

The Use of Integrative Medical Services to Address Psychological Concerns around Infertility in an Indian Academic Medical Centre

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ABSTRACT

Background Alternative and complementary therapies have been gaining popularity as ways to reduce anxiety in patients. **Aim:** This study aimed to assess whether yoga and meditation could decrease the severity of anxiety in Indian women diagnosed with infertility. **Study Setting and Design:** This was a retrospective data analysis of anxiety score of 354 women undergoing treatment at a tertiary infertility hospital between January 2016 and December 2018. **Materials and Method:** Women participated in group yoga, meditation and counselling therapy intervention during their treatment period. A self-reported questionnaire that used the Generalised Anxiety Disorder-7 criteria measured the participants' severity of anxiety at the start of and again at the end of the intervention. **Statistical Analysis:** Demographic analysis and a two-tailed paired *t*-test were applied between groups. **Results:** The results indicated that there was a statistically significant mean reduction (7.3 ± 2.7) in the anxiety scores of the participants between entry (12.94 ± 2.65) and following exposure (5.39 ± 1.99) to the intervention ($P < 0.0001$). The mean reduction in scores remained similar between participants who received ≤ 6 sessions (7.50 ± 2.68) and participants who received > 6 sessions (7.10 ± 2.64) ($P > 0.05$). Among the participants that experienced mild anxiety at baseline ($n = 43$), 72.1% ($n = 31$) reported experiencing minimal anxiety following the intervention ($P < 0.0001$). Among those that experienced moderate anxiety at baseline ($n = 213$), 32.4% ($n = 69$) reported experiencing minimal anxiety post-intervention ($P < 0.0001$). Participants who expressed severe anxiety at baseline ($n = 94$, 26.6%), reported experiencing minimal anxiety (13.8% [$n = 13$]), mild anxiety (81.9% [$n = 77$]) and moderate anxiety (4.3% [$n = 4$]) after exposure to the intervention ($P < 0.0001$). None of the participants reported experiencing severe anxiety post-intervention. **Conclusion:** The benefits of alternative anxiety-reduction therapies for women diagnosed with infertility have been demonstrated in this study. These therapies can be used to complement the routine treatment of such patients.

KEYWORDS: Anxiety, complementary therapy, in vitro fertilisation, positive reinforcement, yoga

INTRODUCTION

Infertility can be classified as primary and secondary. Primary infertility is the inability to achieve a pregnancy within 12 months following unprotected sexual intercourse.^[1] Women who have had a successful

conception and are unable to bear subsequent children are said to be suffering from secondary infertility.^[1]

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Infertility itself is associated with a chronic state of stress. The stress of inability to bear a child has been found to be associated with a host of psychological problems among which anxiety, depression, anger, marital discord, sexual dysfunction and a sense of low self-esteem are some of the major ones.

In India, infertility is often associated with an act of God and punishment for sins committed in past lives.^[2] The women in these circumstances are exposed more frequently to anxiety than infertile men, as they bear the brunt of social ostracism and psychological trauma.^[3]

The chronic state of increased stress induces an elevated level of the stress hormones such as cortisol, which in turn reduces oestrogen (E2) production possibly affecting granulosa cell function within the follicle resulting in deterioration of the egg quality.^[4]

Louis *et al.* assessed salivary stress biomarkers (cortisol and alpha-amylase) and found that increased concentration of alpha-amylase in the saliva were negatively associated with fecundity and concluded that stress negatively reduces the probability of conception, possibly by exerting its effect through the sympathetic medullar pathway.^[5]

Despite the importance of psychiatric disorders in infertile couples, there has been little research on anxiety and depression and ways to alleviate the patient's distress.^[2]

Alternative and complementary therapies such as meditation and yoga have been shown to improve mental health by regulating the connection between body and mind. In previous studies, yoga has been linked to a reduction in anxiety and an improved quality of life.^[6] Stress reduction techniques such as yoga and meditation have been reported widely in the literature to enhance the mental health and wellbeing of cancer patients, pregnant women and healthcare workers.^[7-11] This study aims to assess whether a yoga and meditation intervention can decrease anxiety levels in Indian women diagnosed with infertility.

MATERIALS AND METHODS

Study design and population

A retrospective study was conducted at a tertiary referral *in vitro* fertilisation (IVF) clinic in Bengaluru, India between January 2016 and June 2021. Three hundred and fifty-four infertile women diagnosed and treated for infertility were recruited and enrolled in the intervention between January 2016 and December 2018. All women who sought IVF treatment at the centre were offered psychological counselling and guided meditation sessions in addition to structured group yoga classes on

a regular basis. Women who did not attend these therapy sessions were excluded from the study.

