Chapter – III

PROCEDURE

In this chapter, the selection of subjects, selection of variables, criterion measures, procedure of data collection and statistical techniques employed for analysis of data have been described.

A preliminary investigation in the form of pilot research project was conducted prior to the main research work on the suggestion of Research Degree Committee of L.N.I.P.E.

The pilot study was conducted to find out feasibility of various crucial aspects of the investigation and formulate authentic and reliable parameters for main investigation.

The pilot study was successfully conducted and through various trials, test and experimentation the feasibility of various research parameters for similar studies was well established. The feasibility for main research work was established in terms of:

- a) Subjects Availability
- b) Experimental Grouping
- c) Medical Diagnosis
- d) Testing & Data Collection
- e) Statistical interpretation
Planning and Application of Experimental Treatment and Cost feasibility

Literature review to interpretate and understand research findings. And based on above feasibility finding of the selection of subjects, selection of various criterion measures, procedure of data collection and statistical technique for analysis of data etc. were made.

**Selection of Subjects**

Since the purpose of this study was to see the effect of the exercise on the NIDDM patients, 45 males of different age groups of the Moradabad city, who were suffering from diabetes (NIDDM), were selected as subjects. Those subjects who had the following diabetes' complications, such as any cardiovascular disease, peripheral arterial disease, retinopathy, nephropathy, neuropathy or any other complication were not selected. The selected subjects had history of suffering from diabetes (NIDDM) from two to eight years. It was also ensured that all the selected subjects were medication dependent.

The selected subjects were categorized into following three experimental groups according to age and there were 15 subjects for each group:
<table>
<thead>
<tr>
<th>Categories</th>
<th>Below 40 kg</th>
<th>40 to 50 years</th>
<th>Above 50 to 60 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects</td>
<td>15</td>
<td>15</td>
<td>15</td>
</tr>
</tbody>
</table>

**Total Subjects:** 45

No experimental groups were adopted since all selected subjects were chronic diabetic patients and totally medication dependent

**Selection of Variables & Criterion Tests**

**Variables:**

Effect of exercise therapy was seen on mainly:-

A. Diabetes Mellitus -Type-2 (NIDDM)

  The criterion tests in relation to above related variable were as follows:

**Criterion Tests:**

1) Fasting Blood Glucose Test

2) Post Prandial Blood Glucose Test

3) Hemoglobin A1c (HbA1c) Test.

B. In addition to above, monitoring of medication was also recorded to find out whether drug dependence did reduce significantly or not.
Description of Tests and Criterion Measurers

To find out the effect of exercise therapy on selected problem, the following tests were selected and their scores were considered as criterion measure for this study.

1. Fasting Blood Glucose Test: -

Fasting Glucose/ Sugar Test means to check level of glucose in the blood empty stomach. This test was done with help of the Glucometer. The glucose in the blood was measured in mg / dl. The normal range of Fasting Glucose in the blood is 70 – 110 mg / dl.

2. Post Prandial Blood Glucose Test:-

P.P blood glucose test means to check glucose level in the blood after two hours of the first proper meal taken by the subject. This test was also performed with help of the Glucometer. The glucose in the blood was measured in mg / dl. The normal range of P.P. Glucose in the blood is 100 – 150 mg / dl.
3. Hemoglobin A₁c (HbA₁c) Test:

Hemoglobin is a protein in the body that gives the color red to the blood. It carries oxygen in the blood. The sugar in the blood sticks to this hemoglobin. So the Hemoglobin A₁c blood test shows the percentage of sugar stuck on the hemoglobin. This percentage is directly proportional to the concentration of sugar in the blood. This test is more reliable because red blood cells have an average life span of 90 – 120 days so HbA₁c test gives the percentage of the sugar attached to the hemoglobin for the past 3 – 4 months. HbA₁c testing was conducted at the pathology lab by the pathologist. Its normal value is equal or below 7% which is equivalent to the average blood glucose level 150 mg / dl. Glycated hemoglobin measurements are given below:

<table>
<thead>
<tr>
<th>Interpretation of HbA₁c Test</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>4 – 7%</td>
<td>Excellent Control</td>
</tr>
<tr>
<td>7 – 8%</td>
<td>Fair Control</td>
</tr>
<tr>
<td>8 – 10%</td>
<td>Unsatisfactory Control</td>
</tr>
<tr>
<td>Above 10%</td>
<td>Poor Control</td>
</tr>
</tbody>
</table>
Instruments Reliability

All the instruments used in the study such as Automatic Digital B.P. monitor, Glucometer etc were available in the Arogyadham Center, where this program was conducted. Automatic Digital B.P. monitor was made by well renowned company i.e. Citizen Watch Co. Ltd., Tokyo, Japan and the glucometer was made by well-known company of Germany - Accu-Chek Active (Roche). These instruments already were in used for medical testing. Their calibrations were accepted accurate enough for the purpose of this study.

HbA1c testing was conducted at the pathology lab by the pathologist and estimated by LPLC technique.

Administration of Tests

Test for Fasting Blood Glucose

Objective:

To measure fasting blood sugar level.

Equipment:

Blood glucose monitoring system.
Procedure:

This test was taken empty stomach early in the morning. The finger was cleaned with the savlon / detol which to be pricked. After pricking, the finger was squeezed gently to obtain a drop of blood and was applied to the testing strip, which was already inserted in the glucometer. The meter counted down from 5 to 0 sec followed by a series of beeps till the result was displayed.

Scoring:

The reading shown by the glucometer was considered as the score.

Test for Post-Parandial Blood Glucose

Objective:

To measure Post-Parandial blood sugar level

Equipment:

Blood glucose monitoring system.

Procedure:

This test was same as fasting test but here testing was taken after two hours of the first proper complete meal.

Scoring:

The reading shown by the glucometer was considered as the score.
Test for the HbA1c

This test was conducted by the expert pathologist at pathology center.

Scoring:

The report given the pathologist was considered as the score.
Testing of Subject

- Blood Glucose Test

- Testing of Blood Pressure of subject
Medication Monitoring

The medication of each subject was recorded in terms of total mg and total tablets per day. The total doses per day were recorded prior to the experiment and lastly at the end of the experiment program.

This was done mainly to objectively substantiate and find out whether drug dependence did reduce significantly or not.

Procedure and Collection of Data

The data was collected for the selected variable by administering fasting glucose test, p.p. glucose test and HbA₁c. Fasting glucose test and p.p. glucose test were taken with the help of glucometer at the Arogydham Center by the Scholar under the supervision of the doctor and data of one test i.e. HbA₁c was collected at the pathology lab.

The pre-testing and post-testing of fasting blood sugar was taken empty stomach early in the morning between 6.00 to 8 a.m. of the subjects.

The pre-testing and post-testing of P.P. blood sugar was taken after two hours of the first proper meal taken by the subjects. For the HbA₁c testing, the subjects were tested at the pathology center.
After taking pre testing of all subjects, the experimental treatment of six months, six days per week was given to all the subjects. After completing the treatment post test of all the subjects were taken in the same manner as in the pre test.

The scores were collected in figures and a comparative table of each subject was made to consolidate the data.

Finally the consolidated data was subjected to statistical analysis.

**Description of Experimental Treatment**

Scholar was working as a health & fitness expert and has on his health and therapeutic centre and also working as a physical therapist in a well-known hospital (Shri Sai Hospital) of Moradabad City, since Feb. 2002. Scholar had conducted different yoga & exercise training camps for diabetic & hypertensive persons under the supervision of hospital & doctors.

The practical experience of 1-½ years in the field of rehabilitation and exercise therapy was taken into consideration while preparing exercise program. In addition to this guidelines and recommendations of different organizations and Experts – such as American Diabetes
Association, Ronald J. Sigaland Associates and Chad Boykin etc. were also taken into consideration.

