Original Article

Effectiveness of a Spousal Support Program in Improving the Quality of Life of Male Patients Undergoing Infertility Treatment: A Pilot Study

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Abstract

Background: There are various causes of male infertility. Infertile men usually have a low quality of life (QoL) and a high level of stress compared with men without infertility problems. The present study aimed to examine the effects of a spousal support program to enhance the QoL of male patients undergoing infertility treatment.

Methods: The present quasi-experimental study (pretest-posttest) was conducted among 38 infertile couples in Tokyo (Japan) during April-August 2018. The levels of QoL, distress, and spousal support were measured using self-administered valid and reliable questionnaires. The paired t test was used to analyze pre- and post-intervention data with SPSS software (version 23.0). P<0.05 was considered statistically significant.

Results: There were significant differences between the pre-test and post-test scores for the relational and emotional sub-scales of QoL. The paired t test results showed that the post-test emotional sub-scale (66.9±16.9) was significantly higher than the pre-test emotional sub-scale (58.5±13.5; t (30)=2.2, P=0.04). Similarly, the post-test relational sub-scale (71.2±21.6) was significantly higher than its pre-test score (60.8±13.7; t (30)=2.3, P=0.03). The majority of the participants 23 (74.2%) expressed satisfaction with the program.

Conclusion: The spousal support program was well-received and significantly improved part of the QoL of men who were infertile due to various causes.

Keywords: Health education, Infertility, Male, Quality of life

INTRODUCTION

Infertility is defined as the inability to conceive after 12 months of regular sexual intercourse without the use of birth control.[1, 2] Based on a systematic analysis of 277 demographic and reproductive health surveys, 48.5 million couples are unable to have a child.[3] Patients undergoing infertility treatment often experience considerable stress from the physical burden of treatments and consequently a decline in their Quality of Life (QoL).[4] In particular, female patients experience various types of mental suffering such as stress, anxiety, and depression at higher levels than their male counterparts.[5] Often, the level of stress from infertility is significantly higher in women than in men.[6] Similarly, distress during assisted reproductive technology treatment is significantly higher in women than in men.[7]

In reproduction, QoL is inversely correlated with mental anguish and relieving this mental suffering is necessary for improving the QoL.[8] Couples with shorter infertility duration and the male factor infertility reportedly obtained significantly higher QoL scores.[9] In contrast, the QoL of patients with longer infertility duration reportedly declines continuously in both men and women.[10-12] It is important to maintain the QoL of couples undergoing infertility treatment. Fertility care that considers QoL as a comprehensive approach in clinical practice is of paramount importance.[11] The QoL of infertile patients was reportedly affected by not only their own depression, but also by the depression of their spouses.[13] Therefore, an intervention approach that reduces stress in both men and women and improves their QoL is considered necessary.

Although counseling and educational programs were shown to have significant positive effects on the infertility-induced stress in women, the effects on men were far less significant.[14] Similarly, another study reported that the implementation of a partnership support program that promoted the understanding and cooperation between couples undergoing infertility treatment, only relieved the distress in women.[15] This was because infertile women had a significantly lower QoL than infertile men,[16] which led to the presumption that intervention is less effective for infertile men. Therefore, the main question is what kind of program would effectively improve the QoL of men with infertility.

Male factor infertility has been a determinant of involuntary childlessness in 40%-50% of all infertility cases, hence, males have been often treated for infertility.[17, 18] Notably, male infertility is associated with considerable psychosocial and marital stress.[19] Infertile men often experience infertility-specific anxiety, and socially isolated infertile men are even more vulnerable and prone to severe anxiety.[20] A poor QoL of men undergoing infertility treatment has been associated with less spousal support, prolonged infertility period, and male factor infertility.[21] Thus, men with male factor infertility are considered to require more intervention.

