CHAPTER 3
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The present study assesses the nutritional status, quality of life and knowledge, attitude and practices of PLHIV. It also studies the impact of nutrition intervention in the form of food supplement on health and nutrition profile, quality of life and knowledge, attitude, practices of PLHIV. The study was completed in two phases. Phase I focusing on the Quality of life (QoL), health and nutrition profile of PLHIV was conducted in Delhi; phase II investigated the impact of nutrition supplementation on the health and nutrition profile of PLHIV in two districts (Berhampur and Sambalpur) of Orissa.

A total of 556 PLHIV (400 from Delhi and 116 from Orissa), older than 21 years of age, registered at the ART centres were enrolled for the study. The study also investigated the quality of life of PLHIV and the impact of nutrition supplementation on the same. The study protocol was approved by the Institutional Ethics Committee of Institute of Home Economics, University of Delhi, New Delhi, India.

3.1 PHASE I –
Phase I aimed at examining the health and nutrition status, dietary profile and quality of life of PLHIV. The research design for phase I is shown in Figure 3.1. Phase I was completed in Delhi wherein 400 PLHIV were enrolled over a period of three months. This was a mixed sample – males, females and transgender adults – those on ART and pre-ART patients as well.

![Figure 3.1: Research Design for Phase 1](image)

Data collection over a period of three months on following –
1. Socio-demographic information
2. Clinical and Biochemical Profile
3. Anthropometric Data
4. Knowledge, Attitude and Practices
5. Dietary profile
6. Nutritional Profile
7. Quality of Life
8. Mini Nutritional Assessment

Methodology
3.1.1 Locale
There are nine ART centres functional in the government hospitals of Delhi region. Permission to carry out the research work was obtained from the Head of the Department of Dermatology, ART centre, Guru Teg Bahadur Hospital, Shahdara (GTB Hospital) which falls in the North-eastern region of Delhi. The permission was obtained to complete the work in three months (October 2008 – December 2008).

3.1.2 Sample Selection
At the time of data collection, there were 1800 PLHIV registered at the ART centre of GTB Hospital, taking the stipulated time frame of three months i.e. 12 weeks and five working days per week, the data for phase 1 was collected in 60 working days. A total of 400 PLHIV (males and females) who attended the ART Centre on these days and who met the inclusion criteria were enrolled in the study. The inclusion and exclusion criteria were –

Inclusion Criteria:
• Adults (both males and females) over 21 years of age
• Confirmed HIV-positive status (ART and pre-ART patients)
• Registered at the HIV clinic of the hospital,
• Willing to participate in the study
• On ART for less than 6 months,
• Availability of record of CD4 estimations within last 30 days from the date of data collection

Exclusion Criteria:
• Infants, children, adolescents, pregnant and lactating mothers
• Those with any other chronic disease like CVD or those on pacemaker devices
• PLHIV receiving ART for more than 6 months

3.1.3 Enrollment of Subjects
The subjects who consented to participate in the study were enrolled for the data collection. The subjects were explained about objectives of the study and the data which would be collected from them. All the subjects read the information sheet and gave their consent to participate in the study in the presence of a witness. The information sheet and consent form are given in Annexure 1 and 2. They were convinced that all the information taken would be kept confidential and would only be used for research purposes. Finally, the data was collected from 400 PLHIV (245 males, 144 females and 11 transgender).

3.1.4 Tools and Techniques
Data on socio-demographic profile, clinical profile, anthropometric measurements, biochemical parameters, dietary profile, quality of life, nutritional assessment and knowledge, attitude and
practices was collected from 400 PLHIV using pre-tested questionnaires and standardized tools.

1. Questionnaire cum interview schedule (Hindi/English)

A standardized questionnaire was developed for use in Phase 1 of the study. The questionnaire was translated into Hindi, a language spoken in Delhi. After the initial translation, the questions were translated back to English in order to eliminate the discrepancy in the two sets of questionnaires. Once the translation was complete, both the questionnaires were pretested on 20 PLHIV (10 men and 10 women) and finalized after necessary modifications (Annexure 9 and 10).

The data was collected by personal interview in a closed room at the ART centre to ensure confidentiality. One interview session including reading/understanding of the information sheet and consent form, took around 25 - 30 minutes, therefore, only 10 – 12 subjects could be interviewed on each working day.

A standardized questionnaire, consisting multiple choice questions, was categorized into four sections to gather information on socio-demographic profile; clinical profile; nutrition related knowledge, attitude and practices and dietary profile. Each section of the questionnaire is described below:

Part 1 – Socio-demographic Information

This part of the questionnaire obtained data on the demographic characteristics that were important in describing the sample. The information on the following aspects was collected –
• General profile of the respondents, such as name, age, gender, marital status, educational qualifications, occupation and religion.
• Family profile, including family size, family income and family type.
• Mode of transmission of infection: sexual, blood transfusion or by the use of infected needles and treatment status.

