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3.1 INTRODUCTION

The current study has been designed to investigate the effect of raw diet and yoga on Type 2 diabetes in different stages of disease process. The dependent variables of the study were blood sugar level, blood cholesterol, blood pressure, pulse rate, body weight, BMI, Abdominal girth, HbA1c, quality of life, sleep quality index and mental health. Major aim of the study was to identify the outcome of the raw diet and yoga on various physiological and psychological variables. The study also assessed the difference in the effect of intervention on physiological and psychological changes in prediabetic and Type 2 diabetic group on 1st, 7th and 40th day of intervention. This chapter gives the details about the methodology adopted in this study. The method of research adopted, the description of tools, techniques used, the sample, and the procedure of data collection and the outline of statistical techniques adopted for the analysis of data are described under appropriate titles and presented below.

3.2 RESEARCH METHOD ADOPTED

3.2.1 RESEARCH APPROACH

An experimental evaluative research approach was used for the present study. The main intention of the study was to discover the efficacy of the raw diet and yoga to control prediabetic and Type 2 diabetic and also to find out the effectiveness of raw diet and yoga between both the groups. The experimental approach evaluates and describes the differences in variables in both experimental and control groups.
3.2.2 DESIGN

Pretest-post test control group design was adopted for the current study. Its intended design, samples has been assigned to intervention group and control group using random method.

The research design used for the study is presented in the following manner:

<table>
<thead>
<tr>
<th>Control group-1</th>
<th>O₁</th>
<th>O₂</th>
<th>O₃</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental group-1</td>
<td>O₄</td>
<td>X</td>
<td>O₅</td>
</tr>
<tr>
<td>Control group -2</td>
<td>O₇</td>
<td></td>
<td>O₈</td>
</tr>
<tr>
<td>Experimental group-2</td>
<td>O₁₀</td>
<td>X</td>
<td>O₁₁</td>
</tr>
</tbody>
</table>

O₁-(Day1) pretest data of the control group 1
O₂-(day 7) post test-1 data of the control group 1
O₃-(day 40) post test-11 data of the control group 1
O₄-(day 1) pretest data of the experimental group 1
O₅-(day 7) post test-1 data of the experimental group 1
O₆-(day 40) post test-11 data of the experimental group 1
O₇-(day 1) pretest data of the control group 2
O₈-(day 7) post test-1 data of the control group 2
O₉-(day 40) post test-11 data of the control group 2
O₁₀-(day 1) pretest data of the experimental group 2
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O₁₁-(day7) post test -1 data of the experimental group 2

O₁₂-(day40) post test-11 data of the experimental group 2

X- The intervention used was the raw diet and yoga which is the independent variable in the study.

Raw diet is a therapeutic intervention in which whole, unrefined and raw plant foods, such as clean fruits, vegetables, seeds, nuts, grains and dried up fruits were replaced for normal diet and given to the patients (At least 80-100% uncooked foods). Yoga refers to therapeutic intervention which gives the discipline of the mind, senses and physical body which includes different asanas like Halasana, Bhadrasana, Bugangasana, Dhanurasana, Matsyantrasana, Viparitahkarani, Pachimudhrasana, Ardhamalsendrasana, Ardhahalasana, Chakrasana, Salabhasana, Vakrasana, Naukasana, Vajrasana, Yogamudhra, Tree Pose, Sarvangasana, and Savasana.
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Sample and sampling technique

<table>
<thead>
<tr>
<th>Group</th>
<th>Experimental</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre DM</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>T2DM</td>
<td>30</td>
<td>30</td>
</tr>
</tbody>
</table>

60 prediabetes and 60 diabetes Christian nuns who were visiting JMMCH for treatment and willing to participate in the study

Selected by random sampling

Variable

Independent Variable
- Yoga and raw diet

Dependent variables
- Physical:
  - Height & weight
  - Abdominal girth
  - BMI
- Physiological:
  - FBS, Cholesterol
  - HDL, LDL, TG,
  - HbA1c, BP, pulse
- Psychological:
  - QOL
  - Sleep
  - Mental health

Tools and Techniques

Demographic and clinical data variable
- Pittsburgh sleep quality index
- WHOQOL-scale
- Mental Health Scale

Data Collection

Collecting clinical data variables on 1st, 7th, and 40th day

Pittsburgh sleep quality index
- WHOQOL-scale
- Mental Health Scale

Selected by random sampling

Data Analysis

Descriptive statistics
- Frequency
- Percentage
- Mean
- Median
- Mode
- Standard deviation

Inferential statistics
- Paired “t” test
- GLM
- Repeated measure
- ANOVA
- Independent t test

Figure 4: Pre test – post test control group design adopted for the study
3.3 POPULATION

In this study, the population which consists of all the adult Christian nuns between the age of 30-60 years staying together like a family, praying together and working for the people who are diagnosed with pre diabetes and Type 2 diabetes.

