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Effectiveness of Low-Cost, Virtual Sexual Health Education and Educational Leaflets on Reducing Anxiety and Enhancing Sexual Function Among Infertile Women: A Pilot Randomized Controlled Trial

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ABSTRACT

Background and Aims: Anxiety is one of the common mental illnesses affecting sexual functions among infertile women. Information and education interventions might be effective in facilitating their coping with anxiety disorder which lead to improved sexual functions and psychological wellbeing. This is the first trial to pilot-test the effectiveness of sexual health education, delivered through virtual sessions and educational booklets, in improving both psychological (reduced anxiety scores) and physical (increased sexual function) outcomes among women with infertility in Iran.

Methods: In this triple-blind pilot randomized controlled trial, 90 women seeking medical treatment for infertility were randomly divided into three groups: (a) control, (b) educational booklet, and (c) virtual education. Participants in the virtual education group received six sessions of sexual health education through educational video using the WhatsApp social network. The primary outcomes included anxiety and sexual function scores measured before and 6 weeks after the intervention.

Results: The results showed that, after the intervention, mean state anxiety scores were significantly lower in the booklet (29.27 ± 4.5 , $p < 0.001$) and virtual education groups (13.77 ± 11.6 , $p < 0.001$) compared with the control group (49.26 ± 6.86). Similarly, mean trait anxiety scores significantly decreased in the booklet (27.03 ± 6.29 , $p < 0.001$) and virtual education groups (31.66 ± 11.63 , $p < 0.001$) compared with the control group (45.93 ± 6.52). Post-intervention, there were significant differences between the intervention and control groups in mean scores across four dimensions of sexual function: sexual desire, sexual stimulation, orgasm, and sexual satisfaction. The virtual education and booklet groups did not show a statistically significant difference in the mean scores of state and trait anxiety, and sexual function.

Conclusion: Psychoeducation interventions via virtual education sessions or educational booklets appear to reduce the level of anxiety and positively affect sexual functions associated with infertility. Women seeking treatment for infertility may benefit from psychoeducational interventions, though further studies with larger sample sizes are needed to confirm these findings.

Clinical Trial Registration: The protocol has been registered at the Iranian Registry of Clinical Trials (IRCT20240915063041N1).

Mahdiyeh Karimi and Fatemeh Heshmatnia contributed equally to this study.

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Summary

- This is the first trial to pilot test psychoeducational intervention, delivered via virtual sessions and educational booklets, in Iran aimed at improving both psychological (reduced anxiety) and physical (increased sexual function) outcomes in women with infertility.
- A 6-session virtual education program and educational booklet were developed and utilized.
- Participants in both virtual education session and booklet groups had lower anxiety scores and improved sexual function post-intervention.
- There is potential for addressing mental health concerns of women with infertility through low-cost virtual psychoeducational interventions or educational leaflets.
- Further research with larger sample sizes is needed to confirm these findings and assess their integration into routine care.

1 | Introduction

Infertility, defined as the failure to conceive after 12 months of unprotected intercourse, is a major health and social issue. According to estimates from the World Health Organization, approximately 48 million couples and 186 million individuals worldwide experience infertility [1], with a global prevalence of around 8%–12% globally (approximately 10% in Iran) [2, 3]. The diagnosis of infertility and the subsequent treatment process can be highly stressful, impacting all aspects of a woman's life, including both physical and mental health [4–6]. Among the psychological disorders commonly associated with infertility, anxiety disorders are particularly prevalent [7, 8]. Increased anxiety levels can negatively affect sexual function in women, further diminishing their chances of conceiving [9, 10]. Moreover, anxiety can strain relationships between couples, leading to decreased sexual desire and function, which further reduces the likelihood of fertility [11].

