3

METHODOLOGY

The research design pertaining to the study "**OBESITY RELATED HEALTH RISKS AND ITS IMPACT ON DIETARY INTERVENTION AND LIFE STYLE MODIFICATION**" is presented under the following headings.

Phase I

A. Selection of locale
B. Selection and grouping of subjects
C. Formulation of the tool for the conduct of the study

Phase II

A. Demographic profile of the selected subjects
B. Nutritional status of the selected subjects
   a. Anthropometric measurements
   b. Recording individual food and nutrient intake
   c. Analysis of biochemical parameters

Phase III

A. Selection of the ingredients for the supplement
B. Formulation and organoleptic evaluation of the selected supplement
   a. Formulation of the supplement
   b. Organoleptic evaluation of the selected recipes
C. Analysis of the supplement

Phase IV

A. Orientation to the selected subjects on dietary intervention
B. Dietary intervention for the selected female subjects
C. Lifestyle modification for the selected female subjects
D. Evaluation of the effect of intervention among the selected female subjects
E. Consolidation and analysis of data

PHASE I

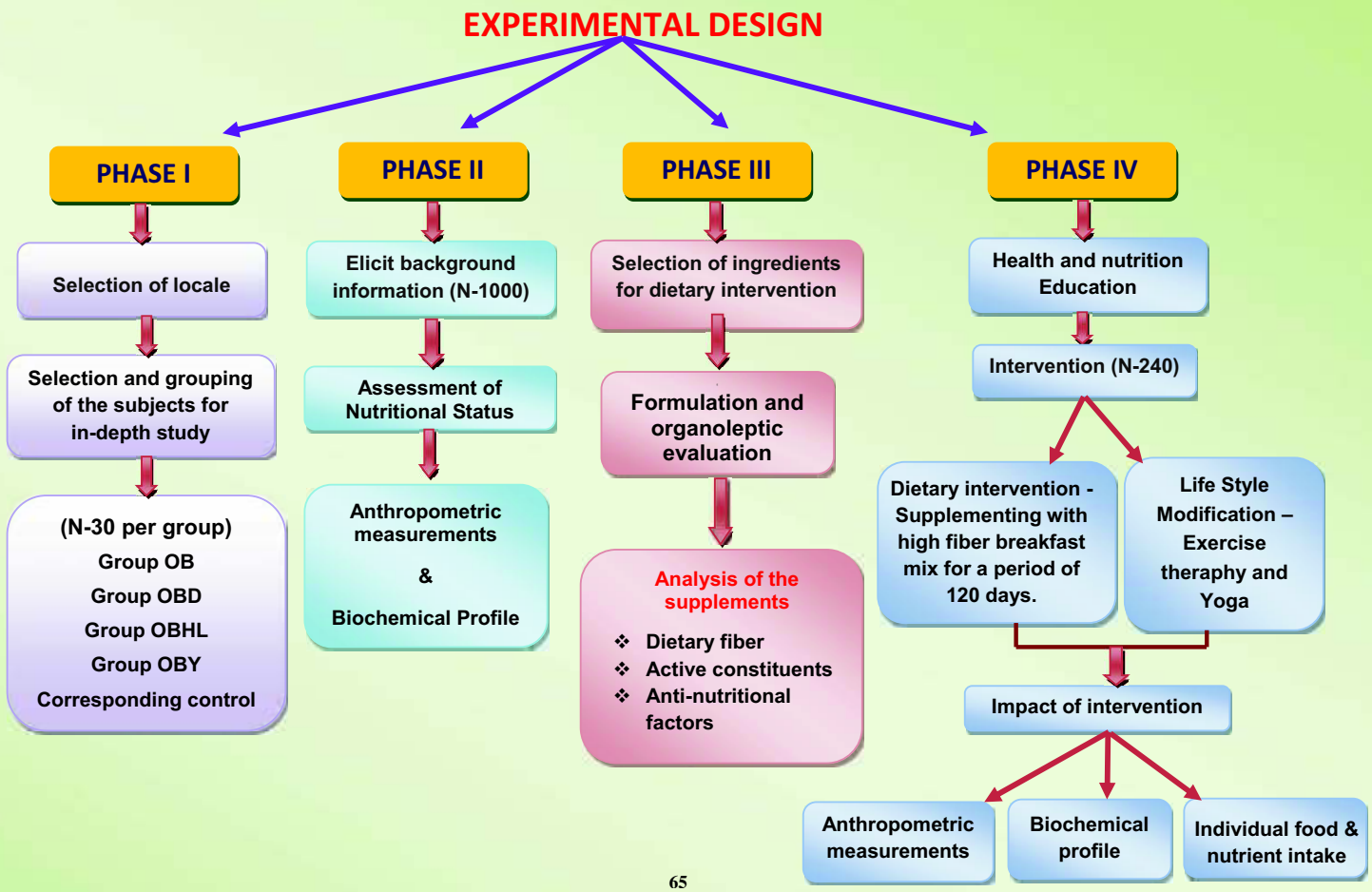
A. SELECTION OF LOCALE

A famous cardiac clinic namely Preetham Cardiac Care in Coimbatore, KR Hospital in Karamadai and KPS Hospitals in Mettupalayam town near Coimbatore were selected as venue for the present study. These hospitals were selected on the basis of easy accessibility and availability of adequate number of obese subjects and they were periodically visiting the hospital for their regular check-ups. The subjects visiting the hospital are from in and around Coimbatore and Mettupalayam. The subjects were very cooperative and gave their consent to participate in the present study. The hospitals have well equipped laboratory with all modern and sophisticated instruments for the analysis of blood parameters. The hospital authorities, doctors, dietician, nursing staff and technicians extended their help and co-operation for the investigator throughout the study period.

B. SELECTION AND GROUPING OF SUBJECTS

For the study, 1000 subjects in the age group of 40- 60 years from both sexes and whose BMI ≥ 30 and total cholesterol level ≥ 200mg/dl based on their willingness to participate were selected for screening. The selected subjects were given orientation regarding the protocol of the study and also briefed on the modalities and purpose of the study. They were also informed about the supplementation and follow-up to be carried out for four consecutive months and the subsequent anthropometric and biochemical assessment before and after the intervention period of 120 days.

Among the 1000 subjects selected, a subsample of 240 (120 experimental and 120 control) female subjects whose age group is between 40- 60 years having BMI ≥ 30 and total cholesterol level ≥220 mg/dl and willing to give consent for intervention study were chosen for the in-depth study.


EXPERIMENTAL DESIGN
PHASE I
Selection of locale
Selection and grouping of the subjects for in-depth study
(N-30 per group)
Group OB
Group OBD
Group OBHL
Group OBY
Corresponding control
