African Journal of Biological Sciences

Journal homepage: http://www.afjbs.com

Research Paper   **Open Access**

EFFECT OF A NOVEL STRUCTURED THERAPEUTIC EXERCISE PROTOCOL ON BLOOD GLUCOSE LEVELS IN INDIVIDUALS DIAGNOSED WITH DIABETES MELLITUS TYPE 2: A RANDOMISED CONTROLLED TRIAL

Dr. Tushar J. Palekar Ph. D[1], Dr. Pramod Palekar (PT)[2], Dr. Praveen Kumar Ph. D[3]
[1]Principal and Professor, Dr. D. Y. Patil College of Physiotherapy, Dr. D. Y. Patil Vidyapeeth, Pimpri, Pune -18
principal.physio@dpu.edu.in

[2]Associate Professor, Dr. D. Y. Patil College of Physiotherapy, Dr. D. Y. Patil Vidyapeeth, Pimpri, Pune -18
gonsalves.nigel@yahoo.com

[3]Dean – College of Health Sciences, Gulf Medical University, Ajman, United Arab Emirates (UAE),
diabeticoriseandmove@gmail.com

Corresponding author: **Dr. Tushar J. Palekar Ph. D**

Abstract
Introduction
Diabetes Mellitus Type 2 (DM2) is a chronic condition associated with elevated blood glucose levels. Exercise has shown to have a prognostic effect on reducing the blood glucose levels among individuals diagnosed with DM2. But, there is a need to study the effect of a novel unique structured therapeutic exercise program on blood glucose levels among individuals diagnosed with DM2.
Materials and methods
A randomised controlled trial was conducted among individuals diagnosed with DM2. A novel unique structured therapeutic exercise program at a moderate intensity as per the Rate of Perceived (RPE) Scale as an intervention was delivered to 65 participants diagnosed with DM2 while the control group received regular glucose lowering medication. Fasting Blood Glucose (mg/dL), Fasting Blood Glucose (mmol/L) and HbA1c (%) are outcome measures that were used to assess the blood glucose levels among the 65 participants diagnosed with DM2.
Results
A statistically significant reduction in blood glucose levels was noted in the experimental group who received the intervention of the novel structured therapeutic exercise among participants diagnosed with DM2.
Discussion
This reduction in blood glucose levels could be attributed to the increased physical activity, increased glucose uptake due to the novel unique therapeutic exercise program among participants diagnosed with DM2.
Conclusion
Thus, we conclude that a novel unique structured therapeutic exercise performed at moderate intensity as per the Rate of Perceived Exertion (RPE) scale helped reduce the blood glucose levels among participants diagnosed with DM2.
Keywords: DM2, Fasting Blood Glucose, Rate of Perceived Exertion (RPE)

INTRODUCTION

Diabetes Mellitus Type 2 (DM2) is threatening the human health globally on a large extent. During the last two decades the global population suffering from DM2 has nearly increased two-fold.[1] As per International Diabetes Federation (IDF) 415 million people are diagnosed with DM2 in 2015 and it is estimated by the year 2040 this number to increase to 642 million.[2] Approximately, 77 million individuals in India are diagnosed with DM2 in the year 2019. And, it is estimated by the year 2030, this number to rise to 101 million and by 2045 to rise to 134 million.[3]

The United Nations Sustainable Development Goals envisage on reducing the number of premature deaths due to DM2 to one-third by the year2030. Similarly, India's national health policy too intends to enhance screening and treatment of those individuals diagnosed with DM2 by 80% and 25% respectively.[3]

A malfunctioning in the feedback loops between insulin action and insulin secretion results in abnormally elevated blood glucose levels in DM2.[4] DM2 is managed non-pharmacologically by the aid of a strict diet and exercise as well as by consumption of anti-hyperglycaemic pharmacological therapy.[5]

Globally, research suggest that exercise helps in normalizing the blood glucose levels among individuals diagnosed with DM2.[6] Also, structured exercise programs too have shown a prognostic effect on blood glucose levels among individuals diagnosed with DM2.[7] There is a need to study the effect of a novel unique therapeutic exercise program for rehabilitation of individuals diagnosed with DM2.[8] Therefore, we opted to conduct a randomised controlled trial to study the effect of a novel unique therapeutic exercise program on blood glucose levels in individuals suffering from DM2.

