



# A PROPOSED PRE TEST – POST TEST DESIGN FOR A THERAPEUTIC EXERCISE PROGRAM FOR REHABILITATION OF INDIVIDUALS SUFFERING FROM DIABETES MELLITUS TYPE 2

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## ABSTRACT

### Introduction

This pre – test post – test study aims to evaluate the effect of a therapeutic exercise program on blood glucose levels in individuals suffering from Diabetes Mellitus Type 2 (DM2). The earlier studies were limited to a particular exercise regimen or a single blood glucose parameter. There is no evidence of the effect of exercise on cognitive function in young adults with DM2.

### Methods/Design:

This is a pre-test post – test design that will enrol 30 adult male participants diagnosed with DM2 of age 35 to 55 years. The outcome measures assessed will include Fasting Blood Glucose (mmol/L), Fasting Blood Glucose (mg/dL), HbA<sub>1c</sub> (%) and Mean Plasma Glucose (MPG) Estimate. The data will be collected and results will be analyzed.

### Discussion:

The results of this pre – test post – test study will provide novel data to indicate whether a structured therapeutic exercise improves the blood glucose levels in individuals suffering from DM2.

**Keywords:** Diabetes Mellitus Type 2, Therapeutic Exercise Protol, Blood Glucose Parameters

**MANUSCRIPT****Introduction**

Diabetes Mellitus Type 2 (DM2) is a chronic metabolic disorder characterised with increased levels of blood glucose over a prolonged period of time.<sup>1</sup> There is an inverse association of the skeletal muscle mass with blood glucose levels.<sup>2</sup> Skeletal muscle mass relative to body weight is inversely associated with insulin resistance.<sup>3</sup> There exists a protective associations of increased muscle mass which is present in those without overt diabetes. However, it is evident that pathomechanics of DM2 causes an atrophy of muscles, due to reduction in the activity of anabolic hormones like IGF-1, testosterone, ghrelin, increased inflammation, higher expression of acrogens that raises protein degradation, and detrimental effects of DM2 on vascular supply to muscles.<sup>3</sup> The raised insulin levels enhance the muscle protein synthetic activity and suppress muscle protein breakdown.<sup>3</sup> DM2 is characterised by a decreased functional  $\beta$  cell mass and inadequate insulin secretion.<sup>3</sup>

There is a lack of literature in the open domain which shows evidence of a well structured novel therapeutic exercise protocol for individuals suffering from DM2. This proposed pre test post test design is intended to understand the effectiveness of novel structured therapeutic exercises inclusive of warm up, aerobic exercise, free exercises and cool down among individuals suffering from DM2.

**METHODS**

The study design will be a pre test – post test experimental study (Flowchart 1) adhering to Standard Protocol Items: Recommendation for Interventional Trials (SPIRIT) guidelines.<sup>4</sup> 30 participants would be included in this study.

Participants would be included if:-<sup>5</sup>

1. Adult Males
2. Individuals diagnosed with DM2 for more than 6 months (Fasting Plasma Glucose >126 mg/dL < 280mg/dL; HbA<sub>1c</sub>> 6.5% < 15.6%)
3. Age between 35 to 55 years
4. Individual on Normal Blood Glucose concentration lowering medications

Participants will be excluded if: -<sup>5</sup>

1. Individuals having a difficulty in attaining sitting position for 30 minutes.
2. Suffering from acute fractures in the spinal region.
3. Individuals with musculoskeletal disorders like strains, sprains, fractures causing an impairment to perform physical activity.
4. Suffering from cardio-vascular disorders.
5. Suffering from neurological disorders.
6. Individuals with DM2 suffering from foot ulcers
7. Individuals undergoing any other form of exercise training
8. Individuals who are hypoglycemic
9. Individuals who are handicapped
10. Females or Transgenders or Non-adult males
11. Individuals who are suffering from cancer
12. Individuals who are having sensory impairment
13. Individuals suffering from Kidney dysfunction or disorders
14. Individuals with pacemaker
15. Individuals with implants of gel or silicon and / or transplant organs

Eligible participants will be identified by the primary researcher and treating physiotherapist. The primary researcher will inform the participant about the study, give them the patient sheet and provide an explanation about the study in brief. The primary researcher will discuss any questions or queries with the participants and gain an informed consent of willing participants.<sup>5</sup>

Baseline and all follow –up assessments of Fasting Blood Glucose (mmol/L) and Fasting Blood Glucose (mg/dL) , HbA1c (%) and Mean Plasma Glucose (MPG) Estimate levels will be done by a trained pathologist who is blinded about the type of study being carried out. The Consultant Diabetologist or General Medicine Practitioner or Consultant Endocrinologist will diagnose the participant as Diabetes Mellitus Type 2 and refer the participant for Diabetic Rehabilitation to the Out-Patient Physiotherapy Department. All participants will attend daily physiotherapy sessions for 12 weeks except on Sundays for diabetic rehabilitation program. <sup>5</sup>

## Interventions

Therapeutic Exercises<sup>5-28</sup>

Therapeutic Exercises will be provided to both all participants in this study in an Out-Patient Physiotherapy Department. Under the therapeutic exercises diabetic rehabilitation, the participants attended daily physiotherapy sessions for 12 weeks except on Sundays for the diabetic rehabilitation programme.