Participants were required to sign an informed consent form that outlined the details of the intervention and associated risks.

The retrospective study was approved by the Institutional Ethics Committee of the Gunasheela Hospital and Fertility Centre, Bengaluru, (Dr. Devika please write the IEC sanction number) Karnataka, India.

Questionnaire

A questionnaire was offered to participants who attended the yoga, meditation and counselling sessions at two different time points, on entry into the study (baseline) and following their last psychological counselling session. A self-reported questionnaire used the Generalised Anxiety Disorder (GAD-7)^[12] measurement tool to determine participants' severity of anxiety symptoms. The GAD-7 questionnaire is a well referred to and useful questionnaire in determining anxiety levels. It consists of 7 questions with a 4-point Likert scale response, ranging from 0 (not at all) to 3 (nearly every day) [Figure 1]. The questionnaire consisted of 7 questions with a 4-point Likert scale response, ranging from 0 (not at all) to 3 (nearly every day) [Figure 1]. The final scores for each of the response options were tallied and totalled to yield an overall score. Scores for the whole scale ranged from 0 to 21, with a greater overall score reflecting a higher severity of anxiety. An anxiety score of 0–4 indicated minimal anxiety, 5–9 indicated mild anxiety, 10–14 indicated moderate anxiety and 15–21 indicated severe anxiety.

Intervention

The GAD questionnaire was filled out twice within the study period: Once on enrolment in the hospital for IVF treatment and once after the therapy sessions. A varying number of sessions of group therapy were given to each of the participating women based on the severity of anxiety, lasting an hour each. The sessions

GAD-7				
Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on the edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

Total score = Add columns + + + +

Figure 1: Generalised Anxiety Disorder 7 questionnaire consisting of 7 question with a 4 point likert scale response adapted from spritzer

were started from the 1st day of ovarian stimulation until the egg retrieval. Yoga, body relaxation techniques, guided visual meditation and positive reinforcement were included in each session. The yoga practice included a combination of deep breathing, Pranayama and Shavasana-based yoga technique as part of the fertility clinic's mindfulness program. The class would focus on gentle yoga movements for 30 min, followed by a guided 15-min meditation and relaxation session by a registered yoga practitioner employed by the fertility clinic. Following the yoga class, a psychological counsellor offered individual counselling to patients to help them cope with any negative emotions.

Data and statistical analysis

The descriptive analysis of baseline demographic and fertility characteristics variables was performed for all the 354 participants enrolled in the study. The continuous variables such as age, weight were analysed as mean and standard deviation (SD). All other categorical variables were analysed as absolute numbers and percentages. All continuous variables were assessed for normal distribution using Shapiro–Wilk test. The GAD-7 score pre- and post-intervention was evaluated for statistical significance using a two-tailed paired *t*-test. The association between the pre- and post-intervention scores were assessed using McNemar's Chi-squared test. The *P* value was set at a 5% level of significance. The data analyses were done using by IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY, USA).

Sample size calculation

For the general population, it varies between 4.75 ± 4.76 and 5.7 ± 4.9 . Among the infertility population, it was estimated as 7.37 ± 5.40 . Therefore, to study a reduction of 25% in the mean GAD-7 score after median of 6 sessions of the intervention. Using the G*Power 3 (Erdfelder, Faul, & Buchner, Behavior Research Methods, Instruments, & Computers, 1996) power analysis programme, it was estimated that ≥ 350 subjects were required, with an α level of 0.05 (two-tailed) and 80% power.

RESULTS

Demographic information

There were 571 infertile participants who were approached to participate in this study, of which 354 (62%) infertile women consented to participate. Data from all participating women were analysed. The mean age of the women who participated in this research study was 30.64 years (SD: 4.8). Most participants were homemakers and identified as unemployed ($n = 246$,

69.5%) compared with participants who were employed ($n = 108$, 30.5%). There were 83.9% ($n = 297$) who reported residing in metropolitan areas compared with 16.1% ($n = 57$) who reported residing in rural areas of India [Table 1].