In infertile couples, self-esteem, social support, sexual satisfaction, and marital satisfaction were found to be significantly associated with QoL.[10] It is therefore recommended that healthcare professionals stimulate active involvement of men during the treatment process and provide coping skills training and couple communication enhancement interventions as part of their counseling.[22] In order to provide full support to men diagnosed with infertility, there is a need for attention to the cause of infertility, the length of the infertility period, and cooperation between couples. Intervention is necessary before the infertility period and before the infertility treatment period becomes too long. So, a program that promotes spousal support, especially for infertile male patients who have a short infertility period should be carefully planned and developed. Besides, a comprehensive study is needed on whether such a program has indeed a positive effect on the QoL and distress scales. Accordingly, the

present study aimed to examine the effects of a spousal support program on improving the QoL of male patients undergoing infertility treatment.

Materials and Methods

The present quasi-experimental study (pretest-posttest) was conducted during April-August 2018 at the Fertility Clinic Tokyo (Tokyo, Japan); a leading fertility clinic in Japan. Potential participants were couples referred to the clinic for infertility treatment. The inclusion criteria were: (i) being within the first year of the infertility treatment and a maximum infertility period of 5 years, (ii) male factor as the cause of infertility, (iii) participation in a spousal support program as a couple, (iv) fluent in Japanese, and (v) no objection against participation by their primary physician. The exclusion criteria were the presence of any sexual dysfunction and suffering from azoospermia. The reason for these exclusions was that sexual dysfunction and azoospermia are organic diseases and the program could put an additional mental burden on the participants.

The sample size was calculated using the estimation method recommended by Polit and Beck (2017),[23] and a similar study.[24] The intervention effect was calculated using alpha level probability=0.05, power=0.80, and large effect size (d=0.80). Based on the below formula, a sample size of 24.5 participants was required. However, assuming a 30% attrition rate, the target sample size was set at 35 participants.

$$n \geq \frac{2*(Z_{1-\alpha/2}-Z_{\beta})^2}{d^2} = \frac{2*(1.960-(-0.842))^2}{0.8^2} = 24.5$$

Out of 53 potential candidates, 38 patients met the inclusion criteria and thus recruited in the study. There were 7 (18.4%) dropouts because of cancellation, lack of data, or failure to return the questionnaire. Eventually, the final analysis included 31 participants, giving a response rate of 81.6% (Figure 1). The nurse manager of the cooperating clinic assisted in recruiting the participants using purposive sampling. Both the nurse manager and the authors confirmed that the participants met the inclusion criteria. The couples were then introduced to the authors by the nurse manager. Prior to the study, the participants were informed both verbally and in writing about the research goals, confidentiality of any disclosed information, and the safety of personal data was guaranteed. The right to withdraw from the study without any penalty was emphasized and the participants were provided with a study withdrawal form. Subsequently, written informed consent was obtained from all participants.

Data Collection

Each participant was asked to return the self-reported questionnaire in a sealed envelope by post or by placing it in a collection envelope in the clinic's waiting lounge. All participants attended the first session which was in the form of a participatory-interactive workshop with the purpose of providing information. The interventions were couple-based and the surveys were conducted among the male participants only. An existing partnership support program for couples undergoing fertility treatment was modified to fit our spousal support program.[15] The original program included a number of small group sessions of 60 minutes, whereas the novelty of our program was the development of 40-minute short courses on a one-to-one basis. This spousal support program consisted of lectures based on the participatory approach. More specifically, the 40-minute intervention was performed by the counselor, which consisted of a 30-minute lecture and 10-minute participation. The lectures covered topics such as (i) gender differences and stress in infertility treatment, (ii) male and female emotions during infertility treatment, (iii) couple cooperation in the treatment stage, (iv) information related to the pregnancy test, and (v) communication techniques through video presentations. The participation component of the intervention was in the form of "exercise and discussion" to establish the participants' feelings and thoughts. For the spousal support

