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ORIGINAL ARTICLE

Development and evaluation of the Adaptation Support Program in Early Pregnancy after the use of assisted reproductive technology

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Abstract

Aim: To evaluate the feasibility, acceptability, and outcome of the Adaptation Support Program in Early Pregnancy after the use of assisted reproductive technology (ART).

Methods: The participants were 57 primiparas who had undergone ART and had received the Adaptation Support Program. The data were gathered by using questionnaires before (Time 1), immediately after (Time 2), and 8 weeks after (Time 3) the intervention between August, 2014 and March, 2015. The data for the 40 women who gave valid answers were analyzed statistically.

Results: Of the respondents, 75% gave a positive evaluation that the program met their expectations and >80% positively evaluated it for its convenience, problem-solving intentionality, satisfaction, and usefulness. The Anticipatory Anxiety for Loss Scale (AALS) and State–Trait Anxiety Inventory (STAI-J) scores decreased significantly at Times 2 and 3 and the Edinburgh Postnatal Depression Scale (EPDS) scores at Time 3. The Post-traumatic Growth Inventory-Japanese (PTGI-J) scores, showing growth as a result of infertility experience, increased significantly at Time 3. The Care Need Satisfaction Scale (CNSS) scores showed a positive correlation with the PTGI-J scores and negative correlations with the AALS and STAI-J, but did not correlate with the EPDS.

Conclusion: This program was evaluated positively. The AALS, PTGI-J, EPDS, and STAI showed significant change after the program and the AALS, PTGI-J, and STAI-J showed significant correlations with the CNSS.

Key words: assisted reproductive technology, early pregnancy, online support program, pregnancy adaptation, women's narratives.

INTRODUCTION

Reproduction is a key developmental task in adulthood; infertility is its crisis. The stress and disappointment that are experienced by women who suffer from infertility have negative impacts on their mental health, marital relationship, and self-esteem (Abbey, Andrews, & Halman, 1994; Bernstein, Mattox, & Kellner, 1988; Gameiro, Moura-Ramos, Canavarro, & Soares, 2010; Garner, 1985; Klock, 2004; Olshansky & Sereika, 2005; Petersen, Sejbaek, Pirritano, & Schmidt, 2014).

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Pregnancy after undergoing fertility treatment is the phenomenon of transition from infertility to becoming a mother and many women in this situation are worried about going back to infertility after a miscarriage (Sandelowski, 1995). Such women engage in psychological preparation in order to minimize the shock that is associated with a miscarriage, even as they could regard their pregnancy as yet unconfirmed and often could receive only inadequate information about pregnancy (Bernstein, 1990; Covington & Burns, 2006; Mori, Ishii, & Hayashi, 2007; Olshansky, 1990). The work that is needed to overcome this uncertainty is special work, different from that required for a natural pregnancy. Pregnancy adaptation after the use of reproductive technology is diverse due to diverse influences of

past loss experiences, perspectives, and coping styles. Pregnancy adaptation after the use of reproductive technology influences mental health (Sakiyama, 2013). Anxiety regarding a miscarriage correlates with a delay in preparation for the maternal role and a decline in maternal self-efficacy (McMahon, Ungerer, Tennant, & Saunders, 1997; Maehara *et al.*, 2012). In addition, the duration of fertility treatment correlates with postpartum depressive symptoms (Csatordai *et al.*, 2007). Therefore, in order to prevent a deviation of mental health, it is important to support pregnancy adaptation by identifying and understanding the impact factors on mental health.

In Japan, many fertility treatment facilities do not have maternity wards. The majority of women who had received fertility treatment have a pregnancy diagnosis in the fourth week of pregnancy and are transferred to a birth facility at 8 weeks. For women who are aged >40 years, the miscarriage rate with a natural pregnancy is 22.6%, but it is 35.0% with assisted reproductive technology (ART) (Saito, 2015). Women at early pregnancy are said to have six main care needs (see the next section), in relation to which they will require guidance, infertility review, peer sharing, and emotional support (Sakiyama, 2015a). However, only 15.0% of the facilities in Japan provide care that covers all these needs (Sakiyama, 2015b). Although there is a tendency for the mental health of pregnant women to stabilize in the second trimester, women who have used ART have high anxiety about a miscarriage and maternal–fetal abnormalities in early pregnancy. These anxieties show a significant correlation with avoidance feelings toward the fetus in the third trimester (Mori, Chen, & Nukazuka, 2005). For this reason among others, support in order to reduce excessive anxiety in early pregnancy is important.

Nurses and midwives are responsible for providing this support at fertility treatment facilities in Japan, which centers on infertility-certified nurses. However, nursing intervention programs for women in early pregnancy, as provided in fertility treatment facilities, have not been studied, in Japan or in other countries. The objective of the present study thus was to evaluate a nursing intervention program to support pregnancy adaptation in early pregnancy after undergoing ART, including: (i) process evaluation (assessment of the feasibility and acceptability of the program); and (ii) outcome evaluation (satisfaction of care needs, reduction of anticipatory anxiety towards the loss of a pregnancy or fetus, integration of infertility experience, and retention of mental health).

