



The Effect of Cognitive Behavioral Therapy on Depression and Obesity in Women with Polycystic Ovarian Syndrome: A Randomized Controlled Clinical Trial

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Abstract

Background: Polycystic ovarian syndrome (PCOS) is a common endocrine disorder that can cause mental and psychological manifestations such as depression in addition to medical aspects like obesity.

Objectives: The aim of this study was to evaluate the effect of cognitive-behavioral therapy on body mass index (BMI) and depression in women with PCOS.

Methods: This randomized controlled trial was conducted on 74 women in Saqez-Iran, 2017. Participants were assigned into two groups of intervention and control through blocked randomization. The intervention group received cognitive-behavioral therapy in 8 sessions of 45 to 60 minutes. Beck's depression questionnaire was completed, and body mass index (BMI) was calculated before and four weeks after the end of the intervention. ANCOVA test was used to analyze the data.

Results: There was no significant difference between the two groups in terms of socio-demographic characteristics ($P > 0.05$). After the intervention, the mean (SD) of depression score in the intervention group was 4.5 (3.9) and in the control group 16.5 (8.6). Based on the ANCOVA test and with adjusting the baseline values, the mean depression score of the intervention group significantly was lower than the control group (adjusted mean difference: -13.8; confidence interval 95% = -10.9 to -16.7; $P < 0.001$). In addition, after the intervention, the mean (SD) of BMI in the intervention group was 27.3 (5.4), and in the control group it was 29.4 (5.5). The intervention group was significantly lower than the control group, based on the ANCOVA test with adjusting the baseline values (-0.6; -0.2 to -0.9; $P < 0.001$).

Conclusions: Cognitive-behavioral therapy is effective in improving depression and decreasing BMI in women with PCOS. Therefore, it is recommended to use this therapeutic approach to improve the physical and psychological health of these women.

Keywords: Body Mass Index, Cognitive Behavioral Therapy, Depression, Polycystic Ovarian Syndrome

1. Background

Polycystic ovarian syndrome (PCOS) or Leventhal-Stein syndrome is the most common endocrine disorder in women of the reproductive age (1, 2). The global prevalence of this disease based on the criteria of Rotterdam including: oligomenorrhea or amenorrhea, hyperandrogenism and, cystic ovarian morphology has been reported as 5% - 10% (2). Several studies have been conducted in Iran in this regard that had different results, however, in the review and meta-analysis of Jalilian et al., the prevalence of this syndrome has been reported as 19.5%, according to the Rotterdam criteria and based on the sonographic standard

alone as 41.4% (3).

PCOS is characterized by absence chronic ovulation, high levels of androgen, inadequate gonadotropin secretion, and abnormal morphology of the ovaries. Clinical disorders of this syndrome include irregular menstrual cycles, amenorrhea, hirsutism, acne, alopecia, and infertility. In women with this syndrome, obesity and insulin resistance are considered as principles of pathophysiology, the increase in insulin stimulates the production of ovarian androgens; therefore, there is a permanent imbalance in the sex hormones of these patients (1, 2, 4, 5). Patients with PCOS face increased risk of endometrial and ovarian cancer, late menopause, type 2 diabetes mellitus, hyper-

tension, lipid disorders, and cardiovascular disease (6, 7). Long episodes of depression, social phobia, eating disorders (8), suicide attempts, and bipolar disorder (8, 9) are more prevalent in this patient.

Hormonal deviations and a negative physical image in these patients cause depression (10), therefore, the prevalence of depression in patients with PCOS is 40% (11). In one study, the prevalence of mild to moderate depression was reported as 23.9% and 25.3%, respectively (12). More than 50% of the patients also have an android-like type of obesity. In this type of obesity, the accumulation of fat in the waist and abdomen is more likely to increase the risk of developing a metabolic syndrome (13). Obesity is known as one of the causes of depression in women for PCOS; however, research has also shown that depression in obese women with PCOS is greater than that of obese women without it (14).

The poor mental care of these patients is associated with high costs, poor treatment outcome, and increased complications (15). More studies only focus on estimating the rate of depression, obesity and the outcome of obesity, or presenting the approaches to treat depression and change in lifestyle in these patients (16). Studies conducted in the field of measuring the quality of life of women with PCOS have concluded that the quality of life of these women is very low. On this basis many gynecology researchers emphasize that patients should receive knowledge about this disease and its associated problems and even suggest that routine screening for the diagnosis of psychiatric diseases should be conducted in this group and these women need to receive education and support (17-21).

