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The Effect of Auricular Acupressure on Women Psychological Distress during Controlled Ovarian Hyperstimulation for *in vitro* Fertilization: A Single-Blind, Randomized, and Sham-Controlled Study

Ying Li,[1] Wanjia Shen,[1] Fengyi Mo,[1] Qing Ma[1] and Lanfeng Xing[1]

[1]Department of Reproductive Endocrinology, Women's Hospital School of Medicine Zhejiang University, Hangzhou, China

There is little research on the psychological state of women in the controlled ovarian hyperstimulation (COH) stage of in vitro fertilization (IVF) treatment. This study explored the effect of auricular acupressure on relieving negative psychology in the women during the COH stage of IVF treatment. Infertile women were enrolled and randomly divided into three groups: control (n = 121), auricular acupressure (n = 126), and sham acupoint (n = 121). The group allocation was blinded to the participants. The auricular acupressure (AA) group selected four auricular points: Shenmen, Kidney, Endocrine, and Internal genitalia. The sham acupoint group (SA) used four irrelevant auricular points and the control group accepted only routine IVF treatment. The intervention lasted from the first day of COH until the day before transvaginal oocyte retrieval. Participants' psychological states were measured using the Symptom Checklist 90 (SCL-90) before and after auricular acupressure. IVF outcomes were followed up. There were significant increases in obsessive-compulsive symptoms, interpersonal sensitivity, depression, and anxiety in the control and SA groups. Additionally, the SA group showed a higher somatization symptom score, after COH. The AA group showed decreased somatization symptom, interpersonal sensitivity, obsessive-compulsive symptoms, depression, and anxiety scores after COH. The AA group showed lower obsessive-compulsive symptoms, depression, and anxiety scores compared to those in the control and SA groups. The auricular acupressure was correlated with higher IVF success. Auricular acupressure may alleviate the psychological and emotional problems of IVF participants during the COH period.

Keywords: auricular acupressure; controlled ovarian hyperstimulation; *in vitro* fertilization; psychological distress
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Introduction

The rapid development of *in vitro* fertilization (IVF) has brought hope to artificial fertility, becoming a widely accepted method of treatment for infertile couples (Inhorn and Patrizio 2015). According to the reports of the European Society of Human Reproduction and Embryology, more than 5 million babies have been born worldwide as a result of IVF treatment worldwide. With the continuous optimization of IVF technology, the psychological fluctuations in women during treatment have gradually attracted the attention of medical staff (Rockliff et al. 2014). It has been demonstrated that infertility, the IVF treatment itself, and the uncertainty of the pregnancy outcome can cause emotional distress to 25%-60% of women undergoing fertility treatment (Kalaitzaki et al. 2020). Controlled ovarian hyperstimulation (COH) stage represents the primary component of the IVF treatment. However, at an early stage of IVF, participants may not be aware of the necessity for psychological support until the signs of psychological distress become more pronounced (Wu et al. 2022). Consequently, it is imperative to implement efficacious and secure interventions to alleviate the psychological distress of women during COH.

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Correspondence: Lanfeng Xing, Department of Reproductive Endocrinology, Women's Hospital School of Medicine Zhejiang University, No.1, Bachelor's Road, Shangcheng District, Hangzhou 310006, China.
email: xinglf@zju.edu.cn

Acupuncture, a traditional Chinese medicine treatment, has gained significant popularity in recent years, particularly in Western countries (Ye et al. 2021). Auricular acupressure is a form of acupuncture treatment that stimulates specific acupuncture points on the ears in order to manage discomfort (Hou et al. 2015). The procedure is non-invasive, simple to implement, and easy to learn (Cheng et al. 2015). Furthermore, it causes minimal side effects and may be executed independently (Cheng et al. 2015). As evidenced by many studies, auricular acupressure can alleviate pressure for infertile women, reduce fatigue in postpartum women, and reduce anxiety of infertile participants prior to embryo transfer (Zhou et al. 2022).

The purpose of this study was to clarify whether auricular acupressure can improve the negative psychological state of female participants undergoing IVF during COH.

