RESEARCH METHODOLOGY

3.1 RESEARCH DESIGN

This chapter explains various tools of research, which were followed to achieve the specific objectives of this study.

In the present study, the research design was experimental and comparative in nature as some variables were controlled. It is a double blind, randomized, controlled clinical trial with three different groups.

3.2 SAMPLE AND SAMPLING

Based on previous research (Shenoy et al., 2010) we have considered Mean±SD change in HbA1C from baseline to 16 weeks as 0.75±0.5 for Group A while in Group B the change considered was 0.1±0.1. To detect the difference between two groups with 95% level of confidence and 90% power we required 26 patients in each group i.e. a total of 78 patients. However, considering few loss to follow-up, total 102 subjects were enrolled in the prospective study. One hundred two patients with T2DM” (28 women and 74 men) were selected on the basis of pre-defined inclusion and exclusion criteria. The following subjects were recruited from “University Health Centre” of “Guru Nanak Dev University”, Amritsar, India and were selected by the process of incidental sampling. This research was done at “Department of Sports Medicine and Physiotherapy”, Amritsar.

Consent of participants was taken before randomization along-with their baseline measurements. Participants were recruited after explaining the study protocols to them. “Demographic information and health history” were obtained from all these participants. The study was given approval by the Ethical committee for the” Faculty of Sports Medicine and Physiotherapy”, Guru Nanak Dev University, Amritsar. Subjects were recruited after the explanation of protocol and clearance from physician.
102 selected subjects were randomly allocated into one of the following three groups by “random lottery approach”:

Group A- “Supervised exercise group with pedometer”

Group B- “Self-reported exercise group with pedometer”

Group C- “Control group”
3.3 INCLUSION CRITERIA

- Established T2DM (>1 year from diagnosis of T2DM)
- No physical activity limitation,
- No exercise training from last 1 year,
- “Not taking insulin”,
- “Males and females aged between 40 to 70 years”.

3.4 EXCLUSION CRITERIA

- Patients with subjective or objective evidence of “coronary artery disease”, “uncontrolled hypertension”, “advanced retinopathy or neuropathy”,
- Severe “orthopaedic/cardiovascular/respiratory” conditions that restricts physical activity,
- Pregnancy and lactation at the time of study,
- Severe end organ damage or chronic diseases: renal/ hepatic failure, any malignancy, nephrotic syndrome, malabsorption.
- Known case of HIV infection,
- Primary or tertiary hyperparathyroidism, granulomatous disorders (e.g. sarcoidosis) and any lymphomas.
Figure 3.2: Subject sampling process.

Eligible Participants (159)

- 26 unable to contact
- 31 not interested

102 Interested Participants randomized at baseline

Group A- Supervised
N=35

Group B- Self Reported
N=35

Group C- Control
N=32

Post intervention assessment at 8 week and 16 week
N=30

N=28

N=32

Analyzed
N=30

Analyzed
N=28

Analyzed
N=32
3.5 INSTRUMENTATION AND OUTCOME MEASUREMENT

Following tools and assessments methods were used to carry out this study:

Subjects were assessed for the following (Anthropometry, Biochemical, and Clinical)

1. **Anthropometric Assessment**: All circumferences and skin fold measurements (four sites) were taken from the right side of the body. All measurements were repeated three times in same conditions and at same positions. Average of the three readings was taken by the same observer was used for the final analysis.

1.1 **Body Mass Index (BMI)**: 

\[
\text{BMI} = \frac{(\text{Kg})}{(\text{height (m)}^2)}.
\]

a) **Height (cm)** - Height was measured without shoes by using a stadiometer. Standing height was assessed through maximum vertical stature for persons who can stand unassisted. Hair ornaments, barrettes braids, jewellery, turban was removed from head before measurement was taken. A fixed stadiometer with “vertical backboard, fixed floorboard along with movable headboard” was used. Patients stood with the heels of their feet against the vertical backboard, with feet pointing outward at approx a 60 degree angle. Body weight was distributed evenly with both feet flat on the floor. The back, buttocks and heels were touching the backboard and feet were placed together. The head was in the Frankfort plane (an imaginary line from the ear canal to just below the lower orbit of the eye, parallel to the floor). Once the subject was positioned, the headboard or a flat ruler was placed on the top of the head with sufficient pressure to compress the hair.

b) **Weight (kg)** - Weighing machine (Acto inc) was used to measure body weight to the nearest 0.1kg. Subject stood still on the platform, with the body weight evenly distributed between both the feet. Subjects were asked to remove all heavy clothes (e.g. jackets, coats, shoes) and empty pockets before recording of weight was done.

