CHAPTER 3

METHODOLOGY

The research methodology carried out in the present study titled “Impact of lifestyle interventions on nutritional status, physical activity and sleep pattern of overweight and obese 18-25 year old women during Covid-19” is detailed in this chapter, as follows:

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PHASE I

3.1 Selection of subjects and preparation of research tools

3.1.1 Selection of locale

The longitudinal research study was conducted between April 2021 to April 2022, among the college-going women in Coimbatore, TN, India (Institutional Human Ethics Committee acceptance number: AUW/IHEC/FSN-19-20/XPD-38), during the second wave of Covid-19. According to 2023 projections from the 2011 Indian census, Coimbatore has an estimated total population of 40,11,678 out of which 20,05,521 are females (World Population Review, 2023). Figure 3.1 shows the political map of India, indicating the State of Tamil Nadu.

Figure 3.1: The political map of India indicating the State of Tamil Nadu

As elaborated in chapter 2, one of the key issues of women's health is obesity. It was important that research that focused on this public health epidemic needed feasible, realistic and viable interventions to be productive. Considering the Covid-19 lockdown norms that existed in the country at the time, it was essential that the locale selected for the present study was easily accessible for the collection of relevant data as well as the effective conduct of the intervention throughout the entire period of study. Having an educational history of over six decades, Avinashilingam Institute of Home Science and Higher Education for Women, Coimbatore was the primary choice to approach for the present study subjects. Once institutional human ethics committee permissions were obtained, a few potential study subjects were initially approached through convenience purposive sampling after which they were encouraged to spread the word about the study to their classmates or friends i.e., snowball sampling. Figure 3.2 shows the map of the Coimbatore district and its zones.

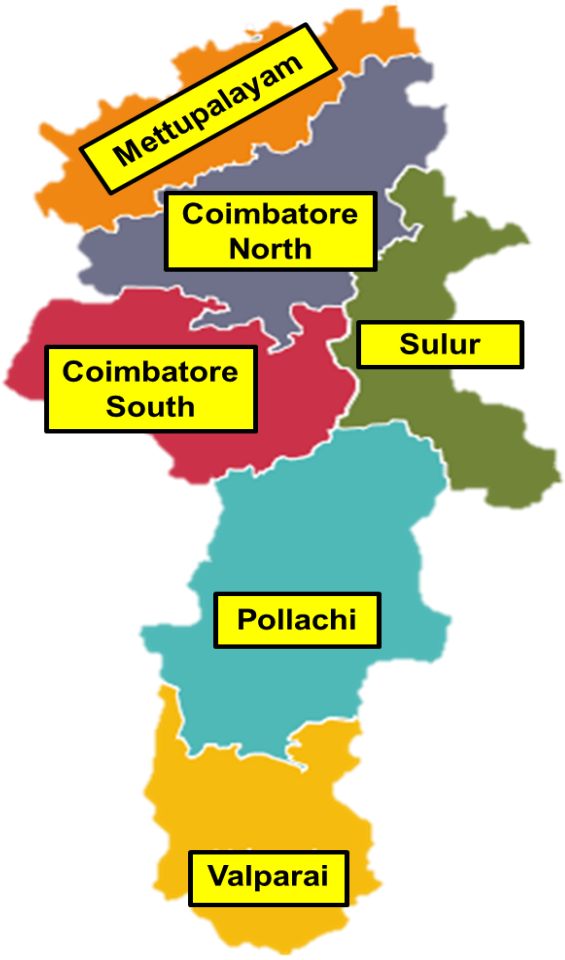

Figure 3.2: The district of Coimbatore

The inclusion and exclusion criteria of the present study has been enumerated below:

a) Inclusion criteria: Participants satisfying the following criteria were included in the present study.

- 18-25-year-old women
- Residents of Coimbatore for at least three years
- Their self-reported height (in meters) and weight (in kilograms) indicated an overweight or obese body mass index (BMI)

b) Exclusion criteria: Participants satisfying the following criteria were excluded from the present study.

- Unwilling to participate or to provide informed consent
- Women who were differently-abled or chronically ill
- Pregnant or lactating women

3.1.2 Calculation of sample size

The women selected for the study were aged between 18-25 years of age. An initial sample size was initially decided using the formula as described below (Daniel and Cross, 2018; Liu *et al*., 2021).

$$n = Z^2 \times \frac{P(1-P)}{d^2}$$

Where: ‘n’ is the sample size, ‘Z’ is the z-score corresponding to level of desired confidence, ‘P’ is the prevalence rate of obesity in school children of Coimbatore and ‘d’ is the margin of error.

For a conventional 95 percent confidence level, as per the Z-Score Table, the score equals 1.96. According to national prevalence studies indicating obesity and overweight among women, the prevalence rate is 6.4 percent and 17.6 percent respectively (IIPS and ICF, 2021). Since the margin of error is also the desired level of precision, it is also conventionally chosen as 2 percent or 5 percent.

Thus: Z = 1.96, P = 6.4% (0.064) and 17.6% (0.0176), and d = 5% (0.05)

Substituting for obesity:

$$n = (1.96)^2 \times 0.064(1 - 0.064) / (0.05)^2$$

$$n = 3.84 \times 0.059 / 0.0025 = 90.62 = 91 \text{ samples}$$

Substituting for overweight:

$$n = (1.96)^2 \times 0.176(1 – 0.176) / (0.05)^2$$

$$n = 3.84 \times 0.145 / 0.0025 = 222.72 = 223 \text{ samples}$$

Taking average of both, 162 samples was obtained. This meant that for the present study to be considered significant, it needed to have a minimum of 162 subjects. Allowing room for drop-outs, it was decided that the entire study needed to have at least 670 subjects. Thus, 670 college-going students from Avinashilingam Institute of Home Science and Higher Education for Women, Coimbatore initially became part of the study. After the study subjects were made to understand the study and its objectives, willing subjects were asked to provide informed consent through signed sheets. Figure 3.3 shows the research design that was implemented throughout this study.