Methods

Study design and ethics

We conducted this randomized, sham-controlled, and single-blind study according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines (Butcher et al. 2022) and with the approval of ethics committee of Women's Hospital School of Medicine Zhejiang University. The flow chart was presented in Fig. 1.

The trial was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Ethics Committees of the Institutional Review Board of Reproductive Medicine, Women's Hospital, School of Medicine, Zhejiang University, China (20190077). The purpose of the study was explained to the participants, along with the participation details and the instruments that were to be used in the study. Furthermore, participants were informed that their participation was entirely voluntary and that they were at liberty to withdraw from the study at any time. The researcher received completed written consent from the IVF participants who agreed to participate in the study. The trial was registered with the Chinese Clinical Trial Register (ChiCTR): ChiCTR 2200056120.

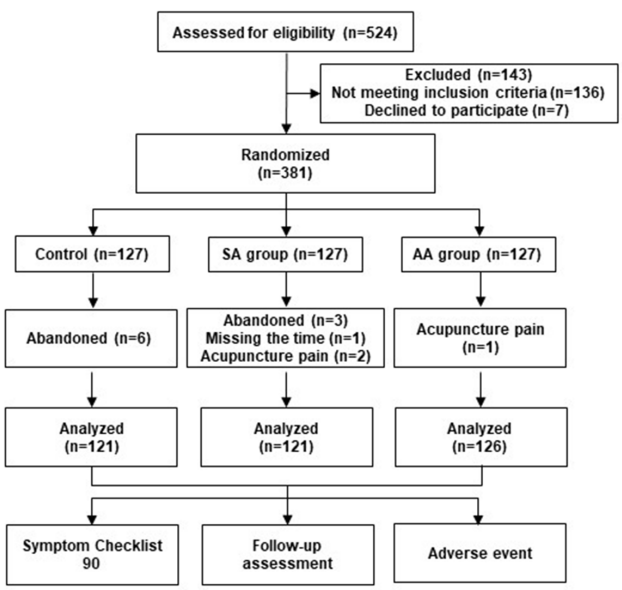

Fig. 1. Flow chart of the progress of participants through the trial. AA: auricular acupressure; SA: sham acupressure.

Participants

The infertile women who underwent IVF following referral to the Reproductive Medicine Center of Zhejiang Province, China (Department of Reproductive Endocrinology, Women's Hospital, School of Medicine, Zhejiang University, China) from September 2020 to February 2021 were included in the study. These women were aged 20-40 years old, received IVF treatment for the first time, and had no structural abnormalities of the uterus, ovaries or the ear. Exclusion criteria were those with mood or psychiatric disorders, history of smoking or drinking, any co-morbidity or uncontrolled systemic diseases, such as hypertension, diabetes that may affect the treatment process, any acupuncture treatment during the previous year, and allergic reactions to auricular acupressure material.

Sample size, blinding and randomization

The sample size was informed by evidence from systematic reviews and clinical advice, and determined using the Power Analysis and Sample Size (PASS 11.0). This study was designed to enroll 114 participants per group in order to achieve 90% power to detect a significant change in psychological status, at the 5% significance level. A 10% attrition rate was assumed, resulting in an estimated sample size of 127 participants per group. A total of 524 infertile women who would undergo IVF were enrolled initially. On the day preceding the commencement of COH procedure, the participants were randomly allocated to one of three groups: the control group, the auricular acupressure (AA) group, and the sham acupoint group (SA) in a 1:1:1 ratio using a random number table. At this juncture, an IVF clinician developed a standard treatment plan. The IVF clinicians, laboratory staff, participants, data collectors, and data analysts were unaware of the group assignment. The blinding was maintained until the completion of the analysis.

Experimental intervention

The auricular points were selected in accordance with the Chinese Standard Ear Acupoints Chart Nomenclature and Location of Auricular Points (GB/T-13734–2008) and consulted with multiple Chinese medicine experts. The acupressure was carried out by two nurses who were trained by a senior acupuncturist. During the treatment period, excessive communication with subjects was avoided, and the clinicians refrained from giving preference opinions.