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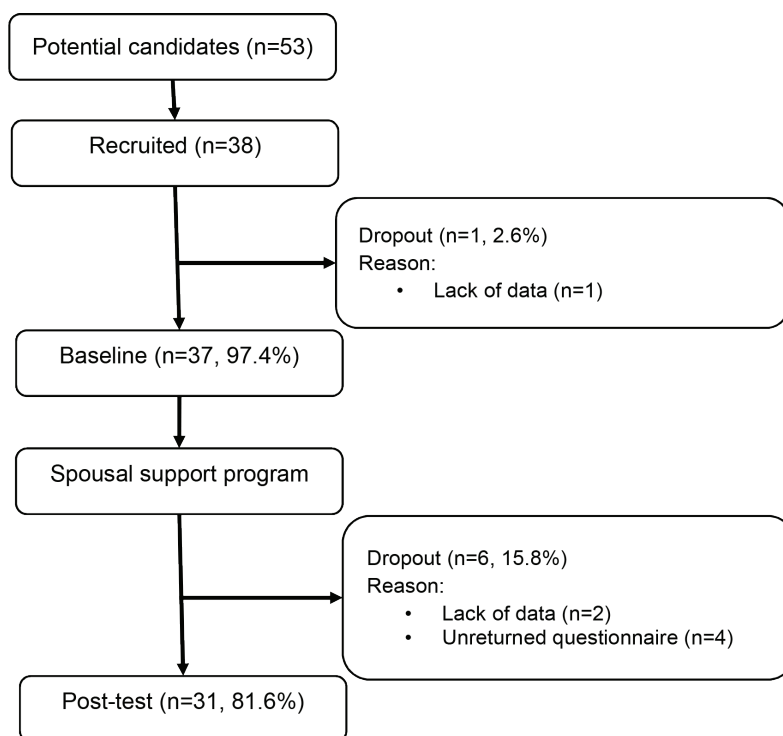
Figure 1: Consort flowchart of the participants.

program, a range of slides, booklets, DVDs, and practice sheets was used. During the participatory exercises, with the use of a dedicated communication form, the couple first described their feelings and thoughts about children and about their treatment. Subsequently, the couple participated in a discussion during which they exchanged their thoughts and feelings. The couples used the communication sheet as guidance during their discussion. Based on the communication sheet, the extent of matched or deviated feelings of a couple about each other was determined. The communication sheet-based discussions were continued at home for 10 days over a 4 weeks period.

The data collection tools consisted of a demographic data sheet, the Fertility Quality of Life (FertiQoL) questionnaire, psychological distress scale, and the spousal support sub-scale of the Jichi Medical School Social Support Scale (JMS-SSS). The demographic characteristics of the participants included age, marital status, children, significant medical history, duration of the marriage, infertility status, and type of fertility treatment. The outcome measures included QoL, distress, and spousal support.

The Fertility Quality of Life Questionnaire

The FertiQoL tool developed by Boivin and colleagues (2011)[25] was used to evaluate the QoL of men and women in terms of their personal experiences with fertility problems. FertiQoL has been translated into 45 languages and includes six sub-scales, namely emotional, mind/body, relational, social, environment, and tolerability. FertiQoL specifically assesses the impact of fertility problems on various life areas. The optional FertiQoL treatment module assesses the environment and tolerability of fertility treatment. FertiQoL consists of 34 items with 5 response categories ranging from 0 (lower QoL) to 4 (higher QoL). A higher score on the total FertiQoL scale or one of the sub-scales (range 0-100) indicates a better QoL.[25] The total FertiQoL score is obtained by dividing the total points of the 34 items by 25.

Boivin and colleagues (2011)[25] reported the Cronbach's alpha coefficient of FertiQoL to be in the range of 0.72-0.92 in 109 men and 1305 women with fertility problems from 6 countries. The face validity was

Table 1: Demographic characteristics of the participants

Participants' attributes		Mean±SD
Age (years)		38.6±7.0
Duration of marriage (month)		60.3±35.9
Duration of infertility (month)		34.7±25
Duration of infertility treatment (month)		21.1±21.2
		N (%)
Marital status	First marriage	28 (90.3)
	Remarried	3 (9.7)
Children	Yes	0 (0)
	No	31 (100)
Significant medical history	Yes	2 (6.5)
	No	29 (93.5)
Cause of male infertility	Oligoasthenozoospermia	31 (100)
Type of treatment	Under consideration	5 (16.1)
	Timing therapy	7 (22.6)
	Ovulation-inducing drugs	3 (9.7)
	Artificial insemination	10 (32.3)
	Assisted reproductive technology	6 (19.4)