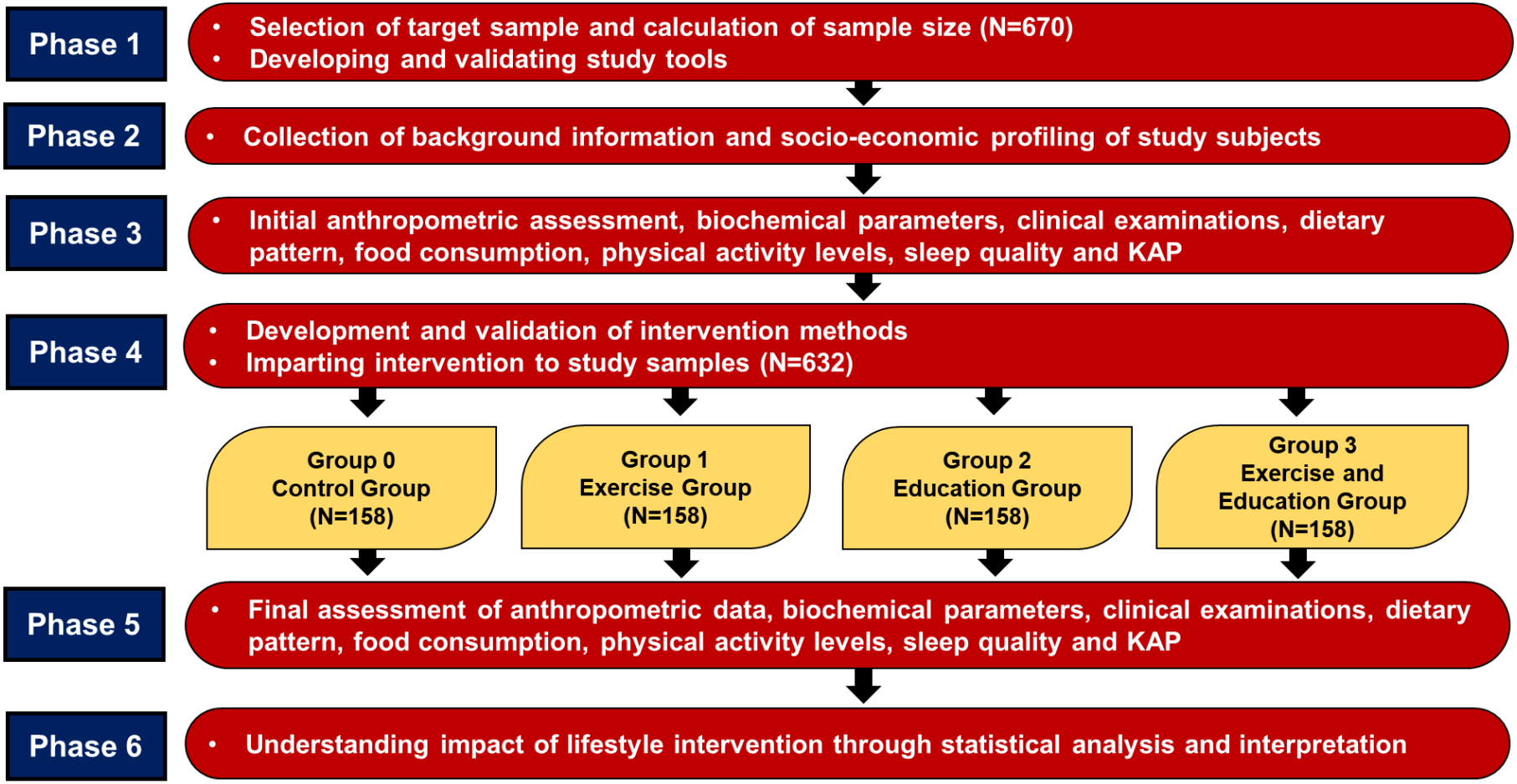

Figure 3.3: Methodology of Research Study

3.1.3 Developing, pilot-testing and validating research tools

One of the definitions of research is that it is a way of analysing problems the solutions of which are to be determined partly or entirely from facts. This indicates that research is a vital and influential tool in actions meant for the progress of humankind. It is a systematic examination or action to derive new information from known facts. whereby answers are discovered through the application of scientific procedures (Pandey and Pandey, 2021). Towards this, data is collected to report the observations of experiments or results of tests using research tools directly or indirectly from subjects via surveys, questionnaires, interviews etc. (Mazhar *et al.*, 2021).

For the present study, pre-tested and validated, structured survey forms and globally accepted questionnaires were used. To collect socio-economic status details, anthropometric assessment, physical examinations, dietary pattern, food consumption, and the Knowledge Attitudes Practices (KAP) of study subjects relating to obesity management, questionnaires were developed by the researcher and tested for construct validity with input from 50 subject and 50 non-subject experts and for reliability using test-retest method, set one month apart. To collect data related to physical activity, the Global Physical Activity Questionnaire (GPAQ) was utilised, while the Pittsburgh Sleep Quality Index (PSQI) questionnaire was used when collecting data about the sleep quality of the study subjects. Due to the lockdown situation existing at the time, the questionnaires were distributed as Google forms (Annexures 3-5).

3.1.4 Obtaining permissions for utilising pre-validated tools for study

Since the GPAQ is a research tool that has been open for public for more than a decade by WHO (2012), no prior permission was recorded before utilising the questionnaire for the present study. At the same time, since the PSQI was Daniel J. Buysse's contribution to the field of human behaviour (Buysse *et al.*, 1989), an online correspondence (via e-mail) was established and a signed permission was obtained from a representative of the original research team to use the PSQI in the present study, provided due credit to the original author was given to any publications that arise out of the research work carried out using the said tool.

3.1.5 Obtaining Institutional Human Ethics Committee approval and disruption of study due to Covid-19

The first institutional human ethics committee application of the study then titled “Obesity Among Children of Working Mothers” was obtained in November, 2019 (Annexure-I) after which permissions were sought from the schools till March, 2020 when the first wave of Covid-19 and the subsequent lockdown hit, causing a pause to the study’s progress. After changing the methodology of the study and title to “Obesity Among Young People” to accommodate the Covid-19 partial lockdown restrictions at the time and availability of the study subjects, a second ethical approval was obtained in March 2021 (Annexure-II), just before the second wave of Covid-19. Soon after, (June 2021) prospective subjects were approached, informed consent (Annexure-III and IV) and initial background information collected (Annexure-V) with the intervention beginning in August, 2021 and lasting till February, 2022. The researcher then worked towards disseminating the findings of the present study through publications which were completed by July and September, 2023 (Annexure-XV). Subsequently, the study data and its findings were presented to the third doctoral committee and the title was once again altered in September, 2023 to better accommodate the findings of the present study to “Impact of lifestyle interventions on nutritional status, physical activity and sleep pattern of overweight and obese 18-25 year old women during Covid-19”.

PHASE II

3.2 Collection of background information and socio-economic profiling of study subjects

According to the American Psychological Association (2023) socio-economic variables includes a blend of factors that include income, the extent of education, the type of occupation, places of residence and sometimes ethnic origin or religious backgrounds because more or less, it is “the position of an individual or group on the socio-economic scale”. Socio-economic variables have been proven to be interconnected with community research, as far as the burden of NCDs is concerned and research conducted across the world’s populations in

the past few years also suggests that differences in socio-economic variables does influence obesity and the health consequences associated with it (Jiwani *et al.*, 2019; Reyes *et al.*, 2020; Sadaf, 2023). The socio-economic variables studied in similar studies from the Indian context include age, type of family, household income, type of house, regions of residence (urban or rural), education, occupation, marital status, pregnancy outcome, use of contraceptives and utilisation of ration card privileges (NNMB, 2017; Al Kibria *et al.*, 2019; Meshram *et al.*, 2022; Purushotham *et al.*, 2023).

Hence, in the present study, the background information studied included the study subjects' age (month and year of birth), level of education, (whether they were pursuing or completed undergraduate, postgraduate or PhD courses), areas of residence (area in Coimbatore), type of family (nuclear, joint, in hostel or as paying guest), family income, practising religion, and if applicable, the age at which the subjects were married. Socio-economic profiling was done by using the modified Kuppuswamy scales to categorise the study subjects into one of five, namely upper, upper middle, lower middle, upper lower and lower based on the family income, education and occupation of the family head of the subjects' families (Sood & Bindra, 2022).

PHASE III

3.3 Assessment of nutritional status and lifestyle pattern of subjects

Collection of initial subject data included assessing their nutritional status including the 'ABCD' approach as well as the lifestyle pattern including their physical activity and sleep patterns and their knowledge, attitudes and practices to manage obesity.

3.3.1 Assessment of nutritional status of subjects

3.3.1.1 Anthropometric assessment of study subjects

Although their self-reported height and weight were considered as a preliminary inclusion criterion, the subjects' anthropometric parameters including their height (in m), weight (in kg), resultant BMI (in kg/m^2), waist circumference (in cm), hip circumference (in cm), resultant waist-to-hip (WHR) ratio and body

composition parameters were recorded using the standard methods of measurements as per ICMR-NIMS (2021) guidelines and are detailed below.

(a) Measuring height

Standing height was measured using the Tanita HR200 stadiometer for adults 20-205 cm made in Japan. The subjects stood erect on the stadiometer platform, without shoes, head perpendicular to the ground and facing directly forward, feet together, and arms hanging by their sides. The measurement was obtained by firmly touching the stadiometer's movable head pointer to the subject's head, after which the reading was noted and recorded from the calibrated scale.

(b) Measuring weight

For the present study, body weight was measured by using InBody 720 Body Composition Analyser made in Seoul, South Korea. After demonstrating that they were not to hold on to any other area for support while on the platform, the subjects were asked to remain barefoot while standing on the platform of the analyser. The body weight of the subject was automatically measured by the InBody machine during this step.

(c) Calculating BMI

Body mass indices (BMI) were calculated as a subject's weight in kilograms divided by the square of their height in meters i.e., kg/m^2. Furthermore, the BMI classification according to Asia-Pacific guidelines (Lim *et al.*, 2017; Kadowaki *et al.*, 2022) was used to categorise the subjects as belonging to normal (BMI values ranging from 18.6 to 22.9 kg/m^2), overweight (BMI values ranging from 23-24.9 kg/m^2) and obese (BMI values above 25 kg/m^2) categories. Plate 3.1 shows the assessment of the height and weight of a study subject.

Plate 3.1: Assessing height and weight of study subject

(d) Measuring waist circumference

The subject was made to stand on a level surface without support, with the weight evenly distributed between both feet, the arms at the sides, and the feet close together, after which a fibreglass tape was snuggly placed around the waist. Subsequently, the smallest circumference between the lowest rib and iliac crest was measured (Hewage *et al.*, 2023). An average of two measurements (in cm) was observed and recorded as the subject's final waist circumference (WC).

(e) Measuring hip circumference

The subject was made to stand on a level surface without support, with weight evenly distributed between both feet, the arms at the sides, and the feet close together, after which a fibreglass tape was snuggly placed around the hip, parallel to the ground by measuring the widest portion around the buttocks (Hewage *et al.*, 2023). An average of two measurements (in cm) was observed and recorded as the subject's final hip circumference (HC). Plate 3.2 shows the assessment of the waist and hip circumference of a study subject.

