The effectiveness of collaborative infertility counseling (CIC) on pregnancy outcome in infertile women undergoing in vitro fertilization: A randomized controlled trial

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Abstract

Background: Infertility is an emotional tension which influences the whole aspects of relationships in infertile couples. A main objective of infertility treatments is elevation of pregnancy rate. The present study aimed to examine the effect of collaborative counseling on pregnancy rate in infertile women, undergoing in vitro fertilization in Mashhad, Iran.

Methods: In this clinical trial, 60 women with primary infertility were selected from an infertility research center and were randomly allocated into intervention (n=29) and control (n=31) groups. The intervention group received individual counseling, based on the collaborative reproductive healthcare model with collaboration of a midwife, a gynecologist and a clinical psychologist in five sessions during a two-month period. The control group received routine care. Positive pregnancy test was considered as a criterion of treatment success at the end of the study. Data were analyzed using statistical tests including independent samples t-test.

Results: There was no significant difference in pregnancy rate between intervention and control groups ($P = 0.298$). Also, there were no significant differences in follicle and embryo numbers between two groups. However, a significant difference was observed between two groups in terms of oocyte numbers where the intervention group had more oocyte ($P = 0.014$).

Conclusion: Overall the findings indicated that the collaborative infertility counseling did not improve treatment success in infertile women undergoing in vitro fertilization

Background

Childlessness is a universal problem which disrupts the whole aspects of people's relationships and affects 80 to 168 million people all over the world [1, 2]. Roughly, 25% of Iranian couples have experienced primary infertility [3]. Without paying attention to cause of infertility, female partners suffer not only further painful treatments, stress, anxiety and sexual problems, but also experience less marital satisfaction than men. Appearance of In Vitro Fertilization (IVF) has intensified this issue [1, 4–14].

There is significant evidence that shows the impact of psychological status on women fertility and outcome of assisted reproductive technologies (ARTs). Studies show that stress can affects the number of oocyte, embryos and positive pregnancy test, also can lead to change the hormone levels that are associated with human fertility [12,15,16]. Researches find that some factors in infertile women such as stress, depression and anxiety have reverse relationship with retracted oocyte number of infertile women and pregnancy rate in ARTs [17, 18]. Infertility counseling is a novel theory that synthesizes medical and psychological aspects of reproductive health. Infertility counsellors should consider the socio-cultural concerns of their clients and adopt holistic approaches to prepare couples for this stressful life phenomenon [1, 19]. Today, with emphasis on bio-psycho-social model, relatively adequate justification has been provided for the cause of diseases and their treatment [12].

The most recent paradigm shift, in the new millennium, occurred with the realization that compliance with protracted fertility treatment depends on the adoption of an integrated approach to fertility care [20].

In this regard, Covington (2007) presented a theoretical framework, known as the collaborative reproductive healthcare model, which is derived from bio-psycho-social model in which all physiological, psychological, personal and social appearances of infertile individuals are taken into consideration. In the collaborative reproductive healthcare model, midwives, psychiatrists, physicians and gynecologists organized a medical group and squired infertile patients from the beginning to the end of treatment [1]. Researcher that pursuing this collaborative counseling model reported that it can reduce the infertile women's perceived infertility-related stress and enhance the marital satisfaction. Thus, they suggested this model as one of the stress management strategies and improve the coping strategies in infertile women undergoing IVF [21, 22, 23]. Valiani et al. reported that relaxation technique could lead to increased success in outcome of pregnancy (positive pregnancy test) after IVF or ICSI ($p < 0.006$) [17]. While Anderheim et al. reported that counseling with midwife not increase the pregnancy rate in infertile women [24].

However, cultural components might affect the outcome of infertility counseling [1, 25]. Whereas a main objective of infertility treatments is elevation of pregnancy rate [17], few studies have been conducted to evaluate the effectiveness of psychosocial intervention in infertility outcome [9, 25, 26–28]. While few studies conducted on infertility counseling, the question still remains: 'can collaborative infertility counseling affect the pregnancy outcome in infertile women?' This study aimed to investigate the effect of collaborative infertility counseling on pregnancy rate for infertile women undergoing in vitro fertilization.

Methods

Design and participants

This was a randomized clinical trial in order to assess the effectiveness of pregnancy outcome in infertile women attending a referral hospital affiliated to Mashhad University of Medical Sciences in Mashahad, Iran. The inclusion criteria were: Iranian nationality, literacy, absence of somatic or psychiatric disease, not being smoker, not receiving oocyte donation and not being a gestational surrogate. The exclusion criteria were: severe family dispute or traumatic events during the study lack of ovarian response to the drugs and leaving the treatment for any reason.

