CHAPTER III

METHODOLOGY

The study was designed to determine the effectiveness of counseling and yoga on stress and coping among women subjected to IVF treatment. The chapter deals with the research design, setting of the study, population, sample, sample size, sampling technique, sample selection criteria, development, description, administration and scoring procedure of the tool and statistical analysis used for the study.

3.1 RESEARCH DESIGN

Randomized pretest-posttest control group design was adopted for this study. This study instituted two groups, one as study group where they underwent counseling and yoga and the other control group where they did not attend counseling and yoga.

Table 6 Schematic representation of research design

<table>
<thead>
<tr>
<th>Group</th>
<th>Pretest (1st day)</th>
<th>Intervention (1st–12th day)</th>
<th>Posttest I (14th day)</th>
<th>Reinforcement (16th – 20th day)</th>
<th>Posttest II (28th day)</th>
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</thead>
<tbody>
<tr>
<td>S</td>
<td>01</td>
<td>X *</td>
<td>02</td>
<td>X *</td>
<td>03</td>
</tr>
<tr>
<td>C</td>
<td>01</td>
<td>*</td>
<td>02</td>
<td>*</td>
<td>03</td>
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</tbody>
</table>

KEY:

R - Randomization
SG - Study Group
CG - Control Group
X - Counseling and booklet for reinforcement
● - Routine care
O1 - Pretest
O2 - Posttest – I
O3 - Posttest - II
3.2 SETTING OF THE STUDY

The study was conducted at G G Hospital, Nungambakkam, Chennai, a Specialized Fertility Research Centre for IVF treatment. The total no of pregnancies achieved per year is 3519, total no of pregnant patients delivered by ART – 1883, and total no of babies delivered by ART is 2416. Total no of ongoing pregnancies is 254, total no of fetal wastage is 1354, lost for follow up is 28. The number of IVF- ET cases is 12, Number of pregnancies is 5, Pregnancy rate is 41.66 (2009 Jan – 2009 Dec), Normal pregnancy is 25%, and outpatient attendance per day is 50.

3.3 POPULATION

In this study it refers to the women seeking technological assistance for reproduction with the problem of infertility. The accessible population for this study included the entire women who were subjected to IVF treatment at G.G. Hospital. But, the target population was all the women subjected to IVF treatment.

3.4 SAMPLE

From the target population, infertility women who have completed all the investigations procedure, confirmed that they are inability to conceive spontaneously, subjected to IVF procedure and who fulfilled the sampling criteria became samples. The investigator adopted randomization in assigning samples to study group and control group respectively until the determined sample size was obtained.

3.5 SAMPLE SIZE/ ATTRITION

The sample comprised of 200 infertile women who were assigned randomly, hundred (100) to study group and hundred (100) to control group for the investigation. The estimation of sample size was determined using similar study literature sources and calculation based on power analysis. The formula used was:
\[ Z = \frac{2(Z\alpha + Z\beta)^2 (P_55+99)}{(P_1 - P_2)} \]

The estimated sample size was around 90. The researcher has increased it by 10% and made it to be as 100 for each group. At the end of the study, there was attrition of samples in the study group of 13 numbers and 20 numbers in study and control group respectively. The reasons were unable to meet the cost of the procedure, nature of the job, and attend the household routines, physical fatigueness and change of habitance. Hence these samples were not included in the study. The researcher was unable to control the attrition. So, there were 87 samples in the study group and 80 samples in the control group. The total number of attrition of sample was 33.

3.6 SAMPLING TECHNIQUE

The investigator prepared four blocks. Each block had a chit numbered 1 to 50, blinding the group allotment (study group or control group) kept aside before the data collection procedure started. The investigator identified the samples with the help of nurse assistants. The samples were asked to pick up the chit from the ballot block. The chit in the block was exposed to determine to which group the infertile women belonged. Thus the allotment of women was categorized into study group and control group with equal chance of occurrence in both the groups.