Table 2: Comparison between the pre-test and post-test scores of each scale (N=31)

Scale	Sub-scale	Pre-test	Post-test	t	P value*
QoL[a]		64.3±9.5	67.7±16.9	1.2	0.24
	Emotional	58.5±13.5	66.9±16.9	2.2	0.04
	Mind/body	71.0±18.9	75.7±22.5	1.0	0.33
	Relational	60.8±13.7	71.2±21.6	2.3	0.03
	Social	65.7±15.3	65.3±19.8	0.1	0.92
	Environment	59.0±16.2	55.9±21.1	1.0	0.35
	Tolerability	74.2±17.5	72.6±21.9	0.4	0.71
Distress[b]		9.5±3.5	8.7±3.7	1.1	0.30
Spousal support[c]		28.1±4.1	28.5±3.6	0.6	0.56

*Paired *t* test, [a]FertiQoL tool, [b]Distress scale, [c]According to the Jichi Medical School Social Support scale (JMS-SSS)

confirmed by local bilingual fertility experts of the developer's translation team. The final FertiQoL item submitted for exploratory factor analysis comprised 24 items from the core set of items and 10 items from the optional treatment module. The 24 core items were conceptualized as reflecting QoL in the emotional, mind-body (cognitive and physical), relational, and social domains. The 10 optional treatment items were conceptualized as indexing treatment environment and treatment tolerability. An additional two items measuring satisfaction with QoL and physical health were retained for the FertiQoL measure to indicate general physical and QoL satisfaction, but they were not included in the factor analysis.

The construct validity of the English version of FertiQoL was confirmed using item analysis and exploratory factor analyses by the developers.[25] In the present study, we used the Japanese version of FertiQoL. The construct validity of the Japanese version was confirmed using correlation analysis, principal component analysis, and confirmatory factor analysis.[26] Principal component analysis was performed to determine whether the factor loading matrix possessed the original six sub-scale structure in the Japanese version of FertiQoL.[26] The principal component loadings of all the 34 items in the six sub-scale structure were "Emotional", "Mind/Body", "Relational", "Social", "Environment", and "Tolerability"

which ranged from 0.33 to 0.83, with 30.8% of the total variance explained.[26] The goodness-of-fit statistic (GFI=0.877), comparative fit index (CFI=0.893), adjusted goodness-of-fit statistic (AGFI=0.855), and root mean square error of approximation (RMSEA=0.059) met the criterion of acceptance value.[26] Although the GFI and CFI were 0.9 or less, the AGFI was 0.85 or more, and it met the criterion of GFI>AGFI. The RMSEA was 0.059 and it met the criterion of <0.08.[26] The Cronbach's alpha coefficient of FertiQoL (Japanese version) was reported to be in the range of 0.62-0.82 in 321 Japanese infertile male patients.[21] The overall Cronbach's alpha of the Japanese version of FertiQoL with 34 items was 0.92 and ranged from 0.67 to 0.86 in the six sub-scales. Although the Cronbach's alpha of the "Relational" sub-scale was 0.67, which was less than 0.7, it was considered acceptable as it was a required sub-scale for this scale. For concurrent validity, the relationships between the Japanese version of the FertiQoL score, the six sub-scale scores of FertiQoL, and the distress scale score were examined by determining Pearson's correlation coefficient. The FertiQoL and distress scale scores showed a significant negative correlation of r=0.669 at the 1% level. The FertiQoL six sub-scale score and the distress scale score also showed a significant negative correlation at the 1% level.[26]

