Chapter III

RESEARCH METHODOLOGY

Methodology of Research includes the steps, procedures and strategies for gathering and analyzing the data in a research investigation. It includes the aspects like research approach, samples, sampling technique, development of data collection tools, intervention, pilot-study, data collection procedures and plan for data analysis.

Research Approach

As the aim of the present study was to assess the stress and coping among women with primary infertility and to evaluate the effectiveness of counseling and relaxation therapy among the couples with primary idiopathic infertility, the quantitative research approach was selected.

Research Design

Research design guides the researcher in planning and implementing the study. According to Hott and Budin (2006), it is a blueprint for the study that maximizes the control over factors that could interfere with the study’s desired outcome. For Phase I, the research design adopted for the study was descriptive survey design. For phase II, the research design adopted for the study was quasi-experimental design. One group Pretest - Posttest design was adopted.
Setting

The study was conducted in Jawaharlal Institute of Post Graduate Medical Education and Research (JIPMER), which is one of the Pioneer medical institutes in Pondicherry.

It was established by the French Government in the year 1823. This medical school was converted into Dhanvantari Medical College at the time of transfer of Pondicherry to Government of India. JIPMER was one of the Central Government Institutes in India. JIPMER was declared as an Institution of National Importance by an Act of Parliament on 14th July 2008. JIPMER is well known for its undergraduate and Post Graduate Medical Courses. JIPMER is a residential Medical Institution with a sprawling campus spread over 195 acres, located on a hillock colloquially known as “Gorimedu” near the Western entrance to Pondicherry. Quite avenues with verdant flora sit comfortably with buildings both old and new, engendering a picture of modernity with a respect for tradition. The campus houses a teaching hospital, the medical and nursing colleges. This 1690 bedded hospital caters to patients from all over South India. Approximately, 5700 patients avail the outpatient services of various departments each day and around 70,000 patients are admitted to the hospital annually (Jipmer Annual Report, 2010-2011).
In the obstetrics and Gynecology department, on an average of 1,10,000 out patients and 20,000 in-patients are treated per year. On an average 15,000 deliveries and 1200 major surgeries are performed every year. Every week obstetrics and Gynecology department runs infertility clinic and renders services to couples with infertility. It serves 400-500 couples suffering from infertility every year. Facilities for Hysterosalphingogram, diagnostic laproscopy, Endometrial biopsy, follicular study, Transvaginal sonogram, semen analysis and ovulation induction are available (Jipmer Annual Report, 2010-2011).

**Population**

Population covers the entire group of subjects under study. According to Ranjit (2008) population refers to the largest body of cases or individual that is being researched, which confirms to the specific set. In this study, for Phase I, the population constituted all women with Primary infertility and for Phase II, the population referred to couples with primary idiopathic infertility.

**Sample and Sampling Technique**

For phase I, a total of 350 women with primary infertility who fulfilled the inclusion criteria were taken as the sample for the study. Simple random technique was used to select the sample, alternate woman with primary infertility, who registered in the clinic, were selected.
For phase II, a total of 50 couples with primary idiopathic infertility who fulfilled the inclusion criteria constituted the sample. Simple random technique was used to select the sample, alternate couple with primary idiopathic infertility, who registered in the clinic, were selected.

**Criteria for Sample Selection**

**Phase I**

**Inclusion criteria**

- Women with primary infertility
  - Attending infertility clinic.
  - Who live with their spouse.
  - Who are willing to participate
  - Who know Tamil/English.
  - With age upto 40 years

**Exclusion Criteria**

- Women with secondary infertility.
- Duration of infertility more than 20 years.

**Phase II**

**Inclusion Criteria**

- Couples with primary infertility
  - With women age upto 40 years.
  - Attending infertility clinic.
- Who are diagnosed to have idiopathic infertility – men with normal semen analysis and woman with normal ovulation and patent fallopian tubes.
- Who live together
- Who are willing to participate
- Who know Tamil/English.

