in the experimental and control groups were 26.0 (5.8) and 26.7 (4.5), respectively ( $P < 0.05$ ). The mean of participants' gestational age in the experimental and control groups were respectively 15.0 (1.1) and 15 (1.2) weeks ( $P < 0.05$ ; Table 1). Study groups did not differ significantly from each other concerning variables such as age, education, number of deliveries, gestational age, body mass index, and employment status ( $P < 0.05$ ; Table 1).



**Figure 1.** Clinical trial flowchart



Table 2 shows the mean scores of participants' depression and anxiety at the three measurement time-points of T1, T2, and T3. At T1, the mean scores of depression and anxiety in the experimental and the control groups were 16.83 (2.7) vs. 16.33 (2.64) and 19.76 (6.33) and 20.24 (6.11), respectively. The differences between the study groups regarding the pretest mean scores of depression and anxiety were not statistically significant ( $P < 0.05$ ). However, the results of the repeated-measures ANOVA test for comparing the variations of depression and anxiety scores showed that at T2 and T3, the mean scores of anxiety and depression in the experimental group were significantly lower than the control group ( $P < 0.001$ ; Table 2). The trend of these variations is depicted in Figures 2 and 3.

## Discussion

The results of this study showed that mindfulness-based interventions produced positive effects during pregnancy. This is in line with the results of the previous studies. For instance, Vieten and Astin implemented an eight-session mindfulness-based educational program for women who were in the second or third trimester of their pregnancy. They found that mindfulness-based intervention significantly reduced anxiety. However, it had no significant effect on depression.<sup>25</sup>

Dunn et al., also conducted a pilot study to investigate the effects of mindfulness-based training on psychological distress among ten multiparous pregnant women.

**Table 1.** Characteristics of participants by groups

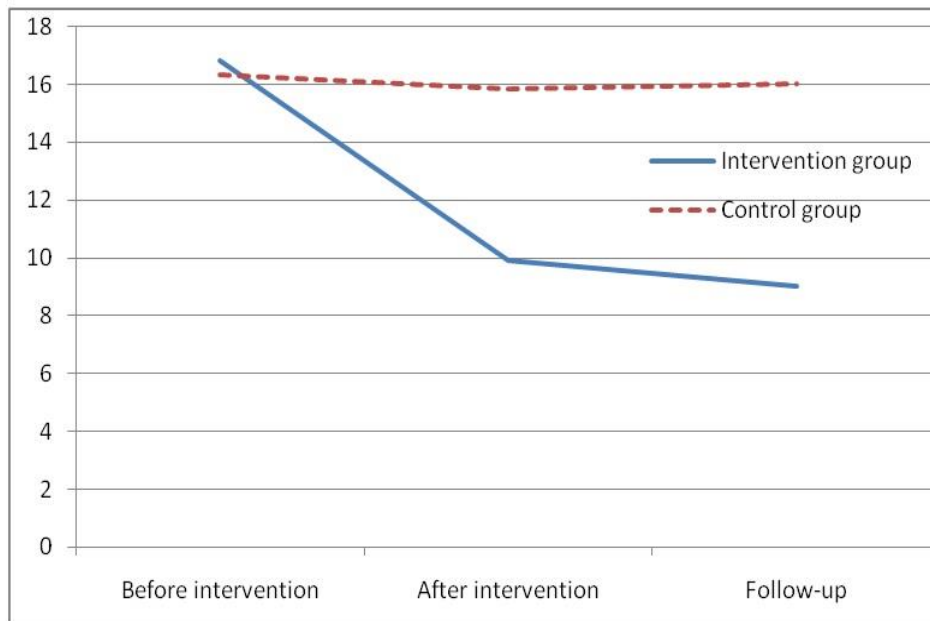
| Variables                          | Intervention group (n=30)<br>Mean (SD) | Control group(n=33)<br>Mean (SD) | P                  |
|------------------------------------|--|----------------------------------|--------------------|
| Age                                | 26 (5.82)                              | 26.73(4.54)                      | 0.569 <sup>b</sup> |
| Education <sup>a</sup>             |  |                                  |                    |
| High school                        | 4 (13.3)                               | 2 (6.1)                          | 0.693 <sup>c</sup> |
| Diploma                            | 17 (56.7)                              | 21 (63.6)                        |                    |
| Bachelor                           | 9 (30)                                 | 10 (30.3)                        |                    |
| Previous childbirth <sup>a</sup>   |  |                                  |                    |
| 1                                  | 19 (63.3)                              | 22 (66.7)                        | 0.782 <sup>c</sup> |
| ≥2                                 | 11 (36.7)                              | 11 (33.3)                        |                    |
| Gestational age (week),in baseline | 15(1.12)                               | 15(1.26)                         | 0.967 <sup>b</sup> |
| BMI                                | 22.91(2.84)                            | 23.13(3.27)                      | 0.838 <sup>b</sup> |
| Job <sup>a</sup>                   |  |                                  |                    |
| Housewife                          | 19 (63.3)                              | 21 (63.6)                        | 0.98 <sup>c</sup>  |
| Employed                           | 11(36.7)                               | 12 (36.4)                        |                    |

