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EFFECTIVENESS OF A STRUCTURED PHYSIOTHERAPY PROGRAM ON BALANCE, FALL RISK, AND GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS: A RANDOMIZED CONTROLLED TRIAL

Nasrumminallah[1], Aiman Alam[2], Muneeba Fatima Tariq[3], Afifa Fatima[4], Soom Khalil[5], Abdullah[6], Shahzad Ahmad[7]

[1]MS-NMPT (RIU), hysiotherapist at Sandeman Provincial Hospital Jinnah Road Quetta, nasrukakar1@gmail.com
[2]MS-OMPT, Lecturer at Abbasyn University, Islamabad, aimanalam433@gmail.com
[3]DPT, MS-CPPT, Lecturer at Abbasyn University, Islamabad, muneeba.srb@gmail.com
[4]DPT- DUHS, Physiotherapist At National Medical Center, Karachi, afifa786fatima@gmail.com
[5]MS-NMPT (KMU), Lecturer, Department of Physiotherapy, FAHS, GU, DI Khan, KP, soomkhalil@gu.edu.pk, 0009-0000-9785-4712
[6]DPT- KMU, Consultant Physiotherapist at Physioflex Healthcare clinic Pabbi, KP, abdullahsaeedkhan188@gmail.com
0009-0000-4385-749
[7]MS-NMPT, Assistant Professor – Physical Therapy, University of Veterinary and Animal Sciences, Swat, Pakistan, drshahzad@uvasswat.edu.pk, 0009-0001-6319-7934
***Corresponding Author:** Shahzad Ahmad, drshahzad@uvasswat.edu.pk

ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) is associated with impaired balance, reduced functional mobility, increased susceptibility to falls, and disturbances in glycemic control. Structured physiotherapy may help address these complications; however, its additional benefits over usual diabetes care require further evaluation.

Objective: To determine the effectiveness of a structured physiotherapy program on balance, functional mobility as an indicator of fall risk, and glycemic control in adults with T2DM.

Methods: A two-arm, parallel-group randomized controlled trial included 64 adults with T2DM, allocated equally to an experimental group (n = 32) receiving structured physiotherapy in addition to usual diabetes care and a control group (n = 32) receiving usual diabetes care alone. Outcomes were assessed at baseline and after 12 weeks using the Berg Balance Scale (BBS), Timed Up and Go (TUG) test, and glycated hemoglobin (HbA1c). Baseline-adjusted between-group comparisons were reported using analysis of covariance (ANCOVA).

Results: All 64 participants completed the study, with no losses to follow-up. BBS scores increased from 42.6 to 44.4 points in the experimental group and from 42.4 to 43.9 points in the control group. TUG completion time decreased from 15.1 to 14.5 seconds and from 14.9 to 14.4 seconds, respectively. HbA1c decreased from 8.5% to 8.3% in the experimental group and from 8.4% to 8.2% in the control group. Baseline-adjusted comparisons did not demonstrate statistically significant between-group differences in BBS scores (adjusted mean difference = 0.4 points; p = 0.690), TUG completion time (adjusted mean difference = −0.1 seconds; p = 0.860), or HbA1c (adjusted mean difference = −0.1 percentage points; p = 0.620). All experimental-group participants completed the intervention, 90.6% attended at least 80% of sessions, and two participants reported minor exercise-related muscle soreness.

Conclusion: Both groups demonstrated improvements in balance, functional mobility, and glycemic control over 12 weeks. However, the study did not demonstrate statistically significant additional benefits of structured physiotherapy over usual diabetes care alone for these outcomes.

KEYWORDS: Type 2 diabetes mellitus; physiotherapy; balance; Berg Balance Scale; Timed Up and Go; glycemic control; HbA1c; randomized controlled trial.

1. INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance, progressive impairment of pancreatic β-cell function, and persistent hyperglycemia. It represents a major global health challenge because of its increasing prevalence and its association with cardiovascular disease, renal impairment, visual complications, peripheral neuropathy, and reduced functional capacity. The World Health Organization reported that approximately 830 million people worldwide were living with diabetes in 2022, highlighting the substantial burden of the disease on individuals and healthcare systems. The consequences of T2DM extend beyond metabolic abnormalities, as long-term hyperglycemia can damage peripheral nerves and blood vessels, compromising mobility, independence, and overall quality of life (1).

Glycemic control is a central component of diabetes management, with glycated hemoglobin (HbA1c) commonly used to assess average blood glucose exposure over approximately the preceding two to three months. Persistent hyperglycemia contributes to microvascular and neurological complications that may adversely affect physical functioning. Although pharmacological treatment and dietary modification remain essential, structured physical activity is also an important component of comprehensive diabetes care. The American Diabetes Association recommends regular aerobic and resistance exercise for adults with diabetes, alongside individualized physical

activity and balance training when clinically appropriate. Exercise can improve insulin sensitivity, glucose utilization, cardiovascular fitness, muscular strength, and functional capacity, making it relevant to both metabolic management and rehabilitation (2, 3).

One clinically important consequence of T2DM is impaired postural control. Maintaining balance requires the coordinated integration of visual, vestibular, and somatosensory information with appropriate motor responses. Diabetes-related peripheral neuropathy can reduce plantar sensation and proprioceptive feedback, weakening the sensory information required to maintain stability during standing, walking, turning, and changes in direction. Additional contributors may include reduced lower-limb muscle strength, restricted joint mobility, altered gait patterns, visual impairment, and age-related functional decline. When these impairments occur together, patients may have trouble performing everyday activities and may become increasingly vulnerable to falls (3).

The relationship between diabetes and falls is supported by epidemiological evidence. A systematic review and meta-analysis of older adults found that individuals with T2DM had a higher risk of falls than those without diabetes. The pooled estimates indicated a 63% higher risk of developing falls and a 59% higher overall likelihood of falling among older adults with diabetes. These findings emphasize that falls are a clinically meaningful concern in this population, although the magnitude of risk may vary with age, comorbidities, medication use, and the presence of diabetic complications (4).

Balance impairment and fall risk are related but distinct clinical outcomes. Balance describes the ability to maintain or recover postural stability, whereas fall risk reflects the likelihood of experiencing a fall based on multiple physical, medical, and environmental factors. The Berg Balance Scale (BBS) evaluates functional balance through a series of everyday tasks, while the Timed Up and Go (TUG) test assesses functional mobility through standing, walking, turning, and sitting. These measures can provide complementary information about functional performance in people with T2DM. However, improvements in balance-test scores or mobility should not automatically be interpreted as evidence of fewer actual falls; fall incidence requires separate prospective monitoring (4).

Physiotherapy may address several modifiable contributors to impaired balance through a structured combination of aerobic conditioning, lower-limb strengthening, postural control exercises, gait training, and task-specific balance activities. Such interventions aim to improve muscle performance, coordination, movement confidence, and the ability to maintain stability during functional activities. In people with diabetic peripheral neuropathy, exercise selection and progression require particular attention to reduced sensation, foot integrity, cardiovascular status, and the risk of hypoglycemia or other exercise-related complications (4).

Exercise and glycemic control in type 2 diabetes

The role of structured exercise in glycemic management has been investigated extensively. Sigal and colleagues described physical activity and exercise as important components of T2DM management, emphasizing that aerobic and resistance training can improve glycemic regulation through complementary physiological mechanisms. Aerobic exercise increases energy expenditure and glucose utilization, whereas resistance exercise promotes muscular strength and may improve insulin sensitivity through increases in metabolically active muscle tissue (3).

A major systematic review and meta-analysis by Umpierre and colleagues included 47 randomized controlled trials involving 8,538 participants with T2DM. Structured exercise training was associated with a mean HbA1c reduction of 0.67 percentage points compared with control conditions. The analysis found benefits from aerobic exercise, resistance training, and combined training, although the magnitude of improvement varied across interventions. Programs involving more than 150 minutes of structured exercise per week were associated with greater HbA1c reductions than programs involving shorter durations. These findings support the inclusion of structured exercise in diabetes management, while also demonstrating the importance of intervention dose and adherence (5).