Part 2 – Clinical Profile

The clinical profile schedule elicited the information pertaining to the signs and symptoms of HIV infection. The schedule was designed to gather data on present (at the time of interview) and past (at the time of registration at the ART centre) symptoms. The schedule contained a list of 10 common symptoms but data on any other symptom as reported by the respondent was also noted.
The interview session elicited data regarding medications taken, including anti-retroviral drugs, or any traditional therapy or alternate medication taken by the subject for strengthening the immune system or for treating infections was also collected.

**Part 3 – Knowledge, Attitude and Practices (KAP)**
Badram (1995) defined knowledge as the capacity to acquire, retain and use information; a mixture of comprehension, experience, discernment and skill; attitude as inclinations to react in a certain situations; to see and interpret events according to certain predispositions; or to organize opinions into coherent and interrelated structures; and practice as the application of rules and knowledge that leads to action. The main purpose of KAP in the present investigation is to explore the nutrition related knowledge, attitude and practices among PLHIV.

The KAP questionnaire was validated after pre-testing it among PLHIV (10 males and 10 females) and necessary modifications were done before the actual data collection (Annexure 9 and 10).

The KAP questionnaire was further divided into three parts –

**Knowledge Section**
Questions included in the knowledge section were designed to test the knowledge of PLHIV on HIV and nutrition in HIV. There were fifteen questions, each with four options, out of which one was correct. Questions framed covered the following topics –
- Risk factors for HIV
- Symptoms of HIV
- Diagnosis of HIV
- Treatment of HIV
- Nutrient requirement in HIV
- Healthy foods to improve health

**Scoring of Knowledge Section**
Each question in the knowledge section only had one correct answer and three wrong answers. Each correct answer was given a score of 1 while each wrong answer was given a score of 0. This way, a respondent can score maximum upto 15 and minimum 0 in this section.

**Attitude Section**
Questions included in attitude section were designed to gauge the prevailing attitudes and beliefs among the subjects regarding the HIV infection. There were fifteen statements provided and the respondents were asked to indicate the extent to which they agree to those statements, on
a pre-determined scale (agree, don’t know, disagree). These statements covered the following topics –

- Demography of HIV
- Precautions to be practised
- Treatment
- Healthy food choices
- Healthy dietary practices during the infection

**Scoring of Attitude Section**

In the attitude section, a numerical value was assigned to each choice given by the respondent. A score of 1 was given to ‘disagree’, score of 2 was given to ‘don’t know’ and a score of 3 was given to ‘agree’. There were eight negatively framed statements for which reverse scoring was done i.e. score of 1 was given to ‘agree’, 2 to ‘don’t know’ and 3 to ‘disagree’. This way, a respondent can score maximum of 45 and minimum of 15 in the attitude section.

**Practices Section**

Questions included in the practice sections were designed to assess the dietary practices of the population with regard to HIV infection. There were fifteen close-ended questions with answers in yes or no. Yes indicated the better dietary practice while no indicated the false one. The dietary practices covered in these questions were –

- Snacking
- Food group consumption
- Exercise
- Fluid intake
- Medication

**Scoring of Practice Section**

In this section, each ‘yes’ response received a score of 1 while each ‘no’ received a score of 0. Therefore, a respondent can score maximum up to 15 and minimum 0 in the practice section.

**Calculating overall KAP score**

After summing up the scores of the individual sections the final KAP score was obtained. The KAP score ranged from 15 to 75. Higher the score, better the respondent’s nutrition related knowledge, attitude and practice.

**Part 4 – Dietary Intake Information**

The objective of this part of the questionnaire was to elicit information pertaining to the dietary
habits of the respondents. This information was necessary as it would throw light on the food choices, method of preparation of food, number of meals taken, snacking pattern, missing of meals and beverage consumption by PLHIV. The questions were framed in simple language which could be easily understood by the respondents.

2. Biochemical Profile

As the researcher was not allowed to carry out the blood examinations therefore, the data on CD4 count and haemoglobin level was taken from the hospital records. A white coloured card issued by NACO is maintained for each patient registered at the ART centre. The blood levels were noted from those NACO records. As per the current system, all patients who are receiving ART medicines get their CD4 count done every six months and those who are not on ART get their CD4 after every three months. The latest CD4 and Hb levels recorded in the NACO cards were taken for the present study.

3. Anthropometric Profile

Jelliffe (1966) defined nutritional anthropometry as the measurement of the variations of the physical dimensions and the gross composition of the human body at different age levels and degree of nutrition. At the level of the individual, anthropometry is used either to identify a person as being in need of special consideration, or to assess that person’s response to some intervention. While, for the populations, the major decisions for which anthropometric data are used relate to whether or not intervention programmes are needed, to whom they should be delivered and what their nature should be (WHO, 1995).