Conceptual framework

Framework of the study

The framework used the key concepts of pregnancy adaptation after undergoing fertility treatment (Sakiyama, 2013) and the needs were focused on care in early pregnancy (Sakiyama, 2015a) (Fig. 1). Women in early pregnancy after undergoing ART adapt to the process under the influence of infertility loss and its attendant difficulties: they must carry out role acquisition and adjustment while suffering from anticipatory anxiety about the loss of a pregnancy or fetus and feeling ambivalence over the transition from an identity as an infertile person to a pregnant identity. Women have six major care needs in this process. To: (i) feel empathy for their anticipatory anxiety that they might lose the fetus; (ii) get information about how to spend pregnancy and childbirth safely after ART; (iii) organize their feelings and experiences through a review of their infertility experience; (iv) prepare to accept the baby as a member of the family by receiving information about birth and child care; (v) make connections with other pregnant women after fertility treatment; and (vi) feel continued interest from their nurses. Satisfying these care needs supports pregnancy adaptation.

Based on care needs, The Adaptation Support Program for Early Pregnancy includes the elements of: (i) guidance; (ii) infertility review; (iii) peer sharing; and (iv) emotional support. In addition, the program is Web-based. It is expected to have the following effects: satisfaction of care needs, a reduction of anticipatory anxiety for the loss of a pregnancy or fetus, integration of infertility experience, and retention of mental health. In this study, process evaluation and outcome evaluation, encompassed by the dotted line in Figure 1, were carried out.

Definition

Pregnancy adaptation. This is identified as the process in which women in early pregnancy, after undergoing ART, cope with anticipatory loss and come to grips with the new reality.

METHODS

Design

This was a program evaluation study using a one-group pre–post-test design.

Participants

The participant sample consisted of 50 primiparas who had undergone ART at two fertility treatment facilities

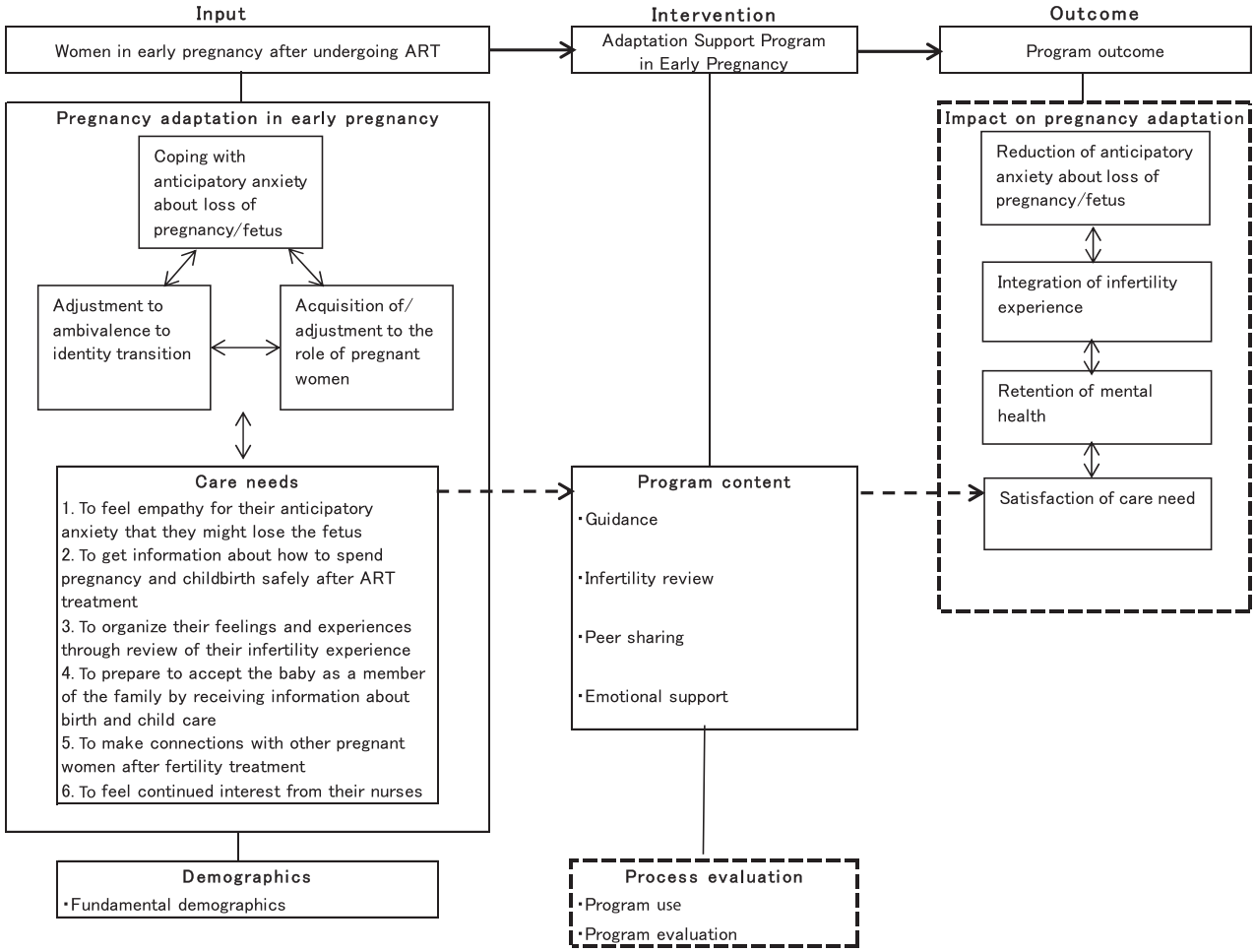

Figure 1 Conceptual framework of the study for the development and evaluation of the Adaptation Support Program in Early Pregnancy after the use of assisted reproductive technology (ART).

in a metropolitan area in Japan. The study exclusion criteria were: (i) gamete provision by a donor; and (ii) mental illness. The ideal sample size was determined to be 63 participants with reference to Cohen's (1992) effect size indicator. However, as this research is in the preliminary phase of verifying effectiveness, a sample size of 35 participants was determined to be feasible. When taking into consideration the miscarriage rate, the final sample size was determined to be 50 participants.

