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The Impact of Counseling Based On the PLISSIT Model on Sexual Function of Infertile Women: A Clinical Randomized Controlled Trial

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ABSTRACT

Background & aim: Infertility has negative effects including sexual dysfunction in infertile women. This study investigated the effect of counseling based on the PLISSIT model on sexual function of infertile women.

Methods: This study was performed on 60 infertile women, who were randomly assigned to two interventions (direct and indirect counseling) and control groups (20 in each group). In the direct counseling group, the intervention included four face to face sexual counseling sessions, once a week, based on the PLISSIT model. In the indirect counseling group, the similar content of counselling was given through booklet and the participants received telephone counseling. Sexual function was measured using female sexual function index (FSFI) pre and four weeks after intervention. One-way ANOVA was used to compare the groups before the intervention and ANCOVA with control of the baseline score after the intervention.

Results: There was no significant difference between the sexual function of three groups at baseline. After the intervention, by controlling the baseline score, a significant difference was observed in the overall score of sexual function in the direct counseling group (mean difference: 5.1, 95% CI: 26.3 to 29.7, P=0.001). In the indirect counseling group, after the intervention, only a significant difference was observed in the pain dimension (mean difference: 0.9, 95% CI: 2.5 to 3.9, P=0.044). **Conclusion:** It seems that PLISSIT based direct counseling improves more the sexual function of women with infertility. So, it is recommended that such counseling program be integrated into the health care program of infertile women.

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Introduction

Infertility is one of the most unpleasant events in today's life. It occurs when one or both couples are unable to conceive. Infertility is often defined as not conceiving after 12 months of regular intercourse without using contraceptive

methods (1). Studies show that the prevalence of infertility was 12.5% among women and 10.1% among men (2). However epidemiological data about infertility in the Iranian population are still unclear but primary infertility is estimated about

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5% (3). Infertility can interfere with the psychological – mental balance of the couples and lead to producing several negative symptoms such as depression - anxiety and even divorce in some cases (4). Infertility is associated with the reduction of sexual activity and always there is a relationship between infertility and sexual dysfunction (5). Sexual dysfunction is defined as a disturbance in desire, stimulation (arousal), orgasm, and sexual pain Prevalence of sexual dysfunction is high in infertile women, but little attention has been paid to this problem, and women are less likely to be treated (7). On the other hand, desirable sex can increase the chances of fertility, so attention to sexual issues is the basic point in the evaluation of infertile couples (8). Physical treatment of infertility alone is not enough and paying attention to the mental needs and even the scientific knowledge of the infertile couples are essential parts in the treatment of infertility (9). The goal of counseling (directly or indirectly) with infertile couple is to create a relationship to solve their problems (10). In an interventional study on infertile women with aim to evaluate the effect of counseling based on the BETTER model on sexual function, it was shown that counseling based on BETTER model led to improved sexual function in infertile women (11). Face to face counseling is one of the most common types of counseling in health care systems. In this way, the counselor provides the counseling process individually, to provide an opportunity to exchange ideas and emotions verbally and non-verbally between the counselor and the client (12). Study shows telephone counseling by using the phone not only reduces costs and facilitates access, but also improves the relationship between counselor and client and removes the barriers of location and time (13). PLISSIT counseling model is one of the practicaltreatment counseling models which can be used easily and at a low cost in medical environments (14). The model consists of four steps for addressing sexual concerns: Permission, Limited Information, Specific Suggestions, and Intensive Therapy (15).

This study was aimed to compare the effect of direct (face to face) and indirect (booklet and telephone) counseling based on PLISSIT model on sexual function of infertile women.

Materials and Methods

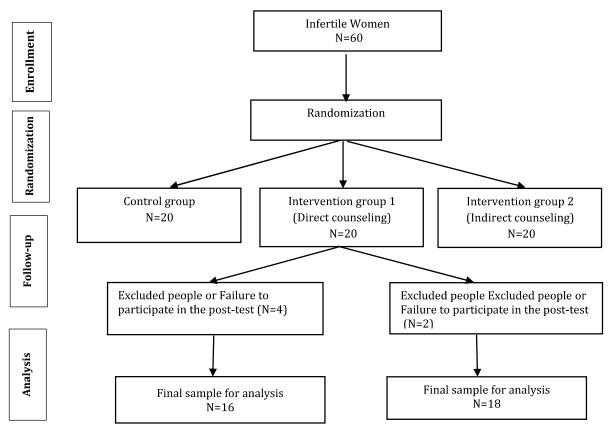
This three-group randomized clinical controlled trial study (two interventions and one control group) was performed on 60 infertile women referred to Motazedi Infertility Center in Kermanshah from February to June 2018. This research was approved by the ethics committee of Kermanshah University of Medical Sciences, under the ethical code of KUMS-1394.124.REC and was registered in the IRCT website under the code IRCT2016052928162N1.