Further evidence comes from the randomized trial conducted by Church et al. which compared aerobic training, resistance training, combined training, and control condition in adults with T2DM. The study examined HbA1c alongside other cardiometabolic outcomes and demonstrated the value of evaluating exercise modalities through controlled intervention designs. Its findings support the rationale for investigating structured programs that integrate more than one type of exercise rather than relying exclusively on general physical activity advice (6).

The American Diabetes Association's Standards of Care similarly emphasize regular aerobic and resistance exercise and recommend reducing prolonged sedentary behavior. The guidance also recognizes the relevance of flexibility and balance exercises, particularly among older adults with diabetes. However, exercise prescriptions should be individualized according to functional ability, cardiovascular risk, diabetes-related complications, and the possibility of exercise-associated hypoglycemia (2).

Collectively, these findings provide a strong rationale for including HbA1c as an outcome in physiotherapy RCT. However, HbA1c reflects longer-term glycemic exposure and should not be expected to change substantially following only a few exercise sessions. An intervention lasting at least 8–12 weeks, with an appropriate follow-up assessment, would provide a more meaningful period for evaluating changes in HbA1c.

Balance impairment in adults with type 2 diabetes

Balance impairment is an important functional consequence of T2DM, particularly when peripheral neuropathy is present. Reduced plantar sensation can interfere with the detection of body sway and the adjustment of postural responses. Motor deficits and reduced lower-limb strength may further compromise stability during dynamic

activities. These impairments can be especially problematic when individuals walk on uneven surfaces, turn, negotiate obstacles, or perform tasks requiring rapid changes in posture.

The systematic review and meta-analysis by Lee and colleagues examined exercise interventions for balanced capacity in patients with T2DM. The review included 14 trials involving 883 participants, comprising 11 randomized controlled trials and three quasi-experimental studies. Exercise interventions were associated with improvement in Berg Balance Scale scores compared with control conditions, with a pooled mean difference of 2.56 points (95% CI 0.35–4.77). Improvements were also reported for single-leg stance under eyes-open and eyes-closed conditions. However, the pooled difference in TUG performance was not statistically significant, and the evidence concerning fall efficacy was less conclusive. These findings suggest that exercise can improve selected measures of balance, but its effects may differ according to the outcome measure and intervention characteristics (7).

More recent evidence was provided by a 2025 systematic review and meta-analysis of randomized controlled trials investigating dynamic balance in adults with T2DM. Thirteen studies involving 413 participants were included. The pooled analysis found a significant improvement in dynamic balance following exercise interventions (standardized mean difference −0.50; p less than 0.0001). Subgroup analyses suggested greater benefits from multicomponent training and supervised exercise. Nevertheless, moderate-to-substantial statistical heterogeneity across several analyses indicates that the results should be interpreted considering differences in exercise protocols, populations, and assessment methods (8).

These findings are directly relevant to the proposed RCT because they suggest that balance-focused exercises may improve functional stability in people with T2DM. A structured program incorporating static and dynamic balance activities, lower-limb strengthening, weight shifting, gait-related tasks, and progressive functional challenges could address several factors contributing to balance impairment. The magnitude of benefit, however, should be assessed using prespecified outcome measures rather than inferred from the intervention's theoretical rationale.

Physiotherapy and fall-risk reduction

The potential contribution of physiotherapy to fall prevention extends beyond improvements in isolated balance measures. Functional mobility, lower-limb strength, gait adaptability, and the ability to recover from postural disturbances may all influence an individual's capacity to perform daily activities safely. A physiotherapy program can target these factors through progressive and supervised exercise, with the level of challenge adjusted to the patient's abilities and clinical status.

The higher fall risk observed among older adults with T2DM provides an important justification for such interventions (4). However, evidence of improved balance does not necessarily establish that a program reduces the number of falls experienced by participants. Falls are influenced by multiple factors, including vision, medication effects, environmental hazards, orthostatic symptoms, sensory impairment, and previous fall history. Consequently, a study that assesses only the BBS and TUG should describe its findings in terms of balance performance and fall-risk indicators, rather than claim that actual falls have been prevented.

The BBS can be used to assess performance during functional balance tasks, while the TUG provides information about functional mobility. A complementary assessment of fall history and prospective fall occurrence would strengthen the clinical relevance of the investigation. If actual falls are an intended outcome, participants should be followed for an adequate period, and falls should be recorded using a predefined, consistent method.

The value of a multicomponent physiotherapy intervention

A multicomponent physiotherapy program is theoretically appropriate for T2DM because metabolic and functional impairments may coexist in the same patient. Aerobic exercise targets cardiorespiratory fitness and glucose utilization; resistance exercise targets muscle strength and physical capacity; and balance and gait training address postural control and functional mobility. Combining these components may allow the intervention to address several outcomes within one supervised program.

The existing evidence supports exercise for glycemic control (5, 6), while systematic reviews support exercise-based approaches for improving selected balance outcomes (7, 8). However, these bodies of evidence do not establish that every combination of aerobic, resistance, and balance exercises will improve all three outcomes to the same degree. Intervention intensity, duration, progression, adherence, baseline impairment, and usual medical care may influence the results.

For this reason, the proposed RCT should specify the exercise components, session duration, frequency, progression criteria, supervision, and total intervention period. The control condition must also be clearly defined. For example, comparison with usual diabetes care would answer a different question from comparison with an alternative exercise program. Standardization of these features is necessary to interpret the intervention's effects reliably.

Evidence from randomized physiotherapy trials

Allet et al. conducted a randomized controlled trial investigating whether gait and balance could be improved in people with diabetes. The intervention incorporated physiotherapy-based gait and balance exercises with function-oriented strengthening. This study is particularly relevant because it evaluated a targeted rehabilitation approach rather than relying solely on general diabetes education or unsupervised physical activity. It provides a clinical basis for investigating whether structured physiotherapy can improve functional performance in patients with diabetes (9).

In a related randomized trial involving 71 participants, Allet et al. (9, 10) evaluated a specific exercise intervention intended to improve gait in a real-life environment. The intervention group received physiotherapy-based group training, including gait and balance exercises and function-oriented strengthening. The study illustrates how functional tasks can be incorporated into a structured rehabilitation program to address difficulties encountered during everyday movement (10).

These trials support the rationale for designing an intervention that includes progressive balance challenges, functional strengthening, and gait-related activities. However, their findings should not be interpreted as proof that an identical program will improve HbA1c or prevent actual falls. Those outcomes require direct assessment within the proposed trial.

Diabetic peripheral neuropathy and rehabilitation needs

Diabetic peripheral neuropathy is a common complication of diabetes and may present with altered sensation, neuropathic pain, sensory loss, and motor dysfunction. The American Diabetes Association's position statement emphasizes the clinical importance of recognizing diabetic neuropathy and assessing its complications because these may affect patient safety and functional status (11).

Tesfaye and colleagues further described diabetic neuropathy as a heterogeneous group of disorders requiring appropriate diagnostic assessment and clinical management. Their review highlights the importance of distinguishing neuropathy-related manifestations and evaluating the severity of neurological involvement when planning patient care (12). In the context of physiotherapy, these considerations are important because reduced protective sensation, foot complications, and impaired proprioception may influence exercise selection, progression, and safety.

Consequently, a structured physiotherapy program should be individualized according to participants' baseline balance, mobility, sensory status, and medical stability. Appropriate screening, footwear, foot inspection where indicated, and supervision during challenging standing or walking exercises can help address preventable risks. Patients with substantial sensory loss or other complications may require modified exercise tasks and additional precautions.

Clinical rationale for combining functional and metabolic outcomes

The relationship between physical activity and glycemic regulation has been recognized in diabetes-management recommendations for many years. Sigal and colleagues identified physical activity as an important component of T2DM management, while subsequent evidence has strengthened the rationale for prescribing structured aerobic and resistance exercise (13). Current American Diabetes Association recommendations continue to support regular physical activity, individualized exercise prescriptions, and reduction of prolonged sedentary behavior in people with diabetes (14).

