CHAPTER – III

METHODOLOGY
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METHODOLOGY

“Prayer is not asking. It is a longing of the soul. It is daily admission of one’s weakness. It is better in prayer to have a heart without words than words without a heart.”

(Mahatma Gandhi).

This chapter deals with the methodology adopted for assessing the effectiveness of low birth weight prevention programme (LBWPP) on the maternal and neonatal outcome of pregnant women with selected risk factors of pregnancy i.e. anaemia, hypertension and diabetes in a selected hospital of Kashmir. It includes research approach, research design, setting, population, sample, sampling technique, variables under study, data collection technique, development of data collection tool, description of data collection tool, description of instruments, development and description of intervention programme i.e. low birth weight prevention programme (LBWPP), content validity of tool and intervention programme, reliability of instruments, reliability of tool, try out/pretesting of tool, pilot study, procedure for data collection and plan for data analysis.

III.1) Research Approach

The present study is a quantitative research study which is conducted systematically and objectively to generate information, to describe new situations, events, or concepts and it aimed at finding out effectiveness of low birth weight prevention program (LBWPP) on maternal and neonatal outcome of high risk pregnant women.

The research approach selected for the present study was quasi-experimental research approach, also called as non-randomized trial or a controlled trial without randomization. In Quasi-experimental design, subjects are not randomly assigned to the treatment conditions. It has a non-intervention group, referred as comparison group rather than control group. (336, p265) The quasi-experimental research approach was found appropriate for the present study because the study in a natural setting like Antenatal
Clinic (ANC), where administration of treatment randomly to some and not to others is difficult.

III.2) Research Design

Time series non-equivalent control group design was found to be most appropriate quasi-experimental design suitable for the present study. This design involves an experimental treatment of one group (experimental group) and observation of two groups of subjects (experimental group and control group) before and after the implementation of the treatment. Research design is depicted in figure 3. In the present study, following steps were undertaken by the researcher:

- The initial/baseline assessment was done for both experimental and control group of study subjects i.e. high risk pregnant women at 16 weeks of gestation because the selected risk factors usually become evident by this time and most of the pregnant women register during this week of gestation.
- Intervention (low birth weight prevention programme (LBWPP) was administered systematically only on experimental group during 16th weeks and 20th of gestation;
- Following the administration of intervention, assessment and observation was done every month at 24, 28, 32 and 36 weeks of gestation to assess maternal outcome among both experimental and control group.
- Both the experimental and control groups were observed for neonatal outcome during intrapartum period and within 24 hours of delivery.

Teresa\textsuperscript{337} suggested screening of all pregnant women for gestational diabetes and other high risk factors and there was no evidence of treatment before 20 weeks to improve maternal and neonatal outcome.
<table>
<thead>
<tr>
<th>Groups</th>
<th>Gestational Week’s</th>
<th>Period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>16</td>
<td>24  28  32  36</td>
</tr>
<tr>
<td>Experimental Group</td>
<td>EO</td>
<td>OE1  OE2  OE3  OE4</td>
</tr>
<tr>
<td>Control Group</td>
<td>CO</td>
<td>OC1  OC2  OC3  OC4</td>
</tr>
</tbody>
</table>

EO: initial observation of experimental group at 16 weeks of gestation

CO: initial observation of control group at 16 weeks of gestation

XX: low birth weight prevention programme (LBWPP) administered to experimental group during 16th weeks of gestation

OE1 to OE4: Observations of experimental group at 24, 28, 32 and 36 complete weeks of gestation for (maternal outcome).

OE5 & OE6: Observations of experimental group during intrapartum period and early neonatal period (neonatal outcome)

OC1 to OC4: Observations of control group at 24, 28, 32 and 36 complete weeks of gestation (maternal outcome).

OC5 & OC6: Observations of control group duringintra-partum period and early neonatal period (neonatal outcome)

**Figure 3:** Schematic representation of research design (Time series non-equivalent control group design)
III.3) Variables under Study:

Variable is a measurable or potentially measurable quality of a person, group, or situation that varies or takes on different values.\textsuperscript{151}

**Independent variable (IV)**

The independent variable in this study includes **low birth weight prevention program**. The components of LBW prevention program are:

i. Information about low birth weight (audio-visual supported).

ii. Antenatal and dietary advises

iii. Demonstrations (testing and monitoring of weight, blood pressure, blood sugar, urine for sugar, counting of fetal movements, pelvic exercises).

iv. Home care package in the form of information booklet.

**Dependent variable (DV).**

The dependent variable in this study includes maternal and neonatal outcome.

- **Maternal outcome** includes
  - gain in weight
  - control over blood pressure
  - control over blood sugar
  - absence of fetal distress
  - need for blood transfusion, and
  - Any emergency hospitalization.

