Research Protocol

The Effect of Abbreviated Online Counseling Based on Mindfulness on the Level of Distress of Women With Infertility Undergoing Assisted Reproductive Methods: A Study Protocol

Negin Salarian[1] , Forouzan Elyasi[2, 3] , Noraddin Mousavi Nasab[3] , Mohammad Esmail Ebrahimi[4] , Zeinab Hamzehgardeshi[2, 5*]

1. Student Research Committee, Mazandaran University of Medical Sciences, Sari, Iran.
2. Sexual and Reproductive Health Research Center, Mazandaran University of Medical Sciences, Sari, Iran.
3. Department of Psychiatry, Psychiatry and Behavioral Sciences Research Center, School of Medicine, Addiction Institute, Mazandaran University of Medical Sciences, Sari, Iran.
4. Department of Psychology, Faculty of Humanities, Hamadan Branch, Islamic Azad University, Hamadan, Iran.
5. Department of Reproductive Health & Midwifery, School of Nursing and Midwifery, Mazandaran University of Medical Sciences, Sari, Iran.

ABSTRACT

Background and Objective: Infertility is a major life event that can induce severe psychological stress in couples, especially women. This protocol-based study aims to assess the effect of an abbreviated online mindfulness-based intervention (MBI) on the distress and quality of life (QoL) of infertile women undergoing assisted reproductive technology fertility treatments.

Materials & Methods: This study outlines a protocol for a randomized clinical trial involving 70 infertile women in Iran, who will be randomly divided into two groups of control (n=35) and intervention (n=35). To collect data, a sociodemographic/medical-fertility form, the general health questionnaire-28 (GHQ-28), Newton's fertility problem inventory, the infertility distress scale (IDS), and the QoL questionnaire for infertile women will be used. The online MBI will provided in groups of seven, once per week, for four weeks, each session for two hours. Data analysis will be performed in SPSS software, version 25.

Discussion: The goal of this protocol-based study is to introduce a clinical trial that assess the effect of online MBI for reducing distress and thereby improving the QoL and mental health of infertile women in Iran. Given the prevalence of infertility and the importance of MBI, the results of the clinical trial can be highly beneficial.

Keywords: Mindfulness, Psychological distress, Infertility, Counseling

* Corresponding Author:
Zeinab Hamzehgardeshi, Professor.
Address: *Department of Reproductive Health & Midwifery, Sexual and Reproductive Health Research Center, School of Nursing and Midwifery, Mazandaran University of Medical Sciences, Sari, Iran.*
E-mail: *hamzehgardeshi@yahoo.com, hamzehgardeshi@mazums.ac.ir*

Introduction

Infertility is defined as the inability to achieve pregnancy after one year or more of unprotected intercourse [1]. Globally, the prevalence of infertility is about 9%. According to study in Iran, in 2020, the infertility rate was 13.2% and the prevalence of primary infertility rate was 17.3%, both are above the global average [2]. The World Health Organization (WHO) recognizes infertility as a significant reproductive health issue [3, 4]. The incidence of infertility increases with aging, such that the prevalence of primary infertility is 7.3-9.1% in married women aged 15-34, 25% in women aged 35-39, and 30% in women aged 40-44 [3, 5]. The prevalence of female infertility in developed countries is 37% [6]. The potential fertility can affect women's social status, dignity, self-confidence, sense of adequacy, and worthiness, while the social pressures of infertility can lead to psychological issues such as sadness, depression, and distress [7, 8]. Psychological problems are related to the nature of infertility, ineffective medical interventions, high treatment costs, and unpredictable outcomes [9]. Although both men and women are emotionally affected by infertility, women suffer from more pressure than men [10, 11]. Infertility can cause huge amount of stress and emotional distress in women [12]. Distress occurs when stress is severe, prolonged, or both. Severe emotional distress is often associated with the diagnosis of infertility. Various definitions exist for distress, but it is commonly defined as a negative emotional state where the individual's adaptive and coping processes fail to restore physiological and psychological balance [13]. Although the cause-and-effect relationship between distress and infertility is not clear, infertility is definitely linked to high distress [12-15].