3.7 SAMPLE SELECTION CRITERIA

3.7.1 Inclusion Criteria

Infertile women who

- have been diagnosed as primary infertile at first time
- had repeated IUI failures
- had registered for IVF treatment
• were in the age group of 20 to 40 years
• have started their 1st day IVF treatment
• stay within Chennai and close proximity for contact
• were willing to participate in the study
• can read or converse either Tamil /English or both

3.7.2 Exclusion Criteria

Infertile women who

• Were undergoing IVF treatment
  - with donor sperm,
  - Surrogate mothers
• Had sexual problems (erectile dysfunction, vaginismus, premature ejaculation etc)
• Diagnosed to have history of psychiatric illness and undergoing treatment for the same.
• Had Co - morbid conditions (diabetes, cardio vascular disease, reproductive system, etc.)
• Were already exposure to counseling and relaxation
• Had undergone counseling previously
• Had practiced yoga already

3.8 DEVELPMENT OF THE TOOL

Extensive review of literature, discussion and views of experts were sought to enhance and develop the tool. The tool consists of 7 sections.
3.9 DESCRIPTION OF THE TOOL

3.9.1 Section 1: Background variables

Consists of questions on

3.9.1. a Demographic variables of infertile women. This includes age, religion, residence, educational status of the women, occupation of the women, family income, types of family, and number of members in the family, nature of marriage, monthly income and financial support.

3.9.1. b Maternal variables include age during marriage, married years, history of infertility in years, years of infertility treatment, use of contraceptives, if yes duration of use and types, and no of I V F attempts. (Annexure - C)

3.9.2 Section 2

Fertility Problem Inventory (FPI, 2000) is a standardized self report tool. FPI identified the level of stress with 5 domains such as Social domain, Sexual domain, Relationship pattern domain, Child free life style domain and Need for parenthood domain. FPI contains a total of 46 items. The author named it as Global stress. (Annexure – D)

3.9.3 Section 3

Coping Check List (CCL, 1989) is a standardized self report tool, used to distinguish the level of coping strategies followed by the women after the assessment of stress with FPI. The CCL contains a total of 70 items with 7 subscales such as Problem Solving, Positive Distraction, Negative Distraction, Acceptance, Religious Coping, Denial, and Local Support. (Annexure – E).

3.9.4 Section 4 Counseling Module consists of
3.9.4 **a Information Counseling** includes the meaning of infertility, causes and investigation associated with infertility and steps of IVF procedure - Session – I. (Annexure– F)

3.9.4 **b Therapeutic** and **Supportive Counseling** include the emotional effects of Infertility, usual coping ability adopted by infertile women-Session–II (Annexure-G).

3.9.4 **c Yoga training** includes demonstration on types of yoga practice. The module has pre performance preparation of yoga and five steps in yoga which includes Spinal flex, Titali asana, Pranayama, Meditation and Shavasana-Session-III. (Annexure– H). The woman was individually counseled and demonstration on relaxation exercise was used in the study as a nursing intervention to reduce the infertility stress & to have better coping as a group approach. The steps and general instructions before performing yoga and advantages were explained. The methods of counseling were informative counseling, supportive counseling, therapeutic counseling and psychological counseling.

3.9.5 **Section 5** Consists of

**Self Instructional Module** on infertility, causes, investigation and treatment procedures including step by step procedure on IVF treatment (Module 1). (Annexure– M)

3.9.6 **Section 6** Consists of

**Emotional reaction** towards infertility with usual coping abilities of women while facing various kinds of problems and tips to manage stressful situation during IVF procedure (Module 2). (Annexure– N)

3.9.7 **Section 7**

**Yoga Performance Check List**, to assess the practice of yoga after the intensive phase during post test 1 (14th day) and posttest 2 (28th day) and was applied only to
women of Study Group women. The scale has pre performance preparation for yoga and the steps for yoga that includes Spinal flex and Knees to chest, Shavasana, Titali asana, Pranayama and Meditation. (Module 3) (Annexure– P)

3.10 ADMINISTRATION

3.10.1 Section 1

Socio demographic and gynecological data sheet were given initially to women of both the Study group and Control group. An individual approach was used to identify the subjects before their treatment period. About 10 to 15 minutes was taken to administer the tool. Privacy and confidentiality was maintained throughout the process.