PHASE II
Elicit background information (N-1000)
Assessment of Nutritional Status
Anthropometric measurements
&
Biochemical Profile
PHASE III
Selection of ingredients for dietary intervention
Formulation and organoleptic evaluation
Analysis of the supplements
Dietary fiber
Active constituents
Anti-nutritional factors
PHASE IV
Health and nutrition Education
Intervention (N-240)
Dietary intervention - Supplementing with high fiber breakfast mix for a period of 120 days.
Life Style Modification – Exercise theraphy and Yoga
Impact of intervention
Anthropometric measurements
Biochemical profile
Individual food & nutrient intake

The selected subjects were divided into four groups of 60 subjects in each group, (experimental (N-30) with corresponding control group (N-30). The first three experimental groups were obese group (OB Group), obese subjects with diabetes (OBD Group) and obese subjects with hyperlipidemia (OBHL Group) were selected for dietary intervention with their corresponding control groups. The fourth experimental group namely OBY group was selected for dietary and lifestyle intervention which has its own similar control group. The groups selected were tabulated below in Table I.

TABLE I

GROUPING OF THE SUBJECTS FOR INTERVENTION STUDY

Experimental Group (N-30/group)	Mode of intervention
Group I- OB (Obese)	Dietary intervention
Group II –OBD (OB + Diabetes)	
Group III-OBHL (OB+ Hyperlipidemia)	
Group IV- OBY (Obese)	Dietary and Lifestyle intervention

Control Group (N-30/group)	Mode of intervention
Group I- OB (Obese)	Nil
Group II –OBD (OB + Diabetes)	
Group III-OBHL (OB + Hyperlipidemia)	
Group IV- OBY (Obese)	

The criteria used for grouping of the subjects for intervention study are as follows:

Inclusion Criteria

- Female subjects in the age group between 40-60 years
- Willing to give consent to take the supplements regularly for a period of four months
- BMI ≥ 30
- Waist to hip ratio ≥ 0.90
- Serum total cholesterol level ≥ 220 mg/dl
- Fasting Blood Glucose (FBG) level ≥ 120 mg/dl
- Periodically visiting the doctors for checkups.
- Free from other complications.

Exclusion Criteria

- Age group < 40 and more than 60 years
- Waist to hip ratio < 0.90 and more than1.4
- Serum total cholesterol level< 200 mg/dl
- Fasting Blood Glucose (FBG) level <120 mg/dl
- Presence of complications and disorders
- Taking too many medicines
- Having cholesterol levels > 320mg/dl
- Inpatients and out patients who are in need of immediate medical care.
- Irregular check-ups.
- Not willing to give consent to participate in the present study.

C. FORMULATION OF THE TOOL FOR THE CONDUCT OF THE STUDY

According to Kothari (2011) interview method of collecting data involves presentation of oral –verbal stimuli and reply in terms of oral- verbal responses.

Personal interview is a survey method of data collection which employs a questionnaire. The components of the personal interview are the researcher, the interviewer, interviewee and the interview environment (Pannerselvam, 2006). A well-structured interview schedule was formulated to elicit background information about the selected subjects.

