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The effect of curcumin on postpartum depression and anxiety in primiparous women: a double-blind randomized placebo-controlled clinical trial

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Abstract

Postpartum depression and anxiety are common problems in primiparous women, which can negatively affect Maternal-infant bonding and lead to sexual disorders. It's important to prevent and treat these issues, especially since medication options during breastfeeding may be limited. Our study aimed to investigate the effect of curcumin, a natural substance known for its beneficial properties, on postpartum depression and anxiety in primiparous women. A randomized controlled clinical trial was conducted on 96 primiparous women in Tabriz City. Participants were randomly assigned to either the intervention group ($n=48$) or the control group ($n=48$) using the random block method. The intervention group received curcumin capsules with a dose of 500 mg, while the control group received a placebo with the same dose once daily for eight weeks. Data was collected using the Edinburgh Postnatal Depression Scale (EPDS) and postpartum-specific Anxiety Scale research short-form (PSAS-RSF) questionnaires. After the intervention, the mean score of depression (mean difference: -2.5; 95% confidence interval: -3.3 to -1.7; $P<0.001$) and anxiety (Mean difference: -1.4; 95% confidence interval: -2.1 to -0.7; $P<0.001$) in the intervention group were significantly lower than the control group. It seems that curcumin can improve the mental health and quality of life of primiparous women postpartum due to its efficacy in reducing postpartum anxiety and depression, easy accessibility, and cost-effectiveness.

Trial registration

Iranian Registry of Clinical Trials (IRCT) IRCT20110524006582N36. Date of registration 20/09/2022. URL https://www.irct.ir/trial/65,162 Date of first registration 20/09/2022.

Keywords Curcumin, Depression, Anxiety, Phytotherapy, Integrative medicine, Childbirth

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Introduction

The period of pregnancy and postpartum is an essential time in a woman's life, characterized by significant physiological and psychological changes [1–3]. The demands of this period can often overshadow a woman's daily life, leading to heightened stress levels [4, 5]. As new roles and relationships are introduced, adapting to these changes can be challenging [6] and may even result in anxiety or depression [7] for the mothers.

Anxiety is a vague and unpleasant feeling leading to symptoms such as fatigue, restlessness, heart palpitations [8], and dizziness [4]. It can be triggered by the fear of childbirth [9], acceptance of commitment and responsibility [10], adaptation to the role of motherhood [11], negative thoughts about body appearance and hormonal changes [12]. With a prevalence of more than 30% in the first month after delivery [13], anxiety is the most common mental disorder in this period [14]. This disorder can lead to a decrease in oxytocin secretion, milk production, breastfeeding, and the mother's self-esteem [15]. While mild anxiety may motivate people to take responsibility and develop healthy habits [16], severe anxiety can be debilitating and increase the risk of postpartum depression if it persists [17].

Postpartum Depression (PPD) is a widespread mental health disorder that can negatively affect new mothers [18]. It can start within the first four weeks after delivery [19] and is characterized by symptoms such as sadness, loss of interest or pleasure, guilt or inferiority, sleep or appetite disturbances, fatigue, and poor concentration [20]. According to the *World Health Organization*, depression is predicted to become the second most common cause of disability and illness in the world [21]. Depression affects 10–15% of postpartum women globally [22], and in Iran, its overall prevalence is reported as 25.3% [23]. Despite its high prevalence, the main cause of postpartum depression is still unknown [24]. There are several reasons for this mood disorder, including physiological, situational, social, and stress-inducing life events [25]. PPD can have a negative impact on the mother's role, leading to disruptions in the mother-child relationship [26]. It also increases the risk of severe depression attacks in the future, recurrence of mood disorders after childbirth in subsequent pregnancies [27], marital issues, and higher divorce rates, particularly in the first two years after delivery [28]. It's essential to note that if left untreated, this condition gradually improves within six months after delivery. However, as the depression's duration increases, so do the complications and their severity [29]. Severe cases and lack of treatment can lead to suicide and infanticide [30].