Control group: participants received routine IVF treatment procedures without acupressure.

AA group: On the first day of COH (the first day of ovarian stimulation with gonadotropins), the subjects

received AA on four acupoints: Shenmen (TF4, located at the bifurcation of the crura of antihelix), Kidney (CO10, on the posterior portion of the concha inferior to the inferior crus of the helix), Endocrine (CO18, located at the bottom part of the incisura intertragica), and Internal genitals (TF2, located at the middle point of the anterior portion of the triangular fossa). After disinfection with 75% ethanol and when dry, a vaccaria seed was applied using paper medical tape to the designated acupoints of the ear. The seeds were pressed with an appropriate strength until the patient felt soreness, or distension around the point, or the local auricle congestive (Deqi sensation), on two ears simultaneously. Auricular acupressure was conducted four times a day, at 08:00, 12:00, 16:00, and 20:00, respectively. To prevent intervention of an external variable, participants were instructed not to receive additional acupuncture intervention during the study period, or to inform the researcher if they had undergone other forms of intervention. The adhesive patch was renewed every three days. Auricular acupressure was continued until the day before transvaginal surgery.

SA group: On the first day of COH the subjects received otopoint pressure massage on four irrelevant acupoints: Tiple energizer (CO17, located in the cavum conchae), Lung (CO14, located at the depression in the center of the concha cavity), Stomach (CO4, located at the commissure of superior concha and inferior concha, just below the disappearance of the crus of the helix), and Large intestine (CO7, located at the inner third of the crus of the helix, lying at the lower portion of the superior concha). The manipulation and treatment time were the same as those in the AA group.

To help researchers recognize the location of acupoints accurately, an ear model with a map of acupoints was provided (Supplementary Fig. S1).

Measurements of psychological status

The participants were assessed for the psychological status on the first day of COH (before the first auricular acupressure treatment [T1]) and the day completing the auricular acupressure (T2). The psychological status of the participants was measured with the Chinese version of Symptom Checklist 90 (SCL-90), which is a multidimensional psychological symptom scale widely used in clinical practice. SCL-90 can objectively and accurately reflect personal conscious symptoms, and is therefore well-suited to the measurement of psychological symptoms and their severity. SCL-90 is characterized by high reliability and good construct validity (Wei et al. 2018). The scale comprises 10 subscales to assess somatization, obsessive-compulsiveness, interpersonal sensitivity, depression, anxiety, hostility, phobia, paranoia, psychotic features, and various symptoms. The first nine subscales were used in this study. Each item was rated on a five-point scale of severity, ranging from 1 (not at all), to 5 (extremely). A higher score indicated a greater prevalence of neurological symptoms and more severe psychological problems.

Follow-up assessments

Follow-up assessments were conducted at 12 months following the COH for each participant. Participants were requested to provide information regarding the current outcome of any IVF cycles since the auricular acupressure, including whether the cycle resulted in a positive or negative pregnancy, as well as other situations that may have occurred, such as an in-cycle, incomplete cycle, miscarriage, or termination. Pregnancy outcome contained the cases who had a live delivery as a result of the studied cycle and who had an ultrasound-confirmed, ongoing pregnancy using the ova from this COH. The non- pregnancy consisted of women who had an incomplete cycle (gonadotropins were started but no oocyte retrieval or no embryo transfer occurred), a negative pregnancy test, or whose pregnancy ended in miscarriage or termination of a nonviable pregnancy.

Adverse events

Any adverse effects related to auricular acupressure were collected participants, except for mild pain on ear.

Statistical analysis

Statistical analysis was performed using SPSS version 22.0 software. Data, such as highest education level, employment type, living area, and fertility diagnosis were described statistically by numbers or percentages, and comparisons among groups were conducted by the Chi-square test. Descriptive data for age, duration of infertility, induction length, and SCL-90 scales were expressed as mean ± standard deviation. A paired t-test was used for intra-group comparisons and ANOVA was used for inter-group comparisons. $P < 0.05$ was set as the threshold for significance.