1.2 **Skinfolds**: Skin fold measurement (four sites) was taken with Harpenden skinfold caliper (to nearest of 1mm) from the right side of subject’s body.

2. **Biochemical Test**: The following investigations were performed on “fasting venous blood sample”.
a) **Fasting Blood glucose (FBG):** Blood glucose monitoring system Elegance CTX10 was used to determine blood sugar levels.

b) **HbA1c:** Nycocard Reader II was used for Nycocard HbA1c test to measure glycosylated hemoglobin.

c) **Lipid profile:** A “fasting venous blood sample” was obtained for lipid profile. Estimation of “total cholesterol (TC)”, “serum triglycerides (TG)” and “high-density lipoprotein cholesterol (HDL-c)” was performed on the sample drawn after 12 hour overnight fast. Bayer’s semi automatic analyzer for measuring lipid profile (HDL, serum triglycerides and total cholesterol levels) was used.

3. **Clinical History and Examination:** Following general physical examinations were performed;

a) **Blood Pressure (BP):** “Blood pressure” was measured by a standard “mercury sphygmomanometer”, Lifecare™

b) **Resting Heart Rate (RHR):** “Polar S410™ heart rate monitor”, Made in Finland was used for monitoring resting heart rate.

c) **Acanthosis Nigricans:** “Brown to black poorly defined”, “velvety hyperpigmentation” of the skin on the nape of neck.

d) **“Buffalo Hump”:** “The subject stands against the wall, feet/shoulders and spine in line with the wall. Angle between the perpendicular lines drawn in midline from occipital prominence to C-7, angle made by the prominent fat pad <100°”.

e) **Double Chin:** A fold of fatty flesh below the chin.

4. **Bone Measurement:** “Bone mass” was obtained in the form of speed of sound score with “Sunlight Omnisense 7000S Ultrasound Bone Sonometer”, that measures speed of sound at distal 1/3 radius and Tibia. The same operator performed all measurements in order to minimize operator and technical inter-variability.

5. **Psychological Questionnaires:** Special permission was sought from the author of the questionnaire to use “the Audit of Diabetes Dependent Quality of Life-19”
(ADDQoL-19) English for S. Asian (Indian), Wellbeing questionnaire (W-BQ12) English and “Diabetes Treatment Satisfaction Questionnaire” (DTSQ) for India.

a) **ADDQoL 19** – Clare Bradley questionnaire was used to assess the “impact of Diabetes on the quality of life” among all subjects. The ADDQoL-19 is a “disease-specific quality of life measure”, which is increasingly being used to examine the patient’s perception of the “impact of diabetes on their quality of life” (Ostini et al., 2012). The ADDQoL was designed to include life domains which diabetes may affect for better or more likely for the worse (Bradley et al., 1999). ADDQoL19 is a 19 item disease specific instrument, designed to measure individual perception of the “impact of diabetes on quality of life” and this instrument has been validated (Prof. Bradley, Royal Holloway, University of London) for Asian Indians. ADDQoL – 19 questionnaire includes 19 life domain specific items to be scored between (-9 to +9) depending on “impact of diabetes on the quality of life”. The quality of life questionnaire included a number of different life domains that may be impacted by diabetes and were of varying importance. The product of impact and importance of life domains is the total quality of life score of that domain. Two overview items were used,

I. Overview item 1(OV 1) to determine generic ‘present QoL’ and

II. Overview item 2 (OV2) to determine “impact of diabetes on quality of life”.

b) **W-BQ12** – Wellbeing questionnaire by “Clare Bradley Royal Holloway University of London” was used with permission to assess “general wellbeing”, positive well being, negative well being and energy among all subjects. The W-BQ12 was used as assessment tool to determine an individual’s psychological wellbeing over time. It includes 12 items to determine GWB, positive wellbeing (PWB), negative wellbeing (NWB) and energy on a scale from 0 (not at all) to 3 (all the time) for T2DM patients.

c) “**Diabetes Treatment Satisfaction Questionnaire**” (DTSQ) – DTSQ was used to measure “patient’s satisfaction” with treatment. This questionnaire consists of a 6
item scale assessing “treatment satisfaction” and 2 items assessing “perceived frequency of hyperglycaemia and hypoglycaemia”.