Sexual health education is a process that shapes an individual's views and beliefs about sexual issues, sexual identity, and intimacy and is often associated with increasing self-confidence, self-esteem, and improved sexual performance [11]. Sexual health education can be delivered through various methods, including face-to-face instruction, educational booklets, and e-learning approaches [12]. As a nonattendance training method, virtual education is based on modern information technologies and offers several advantages over traditional educational methods, such as quick access, time savings, and limiting unnecessary travel [13]. This method received significant attention during the COVID-19 pandemic when participation in in-person training programs was restricted [14, 15].

Previous trials have tested the effectiveness of in-person delivery of sexual health education on improving sexual function among women with infertility [3, 16]. Due to the higher costs associated with in-person counseling, there is no consensus on the most effective methods to educate these women on coping with anxiety and enhancing their sexual functioning in resource-limited settings [17]. Many highly distressed women

are resistant to entering psychological treatments or counseling, primarily due to cost factors and personal reasons, such as a lack of perceived need. Evidence suggests that psychological interventions can effectively reduce psychological distress and are associated with significant increases in pregnancy rates [18]. Unfortunately, healthcare systems often overlook the mental health concerns of couples struggling to conceive, leading to a lack of specific educational programs aimed at alleviating anxiety surrounding infertility and enhancing sexual function, both in Iran and internationally.

As the number of fertility clinics continues to rise in many countries, the cost of infertility treatment remains high, making care unaffordable for some [19]. Developing and implementing strategies to lower intervention costs could help reduce expenses and increase access to infertility treatment services. To our knowledge, no study has examined the effects of low-cost approaches to sexual health education, such as virtual education sessions and educational booklets, on improving psychological outcomes (e.g., reduced anxiety) and physical outcomes (e.g., increased sexual function) in women with infertility in Iran. Therefore, this study is the first to pilot test the effectiveness of virtual sexual health education and educational booklets in reducing anxiety levels and enhancing sexual performance among women with infertility who are seeking medical treatment in Iran.

2 | Methods

2.1 | Design, Population and Settings

This was a pilot, triple-blind, randomized controlled trial (RCT). All women failing to conceive who were referred to the Shiraz Health Center, Southern Iran from December 1, 2020 to June 30, 2021 for further investigation and treatment were invited to participate in the trial. This study was conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines [20].

The inclusion criteria included age between 18 and 44 years, suffering from primary infertility with more than 1 year of unsuccessful attempts to conceive, and no history of underlying medical conditions (e.g., hypertension, depression, epilepsy, heart disease, kidney disease, arthritis, and other debilitating chronic diseases). Additionally, participants should have no history of taking long-term medications (e.g., antidepressants, antiepileptic drugs, beta-blockers, and sedatives drugs, not be using narcotics and alcohol), and not have a severe anxiety level (score of 61–80). Women with a severe anxiety were not included and were referred to mental health specialists for further investigation and treatment.

Consenting participants were randomly allocated into three groups: (a) control, (b) virtual education, and (c) educational booklet. We used triple-blind randomization in which a statistician used random blocking for allocation within the intervention and control groups, based on a random number table of blocks of three. No sample size was predetermined for this pilot trial. Instead, we conducted the trial using two different approaches (one involving virtual education and the other using

an educational leaflet) and recruited all eligible participants, which ultimately determined the sample size. Enrollment in the intervention was done after obtaining written informed consent from all the participants. Ethical approval for this study was provided by the Shiraz University of Medical Sciences Ethics Committee (IR.SUMS. REC.1398.1089).

2.2 | Intervention

The virtual psychoeducation intervention aimed to reconstruct women's attitudes affected by infertility, improve their coping with anxiety, and subsequently enhance their sexual function. This intervention included content related to the anatomy and physiology of the reproductive system in men and women, the physiology of sexual response in men and women, the specific techniques of preparing for sexual intercourse by Masters and Johnson, relaxation techniques, and more. In the virtual education group, sexual health education was provided by the main researcher (MH) in 6 sessions of approximately 30 min (2 sessions a week for 3 weeks) in the form of an educational video through the WhatsApp social network. Each session was followed by question and answer session.

For the educational booklet group, a booklet with similar content was presented including educational pictures and texts. Contact information was provided in case of queries. The control group did not receive any education from the researcher. Data were collected using a structured questionnaire before and 6 weeks after the interventions.