3.10.2 Section 2

FPI was used to collect data from both the groups. The scale is a self rated scale and was used immediately after the intervention and also on the 14th day and on the 28th day in both the study group and the control group. A total of 10 to 15 minutes was taken to administer the tool. Ethical concerns were strictly adhered.

3.10.3 Section 3

CCL was used after collecting the data on FPI in both the groups. The scale is a self rated scale and was used immediately after the intervention and also on the 14th day and on the 28th day in study group women and in control group women. About 15 to 20 minutes was taken to administer the tool. Confidentiality and privacy was maintained during all 3 assessments.

3.10.4 Section 4

The structured intervention was implemented. It contains Information Counseling sessions on concepts of infertility, meaning, causes, investigation and treatment procedures and management of infertility (session I). The initial session
took about 35 to 40 minutes. The individual approach was followed. Subjects were encouraged to clarify their doubts.

3.10.5 Section 5

The second Therapeutic and Supportive Counseling session was on effects of stress in general and infertility related stress in particular and the ways of managing stress and healthy coping. This was done on the second day (session II). The session took about 35 to 40 minutes and an individual approach was followed. Subjects were encouraged to clarify their doubts.

3.10.6 Section 6

The third session was on Yoga. It included demonstration of five steps of yoga and also distributed Self Instructional Module on Yoga containing (i) Spinal flex (ii) Titali asana, (iii) Pranayama, (iv) Meditation and (v) Shavasana. This took about 25 to 30 minutes and group approach was followed. Subjects were helped to clarify their doubts. Everyday self practice at home was insisted for the group (session III).

3.10.7 Section 7

Yoga performance check list was applied only to Study Group Women. The check list was administered on 14th day and on 28th day after the completion of third counseling session.

3.11 SCORING PROCEDURES

Section 1

3.11.1 Socio Demographic variables

The socio demographic variables were interpreted with frequency and percentage distribution. Chi square test was used to compute the relationship between the study and the control group.
Section 2

3.11.2 Fertility Problem Inventory

The tool has both negative and positive items. Positively phrased items were scored as

- 6 – Strongly Agree
- 5 - Moderately Agree
- 4 – Slightly Agree
- 3 – Slightly Disagree
- 2 – Moderately Disagree
- 1 – Strongly Disagree

Reverse scoring was given to negative items. Global stress was calculated by summing all items (or all 5 subscale scores).

Score Interpretation

The possible score is 348. High score indicate high stress. The level of stress as reaction to infertility was divided into 4 quartiles of the obtained scores as low (\leq 220), average (221 - 237), moderate high stress (238 - 249) and high stress (\geq 250) as suggested by the author of the tool (Newton, 2000). The tool was translated in Tamil. The interpretation is higher the score lesser the stress and vice versa.

Section 3

3.11.3 Coping Check List

Score Interpretation

The tool has 70 items with the possible score of 140. It has ‘yes’ or ‘no’ response with the score of 2 for ‘yes’ response and 1 for ‘no’ response. The obtained scores are classified as

- 76 – 100 – always used coping
- 51 -75 - sometimes used coping
≤50 - occasional used coping.

The interpretation is higher the score higher the coping.

Section 4

3.11.4 Yoga performance checklist includes items on the area of Spinal flex, Titali asana, Pranayama, Shavasana and Meditation with responses of “done the step” the score of 2 and “not done the step” with the score of 1.

