CHAPTER III

METHODOLOGY

The study was designed to assess the efficacy of progressive muscle relaxation on stress, anxiety and pregnancy outcome among primigravidae at Sri Ramachandra Hospital. This chapter deals with the research design, setting of the study, population, sample, sample size, sampling technique, sample selection criteria, development, description administration and scoring procedures of the tool, validity and reliability of the tools, pilot study, data collection procedure and statistical analysis used for the study.

3.1 Research design

A quantitative research with evaluative approach was used. The research design adopted for the study was randomized controlled trial. The aim of the study was to determine the efficacy of progressive muscle relaxation on stress, anxiety and pregnancy outcome.

Table 2. Schematic representation of research design

<table>
<thead>
<tr>
<th>Group</th>
<th>Pretest</th>
<th>Intervention</th>
<th>Reinforcement</th>
<th>Posttest</th>
<th>Follow up posttest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study</td>
<td>O₁</td>
<td>* X ◊</td>
<td>◊</td>
<td>O₂</td>
<td>O₃ O₄</td>
</tr>
<tr>
<td>control</td>
<td>O₁</td>
<td>*</td>
<td>-</td>
<td>O₂</td>
<td>O₃ O₄</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6 weeks of Postpartum</td>
</tr>
</tbody>
</table>
Key

R - Randomization

O₁ - Pretest assessment of stress and anxiety

*- Routine care

X - Progressive muscle relaxation (PMR) - video assisted demonstration by researcher and enactment by the participants for two consecutive days and audio guided self practice of PMR

◊ - Issue of audio casette/CD

◊ - Assessment PMR performance for study group (SG) at 23-24 weeks

O₂ - Assessment of stress, anxiety, PMR performance(SG) at 31-32 weeks of GA

O₃ - Assessment of Pregnancy outcome- gestational age at birth, mode of delivery, APGAR score, birth weight of newborn and maternal, foetus/newborn complications

O₄ - Assessment of postpartum depression

3.1.1. Manipulation

After the selection of the primigravidae, they were given information on the impact of stress and anxiety during pregnancy, meaning and benefits of progressive muscle relaxation. Along with routine care the progressive muscle relaxation was taught by the researcher on one-to-one basis to the primigravidae from 21-22 weeks of gestation with the help of a video for two consecutive days with each session lasting for 20-25 minutes followed by enactment by the primigravidae and they were instructed to practice audio guided progressive muscle relaxation daily once from 21-22 weeks to 31-32 weeks of gestation for 10 weeks duration. To ensure daily practice, weekly reinforcement was given through phone, direct reinforcement was given during her antenatal check and also dairy of performance
was maintained by the primigravidae. During their visit to antenatal check up the pregnant women were instructed to perform progressive muscle relaxation under the researcher’s supervision. The performance was assessed by using the check list at 23-24 weeks and at 31-32 weeks of gestation.

3.1.2 Control group

The control group primigravidae were requested to continue with their routine antenatal care and the researcher the completed the assessment at the same time intervals as that of study group.

3.1.3 Randomization

The investigator used randomization to control the individual extraneous variable to secure the comparable group. Block randomization was adopted using five blocks with 50 in each block. Each block had chit for 25 study group and 25 control group participants. Once the sample was selected, explanation was given to the women and written consent was obtained. The chit in the block was exposed to determine to which group the women belonged too. Thus the allotment of subject was randomized.

3.2 Setting of the study

The study was conducted at the Department of Obstetrics and Gynecology, Sri Ramachandra Hospital, which is offering free services to obstetrics and gynecological condition. It consisted of outpatient department with daily attendance of 200 -250 antenatal and postpartum mothers. The out patient department has antenatal, family welfare, gynecology and infertility clinics with amenities of USG, NST and colposcopy. The inpatient department has antenatal ward, labour room, operation theatre, postnatal ward and neonatal intensive care units, with a total beds of 200. There are highly qualified and dedicated consultants delivering obstetrics
services under 8 units, each day’s unit is headed by one senior consultant. All the
days both old and new patients will be given consultation and with the instructional
follow up on the same day every week unless it is emergency. The antenatal OPD has
7-8 private rooms. So it was convenient for the researcher to follow up and reinforce
the mothers on a particular day.