Durant suggested a theory in 2009 that accordingly, the combination of cognitive-behavioral therapy (CBT) with medical science practices in women with PCOS contributes to overcoming barriers for adapting to lifestyle changes and can be a tool for improving or preventing the progression of their disease (22). Rofey et al., (2009) conducted a pretest-posttest study in 12 young individuals suffering from obesity, eating disorders, and depression; they concluded that CBT was effective for patients (10). Correa et al., (2015) reported the effect of CBT on the depression and anxiety of a 19-year-old girl suffering from PCOS (23). Therefore, considering the prevalence of depression (12, 19, 24) and obesity (1, 2, 13) in these patients and the necessity of preventive and therapeutic measures in this regard, as well as considering that based on searches conducted by the researcher, no study has been conducted in this field in Iran. Therefore, this study aimed to examine the impact of counseling based on the cognitive behavioral therapy approach in these patients.

2. Methods

2.1. Design and Participants

This randomized controlled clinical trial was conducted on 74 women with PCOS who referred to private gynecologist's clinics and to the gynecology clinic of Imam Khomeini hospital in the city of Saqaz and complained of one of the symptoms of PCOS (oligomenorrhea, hirsutism, acne, or sonographic picture of a polycystic ovary) and have received a definite diagnosis of PCOS by a collaborator gynecologist of this study (MM) in 2017 - 2018. Imam Khomeini hospital is a governmental and non-referral center. It has 200 beds and different wards including obstetrics and gynecology, pediatrics, NICU, nephrology, general surgery, operating rooms, delivery, emergency, and dialysis wards.

The inclusion criteria included: women aged 18 to 35 years old, having at least a secondary school education, willingness to participate in the study, and providing a phone number for a follow-up. The exclusion criteria included: changing the location to another city in the future months, uncertainty about being able to attend all consultation sessions, having cardiovascular disease, blood pressure, liver disease, severe depression (according to the Beck questionnaire, Score ranges of 29 - 63 were interpreted as severe depression), and taking psychiatric medications.

This study is a part of a larger study in which depression and body mass index (BMI) were considered as secondary objectives. The sample size was calculated in 34 individuals in each group using the G-Power software and based on the initial outcome (quality of life), the study of Aliasghari et al. (25), and taking into account $m_1 = 45.8$ as well as the default of 20% increase in the mean score of quality of life caused by intervention ($m_2 = 54.96$), $Sd_1 = sd_2 = 11.3$, Power = 95% and $\alpha = 0.05$. Considering the attrition of 10% in each group, the final size of 37 patients in each group was determined.

2.2. Sampling

In this study, after obtaining the ethics code from the ethics committee of Tabriz University of Medical Sciences (code: IR.TBZMED.REC.1395.1103) and the registration of the study on the website of Iranian registry of clinical trials (code: IRCT2016111410324N35), sampling was begun. The researcher attended the gynecologic clinic of Imam Khomeini hospital in Saqez city as well as the private clinics of the city and selected women who were referred and complained of a symptom of a polycystic ovary (oligomenorrhea, hirsutism, acne, or sonographic picture of the polycystic ovaries) using an convenience sampling method. After a definite diagnosis of PCOS by a gynecologist, patients were examined for other inclusion and exclusion criteria

and, if they were eligible, they were offered to participate in the study. Next, the objectives and methods of the study were explicitly explained to them and, if they had willingness to participate in the study, the Beck depression inventory was completed through interview after obtaining written informed consent. If their depression score was more than 28, they were excluded from the study and referred to the psychiatrist. Then, the socio-demographic questionnaire was completed by the participants and the height of the patients with the meter and weight of them using the ADE mark of the German scale were measured.

2.3. Randomization

The participants who completed the pre-test questionnaires were randomly assigned into one of the two groups (an interventional group and a control group) using blocked randomization with block sizes of 4 and 6. Randomization was performed by a non-involved person in sampling and data analysis. In order to conceal the allocation, the type of intervention was written on the paper and placed in matte envelopes numbered sequentially. The envelopes were opened according to the entry of the participants and they were placed in the intervention or control group. For the intervention group, counseling was implemented based on the CBT approach.