Intervention

Adaptation Support Program in Early Pregnancy after undergoing assisted reproductive technology

This Web-based online program covered guidance, infertility review, peer sharing, and emotional support, based on support needs (Sakiyama, 2015a).

Purpose of the program

The purpose of the program was to support pregnancy adaptation in early pregnancy after undergoing ART.

Program elements and methods

The program's elements consisted of guidance, infertility review, peer sharing, and emotional support, based on care needs (Sakiyama, 2015a). The program method was based on the existing needs of the nursing care program and therefore involved: (i) online resources; (ii) online review; (iii) mental health assessment; (iv) nursing consultation; and (v) referral to psychological counseling (Sakiyama, 2014). The program media consisted of a "Web-based resource" and a "review sheet" to support guidance and infertility review; the

Table 1 Content and presentation timing of the Web-based resources

Presentation timing	Major item	Subitem
4th or 5th week of pregnancy (at diagnosis of the gestational sac)		Signs of pregnancy
		Changes in mother and baby development in early pregnancy
	Normal/abnormal and self-care in early pregnancy	Early pregnancy life
		Minor troubles and self-care in early pregnancy
		Early pregnancy abnormalities
	ART and your pregnancy	Hormone replacement therapy after pregnancy diagnosis
	Psychology of pregnant women who had undergone ART	Psychology of pregnant women who had undergone ART
		How to relieve anxiety and tension
6th or 7th week of pregnancy (at the fetal heartbeat check)	Normal/ abnormal and self-care in early pregnancy	Delivery of pregnancy notification and maternity and child health handbook
		Support system surrounding pregnancy
	ART and your pregnancy	ART and your pregnancy
		ART and your fetus
	The worry of women trying hard at work	Benefits/disadvantages of pregnancy over 35
		Benefits/disadvantages of working womens' pregnancy
		Decision-making on birth facilities
	Decision-making in early pregnancy	Decision-making on prenatal testing
	Psychology of pregnant women who had undergone ART	Support for frozen embryo and psychological preparation for restarting treatment
		To build relationships with staff at the birth facility

ART, assisted reproductive technology.

Web-based resource contained narrative videos by peers in order to enable peer sharing.

The online resource content covered "what is normal/abnormal and self-care in early pregnancy," "risk associated with pregnancy after undergoing ART," "risk associated with the background of pregnant women after undergoing ART," "decision-making in early pregnancy," and "the psychology of pregnant women after undergoing ART," based on the needs of the nursing care program (Sakiyama, 2014). It was presented twice at specific stages of pregnancy (see Table 1) and the questions were answered by Web consultation. The time that was required for the online resource browsing was 20 min each time.

The review sheet consisted of a description of infertility experience, resetting goals, and the prediction of available support, based on the concept of pregnancy adaptation (Sakiyama, 2013); the researcher provided the women with feedback on their submitted review sheets.

The women's mental health was assessed and emotional support was carried out in ways that reflected their assessed mental health levels. Emotional support included: (i) mental health assessment (Step 1); (ii) nursing consultation (Step 2); and (iii) referral to psychological counseling (Step 3). This is based on the concept of the Stepped Care Model that is recommended by the National Institute for Health and Care Excellence's (1996) guideline. This model setting intervention for every step has been validated in the mental health field and has been applied to mental health screening and counseling during pregnancy (Honikman, Heyningen, Field, Baron, & Tomlinson, 2012). This support was maintained until the women's transfer. The Edinburgh Postnatal Depression Scale (EPDS), developed to evaluate postpartum depression, was used in the mental health assessment. Its validity and reliability have been confirmed and a cut-off point for screening has been established (Okano *et al.*, 2009). That is, the pregnant EPDS score has been shown to correlate with the postpartum EPDS score and the cut-off point in pregnancy has been set at 9 points, which is similar to the postpartum cut-off point (Mizuno & Goto, 2013;

Sugishita & Kamibeppu, 2013). Therefore, its use in pregnancy is supported. The EPDS mean scores in the second trimester have been shown to be 3.24 ± 3.26 (Haruna, Shiraishi, & Matsuzaki, 2007) and mean scores of <9 points in pregnancy have been shown to be 3.51 (Sugishita & Kamibeppu, 2013). Therefore, the EPDS scores were broken down into three levels: (i) ≤6 points (Step 1); (ii) 7–8 points (Step 2); and (iii) ≥9 points (Step 3). The researcher asked the author of the EPDS about the validity of its use in early pregnancy screening and received a supportive answer and permission to use the tool. The intervention period was ~3 weeks, but the online resources were free to view until mid-pregnancy.

Intervention protocol

At the 5th week of pregnancy, the gestational sac is diagnosed. The purpose and content of this program had been explained to the women before then and it had been explained how to use the online resources and online review with a computer and the women had been given their log IDs. The EPDS questionnaire was distributed before the program's implementation and the following was explained: (i) the EPDS is a scale to measure mood after birth, but it can be used during pregnancy; (ii) high scores indicate a depressive tendency; and (iii) the measurement in this research was not to diagnose a disease, but rather to understand your situation and help you find sources of distress and solutions. The EPDS scores were calculated and the participants' results were explained to them, as follows: (i) "your mood is stable" (Step 1); (ii) "the score is slightly higher, but it does not indicate a depressive tendency, so I recommend nursing consultation" (Step 2); and (iii) "the score is high and I recommend psychological counseling" (Step 3). If the women in Steps 2 and 3 so desired, program methods and schedules were adjusted to allow an intervention: a nursing consultation or psychological counseling of 40 min. The contents of the online resources were updated 1 week after the first viewing, making it possible to conduct an online review. If the review sheet was written and sent, the researcher checked the sheet and provided the women with feedback.