3.3 Population

The target population for the study includes the primigravidae with minimal to
moderate stress and mild to moderate anxiety. The accessible population for the study
included the entire primigravidae with minimal to moderate stress and mild to
moderate anxiety who are attended the antenatal outpatient department, Sri Ramachandra Hospital.

3.4 Sample

The sample consisted of primigravidae with 21-22 weeks of gestation with and
those who fulfilled inclusion and exclusion criteria with minimal to moderate stress,
mild to moderate anxiety during the data collection period.

3.5 Sample size

The sample comprised of 250 women equally distributed in the study and
control groups. The sample size was determined by power analysis and effect size.
The formula used was

\[ z = \frac{2(Z_\alpha + Z_{1-\beta})(p_1o_1 + p_2o_2)}{p_1 - p_2} \]

\[ p_1 = .40 \]
\[ p_2 = .25 \]

Power (80%) = 80
Alpha error $\% = 5$

Side = 2

Sample size (N) for both arms = 209

The researcher increased the population to 20% in anticipation with attrition and kept it as 125 for each group. At the end of the study there was an attrition of samples due to various reasons like change of delivery place, change of habitation etc.

3.6 Sampling criteria

Inclusion criteria

Low risk primigravidae

- at 21-22 weeks of gestational age
- booked at Sri Ramachandra Hospital (SRH)
- planning to undergo delivery and postnatal care at SRH
- understand Tamil /or English
- having minimal to moderate stress based on Calvin Hobel scale for pregnancy specific stress mild to moderate anxiety as per Spielberger, C.D state and trait anxiety inventory
- normal hearing

Exclusion criteria

Primigravidae

- associated with medical and obstetrical complications
- practising any other relaxation technique
- using substance such as tobacco, inhalation of snuff
- preexisting psychiatric problem and on drug
- physically challenged
- not willing to participate
3.7 Sampling Technique

All the primigraviae with minimal to moderate stress and mild to moderate anxiety, those meeting inclusion criteria during data collection were selected.

Assessed for eligibility (N=361)

Randomization (by block) = 250

Assigned to study group -125

Attrition (05)
- Discontinued the therapy - 1
- Muscle injury - 1
- Changed the follow up setting
  - for delivery - 1
  - for postnatal care - 2

Analyzed n = 120

Assigned to control group -125

Attrition (06)
- Changed the follow up setting
  - for delivery - 2
  - for postnatal care - 4

Analyzed n = 119

Figure 2. Flow chart of participants’ recruitment

3.8 Development and description of the tool

Extensive review of literature, discussion and views of experts enhanced the development of the tool. The tool consists of IX parts

3.8.1 Part I- Background variables. Section A: included demographic variables developed by the researcher to collect data on participants of the study (Appendix-C1) which included age, education, location, nature of work, family type, income,
attending antenatal classes and source of health information through family members, friends, newspaper and magazine, T.V and radio and professional.

**Scoring and interpretation**

No score was allotted. The data were used for descriptive analysis.

**Administration**

The background variable questions were answered by primigravidae during data collection.

**Section B**: deals Socio-psychoeconomic variables, which includes the social support variables such as support from husband, family members and friends/peers, psychological variables includes understanding between partners, feeling cared, respect for the feeling/values, someone to have trust & confident, understanding in work environment.

Abuse - Physical, verbal, sexual

Substance abuse by the spouse- Alcohol, Smoking, Others

Economical Variable - Economical independency, Economical commitment

**Scoring and interpretation**

No score was allotted. The data were used for descriptive analysis

**Administration**

The background variable questions were answered by primigravidae during data collection.