MATERIALS AND METHODS

Firstly, an ethical approval was taken from an Institutional Ethical Committee. Those participants who were diagnosed cases of DM2 and gave consent to participate in this randomised controlled trial were included in the study. 65 participants were included in this study.
Participants were included if:-[8]
1. Adult Males
2. Individuals detected with DM2 for greater than 6 months (Fasting Plasma Glucose >126 mg/dL < 280mg/dL; HbA_1c> 6.5% < 15.6%)
3. Age between 35 to 55 years

4.　Individual on Normal Blood Glucose concentration lowering medications

Participants was excluded if: - [8]

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 were identified by the primary researcher as well as treating physiotherapist. The primary researcher informed the participants about the study, gave them the patient information sheet and provided an explanation about the purpose of the study in brief. The primary researcher clarified any questions or queries with the participants. [8]

Baseline and all follow –up assessments of Fasting Blood Glucose (mmol/L) and Fasting Blood Glucose (mg/dL), and HbA1c (%) levels were collected by a trained pathologist who was blinded about the type and purpose of study being carried out. The Consultant Diabetologist or General Medicine Practioner or Consultant Endocrinologist diagnosed the participant if he was suffering from DM2 and refer the participant for Diabetic Rehabilitation to the Out-Patient Physiotherapy Department. All participants attended daily physiotherapy sessions for 12 weeks except on Sundays for diabetic rehabilitation program. [8]

The Consultant Diabetologist certified whether the participant was fit to participate in the Therapeutic Exercise program for the rehabilitation of individuals suffering from DM2.The primary researcher or treating physiotherapist also assessed if the participant was fit or eligible to undergo physiotherapy treatment or Diabetic Rehabilitation Program.

Randomisation and Group Allocation

65 participants were randomly allocated into two different groups viz. Experimental group (n=33) which received Therapeutic Exercises and the Control group (n=32) received only the normal glucose lowering medications as prescribed by the Consultant Diabetologist or referring medical practioner.

Interventions for Experimental Group

Therapeutic Exercises

Therapeutic Exercises was provided to 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: Were followed for 3 days per week on alternate days for 12 weeks

Table 1: Therapeutic Exercise Programme[8]

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 was repeated 8 times and each sequence was performed for 3 sets. (Table 1)

Table 2:
Week wise sequence of aerobic exercises[8]

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	Oblique"s- Side to Side	Punch downward	Step kick forward

		upward		with alternate hands	down down
Spot Walking	Spot Walking	Spot Walking	Spot Walking	Spot Walking	Step Up Up Down Down
High Knees	Kick forward with arms outstretched	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 2 shows the Week wise sequence of aerobic exercises[8]

Table 3: Free Exercises for the core muscles were performed every Tuesday for 12 weeks[8]

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

Table 3 shows the Free Exercises for the core muscles were performed every Tuesday for 12 weeks[8]

Table 4: Upper extremity resisted exercises were performed on every Thursday and lower extremity resisted exercises were performed on every Saturday for 12 weeks.[8]

Sr. No.	Exercise	Hold	Rest
Upper Extremity			
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
Lower Extremity			
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

Table 4 shows the Upper extremity resisted exercises were performed on every Thursday and lower extremity resisted exercises were performed on every Saturday for 12 weeks

Table 5: Progression of Free exercises week wise is as follows:-[8]

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

Table 5 shows the Progression of Free exercises week wise is as follows
Cool Down: Followed with a cool down period 5 minutes of Savasana.[8]

The novel unique structured therapeutic exercises were performed at a moderate intensity of 12 – 13 on the Rate of Perceived Exertion (RPE) Scale.[9] The participants were regularly asked while performing the therapeutic exercises about the perceived exercise intensity as per the Rate of Perceived Exertion (RPE) Scale. [10]

Outcome Measure Assessment
After every 24 sessions at week 4, week 8 and week 12 for both groups the outcome measures were reassessed to check for changes in blood glucose parameters.[8] A set guidelines for precautions, safety and termination criteria of therapeutic exercise session were followed.[8]

Results

The pre intervention and post intervention of fasting blood glucose (mmol/L), fasting blood glucose (mg/dL) and HbA$_1$c (%) levels were collected and the data was statistically analysed

for both the groups. The data was analysed for normality and paired sample t tests were used for normally distributed changes. Mean changes with 95% confidence intervals (CI) were reported. A 5% level of significance was used for all the tests.