Preventive interventions are crucial in addressing postpartum anxiety and depression [31]. However, the use of psychoactive drugs by nursing mothers can cause several problems, such as severe sleepiness, decreased response to cries, changes in sexual function, fatigue, confusion, low blood pressure, tachycardia, etc. These drugs also have sedative effects on the infant who receives breast milk. Therefore, their use during breastfeeding is limited [32]. While some mothers may choose not to take medication during breastfeeding due to concerns about potential side effects on their babies, herbal remedies, including curcumin, have garnered attention for their potential therapeutic benefits [33–36].

Curcumin is a potent substance found in the rhizome of the turmeric plant, scientifically known as *Curcuma Longa* [37]. It belongs to the ginger family and has been popularly used as a cooking spice for more than 4,000 years in South Asian countries [38, 39]. Due to its affordability, effectiveness, and rich source of antioxidants, it has also been used for many years in the treatment of various diseases [40]. Studies suggest that an effective dose of curcumin is typically between 500 and 2,000 mg per day [41, 42]. The effects of curcumin usually become apparent after 4–8 weeks [43]. This phenolic compound exhibits a broad biological spectrum and various pharmacological effects [44], such as anti-inflammatory and antioxidant effects, making it a valuable ingredient for many health supplements [45]. Curcumin has strong antioxidant properties, nearly three times greater than vitamin C and over 1.5 times greater than vitamin E. It acts as a free radical scavenger and boosts the production of glutathione, protecting cells from damage. Additionally, curcumin regulates pro-inflammatory cytokines like IL-4, IL-6, IL-8, and TNF-α [46, 47]. Curcumin plays role in the secretion of serotonin and dopamine, as well as inhibiting *monoamine oxidase (MAO)* and regulating the *hypothalamus-pituitary-adrenal axis* [48]. It has been used as a complementary treatment in certain cognitive and psychological disorders, with numerous clinical trials on mouse models demonstrating its antidepressant properties [49]. Additionally, epidemiological studies have indicated that individuals who consume curcumin daily exhibit better brain function and higher cognitive abilities [50, 51].

Controversies in the field revolve around the optimal management of postpartum mood disorders and the comparative efficacy of pharmaceutical versus complementary interventions. Recent reviews in 2021 include advancements in understanding the neurobiological mechanisms underlying postpartum depression and the exploration of novel treatment modalities [52, 53].

In conclusion, while postpartum anxiety and depression pose significant challenges, ongoing research endeavors offer promise in improving preventive strategies and therapeutic interventions. The exploration of curcumin's role in this context highlights the importance of holistic approaches to maternal mental health. We

aimed to investigate the effect of curcumin on postpartum depression and anxiety in primiparous women.

Materials and methods

Study type and participants

This randomized controlled trial was conducted on 96 primiparous women in Al-Zahra and Taleghani educational centers in Tabriz city, 2023.

Inclusion criteria include women aged 18 years and older, living in Tabriz city and its suburbs, not having a chronic disease such as liver or kidney disease, not having a history of depression or any other mental disorder, not consuming alcohol and drugs, giving birth within at least last 12 h, natural birth or cesarean section, recent low-risk pregnancy, desire to participate in the study, having a care file at the nearest health center of residence, having a contact number, not changing the location during the study period, and not taking drugs that cause depression symptoms.

Exclusion criteria include the diagnosis of prenatal depression, the death or hospitalization of a newborn in the intensive care unit, the hospitalization of the mother due to complications after childbirth, people who have had unfortunate events after delivery, such as the death or hospitalization of a family member, divorce, the use of anticoagulants.

Sample size

To determine the sample size, we used G-Power software and a previous research by Gary et al. on depression ($m1 = 12.6$, $m2 = 10.08$, $sd1 = sd2 = 4.7$, $n = 44$) and anxiety ($m1 = 42.3$, $m2 = 33.84$, $sd1 = sd2 = 6.6$, $n = 12$), assuming a 20% reduction in average scores post-intervention. Our calculations were based on the depression data, with $\alpha = 0.05$, $\beta = 0.2$, and a dropout rate of 10%. Ultimately, we determined a sample size of 48 participants per group.