Intervention

The researchers recognized the participants with inclusion criteria at the beginning of the IVF treatment cycle (primary ultrasonography on days of 2 and 3 in menstrual cycle) in Milad center. All of the participants have answered the study questionnaires at the entrance to the study. During the study, the

control group received routine care. However, in addition to the routine care, the intervention group received five sessions of individual counseling with content on the causes and treatments of infertility, proper communication with social network, problem focused coping strategies and stress management techniques (i.e. the Jacobson relaxation technique, to be practice at least five times a week). The counseling program was administered in the presence of a midwife (the first author), a gynecologist and a clinical psychologist. Each session lasted for 45–60 minutes, and was held during IVF treatment cycle that lasting between 8–9 weeks. Every session consisted of a combination of a short speech, question and answering, and role-playing. At the end of the first session, an audio CD, an educational pamphlet about the relaxation techniques, and a checklist to record the frequency of relaxation techniques at home were given to each participant. The faculty members in Mashhad University of medical sciences confirmed the content validity of the educational pamphlet and the audio CD. The structure of the collaborative counseling sessions is presented in Additional File 1.

Outcomes

The primary outcome was positive pregnancy test as indicated by hcG blood pregnancy test. Laboratory personnel not connected and not aware of the study carried all tests out two weeks after completion of intervention in the same hospital. Secondary outcomes were number of follicles, oocytes and embryos. Sonographist and a laboratory technician determined follicle, oocyte and embryo number, respectively.

Randomization

The first participant was allocated into the control group through coin tossing, and then, the second women assigned to the intervention group. This was done for every participant until the required sample size for each group was achieved. Since the main investigator was responsible for providing counseling thus there was no possibility for blinding.

Statistical analysis

The statistical analyses were performed using SPSS version 11.5 (SPSS, Inc. Chicago, Illinois, USA). We used intention-to treat analysis and thus the data analyses were performed for the study groups based on the initial random allocation. The Kolmogorov-Smirnov test was used to assess the normal distribution of data. Descriptive statistics including mean, standard deviation, frequencies and percentages were used to explore the data. Independent sample t-test, Chi-Square or Fisher's exact test and Mann-Whitney U test (where necessary) were used for group comparison. $P\text{-value} \leq 0.05$ was considered statistically significant.

Ethics

The Ethics Committee of Mashhad University of Medical Sciences approved the study (511/1388). Infertile women consented to participate in this study with endorsing a written informed consent letter. The questionnaires were anonymous, and personal information was kept confidential. The participants were informed of their right to leave the study at any time. The study is registered at the Iranian Registry of Clinical Trials (<http://en.irct.ir/trial/8359>).

Results

In all 116 women were approached and 80 were randomly assigned into the intervention and control groups. However, the final sample consisted of 60 women including 29 women in the intervention group and 31 women in the control group (Figure1).

The two groups were not significantly differed in terms of demographic characteristics, and infertility-related data (Table 1).

As demonstrated in Table 2, 31% of participants in intervention group and 45.2% participants in control group have positive pregnancy test. Fisher exact test indicate that there was not statistically difference between two groups regarding positive pregnancy test ($P = 0.298$).

An independent samples t-test showed that two groups were not statistically differed regarding the number of follicle and embryo but oocytes number was statistically different between two groups at the end of the study ($P = 0.014$) (Table 3).

Discussion

This study was conducted to determine the impact of collaborative infertility counseling on pregnancy rate in infertile women undergoing IVF treatment. The results of this randomized controlled clinical trial not confirmed the research hypothesis. The findings showed that collaborative infertility counseling not improved pregnancy rate, although the number of follicles, oocytes and embryos in intervention group was increased.

In a systematic review, Boivin et al. indicated that pregnancy rates were unlikely to be affected by psychosocial interventions. They suggested that more investigations are needed to prove that psychosocial interventions could improve pregnancy rate. However, the same systematic review acknowledged that three of eight studies showed a significant increase in pregnancy rate within 3 to 18 months following a number of psychosocial interventions [29]. On the contrary, Hamerli et al. in a meta-analysis reported that despite the absence of clinical effects on mental health measures, psychological interventions were found to improve some patients' chances of becoming pregnant [30]. One explanation for such observation might relate to the fact that elevation in pregnancy rate was due to improvement in couple sexual relation in intervention group. There is evidence that relaxation technique can lead to increased success in outcome of pregnancy (positive pregnancy test) after IVF [17]. Perhaps relaxation could reduce stress and increase pregnancy rate.