Therapeutic Exercise Programme: To be followed for 3 days per week on alternate days for 12 weeks

**Table 1:** Therapeutic Exercise Programme

Day	Exercise Type
Monday	Aerobic Exercise
Tuesday	Free Exercises
Wednesday	Aerobic Exercise
Thursday	Free Exercises
Friday	Aerobic Exercise
Saturday	Free Exercises

**Warm Up:** General range of motion exercises for all peripheral joints.

### Aerobic Exercises

Each activity in the sequence will be repeated 8 times and each sequence will be performed for 3 sets.

Sequence 1:Week 1 and 2



Image 1: Sequence 1 - Spot Walking



Image 2: Sequence 1 - Tap outs



Image 3: Sequence 1- Skater - Tap behind foot



Image 4: Sequence 1 – Spot Walking



Image 5: Sequence 1 – 'V' Walks



Image 6: Sequence 1 – High Knees





Image 7: Sequence 1 – Kick Forward



Image 8: Sequence 1 - Knee Curls

Sequence 2 - Week 3 and 4



Image 9: Sequence 2 - Sidestep



Image 10: Sequence 2 - Knee Up



Image 11: Sequence 2 – Knee Up with hand rotation to same side



Image 12: Sequence 2 – Kickforward





Image 13: Sequence 2 -- Kick forward with arms outstretched



Image 14: Sequence 2 - Knee Up with Pull down



Image 15: Sequence 2 — Squat

Sequence 3: Week 5 and 6



Image 16: Sequence 3 - Wide squat throw ball forward



Image 17: Sequence 3 - Wide squat throw ball diagonally upwards