**Target population:** All adult Christian nuns who are diagnosed with pre diabetes and Type 2 diabetes.

**Accessible population:** Adult Christian nuns seeking medical treatment in Jubilee Mission Medical College Endocrinology and Medicine OPD who fulfils the inclusion criteria. The investigator selected the centre part of the Kerala where there is more incidents of diabetes and feasible to conduct interventional study with provision of adequate space and privacy for the patients. This particular centre cater Patients from Thrissur, Ernakulum and Palakkadu district and they were allowing to take patients for this study. Six zones from Thrissur were selected for giving one week yoga and raw diet training because of availability of comfortable place to come and stay for the participants for one week training.

3.4 SAMPLE

The study Sample consists of a total of 120 samples, 60 pre diabetic and 60 Type 2 diabetic patients. Each groups were again divided into two groups one experimental and one control group with 30 samples. The sample size were estimated by using the following formula

\[ n = S_1^2 + S_2^2 \times \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2}{(X_1-X_2)^2} \]
Previous study mean($X_1,X_2$) and Standard deviations ($S_1,S_2$) were taken for sample size calculation. They were

$X_1=308, \ X_2=251$

$S_1=52, \ S_2=57$

The alpha level used in determining the sample size in the study was 0.01. Power of the study was 90%

$Z_{\alpha}$ was 2.58 for 1% level of significance

$Z_{1-\beta}$ was 1.28 at 90% statistical power.

$\alpha=2.58$ (with 0.01% significance)

$\beta=1.28$ (with 90% power)

$n=\frac{52^2+57^2 \times (2.58+1.28)^2}{(308-251)^2}$

$n=2704+3249 \times 14.89
53249$

$n=5953 \times 0.00458=27$

10% dropout was assumed and Total sample in one group is calculated as 30.

Total sample for four groups were calculated as 120.

3.4.1 Sampling Criteria

Adult Christian nuns between the age of 30-60 years, representing three districts and educated above 10th standard who were diagnosed with pre diabetes and Type 2 diabetes were recruited for the study.
3.4.2 Inclusion Criteria

Adult Christian nuns between the age of 30-60 years who were diagnosed with pre diabetes and Type 2 diabetes, Prediabetic patients with range of FBS 100-125mg\dl and Type2 diabetic with FBS>126mg\dl, without complications ,with in 5 years of diagnosis, HbA1c <8%, willing to partake in the study and were available during the intervention period were included in the study.

3.4.3 Exclusion Criteria

Prediabetic and Type 2 diabetic patients with unsteady health condition balanced with low-calorie, vegan food, and practicing yoga regularly, on alternative therapies, those who were not willing to participate in the study, having co-morbid chronic medical and surgical conditions and diabetic complications were excluded from the study.

3.4.4 Sampling

Sampling technique:

Accessible population was Type 2 diabetic and prediabetic christian nuns those who are visiting JMMCH medicine and endocrinology OPD for treatment at the time of study period. Patients who fulfilled the inclusion criteria and those who were willing and present during study period were screened and selected from OPD register. After explaining the study and procedure details individual written consent is taken from the participants those who were willing to participate in the study. The randomization in the study was stratified according to place and base-line fasting plasma glucose values in order to obtain the best possible comparability between groups. Collected patients
names were categorized into prediabetic and Type2 diabetic group based on their FBS values. 60 prediabetic and Type 2 diabetic patients again divided into strata according to their demographic (Thrissur, Ernakulum and palakkad). Experimental group and control group samples from each strata were drawn by simple random sampling using lottery method.

3.4.5 Distribution of Socio Demographic and Clinical Data Variables

This section describes the distribution of samples based on sociodemographic and clinical data. It includes age, gender, education, Family Type, Residence, Occupation, and Type of diabetes, Duration of Illness, Stage, and Treatment.