Table 6: Baseline characteristics of Participants in the study

PARAMETERS	BASELINE	
	EXPERIMENTAL GROUP	**CONTROL GROUP**
Age (years)	Mean = 45.78; Range 36 -55	Mean = 44.96; Range 35 - 55
Duration since diagnosed with DM2 (years)	Mean = 7.43; Range 1 - 14	Mean = 7.51; Range 2 - 16

Table 6 shows the Baseline characteristics of Participants in the study

Graph 1 depicts the baseline characteristics of all participants in the study
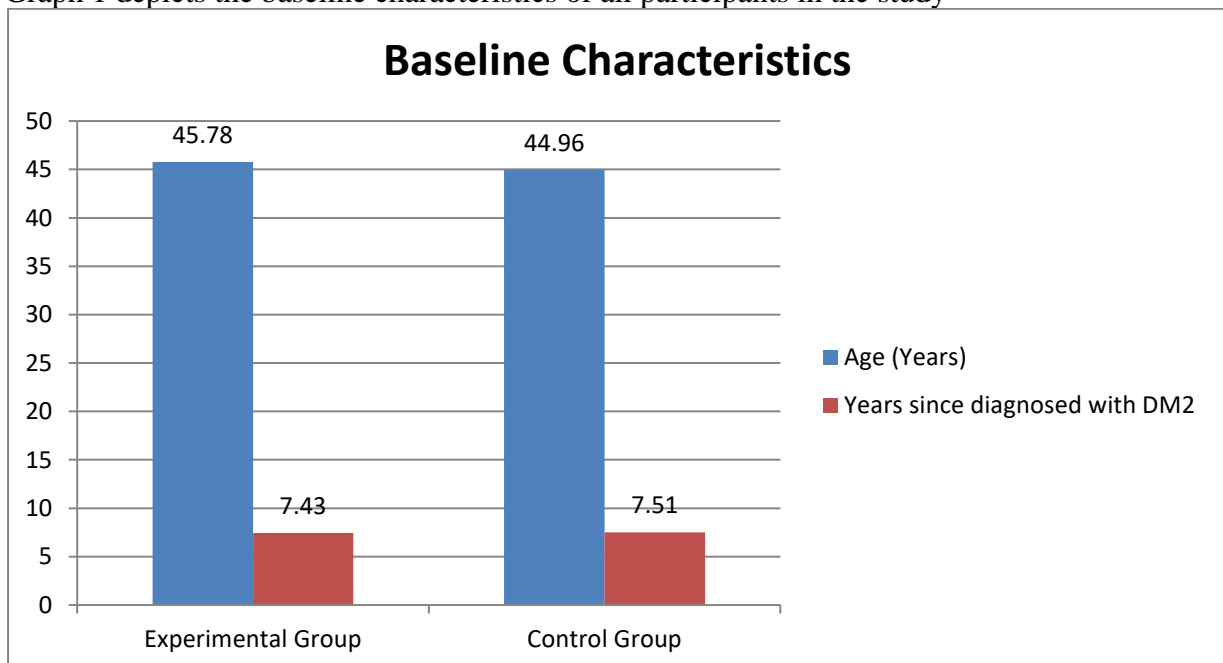
Graph 1 shows the Baseline Characteristics of all Participants in this study

Table 7: Pre intervention and Post intervention data of participants included in the study