Plate 3.2: Assessing (a) waist circumference and (a) hip circumference of study subject

(f) Calculating Waist-to-Hip Ratio

The waist-to-hip ratio (WHR) is a known indicator for non-communicable diseases including abdominal adiposity in women of all ages across the human life-cycle (Banson *et al.*, 2023; Cai *et al.*, 2023; Pasqual *et al.*, 2023; Widjaja *et al.*, 2023). WHR was determined by dividing the above obtained waist circumference by the above obtained hip circumference (both in cm) i.e., WHR = WC/HC (Hewage *et al.*, 2023). Alternatively, the body composition analyser also measured WHR, which was tested and verified for accuracy.

(g) Assessing Body Composition using Bioelectrical Impedance Analysis

Body composition is a measure to identify various compartments within the body including the fat content of the body which is expressed as body fat percentage. Assessing body composition can be considered via a holistic approach by measuring weight / BMI, or via dividing the body into fat free mass (FFM) and fat mass (FM), or via dividing the body into molecules such as water, protein, and fat, etc. (Campa *et al.*, 2021; Saltzman & Mogensen, 2013).

Body composition can be measured using skin-fold measurements, air displacement plethysmography, densitometry or weighing under water, dual energy x-ray absorptiometry or DEXA, computed tomography or magnetic resonance imaging, and bioelectrical impedance analysis. All of these, except the last are comparatively expensive and require specialised equipment that is often bulky and expertise in their handling which makes them difficult to use in surveys covering large areas and populations (Dehghan and Merchant, 2008; Marra *et al.*, 2019; Salmón-Gómez, *et al.*, 2023).

Bioelectrical Impedance Analysis (BIA) is a non-invasive method to measure body composition that provides valid information about parameters in the human body that are bioelectrical that can reflect the apparent health and nutritional status of an individual (Popiolek-Kalisz and Szczygiel, 2023). As early as 2008, BIA has been a popular tool to measure body composition as a means to identify individuals at risk for chronic diseases (Dehghan and Merchant, 2008). This tool has seen wide-spread acceptance on a global scale and is still being used to point out probable risk factors for body composition associated disorders such as cardiovascular diseases, non-alcoholic fatty liver disease, chronic kidney disease, and most recently, Covid-19 in individuals with overweight or obesity (Bellafronte *et al.*, 2021; Chen *et al.*, 2020; Moonen *et al.*, 2021; Popiolek-Kalisz and Szczygiel, 2023). If one were to scrutinise the body composition analyser market in the country, there are a host of company names and models that are available for public research purposes. Since early 2000, InBody Co., Ltd. (Seoul, South Korea) has been recognised as a global leader in the body composition analysis industry and has been used for research related to obesity across the human life cycle (Gažarová & Šoltís, 2023; Jensky-Squires *et al.*, 2008; McLester *et al.*, 2020).

For the present study, the InBody 720 body composition analyser was available for use at The Bharat Ratna Prof. C.N.R. Rao Research Centre in the Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore. Due to the Covid-19 guidelines prevalent at the time, the biochemical parameter assessment was conducted in campus one, with the help qualified, outsourced personnel.

According to the InBody User Manual, “the body composition analyser InBody 720 is accurate for all body types and for any possible distribution of body water, measuring the progress of clinical treatment, weight loss program or exercise therapies reliably”. Using a minimal range of frequency (from 1KHz to 1MHz), InBody measures the resistance of body tissues to the alternating current, thus measuring the amount of body water accurately (InBody Inc., 2000). InBody diagnoses obesity and oedema while carrying out a nutritional evaluation, goals for manage the weight, balance, strength and control of the body, basal metabolic rate (BMR) and an overall fitness score (Jensky-Squires *et al.*, 2008; McLester *et al.*, 2020; Ranjan *et al.,* 2022; Gažarová & Šoltís, 2023). Plate 3.3 shows the assessment of the body composition of a study subject.

Plate 3.3: Assessing body composition of study subject using bioelectrical impedance analysis method

To measure body composition, the subjects were asked to stand barefoot on the InBody’s stand with their arms at an angle of approximately 15 degrees on either side and fingers curled around the electrode surface and thumbs lightly resting on the thumb electrodes. After the analyser detects a stabilised posture and weight, it will automatically begin recording the body composition of the subject. Care was taken to ensure that the measurement of body composition was taken during the day to avoid humidity related variations, and 2 hours after a meal

to avoid food mass related inconsistencies and during non-menstruating time period of the subjects to avoid fluctuations in total body water.

Although InBody's body composition analysis is extensive, the following parameters have reportedly been used to study and assess obesity in individuals as mentioned in the sections above.

i. **Skeletal muscle mass -** this indicates the muscle mass of the limbs
ii. **Percent body fat -** indicates the percentage of body fat to body weight
iii. **Basal metabolic rate -** indicates minimum energy required to function
iv. **Overall fitness score -** an arbitrary score based on the measured muscle and fat mass

3.3.1.2 Assessment of biochemical parameters of study subjects

According to the British Heart Foundation (2023), blood tests are carried out to assess how the human body copes with illness, injury, inflammation, infection and at times, medication. The use of blood tests is a recognized and ethically accepted practice which has precedence in previously conducted community health-based research in India (Vicziany & Hardikar, 2018). As per existing evidence, various parameters can be analysed from the blood samples. For instance, haemoglobin was assessed to detect cases of anaemia, while random blood sugar was to detect diabetes (Shaked *et al.*, 2019) and thyroid function tests was to detect thyroid gland dysfunctions in women (Ahmed & Mohammed, 2020).

In the present study, for conducting tests of random blood glucose, haemoglobin and thyroid function tests including triiodothyronine (T_3), thyroxine (T_4) and thyroid stimulating hormone (TSH), all the whole blood samples were collected following the good clinical laboratory practice guidelines (GCLPG by ICMR, 2021). The services of a National Accreditation Board for Hospitals and Healthcare Providers (NABH) accredited laboratory based in and having lab services across Coimbatore was utilised by the researcher to test the blood of the study subjects after obtaining permission from the institutional human ethics committee. Plate 3.4 shows the assessment of biochemical parameters of study subjects.

Plate 3.4: Assessment of biochemical parameters of study subjects in progress

The subject's upper arm was firmly tied in a rubber band known as a tourniquet, which made it simpler to locate the vein within the elbow by drawing it to the surface. Next, a sterile alcohol swab was used to clean the skin surrounding the vein. A container of 3 ml capacity was connected to a needle that was then inserted into the vein. Once the blood filled the bottle, the needle was removed and discarded while the blood bottle was closed with a lid, labelled (with the subject's name and date of birth) and placed into its holder. The blood samples were collected twice throughout the study – once before and after the intervention where the samples were stored for a period of 7 days and then discarded. Both the blood tests were conducted at the health centre of the main campus of the Avinashilingam Institute.

3.3.1.3 Clinical examinations and assessment of morbidity pattern of study subjects

(a) Clinical examination

In their much-cited-since-publication book chapter on physical examination, Campbell and Lynn (1990), they describe physical examinations as the process of assessing objective anatomic findings through the use of sight (observation), touch (palpation), and sounds (percussion and auscultation) with or without using specialised instruments. Plate 3.5 shows the clinical examination of a study subject.

Plate 3.5: Clinical examination of study subject in progress

For the present study, the researcher conducted the physical examination of the study subjects with the assistance of a qualified (MBBS, MD) medical practitioner for physically observable signs and symptoms of diseases. In the presence of the researcher, the subjects were observed by the medical practitioner after which they were informed of the observations as well as possible self-treatment options on the spot. The pre-tested checklist which was used to record the medical practitioner's observations and recommendations had queries on deficiency symptoms related to the hair, skin, eye, mouth, teeth, and musculature including nutritional oedema, problems with vision, texture of skin, anaemia, muscle wasting, oral health and dental hygiene etc. (Annexure-VI).

(b) Morbidity pattern

The National Cancer Institute of USA defines morbidity as "having a disease or a symptom of disease", or the "amount of disease present within a population" (NIH-NCI, 2023). Obesity has been reported to cause physical and psychological health concerns, where the higher the BMI of an individual, the higher the chances of developing multiple NCDs, and other morbidity determinants which can even lead to financial burdens and drainage of healthcare resources in developing nations (De Siqueira *et al.*, 2020; Misra *et al.*, 2019; Poly *et al.*, 2021).