The first step in the nutrition care of PLHIV is the nutritional assessment which includes nutritional anthropometry. The initial assessment should be done as early as possible after the detection of virus as it will allow the nutritionists to implement the dietary interventions which may help to reduce the nutritional complications associated with HIV. Ideally, every PLHIV should receive individualized nutrition assessment and counselling (Tumilowicz, 2010).

In the present study, the anthropometric measurements used to identify the nutritional status of PLHIV were – height, weight, waist circumference (WC), hip circumference (HC), mid upper arm circumference (MUAC) and calf circumference (CC). Based on these, body mass index (BMI) and waist-to-hip ratio (WHR) were calculated. Also, with the help of bio-electric impedance analysis body fat percentage, resting metabolic rate (RMR), skeletal muscle percentage and visceral fat were determined. All the measurements were taken after wearing surgical gloves to avoid the direct contact with the subjects body.
**Height**

Height of an individual is made up of the sum of four components – legs, pelvis, spine and skull. The height of the subjects was taken by the following method –

Stadiometer was fixed to the flat wall at a height of 2 meters from ground. Subjects were instructed to remove their shoes and stand straight with heels, buttocks and shoulders touching the wall where the tape was fixed. The scale was then lowered to rest flat on the top of their head to read the height to the nearest 0.5cm. The measurement was taken to the nearest 0.1 cm.

**Weight**

Body weight is the sum of protein, fat, water and bone mass in the body. Body weight is used to assess the severity of undernutrition in subjects with relatively uncomplicated, nonedematous forms of semi starvation (Heymsfield et al, 1984). Weight loss is an important index of presence, severity and progress of many diseases. Rapid unintentional weight loss is highly predictive of mortality and morbidity. The weight of the subjects was taken by a digital weighing machine (Omron Body composition analyzer). Subjects wore minimal clothing and were without shoes and socks while weighing. The weight was recorded to nearest 100g. The weight was taken before the meal and the accuracy of the weighing machine was checked periodically with known weights.

**Mid Upper Arm Circumference (MUAC)**

The arm contains both subcutaneous fat and muscle; a decrease in MUAC may therefore reflect a reduction in either muscle mass or subcutaneous tissue (or both). In PLHIV, as the disease progresses and with ART effect, a body fat redistribution is seen from the extremities to the central region of the body, therefore, MUAC was measured in the subjects (Gervasoni et al, 1999; Viraben and Aquilina, 1998).

The MUAC of the subject was measured using a non-stretchable tape by the following–method–

1. The subject was made to stand erect with left arm hanging free by the side with the palm facing inwards.
2. The left arm was bent at 90 degree angle at the elbow to mark the mid point. The forearm was placed with palm down. The tip of the acromion process of the shoulder blade at the outer most edge of the shoulder and the tip of the olecranon process of the ulna were located and marked. The distance between these two points was taken and the mid point was marked.
3. A non-stretchable tape was wrapped around the arm at this point and the measurement was taken to the nearest 0.1cm (Gibson, 1990).
**Waist and Hip Circumference**

The waist circumference is found to better correlate to the abdominal fat than waist-to-hip ratio (Daniels et al, 2000; Pouliot et al, 1994; Despres et al, 1989). Waist circumference is a preferred anthropometric measurement for the assessment of abdominal fat (WHO, 2000). In order to measure the waist circumference the following procedure was adopted using a non-stretchable tape –

1. The subjects were made to stand erect with abdomen relaxed, arms at the sides, feet together and weight equally divided over both legs.
2. Subjects wore minimal clothing and were asked to breathe normally and to breathe out gently.
3. Waist measurements were taken just above the umbilicus.

No specific cut-offs for waist circumference have been developed for PLHIV, therefore, the cut-offs used in the present study are those of the joint recommendations of World Health Organization and the International Association for the Study of Obesity and the International Obesity Task Force (2000) for Asians which is >80cm for women and >90cm for men.

The Hip circumference measurements were taken with the help of a non-stretchable tape and the following procedure was adopted –

1. The subjects were made to stand erect with arms at the side and feet together.
2. The measurement was taken at the point of maximum circumference over the buttocks.
3. The measurements were taken to the nearest millimetre.

**Calf Circumference**

Calf circumference measurements are commonly used in assessing malnutrition among geriatric patients. Visweswara et al (1978) also demonstrated calf circumference along with calf skinfold as a good indicator of protein-energy malnutrition among children. Calf circumference was measured in the present study with an objective to understand the body fat redistribution from extremities to the central region and to calculate the MNA score.

The calf circumference of subjects was measured with the help of a non-stretchable tape using following procedure –

1. The subjects were made to stand with their weight equally distributed among both the legs.
2. The patient was asked to uncover the calf.
3. The tape was wrapped around the calf at the widest point and the measurement was noted to the nearest millimetre.
4. Additional measurements above and below the point were made to ensure that the first measurement was the largest.
**Body Mass Index**

Body Mass Index (also termed as Quetlet’s Index) is extensively used to classify overweight and obesity in adults. It is also commonly employed anthropometric index in nutrition surveys as the measurements of height and weight are easy, quick, relatively non-invasive, and more precise than skin fold thickness. Low values of BMI are associated with decline in work output, productivity, and income generating ability, as well as compromised ability to respond to stressful conditions (Ferro-Luzzi et al, 1992).