Ramezanzadeh et al. reported that psychiatric intervention improved pregnancy rates in infertile couples. So that, patients in the experimental group received 6–8 sessions of psychotherapy (individually) before the onset of infertility treatment and taking fluoxetine (antidepressant drug) at 20–60 mg per day during the psychotherapy period [12]. Notably, participants in mentioned research selected from depressed people that justify the positive effect of this intervention. Li et al. reported that pregnancy rates increased after 6 months follow up in their research [11]. In Li study, participants reported best quality of sleep. Perhaps this is beneficial for promoting their self-compassion, adaptive emotion regulation and infertility-related coping strategies, which, in turn, may influence the fertility quality of life and pregnancy rates. Scientific evidence shows that many factors affect the pregnancy rate [11]. Kapfamer et al. and Boivin reported that stress in initial of study is not related to viable pregnancy [29,31]. Overall this meta-analysis shows a lack of association between pretreatment emotional distress and pregnancy outcome in women undergoing a cycle of treatment with an assisted reproductive. Hashemi et al. reported that high or low levels of state or trait anxiety have no effect on the pregnancy rate after ART treatment [32]. Demyttenaere et al. also offered that personality-dependent stress responses are important for the conception rate in stimulated cycles. On the other hand women undergoing IVF were found to have different biophysical responses to psychosocial stressors compared to controls [33].

The controversy of the results in previous studies about the effects of stress or anxiety on the success of infertility treatment were probably consequence of different types or levels of anxiety, various mythologies, small and inadequate samples, different tools to assess stress or anxiety or shortcomings of studies in controlling for potential confounding variables on fertility. However as far as our study concerns the findings suggest that still firm evidence does not exist to support that such interventions could improve pregnancy rate. Indeed it seems that there is need for multi-center studies with bigger sample size or even a collaborative studies including samples from different countries to provide solid evidence for policy and practice.

This study had some limitations. The mainly statistical methods used in this study were independent samples t-test, Mann-Whitney test and Chi-Square, which is too simple for clinical data and small samples. Thus the results should be interpreted with caution. In addition this work did not evaluated psychological status of women at baseline while could have evaluated the psychological status such as stress and anxiety at baseline to see if women were similar in these respects. As such it is recommended that the future studies perform such assessments at baseline.

Conclusions

Overall the findings indicated that the collaborative counseling did not improve pregnancy rate in infertile women. However, it might increase oocyte numbers that in turn could be a sign for an increased chance of pregnancy.

Declarations

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Authors' Contribution:

MRB was the main investigator and wrote the first draft. RLR was the study supervisor and contributed to analysis and interpretation of the data. AM contributed to important intellectual content: and final manuscript. All authors read and approved the manuscript.

Conflicts of interests:

The authors declarer that they have no conflict of interests.

Availability of the data

The data presented in this study are available form the corresponding author in request.

Ethics

The ethics committee of Mashhad University of Medical Sciences approved the study. All participants were asked to complete the informed consent form.

Consent to publish

Not applicable

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None.

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Tables

Table 1: Characteristics of the participants in two groups

	Control (n = 31)	Intervention (n = 29)	
	No. (%)	No. (%)	P*
Age groups			0.169
20-24	4 (12.9)	3 (10.3)	
25-29	17 (54.8)	11 (37.9)	
30-34	8 (25.8)	7 (24.1)	
35-40	2 (6.5)	8 (27.6)	
Education			
Primary	8 (25.8)	4 (13.8)	0.109
Secondary	17 (54.9)	16 (55.1)	
Higher	6 (19.4)	9 (31.0)	
Cause of infertility			0.597
Male	16 (51.6)	10 (34.5)	
Female	8 (25.8)	9 (31.0)	
Both	3 (9.7)	4 (13.8)	
Unknown	4 (12.9)	6 (20.7)	
Hope for treatment success			0.173
Very high	10 (34.5)	9 (31)	
High	9 (31.0)	12 (41)	
Somewhat	4 (13.8)	4 (13.8)	
Low	6 (20.7)	4 (13.8)	
	Mean ± SD	Mean ± SD	
Awareness of diagnosis, month	6.08 ± 4.31	5.62 ± 4.26	0.629
Duration of treatment, month	4.03 ± 4.24	3.83 ± 3.97	0.934
Number of IUI cycles	1.16 ± 1.43	1.34 ± 1.34	0.480
Number of IVF cycles	0.32 ± 0.54	0.44 ± 1.18	0.530

* Derived from chi-square and [Mann-Whitney U test](#) as necessary

IUI: intra uterine insemination, IVF: in vitro fertilization

Table 2: Differences in the pregnancy test between two groups

	Control (n = 31)	Intervention (n = 29)	
	No. (%)	No. (%)	P*
Positive	14 (45.2)	9 (31)	
Negative	17(54.8)	20 (69)	
			0.298

* Derived from Fisher's exact test.

Table 3: Comparison of treatment outcomes in two groups

	Control (n = 31)	Intervention (n = 29)	
	Mean $\pm$ SD	Mean $\pm$ SD	P*
Follicle number	13.50 $\pm$ 4.4	15.1 $\pm$ 5.3	0.242
Oocyte number	8.0 $\pm$ 3.8	10.9 $\pm$ 4.3	0.014
Embryo number	5.8 $\pm$ 2.9	7.3 $\pm$ 3.2	0.082

* Derived from independent samples t-test.

Figures

Figure 1

The study flowchart

Supplementary Files

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