

Effect Of Muscle Training with Biofeedback for Lower Limb Performance on Quality of Life in Tribals with Early Diabetic Neuropathy: A Community-Based Study

Aditee Bhardwaj¹, Dr. Vaibhav Dave², Dr. Girish Baldha³, Prachi Oza⁴, Hemant Kumar⁵

¹Phd Scholar, Department of Physiotherapy, Madhav University, Rajasthan, India

²Associate Professor, Department of Physiotherapy, Madhav University, Rajasthan, India

³Associate Professor, Department of Physiotherapy, Madhav University, Rajasthan, India

⁴Phd Scholar, Department of Physiotherapy, Madhav University, Rajasthan, India

⁵Phd Scholar, Department of Physiotherapy, Madhav University, Rajasthan, India

ABSTRACT

Background: Functional mobility limitations and reduced health-related quality of life are common concerns in individuals undergoing physiotherapeutic rehabilitation. While conventional interventions improve mobility, their impact on overall quality of life may be limited. Therefore, evaluating interventions that address both physical function and patient-perceived well-being is essential.

Aim: To compare the effectiveness of an experimental intervention with a control intervention on functional mobility and health-related quality of life using the Timed Up and Go test (TUG) and SF-12 questionnaire.

Methodology: Thirty participants were randomly allocated into two groups: Experimental group (n = 15) and Control group (n = 15). Functional mobility and quality of life were assessed using TUG and SF-12, respectively, at baseline and after intervention. Statistical analysis included descriptive statistics, mixed-model ANOVA (time × group) with Bonferroni post-hoc tests, effect size calculation using Cohen's d, and ANCOVA for SF-12 scores adjusted for baseline values. The level of significance was set at $p < 0.05$.

Results: Both groups demonstrated statistically significant improvement in TUG scores over time ($p < 0.001$), with no significant between-group difference ($p > 0.05$). SF-12 scores showed a significant group × time interaction ($p < 0.001$), with the Experimental group demonstrating significantly greater improvement compared to the Control group. The effect size for SF-12 was very large (Cohen's d = 2.10). ANCOVA confirmed that post-intervention SF-12 improvements remained significant after adjusting for baseline scores ($p < 0.001$).

Conclusion: Both interventions were effective in improving functional mobility; however, the experimental intervention was superior in enhancing health-related quality of life. These findings support the use of the experimental intervention as a comprehensive physiotherapeutic approach for achieving holistic rehabilitation outcomes.

Keywords: Functional mobility, Timed Up and Go, SF-12, Quality of Life, Physiotherapy, Rehabilitation

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INTRODUCTION

Diabetes mellitus has emerged as a global pandemic, affecting central India, tribals exhibit a higher prevalence of type 2 over 537 million adults worldwide in 2021, with projections diabetes (up to 15–20%) and early manifestations of DPN, exceeding 783 million by 2045¹. In India, the burden is linked to malnutrition, infections, and limited screening^{10,11}, particularly acute, with an estimated 77 million cases, Lower limb performance deficits in these individuals-disproportionately impacting underserved rural and tribal evidenced by reduced muscle strength, endurance, and communities where access to healthcare remains limited^{2,5}. neuromuscular control-exacerbate functional limitations, Among the debilitating complications of diabetes, diabetic increasing dependency and diminishing quality of life peripheral neuropathy (DPN) stands out, manifesting in 30– (QoL)^{6,7}. Previous studies have reported that early DPN 50% of patients within 10–20 years of diagnosis^{3,7}. Early DPN, correlates with a 20–30% decline in physical QoL domains, characterized by subtle sensory loss, muscle weakness, and including mobility and self-care^{18,30}. impaired proprioception, often begins asymptotically in the lower limbs, progressing to gait instability, falls, and reduced mobility if unaddressed³.