As BMI is a good indicator of nutritional status of an individual, it forms an important part of the comprehensive care package for PLHIV (clinical, psychological, social, legal and nursing care). The BMI was calculated using the following formula –

\[
\text{BMI} = \frac{\text{weight (kg)}}{\text{height (m)}^2}
\]

Based on the values obtained, the nutritional status of the subjects was categorized as follows—

<table>
<thead>
<tr>
<th>Category</th>
<th>Asian Population</th>
<th>International Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt;18.5</td>
<td>&lt;18.5</td>
</tr>
<tr>
<td>Normal</td>
<td>18.5 – 22.9</td>
<td>18.5-24–9</td>
</tr>
<tr>
<td>Pre – Obese</td>
<td>23 – 27.5</td>
<td>25 – 29.9</td>
</tr>
<tr>
<td>Obese</td>
<td>&gt;27.5</td>
<td>&gt;30</td>
</tr>
</tbody>
</table>

Source: WHO 2004; 2000; 1995

**Waist-to-Hip Ratio (WHR)**

Waist-to-Hip ratio (WHR) is a method to distinguish fatness in lower trunk (hip and buttocks) and fatness in upper trunk (waist and abdomen areas) (Gibson, 1990). Lower trunk fatness is referred to as ‘gynoid obesity’, common among females; while upper trunk or central fatness is called ‘android obesity’ and is more common among males. WHR >1.0 for men and >0.8 for women indicate abdominal fat accumulation and are taken as cut-offs by WHO (2000a). The formula used for calculating WHR is –

\[
\text{WHR} = \frac{\text{Waist circumference (WC)}}{\text{Hip circumference (HC)}}
\]

**Bioelectric Impedence Analysis**

The following four measurements were made with the help of an electronic device called OMRON body composition analyzer (HBF 500) which works on the principle of bio electric impedance analysis (BIA). The Omron HBF-500 incorporates both hand-to-hand and foot-to-foot electrical impedance technology. Perez et al (2009) have demonstrated the reliability of the instrument.
BIA is based on the principle that the electrical conductivity through body fluid is much greater in fat free mass than in fat mass, because fat free mass contains all body fluids and electrolytes. For body composition analysis, the following steps were followed –

1. The machine was calibrated individually by entering the subjects age, gender and height.
2. The subjects were asked to remove the metal ornaments from their hand and feet as it may interfere in the readings.
3. The subjects were then asked to stand on the OMRON machine barefoot with their feet touching the steel electrodes and holding the hand electrodes at their shoulder level.
4. The readings for weight, BMI, body fat percentage, resting metabolic rate, visceral fat and skeletal muscle percentage was noted.
5. The BMI values recorded by the machine were also correlated with the formula to avoid discrepancies.

**Body fat percentage**

The body fat content is the most variable component of the body, differing among individuals of same sex, height and weight. On an average, the fat content of women is higher than that of man. The normal levels of body fat are taken as 8-21.9 per cent for males in the age-group of 20-60 years and 21-33.9 per cent for females in the age group of 20-60 years (Gallagher et al, 2000).

In Omron HBF 500, an extremely weak electric current of 50kHz and 0.5mA is sent through the body to determine the amount of total body water. The weak electrical current is not felt while operating the Body Fat Analyzer. The body fat percentage is calculated by a formula that uses the measured body water along with five factors; electric resistance, height, weight, age and gender. The formula used by OMRON HBF 500 to calculate body fat percentage is –

\[
\text{Body fat \%} = \frac{\text{Body fat mass (kg)}}{\text{Body weight (kg)}} \times 100
\]

**Skeletal Muscle Percentage**

Skeletal muscle is the muscle attached to the bones of the body to create movement. Skeletal muscle mass can be increased with exercise which may be desirable in changing the body composition and reducing body fat levels.

An average adult male is made up of 42 per cent of skeletal muscle and an average adult female is made up of 36 per cent (Marieb et al, 2007).

**Visceral Fat**

Visceral fat or abdominal fat is located in the abdominal cavity and is different from the subcutaneous fat which is majorly the fat beneath the skin. Fat in the lower body, as in thighs and buttocks, is subcutaneous, whereas fat in the abdomen is mostly visceral (Harvard, 2007).
In OMRON HBF 500 the area covered is 0 – 300cm², and the visceral fat is shown in 30 different levels. Higher the reading, higher the visceral fat level in the body.