2.4. Intervention

The intervention group received counseling based on the cognitive-behavioral approach in eight sessions of 45 - 60 minutes at intervals of 1 week and for eight consecutive weeks. Each group included at least eight people and a maximum of ten people. Meetings were held at Khatamal-Anbia clinic in the conference room. The Sundays were considered as meeting days while all the participants were called and reminded. Ethical criteria including privacy of the participants, support for their welfare and comfort, and leaving the study at any stage was provided to all participants. Cognitive-behavioral therapy was provided based on the training of specific content each week, reviewed and practiced by participants during the week, and repeated in the next session. In all the sessions, the principles and techniques for counseling were used to generate effective communication. The atmosphere of consultation sessions was coupled with respect, intimacy, strengthening self-esteem and providing the opportunity for participation in group discussions. At the end of each session, participants were requested to practice the trainings during the week and to attend the next session with readiness.

Cognitive - behavioral therapy sessions included as:

2.4.1. First Session

Understanding the anatomy and physiology of the reproductive system; definition of the ovaries; how ovaries work; definition of cognitive-behavioral therapy; repeating the positive statement of self-love; trying for your own health.

2.4.2. Second Session

Repetition of previous session assignments; factors affecting ovarian function and definition of PCOS; respiratory technique; time technique.

2.4.3. Third Session

Retrieve previous session assignments; explain how breathing and nutrition affect the health of the ovaries; tracking ineffective nutritional thoughts; provide information about appropriate and inappropriate foods in PCOS

2.4.4. Fourth Session

Retrieve previous session assignments; provide information on the impact of exercise on PCOS; explain the types of exercise and choosing it based on local limitation; practicing some of the exercise.

2.4.5. Fifth Session

Retrieve previous session's assignments; relaxation and stress control based on it; visualizing the mind.

2.4.6. Sixth Session

Retrieve previous session's assignments; how the mind affects the body; depression recognition; meditation.

2.4.7. Seventh Session

Retrieve previous session's assignments; recognition of happiness; positive self-expression; record thoughts in mind.

2.4.8. Eighth Session

Monitoring the status; evaluating progress through the discussions between the participants themselves.

2.5. Measurements

In this study, socio-demographic and Beck depression questionnaires were used. The socio-demographic questionnaire includes questions about age, marital status, place of residence, number of pregnancies, the number of births, the number of children, the inclination to pregnancy, the level of education, occupation, the level of education and occupation of the spouse, having certain diseases such as diabetes, kidney disease, respiratory disease,

AIDS, hepatitis, abnormal uterine bleeding, infertility, and hypothyroidism. Validity of this questionnaire was assessed through content and face validity.

The Beck depression inventory includes 21 items in the areas of sadness, pessimism, feeling of failure, self-dissatisfaction, guilty feelings, expectations of punishment, self-denial, self-accusation, suicidal idea, crying, restlessness, social withdrawal, disobedience, body image change, difficulty in work, insomnia, tiredness, change in appetite, body weight loss, mental retardation, and reduced sexual interest. The participant selects 1 of 4 options, which shows the severity of the depression symptom of her own for each item. Each item has a score between 0 to 3 and therefore, the total score of the questionnaire is from 0 to 63. Score 0 - 13 indicates minor depression, score 14 - 19, mild depression, score 20 - 28 indicates moderate depression, score 29 - 63 shows severe depression. Its validity and reliability in Iran were determined by Dabson et al., (2007) (Cronbach's alpha = 0.913) (26). Mirghafourvand et al., (2017) (27) also used the Iranian version of this questionnaire in their study on women with PCOS. This questionnaire was completed before intervention and 4 weeks after the end of intervention by the participants.

Height was measured using meter and the weight of patients was measured using the scale from the ADE company, Germany before intervention and 4 weeks after the end of intervention. BMI was calculated by this formula: weight in kilograms divided by the square of the height in meters.

2.6. Statistical Analysis

Data was analyzed using SPSS software version 21.0 (IBM Corp., Armonk, N.Y., USA). To determine the normality of quantitative variables, Kolmogorov-Smirnov test was used and all data were normal. Independent t-test, Chi-square, Chi-square for trend, and Fischer's exact tests were used to compare the socio-demographic characteristics of the study groups. Independent t-test was used to compare the groups in terms of mean depression score and BMI before intervention, however, after the intervention, ANCOVA test was used. All analysis were done based on intention-to-treat. P value less than 0.05 was considered significant. The power of ANCOVA test was approximately equal with 0.95.