Psychological Distress Scale

The Japanese version of the distress scale developed by Asazawa and Mori (2015) was used to evaluate the psychological distress of infertility couples.[27] This scale consists of the following 3-item inventory: (i) "Do you feel stressed by the treatment?" (ii) "Do you feel depressed because of the treatment?" and (iii) "Do you have anxiety from the treatment?" The response categories range from 1 (strongly disagree) to 5 (strongly agree). Higher scores indicate the presence of a higher distress level. The instrument had acceptable reliability (i.e., the Cronbach's alpha coefficient was found to be 0.89 from the data of 466 Japanese

infertile couples) which confirmed its internal consistency, and experienced midwives confirmed its content validity.[27] The construct validity was confirmed using item analysis and exploratory factor analysis. Exploratory factor analysis was used to determine the construct validity of the Distress.[21] The factors with an eigenvalue of higher than one were extracted and a one-factor structure was obtained for the scale.[21] The extracted factors explained 81.2% of the total variance.[21] The Cronbach's alpha coefficient of the distress scale was determined to be 0.88 in 321 Japanese infertile male patients.[21]

Spousal Support

The 8-item spousal support sub-scale of the Jichi Medical School Social Support Scale (JMS-SSS) was used to measure spousal support. The sub-scale of the functional support scale was used to measure emotional support, which is an important factor in the spousal relationship of infertile couples. JMS-SSS was developed as a questionnaire to measure the availability of functional social support for community residents.[28] The 24-item questionnaire measures the availability of social support from each of the three sources, namely spouse, friends, and non-spousal family support. The scale has four response categories ranging from 1 (lower support) to 4 (higher support), and the score of a spouse range from 8 to 32 points. Higher scores indicate a higher level of support. As shown by internal consistency analysis, the Cronbach's alpha coefficient was reported to be 0.89 for 2,150 Japanese community residents aged 40 to 69 years.[28] The construct validity was confirmed using exploratory factor analysis and correlation analysis. Exploratory factor analysis was used to determine the construct validity of the spousal support. The factors with an eigenvalue of higher than one were extracted and a one-factor structure was obtained for the scale. The extracted factors explained 53.2% of the total variance. Cronbach's alpha coefficient of spousal support was found to be

0.86 in 321 Japanese infertile male patients. As the QoL of infertile male patients is significantly associated with spousal support, it was included in the survey as a secondary outcome.[21]

Pre-test and post-test evaluation data were collected. Pre-test data were requested on the day of the intervention at the clinic's private room. The post-test survey was conducted 4 weeks later at the participant's home. The post-test evaluation was set after 4 weeks to avoid any psychological changes among the participants in case the treatment policy changed with time or the infertility treatment was discontinued because of pregnancy.

A program evaluation was conducted among the participants using a 4-item self-developed questionnaire. The survey evaluated participants' opinions on program satisfaction, program availability, match of expectations, and adequacy of intervention time. A 5-point Likert scale was used for each item, with higher scores indicating a more positive acceptance of the intervention.

Data Analysis

The data were analyzed using SPSS software (version 23.0). A pre- and post-comparison test was carried out using a parametric test since the scales were normally distributed according to the Shapiro-Wilk test. Pre- and post-intervention changes in the participants were analyzed using the paired *t*

test. Subgroup analysis was conducted using the Wilcoxon signed-rank test due to the small number of participants. A frequency distribution table was created from the 4 items of the process evaluation. $P<0.05$ was considered statistically significant.

Ethical Considerations

The study was approved by the Ethics Committee for Epidemiological Studies of Tokyo Health Care University, Tokyo, Japan (approval number: 29-30; April 5, 2018). In accordance with the Declaration of Helsinki, a written explanation of the study objectives and methods was provided. In addition, protection of data anonymity and voluntary participation was guaranteed.

