METHODOLOGY

Research involves formulating the problem to be investigated, selecting a suitable research design, choosing and applying appropriate procedures for data collection, and analyzing and communicating the process and findings through a written report. Research methodology refers to the research decisions taken within the framework of specific determinants unique to the research study. Methodology refers to the theoretical analysis of the methods appropriate to a field of study or to the body of methods and principles particular to a branch of knowledge.

A cross-sectional survey design was used in the study, involving face-to-face, individual or small group interviews with respondents. The samples studied were type 2 diabetics and were monitored for the duration of four months from the time of enrolment. Data was collected and Confidentiality maintained by using a pre-assigned identification number, instead of subject’s names. Each subject signed an informed consent form before data were collected.

Methodology used in the present study has been discussed under the following headings:

3.1 Phase I – Experimental Study
   3.1.1 Standardization of Recipes
   3.1.2 Proximate Analysis
   3.1.3 Estimation of Glycemic Index (Invivo human study)
   3.1.4 Calculations of Glycemic Index of each millet recipes (Invivo human study)

3.2 Phase II – Sample Selection
   3.2.1 Identification of the tertiary diabetes centre
   3.2.2 Locale of the Study
   3.2.3 Identification of the samples
3.3 Phase III – Standardization in Study Design

3.3.1 Rapport building
   3.3.1.1 Interview schedule

3.3.2 Assessment of Nutritional Status
   3.3.2.1 Anthropometry
      3.3.2.1.1 Anthropometry Indices
   3.3.2.2 Biochemical Status
   3.3.2.3 Clinical Examination
   3.3.2.4 Dietary status

3.3.3 Physical Activity
3.3.4 Knowledge, Attitude and Practice

3.4 Phase IV- Intervention Programme

3.4.1 Dietary Intervention
3.4.2 Education Intervention

3.5 Phase V- Statistical Analysis

3.5.1 Descriptive Statistics
3.5.2 Inferential Statistics
3.5.3 Analysis of Variance (ANOVA)
3.5.4 Correlation Analysis

3.1 Phase I – Experimental Study

Milletts such as Foxtail, Pearl, finger millet and sorghum were used to assess their impact in the management of type 2 diabetes.

3.1.1 Standardization of Recipes

Four Recipes using each processed millets of 4 exchanges (120gm) were standardized for a meal in the laboratory and these millets in the form of flour and recipes were subjected for Proximate analysis and Glycemic index, Nutritive values were calculated using ICMR Guidelines (C.Gopalan, et,al 2009) and subjected for sensory evaluation using “10 point hedonic Scale. Bradley, J, E.,et.al, (2010)
**Sensory Evaluation:** Sensory evaluation was done by a panel of ten trained judges. This was done using a 10 point hedonic scale. Sensory characteristics like colour, appearance, texture, flavour and taste were evaluated. A sample evaluation card is affixed in (Annexure 1.)

**Recipes include:**

Foxtail Millet (Navanae): Foxtail Millet Khichidi, Methi Foxtail Rice Bath, Veg Foxtail Rice bath and Foxtail Rice Idli.
Sorghum (Jowar): Sorghum Ball, Sorghum Roti, Mix Veg Sorghum Thalipathu and Drumstick leaf Sorghum Roti.
Pearl Millet (Sajjae): Bajra Roti, Bajra Khichidi, Bajra Idly and Mix veg Bajra Roti.

3.1.2 Proximate Analysis

Proximate analysis of millets in the form of millet rice (Foxtail millet) and millet flour (Bajra, Jowar and Ragi) and for the standardized recipes (one from each) Ragi Roti, Bajra Roti, Jowar Roti and Foxtail millet rice bath were subjected for proximate analysis in an NABL Accredited Laboratory.
in Bangalore. Elements such as Moisture, Ash, Carbohydrate, Protein, Total Fat, Total Dietary Fibre (Soluble, Insoluble and Crude) and Total Energy were analysed using Physiochemical composition of tested foods with AOAC standard (18th edition) methods for moisture No: 986.21, Ash No: 923.09, Crude fibre No: 962.09, Protein (NX 6.25) No: 984.13, Total Fibre No: 925.06, by difference method Carbohydrate was estimated and by calculation total energy was estimated (Annexure 2) later these millet recipes were also subjected for estimation of Glycemic Index as per WHO protocol (Invivo method).