Inclusion criteria were: proved infertility (primary or secondary), willingness participate in the study, having a phone (fixed or mobile), ability of reading and writing, at least one sexual problem (FSFI index score = 28 or less), being available over the next month from the start of the study, no history of psychoactive drugs, drug addiction or physical and mental illness. Exclusion criteria were: no sexual relations during the study period, sexual abuse, extreme marital conflicts (based on self-report), the occurrence of a bad event (death of loved ones, incidents with disabilities, etc.) during the last 6 months, unwillingness to continue the intervention, and failure to respond to the questionnaire.

The sample size was calculated as 18 people in each group using G-power software version 3 and by considering the $M_1=25.3$, $M_2=29.0$ (assuming a 15% increase in sexual function due the intervention), effect size= 0.973, $sd_1=sd_2=3.8$, with 95% confidence, $\alpha=0.05$, and 80% power (16). Considering to the possibility of 10% loss, the final sample size was increased to 20 people per group.

collection tools included Data demographic questionnaire and the female sexual function index (FSFI). The female sexual function index has 19 items divided into six subscales: desire, subjective arousal, lubrication, orgasm, satisfaction, and pain, with each question about one subscale. Arousal, lubrication, orgasm, and pain subscale scores range from 0 to 6, the desire subscale from 1.2 to 6, and the satisfaction subscale from 0.8 to 6, with higher scores reflecting higher sexual function. The maximum score is 36 and the score less than 28 indicates undesirable sexual performance

Figure 1. CONSORT Flowchart



(16). The validity and reliability of this questionnaire was confirmed in Iran by Mohammadi et al. (17). The researcher performed the intervention after completing a workshop on sexual problems and validation of skills in the implementation of the PLISSIT model. Before completing the questionnaire, a written consent was obtained from all eligible women and they were asked for a reliable telephone number. In the next stage, the demographic questionnaire and the FSFI questionnaire were completed by all samples.

Subjects were randomly assigned into three groups (two interventions and one control groups) using randomized blocks with block size of tree and six and allocation ratio of 1:1. For allocation concealment, numbered envelopes were prepared and the type of intervention was written on a paper and placed in identical opaque sealed envelopes with consecutive numbers,

Random allocation was performed by a person uninvolved in sampling and data collection. In the direct counseling group, the intervention was face to face sexual counseling once a week based on the PLISSIT model (Permission- Limited Information-Specific Suggestion-Intensive Therapy) at least 4 sessions (90 min) in the private room by the researcher. In the indirect counseling group, the booklet with scientific content based on direct counseling sessions was given to the subjects and the counselor conducted telephone counseling. The scientific content of the booklet was exactly in line with the content taught in face-to-face counseling. This content was approved by ten professors of gynecology, midwifery, anatomy, psychiatry, counseling and psychology and their suggestions were recorded in the final edition. The FSFI index was completed in two stages, before the intervention and 4 weeks after the end of the intervention. The control group received no



intervention, and at the end of the study, they received a booklet which with scientific content taught in the intervention groups.

Data were analyzed by SPSS software (version 21). First, normality of quantitative data was confirmed by Chi-Square test. For statistical analysis, chi-square test was used to compare the quantitative variables in three groups (direct, indirect, and control groups). Kolmogorov-Smirnov test was used to compare the quantitative variables. One-way ANOVA was used to compare the groups before the intervention and ANCOVA with control of the baseline score after the intervention. P< 0.05 was considered statistically significant.

Results

A total of 60 patients were studied in three groups. Four cases of the direct group and 2 cases of the indirect group were excluded from the study because of losing the study condition, and finally, the intervention was performed on 54 patients (Figure 1).