- **Neonatal outcome** includes:
  - mode of delivery (vaginal/assisted/caesarean)
  - birth status of baby (live/distressed/dead)
  - gestational age (full term/preterm/very preterm)
  - birth weight (normal/low/very low)
  - Apgar score (normal/mild asphyxia/severe asphyxia)
  - presence or absence of congenital anomalies
  - early neonatal condition
III.4) Diagrammatic Presentation OF RESEARCH METHOD

The overall schematic representation of research method is given below in figure 4

**Key**
- NICU: Neonatal Intensive Care Unit
- PW: Pregnant Women
III.5) The Setting

The setting of the present study was antenatal clinic (ANC), labour room, postnatal wards and neonatal intensive care unit (NICU) of Sher-i-Kashmir Institute of Medical Sciences (SKIMS), Soura, Srinagar which is a referral and tertiary care Hospital. The antenatal services of this hospital are available to many districts of the valley. The main districts which avail its maternity services are Srinagar and Ganderbal which covers a population of 60,000. This hospital is also utilized by medical and nursing students of various medical and nursing colleges of Srinagar for their clinical experience. The setting was selected for the study because it was familiar to the researcher and easily accessible. The antenatal clinic was on the ground floor and had rooms for registration, general antenatal checkup, checkup of high risk cases, ultrasonography room, immunization room, pre-anesthetic checkup (PAC) room, room for health teaching and a waiting hall. The health teaching room was convenient for the researcher to utilize for assessment and implementing the low birth weight prevention program. The labour room and postnatal ward was situated on the ground floor of adjacent building. The yearly attendance of patients in Maternity OPD was 41,227, out of which the high risk cases included about 16000 approximately. The daily antenatal attendance was 150 cases approximately. The attendance per day of high risk women is 27% on average.

III.6) Population

Population is the entire set of individuals or elements, which meets the sampling criteria. Population is the total number of units from which data can potentially be collected.

In this study population refers to all the pregnant women attending the antenatal clinic of Sheri-Kashmir Institute of Medical Sciences (SKIMS), Soura, Srinagar.

Target population

The population of interest from which the data can potentially be collected. It is the population to whom researcher wishes to study and generalize the findings. In this study, target population was all those high risk pregnant women who were anemic, hypertensive or diabetic.
**Accessible population**

It is the aggregate of cases that conform to the designated criteria to which the researcher is accessible. In this study, accessible population was all pregnant women with anaemia, hypertension or diabetes who attended the antenatal clinic (ANC) of selected hospital during the study period.

### III.7) Sample

Sample may be defined as representative unit of a target population, selected by investigators to participate in their research project.\(^{340}\)

The pregnant women with selected risk factors who fulfilled the sampling criteria formed sample of the study. The sample comprised 300 pregnant women with selected risk factors.

**Sample Size**

The sample size was calculated by using power analysis for 27% of high risk pregnant women. The formula\(^ {341}\) used was: \( n = \frac{t^2 \cdot p \cdot (1-p)}{m^2} \); Where, \( n \)=required sample size,

\[ t = \text{confidence level at 95\% (standard value of 1.96)} \]

\[ p = \text{estimated prevalence of high risk pregnancy (27\%)} \]

\[ q = 1 - p = 1 - 0.27 = 0.73 \]

\[ m = \text{margin of error at 5\% (standard value of 0.05)} \]

Therefore

\[ n = \frac{1.96 \times 1.96 \times 0.27 \times 0.73}{0.05 \times 0.05} = 302.87, \text{approximately 300} \]

The required sample size depended on the daily average attendance of high risk pregnant women in general which was 27\% and was calculated to be approximately 300 and researcher assigned 150 for each group. There was attrition of sample due to various reasons like change of habitance, consultation with private practitioner etc. The researcher was unable to control the attrition, so there were only 149 sample subjects in experimental group and 142 sample subjects in control group.

Distribution of subjects in each group is presented in following table 2.
TABLE 2  Distribution of sample subjects as per risk factors during pregnancy
\(N=291\)

<table>
<thead>
<tr>
<th>S. No.</th>
<th>High-Risk Factor</th>
<th>No. of Subjects</th>
<th>Experimental Group</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>1</td>
<td>Anaemia</td>
<td>126</td>
<td>66</td>
<td>52.38</td>
</tr>
<tr>
<td>2</td>
<td>Hypertension</td>
<td>110</td>
<td>55</td>
<td>50</td>
</tr>
<tr>
<td>3</td>
<td>Diabetes</td>
<td>55</td>
<td>28</td>
<td>50.91</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>291</td>
<td>149</td>
<td>50.91</td>
</tr>
</tbody>
</table>

Sampling Technique

Sampling is a subset of population. It is representative of those critical characteristics which the investigator plans to study.\(^{342}\)

Multiphase sampling techniques were used. Initially purposive sampling technique was used to select the sample of high risk pregnant women with anaemia, hypertension and diabetes. Then simple random sampling was used to draw the study subjects from each of the selected high-risk category of pregnant women. Pregnant women having anaemia, hypertension and diabetes (A, H, D), were identified during their antenatal visit to the antenatal clinic. Every day the researcher prepared a list of the high risk pregnant women with number name i.e. Anaemia (A\(_1\), A\(_2\)...), Hypertension (H\(_1\), H\(_2\)...) and Diabetes (D\(_1\), D\(_2\)...). These number names were written on a chit of paper and placed in a bowl. Then out of total chits, 60% of chits were drawn. Same technique was followed on subsequent days till required number of sample subjects was achieved. The first 150 sample subjects were assigned to experimental group and next 150 sample subjects were assigned to control group.