Table 1: Shows the distribution of samples according to socio demographic variables. 50% of samples were Prediabetic and other 50% were diabetes. 55.8% of
them were having diabetes since less than one year. 46.7% were in the age group of 51-60 years. All the samples were females. Out of 120 samples, 92.5% of them were having professional education. Majority (76%) of the samples were from rural area. 54.2% belong to joint family.

Table 3.1

<table>
<thead>
<tr>
<th>Variables</th>
<th>Prediabetic</th>
<th>Type2 Diabetic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Experimental</td>
<td>Control</td>
<td>Experimental</td>
</tr>
<tr>
<td></td>
<td>n=30 (%)</td>
<td>n=30 (%)</td>
<td>n=30 (%)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-40 years</td>
<td>11 (36.7)</td>
<td>8 (26.7)</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td>41-50 years</td>
<td>11 (36.7)</td>
<td>8 (26.7)</td>
<td>16 (53.3)</td>
</tr>
<tr>
<td>51-60 years</td>
<td>8 (26.7)</td>
<td>14 (46.7)</td>
<td>13 (43.3)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>30 (100)</td>
<td>30 (100)</td>
<td>30 (100)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>College</td>
<td>3 (10.0)</td>
<td>-</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td>Technical</td>
<td>1 (3.3)</td>
<td>-</td>
<td>4 (13.3)</td>
</tr>
<tr>
<td>Professional</td>
<td>26 (86.7)</td>
<td>30 (100)</td>
<td>25 (83.3)</td>
</tr>
<tr>
<td>Family Type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nuclear</td>
<td>9 (30.0)</td>
<td>25 (83.3)</td>
<td>4 (13.3)</td>
</tr>
<tr>
<td>Joint family</td>
<td>21 (70.0)</td>
<td>5 (16.7)</td>
<td>26 (86.7)</td>
</tr>
<tr>
<td>Residence</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>24 (80.0)</td>
<td>30 (100)</td>
<td>11 (36.7)</td>
</tr>
<tr>
<td>Urban</td>
<td>6 (20.0)</td>
<td>-</td>
<td>19 (63.3)</td>
</tr>
<tr>
<td>Occupation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non professional</td>
<td>1 (3.3)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Professional</td>
<td>29 (96.7)</td>
<td>30 (100)</td>
<td>30 (100)</td>
</tr>
<tr>
<td>Duration of illness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1year</td>
<td>-</td>
<td>-</td>
<td>6 (20)</td>
</tr>
<tr>
<td>1-2 years</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2-3 years</td>
<td>-</td>
<td>-</td>
<td>4 (13.3)</td>
</tr>
<tr>
<td>&gt;3years</td>
<td>-</td>
<td>-</td>
<td>20 (66.7)</td>
</tr>
</tbody>
</table>

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Figure 5. Distribution of sample according to age

Figure 6. Distribution of sample according to educational status
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Figure 7. Distribution of sample according to family type

Figure 8. Distribution of sample according to area of residence
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3.5 SETTING OF THE STUDY

The setting of the study for the control group was endocrinology and medical outpatient department of Jubilee Mission Medical College Hospital Thrissur. The intervention was carried out in the selected 6 zones of Thrissur with the cooperation of religious organization. Patients were identified by attending special clinical department of Jubilee Mission Medical College Hospital Thrissur. Participants were recruited with the help of medical records and personal enquiry with the participants. They were from three districts, Thrissur, Ernakulam and Palakkadu. Among these three districts six zones of Thrissur were chosen because of easy access of the samples.

3.6 DESCRIPTION OF THE TOOLS

The tool was prepared and selected on the basis of the objectives of the study. The following steps were adopted prior to the development of the tool:

Figure 9. Distribution of samples according to duration of illness
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- Review of relevant literature (text books, journals, periodicals, website etc).
- Discussion with colleagues.
- Personal consultation and discussion with experts.
- Investigator’s observation and experience in clinical area.

The tools which are used for the present study were:

- Tool I: Baseline Performa.
- Tool II: Pittsburgh sleep quality index
- Tool III: WHOQOL assessment Tool
- Tool IV: Mental Health Scale (M.H.S.)