Fertility characteristics

Most participants were diagnosed with primary infertility ($n = 256$, 75.1%) compared with secondary infertility ($n = 88$, 24.9%). The majority of participants responded well to their fertility treatment ($n = 335$, 94.6%) compared to those who had a poor response to their fertility treatment ($n = 19$, 5.4%).

The majority of the participants ($n = 255$, 72.9%) attempted IVF treatment on one occasion, followed by two attempts ($n = 65$, 18.4%) and three or more attempts ($n = 19$, 5.3%).

Anxiety scores

The majority of participants ($n = 213$, 60.2%) reported moderate anxiety, followed by severe anxiety ($n = 94$, 26.6%), with very few reporting minimal-to-mild anxiety ($n = 47$, 13.2%) at baseline. On follow-up (12 months following enrolment in the study), 97.5% of participants ($n = 345$) reported minimal to mild anxiety, compared to 2.5% ($n = 9$) with moderate-to-severe anxiety. There was a statistically significant mean reduction in anxiety scores between entry into the study at baseline and

Table 1: Demographic and fertility characteristics of the participants

	<i>n</i> (%)
Total participants	354
Baseline characteristics	
Mean age (years)*	30.6±4.8
Weight (kg)*	63.0±10.9
Median years of marriage (years) [#]	6.0 (4.0-10.0)
Employed participants	108 (30.5)
Unemployed participants	246 (69.5)
Participants from an urban area	297 (84)
Participants from an rural area	57 (16)
Fertility characteristics	
Participants with primary infertility	266 (75)
Participants with secondary infertility	88 (25)
Participants with poor fertility treatment response	19 (5)
Participants with good fertility treatment response	335 (95)
Previous IVF attempts	
Participants with 0 IVF attempts	12 (3)
Participants with 1 IVF attempts	257 (73)
Participants with 2 IVF attempts	65 (18)
Participants with 3 IVF attempts	16 (5)
Participants with 4 IVF attempts	3 (1)

*Mean±SD, [#]Median with IQR. SD: Standard deviation, IVF: *In vitro* fertilisation, IQR: Interquartile range

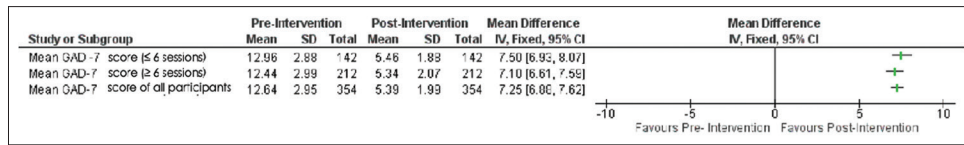


Figure 2: The mean difference of the GAD 7 scores of the participants pre and post intervention ($P < 0.0001$) and the comparison of the mean difference of GAD 7 scores for participants who took part in ≤ 6 session of therapy and > 6 sessions of therapy ($P = 0.178$). GAD 7: Generalised Anxiety Disorder

following exposure to the intervention (mean reduction: 7.3 ± 2.7), ($P < 0.0001$) [Figure 2].

There was a clear difference in the number of participants who had benefited from the study intervention [Table 1]. Participants with a minimal level of anxiety pre-intervention remained the same after the intervention regarding their infertility. Among participants that presented with mild anxiety ($n = 43$) at baseline (pre-intervention), 72.1% ($n = 31$) reported experiencing minimal anxiety post-intervention and 27.9% ($n = 12$) reported that their anxiety levels remained unchanged at 12 months' post-intervention.

Among the 213 participants that reported experiencing moderate anxiety at baseline, 32.4% ($n = 69$) reported a reduction in their anxiety levels reflecting minimal anxiety relative to their infertility following exposure to the intervention. Participants with moderate anxiety showed a further decrease in 65.3% ($n = 139$) to mild anxiety levels. 2.3% ($n = 5$) remained unchanged, still experiencing moderate anxiety and post-intervention. The proportion of participants who reported experiencing minimal, mild, or moderate anxiety after exposure to the intervention was 13.8% ($n = 13$), 81.9% ($n = 77$) and 4.3% ($n = 4$), respectively, for participants who expressed severe anxiety at baseline ($n = 94$, 26.6%) ($P < 0.0001$). There were no participants that reported severe anxiety following exposure to the intervention [Figure 3].

Analysing the number of sessions and their effectiveness in treating anxiety, the mean reduction in scores remained similar between participants who received six and fewer sessions and participants who received more than six sessions ($P > 0.05$). Furthermore, when analysing the number of participants in each anxiety group post-intervention, there was no significant difference in the number of patients in each group-based relative to the number of therapy sessions received ($P > 0.05$) [Figure 2].

