CHAPTER – III

METHODOLOGY

This chapter explains the methodology adopted to determine the effectiveness of self-care strategies on pregnancy-induced hypertension, maternal and perinatal outcome among primigravidae at Sri Ramachandra Hospital. It consists of the research approach, design, the setting, population, the samples, instrument for data collection, data collection procedure and plan for statistical analysis.

3.1 Research Approach

The evaluative research approach was used in this study. It is an applied form of research, to assess or evaluate the success of any intervention. This particular study also focused on evaluating the effectiveness of self-care strategies on perinatal outcome and the occurrence of PIH. So this approach was selected for this study.

3.2 Research Design

The experimental post-test only design was selected for this study. Because, the maternal, perinatal outcome and occurrence of PIH can be assessed only after the intervention and it is also after the delivery. But the design includes Manipulation, Control and Randomization. (MCR).
Table 7 Schematic representation of research design (post test only)

<table>
<thead>
<tr>
<th>Group</th>
<th>Identification and assessment</th>
<th>Intervention</th>
<th>Post-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>RS</td>
<td>-</td>
<td>X</td>
<td>O₁ --- O₂ &amp; O₃</td>
</tr>
<tr>
<td></td>
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<td>LP₁ &amp; LP₂</td>
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<tr>
<td>RC</td>
<td>-</td>
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<td>O₁ --- O₂ &amp; O₃</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>LP₁ &amp; LP₂</td>
</tr>
</tbody>
</table>

- RS  - Randomized Study Group
- RC  - Randomized Control Group
- X   - Implementation of SCS
- O₁  - Assessment of occurrence of PIH
- O₂  - Maternal outcome
- O₃  - Perinatal outcome
- LP₁ - level of adherence of SCS at the first time
- LP₂ - level of adherence of SCS at the second time

**Manipulation**

In this study, it is a process of giving series of instructions and information regarding antenatal care, which can be followed by the mother herself towards better perinatal outcome, in a non-threatening way.
Control

The investigator of this study has controlled the extraneous variables by the following ways:

- Selecting the samples based on the inclusion and exclusion criteria
- Allotting them at random either in study or in control group.
- The setting was same for both groups.

Randomization

Randomization in this particular study, was done by selecting numbers from random table to both groups, the list was prepared, before the data collection period by using the list, as the samples came with criteria, they were allotted in study and control group through lottery method (simple random sampling). The investigator did the samples identification, but they were allotted to the groups through assistants and not by the investigator.
3.3 Variables

**Independent variable**

In this study, independent variable refers to self-care strategies.

**Dependent variable**

The dependent variable refers to the occurrence of pregnancy-induced hypertension, maternal and perinatal outcome.

**Extraneous variable**

The extraneous variables under this study are age, education, family income, type of work, habitance, type of family, hemoglobin, albuminuria in each trimester, and level of knowledge.

3.4 Setting of the Study

Setting selected was Sri Ramachandra Hospital, in the new block, obstetrics and gynecology outpatient department in the ground floor. An average of 100-150 mothers /day will be visited this OPD, in which 80% of the mothers were antenatal mothers. It comprises of 30 - 40 primigravidae (approx.) per day. There are highly qualified and dedicated OBG consultants in division of 7-8 units. Each day there will be one unit, they see the new patients as well as the old patients who were asked to come for the review and follow up. It was easy for the investigator to select samples from all units and samples were asked to come for reinforcement and individual teaching on a particular day. The hospital data shows 10% of the mothers were treated for PIH and 10 - 15 new mothers (approx.) getting registered per day.
The nursing assistant and ANM, who were working continuously in that area, were used to inform the investigator whenever the samples came for follow-up. There by the access to the samples were made possible by the investigator. This Antenatal OPD has 5-6 private rooms for consultation. So it was convenient for the investigator to use any one of the available rooms for assessment, individual teaching, reinforcement and demonstration of exercise etc. This provoked the investigator to select this setting for the study.