Criteria for Selecting Sample Subjects:

a) Inclusion criteria
   - Pregnant women with the three selected risk factors such as anaemia, hypertension or diabetes.
   - Pregnant women between ages of 15-45 years.
   - Pregnant women irrespective of their socio-economic status.
   - Pregnant women irrespective of their gravidity.
- Pregnant women with gestational age of 16 weeks.
- Pregnant women who were willing to participate.
- Pregnant women who could understand and read Urdu/English or both.

**b) Exclusion criteria**

- Women with normal gestation.
- Pregnant women who were not registered.
- Pregnant women with any co-morbid condition.
- Pregnant women with risk factors other than anaemia, hypertension and diabetes.

III.8) Data Collection Tools and Techniques:

One of the important tasks for any scientific study is to collect systematically observable and measurable evidences upon which the investigator can base his/her findings. Data collection tools employed to collect the data for conducting the present study included interview schedule, assessment proforma and observation checklist. These tools were found to be practicable and suitable.

III.8.1) Development of tool:

Data collection tools were prepared on the basis of:

- Objectives of the study.
- Extensive review of literature including books, periodicals, monographs, related research and non-research material.
- Proforma used in related published and unpublished thesis.
- Theoretical framework developed for the study.
- Expert and valuable suggestions of supervisor guide, statistician and experts from obstetrics, neonatology and nursing.
- Personal knowledge and experience of the researcher.

A number of tools used by foreign, national and local researchers were explored, reviewed, examined and referred. A few of them are mentioned below:-

**Foreign:** Tamim et al.,\(^\text{19}\) Ayoola et al.,\(^\text{288}\) Owe,\(^\text{327}\) Ehrenberg et al.,\(^\text{285}\) Dailey,\(^\text{284}\) Manuck et al.,\(^\text{343}\) Magnussen,\(^\text{190}\) Payne,\(^\text{287}\) Melamed et al.,\(^\text{108}\) Jehan,\(^2\) Mortensen et al.,\(^\text{27}\) Moutquin,\(^\text{344}\) Mohsin and Jalaludin,\(^\text{345}\) Leung et al.,\(^\text{26}\) Wisbong.\(^\text{289}\)
National: Malhotra,²⁹ Singh,³⁴⁶; Agarwal et al., ³² and Banerjee et al.²⁸³

Local: Mir,³⁴; Shah,³⁴⁷; Qadir,¹⁶; Faizii,⁸³; Ghulam,³⁴⁸; Zargar,³³; Amin and Imtiyaz,³⁵; Mirza,³⁸; Jabeen,²¹²; Ali,³⁶; Chillo,⁸⁴; Ali,⁹⁰ and Kousar.³⁴⁹

Tools used by Nisha,³⁵⁰; Mattoo,³¹⁸; Mani,³⁰⁶ and Sushila,⁵ were especially of great help in framing the items for the present study.

Books which were explored include: Dutta,¹⁴; Dawn,³⁵¹; Bobak,⁵⁸; Marlow,³⁵²; Barbara,³⁵⁴; and Ghai.³

### III.8.2) Description of the Tool:

The tool comprised three parts: (Appendix-G&S).

**Part I - Interview Schedule**

**Part II - Assessment Proforma**

**Part III - Observation Checklist**

A brief description of these tools is given below. Scoring key was developed and based on scoring; categorization of data was done for the items wherever necessary.

**Part I - Interview Schedule:**

Interview Schedule consisted of three sections:

**Section 1: Socio-demographic Characteristics.** It comprised ten items such as age, socioeconomic status (SES including place of residence, education and occupation of woman and her husband, income and type of family.), number of living children and exposure to smoke/pollutants. Each item had two/three/four sub-items.

For socioeconomic status (SES) **Kuppuswamy SES Scale⁴** meant for both urban and rural area was modified and adopted and scored.

Maximum score was 50 and minimum score was 07.

Socioeconomic status (SES) was categorized into three categories based on scoring

1. High socio economic status (score 35-50)
2. Middle socio economic status (score 23-34)
3. low socio economic status (score 07-22)

**Exposure to smoke:** Each item was scored according to the severity of exposure. Maximum score was 13 and minimum score was 01. Exposure to smoke was categorized into three categories based on scores

1. Mild exposure (Score of 01-02, woman obtains this score when she is exposed to household smoke or passive smoking by husband or colleagues).
2. Moderate exposure (Score of 03-06, woman obtains this score when she is exposed to household smoke and passive smoking by husband or colleagues).
3. Severe exposure (Score of 07-13, woman obtains this score when she smokes cigarette or hukka and is exposed to household smoke or to passive smoking by husband or colleagues).

**Section II: Clinical profile:**

It comprised 05 items with sub items under each item which included gravidity, past clinical profile, family clinical profile, clinical profile during past pregnancy and clinical profile during present pregnancy.

Items in this part of tool included open as well as closed ended questions indicating their clinical status. The item consisted of following number of sub-items:

1. Gravidity comprised 04 sub-items
2. Past clinical profile comprised 09 sub-items.

The items included presence or absence of any significant medical illnesses in past.