Results

Participant characteristics

Among the initial 524 participants, 136 women did not meet the inclusion criteria, and seven women declined to participate. Then, a total of 381 women were randomized to three groups in this trial (Fig. 1). During the intervention, 13 cases dropped out or withdrew, because of not adhering to the times, acupuncture pain, or abandoning IVF treatment. Finally, 368 participants completed this trial, with 121 in the control group, 121 in the SA group, and 126 in the AA group, respectively. As shown in Table 1, there were no significant differences among the control group, AA group, and SA group in any of the baseline characteristics, including age, duration of infertility, education, fertility diagnosis, employment type, and living area of the participants. There was no significant difference in the duration of acupressure treatment among the AA and SA groups.

The intra-group comparison of psychological symptoms

Table 2 presents the within- and between-group com-

Table 1. The baseline characteristics of the participants.

Items	Control group (n=121)	SA group (n=121)	AA group (n=126)	P
Ages (years)	30.56 ± 3.73	31.13 ± 3.43	31.11 ± 3.97	0.399
Duration of infertility (years)	3.22 ± 2.55	3.08 ± 2.37	3.37 ± 2.47	0.639
Induction length (days)	10.30 ± 0.97	10.10 ± 0.79	10.33 ± 0.95	0.095
Fertility Diagnosis				
Female factor	77/121 (63.6%)	69/121 (57.1%)	70/126 (55.6%)	0.051
Male factor	22/121 (18.2%)	13/121 (10.7%)	29/126 (23.0%)	
Both	12/121 (9.9%)	26/121 (21.6%)	17/126 (13.5%)	
Unexplained	10/121 (8.3%)	13/121 (10.7%)	10/126 (7.9%)	
Highest education				
Low	34/121 (28.1%)	27/121 (22.3%)	37/126 (29.4%)	0.425
Medium	18/121 (14.9%)	24/121 (19.8%)	27/126 (21.4%)	
High	69/121 (57%)	70/121 (57.9%)	62/126 (49.2%)	
Employment Type				
Full-time	87/121 (71.9%)	83/121 (68.6%)	93/126 (73.8%)	0.657
Non-employment	34/121 (28.1%)	38/121 (31.4%)	33/126 (26.2%)	
Living Area				
City	50/121 (41.3%)	48/121 (39.7%)	53/126 (42.1%)	0.990
Town	36/121 (29.8%)	39/121 (32.2%)	39/126 (31.0%)	
Country	35/121 (28.9%)	34/121 (28.1%)	34/126 (27.0%)	

Data are show as mean ± SD or frequencies (percentages). AA: auricular acupressure; SA: Sham.

Table 2. The levels of psychological symptoms and the IVF outcomes.

SCL-90 scales	Time-point	Control group (n=121)	SA group (n=121)	AA group (n=126)
Somatization	T1	1.39 ± 0.30	1.37 ± 0.32	1.43 ± 0.31
	T2	1.45 ± 0.30	1.49 ± 0.26	1.37 ± 0.30
Obsessive compulsive	T1	1.67 ± 0.37	1.59 ± 0.31	1.66 ± 0.32
	T2	1.83 ± 0.40	1.82 ± 0.34	1.53 ± 0.45
Interpersonal sensitivity	T1	2.48 ± 0.40	2.51 ± 0.42	2.57 ± 0.40
	T2	2.99 ± 0.35	2.98 ± 0.34	2.95 ± 0.33
Depression	T1	1.49 ± 0.33	1.52 ± 0.30	1.47 ± 0.37
	T2	1.83 ± 0.33	1.81 ± 0.33	1.31 ± 0.33
Anxiety	T1	1.59 ± 0.37	1.59 ± 0.38	1.50 ± 0.36
	T2	1.97 ± 0.34	1.98 ± 0.36	1.34 ± 0.35b
Hostility	T1	1.41 ± 0.41	1.45 ± 0.44	1.35 ± 0.28
	T2	1.42 ± 0.36	1.43 ± 0.38	1.31 ± 0.31
Phobic anxiety	T1	1.19 ± 0.35	1.18 ± 0.25	1.20 ± 0.26
	T2	1.20 ± 0.29	1.18 ± 0.28	1.18 ± 0.27
Paranoid ideation	T1	1.22 ± 0.35	1.26 ± 0.31	1.27 ± 0.29
	T2	1.21 ± 0.31	1.22 ± 0.28	1.22 ± 0.29
Psychoticism	T1	1.20 ± 0.31	1.23 ± 0.30	1.22 ± 0.24
	T2	1.19 ± 0.27	1.21 ± 0.29	1.18 ± 0.27
Total score	T1	125.17 ± 23.72	126.24 ± 21.98	126.76 ± 22.62
	T2	141.03 ± 21.41	142.28 ± 20.43	123.97 ± 22.42