Sampling

The Sampling started after obtaining permission from the ethics committee of Tabriz University of Medical Sciences (ethics code: IR.TBZMED.REC.1401.474) and registering in Iranian Clinical Trial Registration Center (code: IRCT20110524006582N36). The researcher was referred to the selected hospitals and evaluated all women aged 18 and over who had given birth by accessible sampling method in terms of eligible criteria. If they were eligible, a written informed consent was obtained. The questionnaires of socio-demographic characteristics, the Edinburgh Postnatal Depression Scale (EPDS) and postpartum-specific Anxiety Scale research short-form (PSAS-RSF) were filled out by the researcher through an interview. Participants were included in the study if they scored 12 or less in EPDS; a score above 12 indicates the presence of depression, and the person was referred to a mental health service provider.

Randomization

The participants in this study were randomly assigned to intervention and control groups using a quota sampling method based on the delivery rate in Al-Zahra and Taleghani hospitals. A random number generator was used to create blocks of four and six, with an allocation ratio of 1:1. A person not involved in sampling and data collection performed the blocking. In order to conceal the allocation, drugs and placebo were placed in similar numbered bottles. Participants were given the bottles as they entered the study; they were reminded that the follow-up would be eight weeks after the intervention.

Intervention

The intervention group received 500 mg capsules of curcumin [54], while the control group received a placebo. Curcumin and placebo capsules were prepared by Adineh Company in a completely similar way. Each capsule contained, Curcumin (Curcuma longa extract) 500 mg, Excipients (fillers, binders, etc.) q.s. (quantum satis) to 1 capsule.

To ascertain the reliability of the capsules, rigorous quality assurance measures were implemented throughout the manufacturing process. We ensured accuracy and consistency in the capsule manufacturing process by implementing rigorous quality assurance measures; this included testing the raw materials for purity and potency, adhering to GMP (Good Manufacturing Practices), and conducting comprehensive quality control checks at key stages of the encapsulation process. We also sought third-party verification to confirm the suitability of the capsules for use in our study and conducted various tests to ensure their reliability and efficacy. The capsules were taken daily with a glass of water two hours after meals from the seventh day after delivery for eight weeks. Each participant was given a sealed and numbered envelope containing a drug/placebo to be consumed for eight weeks. They were reminded that the follow-up is eight weeks after the start of the intervention. During the intervention, the participants were contacted by phone once a week to inquire about the baby's weight; they were also reminded to mark the use of capsules in the checklist and report any side effects. In case of annoying side effects, the intervention was stopped. After the end of this period, the questionnaires of EPDS and PSAS-RSF were filled out by referring to the nearest health center.

Data collection tools

The data were collected using socio-demographic characteristics, EPDS, PSAS-RSF, and the checklists of side effects.

Socio-demographic characteristics

It included personal and demographic information of people: name, surname, phone number, age, marriage age, weight, height, education level, occupation, residence, and monthly income adequacy.

Edinburgh postnatal depression scale

This questionnaire was developed in 1978 and revised in 1994 to measure depression during pregnancy and postpartum [55]. It consists of 10 four-option items, with some options arranged from low to high intensity (1, 2, 4) and others from high to low intensity (3, 5, 6, 7, 8, 9, 10). Each item is scored on a scale of 0–3, and the total score ranges from 0 to 30. It takes around 5 min to complete, and the mother selects the answers that reflect her feelings during the past week. A score of 12 or above indicates depression. The Cronbach's alpha value for this tool is 0.70, and its validity with the Beck scale is 0.44. The questionnaire has been validated in Iran with a reported Cronbach's alpha value of 0.86 [56].

Postpartum specific anxiety scale research short-form

PSAS is used to measure the anxiety specific to mother and baby [57]. The short form of this questionnaire contains 16 self-report items with four subscales: psychological adaptation to motherhood (items 1–4), practical anxiety of caring for a baby (items 5–8), anxiety of competence and attachment (items 9–12), and the safety and welfare anxiety of the baby (items 13–16) [58]. It is scored based on the Likert scale: (1) rarely, (2) sometimes, (3) often, and (4) always. The total score ranges between 16 and 64. The psychometric properties of this tool were validated in Iran [59].