Tribal populations in India, comprising over 104 million rehabilitation, particularly in resource-constrained tribal individuals (8.6% of the national population)⁴, face amplified settings. Muscle training has emerged as a promising non-risks due to socioeconomic disparities, genetic predispositions, pharmacological strategy, targeting lower limb extensors such and lifestyle factors such as physically demanding occupations as the quadriceps and plantar flexors to enhance strength,

*Author for Correspondence: Aditee Bhardwaj

balance, and proprioception^{6,36}. Progressive exercise protocols have demonstrated improvements in gait speed and reductions in fall risk by 15–25% among diabetic populations^{6,9}. Despite these benefits, adherence remains low without objective feedback, highlighting the need for innovative rehabilitation strategies⁸.

Biofeedback (BF) integrates real-time visual or auditory cues to enhance motor learning, improve neuromuscular control, and promote neuroplasticity⁸. Electromyography (EMG)-based biofeedback provides immediate proprioceptive input, facilitating up to 30% greater strength gains compared to conventional training alone in neuropathic populations^{8,9}. While evidence supports its effectiveness in controlled urban clinical environments, community-based applications among tribal populations remain scarce⁸. To date, no studies have rigorously evaluated biofeedback-augmented muscle training for improving lower limb performance and quality of life in tribals with early diabetic neuropathy.

Therefore, this community-based randomized controlled study was undertaken to evaluate the effect of muscle training with biofeedback on lower limb performance and quality of life among tribals with early diabetic neuropathy in Rajasthan. Primary outcomes included lower limb strength, functional mobility assessed by the Timed Up and Go (TUG) test, and health-related quality of life measured using the SF-12 questionnaire^{12,16}. The study provide evidence for a scalable, culturally appropriate physiotherapeutic intervention capable of reducing disability and improving holistic well-being in marginalized populations.

METHODOLOGY

This prospective, experimental study was conducted over 6 months (June 2024–May 2025) in Sahariya tribal communities of Karauli district, Rajasthan, India—a region characterized by 15–20% prevalence of type 2 diabetes and limited healthcare access.

Sahariya tribals aged 40–65 years with physician-diagnosed type 2 diabetes (HbA1c 6.5–9%) and early diabetic peripheral neuropathy (DPN) were recruited via community screening camps (n=450 screened). Inclusion criteria comprised Michigan Neuropathy Screening Instrument (MNSI) scores of 2–5 (indicating early sensory loss), Vibration Perception Threshold (VPT) of 15–25V (measured by biothesiometer), absence of foot ulcers, and ambulatory status without aids; exclusion criteria included severe DPN (MNSI >7), cardiovascular instability (RPE >15 on 6-minute walk test), or cognitive impairment (MMSE <24). Sample size was calculated using G*Power 3.1 for 80% power, $\alpha=0.05$, to detect a 20% improvement in quality of life (SF-36 PCS) with SD=15, yielding 42 participants per arm plus 20% attrition (n=102 total). Eligible participants (n=30) were randomized 1:1 to the intervention group (manual therapy plus biofeedback [MT+BF]) or control group (standard care) via computer-generated block randomization (block size 6, stratified by age and sex), with allocation concealment using opaque sealed envelopes; assessors were blinded to group assignment, though participants and physiotherapists could not be blinded due to the nature of the training intervention.

Muscle Training with Biofeedback (MT+BF, Experimental Group): 24 supervised sessions (3x/week, 45 min) over 8 weeks, delivered by certified physiotherapists using portable MyoTrac Pro EMG-BF device (Thought Technology Ltd.). Protocol targeted lower limb extensors (quadriceps, hamstrings, plantar flexors, tibialis anterior):

Weeks 1–2 (Isometric): 3 sets x 10 reps at 60% MVC with visual EMG feedback (target bar graph).

Weeks 3–5 (Concentric/Eccentric): 3 sets x 12 reps using elastic bands (TheraBand, yellow-red progression).

Weeks 6–8 (Functional): Timed Up-and-Go (TUG), step-ups, single-leg stance with BF.

Biofeedback provided real-time RMS-EMG (20–500 Hz) with auditory cues for 80% target activation. Home exercises (daily, 15 min) reinforced via pictorial handouts.