3. Results

This study began in March of 2017 and was completed in June of 2017. A total of 90 women were selected based on the eligibility criteria. There were 74 women who were enrolled in the study and who were assigned into 2 groups of counseling and control. All women were followed up

with until the end of the study; there was no attrition in the study population (Figure 1).

The 2 groups of counseling and control did not differ significantly in terms of socio-demographic characteristics. The mean (standard deviation) of age was 28.44 (4.24) in the intervention group and 27.44 (4.6) in the control group. The majority of women (78.4% in the intervention group and 73% in the control group) were married. More than 1/4 of the participants (28.4%) had a university education and most of them (75.5%) were housewives. About half of the husbands (49%) were Freelancers and 28 of them had a university education. Most of them (91.9%) were urban and 59.5% had no specific disease, 15 had infertility and 11 had hypothyroidism (Table 1).

The mean (standard deviation) of depression score before intervention was 16.4 (0.6) in the intervention group and 13.7 (5.7) in the control group. Based on independent t-test, there was a significant difference between the 2 groups ($P < 0.014$). After intervention, the mean (standard deviation) of depression score was 4.5 (3.9) in the intervention group and 16.5 (8.6) in the control group. Based on the ANCOVA test and with adjusting the baseline values, the mean depression score had a significant difference in the intervention group compared with the control group (Adjusted mean difference: -13.8; Confidence Interval 95% = -10.9 to -16.7; $P < 0.001$).

The mean (SD) of BMI before intervention was 27.6 (5.9) in the intervention group and 29.2 (4.9) in the control group. Based on the independent t-test, there was no significant difference between the 2 groups. After intervention, the mean (SD) of BMI in the intervention group was 27.3 (5.4) and 29.4 (5.5) in the control group. Based on the ANCOVA test and with adjusting the baseline values, the mean BMI was significantly lower in the intervention group than in the control group (-0.6; -0.2 to -0.9; $P < 0.001$) (Table 2).

4. Discussion

The results of this study showed that counseling with cognitive-behavioral therapy approach reduced depression and BMI in women with PCOS. According to a case report, Correa et al., examined the effect of CBT on depression and anxiety of a 19-year-old girl with PCOS. Intervention in 11 personal and family sessions was conducted to accept lifestyle changes by the patient using CBT techniques and exercise training. This study showed that the use of CBT techniques was very effective in lowering BMI and decreasing depression, as well as regulating menstruation and reducing the menstrual bleeding of a girl (23).

Rofey et al., (2009) conducted a pre-test and post-test study with the CBT approach on 12 young individuals suf-