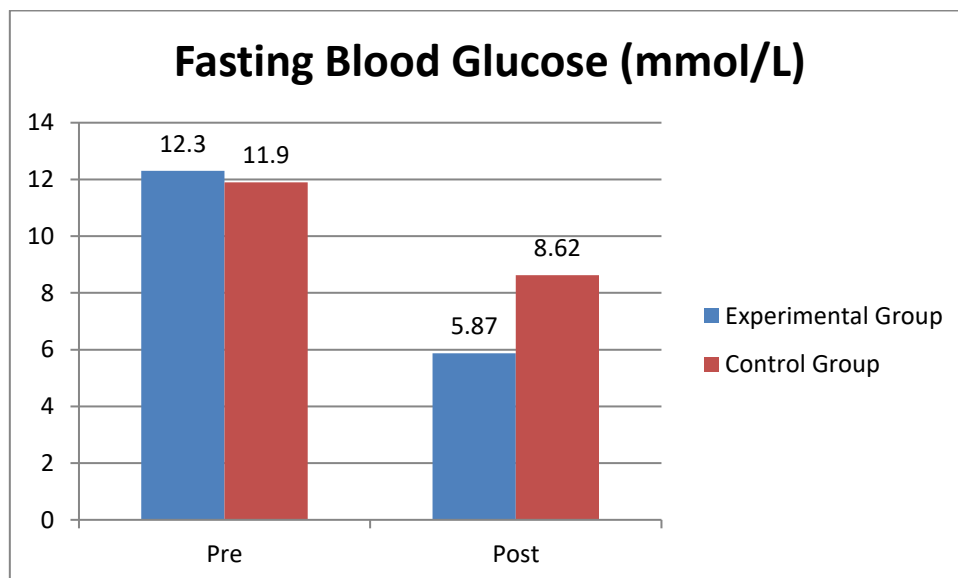| OUTCOME MEASURES	EXPERIMENTAL GROUP (n=33)		CONTROL GROUP (n=32)	
	PRE	**POST**	**PRE**	**POST**
Fasting Blood Glucose (mg/dL) Mean (SD)	222.21 (24.54)	106.46 (26.37)	214.84 (18.91)	155.96 (17.74)
Fasting Blood Glucose (mmol/L) Mean (SD)	12.30 (1.045)	5.87 (0.987)	11.90 (1.364)	8.62 (1.468)
HbA$_1$c	11.31 (1.426)	5.85 (0.908)	11.24	10.73

Table 7 shows the Pre intervention and Post intervention data of participants included in the study

Graph 2 demonstrates the graphical representation of Fasting Blood Glucose (mg/dL) for all participants in the study
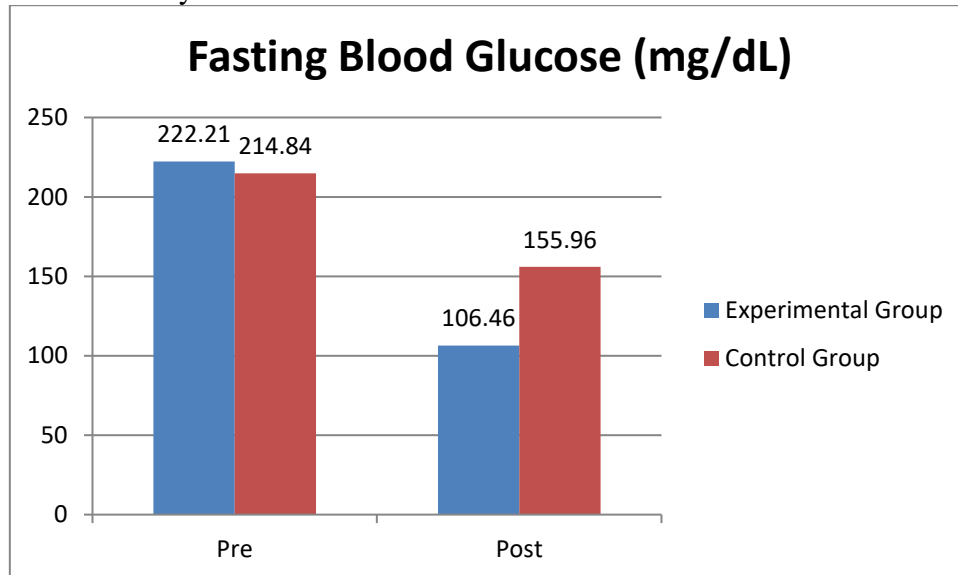