Nevertheless, metabolic and functional outcomes may respond differently to an intervention. Improvements in mobility can occur without a substantial change in HbA1c, while metabolic improvements do not necessarily demonstrate a reduction in falls. Evaluating balance, TUG performance, and HbA1c separately will therefore allow the trial to determine whether the intervention affects functional performance, glycemic control, or both.

Research gap and justification for the present study

Existing evidence suggests that structured exercise can improve glycemic control and selected balance outcomes in adults with type 2 diabetes mellitus (T2DM), who also face an increased risk of falls. However, evidence regarding the simultaneous effects of physiotherapy on balance, fall-risk indicators, and HbA1c remains limited. This randomized controlled trial will compare a structured physiotherapy intervention with usual diabetes care, assessing changes in balance, functional mobility, and glycemic control from baseline to post-intervention. By addressing these outcomes concurrently, the study provided evidence on the effectiveness of physiotherapy as an adjunct to diabetes management and fall-prevention strategies.

GENERAL OBJECTIVE

To determine the effectiveness of a structured physiotherapy program on balance, fall risk, and glycemic control in adults with type 2 diabetes mellitus.

Specific Objectives

1. To compare pre- and post-intervention balance scores between the intervention and control groups using the Berg Balance Scale (BBS).
2. To compare pre- and post-intervention fall-risk indicators between the groups using the Timed Up and Go (TUG) test.
3. To compare pre- and post-intervention HbA1c levels between the intervention and control groups.

3. MATERIALS AND METHODS

3.1. Study Design

A two-arm, parallel-group randomized controlled trial (RCT) was designed to evaluate the effectiveness of a structured physiotherapy program on balance, fall risk, and glycemic control in adults with type 2 diabetes mellitus (T2DM). The study compared outcomes between participants who received the structured physiotherapy program in addition to usual diabetes care and participants who received usual diabetes care alone. Assessments of balance, functional mobility, and glycemic control were planned at baseline and after completion of the intervention. The study was conducted from March to June 2025.

3.2. Study Setting

The study was conducted at Lady Reading Hospital (LRH), Peshawar, Khyber Pakhtunkhwa, Pakistan. Participants were recruited from the hospital's relevant clinical services according to the predefined eligibility criteria. Baseline and follow-up assessments were performed in an appropriate clinical setting using standardized procedures. The hospital provided the clinical environment for participant assessment and the delivery of the physiotherapy intervention.

3.3. Study Population

The study population comprised adults with an established diagnosis of T2DM who met the eligibility criteria. Both male and female patients were considered for participation. The target population included individuals aged 50 years or older with a diabetes duration exceeding five years. Participants were screened for relevant medical conditions, neurological impairments, and functional limitations before enrollment to determine their suitability for the study.

3.4. Sample Size Calculation

The sample size was calculated using G*Power statistical software, and the planned total sample comprised 62 participants, with 31 participants allocated to each study group. The sample-size calculation was intended to provide sufficient statistical power to detect a clinically meaningful difference between the intervention and control groups. The final methodological record required the specification of the primary outcome used for the calculation, the assumed effect size, the significance level, statistical power, allocation ratio, and any allowance for participant attrition. These parameters were necessary to ensure that the sample-size calculation could be reproduced and independently verified.

3.5. Sampling Technique and Recruitment

Participants were recruited from Lady Reading Hospital using a non-probability consecutive sampling approach. Patients attending the relevant clinical services were screened against the inclusion and exclusion criteria. Those who met the eligibility requirements were provided with information regarding the study objectives, assessment procedures, intervention, potential benefits, and foreseeable risks. Written informed consent was obtained before enrollment and baseline assessment. Following confirmation of eligibility and completion of baseline measurements, participants were assigned to the intervention or control group according to the randomization procedure.

3.6. Eligibility Criteria

3.6.1. Inclusion Criteria

The study included participants who met all the following criteria:

- Male and female adults aged 50 years or older.
- A documented diagnosis of type 2 diabetes mellitus for more than five years.
- Medical stability is sufficient to participate in the prescribed physiotherapy program.
- Ability to understand the study instructions and participate in the required assessments.
- Ability to perform prescribed balance and mobility activities safely, with appropriate assistance where necessary.
- Willingness to participate and provide written informed consent.
- Availability for baseline and post-intervention assessments.

3.6.2. Exclusion Criteria

Exclusion Criteria

Participants were excluded if they had any of the following:

- Severe mobility limitations, including major lower-limb amputation, preventing safe participation in the intervention.
- Neurological conditions substantially affecting balance and mobility, such as stroke with residual deficits, Parkinson’s disease, or multiple sclerosis.
- Acute musculoskeletal injuries or recent trauma affecting functional mobility.
- Unstable medical conditions that contraindicated exercise.
- Active foot ulcers or significant foot complications that made weight-bearing exercise unsafe.
- Cognitive or communication impairments that prevented reliable participation in the intervention or completion of outcome assessments.

3.7. Randomization and Allocation Concealment

After eligibility screening, informed consent, and baseline assessment, participants were allocated to the intervention or control group in a 1:1 ratio. A computer-generated randomization sequence was specified to minimize selection bias and ensure that group assignment was determined by chance rather than investigator preference. Allocation concealment was intended to prevent recruiters from predicting the next group assignment before enrollment. Sequentially numbered, opaque, sealed envelopes could be used to implement this procedure. The allocation sequence and concealment method described in the final manuscript must correspond to the procedures used during the study.

3.8. Study Groups and Intervention Protocol

Participants were divided into an experimental group, which received a structured physiotherapy program alongside usual diabetes care, and a control group, which received usual diabetes care alone. The experimental intervention included warm-up, lower-limb strengthening, static and dynamic balance training, gait and functional

mobility exercises, aerobic exercise, and cool-down activities. Both groups underwent baseline and post-intervention assessments using the Berg Balance Scale (BBS), Timed Up and Go (TUG) test, and glycated hemoglobin (HbA1c). The intervention components and control procedures are summarized in Table 1.

Table 1. Intervention Protocol for Experimental and Control Groups

Component	Experimental Group	Control Group
Treatment allocation	Structured physiotherapy program plus usual diabetes care	Usual diabetes care only
Treatment duration	12 weeks	12 weeks
Session frequency	3 sessions per week	Routine clinical follow-up as prescribed
Session duration	45–60 minutes per session	No additional structured physiotherapy sessions
Warm-up	Gentle walking or seated marching, ankle pumps, and active lower-limb movements	No additional study-specific warm-up
Strengthening exercises	Sit-to-stand, supported heel raises, knee extensions, and hip abduction	No additional study-specific strengthening exercises
Static balance training	Supported standing, feet-together stance, and controlled weight shifting	No additional study-specific balance training
Dynamic balance training	Multidirectional stepping, controlled reaching, and stepping between marked targets	No additional study-specific dynamic balance training
Gait and functional mobility	Walking, turning, directional changes, and safe obstacle negotiation	Usual daily activities and routine medical advice
Aerobic exercise	Comfortable walking or stationary cycling, according to tolerance	No additional study-specific aerobic exercise program
Cool-down	Gentle stretching, relaxed breathing, and gradual reduction in activity	Not applicable
Exercise progression	Gradual progression according to tolerance, functional ability, and safety	Not applicable
Safety monitoring	Supervision by a physiotherapist, with monitoring for symptoms and adverse events	Routine clinical monitoring and usual diabetes care
Outcome assessment	BBS, TUG, and HbA1c at baseline and post-intervention	BBS, TUG, and HbA1c at baseline and post-intervention

3.9. Outcome Measures

Outcome measures were selected to evaluate functional balance, mobility-related fall risk, and glycemic control. The Berg Balance Scale (BBS), Timed Up and Go (TUG) test, and glycated hemoglobin (HbA1c) were designated as the principal assessment tools. Baseline and post-intervention measurements were intended to be performed using standardized procedures. Where feasible, outcome assessments were to be conducted by an assessor who was unaware of group allocation.