Utmost consideration and care was taken about every subject’s pathological state & physical ability to prepare exercise program. Before following this experimental program, it was consulted by different doctors of this field, books and different websites.

**Comprehensive details of program were as follows:-**

- Total time period of the treatment was 6 months.
- Program was conducted 6 days / week
- Time duration per session: – 45min. to 60min.

**Exercise program was containing the following contents:-**

- Cardio-respiratory endurance training program.
- Muscular strength & muscular endurance training program.
- Flexibility Training Program
- Yoga.
Model of Exercise Program

- Physical activity\(^1\) regimens at an intensity of 50–80% \(VO_2\text{max}\), three to four times a week for 30–60 min a session

- At least\(^2\) 20 minutes, 3 times per week, to get results from aerobic exercise. Your target heart rate – 60% to 80% of the maximum

- **Recommendations: Aerobic exercise\(^3\):** - The amount and intensity recommended for aerobic exercise vary according to goals. To improve glycemic control, assist with weight maintenance, and reduce risk of CVD, we recommend at least 150 min/week of moderate-intensity aerobic physical activity (40–60% of \(V' O_2\text{max}\) or 50–70% of maximum heart rate) and/or at least 90 min/week of vigorous aerobic exercise (_60% of \(V' O_2\text{max}\) or _70% of maximum heart rate). The physical activity should be distributed over at least 3 days/week and with no more than 2 consecutive days without physical activity.

- **Recommendations: Resistance Exercise\(^4\)** In the absence of contraindications, people with type 2 diabetes should be encouraged to perform resistance exercise three times a week, including all major

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\(^2\) Chad Boykin, “Diabetes Fitness: Beginning an Exercise Program”

\(^3\) Ronald J. Sigaland Associates, “Physical Activity / Exercise and Type 2 Diabetes” *Diabetes Care* 27:10 (Oct 2004) p: 2528

\(^4\) Ibid. p. 2532
muscle groups, progressing to three sets of 8–10 repetitions at a weight that cannot be lifted 8–10 times (8–10 RM).

**Monday / Thursday**

**Cardio-respiratory Endurance training program:**

**Mode:**

Brisk walking, Jogging and Aerobics exercises

**Intensity:**

For first month 60-65 %

For the next two months 65 - 70%

For the last three months 70 - 75%

**Total Duration:**

For first month: - 45 minutes per day.

For next five months: - 60 minutes per day

10 Min. for Warm up exercises

25 to 40 Min. for Main training part

10 Min. for cool down exercises
Tuesday /Friday

Muscular strength & Muscular Endurance Training Program:

Mode:

With the help of weight machines and with out weights

A: - Selected Exercises for Muscular Strength training:

a) Seated Chest Press    d) Latpull down
b) Seated Shoulder Press e) Biceps Curl
c) Seated Leg Press      f) Triceps Curl

Intensity:

For first month approximately 60 % of 1r.m

For the next two months approximately 65 % of 1r.m

For the last three months approximately 70 % of 1r.m

Sets: 3 to 5 sets

Repetitions: 10 to 15

Total Duration: 45 to 60 minutes
B: - Selected Exercises for Muscular Endurance training:

a) Modified Push-Ups
c) Squats without weight
b) Bend Knees Sit-Ups
d) Heel Raise
c) Back Extension

Intensity:
3 sets of each exercise with 60% of maximum repetitions in one set
with 30 seconds rest, after every set of exercise
Wednesday / Saturday

Yoga: Asanas, Meditation, Pranayams, Kriyas:

A. Suryanamaskar: 5 to 10 rounds

B. Sequence of Asanas

1. Ardh Pawanmuktasan
2. Pawanmuktasan
3. Vipritkarni
4. Halasan
5. Naukasan
6. Bhujangasan
7. Salbhasan
8. Makrasan
9. Pachimotasan
10. Ardh machyendrasan
11. Vajrasan
12. Yog mudra

- Each asana was performed for 30 seconds and after every asana, Savasana and Makraasan was performed.