2.3 | Outcomes

The primary outcomes were anxiety and sexual function. Anxiety was measured using Spielberger's State-Trait Anxiety Inventory (STAI), and sexual function was measured using Female Sexual Function Index (FSFI). The STAI is a self-reporting scale with 40 questions, 20 of which measure state anxiety and 20 measure trait anxiety. The scoring of the items of this scale is based on a 4-point Likert scale from "very little" (0.5) to "very much" (2) [21]. The total scores of each of the two scales (situational and personality anxiety) range from 20 to 80. A score of 0–19 is normal, 20–40 is mild anxiety, 41–60 is moderate anxiety, and 61–80 is severe anxiety. We used the Iranian version of this scale, whose psychometric properties have been confirmed with a Cronbach's α of 0.97 in a previous study [22].

The 19-item FSFI measures women's sexual function in six independent domains of desire, arousal, lubrication, orgasm, satisfaction, and pain. By adding the scores of these six domains, the total score of the scale is obtained, and a higher score indicates better sexual function. This index was translated into Persian and validated by Fakhri et al [23]. The overall test-retest reliability coefficients for each domain ranged from 0.73 to 0.86 and the internal consistencies were within the acceptable range (0.72 to 0.90).

The covariates included age, occupation, highest educational attainment, causes of infertility, duration of infertility, and

medical treatment used. The questionnaire was administered in Persian, utilizing the scales that had been previously translated and validated for use in the Iranian population [21–23]. While the individual scales were validated, the entire questionnaire was not revalidated, as no modifications were made to the validated tools.

2.4 | Data Analysis

We tested for differences across the study arms using chi-square tests for categorical variables and non-parametric analysis of variance (ANOVA) tests for continuous variables. ANOVA was used to compare differences between the three groups (control, booklet, and virtual) in both pre- and post-intervention scores for anxiety and sexual function. Post hoc comparisons were conducted using Tukey's test to identify specific group differences. Within-group comparisons of pre- and post-intervention scores for anxiety and sexual function were conducted using paired *t*-tests. The significance level for all analyses was set at $p < 0.05$, and all tests were two-sided. All analyses were conducted using SPSS Version 24 software.

3 | Results

Between December 1, 2020 and June 30, 2021, 120 women were approached and 98 women who met the eligible criteria were invited to the study, with all consenting to participate (Figure 1). However, two women did not complete the posttest questionnaire and six women were excluded due to their mental health condition worsening. The remaining 90 women were randomly allocated into three groups. Between the intervention and control groups, there were no significant differences in general characteristics, including age, duration and causes of infertility, occupation, education, and medical treatments received (Table 1).

3.1 | Women's Anxiety Scores Pre- and Post-Intervention

The mean scores of trait and state anxiety before and after the intervention are presented in Table 2. Before the intervention, there was no significant difference between the mean scores of the three groups in trait (control: 41.46 ± 9.57 , booklet: 37.33 ± 9.25 , virtual: 39.96 ± 9.91 , $p = 0.245$) and state anxiety (control: 42.93 ± 8.38 , booklet: 41.20 ± 7.82 , virtual: 42.07 ± 10.31 , $p = 0.753$) as shown by the ANOVA test. After the intervention, there was a statistically significant difference between the three groups in mean trait (control: 45.93 ± 6.52 , booklet: 27.03 ± 6.29 , virtual: 31.66 ± 11.63 , $p < 0.001$) and state anxiety scores (control: 49.26 ± 6.86 , booklet: 29.27 ± 4.5 , virtual: 13.77 ± 11.6 , $p < 0.001$).

Tukey's post hoc test showed that there was a significant difference between the mean scores of trait and state anxiety in the virtual and booklet education groups compared with the control group. However, there was no statistically significant difference between the virtual and booklet education groups, although the average trait and state anxiety scores were lower in the booklet group compared with the virtual education group.