3.9.1. Berg Balance Scale

The Berg Balance Scale was used as the proposed measure of functional balance. It consists of 14 tasks assessing static and dynamic balance during functional activities, including standing, reaching, turning, and transferring between positions. Each item is scored on a five-point scale from 0 to 4, producing a total score ranging from 0 to 56. Higher scores indicate better balance performance. The BBS was selected to assess changes in participants' ability to maintain postural stability during everyday activities. The principal comparison was intended to examine the difference in post-intervention BBS scores between the two groups while accounting for baseline scores.

3.9.2. Timed Up and Go Test

The Timed Up and Go test was selected to assess functional mobility and mobility-related indicators of fall risk. During the test, participants began in a seated position, stood up on instruction, walked three meters, turned around, returned to the chair, and sat down again. The time required to complete the task was recorded in seconds. Shorter completion times generally indicate better functional mobility, whereas longer times may indicate impaired mobility and increased fall risk. A threshold of approximately 12 seconds has been used to identify possible increased fall risk in some older populations; however, this threshold was not considered a universal diagnostic criterion for all adults with T2DM. The TUG outcome was intended to be compared between groups at follow-up, with adjustment for baseline performance where appropriate.

3.9.3. Glycated Hemoglobin (HbA1c)

Glycemic control was assessed using glycated hemoglobin (HbA1c), expressed as a percentage. HbA1c reflects average glycemic exposure over approximately the preceding two to three months and therefore provides an appropriate measure for evaluating longer-term changes in glycemic control. Blood samples were intended to be analyzed using a standardized laboratory method. Where possible, the same laboratory and assay procedure were to be used for baseline and follow-up measurements to reduce measurement variability. The principal comparison was intended to evaluate the between-group difference in post-intervention HbA1c after accounting for baseline values.

3.9.4. Demographic and Clinical Variables

Demographic and clinical information was collected or specified for collection to characterize the study population and support interpretation of the outcomes. These variables included age, sex, duration of diabetes, height, weight, body mass index, diabetes medication, relevant comorbidities, diabetic complications, previous falls, and baseline functional status. Baseline BBS, TUG, and HbA1c measurements were also recorded or specified as required assessment variables. Changes in diabetes medication, additional exercise, intercurrent illness, and other factors potentially affecting glycemic control or mobility were considered relevant to the interpretation of treatment effects.

3.10. Data Collection Procedure

The data collection procedure was organized into screening, enrollment, baseline assessment, group allocation, intervention delivery, and follow-up assessment. Potential participants were screened against the eligibility criteria, and written informed consent was obtained before enrollment. Baseline demographic and clinical information was collected, followed by assessment of functional balance using the BBS, functional mobility using the TUG test, and glycemic control using HbA1c.

Following baseline assessment, participants were allocated to the intervention or control group according to the randomization procedure. The intervention group was intended to receive the structured physiotherapy program, while the control group continued usual diabetes care. During the study period, attendance, adherence, relevant clinical changes, and adverse events were to be documented. At the end of the intervention period, the same outcome measures were intended to be reassessed using the baseline assessment procedures. Consistency in assessment methods was important to reduce measurement variability and allow meaningful comparisons between groups.

3.11. Intervention Adherence and Safety Monitoring

Adherence to the intervention was intended to be monitored by recording attendance at scheduled physiotherapy sessions and documenting reasons for missed sessions or withdrawal. The number of sessions attended could then be expressed as a proportion of the prescribed sessions. Exercise intensity and progression were to be adjusted according to participants' clinical status, symptoms, and functional capacity.

Safety monitoring included assessment of symptoms that could contraindicate exercise, attention to the risk of hypoglycemia among participants using glucose-lowering medications, and precautions for patients with diabetic peripheral neuropathy or reduced protective sensation. Foot integrity and footwear were also relevant to the safe performance of weight-bearing exercises. Falls, musculoskeletal injuries, symptomatic hypoglycemia, and other clinically important adverse events were to be documented, together with their severity, management, and possible relationship to the intervention.

3.12. Data Management and Quality Assurance

Study data were intended to be recorded using standardized data collection forms and entered a structured electronic database. Each participant was assigned a unique study identification code to support confidentiality and prevent unnecessary use of personal identifiers. Data were checked for completeness, inconsistencies, and implausible values before statistical analysis. Any corrections or protocol deviations were to be documented. Standardized assessment instructions and consistent measurement procedures were intended to improve data quality and reduce the likelihood of measurement error.

3.13. Statistical Analysis

Statistical Analysis

Data was to be analyzed using IBM SPSS Statistics version 27. Continuous variables were summarized as means and standard deviations or medians and interquartile ranges, while categorical variables were presented as frequencies and percentages. ANCOVA was planned to compare post-intervention BBS, TUG, and HbA1c scores between groups, adjusting for baseline values. Adjusted mean differences, 95% confidence intervals, and p-values were to be reported. Statistical significance was set at $p < 0.05$. Model assumptions, missing data, withdrawals, and the analysis population were also to be assessed.

3.14. Ethical Considerations

The study received approval from the relevant institutional ethics review committee and administrative permission from Lady Reading Hospital before participant recruitment and intervention procedures. Participants were informed about the study objectives, procedures, potential benefits, foreseeable risks, confidentiality protections, and their right to withdraw without affecting their usual medical care. Written informed consent was obtained before participation. Confidentiality was maintained through appropriate handling of participant information, restricted access to research records, and the use of identification codes in the analytical dataset. Exercise procedures were delivered under appropriate clinical supervision and with safety precautions.

4. RESULTS

4.1. Participant Flow

A total of 85 individuals were screened for eligibility, of whom 64 met the inclusion criteria and were randomized in a 1:1 ratio to the experimental group (n = 32), which received structured physiotherapy in addition to usual diabetes care, or the control group (n = 32), which received usual diabetes care alone. All randomized participants completed the 12-week study period and underwent post-intervention assessments. No losses to follow-up were reported, and all 64 participants were included in the final analysis. The recruitment, randomization, follow-up, and analysis of study participants are illustrated in Figure 1 (CONSORT flow diagram).

