5. METHODS

5.1 Design 1

5.1.1 Materials and Approaches:

Definitive and systematic study of developing an IYAT *yoga* module for treating hypothyroidism, anchored in the *pañca kośa* module tackles the physical, social, spiritual, and psychological concerns associated with hypothyroidism condition, as mentioned in the *thaittiriya upaniṣad* five layers of human existence. The module proposes several great *yogic* methods that should be learnt and performed in three months. In the primary trial, the individuals are given ninety minutes of practise sessions each day, five days a week. (Design 2). *Kośa* wise technique is one of the effective *yogic* techniques as it manages the hypothyroid condition, which is why the technique is considered for developing the IAYT program. The *kośa* technique is taught to each individual based on their capacity to learn and practise, avoid monotony, and manage time. The IAYT is a ninety-minute practise session that involves loosening exercises that cover all of the important joints from head to toe. Two numbers of standing *āsanās,* two numbers sitting *āsanās* that includes four numbers inverted postures, two numbers of *prāṇayāma*, one number meditation and three types of relaxation techniques. Finally, institutional ethic clearance is obtained for the study, and the entire development process of the module is carried out in three steps.

5.1.2 Step 1: Constructions of the Module

By analysing the clinical aspects of hypothyroidism and the principles of IAYT, a systematic collection of *yogic* activities was largely given with a brief comment (attachment 9.0). Here the main focus is on some essential *yogic* techniques that offer unique benefits to the subjects. The benefits are as follows:

Thyroid gland relaxing, toning, stretching, stimulating, and massaging. Improves digestion and the correct production of digestive enzymes, as well as the digestive system and, in particular, the liver. Toxins are removed from the body by breath, sweating, and excretion. The peace of the mind and tranquilly sharpen the intellect when you use tactics that build emotional intelligence in the mind.

These *yogic* practices were discovered after a careful examination of *yogic* scriptures and other hypothyroidism-related scientific research publications (Chatterjee & Mondal, 2017; Kiran & Neeta, 2017; Nilakanthan et al., 2016). The draft module contains detailed information about the *yogic* techniques, several practice rounds recommended, and approximate practice time. The detailed and necessary justification was provided against each *yogic* technique by referring to a scientific paper, *yogic* texts, empirical knowledge, and expert consultation (Iyengar, 2008; Kuvalayananda, 1993; Muktibodhananda, 1985; Raghuram & Nagendra, 2004). In addition, the draught includes a column (five-point Likert scale) that lists the comments and significance associated with each technique. Column 1 not relevant, column 2 little relevant, column 3 moderately relevant, column 4 very relevant, column 5 extremely relevant. A remark space is also included in the module, where the reviewer can leave feedback. Attachment 9.0 describes the detailed module, which includes the *yogic* practises related to each sheath.

5.1.3 Step 2: Validation of the Module

Fifty subject matter experts (SMEs) were asked to validate the model. Ten medical professionals rejected owing to a lack of time, and four *yogic* specialists did not return the form. Total fourteen SMEs declined to participate and thirty six subject matter experts including six *yoga* experts - four PhDs in *yoga* and two *yoga* experts more than fifteen years of experience, ten medical practitioners including *Āyurveda*, Naturopathy, and Allopathic endocrinologists and eight MDs, twelve *yoga* therapists are MSc/DYT in *yoga* therapy are validated the module.. All the experts who have validated the module provided written consent. In addition, content validity, face validity, and relevance of each technique were obtained from all the experts.

5.1.4 Step 3: Analysis of the Data

The data obtained from 36 experts was examined using the content validity ratio (CVR); an average of the mean, mode, and median of the relevance scores was generated using SPSS software version 23. The formula CVR= (Ne-N/2)/ (N/2) was used to compute the content validity ratio. The number of panelists expressing the essential is referred to as the Ne. The total number of panelists is denoted by the letter N. The mean, standard deviation, and standard deviation of the mean, as well as the mode and median, were determined.