RESULTS

The characteristics of the participants are shown in Table 1. To examine the effects of the spousal support program, a pre- and post-evaluation was carried out. Based on the results of the paired *t* test, there were no significant differences between the pre-test and post-test scores in the 3 scales (QoL, distress, and spousal support). Subsequently, the paired *t* test was used to evaluate the sub-scales of QoL. The results showed a significant difference between the pre-test and post-test scores for the relational and emotional sub-scales of QoL. The post-test emotional sub-scale was significantly
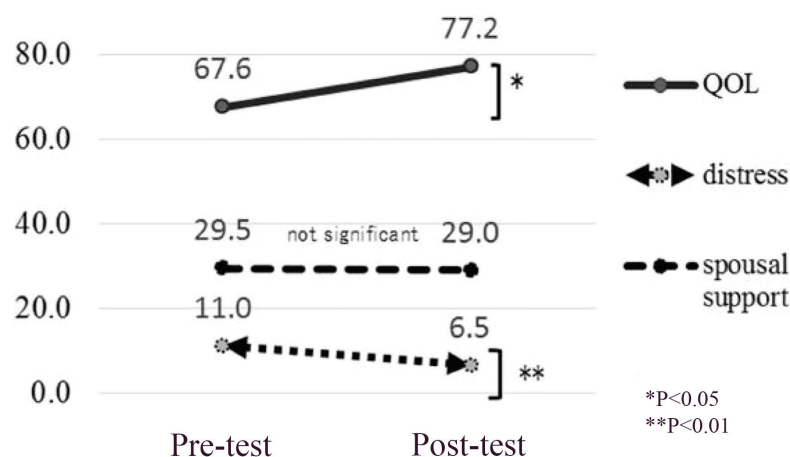
Figure 2: Comparison of the pre-test and post-test scores of QoL, spousal support, and distress of the participants in the high-age group (N=14).

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higher than the pre-test emotional sub-scale (P=0.04). Similarly, the post-test relational sub-scale was significantly higher than its pre-test score (P=0.03) (Table 2). There were no significant differences between the pre-test and post-test scores for the mind/body, social, environment, and tolerability sub-scales of QoL. The Wilcoxon signed-rank test was conducted for each scale according to the participants' attributes. The participants were assigned to two groups according to the average age of the study. Based on the Wilcoxon signed-rank test, in the high-age group (range 39-66), there were significant differences between the pre-test and post-test scores in the QoL scale (P=0.04) and distress scale (P=0.01) (Figure 2).

Based on the response of the participants, 23 (74.2%) of them were satisfied with the treatment methods, 24 (77.5%) were positive about the availability of the program, 21 (67.8%) indicated a high match between their expectations and the implementation, and 18 (51.6%) felt that the implementation time was appropriate (Figure 3).

Discussion

The spousal support program for infertile men had a positive effect on the emotional and relational sub-scales of QoL. In addition, the program effectively increased some of the QoL sub-scales in men. However, the partnership program neither increased QoL nor decreased the distress in men.[15] This led to the conclusion that participation in the spousal support program had a beneficial effect on men with male factor infertility undergoing treatment. It was also demonstrated that the patients in the high-age group showed significant improvements in both QoL and distress. Based on the World Health Organization Quality of Life Instruments (WHOQOL-BREF), infertile men over 36 years of age had a lower score in the social relationship sub-scale than infertile men aged 35 years or younger.[29] This indicated that the social pressure felt by infertile men affected their QoL more severely as they grow older.[29] It has been reported that marital stressor and guilt-and-blame had a significant effect on the social stressor in a large number of infertility outpatients.[30] It is speculated that the elder male patient feels responsible for his infertility and feels guilty towards his spouse. However, QoL has been reported to decline during infertility treatment regardless of age.[12] A previous study reported that the younger aged had a better QoL since they scored higher on the general health scale.[31] Considering the contradictory results on the correlation between QoL and age in infertile men, further detailed studies on men with male factor infertility are recommended.

