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Effect of Acupressure on Anxiety in Infertile Women Undergoing *in vitro* Fertilization/Intra Cytoplasmic Insemination Treatments

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ABSTRACT

Aims This study aimed to determine the acupressure effect on anxiety in infertile women undergoing in vitro fertilization/intracytoplasmic insemination treatments.
Materials & Methods The present study is a randomized controlled trial of infertile women undergoing in vitro fertilization/intracytoplasmic insemination treatment. It was performed at Milad in vitro Fertilization Center, Mashhad University of Medical Sciences, from September 2015 to August 2016. The sample size was 144 participants. The participants were randomly divided into three groups of real acupressure, sham acupressure, and control using a Fleiss randomization table. Acupressure points were P6 and H7 on the participant's hands. Beck Anxiety Inventory was used for assessing anxiety and a demographic questionnaire. Data were analyzed through paired samples t-test, Chi-square test, Fisher exact, One-way analysis of variance, Kruskal Wallis test, General Linear Model, and Multinomial logistic by SPSS 16.
Findings The mean age of women was 30.84±5.34. There was a significant difference in anxiety reduction rate in all groups ($p<0.001$).
Conclusion The acupressure intervention at the points of P6 and H7 on the participant's hands reduces anxiety. Therefore, due to the effect of anxiety on the pregnancy rate in women undergoing in vitro fertilization/intracytoplasmic insemination, acupressure in these women is recommended.

Keywords Acupressure; Anxiety; Infertility; Women; Pregnancy Rate

CITATION LINKS

[1] The comparison of psychological well-being and marital satisfaction in the ... [2] Speroff's clinical gynecology endocrinology and ... [3] National, regional, and global trends in infertility ... [4] The trend of infertility in Iran, an original review ... [5] Stressful life events are associated with a poor in-vitro ... [6] Grief management in infertile ... [7] Anxiety of infertile women undergoing IVF-ET: Relation to the grief ... [8] Women's emotional adjustment to IVF: A systematic review of 25 years of ... [9] Anxiety and depression in women undergoing infertility ... [10] Primary infertility and health-related quality of life in Upper ... [11] The use of gonadotropin-releasing hormone (GnRH) agonist to induce oocyte maturation after cotreatment with GnRH antagonist in high-risk patients undergoing in vitro fertilization prevents the risk of ovarian ... [12] A matched controlled study to evaluate the efficacy of ... [13] Acupuncture for infertility: Is it an effective ... [14] Effect of acupressure on the sleep disturbances of Taiwanese ... [15] The evidence for Shiatsu: A systematic review of Shiatsu and ... [16] The effect of acupressure on quality of sleep in Iranian ... [17] The effect of acupuncture on psychosocial outcomes ... [18] Auricular acupressure reduces anxiety levels and improves ... [19] Design and analysis of clinical ... [20] An inventory for measuring clinical ... [21] Assessment of anxiety in pregnancy following ... [22] Effect of acupuncture on symptoms of anxiety ... [23] The impact of acupuncture on in vitro ... [24] Effects of acupuncture on anxiety in infertile ... [25] Complementary and alternative approaches ... [26] Effect of acupressure on anxiety among women ... [27] Acupuncture for the mental and emotional ... [28] The perception and experience of infertile women who ... [29] A randomized double blind comparison ...

Introduction

Infertility for couples is a negative event that can become a major stressful event in one's personal life [1]. Infertility affects couples worldwide by 10-15% [2]. The highest infertility prevalence is reported for South Asia, Sub-Saharan Africa, North Africa/Middle East, Central/Eastern Europe, and Central Asia. In the Middle East, Iran has a high infertility prevalence of 10.9-13.2% based on different studies [3]. Other study results showed an increasing trend in the infertility rate in Iran during 2001-2011 [4]. Infertility, treatment expectation, and unsuccessful treatment can cause stress, anxiety, frustration, disappointment, depression, and emotional responses. These factors can affect the hypophysis-hypothalamus axis causing negative responses to treatment. Also, *In Vitro* Fertilization (IVF), Intra Cytoplasmic Insemination (ICSI), and other infertility treatments create additional stress and anxiety for patients [5-9]. IVF/ICSI assisted reproductive techniques are stressors in infertility, so 30% of couples leave the treatment process unfinished due to high stress [10].