Measures and measurement instruments

In the process evaluation, measurement tools 2 and 3 below were used after the intervention (Time 2: 8th week of pregnancy). In the outcome evaluation, measurement tools 5–9 were used before the intervention (Time 1: 5th week of pregnancy), after the intervention (Time 2), and 8 weeks after the intervention (Time 3: 16th week of pregnancy). Furthermore, measurement tool 4 was used at Times 2 and 3 to measure an outcome variable, the satisfaction of a care need, measurement tool 5 was used for an outcome variable of the anticipatory anxiety of a loss of the pregnancy or fetus, measurement tools 6 and 7 were used for the outcome variable of integration of infertility experience, and measurement tools 8 and 9 were used for the outcome variable of retention of mental health. Time 1 was selected because the diagnosis of the gestational sac defines pregnancy in fertility treatment facilities. Time 2 was selected as the time of the final consultation at fertility treatment facilities. Time 3 was selected as the final point of early pregnancy. In the process of constructing the measurement scales, the content and face validity of the items were examined by asking five clinicians and reproductive nursing researchers about the appropriateness of the content and the ease of response. The study protocol is shown in Figure 2 and the list of variables in Table 2.

Sociodemographic characteristics

The participants' age, pregnancy experience, miscarriage experience, infertility period, fertility treatment period, infertility cause, treatment method, number of embryo transfers, and progress of pregnancy were collected from the medical records.

Use of the program

The use of online resources, online review, nursing consultation, and/or psychological counseling was confirmed.

Program evaluation

This scale consisted of the following five items: "meets expectations," "convenience," "problem-solving intentionality," "satisfaction," and "usefulness." A 5-point scale was used; higher scores indicated better evaluations. In addition, the participants were asked to provide their opinion of the program through free description.

Care Need Satisfaction Scale

The Care Need Satisfaction Scale (CNSS) consists of four factors that are made up of 21 items: "satisfaction of the need to review infertility experience and pregnancy," "satisfaction of the need to share and reduce anxiety and worry," "satisfaction of the need to connect with a peer," and "satisfaction of the need to take on role behavior related to birth and child care." A 5-point scale

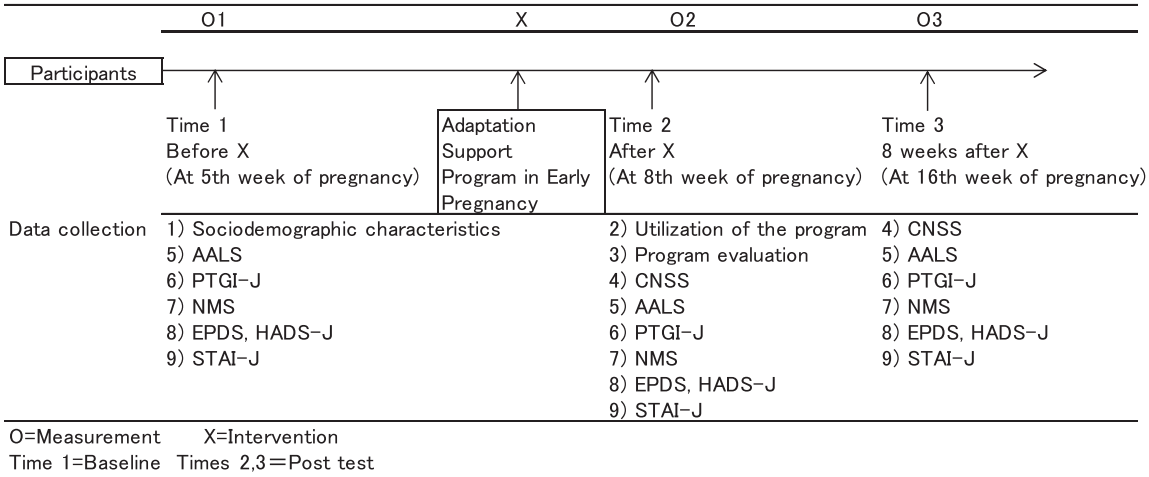

Figure 2 Study protocol for the evaluation of the Adaptation Support Program in Early Pregnancy. The number in the data collection is aligned with the number of measurement instruments that is used in the article. AALS, Anticipatory Anxiety for Loss Scale; CNSS, Care Need Satisfaction Scale; EPDS, Edinburgh Postnatal Depression Scale; HADS-J, Hospital Anxiety and Depression Scale-Japanese; NMS, Negative Modification Scale; PTGI-J, Post-traumatic Growth Inventory-Japanese; STAI-J, State–Trait Anxiety Inventory-Japanese.

was again used; higher scores again indicated higher care need satisfaction. The Cronbach's α of the whole measure was 0.92 and that of the subscales ranged from 0.75 to 0.87. The correlation coefficient between measurement tools 3 and 4 was 0.62. The criterion validity was confirmed because the correlation coefficient with the score of measurement tool 3 was 0.62.