A total of 5 steps scores include (Appendix - E section E)

| Step 1  | - | Spinal Flex | with a score of - | 7 |
| Step 2  | - | Titali Asana | with a score of - | 15 |
| Step 3  | - | Pranayama | with a score of - | 8 |
| Step 4  | - | Meditation | with a score of - | 15 |
| Step 5  | - | Shavasana | with a score of - | 3 |

Total score = 48

The Level of practice was graded and interpreted as follows (Appendix - E section F)

| Good practice | ≤ 50 |
| Average practice | 26 – 50 |
| Poor practice | ≥ 25 |

3.11.4 Pregnancy outcomes includes if women achieved positive results on the day of confirmation with responses of “Negative result” the score of 1 and “Positive result” with the score of 2.

3.12 MEDIUM OF INSTRUCTION

The entire above said tools were translated into Tamil and was used for the study (Annexure - E section G). Content validity for English to Tamil and back translation was obtained from experts in English and Tamil (Appendix – E section H)
3.13 VALIDITY OF THE TOOL

The content validity of the tool was validated by various experts from the fields of national and international nursing, gynecologists, epidemiologists, clinical psychologists, psychiatrists, yoga practitioners and research experts (Appendix –E section I). Apart from these, validity for standardized tools that is FPI permission was obtained from the author herself Dr. Christopher R. Newton and for CCL validity, permission to use the tool was obtained from Dr. Rao, et al. Suggestions and modifications given by the experts were incorporated and the tools were modified for the main study.

3.14 RELIABILITY OF THE TOOL

The tools were subjected for reliability tests. The Tamil version of FPI was subjected for split-half method. The ‘r’ value obtained was 0.83. (Positive correlation). The Tamil version of CCL was subjected for reliability with split-half method and the ‘r’ value obtained was 0.74 (Positive correlation). The yoga performance check list reliability was checked using inter rater method. The inter rate observer along with the investigator was also a trained yoga instructor, families with yoga practices used for the study. The obtained ‘r’ value for practice score was 0.82 (Positive correlation). Since these tools were found to be reliable and valid they were used further to proceeds with the data collection for the study.

3.15 PILOT STUDY AND REVISION

The pilot study was conducted at the infertility clinic of Sri Ramachandra Hospital. The outcome was evaluated in the counseling room of infertility clinic, SRH, Chennai. In order to ensure validity and reliability of the tool and feasibility for giving intervention, the pilot study was conducted during the month of April, 2005.
20% of the samples were selected randomly from infertile women, who fulfilled the inclusion and exclusion criteria. The data collection procedure was adopted as it was planned for the main study. It was completed in the month of June 2006. But after assuring the feasibility, the main study was started in June 2005. Though the pilot study proved a way for feasibility, some modifications were done in the tool as per the suggestions given by experts.

- **Statement of the Problem** – the investigator removed the ‘in reducing stress’ because the experimental study itself may or may not bring down stress.

- **Operational Definition** - Stress is an unpleasant experience of women who is unable to conceive spontaneously and hence seek technological assistance in reproduction as measured by Fertility Problem Inventory which consists of 46 items developed by Newton Christopher (2000) and the scores were obtained on all level of stress.

- **Female Infertile Partner** is the women who were in the fertile age group yet unable to achieve conception or become pregnant to term after a year or more with regular unprotected intercourse.

- **In coping check list question no 17** says that ‘Try to make yourself feel better by having a drink (alcohol) or by smoking’. Most of the samples had ambiguity in answering that question yet it was suggested to have it like this since it was a standardized tool and whatever response got would be included.

- **Related to study**, variables were grouped under general, gynecological and stress management.

- **Posttest 3** was not practically possible for both dependent variables. 3 repeat dependent variable measurement was made into two repeat measurements.
• ‘Separate rooms, interference of family in treatment, substance use by you and substance use by spouse’ were removed from the gynecological variable as it does not show any significant distribution and correlation.