The subjects were tested on two occasions for Bone mass, ADDQoL, WBQ-12 and DTSQ using identical protocols [“0 week (before training)” and “16 week (after 16 weeks of training)”]. The outcome measures (FBG, Hba1c, lipid profile and cardiovascular parameters) were measured at 0 week (before training), 8th week and after 16 weeks of training.

**Compliance:** Level of compliance expected is at least 85%. Compliance for the intervention was checked by taking following measures in the self reported group:

a) Biweekly telephonic calls

b) Log book maintenance by enrolled individuals

### 3.6 METHODOLOGY AND EXPERIMENTAL PROTOCOL

Pre study medical screening was done for all subjects and subjects were included only if they fulfilled the inclusion criteria.

A semi-structural questionnaire was used to gather necessary information like age, past medical history, medication, smoking and drinking habits etc from all subjects.

**Procedure**

“Clinical trial registry India (CTRI)” [CTRI/2012/10/003034)] approved this trial.

“Random lottery method” was used for randomly allocation of subjects into one of three groups

Group A- “Supervised exercise group with pedometer”,

Group B- “Self-reported exercise group with pedometer” and

Group C- “Control group”

Few initial sessions of “familiarization with pedometer” and the “understanding of Borg scale” were given to all the participants in Group A and Group B. Subjects in
Group A and Group B received similar instructions described by Tudor Locke et al., (2002) about “handling and placement of the pedometer”. Use of “Borg scale” (Rate of perceived exertion) with target perceived intensity of “moderate, somewhat hard or hard” is sometimes recommended as a possible alternative to heart rate based on maximal exercise testing. RPE scales are reported as valid and reliable for assessing the level of exertion during aerobic exercise (Borg et al., 1967). RPE is a subjective measure which provides exertion rating and gives a fairly good estimate of actual heart rate during physical activity. Two initial sessions of physical activity for familiarization with RPE scales were given to the subjects in Group A to let them understand the relation between capability of doing physical activity and required effort intensity. Subjects in Group A were taught to adjust the intensity of the activity by speeding up and slowing down the speed of walking through RPE scale. No dietary modification was advised while this intervention as they were asked to continue with the diet prescribed by their physician. Patients were advised to eat 1-2 hrs before exercise to avoid hypoglycaemia and maintain hydration levels.

Baseline readings of all the parameters were recorded before randomization. Baseline pedometer data of 7 days was collected for both the interventional groups, to estimate their number of steps per day by using pedometer.

**Supervised Exercise with Pedometer (Group A)**

In this group we aimed at achieving around 4000 steps in 30-40 minutes/session/day under the supervision of physiotherapist. Participants walked using pedometer to achieve a target of 150 min/ week moderate intensity of physical activity (Sigal et al., 2004). Intensity of exercise was increased gradually. Subjects in Group A did warm up for at least 5 minutes, keeping their target RPE in the ‘light’ range on the borg scale, then they were instructed to increase intensity up-to their target heart rate range ‘somewhat hard’ (12-14) on RPE. Subjects in Group A were encouraged to increase their step counts up-to 4000 in 30-40 minutes/session/day and maintain it till the end of 16 weeks. All the participants were asked to report for physical activity
sessions as per their schedule and were instructed to walk with pedometer under supervision for 5 days a week. A log book was maintained for all the participants. Each session took 45 – 50 minutes which included warming up and cooling down.