3.6.1 Tool: Section A: Baseline preformed

This section had 15 categories such as age, gender, education, Family Type, Residence, Occupation, and Type of diabetes, Duration of Illness, Stage, and Treatment. The investigator would place the tick mark (‘✓’) against the column provided as per respondent’s response. Weight in kg, Height in cm, Abdominal circumference, Bp, and pulse were checked by the investigator and the blood values result like FBS, Cholesterol, HDL, LDL, TG and HbA1c were collected from samples records on the first, seventh and 40th day by the investigator.

3.6.2 Pittsburgh sleep quality index

Sleep quality of the samples were assessed by using Pittsburgh sleep quality index. This is developed by Buysse et al in 1989. It is a standardized tool to assess the sleep quality and sleep pattern. This instrument helped to identify good and poor sleep by assessing seven aspects of sleep mainly sleep quality, sleep latency, sleep duration,
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sleep efficiency, sleep disturbance, use of sleep medication, and day time dysfunction. Participants one month sleep habits were evaluated by asking the patient to evaluate and mark their one month sleep pattern.

**Scoring:**

1. **Subjective sleep quality:** This consists of question two and five (a) score.
   
   Question two carries three marks. (It is divided like 15 minutes sleep carries zero score, 16-30 minutes carries one score, 31-60 minutes carries two score and more than 60 minutes carries three score).

   Question 5a carries three marks. (It is divided like, if total is zero = zero, one to two = one, three to four = two, five to six = three). Both questions scores will be added together to get the total score of the sleep quality.

2. **Sleep latency:** This consists of question three and four score. (If score is more than seven = zero, six to seven = one, five to six = two, less than five = three).

3. **Sleep duration:** This consists of question four score. (Total hours of sleep) / (total hours in bed) x 100): if score is more than 85% = zero, 75% to 84% = one, 65 to 74% = two, less than 65% = three.

4. **Habitual sleep efficiency:** This consists of question five score: it includes total score from 5b to 5j, if total score is zero = zero, one to nine = one, ten to eighteen = two, nineteen to twenty seven = three.

5. **Sleep disturbances:** This consists of question six score (total of six score).

6. **Use of sleeping medication:** This consists of question 7 and eight score. (If we get two = one, three to four = two, five to six = three).
7. Daytime dysfunction: Total of the seven section scores jointly. Zero to three score is kept as base. In this three mirror negative insignificant value total of five or more than that reflect poor sleep. Total sleep score Minimum Score = 0 (better); Maximum Score = 21 (worse).

Validity and Reliability:

Pittsburgh sleep quality index tool checked for validity and reliability. Internal consistency coefficient was calculated by Cronbach’s alpha that provides 0.84 score. All seven components score reveals good reliability of the tool. Previous research study reports also shown high validity and reliability. Therefore this instrument has been used to assess the sleep quality of patients.

3. 6.3 WHOQOL Assessment Tool

The WHOQOL assessment Tool has been developed by World Health Organization Geneva in 1996. The WHOQOL assessment Tool compresses 26 statements and provides a wide and broad estimation, of quality of life. Overall quality of life and general health aspects questions were included in the initial part of the tool. 26 questions are organized under four Components which includes physical domain, psychological domain, social domain and environmental domain.

Domain1: Physical domain consist of Physical health, Activities of daily living, reliance on therapeutic substances and health checkup, liveliness, tiredness, Mobility, aches, distress Sleep, relaxation and work capability Questions-Q3 + Q4 + Q10 + Q15 + Q16 + Q17 + Q18).
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**Domain2:** Psychological domain consist of physical representation, outer look, unenthusiastic feelings, optimistic feelings, sense of worth, holiness, faith, individual values, philosophy knowledge, memory and attentiveness (Questions-Q5 + Q6 + Q7 + Q11 + Q19 + Q26).

**Domain3:** Social domain consists of social relationships personal relationships, social support and spiritual activity (Questions- Q20 + Q21 + Q22).

**Domain4:** Environmental domain consist of surroundings, economic assets, autonomy, bodily security, protection, wellbeing, societal care, ease of access and excellence, house setting, opportunity for acquiring novel information and skill, partaking in and opportunity for activity / free time activities, Physical atmosphere (toxic waste / sound / traffic / weather) and transportation (questions- Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24 + Q25).