Currently, the use of psychological interventions for infertile people is increasing [16-20]. The interventions include cognitive-behavioral therapy, mindfulness-based intervention (MBI), mind-body interventions, acceptance and commitment therapy, herbal therapy, internet-based interventions, and emotion/problem-oriented interventions [16-20]. In a recent study, the MBI was shown to successfully improve the mental health of women undergoing their first in-vitro fertilization (IVF) [21]. The clinical efficacy MBI has also been reported. This psychotherapy method is widely used for treating those experiencing distress in various medical and psychiatric conditions [22-25]. Recent studies have shown that MBI can break the vicious cycle of negative thoughts associated with infertility [22-25]. However, a study showed the ineffectiveness of a social-psychological intervention in altering mental health and pregnancy rates [20]. Systematic reviews have shown that the effectiveness of MBI in couples or individuals with infertility is greater than that of other psychological treatments in reducing psychological symptoms, stress, and anxiety [23]. Evidence suggests that MBIs are more effective than traditional cognitive therapy, behavioral therapy, or cognitive-behavioral therapy in treating infertility, because they address a broader range of problems, including interpersonal, marital, social, occupational, and psychological problems [26-31].

Patients undergoing infertility treatments often find the related information on the Internet [32-34]. A systematic review of 19 studies by Zillien et al. showed that the main reasons for the use of the Internet by infertile couples are the availability of a large amount of diverse information and the provision of emotional, social, and psychological support, which can lead to perceived improvements in knowledge, emotional state, relationships, and self-efficacy. However, they have concerns about the quality of information and its potential negative effects [32]. Internet-based interventions are a promising new approach for infertile patients, which need further development and testing [35-39]. Most of these programs are less expensive and can be affordable for users [27]. To our knowledge, there is no clinical trial on the effect of internet-based MBI on the emotional distress of infertile women in Iran or other countries. Therefore, this study aims to examine the effect of an online MBI on the infertility-related distress and stress and quality of life (QoL) of infertile women under treatment.

Materials and Methods

Study design, sampling, and allocation

This is a protocol study outlining a double-blind randomized controlled clinical trial. Considering the main goal of this study, the sample size is determined 30 per group based on a previous study [39] and using the Equation 1, where the first type error (α)=0.05, second type error (β)=0.20, number of repetitions (m)=3, correlation coefficient between pre-test and post-test phases (r)=0.2, and effect size=0.5. To increase the study's accuracy and considering the potential sample dropouts, the sample size will be determined as 35 per group (total=70).

$$1.\ n = 2 \times \frac{\left[Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right]^2 [1 + (m-1) \times r]}{m \times \left(\frac{\mu_1 - \mu_2}{\sigma}\right)^2} =$$

$$2 \times \frac{[1.96 + 0.84]^2 [1 + (3-1) \times 0.20]}{3 \times 0.5^2}$$

Table 1. Time schedule for conducting different parts of the study

Activity	Time to Complete	Timeline (m)									
		1	2	3	4	5	6	7	8	9	10
Obtaining proposal approval and code of ethics	Two months		*	*							
Sampling and data collection	Two months				*	*					
Intervention	Two months					*	*				
Data analysis	Two months							*	*		
Writing the article	Three months									*	*

Current Psychosomatic Research

The participants will be selected based on inclusion criteria using a convenience sampling method from among infertile women undergoing infertility treatments referred to health centers, clinics, private offices, and infertility centers in Mazandaran Province, Iran. Inclusion criteria are: Iranian nationality, fluency in Persian, having a smartphone and being able to use them, age <45 years, diagnosed infertility, undergoing assisted reproductive techniques (IVF, IUI), and an anti-müllerian hormone level >1.5 ng/mL [40]. Exclusion criteria are: Intention to use donated embryos or eggs or surrogacy, canceling or terminating the treatment plan for any reason by the physician, receiving psychological or psychiatric counseling at the time of the study or in the past month, having major psychiatric disorders, having systemic diseases such as diabetes, hypertension, hyperlipidemia, and thyroid disorders (based on the medical records or self-report), experiencing the death of a relative or a major accident at least three months before the intervention, pregnancy detected by a blood test during the study, use of psychiatric medications (based on self-report), having an adopted child, smoking, smoking cigarette, hookah or alcohol consumption, history of previous marriage, and the need to receive prescribed psychotropic medications or psychotherapy counseling during the study. Using the block randomization method (14 blocks of five), participants will be assigned into two groups of intervention and control (Figure 1). In this study, due to the counseling and therapeutic nature, participants will be aware of the intervention. However, the data analyzer and the one conducted sampling will be unaware of allocation at the time of evaluation. The time schedule for conducting different parts of the study is provided in Table 1.