Since most of the IVF cycles do not occur pregnancy [11], and because of the low IVF success rate in each cycle and because IVF is an expensive procedure, many patients refer to CAM (complementary and alternative medicine) treatments to increase the success rate of IVF/ICSI [12]. Nowadays, traditional medicine may also be used as part of infertility treatment. Acupuncture may modify ovulation by adjusting the central and peripheral nervous systems, the neuroendocrine and endocrine systems, the ovarian blood flow, and metabolism. Secondly, acupuncture can improve IVF-ET outcome, and the mechanisms may be connected to the increased uterine blood flow, inhibited uterine motility, and the numb of depression, anxiety, and stress [13]. Acupressure is an adjunctive therapy similar to acupuncture that uses pulse diagnosis [14, 15]. By stimulating certain points of the body, Acupressure balances the flow of vital energy and can heal health problems. Acupressure as complementary medicine is used in some countries, especially in East Asia and recently in Iran [16].

The study of Smith *et al.* was conducted to determine the effectiveness of acupuncture on infertility stress; their study results showed acupuncture was effective in reducing anxiety in the acupuncture group [17]. Qu *et al.* also showed that auricular acupressure reduces anxiety levels and improves IVF outcomes [18]. Although the effect of acupressure has been measured in this study, the ear points have been intervened by acupressure. However, there has not been any research about the acupressure effect on infertility anxiety on H7 and P6 acupoints (points of Heart 7 and Pericardium 6).

Concerns of infertile women about diagnostic and therapeutic measures and concerns about others becoming aware of their problems exacerbate anxiety and depression and other psychosocial consequences of infertility in these individuals. On the other hand, the researcher's encounter with infertile people who referred to the Acupuncture and Chinese Medicine Center of Mashhad University of Medical Sciences for treatment and seeing the satisfaction of some of them with the results of treatment and relief of their mental problems was a motivation for the researcher to conduct the research. Since anxiety can affect the pregnancy rate, and due to not finding a study in this regard, the present st to determine the acupressure effect on anxiety in infertile women undergoing IVF/ICSI treatment.

Materials and Methods

This study is a randomized controlled clinical trial on infertile women undergoing IVF/ICSI treatment. It was performed in Milad IVF Center, Mashhad, Iran, from September 2015 to August 2016. Milad IVF center is the only academic center for infertility treatment in eastern Iran. The sample size was obtained using the formula after the preliminary study (Consisting of the ten infertile women in each group). The formula of mean estimation in two independent groups was used to determine the sample size. Considering a 5-10% probability of sample loss, with 95% confidence and 80% power, the sample size was 48 in each group. The sampling method was purposefully based on inclusion criteria. Next, the participants completed the Beck Anxiety Inventory questionnaire. Participants with severe anxiety and/or without anxiety were excluded. This was a double-blind study; For this purpose, one of the researchers (Esmaily H.) created random sequence statistics. Inclusion and exclusion criteria were assessed by the project co-worker (Khadivzadeh T.). Participant registration was done by the researcher. The researcher allocated the participants to the groups. Block size was 48, and each block was randomly chosen to determine the assignment of all 144 participants using the Fleiss randomization table [19]. Subjects were randomly divided into real acupressure, sham acupressure, and control groups. Inclusion criteria were: women aged between 20 to 45 years, native Iranian, female and/or male infertility, primary infertility, mild and/or moderate anxiety by using Beck Anxiety Inventory and undergoing IVF/ICSI treatment. Exclusion criteria were: use of acupressure or acupuncture during the past three months, experiencing stressful events during the study, abnormal uterine cavity, unwillingness to participate in the study, use of antidepressants and/or anti-anxiety drugs, and having psychological disorders.

The Beck Anxiety questionnaire was used for anxiety level assessment. In the Beck study, the internal consistency of the Beck Anxiety Scale (α=0.92) and its

test-retest reliability after one week was determined (r=0.75) [20]. Hashemieh *et al*. conducted a study to investigate the severity of anxiety and its relationship with midwifery and infertility factors in pregnant women using assisted reproductive methods. The scientific validity of the translated version of the Beck Anxiety Inventory was determined by its formal and content validity. Cronbach's alpha coefficient for internal correlation was 0.85 [21]. The test used was a translated and validated Persian version of Beck's anxiety Inventory. A full 21-items Beck Anxiety Inventory was administered. This scale is a widely used measure for the intensity of anxiety. Each item describes a specific behavioral manifestation of anxiety. Scores on each item can range from 0 (indicating no anxiety symptomatology) to 3 (indicating a severe level of symptomatology). Total scale scores can thus range from 0 to 63. Scores of 26 or above indicate clinically significant anxiety. The classification of anxiety scores involves:

- Without anxiety=0-7
- Mild anxiety=8-15
- Moderate anxiety=16-25
- Severe anxiety=26-63 [20]

After the intervention, the Beck Anxiety Inventory was completed again by all three groups. An employee outside the research team completed the questionnaires intending to blind or mask the study group assignment.