Image 18: Sequence 3 - Wide squat throw ball diagonally downwards



Image 19: Sequence 3 - Wide squat throw ball upward

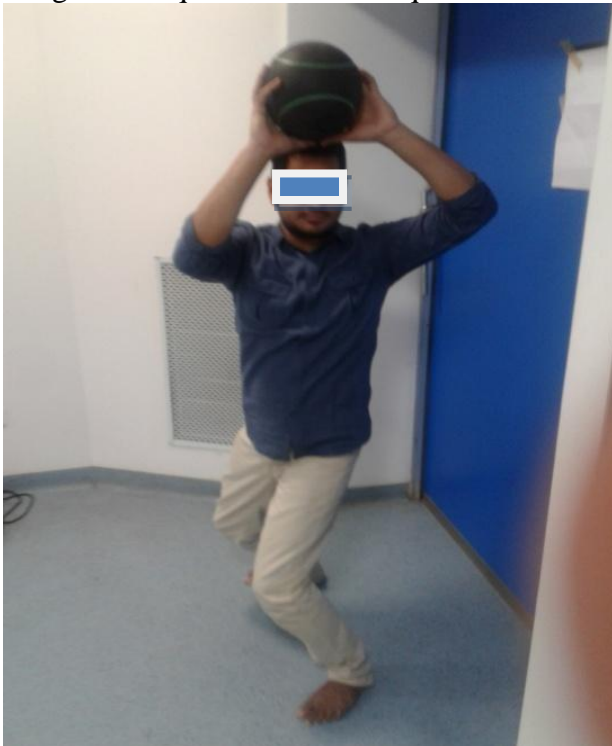


Image 20: Sequence 3 - Wide squat throw ball sideways



Image 21: Sequence 3 - Wide squat bounce ball on ground

Sequence 4 - Week 7 and 8



Image 22: Sequence 4 - Medicine ball diagonal pattern down to up





Image 23: Sequence 4 - Medicine ball diagonal pattern up to down

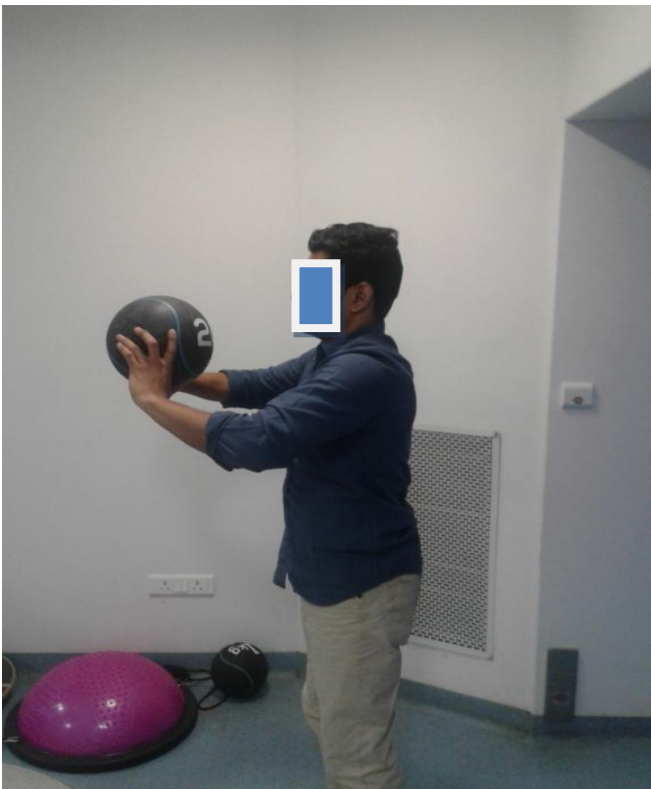


Image 24: Sequence 4 - Medicine ball chest throw



Image 25: Sequence 4 - Oblique"s-Side to Side



Image 26: Sequence 4 - Triceps throw



Image 27: Sequence 4 - Biceps throw

Sequence 5 - Week 9 and 10

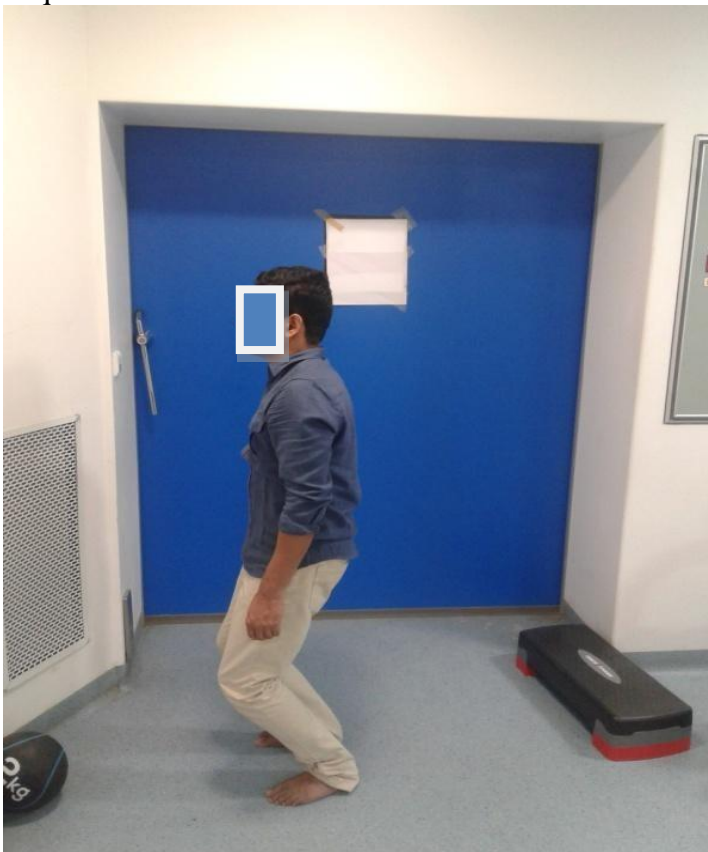


Image 28: Sequence 5 - Mini Squat

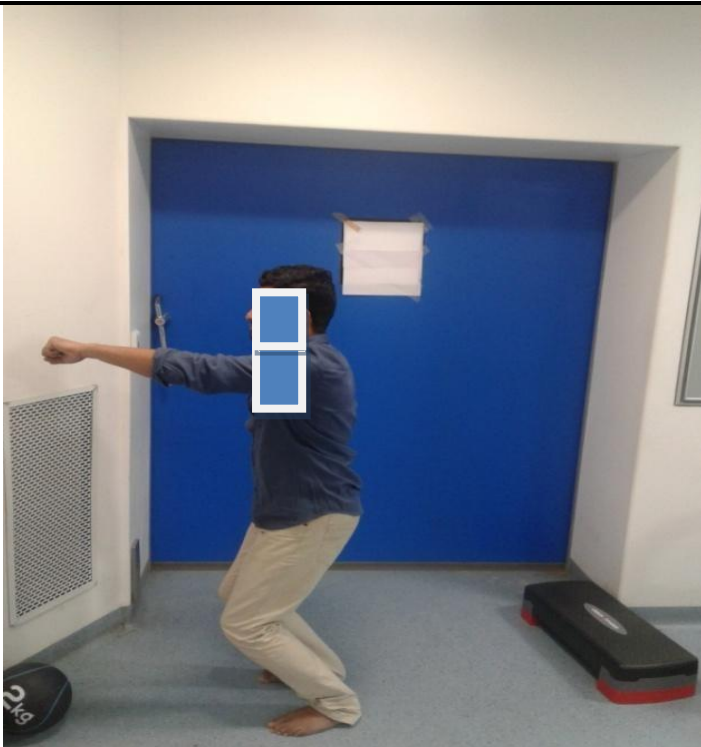


Image 29: Sequence 5 - Mini Squat Punch forward with alternate hands



Image 30: Sequence 5 - Mini Squat Punch Upward with alternate hands





Image 31: Sequence 5 - Punch downward with alternate hands



Image 31: Sequence 5 - Punch Sideways alternately in each direction





Image 32: Sequence 5 - Punch Sideways Up with alternate hands

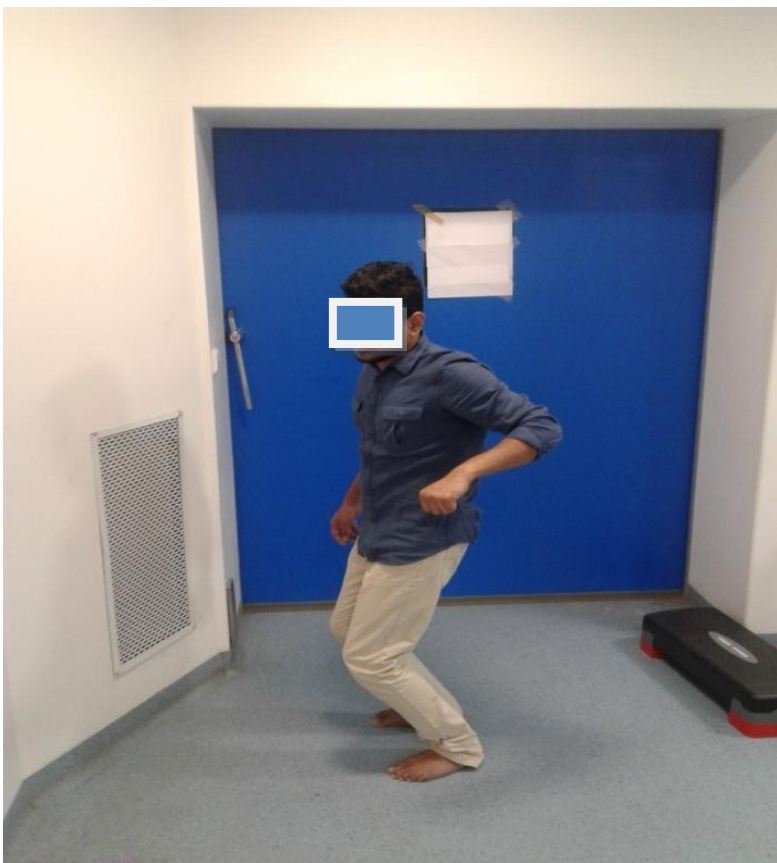


Image 33: Sequence 5 - Punch Sideways Down with alternate hands

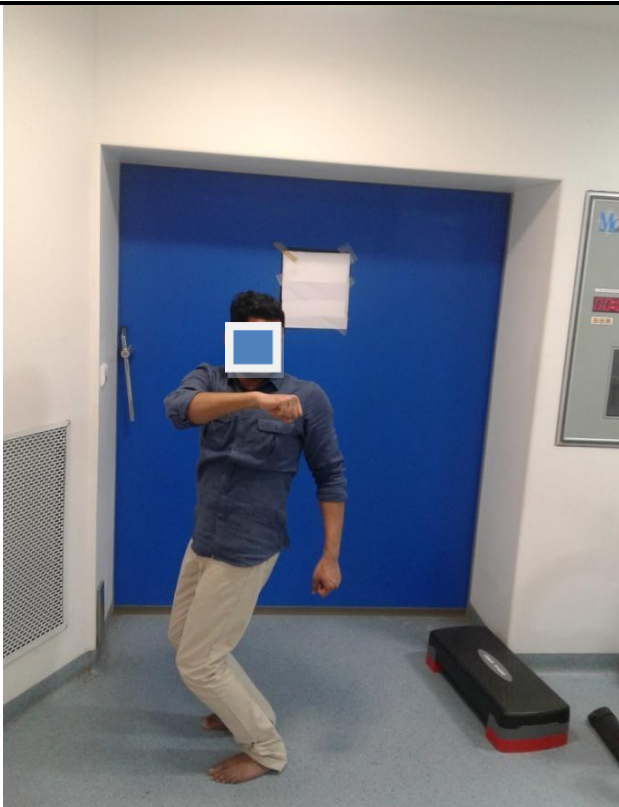


Image 34: Sequence 5 - Punch Sideways Behind with alternate hands

Sequence 6 - Week 11 and 12