PHASE II

A. DEMOGRAPHIC PROFILE OF THE SELECTED SUBJECTS

The demographic profile, lifestyle pattern, dietary pattern and also personal and family history were recorded for all the 1000 subjects using an interview schedule.

The background information such as name of the subject, age, sex, educational qualification, occupation, activity pattern, income level, type and composition of the family was collected. The information on food habits and dietary practices were recorded. A 24- hour recall method was used to record the dietary intake of the subjects.

The lifestyle pattern such as exercise pattern, smoking habits, alcoholic habits, consumption of tea, coffee, health drinks, tobacco, and pan masala were collected using the interview schedule. The details of family history, frequency of diseases, symptoms and complications experienced were also recorded.

B. NUTRITIONAL STATUS OF THE SELECTED SUBJECTS

a. Anthropometric measurements

Anthropometry is the universally applicable, inexpensive and non-invasive method available to assess the composition of fat distribution in the human body. Combined with the dietary, questionnaire data, and the biochemical determinations, anthropometry is essential to assist in describing the data collected from persons. It reflects both health and nutritional status and predicts performance, health and survival (Ray *et al*., 2011). Hence, it is used in various intervention programmes to monitor health and nutrition status of the selected population. Among the various anthropometric measurements, height, weight, body mass index and waist to hip ratio were recorded for all the 1000 subjects to obtain reliable data.

i. Measurement of Height

The measurement of height is a standard component of most fitness assessments. Subjects were asked to stand erect on a flat surface with heels together and upper limbs hanging closely to the sides of the body. The investigator stood on the left side of the subject. The anthropmeter rod (after assembling the four pieces and the sliding head piece properly), held in the right hand, should be placed at the back of the subject, touching heels, buttocks and back of the head. The chin of the subject should be held by the left hand and the occipital protuberance is supported by the little finger of the right hand, while holding the rod with thumb and index finger. The head should be positioned such that the imaginary line drawn from tragus of the ear to the infra-orbital margin i.e. lower border of the socket of the eye (Frankfurt horizontal plane) is parallel to ground.

By holding the head in this position, a gentle upward pull is applied (taking care that the subject does not lift his/her heels) to straighten any curvature in the spinal cord. Then the sliding head piece of the rod was brought down so as to

touch the crown firmly pressing the hair, taking care that the blade is in the sagital plane (mid-line of the body). At this juncture, the height was read from the window of the headpiece. This process was repeated thrice and the consistent reading was obtained. Height was recorded in cms, up to the nearest mm (ICMR, 2011).

ii. Measurement of weight

Body weight is the most widely used simplest reproducible anthropometric measurement for the evaluation of nutritional status of the population. It is a more sensitive measure of nutritional adequacy than height and reflects recent nutritional status. Weight also provides a crude evaluation of overall fat and muscle stores.

For reliability, weight was recorded in the morning (12 hours since eating). Body weight can be affected by fluid in the bladder (weigh after voiding the bladder). Other factors to consider are the amount of food recently eaten, hydration level, the amount of waste recently expelled from the body, recent exercise and clothing.

To record the actual body weight, the subjects were made to stand on the platform of the digital electronic weighing balance without footwear with minimal clothing, ensure that he/she does not hold any other person for support (Ray *et al.,* 2011). Weight was recorded in kg to the nearest 100g for the selected 1000 obese subjects.

iii. Body Mass Index (BMI)

Several indexes and ratios can be derived from anthropometric measurements. Perhaps the most well-known indicator of body fatness is the Body Mass Index or “BMI. According to WHO, BMI is s simple index of weight and height that is commonly used to classify underweight, over weight and obesity in adults. The BMI was calculated to find out the grade of obesity of the selected subjects. The body mass index (Quetelet index) was calculated by dividing the individual’s weight in kilogram by the square of his or her height in meters.

After the computation of BMI, subjects were classified according to the norms given by the ICMR (2011) as mentioned below in Table II.

TABLE II

CUT OFF VALUES FOR DIFFERENT GRADES OF OBESITY

BMI classification*	Obesity grade
18.50 – 24.99	Normal
≥25.00	Overweight
25.00-29.99	Pre obese
30.00- 32.49	Mild Obese class I
32.50-34.99	Moderate Obese class I
35.00- 37.49	Mild Obese class II
37.50-39.99	Moderate Obese class II
≥40.00	Obese class III

** Ray et al., 2011 (NIN – Methodologies for fitness assessment, 2011).*

iv. Measurement of Waist and Hip circumference

The Waist Hip Ratio (WHR) has been used as an indicator or measure of the health of a person, and the risk of developing serious health conditions. Research shows that people with "apple-shaped" bodies face more health risks than those with "pear-shaped" bodies. WHR used as a measurement of obesity is a possible indicator of other more serious health conditions (WHO, 2008).