Data are show as mean ± SD.
AA: auricular acupressure; SA: Sham acupoint; T1: the time-point on the morning of the first day of COH treatment (before the first AA treatment); T2: the time-point after the last AA treatment; SCL-90: Symptom Checklist 90.

parisons of SCL-90 scores. In the control group, testing after the COH stage found that obsessive compulsive, interpersonal sensitivity, depression, and anxiety scores were increased compared with those before COH ($P < 0.01$; Fig. 2A left panel). There was also an increase in the total SCL-90 score after COH ($P < 0.001$; Fig. 2A right panel). In SA group, testing after the COH stage found that somatization, obsessive compulsive, interpersonal sensitivity, depression, and anxiety scores were increased compared with those before COH ($P < 0.05$; Fig. 2B left panel). An upregulation of the total SCL-90 score was also found after COH ($P < 0.001$; Fig. 2B right panel). In AA group, testing after the COH stage found that interpersonal sensitivity score was increased, but obsessive compulsive, depression, and anxiety scores were reduced, compared with those before COH ($P < 0.05$; Fig. 2C left panel). However, there was no significant difference between the total SCL-90 score pre- and post-treatment in AA group (Fig. 2C right panel).

The inter-group comparison of psychological symptoms

After inter-group comparison of psychological symptoms, compared with the control group, the auricular acupressure group had greater improvement in scores of obsessive compulsive, depression, and anxiety ($P < 0.05$; Fig. 3A). Compared with the sham group, the auricular acupressure group had greater improvement in scores of somatization, obsessive compulsive, depression, and anxiety ($P < 0.05$; Fig. 3B).

The outcome of the first IVF cycle

All the participants were followed for the IVF outcomes that resulted from the studied COH. The percentages for pregnancy outcome were 58.7% (71/121), 61.2% (74/121), and 73.0% (92/126) in the control, SA, and AA group, respectively (Fig. 4). Chi-square tests revealed that auricular acupressure significantly improved the percentages of pregnancy ($P < 0.05$) compared to non-intervention and sham auricular acupressure.

Adverse events

No adverse events were found in any group during the whole period of study, indicating that auricular acupressure was relatively safe for women with COH.

Discussion

Ovarian stimulation with gonadotropins in IVF cycles sometimes causes the ovarian hyperstimulation syndrome, a potentially life-threatening iatrogenic complication (Palomba et al. 2023). During COH treatment, the participants had to go to the hospital many times, which disrupted their daily routine and affected their normal work schedules. A series of invasive procedures, such as frequent drug injections, ultrasound examinations, and daily sex hormone testing, may affect participants' quality of life; participants feel fatigued, which can lead to emotional changes (Domar 2018). The higher the couple's pessimism is, the longer the COH sustains; the higher the partner psychological distress is, the lower the fertilization rate is (Quant et al. 2013). It has been reported that women scored higher psychological distress than their male partners in the context of preparing for IVF (Wichman et al. 2011). Few studies have reported on the provision of psychological support by fertility centers to participants during COH treatment. The present study provides the evidence for an auricular acupressure intervention in reducing the severity of psychological distress in women during COH undergoing IVF treatment.