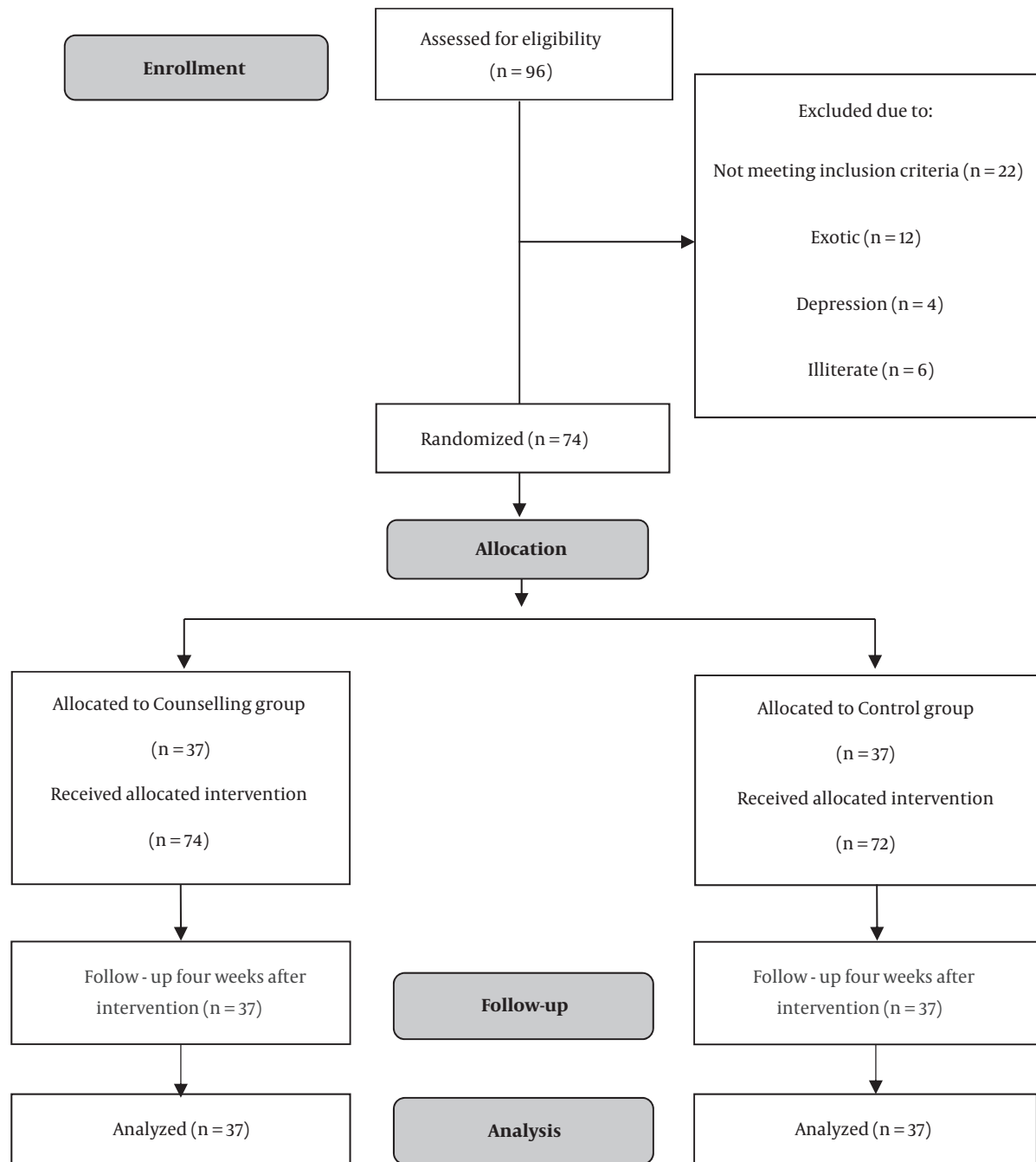


Figure 1. Flowchart of the Study

fering from obesity, eating disorders, and depression. The intervention was completed in 8 weeks and the sessions were individual and family-oriented to change the lifestyle. The result was that the weight of participants significantly reduced from a mean of 104 kg to 93 as well as a mean de-

pression score of 17 to 9.9 (10).

Turner et al., in the UK, in a pretest-posttest study, treated 179 adolescents who had an eating disorder (nervous diarrhea or neurasthenia) based on the DSM-IV criteria, with CBT treatment. In this study, intervention was per-

formed in 10 sessions. During the 1st 6 sessions, significant changes in eating disorders and long-term mood changes including depression and anxiety were observed (28).

Bayat and colleagues, in Semnan (2015), in a randomized controlled clinical trial, 30 obese children with a BMI higher than 95 percentile, considered CBT to be effective in reducing body mass index (29). Another study in Tehran, in 2008, based on the DSM-IV criteria for 90 patients with major depressive disorder, showed the effect of cognitive-behavioral therapy in combination with mindfulness based cognitive therapy in reducing depression in patients (30).

The results of preliminary results on overweight/obese women with PCOS 18 - 45 years showed that weekly CBT for 8 weeks significantly resulted in weight loss and improved QOL in obese women with PCOS and depressive symptoms (31). In addition, in a study conducted on obese patients planned for bariatric surgery, in the intervention group compared with controls, the CBT-patients showed significantly less dysfunctional eating, less anxiety and depression symptoms, and a larger weight loss at follow-up (32). Based on the results obtained in the above-mentioned studies and the present study, it can be concluded that cognitive-behavioral therapy can play a significant role in reducing depression score and BMI in individuals and it is also better to use this therapy for all patients with mental diseases and obese patients.

The strengths of this study were to observe all the principles of a clinical trial, including random allocation and allocation concealment, which was done to prevent selection bias. First, considering that this study was conducted on women with mild to moderate depression and also with a higher education, the results of this study cannot be generalized to women with severe depression and illiterate women or with an elementary education. Another limitation is due to the short duration of the follow-up due to the fact that 6 months is usually necessary for behavior changing in a person. Thus, it is recommended the studies with long follow-up periods be conducted.