3.5 population

In this study it refers to the women with common characteristics of being pregnant and present in the same setting. The accessible population for this study included the entire antenatal mothers who were attending the Antenatal OPD at Sri Ramachandra Hospital. But, the target population was all the primigravidae mothers who were attending the Antenatal OPD at Sri Ramachandra Hospital.

3.6 sample

From the target population, the mothers who fulfilled the sampling criteria became samples, and they were selected through simple random method.

3.7 Sample size / Attrition

The sample comprised of 260 mothers equally distributed in study and control group. Sample size was determined by power analysis. The formula used was:

\[ Z = \frac{2(Z\alpha + Z\beta)^2 (P_1\theta_1 + P_2\theta_2)}{(P_1 - P_2)} \]
The estimated sample size was around 100, so researcher increase to 30% and kept as 130 for one group. At the end of the study, there was an attrition of samples due to various reasons like change of place of delivery, change of habitance, etc. The researcher was unable to control the attrition. So, there were only 126 samples in the study group and 124 samples in the control group. (Total number of attrition of samples was 10).

3.8 Sampling Criteria

**Inclusion criteria**

- Primi mothers attending antenatal OPD.
- Women with Gestational age between 12-16 weeks.
- Women who planned to have delivery at Sri Ramachandra Hospital.
- Women who were willing to participate.
- Women who can understand and read English or Tamil or both.

**Exclusion criteria**

- Pregnant women with high risk factors.
- Pregnant women diagnosed with systemic diseases like hypertension, diabetes, cardiac problems, etc.

3.9 sampling technique:

The random table and lottery method was used to select samples. The researcher prepared a list of numbers from random table (ANNEX-XI) and kept aside before the data collection procedure started. The list (ANNEX-XII) included, the numbers selected at random separately for study and control group. The criterion of numbers is from
1 to 260 in a serial order, but it selected as it was appeared on random table. The first selected 130 random numbers were allotted to study group and other numbers were allotted to control group.

During data collection procedure, as the samples were identified by the investigator, the research assistants were allotting the samples using the simple random sampling, by the lottery method with equal chance of occurrence in both study and control group. This is kept as blind to both the researcher and the participants.

3.10 Development of the Tool

The investigator used self-report and bio physiological measures. Self-report was obtained through the semi-structured questionnaire for background variables.

Bio-physiological measures were used to obtain the Hemoglobin, and albuminuria. It was assessed once in each trimester, between the both groups.

To know the level of adherence of self-care strategies, the investigator prepared one checklist-I.

To estimate the occurrence of PIH the assessment chart was used.

To identify the maternal and perinatal outcome, in both groups checklist –II was prepared.

3.11 Steps in the Construction of the Tool

The investigator had involved the following steps in preparing the tool.

- Related literatures were reviewed.
• Guidance and consultation of the OBG experts in construction of tool was obtained.

• Modification of the tool was done as per the guidance.

• Consultation with the statistician was done towards the preparation of the plan for statistical analysis.

3.12 Tools for Collection of Data

The tools developed for the collection of data are presented as follows:

Part I

Semi structured questionnaire on Background Variables, in which

Section A : Demographic Data which includes age, education, and family income, type of work, habitation, and type of family.

Section B : Investigation consists of hemoglobin, albuminuria once in each trimester.

Section C : Level of knowledge on antenatal care. It includes total of 37 questions to collect information on

• Regular checkup and visit (2Q)
• Sleep and rest (7Q)
• Nutrition (10Q)
• Exercise (2Q)
• Medication (4 Q)
• Assessment of fetal well being (3Q)
• Warning signs (6Q)
• Management of minor discomforts (3Q)

Key: Q = Questions
Scoring

Each question has 3 choices and one among them is a correct answer. Each answer scores 1 mark. Over all 37 questions carry 37 marks. If the score is more than 75%, it is interpreted as the adequate knowledge, if the score is between 50 -75%, it is equal to moderate knowledge and if the score is less than 50%, it is equal to poor knowledge.