<table>
<thead>
<tr>
<th>Visceral fat level</th>
<th>Reading on the monitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1 – 9</td>
</tr>
<tr>
<td>+</td>
<td>10 - 30</td>
</tr>
</tbody>
</table>

**Resting Metabolic Rate**

Resting metabolic rate is measured when the person is at rest in a comfortable environment and no fasting is required. RMR is slightly higher than BMR (usually 10%). RMR is also account for 65 – 80 per cent of total daily expenditure (Renkem et al, 1996; Drinkwater et al, 1986). Resting energy expenditure is measured in kcal/24 hours.

### 4. QUALITY OF LIFE

World Health Organization (WHO 1995) defines quality of life as an individual’s perception of their position in life in the context of culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. This definition reflects the view that quality of life refers to a subjective evaluation, which is embedded in a cultural, social, and environmental context.

In the present study, the quality of life of PLHIV was assessed using the brief version of WHO quality of life instrument specifically designed for PLHIV called WHOQOL-HIV BREF scale (English and Hindi version). Since, the scale cannot be translated into any native language without prior permission from WHO, the Hindi version of the scale was obtained from the Department of Mental Health and Substance Dependence, World Health Organization, Geneva, Switzerland (WHO, 2003) (Annexure 11 and 12).

The scale has 31 items. The scale consists of six domains namely, physical, psychological, level of independence, social relation, environment, and spiritual/religion/personal beliefs. In this scale responses were to be given on a five-point rating scale, where 1 indicated low, negative perception and 5 indicated high, positive perception. The respondent was asked to focus on his or her experiences in the past 2 weeks, while rating the questions. The domains Physical, level of independence, social relation and spiritual/religion and personal belief each consist of four items, psychological domain consist of five items and environment domain consist of eight items.

The domain scores were scaled in a positive direction where higher scores denoted higher quality of life. Some items were not scaled in a positive direction (e.g. Pain and Discomfort, Negative Feelings, Dependence on Medication, Death and Dying), meaning that for these facets higher scores do not denote higher quality of life. These need to be recoded so that high scores reflect better QoL. For scoring all the responses were checked if they fell in the desired range of
1-5. There were six negatively phrased items (Q3, Q4, Q5, Q8, Q9, Q10 and Q31) which were recoded (1=5, 2=4, 3=3, 4=2, 5=1) in order to transform the negatively phrased questions to positively framed ones. The mean score of items within each domain was used to calculate the domain score i.e. all the items that fell under a particular domain were summed up. The mean domain scores obtained were then multiplied by 4 in order to make them comparable with the scores used in WHOQOL scale. The final domain scores ranged between 4 -20, where higher score indicated a better quality of life.

For filling up the WHOQOL-HIV BREF scale the subjects were told to answer the questions from what they felt over past two weeks and not what they felt in general. Those who could understand English, the English version of scale was used and for those who could not understand English, hindi version was used. For illiterate subjects, the questions were spoken and the responses were marked.

5. DIET AND NUTRITION PROFILE

Part 1- Mini Nutritional Assessment
People with HIV infection are often found to have depleted nutritional status due to decreased food intake, malabsorption and increased utilization and excretion of nutrients which hasten the progression towards AIDS (Semba and Tang, 1999). Weight loss and wasting (Macallan, 1999), reduced BMI (Theibaut et al, 2000) and altered biochemical parameters (Periquet et al, 1995) are often found among PLHIV. Because PLHIV have increased susceptibility towards malnutrition, therefore, their screening for risk of malnutrition is important. There is no specific tool developed for PLHIV to assess their nutritional status, therefore, in the present study, Mini Nutritional Assessment (MNA) developed by Nestle which is a screening and assessment tool used to identify elderly patients at risk of malnutrition was used (Nestle, 1994) (Annexure 13).

The tool was used as it is given by Nestle and no modifications were made. The instructions given in the manual of the tool were followed for eliciting information. The tool is divided into two parts – Screening and Assessment. If the respondent score 11 or less in the screening part, then the assessment questions are asked and if the respondent score 12 or more in screening, he/she is said to be in normal nutrition state and the assessment part is omitted.

Part 1 – Screening
This part contains 6 multiple-choice questions relating to food intake, weight loss, mobility, psychological health and BMI. The score of each question is added to obtain the screening score. A score of 12 points or greater indicates no nutrition risk and assessment part of the questionnaire is omitted. A score of 11 points or less indicates risk of malnutrition and the interview is continued to complete the assessment part.
Part 2 – Assessment

This part contains 12 multiple-choice questions relating to drug intake, physical health, food group consumption, meal intake, fluid intake, mode of feeding, MUAC and Calf circumference. The score on each question is added to obtain the assessment score (maximum 16).

Final MNA Score -

The screening and assessment scores are added to obtain the total malnutrition indicator score (maximum 30 points). If the final score is greater than 23.5 points, the patient is in normal state of nutrition. If the score ranges from 17 to 23.5 points, the patient is at risk of malnutrition and if score is below 17 points, the patient is said to be malnourished.