Most of the couples (40.4%) were in the age range of 31-35 years with an average of 5.8±4.3 years infertility (Table 1).

Table 1. Mean and standard deviation of the demographic variables

Variables	Mean ± SD	P-value	Test
Women's age	29.43 ± 5.5	0.737	K.S*
Men's age	33.81 ± 5.7	0.696	K.S
Marriage duration	7.56 ± 4.2	0.078	K.S
Infertility duration	5.8 ± 4.3	0.804	K.S

^{*} Kolmogorov Smirnov Test

Table 2. Demographic and reproductive data of the groups

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^{*} Due to limited samples, there were no conditions for the chi-squared test, so P-Value could not be calculated

The Kolmogorov-Smirnov test showed that the age of men and women had a normal distribution and the life span and infertility had no normal distribution. Based on the ANOVA test,

the three groups were matched and the ability to compare or carry intervention was possible

(Table 2). Kruskal-Wallis test confirmed the correlation between the groups in terms of span



Table 3. FSFI domains changes before and after the intervention in the study groups

		J				, ,	•		
	Groups								
	Direct		Indirect		Control		P- value		
FSFI [†] domains	Before (n=20)	After (n=16)	Before (n=20)	After (n=18)	Before (n=20)	After (n=20)	•		
	M+SD¶	M+SD¶ MD(95%C I) §	M+SD¶	M+SD¶ MD(95%C I) §	M+SD¶	M+SD¶	pre∞	Direct post [£]	Indire ct post [£]
Sexual Desire	3.5±0.7	4.4±0.68 0.6 (4.0 to 4.7)	3.3±0.8	4.0±0.8 0.2 (3.6 to 4.4)	3.7±0.9	3.8±1.0	0.21	0.127 df=2.0 4	0.764 df=0.6 7
Sexual Arousal	3.7±1.0	4.6±0.1 0.7 (4.5 to 4.6)	3.6±0.8	4.0±0.5 0.09 (3.7 to 4.2)	3.8±0.8	3.1±0.6	0.76 4	0.022 df=9.8 6	0.917 df=4.9 9
Lubrication	3.0±0.58	4.7±0.9 1.1 (4.2 to 5.1)	2.9±0.8	3.8±0.7 0.2 (3.4 to 4.1)	3.1±0.7	3.6±0.9	0.61 7	0.001 df=3.6 4	0.803 df=0.7 5
Orgasm	3.6±0.6	4.7±1.0 0.9 (4.2 to 5.2)	3.4±0.9	3.8±0.6 0.02 (3.5 to 4.0)	3.7±0.6	3.8±0.5	0.46 8	0.001 df=3.5 2	1.000 df=0.0 1
Satisfaction	3.9±1.2	4.1±1.0 0.2 (3.6 to 4.6)	4.2±1.0	4.3±0.7 0.4 (3.9 to 4.6)	4.7±0.8	4.8±0.8	0.06 6	0.084 df=2.3 3	0.262 df=2.0 3
Pain	3.1±1.9	4.8±1.1 2.4 (4.2 to 5.4)	2.7±1.1	3.2±1.4 0.9 (2.5 to 3.9)	2.2±1.2	2.3±1.1	0.07 3	0.001 df=6.7 7	0.044 df=2.2 1
Total FSFI	20.8±2.4	28.0±3.2 5.1 (26.3 to 29.7)	20.1±3.7	23.3±2.3 0.96 (22.1 to 24.4)	23.2±3.0	22.3±3.2	0.50 3	0.001 df=5.3 1	0.056 df=1.0 9

¶Mean and standard deviation

life and infertility. The results of the study groups in terms of demographic and midwifery variables were similar. Based on the One-Way ANOVA test, before the intervention, there was no statistically significant difference among the three groups in terms of total score of sexual function (P=0.503). Also, before the intervention. there was no statistically significant differences between the three groups in terms of sexual function dimensions, including sexual desire (P= 0.212), sexual arousal (P= 0.764), lubricant (P= 0.617), sexual orgasm (P=0.468), sexual satisfaction (P=0.066), and pain (P=0.073). After the intervention, by controlling the baseline score by ANCOVA test in the direct counseling group, a statistically significant difference was observed in the total score of sexual function (mean difference: 5.1, 95% CI 26.3 to 29.7, P=0.001), pain (P=0.001), orgasm (P=0.001), lubricant (P=0.001) and arousal (P=0.022). In the indirect counseling group, after the intervention,

only a statistically significant differences were observed in the pain dimension (mean difference: 0.9, 95% CI: 2.5 to 3.9, P=0.044) (Table 3).