**3.8.2 Part II - Stress scale**

The tool was based on Calvin Hobel scale for pregnancy specific stress (Appendix -C2). It consisted of six components such as stress related to responsibilities, relationship, discomfort/illness, foetus, labour and newborn care. It consisted of 25 items. Each item was rated as never, almost never, sometimes, fairly
often and very often. Tamil version of the tool was used. Written consent was obtained from the author to use the tool.

Table 3. Description of the aspects of the stress scale

<table>
<thead>
<tr>
<th>Aspects</th>
<th>No of items</th>
<th>Minimum to Maximum score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stress related to responsibilities</td>
<td>2</td>
<td>0 – 8</td>
</tr>
<tr>
<td>Stress related to relationship</td>
<td>5</td>
<td>0 – 20</td>
</tr>
<tr>
<td>Stress related to discomfort/ illness</td>
<td>3</td>
<td>0 – 12</td>
</tr>
<tr>
<td>Stress related to foetus,</td>
<td>5</td>
<td>0 – 20</td>
</tr>
<tr>
<td>Stress related to labour</td>
<td>6</td>
<td>0 – 24</td>
</tr>
<tr>
<td>Stress related to newborn care</td>
<td>4</td>
<td>0 – 16</td>
</tr>
<tr>
<td>Total</td>
<td>25</td>
<td>0 – 100</td>
</tr>
</tbody>
</table>

Scoring and interpretation

The item number 1,2,3,4,5,8-25 were scored as 0,1,2,3 & 4. The item number 6 and 7 were reverse scoring as 4,3,2,1,0. Total stress scores ranged from 0 – 100. Interpreted as minimal stress (1-25) mild (26-50), moderate (51-75) and severe (76-100) stress.

Administration

The primigravidae were evaluated during the pretest (21-22 weeks of GA) and posttest period (31-32 weeks of GA)

3.8.3 Part III - State Trait Anxiety Inventory

The standardized state – trait anxiety inventory (STAI) of Spielberger, C.D was used. Written consent was obtained from the author to use the tool. It is a widely used standardized scale for measuring state and trait form of anxiety. It comprises of two
separate self report for measuring the state anxiety (S-anxiety) and trait anxiety (T-anxiety). Tamil version of the STAI was used in this study (Appendix-C3)

**State anxiety**

The S-anxiety was evaluated with state-trait anxiety inventory STAI Y-I. It consisted of 20 statements that evaluate how respondents feel ‘right now’ at this moment and the intensity of their feeling of anxiety on a four point rating scale with the following four ratings: 1. Not at all 2. Some what 3. Moderately so 4. Very much so.

**Scoring and interpretation**

The scale has both positive and negative statements. The positive statements were 3, 4, 6, 7, 9, 12, 13, 14, 17, & 18 the options were scored as 1, 2, 3 & 4. The negative statements were 1, 2, 5, 8, 10, 11, 15, 16, 19 & 20, therefore reverse scoring was used. Total S-anxiety scores ranged from 20 – 80. The summed up scores indicated the S-anxiety. Interpreted as mild (21-40) moderate (41-60) and severe (61-80) anxiety.

**Trait anxiety**

Using the form Y-2 the trait anxiety was measured. In the T-anxiety scale participants reported “generally how they feel” by rating themselves on the 4 points rating scale with the following four ratings: 1. Almost never 2. Sometimes 3. Often 4. Almost always.

**Scoring and interpretation**

The scale has both positive and negative statements. The positive statements were 22, 24, 25, 28, 29, 31, 32, 35, 37, 38, & 40 the options were scored as 1, 2, 3 & 4. The negative statements were 21, 23, 26, 27, 30, 33, 34, 36, & 39, therefore reverse scoring was used. Total trait anxiety scores ranged from 20 – 80. The summed up scores
indicated the T- anxiety. Interpreted as mild (21-40) moderate (41-60) and severe (61-80) anxiety.

Over all anxiety is interpreted as mild (41-80) moderate (81-120) and severe (121-160) anxiety.

