CHAPTER 5

5.0 METHOD

5.1 PARTICIPANTS

5.1.1 SAMPLE SIZE

The sample size of the study was calculated by Cohen's formula using G power soft with alpha 0.05 and powered at 0.80 for an effect size of 0.3 of PPBS based on the earlier study of (McDermott et al., 2014). Calculated sample size 147 for each.

5.1.2 SOURCE OF SAMPLE

The source of sample was from the Jawaharlal Nehru Institute of Medical Sciences (JNIMS), Imphal, Manipur attending as OPD patients.

5.1.3 INCLUSION CRITERIA

The participants who have been diagnosed as T2DM patients by the physicians of Endocrinology Department of JNIMS, Hospital on the basis of clinical test results of metabolic parameters and having fasting blood glucose > 120 mg%. had been included, b) T2DM patients of both genders age ranging from 25 to 80 years old and suffering from T2DM for more than one year up to maximum of 20 years, and c) not attending to any physical exercise and yoga practice.

5.1.4 EXCLUSION CRITERIA

Participants with history of T2DM more than 15 years, amputation of limbs, severe neuropsychiatric problems and associated with major complications of diabetes such as renal failure, history of coronary or cardiovascular complications, proliferative retinopathy were excluded. Pregnant woman patient with T2DM and severe obesity (BMI > 40) were also excluded.

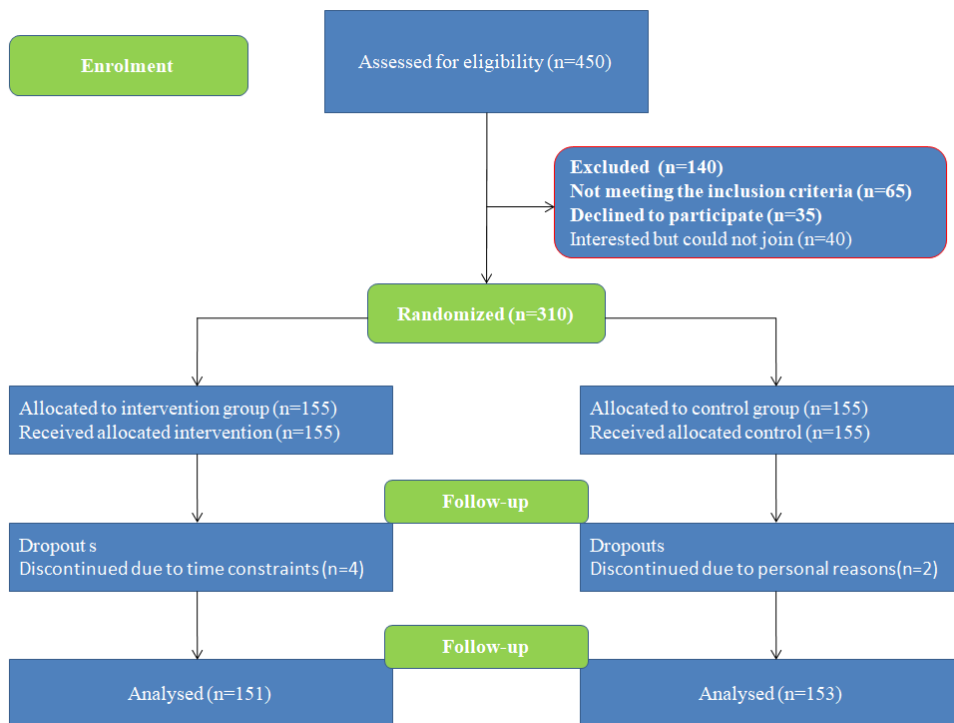#### 5.1.5 ETHICAL CLEARANCE AND INFORMED CONSENT

Ethical clearance for the present study was obtained from Institutional Ethical Committee of Jawaharlal Nehru Institute of Medical Sciences, Imphal, Manipur vide office No Ac/02/IEC/JNIMS/2016/R Dated, Imphal, the 22nd Oct 2016. All the recruited T2DM patients

read and voluntarily signed written informed consent form before the commencement of the study.

5.2   DESIGN AND SETTING

The present study was a randomized controlled trial. It was not possible to have blinding on yoga interventional study. The Senior Doctor of the Endocrinology Department of JNIMS Hospital and the Senior Yoga therapist/Yoga teachers including the research supervisor and researcher were blind during the process of randomization of patients' selection. Further, there was no chance of cross-over of participants since the control group were kept under conventional treatment.