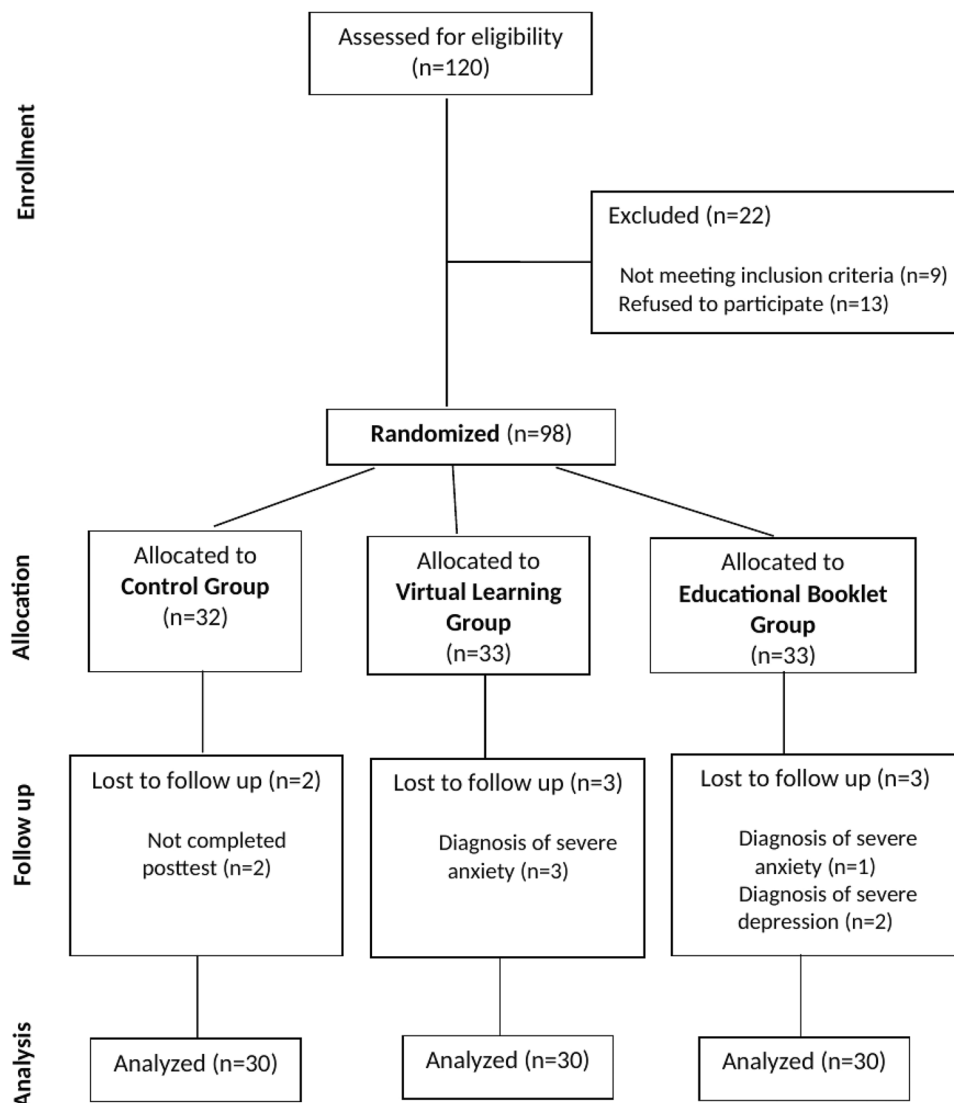


FIGURE 1 | Flow of participants through the study.

The results of the paired *t*-test showed that the mean scores in virtual and booklet education groups significantly decreased in both anxiety dimensions. In contrast, the mean scores in the control group increased after the intervention.