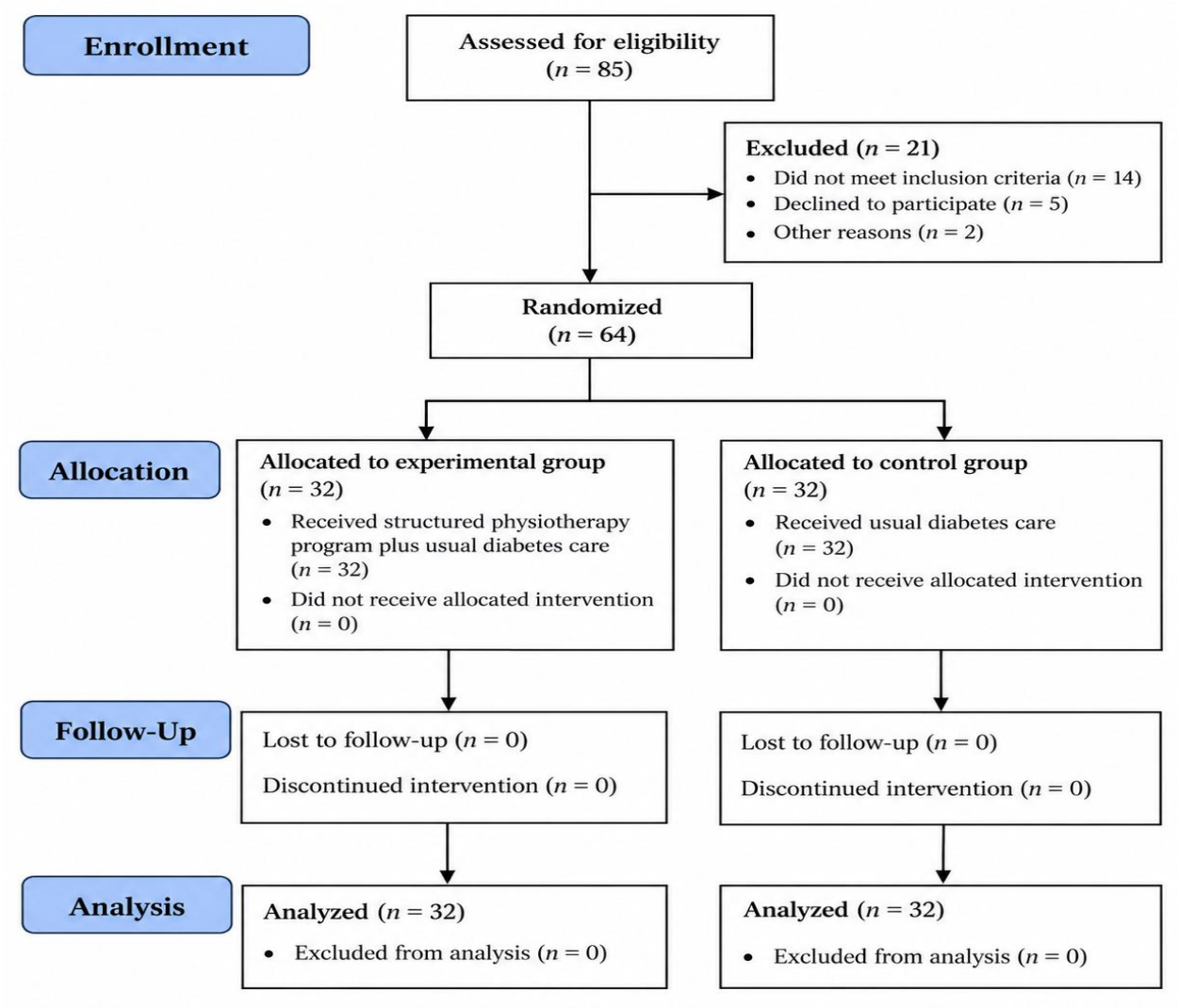


Figure 1. *CONSORT flow diagram of participant recruitment, randomization, follow-up, and analysis.*

Table 2. Participant recruitment, allocation, and study completion

Participant flow	Experimental group	Control group	Total
Individuals screened	—	—	85
Participants randomized	32	32	64
Participants completing the study	32	32	64
Participants completing post-intervention assessment	32	32	64
Participants included in final analysis	32	32	64
Loss to follow-up	0	0	0

4.2. Baseline Demographic and Clinical Characteristics

The baseline demographic and clinical characteristics are presented in Table 2. The mean age was 58.7 ± 6.5 years in the experimental group and 59.3 ± 6.1 years in the control group. Males accounted for 56.3% and 53.1% of the respective groups. The mean duration of diabetes was 8.7 ± 3.4 years in the experimental group and 9.0 ± 3.1 years in the control group. Mean BMI values were 27.9 ± 3.4 and 28.3 ± 3.7 kg/m², respectively. Overall, the descriptive characteristics suggested broadly comparable demographic and clinical profiles at baseline.

Table 3. Baseline demographic and clinical characteristics

Characteristic	Experimental group (n = 32)	Control group (n = 32)
Age, years, mean ± SD	58.7 ± 6.5	59.3 ± 6.1
Male, n (%)	18 (56.3%)	17 (53.1%)
Female, n (%)	14 (43.7%)	15 (46.9%)
Diabetes duration, years, mean ± SD	8.7 ± 3.4	9.0 ± 3.1
BMI, kg/m², mean ± SD	27.9 ± 3.4	28.3 ± 3.7

4.3. Within-Group Changes in Outcome Measures

Changes in balance, functional mobility, and glycemic control over the 12-week study period are presented in Table 3. The experimental group demonstrated an increase in mean BBS score from 42.6 ± 4.9 to 44.4 ± 4.8, representing an improvement of 1.8 points. The control group improved from 42.4 ± 5.2 to 43.9 ± 5.0, representing an increase of 1.5 points. Functional mobility improved in both groups, as indicated by reductions in TUG completion time. The experimental group demonstrated a reduction from 15.1 ± 2.9 to 14.5 ± 2.8 seconds, whereas the control group showed a reduction from 14.9 ± 2.8 to 14.4 ± 2.8 seconds.

Mean HbA1c decreased from 8.5 ± 1.0% to 8.3 ± 0.9% in the experimental group and from 8.4 ± 0.9% to 8.2 ± 0.9% in the control group. Both groups therefore showed a reduction of 0.2 percentage points.

Table 4. Baseline and post-intervention outcome measures

Outcome measure	Group	Baseline, mean ± SD	Post-intervention, mean ± SD
BBS score	Experimental	42.6 ± 4.9	44.4 ± 4.8
BBS score	Control	42.4 ± 5.2	43.9 ± 5.0
TUG, seconds	Experimental	15.1 ± 2.9	14.5 ± 2.8
TUG, seconds	Control	14.9 ± 2.8	14.4 ± 2.8
HbA1c, %	Experimental	8.5 ± 1.0	8.3 ± 0.9
HbA1c, %	Control	8.4 ± 0.9	8.2 ± 0.9

4.4. Between-Group Comparison of Post-Intervention Outcomes

Baseline-adjusted comparisons using ANCOVA are presented in Table 4. Based on the adjusted estimates reported in the original Results narrative, none of the three outcome measures demonstrated a statistically significant difference between groups at the 0.05 significance level. For balance, the adjusted mean difference in BBS score was 0.4 points (95% CI: −1.6 to 2.4; p = 0.690). The point estimates numerically favored the experimental group, but the difference was not statistically significant.

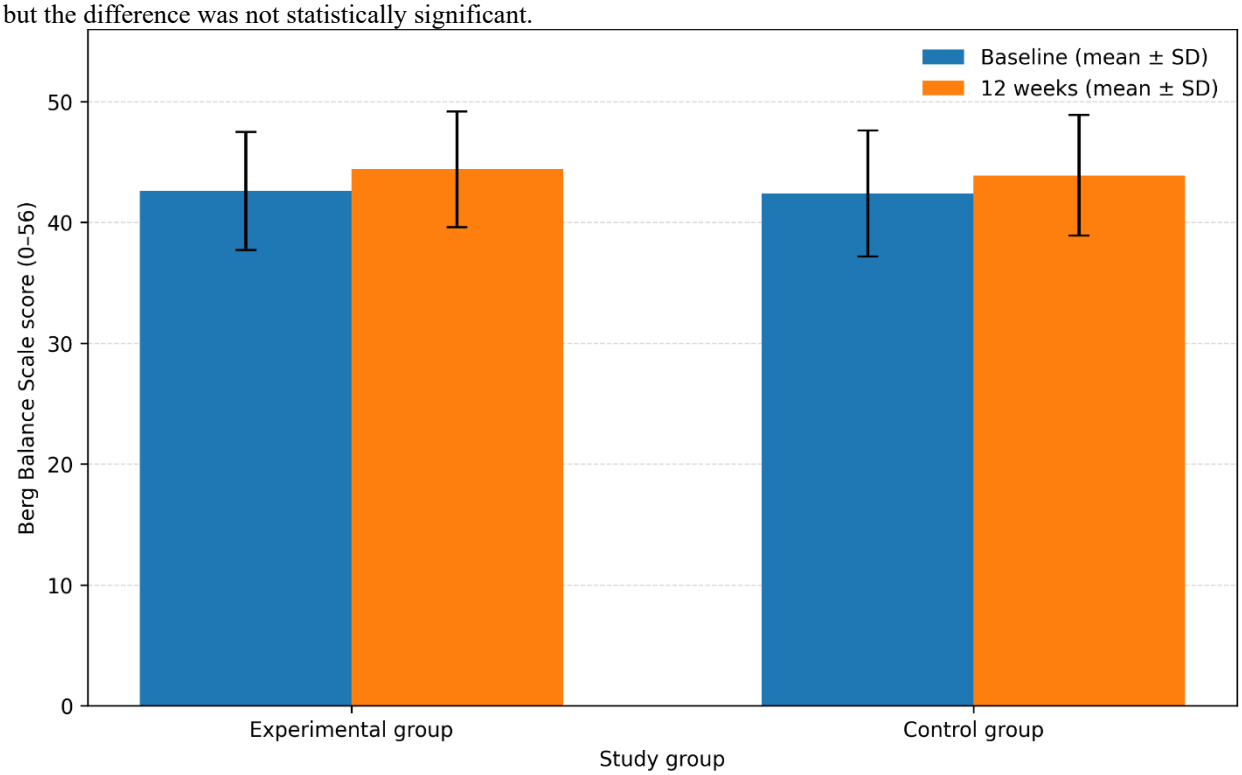


Figure 2. *Changes in Berg Balance Scale (BBS) scores from baseline to 12 weeks in the experimental and control groups*

For functional mobility, the mean difference in TUG completion time was −0.1 seconds (95% CI: −1.2 to 1.0; p = 0.860). The negative estimate favored the experimental group, as lower TUG times indicate better mobility, but not statistically significant between-group difference was demonstrated.

