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Effect of music therapy on the anxiety levels and pregnancy rate of women undergoing in vitro fertilization-embryo transfer: A randomized controlled trial

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ABSTRACT

Purpose: The aim of this study was to determine the effect of music therapy on the anxiety levels and pregnancy rates of women who underwent in vitro fertilization-embryo transfer.
Methods: This prospective randomized controlled trial was conducted with 186 infertile women who presented to the In Vitro Fertilization Unit at the American Hospital in Turkey between April 2015 and April 2016. The infertile women who met the inclusion criteria were assigned to the music therapy group or the standard therapy group through block randomization. The study data were collected using the Personal Information Form, and State-Trait Anxiety Inventory. Early treatment success was determined by serum beta human chorionic gonadotrophin levels seven or ten days after the luteal day zero. For the analysis, descriptive statistics, chi-square test, Fisher's exact test, independent sample *t*-test were used.
Results: After the embryo transfer, the mean state anxiety scores decreased in both groups, and the mean trait anxiety score decreased in the music therapy group; however, the difference was not statistically significant ($p > 0.05$). Clinical pregnancy rates did not differ between the music (48.3%) and standard (46.4%) therapy groups.
Conclusion: After the two sessions of music therapy, state and trait anxiety levels decreased and pregnancy rates increased, but the difference was not significant. Therefore, larger sample sizes and more sessions are needed to evaluate whether music therapy has an effect on clinical outcomes.

1. Introduction

Infertility is defined as the inability to conceive after 12 months or more of regular unprotected sexual intercourse or to carry a pregnancy to term (WHO, 2014). It has been stated that infertility rate varies between 5% and 30% in couples in reproductive age all over the world (Boivin, Bunting, Collins, & Nygren, 2007; Gurunath, Pandian, Anderson, & Bhattacharya, 2011; Mascarenhas, Flaxman, Boerma, Vanderpoel, & Stevens, 2012; Oakley, Doyle, & Maconochie, 2008; Thoma et al., 2013). Although there are no accurate data about the prevalence of infertility in Turkey, it is estimated that 10–20% of the couples are diagnosed with infertility and that the problem is gradually increasing (Karaca & Unsal, 2012; Kirca & Pasinlioglu, 2013).

Infertility is not only a physiological problem but also a life crisis which affects couples psychologically, familially, socially and culturally and disrupts their adjustment mechanisms (Asci & Beji, 2012; Cousineau & Domar, 2007; Sezgin & Hocaoglu, 2014). In studies conducted on the issue, couples usually define infertility as the most stressful experience in their lives (Greil, Slauson-Blevins, & McQuillan, 2010; Herrmann et al., 2011). Couples begin to look for treatment options in order to overcome this stressful life crisis and they regard assisted reproductive techniques such as in vitro fertilization-embryo transfer (IVF-ET) as a solution. However, the addition of a long, expensive, and painful treatment process to this multifaceted effects of infertility increases the possibility of psychological problems in couples (Boivin, Griffiths, & Venetis, 2011; Chen et al., 2016; Kissi et al., 2013; Klemetti, Raitanen, Sihvo, Saarni, & Koponen, 2010; Pasch et al., 2012; Zivaridelavar, Kazemi, & Kheirabadi, 2016). Couples, women in particular, are reported to experience anxiety during the infertility treatment process and high levels of anxiety affect conception rates negatively, and failed treatments increase the risk of anxiety disorders and depression (Gourounti, Anagnostopoulos, & Vaslamatzis, 2011; Hashemi, Simbar, Ramezani-Tehrani, Shams, & Majd, 2012; Pasch et al., 2012; Verhaak, Smeenk, Nahuis, Kremer, & Braat, 2007). The importance of

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providing help for couples to overcome negative emotions and preparing them for the treatment process and results of infertility treatment has been emphasized (Pasch et al., 2012; Verhaak, Smeenk, Nahuis, Kremer, & Braat, 2007).

In spite of the improvements in infertility treatment, the rate of live births is still below 50% today (Boivin et al., 2007; Murphy et al., 2014), and the use of complementary and alternative medicine (CAM) an important dimension affecting treatment success has been neglected for many years (Murphy et al., 2014). In recent years, the use of complementary and alternative treatment has increased significantly because it is cost effective and easy to access, and because the individuals do not experience anxiety related to invasive procedures or the side effects of chemical medicines (Ayaz & Yaman, 2010; Clark, Will, Moravek, & Fisseha, 2013). Approximately 30–60% of infertile couples have been reported to try complementary and alternative treatment methods in order to increase treatment success and reduce anxiety (Ayaz & Yaman, 2010; Boivin & Schmidt, 2009; Sela et al., 2011). The most common complementary and alternative methods used for the treatment of infertility are acupuncture, homeopathic and herbal medicines, psychotherapy, energy healing, massage, aromatherapy, and music therapy (Avcibay & Beji, 2013; Ayaz & Yaman, 2010; Bardaweel, Shehadeh, Suaifan, & Kilani, 2013; Clark et al., 2013).