**Administration**

The primigravidae evaluated themselves during the pretest, posttest period

**3.8.4 Part IV - Pregnancy outcome**

Data on pregnancy outcome such as gestational age at birth(weeks), Mode of delivery, APGAR score and birth weight of newborn (kgs) were obtained from the medical record of the mother. (Appendix - C4)

**3.8.5 Part V - Maternal complications.**

Maternal complications. included occurrence of Pregnancy induced hypertension(PIH), Gestational diabetes mellitus(GDM), Abruptio placenta, Anemia, Antepartum -Hemorrhage/ shock, Premature rupture of membrane, Preterm premature rupture of membrane, Induced labour, Prolonged labour, Obstructed labour, Reproductive tract injury, Wound healing and postpartum hemorrhage were obtained from the medical record of the mother. (Appendix- C5)

**Scoring and interpretation**

The score were interpreted as follows. If any complication the response was ‘yes’ and the score was 1 and if no complication the score was 0 with total score of 13. Higher the score indicated higher complications.

**3.8.6 Part VI - Foetal/newborn complications**

Foetus / newborn complications included the details of Intra uterine growth retardation(IUGR), foetal distress, neonatal - asphyxia, hypoglycemia, respiratory
distress, neonatal jaundice, seizures, birth injuries and neonatal death which were obtained from the medical record of the mother and baby (Appendix –C6).

**Scoring and interpretation**

The scores were interpreted as follows. If any complication then the response was ‘yes’ and the score was 1 and no complication the score was 0 with total score of 9. Higher the score indicates higher the complications.

### 3.8.7 Part VII - Postpartum depression

Edinburgh postnatal depression scale (EPDS) was used to assess the postpartum depression. It is a widely used standardized scale developed by Cox et al., (1987) for measuring postpartum depression. It is a 10-item self-report scale assessing symptoms of depression such as dysphoric mood, anxiety, and feeling of guilt, suicidal ideas. Each item was scored on a four point scale (0-3) and rates the intensity of depressive symptoms during the previous 7 days. The scale was specifically designed to screen for postpartum depression. Tamil version of the tool was used in this study. (Appendix -C7)

**Scoring and interpretation**

The scale has both positive and negative statements. The positive statements were item number 1, 2 and 4, the options were scored as 0, 1, 2  & 3. The negative statements were 3, 5, 6, 7, 8, 9, and 10 therefore reverse scoring 3, 2, 1 & 0 was used. Total scores ranged from 0 – 30. The score 12 and above indicated postpartum depression.

**Administration**

The primigravidae evaluated themselves during the follow up posttest at 6 weeks of postpartum period.
3.8.8 Part VIII – Progressive muscle relaxation (PMR) performance check list

This was developed for this study by the researcher to measure the practice level. It was applied only to the study group participants. The scale has pre performance preparation (Prerequisite guidelines ) and steps of progressive muscle relaxation (Core guidelines). (Appendix C8 ) The details of assessment are as follows

Prerequisite guidelines:
Pre performance preparation – 5 scores

Core guidelines includes

Steps of PMR
PMR for Arms - 13 scores
PMR for face, neck and shoulders- 12 scores
PMR for Chest - 4 scores
PMR for Lower extremities and whole body - 11 scores

Scoring and interpretation

The score range from 1 to 45. A score one was given for correct performance and zero was given for wrong practice. The level of performance was categorized under prerequisite and core guidelines.

Administration

PMR performance check list was administrated by the researcher during the 23-24 weeks and 31-32 weeks and it was applied only to the study group.

3.8.9 Part XI- Daily performance dairy

Daily performance dairy was maintained by the study participants. It consists of the vertical column from the first day to 30 or 31 day of the month and horizontal column consists of date / day, time of performance and performed or not. The diary was prepared by the researcher. Participants were requested to maintain the diary after the
The researcher described daily performance by writing time and putting tick mark. Weekly the researcher reminded the participants through the phone about performing PMR and keeping the diary. Direct reinforcement was given during the regular antenatal checkup. The study participants maintained dairy throughout the study period (Appendix-C).