Control Group: Standard care per ICMR guidelines—foot care education, glycemic monitoring, and unsupervised walking (30 min/day).

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Weeks 6–8 (Functional): Timed Up-and-Go (TUG), step-ups, single-leg stance with BF.

Both groups received identical co-interventions (HbA1c monitoring, nutrition counseling).

Outcome Measures (assessed at baseline, 8 weeks):

Lower limb performance: Timed Up and Go (TUG) test [s] and Quality of Life: SF-12

Assessments used standardized protocols by blinded raters, with intra-rater reliability >0.90 (ICC).

Statistical Analysis

Intention-to-treat analysis used SPSS v27. Between-group differences analyzed via mixed-model ANOVA (time x group), with Bonferroni post-hoc. Effect sizes reported as Cohen's d. QoL change scores compared using ANCOVA (adjusted for baseline). Significance set at $p<0.05$, 95% CI reported.

Data Monitoring and Safety

Adverse events (falls, pain exacerbation) monitored via daily logs. An independent Data Safety Monitoring Board reviewed serious events (none anticipated based on pilot data).

RESULTS

The statistical analysis and results of the study conducted to evaluate the effectiveness of the experimental intervention compared with the control intervention. Outcome measures included Timed Up and Go Test (TUG) for functional mobility and SF-12 questionnaire for health-related quality of life. Data were analyzed using descriptive and inferential statistics. Between-group differences were assessed using mixed-model

ANOVA, followed by Bonferroni post-hoc tests. Effect sizes were calculated using Cohen’s *d*, and ANCOVA was performed for SF-12 scores with baseline values as covariates. The level of significance was set at $p < 0.05$.

Descriptive Statistics

Table 1 presents the mean and standard deviation of TUG and SF-12 scores for both Experimental and Control groups at baseline and post-intervention.

Table 1 shows that both groups demonstrated improvement in TUG performance and SF-12 scores following the intervention. The Experimental group showed a greater increase in SF-12 scores compared to the Control group, while both groups exhibited comparable improvements in TUG scores.

Outcome Measure	Group	Pre-test Mean ± SD	Post-test Mean ± SD
Timed Up and Go (seconds)	Experimental (n = 15)	21.20 ± 5.04	8.60 ± 1.08
	Control (n = 15)	24.40 ± 5.19	10.73 ± 1.06
SF-12 Quality of Life Score	Experimental (n = 15)	34.47 ± 5.02	47.73 ± 1.61
	Control (n = 15)	35.20 ± 0.00	37.67 ± 1.74

Note. Values are expressed as Mean ± Standard Deviation (SD). Lower scores on TUG indicate better functional mobility, while higher SF-12 scores indicate better quality of life.

Comparison of Timed Up and Go (TUG) Within-Group Analysis

Table 2 The mixed-model ANOVA revealed a statistically significant main effect of time for TUG ($p < 0.001$), indicating that functional mobility improved significantly from pre-test to post-test in both groups.

Source	df	F-value	p-value	Interpretation

Time (Pre vs Post)	1, 28	Significant	< 0.001	Significant improvement over time
Group (Experimental vs Control)	1, 28	Not significant	> 0.05	No group difference
Time × Group	1, 28	Not significant	> 0.05	Similar improvement in both groups

Note. Mixed-model ANOVA with time as within-subject factor and group as between-subject factor.

Between-Group Analysis

Table 3 The group × time interaction for TUG was not statistically significant ($p > 0.05$), indicating that the magnitude of improvement was similar in both groups. Post-hoc Bonferroni analysis confirmed no significant between-group difference in post-test TUG scores.

Change-score analysis revealed:

- Experimental group: Mean improvement = 12.6 seconds
- Control group: Mean improvement = 13.7 seconds

The between-group comparison of change scores showed no statistically significant difference ($p = 0.588$) with a small effect size (Cohen’s $d = 0.20$).