Interview technique was adopted as respondents could not understand the diet related questions. All the subjects were given a score of 0 (as all the subjects were HIV positive) in fourth question of screening part as it said “Has suffered psychological stress or acute disease in the past three months”. The BMI, MUAC and calf circumference values were taken from the anthropometric profile of the subjects. Filling up of each performa took around 3-5 minutes.

Part 2 – 24-hour dietary recall

The 24-hour dietary recall involves the collection of detailed information on all foods and beverages consumed by a subject in the previous day or past 24 hours (Gibson, 1990; Bingham, 1987; Pekkarinen, 1970). The accuracy of the dietary intake data is dependent on the subjects memory. The method has several advantages which are listed as follows (Cassidy, 1994; Briefel et al, 1992)–

1. It is based on actual intake and thus, is used to estimate absolute rather than relative intake of macro and micro nutrients.
2. It is an open-ended method therefore, can accommodate any food or food combination.
3. Allow an unlimited level of specificity on the type of food, food source, food processing method, etc.
4. The method is highly individualized and sensitive to cultural differences.
5. The method does not require literacy among the respondents.
6. Minimal respondent burden, as it does not consume much of respondents time and resources.

The major limitation of this method is its reliance on memory, both for identification of foods eaten and for quantification of portion sizes. Also, it relies on the degree of motivation of the respondent and the persistence of the interviewer (Acheson et al, 1980).

In the present study, one day 24-hour recall method was used. Initially, a 24-hour recall for two days was planned, however, it was time consuming and not feasible. The following steps were
followed to conduct the interview –

The subjects were asked to recall the previous day’s food intake in terms of common household measures. All the foods and beverages consumed the previous day were recorded with details of ingredients, method of preparation, etc. Standardized household measures like katoris, spoons, glasses, etc. were shown to facilitate the estimation of serving size. The foods recorded were then converted into raw ingredients and amounts on the basis of standardized recipes.

Based on the information obtained by 24-hour recall method, the cooked foods were converted to raw amounts and the nutrients were calculated. The nutrients were calculated using software called DietSoft version 1.1.6. The software has been developed by the Department of Dietetics, All India Institute of Medical Sciences (AIIMS). The nutrients in the software are based on the values published in the “Nutritive value of Indian Foods” by ICMR (1999).

**Nutrient Adequacy Ratio (Nar)** –

Diet quality can be assessed by taking into account the single nutrient intake and RDA differentiated by age, sex, physical activity, etc. The concept of Nutrient adequacy ratio was introduced by Madden and Yoder (1972) which is calculated by dividing the actual nutrient intake by the respondent by the RDA of that nutrient. NAR is defined as the ratio of intake of particular nutrient to its recommended dietary intake or RDA.

\[
NAR = \frac{\text{Subject’s daily nutrient intake}}{\text{RDA of that nutrient}}
\]

Guthrie and Sheer (1981) have reported that a NAR of 0.66 for a particular nutrient reflects dietary adequacy of that nutrient since the intake meets at least two-thirds of the recommended dietary allowances. Since, there are no special RDA’s laid down for PLHIV, the comparisons of the intakes in the present study are made to the RDA’s for Indian adults laid down by ICMR (2010).

3.2 **PHASE II –**

The Phase II of the study which aimed to study the impact of nutritional assessment on health and nutrition profile of PLHIV was completed in Orissa. Nutrition supplementation was being carried out at Orissa by WFP and not in Delhi, therefore, Orissa was chosen as the study locale. Research Design for Phase II is shown in figure 3.2.
3.2.1 Locale

There are four ART centres functional in the government hospitals of Orissa. The names of which are –

1. MKCG Medical College, Berhampur, Ganjam
2. SCB Medical College, Cuttack
3. VSS Medical College, Burla, Sambalpur
4. DHH, Koraput

Of these, the supplementation by World Food Programme (WFP) was planned at MKCG Medical College, Berhampur. Therefore, the permission to carry out the research work was obtained at the ART centre of MKCG Medical College, Berhampur (Experimental Group) and the permission to gather data for control group was obtained at VSS Medical College, Burla (Control group). The graphical representation of both the locales in Orissa is shown in figure 3.3.

![Image of Orissa map showing locales of Berhampur and Sambalpur]

**Figure 3.3: Locale of Berhampur and Sambalpur**

Geographical description of the study centres –
Berhampur is located in the east coastal district of Orissa called Ganjam which covers an area of 8,706 sq kilometres and has a population of 31,60,635 (While, Sambalpur is a north-western district of Orissa covering an area of 6,702 sq kilometers and has a population of 9,35,613 Census of India, 2001). The experimental group was taken from MKCG Medical College, Berhampur while the control group was taken from VSS Medical College, Sambalpur.