Anticipatory Anxiety for Loss Scale

The Anticipatory Anxiety for Loss Scale (AALS) consists of two factors that are made up of 10 items: "stagnation of joy over the pregnancy" and "worry about the loss of a normal pregnancy." A 7-point scale was used; higher scores indicated higher anticipatory anxiety for the loss of the pregnancy or fetus. The Cronbach's α of the whole measure was 0.76 and that of the subscales ranged from 0.76 to 0.89. The correlation coefficient between measurement tool 9 had been shown as 0.46. The criterion validity was confirmed because the correlation coefficient with the score of the Hospital Anxiety and Depression Scale-Japanese (HADS-J) was 0.46.

Post-traumatic Growth Inventory-Japanese

The Post-traumatic Growth Inventory-Japanese (PTGI-J) measures growth after a critical event; its reliability and validity have been established (Taku, 2005). It consists of four factors that are made up of 18 items: "relationship with others," "new possibilities," "strength as a human being," and "appreciation for spiritual modification and life." A 6-point scale was used; higher scores indicated more growth through the infertility experience.

Negative Modification Scale

The Negative Modification Scale (NMS) consists of one factor with the four items: "I found it hard to trust others," "I have lost a lot of things," "I feel blame and disgust toward myself," and "I have lamented my life." A 6-point scale was used; higher scores indicated more negative modification due to the infertility experience. The Cronbach's α was 0.78.

Edinburgh Postnatal Depression Scale

The Edinburgh Postnatal Depression Scale (EPDS) measures postnatal depression, as discussed above (Okano *et al.*, 2009). This scale consists of 10 items and uses a 4-point scale. As its use in pregnancy is under consideration, its criterion-related validity has been confirmed against "depression" on the HADS-J, the reliability and validity of which have been established (Zigmond, Snaith, & Kitamura, 1983). The resulting correlation coefficient was 0.38.

State–Trait Anxiety Inventory-Japanese

The State–Trait Anxiety Inventory-Japanese (STAI-J) measures anxiety. Its reliability and validity have been established (Hidano, Hukuhara, Iwawaki, Soga, & Spielberger, 2000). It consists of two factors that are

Table 2 List of the measuring concepts and measuring tools

Measuring concept	Subordinate concepts and number of items	Measuring tool Author	Scale level Answering method Number of items	Validity and reliability Reliability factor	Time
Satisfaction of care need	Satisfaction of need to review infertility experience and pregnancy (7 items) Satisfaction of need to share and reduce anxiety and worry (6 items) Satisfaction of need to connect with a peer (4 items) Satisfaction of need to take on role behavior related to birth and child care (4 items)	4. Care Need Satisfaction Scale The present researcher	Ordinal scale 5-point scale 21 items	Confirmed Cronbach's α = 0.92	Times 2, 3
Anticipatory anxiety for loss of pregnancy/fetus	Stagnation of joy over the pregnancy (5 items) Worry about loss of normal pregnancy (5 items)	5. Anticipatory Anxiety for Loss Scale The present researcher	Ordinal scale 7-point scale 10 items	Confirmed Cronbach's α =0.76	Times 1, 2, 3
Integration of infertility experience	Relationship with others (6 items) New possibilities (4 items) Strength as a human being (4 items) Appreciation for spiritual modification and life (4 items)	6. Post-traumatic Growth Inventory-Japanese (Taku, 2005)	Ordinal scale 6-point scale 18 items	Confirmed Cronbach's α = 0.93	Times 1, 2, 3
	Negative modification (4 items)	7. Negative Modification Scale The present researcher	Ordinal scale 6-point scale 4 items	Confirmed Cronbach's α = 0.78	Times 1, 2, 3
Retention of mental health	Depression (10 items)	8. Edinburgh Postnatal Depression Scale (Okano *et al.*, 2009)	Ordinal scale 4-point scale 10 items	Confirmed Cronbach's α = 0.82	Times 1, 2, 3
	Anxiety (7 items; not used at this time) Depression (7 items)	8. Hospital Anxiety and Depression Scale-Japanese (Zigmond *et al.*, 1983)	Ordinal scale 4-point scale 7 items	Confirmed Cronbach's α = 0.83	Times 1, 2, 3
	State anxiety (20 items; not used at this time)	9. State-Trait Anxiety Inventory-Japanese	Ordinal scale	Confirmed	Times 1, 2, 3

Table 2 Continued

Measuring concept	Subordinate concepts and number of items	Measuring tool Author	Scale level Answering method Number of items	Validity and reliability Reliability factor	Time
	Trait anxiety (20 items)	(Hidano *et al*., 2000)	4-point scale 20 items	Cronbach's $\alpha = 0.53$	
Program evaluation	Meets expectations	3. Program evaluation	Ordinal scale		Time 2
	Convenience	The present researcher	5-point scale		
	Problem-solving intentionality		5 items		
	Satisfaction				
	Usefulness				

Time 1, Baseline; Times 2, 3, post-test.

made up of 20 items: "state anxiety" and "trait anxiety." Only trait anxiety was used here (as state anxiety is covered in measurement tool 5 above), on a 4-point scale with higher scores indicating higher trait anxiety.

Procedure

Recruitment

In the two cooperating facilities, convenience sampling was carried out by a researcher through mediation of the doctors or nurse managers at 5 weeks of pregnancy (after diagnosis of the gestational sac).

Data collection

The data collection was carried out between August, 2014 and March, 2015 at three time points. At Time 1, the questionnaire was distributed in person after obtaining informed consent for participation and collected after it was filled out. At Times 2 and 3, it was distributed by mail and then collected.