**Scoring**

Each domain scores indicate an individual’s view of every domain. Domain scores are marked in an optimistic way (ie. upper scores stand for higher quality of life). Domain scores are calculated based on each item in the particular domain. If an item is missing in the domain, mean of the other items are taken. Where two or more questions are omitted, that particular domain is not taken for final calculation (this is exceptional only for social domain, because social domain is having only three questions. All questions from assessment have a range of 1-5 (1 = 1, 2 = 2, 3 = 3, 4 = 4, 5 = 5) except 3 negatively phrased items. Negatively phrased questions Q3, Q4 and Q26 are coded as 1 = 5, 2 = 4, 3 = 3, 4 = 2, 5 = 1. This allows the negative questions to positive
questions. Each domain questions calculate the domain scores. Upper scores indicate higher quality of life.

**Reliability and Validity:**

WHOQOL tool has been checked for reliability and validity. Reliability coefficient Cronbach’s alpha score is 0.86 for all four domains of the tool. WHOQOL tool has been used in different settings in previous research studies, all worldwide studies has shown high validity and reliability. So that this scale can be adapted to assess the quality of life of prediabetic and Type 2 diabetes patients.

### 3.6.4 Mental Health Scale (M.H.S.) Scale

M.H.S. Scale is Newly developed scale by P. Gireesan & Dr.H.Sam Sananda Raj, Department of Psychology, University of Kerala, Trivandrum in 1990 for assessing positive mental health. 72 positively & negatively worded item scale with five response categories.

**Scoring:**

The scoring is done as follows. A score of 5, 4,3,2,1 are given to the category ABCD & E. for a positive statement. A score of 1,2,3,4 & 5 is given to the category ABCD & E for a negative statement. A reply sheet is not calculated on the basis of the respondent marked more than one response for a question and missed the item without making any one of the response. Score three is provided for one or two missed items in a section. The total count obtained in each category is taken and is multiplied by its respective score. The scores then obtained for the separate categories of subscale are then summed to obtain the total mental health status score of each
individual. The maximum score obtained for each sub scale is 60 and minimum score is 12. Then maximum score for the whole test is 360 and minimum is 72.

Validity and Reliability:

The Mental Health Scale (M.H.S.) validity and reliability checked. It provides reliability coefficient cronbach’s alpha score of 0.87 for all six sections. Several previous research studies used the Mental Health Scale (M.H.S.) in a variety of settings have supported high validity and reliability. The scale can be adapted to assess the mental health of prediabetic and Type 2 diabetes patients.

3.6.4 TESTING OF THE TOOL

Development of Criteria Check List

Criteria check list for validation of the tool was developed by the investigator. Each validator was requested to go through the 15 items in the baseline proforma, Pittsburgh sleep quality index, Mental Health Scale, and WHOQOL scale. There were two columns, against each item number in the checklist- namely, ‘agree’ and ‘disagree’. The validator was asked to put ‘✓’ mark against the specific column. Suggestions were mentioned in the ‘Remarks’ column.

Content Validity of the Tool

The prepared tools (baseline preformed of prediabetic and Type 2 diabetics) along with the objectives, hypotheses, operational definitions, blueprint were given to 5 for content validation. The experts were two psychologists, one medical expert, and two nursing experts. The experts were given 100% agreement on the statement of the problem, objectives, hypotheses and operational definitions. Based on the suggestions
given by the validators, modification of a few items was done. 2 items which were
irrelevant were deleted from the baseline Performa. Other tools used were standardized
Pittsburgh sleep quality index, Mental Health Scale (M.H.S.) and WHOQOL-scale.

Pre testing of the Tool

The investigator obtained permission from the director for the setting and
items tried on 12 samples fulfilling the sampling criteria. It was carried out in
Jubilee Mission Medical College Hospital on 2012 September 1st to October 15th.
The investigator was able to assess and it was found comprehensive and
understandable.