3. Family clinical profile comprised 09 sub-items.

The items included presence or absence of any significant disease in immediate family members which could have had impact on the pregnancy of women.

4. Clinical profile in past pregnancy consisted of 02 items, each with 07 sub items which indicated association of any obstetric problem in their past pregnancy (excluding primigravida).
5. Clinical profile during present pregnancy: consisted of 07 sub-items which included existence of any disease during present pregnancy.
Section III: Dietary pattern:

It comprised 4 items and each item had two options (yes/no) or three options (always/sometimes/never). Tools used by Amin and Ali\textsuperscript{35}, Shah\textsuperscript{347}, Kousar\textsuperscript{349}, Mattoo\textsuperscript{318}, Sushila\textsuperscript{5}; Thilothammal et al\textsuperscript{229} were of great help.

Nutritional status was categorized into three categories based on scores.

1. Good nutritional status (score of 25-37)
2. Average nutritional status (score of 15-24)
3. Poor nutritional status (score of less than 15)

Scoring index was as follows:

‘Yes’ option – 01; ‘No’ option – 0;

‘Always’ – 02; ‘Sometimes’ – 01; ‘Never’ – 0

Maximum number of score = 37 and minimum number of score = 0

Part II-Assessment proforma

Assessment proforma was used to collect data related to clinical parameters during initial and subsequent weeks of gestation and data related to maternal problems during pregnancy in order to assess maternal outcome during pregnancy period. It comprised two sections (section I and section II)

Section I- Proforma for baseline and subsequent assessment of clinical parameters

It was used to collect baseline information of subjects during first visit to antenatal clinic at 16\textsuperscript{th} week of gestation and then monthly at 24\textsuperscript{th}, 28\textsuperscript{th}, 32\textsuperscript{nd} and 36 weeks of gestation. It consisted of 07 items such as weight (Kg), haemoglobin (g%), blood pressure (mmHg), fasting blood sugar (mg/dl), fundal height (cm), fetal heart rate (bpm) and fetal movement.

Section II- Checklist for assessment of maternal outcome during pregnancy:

This part comprised 10 items indicating presence or absence of problems. It included items related to infections, fetal distress, uncontrolled edema, persistently high blood pressure, convulsions, diabetic complications, vaginal bleeding, premature rupture of
membranes, need for blood transfusion, any emergency hospitalization and reason for it. These items were scored. No’ option-01 score; and ‘Yes’ option-0 score. Maximum score was 56 (4 weekly score=14) and minimum score was 0.

Based on the scores obtained by the respondents, maternal outcome during pregnancy was categorized into three categories:

1. Good outcome  (51 – 56)
2. Average outcome  (41 – 50)
3. Poor outcome  (below 40)

**Observation checklist:**

The observation checklist was used to assess neonatal outcome. It comprised two sections (section I and section II)

Section I:- Checklist for Immediate Neonatal Assessment

It was used at the time of birth to assess immediate neonatal outcome and consisted of 08 items which included mode of delivery, number of fetuses, birth status of baby, gestational period, birth weight, Apgar score, presence/absence of congenital anomalies and presence/absence of birth trauma.

**Section II- Checklist for Early Neonatal Assessment**

It was used within 24 hours of birth to assess early neonatal outcome and comprised 08 items which included transfer of neonate, presence of infection/jaundice/convulsions, behaviour, acceptance of feeding, reason for admission in NICU and baby’s condition.

Each item in both sections had three options and each option was assigned a score of 3 for good status, 2 for average status and 1 for poor status on the basis of assessment during immediate neonatal period (at the time of birth) and early neonatal period (within 24 hours of birth).

Scoring key used by Nisha in her tool was consistent with scoring key of present tool. Scoring index: Maximum score: 24 Minimum score: 08

Based on scores, **Neonatal outcome** was categorized into three categories separately for immediate and early neonatal period:
(1) Good outcome  (20 – 24);
(2) Average outcome  (13 – 19);
(3) Poor outcome  (08-12)

Tabular Form of the Tool

**TABLE- 3 Tabular Form of the Tool**

<table>
<thead>
<tr>
<th>Type of tool</th>
<th>Sections</th>
<th>No. of items</th>
<th>Sub Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Interview Schedule</td>
<td>I - Socio-demographic Characteristics</td>
<td>10</td>
<td>43</td>
</tr>
<tr>
<td></td>
<td>II - Clinical Profile</td>
<td>06</td>
<td>42</td>
</tr>
<tr>
<td></td>
<td>III - Dietary Pattern</td>
<td>04</td>
<td>22</td>
</tr>
<tr>
<td>2. Assessment Proforma</td>
<td>I - Proforma for baseline and subsequent assessment</td>
<td>07</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>II - Checklist for Assessment of</td>
<td>10</td>
<td>07</td>
</tr>
<tr>
<td></td>
<td>Maternal Outcome during pregnancy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Observation Checklist</td>
<td>Checklist for Immediate and Early Neonatal Assessment</td>
<td>08 each</td>
<td>24</td>
</tr>
<tr>
<td>4. Self-Care Activity</td>
<td>Activities adhered to</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Compliance Checklist</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**III.8.3) Data Collection Technique:**

Data collection techniques employed to collect the data for conducting the present study included interview, observation, record analysis, assessment and measurement. These methods were found to be practicable and suitable.