Image 35: Sequence 6 - Step Up Up Down Down -Step Up



Image 36: Sequence 6 - Sequence 6 - Step Up Up Down Down b. Step Up Up



Image 37: Sequence 6 - Step Up Up Down Down c. Step Up Up Down



Image 38: Sequence 6 - Step Up Up Down Down d.Step Up Up Down Down



Image 39: Sequence 6 - Step Knee down down





Image 40: Sequence 6 - Step Ham Curl down down



Image 41: Sequence 6 - Step leg back down down





Image 42: Sequence 6 - Step kick forward down down



Image 43: Sequence 6 - Step leg sideways down down

Table 2: Week wise sequence of aerobic exercises

Sequence 1	Sequence 2	Sequence 3	Sequence 4	Sequence 5	Sequence 6
Spot Walking	Spot Walking	Spot Walking	Spot Walking	Spot Walking	Step Up Up Down Down
Tap Outs	Side Step	Wide squat throw ball forward	Medicine ball diagonal pattern down to up	Mini Squat	Step Knee down down
Spot Walking	Spot Walking	Spot Walking	Spot Walking	Spot Walking	Step Up Up Down Down
Skater - Tap behind foot	Knee up	Wide squat throw ball diagonally upwards	Medicine ball diagonal pattern up to down	Mini Squat Punch forward with alternate hands	Step Ham Curl down down
Spot Walking	Spot Walking	Spot Walking	Spot Walking	Spot Walking	Step Up Up Down Down
Side Steps	Knee Up with hand rotation to same side	Wide squat throw ball diagonally downwards	Medicine ball chest throw	Mini Squat Punch Upward with alternate hands	Step leg back down down