Yoga practices with fewer than 0.5 ratios (Kumar et al., 2020) or an average of mean, mode, or median less than four were eliminated. The Cronbach alpha value was used to assess the internal consistency.

5.1.5 Feasibility Study: Design 1

The authenticated module was given to 35 women with hypothyroidism as part of an experiment to see if they would accept and be able to do the postures and *yogic* methods. Thirty-five women between the ages of 25 and 50 have been diagnosed with hypothyroidism and are receiving therapy from allopathic, homoeopathic, or *Āyurvedic* doctors. As a result, these ladies are under consideration for a potential check. Women having a history of surgery or any medical condition that prevents them from experimenting with tools or the IAYT *yoga* module are excluded from the research. Each subject signed a formal consent form, and it is recommended that subjects follow all of the recommended protocols precisely under observation.

5.2 DESIGN 2

5.2.1 PARTICIPANTS

Sources of subjects, both male and female clinically diagnosed as hypothyroidism, were selected from reputed *yoga* centres and registered diagnostic centres in Bengaluru. The participants were selected by randomisation between the age group 25 years to 50 years.

5.2.2 Sample Size

Sample size as per previous study was 45 numbers (Chatterjee & Mondal, 2017). By considering p-value 0.01, Power-0.80, Es-0.4, the sample size found by using G-power software was 44. In the present study, sample size is 55 by adding 25% of attrition. This is further rounded off to 60 females with 30 subjects for IAYT group and 30 subjects for wait list control group and in Ethic committee recommended to male subjects, at the time of intervention fourteen male subjects were added seven each in *yoga* intervention IAYT group and waitlist control group.

5.2.3 Selection and Source of Participants

The study included both male and female volunteers between the ages of 25 and 50.The research included subjects taking *yoga* training courses at a reputed *yoga* centre in Bengaluru and a nearby reputed diagnostic center.

5.2.4 Inclusion Criteria

1. Subjects keen to participate in this program.
2. Subjects aged between 25 to 50 years.
3. Subjects who are diagnosed to have hypothyroid disorder.
4. Subjects are able to follow treatment instructions and respond to survey questions in English to a satisfactory level.
5. Subjects under hypothyroid medicine for six months to less than five years.

5.2.5 Exclusion Criteria

1. Participants with a physical limitation or medical condition that would make administering tools or the planned IAYT intervention were excluded from the research.
2. Pregnant subjects or subjects who have undergone surgery in the last six months were excluded from the study.
3. Subjects who are suffering from hypertension and especially those who are taking beta blockers were excluded.

5.2.6 Ethic Consideration

1. Informed Consent: The subjects gave their informed consent in the form of a signed document. The university's ethic committee obtained ethic approval.
2. Also, stipulated guidelines and compliances of the University for carrying out the research study were met.
3. Trained *yoga* therapists were deployed to conduct IAYT intervention. The researcher was not in direct contact with the intervention or the subjects.
4. IAYT interventions were provided in a clean, airy environment ensuring general safety measures.

5.3 DESIGN 2 OF THE STUDY

A sample of seventy four with hypothyroidism subjects is split into two groups they are IAYT *yoga* intervention and waitlist control groups. Subjects in the *yoga* intervention group are given five sessions per week *yoga* course for ninety minutes per day weekly five days for over three months as a complementary therapy to hypothyroid dysfunction. Waitlist control group subjects were instructed not to perform any exercise regimen during the study period. Once the study period was completed and post data was collected, IAYT intervention was provided for control group subjects. In addition, an available record log book was maintained to check their lifestyle and diet, WHO Quality of Life was assessed before and at the end of the program. Thyroxin medicine was kept stable throughout the study in both the groups.