**Self Reported Exercise Group with Pedometer (Group B)**

In this group participants were instructed to wear pedometer for 5 days in a week from “morning to night till sleeping” for 16 weeks except bathing and swimming. Tudor-Locke *et al.*, 2002 have proposed that daily steps in excess of 8000 may be roughly equivalent to the accumulation of 30 min of moderate-intensity activity on a single day. Bennett *et al.*, 2006 suggested that any 3 days (weekday or weekend) are sufficient for the “reliable estimation of physical activity” performed in a free-living week but in our current study we have taken pedometer based intervention and monitoring for 5 days a week. A diary was provided to all the participants so that they can record their number of steps/day. Participants were trained about handling of the pedometer and were instructed to report after 8 weeks for second readings. Investigator contacted the participants on phone to get updated step counts on weekly basis. They were told to achieve target of 10,000 steps/day during intervention period without any consideration to intensity and duration. Participants could contact the researcher at any point of time for any difficulty related either to exercise protocol or the handling of pedometer. Subjects were instructed to set the pedometer to zero early morning and record the steps before going to bed.

**Control Group (Group C)**

Participants were asked to maintain their lifestyle and were encouraged to walk. They were not enrolled in any other intervention throughout 16 weeks. Neither pedometers nor step count data were collected.
Figure 3.3: Exercise adherence decision path for Group A and Group B.

\[ \text{Mean} = \frac{\sum X}{N} \]

3.7 STATISTICAL ANALYSIS OF THE DATA

Paired t-test was used within the groups to compare Mean±SD for the parameters at baseline, 8 weeks and 16 weeks. Differences between the groups were compared using analysis of variance (ANOVA). Statistical difference was further analyzed by Post hoc analysis using Bonferroni method. STATA 11.0 statistical software was used for data analysis. In this study P-value less than 0.05 has been considered as statistically significant.

3.7.1 Descriptive Statistics

1. Arithmetic mean (\(\bar{X}\))

It gives the average value of the whole range of the data given and it is obtained by adding together all the items and dividing this total by the number of items and is calculated using the formula:

\[ \bar{X} = \frac{\sum X}{N} \]
Where,

\[ \bar{X} = \text{Arithmetic mean} \]

\[ \sum X = \text{Sum of all variables} \]

\[ N = \text{Total Number of Individuals} \]

2. **Standard deviation (SD)**

It gives the degree of dispersion or deviation of the recorded data from the mean. It can be calculated by using the following formula:

\[ S.D. = \frac{\sum (X - \bar{X})^2}{N} \]

Where,

S.D. = Standard deviation

\[ \bar{X} = \text{Variables from the mean} \]

\[ N = \text{Total number of variables} \]

3. **Standard error (SE)**

It enables the measurement of the magnitude of sampling error. It is calculated by using the following formula;

\[ S.E = \frac{S.D}{\sqrt{N}} \]

Where,

S.E = “Standard Error”

S.D = “Standard Deviation”

\[ N = \text{“Total number of individuals”} \]
3.7.2 Statistical Tests

Following tests were used to analyze the data for level of significance.

1. **One way analysis of variance for different subject design (ANOVA)**

The ANOVA simply tell us if significant or non-significant differences exist in the results from different conditions. When we calculate ANOVA, we need to prepare a table for source of variance in the scores. After calculating F value, P value is looked for in the table at the appropriate degree of freedom.

<table>
<thead>
<tr>
<th>Source of Variance</th>
<th>Sum of Squares(SS)</th>
<th>Degree of freedom (df)</th>
<th>Mean Squares (MS)</th>
<th>F ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variation between parameters</td>
<td>$SS_{bet}$</td>
<td>$df_{bet}$</td>
<td>$MS_{bet}$</td>
<td>$F_{bet}$</td>
</tr>
<tr>
<td>Variation between subjects</td>
<td>$SS_{bet}$</td>
<td>$df_{subject}$</td>
<td>$MS_{subject}$</td>
<td>$F_{subject}$</td>
</tr>
<tr>
<td>Variation due to random error</td>
<td>$SS_{error}$</td>
<td>$df_{error}$</td>
<td>$MS_{error}$</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>$SS_{total}$</td>
<td>$df_{total}$</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. **Bonferroni Test**: Bonferroni procedure can be used when there are equal variances in the groups.

“$J^*(J-1)/2$”

$J$- Number of groups

If this “value is greater than 1”, then a significance level of 1 is used. If this is “greater than 0.05”, the difference between groups is not considered significant.