Figure 3 shows that participants' anxiety levels were significantly reduced from 60% to 3% for those who exhibited moderate anxiety at baseline compared with those experienced at the end of the intervention. In addition, the anxiety levels of participants who showed severe anxiety at the beginning of the intervention

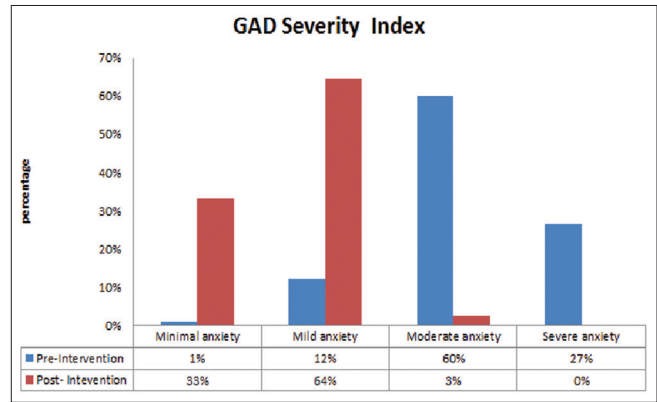


Figure 3: The reduction in severity of anxiety in the participants following the therapy intervention in relation to the severity of anxiety prior to intervention ($P = 0.0001$)

had significantly decreased by the end of the study ($P < 0.001$).

DISCUSSION

The observations from this study demonstrate the benefits of yoga and guided meditation on mental health and psychosocial well-being in women undergoing treatment for infertility.^[13,14] We found that here was a significant reduction in anxiety scores in women with all levels of anxiety post-intervention. Reduction of anxiety is important to women with fertility issues and at present, there is a paucity of research conducted on the benefits of a stress-management intervention for IVF patients. Many reports have shown that complementary therapies can relieve anxiety and depression in women and couples who pursue assisted reproductive methods, improving their overall quality of life.^[13,15-17] Given the positive outcomes presented in this study, clinicians should consider offering information regarding alternative therapies in conjunction with standard mainstream fertility practices for improving emotional, psychosocial and physical wellbeing during the assisted reproductive trajectory.^[18-20]

Studies conducted by Valoriani *et al.* and Oron *et al.* found that yoga and meditation improved the quality of life of women who had undergone standard fertility treatment to address negative feelings associated with infertility. Both authors reported a reduction in anxiety and depression in their study cohorts.^[10,21] The literature also demonstrates the physical benefits of yoga practice,

with studies highlighting a decrease in serum markers of stress and an increase in immune function.^[22-26] Yoga has also been shown to be effective in reducing post-traumatic stress disorder, insomnia, anxiety and stress compared to a control group.^[27] Khalsa postulated that mind-body awareness has an intrinsic positive impact on an individual's thought process and behaviour and significantly improves resilience.^[28]

Chan *et al.* studied integrative body, mind and spirit among 250 women randomly assigned to two groups (one group received the intervention and the other group served as a control group). Study findings revealed that the intervention group that received spiritual well-being, which included guided meditation and breathing in addition to other holistic methods, reported a statistically significant decrease in anxiety, a finding similar to those reported in this current study.^[29] In addition, a study performed by Kim *et al.* also reported a decrease in anxiety and uncertainty in women undergoing IVF in the intervention group compared to controls.^[30]

There are several strengths associated with this study, including the opportunity to evaluate anxiety levels using a structured yoga, guided meditation and psychological counselling model among infertile women in India using a large sample size.

Limitations

The limitations of this study included a non-randomised study design which may have led to selection bias in patients participating in this study. Furthermore, as this single-site study reported outcomes based on a cohort of Indian women, these results may not generalise to other populations.

CONCLUSION

This study shows the benefits of stress reduction techniques such as meditation, yoga and counselling in reducing anxiety in infertility, which can have an empowering and profound effect on clinical outcomes and patient success in conception. The findings of this study may help healthcare providers to institute complementary and alternative therapies and services to better the emotional and physical well-being of women who undergo stressful assisted reproductive methods to achieve parenthood. Future research should consider conducting a randomised control study to measure the long-term impact of a similar intervention on a comparison population.

Data availability statement

The data used pertaining to the study is in the manuscript and available upon reasonable request from the corresponding author.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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