3.2.2 Study duration –
The data for experimental group was collected over a period of eight month (baseline, midline at four months and endline at eight months). While for the control group, the difference between baseline and endline was eleven months. The endline data for control group could not be collected at eight months due to difficulty in obtaining permission from Orissa State AIDS Control Society (OSACS), hence the endline was completed at eleven months.
3.3.3 Sample Selection

For Phase II, PLHIV were enrolled by random sampling technique. A total of 100 PLHIV were to be enrolled using the following statistical formula.

\[
    n = \left( z_\alpha + z_\beta \right)^2 \times \left( SD_1^2 + SD_2^2 \right) / (x_2 - x_1)^2
\]

Where - 
- \( z_\alpha \) – level of significance (95%)
- \( z_\beta \) – power (90%)
- \( SD_1 \) – standard deviation before intervention
- \( SD_2 \) – standard deviation after intervention
- \( x_2 \) – mean of CD4 after intervention
- \( x_1 \) – mean of CD4 before intervention

**Experimental Group:** The experimental group refers to the group receiving the nutritional supplement of NutriPlus and counseling by the counselor. At baseline, a total of 153 PLHIV receiving ART were enrolled by random sampling technique at the baseline and the study was finally completed on a total of 96 subjects.

**Control Group:** Control group did not received NutriPlus as supplement and only received ART medicines and counseling by the counselor. Using the above statistical formula, a total of 100 control group subjects were to be taken from the VSS Medical college, Sambalpur, Burla. Due to working limitations (new ART centre, low enrollment of PLHIV receiving ART), the baseline data was collected from a total of 33 PLHIV by random sampling technique (i.e. Any adult PLHIV receiving ART, attending the ART clinic during the study duration and meeting the inclusion criteria for the study) and the study was finally completed on a total of 20 subjects.

**Inclusion criteria:**
- Adults (males + females) over 21 years of age
- Confirmed HIV positive status
- Registered at the ART clinic of hospital
- Were on ART regimen not more than 6 months
- Receiving food supplement and counseling from the centre (only for experimental group).
- Willing to participate in the study
- Availability of record of CD4 estimations within last 30 days from the date of data collection

**Exclusion criteria:**
- PLHIV who are not on ART regimen
- Infants, children, adolescents, pregnant and lactating mothers
- Those with any other chronic disease like CVD or those on pacemaker devices
• Those not taking the food ration or attending the counseling session at the ART centre (only for experimental group).

3.3.4 Enrollment of Subjects
The subjects who volunteered to participate in the study were enrolled for the data collection. The volunteers were told in the beginning what the study aimed at and what data we need to collect from them. All the volunteers read the information sheet and gave their consent to participate in the study in the presence of a witness. They were convinced that all the information taken would be kept confidential and would only be used for the research purpose. The information sheet and consent form were available in English as well as the local language of Orissa i.e. Oriya.

3.3.5 Intervention:
The intervention in the study design was the food supplement (NutriPlus) and nutrition counselling (by the counsellor at the ART centre). The food supplement was given only to the PLHIV who were on ART regimen. This was by the mutual understanding of OSACS and WFP, therefore, in the present study for Phase II, only those subjects who were on ART were enrolled and received nutritional supplementation.

The experimental group received the nutritional supplement in the form of NutriPlus powder. NutriPlus is a micronutrient fortified food supplement which was provided to the PLHIV through ART centre on a monthly take-home ration of 3kg. It is a wheat (75%) and soya (25%) blend which can be adapted to various recipes. The recommended dose of the supplement was 100g/day for adults and 50g/day for children. The supplement package was also provided with a measuring spoon of 25g for ease of measurement. The complete nutritional information of the supplement is shown in Table 3.1.

<table>
<thead>
<tr>
<th>Nutritional Content</th>
<th>Total value per 100g after processing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moisture (g)</td>
<td>4</td>
</tr>
<tr>
<td>Protein (g)</td>
<td>18</td>
</tr>
<tr>
<td>Fat (g)</td>
<td>6</td>
</tr>
<tr>
<td>Crude fibre (g)</td>
<td>2</td>
</tr>
<tr>
<td>Carbohydrate (g)</td>
<td>59</td>
</tr>
<tr>
<td>Energy (kcal)</td>
<td>368</td>
</tr>
<tr>
<td>Calcium (mg)</td>
<td>591</td>
</tr>
<tr>
<td>Iron (mg)</td>
<td>15</td>
</tr>
<tr>
<td>Zinc (mg)</td>
<td>5</td>
</tr>
<tr>
<td>Copper (mg)</td>
<td>0.8</td>
</tr>
<tr>
<td>Magnesium (mg)</td>
<td>200</td>
</tr>
</tbody>
</table>
Vitamin A (mcg) 523
Vitamin E (mg) 15
Vitamin D (mcg) 5
Thiamine (mg) 1
Riboflavin (mg) 1
Niacin (mg) 15
Pyridoxine (mg) 1
Vitamin C (mg) 40
Folic acid (mcg) 102
Vitamin B12 (mcg) 2

The supplement was given to the subjects every month at the time they came to ART centre to collect their medicines. The pharmacist at the ART centre, gave the subjects their monthly dose of medicines and 3kg of NutriPlus powder and got their signatures/thumb impression on the register.