IRCT 201506072924N2 registered 15 December 2015 retrospectively. A written consent form was obtained from all participants. Then, a demographic information questionnaire and Beck Anxiety Inventory were completed for the study participants. Patients received acupressure treatment three times a week for four weeks in the intervention group with ICSI treatments. The present study used the points used in studies [17, 22] and the advice and guidance of a consultant professor who specializes in acupuncture and Chinese medicine to determine the two points of Hart 7 and Pericardium 6. Acupressure was performed on the H7 and P6 acupoints for three minutes maximum by finger pressure with the intent of creating a feeling of heaviness in the targeted area. The sham acupressure group received acupressure in an area that covered only 2 cm of the real acupoints. The duration of acupressure in the sham group was similar to that of the entire group. The control group did not receive any acupressure treatment. The researcher is already trained and approved by the acupuncturist. The participants were trained on finding and pressing the acupressure points by the researcher. Then, every three sessions, one session was performed by the researcher, and the participants were monitored for the correct performance of acupressure. Therefore, four sessions of acupressure therapy were carried out by the researcher (MHB) and eight sessions by the participants at home. A checklist was given to them to ensure that acupressure was performed on specified days and control possible complications or reactions from acupressure. They should have their checklist at the end of the intervention, and on the day they arrive at Milad Infertility Center. In addition to checklists, participants were also followed up by telephone to do and not forget the intervention. Acupressure was performed maximum until a day before embryo transfer.

Data analysis was carried out through the descriptive and analytic statistics. A paired-samples t-test was used to compare the mean of anxiety scores before and after the intervention in each group. Chi-square test and Fisher exact test were used for assessing descriptive and percent of qualitative nominal variables. ANOVA (one-way analysis of variance) was used to analyze the quantitative data. We used the Kruskal Wallis test for assessing qualitative ranking variables, General Linear Model and Multinomial logistic were used to determine the effect of confounding variables on anxiety. The level of significance was 0.05. SPSS software (Statistical Product and Services Solutions, version 16, SPSS Inc, Chicago, IL, USA) was used to analyze the data.

Findings

One hundred and forty-four participants took part in the study, and then 12 participants were withdrawn from the study due to canceling the cycle, discontinuing intervention, costs, and Ramadan month. Finally, data analysis was done on the 132 participants (Figure 1).

The non-parametric Kolmogorov-Smirnov test was used to determine the normality of the distribution of quantitative variables such as age, weight, duration of the marriage, and duration of treatment. The test results showed that the distribution of age and weight variables had a normal distribution (p>0.05). The mean age of women was 30.84±5.34. There was no significant difference in age and weight, marriage duration, and treatment duration variables between study groups (Table 1). The results showed that 51 (35.5%) of women and 55 (38.2%) of their husbands had a university education. Most women were housewives, 110 (77%), and 56 (39.5%) of their husbands were self-employed. According to the results, the ovulation factor and the husbands' job showed statistically significant differences in all three groups. Also, there was no significant difference in all three groups for wives' and husbands' education.

There was a significant difference between acupressure and sham groups after the intervention, and also, there was a significant difference between before and after the intervention in all groups (Table 1).

As shown in Table 2, we entered qualitative variables in the multiple linear regression to model such items as the husband's job, treatment duration, anxiety

before intervention, infertility factor (male, ovulation, and tubal), and previous treatments (induction ovulation), and groups. The dependent variable is the anxiety score after the intervention. Variables with p<0.2 were entered into the model. Then, variables were deleted using the backward method until finally, the variable of the group remained, and malefactor, induction ovulation, duration of treatment, and husband's job. Anxiety in the real acupressure group was 3.38 units less than the control group (p=0.039). Anxiety identified in participants without male infertility was 3.70 units less than male infertility (p<0.010). For one unit (month or day) increase in treatment duration, mean anxiety after treatment decreased as 0.47 (p=0.013). The primary anxiety score was effective on anxiety after the intervention. Husband's job was not significantly related to anxiety score after treatment.