❖ **Waist circumference**

In the recent past, particularly with increasing incidence of obesity, considering the significance of abdominal adiposity in diet related chronic diseases, waist and hip circumferences were used to evaluate the abdominal adiposity in subjects. The subjects were asked to stand erect with weight evenly balanced on both feet placed about 25-30 cms apart. Mark the level of the lowest rib margin. The iliac crest in the mid axillary line was felt and a mark was made. The measuring tape was passed around the waist horizontally midway between the lowest rib margin and the iliac crest and the circumference in cms was measured up to the nearest mm. The observer was made to sit on a stool in front of the

subject while taking the measurement. All the adult males with waist circumference of ≥ 102cm and women with ≥ 80cm were identified as the abdominal obese (ICMR, 2011).

❖ **Hip circumference**

For measuring the hip circumference, a tape was placed horizontally over the buttocks and the circumference was measured at the point yielding the maximum circumference in cms up to the nearest mm. The waist circumference should be taken at the narrowest circumference between the ribs and hips (Mrkedal, 2011).

All the adult men with the waist to hip ratio of ≥ 0.90 and women with ≥ 0.85 will be identified as obese. For all the selected 1000 subjects WHR was computed by dividing subject's waist circumference in cms by hip circumference in cms and compared with the standard values.

b. Recording individual food and nutrient intake

Dietary survey constitutes an essential part of any complete study of nutritional status providing essential information on nutrient intake, sources of nutrients, food habits and attitudes. The aim of any dietary survey is to find out the habitual nutrient intakes of individuals.

The 24-hour recall method has been widely used in population studies. It was used to find out the quantity of foods consumed by the selected subjects. Subjects are asked to recall all food and drink consumed over a specified period, usually 24 hours. Questions are asked about each eating occasion, starting with early morning going through the entire day and including night time. The raw equivalents were calculated to find the food and nutrient intakes of the subjects (ICMR, 2010). The cooked amount of each food item consumed by the subject was then converted back into raw foodstuff using the formula given below. These raw quantities of various food stuffs consumed through different food preparations were calculated and summed up so as to obtain the total consumption of a particular food item during the past 24-hour period.

$$R_i = \frac{T_R \times C_I}{T_C}$$

Where R_i = Raw amount of a particular foodstuff consumed by the individual from a given preparation

T_R = Total raw quantity of the foodstuff used in that preparation

C_I = Intake of the cooked amount of that preparation

T_C = Total cooked quantity of the food prepared

The nutrient intake of the subjects was computed for the experimental (N-15) groups and control (N-15) groups using the food composition table as per Nutritive Value of Indian Foods (2012) and compared with their recommended dietary allowances.

c. Analysis of biochemical parameters

Davidson (1990) has reported that biochemical estimation is the most sensitive indicator of the health condition of an individual.

❖ **Blood glucose**

Subjects selected for the intervention study were asked to come to the biochemical laboratory in the respective hospital early morning around 7 o' clock after 12 hours of fasting to give the blood sample. A sample of five millilitre of blood was collected with the help of a technician and analyzed for fasting blood glucose level and glycosylated haemoglobin, and then the subjects were asked to consume the breakfast. Two hours after the breakfast consumption, another sample of blood was collected and analyzed for the post prandial blood glucose level. Blood glucose was estimated by GOD-PAP method

Enzymatic calorimetric determination of glucose (GOD PAP)

$$\text{Glucose} + O_2 \xrightarrow{\text{Glucose Oxide}} \text{Gluconic acid} + H_2O_2$$

$$2H_2O_2 + \text{Phenol} + \text{4-Aminoantipyrine} \xrightarrow{\text{Peroxidase}} \text{Red quinine} + 4H_2O$$

❖ Glycosylated haemoglobin (HbA_1C)

Sugar in the blood stream can become attached to the haemoglobin in red blood cells. This process is called glycosylation. Once the sugar is attached, it stays there for the life of the red blood cell, which is about 120 days. The higher the level of blood sugar more is the sugar attached to red blood cells. The HbA_1C test measures the amount of sugar sticking to the haemoglobin in the red blood cells. Thus the HbA_1C test can measure the amount of glycosylation that has occurred revealing the average blood glucose levels during the preceding three to four months before the test. The important advantage of HbA_1C testing is that the sample can be drawn at any time, because it is not affected by short term changes like food intake, exercise, stress and hypoglycemic agents. HbA_1C can delay or prevent the development of serious eye, kidney and nerve disease in people with diabetes.

Glycosylated haemoglobin was estimated by chromatographic – spectrometric ion exchange method for the experimental and control groups.

❖ Serum lipid profile

From each subject, five ml of blood sample was collected from the antecubital vein preferably before breakfast to avoid the influence of food digestion on blood composition. Care was taken to avoid hemolysis during the collection of blood for serum separation. Blood was allowed to clot for nearly 3 hours at room temperature. Then the clot was centrifuged and supernatant serum was removed and stored in well stoppered bottles in a freezer and used for the analysis of lipids.