A recent systematic review points out that social isolation is a determinant of an individual's poor health thus leading to increased morbidity and mortality

which could be due to detrimental ways of living including but not limited to “smoking, excessive alcohol intake, poor nutrition, and/or physical inactivity” (Naito *et al.*, 2023) that may contribute to obesity. During the Covid-19 pandemic also, populations were physically and therefore socially distanced the influence of which were expected to be seen in the present study as well, thereby justifying the need to study the prevalence of morbidity among the study participants.

Self-reported responses from subjects were used to detect the morbidity pattern up until three months prior to the study. The pre-tested questionnaire (Annexure-VII) included queries on Covid, episodes of cold/fever, bouts of diarrhoea, nausea/vomiting and their frequency, whether subjects consumed medication for the above morbidities and the presence or absence of food allergies.

3.2.4 Assessing dietary pattern, food and nutrient intake of study subjects

Dietary pattern or preferences and food consumption can be assessed through dietary surveys which in turn help towards modifying aspects of an individual’s lifestyle such as weight control and diet management as a method to overcome obesity and its co-morbidities. Presently, the most prevalent methods to assess dietary pattern and food consumption and nutrient intake include food frequency questionnaires, 24-hour-recalls and food records (Archundia-Herrera & Chan, 2018).

(a) Dietary pattern

Dietary surveys are used to “collect data on consumption and food expenditures at the household level” (Tucker, 2023). Thus, in the present study, the questions to understand dietary preferences of the subjects were included in the main questionnaire. The questions included their preferences (as vegetarians, non-vegetarians and other categories in between), the number of meals they consumed per day (out of seven – namely early morning, breakfast, mid-morning, lunch, evening snack, dinner and post-dinner), and the frequency to eat out/order in food (Annexure-VII).

(b) Food Frequency Questionnaire

Food Frequency Questionnaires (FFQs) assess the usual food intake of an individual over a specified period of time, as well as how frequently they consume

certain food items, that are often categorised into a list with multiple food items that are similar in their nutrient profiles (Bailey, 2021). In this study, a modified FFQ which suited the local population and for ease of understanding by the student community was used to measure food consumption (Annexure-VIII). The first part of the FFQ included a section on food groups and some commonly consumed foods and the frequency of their consumption. The food groups were namely cereals, pulses, lean and other types of meat, vegetables, green leafy vegetables (GLVs), fruits, fat, nuts and sugar while the commonly consumed foods included pastry items, fried foods, spreads, pickles, frozen foods, ice-cream, chocolates, sweets, carbonated drinks and from fast food chains. The frequency the subjects were asked was whether they consumed the above foods daily, weekly once or twice, monthly once or twice, or rarely.

(c) 24 Hour Recall

A twenty-four-hour recall assesses an individual's food intake over 24 hours of the previous day and need to be measured on non-consecutive, and random days to be effective. There is evidence where twenty-four-hour recalls have been conducted through a telephonic or in-person interview, or online methods of communication (Bailey, 2021). In this study, to understand the average amounts of food consumed, a twenty-four-hour recall method was used. For increased accuracy and reducing incorrect estimations three-day twenty-four-hour recall data i.e., two weekdays and one day during the weekend was recorded from all the study's subjects. Since it was physically impossible to collect the twenty-four-hour recall in person due to the Covid-19 lockdown, video calls were conducted where the subjects were shown how to measure their food to report approximately accurate measurements and quantities of food (Annexure-IX). The obtained lists of foods, their quantities along with their mode of preparation were used to calculate the average calories each subject consumed using the Indian Food Composition Tables (Longvah *et al.*, 2017).

3.3.2 Assessment of lifestyle pattern of study subjects

3.3.2.1 Assessing physical activity pattern of study subjects

The Global Physical Activity Questionnaire (GPAQ) was developed by WHO in 2002 to estimate the prevalence physical activity worldwide (WHO, 2012;

WHO, 2023). Consisting of 16 questions, the questionnaire gathers data on three domains related being physically active including activity at current occupation, preferred mode of transport and recreational time as well as time spent as sedentary behaviour (Cleland *et al.*, 2014). Metabolic equivalents (METs) are defined as the number of calories burned when a person is at rest or sitting in a relaxed manner (approximately equivalent to 1 kcal/kg/h) and is commonly used to express the intensity of physical activities. This is also the base for the interpretation of the GPAQ data (Adıgüzel *et al.*, 2021). There is evidence that suggests that there is comparability in the GPAQ responses whether or not it was conducted by an interviewer or filled in by the subjects themselves (Chu *et al.*, 2015). The GPAQ has found relevance on a global scale as an effective method over several years for comparing physical activity with other lifestyle variables among different populations across different ages of the human lifespan (Bull *et al.,* 2009; Cleland *et al.,* 2014; Sathish and Mathews, 2023; Strain *et al.,* 2020 and Tavakol *et al.*, 2023).

Thus, the GPAQ, with locally modified show cards was used to identify the subjects' physical activity levels in the present study as well (Annexure-X). Since this questionnaire mostly included yes/no and other quantitative data such as date/time as replies to the questions, it was converted as is into a Google form to record the data. Once the questionnaire was filled up by the participants and clarifications were made, the total physical activity in METs (in minutes per week) i.e., in the form of a score was calculated for each subject to understand on an average, the extent of physical activity done by them per week.

3.3.2.2 Assessing sleep quality of study subjects

The Pittsburgh Sleep Quality Index (PSQI) is a questionnaire that is self-administered to assess an individual's quality of sleep and disturbances over the time period of one month. It consists of nineteen questions that subjectively study the seven components of sleep: "quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction", the total of which provides a score that distinguishes between good and poor sleepers; thereby finding real time applications in psychiatry and research (Sancho-Domingo *et al.*, 2021). In their original publication, Buysse *et al.*,

(1989) have indicated that PSQI's total score ranges from 0-21, where the sleep quality is best if it is below 5 and worst the closer it is to 21. PSQI's reliability has been verified with the Cronbach alpha test (0.83) which indicated a high level of internal consistency. This tool has therefore been found to be relevant towards detecting sleep related disorders for populations across the globe, over the previous decade including the during the Covid-19 pandemic (Besedovsky *et al.*, 2019; Mahmud *et al.*, 2023; Mollayeva *et al.*, 2016).

In the present study, Google Forms were used to record the sleeping pattern of the subjects through the PSQI questionnaire (Annexure-XI) due to the Covid-19 lockdown existing at the time. The PSQI was administered twice throughout the study period; once each before and after the lifestyle intervention. Once the responses were recorded, the extent of each subject's sleep quality was calculated through the score obtained by following the PSQI scoring method and recorded for further analysis.

3.3.2.3 Understanding KAP of study subjects relating to obesity management

A Knowledge, Attitude and Practices (KAP) survey has been effectively recognised as an investigative method in nutrition research as a method to observe individuals' opinions or statements regarding a topic of interest through standardized questionnaires. KAP surveys have been used for multidisciplinary research ranging from psychiatry (Andrade *et al.*, 2020), to global health (Gupta *et al.*, 2015; Liu *et al.*, 2020; Murty *et al.*, 2016; Sienso *et al.*, 2022).

In the present study, the KAP questionnaires (Annexure-XII) were necessary to understand the existing level of awareness the subjects had, regarding obesity and its management. As the KAP questionnaires were distributed online due to Covid-19, the subjects were informed that there were no right and wrong answers and encouraged to be honest and truthful in their responses and not fill in the forms using the internet so that their responses would aid in tailoring the education modules that they would receive as the study progressed.

The knowledge section of the questionnaire included questions on general definitions of terms such as nutrients, recommended dietary allowances, calorie

addition, food groups etc. The attitudes section included questions on the opinions or thoughts of subjects relating to process of nutrition, measuring food, concepts of dieting etc. and the practices section included questions on cooking methods, daily fluid intake, daily physical activity etc. With 15 questions each, the total score of each KAP questionnaire was recorded out of 45 marks. This score was used to determine the areas to be focussed on while planning the study's intervention.

PHASE IV

3.4 Identification and validation of study intervention methods

An intervention is a purposeful involvement by the researcher in his/her project or program in the hopes of influencing processes or events, which can later be measured in order to draw meaningful inferences (Belcher & Palenberg, 2018). In his much-quoted book on the 'Field trials of health interventions', Hodgson (2015), defines health related interventions as activities that are undertaken with three primary objectives: "improving human health by preventing diseases, reducing the severity or duration of an existing disease, or by restoring function lost through disease or injury" (Hodgson, 2015).