**Exclusion Criteria**

- Couples with secondary infertility.
- Couples who are with organic causes of infertility.

**Data Collection Techniques & Instruments**

The most trustworthy evidence that can be used in evaluating the outcome of research investigation is by developing appropriate instruments to examine the study variables. Treece and Treece (1986) stated that the instruments selected in a research should be to obtain data for drawing conclusions pertinent to the study.

**Development of the Data Collection Instrument**

An extensive literature search was done to find out the availability of any standardized tool to apply for this study. The researcher got standardized instruments to collect the data regarding stress and coping and developed an instrument to measure data regarding knowledge on conception. Tool was developed in English for data collection process. Then it was translated into Tamil (local language) and the Tamil translation
was retranslated to English for validity of the translated version. The translated instrument was found to be congruent with the original instrument.

The interviewing was considered to be the most efficient and objective method of deriving necessary information from the clients. This method was followed because direct questioning is appropriate in collecting the data from women with primary infertility and couples with primary idiopathic infertility.

**Description of the Instrument**

**The final tool consisted of 4 sections such as**

- **Section 1** - Socio Demographic and clinical data – prepared by the researcher.

- **Section 2** - Stress scale – standard tool

- **Section 3** - Coping Scale- Standard tool

- **Section 4** - Questionnaire on knowledge of conception – prepared by the researcher.

**Section: I Socio Demographic and Clinical data**

Section I assessed the Socio Demographic data using the Structured Questionnaire which had 12 items to assess the age, religion, residence, family system, educational status, occupation, spouse education status, spouse occupation, family monthly income and number of years of married life, body mass index and type of diet.
Section I also assessed the Clinical data using the Structured Questionnaire which had 21 items to assess the age at menarche, age at marriage, menstrual cycle, dysmenorrhea, family history of infertility, social support, privacy at home, duration of the treatment, habit of consuming alcohol, smoking, consuming recreational drugs, occupational exposure, habit of regular exercise, type and mode of inner garments and investigations done.

Section: II Stress scale

The fertility problem inventory, which was developed by Christopher Newton was used to measure the level of couple’s infertility related stress (Newton 1999). It is a rating scale with six points (1-6) and had a total of 46 items. Stress is grouped under five domains; namely social concern, sexual concern, relationship concern, acceptance of child free lifestyle and need for parenthood.

Section: III Coping scale

Copenhagen Multicenter Psychosocial infertility coping scale developed by Dr. L. Schmidt was used to measure the coping ability of the couples with infertility (Schmidt, 2005). It is also in the form of a rating scale with 4 points (0-3) and had a total of 20 items. Coping is grouped under four domains; namely active avoidance, active confronting coping, passive avoidance coping and meaning based coping.
Section : IV Questionnaire on knowledge of conception

This section was developed by the researcher. This section assessed the couple’s knowledge regarding Sperm, Ovum, fertility period, fertilization, factors enhancing fertilization and implantation, using 23 multiple choice questions.

Scoring Procedure

Section I

For Socio demographic and clinical data, no score was allotted.

Section II

For the stress scale, the rating scale was scored from 1-6, for all the 46 items. The maximum score was 6 and the minimum score was 1 for each item. The total maximum score was 276 and minimum score was 46.

<table>
<thead>
<tr>
<th>Items</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strongly disagree</td>
<td>1</td>
</tr>
<tr>
<td>Moderately disagree</td>
<td>2</td>
</tr>
<tr>
<td>Slightly disagree</td>
<td>3</td>
</tr>
<tr>
<td>Slightly agree</td>
<td>4</td>
</tr>
<tr>
<td>Moderately agree</td>
<td>5</td>
</tr>
<tr>
<td>Strongly agree</td>
<td>6</td>
</tr>
</tbody>
</table>
Section III

For the coping scale, the rating scale was scored from 0 to 3, for all the 20 items. The maximum score was 3 and the minimum score was 0 for each item. The total maximum score was 60 and total minimum score was 0.