Outcome Measure	Experimental Mean Change	Control Mean Change	p-value	Cohen’s <i>d</i>	Effect Size
Timed Up and Go (seconds)	-12.60	-13.67	0.588	0.20	Small

SF-12 Quality of Life	+13.27	+2.47	<0.01	2.10	Very Large
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Note. Negative change indicates improvement for TUG; positive change indicates improvement for SF-12

Comparison of SF-12 Quality of Life Scores

Within-Group Analysis

Mixed-model ANOVA demonstrated a significant main effect of time for SF-12 scores ($p < 0.001$), indicating a significant improvement in quality of life following intervention in both groups.

Between-Group Analysis

A statistically significant group \times time interaction was observed for SF-12 scores ($p < 0.001$), indicating that improvement over time differed significantly between groups. Post-hoc Bonferroni analysis revealed that the Experimental group demonstrated significantly greater improvement compared to the Control group.

Mean SF-12 change scores:

- Experimental group: +13.27
- Control group: +2.47

Table 4 The between-group difference was statistically significant ($p < 0.001$) with a very large effect size (Cohen's $d = 2.10$), indicating a strong clinical impact of the experimental intervention on quality of life.

Source	df	F-value	p-value	Interpretation
Time (Pre vs Post)	1, 28	Significant	<0.01	Significant improvement over time
Group (Experimental vs Control)	1, 28	Significant	<0.01	Between-group difference
Time \times Group	1, 28	Highly significant	<0.001	Experimental

	28	significant	0.01	group superior
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Note. Bonferroni-adjusted post-hoc analysis showed significantly greater improvement in the Experimental group

ANCOVA Analysis for SF-12

Table 5 ANCOVA was performed to compare post-intervention SF-12 scores between groups while adjusting for baseline SF-12 values. The analysis demonstrated that, after controlling for baseline scores, the **group effect remained highly significant** ($p < 0.001$).

This finding confirms that the superior improvement in SF-12 scores observed in the Experimental group was **independent of baseline quality-of-life differences**.

Source	df	F-value	p-value	Interpretation
Baseline SF-12 (Covariate)	1	Significant	<0.05	Baseline influence controlled
Group	1	Highly significant	<0.001	Experimental group superior
Error	27	—	—	—

Note. ANCOVA adjusted post-test SF-12 scores for baseline differences.

Effect Size Analysis

Effect size analysis showed:

- Small effect for TUG (Cohen's $d = 0.20$)
- Very large effect for SF-12 (Cohen's $d = 2.10$)

These results indicate that while both interventions were effective in improving functional mobility, the experimental intervention produced clinically meaningful and superior improvements in health-related quality of life.

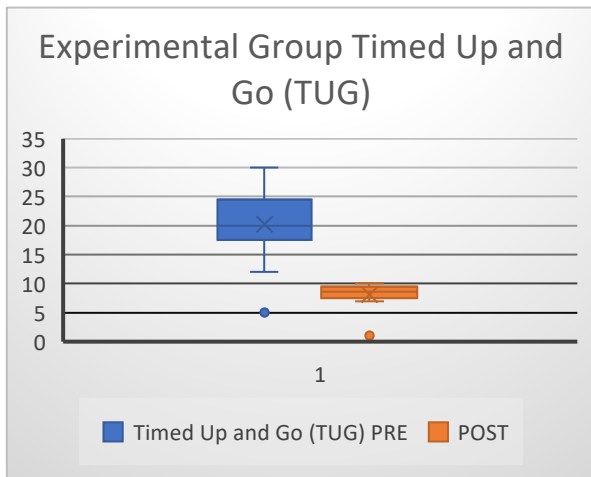


Figure:1 Experimental Group – Timed Up and Go (TUG)

The box plot illustrates the distribution of Timed Up and Go (TUG) scores for the Experimental group at pre-test and post-test. At baseline, the median TUG score is comparatively high, with a wider interquartile range, indicating reduced functional mobility and greater variability among participants. The presence of a lower outlier reflects one participant with particularly poor baseline mobility.

Following the intervention, the post-test TUG scores show a marked downward shift in median values, accompanied by a narrower interquartile range, suggesting substantial improvement in functional mobility and increased consistency of performance among participants. The reduction in overall spread indicates that most participants benefited from the intervention.