This study also encouraged preventive measures against obesity, and it was based on the data of the pre-study responses of the KAP related to the management of obesity and in lieu of the Covid-19 situation existing at the time of the study, that the intervention methods were chosen to be as follows. Firstly, developing nutrition education modules through PowerPoint presentations, posters focusing on general health, a calendar for the following year (2023) with positive messages along with nutrition counselling and secondly, identifying online exercise routines that could be followed by prospective study subjects.

3.4.1 Preparing nutrition education modules

There are mainly two types of interventions – preventive and therapeutic. Out of the many preventive interventions that exist in community health today, nutritional and educational/behaviour change interventions are considered integral because "food and nutrition are major determinants of human health and disease" and almost "all health interventions must have an associated educational component for their effective deployment" (Hodgson, 2015). Studies conducted

during the period of Covid-19 also included and advocated for nutrition education and behaviour change as interventions in the form of lectures, discussions, demonstrations etc. (Jehi, 2022; Sumarto *et al.*, 2023; Wilkins, 2020).

Nutrition education in the present study was decided to be imparted as PowerPoint presentations. The topics covered were grouped into ten broad categories. Table 3.1 outlines the content of the nutrition education modules developed by the researcher as an intervention for the study.

Table 3.1: Topics covered in nutrition education modules

Sl. No.	Module Name	Topics Covered	No. of slides
1	"A Glance at Nutrition"	General information of nutrition, purpose of nutrition, nutrients, type of nutrients, vitamins & minerals, RDA, EAR, review	19
2	"Drinking Water: A Conscious Choice"	Water in human bodies, essential functions of water, how much water we need, estimation of water in foods, foods with high water content, how to make sure to enough drink enough water, review	10
3	"Measuring Your Food Intake: Steps We Can Do at Home"	Why should we measure our food, calorie counting vs. nutrient counting, DIY steps to measure food, review	10
4	"Exercising to Stay Healthy"	Lifestyle activity levels, occupations and activity levels, why do we need physical activity, intensity of physical activity, types of physical activity, physical activity & weight loss, exercise recommendations, review	13
5	"Dietary Modification #1: Dietary Fibre"	What is dietary fibre, types of fibre, how does dietary fibre help, fibre intake & weight loss, fibre-rich food groups, fibre-rich foods, review	10
6	"Dietary Modification #2: Protein"	Protein, types & functions of protein, protein & weight loss, protein-rich foods, improving protein content in diet, review	9
7	"Dietary Modification #3: Sugar & Salt"	Sugar, types of sugar, salt, 5 notes to keep in mind, recommendations, what happens if we eat too much, visible & invisible sugar & salt, ways to prevent lifestyle related NCDs, review	11
8	"Dietary Modification #4: Essential Fats"	What is fat, why do we need dietary fats, types of fat, SFA, MUFA, PUFA, consequences of not watching your dietary fat, how can we keep our fat intake in check, review	10
9	"Dietary Modification #5: Processed Foods"	Why is food processed, pros & cons, types of processed foods, why to restrict processed foods, can we avoid processed foods, review	10
10	"Using Different Cooking Methods"	Why understand cooking, improving nutrition via cooking, tips to avoid nutrition loss, mutual supplementation, household examples of mutual supplementation, methods of cooking, review	10

The information was compiled using existing literature available in course books, library references, and sources from the internet. Plate 3.6 shows the screenshots of the first slides of the nutrition education. Annexure-XIII details the information covered in each of the modules.

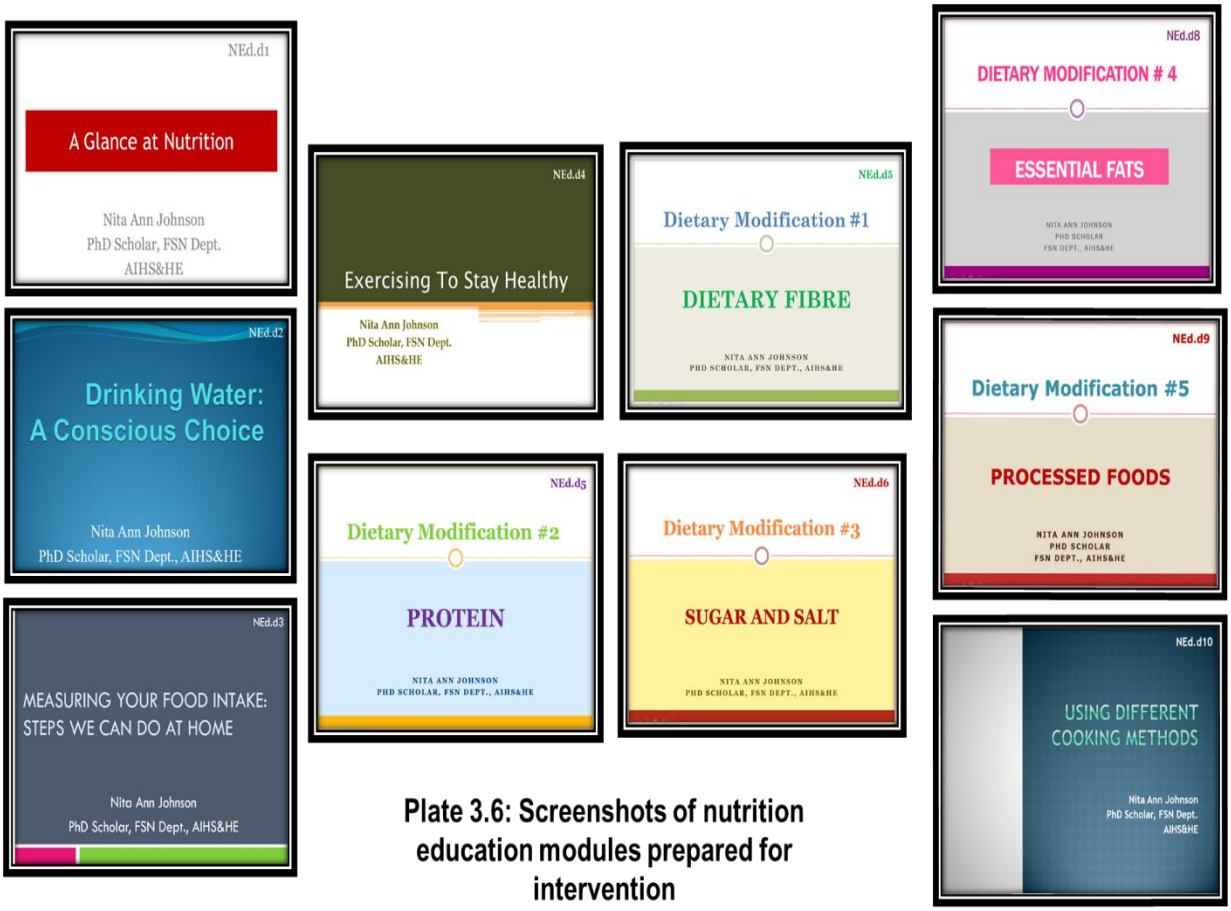

Plate 3.6: Screenshots of nutrition education modules prepared for intervention

Each PowerPoint focused on introducing the selected topic, describing it in an easy-to-understand manner as well as including a slide for a short review session. Each nutrition education session lasted for twenty minutes including the time for questions or clarifications from the subjects.

3.3.2 Identifying exercise routines according to physical activity pattern

Exercise interventions need to be based on “an individual's physical functioning” and have been used as a lifestyle modification intervention in multiple research studies conducted across different age groups in their homes, places of work, schools and/or colleges (Angulo *et al.*, 2020; Armstrong *et al.*, 2022; Grimani *et al.*, 2019; Pojednic *et al.*, 2022). Evidence that suggests exercise interventions as beneficial solutions to individuals with obesity and other NCDs has been

reported in studies done by Bullard *et al.* (2019), Ehtesham *et al.* (2021), Nitschke *et al.* (2022) and Petridou *et al.* (2019). However, while following exercises, it is essential to maintain good posture to carry out the exercise as well as to prevent bodily harm such as temporary or permanent disability (Hannan, 2021; Kanase *et al.*, 2021).

Hence, in the present study, exercise routines were identified in the form of YouTube videos with the help of a licensed physiotherapist (featured in the video) and experienced physical instructors with doctoral degrees in physical education to ensure the study participants' safety and to avoid possible health risks and complaints that may accompany long-term exercise interventions. The subjects were encouraged to follow the YouTube video (30 minutes) daily for five days a week for six months i.e., 26 weeks. Plate 3.7 shows the aerobic activity intervention in progress.