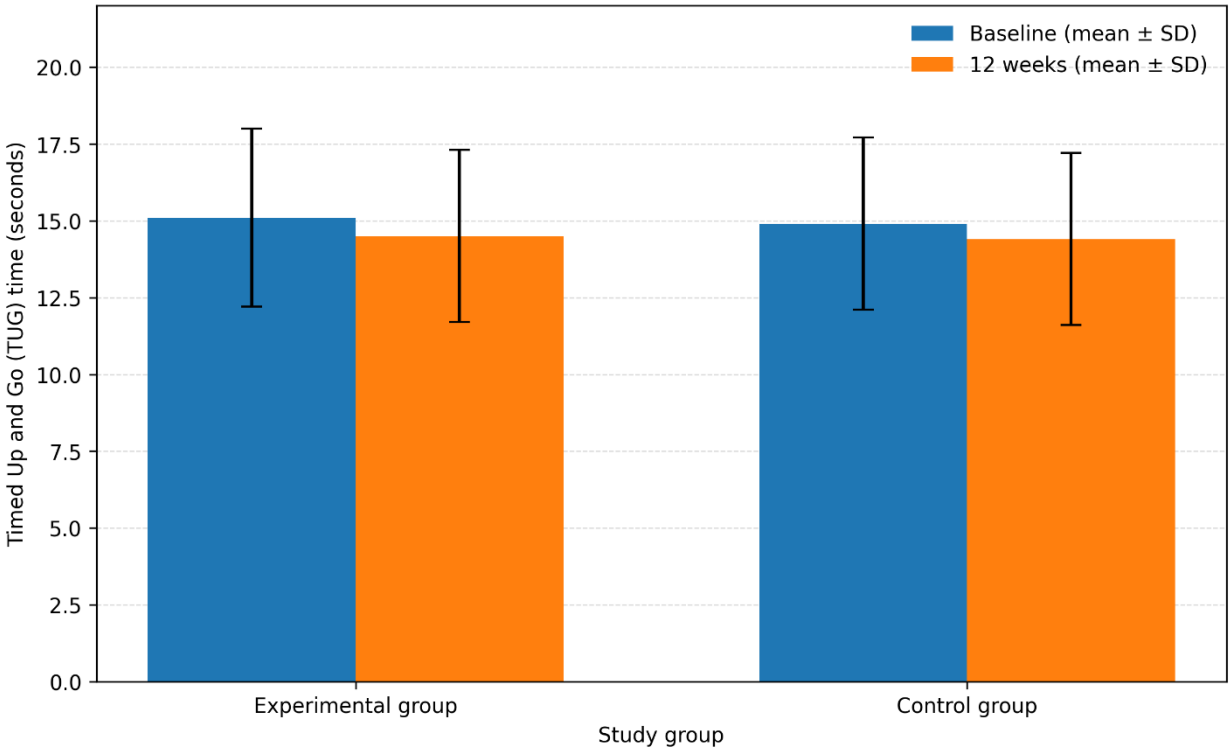


Figure 3. *Changes in Timed Up and Go (TUG) completion time from baseline to 12 weeks in the experimental and control groups*.

For glycemic control, the mean difference in HbA1c was −0.1 percentage points (95% CI: −0.5 to 0.3; p = 0.620). This difference was also statistically nonsignificant.

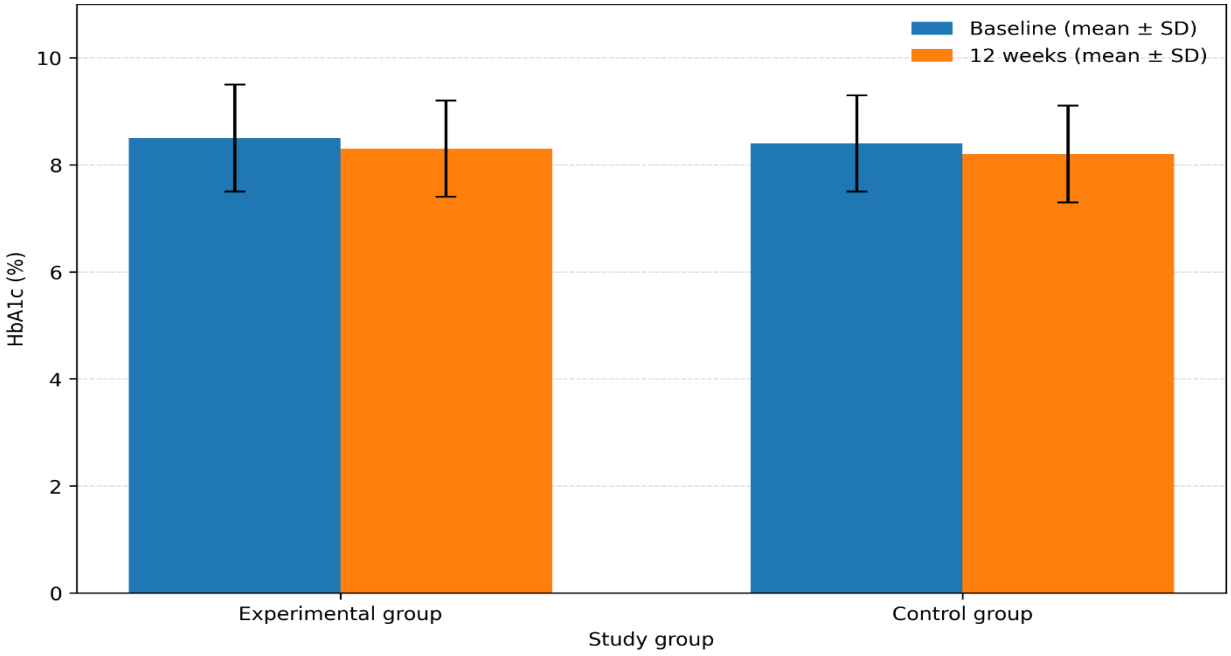


Figure 4. *Changes in glycated hemoglobin (HbA1c) levels from baseline to 12 weeks in the experimental and control groups*

Overall, the comparisons did not establish the superiority of structured physiotherapy plus usual diabetes care over usual diabetes care alone for balance, functional mobility, or glycemic control at 12 weeks.

Table 5. Baseline comparison of post-intervention outcomes

Outcome measure	Mean difference (experimental − control)	95% CI	p-value
BBS score	0.4	−1.6 to 2.4	0.690
TUG, seconds	−0.1	−1.2 to 1.0	0.860
HbA1c, percentage points	−0.1	−0.5 to 0.3	0.620

4.5. Between-Group Differences in Change Scores

The descriptive changes calculated from the baseline and post-intervention means are presented in Table 5. The experimental group demonstrated a 1.8-point increase in BBS score compared with a 1.5-point increase in the control group, producing a difference in mean changes of 0.3 points. TUG completion time decreased by 0.6 seconds in the experimental group and by 0.5 seconds in the control group, resulting in a difference in mean changes of −0.1 seconds. For HbA1c, both groups demonstrated a reduction of 0.2 percentage points, resulting in no difference in mean changes.