Graph 2 shows the Fasting Blood Glucose (mg/dL) for all participants in the study

Graph 3 demonstrates the graphical representation of the results of the Fasting Blood Glucose (mmol/L) for all participants in this study

Graph 3 shows the Fasting Blood Glucose (mmol/L) for all participants in this study

Graph 4 demonstrates the graphical representation of results of HbA$_1$c (%) of all participants in this study
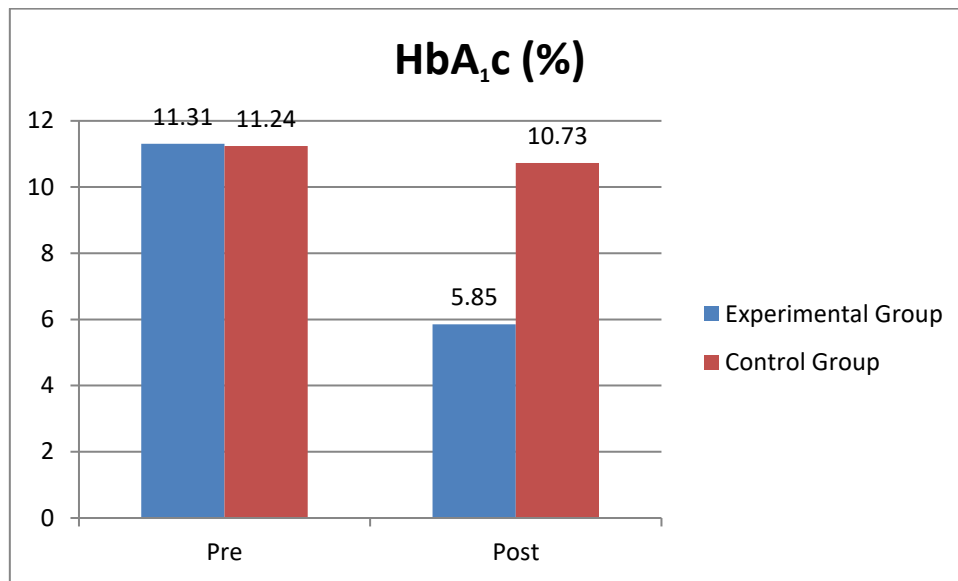

Graph 4 shows the HbA$_1$c (%) for all participants in this study

Table 8 demonstrates the pre-post difference among the outcome measures used for assessment for all participants in this study

| OUTCOME MEASURES	EXPERIMENTAL GROUP (n=33)	CONTROL GROUP (n=32)	P VALUE
Fasting Blood Glucose (mg/dL) Mean	115.75	58.878	< 0.0001
Fasting Blood Glucose (mmol/L) Mean	6.496	3.312	< 0.0001
HbA$_1$c	5.44	0.509	< 0.0001

Table 8: demonstrates the pre-post difference among the outcome measures used for assessment for all participants in this study

Graph 5 demonstrates the pre-post difference between the two groups for Fting Blood Glucose (mg/dL) for all participants in this study

Fasting Blood Glucose (mg/dL)