The results of the current study showed that the obsessive compulsive, interpersonal sensitivity, depression, and anxiety increased during COH treatment. This is consistent with a previous finding, which showed that psychological distress always plagued participants and tended to increase during treatment (Awtani et al. 2019). Nerve fibers are extremely abundant in the auricle, making it more sensitive to external stimuli (Wang et al. 2013). In Traditional Chinese Medicine meridian theory, many acupuncture points are distributed on the auricle, and the acupoints correspond to the main organs or systems of the body (Yang et al. 2017). When a disease occurs in a certain part of the human body, it is reflected in the corresponding acupuncture points on the ear, and an improvement in the conditions can be achieved by pressing the spots and helping the body to heal naturally (Wang et al. 2013). Hormones and neurotransmitters released by the hypothalamic-pituitary-adrenal axis and sympathetic nervous system influence the psychological state of IVF participants to some extent (An et al. 2013). Auricular acupressure can reduce excessive stress in participants by regulating sympathetic nerves and increasing the secretion of endorphins in the body, making participants feel relaxed and calm and relieving their psychological distress (Pirnia et al. 2019). There are studies suggesting that acupuncture treatment may be associated with increased emotional resilience throughout the IVF process (Hullender Rubin et al. 2018). In this study, 386 infertile women undergoing IVF were investigated to assess whether auricular acupressure could relieve their psychological and emotional issues. Results showed that auricular acupressure was statistically significantly effective in reducing somatization symptoms, obsessive-compulsiveness, anxiety, and depression in IVF women.

Psychological distress in participants with COH reduces ovarian sensitivity to gonadotropins, resulting in a decrease in the number of follicles produced during ovulation, and the number of mature follicles is an important factor in predicting pregnancy (Winkelman et al. 2016). A recent mate-analysis reported that the participants' poor psychological state prior to transvaginal oocyte retrieval was a relevant factor in predicting pregnancy outcomes (Kushnir et al. 2017). Indeed, the potential impact of psychological factors on pregnancy rates is one of the most controversial areas in reproductive medicine (Amorim et al. 2018). However, excessive psychological pressure can affect participants' confidence in treatment and lead to pre-