<sup>a</sup>Data are presented as N (%), <sup>b</sup>Independent-samples t-test was used. <sup>c</sup>Chi-square test was used.

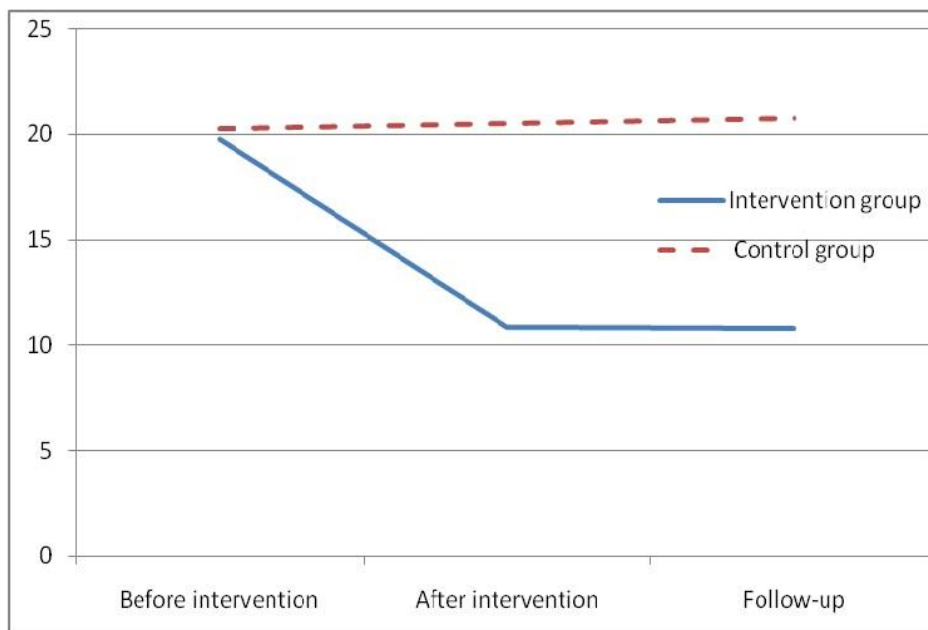
**Table 2.** The mean scores of depression and anxiety at the three time-points

| Variables  | Pre-test group |              | Post-test group |              | Follow-up group |             | Statistical indicator |
|------------|----------------|--------------|-----------------|--------------|-----------------|-------------|-----------------------|
|            | Intervention   | Control      | Intervention    | Control      | Intervention    | Control     |                       |
| Depression | 16.83 (2.7)    | 16.63 (2.64) | 9.93 (2.81)     | 15.84 (2.77) | 9.03 (2.95)     | 16.03(2.45) | F=45.97, P* <0.001    |
| Anxiety    | 19.76 (6.33)   | 20.24 (6.11) | 10.86 (4.48)    | 20.54 (6.75) | 10.80 (6.8)     | 20.78(6.18) | F=34.75, P* <0.001    |

\* Repeated measures ANOVA



**Figure 2.** Variations of depression scores in the two study groups



**Figure 3.** Variations of anxiety scores in the two study groups

3 the control groups were respectively in the 12<sup>th</sup>-28<sup>th</sup> and 17<sup>th</sup>-29<sup>th</sup> weeks of their pregnancy. They used EPDS and the Depression Anxiety Stress Scale (DASS) for data collection and reported that mindfulness-based intervention significantly reduced the EPDS and the DASS scores.<sup>26</sup>