TRIAL PROFILE

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┌──────────────┐        ┌────────────────────────────────────┐
│  Enrolment   │        │ Assessed for eligibility (n=450)   │
└──────────────┘        └────────────────────────────────────┘
                                          │
                                          │      ┌─────────────────────────────────────────┐
                                          ├─────►│ Excluded  (n=140)                        │
                                          │      │ Not meeting the inclusion criteria (n=65)│
                                          │      │ Declined to participate (n=35)           │
                                          │      │ Interested but could not join (n=40)     │
                                          ▼      └─────────────────────────────────────────┘
                              ┌────────────────────┐
                              │ Randomized (n=310) │
                              └────────────────────┘
                    ┌─────────────┴──────────────┐
                    ▼                            ▼
  ┌─────────────────────────────────┐  ┌─────────────────────────────────┐
  │ Allocated to intervention group │  │ Allocated to control group      │
  │ (n=155)                         │  │ (n=155)                         │
  │ Received allocated intervention │  │ Received allocated control      │
  │ (n=155)                         │  │ (n=155)                         │
  └─────────────────────────────────┘  └─────────────────────────────────┘
                    │         ┌───────────┐          │
                    │         │ Follow-up │          │
                    ▼         └───────────┘          ▼
  ┌─────────────────────────────────┐  ┌─────────────────────────────────┐
  │ Dropout s                       │  │ Dropouts                        │
  │ Discontinued due to time        │  │ Discontinued due to personal    │
  │ constraints (n=4)               │  │ reasons(n=2)                    │
  └─────────────────────────────────┘  └─────────────────────────────────┘
                    │         ┌───────────┐          │
                    │         │ Follow-up │          │
                    ▼         └───────────┘          ▼
  ┌─────────────────────────────────┐  ┌─────────────────────────────────┐
  │       Analysed (n=151)          │  │       Analysed (n=153)          │
  └─────────────────────────────────┘  └─────────────────────────────────┘
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5.3   VARIABLE STUDIED

5.3.1   DEMOGRAPHIC, ANTHROPOMETRIC, AUTONOMIC AND GLYCEMIC CONTROL AND LIPID PROFILE

The demographic and anthropometric details of the participants namely, Body Weight (BW), Body Mass Index (BMI), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), and Pulse Rate (PR) were measured at OPD of JNIMS. Further, the clinical test of both intervention as well as control groups on Fasting Blood Glucose(FBG), Post Prandial Blood Glucose(PPBG), Glycosylated haemoglobin (HbA1c), and Lipid parameters i.e. Total cholesterol(TC), Triglycerides(TG), High Density Lipoprotein(HDL), Low Density Lipoprotein(LDL), Very Low Density Lipoprotein(VLDL) were estimated at the clinical laboratories of JNIMS.

5.3.2   QUALITY OF LIFE INSTRUMENT FOR INDIAN DIABETES PATIENTS QUESTIONNAIRE (QOLID)

Subjects of both intervention and control group were assessed using the QOLID questionnaire developed by (Nagpal, Kumar, Kakar, & Bhartia, 2010) which consists of eight domains covering 34 items   which comprehensively include aspects of quality of life namely Role limitations due to physical health(RLDPH) with 6 items, Physical endurance (PE) with 6 items, General health (GH) with 3 items, Treatment satisfaction (TS) with 4 items, Symptom botherness (SB) with 3 items, Financial worries(FW) with 4 items, Emotion/ Mental health (ME) with 5 items and Diet satisfaction (DS) with 3 items. The scoring methods applied under items of RLDPH, PE, SB, and DS were Always -1, Frequently-2, Often-3, Sometimes-4 and Never-5. In case of item under GH, the scoring applied was Poor-1, Fair-2, Good-3, Very good-4 Excellent-5. The items of TS and MH also had 5 scores rating as Very dissatisfied-1, Moderately dissatisfied- 2, Neither satisfied nor dissatisfied-3, Moderately satisfied-4 and Very satisfied-5. The scoring under FW item had A lot-1, Highly-2, Little-3, Very-4 and Not- at all- 5. In item 5 of Mental Health, scoring was done as Not-at-all-1, A little-2 Moderate-3, Very much-4 and An extreme amount- 5. Assessment of these domains and items had high internal consistency (Cronbach's alpha of 0.719). The standard score was calculated by the following formula i.e., Standard score= (Add the sub scores divided by the maximum score) X 100.

5.3.3 CURRENT HEALTH SATISFACTION QUESTIONNAIRE (CHES-Q)

The pragmatic measurement of health satisfaction of both the yoga intervention group and control group was conducted by using the Current Health Satisfaction Questionnaire (CHES-Q) developed by (Traina et al., 2015).The CHES-Q has 14 items with 11 items focusing on satisfaction with weight, energy, appetite, sleep, physical functioning, social interactions, attitude, mood, blood sugar levels, blood pressure, and current health, and three items assessing knowledge of current blood sugar levels, blood pressure levels and diabetes as these items are linked to health satisfaction. Each item is rated with 7- point scale where 1= strongly disagree, 2=disagree, 3 = somewhat agree, 4 = neither agree nor disagree, 5 = somewhat agree, 6 = agree and 7 = strongly agree. Internal reliability of the scale in the present study was adequate (Cronbach's alpha of 0.621).

5.4 INTERVENTIONS

The experimental group was prescribed oral anti- glycaemic agents and in addition followed a yoga intervention for one and half hour daily for 6 days a week for 16 weeks. The detail of the yoga module followed in the present study is shown in Table-1.

