CHAPTER III
METHODOLOGY

INTRODUCTORY STATEMENT

Research is a systematic and refined technique of thinking, employing specialized tools, instruments and procedures in order to obtain a more adequate solution of a problem than would be possible under ordinary means. It starts with a problem, collects data or facts, analyse them critically and reaches to decision based on the actual evidence. The purpose of any research work is to discover the answer to the question through the application of a scientific procedure.

According to Young P.V., “Research is a systematic method of exploring, analyzing and conceptualizing social life in order to extend, correct or verify knowledge aids in the construction of a theory or in the practice of an art.”

In pursuit of the research, the most important thing to be decided by the researcher is the selection of research problem. A researcher by choosing a topic of his/her liking can pursue his/her own interest to the farthest limit. The selection of topic is a commitment of one’s time and efforts in a particular direction.

The main aim of the research is to find out the truth which is being hidden and which has not been discovered yet.

Present study entitled “effect of Spirulina supplementation on blood glucose and blood pressure levels of selected diabetics and hypertensives of Bhilai township” is an attempt to find out importance of ‘spirulina’ which is considered as an earths super food in combating these two non-communicable diseases.
3.1  RESEARCH DESIGN

An action research study was made in planning and formulating the research project. A research design is the plan, structure and strategy of investigation conceived, so as to obtain answer to research questions and to control variance.

All the independent variables involved in the present study are ‘attribute’ variables being beyond the investigators control. They can not be manipulated by investigator, hence present investigation be called ‘Ex post facto’ in character Kerlinger Fred N (1986).

To obtain answer of research questions and to control variance, research plan is adopted in this case, as the overall scheme of research. Keeping these guidelines in view, accordingly specific objectives were set in, to provide basis for investigation. In the light of above objectives, the scope of study was delineated and techniques of investigation were followed, tools were used and pattern of statistical analysis was decided.

3.2  DESCRIPTION OF STUDY AREA

Study was carried out in Bhilai township of Durg distt. of Chhattisgarh state. Durg district extends between the latitudes 20º 23’ N and 22º 02’N and longitudes 80º 48’E and 81º 57’E. The climate of district is moderate but on a warmer side in summer season. In summer the temperature goes to maximum 43-46 degree celsius. Average rainfall is around 1024 mm/years. Durg comes under the basin of Sheonath and Mahanadi river Khanna C L (2004).

THE DISTRICT AT A GLANCE (AS PER 2001 CENSUS)

The administrative set up

1. Geographical area (sq kms) – 8702 (6.32% of the total area of the state)
2. Number or subdivisions – 60
3. Number of Tehsils – 11
4. Number of Community Developmental blocks – 12
5. Number of Gram Panchayats – 998
6. Number of Villages – 1803
7. Number of Towns – 21
8. Forest region – Minimum (28%) forest
The People/Population

Total population of the district – 28,01,757
Male population – 1,113,785
Female population – 1,387,972
S.C. population – 12.79%
S.T. population – 12.41%
Percentage of district population to the state – 13.47%
Density of population – 328/sq km
Sex ratio (number of female/1000 males) – 982
Tribal population of Chhattisgarh state – 35.77%
Major tribes of Durg district – Halba, Kanwar and Kamar

Education

Literacy Rate (%) – 75.6%
Male Literacy Rate – 86.4%
Female Literacy Rate – 64.6%
Schedule Caster – 71.1%
Male Literacy Rate – 84%
Female Literacy Rate – 58-2%
Schedule Tribes – 73.3%
Male Literacy Rate – 95.3%
Female Literacy Rate – 61.6%
Villagers (rural) – 71.3%
City dwellers (urban) – 82.3%

Agriculture and Irrigation (2002-2003)

Total area – 694 Thousand Hectare
Sowing area – 545 Thousand Hectare
Irrigational area – 296 Thousand Hectare
Irrigated area – 178 Thousand Hectare
Chhattisgarh is backward from educational point of view. Educational organizations of Chhattisgarh state are as below [Govt. of C.G. (2005)]

<table>
<thead>
<tr>
<th>Type of School</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre Primary Schools</td>
<td>839</td>
</tr>
<tr>
<td>Primary Schools</td>
<td>31907</td>
</tr>
<tr>
<td>Middle Schools</td>
<td>7098</td>
</tr>
<tr>
<td>High Schools</td>
<td>1176</td>
</tr>
<tr>
<td>Higher Secondary Schools</td>
<td>1386</td>
</tr>
<tr>
<td>Colleges in the state</td>
<td>169</td>
</tr>
</tbody>
</table>

3.3 SELECTION OF SAMPLES

In order to get a proper estimate of health status particularly hypertension and diabetes, it is necessary to select samples of at least moderate size. In order to obtain a true representative sample, the sample should be selected at random Swaminathan M (1995).

For the present study probability sampling design was used, in which stratified random sampling was done in order to select the sample. The purpose of stratification is to increase the efficacy of sampling by dividing a heterogeneous universe into more and more homogenous one within each stratum.