3.2 | Women's Sexual Function Scores Pre- and Post-Intervention

Before the intervention, there was no statistically significant difference between the three groups in mean scores of sexual function (control: 20.70 ± 2.60 , booklet: 21.26 ± 4.29 , virtual: 20.36 ± 3.00 , $p = 0.583$). However, after the intervention, there was a statistically significant difference between the three groups (control: 15.83 ± 7.52 , booklet: 23.34 ± 2.40 , virtual: 22.02 ± 4.29 , $p < 0.001$). A significant difference was found between the mean scores of sexual function in the virtual and booklet education groups compared with the control group, but no significant difference was found between the two intervention groups.

Following 6 sessions of virtual education, the results of the ANOVA test showed improvements in mean scores across four

dimensions of sexual function: sexual desire (control: 2.92 ± 1.04 , booklet: 4.84 ± 0.64 , virtual: 4.62 ± 1.20 , $p < 0.001$), sexual stimulation (control: 2.69 ± 1.44 , booklet: 4.98 ± 0.64 , virtual: 4.43 ± 1.26 , $p < 0.001$), orgasm (control: 2.54 ± 1.34 , booklet: 3.90 ± 0.60 , virtual: 3.40 ± 0.86 , $p < 0.001$), and sexual satisfaction (control: 2.92 ± 1.81 , booklet: 5.17 ± 0.75 , virtual: 4.72 ± 1.34 , $p < 0.001$) between the intervention and control groups. However, there was no significant difference in mean scores of sexual pain and sexual lubrication between intervention and control groups (Table 3).

The paired *t*-test results showed that overall sexual function scores significantly improved in the virtual education and booklet groups. In contrast, the control group showed a significant decrease in overall sexual function scores.

4 | Discussion

The present study was the first pilot RCT conducted among Iranian women with infertility to test the effects of sexual health education delivered through virtual sessions and educational

TABLE 1 | General characteristics of the participants.

| | Virtual education (N = 30) n (%) | Educational booklet (N = 30) n (%) | Control (N = 30) n (%) | p value |
|---|-------------------------------------|---------------------------------------|---------------------------|---------|
| Age in years (mean \pm SD) | 33.2 (\pm 7.1) | 33.6 (\pm 7.8) | 38.3 (\pm 6.3) | |
| Duration of infertility in years (mean, range) | 4 (2–6) | 4 (3–8) | 5 (4–7) | 0.094 |
| Occupation | | | | |
| Housekeeper | 25 (83.3) | 29 (96.7) | 28 (93.3) | 0.263 |
| Other | 5 (16.7) | 1 (3.3) | 2 (6.7) | |
| Highest educational attainment | | | | |
| Middle school or below | 6 (20) | 9 (30) | 3 (10) | 0.291 |
| Diploma | 12 (40) | 14 (46.7) | 16 (53.3) | |
| Higher education | 12 (40) | 7 (23.3) | 11 (36.7) | |
| Cause of infertility | | | | |
| Ovarian cysts | 4 (13.3) | 5 (16.7) | 7 (23.3) | 0.12 |
| Low sperm count | 2 (6.74) | 4 (13.3) | 2 (6.7) | |
| Ovarian weakness | 3 (10) | 4 (13.2) | 8 (26.7) | |
| Weakness of sperm | 8 (26.7) | 6 (20) | 6 (20) | |
| Unknown cause | 1 (3.3) | 7 (23.3) | 3 (10) | |
| Other causes | 12 (40) | 4 (13.3) | 4 (13.3) | |
| Medical treatment received | | | | |
| None | 17 (56.7) | 18 (60) | 16 (53.3) | 0.867 |
| HCG-HMG | 1 (3.3) | 1 (3.3) | 0 (0.0) | |
| IUI | 5 (16.7) | 2 (6.7) | 3 (10) | |
| IVF | 4 (13.3) | 5 (16.7) | 8 (28.7) | |
| IVF-IUI | 3 (10) | 4 (13.3) | 3 (10) | |

Abbreviations: HCG, human chorionic gonadotropin; HMG, human menopausal gonadotropin, IUI, Intrauterine insemination; IVF, In vitro fertilization.