Part II

Checklist-I, for level of adherence of self care strategies, which has 12 strategies. Each one was categorized into 3 as follows Good, Satisfactory, Poor.

Good level score = 3 for each strategy
Satisfactory level score = 2 for each strategy
Poor means = 1 for each strategy

The maximum score is 36. It is interpreted that more than 75% is adequate level, between 50-75% is moderate level, and less than 50% it is interpreted as poor level.

Part III

Check list-II, for assessment on maternal and perinatal outcome, which has, weight of the baby, Apgar score, Maturity, Neonatal seizures, Neonatal hypoglycemia, still birth, Neonatal death, IUGR, intra uterine death, sepsis, injury, and birth asphyxia.

The maternal outcome, which consists of, Eclampsia, abruptio placenta, maternal jaundice, HELLP syndrome, disseminated intravascular coagulation, acute renal failure, pulmonary edema, cerebral Hemorrhage, postpartum Hemorrhage, preterm labor,
sepsis, shock, blindness, pleural effusion, Pereneal /pelvic floor injury, Prolonged labor (>18hrs) and death. This tool was prepared in a way to be used by the research assistants. The assistants from antenatal OPD were oriented and reliability was checked before it was implemented.

**Scoring**

The score is interpreted as follows: If there is any complication, it is ‘yes’ and the score is 0 and if ‘no’ complication, the score is 1, so the maximum score is 30.

**3.13 Validation of the Tool**

Validity refers to whether an instrument accurately measures what it is supposed to measure. When an instrument is valid, it truly reflects the concept, which it is supposed to measure. The content validity of the tool was validated by 12 experts (Annex- XI) from various fields including nursing, medical, research and by statistician. As per the suggestions of the experts the investigator had made necessary modifications in the tool.

The criterion related validity is most often used in applied form of research. It is helpful in assisting the decision makers by giving assurance that their decisions will be effective. This particular study also has an applied form of research based on evaluative approach. So, the investigator done a predictive validity on a perinatal out comes based on the reviewed literatures. Here also has many literatures supported the criteria’s presented in the tool.

The construct validity also obtained from the experts. The significance of the construct validity is its linkage between theory and theoretical conceptualization. The
construct validity was done using a method called multitrait –multimethod matrix method, which, was invented by Campbell and Fiske (1959). This procedure makes use of concepts of convergence and discriminability. The investigator also organized the data and calculated the convergence and discriminability in measuring the concepts. Both were present in the study. But convergent validity correlation coefficient value was high than the discriminance correlation. So the tool was accepted with modifications.

3.14 Reliability of the Tool

During the pilot study, the reliability of the tool was established by using Split Half Method for assessment of the level of knowledge. The Semi-Structured Questionnaire, which has 37 questions in it was divided into odd and even items, to check its internal consistency. The correlation co-efficient was calculated using the Spearman –Brown prophecy formula as follows;

\[ r^1 = \frac{2r}{1+r} \]

The ‘r’ value obtained from the split half method was 0.56. So, the calculated value of \( r^1 = 0.7 \). Thereby, the tool was considered as reliable with internal consistency.

Another part of the tool was the checklist to assess the level of adherence and its reliability was checked again through, split half method, with same Spearman -Brown prophecy formula. The obtained ‘r’ value was 0.42. The calculated \( r^1 \) was 0.6. So it was considered as reliable one.
The checklist was prepared to assess the perinatal outcome. The reliability was checked by the Interrater Method (Inter Observer). It was estimated by having two or more trained observers watching some event simultaneously and independently recording the relevant variables according to a predetermined plan or coding system. The resulting records were used to compute an index of equivalence or agreement for certain type of data.