4.1. Conclusion

The results of this study show that CBT in women with PCOS can reduce their depression and obesity, and may ultimately lead to a better quality of life and, consequently, to improve the health of these women. Considering the acceptance of the fact that women, as the mother and the wife, are the main pillar of the family. Any damage to their physical and mental health will disrupt the health of the family and children and ultimately the health of the community. It must be accepted that women with PCOS, like those suffering from other chronic diseases, is endangered by long-term physical and mental health risks. Therefore,

there should be a way for these women to know all the problems associated with the disease and how to deal with it. It is also necessary to use expert counseling to reduce the physical and psychological problems of these women and ultimately improve their health.

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Footnotes

Authors' Contribution: Leila Abdollahi made a substantial contribution to the conception of the study, the recruitment of women, the data collection, and drafted the manuscript. Mojgan Mirghafourvand (Corresponding author) was involved in the design of the study and performed the analysis. Mojgan Mirghafourvand, Jalil Babapour Kheyradin, and Mozhdeh Mohammadi supervised throughout the study and made a substantial contribution to the conception of the study. All authors revised the article, gave their comments on it, and approved this final version.

Conflict of Interest: The authors declare no conflicting or financial disclosures.

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Table 1. Socio- Demographic and Obstetrics Characteristics of the Participants (N = 37)

Characteristics	CBT Group	Control Group	P Value
Age, y	28 (4.4)	27 (4.6)	0.935 ^b
Marital status			0.782 ^c
Single	8 (21.6)	10 (27)	
Married	29 (78.4)	27 (73)	
Job			0.056 ^c
House keeper	32 (86.5)	24 (64.6)	
Employed	5 (13.5)	13 (35.1)	
Location			1.000 ^d
Urban	34 (91.9)	34 (91.9)	
Rural	3 (8.1)	3 (8.1)	
Level of Education			0.604 ^e
Secondary school	11 (29.7)	13 (35.1)	
High school	8 (21.6)	6 (16.2)	
Diploma	10 (27.0)	5 (13.5)	
University	8 (21.6)	13 (35.1)	
Husband's education			0.823 ^c
Primary school	2 (6.7)	4 (14.8)	
Secondary school	4 (13.3)	6 (6.22)	
High school	5 (16.7)	0 (0.0)	
Diploma	11 (36.7)	6 (2.22)	
University	17 (56.7)	11 (40.7)	
Husband's job			0.335 ^c
Worker	2 (6.7)	4 (14.8)	
Employed	6 (20.0)	7 (25.9)	
Shopkeeper	7 (23.3)	3 (11.1)	
Others ^f	15 (50.0)	13 (48.1)	
Disease			0.314 ^d
No specific disease	22 (59.5)	22 (59.5)	
AUB	1 (2.7)	3 (8.1)	
Infertility	6 (16.2)	9 (24.3)	
Hypothyroidism	8 (21.6)	3 (8.1)	
Number of pregnancy			0.391 ^d
0	21 (58.8)	27 (73.0)	
1	11 (19.7)	7 (18.9)	
2	4 (10.8)	3 (8.1)	
3	2 (2.7)	0 (0.0)	
Number of parity			0.210 ^d
0	22 (59.5)	29 (78.4)	
1	13 (35.1)	6 (16.2)	
2	2 (5.4)	2 (5.4)	
Number of children			0.210 ^d
0	22 (59.5)	29 (78.4)	
1	13 (35.1)	6 (16.2)	
2	2 (5.4)	2 (5.4)	
Pregnancy tendency			0.412 ^c
Yes	15 (53.6)	18 (66.6)	
No	12 (46.4)	9 (33.4)	

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Table 2. Comparison of Depression and BMI Before and After Intervention in Intervention and Control Group (N = 37)^a

Groups	Intervention Group	Control Group	MD (CI 95%)	P Value
Depression				
Before intervention	16.5 (6.0)	13.0 (5.7)	3/5 (0.7 to 6.1)	0.014 ^b
4 weak after intervention	4.5 (3.9)	16.5 (8.6)	-13.8 (-16.7 to 10.9)	< 0.001 ^c
BMI				
Before intervention	27.6 (5.9)	29.2 (4.9)	-1.5 (-4.0 to 1.0)	0.236 ^b
4 weak after intervention	27.3 (5.4)	29.4 (5.0)	-0.6 (-0.9 to -0.2)	< 0.001 ^c

Abbreviation: MD (CI 95%), Mean Difference (Confidence Interval 95%).

^aValues are expressed as mean (SD).

^bP values based on independent t-test.

^cP values based on ANCOVA.

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