A group counselling session was conducted by the researcher for PLHIV of the experimental group. The session aimed at informing the subjects about the nutrition intervention in the form of food supplement, method of consuming the supplement and also demonstrated the preparation of few commonly consumed dishes by incorporating the supplement. The importance of nutrition during HIV was also explained by the counsellor at the ART centre using a flipbook developed by WFP. In the control group, the researcher did not conduct any counseling to PLHIV. The counsellor at these ART centres counselled the patients as they were routinely doing so earlier.

3.3.6 Data Collection

The same questionnaire used in Phase I of the study was used for collecting data for Phase II. The questionnaire was in English and Hindi language. For those subjects who could not understand either of the two languages, a help of the translator (a local resident of Berhampur who worked as field officer for a community care centre) was taken.

All the tools used in Phase I of the study were used for collecting data in Phase II as well. These included -

• Socio-demographic information
• Clinical Profile – symptoms, CD4 count and Hb level
• Anthropometric Profile – height, weight, waist circumference, hip circumference, MUAC, calf circumference, BMI, WHR, body fat percentage, skeletal muscle percentage, resting metabolic rate and visceral fat.
• Nutrition related Knowledge, attitude and Practices
• Dietary Information
• Nutrition Profile – using 24 hour recall method
• Quality of life – using WHOQOL-HIV BREF scale
• Mini Nutritional Assessment – using MNA scale developed by Nestle

**Follow Up Checklist**
A separate follow-up checklist was used for the experimental group subjects in Phase II for monitoring. A follow-up checklist was prepared which gathered information from the experimental group subjects pertaining to the supplement consumption and counselling attended. The questions in follow-up checklist elicited information like number of times the supplement was consumed, sharing among family members, problems faced after consumption, difficulty in obtaining the supplement from ART centre, mode of consumption, etc. It also gathered information about the counselling sessions attended and if they were satisfied (Annexure 14).

The administration of the checklist started from the second month of supplementation. The checklist was filled by the researcher at the midline (4 months) and the endline (8 months) while collecting the data from the subjects. The checklist was left with the counsellor of the ART centre who filled the checklist while counselling the subject.

### 3.3.7 Data Analysis
For Phase 1 of the study, the data was analysed for males, females and transgender PLHIV separately. Anthropometric and biochemical analysis was carried out separately for those on ART and those not on ART treatment; according to the number of symptoms facing (0-4 and 5-8) and according to the Mini-nutritional assessment (MNA) stage (normal, at-risk, malnourished). CD4 count cut-off levels (<200, 200-500 and >=501) was another criteria taken for analysis of anthropometric measurements of the sample. Quality of life of subjects was studied according to their standing in the MNA stage. Mean score of knowledge, attitude and practices was analysed according to the educational level of the subjects and according to their treatment status as well. Apart from mean quality of life scores (QoL), difference in the scores was also analysed according to the socio-demographic profile (marital status and income).

In Phase 2, to assess the effect of intervention, the data was analysed under following heads –

- Baseline characteristics – Defines all the variables of control and experimental group subjects at the baseline.
- Effect of intervention (as per per protocol analysis and intention to treat analysis) – Illustrates the effect of intervention on the groups. Defines variables in terms of baseline and endline and the effect of intervention in terms of significance and percent change.
- Difference in the variables (like CD4, Haemoglobin, Weight and BMI) between those consuming full doze (100g/d) and half doze (50g/d)of the supplement.
- Acceptability of the food supplement
Statistical Analysis
The questionnaire was pre-coded before data collection. The data was analyzed using Statistical Package for Social Sciences (SPSS, version 11), STATA (version 9) and DietSoft (version 1.1.6).

Data were presented as number (percentage) or mean±SD/ median (Range) as appropriate. The difference in means of various parameters between ART and pre ART groups were compared using student’s t test/Wilcoxon ranksum test if data were not normally distributed. The difference in means of various parameters among three groups of gender and CD4 count using one-way Analysis of variance (ANOVA) followed pair-wise comparison using Bonferroni test and medians were compared using Kruskal-Wallis test if data were not normally distributed. The strength of relationship between quality of life and Hb, CD4 and various demographic variables were assessed using Pearson correlation coefficient/Spearman rank correlation. Univariate and multiple linear regressions were carried out to find the factors affecting CD4 count, BMI and MNA stage.

The categorical and continuous baseline characteristics between experimental and control groups were compared using Chi-square/Fisher’s exact test and student’s t test. The outcome parameters were compared between the groups at the end of the study using Analysis of Covariance (ANCOVA) adjusting for the respective baseline outcome variable. Also, the difference in the months of supplementation between the experimental and control group was adjusted while doing the endline analysis. The endline analysis was carried out using per protocol analysis i.e. including only those who completed the study. The level of significance was determined at 5 percent (p<0.05).
Methodology