In present study, 193 subjects residing in various location of Bhilai township between 40-60 year of age group were screened for their blood glucose levels. Out of which 134 were newly diagnosed non-insulin dependent diabetic patients with fasting blood glucose levels between 120 and 160 mg/dl. Similarly out of 143 freshly detected hypertensive patients between 40-60 yrs of age who were not taking any anti hypertensive drugs and were either from pre-hypertension stage or from hypertension stage I or II from Bhilai township, 120 Diabetic and 120 Hypertensive were selected for final study.
3.4 TECHNIQUE ADOPTED FOR MOTIVATING

In studied population, to acquire acquaintance and co-operation, purpose of the study programme was explained. The subjects were requested to extend their co-operation in this respect. This was facilitated by arranging meeting at B.M. Shah hospital and medical research centre Bhilai. In order to explain the objectives of the present study to the respondents, mode of the study programme was also explained with the valuable guidance of Dr. Sudhir Gangay. Three diabetic and two hypertensive camps were organized in B.M. Shah hospital where free check-up of patients was done alongwith nutrition education.
3.5 TOOLS AND TECHNIQUES FOR DATA COLLECTION –

Collection of data is most important step in any research work. To get the required information of the subjects survey was conducted with the help of questionnaire cum interview method along with blood pressure, blood sugar and body weight measurements.

**Pilot survey**

A pilot survey was conducted on 30 subjects to know the characteristics of population under study. The questions which were found ambiguous were eliminated and necessary modifications were made. This pre-testing system of the questions helped in the physical layout for the final questionnaire.

**Final survey**

The final data was collected using questionnaire cum interview method, which was done by the pre-designed and pre-tested questionnaire. Certain observations were made and data was collected on the following features:

**Lifestyle assessment**

Questionnaire method was used for life style assessment. Questionnaire is a format containing a list of questions sequentially ordered to obtain information relevant to the objectives of the study. The questionnaire was designed according to the set specifications and specific goals being kept for the study (Appendix-1) Information regarding food intake, dietary habit, and type of food consumption was noted.

**(i) Occupational Status** - Categorized as business / service / none, solely for study purpose.

**(ii) Activity** – Activity levels have been categorized into sedentary, moderate and heavy as suggested by Gopalan C. et al. (1991) – Appendix
(iii) **Type of exercise** – Type of physical activity was defined as any type of non-occupational physical exercise at least once a week and was graded in qualitative terms such as none, walking, yoga and outdoor games suggested by Easwaran P.P et.al. (2001).

**Walking** – The amount of walking was categorized as 5 km, 1 km, 2 km, >2 km and rest of the subjects were defined as physically inactive suggested by Easwaran P.P. et.al. (2002).

(iv) **Faulty addictions** – To classify different types of faulty food addictions suggested by Easwaran P.P.

**DIETARY SURVEY**

Daily consumption of different food items and their quantity taken was categorized. Diet survey was carried out using 24 hours recall method for one day. Special mention was made for salt, sugar and cooking fat.

- Quantity of cooked food taken was converted into raw equivalent in terms of grams or mililitres.
- Nutrient content was estimated by using food composition tables Gopalan C. et al. (1989).
- The nutritive value of diet was compared to standard nutritional allowances especially in terms of calories, protein, fat, carbohydrate & sodium etc. Mahtab S. Bamji et al (1996)].

**ANTHROPOMETRIC MEASUREMENTS**

- **Height** – The measurement of height was done with the help of anthropometer. The subjects were measured with their shoes off, standing erect on a levelled surface, without shoes, looking straight with heels together and toes apart.
- **Weight** – The weight of the subjects was measured in kg on electronic weight machine (digital). The weight was taken with minimum clothes and no shoes.
Body mass index was calculated using height and weight measurements.

**BIOCHEMICAL ASSESSMENT**

- **Measurement of Blood Sugar** –
  Blood sugar level was measured by using accu-check. Fasting blood sugar and post prandial blood sugar was measured four times in the entire course of study i.e. before starting spirulina supplementation, after 30 days, after 60 days and lastly when the supplementation was over.

<table>
<thead>
<tr>
<th>Condition</th>
<th>2 hour glucose (mg/dl)</th>
<th>Fasting glucose (mg/dl)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt;140</td>
<td>&lt;110</td>
</tr>
<tr>
<td>Pre diabetes</td>
<td>Impaired fasting glycaemia</td>
<td>&lt;140</td>
</tr>
<tr>
<td></td>
<td>Impaired glucose tolerance</td>
<td>≥140</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>≥200</td>
<td>≥126</td>
</tr>
</tbody>
</table>

Four categories of blood sugar level as per 1999 WHO criteria

- **Measurement of Blood Pressure** –
  Blood pressure was measured by the use of either conventional sphygmo-manometer or automated machine. For accurate reading blood pressure was taken 1 hour after caffeine intake, 30 minutes after smoking or strenuous exercise and without any stress. The patient was asked to sit upright in a chair with both feet flat on the flour for a minimum of 5 minutes prior to taking a reading. The systolic & diastolic pressure was measured initially before starting supplementation, after 30 days & 60 days of supplementation and lastly after the supplementation was over i.e. 90 days. Thus blood pressure level was recorded four times in the entire study.
Effect of Spirulina Supplementation on Blood Glucose and Blood Pressure Levels of Selected Diabetics and Hypertensives of Bhilai Township

Methodology

Categories of blood pressure as per the recommendation of American Heart Association include:

- **Measurement of HbA1C**

  Test for HbA1C (glycated haemoglobin) was performed in the pathology lab twice in the entire course of study initially before starting supplementation and then after 100 days.

