CHAPTER – IV

METHODOLOGY

This chapter deals with study locale, research approach, study variables, samples, sampling technique, selection and development of data collection instruments, pilot study, the difficulties faced by the investigator, method of data collection, and plan for data analysis. On the whole it gives the general pattern for gathering and processing research data.

4.1 Study Locale

The study was conducted at Centre for Reproductive Medicine, Apollo Hospitals, Chennai. The centre is well equipped with modern treatment modalities to treat both male and female infertility.

The Apollo main hospital has 600 beds for all the specialties including infertility. The investigation facilities such as hormonal studies, ultrasound, hysterosalpingogram, endometrial biopsy and laparoscopy are available. It also has a well equipped IVF lab in which Intra Uterine Insemination, Fallopian Sperm Perfusion, Gamete Intra Fallopian Transfer (GIFT) Zygote Intra Fallopian Transfer (ZIFT) Intra Cytoplasm Injection of Sperm (ICIS) are performed by the infertility specialists and embryologists.

The outpatient department conducts infertility clinics everyday and on an average 50 – 75 patients are attending the clinics every month. 3 – 4 patients undergo GIFT or ZIFT every month.

4.2 Research Approach

A survey approach was used, because the primary objective of the study was to describe the bio-psycho-social dimensions and health behaviour of infertile women.

Survey approach is concerned with gathering information from a segment of the population. It is impossible to collect data from every individual, and therefore a sample is
selected from the population and information is obtained from the sample. There are specific research techniques that are frequently used with any survey design.

4.3 Research Design

A descriptive correlation design was selected for the present study, where the researcher has attempted to describe the variables and the relationship between the variables. This is a non experimental design.

The design was helpful in describing the bio-psycho-social dimensions and health behavior of infertile women and in establishing the relationship between the bio-psycho-social variables and health behavior in infertile women. The variables and their measuring instruments are detailed in Table 1.

4.4 Variables under Study

Table 1. Variables and Their Measuring Instruments

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<thead>
<tr>
<th>Description</th>
<th>Measure Variable</th>
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<tr>
<td>Demographic details</td>
<td>Age, educational status, religion, occupation, type of family, marriage and years of infertility</td>
<td>Demographic Variable Proforma</td>
</tr>
<tr>
<td>Biological dimension</td>
<td>Causes (diagnosis), Investigations and treatment of female infertility</td>
<td>Biological Variable Proforma</td>
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<tr>
<td>Psychological dimension</td>
<td>Quality of life, Self-concept</td>
<td>WHO – General Well-being Index (1998 version)</td>
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### Social Dimension

<table>
<thead>
<tr>
<th>Anxiety</th>
<th>Marital Adjustment Scale. (Spanier, 1976).</th>
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<tr>
<td>Depression</td>
<td>Family Support Scale for Infertile Women. (Modified from the scales developed by Sam (2000) &amp; George (2000) for oral cancer and Breast cancer patients, respectively.)</td>
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<tr>
<td>Stress</td>
<td>Marital adjustment</td>
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<tr>
<td></td>
<td>Family support</td>
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### Health behaviour

<table>
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<th>Anxiety Scale (Ellen et al 2003)</th>
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<td>Depression Status Inventory. (Zung 1974)</td>
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<td>Questionnaire to assess stress reactions to infertility. (The Fertility Problem Inventory developed by Newton 2000 was modified by the researcher).</td>
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<tr>
<td>Anxiety</td>
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</table>

### 4.5 Population, Sample and Sampling Technique

Population denotes the entire group of subjects under study. According to Treece and Treece (1993) population refers to the largest body of cases or individuals being researched, which confirms to the specific set of particulars. In the present study the accessible population
refers to all the diagnosed infertile women attending the infertility clinics at Apollo Hospitals, Chennai during January – June 2005. A total of 240 women visited the clinic during the time period.

The sample consisted of the subset of the units from the defined population. Non probability purposive sampling technique was used in selecting 200 infertile women for the present study. Data were collected during the month of January – June 2005. On an average 2 – 3 women were interviewed per day after taking their consent.