Side effects Checklist

The study recorded any adverse events that occurred, along with their severity.

The validity of the socio-demographic questionnaire and the side effects checklist were determined using content and face validity methods. The questionnaires were given to faculty members and modified based on their feedback. The EPDS and PSAS-RSF were standard tools and have already been psychometrically evaluated in Iran.

Statistical analysis

SPSS version-26 was used for statistical analysis in this study. The Kolmogorov-Smirnov (K-S) test was used to assess the normality of the quantitative data. To evaluate the homogeneity of the study groups in terms of socio-demographic characteristics, independent t-tests, chi-square, chi-square by trend, and Fisher's exact tests were conducted. Independent t-tests were used to compare the mean scores of depression and anxiety between groups before the intervention; ANCOVA tests were used after the intervention by adjusting baseline values. $P < 0.05$ was considered significant.

Results

A total of 120 people were evaluated for this study between April and August 2023. Ten women declined to participate; five women were excluded due to their baby's hospitalization in NICU, five due to their hospitalization, and four due to the use of anticoagulants. Of the 96 women assigned to study groups, 11 dropped out. Gastrointestinal complications led to four dropouts in the curcumin group and one in the placebo group; unwillingness to continue caused two dropouts in the curcumin group and four in the placebo group. Ultimately, 83 participants completed the study (see Fig. 1).

The mean (SD) age was 28.0 (7.6) in the intervention group and 29.1 (7.0) in the control group. The mean (SD) age of marriage was 22.3 (6.8) in the intervention group and 23.2 (6.3) in the control group. The mean (SD) BMI was 29.5 (5.6) in the intervention group and 29.5 (5.1) in the control group. Almost half of the people in the intervention group (43.7%) and more than half in the control group (56.3%) had a diploma or higher education. Socio-demographic characteristics are shown in Table 1; there was no statistically significant difference between the study groups in this respect ($P < 0.05$).

The mean (SD) depression score was 2.1 (1.9) before the intervention in the curcumin group, which decreased to 1.8 (1.3) after the intervention. It was 2.2 (2.0) and 4.4 (2.6) in the control group before and after the intervention, respectively. Based on the independent t-test, there was no statistically significant difference between the groups before the intervention ($P = 0.879$). Based on the ANCOVA test with adjusting the baseline scores, the mean depression score in the curcumin group was significantly less than the control one after the intervention (MD: -2.5; 95% CI: -3.3 to -1.7; $P < 0.001$) (Table 2) (Fig. 2).

The mean (SD) anxiety score was 20.5 (1.7) before the intervention in the curcumin group, which decreased to 18.6 (1.3) after the intervention. It was 20.1 (1.6) and 20.1 (1.7) in the control group before and after the intervention, respectively. Based on the independent t-test, there was no statistically significant difference between the groups before the intervention ($P = 0.258$). Based on the ANCOVA test with adjusting the baseline scores, the mean anxiety score in the curcumin group was significantly less than the control one after the intervention (MD: -1.8; 95% CI: -2.3 to -1.3; $P < 0.001$) (Table 3) (Fig. 3).

In terms of side effects, four individuals in the intervention group and one person in the placebo group reported