Estimation of Total Cholesterol (TC) and High Density Lipoprotein Cholesterol (HDL-C) was done using the enzymatic method suggested by Friedwald (1972). In this procedure, serum low density lipoprotein and very low density lipoprotein are selectively precipitated by Mg^{2+} ions and phosphotungstate and removed by centrifugation. Cholesterol associated with HDL fractions remaining in the solution was carefully estimated by enzymatic method.

Triglycerides were estimated using the enzymatic method, suggested by Friedwald (1972). The intensity of the colour developed is directly proportional to the triglyceride concentration and was measured photometrically at 540nm.

Very Low Density Lipoprotein (VLDL) cholesterol level was calculated from the estimated triglyceride level using the following formula.

$$\text{VLDL cholesterol} = \frac{\text{Triglyceride}}{5}$$ where 5 is a constant factor

The Low Density Lipoprotein (LDL) cholesterol values were calculated from high density lipoprotein cholesterol, total cholesterol and VLDL cholesterol values using the following formula.

LDL cholesterol = Total cholesterol – (HDL cholesterol + VLDL cholesterol)

For all the selected 1000 obese subjects the above mentioned blood profile were noted from the hospital record at the start of the study period to select the subjects for the nutrition intervention.

The biochemical indices of metabolic control (Blood sugar- Fasting, Postprandial, HbA_1C and Total cholesterol, LDL Cholesterol, HDL Cholesterol, VLDL Cholesterol and Triglycerides) of the selected 240 female obese subjects (Experimental and control groups) were analyzed using the above procedure to find out the effect before and after the intervention period.

PHASE III

A. SELECTION OF THE INGREDIENTS FOR THE SUPPLEMENT

Dietary fiber and whole grains contain a unique blend of bioactive components including resistant starches, vitamins, minerals, phytochemicals and antioxidants. As a result, research regarding their potential health benefits has received considerable attention in the last several decades.

Bran from a wide array of cereal grains have been shown to have an effect on postprandial glucose levels, serum cholesterol, colon cancer, and body mass (Ulmius *et al.,* 2009). Keeping all this in mind the investigator selected the below listed ingredients for the supplementation. The details about the foods selected for the supplementation are given below.

❖ **Green Gram**

Scientific name	*Vigna radiata*
Native	Indian subcontinent
Active constituents	Enzymes - Phosphoglucomutase, arabinolunase, galactokinase; Saponins - saponin I, II and III.
Action	Tonic, diuretic, laxative and galactagogue.
Diseases that may be cured	Polyuria, fever, appendicitis and inflammations.
Functions	• Promotes bone health, reduce some menopausal symptoms, • anti-inflammatory benefits, regulate fat metabolism, hormones, and central nervous systems

Cereal proteins are deficient in lysine and tryptophan whereas pulse proteins are very good source of lysine. Hence, blending cereal with pulses in suitable proportions compliments the essential amino acids and forms proteins of high biological value. Both cereal and pulse also contain a few non-nutritive phyto-chemicals and micronutrients. (Malleshi, 2001). So it was thought that it would be worthwhile to consider a supplementation study with selected cereal and pulse in combination with brans.

❖ **Wheat and wheat bran**

Scientific name	*Triticum aestivum*
Native	Near East and Ethiopian Highlands
Active constituents	Gliadin protein, Gluten, fiber, lignans, manganese
Action	Antioxidants, Laxative, Phytonutrient
Diseases that may be cured	Diabetes, Hypercholesteremia, hyper tension, obesity
Functions	❖ Controls obesity (especially in women) ❖ Controls Type 2 diabetes ❖ Reduces chronic inflammation ❖ Prevents gallstones ❖ Promotes women's gastrointestinal health ❖ Protects against breast cancer ❖ Protects against coronary diseases

Wheat has a natural property of controlling weight amongst all. Dietary intake of beta-glucans is potentially beneficial in the treatment of diabetes and associated cardiovascular risks. Studies have shown that beta-glucans could reduce hyperglycemia, hyperlipidemia, and hypertension. Diet rich in high-fiber is a healthy way to control high blood sugar.

PLATE I

INGREDIENTS SELECTED FOR THE SUPPLEMENT

Oat bran

Whole wheat

Wheat bran

Green gram

❖ **Oat Bran**

Scientific name	*Avena sativa*
Native	Indian subcontinent
Active constituents	Enzymes, Lignans , beta-glucan, dietary fiber
Action	Antioxidants, phytonutrient
Diseases that may be cured	atherosclerosis, ischemic stroke, diabetes, insulin resistance, obesity, and premature death
Functions	• Beneficial action on reducing cholesterol. • Preventative action against diabetes • Protecting against cancer of the colon and rectum. • Fight against excess weight. • Benefits gluten intolerant people

Oat beta-glucan lowered postprandial glycemia (Tappy *et al.*, 1996; Jenkins *et al.*, 2002). It was also shown that oat bran flour was more effective than oat bran crisp. The effect of beta-glucans to reduce blood glucose could be mediated possibly by delaying stomach emptying so that dietary glucose is absorbed more gradually. Oats were first found to have a cholesterol-lowering effect and the active component was identified as beta-glucans (Jenkins *et al*., 2002). Oats reduced both serum total cholesterol and LDL cholesterol. Many of the foods that contain fiber also contain antioxidants which are generally good for cells and overall health. Soluble fiber from oats lowers cholesterol levels in the blood. Oat bran as a cereal does not contain gluten a type of sugar; it is harmless for people suffering from digestion related disorders.