**Interview:** Interview was found to be most appropriate and practical to explicit information about demographic characteristics, dietary pattern, clinical profile including medical and obstetrical history and family health status from respondent.

With a skillful interviewer, the interview is often superior to other date gathering devices. \(^{356}\) By adopting this technique, the investigator could explain the purpose of the study and make sure that all the questions were understood and responded by the respondents. Sushila\(^5\) and Nisha\(^{350}\) have used interview as data collection technique.
**Record Analysis:** Records such as Antenatal OPD Cards, laboratory records, delivery sheets and new born assessment sheets were analyzed to collect required data/information.

Record analysis is an important source to gather a lot of information. Hospital records, patient charts, physicians order sheets, care plan statements constitute rich data source to which nurse researchers may have access. Data collected from records is economical and less time consuming, inexpensive and accessible.\(^\text{336}\)

**Qadir**\(^\text{16}\) has analyzed records while collecting data for her study at Srinagar on “Determinants of infant mortality in Kashmir valley- analysis from a birth cohort.”

**Assessment and Measurement:** It was done by use of assessment proforma to explicit information about physical and physiological measures during various weeks of gestation in order to assess maternal outcome during pregnancy. Various instruments were used to conduct physical and antenatal examination of high risk pregnant women. The instruments included weighing machine, B.P apparatus, fetoscope, measuring tape and thermometer.

**Mattoo**\(^\text{318}\) used the observation method to do the measurement and assessment of women. The assessment and observation was initially done at 16\(^\text{th}\) week of gestation to collect base line information, then it was done monthly at 24\(^\text{th}\), 28\(^\text{th}\), 32nd and 36th week of gestation to assess maternal outcome of women.

**Observation:** Observation was done with the help of observation checklist to explicit information about neonate at the time of birth and within 24 hours of delivery to assess neonatal outcome.

Observational methods are quite versatile to gather a variety of information about characteristics and conditions of individuals, verbal and non-verbal communication, activities and behaviours, skill attainment and performance etc.\(^\text{336}\)

It is intrinsically appealing in its ability to capture and record behaviours and events. With an observational approach, the observations made by observers are used as measuring instruments and provide a uniquely sensitive and intelligent tool. **Nisha,\(^\text{350}\)** **Ali**\(^\text{85}\) and **Fazili**\(^\text{83}\) have used interview and observationas as data collection techniques while collecting data for their studies.
Self-Care Compliance Checklist (Appendix H & U)

This checklist included items related to various activities like:

- Rest, sleep, diet, exercises, prescribed medicine, antenatal checkups, personal hygiene,
- Monitoring and recording of blood pressure, weight, blood sugar, urine sugar, fetal movement;
- Daily observation for edema,
- Report when asked for emergency admission,
- Attendance to phone calls/ antenatal advises/ counselling sessions;
- Avoidance of smoke/hukka, pollutants, high heels, heavy weight, long journey, coffee etc.
- Keeping legs elevated
- Provided help for household activities
- Informed immediately during any complication
- Did not skip any meal
- Did not keep fast

III.9) Development of Intervention Program

The researcher had prepared the content of intervention program (low birth weight prevention program-LBWPP) on the basis of following:

- Extensive review of literature including books, periodicals, monographs, related research material.
- Interventions used in related studies.
- Expert and valuable suggestions of supervisor/guide and other experts from obstetrics, neonatology and nursing.
- Personal knowledge and experience of the researcher.

A number of related interventional studies which had been conducted by many nurse researchers and medical researchers were explored, reviewed and referred. A few of them are mentioned below:-

- The studies reviewed related to prenatal care included Peggy, Gupta, Bull, Khodakkarami, Al-Nsour, Gustafson, Di Joseph
The studies reviewed to prepare Information about low birth weight/preterm birth included Iams, Nyberg and Freda, Goldenberg, Goldstein, Vonderpool and other preterm birth prevention studies.

The studies reviewed to prepare Home Care Package included Marsh et al., Pitzer, Reece et al., Shoba, Claesson, O’ Sullivan, Shi Wu Wen et al., found that written information, individual/group sessions by midwives is of great help while conducting intervention program during pregnancy. Ananth, Shalini and Sehgal, Rang and Darbari, Mitchell too have advocated the use of written information to have better outcome.

**Description of Intervention Program:**

Low birth weight prevention programme-LBWPP (**APPENDIX-I,T**)

Intervention was pharmacological and non-pharmacological and included following components:

1) **Information about low birth weight and preterm birth** (audio-visual supported).
   The researcher prepared the information about low birth weight prevention supported by audio-visual aids in English, which was translated in Kashmiri and then retranslated to English. The content was edited by English, Kashmiri and computer experts. The areas of content included following:(**APPENDIX-I**)
   - Meaning and causes of low birth weight (LBW)
   - Dangers of low birth weight (LBW)
   - Prevention of low birth weight (LBW)
   - Causes of preterm labour, its warning symptoms and prompt action.