As a direct result of our spousal support program, the couples in the present study regained a stable relationship which was attributed to improved QoL of the male participants. A previous study suggested that male patients were in special need of tender loving care from their partners and caregivers.[32] Most men undergoing infertility treatment feel distressed, which has a negative effect on their QoL.[12] In particular, patients with male factor infertility experience a high level of distress.[20] Moreover, another study demonstrated that the longer the treatment
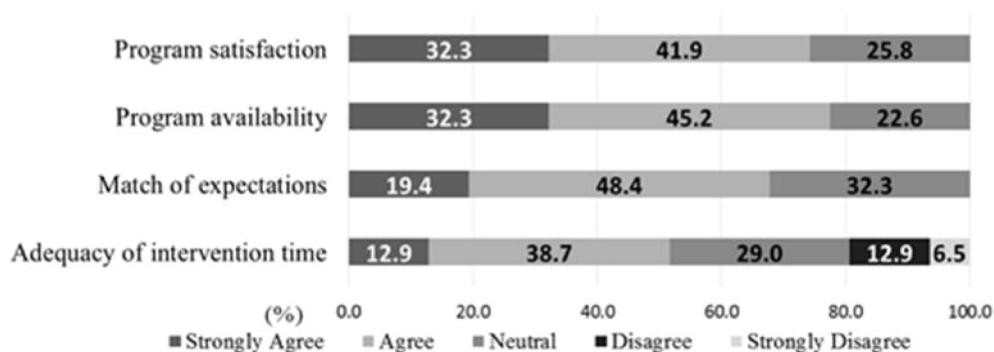

Figure 3: Process evaluation of the participants (n=31)

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takes the greater the negative impact on the relationship with the spouses is, which manifested itself as immense marital stress in many infertile male patients.[33] Prolonged treatment also increased relationship instability,[34] and caused a decline of marital satisfaction.[10] To minimize the decline in the QoL of infertile men, it is recommended that medical staff provide a spousal support program at the early stage of treatment. Regardless of the cause of infertility, it is important to understand that infertility treatment is not a unilateral responsibility and requires both partners to work together in the process. The couple must understand not only what the treatment entails, but also made aware of the psychological change of the partner caused by the treatment.

The response of the participants indicated a high level of satisfaction with the spousal support program and program availability. The contents and methods of the program were considered to meet the needs of the infertile male participants. However, some of the participants felt that the intervention time was long, and some people already knew part of the program contents. Since most of the male participants had full-time jobs,[12] they could only visit the clinic during weekends, holidays, or on their way home from work, which meant that they had to juggle with their time. As a direct result, in the future, we would like to propose and develop a program that facilitates the participation of couples with male factor infertility in the comfort of their homes.

The main limitation of the present study was that the score of the spousal support scale used for measuring the quality of the couple's relationship did not show any changes, although there was an increase in the score of the relational QoL sub-scale. Note that the relational sub-scale rates the QoL in terms of infertility, whereas the spousal support scale measures the general support from the spouse. This may justify why the score of the spousal support scale did not change. It is also possible that this scale was not applicable to this survey.

In addition, the participants rated the availability of the program at 77.5%, which was low due to the limited availability of services in the health care system and the fact that the content of the program was modified to fit our spousal support program. However, achievements that outweighed limitations were valuable data that demonstrated significant QoL improvement due to the spousal support program and the fact that the program was well-received. Moreover, the findings of the present pilot study could be used to conduct large-scale and detailed studies in the future. We plan to apply our findings to similar groups and to disseminate the program to couples in the early stage of treatment in human reproductive clinics. We would like to underscore the importance of conducting an intervention study consisting of a control group and a comparative group to verify the effects.

CONCLUSION

A significant increase in the emotional and relational sub-scales of QoL was observed among the infertile male participants. The participants in the high-age group had a significant decrease in distress and an increase in QoL. The majority of the participants were satisfied with the intervention and acknowledged the need for such interventional programs. In the future, to obtain a basis for determining the effect, it is necessary to use study designs that limit the threats to internal validity. The design could be in the form of large-scale two-group comparison and a longitudinal randomized controlled trial, including a setting in which the comparison groups do not receive the program. Consequently, verification of the effect of improving the suffering of both men and women is expected to be further enhanced.

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