Spot Walking	Spot Walking	Spot Walking	Spot Walking	Spot Walking	Step Up Up Down Down
'V' Walks	Kick forward	Wide squat throw ball upward	Oblique"s- Side to Side	Punch downward with alternate hands	Step kick forward down down
Spot Walking	Spot Walking	Spot Walking	Spot Walking	Spot Walking	Step Up Up Down Down
High Knees	Kick forward with arms outstretche d	Wide squat throw ball sideways	Triceps Throw	Punch Sideways alternately in each direction	Step leg sideways down down
Spot Walking	Spot Walking	Spot Walking	Spot Walking	Spot Walking	Step Up Up Down Down
Kick Forward	Knee Up with Pull down	Wide squat bounce ball on ground	Biceps Throw	Punch Sideways Up with alternate hands	
Spot Walking	Spot Walking	Spot Walking	Spot Walking	Spot Walking	
Knee Curls	Squat			Punch Sideways Down with alternate hands	
Spot Walking	Spot Walking			Spot Walking	
				Punch Sideways	

				Behind with alternate hands	
				Spot Walking	

**Table 3:** Free Exercises for the core muscles to be performed every Tuesday for 12 weeks

Sr. No.	Exercise	Hold	Rest
1	Pelvic Bridging	8 seconds	3 seconds
2	Supine Straight Leg Raise	8 seconds	3 seconds
3	Quadripod - Raise 1 upper extremity alternatively	8 seconds	3 seconds
4	Quadripod - Raise 1 lower extremity	8 seconds	3 seconds
5	Bird Dog	8 seconds	3 seconds
6	Modified Crunches	8seconds	3 seconds