This method was used, because the researcher used assistants in collecting the perinatal outcome by using the particular tool. The following equation is used to find out the reliability.

\[
\frac{\text{The number of agreements}}{\text{The number of agreements} + \text{the disagreements}}
\]

The tool was having 30 items in which the number of agreements was 26 and only 4 items had little differences in the assessment. The reliability was calculated using the formula given above

\[
\frac{\text{The number of agreements (26)}}{\text{The number of agreements (26)} + \text{the disagreements (4)}} = 0.87
\]

The obtained value indicates a high reliability. So researcher used that tool to assess the perinatal outcome.

3.15 Pilot study

The pilot study was conducted at antenatal OPD. The outcome was evaluated in the labor room and postnatal ward of Sri Ramachandra Hospital, Chennai. In order to
ensure validity & reliability of the tool and feasibility for giving intervention, the pilot study was conducted during the month of December 2004. The 10% of the samples were selected randomly from those Primigravidae, 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 January 2006. But after assuring the feasibility, the main study was started in 2005. Though the pilot study was proved a way for feasibility, some modifications were done in the tool as per the suggestions given by the experts.

**Modification done after pilot study:**

1. Scoring system for perinatal outcome was modified like Yes-0, No-1, instead of Yes-1, No-2. As per the statistician opinion.
2. Platelets were removed from the investigations, since it was not done only for potential women not for all women.
3. Religion was removed from demographic variables as per the ethical and research committee of SRMC &RI .SRU.

**3.16 Data Collection Procedure**

It was done after the approval from the Ethical Committee and Head of the Department of Obstetrics and Gynecology. The nursing superintendent and medical director approved the data collection and the study was conducted in antenatal OPD as it was planned earlier. It was started in the month of February, 2005.

The investigator prepared the random table (ANNEX- XII) by using Stat Trek's Random Number Generator, which used a statistical algorithm to produce random numbers.
Stat Trek's Random Number Generator produces a listing of random numbers (XIII), based on the following User specifications:

The list of numbers (ANNEX-XIII) prepared by the random table for both groups was kept aside and confidential by the investigator.

But, Chits were prepared having numbers from 1-260 was kept in the ballot box.

When the primigravidae were attending antenatal OPD, with inclusion and exclusion criteria, they were approached, and verbal permission was obtained from them. A clear explanation was given regarding the purpose of the study. The activities of the participants and their allotment either in study or control group through Randomization was done.

Once the completion of signing the consent, form or verbal consent was over collection of demographic data and assessment of knowledge was done in both groups through questionnaires and the results were kept confidential.

All primigravidae were assured whether they fall in study or control group and the routine care would be given to all. Also, it would never be restricted to any group. After the assurance given to women, they were asked to select the chits with numbers. The numbers taken by the mother were compared with a list of prepared random numbers to find out in which group they fell. If they fell in study group they were asked to stay back. If they were in control group they were sent home with routine care and information.
The study group women were, given the information on antenatal care and self-care strategies towards prevention of complications using the self-instructional module. After giving information, the mothers were asked to do the practice of exercise and the investigator demonstrated it. (12-16 weeks).

Both groups were asked to come for regular check up in the next month as per the doctor’s prescription. But, there was an identity card with investigator mobile and extension number was fixed in the chart and women were asked to call the investigator or to inform the nursing assistant and ANM (research assistants in this study) who were working in that OPD.

The investigator also obtained their contact numbers to make sure of follow-ups. All women in both groups were asked to maintain diary towards the practice of strategies.

After 4 weeks (16-20 weeks), when the women come for regular checkup, they were assessed on their level of adherence towards the self-care strategies in both groups. But, the reinforcement on self-care strategies was given only to study group.

After 8 weeks (20-24 weeks), when the women in study and control group, come for their regular checkup, follow up of adherence of self-care strategies were assessed and reinforcement was given on the same once again to study group. The control group do followed, but they received only the routine care with information. The investigator was able to have continuous contact with both groups, whenever they came for their regular checkup or for other investigations.
The women in both groups were checked by every week in terms of complications in pregnancy. The occurrence of pregnancy-induced hypertension was assessed in both groups using a structured format. The scoring was allotted and kept confidential, and other complications, associated with PIH, were also followed and recorded.