Table 6. Comparison of mean changes in outcome measures

Outcome measure	Experimental group: change	Control group: change	Difference in mean changes
BBS score	+1.8	+1.5	+0.3
TUG, seconds	−0.6	−0.5	−0.1
HbA1c, percentage points	−0.2	−0.2	0.0

4.6. Intervention Adherence and Safety

Intervention adherence and safety outcomes are presented in Table 6. All 32 participants assigned to the experimental group completed the 12-week physiotherapy program, corresponding to a completion rate of 100%. Of these participants, 29 (90.6%) attended at least 80% of scheduled sessions. Two participants (6.3%) reported minor exercise-related adverse events in the form of transient muscle soreness. Neither event resulted in discontinuation, and no participant withdrew from the study because of an adverse event.

Table 7. Intervention adherence and safety

Parameter	Experimental group (n = 32), n (%)
Participants completing the intervention	32 (100%)
Participants attending ≥80% of sessions	29 (90.6%)
Participants reporting exercise-related adverse events	2 (6.3%)
Participants discontinuing because of adverse events	0 (0%)

4.7. Missing Data and Analysis Population

Complete baseline and post-intervention data were available for all 64 randomized participants for BBS, TUG, and HbA1c. No missing outcome observations were reported in either group. Accordingly, all randomized participants were represented in the outcome dataset.

Table 8. Completeness of outcome data

Outcome measure	Experimental group, n (%)	Control group, n (%)	Total, n (%)
BBS	32 (100%)	32 (100%)	64 (100%)
TUG	32 (100%)	32 (100%)	64 (100%)
HbA1c	32 (100%)	32 (100%)	64 (100%)

4.8. Overall Summary of Results

The study evaluated the effects of adding structured physiotherapy program to usual diabetes care on balance, functional mobility, and glycemic control over 12 weeks. Both the experimental and control groups demonstrated descriptive improvements in all three outcomes. The experimental group showed a 1.8-point increase in BBS score and a 0.6-second reduction in TUG completion time, compared with increases of 1.5 points and reductions of 0.5 seconds, respectively, in the control group. HbA1c decreased by 0.2 percentage points in both groups. The reported baseline-adjusted comparisons did not demonstrate statistically significant between-group differences in balance (adjusted mean difference = 0.4 points; p = 0.690), functional mobility (adjusted mean difference = −0.1 seconds; p = 0.860), or glycemic control (adjusted mean difference = −0.1 percentage points; p = 0.620). These results did not establish additional benefits of physiotherapy intervention over usual diabetes care alone. Intervention completion was 100%, and 90.6% of experimental-group participants attended at least 80% of scheduled sessions. Two participants reported minor exercise-related adverse events, neither of which resulted in discontinuation.

Complete outcome data were available for all 64 randomized participants. Overall, the findings indicate that both groups improved during the study period, but the available results do not establish statistically significant superiority of structured physiotherapy for the measured outcomes. These nonsignificant findings should not be interpreted as proof of equivalence or ineffectiveness.

5. DISCUSSION

5.1. Principal Findings

This randomized controlled trial evaluated the effectiveness of a structured physiotherapy program, delivered alongside usual diabetes care, on balance, functional mobility, and glycemic control in adults with type 2 diabetes mellitus (T2DM). The principal findings indicated that both the experimental and control groups demonstrated improvements in the measured outcomes over the 12-week study period. However, the reported baseline-adjusted comparisons did not demonstrate statistically significant between-group differences in Berg Balance Scale (BBS) scores, Timed Up and Go (TUG) completion time, or glycated hemoglobin (HbA1c). The experimental group demonstrated a slightly greater numerical improvement in balance and functional mobility than the control group, whereas the reduction in HbA1c was identical in both groups. These findings suggest that the additional physiotherapy program did not demonstrate a statistically significant advantage over usual diabetes care for the outcomes assessed during the study period. Nevertheless, the absence of statistically significant differences should not be interpreted as evidence that physiotherapy is ineffective, because the precision of the effect estimates, statistical power, intervention characteristics, and clinical importance of the observed changes must also be considered. The findings are relevant to the existing literature, which supports structured exercise as an important component of diabetes management while indicating that its effects may differ according to the outcome measured, intervention protocol, participant characteristics, and duration of treatment (7, 8). The present study contributes to this evidence by examining functional and metabolic outcomes within the same controlled investigation.

5.2. Effect of Structured Physiotherapy on Balance

Balance performance improved in both study groups during the intervention period. The experimental group demonstrated an increase in mean BBS score from 42.6 to 44.4 points, whereas the control group improved from 42.4 to 43.9 points. Although the numerical improvement was slightly greater in the experimental group, the baseline-adjusted comparison did not demonstrate a statistically significant between-group difference (adjusted mean difference = 0.4 points; 95% confidence interval [CI]: −1.6 to 2.4; $p = 0.690$). These findings differ in their direction and statistical interpretation from evidence suggesting that exercise-based interventions can improve balance in adults with T2DM. A systematic review and meta-analysis by Lee and colleagues reported a pooled improvement in BBS scores of 2.56 points (95% CI: 0.35–4.77) following exercise interventions compared with control conditions (7). Similarly, a 2025 systematic review and meta-analysis reported significant improvements in dynamic balance following exercise interventions, with potential benefits from multicomponent training and supervised exercise (8).

Several factors may help explain the differences between the present findings and those reported in previous studies. The effects of physiotherapy may depend on the frequency and duration of training, exercise intensity, progression of balance challenges, participants' baseline functional limitations, and adherence to the prescribed intervention. Differences in the populations and balance assessment methods used across studies may also influence the magnitude of observed effects. Furthermore, the relatively small sample of 64 participants may have limited the precision with which modest between-group differences could be detected.

5.3. Effect of Physiotherapy on Functional Mobility and Fall-Risk Indicators

Functional mobility improved in both groups, as reflected by reductions in TUG completion time. The experimental group demonstrated a decrease from 15.1 to 14.5 seconds, while the control group improved from 14.9 to 14.4 seconds. The baseline-adjusted comparison showed an estimated between-group difference of −0.1 seconds (95% CI: −1.2 to 1.0; $p = 0.860$), indicating no statistically significant additional benefit of the physiotherapy intervention. This finding should be considered alongside the broader evidence supporting exercise-based rehabilitation for gait and functional performance in people with diabetes. Allet et al. investigated physiotherapy-based gait and balance training incorporating function-oriented strengthening and demonstrated the relevance of targeted rehabilitation approaches for addressing movement difficulties in this population (9, 10). Such interventions are intended to improve the physical capacities required for walking, turning, transferring, and performing everyday activities. The absence of a statistically significant difference in the present study may reflect similarities in the observed changes between groups, the specific intervention characteristics, or variability in individual responses. It is also possible that the study was insufficiently powered to identify a modest treatment effect. However, these explanations remain possibilities rather than established reasons for the observed findings.

An important distinction is that TUG performance represents a measure of functional mobility and a potential indicator of fall risk; it does not directly quantify the occurrence of falls. Although diabetes-related neuropathy, reduced proprioception, lower-limb weakness, and impaired postural responses may contribute to increased fall susceptibility, actual falls are influenced by additional factors, including vision, medication effects, environmental hazards, and previous fall history (11, 12).

Accordingly, the present findings do not establish that the physiotherapy program reduced actual falls. Future trials should include prospective fall monitoring, documented fall history, and a predefined method for recording fall events if fall prevention is intended to be evaluated as a primary clinical outcome.

5.4. Effect of Structured Physiotherapy on Glycemic Control

Glycemic control, assessed using HbA1c, improved to a similar extent in both groups. Mean HbA1c decreased from 8.5% to 8.3% in the experimental group and from 8.4% to 8.2% in the control group. The baseline-adjusted comparison indicated a difference of −0.1 percentage points (95% CI: −0.5 to 0.3; p = 0.620), which was not statistically significant. These findings contrast with the broader evidence supporting structured exercise as an adjunct to standard diabetes management. Umpierre and colleagues reported a mean HbA1c reduction of 0.67 percentage points associated with structured exercise interventions compared with control conditions in a meta-analysis of randomized controlled trials involving adults with T2DM (5). Evidence from the trial by Church et al. also supports investigating structured aerobics, resistance, and combined exercise approaches for glycemic and cardiometabolic outcomes (6). Current diabetes-management recommendations similarly recognize regular aerobic and resistance exercise as important components of comprehensive care (3, 14).