5.4 VARIABLES STUDIED

Following parameters (dependent variables) were studied:

Primary Variables:

1. Thyroid function indicators such as T3, T4, TSH, Free T3, Free T4.
2. Sex Hormone Binding Globulin (SHBG): SHBG levels in the blood fluctuate due to sex, age, hypothyroidism, obesity, and liver illness. Hypothyroidism is linked to low SHBG levels.
3. C - reactive protein (CRP): CRP is increased in hypothyroid patients long before other metabolic derangements of hypothyroidism take place.
4. Thyroid peroxidase antibody (TPO Antibodies): Most common cause of hypothyroidism is autoimmunity. I do not measure autoantibodies, will not know the cause of hypothyroidism.
5. Thyro globulin (Tg) Antibodies.
6. Serum Cortisol at 8 am.

Secondary Variables:

7. Body Weight and BMI
8. Quality of Life.

T3, Free T3, Free T4, T4, TPO Antibodies, Tg Antibodies, Weight, BMI, TSH, SHBG, CRP, Serum Cortisol, Body and Quality of Life were evaluated/calculated pre and post intervention for the IAYT group. In addition, pre and post data of the control group were obtained with a gap of three months. The T3, Free T3, T4, Free T4, TSH, Tg Antibodies, SHBG, CRP, TPO Antibodies, and Serum Cortisol data was collected from the laboratory

test reports. In addition, BMI was calculated by recording the Weight (using an electronic weighing scale) and subjects' height.

Quality of Life was evaluated using WHO QOL - BREF generic version of the assessment with field trial version in December 1996. This five point Likert self reporting Questionnaire has 26 items about physical health, emotional state, social relationship, and environment. Demographic data are collected before the intervention commencement using a printed demographic form containing general demographic and anthropometric information about the subject. This family history, professional history, social history, sleep pattern, food habits, and physical activities levels are recorded and monitored. Daily routine, diet, and medicine scores were recorded of all the experimental and control group subjects in the log book.

5.5 INTERVENTIONS

The IAYT intervention (independent variable) is the customized IAYT based *yoga* program for this project, which addressed issues at *pañca kośa* level and includes practices such as *āsanās, prāṇayāma*, meditation, relaxation, prayers/chanting, and knowledge point. The IAYT practices that predominantly influence different *kośās* are listed below in table 2.

5.6 Table 2: Integrated *yoga* module for hypothyroidism – *pañca kośa* practices

Practices	***Kośa***	**Duration**
Breathing Practices, Loosening Exercises *Sūryanamaskāra, āsanās* (Standing, Sitting, Inverted, Supine and Prone *āsanās*), *Kriyās and Diet*	*Annamaya kośa*	40 minutes
Prāṇayāma, Bandās and *Mudrās*	*Prāṇamaya kośa*	15 minutes
Meditations and chanting	*Manomaya kośa*	20 minutes

Knowledge Points, especially on food habits, sleep pattern, sunlight exposure.	*Vijñānamaya kośa*	5 minutes
Relaxation	*Ānandamaya kośa*	10 minutes

5.7 DATA EXTRACTION

Both the intervention and waiting group's data collected at the beginning and completion of the trial period. The data had been collected using standard processes. The information gathered was then placed into an excel spreadsheet for analysis.

5.8 DATA ANALYSIS

Version 23 of the Statistical Package for Social Sciences (SPSS) was used to analyse the data. A parametric test is done considering the case of the normal distribution as the subject population is greater than 30. In each of the two groups, the clinical parameters are split to pre and post data. Within each of the two groups, data is analyzed pre and post using paired sample t-test. Between the two groups, post data is analyzed using an independent measure t-test. Also Repeated Measures Analysis of Variance (RM-ANOVA model) was used to assess difference between means of inter- and intra group followed by Bonferroni post tests. Changes with $p < 0.05$ were considered statistically significant. Correlation between Post IAYT yoga and Post Control group was analysed, individual total percentage change was also calculated. The significance value is categorized as below in table 3:

5.9 Table 3: Categorization of significant values

P<0.001	Exponentially significant
P<0.01	Highly significant
P<0.05	Significant

5.10 Consort Flow Chart

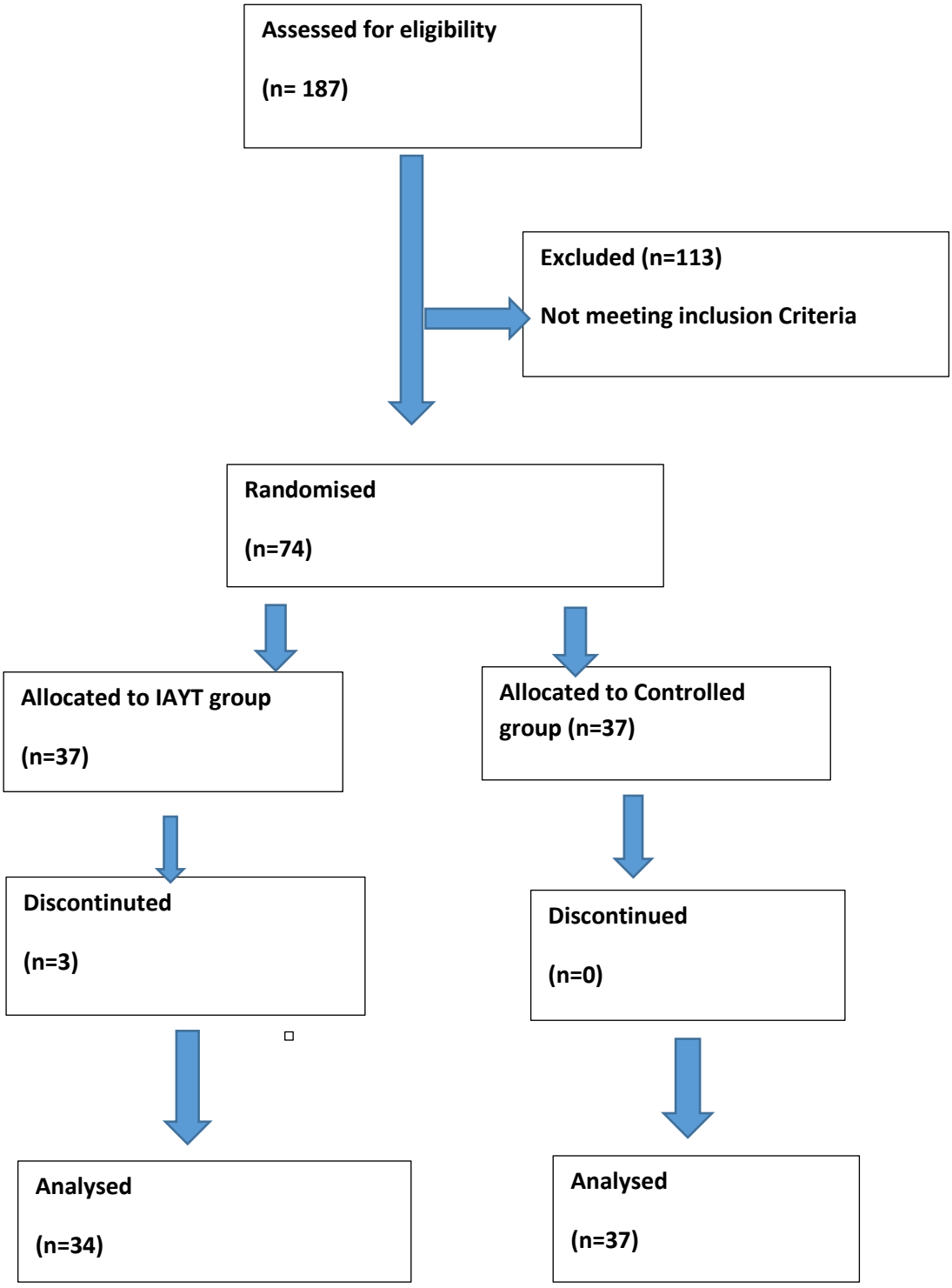

Figure 8: Consort flow chart diagram of the clinical trial.

The current chapter discussed about the materials, methods, modules and design of the study. The next chapter discusses about the results of design 1 and design 2 of the study.