Data analysis

Some analyses were carried out by using IBM SPSS for Windows v. 22.0 J (SPSS, Tokyo, Japan). Measurement tool 6 was analyzed with a one-way repeated-measures ANOVA and Bonferroni's multiple comparison. Measurement tools 5and 7–9 were analyzed with the paired Friedman's test and paired comparisons. For measurement tool 4, a correlation analysis was carried out from 5–9. The content of the free comments was encoded and labeled and categories were created based on similarities and differences, with reference to Gregg, Asahara, and Yokoyama (2013).

Ethical considerations

The following points were explained orally to each participant, with written documents also handed out: the purpose of the study, respect of free will in terms of study participation and withdrawal, compliance with confidentiality obligations by the researcher, and avoiding disadvantage to the participants in cases of miscarriage or non-cooperation with the study. The consent form then was signed. The study was approved by the relevant ethical review board at St. Luke's International University, Tokyo, Japan (Approval no. 14–044).

RESULTS

Sixty women were asked to cooperate in the study; 57 agreed (95.0% response rate). Seventeen participants

Table 3 Program use (n = 40)

	Web consultation use		Online review use		Nursing consultation use		Referral to psychological counseling	
Step	No	Yes	No	Yes	No	Yes	No	Yes
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
1 (n = 30)	18 (60.0)	12 (40.0)	20 (66.7)	10 (33.3)	30 (100.0)	0 (0.0)	30 (100.0)	0 (0.0)
2 (n = 6)	2 (33.3)	4 (66.7)	2 (33.3)	4 (66.7)	5 (80.0)	1 (20.0)	6 (100.0)	0 (0.0)
3 (n = 4)	1 (25.0)	3 (75.0)	2 (50.0)	2 (50.0)	3 (75.0)	1 (25.0)	4 (100.0)	0 (0.0)
Overall	21 (52.5)	19 (47.5)	24 (60.0)	16 (40.0)	36 (90.0)	4 (10.0)	40 (100.0)	0 (0.0)

dropped out of the study at Time 2. The reasons for dropout were as follows: 11 participants had an early miscarriage, one participant became nervous about hospitalization for a threatened miscarriage, one participant did not provide a reason, and four participants simply did not submit the questionnaire. The dropout rate was 29.8% and the dropout rate, excluding an early miscarriage, was 10.6%. The data for 40 participants thus were analyzed.

The mean age of the participants was 36.0 ± 4.2 years, the mean infertility period was 4.6 ± 2.2 years, the mean treatment period was 2.3 ± 1.5 years, and the mean number of embryo transfers was 2.1 ± 2.6. Furthermore, 65% of the participants did not have previous pregnancy experience and 72.5% did not have previous miscarriage experience.

Process evaluation

Use of the program

Step identification was constructed from a Step 1 group of 30 participants (75.0%), a Step 2 group of six participants (15.0%), and a Step 3 group of four participants (10.0%). All the participants used the online resources, which was a common program feature at all steps (Table 3). The use of the Web consultation was 47.5% and that of the online review was 40.0%; both were higher in the Step 2 and Step 3 groups. The nursing consultation was used by one participant in the Step 2 group. One participant in the Step 3 group used nursing counseling instead of psychological counseling; others in the Step 3 group did not use the psychological counseling because, in the words of one, "I think that it will be calm if I can check the fetal heartbeat, so it is not necessary."

Program evaluation

Seventy-five percent of the participants evaluated the program positively, in terms of "meets expectations," responding "I think so" or "I think a little"; 87.5% evaluated its "convenience" positively; 82.5% evaluated positively the "problem-solving intentionality"; 85.0% evaluated "satisfaction" positively; and 90.0% evaluated "usefulness" positively.

Regarding opinions of the program, two categories were extracted, "Positive evaluation for the program" and "Improvements for the program." The former category was composed of the following seven subcategories: (i) usefulness of Web access; (ii) acquisition of proper information through the Web-based resource; (iii) usefulness of peer narrative; (iv) reflection of thoughts and feelings by infertility review; (v) self-awareness by mental health assessment; (vi) reassurance to get a Web consultation; and (vii) mental stability due to program participation. The latter category was composed of the following four subcategories: improvement of the Web-based resources, support for browsing on smart phones and improvement in the number of characters and font size, and improvement of the quantity and content of the Web-based resources, including an increase in Web-based resources and peer narratives. In contrast, changes to the physical use of the Web included a difficulty in viewing due to morning sickness. The opinion that an infertility review was not required was said by three participants. They were "unable to reflect by infertility review" and "it is necessary to take a little more time to reflect [about] infertility experience."

Program use and reaction of the participants to the outcome of an early miscarriage

Eleven participants had an outcome of an early miscarriage. They had been using the Web consultation because they were worried about their symptoms, such as bleeding and abdominal pain, before being diagnosed with the miscarriage. In addition, four participants had used the Web consultation after a miscarriage. All these participants wrote in the free responses on Web consultation: "I am asking for additional counseling services for myself." Three participants wrote in the free responses, "because I found that I have the possibility to become pregnant, I will try to do my best going

Table 4 Mean score and comparison of outcome variables before and after the intervention (n = 40)

Item	Time 1 Mean	Time 2 Mean	Time 3 Mean	Time 1 *vs* 2 *P*-value	Time 1 *vs* Time 3 *P*-value
AALS	40.70	36.07	34.13	<0.01	<0.01
PTG I-J[†]	47.93	49.22	53.10	1.00	0.04
NMS	9.33	4.50	8.33	0.25	0.74
EPDS	4.18	3.30	2.87	0.58	0.01
STA I-J	43.18	37.82	36.95	<0.01	<0.01

[†] Paired Friedman Test: one-way repeated-measures ANOVA.

forward." One participant described, "I want to do my best again by accepting disappointing results."