**METHODOLOGY 1**

![Flowchart showing the methodology](image)

**Fig 1: Experimental Study**

Influence of minor millet and education intervention in the management of Type 2 diabetes mellitus
3.1.3 Estimation of Glycemic Index (Invivo Human Study)

A step by step procedure to estimate the GI of tested samples: As per WHO (2010) and FAO protocol.

**Step 1:** Ten healthy non-smoking, normal BMI, male volunteers aged between 29-32 years were selected as subjects for the estimation of Glycemic Index. The volunteers had no family history of diabetes or any food allergies, were not on any medication and also were not on weight loss diet. Since, Estimating glycemic index can only be done in a controlled environment with a control substance and the test food sample.

**Step 2:** 50 gm of glucose in 300ml water was given to the samples (10 volunteers).

**Step 3:** A single venous blood sample was taken in the fasting state and at 30 min, 1 hr, 1 hr 30 min and 2 hours. After consuming each sample was analyzed using glucometer optium exceed and strips with LOT no: 49867 to produce a graph of glucose levels over time. The area under the resulting curve is measured, and it is called as incremental area under the blood glucose response curve, or IAUC.

**Step 4:** The test food was administered to the volunteers after they have been in fasting mode for at least 10-12 hours. The test was performed in the morning along with a drink of water which was often given with the test meal.

**Step 5:** The blood plasma glucose level for the next two hours was produced in a graph the same way as charted for 50gm glucose. The IAUC was also calculated similarly as glucose.
**Step 6:** By dividing the IAUC of the test food by the IAUC of the control food and multiplying it by 100. The GI of the test food for each test subject was calculated. (Annexure 3)

**Step 7:** The Mean was calculated by adding the sum and dividing by 10.

### 3.1.4 Calculations of Glycemic Index of each millet recipes

The incremental area under the curve (IAUC) was calculated for each meal in every volunteer separately (as the sum of the surface of triangles and trapezoids between the B-glucose curve and horizontal baseline going parallel to x-axis from the beginning of B-glucose curve at time 0 to the point at time 120 min) to reflect the total rise in B-glucose concentration after eating the tested food.

The IAUCS for the standard reference food (i.e. 50 g of pure glucose) was obtained, in the IAUC/IAUCS calculations, all B-glucose values in the course of the test lower than the first value (at time 0) were equalized to the respective first value. In each volunteer, the GI (%) was calculated by dividing the IAUC for the tested food by the IAUCS for the standard food and multiplying by 100.

**IAUC** – Incremental Area Under the blood glucose response Curve for the tested meal

**IAUCS** – Incremental Area Under the blood glucose response Curve for the standard meal
METHODOLOGY 2

Step 1 • 10 healthy volunteers were selected to perform a formal experiment. Since, Estimating glycemic index can only be done in a controlled environment with a control substance and the test food sample.

Step 2 • 50 gm of glucose in 200ml water was given to the samples (10 volunteers)

Step 3 • Blood glucose levels of the test subjects over the next two hours was noted. The blood plasma glucose level was recorded with the interval of 15 minutes increments (0 hr, 15 min, 30 min, 45 min, 1 hr, 1 hr 30 min and 2 hourly) to produce a graph of glucose levels over time. The area under the resulting curve was measured, and it is called the incremental area under the blood glucose response curve, or IAUC.

Step 4 • The test food to the test subjects after they have been in fasting mode for at least 10 hours was administered; the test was performed in the morning along with a drink of water which was often given with the test meal.

Step 5 • The blood plasma glucose level for the next two hours was plotted the same way as charted for 50gm glucose. The IAUC was also calculated same as glucose.

Step 6 • By dividing the IAUC of the test food and the IAUC of the control food then multiplying it by 100. The GI of the test food for each test subject was calculated.

Step 7 • Mean was calculated by adding the sum and dividing by 10

Fig 2: Estimation of Glycemic Index of standardized recipes (one from each millet group)
3.2 Phase II- Sample Selection

3.2.1 Identification of the tertiary diabetes centre

Preliminary Survey was conducted to collect more data about the topic, by consulting Professors from Minor Millet Scheme, Griha Krishi Vidhya Kendra (GKVK), Pristine Organics Bangalore and Personal training instructors, Health care professionals like doctors/ Diabetologist, Diabetes educators and Agriculturist from North Karnataka. Specialized Diabetes Center in and around Bangalore City was surveyed for the study. The survey was done through the information of Diabetes Centre provided in the Medical directory and through the members of Research Society for the study of Diabetes in India - Karnataka Chapter (KRSSID)

3.2.2 Locale of the Study

The intervention trials on volunteers for estimating Glycemic Index were carried out at Karnataka Institute of Diabetology, Jayanagar, Bannerghatta road, inside Jayadeva Institute of Cardiology Campus.