**Scoring and administration**

To keep the dairy handy and to avoid the problem of misplacement, the dairy was compiled in three papers and attached with the outpatient record of the participants.

**3.9 Validity and reliability of the tool**

All the instruments were reviewed for face and content validity by medical and nursing experts and they were pilot tested to assess the usability and ease of administration. Content validity of the tool was established by experts comprising educationist, psychologist, nurse educators, and obstetricians (Appendix-E).

**3.9.1 Stress scale**

The content and face validity of stress scale was determined by four experts. The scale was also translated into local language by four experts. Two nurses with M.Sc nursing qualification who had fluency in the chosen language and two experts with M.A M. Phil qualification in English using combined translation technique. Two experts translated local language and two experts translated the tool into English. The translated version of stress was pre-tested on 100 antenatal mothers to identify feasibility in data collection and no problems were found. The reading level of instrument was found to be appropriate and easy to understand. The ‘r’ obtained was 0.91.
3.9.2 State trait anxiety inventory

It is a standardized tool. The original tool had an established validity. The adopted tool was translated into the language of Tamil. The Tamil version STAI was tested for reliability using test and retest method at two weeks with sample of 100 primigravidae. The 'r' obtained was 0.83.

3.9.3 Edinburgh postpartum depression scale

It is a standardized tool. The original tool had an established validity. The adopted tool was translated into language of Tamil. The Tamil version of Edinburgh postpartum depression scale was tested for reliability using test and retest method at two weeks with sample of 100 primigravidae. The 'r' obtained was 0.87.

3.9.4 Progressive muscle relaxation performance check list

Performance check list reliability was checked using inter-rater method. The inter-rater observer to the study was a clinical psychologist who knew about the progressive muscle relaxation. The obtained 'r' value for practice score was 0.89. Since these tools were found to be reliable and valid they were used further to proceed with the data collection needed for the study.

3.10 Progressive muscle relaxation intervention

It refers to the interactive teaching learning session (Appendix-D). It was designed by the researcher and reviewed by two experts in this area. The investigator explained about the progressive muscle relaxation with help of video and participants were seated in comfortable position to watch the video. It consisted of the impact of stress and anxiety during pregnancy, meaning, benefits and techniques of progressive muscle relaxation. The intervention was administered for two consecutive days followed by the enaction on same day under the supervision of investigator. The video
session shown to the primigravidae lasted for 20-25 minutes in Tamil (Appendix-D1) and English. The objectives of the content included are as follows

- Describe the impact of stress and anxiety on pregnancy
- Understand the meaning of progressive muscle relaxation
- List the benefits of progressive muscle relaxation
- Demonstrate the steps included in the progressive muscle relaxation

Preliminary guidelines - preliminary preparation

Core guidelines - Relaxation of

- Arms
- Face, neck, shoulder
- Chest
- Lower extremities and whole body

3.11 Pilot study

The pilot study was conducted during the period of June 2009 to December 2010 at obstetrics unit of Sri Ramachandra Hospital. Formal permission was obtained from head of the department of obstetrics. The pilot study was conducted to ensure feasibility. Though the pilot study demonstrated feasibility some modification were done in the tool as suggested by the experts.

The modification done after pilot study were

- Religion was removed as per SRU Ethical Committee suggestion
- Post assessment of stress and anxiety was performed at 32 weeks instead of 36 weeks as few mothers delivered earlier
- Audio cassette was distributed instead of video cassette because it was easy for the participant to follow the steps of progressive muscle relaxation
3.12 Ethical Consideration

An approval to conduct the study was obtained from the SRU’s Ethical Committee. The ethical consideration criteria were based on the Indian council of medical research guidelines of biomedical research in human beings.

Information essential for consent included description of the purpose of the study, the research activities and the usefulness of the study outcome, assurance of privacy and confidentiality to answer any questions that a potential subject has and the option to withdraw themselves from the study at any time (Appendix -A)

3.13 Data collection procedure

Data collection procedure for study group

1. The researcher introduced herself to the participants and obtained informed consent from those who met the inclusion criteria.