The differences between the present findings and the broader literature may reflect variation in exercise dosage, intensity, frequency, duration, adherence, baseline glycemic status, and concurrent diabetes treatment. HbA1c reflects average glycemic exposure over approximately two to three months, making the timing of assessment relevant when evaluating an exercise intervention. Furthermore, changes in medication, dietary behavior, physical activity outside intervention, and other aspects of diabetes management may influence glycemic outcomes.

In the present study, the identical 0.2-percentage-point reduction in HbA1c in both groups indicates that the additional physiotherapy program did not demonstrate a measurable advantage over usual diabetes care for glycemic control. However, the result does not establish that exercise has no metabolic benefit. Instead, it suggests that the specific intervention, as evaluated over 12 weeks, did not produce a statistically significant additional reduction in HbA1c under the study conditions. Future research should document exercise intensity and progression, attendance, diabetes medication changes, dietary factors, and physical activity outside the intervention. Such information would help clarify the relationship between intervention exposure and changes in glycemic control.

5.5. Intervention Adherence, Feasibility, and Safety

The intervention demonstrated high completion and adherence rates. All 32 participants assigned to the experimental group completed the 12-week program, and 29 participants (90.6%) attended at least 80% of scheduled sessions. Two participants (6.3%) reported minor exercise-related adverse events in the form of transient muscle soreness, and neither event resulted in intervention discontinuation.

These findings suggest that the structured physiotherapy program was feasible for the enrolled participants and that most participants were able to participate regularly. High adherence is important when evaluating supervised exercise interventions because the amount of exercise completed may influence functional and metabolic responses.

The reported adverse events were minor, and no intervention discontinuations due to adverse events occurred. Nevertheless, these observations should be interpreted cautiously because the sample was relatively small and the intervention lasted only 12 weeks. The findings do not establish the safety of the program in all adults with T2DM, particularly those with substantial peripheral neuropathy, active foot complications, cardiovascular instability, or severe mobility limitations.

The existing literature emphasizes the need to individualize exercise prescriptions according to functional ability, medical stability, and diabetes-related complications (11, 12). Appropriate supervision, exercise progression, attention to foot integrity, and monitoring for symptoms of hypoglycemia remain important considerations when delivering physiotherapy to this population. Overall, the adherence and safety findings support the practical feasibility of the intervention in the selected study population, although larger studies with systematic adverse-event monitoring are needed to establish its safety and acceptability more comprehensively.

5.6. Clinical Implications

The findings have several implications for physiotherapy practice and multidisciplinary diabetes management. First, balance and functional mobility should remain important components of rehabilitation assessment in adults with T2DM, particularly among individuals who may have peripheral neuropathy, reduced lower-limb strength, or difficulty performing everyday activities. The BBS and TUG provide complementary information about functional balance and mobility and may help clinicians identify areas requiring intervention.

Second, the results highlight the importance of distinguishing improvements observed within a treatment group from additional benefits attributable to the intervention. Although both groups improved during the study period, the baseline-adjusted comparisons did not establish a statistically significant advantage of structured physiotherapy. Clinical decisions should therefore be informed by the wider evidence base, individual patient needs, treatment goals, and appropriate exercise prescriptions rather than by the present findings alone.

Third, physiotherapy should be viewed as one component of comprehensive diabetes care rather than a replacement for pharmacological treatment, dietary management, or routine medical follow-up. Exercise-based rehabilitation may address functional limitations and support physical activity, but metabolic and functional outcomes should be evaluated independently because improvement in one domain does not necessarily imply improvement in another.

Finally, future research should examine whether more intensive or longer-duration interventions, targeted balance training, or individualized combinations of aerobics, resistance, and functional exercise produce clinically

meaningful benefits. Including actual fall incidence, patient-reported functional outcomes, and longer-term follow-up would also strengthen the clinical relevance of subsequent trials.

5.7. Strengths and Limitations

An important strength of this study was its randomized controlled design, which was intended to compare a structured physiotherapy program with usual diabetes care. The inclusion of functional and metabolic outcome measures enabled assessment of balance, mobility-related fall-risk indicators, and glycemic control within the same investigation. The study also reported intervention adherence, adverse events, and participant retention, providing additional information about intervention feasibility.

Several limitations should be considered when interpreting the findings. First, the total sample comprised 64 participants, which may have limited the precision of the treatment-effect estimates and the ability to detect modest between-group differences. The available information does not establish whether the study was adequately powered for each outcome.

Second, the intervention and follow-up period was limited to 12 weeks. Although this duration allowed assessment of short-term changes, it did not establish whether any improvements were maintained over a longer period. Third, the use of BBS and TUG provided information about functional balance and mobility but did not directly establish whether the intervention reduced the number of actual falls. Fourth, although adherence and selected adverse events were reported, more detailed information about exercise intensity, completed session dose, diabetes medication changes, and other factors affecting glycemic control would improve interpretation.

Fifth, the reported between-group differences were not statistically significant, and their clinical importance cannot be determined solely by p-values. Confidence intervals and clinically meaningful thresholds should be considered when evaluating whether the observed effects might be important to patients. Finally, the interpretation depends on the accuracy of the underlying statistical analyses. The adjusted estimates, confidence intervals, and p-values should be verified against the original statistical output before the findings are treated as definitive.

These limitations indicate that the results should be interpreted as preliminary evidence concerning the effectiveness of the specific intervention rather than as a definitive assessment of physiotherapy for all adults with T2DM.

5.8. Recommendations for Future Research

Future randomized controlled trials should recruit adequately powered samples based on a prespecified primary outcome and a clinically meaningful expected effect. Intervention protocols should describe exercise frequency, intensity, session duration, progression, supervision, and adherence in sufficient detail to permit replication.

Researchers should also consider stratifying or adjusting analyses for clinically relevant characteristics, including baseline balance impairment, peripheral neuropathy, diabetes duration, and previous falls. Prospective monitoring of actual falls would be necessary to establish whether improvements in balance or mobility translate into a reduction in fall incidence.

Longer follow-up periods could determine whether functional improvements are sustained and whether changes in glycemic control become more apparent with continued exercise. In addition, documenting medication changes, dietary behavior, and physical activity outside the intervention would improve interpretation of metabolic outcomes.

Finally, future studies should report adjusted effect estimates, confidence intervals, and appropriate statistical tests alongside p-values. This approach would support a more complete assessment of both statistical uncertainty and clinical relevance.

6. CONCLUSION

This randomized controlled trial evaluated the effectiveness of a structured physiotherapy program added to usual diabetes care for improving balance, functional mobility, and glycemic control in adults with type 2 diabetes mellitus. Both the experimental and control groups demonstrated improvements in BBS scores, TUG completion time, and HbA1c over the 12-week study period. However, the reported baseline-adjusted comparisons did not demonstrate statistically significant between-group differences in any of the three outcomes.

The experimental group showed slightly greater numerical improvements in balance and functional mobility, while HbA1c decreased by the same amount in both groups. Consequently, the findings did not establish an additional benefit of the structured physiotherapy program over usual diabetes care alone for the measured outcomes. The intervention demonstrated high completion and adherence rates, with only minor reported exercise-related adverse events and no discontinuations due to adverse events.

These findings should not be interpreted as evidence that physiotherapy is ineffective or that the two treatment approaches are equivalent. Rather, they indicate that a statistically significant additional effect was not demonstrated under the conditions of this study. Larger, adequately powered randomized controlled trials with detailed intervention reporting, longer follow-up, and direct measurement of fall incidence are warranted to clarify the effects of structured physiotherapy on functional and metabolic outcomes in adults with T2DM. In conclusion, structured physiotherapy remains a relevant component of comprehensive rehabilitation for people with T2DM, but the present findings do not establish its superiority over usual diabetes care alone for balance, functional mobility, or glycemic control after 12 weeks.

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