B. FORMULATION AND ORGANOLEPTIC EVALUATION OF THE SELECTED SUPPLEMENT

a. Formulation of the supplement (high fiber breakfast mix)

Supplements were tried out using cleaned whole wheat, green gram, wheat bran and oat bran. The selected foods were cleaned, dried, roasted and powdered

separately. For standardization, this mix was tried in different combinations and made up to 100g keeping in mind their nutrient content including dietary fiber, cost of the mix and suitability for various recipes. The combinations tried were tabulated below in Table III.

TABLE III

COMPOSITION AND NUTRIENT CONTENT OF THE SUPPLEMENT

Ingredients	Weight (g)	Nutrients					Cost (Rs)
		Energy (Kcal)	Protein (g)	Fat (g)	Carbohydrate (g)	Fiber (g)	
Variation A							
Oat Bran	10	272.17	18.26	2.3	67.46	14.51	5.44
Wheat Bran	10						
Whole Wheat	40						
Green Gram	40						
Variation B							
Oat Bran	20	**235.54**	**18.76**	**3.4**	**70.92**	**16.90**	**6.68**
Wheat Bran	20						
Whole Wheat	30						
Green Gram	30						
Variation C							
Oat Bran	25	256.49	19.02	3.96	72.7	18.16	7.30
Wheat Bran	25						
Whole Wheat	25						
Green Gram	25						
Variation D							
Oat Bran	30	251.84	19.28	4.53	74.48	19.38	7.92
Wheat Bran	30						
Whole Wheat	20						
Green Gram	20						
Variation E							
Oat Bran	40	241.67	19.79	5.64	77.98	21.74	9.16
Wheat Bran	40						
Whole Wheat	10						
Green Gram	10						

From the above combinations tried, Variation A contains 272.17 kilocalories of energy, 18.26 g of protein, 2.3 g of fat, 67.46 g of carbohydrate and 14.51g of fiber but this combination was not accepted as it do not suit well for the recipes tried. The nutritive value of 100g of the variation B mix reveals that it provides 235.54 kilocalories of energy, 18.76 g of protein, 3.4 g of fat, nearly 71 g of carbohydrate and 16.9 g of fiber. It is clear that the mix provides one third of the daily requirement recommended by ICMR (2011) for an Indian adult woman.

Variation C and D supplied more fiber ie 18.16g and 19.38 g respectively and were unacceptable because of the texture and flavour of bran and these combinations were not suitable for human consumption, similarly they provide more calories and fat than the recommended allowances. The cost of the mix works out around Rs 7.30 for variation C and Rs 7.92 for variation D. The investigator thought that excess calorie and fat may induce weight gain and those combinations may induce various side effects such as constipation and diarrhoea it was also quite costly and it is difficult to afford per individual daily. Thus variation C and D were rejected as they were not suitable for human consumption.

With regard to variation E, it provides 241.67 Kcal, 19.79g of protein, 5.64g of fat, 77.98 g of carbohydrate and 21.74g of fiber. This combination provides more fiber and more fat. Also the cost of this combination was Rs 9.16 per 100g which was very high when compared with the other combinations and thus this combination was eliminated. Finally the investigator decided that variation B would be suitable for the selected obese subjects as that would supply required calorie and fiber for an adult individual. Further this was also cost effective and suitable for the selected recipe preparations.

b. Organoleptic evaluation of the selected recipes

Sensory evaluation is a multidisciplinary science that involves human panelists and their senses of sight, smell, taste, touch and hearing to measure the sensory characteristics and acceptability of food products. Thus the quality of food is judged in terms of appearance, color, taste, texture and flavour (Chandrasekhar, 2002).

For the organoleptic evaluation of these recipes, the investigator tried with 100 g of the formulated mix and compared it with the standard recipe. This powder was tried in different ratios for various recipes like pongal, roti, kitchadi, adai, chapathi, upma, dosa and porridge. The above mentioned combinations were prepared in the foods laboratory of Avinashilingam Institute for Home Science and Higher Education for Women University, Coimbatore. The average scores obtained are given in Table IV.