C. Kriyas-

a) Kapalbhati
b) Agnisar

D. Bandh

a) Uddiayan Bandh

E. Pranayamas

a) Bhastrika
b) Anulom-Vilom

F. Savasan

Sunday

Rest
Administration of the Experimental Treatment / Exercise Program

Before starting the exercise program all the subjects were checked by the doctors. After medical check up, their fitness level was checked by the scholar. The following tests were conducted before starting the exercise program:

Fasting, P.P. blood glucose and HbA₁c test: - to measure the blood glucose level.

Blood Pressure: - before and after the exercise session to check the exercises load.

Resting Heart Rate: - to calculate target heart rate for cardio-respiratory endurance training program. The intensity of the cardio-respiratory endurance training program was kept in between 60 to 75%.

Muscular strength & muscular endurance test: - to measure the maximum muscular strength and muscular endurance of the subject. During the exercise program the intensity was 60 to 70%.

After completion of the duration of experimental treatment (i.e. six months) again testing of Fasting, P.P. blood glucose and HbA₁c were conducted in the same manner as in pre-test, under the supervision of the doctor to see the effect of exercise therapy on the diabetic subjects.
The form given below was used to keep the record of each subject during the experimental treatment.

<table>
<thead>
<tr>
<th>S.No</th>
<th>Date:---</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Subject’s Name: - 
Age: -

Resting HR: 
Resting B.P.: - 
B.P. After exercise: -

Record of blood glucose test

<table>
<thead>
<tr>
<th>Fasting Glucose Test</th>
<th>P.P. Glucose Test</th>
<th>HbA1c</th>
<th>Diff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Test</td>
<td>Post Test</td>
<td>Pre-Test</td>
<td>Post Test</td>
</tr>
</tbody>
</table>

A. Exercises selected for strength training

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Selected Exercises</th>
<th>1 RM</th>
<th>60%</th>
<th>65%</th>
<th>70%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Seated Chest Press</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Seated Shoulder Press</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Seated Leg Press</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Latpull Down</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Biceps Curl</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Triceps Curl</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
B. Exercises selected for muscular endurance training.

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Selected Exercises</th>
<th>Maximum</th>
<th>60%</th>
<th>60%</th>
<th>60%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Modified Push-Ups</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Bend knees Sit-Ups</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Back Extension</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Full Squat</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Heel Raise</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Intensity for Endurance training

Target heart rate

\[ \text{Target heart rate} = X\% \times (\text{HRmax} - \text{RHR}) + \text{RHR} \]

Where \( X \) = intensity in percentage;  \( \text{HRmax} = (220 - \text{AGE}); \)

\( \text{RHR} = \) Resting Heart Rate

<table>
<thead>
<tr>
<th>Days/ Months</th>
<th>Intensity</th>
<th>Target HR</th>
</tr>
</thead>
<tbody>
<tr>
<td>For first one month</td>
<td>60-65%</td>
<td></td>
</tr>
<tr>
<td>For next two months</td>
<td>65-70%</td>
<td></td>
</tr>
<tr>
<td>For last three months</td>
<td>70-75%</td>
<td></td>
</tr>
</tbody>
</table>

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5 Melvin H. Williams, "Aerobic Exercise", Lifetime Fitness and Wellness: A personal Choice 2nd ed. (USA – Wm. C. Brown Publishers) p. 39
Statistical Techniques

For analyzing the data of the study, T-test was used to find out the effect of exercise therapy on different age-group patients with diabetes mellitus (NIDDM) at .05 level of confidence.

Further Analysis of Covariance was used to compare significance of effect of exercise among the three age group diabetic patients.

ANCOVA was used to compare the three age groups in term of exercise effect on three-criterion test namely:

a) Fasting Blood Sugar Test  
c) HbA1c Test
b) P.P. Blood Sugar Test

Percent comparison was also made to find out the effect on drug dependence among subjects.