• Sample Size was changed into 100 to study group and 100 to control group.

• Tool-on Reaction to Infertility Inventory has been changed into Fertility Problem Inventory as it is mentioned in the original tool by author.

• Setting- the pilot study was initiated at SRH, Infertility Clinic, E3 ward. The investigator experienced inadequate in getting subjects are in that setting for a period of 3 months, only

• 3 to 4 women who met the inclusion criteria were available during the pilot study from August to October, 2005. Based on the observation from the pilot study, a suitable setting to conduct the study was looked for among 4 hospitals through lottery method (multistage), one center G. G Hospital was selected, where the investigator could get an average of 8 to 10 samples per batch monthly.

• Sampling Technique - Among them, who fell under the inclusion criteria were selected by simple random technique with lottery method.

• The design of the study was changed from quasi-experimental to true experimental as mentioned in the proposal with 2 groups (study group and control group).

3.16 DATA COLLECTION PROCEDURE

The study was carried out after obtaining approval from the concerned authorities G.G. Hospital, Nungambakkam, Chennai (Appendix – E section J). Skeletal framework of the study before initiating the data collection was proposed to the ethical committee at SRU and permission was granted by the Ethical Committee
Chairperson to proceed with the study (Appendix – E section K). The data collection procedure was done in the IVF clinic. The investigator prepared 200 chits (100 for the study group and 100 for the control group) which were kept in a ballot box. As the infertile women attending IVF clinic on their first day IVF treatment with the consideration of inclusion and exclusion criteria, were approached, and clearly explained about the study and verbal consent was obtained from them. The study participants were asked to pick up the chit and according to the chit picked up from the ballot box, either the study or the control group were allotted through simple random technique and thereby randomization was done. After obtaining the written consent the investigator collected related data and conducted pretest assessment of stress and coping for both the groups using questionnaires and the results were kept confidential. Each group woman was interviewed separately according to their convenient timings in the given private room to ensure their privacy. They were allowed to withdraw from the study at any given point of time. The importance was given for their physical comfort. The study participants clearly instructed that they into either the study group or the control group. Both the groups received routine care. On the first day of their IVF treatment, women of the study group were given informative counseling on infertility related information which included meaning of infertility, causes, investigation procedures and treatment procedures including steps of IVF procedure by use self – instructional module (session 1). It is an individual approach. At the end of the session module 1 was issued for reinforcement that can be reviewed in the home set up, where as for the control group the routine care was followed. The entire session was programmed for 30 minutes. At the end of the session an interactive session was followed to clarify doubts. On the 2nd day of IVF treatment, women of the study group were given therapeutic counseling on effects of
infertility on women’s emotions and usual coping abilities followed by women while facing various kinds of problems and discussions on coping strategies to manage stress in everyday life using module (session 2). It is an individual approach. At the end of the session module 2 was issued for reinforcement that can be reviewed in the home set up, where as for the control group the routine care was followed. At the end of the session an interactive session was followed to clarify doubts. The entire session was programmed for 30 minutes. On the 3rd day of IVF treatment, women of the study group were helped by demonstrating 5 steps of Yoga (session 3). It was continued up till the 12th day of their treatment. It is a group approach (5 – 6 members). Both groups were asked to come on the 14th day of their treatment as per the doctor’s advice. The investigator obtained the subjects contact numbers to make sure of regular follow-ups. The study participants were followed up on every visit. On the 14th day the posttest I was done to determine the level of stress and coping using FPI, CCL and Yoga Check List.