<table>
<thead>
<tr>
<th>Items</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not used</td>
<td>0</td>
</tr>
<tr>
<td>Used somewhat</td>
<td>1</td>
</tr>
<tr>
<td>Used quite a bit</td>
<td>2</td>
</tr>
<tr>
<td>used a great deal</td>
<td>3</td>
</tr>
</tbody>
</table>

Section IV

The questionnaire on knowledge on conception had 23 multiple choice questions. Each question had 4 options, with one correct answer. The total score was 23.

<table>
<thead>
<tr>
<th>Type of answer</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct answer</td>
<td>1</td>
</tr>
<tr>
<td>Incorrect answer</td>
<td>0</td>
</tr>
</tbody>
</table>
Interpretation of the score

Section II: Stress scale

The level of stress was determined, based on their total score.

- 46 - 103 – Low stress
- 104-160 – Average stress
- 161-217 – Moderately high stress
- 218-276 – Very high stress

Section III: Coping scale

The coping ability was determined, based on their total score.

- ≤ 20 – Low coping
- 21-40 – Medium coping
- 41-60 – High coping

Section IV: Knowledge on conception

The overall score on the questionnaire revealed the level of knowledge of couples related to conception and the score was interpreted as shown below:

- < 50% - Inadequate knowledge
- 50% - 75% - Moderately adequate knowledge
- >75% - Adequate knowledge
Description of the Intervention

The interventions used in the study were counseling, relaxation therapy and education on knowledge of conception.

Counseling

Individual counseling was given to the couples by the researcher. On selection of the study subject, a brief introduction about the self was given to the subjects followed by detailed explanations regarding the study.

- Created a calm and quiet environment
- Time was given for relaxation
- Couples were encouraged to express their feelings and difficulties.
- Emotional support was given.
- Clarified their doubts regarding investigation and treatment.
- Clarified their myths regarding infertility
  - Infertility is not just a woman’s problem and men are equally responsible for the infertility. In 35% of couples the reason for infertility lies with the male partner. In 35% cases female factors are responsible, in 20% couples it is a combination of both and finally in 10% cases the cause of infertility is idiopathic.
  - Infertility is not the result of sin.
  - Infertility is not the punishment given by the God.
- Adopt one child and you will get pregnant is one of the myths.

- Encouraged positive thinking

An example of a thought common to couples with infertility is “I’ll never have any children.” One way to challenge this thought is to restructure it as “This process is very painful for me but there is a good chance that I will eventually have children.”

- Taught lifestyle management
  - Avoid alcohol.
  - Stop smoking.
  - Body Weight: Both low and high Body Mass Index (BMI) in a woman are unfavourable to fertility. The aim should be a BMI of between 19 and 29.
  - Drugs: Recreational drugs such as marijuana cocaine and others should be avoided.
  - Occupational: Numerous environmental and occupational factors are under suspicion as predisposing to infertility. An occupational history may reveal some that should be avoided if possible such as pesticides, certain metals, heat and X rays.
  - Exercise: Regular exercise to be practiced.
  - Advised to follow balanced diet
  - Clothing:- Advised male to avoid tight nylon inner garments.
Taught relationship between stress and infertility.

- Domar (1992) stated that it is widely accepted that the emotional factors may be a contributory cause of infertility. It has been theorized that emotional tension may reduce fertility through numerous pathways, like tubal spasm, disturbed ovulation, decreased coital frequency, and even impaired spermatogenesis. It has also been suggested that infertility itself evokes emotional disturbances which in turn impede the normal functioning of the reproductive system, a vicious cycle of infertility-emotional tension - infertility is created.

Taught stress coping strategies

- With the myriad of feelings surrounding infertility, good coping skills are essential. Here are a few tips given by Michelle (1999) to manage and lower the stress of infertility:

  - Acknowledge your feelings: Holding everything inside does not help. It actually takes more mental energy to hold your feelings back than to express them. Allow yourself time to feel the sadness, anger, and frustration.

  - Seek support: Through friends or relatives.