Image 44: Pelvic Bridging

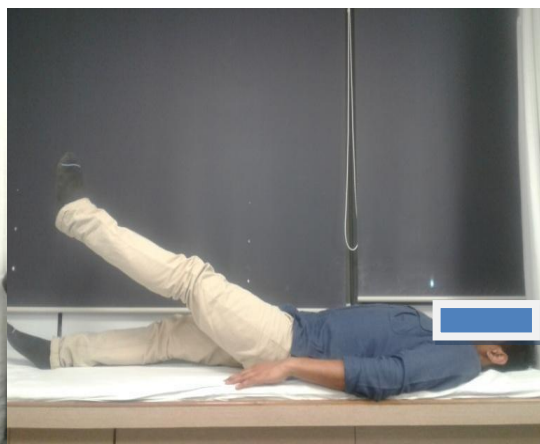


Image 45: Supine Straight Leg Raise

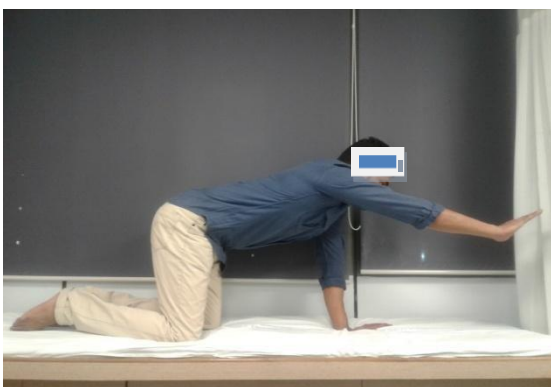


Image 46: Quadripod - Raise one upper extremity

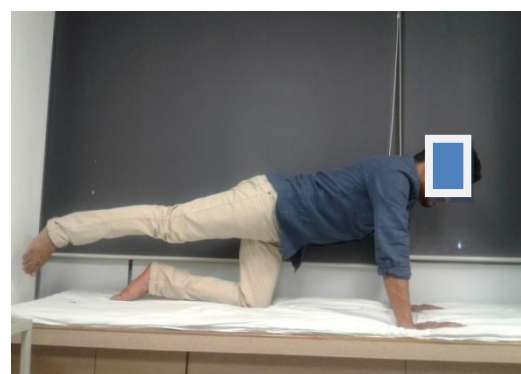


Image 47: Quadripod - Raise one lower

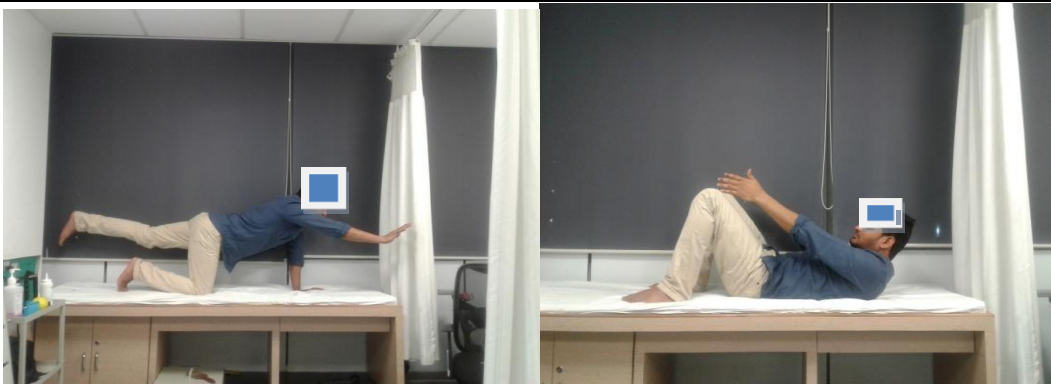


Image 48: Birddog

Image 49: Modified Crunches

**Table 4:** Upper extremity resisted exercises to be performed on every Thursday and lower extremity resisted exercises to be performed on every Saturday for 12 weeks.

Sr. No.	Exercise	Hold	Rest
<b>Upper Extremity</b>			
1	Shoulder Flexion to 90 degree	8 seconds	3 seconds
2	Shoulder Abduction to 90 degree	8seconds	3 seconds
3	Bicep Curls	8 seconds	3 seconds
4	Tricep Curls	8 seconds	3 seconds
5	Wrist Curls- Flexion	8 seconds	3 seconds
6	Wrist Curls - Extension	8 seconds	3 seconds
<b>Lower Extremity</b>			
7	Dynamic Quadriceps	8 seconds	3 seconds
8	Hip Flexion above 90 degree in sitting	8 seconds	3 seconds
9	Side Lying Straight Leg Raise	8 seconds	3 seconds
10	Hamstring Curls	8 seconds	3 seconds
11	Heel Raises	8 seconds	3 seconds
12	Toe Raise	8 seconds	3 seconds