Music therapy is defined as a field of expertise using music and music activities in meeting individuals' physical, psychological, social and mental needs (Fleury, Approbato, Silva, & Maia, 2014; MacDonald, Kreutz, & Mitchell, 2012). Music therapy can reduce a patient's anxiety and stress, alleviate his/her pain, modify a number of physiological parameters and improve the quality of life in clinical medicine (MacDonald et al., 2012; Mattei & Rodriguez, 2013; Nilsson, 2008). Music therapy is a beneficial non-pharmacological intervention, easy to apply and of low cost (MacDonald et al., 2012; Stocker, Hardingham, & Cheong, 2016). Its benefits in reproduction treatment can therefore be easily tested (Fleury et al., 2014).

The purpose of nursing care in the process of infertility treatment is to help individuals to overcome the effects of infertility and to offer care in order to increase their levels of well-being. Nurses should know which intervention is the most suitable to achieve this goal (Allan, 2013; Anwar & Anwar, 2016; Wilson & Leese, 2013). Accordingly, in recent years, there has been a significant increase in the number of studies about complementary and alternative treatment methods which contribute to the success of IVF-ET and reduction of anxiety, but there is a gap in the literature related to the use of music therapy in infertility treatment (Murphy et al., 2014; Stocker et al., 2016). The present study aims to determine the effect of music therapy on the anxiety levels and pregnancy rates of infertile women and to provide evidence on this issue for nurses. The results to be obtained from the research are expected to guide nursing practices and contribute to the solution of this current problem.

2. Methods

2.1. Study design

This prospective single-blind parallel randomized controlled trial was conducted with 186 infertile women who were attending the In Vitro Fertilization Unit at the American Hospital in Istanbul, Turkey between April 2015 and April 2016.

The hypotheses of the study were as follows:

H1. The state anxiety levels of women who have music therapy will be lower than those of women who do not have music therapy.

H2. The trait anxiety levels of women who have music therapy will be lower than those of women who do not have music therapy.

H3. The pregnancy rates of women who have music therapy will be higher than those of women who do not have music therapy.

2.2. Sample

This was a prospective single-blind parallel randomized controlled trial conducted at a hospital–based reproductive medicine clinic. The study population comprised 812 infertile women attending the In Vitro Fertilization Unit at the American Hospital between April 2015 and April 2016. They were aged from 22 to 45 and they required IVT-ET.

The minimum sample size was calculated with the PASS (Power Analysis and Sample Size) 11 Statistical Software (NCSS LLC, Kaysville, Utah, USA). The sample size was calculated using the following values: alpha (a) = 0.05, beta (b) = 0.20 and 1-b = 0.8, and based on the calculations, 80 individuals were assigned to each group. To achieve power for effect size, additional 20 participants were recruited, bringing the total number of participants to 100 for each group.

The inclusion criteria were as follows: Women aged between 20 and 25 years, having been diagnosed with primary infertility for at least 1 year, undergoing IVF-ET, able to speak Turkish, literate and agreeing to participate in the study. The exclusion criteria were as follows: Having a diagnosis of secondary infertility, having a diagnosis of a physical or mental illness, having hearing impairments, having perception disorders, having communication problems.

The study was completed with 186 infertile women because of the cancellation of the embryo transfers of 11 women from the music therapy group, and 3 women from the standard therapy group (music therapy group: 89, standard therapy group: 97).

2.3. Randomization and allocation

Of the infertile women, 200 who met the criteria were randomly assigned to the music therapy group or the standard therapy group using the Stata 9.0 (StataCorp, College Station, TX, USA) Statistical Software. Randomization was achieved using a permuted block algorithm stratified according to age and anxiety levels. Hence, when an infertile woman of a particular age and anxiety level was assigned to the music therapy group, the next infertile woman with these characteristics was automatically assigned to the standard therapy group. The infertile women were blinded to group assignment and anxiety measurements.

2.4. Data collection tools

The study data were collected with the Personal Information Form, and State-Trait Anxiety Inventory (STAI).

2.4.1. Personal information form

The form developed by the researchers through a literature review consists of 12 items questioning infertile women's socio-demographic characteristics, history of infertility, treatment protocols and pregnancy test results (Murphy et al., 2014; Stocker et al., 2016).

2.4.2. State-Trait Anxiety Inventory (STAI)

The validity and reliability analysis of the scale, developed by Spielberger in order to determine individuals' state and trait anxiety levels, was performed by Oner and Le Compte (Oner & Le Compte, 1983; Spielberger, 1983). The Cronbach alpha for the State-Trait Anxiety Inventory ranges from 0.83 to 0.87 (Oner & Le Compte, 1983). The scale is a self-assessment questionnaire and, consists of 40 items rated on 4-point Likert scale. The scale consists of two sub-dimensions: the “state anxiety” has 20 items and is used to determine what is felt at a specific moment under certain conditions, and the “trait anxiety” has 20 items and is used to determine what has been felt in the last seven days. The scale includes reversed and non-reversed items. The score obtained from the reversed items is subtracted from the score obtained from the non-reversed items. Then, 50 points are added to this score for the state anxiety dimension and 35 points for the trait anxiety dimension, giving the total score. The score obtained from the two sub-dimensions ranges between 20 and 80. Higher scores indicate that the anxiety level