Translation of tool

Before administering the tool to the respondents, the English version of the
Pittsburgh sleep quality index Questionnaire, WHOQOL scale and Mental Health Scale
(M.H.S.) were translated to Malayalam by a Professor in Malayalam for greater
accessibility. A Professor of English who has a post graduation in Malayalam has gone
through the Malayalam version of the scale for making corrections in language and
editing. Malayalam version of the tool was further submitted to two experts in the field
of Psychology and medicine for their comments to ensure the face validity of the tool.
The tool was administered to 12 samples. The suitability study was done in jubilee
mission medical college. The high reliability of the Malayalam version of the scale
indicates that the scale is suitable for use in our culture. Malayalam version of
Pittsburgh sleep quality index, WHOQOL scale and Mental Health Scale (M.H.S.) were
given in appendix II.
Reliability of the Tool

To check the accuracy, precision, equivalence and homogeneity, the investigator administered to 12 prediabetic and 12 diabetic samples on 2012 September 9th to 13th. Inter rater technique was used to find the stability and reliability of the items. The reliability based on reliability coefficient (Cronbach’s alpha) was 0.84, 0.87 and 0.86 for Pittsburgh sleep Quality index, Mental Health Scale (M.H.S.) and WHOQOL scale respectively. Hence the tool was considered to be reliable. The reliability of the weighing machine, BP apparatus and glucometer were compared with other instruments for compatible reading and recording.

3.7 ETHICAL CONSIDERATIONS

The current study was presented to the ethics committee for the clarification and proceedings of the study. Doctors from endocrinology and medicine were present during the ethics committee meeting. Ethics committee approval obtained from a Research centre of a Private medical college concerned. Informed consent was taken from the participants before starting the intervention. Details of the study were given to the subjects before introducing the experiment. All participants were well aware of the study and given their written consent before the study. The nature and purpose of the intervention explained well and was assured secrecy and privacy of the subjects. Freedom was given to the samples to withdraw anytime from the study if they feel to do so.

3.8 PILOT STUDY

Feasibility of the study was checked by conducting Pilot study in the month of July. The prime focus was to assess the adequacy and practicability of intervention and
tool. The aim was explained and confidentiality was guaranteed to the subjects. Based on the FBS level 3 Prediabetic and 3 Type2 diabetic samples were selected and the yoga and raw diet was administered to the experimental group in a residential area at the same time control group samples were selected and same information’s were collected from them. The investigator obtained the baseline perform from samples and assessed the efficacy of the treatment outcome on 1st, 7th and 40th day by using physiological variables, Pittsburgh sleep quality index, Mental Health Scale (M.H.S.) and WHOQOL Assessment Tool. It took 30-45mt to complete the assessment. The study was found to be feasible and practical. The investigator then proceeded with the main study.

### 3.9 DATA COLLECTION PROCEDURE

The investigator selected the samples from outpatient departments of Jubilee Mission Medical College Thrissur. Each patient had a preparatory interview by the researcher who introduced study and evaluated her clinical condition, a total of 120 Christian nuns aged 30-60 years were selected for the study. Adequate guidance and counciling was given to all the Participants in the experimental group to compliance with raw diet and yoga. The subjects in the control groups were given general verbal information about the study. Participants were recruited from outpatient departments of jubilee mission medical college using enrolment register during the summer of 2013. Details of the study objectives and purpose were explained well and had assured secrecy and privacy of the subjects before introducing the experiment. All Participants were well aware of the study and informed written consent was taken from the participants before starting the intervention. Freedom was given to the samples to withdraw anytime from the study during these six weeks of study period if they feel to
do so. Participants grouped into two (Prediabetic & Type2 diabetes based on their fasting blood sugar value (figure 4). After random selection of subjects into control and experimental group, the Investigator collected their phone number and address to inform the intervention schedule.

The patients in the Control group continued with their routine treatment. Data were collected on 1st 7th and 40th days. The patients in the control group were given general oral information about diet and yoga at the end of data collection at the time of monthly visits, but no specific group programs were offered to them. One week yoga and raw diet training were given to the experimental group. Due to the availability of comfortable place for conducting one week training for experimental group the investigator organized camp in six zones from Thrissur districts of Kerala state. Experimental group had stopped the medicine when they started the study intervention with their treating doctor permission. Their blood sugar levels, cholesterol, HDL, LDL, TG, and HbA1c were noted from the case sheets and, blood pressure, pulse rate, body weight, Height, Abdominal Girth and BMI were measured by the investigator. The same measures were noted at subsequent follow ups of the camp (1st day, 7th day, after 40days).