  - Talk to your partner: Talk about your feelings together. Keep in mind though men and women cope with stress in different ways. Women are more likely to express their sadness, while men tend to hold things inside.
• Learn as much as you can: The more you know about infertility, the more in control you will feel.

• Don’t let infertility take over your life: Make sure you fill your life and your relationship with other things. If it seems like infertility is all you talk about together, set a specified time each day for the topic, and use the rest of the day to talk about other things.

• Keep sex fun: For infertility couple sex can quickly become more like a chore, than a fun way to express love for each other. Try to keep things loving and exciting. Light candles, play fun music, or watch romantic movies, whatever makes you both feel good.

**Relaxation therapy**

Relaxation therapy was given to couples by the researcher. Relaxation therapy includes deep breathing exercise, meditation and progressive muscle relaxation, which was given one after another.

**Deep breathing exercise**

**General Instruction**

- Void before this exercise
- Avoid doing this exercise, immediately after food.

**Position**

Comfortable sitting position

**Time duration**

10 minutes in morning and evening
Dress code

Casual dress.

Procedure

- Sit comfortably
- Close your eyes and concentrate on your breathing.
- Keep both hands on abdomen just below the rib cage.
- Take deep breath through the nose, you can feel your hands moving upward.
- Then open your mouth a little bit, and slowly expel the air.
- Count the breath each time, this prevents wandering of the mind.
- Continue this for 10 minutes.

Benefits

- Deep breathing decreases electrical impulses in the brain, which indicates mind relaxation.
- It also gives physical, mental, and spiritual wellbeing.

Meditation

Position

- Comfortable sitting position with straight spine.

Time duration

- 15 minutes in morning and evening.

Dress code

- Casual dress
Procedure

- After deep breathing exercise.
- Sit on the floor, chair or in bed with spine in straight line.
- Focus your attention on one place.
- Close your eyes a little bit and focus on the same place.
- If you want to utter some words, you can do that also.
- Continue this for 15 minutes
- Then open your eyes.

Benefits

- Gives mental peace.
- Decrease heart rate and respiratory rate
- Decreases muscle tension.
- Decreases Lactate level which indicates decrease in stress level
- Weak electrical resistant skin strength increases. (This indicates that mind is relaxed)
- It produces changes in ECG and in EEG, which indicates that mind is relaxed.

Progressive Muscle relaxation

Position

Supine position

Time duration

10 minutes in morning and evening.

Procedure

- Assume supine position
- Close your eyes
- Take deep breathing
First, tighten your facial muscle
Then slowly relax the muscle
Now, tighten your muscles from shoulder to wrist.
Then slowly relax it
Now, tighten your muscle from wrist to fingers.
Then, slowly relax it
Now, tighten your abdominal muscles
Then, slowly relax it.
Now, tighten the muscle from thigh to ankle
Then, slowly relax it
Now, tighten the muscle from ankle to toes
Then slowly relax it.

**Benefits**

- Decreases heart rate
- Decreases blood pressure
- Decreases muscle tightness

**Knowledge on conception**

Couples were given group teaching on concepts of conception using flash cards which consisted of various aspects of conception and it was arranged under the following captions.

- Female reproductive organs
- Sperm
- Ovum
- Ovulation
- Fertile period
Fertilization

Factors affecting fertilization

Implantation

The doubts of the couples were clarified at the end of the session.

**Content Validity**

Six experts scrutinized the data collection instruments. The expert team included one obstetrician, one psychologist, one sociologist and three nursing professors. The corrections and suggestions given by the experts were incorporated in the tool after discussion with the research guide and the tool was finalized.

**Pilot Study**

Permission was obtained from the institutional human ethical committee to conduct the study. The pilot study was conducted among 10 women with primary infertility in phase I and among five couples with primary idiopathic infertility in phase II. The subjects were able to understand the interventions and followed the procedures taught by the investigator. The instrument was found to be feasible and practicable for the pursuit of the study.