TABLE 2 | Comparison of anxiety scores before and after the interventions.

| | | Virtual education (N = 30) mean (\pm SD) | Educational booklet (N = 30) mean (\pm SD) | Control (N = 30) mean (\pm SD) | p value |
|---------------|---------|--|--|--------------------------------------|---------|
| State Anxiety | Before | 42.07 (\pm 10.31) | 41.20 (\pm 7.82) | 42.93 (\pm 8.38) | 0.753 |
| | After | 13.77 (\pm 11.6) | 29.27 (\pm 4.5) | 49.26 (\pm 6.86) | < 0.001 |
| | p value | < 0.001 | < 0.001 | 0.002 | — |
| Trait Anxiety | Before | 39.96 (\pm 9.91) | 37.33 (\pm 9.25) | 41.46 (\pm 9.57) | 0.245 |
| | After | 31.66 (\pm 11.63) | 27.03 (\pm 6.29) | 45.93 (\pm 6.52) | < 0.001 |
| | p value | < 0.001 | < 0.001 | 0.025 | — |

booklets on reducing anxiety and improving sexual function. Post-intervention, there was a significant decrease in the mean scores of both state and trait anxiety, along with an increase in sexual function scores, when comparing the intervention groups to the control group. However, the two intervention groups (virtual education vs. booklet) did not show a statistically significant difference in the mean scores of state and trait anxiety, and sexual function.

Although the group of educational booklets showed a greater decrease in anxiety levels, no significant difference was found

between the two intervention groups after the intervention. This lack of significant difference may be attributed to the booklet's consolidated format, which allows patients to read all the information at their convenience. In contrast, the six virtual education sessions were sent separately and scheduled for specific dates and times, necessitating a greater time investment from participants. These intervention approaches can be customized to meet patients' needs. For instance, more literate patients may prefer the cost-effective, booklet-based intervention, while others may benefit from the interactive nature of virtual sessions.

TABLE 3 | Comparison of sexual function scores before and after the interventions.

| Variable | | Virtual education (N = 30) mean (\pm SD) | Booklet education (N = 30) mean (\pm SD) | Control (N = 30) mean (\pm SD) | p value |
|---------------------|---------|--|--|--------------------------------------|---------|
| Sexual desire | Before | 3.72 \pm 0.71 | 4.12 \pm 0.85 | 3.72 \pm 0.74 | 0.075 |
| | After | 4.62 \pm 1.20 | 4.84 \pm 0.64 | 2.92 \pm 1.04 | < 0.001 |
| | p value | < 0.001 | < 0.001 | 0.002 | — |
| Sexual stimulation | Before | 3.83 \pm 0.63 | 4.15 \pm 0.95 | 3.76 \pm 0.79 | 0.141 |
| | After | 4.43 \pm 1.26 | 4.98 \pm 0.64 | 2.69 \pm 1.44 | < 0.001 |
| | p value | 0.007 | < 0.001 | 0.001 | — |
| Sexual lubrication | Before | 2.76 \pm 0.7 | 2.78 \pm 0.78 | 3.30 \pm 0.72 | 0.008 |
| | After | 2.81 \pm 0.84 | 2.91 \pm 0.4 | 2.66 \pm 1.46 | 0.627 |
| | p value | 0.781 | 0.331 | 0.05 | — |
| Orgasm | Before | 3.38 \pm 0.81 | 3.41 \pm 1.11 | 3.4 \pm 0.54 | 0.993 |
| | After | 3.40 \pm 0.86 | 3.9 \pm 0.6 | 2.54 \pm 1.34 | < 0.001 |
| | p value | 0.947 | 0.025 | 0.004 | — |
| Pain | Before | 2.52 \pm 0.92 | 2.66 \pm 1.18 | 2.58 \pm 0.87 | 0.852 |
| | After | 2.04 \pm 1.04 | 1.53 \pm 0.57 | 2.09 \pm 1.36 | 0.079 |
| | p value | 0.018 | < 0.001 | 0.129 | — |
| Sexual satisfaction | Before | 4.14 \pm 1.05 | 4.14 \pm 1.13 | 3.93 \pm 1.11 | 0.705 |
| | After | 4.72 \pm 1.34 | 5.17 \pm 0.75 | 2.92 \pm 1.81 | < 0.001 |
| | p value | 0.014 | < 0.001 | 0.014 | — |
| Sexual function | Before | 20.36 \pm 3.00 | 21.26 \pm 4.29 | 20.7 \pm 2.6 | 0.583 |
| | After | 22.02 \pm 4.29 | 23.34 \pm 2.4 | 15.83 \pm 7.52 | < 0.001 |
| | p value | 0.025 | 0.004 | 0.003 | — |