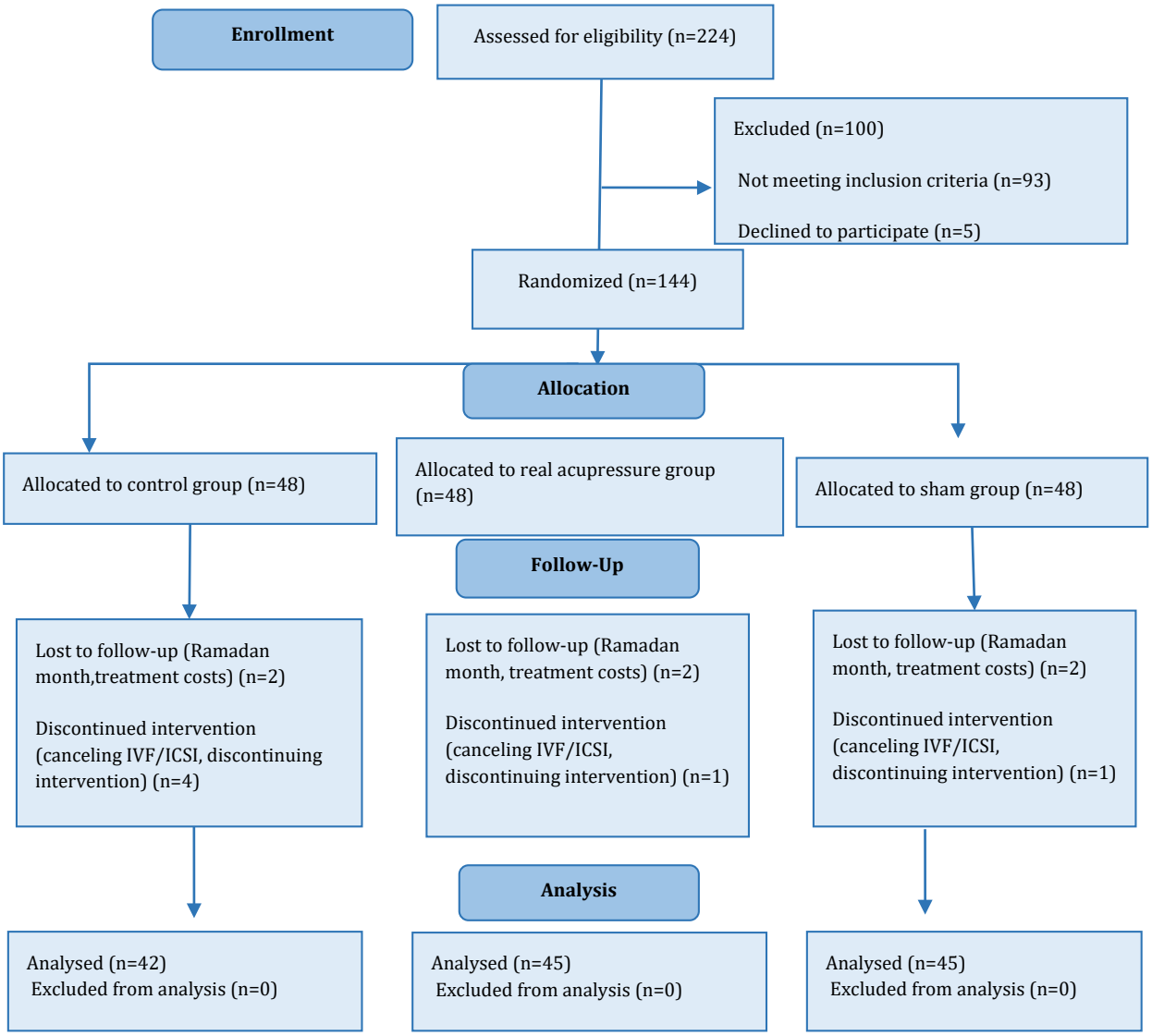

Figure 1) Recruitment and participant flow through the trial based on consort diagram

Table 1) Mean±SD results of socio-demographic characteristics and Beck anxiety questionnaire in participants (N=132)

Variables	Real acupressure	Sham acupressure	Control group	P-value
Age (year)	30.00±4.93	30.96±6.04	31.08±5.03	0.840*
Weight (Kg)	67.41±10.48	68.38±13.26	66.60±13.03	0.660*
Marriage duration (year)	7.72±4.10	8.99±5.37	8.50±4.92	0.580**
Treatment duration (year)	4.11±3.71	4.56±4.47	2.84±2.82	0.060**
Anxiety				
Before intervention	17.38±5.14	15.86±4.99	17.45±5.03	0.20
After intervention	8.07±4.38	11.91±8.06	12.23±8.06	0.06
p-value	<0.001	<0.001	<0.001	-