  HbA1C is the average of blood sugar for the last 100 days and it is not affected by diet. In normal 120 days lifespan of red blood cells glucose molecules react with haemoglobin forming Glycolated haemoglobin. In individual with poorly controlled diabetes the level of HbA1C is much higher. In normal Indian the HbA1C range should be as follows:

  - A non diabetic should have an HbA1C result between 4% to 6%.
  - In diabetics HbA1C level should be 6.5% or higher.
  - In pre diabetics HbA1C is 5.7% to 6.4%.

**SPIRULINA SUPPLEMENTATION**

The selected hypertensives and diabetics were divided into two groups i.e. control and experimental. Spirulina capsules (Hellorina) were supplemented to the diets of the experimental group. One capsule contributed 0.5 gm. of spirulina. Four capsules contributing 2 grams of spirulina were given to each subject (in the experimental group) for a period...
of 90 days. Control group was given only nutrition education for life style modification.

**Experimental Method: (Diet counseling)**

A systematic diet counseling was developed for the experimental purpose. Life style modification and non pharmacological options were offered to the patients before any initiation of drug therapy. Importance of balanced diet and use of DASH diet was suggested (Education planning group (1996)).

### 3.6 STATISTICAL MEASURES

Various non parametric and parametric statistical methods were used in this study, based on the nature of data and the type of information required.

**Percentage** – Simple comparisons were made on the basis of percentage calculations.

**Frequency** – The number of observations in each group is called frequency. It shows at a glance how many individual observations are in a group and where the main concentration lies. It also shows the range and shape of distribution. Therefore in the present study, to see the difference between distribution of subjects among different groups frequency was calculated.

**‘t’ test** - To compare various dimensions taken for the present study between study groups, student’s ‘t’ test was applied.

**Gain score** - In the present study data were collected twice i.e. pre-test and post-test for experimental as well as for control group. In order to find out the efficacy of Spirulina supplementation on blood glucose and blood pressure level and gain score was calculated.

To calculate gain score, scores of post-test were deducted from pre-test scores. The obtained gain score for control and experimental group was then
compared with the help of ‘t’ test to find out the efficacy of spirulina supplementation. Statistical analysis was done by computer software SPSS 6.0

3.7 OPERATIONAL DEFINITIONS

**Health** – Health is a state of complete physical, mental, social and spiritual well being and not merely the absence of disease or infirmity.

**Dietary Habits** – Certain general patterns of food selection categories, the diet of a person associated with love, affection, warmth, self image and social prestige, influenced by urban or rural living, income, family size, age, sex, family tradition, cultural background and availability of food in a geographical area.

**Nutrients** – Nutrients are those chemical substances in food that are needed by the body. They are divided into six classes - protein, fats, carbohydrates, minerals, vitamin’s and water.

**Nutrition** – Nutrition is the science of food, the nutrients and other substances their in; their action, interaction and balance in relation to health and diseases. It can be defined as the process by which the organism ingests, digests, absorb, transports and utilizes nutrients and disposes their end products.

**Nutritional status** – It is the condition (state) of health of an individual which is influenced by the utilization of nutrients in the body. It can be defined as the level of nourishment in an individual.

**Balanced diet** – A balanced diet is defined as diet which contains different types of foods in such quantities and proportion that the need for calories, minerals, vitamins and other nutrients is adequately met.\(^{10}\)

**Recommended Daily Allowances (RDA)** – RDA is defined as the nutrient present in the diet which satisfies the daily requirement of nearly all individuals in a population.
Diet therapy is the use of food as an agent for the treatment of disease. The use of DASH (Dietary Approaches to Stop Hypertension) has been advised to hypertensive patients in the present study.

Life style pattern means way in which a person or a group of people live and work. In present study life style pattern has been assessed in the form of occupation, physical activity pattern and faulty food addictions etc.

Faulty food habits mean habit of eating food which is wrong or not recommended for the present study, faulty addiction like alcoholic beverages, smoking and tobacco have been considered in faulty food habits.

Diet counselling refers to a teaching cum guidance therapy in which the subjects were made aware, guided and perceived to achieve good food habits and life style.

Glycated Haemoglobin HbA1C - Average of blood sugar for the last 100 days which is not affected by diet.

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