The intervention trail on type 2 Diabetics were carried out in various diabetes centers in and around Bangalore, Crease Diabetes Centre, Banashankari 2nd Stage, Bangalore, Nano Diagnostics J.P Nagar 1st Phase, Bangalore, Sathnur primary Centre and Manasa Hospital, Malur.(Annexure 5)

3.2.3 Identification of the Samples

A purposive randomized sampling method was adopted and the, study sample comprises of 250 Type 2 diabetics from both rural and urban areas of Bangalore, Karnataka. The age group of subjects was between 30-60 years with very minimal knowledge on diabetes and without any other associated complications like Heart Disease, Nephropathy, Neuropathy and Retinopathy and on only oral hypoglycemic agents.

Again these samples were sub-divided into control and experimental groups (50 subjects from each experimental group and 50 from control group)
each experimental group was subjected to specific millets like Pearl millet, Foxtail Millet, Finger Millet and Sorghum, with regular observation and reviews for 4 months.

3.3 Phase III- Standardization in Study Design

3.3.1 Rapport Building

A personal rapport was established with Type 2 Diabetics and their family members in order to create a comfort zone and elicit accurate basic information. Pre test was conducted to both experimental and control group to assess the Nutritional status, by examining anthropometry measures, biochemical parameters, dietary assessment along with existing knowledge, practices and attitude towards their Glycemic control using a standardized questionnaire.

3.3.1.1 Questionnaire/interview Schedule

A detailed questionnaire was prepared under the various headings such as general information, lifestyle pattern, anthropometric measurements, dietary history, frequency of food consumption, 24 hrs dietary recall, bio-chemical tests, medical history, physical activity. The questionnaire was then given to nutritionists, teaching faculties and statistics experts for their suggestions. Based on the expert suggestions, necessary modifications were accordingly made in the questionnaire. (Annexure 4)

- **Basic information**: Basic information of the respondents regarding age, sex, family income, type of family, qualification and contact details were collected.

- **Medical history**: Family history pertaining to type 2 diabetes and other degenerative diseases such as heart disease and hypertension

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Influence of minor millet and education intervention in the management of Type 2 diabetes mellitus
3.3.2 Assessment of Nutritional Status

Nutritional status of the respondents from both from experimental and control were analysed using ABCD approach (Gopalan et.al 2010)

3.3.2.1 Anthropometry

Anthropometric status of both male and female subjects included height (Ht), weight (Wt), waist, body fat percentage, muscle mass, bone mass water percentage and visceral fat. Anthropometric assessment included measurement and recordings of subjects at baseline and once / week for 16 consecutive weeks.

*Height:* The subjects were instructed to stands erect & bare footed on a stadiometer with a movable head piece. The head piece is levelled with skull vault and height is recorded to the nearest 0.5 cm.

*Weight and Body Composition:* The measurements for, weight, body mass index and body composition for all the subjects (%body fat, Muscle Mass, Bone Mass, water % and Visceral Fat) were measured using leg-to-leg bioelectrical impedance method (Tanita BC 420 MA, Tanita Corp., Tokyo, Japan), which has been validated for Asian children, adolescents and Adults.

For the estimation of bioelectrical impedance, subjects were evaluated after an overnight fast. They were instructed to avoid drinking fluids and void urine 1 h prior to the measurements and just before the test. Gender and height details were manually entered into the software of the apparatus. The subjects were instructed to stand on the base of the apparatus, so that both feet were in firm contact with the surface and that the hands were not touching any surface, the values were directly stored in the software and a print out was also been taken to give as reference to the subjects (annexure 8).

*Waist Circumference:* Waist circumference is measured at the level of the umbilicus to the nearest 0.5 cm.
The subjects were instructed to stand erect with relaxed abdominal muscles, arms at the side, and feet together. The measurements were taken at the end of a normal expiration.

Waist circumference predicts mortality better than any other anthropometric measurements.

3.3.2.1.1 Anthropometry Indices

The anthropometric status were interpreted using the indices like BMI and Body Composition, which are used in the community. It has been proposed that waist measurement alone can be used to assess obesity, and two levels of risk have been identified.

<table>
<thead>
<tr>
<th>Level</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>&gt; 94 cm</td>
<td>&gt; 80 cm</td>
</tr>
<tr>
<td>Level 2</td>
<td>&gt; 102 cm</td>
<td>&gt; 88 cm</td>
</tr>
</tbody>
</table>


Level 1 is the maximum acceptable waist circumference irrespective of the adult age and there should be no further weight gain. Level 2 denotes obesity and requires weight management to reduce the risk of type 2 diabetes & CVS complications.