4.6 Sampling Criteria

4.6.1 Inclusion criteria

Women suffering from primary infertility and in the process of investigation and treatment participated in the study. The infertile women who know earlier Tamil or English and agreed to participate were included in the study.

4.6.2 Exclusion criteria

Women suffering from secondary infertility, unwilling to participate in the study and unable to communicate in Tamil or English were excluded from the study.

4.7 Selection and Development of Study Instruments

Treece and Treece (1996) states that the instruments selected in a research should be the best to obtain data for drawing conclusions pertinent to the study. The questioning technique was adopted for the data collection. In human science using questionnaires can collect a great deal on information. The instruments selected for use in the present study were,

1. Demographic Variable Proforma
2. Biological Variable Proforma
5. Anxiety Scale (Ellen et al 1998)
6. Depression Status Inventory (Zung 1974)
7. Stress Reactions to Infertility Inventory
8. Marital Adjustment Scale (Spanier 1974).
10. Attitude Scale towards Treatment Options of Infertility.
11. Questionnaire on Treatment Seeking Behavior in Infertile Women

1. Demographic Variable Proforma

The demographic details of infertile women were studied using a Proforma prepared by the investigator.

Description

The demographic profile of infertile women attempts to provide an overview of the demographic details of the infertile women. The demographic variables of infertile women such as age, educational status, occupation, and type of family, type of marriage and years of infertility were included.

Administration

The demographic details were collected through interviewing the participants by the researcher the responses of the participants were entered in the demographic variable proforma.

Scoring

The answers were noted down and depending upon the responses, the data obtained were tabulated and frequencies were calculated.

Interpretation

Frequency and per cent were calculated and the results were discussed accordingly. The association between the demographic variables and the psycho-social variables of infertile women were interrupted through chi-square analysis wherever necessary.
2. Biological Variable Proforma

A proforma was prepared by the researcher to identify the biological variables of infertile women.

Description

The biological profile of infertile women attempts to provide an overview of the biological status of the infertile women. The biological variables of infertile women such as menstrual cycle, sexual patterns, ovulation, causes of infertility, investigations done, the methods of treatment used by the infertile women and the semen characteristics of their husband.

Administration

The biological details were collected through interviewing the participants as well as referring the clinical records by the researcher. The responses of the participants were entered in the biological variable proforma. The participants were assured that the information collected will be kept confidential.

Scoring

The answers were noted down and depending upon the responses, the data obtained were tabulated and frequencies were calculated.

Interpretation

Frequency and per cent were calculated and the results were discussed accordingly. The association between the biological variables and the psycho-social variables of infertile women were interrupted through chi-square analysis wherever necessary.


The quality of life of infertile women was studied by using the General Well-being Index developed by World Health Organization.
Description

The instrument is developed by WHO which has five questions measuring the quality of life in any individual. Each of the question has five response categories ranging from “All of the time” to “At no time” with a score from 5 to 0 respectively.

Psychometric Properties

The reliability coefficient of the Tamil version of the tool was computed by using the Cronbach Alpha method and it was \( r = 0.90 \).

Administration

The General Well-Being Index was filled by the participants. The responses of the participants were classified and interpreted.

Scoring

There were 5 questions and each one had a score ranging from 0 – 5 based on the participant responses. The raw score was calculated by totaling the figures of the 5 answers. The raw scores ranged from 0-25.

Interpretation

‘0’ representing worst possible and 25 representing best possible quality of life. The correlation between quality of life and other psycho-social variables were also calculated by using correlation co-efficient. The association between demographic variables and the quality of life were also computed and interpreted.

4. A Semantic Differential Scale on Self-concept (SDSC)

To measure the self-concept in post myocardial infarction patients a semantic differential scale was prepared by Avillo (1971). The adjectives are not specific to myocardial infarction patients but have general meanings. However the word “heart attack” was replaced with “infertility” in the instruction to participants and used in the present study to collect data regarding self-concept in infertile women.
Description

The scale was developed as an interval scale with 12 pairs of adjectives. Twelve negative adjectives are listed on the left side of the scale and twelve positive adjectives are listed on the right side of the scale. Each set of positive and negative adjectives are connected by a 7 point continuum on which the respondent is to indicate the point which best described her feelings about self at a particular point of time. The scale was used in the present study to measure the self-concept of infertile women.