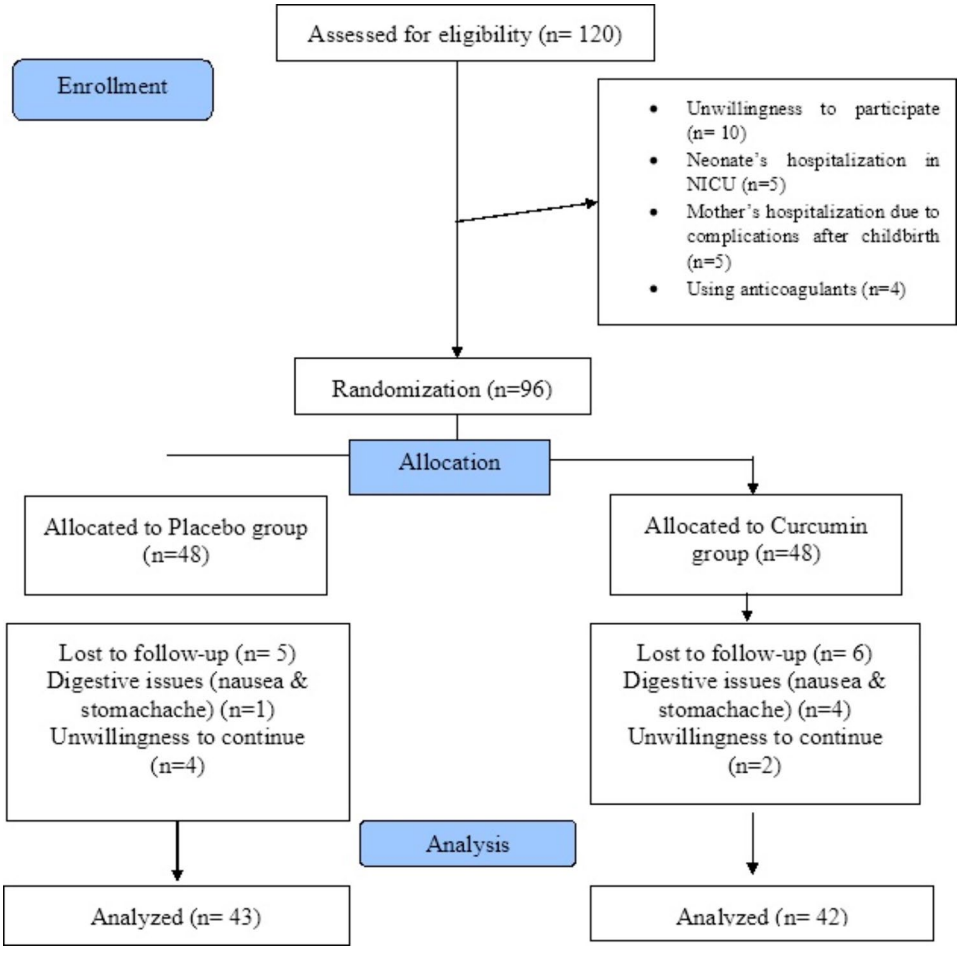

Fig. 1 CONSORT Flow chart of the study

gastrointestinal symptoms, such as nausea and stomach pain.

Discussion

Our study findings indicate the efficacy of curcumin in reducing postpartum depression and anxiety among primiparous women.

Intervention with curcumin led to a significant decrease in mean anxiety scores, consistent with findings from studies examining curcumin's anxiolytic effects in other populations. Asadi and colleagues (2020) designed a randomized controlled trial to investigate the effectiveness of Nano-curcumin supplementation on anxiety in 80 patients with diabetic polyneuropathy. The participants were given 80 mg Nano-curcumin capsules or placebo daily for eight weeks. After the intervention, a significant decrease in the mean anxiety score was observed in the Nano-curcumin group compared to the placebo group [60]. Another crossover trial was conducted by Esmaili et al. (2015) to investigate the effectiveness of curcumin on anxiety in 30 obese patients. The intervention group received 1 gram of curcumin daily for 30 days. After two weeks, each person was transferred to the alternative diet for another 30 days. The intensity of anxiety was assessed at the beginning and in weeks 4, 6, and 10 of the trial using the Beck Anxiety Inventory (BAI). The results showed a significant effect of curcumin on reducing anxiety in obese people [61]. The findings of the studies mentioned above align with the outcomes of the present study. The mechanism underlying curcumin's anxiolytic effects may involve its modulation of monoamine oxidase (MAO) activity that leads to increase concentrations of neurotransmitters such as norepinephrine, serotonin, and dopamine in the synapse [62]. Additionally, curcumin's ability to regulate the hypothalamus-pituitary-adrenal (HPA) axis and attenuate oxidative stress may contribute to its anxiolytic properties, providing a neuroprotective effect against stress-induced anxiety [63].