Outcome evaluation

Comparison of the measurement variables before and after the intervention

The AALS and STAI-J decreased significantly immediately after the intervention (Time 2) and remained significantly lower at 8 weeks after the intervention (Time 3) (Table 4). The EPDS had decreased significantly at Time 3 (but not at Time 2). The PTGI-J had increased significantly at Time 3.

Comparison between the high- and low-Negative Modification Scale groups before and after the intervention

Based on the mean score (9.33 points) of the NMS before the intervention (Time 1), the participants were divided into a high-score group (≥10 points) and a low-score group (≤9 points). In the high-score group, the NMS had significantly decreased at Time 2 (11.25 points) and still at Time 3 (10.70 points) (P = 0.04).

Correlation of the Care Need Satisfaction Scale and the other measurement variables

The CNSS showed weak negative correlations with the AALS at Times 2 and 3 and with the STAI-J at Time 3. In addition, the CNSS showed a comparatively strong positive correlation with the PTGI-J at Times 2 and 3 (Table 5). In other words, the participants who felt a higher care need satisfaction level had lower anticipatory anxiety for loss and trait anxiety and higher growth by their infertility experience. In contrast, the CNSS showed no correlation with the NMS or EPDS; however, it did show a weak negative correlation with the NMS in the high-score group at Time 3 (r = −0.33, P = 0.04), meaning that the participants who felt a higher care need satisfaction level had lower negative modification by their infertility experience.

DISCUSSION

Process evaluation of the program

Consent to participate was not obtained from three women and so the dropout rate, excluding miscarriage, was 0.6%. It is said that a desirable follow-up rate is ≥80% (Kumagai, Iiyama, Horita, Miyamura, & Syuin, 2011). Therefore, the program can be said to have been continuously accessible to women in early pregnancy after ART.

About half of the participants with the outcome of a miscarriage were using the online resource and the Web consultation before being diagnosed with a miscarriage. This means they were seeking to obtain information on pregnancy. This also provided them with the opportunity to consult on worries regarding miscarriage. In general, even these women who experienced a miscarriage asserted a positive outlook and that they would continue to do their best to become pregnant again. Also, many women personally sought continued counseling, which they asserted was valuable. These results indicate not only that miscarriage is a negative experience for pregnant women who have undergone ART, but that also early pregnancy support should become a consistent area of continuing support to be provided by nurses.

Regarding the impressions of the whole program, although a positive evaluation that it met expectations was shown to be slightly low, at 75.0%, its convenience, problem-solving intentionality, satisfaction, and usefulness were positively evaluated by >80% of the women. Therefore, the evaluation was generally good. In particular, the online resource was used by all the participants and the Web consultation was used by approximately half. Many women who suffer from infertility have searched for information online (Himmel, Meyer, Kochen, & Michelmann, 2005; Kahlor & Mackert, 2009); it shows an affinity for guidance using online resources. In addition, intervention by using a combination of websites and email has been shown to be effective (Oka *et al.*, 2005), again corresponding to the positive evaluation of interactive

Table 5 Correlations of the Care Need Satisfaction Scale (CNSS) and the other outcome variables after the intervention (n = 40)

	AALS				PTGI-J†				NMS				EPDS				STA I-J			
	Time 2		Time 3		Time 2		Time 3		Time 2		Time 3		Time 2		Time 3		Time 2		Time 3	
Variable	*r*	*P*-value	*r*	*P*-value	*r*	*P*-value	*r*	*P*-value	*r*	*P*-value	*r*	*P*-value	*r*	*P*-value	*r*	*P*-value	*r*	*P*-value	*r*	*P*-value
Satisfaction of need to review infertility experience and pregnancy	–0.22	0.05	–0.35	<0.01	0.59	<0.01	0.66	<0.01	0.05	0.67	–0.19	0.09	0.02	0.86	0.00	0.99	–0.02	0.82	–0.29	0.01
Satisfaction of need to share and reduce anxiety and worry	–0.28	0.01	–0.32	<0.01	0.31	0.05	0.43	<0.01	0.04	0.67	–0.11	0.32	0.03	0.78	–0.14	0.23	–0.09	0.41	–0.28	0.01
Satisfaction of need to have connection with peers	–0.21	0.06	–0.28	0.01	0.67	<0.01	0.55	<0.01	0.02	0.83	–0.26	0.03	0.10	0.36	–0.05	0.65	–0.15	0.16	–0.33	<.01
Satisfaction of need to take on role preparing for birth and parenthood	–0.25	0.03	–0.39	<0.01	0.25	0.11	0.30	0.05	–0.23	0.05	–0.31	<0.01	–0.07	0.51	–0.08	0.50	–0.15	0.17	–0.29	0.01
Total score	–0.31	<0.01	–0.38	<0.01	0.58	<0.01	0.60	<0.01	0.00	0.96	–0.22	0.05	0.08	0.48	–0.05	0.66	–0.07	0.48	–0.32	<0.01

† Pearson's correlation coefficient.

Kendall's rank correction coefficient. AALS, Anticipatory Anxiety for Loss Scale; EPDS, Edinburgh Postnatal Depression Scale; NMS, Negative Modification Scale; PTGI-J, Post-traumatic Growth Inventory-Japanese; STAI-J, State–Trait Anxiety Inventory-Japanese.

communication through Web consultation in the current study.