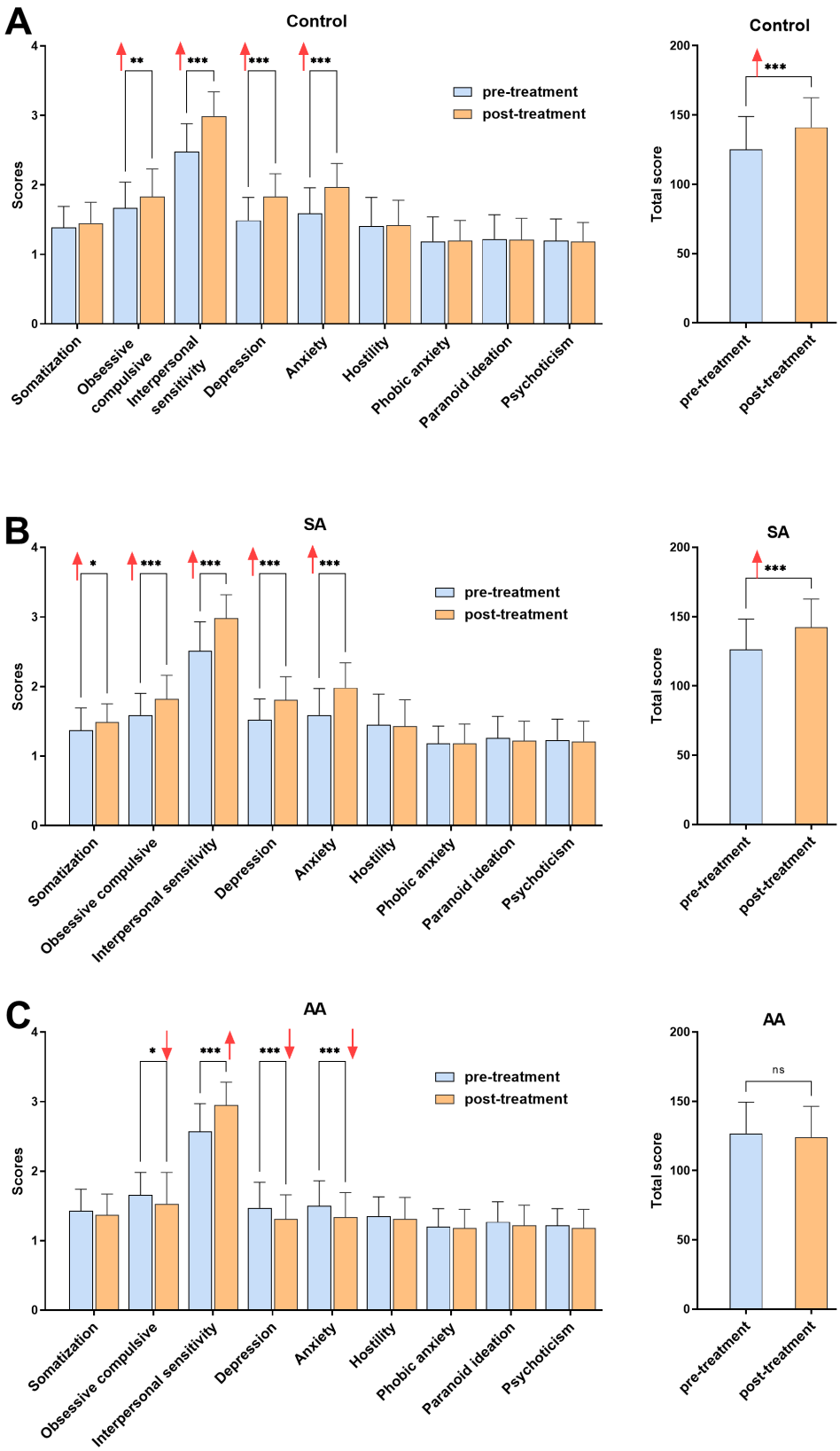

Fig. 2. The intra-group comparison of psychological symptoms based on SCL-90 scales in control group. (A), sham acupressure (SA) group (B), and auricular acupressure (AA) group (C). Two-way ANOVA analysis was used for intra-group comparison of single item, while paired t-test was used for intra-group comparison of total scores.

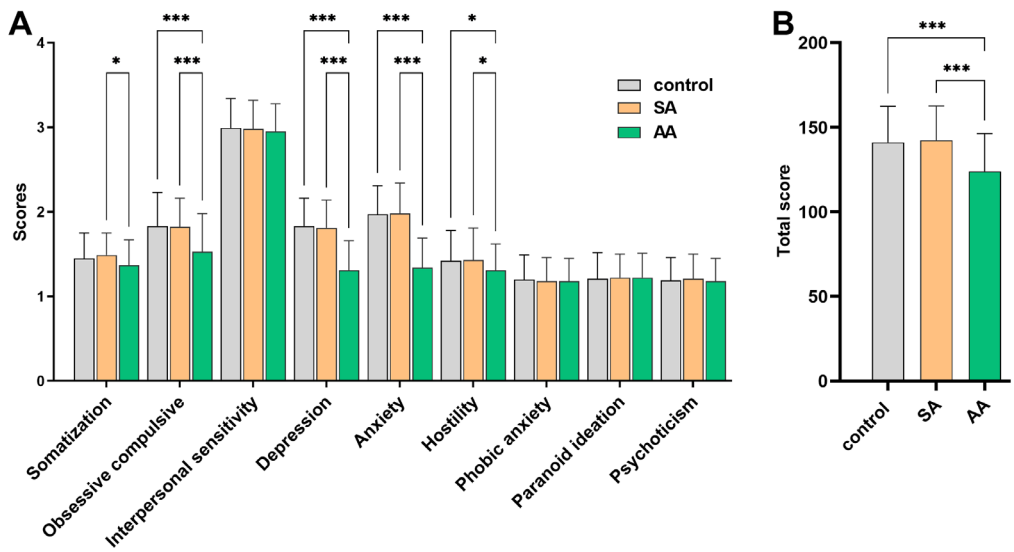

Fig. 3. The inter-group comparison of psychological symptoms in each scale.
(A) and total score (B) based on SCL-90 scales among control group, sham acupressure (SA) group, and auricular acupressure (AA) group. ANOVA analyses were used.