Data collection tools

The data will be collected before the intervention, immediately after, and four weeks after the intervention from the two groups using five instruments:

The sociodemographic/medical-fertility form: This form surveys demographic and family related information (age, educational level, husband's educational level, occupation, husband's occupation, place of residence, duration of marriage, menstrual status, body mass index, and socio-economic status) as well as the information related to infertility and its treatment (infertility period, treatment period, and the cause of infertility);

General health questionnaire-28 (GHQ-28): This tool is a widely used screening tool designed by Goldberg in 1972 to identify mental disorders in medical settings and various situations. It has been translated into 38 languages and is utilized globally. The original version has 60 items, while its shorter forms have been developed with 12 and 28 items. The 28-item version has higher validity, sensitivity, and specificity compared to other versions [41]. The reported validity and reliability rates of 83% and 87%, respectively. For the Persian version, Taghavi assessed the test re-test reliability, split-half reliability, and internal consistency whose coefficients were 0.70, 0.93, and 0.90, respectively. The correlation coefficients between the subtests ranged from 0.72 to 0.87 [41].

Fertility problem inventory (FPI): This tool was developed by Newton et al. in 1999 to measure the infertility-related stress. It has 46 items and five domains: Social concern (10 items), sexual concern (8 items), relationship concern (10 items), rejection of childfree lifestyle (8 items), and need for parenthood (10 items). The items are rated on a 6-point scale ranging from 1 (completely
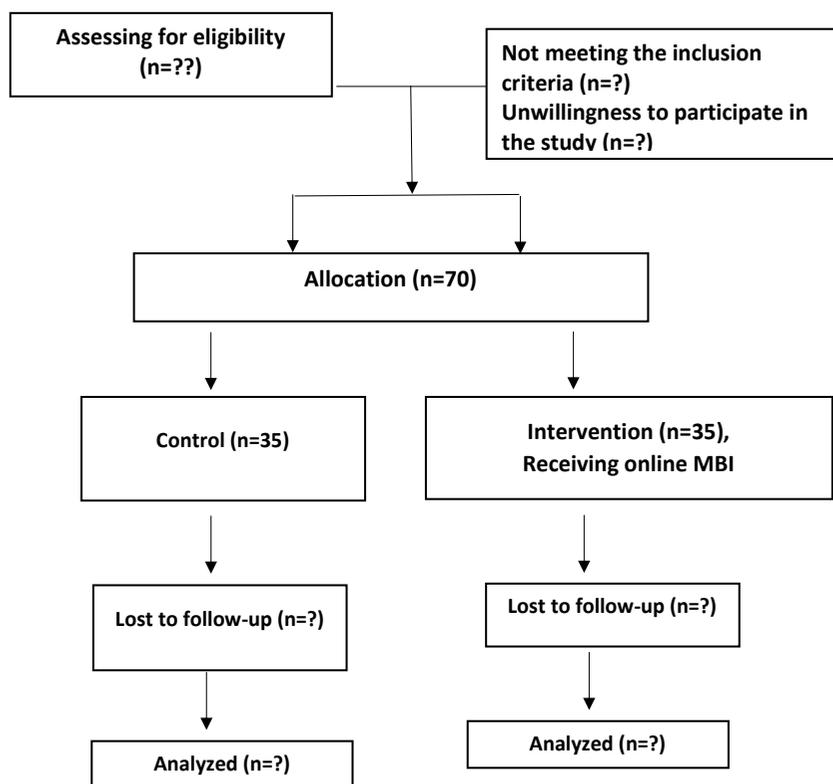
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Figure 1. CONSORT diagram of the study

disagree) to 6 (completely agree). The total score for the social concern, relationship concern, and need for parenthood domains range from 10 to 60, while for the sexual concern and rejection of childfree lifestyle domains, the total score ranges from 8 to 48. The score for the overall scale ranges from 46 to 276, with higher scores indicating greater infertility-related stress [42]. The validity and reliability of the Persian FPI were assessed in Iran by Alizadeh et al. in 2006 on 30 infertile individuals (15 men and 15 women) at Imam Khomeini Hospital. Cronbach's α values were reported as 0.78 for social concern, 0.77 for sexual concern, 0.78 for relationship concern, 0.75 for rejection of childfree lifestyle, 0.84 for the need for parenthood, and 0.91 for the overall scale, confirming its reliability to be used in Iranian samples [43].