Psychometric Properties

The reliability coefficient of the Tamil version of the tool was computed by using the Cronbach-Alpa method and it was $r = 0.9079$.

Administration

The participants were asked to mark their responses for each of the 12 items on the scale at a point which best described their level of self-concept during the time of administration. The responses of the participants were classified and interpreted.

Scoring

The responses are scored as a likert type scale with a point score assigned for each adjective pair that corresponds to the space marked on the continuum. The range of score for each question was 1 to 7 and the total score was from 12 to 84.

Interpretation

A high total score is interpreted as high positive self-concept, a low total score as low self-concept. The scores were arbitrarily classified into low ($\leq 36$), moderate ($37 - 60$) and high levels ($61 - 84$) of self-concept.

5. Anxiety Scale

A screening test for anxiety and depression was developed by Ellen et al to assess anxiety and depression among the patients attending primary care settings. The same tool was used to assess the level of anxiety experienced by infertile women.
Description

The questionnaire is very simple and easy to use. It has nine questions to assess anxiety. The respondents need to answer ‘yes’ or ‘no’ for the questions.

Psychometric Properties

The author has reported the reliability of the instrument as $r = 0.90$ and the tamil version of the tool was tested for its reliability by computing Cronbach -alpha method and it was found to be reliable ($r = 0.8167$).

Administration

The respondents were asked to answer ‘yes’ or ‘no’ for the 9 questions printed on the anxiety scale, based upon their status at the time of administration of the test.

Scoring

If ‘yes’ is answered for a question a score of 1 was assigned and if their answer is no a score of 0 was assigned. The total score ranged from 0 – 9.

Interpretation

If ‘yes’ is answered for more than 5 questions the anxiety level will be interpreted as clinically significant.

6. The Depression Status Inventory (DSI)

Depression as an effect extends on a continuum from normal mood swings to a pathological state. (Zung 1974). In the present study the depression of infertile women was assessed using the depression status inventory developed by Zung in 1974.

Description

The depression status inventory is a 20 item semi structured, interviewer rated or self-administered instrument. The scale addresses itself to the most commonly found characteristics of depression divided into the following categories:

Pervasive affective disturbances  (Two items).
Physiological disturbances  (Eight items).

Psycho motor disturbances (Two items).

Psychological disturbances  (Eight items).

Each of the items is judged on a 4-point scale of severity of observed or reported responses. They are defined as follows:

1 = None or insignificant in intensity or duration, present none or little of the time in frequency.

2 = Mild in intensity or duration, present some of the time

3 = moderate severity, present at a good part of a time

4 = Severe in intensity or duration, present most all of the time in frequency.

Psychometric Properties

The concurrent validity of DSI was measured by correlation with the MMPI. As expected, the highest coefficient was obtained between the DSI and MMPI depression subscale; an r = of 0.70. The correlation with Hamilton depression scale was significant; an r = of 0.79 (P < 0.01).The reliability coefficient of the Tamil version of the following tools were computed by using the Cronbach – Alpha method and it was r = 0.8167.

Administration

The participants were asked to mark their responses for each of the 20 items on the scale at a point which best described their level of depression during the time of administration. The responses of the participants were classified and interpreted.

Scoring

The total raw score from the DSI is converted to an index by dividing the sum of the raw scores obtained on the 20 items by the maximum possible score of 80, and multiplying the resulting decimal fraction by 100.
Interpretation

The indices of 49 or less are considered normal, those with indices between 50 – 59 are considered to have mild or moderate depression, those with indices of 60 – 69 are considered to have moderate to severe depression, those with indices of 70 or more are considered to have severe depression. (Zung 1974).

7. Stress Reactions to Infertility Inventory

A reaction to infertility inventory was developed for assessing the physical, emotional, sexual, social, rejection of child-free life style and need for parenthood reactions of infertile women. The tool was developed based on the fertility problem inventory by Newton (2000).