Body Mass Index (BMI) is a simple index of weight-for-height that is used to classify underweight, overweight and obesity in adults. It is defined as the weight in kilograms divided by the square of the height in metres (kg/m²).
### The International Classification of adult underweight, overweight and obesity according to BMI

<table>
<thead>
<tr>
<th>Classification</th>
<th>BMI (kg/m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Principal Cut-off points</td>
</tr>
<tr>
<td>Underweight</td>
<td>&lt;18.50</td>
</tr>
<tr>
<td>Severe thinness</td>
<td>&lt;16.00</td>
</tr>
<tr>
<td>Moderate thinness</td>
<td>16.00 - 16.99</td>
</tr>
<tr>
<td>Mild thinness</td>
<td>17.00 - 18.49</td>
</tr>
<tr>
<td>Normal range</td>
<td>18.50 - 24.99</td>
</tr>
<tr>
<td>Overweight</td>
<td>≥25.00</td>
</tr>
<tr>
<td>Pre-obese</td>
<td>25.00 - 29.99</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Obese</td>
<td>≥30.00</td>
</tr>
<tr>
<td>Obese class I</td>
<td>30.00 - 34.99</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Obese class II</td>
<td>35.00 - 39.99</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Obese class III</td>
<td>≥40.00</td>
</tr>
</tbody>
</table>


#### 3.3.2.2 Biochemical Status

It is used to assess the body stores, usually altered by lack of nutrients or hormonal imbalances. In the present study Fasting, Post Prandial Blood Glucose and Glycosilated Hemoglobin (HbA1c) is estimated.

The fasting blood sugar and HbA1c test was performed after they have been in fasting mode for at least 10-12 hours; the post prandial blood sugar test was performed in the morning along with a drink of water which was often given with the breakfast meal.
HbA1c was performed to see the average glycemic control for 4 months duration at the beginning of the intervention programme to the end of the intervention.

A single venous blood sample was taken in the fasting state for both HbA1c and FBS and for post prandial, 2 hourly after consuming breakfast meal, later it was analysed using glucometer optium exceed and strips with LOT no: 49867 by a well-equipped NABL accreditation lab with well experienced lab technician. The blood sample was sent to a laboratory that uses an NGSP-certified method for analysis to ensure the results are standardized.

Normal values for Fasting and post prandial blood sugar

<table>
<thead>
<tr>
<th>Test</th>
<th>Normal value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FBS</td>
<td>70-110 mg/dl</td>
</tr>
<tr>
<td>PPBS</td>
<td>100 - 140 mg/dl</td>
</tr>
</tbody>
</table>

Adapted from ADA Guidelines 2011

The following table provides the percentages that indicate diagnoses of normal, diabetes, and prediabetes according to A1C levels.

<table>
<thead>
<tr>
<th>Diagnosis*</th>
<th>A1C Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>below 5.7 percent</td>
</tr>
<tr>
<td>Diabetes</td>
<td>6.5 percent or above</td>
</tr>
<tr>
<td>Prediabetes</td>
<td>5.7 to 6.4 percent</td>
</tr>
</tbody>
</table>

*Any test for diagnosis of diabetes requires confirmation with a second measurement unless there are clear symptoms of diabetes. Adapted from ADA Guidelines 2011

**Blood Pressure**

Blood pressure was measured using an automated electronic device by the procedure listed below:

- The type 2 Diabetics were ensured to sit or lay down for at least five minutes to relax.
• The diabetics were asked to remove any tight clothing from around her or his arm and supported at the level of her or his heart.

The diabetics were also given instruction to refrain from talking or eating during the procedure as this can result in an inaccurate higher blood pressure.

The readings of systolic and diastolic blood pressures were documented in the protocol for consistent reviews.

![Blood Pressure Chart]

Source: ADA guideline 2010

**3.3.2.3 Clinical Examination**

Indicates the signs and symptoms occurred due to any deficiency. In the current study clinical signs related to type 2 Diabetes such as Emaciation, Fatigue, Pallor of eye, breathlessness, Giddiness, Frequent Urination, Dry Scaly Skin, Sleep, Body ache, Burning sensation, Bowel Habits, Acidity and Indigestion were regularly examined.