Women were asked to do in front of the investigator and rating score was given as ‘not done step’ were reinforced to do correctly; ‘done step’ and the women were motivated and encouraged to continue the same. There were 13 women who did not report to the investigator in the study group where as in the control group 20 women did not report to the investigator. The reason for not attending could be due to time constraints, change of residence, and nature of job, household activities, and physical fatigue. Women were asked to do the steps of yoga in front of the investigator and rating score was given as ‘not done step’ were reinforced to do correctly; ‘done step’ and the women were motivated and encouraged to continue the same. 16th day to 20th day during women’s hospitalization the women were motivated, encouraged and women were reinforced to continue the coping style which was
discussed earlier by the investigator. Every day, the investigator conversed with all study group women and reinforced them to continue regular practice of coping style and yoga steps. On the 28th day, women in both the study and control group came back for their pregnancy confirmation. They were asked to do yoga steps in front of the investigator and rating score was given as and ‘not done step’ were reinforced to do correctly; ‘done step’ were motivated and encouraged to continue the same. The post test II was done using same FPI, CCL and Yoga Check List (on the day before confirmation of pregnancy). The control group was followed but they received only the routine care. The investigator had continuous contact with both the groups, when they were away from hospital.

The data were collected for a period of 10 months from infertility women. General timing for data collection was between 9.30-10.30am and 2.30 p.m-3.30p.m every day. This period was selected as per the availability & convenience of the women. The result on the pregnancy confirmation was prepared from the hospital record. The list of the positive and negative report was prepared by the investigator.

3.17 WEANING PHASE

Stress assessment with FPI and Coping with CCL scale at the end of the 28th day was assessed for all study group and control group women. They were reassured, reinforced, encouraged and motivated them to follow less stress life style that could enhance women in both the groups to empower themselves. The investigator provided ample of time for them to understand and accept the participation in the study. Even then there were 13 women in study group and 20 women in control group whom the researcher was unable to identify during post test I and post test II, because they did not report to investigator. The investigator was able to follow up the women in study
group with their contact numbers and addresses. Women were given the investigator’s contact number and asked to contact the investigator if there were any queries or problems. The information collected was kept confidential. The privacy was maintained for the women during data collection and their doubts were clarified. The ethical and scientific principles were adhered by the investigator throughout the study.
DATA COLLECTION PROCEDURE

Fig 3 Schematic representation of data collection procedure
3. 18 DATA ANALYSIS AND STATISTICAL METHOD USED

The study used descriptive statistics including frequency, percentage, mean and standard deviation to assess the study related variables (demographic, maternal and stress management variables) and describe the dependent variables (stress, coping and yoga practice) and pregnancy outcome. To find the existence of homogeneity between the study group and control group the nonparametric test of Karl Pearson’s chi-square distribution was used to find the dispersion of variables in the study and control groups. To test the effect of independent variable (counseling and yoga), the study adopted independent ‘t’ test to compare the data between the groups. And paired ‘t’ test was used to compare the data within the group. ANOVA and chi-square were used to associate the study related variables with outcome variables. Correlation was used to assess the relationship between the outcome variables. Regression analysis was used to find the relationship between the outcome and study related variables. The statistical package used was SPSS 17.00.

Table 7 Plan for data analysis

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<thead>
<tr>
<th>Methods</th>
<th>Type of statistics</th>
<th>Purposes</th>
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<tbody>
<tr>
<td>Descriptive Statistics</td>
<td>Frequency, percentage,</td>
<td>Assess the study related variables.</td>
</tr>
<tr>
<td></td>
<td>Mean, SD</td>
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<tr>
<td>Inferential Statistics</td>
<td>Paired ‘t’ test</td>
<td>Compare the data within the group.</td>
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<td></td>
<td>Student ‘t’ test</td>
<td>Compare the data between the groups.</td>
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<td>Repeated measures of</td>
<td>Compare the data between the groups in different</td>
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<td></td>
<td>ANOVA</td>
<td>durations</td>
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<td></td>
<td>Chi square and ANOVA</td>
<td>Associate the study related variables with outcome.</td>
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<td></td>
<td>Correlation</td>
<td>Relationship between the outcomes.</td>
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<td></td>
<td>Regression</td>
<td>Relationship between the outcome and study</td>
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<td>variables.</td>
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