Description

The tool has a total of 58 items to assess the reactions of infertile women in terms of physical (6), emotional (6), social (10), sexual (8), relationship concern (10), rejection of child free life style (8) and need for parenthood (10) reactions. The responses were marked on a 6 point scale ranging from strongly agree to strongly disagree.

Psychometric Properties

The reliability of the stress reaction to the infertility inventory was computed by using Cronbach-alpha method and it was $r = 0.8228$.

Administration

The stress reactions to infertility inventory was self administered to the participants and the participants were asked to mark their responses to each of the 58 questions on the 6 point scale with options ranging from strongly agree to that of strongly disagree.

Scoring

The alternate responses are marked on a scale with a score of 6, 5, and 4,3,2,1. The possible score is 348. High score indicate high stress.
Interpretation

The levels of stress as reaction to infertility was divided into 4 quartiles of the obtained scores as low (≤ 220), average (221 – 237), moderate high stress (238 – 249) and high stress (≥ 250) as suggested by the author of the tool (Newton 2000).

8. Marital Adjustment Scale (MAS)

The questionnaire developed by Spanier (1974), to assess the agreements or disagreements between the couple, is used in the present study to assess the marital adjustment of infertile women.

Description

The Marital Adjustment Scale developed by Spanier has 32 questions. The extent of agreement or disagreement between the couples for each item is measured on a 6 point scale ranging from always agree to that of always disagree. The questions involve about how they handle the family finances, recreation, religious matters, demonstration of affection, sex relation, making major decisions, leisure time activities, career decisions, fighting, stimulating exchange of ideas, working together on a project etc.

Psychometric Properties

The reliability of the tool was r- 0.9079. It is a standardized tool used in various researches since 1974.

Administration

The Marital Adjustment Scale was self administered to the participants and the participants were asked to mark their responses to each of the 32 questions on the 6 point scale with options ranging from strongly agree to that of strongly disagree.

Scoring

It contains 32 items; items 1 to 22, 25 to 28 and 32 had scores ranging from 0 to 5; 0 to 4 scores were allotted to items 22 and 24; items 29 and 30 have 0 to 1 score and Item 31 has 0 to
6 scores, according to the number of alternate responses for each item. The maximum possible score is 151.

**Interpretation**

A score of 100 and above indicates marital adjustment and less than 100 indicate marital distress.

9. Family Support Scale

The scale developed by Sam (2000) and George (2000) for measuring the social support of oral cancer and breast cancer patients respectively, were modified by the researcher to measure the family support of infertile women.

**Description**

The scale measures the supportive function provided by the identified net work members consists of 16 items. The three types of supportive functions: Informational, emotional and economical containing 5, 6 and 5 items respectively.

**Psychometric Properties**

The reliability of the instrument was developed by using Cronbach-alpha method and the reliability coefficient was $r = 0.8167$.

**Administration**

The family support scale was self administered to the participants and the participants were asked to mark their responses to each of the 16 questions on the 4 point scale with options ranging from strongly agree to that of strongly disagree.

**Scoring**

The response categories are in the scale format with a score of 3, 2, 1, 0 respectively. The possible score is 48. Higher scores indicate high family support.

**Interpretation**

The scores on family support were arbitrarily divided into high (49 – 64), moderate (32 – 48), and low (16 – 31) level of family support.
10. Attitude Scale of Infertile Women towards Treatment Options

The scale was developed by the researcher to assess the attitude of infertile women towards treatment options.

Description

The scale had 24 questions to measure their attitude toward ovulation induction (3 items), artificial insemination (5 items), tubal surgeries (4 items), invitro fertilization (4 items), surrogacy (4 items) and adoption (4 items) as the treatment options available for female infertility. The responses were measured on a scale with a score of 4,3,2,1 for 5 alternate responses.

Psychometric Properties

The reliability of the instrument was developed by using Cronbach-alpha method and the reliability coefficient was \( r = 0.6883 \).

Administration

The scale was self administered to the participants and the participants were asked to mark their responses to each of the 24 questions on the 5 point scale with options ranging from strongly agree to that of strongly disagree.