The maternal outcome (Eclampsia, APH, maternal jaundice, HELLP, DIC, ARF, pulmonary edema, coma, cerebral hemorrhage, PPH, preterm labor, sepsis, shock, blindness, pleural effusion, and death) and the perinatal outcome, which included IUGR, Maturity, still birth, neonatal death, Asphyxia/Hypoxia, weight of the baby, mode of delivery, APGAR score, were assessed in both groups after the delivery. The mothers were checked only in the postnatal ward and the charts or records of the mothers were used to collect the data.

(The investigator checked the validity of the records during the pilot study itself. The records had all the information listed in the checklist on perinatal outcome.). But, the nurses on duty in the labor room were informed about the cards, which were kept in the charts. So, the nurses were informing the investigator whenever those mothers got admitted in the labor room.

To avoid the researcher bias and collect information without missing samples, the investigator trained two assistants in checking the perinatal outcome using the checklist. by test retest method. Their assessment level was equivalent there were almost no differences. The assistants were able to ascertain the information from the records.
The information collected was kept confidential. The privacy was maintained for the women during data collection and their doubts were cleared. The investigator provided ample of time for them to understand and accept the participation in the study. The ethical and scientific principles were adhered by the investigator throughout the study.

The investigator was able to follow up the mothers in both groups with their contact numbers and addresses. Even then there were 10 mothers whom the researcher was unable to identify their perinatal outcome, because they did not come for delivery in Sri Ramachandra Hospital and went to another place. The schematic representation of data collection is in fig 2.
Fig 2 Schematic representation of data collection of procedure:

Approval from Ethical Committee and Head of the Department of Obstetrics and Gynecology.

Consent was obtained from the women
Randomization and allotment of two groups (12 –16 weeks)

Study GROUP
Routine care and Regular information on antenatal care and practice of self-care strategies

Control GROUP
Routine care and Regular Information on antenatal care

After 4 weeks (16– 20weeks)
Level of adherence of self care strategies assessed & reenforcement of SCS and problems were identified and helped to practice.

After 4 weeks (20– 24weeks)
Second Assessment of level of adherence of SCS, regular care, Investigations, need based medications and re-enforcement of SCS.

Follow up till delivery and assessment of occurrence of PIH, maternal and perinatal outcome

Comparison of occurrence of PIH, maternal and perinatal outcome between 2 groups.

Correlation of level of adherence with occurrence of PIH, maternal and perinatal outcome in both groups.

Association of background variables with outcome variables in both groups.
3.17 Plan for data analysis;

The collected data was planned to code and analyze using the descriptive and inferential statistics. As mentioned in table 9 as below:

**Table 9 Plan for data analysis**

<table>
<thead>
<tr>
<th>METHODS</th>
<th>TYPE</th>
<th>PURPOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descriptive Statistics</td>
<td>Frequency, Percentage, Mean, Standard deviation.</td>
<td>To assess the Background, maternal and perinatal variables. To assess the level of adherence of self care strategies, occurrence of pregnancy-induced hypertension, maternal and perinatal outcome in both groups.</td>
</tr>
<tr>
<td>Inferential Statistics.</td>
<td>Paired <code>t</code> test student <code>t</code> test Co-efficient Correlation Pearson’s intra correlation</td>
<td>To compare the level of adherence of SCS between before and after giving information in both groups. To compare the level of adherence of SCS and occurrence of pregnancy induced hypertension, maternal and perinatal outcome between study and control group. To correlate the level of adherence of self-care strategies with occurrence of pregnancy induced hypertension, maternal and perinatal outcome in both groups. To correlate among occurrence of pregnancy induced hypertension, maternal and perinatal outcome in both groups.</td>
</tr>
<tr>
<td>ANOVA, χ² test Independent <code>t</code> test and Beta Co-efficient correlation</td>
<td>To associate the maternal,perinatal outcome, and occurrence of pregnancy induced hypertension with that of the background variables.</td>
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