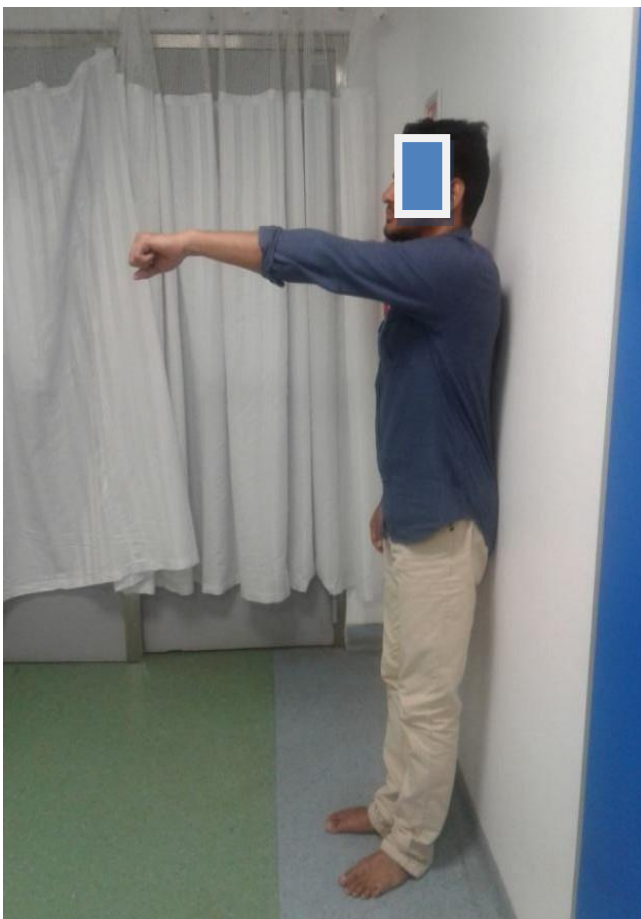


Image 50: Shoulder flexion to 90 degree

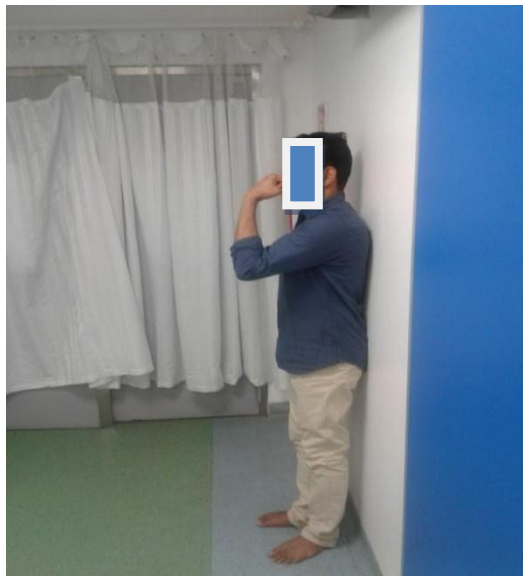


Image 51: Shoulder Abduction to 90 degree

Image 52: Biceps Curl



Image 53: Triceps Curl

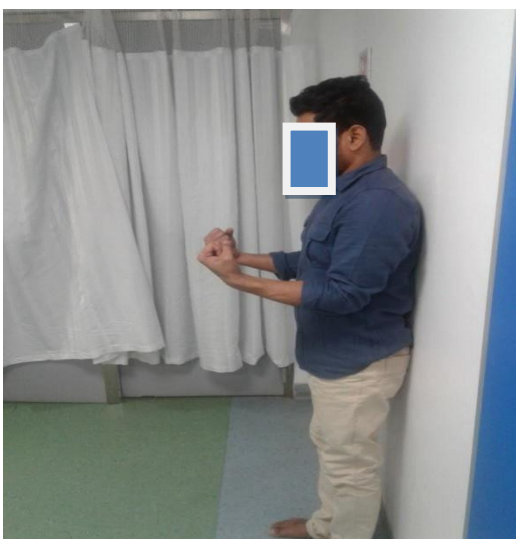


Image 54: Wrist Curls - Flexion





Image 55: Wrist Curls - Extension



Image 56: Dynamic Quadriceps



Image 57: Hip flexion above 90 degree in sitting



Image 58: Heel Raises



Image 59: Toe Raises



Image 60: Side Lying Straight Leg Raise



Image 61: Hamstring Curl

**Table 5:** Progression of Free exercises week wise is as follows:-

Week	Repetitions
1 - 3	5
4-6	8
7-9	10
10-12	12

**Cool Down:** Followed with a cool down period 5 minutes of Savasana.



### Cool down - Savasana

If the participant is unable to perform the exercises he will be supported to perform the exercises. All therapeutic exercises will be performed under the supervision of a trained physiotherapist.