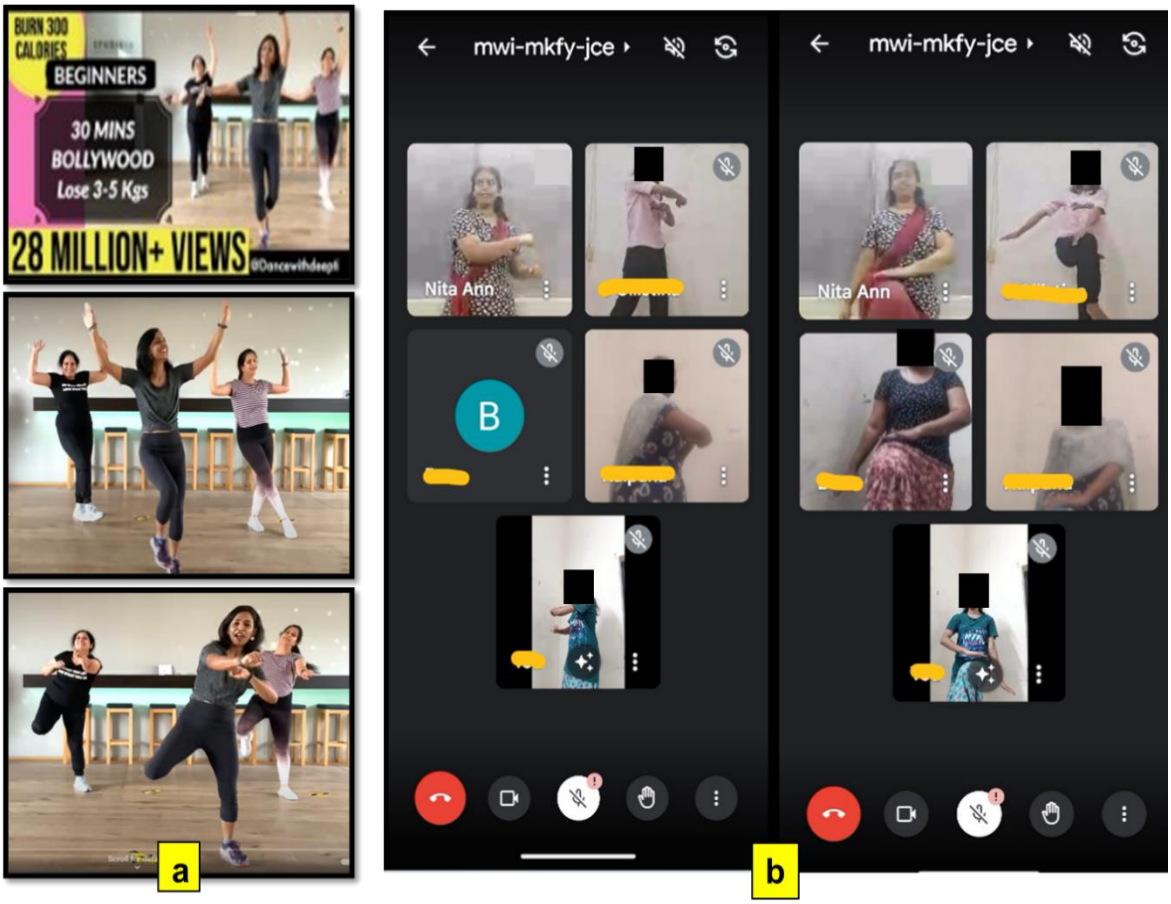

Plate 3.7: (a) Screenshots from YouTube video used as intervention and (b) Screen recording of a shared GMeet workout session

3.3.3 Creating balanced diet plans according to body weight

Dietary counselling is a “process by which a health professional with special training in nutrition helps people make healthy food choices and form healthy eating habits” (NIH-NCI, 2023). In previous studies carried out among obese young women, diet counselling has contributed to an improvement in their body composition, dietary practices and (Calleja *et al.*, 2020; Juchacz *et al.*, 2021; Scannell *et al.*, 2022).

SAMPLE MEAL PLAN FOR A DAY

Meal	Food Group	Examples	Serving Amount
Breakfast	Milk	Curd Tea, Coffee	½ cup
	Sugar		1 cup
	Cereals	Idli/Dosa + Sambaar, Upma + Chutney, Ragi Vermicelli + Roasted Dal	2 nos., 1 cup solid, ¼ cup liquid
	Pulses		
Lunch	Cereals	Rice	½ cup
	Egg/Meat	Egg, Fish or Chicken Curry	¼ cup
	Vegetable	Veg Curry	¼ cup
	Vegetable	Veg Stir Fry/Poriyal	½ cup
Snacks	Milk	Curd	½ cup
	Fruit	Seasonal	1 no
	Cereals	Biscuit, Rusk, Wheat/Atta cake	2-3 nos.
	Milk	Tea, Coffee	1 cup
	Sugar		
Dinner	Cereals	Roti	2 nos.
	Pulses	Roasted Dal/Paruppu	½ cup
	Vegetable	Sautéed Veg	¼ cup
	GLV	Keerai Poriyal	½ cup

Figure 3.4: Sample meal plan provided for subjects

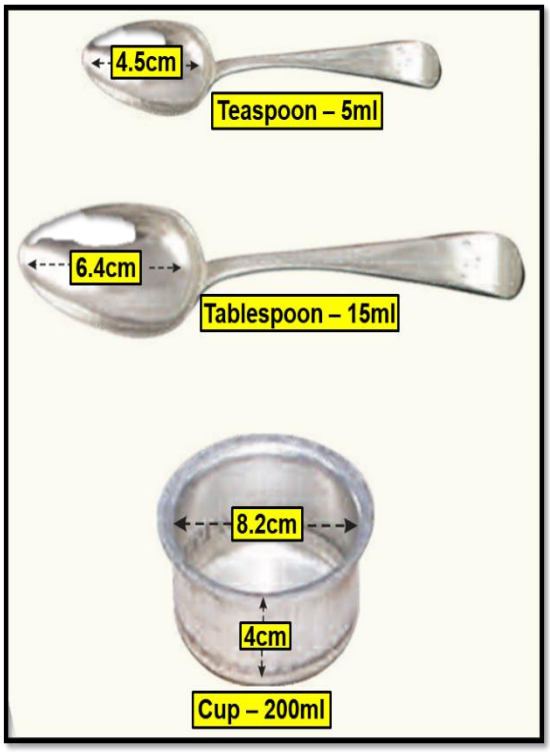

Plate 3.8: Measurements of household utensils sent to subjects as a household method for measuring food

After examining the initial 24 hour recall data, it was decided that diet counselling i.e., awareness about the subject’s diet and helpful modifications wherever required may be made. The subjects were not required but encouraged to follow the recommended diet to aid in managing their obesity. Figure 3.4 shows a sample diet plan that was provided to the subjects, as modified from the ICMR-NIN recommendations (Dietary Guidelines for Indians, 2011). This was modified based on the subject’s likes/dislikes, and/or allergies to promote their voluntary adherence to the recommended diet plan. Since the measurements used in the

sample meal plan were in ‘cups’, photos of a cup and spoons the subjects could use to measure their food were sent to them (Plate 3.8). The aim behind such a plan was to inculcate the practice of consuming balanced diets in their day-to-day lifestyles, rather than calorie counting.

3.3.4 Preparation of health posters and calendar

One calendar with positive messages for the next year (2023) and five posters that were of A3 size; 294x20mm in dimensions were also prepared for the study participants to encourage them to adapt the lifestyle changes brought about by the intervention as a form of long-term form of management of obesity. Figure 3.5 shows the prepared calendar while figure 3.6 shows the health posters.