These results align with previous studies supporting the efficacy of various educational methods in reducing anxiety across different pathological conditions [24–28]. The unique aspect of our intervention lies in its tailored content and approach, specifically addressing the mental health concerns of women with infertility. However, it is important to note that our study was a pilot with an initial cohort of 90 women, who were highly motivated to seek medical treatment. Further follow-up translational studies with a larger sample size are necessary to validate these findings and to facilitate the scaling up of both the virtual education and booklet programs.

Additionally, our findings indicate that psychoeducational approaches, regardless of their implementation method, may significantly improve sexual function, primarily by alleviating anxiety associated with infertility. Despite the low sample size, our study sheds light on the need for healthcare systems to integrate comprehensive sexual health education into infertility treatment protocols. Such integration could potentially help address not only the physical aspects of infertility but also the psychological dimensions, ultimately leading to improved outcomes for women and couples [29–35]. Future research with a larger sample size should explore the long-term effects of these interventions, including potential impacts on relationship dynamics and overall quality of life for individuals facing infertility.

Limitations of this pilot study include the relatively small sample size of 90 women recruited solely from a hospital

setting, which limits the generalizability of the findings to broader populations. The small sample size may not adequately capture the variability in important variables and confounding factors, such as the type of infertility, the duration of infertility, and the number of failed treatment cycles. These factors can significantly influence sexual performance but were not fully addressed in this study due to the constraints of the pilot study. Additionally, the use of an interview method for measuring the effectiveness of the education programs at pre- and 6 weeks post-intervention introduces the potential for interviewer bias and subjectivity in responses. Furthermore, the short follow-up period of 6 weeks may not capture longer-term impacts of the interventions on stress, anxiety and sexual function.

Future studies with larger, more diverse samples recruited from multiple settings and longer follow-up periods are warranted to provide more robust evidence of the effectiveness of virtual education and educational booklet approaches in this population. Continued research and program development in this area are essential for fostering a supportive environment that addresses the multifaceted challenges faced by these women.

5 | Conclusion

This pilot RCT shows that sexual health education, whether delivered through virtual education sessions or educational booklets, effectively reduces anxiety and enhances sexual performance in

women with infertility. Interestingly, both intervention methods yielded comparable effects, suggesting that either approach could be tailored to meet the specific needs of individual patients. To substantiate these findings further, a translational study involving a larger and more diverse population of women, along with an extended follow-up period, is strongly advised. We recommend that the mental health concerns of women with infertility can potentially be addressed by integrating low-cost virtual education sessions and educational booklets into routine care.

Author Contributions

Mahdiyeh Karimi: conceptualization, methodology, writing – original draft, formal analysis, project administration, resources, investigation. **Fatemeh Heshmatnia:** conceptualization, methodology, writing – original draft, formal analysis, resources. **Sara Azima:** software, methodology, formal analysis, visualization, writing – review and editing. **Marzieh Akbarzadeh:** software, formal analysis, resources, project administration, writing – review and editing. **Subash Thapa:** conceptualization, writing – review and editing, formal analysis, methodology, writing – original draft, supervision.

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Disclosure

All authors have read and approved the final version of the manuscript. S.T. had full access to all of the data in this study and takes complete responsibility for the integrity of the data and the accuracy of the data analysis.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Transparency Statement

The lead author Subash Thapa affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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