After every 24 sessions at week 4, week 8 and week 12 post admission to diabetic rehabilitation program the outcome measures would be reassessed to check for changes in blood glucose parameters. If the participant shows signs of hypoglycemia then the reassessment would be taken earlier. The participants would be recommended to take an opinion of the general physician or endocrinologist or diabetologist to modify the medications dosage as required along with their reports.<sup>5</sup>

### Safety:<sup>5</sup>

1. Participant would be brought to lie down in the supine lying position and made to relax.
2. The participant would be given water to drink.
3. All vital signs would be assessed immediately like blood pressure, heart rate, pulse rate, Oxygen Saturation and respiratory rate.
4. If necessary the participant would be advised to consult a general medical practitioner or any other specialist doctor like Diabetologist.

### Precaution:<sup>5</sup>

1. Participant will be advised to drink about 500 ml to 1 L of water between 1 hour prior, during and after the intervention.
2. Oral rehydrating solution will be kept at handy in the exercise therapy arena.
3. Exercise therapy arena will be well ventilated and light up.

4. Water will be provided to the participant to rehydrate themselves.

### **Delivery of the intervention<sup>5</sup>**

Due to the physical nature of the intervention, the primary researcher and / or the treating physiotherapist will not be blinded. The primary researcher will himself administer the interventions to the participants in each of the two groups. The therapeutic exercises will be progressed when able to be completed with minimal fatigue and no significant cause of pain due to the therapeutic exercises. Consistency and adherence will also be monitored by the recording of treatment in the participants diabetic rehabilitation record. The diabetic rehabilitation record includes each exercise performed, the number of repetitions, of each exercise performed, any variations in the exercises performed and reasons for any variations such as adverse events.

### **Performance Quality<sup>5</sup>**

The performance quality will be monitored by the primary researcher. The primary researcher will reassess each participant at the start of each session, and the exercises modified accordingly. If there is any episode of adverse event or pain, the primary researcher will use his/ her clinical reasoning to reduce intensity of particular aggravating exercise or add specific manual physiotherapy treatment as required. The primary researcher will record the details of each treatment session, and will include the type of exercises and dosage. Any changes to the exercises or adverse responses will be noted.

### **Outcome Measures**

Demographic information to be collected from all participants includes: name, age, duration since onset of disease of DM2, number of sessions, Fasting Blood Glucose (mmol/L), Fasting Blood Glucose (mg/dL), HbA<sub>1c</sub> (%), and Mean Plasma Glucose (MPG) Estimate.<sup>5</sup>

### **Adverse Events**

Any adverse events or responses will be noted in the participant notes located in the participant's diabetic rehabilitation record file. The primary researcher will check for events of hypoglycaemia, dizziness, fainting, breathlessness or any other adverse event to be noted in the participant's diabetic rehabilitation record file.<sup>5</sup>

### **Data and Statistical Analysis**

Participant characteristics and baseline data in this study will be summarized by descriptive statistics. All data will be analysed with intention to treat principles. The collected data would be evaluated for normality. Paired 't' tests will be used for intra- group statistical analysis and unpaired 't' tests will be used for inter-group statistical analysis.<sup>5</sup>

## **DISCUSSION**

The study aims at understanding the feasibility of a therapeutic exercises protocol on blood glucose levels in individuals suffering from DM2. This is the first study intended to study the effect of a uniquely designed therapeutic exercise protocol on blood glucose parameters in individuals suffering from DM2. This is particularly relevant as the number of individuals with DM2 is rapidly increasing worldwide and especially in India. Many studies striving to achieve better outcomes for blood glucose levels in individuals with DM2. The main aim in the management of DM2 should be DM2 Remission during the DM2 Reversal journey.

Lawson C. et al in 2018 stated that exercise training yields both central and peripheral adaptations for patients with DM2 which clinically translated into anti-remodelling effects, increased exercise capacity and reduced morbidity. Also, individuals with DM2 actively involved in any kind of exercise training may benefit from improved prognosis, QoL and anatomic function.<sup>29</sup>

Mukherji A. et al in 2022 stated that providing a thrice weekly structured exercise protocol is more beneficial in the long run and a need to improve patient adherence is a must.<sup>30</sup> Popaliya A. et al in 2023 stated that a structured exercise program is effective in improving postural control and gait in individuals suffering from DM2.<sup>31</sup> Kour H. et al in 2015 were conducting a research study for the evaluation of the effect of structured exercise therapy on neurophysiological and cognitive functions of young adults with DM2.<sup>32</sup>

Similarly, this study will provide a novel data to indicate whether exercise improves cognition for a vulnerable group of adult males aged between 35 to 55 years and will set the stage for larger trials to further examine the effects of exercise on blood glucose levels.

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