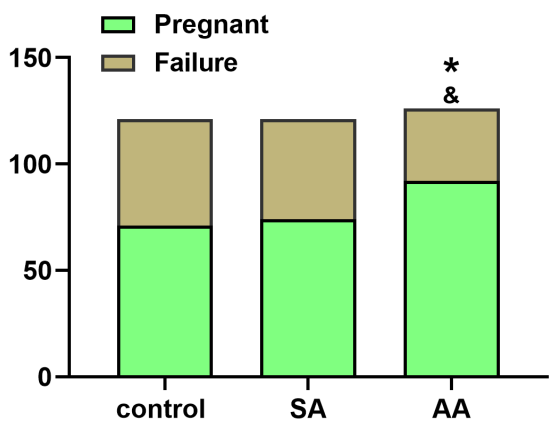

Fig. 4. The IVF outcome based on the studied COH stage in control group, sham acupressure (SA) group, and auricular acupressure (AA) group.
Chi-square test was used.

mature abandonment of IVF treatment (Kim et al. 2018). Therefore, it is necessary to pay attention to the psychological state of IVF women during COH treatment and provide safe and effective psychological interventions. In this study, the auricular acupressure group selected Shenmen, Kidney, Endocrine, and Internal genital points for auricular acupressure. According to modern research, Shenmen can help relieve stress and calm the mind; the kidney can reduce the over-excitation of the autonomic nervous system, and is often used to treat various hormones; and the internal genitalia acupoint can regulate the function of the female reproductive system (Hullender Rubin et al. 2018). In order to accurately verify the effect of auricular acupressure and exclude the placebo effect, a sham acupoint group was used in this study, and auricular acupressure intervention was performed on acupoints without psychotherapeutic function. The psychological distress of the sham acupoint group hadn't improved after the intervention.

It is worth noting that scores on the interpersonal sensitivity subscale of the three groups increased during IVF treatment. This may be because the formation of emotions is related to internal factors, such as personality and cultural background, which are difficult to change in a short period of time (El Kissi et al. 2013). Alternatively, during IVF treatment, repeated hospital visits affect work and life, leading to an increase in participants' inner guilt and frustration (Li et al. 2019). The intense focus on treatment limits participants' social activities, resulting in perceived social isolation (Li et al. 2019). Infertile women are more sensitive to external comments, typically feel embarrassed when discussing infertility issues (Nahar and van der Geest 2014), and are reluctant to express their inner thoughts. These factors lead to strained tense interpersonal relationships; having social connections is essential for an individual to maintain mental health and achieve positive well-being (Engels et al. 2019). This suggests that it is necessary to assess participants' emotional state in a time-dependent manner in clinical work (Zaig et al. 2013), and to implement intervention measures as soon as possible, to provide social support for more ideal curative effects.

Limitations

The limitations of the study include the small sample size, the use of a single reproductive medicine center, a short research period, and lack of investigation into the underlying mechanism of auricular acupressure.

Furthermore, the study was designed to be single-blinded. Further support for the application of auricular acupressure during IVF treatment is to be provided by future multi-center, randomized, controlled trials.

Conclusion

It can be concluded that auricular acupressure can assist in the alleviation of somatization symptoms, obsessive-compulsive symptoms, depression, and anxiety experienced by women undergoing ovulation induction in an IVF cycle. It is noteworthy that an increase in interpersonal sensitivity was observed in the female participants during the course of their IVF treatment. The findings highlighted the necessity for further support for women with high levels of interpersonal sensitivity during IVF treatment. It is proposed that interventions to reduce interpersonal sensitivity in participants can be combined with auricular acupressure, thereby enhancing the effectiveness of auricular acupressure.

Author Contributions

Y.L. and L.F.X. designed the research study. W.J.S., F.Y.M. and Q.M. performed the research and analyzed the data. Y.L. and L.F.X. wrote the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

Conflict of Interest

The authors declare no conflict of interest.

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Supplementary Files

Please find supplementary file(s);
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