Figure 3.5: The calendar with positive messages developed by the researcher and distributed to the subjects

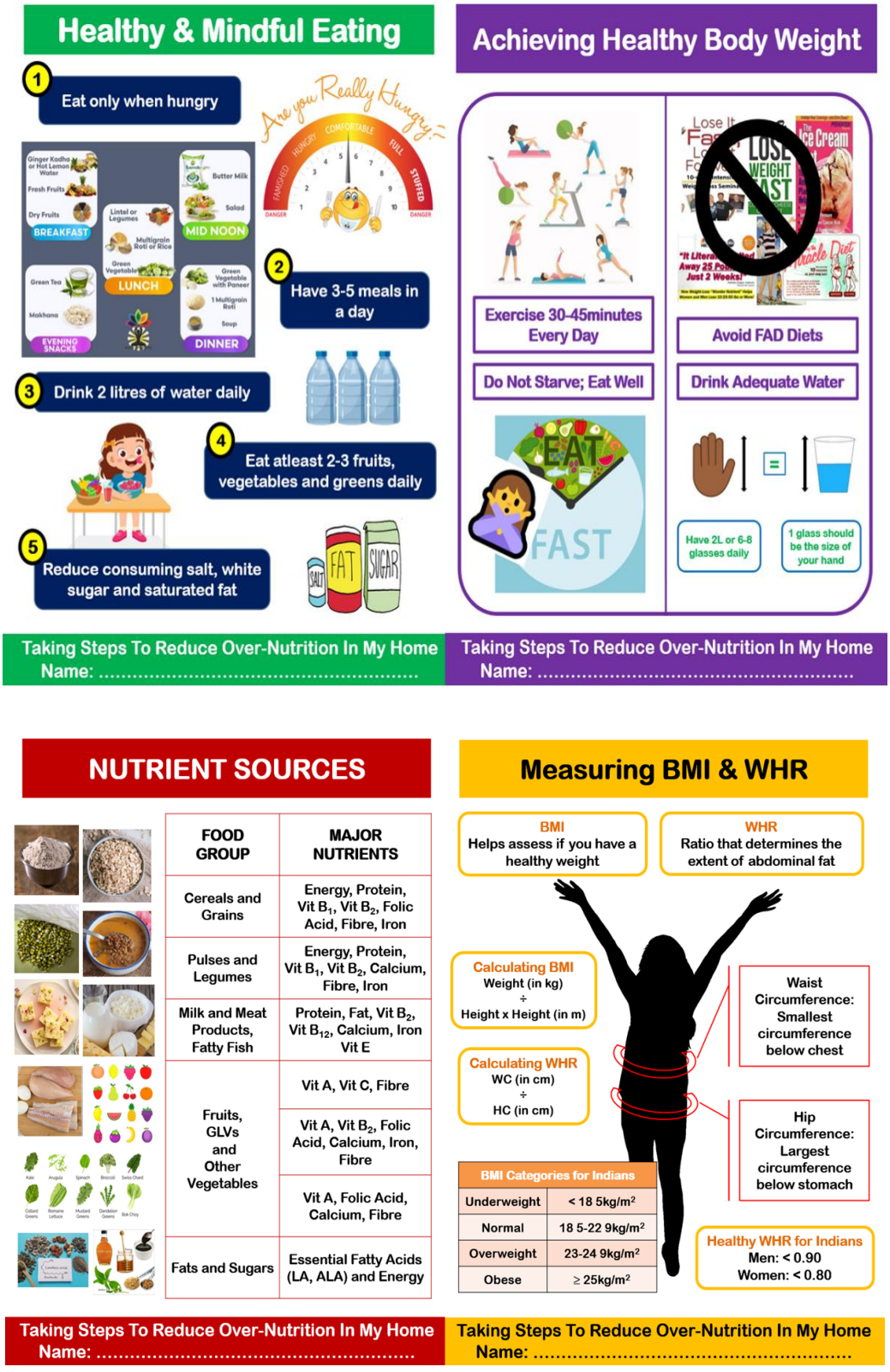

Figure 3.6: The health posters developed by the researcher and distributed to the subjects

The first poster enumerated five tips for 'healthy and mindful eating', the second poster graphically outlined four key tips when 'achieving a healthy body

weight', the third poster described the main nutrients present in common foods in a table titled 'nutrient sources' and the fourth poster described with the help of an illustration, what to do when 'measuring BMI and WHR'. The final poster included the figure 3.4 above as its content and was titled 'sample meal plan for a day'.

3.4.5 Validation of intervention methods

To validate the prepared intervention methods of nutrition education modules, and exercise routines, one hundred women who were subject experts (N=50) and non-subject experts (N=50) were approached for pilot studies. For the nutrition education modules, the subject experts included women who had an educational background in nutrition while the subject experts validating the exercise routines were women with an educational background in physical education. These women were aged in between 18-25 years, to ensure that the developed education and exercise modules would be tailored to the prospective subjects of the study, also within this age group. The step-by-step validation along with the validation results has been explained in Chapter 4, section 4.4.

PHASE V

3.5 implementing interventions of lifestyle modifications for study subjects

Once the samples were selected and intervention methods were identified, it was time to implement them. Implementing modifications in an individual's lifestyle refers to changing their "health behaviours such as physical activity and diet" in hopes of supporting beneficiary changes to their physical health (Bradley, 2022). Most recently, Cifuentes *et al.* (2023), and Tariq *et al.*, (2022) have employed different lifestyle interventions as part of their research study and have found that the said interventions have effectively combated obesity in women.

In the present study, as outlined in Figure 3.3, there were primarily two interventions – of physical activity through aerobic exercises, nutrition education and nutrition counselling. The subjects were randomly assigned using a computerised system into one of the four intervention groups (Figure 3.3) such that there were 158 subjects in all the four groups. There was no intervention imparted for the participants of Group zero, as they were the control group.

Subjects of experimental Group 1 were imparted a physical activity intervention while subjects of experimental Group 2 were imparted a nutrition education and nutrition counselling intervention. Subjects of experimental Group 3 were imparted a combination of both the physical activity as well as the nutrition education and nutrition counselling interventions.

3.4.1 Improving physical activity levels through exercise routines

For those subjects who were provided an exercise routine, the video link to the exercises were shared to the study subjects and the guidelines was to follow the aerobic exercise routines for 30-45 minutes per day for five days a week, for twenty-six weeks. Under the supervision of the researcher, regular Google Meet sessions were conducted to encourage its continuity and to maintain hundred percent participation from the study subjects.

3.4.2 Imparting nutrition education and nutrition counselling

For those subjects who were provided nutrition education, it was carried out through Google meet in batches. Each batch included 20-30 study subjects to allow for a higher chance of interaction during the nutrition education and counselling. Care was taken on the part of the investigator to ensure that each session lasted not more than 10-20 minutes so as to not disrupt the daily schedules of the study subjects.

PHASE VI

3.6 Assessing impact of lifestyle interventions on subjects

The impact of an intervention refers to the “primary and secondary effects produced” by it. This can include the consequent changes that were direct or indirect (Belcher & Palenberg, 2018). The Food and Agriculture Organization of the United Nations in its impact evaluation brief (FAO, 2021) has recorded that it is “the extent to which the intervention has generated or is expected to generate significant positive or negative, intended or unintended, higher-level effects” on the day-to-day living of individuals.

Once the interventions as mentioned in the previous sections, were carried out for 26 weeks, the study subjects were once again reassessed for their dietary

pattern, physical activity, sleep quality and KAP utilising the developed questionnaires as before the intervention and the responses of all the 632 study subjects (164 sub-samples) were recorded as post-intervention data.

3.6.1 Impact on nutritional status of subjects

3.6.1.1 Anthropometric parameters

Anthropometric measurements of weight, BMI, waist and hip circumferences, WHR were re-collected to compare differences of the pre- and post-intervention assessments. Body composition analysis was carried out for the sub-samples (N=164), rather than the whole study population, keeping in mind the Covid-19 restrictions existing at the time.

3.6.1.2 Biochemical parameters of subjects

Blood tests were administered again to the subjects after the intervention period of twenty-six weeks. Due to the partial lockdown but steady re-opening of college institutions, and interest of the subjects, the blood samples were collected at the Institution and analysed once again, for 164 sub-study subjects.

3.6.1.3 Clinical parameters of subjects

After consulting with the medical professional who had assessed the subjects before the study's initiation, the clinical examination of the sub-subjects were assessed and their morbidity patterns studied.

3.6.1.4 Dietary pattern, food and nutrient intake

Potential differences due to the intervention in terms of dietary behaviour and food consumption were determined through a second three-day 24 HR assessment and comparing the before and after data records.

3.6.2 Impact on lifestyle pattern of subjects

3.6.2.1 Physical activity pattern of subjects

Re-utilising the GPAQ to compare pre- and post-intervention data helped to understand if the implemented aerobic exercise routine had bought about any changes for the subjects' daily physical activity levels.

3.6.2.2 Sleep quality of subjects

The PSQI questionnaire was reconducted to determine possible changes in the post-intervention sleeping behaviours and schedules of the study subjects.

3.6.2.3 Knowledge, attitudes and practices of subjects

After rearranging the questions on the KAP questionnaire, the subjects were asked to refill the post-intervention KAP survey. This aided in identifying changes in understanding the subjects' awareness regarding obesity management after the intervention period.

3.7 Statistical analysis and Interpretation

Statistics has various definitions by different authors due to its wide scope in every field of study. Statistics are either "numerical statement of facts" or "whole principles and techniques used in collecting and analysing" data or "the science which deals with the collection, analysis and interpretation of numerical data" (Gupta & Kapoor, 2020). Statistics also "allows researchers to design studies such that the findings from the studies" can then be generalised for future studies in different populations (Bobbitt, 2022). Recently, scientific organisations and scientists across international and national borders had to employ statistics for analysing data trends related to public health which helped towards developing and implementing policies to tackle Covid-19 (Pearce *et al.*, 2020).