TABLE IV

ORGANOLEPTIC EVALUATION OF THE SELECTED RECIPES

Recipes	Criteria						Total Score (Max-30)
	Appearance	Texture	Flavour	Colour	Taste	Overall acceptability	
Chappathi	4.5	4.4	4.6	4.4	4.4	4.4	26.7
Adai	4.6	4.3	4.5	4.5	4.4	4.4	26.7
Dosa	4.0	4.2	3.8	4.6	4.8	4.1	25.5
Roti	3.3	3.2	3.7	3.8	3.2	3.0	20.2
Kitchadi	3.9	2.0	2.0	2.0	3.1	3.9	16.9
Uppma	2.1	3.1	2.7	3.4	3.3	2.9	17.5
Porridge	2.2	2.0	1.9	3.0	2.0	2.1	13.2
Pongal	2.0	2.0	2.7	2.0	2.0	2.0	12.7

To evaluate these recipes as a first step recipes namely porridge and pongal were eliminated because of the dominated flavour of the bran in these recipes, the texture of these two recipes was not acceptable with low score of 13.2 and 12.7 respectively. The recipes kitchadi and uppma had the score of 16.9 and 17.5 respectively and these two were also eliminated because it required more oil for preparing when compared to other recipes and was not in the acceptability range. Finally the recipes such as chappathi, adai, dosa and roti with their total scores of 26.7, 26.7, 25.5 and 20.2 respectively, nearer to the scores (maximum 30) obtained for the standard recipes. The appearance, texture, flavour, colour and taste were all in the acceptable range. These recipes were selected as they can be cooked with less oil or no oil.

PLATE II

FORMULATED RECIPES FOR THE SUPPLEMENT

Chappathi

Rotti

Dosa

Adai

C. ANALYSIS OF THE SUPPLEMENT

The selected supplement was analysed for total dietary fiber, dietary fat, active constituents, essential fatty acids, total sugars and anti-nutritional factors for its suitability for human feeding trials in the Stanes Herbal Division and Phyto Pharma Testing Lab, Coimbatore using standard procedures and just to confirm the results one more sample was also analysed by the SGS India Pvt Ltd, Chennai both are NABL accredited laboratories.

PHASE IV

A. ORIENTATION TO THE SELECTED SUBJECTS ON DIETARY INTERVENTION

Education campaigns were conducted at the selected locale which enabled the investigator to select 1000 subjects and also proceed with the supplementation study. Awareness campaigns really helped the investigator to map out the subjects and carry out the study in easy and quick manner. This method of conducting the campaigns proved very effective and fast when compared to meeting the subjects individually and explain them about the present study.

To conduct awareness campaigns to the participants the authorities of the hospitals/ clinics helped by providing place and other facilities to the investigator. As a first step an invitation for the conduct of educational campaign was sent to all the selected obese subjects. This was done with the help of the doctors and their assistants. Numerous pictures relating to concepts were collected from books, journals, pamphlets and materials available with doctors and dieticians. Slides were also developed with the help of collected resources. The developed slides consisted of the following heads; Introduction to obesity, prevalence, symptoms, classification, causes, diagnosis, risk factor, complications, role of the supplement in reducing the weight and bad cholesterol, significance of dietary fiber, management of diabetes by means of diet, drug, exercise, education and monitoring of blood glucose.

PLATE III

PROCESSING AND PACKING OF THE SUPPLEMENT

Milling

High fiber rich mix

Packing

Distribution

The awareness campaign was well organized with the developed slides. These campaigns gave the investigator an opportunity to:

- Provide general information on selection of foods for proper health and adequate amount of food intake to maintain energy needs and the importance of fiber rich diet.
- Educate on the nature of the disease and the possibility of development of acute and long term complications like diabetes and hypercholesterolemia, if weight, blood sugar and serum cholesterol are not kept under control.

- Create awareness and to explain the importance of good dietary habits, exercise pattern, yoga practice for the management of obesity.

- Impart knowledge on nutritional significance and health benefits of foods included for the supplementation study.

- The subjects who were willing to join the intervention programme were briefed about the modalities of the study and written consent was obtained from them. This was considered as a precautionary measure to make sure that the subjects fully understood the nature of the study and their role in it.

They were also briefed during their regular visits about the blood test to be taken before and after the supplementation period of 120 days. The subjects selected for the human feeding trials visit the hospitals in the specified dates to have their fasting blood glucose level and the total lipid profile level checked. After their breakfast they stayed back to have their post prandial blood glucose check-up done. During their visits they were given the supplements for the next consecutive period of 15 days.

B. DIETARY INTERVENTION FOR THE SELECTED FEMALE SUBJECTS

Diet had a profound role in the control of obesity and its risk factors like diabetes and hypercholesterolemia. A holistic approach to tackle obesity epidemic needs an array of activities which includes dietary management which aims at

weight maintenance or weight loss without compromising appropriate calorie intake and normal nutrition. Due emphasis should be given to initiate and maintain healthy eating patterns. After analyzing the selected supplements using various parameters (dietary fiber, active constituents and antinutritional factors), three different groups were subjected to study the effect of supplementation of high fiber foods on obesity. For each group 60 obese subjects (Experimental-30 and control-30) were selected for dietary intervention. To find out the individual acceptability by the subjects dietary intervention trial was carried out for a period of one week and the feed back was recorded to test the suitability of the supplement. The subjects expressed some discomfort with regard to the digestion and elimination in the first two days and later they became normal and they started consuming the supplement with great enthusiasm.