2) **Antenatal and dietary advises.** It included following areas:
   a) Advises related to rest and sleep, personal hygiene, relaxation, regular antenatal check-ups, help of husband, care of associated problems, telephone calls, extra visits, seeking professional assistance, follow up.
   b) Advises related to situations to be avoided such as excessive fatigue, smoking, drugs, pollutants, coffee, long travel, jerky movements, lifting heavy weight, long standing, high heels, infection, loneliness and loose temper.
c) Dietary counselling about fetal growth, weight gain patterns, effect of nutrition on fetal growth, needs of diet, importance of nutrients, sources of nutrients, dietary advices, iron and folic acid supplementation, consultation with nutritionist etc.

A pictorial /diagrammatic flip chart was prepared by the investigator which was used during antenatal advises and dietary counselling.

3) Demonstrations included testing and monitoring of weight, blood pressure, blood sugar, urine sugar, fetal movement, edema, exercises (pelvic floor-Kaegle’s exercise).

4) Home care package in the form of information booklet. It was prepared separately for anaemia, hypertension and diabetes. It included following content area:

- Information,
- Warning symptoms specific to anaemia, hypertension and diabetes,
- Care and preventive measures, and
- Daily diet menu specific to the risk factor of pregnancy.

It was prepared in English and was translated in Urdu and retranslated to English by an expert. (Appendix I & T)

III.10) Validity 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 obtained from 20 experts from various fields which included experts from nursing, obstetrics, social and preventive medicine, neonatology, paediatrics, education, research and statistics. (Appendix – K, L, M&O)

As per their expert suggestions, the investigator had made necessary modifications in the tool. There was 90% agreement on the content of all the items.

III.11) Validity of the Interventional Program

In order to measure the content validity of the interventional program, it was submitted to 20 experts, chosen on the basis of their experience, clinical expertise and interest in the problem area. They were requested to verify the contents of the interventional program including home care package/information booklet, for its clarity, relatedness and meaningfulness. (Appendix-K, L&N)
The inputs received from experts were incorporated. As per their expert suggestions, and the suggestions of supervisor/guide, the necessary modifications were made in the interventional program. This included addition of general information regarding pregnancy, nutrition, fetal growth, antenatal and dietary advises in the introductory part of home care package. It was then translated into Urdu and retranslated into English to find out translation validity which was 99% valid.

**III.12) Reliability of Tools**

Reliability is the degree of consistency and accuracy with which it measures the attribute it is supposed to measure. A reliable measure is one that maximizes the true score component and minimizes the error component.  

**Reliability of Instruments/Devices** used during study e.g. weighing machine, B.P apparatus, fetoscope, measuring tape and thermometer; was done by immediate test-retest method which had shown stability in results when tested twice (on two occasions) on same person.

**Reliability of the Data Collection Tool**

In order to ascertain the reliability of data collection tool; split half method and interrater consistency was used. The tool was administered to 20 women during pregnancy in antenatal clinic and 15 women during their intrapartum period.

The interview schedule, which had 20 items in total, was divided into odd and even items to check its internal consistency. The correlation coefficient was calculated using the spearman Brown prophecy formula as follows:

$$r_1 = \frac{2r}{L + r}$$

The ‘r’ value obtained from the split half method was 0.89, the calculated value of $r_1$ = 0.94, thereby the interview schedule of the tool was considered reliable with internal consistency.

The reliability of assessment proforma (to assess maternal outcome) and observation checklist (to assess neonatal outcome):

The reliability coefficient was found by Interrater consistency method (inter observer). It was estimated by 2 clinical instructors under the proper guidance of researcher. They independently and simultaneously observed and recorded the responses of assessment
proforma and observation checklist according to a predetermined plan. The following equation was used to find out the reliability

\[
\frac{\text{No. of Agreements}}{\text{No. of Agreements + Disagreements}} = \frac{20}{20 + 1} = 0.95
\]

Assessment proforma was having 21 items in different sections, in which the number of agreements was 20 and only 01 item had little disagreement in the assessment. The reliability was calculated as $17/17 = 0.95$. The obtained value indicated a high reliability. Thus the researcher used this part of the tool to assess maternal outcome.

Similarly reliability was calculated for observation checklist which had 16 items in which the number of agreements was 15 and only 01 item had little disagreement in the assessment. The reliability was calculated as $15/15 = 0.94$. The obtained value indicated a high reliability. Thus the researcher used this part of the tool to assess neonatal outcome.

**Try Out/ Pre-testing of tool:**

Before pilot study, the pilot pretesting/try-out of the tool and instruments, to be used for data collection, was done. The tool was administered to 5 women during pregnancy in antenatal clinic and 5 women during their intrapartum period in April 2011, to check the items for clarity, relevance and ambiguity and to determine the time taken for collecting the data. The subjects chosen were similar in characteristics to those of the population under study. Tool was pre-tested to determine its clarity.