Experimental Group: 115.75
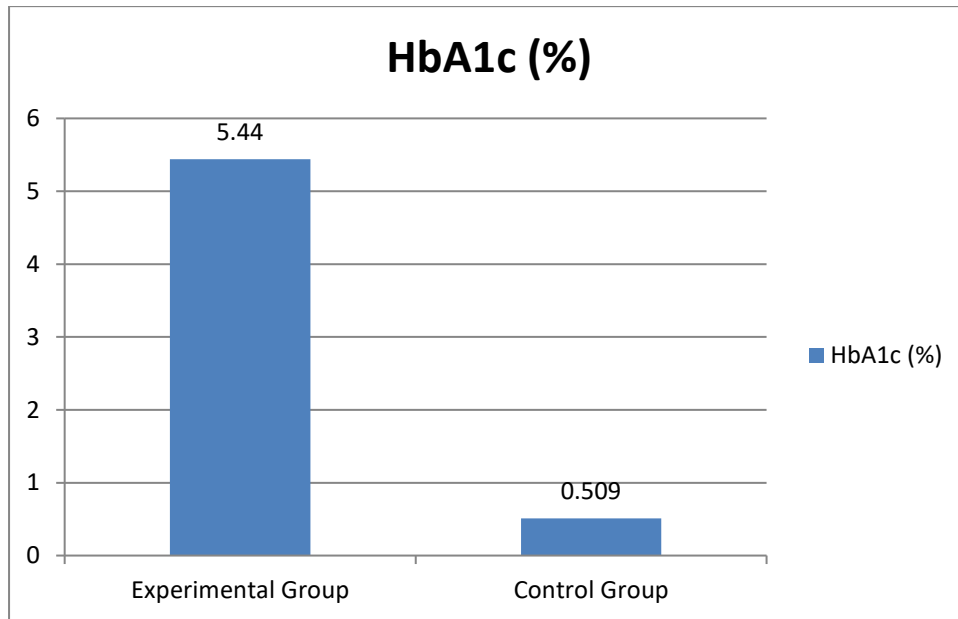Control Group: 58.878
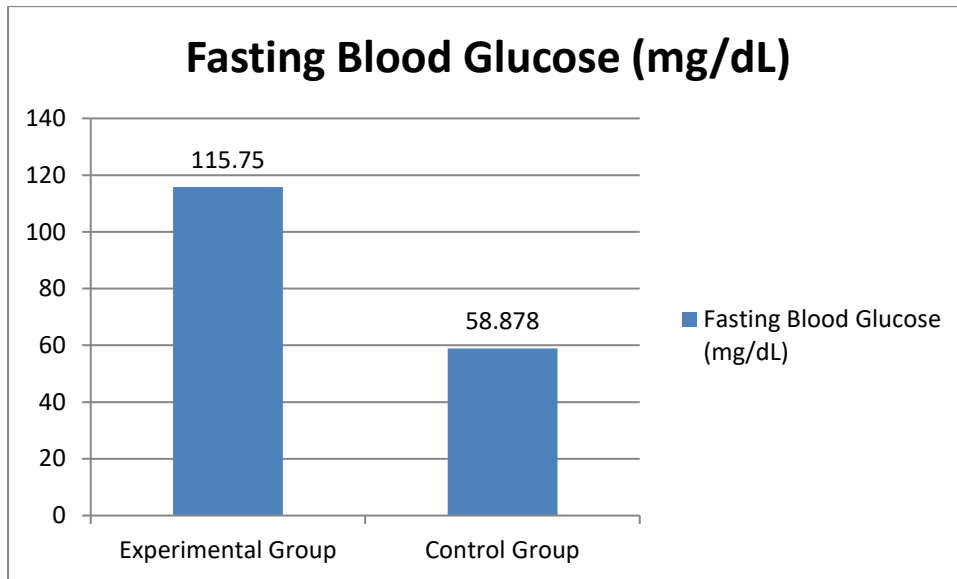
Graph 5: Pre-Post difference between the two groups for Fasting Blood Glucose (mg/dL) for all participants in this study

Graph 6 demonstrates the pre – post difference between the two groups for Fasting Blood Glucose (mmol/L) for all participants in this study

Fasting Blood Glucose (mmol/L)