Discussion

According to the results of the present study, the effect of counseling compared to the control group was well confirmed on the improvement of the FSFI score, and in terms of the type of counseling, direct counseling was more effective for improvement of the FSFI score than indirect counseling. The six indexes of the FSFI before and after the intervention were measured in all groups and the results were positive and effective, especially in the direct counseling group. It can be concluded that counseling based on the PLISSIT model will improve the Female Sexual Function Index. Similar to the results of the present study, Rostamkhani et al., investigated the effect of counseling based on the

[§] Mean difference (95% Confidence interval)

[∞] One-way ANOVA

[£] ANCOVÁ



PLISSIT model on the sexual function of married women; they reported that all domains of FSFI significantly increased after the intervention (18). In the present study, overall score of the female sexual function index significantly increased in both direct counseling groups and indirect counseling after the intervention compared to before the intervention. The counseling was effective on the promotion of female sexual function index scores, and of course, the effectiveness of direct counseling was confirmed. In the study of Yousefzadeh et al. in Mashhad. which examined the adjustment by presenting direct counseling and classes, it was accompanied by an improvement in the FSFI score (19). Hezbiiyan and colleagues in their study, which examined the effect of postpartum sexual counseling, they reported an increase in the mean score of sexual performance after the intervention through counseling (20). PLISSIT counseling model is one of the practicaltreatment counseling models which can be used easily and at a low cost in medical environments. In the study conducted by Mehrabi et al. in Iran which used this model on women's sexual performance, the mean score of the FSFI increased after the intervention that was similar to the present study (21). In the study conducted by Torkzahrani et al. on the effect of counseling based on the PLISSIT model on the sexual performance index of lactating women. significant improved sexual performance was observed in all areas of the FSFI (22). The study by Farnam et al. examined the effect of the PLISSIT model on women's sexual problems and showed that this model was effective in reducing the rate of sexual distress in women (23). Malakouti et al. measured the effect of the PLISSIT model during 4 sessions of 90 minutes, and reported improved sexual function and couple intimacy and increased hope in spouses (24). Shahbazi et al. in their study expressed the effect of improving women's sexual function based on the PLISSIT model in pregnant women (25). In the previous studies, in which direct or indirect and sometimes telephone counseling was used, the PLISSIT model was confirmed as an effective way to improve female sexual function index score

It seems that most infertility treatment centers do not pay special attention to the type of marital relationship between infertile couples, and even in their biographies, there is no attention to this important issue. Women whose only goal, hope, and aspiration is to have a positive pregnancy test and have a child, defined sex as a means to fulfill one's long-held desire. The routine medical therapies for the fertility process may be achieved more effectively when we are focusing, educating, and recognizing sexual issues. Midwifery counselors along with gynecologists at this stage can improve infertility treatment.

One of the strengths of the present study is that the intervention was performed on infertile women who had visited the counseling center before the infertility treatment. The increase in the improvement of marital relations may be effective in the treatment of infertility in the future. One of the limitations of the present study was dissatisfaction of infertile spouses to participate in the study and also taboo of sexual issues along with infertility. Kermanshah has faced many problems due to imposed war and the welfare level of people is low, also Kurdish ethnic prejudices prevent the easy expression of women's problems and even the freedom to treat sexual and marital issues; therefore, holding these consultations was difficult. Hence, the duration of the project was prolonged.

Conclusion

According to the results of the present study, many women expressed the usefulness of the provided consultation based on PLISSIT model in the improvement of their marital relations. However, indirect counseling through booklets and telephones, which examined the sexual issues and problems of infertile women was also very effective, because the issues that they were unable to talk about it due to shame were more easily expressed in indirect counseling due to the loss of physical distance and lack of presence. Finally, it can be concluded that counseling will have a significant impact on improving the sexual function of infertile women and it is recommended as an effective step along with the infertility treatment process.

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Conflicts of interest

Authors declared no conflicts of interest.

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