The assistance for the organization of the holistic health camp was received from religious organization. Combination of Raw diet and yogasana were followed in the camps. Experimental group subjects were not taking any medicines during study period. A calm, loving and friendly atmosphere of mutual help and cooperation were ensured in the camp atmosphere. The camp organizers and campers lived together for all the seven days in simple dormitory accommodation. Subjects were provided with raw food and yogasana throughout the package period. Effort was taken to avoid
commercial food as far as possible. Naturally cultivated fruits, vegetables and other raw foods, especially the seasonally available jackfruits, coconut, banana, orange, amla, cucumber, dates, ground nuts etc. were preferred. The personally preferred natural food of each subject was given priority as the personal liking is very much related to bodily requirements. Every morning and evening during the camp period a basic course in yogasana training were given to patients. which includes different asanas like Halasana, Bhadrasana, Bugangasana, Dhanurasana, Matsyanthrasana, Viparithakarani, Pachimudrasana, Ardhamalsendhrasana, Ardhalasanasana, Chakrasana, Salabhasana, Vakrasana, Naukasana, Vajrasana,Yogamudhra, Tree Pose, Sarvangasana, And Savasana. The following steps depicts the sequence.

The explanation about the yogic exercise is given first. Well ventilated room was selected for the yoga practice. Instruction was given to use clean mat and comfortable simple dress. Stomach should be empty and clean peaceful environment will be the preferred place to practice yoga. Each step should be performed in front of the trainer for one week and followed each step slowly and softly. Yoga asana has to be practiced with a positive attitude and conscious awareness of spirituality. Yoga practice to be done in morning and evening at least 30 minutes, preferably same place and time. Participants were advised to do an asana within their capability but total time should be 30 minutes for each round that is morning and evening. During this one week yoga and raw diet training period very few members from the experimental group reported sensation of slight headache and tendency to eat cooked food in the initial period but it subsided towards end of the week. Headache noticed in individuals who take tea or coffee three or four times on a regular basis previously. They were advised to take plain water. After 7 days the campers were advised to go home and practice the
diet and yogasana at home for a total of 40 days. A follow up were made during the intervention period for identifying personal feelings and compliance with diet and yoga. Campers gathered together on the 40th day to assess physiological and psychological variables.

**Biochemical Measurements**

Participants had not taken any food items after 10 pm in the night and in the morning before drawing the blood for FBS, total Cholesterol, HDL, LDL, TG and HbA1c. Besides, CHO-POD method was used to quantify cholesterol, GPO-POD for triglyceride, IFCC for HDL, HKG6P-DH for FBS and glycocelated hemoglobin was done with high-performance liquid chromatography (HPLC) by means of Bio-Rad Variant II apparatus. With this technique, a detailed quantitative profile of above biochemical fractions was obtained from biochemistry laboratory of Jubilee mission medical college and Jeeva laboratory. Samples were collected by laboratory staff in a standardized medicated test tube to avoid the error in the result.

**Obesity and body mass index assessment**

Obesity and body mass index were calculated by measuring the height and weight of the participants in the morning. Height and weight were transformed to body mass index. The unit of measurement was kg/m². Abdominal Girth was taken with inch tape. Measurement was taken during mid respiration. While measuring the Abdominal girth umbilicus was taken as the main landmark.

**Blood pressure**

Blood pressure was taken with sphygmomanometer. Readings were taken in the morning with same instrument for all participants. After counting the pulse rate, the
blood pressure was measured. Same procedure was continued after seven and after 40 days. Three valid blood pressure measures were used for analyses.

3.10 STATISTICAL ANALYSIS

A master sheet was prepared by the investigator to analyze the data. The data were analyzed using both descriptive and analytic statistics on the basis of the objectives and hypotheses of the study. The analyzed data were presented in tables and figures. Base line demographic and clinical characteristics were described by using frequency and percentage. Mean & Median were used to describe the study samples baseline characteristics. The significant differences between the mean scores of the variables were calculated by paired t test. GLM Repeated Measures ANOVA was used to identify the significant difference between the different levels of physiological variables in the experimental and control groups. The comparisons of the pre and post-intervention outcomes between the groups were analyzed by using t test. Mean difference analysis was carried out to find out whether there is significant difference between experimental groups.

3.11 SUMMARY:-

Research methodology gives a more focused view of the entire process of tackling a research problem in a systematic and scientific manner. This chapter has dealt with research approach, research design, and variables, setting of the study, population, samples, sampling technique, sampling criteria, tool construction, content validity, pilot study, data collection process and plan for data analysis. This chapter is very important in the analysis and interpretation of the data.