Clinical Examination of the respondents were done by the researcher, who is also a Diabetes Educator.
3.3.2.4 Dietary Status

Nutrient Profile
Nutrient information was calculated using a pretested 24-hour food recall questionnaire prepared as per Asian Indian food articles according to the guidelines of (Gopalan et al., 2007), National Institute of Nutrition, Hyderabad, India. The first section of the questionnaire dealt with general information concerning the subject. The second section of the questionnaire dealt with dietary habits, frequency of eating out and the type and amount of fat used as the cooking medium. subjects were given separate typewritten handouts to be filled to assess the monthly consumption by the respondents and these data were randomly rechecked by telephone interviews. The third section includes frequency of consumption of various food which includes daily, weekly, bi-weekly and monthly basis. The fourth section of the questionnaire comprised the 24-hour nutrient intake, listing the details of morning tea, breakfast, mid-morning snack, lunch, evening tea, dinner and bedtime snack for 2 non-consecutive days, one of them a weekend. It was administered to all the subjects, and was recorded. Standardised sets of common utensils and cups, utilized in Indian households, were used to assess the portions of food articles.

Daily intake of nutrients was finally calculated by Data analysis of the dietary parameters which was carried out using software Care Dynamics developed by Seed Health Care. This software was previously used in the research studies and the standard nutritive values of Indian foods (Gopalan et al., 2007) were pre fed in the software for nutrients such as Energy, Carbohydrate, Protein, Fat and Fibre. (Annexure 9)

3.3.3 Physical Activity
24 hour recall interview method was used to record and administer physical activity using a standardized physical activity recall questionnaire (FAO, WHO, UNU, 1985) The number of hours spent on sleeping and undertaking moderate, hard, and very hard activities in the past day was recalled. The
remaining amount of time was not counted as it is presumed to have been spent in light activities, which was also recorded. Examples of the types of activities in each category were provided, and the recall was taken on weekend days and weekdays.

The data regarding physical activity was pre fed along with the energy expenditures in the software care dynamics, to evaluate the respondent’s activity level and TEE (total energy expenditure).

Using factorial method the database of the software gives the actual energy expenditure and along with the dietary recall it calculates and reports the total energy requirement of that particular respondent. Accordingly a tailor made diet chart was prepared and prescribed to all the respondents of experimental group.

3.3.4 Knowledge, Attitude and Practice
A set of questions were framed pertaining to diabetes and millets, to analyse the knowledge level of the respondents, attitude towards the disorder and their practices. These were useful to develop the education modules and decide with the type of intervention programme for the respondents accordingly.

Twenty statements regarding knowledge, ten statements regarding attitude and five statements regarding practice were framed pertaining to Millet, Nutrition and Diabetes. The range of response were Yes , No or Don’t Know (Annexure 4). Each response was given a score namely:

<table>
<thead>
<tr>
<th>Response</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td>Do not Know</td>
<td>1</td>
</tr>
<tr>
<td>No</td>
<td>0</td>
</tr>
</tbody>
</table>

Based on these scores the total score for nutrition knowledge Attitude and practice was computed. The total scores thus obtained by the respondents
was grouped into low, medium and high in both experimental and control groups. Mean and standard deviation were worked for combined sample the categories of low, medium and high was computed based on Mean ± SD

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>≤ 55</td>
</tr>
<tr>
<td>Medium</td>
<td>56-72</td>
</tr>
<tr>
<td>High</td>
<td>≥ 73</td>
</tr>
</tbody>
</table>

**3.4 Phase IV- Intervention Programme**

The intervention programme was conducted to the type 2 Diabetics of experimental group for 4 months with a daily review in the beginning of the study to build up the rapport, later was reviewed thrice in a week for 4 months. The type 2 diabetics were introduced to the education modules developed for the intervention programme through lecture method, individual counselling, visual aids, interaction sessions, Demonstrations and group discussions.

**3.4.1 Dietary Intervention**

Dietary intervention was conducted on the following aspects:

- **Recipe demonstration**: Standardized Millet recipes were demonstrated to the samples along with one on one counselling involving their family member for effective impact.

- **Diet Prescription**: Tailor made diet chart was prescribed to the experimental group irrespective of millets, considering their Age, BMI, current weight, Physical activity, Diet pattern, using Factorial Method (using the software Care Dynamics).

- **Incorporation of Millet in the day’s menu**: 4 exchanges of minor millets (Finger millet flour /Ragi flour, Sorghum /Jowar flour, Foxtail
millet/navanae rice, Pearl millet/Sajjae flour) in any of the meal in a day’s menu was advised for each experimental group of 50 samples for 4 months. These millets were packed in a zip-lock cover and was distributed once in 4 days with a help of a social worker who was appointed and trained to monitor their consumption on a regular basis.