In addition to its effects on anxiety, intervention with curcumin significantly reduced the mean score of depression in our study. A study by Lopresti et al. (2014) investigated the potential benefits of curcumin in treating major depressive disorder (MDD). It was *a* randomized, double-blind, placebo-controlled trial involving

Table 1 Socio-demographic characteristics of the participants ($n=96$)

Characteristic	Curcumin ($n=48$)	Placebo ($n=48$)	*P*-value
	Mean (SD)	Mean (SD)	
Age (Year)	28.0 (7.6)	29.1 (7.0)	0.489†
Marrige age (Year)	22.3 (6.8)	23.2 (6.3)	0.478†
BMI	29.5 (5.6)	29.5 (5.1)	0.992†
	Number (Percent)	Number (Percent)	
Education			0.342‡
Elementary	18 (37.5)	15 (31.3)	
High school	9 (18.8)	6 (12.5)	
Diploma	11 (22.9)	15 (31.3)	
University	10 (20.8)	12 (25.0)	
Job			0.504§
Housewife	44 (91.7)	42 (87.5)	
Employed	4 (8.3)	6 (12.5)	
Husband education			0.544‡
Primary	8 (16.7)	5 (10.4)	
Elementary	12 (25.0)	12 (25.0)	
High school	6 (12.5)	6 (12.5)	
Diploma	13 (27.1)	17 (35.4)	
University	9 (18.8)	8 (16.7)	
Husband job			0.302§
Employed	6 (12.5)	4 (8.3)	
Worker	24 (50.0)	21 (43.8)	
Shopkeeper	5 (10.4)	12 (25.0)	
Other	13 (27.1)	11 (22.9)	
Income sufficiency			0.515‡
Somewhat sufficient	34 (70.8)	31 (64.6)	
Completely sufficient	14 (29.2)	17 (35.4)	
Home type			0.540¥
Private	19 (39.6)	15 (31.3)	
Rental house	27 (56.3)	32 (66.7)	
With parents	2 (4.2)	1 (2.1)	

†Independent t-test; §Chi-square test; ¥ Fisher's exact test; ‡ Liner by liner association

56 patients diagnosed with MDD. Participants were administered 500 mg of curcumin twice a day. The Inventory of Depressive Symptomatology self-rated version (IDS-SR30) was used to measure the effectiveness of the treatment. The results from the surveys conducted from the 4th to the 8th week indicated that the intervention group treated with curcumin showed a significant reduction in depression levels [64]. Another study by Kanchanatawan et al. (2018) investigated the efficacy of curcumin treatment in patients with MDD. The study was conducted over 12 weeks and involved 65 patients. The curcumin dose was gradually increased from 500 to 1500 mg. The results were recorded at the baseline, 2, 4, 8, and 12 weeks after the start of treatment. The study found that curcumin significantly reduced the mean depression score compared to the placebo [65]. Matias et al. (2021) conducted a systematic review in MEDLINE, PubMed, EMBASE, and Cochrane databases to evaluate the antidepressant effect of curcumin. The authors found 10 articles that met the necessary criteria out of a total of 185 ones initially identified. The results indicated that curcumin can improve depression and anxiety symptoms in humans. The antidepressant mechanisms of curcumin are multifaceted, involving its modulation of neurotransmitter pathways, neurotrophic factors, and inflammatory cascades. Curcumin enhances the availability of serotonin and dopamine by inhibiting MAO activity and promoting their synthesis, leading to improved mood regulation [66]. Moreover, curcumin upregulates brain-derived neurotrophic factor, which plays a crucial role in neuroplasticity and neuronal survival, contributing to mood stabilization and resilience against depressive symptoms [67].

Despite the promising findings, it's essential to acknowledge the variability in curcumin formulations and dosages across studies. Standardized approaches are necessary to establish the full therapeutic potential of curcumin in treating depression and anxiety. Moreover, large-scale clinical trials are warranted to validate the efficacy of curcumin in diverse populations and settings [68].

The growing interest in herbal supplements, including curcumin, reflects a shift towards natural and holistic approaches to mental health. Curcumin's cost-effectiveness and favorable side effect profile make it a promising adjunctive therapy for improving mood and alleviating symptoms of anxiety and depression, particularly in women during the postpartum period [69, 70]. In conclusion, while our study adds to the body of evidence supporting the use of curcumin in managing postpartum depression and anxiety, ongoing research efforts are needed to address remaining controversies and establish standardized guidelines for its clinical use.