Scoring and Interpretation:

The maximum possible score was 96. A high score indicate high positive attitude towards treatment options. The levels of attitude towards treatment options were divided arbitrarily into 3 levels of high positive (73 - 96), moderately positive (49 – 72), and low positive (24 – 48) attitude.

11. Questionnaire on Treatment Seeking Behavior in Infertile Women

A questionnaire was developed by the researcher to identify the treatment seeking behavior of infertile women.
Description

The scale consisted of 10 items, with 2 items respectively to measure the behaviors of sequential tracking, back tracking, paralleling, and taking a break and withdrawal. The responses were marked on a 4 point scale which states most of the time, sometimes, rarely, never as the response categories.

Psychometric properties

The reliability of the instrument was developed by using Cronbach-alpha method and the reliability coefficient was $r = 0.7954$.

Administration

The scale was self administered to the participants and the participants were asked to mark their responses to each of the 10 questions on the 4 point scale with options ranging from most of the time to never.

Scoring and Interpretation

The responses were marked on a scale with scores 4,3,2,1 respectively. The level of treatment seeking behaviour was arbitrarily divided into 3 levels as highly irregular (31 – 40), moderately irregular (21 – 30) and less irregular (10 – 20). The tool was translated in Tamil.

4.8. Pilot Study

The pilot study was conducted at Apollo Hospitals, Chennai. The samples of the study were 10 infertile women selected as per the inclusion criteria. The investigator obtained permission from Director of the hospital. The subjects were explained about the purpose of the study and informed consent was taken from them.

4.9. Data Collection

The investigator obtained the formal administrative permission to conduct the study at Apollo Hospitals, Chennai. In order to get an open and honest response from the infertile women, they were explained about the purpose and usefulness of the study. The study
participants were assured of maintaining anonymity. The infertile women who were willing to participate in the study, indicating their voluntary participation were included in the study.

The investigator collected data from January to June 2005, from 200 infertile women who were attending the outpatient department, at the selected hospital using purposive sampling technique, until the specified samples were obtained. Most of the patients were interviewed in OPD. Data were collected through the self administered scales and questionnaires. Those having difficulty in reading were helped by the interviewer by reading the questions. At the end the subjects were thanked for their participation and co-operation.

4.10 Problems Faced During Data Collection

The problems faced during the process of this study were;

- In between filling up the questionnaires, the Patients were called for consulting the doctor or for ultra sound follicular study. Hence it took a longer time to collect data from them.

- Some of the potential infertile women or their husbands showed unwillingness to participate in the study.

- As the study was conducted only on female infertile patients, the husbands of few patients were showing their discontentment and suspicion of the purpose of the study. Few potential subjects were not allowed by their husband to participate in the study.

- Most of the patients expressed that the questionnaires are time consuming to fill up the responses.
Plate – I: Discussion for Identification of women with Infertility at the Out Patient Department

Plate – II: Interaction of the Researcher with Infertile Women at the Out Patient Department
Plate – III: Researcher explaining the purpose of the study to infertile women at the Out Patient Department

Plate – IV: Administration of Research tools to infertile women at the Out Patient Department
Plate – V: The process of data Collection from Infertile Women at the Out Patient Department
4.11 Plan for Data Analysis

The data collected should be analyzed to get effective results. Hence a plan for data analysis is vital and in the present study data was analyzed by using descriptive and inferential statistics.

The demographic and biological variables were analyzed in frequently and per cent of distribution.

The data on psycho-social and health behaviour variables are presented in frequency polygon and summarized in mean, median, standard deviation and the distribution in frequency and per cent.

In order to find out the relationship between psycho-social-health behavioural variables correlation coefficients were completed.

The association between demographic and biological variables and psycho-social-health behavioural variables was identified through chi-square values.

To predict and determine the influence of psycho-social-health behavioural variables on reactions to infertility, path analysis was used to test the causal relationships.

Summary

This chapter has dealt with the research approach, design, setting, population sample and sampling technique, description and validation of data collection tools, reliability of the tools, pilot study, data collection and plan for data analysis.