**Reliability**

Test- retest was used to assess the reliability. The obtained reliability score for stress scale was 0.9, for coping scale it was 0.9 and for knowledge questionnaire it was 0.92.
Ethical consideration

The following ethical factors were considered during the period of study.

1. The study was approved by the research committee of the Annamalai University and Jipmer.

2. The content validity of the tool was obtained from the experts and the guide.

3. Ethical clearance was obtained from Jipmer Ethical Committee.

4. Informed written consent from the respondents was taken on the selection of the subjects.

5. Full confidentiality was maintained throughout the study.

The Data Collection Procedure

Phase I

Women with primary infertility, who satisfied the inclusion criteria were selected by simple random technique, alternate woman with primary infertility who registered in the clinic were selected and rapport was established. Then the woman was accompanied to the adjacent room in the infertility clinic and given comfortable external environment and offered a seat. A brief introduction about the researcher and detailed explanations regarding the purpose of the study was given, and the written consent was obtained. Socio demographic and clinical data were collected using structured interview schedule. The data regarding the stress and coping were collected using the respective scales.
To collect the data, the researcher spent thirty minutes with each woman.

**Phase II**

Couples with primary idiopathic infertility, who satisfied the inclusion criteria were selected by simple random technique, alternate couple with primary idiopathic infertility who registered in the clinic were selected and rapport was established. Every week 2 to 3 couples were given intervention. The couple was accompanied to the adjacent room in the infertility clinic and given comfortable external environment and offered seat. A brief introduction about the researcher and detailed explanations regarding the purpose of the study was given and the written consent was obtained. A Pretest was conducted to assess their stress level, coping level and knowledge on conception, using structured interview schedule. After that they were advised to come after 15 days for first session.

**Session I**

It was conducted on 15th day. Rapport was established. Group teaching was given on anatomy and physiology of conception using flash cards for twenty minutes.

**Counseling**

Group teaching was given on life style management for fifteen minutes. Emotional support was given.
Relaxation therapy

Deep breathing, meditation, progressive muscle relaxation were demonstrated and the samples were asked to do them besides handouts explaining the steps and benefits were also given. Advise was given to practice relaxation therapy daily in the morning and evening for thirty five minutes and to maintain the diary given by the investigator.

Session II

It was conducted on 30th day.

Counseling

Discussed the relationship between the stress and infertility and the stress coping strategies. Clarified their doubts regarding investigation and treatment.

Relaxation therapy

Checked the couple’s diary and motivated them to do and also clarified their doubts regarding the relaxation therapy.

Session III

It was conducted on 45th day.

Counseling

Clarified the myths regarding infertility and encouraged positive thinking.
Relaxation therapy

Checked the couple’s diary and motivated them to do and also relaxation therapy was reinforced.

Session IV

It was conducted on 60th day.

Counseling

Encouraged positive thinking.

Relaxation therapy

Checked the couple’s diary and motivated them to do and also relaxation therapy was reinforced.

After the 4 sessions, the couples were instructed to come after 15 days and a post-test was conducted to assess their stress level, coping ability and knowledge on conception. Advise was given to the couples to follow the stress coping strategies and to practice the relaxation therapy for one year and asked them to come for regular follow-up till one year, to assess their conception rate.
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Plan for Data Analysis

The data analysis planned to include both descriptive and inferential statistics.

1. Analysis of subject’s socio demographic and clinical profile in the form of frequency and percentage distribution.

2. Means and percentages were used to identify the level of stress and coping.

3. Pearson correlation test was used to identify the correlation of stress level with coping level.

4. Chi-square test was used to correlate the stress level with selected socio-demographic variables.

5. Stepwise multiple regression analysis was used to assess the relationship between stress and selected variables.

6. Paired ‘t’ test was used to evaluate the effectiveness of counseling and relaxation therapy in relation to stress level, coping ability and knowledge level.

7. Chi-square test was used to evaluate the conception rate.

8. Kruskal-Wallis test was used to identify the correlation of mean knowledge score with selected socio demographic variables like age, education and occupation.