In this study, all the data obtained before and after the intervention was studied and interpreted by using the Statistical Package for the Social Sciences (SPSS) software's version 26 for Windows (SPSS Inc., Illinois, USA). Statistical analyses were applied on the data that had been consolidated, checked for redundancies and cleaned for outliers.

- Descriptive statistics and measure including percentages, measures of central tendency (frequency, mean, median, range and standard deviation) and measures of dispersion were used to represent and tabulate all baseline data.
- Inferential statistics were used to understand the influences and associations of the provided interventions on the dietary pattern, physical

activity levels, sleep quality and the KAP of the study subjects such as paired ‘t’ tests.

- To understand intra-group variability between the four intervention groups on their physical activity levels, sleep quality and KAP, analysis of variance (ANOVA) and analysis of co-variance (ANCOVA) tests were utilised.
- To predict the degree of possible influence of the employed intervention (exercise and education) on the lifestyle parameters of the subjects, multiple regression analyses were employed.
- Both $p \leq 0.05$ and $p \leq 0.01$ levels of significance were selected to calculate the significant or critical differences of the employed interventions among the control and experimental groups.

3.8 Validation of study data

In the present study, the anthropometric measurements of height, weight, body mass indices and waist-to-hip ratios were carried out among the 632 participant women subjects over a period of six months by the researcher where she recorded the data from the study subjects, tailored the lifestyle interventions and assessed their impact on the status of obesity among the over-nourished women participants. The clinical examinations, biochemical analyses and body composition analyses using the InBody 720 body composition analyser was conducted for 164 consenting subjects due to the Covid-19 restrictions existing at the time. The data obtained from the InBody 720 body composition analyser was validated for body composition measurements by comparing the obtained measurements of weight, percent body fat, and estimated BMR using a standardized, non-spring balance weighing scale, skin fold callipers, and the Harris-Benedict basal metabolic rate equation respectively (Luy & Dampil, 2018) with 5 per cent variability and using standardized procedures. This was carried out twice throughout the study period – once before the initiation of the study and once after the intervention period of the study. The lifestyle interventions of exercise routines and nutrition education were pre-tested and validated on a representative sample after which it was administered to the study subjects for a period of twenty-six weeks i.e., six months. The researcher herself had recorded the anthropometric and body composition measurements, thereby eliminating probability of estimation error and bias in data collection.

3.9 Conceptual framework of study

Conceptual frameworks, models, and diagrams are widely used in public health research to show the relationships between health exposures and outcomes i.e., “diagram of proposed relationships among a set of concepts, factors, or variables about a particular hypothesis, question, context, problem or topics” (Paradies & Stevens, 2005). In prior community health studies, theoretical frameworks have been developed and used to interpret statistical models, identify knowledge gaps, direct future research, and aid the transfer of research into policy and practice (WHO, 2010; Dalen *et al.*, 2015; NASEM, 2016; Ryvicker, 2018; Estecha Querol *et al.*, 2021). In the present study, a combination of the all the above cited works were employed to effectively understand the possible connections between individual, community or societal factors on the direct and indirect determinants of the disease outcome that was overweight and obesity. The conceptual framework of the present study is displayed as Figure 3.7.

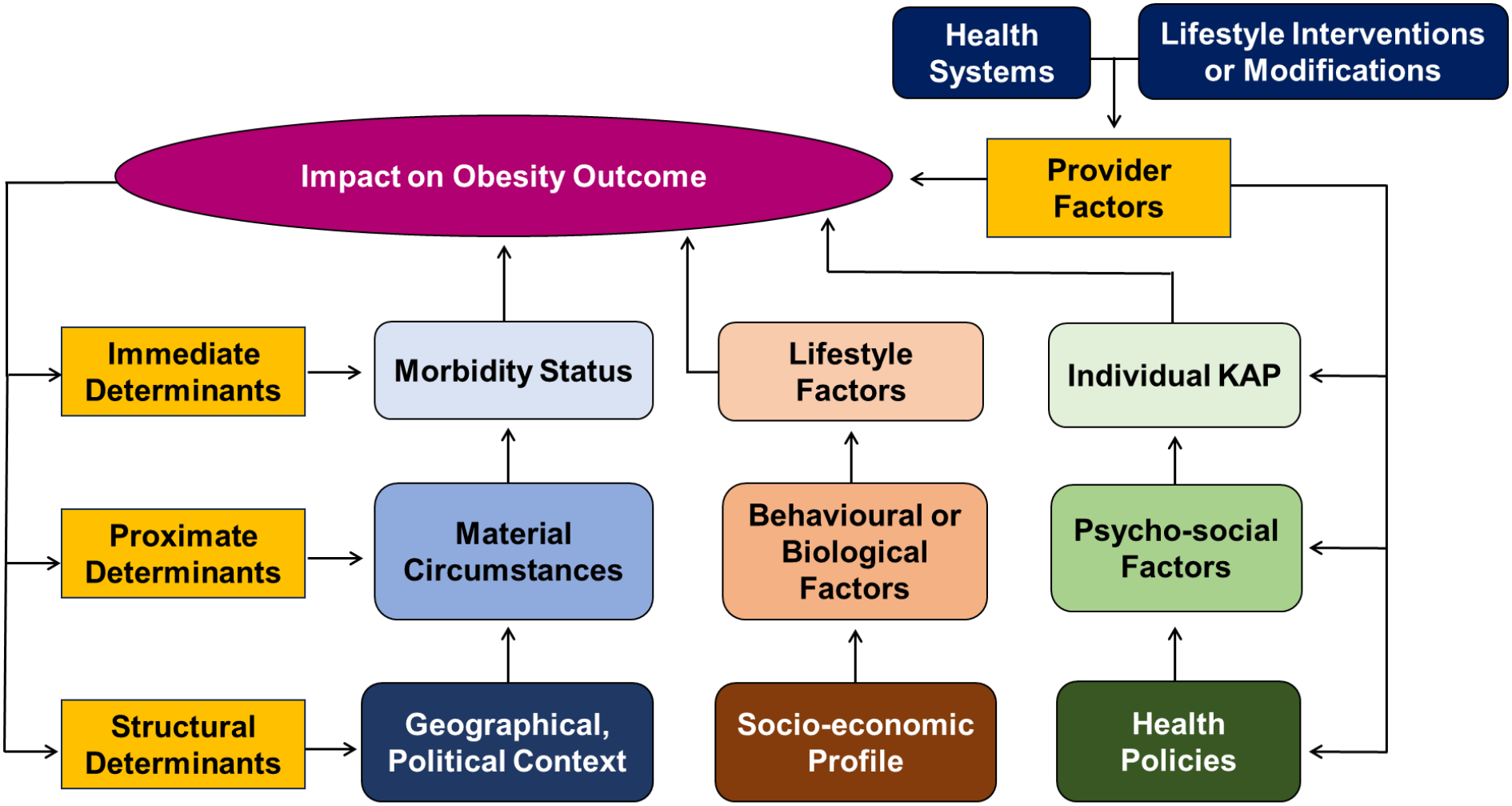

Figure 3.7: The conceptual framework of the study

Here, structural determinants include the geographical and political context, health policies in effect and socio-economic background of the subjects existing during the study period. Under geographical and political context, it would include the Covid-19 regulations existing at the time as well as the lockdown environment prevailing in the state of Tamil Nadu. The socio-economic profile would include the age, gender, education level and family income of the subject and the health policies would include the accessibility to quality healthcare. Material circumstances would include the living and working conditions, food availability, connectivity to the outside world etc. prevalent at the time which could affect the morbidity status of an individual. Behavioural and biological factors include the modifiable lifestyle factors of a subject including their dietary pattern, physical activity and sleep pattern. The existing health policies are likely to influence the psycho-social factors of an individual that includes their individual reactions or responses to the home, work or college environment, their preference to be physically active, practice mindful eating etc. that are likely to in turn affect the accumulation of Knowledge, Attitudes and Practices (KAP) of a subject.

The provider factors include the interventions and health systems that may affect the incidence of obesity outcome along with the morbidity status, lifestyle factors and individual KAP of the subject. Ultimately this disease outcome of obesity is likely to transcend generations and become a cyclical global health problem due to its direct and continued influence on the rest of the determinants and factors. Although it is essential to examine the complexity of the incidence of obesity from the grassroot levels, the scope of the present study is focused on the immediate and proximate determinants, as outlined in Chapter 1.