**Modifications done after Pre-Testing of Tool:**

Data collection tool was further modified after pretesting of tool and as per the suggestions of statistician and expert supervisor. These modifications included:

- The common investigations were deleted from section I of assessment proforma as those were not done for potential women but routinely for all pregnant women.
- The items related to exposure to smoke and dietary pattern were scored as per the statistician’s opinion.
III.13) Pilot Study

Pilot study is a smaller version of a proposed study conducted to refine the methodology. It is developed much like the proposed study, using similar subjects, the same setting, the same treatment, and the same data collection and analysis technique. Thus a pilot study could be used to develop a research plan rather than to test an already developed plan.

The researcher conducted the pilot study in order to:-

- To verify the feasibility and practicability of the study.
- To develop or refine a research treatment.
- To develop a protocol for the implementation of intervention and determine the time taken for giving intervention.
- To examine the reliability and validity of the research instruments.
- To provide trial run of data collection technique and determine the time taken for data collection.
- To refine the data collection and analysis plan, and
- To give the researcher experience with the subjects, setting, methodology, and methods of measurement.

Formal permission was obtained from Medical Superintendent, SKIMS, Srinagar, and from head of department, Gynae and Obstetrics, SKIMS, Soura, Srinagar to conduct the pilot study.

The pilot study was conducted in the same setting (antenatal clinic) from April 2011 to August 2011 on 30 subjects (10% of final sample subjects) who fulfilled the inclusion criteria. These women were selected randomly, 15 for experimental group and 15 for control group. The number of women was 8 with anaemia, 5 with hypertension and 2 with diabetes in each group. The data collection procedure was adopted as it was planned for the main study. These women were not included in the final study. Various aids like photos of low birth weight babies had been collected. The nutritionist was consulted for the provision of therapeutic diet charts for respective problems (Appendix-J). Audio-visual assisted information about low birth weight baby and its preventive measures was prepared and implemented, followed by antenatal and dietary advises, demonstrations and distribution of home care package (Appendix-T).
The time taken for completion of interview was 05 minutes, and for observation was 05 minutes. It took 40-60 minutes to make assessment and implement the intervention program i.e. about 10-15 minutes to complete assessment of physical and physiological parameters from each subject; 10-15 minutes for providing information about low birth weight and preterm baby, 05-07 minutes for antenatal and dietary advises; 20 minutes for demonstrations and 02-03 minutes for distribution of homecare-package.

Data collection tool and intervention package was further modified according to the findings of pilot study and as per the suggestions of statistician and expert supervisor/guide and was found to be valid, reliable and feasible for the purpose of final study.
**Planned Intervention**

**TABLE-4  Planned Specification of program tasks during various gestational weeks, intrapartum period and early neonatal period**

<table>
<thead>
<tr>
<th>Tasks</th>
<th>Period of conducting</th>
<th>Specification of program tasks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task I</td>
<td>16(^{th}) weeks</td>
<td>- Identify pregnant women with selected risk factors.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Take informed consent.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Collect and record baseline data. Assess parameters.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Mark the cards as “women under study.”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Identify experimental group first.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Identify control group after completing the selection of experimental group.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Give information about low birth weight and preterm birth.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Give antenatal and dietary advises</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Show demonstrations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Distribute home care package</td>
</tr>
<tr>
<td>Task II</td>
<td>20(^{th}) weeks</td>
<td>- Reinforce the intervention.</td>
</tr>
<tr>
<td>Task III</td>
<td>24(^{th}), 28(^{th}), 32(^{nd}) &amp; 36(^{th}) weeks</td>
<td>- Reassess parameters.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Observe maternal outcome.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Continue advises</td>
</tr>
<tr>
<td>Task IV</td>
<td>At birth &amp; within 24 hours of delivery</td>
<td>- Observe neonate for immediate and early neonatal outcome.</td>
</tr>
</tbody>
</table>
III.14) Data Collection Procedure

An administrative approval was obtained from Ethical Committee, Medical Superintendent, and Head of the Department Obstetrics and Gynaecology, SKIMS, Soura, Srinagar. Permission was taken to utilize a separate room in antenatal clinic for collecting data and implementing the intervention. The antenatal staff including obstetricians, nurses, technicians, and medical record staff were contacted and informed about the purpose of the study to gain their cooperation.

Data collection was done from 1st September 2011 to 31st August 2012.

Data collection schedule

Pregnant women having anaemia, hypertension and diabetes (A, H, D), were identified during their antenatal visit to the antenatal clinic. Every day the researcher prepared a list of the high risk pregnant women with number name i.e. Anaemia (A₁, A₂…), Hypertension (H₁,H₂…) and Diabetes (D₁, D₂…). These number names were written on a chit of paper and placed in a bowl. Then out of total chits, 60% of chits were drawn. Same technique was followed on subsequent days till required number of sample subjects was achieved. The first 150 sample subjects were assigned to experimental group and next 150 sample subjects were assigned to control group.

At 16th week of gestation, high risk pregnant women having anaemia, hypertension and diabetes (A, H, D) were identified keeping in view inclusion criteria. They were explained about the purpose of the study and consent was obtained from them (Appendix-Q, & W). Ample of time was provided to the study subjects to understand and to accept the participation in the study. Once the completion of signing the consent form was over (Appendix-R & W), the data on demographic characteristics, nutritional data and clinical data was obtained. Then baseline assessment was done for both experimental group and control group. Recording was done then and there to maintain accuracy. A minimum number of six and maximum number of eight were studied per day.