Table-1: Common protocol for yoga intervention to Type2 Diabetes mellitus patient			
A. BREATHING PRACTICES	Repeat	time	Mon, Tue, Wed, Fri
Hand Stretching	3x5	3 min	
Hands in and out	5	1 min	
Ankle raise breathing	5	1 min	
Tiger breathing	5	1 min	
Alternate leg rising	5x2	1 min	
B. LOOSENING EXERCISES			Mon, Tue, Wed, Fri
Bhastika stimulation	20	1 min	
Wrist and Elbow Twisting	10	1 min	
Shoulder rotation	10	1 min	
Neck movement	5x2	1 min	
Trunk twisting, forward& backward	5x2	1 min	
Side bending	10	1 min	
Hip rotation	10	1 min	
Knee extension	10	1 min	
Ankle rotation	10x2	1 min	

Back stretch	5x2	1 min	
C. **SURYANAMASKARA (**sun salutation*)*	12	10 min	
D. **QRT**		3 min	
E. **YOGASANAS (in sequence)**		30 min	Mon, Thu, Fri
STANDING:			
i. *Ardhakaticakrasana* (each side)(side semicircle*)*		2 min	
ii. *Padahastasana(*head bending*)*		1.5 min	
iii. *Ardhacakraasana*(semicircle)		1.5 min	
iv. *Parivrutatrikonasana*(alternate toe touching)		2 min	
SITTING:			
*i. Pacimotanasana(*sittinghead bending*)*		1.5 min	
*ii. Ustrasana(*camel posture*)*		1.5 min	
*iii Sasankasana(*rabbit posture*)*		1.5 min	
iv. *Vakrasana or Ardha-Masyendrasana (*Spine twist*)*		1.5 min	
PRONE:			
*i. Bhujangasana(*Cobra posture*)*		1.5 min	
*ii Salabhasana(*locust posture*)*		1.5 min	
*iii Naukasana or Dhanurasana(*Boat or Bow posture*)*		2 min	
SUPINE:			
*I Sarbangasana with Halasana (*whole body posture*)*		2 min	
Ii Matsyasana(fish posture*)*		1.5 min	
*iii. Pawanmuktasana/ SuptaBhadrasana (*air cleansing tech)		1.5 min	
F. **DRT**		7 min	
G. **KRIYAS**		30 min	Wed, Sat
i. *UddhyanaBandha(*diaphragm locks*)*	5		
ii. *Agnisar(*abdominal flap*))*			
iii. *Nauli(I, II, III)(*abdominal movement*)*	3x5		
iv. *Neti* (nasal wash)			
v. *Dhaut*i (yogic vomiting)			
vi. *SankhaPrakshalana*(yogic bowel cleansing)			
H. **DRT(Deep relaxation technique)**		5 min	
I. **PRANAYAMA (Yogic breathing)**		30 min	Tue, Thu, Fri
i. *Kapalabhati*(blasting breath)		6 min	
ii. Sectional Breathing(preparation for *pranayama*)			
a. Abdominal breathing	5	3 min	
b. Thoracic breathing	5	3 min	
c. Clavicular breathing	5	3 min	
d. Full yogic breathing	5	3 min	

e. *Nadisudhi*(alternate nose breathing)	9	3 min	
f. *Sitali, Sitkari, Sadanta(cooling breath)*	9	3 min	
g. *Bhramhari pranayama(bee breathing)*	9	3 min	
h. *Nadanusandhana(sound resonance merger)*	5	3 min	
J. **DHARANA AND DHYANA (Meditation)**		3 min	
k. **CYCLIC MEDITATION** (stimulation &relaxation tech)		30 min	Tue, Wed, Sat
L. Educational theory to patients using Charts, Picture Diagrams		30 min	Mon, Thu, Fri
Education on Yoga Breathing theory			
Education on Diet, health and disease			
Education on body and mind medicine			
Education on yoga and spirituality			
Education on diabetes diet.			
Education on non-objective Happiness			
M. **BHAJAN (Devotional Songs)**			Sun

DATA EXTRACTION

Clinical test Fasting Blood Glucose (FBG), Post Prandial Blood Glucose (PPBG), Glycosylated haemoglobin (HbA1c), and Lipid parameters were estimated using international standard techniques at the nationally recognized (NABL accredited) clinical laboratories.

5.4.1 QUALITY OF LIFE INSTRUMENT FOR INDIAN DIABETES PATIENTS QUESTIONNAIRE (QOLID):

The standard score was calculated by the following formula i.e., Standard score= (Add the sub scores divided by the maximum score) X 100.

5.4.2 CURRENT HEALTH SATISFACTION QUESTIONNAIRE (CHES-Q)

Sum of each items was consider for the final score.

5.5 DATA ANALYSIS

All statistical analysis was computed using R studio. Independent 't' test and Chi-square tests for Independence were applied for baseline differences between experimental and control group. To compare the differences of pre to post intervention two-way mixed analysis of variance (ANOVAs) were also applied with (experiment or control) as between subject factor and time(pre or post intervention) as a within subject factor. Group x Time difference on each outcome measures were assessed. To evaluate the effect of the experimental condition in

compare to the control condition for each outcome variable, effect sizes were computed, where the value of partial eta squared (η^2) represents very small (<0.01), small (0.01–0.05), medium (0.06–0.13), and large (≥ 0.14).