Table 2 Comparison of the mean score of depression among study groups

Variable	Curcumin		Placebo		Mean difference (95% confidence interval)	*P*-value
	n	Mean (SD†)	*n*	Mean (SD†)		
Depression (Score range: 0 to 30)						
Before intervention	48	2.1 (1.9)	48	2.2 (2.0)	-0.06 (-0.8 to 0.7)	0.879‡
After intervention	42	1.8 (1.3)	43	4.4 (2.6)	-2.5 (-3.3 to -1.7)	< 0.001§

† Standard Deviation; ‡Independent t-test; § ANCOVA with adjusting baseline values

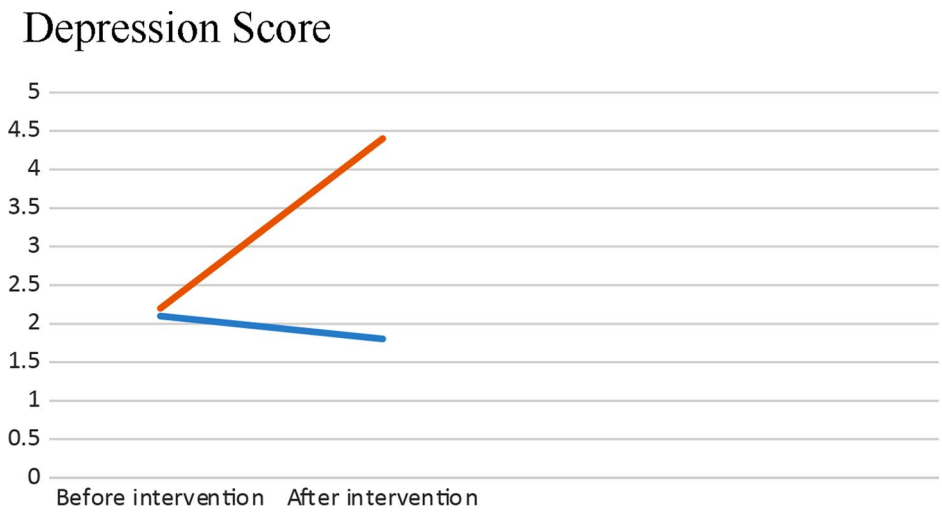

Fig. 2 Graphical representation of depression

Table 3 Comparison of the mean score of anxiety among study groups

Variable	Curcumin		Placebo		Mean difference (95% confidence interval)	*P*-value
	n	Mean (SD[†])	*n*	Mean (SD[†])		
Anxiety (Score range: 16 to 64)						
Before intervention	48	20.5 (1.7)	48	20.1 (1.6)	0.3 (-0.2 to 1.0)	0.258[‡]
After intervention	42	18.6 (1.3)	43	20.1 (1.7)	-1.8 (-2.3 to -1.3)	< 0.001[§]
Mental adaption						
Before intervention	48	5.4 (0.7)	48	5.3 (0.8)	0.06 (-0.2 to 0.3)	0.685[‡]
After intervention	42	5.2 (0.7)	43	5.2 (0.7)	-0.1 (-0.3 to 0.1)	0.313[§]
Practical anxiety						
Before intervention	48	5.2 (0.7)	48	5.1 (1.0)	0.04 (-0.3 to 0.4)	0.824[‡]
After intervention	42	4.6 (0.5)	43	5.1 (0.8)	-0.5 (-0.7 to -0.4)	< 0.001[§]
Attachment						
Before intervention	48	5.1 (0.9)	48	4.9 (0.7)	0.1 (-0.2 to 0.4)	0.411[‡]
After intervention	42	4.5 (0.7)	43	5.0 (0.8)	-0.6 (-0.9 to -0.3)	< 0.001[§]
Safety						
Before intervention	48	4.7 (0.7)	48	4.6 (0.8)	0.1 (-0.1 to 0.4)	0.350[‡]
After intervention	42	4.3 (0.5)	43	4.7 (0.8)	-0.4 (-0.6 to -0.2)	< 0.001[§]