2. The women were seated comfortably and the pretest was conducted among women through background variables including demographic and socio-psychoeconomic variables, level of stress and anxiety were assessed.

3. The woman was seated in comfortable position to watch a video assisted teaching on progressive muscle relaxation for 20-25 minutes on one-to-one basis for two consecutive days along with routine care.

4. After watching the video assisted teaching the participant enacted under the supervision of the researcher. The investigator gave the audio cassette/CD on progressive muscle relaxation and performance diary to the participant to maintain at home to improve the performance of PMR.

5. Two weeks later at 23-24 weeks the study group participants were assessed for PMR performance.
6. The reinforcement was given through telephone every week and direct reinforment was given to the women as they were coming for regular antenatal check up and were insisted on the importance of practising PMR daily to reduce stress and anxiety.

7. The posttest was conducted on 31-32 weeks for the study group when they came for follow up and the participants were assessed for their stress and anxiety. The participants were asked to perform PMR which was assessed with the help of PMR performance checklist.

8. After delivery information was obtained from the medical record about pregnancy outcome such as gestational age at birth, mode of delivery, APGAR score and birth weight of newborn and maternal and foetus/newborn complications.

9. At 6 weeks postpartum, when the mother visited the family welfare clinic for postpartum check up, the postpartum depression was assessed.

**Data collection procedure for the control group**

1. The researcher introduced herself to the samples of the control group and got their consent to participate in the study. The subjects were assessed for background variables including demographic and socio-psychoeconomic variables, level of stress and anxiety.

9. When the participants came for follow-up on the 31-32 weeks, their level of stress and anxiety was measured along with routine care. Information was obtained from the medical record about pregnancy outcome such as gestational age at birth, mode of delivery, APGAR score, birth weight of newborn and maternal and foetus/newborn complications.
2. At 6 weeks postpartum, when the mother visited the family welfare clinic for postpartum natal check up, the postpartum depression was assessed,

4. After that video assisted teaching was given on PMR. The investigator gave the audio cassette / CD on progressive muscle relaxation to the control group participant. Everyone was encouraged to come for the follow-up care, still the researcher faced some attrition in the study.

**Figure 3. Schematic representation of data collection**
3.14 Attrition of the sample

In the study group after recruitment one participant discontinued the progressive muscle relaxation (PMR) and another mother got muscle injury so she stopped practising PMR. Again one mother changed her setting for delivery and two mothers did not come for follow up may due to cultural reason. Totally five women lost their follow up in study group. In the control group two mothers changed their setting foe delivery and four mothers did not come for follow up. Totally six mothers lost follow up in the control group.

3.15 Data analysis plan

Descriptive statistics was used to arrange the data in a scientific way. Inferential statistics was used to test the hypotheses. Data were analyzed using the statistical package for the social sciences (SPSS version 16). p value of <0.05 and more than that was considered significant.

<table>
<thead>
<tr>
<th>Method</th>
<th>Type of statistics</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descriptive</td>
<td>Frequency, percentage, mean, standard deviation</td>
<td>Assess the sample characteristics and study variables</td>
</tr>
<tr>
<td>Inferential</td>
<td>Paired ‘t’ test</td>
<td>Compare the study variables before and after the intervention within the group</td>
</tr>
<tr>
<td></td>
<td>Independent ‘t’ test</td>
<td>Compare the study variables before and after the intervention between the groups</td>
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<tr>
<td></td>
<td>Chi square</td>
<td>Assess the homogeneity of samples between the groups.</td>
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<td>Method</td>
<td>Description</td>
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<tr>
<td>Pearson’s Correlation</td>
<td>Identify the relationship between stress anxiety, pregnancy outcome and performance of progressive muscle relaxation</td>
<td></td>
</tr>
<tr>
<td>ANOVA</td>
<td>Associate background variables with selected outcome variables.</td>
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</tr>
<tr>
<td>Regression</td>
<td>Evaluate the role of independent variables and the dependent variables.</td>
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</table>