Experimental Group: 6.496
Control Group: 3.312
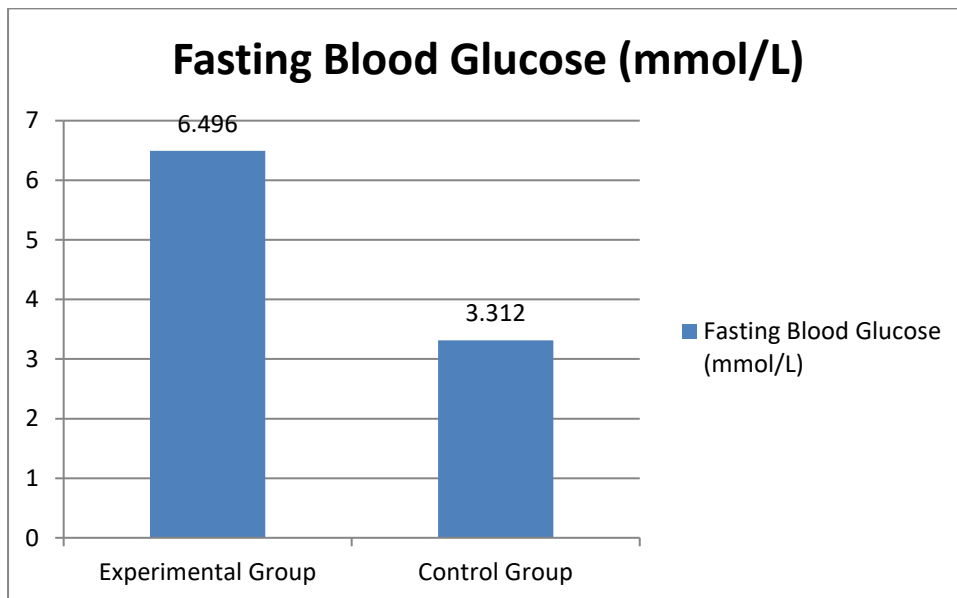
Graph 6: Pre – post difference between the two groups for Fasting Blood Glucose (mmol/L) for all participants in this study

Graph 7 demonstrates the pre – post difference between the two groups for HbA$_1$c (%) for all participants in this study

HbA1c (%)

A bar chart titled "HbA1c (%)". The y-axis ranges from 0 to 6. The Experimental Group bar reaches 5.44 and the Control Group bar reaches 0.509. Legend: HbA1c (%).

Graph 7: Pre – post difference between the two groups for HbA$_1$c (%) for all participants in this study

DISCUSSION

This randomised controlled trial presents findings of a novel unique structured therapeutic exercise program for individuals suffering from DM2. The current study elucidated the effect of a novel unique structured therapeutic exercise program on blood glucose levels viz fasting blood glucose (mg/dL), fasting blood glucose (mmol/L) and HbA$_1$c (%) among individuals diagnosed with DM2. There has been a reduction in the blood glucose levels among individuals diagnosed with DM2 in this study.

This reduction in blood glucose levels could be related due to an increased metabolism and increased glucose uptake in the muscles. Increase in lean muscle mass could also be attributed as a cause of the reduction in blood glucose levels due to the novel unique structured therapeutic exercise program among individuals diagnosed with DM2. Also, an increased synthesis of nitric oxide could be attributed to the reduction of blood glucose levels among the participants in this study who have been diagnosed with DM2.

Similarly, Yanai H. et al in a narrative review stated that structured exercise durations of more than 150 min/ weeks were associated with HbA1c reduction of 0.89%, while structured exercise duration of 150 min or less per week were associated with HbA1c reduction of 0.36%. [11] In our study, the novel unique structured therapeutic exercise program was performed for almost more than 150 min/ week, hence, this could have led to the reduction in the blood glucose levels in individuals diagnosed with DM2.

In another study by Shakil-ur-Rehman S. et al found prognostic effect of a 25 week structured supervised aerobic exercise therapy program along with routine medical management on fasting blood glucose and glycaemic control among individuals with diagnosed with DM2.[12]

In our study, we had an intervention program of structured therapeutic exercise for 12 weeks which has resulted in reduction in blood glucose levels among individuals suffering from DM2. If our intervention period would have been longer, maybe the magnitude of reduction of blood glucose levels could have been greater.

Yet, in another study, Soleimani A. et al in 2023, found a very peculiar result that moderate intensity exercises among individuals suffering from DM2 yields a lowering of fasting blood glucose levels. The authors have attributed this lowering of blood glucose levels to an increase in physical activity and reduction in sedentary lifestyle among individuals suffering from DM2.[13] Similarly, in our study too, a lowering of blood glucose levels viz Fasting Blood Glucose (mg/dL), Fasting Blood Glucose (mmol/L) and HbA$_1$c (%) mainly due to the increased physical activity achieved by performing the therapeutic exercises at moderate intensity among the participants who suffer from DM2.