In another study, Duncan and Bardacke employed a one-group non-controlled design and implemented a mindfulness-based educational program for 27 pregnant women. The women were in the third trimester of pregnancy and most of them (92.6%) were experiencing their first pregnancy. Women's husbands had also participated in the educational sessions. The findings revealed that mindfulness was effective in alleviating depression, anxiety, and negative affect and in enhancing positive affect and well-being. Given the facts that their study was non-controlled and some of their participants had previously participated in Yoga training courses, the findings reported by Duncan and Bardacke might have been affected by participants' previous experiences.<sup>27</sup>

Recently, a study was conducted on 39 women with major depression disorder (27 women) and bipolar-spectrum disorder (12 women) in order to assess the effects of an eight-week mindfulness-based cognitive therapy. The participating women either were pregnant (12 individuals), had planned for pregnancy (11 individuals), or were in their postnatal period (26 ones). The findings showed that mindfulness-based cognitive therapy significantly alleviated major depression disorder and had no significant effect on bipolar-spectrum disorder.<sup>28</sup>

As mentioned earlier, depression and anxiety are comorbid conditions.<sup>29</sup> Therefore, the effectiveness of treatments can be enhanced through adopting treatment strategies which can alleviate both of them. This is of paramount importance to pregnant women because simultaneous and rapid alleviation of mother's depression and anxiety can reduce

the negative effects of these two conditions on fetus.

Mindfulness is rather a new concept in psychotherapy and has attracted therapists and researchers' attention in recent years. It teaches people to focus on the present moment, identify their own experiences, cultivate a non judgment attitude, accept their experiences, reduce reactivity towards them, and effectively manage them.<sup>30</sup>

Mindful attention requires preventing habitual reactions and creating non judgment attitude towards, acceptance of, and detach from internal experiences.<sup>31</sup>

People who receive CBT need executive functions such as keeping attention, deliberate actions, affect regulation, behavior control, problem solving, and motivation in order to get the most from CBT.<sup>32</sup> Executive functions are mainly performed in the prefrontal area of the brain.<sup>33</sup> When people access their executive functions and use them for self-regulation, their distress is reduced. On the other hand, people suffering from depression experience distress due to having limited access to their executive functions. Accordingly, during sensitive courses of emotional excitements such as pregnancy, executive functions can be used and promoted for alleviating depression and anxiety.<sup>32</sup> The effectiveness of cognitive behavior therapies can be enhanced through integrating mindfulness-based executive functions.<sup>34</sup> Moreover, emotional dysregulation are related to the dysfunction of the front limbic region, i.e. where prefrontal activity is reduced and amygdale is stimulated.<sup>35</sup> Mindfulness-based exercises can stimulate the activity of the prefrontal cortex.<sup>36</sup>

Evidence shows that integrating CBT with mindfulness-based interventions produces more significant results compared with single therapy.<sup>30,37</sup> Great effectiveness of mindfulness-based interventions has required clinicians to use these interventions to enhance the effectiveness of their treatments. MiCBT is one of these

interventions and further investigations are still needed for assessing and confirming their effectiveness.

This study has some limitations. One of the study limitations was related to lack of background knowledge about the study subject matter due to its novelty.

Mindfulness interventions are among the most appropriate and effective strategies for managing psychological problems.<sup>38</sup> Nonetheless, given their novelty, few studies have been conducted so far on these interventions.

Moreover, we could not retrieve a random sample of pregnant women from all healthcare centers located in Kashan, Iran. We also were not able to assess the long-term effects of MiCBT in the postnatal period. Future studies are recommended to perform long-term follow-up assessments in order to evaluate the effects of MiCBT on different pregnancy-related outcomes such as emotional well-being, postnatal depression, and mother-infant relationships.

## Conclusion

The results of this study indicated that MiCBT is effective in alleviating pregnant women's depression and anxiety even for one month after implementing it.

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## Ethical issues

None to be declared.

## Conflict of interest

The authors declare no conflict of interest in

this study.

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