*ANOVA; **Kruskal Wallis

Table 2) Acupressure on the anxiety with control of confounding variables

Parameter	B	Std. Error	Sig.	95% Confidence Interval	
				Lower Bound	Upper Bound
Beck anxiety inventory (before intervention)	0.298	0.125	0.019	0.051	0.546
Treatment Duration	-0.467	0.185	0.013	-0.833	-0.100
induction ovulation					
No=0.00	-3.166	1.589	0.049	-6.314	-0.017
Yes=1.00	0[a]	-	-	-	-
Male factor					
No factor=0.00	-3.695	1.418	0.010	-6.505	-0.886
Factor=1.00	0[a]	-	-	-	-
Group					
Real	-3.378	1.618	0.039	-6.584	-0.171
Sham	-2.423	1.666	0.149	-5.724	0.877
Control	0[a]	-	-	-	-
Husband's job					
Employee =1.00	-1.089	1.609	0.500	-4.277	2.099
Worker =2.00	-0.636	1.524	0.677	-3.656	2.384
Self-employed =3.00	0[a]	-	-	-	-

a. This parameter is set to zero because it is redundant

Discussion

The present study aimed to determine the acupressure effect on anxiety in infertile women undergoing IVF/ICSI treatment. According to the results obtained, there was a significant decrease in anxiety level compared with another two groups. These results agree with the reported findings [17, 22, 23]; Researchers have shown a decrease in anxiety in the acupuncture group. The results of a systematic review article by Hassanzadeh Bashtian *et al.* also showed that acupuncture could decrease anxiety in infertile women [24]. Acupressure is based on acupuncture, which uses pressure at specific points instead of needles [25]. In the studies [17, 22, 23], 4 points and more were used for acupuncture. However, according to the acupuncturist, for preventing bias in the analysis, two of the points used in the above studies were used in our study, which could be the reason for the similarity of the results.

In agreement with our study, although Joseph's study was about intrauterine insemination (IUI), results showed a positive effect of acupressure on anxiety reduction among women undergoing IUI [26].

In line with our study, Qu *et al.'s* results showed that auricular acupressure effectively reduces anxiety and improves IVF outcomes. They have shown that anxiety in auricular acupressure was less than in sham and control groups [18]. However, our study used acupressure on the H7 and P6 acupoints, but ear acupressure was used in the above study. One of the strengths of this study was the use of three groups of real acupressure, sham acupressure, and control group to study the effect of acupressure, which we also used in our study.

Grant's review showed acupuncture had positive effects on reducing anxiety, stress, and improvement of psychological coping [27]. A qualitative study by Hassanzadeh Bashtian *et al.* also showed that acupressure could cause health promotion in all aspects by decreasing anxiety in infertile women who received ICSI treatments [28]. Their results also were similar to their results in this study.

In a randomized, double-blind trial study, so et al. compared the effects of real acupuncture and placebo in IVF treatment in Hong Kong. They observed a decrease in anxiety following acupuncture in both real and placebo acupuncture groups. They also did not observe a significant difference in anxiety changes between the two groups [29]. However, in the present study, anxiety was significantly reduced in the acupressure intervention group compared to the placebo. The anxiety questionnaires used in the three studies [22, 23, 29] differed from the questionnaire used in our study. In line with the present study, in the two studies [22, 23], the level of anxiety in the acupuncture group was lower than their control group, and the results of the So *et al.* [29] do not agree with the present study.

The strong points of our study include no reported side effects in the real and sham acupressure groups during the research period. Acupressure techniques can be easily taught to patients to manage anxiety themselves.

There are more points in acupuncture than in acupressure. In acupressure, increasing the points used can lead to bias in the analysis of findings, so fewer points were used in the present study. Findings were collected from women with primary infertility and could not be generalized to secondary infertility. It is also recommended to study the effect of acupressure with another method on the psychological problems of infertile women.

Conclusion

Acupressure effectively calms and reduces anxiety in infertile women; these services can be provided along with other infertility services in centers. That requires the required workforce and staff training.

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Ethical Permissions: The Ethics Committee of the Mashhad University of Medical Sciences approved the study with reference number IR.MUMS.REC.1394.313. The

intervention does not impose any physical, psychological, or financial harm on the participants.

Conflicts of Interests: This study was derived from a Ph.D. thesis approved and financially supported by the Vice-Chancellor for Research in Mashhad University of Medical Sciences with a proposal code of 940238.

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