Infertility distress scale (IDS): The IDS is a 21-item tool designed by Akyuz et al. in Turkey in 2008 to assess distress among infertile individuals. It has a Cronbach's α value of 0.933, indicating a high reliability [44]. For Iranian samples, the IDS's validity and reliability were evaluated in 2010 by Arab Sheybani et al. on 300 women, including 145 fertile and 155 infertile. Their study confirmed that all 21 items correlated significantly with the overall scale, and the Cronbach's α for the overall scale was 0.91. Its subscales could explain 88% of the

total variance with an eigenvalue greater than 1, demonstrating its adequacy for measuring infertility distress in Iranian women [45].

QoL scale for infertile women: This is a 25-item tool designed by Kiani et al. in 2020. It has seven subscales: Psychological effects, sexual life, family and social effects, related concerns, physical effects, adaptive approaches, and inhibitory factors preventing adaptation. The tool has acceptable validity and reliability. Its concurrent validity is 0.61, with the intraclass correlation coefficient of 0.97, and a Cronbach's α value of 0.87 [46].

Visual analog scale for satisfaction with intervention: The visual analog scale will be used in this study to measure participants' satisfaction with the counseling sessions. It asks respondents to rate their level of satisfaction on a scale from 0 (not satisfied at all) to 10 (very satisfied). Scores are categorized as follows: 1-3 for low satisfaction, 4-7 for moderate satisfaction, and 8-10 for high satisfaction [47].

Intervention

The intervention group will receive online MBI at four sessions on Skyroom platform, after inviting them using the link sent on social network such as WhatsApp.

The session 1 includes mindful breathing and body scan mediation; session 2: Guided imagery, kindness, and compassion; session 3: Mindful eating and mindful movements such as walking; session 4: Mindful conversations and observation of emotions. Women in the control group will receive routine care from their treatment centers or private physicians. After the end of the study, one MBI session will be provided to the control group.

Data analysis

Data will be analyzed in SPSS software, version 25. Normality will be assessed using the Shapiro-Wilk test. Descriptive statistics (Mean±SD, median, and percentages) will be used for describing the data. Inferential statistics will be parametric tests such as t-test, ANOVA (for comparing means), and Pearson's correlation test for quantitative data. Non-parametric tests such as Mann-Whitney U test, Kruskal Wallis test, and Spearman's correlation test will be used if the normality was rejected. Repeated measures ANOVA or ANCOVA will assess changes in scores over time. The intention-to-treat analysis will be used if the participants left during the study. Multiple linear regression and general linear models will assess the effect of sociodemographic factors on the dependent variables. The significance level for all tests will be set at 0.05.

Discussion

The primary goal of this study is to use MBI for improving the mental health of infertile women in Iran. Infertility can lead to various psychological responses in couples, such as reduced self-esteem, anger, sadness, difficulties planning for the future, social isolation, feelings of emptiness, jealousy of other couples with children, anxiety, and depression.

Mindfulness refers to deliberate, non-judgmental attention to thoughts, emotions, and sensations in the present moment. Since the emotional distress caused by infertility significantly affects treatment processes and all aspects of life, especially in infertile women, this study will use online method to provide better accessibility and effectiveness for the participants and, if successful, introduce a new psychological method to the therapists to help them focus on or address emotional distress, when necessary. This protocol-based study may help alleviate the emotional distress of infertile women and thus improve their mental health.

Limitations

The use of virtual networks for recruitment or intervention may avoid the women with a lack access to the Internet or smartphones from participating in this research. Additionally, data collection will be done using self-report tools.

Strengths

This protocol has a registered IRCT code. The use of online method will eliminate the need for commuting and will reduce costs for participants. Another strength is the blinding of the rater. The session contents will be developed based on a protocol assessed by experts that are not a member of the research team.

Ethical Considerations

Compliance with ethical guidelines

All ethical principles will be considered in this study. Ethical approval has been obtained from the Ethics Committee of Mazandaran University of Medical Sciences (Code: MAZUMS.REC.332) and was registered by Iranian Registry of Clinical Trials (IRCT) (Code: IRCT20160619028528N7).

Authors' contributions

Investigation: Negin Salarian and Zeinab Hamzeh Gardeshi; Data collection: Forouzan Eliasi and Negin Salarian; Writing and final approval: All authors.

Conflict of interest

The authors declared no conflict of interest.

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