However, the use of the online review was as low as 40% and the opinions in the free description were split, suggesting individual differences in preferences and timing. It is necessary to respect individual women's preferences without forcing an early pregnancy review.

All the participants used the mental health assessment in Step 1. There were six participants in the Step 2 group and four in the Step 3 group also. However, only one participant in the Step 2 group used the nursing consultation, as no referral to psychological help was available in the Step 3 group. In other words, support was not effectively tailored by the Step. This might be related to a lack of familiarity among the participants with nursing consultation or psychological counseling and of understanding how to access it. Regarding this, it has been stated that Asians tend to emphasize group harmony, rather than personal profits, and do not use social support in coping with stress (Taylor *et al.*, 2004). In fact, all the participants in the Step 2 and 3 groups had used the Web consultation, online review, or nursing consultation, all of which require individual correspondence. In other words, they had been able to access support themselves, according to their preference and in their own way. Therefore, freedom of choice was protected for the women, but the issue of the low use of emotional support remained.

Outcome evaluation of the program

The intervention made anticipatory anxiety for loss low enough to allow the participants to feel care need satisfaction and it was maintained at this low level until the second trimester. These results suggest the value of sharing and solving anxieties and worries, including around self-care, in early pregnancy, before transfer to a birth facility. It is also necessary to support behavior related to birth and child care in early pregnancy.

The intervention also showed that the possibility of growth due to the infertility experience occurred when the care need satisfaction was felt. According to the relationship between the PTGI-J and CNSS subscales, for the integration of infertility experiences it is necessary for nurses to tell women of their peers' experience and support the review of infertility experience and pregnancy. In addition, such support is necessary before transfer to a birth facility. In the negative modification high-score group, negative modification after 8 weeks was low enough that care need satisfaction was felt through the intervention. At the 8th week of pregnancy, however, the increase in the PTGI-J and the decrease in negative modification were not significant because the strength of anticipatory anxiety for loss suppressed both.

In contrast, it was shown that care need satisfaction and the improvement of depressive symptoms might be irrelevant. There are three possible reasons. The first reason is that different needs exist for the improvement of depressive symptoms across patients. The second reason is that the support that was tailored to the Steps was not used effectively. The third reason is that negative self-evaluation strengthens expectations for this program and thus the sense that adequate care has not been provided (Hashimoto & Munakata, 2013). These results indicate that it is necessary to examine the program's content and methods in order to improve participants' depressive symptoms during pregnancy. In addition, it was shown that trait anxiety was low enough for care need satisfaction to be felt at 8 weeks. Trait anxiety is formed through negative thoughts due to past pain experiences and cannot be solved in a short time. However, it can be reduced and solved over time by eliminating the anxiety state repeatedly (Sakata, 2004). Therefore, a reduction of anticipatory anxiety for loss should lead to satisfaction of the care need and a reduction of trait anxiety.

Evaluation of, and issues regarding, the Adaptation Support Program in Early Pregnancy

This program generally was able to achieve its purpose. It was highly feasible and acceptable to the participants and relationships were shown between many outcome variables and care need satisfaction. Nurses often have the impression that providing support around miscarriage to women undergoing fertility treatment is difficult and they tend to hesitate in providing such support in early pregnancy, as this might tend to increase the negative impact of a subsequent miscarriage (Sakiyama, 2016). The present results can help to dispel these impressions and improve nursing practice.

In future research, it will be necessary to further consider the exigencies of smart phone use, interface improvement, and providing more Web-based resources and peer narratives. In addition, it is necessary to consider the presentation methods and timing for Web-based resources and the influence of women's physical condition (e.g. strong morning sickness) on Web use. Also, the infertility review needs to respect women's preference and emotional support requires devices to effectively use support that is tailored to the Steps.

Limitations of the study

This study was aimed at program evaluation and the sample size was small. Therefore, it is difficult to generalize the results. The infertility review and emotional support are unlikely to have been as effective as they might have been, given the need to respect participants' preference about engaging in them. Also, different needs can exist for an improvement of depressive symptoms. It also will be necessary to verify the program's effect with comparative groups of appropriate size and it is necessary to consider the end point, as well.

CONCLUSION

Seventy-five percent of the participants who were evaluated found that the program met their expectations positively. More than 80% evaluated convenience, problem-solving intentionality, satisfaction, and usefulness positively. Regarding opinions of the program, positive evaluations mentioned the ease of the acquisition of proper information by using Web-based resources, usefulness of peer narratives, valuable opportunity for reflection on thoughts and feelings through the infertility review, and improved self-awareness through mental health assessment. Suggested improvements included an improvement of the Web-based resources (their quantity and quality). As for the effects of the program, the AALS and STAI-J decreased significantly after the intervention and after 8 weeks. The EPDS decreased significantly after 8 weeks. The PTGI-J showed that growth through infertility experience increased significantly after 8 weeks. The CNSS showed a positive correlation with the PTGI-J and a negative correlation with the AALS and STAI-J. However, the CNSS did not correlate with the EPDS. Thus, the program is feasible and acceptable to the participants, many outcomes promoted care need satisfaction, and this program was generally able to achieve its purpose.

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DISCLOSURE

The author declares no conflict of interest.

AUTHOR CONTRIBUTIONS

T.S. conceived and designed the study, acquired and analyzed the data, drafted and revised the manuscript, and approved the final version of the manuscript.

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