In another study by Rawat A. et al in 2024, the researchers found that a novel structured therapeutic exercise found results in the reduction of blood glucose levels among individuals diagnosed with DM2 in a pre test – post test study design.[14] Similarly, in our study too while following the same novel structured therapeutic exercise we have found a reduction in blood glucose levels among individuals diagnosed with DM2.

CONCLUSION

Thus, we can conclude that novel uniquely designed structured therapeutic exercises have a prognostic effect on lowering the blood glucose levels among individuals who are suffering from DM2. But, larger clinical trials are required which will be needed to generalise this research findings.

References

1. Zimmet P., Magliano D., Herman W., Shaw J.; Diabetes: a 21st centurychallenge; Lancet Diabetes Endocrinology; 2014; Pg. 56 – 64

2. International Diabetes Federation; IDF Diabetes Atlas; 7th edition; Brussels; 2015

3. Barman P., Das M., Verma M.; Epidemiology of type 2 diabetes mellitus and treatment utilization patterns among the elderly from the first wave of Longitudinal Aging study in India (2017-18) using a Heckman selection model; BMC Public Health; 2023

4. Galicia-Garcia U., Benito-Vicente A., Jebari S., Larrea-Sebal A., Siddiqi H., Uribe K. et al.; Pathophysiology of Type 2 Diabetes Mellitus; International journal of Molecular Sciences; 2020.

5. Brunetti L., Kalabalik J.; Management of Type 2 Diabetes Mellitus in Adults; Pharmacy and Therapeutics; 2012; Volume 37; Issue 12; Pg 687 – 696

6. Syeda A., Battillo D., Visaria A., Malin S.; The importance of exercise for glycemic control in type 2 diabetes; American Journal of Medicine Open; 2023; Volume 9

7. Sargeant J., Lawson C., Gulsin G., Yates T., McCann G.; Physical activity and structured exercise in patients with type 2 diabetes mellitus and heart failure; ; Practical Diabetes; 2018

8. Palekar T., Rawat A., Goel N., Shaikh F., Wanjara N.; A Proposed Pre Test – Post Test Design For A Therapeutic Exercise Program For Rehabilitation Of Individuals Suffering From Diabetes Mellitus Type 2; International Journal of Research and Analytical Reviews; 2024

9. Flairty J., Scheadler C.; Perceived and Heart-Rate based intensities during Self-paced Walking: Magnitudes and Comparisons; International Journal of Exercise Sciences; 2020; Volume 13; Issue 5; Pg. 677 – 688

10. Day M., McGuigan M., Brice G., Foster C.; Monitoring Exercise Intensity During Resistance Training Using The Session RPE Sclae; Journal of Strength and Conditioning Research; 2004; Volume 18; Issue 2; Pg 353-358

11. Yanai H., Adachi H., Masui Y., Harigae T., Sako A., Waragai Y., et al.; Exercise Therapy For Patients With Type 2 Diabetes: A Narrative Review; Journal of Clinical Medicine Research; 2018; Volume 10; Issue 5; Pg 365 – 369

12. Shakil-Ur-Rehman S., Karimi H., Gillani S.; Effects of supervised structured aerobic exercise training program on fasting blood glucose level, plasma insulin level, glycemic control, and insulin resistance in type 2 diabetes mellitus; Pakistan Journal of Medical Sciences; 2017; Volume 33; Issue 3; Pg 576 – 580.

13. Soleimani A., Soltani P., Karimi H., Mirzaei M., Yavari M., Esfahani M. et al.; The effect of moderate – intensity aerobic exercise on non-proliferative diabetic retinopathy in type II diabetes mellitus patients: A clinical trial; Microvascular Research; 2023; Volume 149

14. Rawat A., Palekar T., Vig B., Wanjara N., Shaikh F.; Effect of a novel structured therapeutic exercise program on blood glucose levels in individuals suffering from diabetes mellitus type 2; Journal of Emerging Technologies and Innovative Research (JETIR); April, 2024; Volume 11; Issue 4