Implementation of Intervention

Once the baseline assessment (pre-test at 16th week) was completed for both experimental group and control group, the subjects of experimental group were given intervention and following procedure was adopted for administration of intervention.
- Information about low birth weight and preterm birth was given which was audio-visual supported.
- Antenatal and dietary advises was given with use of a pictorial flip chart. It was given individually or in small groups of 7-8 subjects as per requirement.
- Demonstrations were given on:
  a) exercises (such as pelvic exercises e.g. Kegel exercises.
  b) self-monitoring and recoding of:
     i. weight,
     ii. blood pressure,
     iii. fetal movements,
     iv. testing of blood sugar with glucometer (for diabetic subjects).
     v. testing of urine sugar with urostick strips (for diabetic & hypertensive subjects).

The subjects were asked for return demonstration and to do the practice of exercises.

- **Home Care Package** in the form of information booklet was explained and distributed among the study subjects according to their respective high risk factor.

- **Each woman was provided with Self Care Activity Compliance Checklist** after she had been provided with the verbal and written information and was advised to fill it up when she performs any activity.

- At 20th week of gestation during their scheduled follow up, the subjects of experimental group were asked to assemble in college hall where the intervention was strengthened and they were given the audio-visual supported information about low birth weight and preterm birth in groups of 30-40, reinforced for antenatal and dietary counselling; and demonstrations, cleared their doubts, if any.
  They were offered juice and biscuits as compensation.

The study subjects were asked to come for regular check-up (follow up) as per the doctor’s prescription, and their cards were marked as ‘mother under study (E’) for experimental group and as ‘mother under study (C)’ for control group. The researcher recorded and preserved their contact numbers to ensure follow up at 24th, 28th, 32nd and 36th week. On these follow up weeks, their parameters were reassessed for maternal outcome. The experimental group was continuously given advises and care whereas control group received only routine care.
The neonates were assessed in the labour room, at the time of birth, for immediate neonatal outcome or their records were assessed. These neonates were again assessed within first 24 hours of delivery in postnatal wards/ neonatal intensive care unit (if any was admitted there) for early neonatal outcome.

The privacy was maintained for the women during data collection and the information collected was kept confidential. The ethical and scientific principles were adhered to by the researcher throughout the study.

The researcher was able to follow up the women in both groups through their contact numbers and addresses. **At the end of the study, there was attrition of 09 subjects.**

Tabular Form of Implementation of Intervention

**TABLE- 5 Tabular Form of Implementation of Intervention**

<table>
<thead>
<tr>
<th>Experimental Group</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Provided information about low birth weight and preterm birth (Audio-visual supported).</td>
<td>Routine Antenatal Care which included antenatal check-up and doctor’s prescription.</td>
</tr>
<tr>
<td>▪ Given antenatal and dietary advises with use of a pictorial flip chart.</td>
<td></td>
</tr>
<tr>
<td>▪ Given demonstrations on exercises, self-monitoring and recoding of weight, blood pressure, fetal movements, testing of blood/urine sugar and pelvic exercise.</td>
<td></td>
</tr>
<tr>
<td>▪ Distributed home care package</td>
<td></td>
</tr>
</tbody>
</table>
III.15) Plan of Data Analysis

A plan for data analysis was developed by the researcher. It was planned that the present data would be computed/ entered in Microsoft Office Excel, organized, analyzed and interpreted using appropriate descriptive and inferential statistics as depicted in table 5.

Table 5 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 distribution of high risk pregnant women according to risk factors, socio-demographic characteristics, nutritional status and clinical profile in past and present pregnancy.</td>
</tr>
<tr>
<td>Inferential statistics</td>
<td>Chi square test ($X^2$), ‘t’ test</td>
<td>-To compare experimental and control group of subjects according to socio-demographic characteristics.</td>
</tr>
<tr>
<td></td>
<td>Chi square test ($X^2$) and Odds Ratio (OR)</td>
<td>-To compare physical and physiological parameters at various weeks of gestation between experimental and control group of subjects.</td>
</tr>
<tr>
<td></td>
<td>Multivariate Logistic Regression Analysis</td>
<td>-To compare maternal and neonatal outcome between experimental and control group of high risk pregnant women.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>To associate maternal and neonatal outcome with selected risk factors of pregnancy and with socio-demographic characteristics of subjects.</td>
</tr>
</tbody>
</table>

III.16) Summary

This chapter dealt with the methodology adopted for assessing the effectiveness of low birth weight prevention programme (LBWPP) on the maternal and neonatal outcome of pregnant women with selected risk factors of pregnancy i.e. anaemia, hypertension and diabetes in a selected hospital of Kashmir. It included research approach, research design, variables under study, setting, population, sample, sampling technique, development and description of data collection tool, data collection technique, description of instruments,
development and description of intervention program, content validity of tool and content validity of intervention programme (LBWPP), reliability of tool, try out/ pretesting of tool, pilot study, procedure for data collection and plan for data analysis.

It gave an overall description of methods and procedures adopted for conducting the study i.e. how the sample was selected, how the data was collected, how the intervention was implemented so the data was made available for analysis and interpretation.