[†] Standard Deviation; [‡]Independent t-test; [§] ANCOVA with adjusting baseline values

Strengths and limitations

The study followed all clinical trial principles, including random allocation and allocation concealment. The researcher, the participants, and the analyst were unaware of group allocation. We used standard questionnaires, all of which have been psychometrically evaluated in Iran. However, the study had some limitations, such as a short follow-up period, the limited number of participants, and the small sample size. The effects of curcumin usually become apparent after 4–8 weeks [43]. Initially, women were hesitant to take curcumin due to concerns about its impact on breastfeeding. However, after receiving detailed information and being reassured about the safety of the drug, they became more willing to take it. There is no detailed information available on the respondents' honesty. We acknowledge the merit of exploring combination therapies in future research endeavors, especially in contexts where synergistic effects or enhanced therapeutic outcomes may be anticipated.

Conclusion

In summary, our study highlights the potential of curcumin as a promising adjunctive therapy for managing postpartum anxiety and depression in primiparous women. The significant reductions observed in anxiety and depression scores highlight the therapeutic benefits of curcumin in promoting maternal well-being during the postpartum period. Moving forward, future clinical trials should delve deeper into the mechanisms of action underlying curcumin's therapeutic effects and explore its long-term safety and efficacy in diverse populations. Such endeavors will not only enhance our understanding

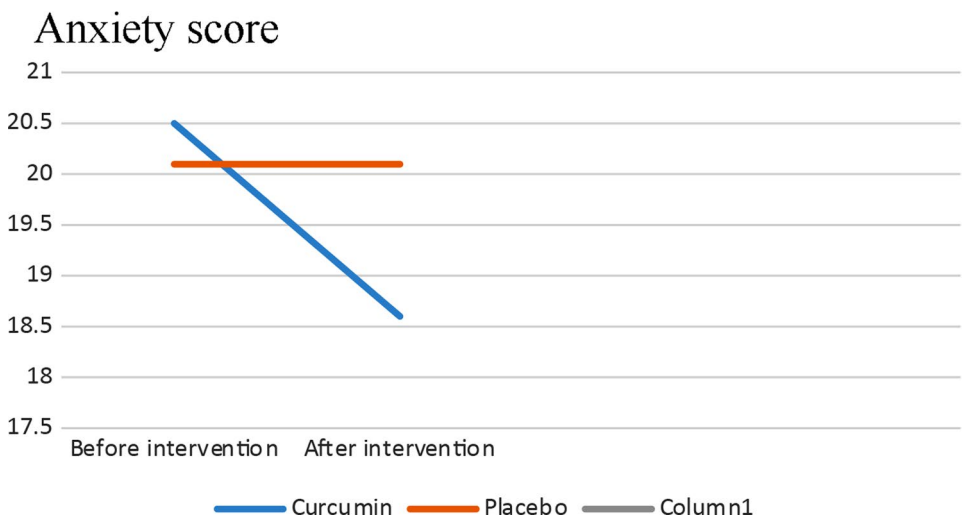

Fig. 3 Graphical representation of anxiety

of curcumin's role in postpartum mental health but also inform evidence-based guidelines for its clinical use.

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Author contributions
EPH, MM, MK contributed to the design of the study and writing the manuscript. MM Analyzed data, revised the manuscript. ESH designed the protocol, MK supervised research and revised the manuscript. All authors have critically read the text and contributed with inputs and revisions, and all authors read and approved the final manuscript.

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Data availability
The datasets generated and/or analyzed during the current study are not publicly available due to limitations of ethical approval involving the patient data and anonymity but are available from the corresponding author on reasonable request.

Declarations

Ethical approval
This study was approved by the ethics committee of the research and technology deputy of Tabriz University of Medical Sciences (IR.TBZMED.REC.1401.474). The informed written consent was obtained from all participants. All methods were carried out in accordance with relevant guidelines and regulations.

Competing interests
The authors declare no competing interests.

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