- **Dietary Review**: a daily review in the beginning of the study was done to build up the rapport later was reviewed thrice in a week for 4 months so as to ensure whether the samples are consuming the meal as per recommendation.

### 3.4.2 Education Intervention

Diet and medication alone can’t do magic as it is a collaborative approach, for an effective glycemic control education intervention is also important which involved:

- **Education tools and Modules**: The tools and Modules were formulated by referring various journals, books, literature survey and browsing websites for the intervention programme. The tools and modules were designed wherein it was self-explanatory and more of audio visuals like PowerPoint presentations, recipe book and Tiffin/Lunch box modules. Formulated tools were given to panel of experts and their inputs were considered and modifications done accordingly before conducting the study. The above mentioned tools formulated in English was translated to local language (Kannada) to evolve better response

- **Dramatization**: A theme on type 2 diabetes was selected and with the involvement of the localities along with the sample from experimental group a street play was performed, so that the final message from the concept would easily reach the respondents.
• Lectures: Nutrition Experts, Diabetes Educators and Diabetologist were invited to give a lecture on diabetes and their management.

• Diabetologist consultation: Diabetologist were also invited once in a month for consultation, to advice medication and have a routine check up. (Annexure 10)

• Feedback after the Intervention: A feedback of the intervention programme was obtained from the diabetics at the end of each session, so that to improvise the method (Annexure 11).

• Post Test: Post test was conducted to both control group and experimental group to assess their Nutritional status along with knowledge, attitude, practice and glycemic control after the intervention programme. By using a standardized questionnaire for anthropometry indices, biochemical parameters, clinical and dietary evaluation, which was used in the pre-test, so as to assess the effectiveness of the intervention programme.
METHODOLOGY 3

Randomization of Sample

Pre-test
- Collection of general information
- Anthropometric assessment
- Biochemical Investigation
- Clinical Status
- Dietary Status

Control Group
n = 50
Exposure to
Normal diabetic diet without incorporating any of the millets for 4 months

Experimental Group n = 200
(50 each for individual millet)
Exposure to
Incorporating individual millet in a day’s menu (4 exchanges in any of the meal) for 4 months respectively.

Post-test
Anthropometric assessment every month once for a period of 4 months
Biochemical Investigation after 4 months of intervention

The Data were subjected for statistical analysis

Fig 3: Standardized Study Design

Influence of minor millet and education intervention in the management of Type 2 diabetes mellitus
3.5 Phase V - Statistical Analysis

Statistical tools used in this research study are as follows:

3.5.1 Descriptive Statistics

Number, percentage, mean and standard deviation

3.5.2 Inferential Statistics

a) Chi-square Test: The chi-square test is generally used to evaluate differences between experimental or observed data and expected or hypothetical data. It is used to measure the association between control and experimental group for demographic data. The formula for calculating Chi-square ($\chi^2$) value is affixed in Annexure 12 (a)

b) Paired ‘t’ Test: The paired t-test, also referred to as the paired-samples t-test or dependent sample t-test, is used to determine whether the mean of a dependent variable (weight, BMI, fat (%), waist and hip circumference) is the same in two study groups (pre and post). The formula used for paired ‘t’ test is affixed in Annexure 12 (b)

c) The Student’s t-Test: Is one of the important statistical test which is used to measure the significant difference in the mean values of two groups (control and experimental group). The formula used for student’s ‘t’ test is affixed in Annexure 12 (c)

3.5.3 Analysis of Variance (ANOVA)

This test compares the means of two or more samples and tests whether they belong to the same population (i.e., they are all the same); or whether they come from different populations (i.e., one or more are different). ANOVA is generally used in sensory evaluation of products. It has been used to test the significant difference between calcium beverages with respect to sensory components. The statistics used in the procedure of ANOVA is ‘F’ test. The formula for calculating ‘F’ value is affixed in Annexure 12 (d)
3.5.4 Correlation Analysis:

Karl Pearson’s correlation coefficient (r), is used to measure the relationship between two interrelated variable i.e, one dependent and other independent variable. The formula for calculating correlation is given in Annexure 12 (e)

Note: The study was approved by the Institutional Bioethics Committee involved (Nutri-Explore ethics committee, Bangalore University Study No: NEEC 005) (Annexure 5) and subjects were also given informed consent (Annexure 6).