The subjects in the experimental groups were supplemented with the mix which fulfills the requirement of the breakfast as a whole for a period of 120 days. The ingredients were cleaned, dried, powdered and neatly packed in air tight packets of 100 g each. Each subject was given 15 packets at a time with the request that the contents of each packet to be cooked daily and consumed for their breakfast in the form of roti, chappathi, adai and dosa with no or less oil as per their desire. During the intervention period the subjects were asked to drink 1.5 to 2.0 liters of water daily. They were asked to visit the hospitals every fifteen days for review and to receive the supplement for the next fifteen days. The control group did not receive any supplementation but they were asked to come to the regular checkups.

C. LIFESTYLE MODIFICATION FOR THE SELECTED FEMALE SUBJECTS

The World Health Organization and the National Institutes of Health have recommended that obese adults, as well as those who are overweight having co morbid conditions, lose 10 per cent of their initial weight. A comprehensive program of lifestyle modification is considered as the first option for achieving this goal. Lifestyle modification, also referred to as behavioral weight control, includes 3 primary components: diet, exercise, and behavior therapy.

Unfortunately obesity is a chronic condition and there is no 'quick fix' solution or treatment that is effective for all overweight or obese individuals. Furthermore, after following weight loss programs, relapses of weight gain are extremely common. This emphasizes the importance of a lifetime commitment to healthy eating and exercise practices. A range of different treatment options are available for obesity. Lifestyle modification (with a reduction of energy intake and an increase in physical activity) is essential in all treatment strategies. Positive changes in eating and exercise behaviour are essential for sustained reductions in weight. Yoga is a healthy life-style pattern widely used in India, as one of the traditional heritage having immense role in mind and disease control. Keeping this in mind the investigator opted to give yoga and relaxation therapy to the selected obese subjects (OBY group (N-30)) along with the dietary intervention.

To conduct yoga classes for the subjects in the OBY group the investigator approached the authorities of the yoga classes for providing experts to give training and also the place and other required facilities to conduct the campaign for a period of five weeks. The investigator also briefed about the date, time, duration and the type of training appropriate to the selected obese subjects. The obese female subjects who expressed their willingness to join the training programme were given a printed consent form (developed by the investigator) in local language or in English. This was considered as a precautionary measure to make sure that the subjects fully understood the nature of the training, its importance in weight loss and the biochemical parameters to be assessed before and after the intervention period. Using the inclusion criteria and exclusion criteria 30 subjects were selected for the training in yoga and relaxation therapy.

As the selected subjects were women and most of them were housewives the convenient time for the training was fixed as per their desire. The subjects usually visited the yoga centre on the specified dates between 11Am -12 Noon for a period of five weeks. During their training period they were taught about the different asanas, pranayama, cleansing practices and exercises to reduce their weight and keep their mind and body relaxed and to modify their behaviour pattern.

PLATE IV

INTERVENTION TO THE SELECTED SUBJECTS

Dietary intervention

Lifestyle modification

This campaign was well organised and the subjects were also very much satisfied with the training given. At the end of five weeks feedback was obtained from the subjects and they were asked to follow the asanas for a period of 120 days of intervention period. The formulated dietary supplement was also given for all the subjects in the experimental group (OBY) and they were asked to consume the same during the intervention period.

Selected subjects were asked to visit the yoga centre on the specified dates of every fifteen days for review and to receive the supplement for the next fifteen days. The fasting blood glucose, post prandial blood glucose levels, glycosylated haemoglobin and total lipid profile were analysed for all the subjects initially and finally after following the intervention practices for a period of 120 days to assess the effect of training after the intervention period. The control group did not receive any dietary supplement or yoga practice but they were asked to visit for their regular checkups to be done initially at the onset of the study and at the end of the study period.

D. EVALUATION OF THE EFFECT OF INTERVENTION ON THE SELECTED SUBJECTS

To know the effect of supplementation, the anthropometry measurements, diet recall and biochemical profile (Blood Glucose, HbA_1C and serum Lipid profile) of the experimental groups were recorded before and after intervention period of 120 days (Appendix II). Same procedure was followed for the control group so that comparison was done effectively.

E. CONSOLIDATION AND ANALYSIS OF DATA

The data collected were systematically consolidated and statistically analyzed using SPSS software version 20.0 for arriving at the results of the effect of intervention on blood glucose and serum lipid levels among the selected obese subjects and the findings are tabulated and discussed in Chapter IV Results and Discussion.