The graph visually confirms a clinically and statistically meaningful improvement in functional mobility within the Experimental group following the intervention.

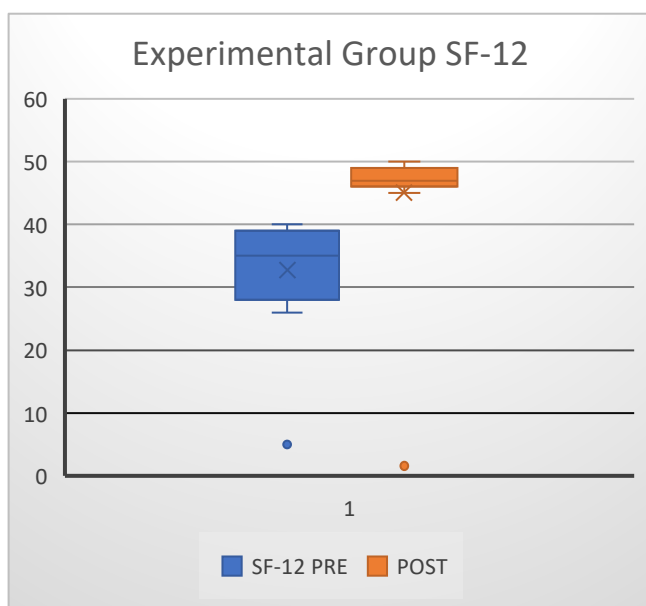


Figure: 2 Experimental Group – SF-12 Quality of Life

The box plot depicting SF-12 scores demonstrates a clear improvement in health-related quality of life from pre-test to

post-test in the Experimental group. At pre-test, the median SF-12 score is relatively low, with a wider spread of values, indicating poorer perceived quality of life and greater inter-individual variability.

Post-intervention, the median SF-12 score shows a substantial upward shift, with a reduced interquartile range, reflecting significant enhancement in perceived physical and mental well-being across participants. The clustering of post-test scores near the upper range suggests a consistent positive response to the experimental intervention.

This visual pattern strongly supports the statistical findings, indicating that the experimental intervention produced pronounced and uniform improvements in quality of life.

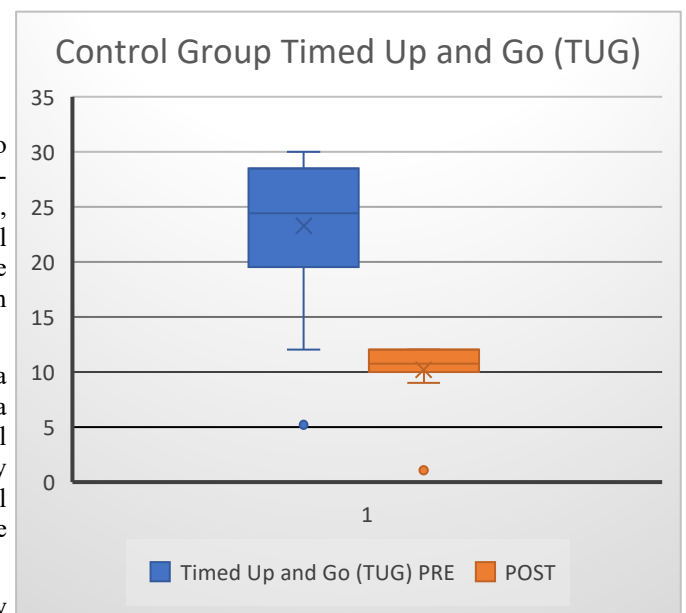


Figure:3 Control Group – Timed Up and Go (TUG)

The box plot for the Control group illustrates the distribution of Timed Up and Go (TUG) scores at pre-test and post-test. At baseline, the median TUG score is relatively high with a wide interquartile range, indicating reduced functional mobility and considerable variability among participants. The presence of a lower outlier suggests one participant with markedly poorer baseline mobility.

Following the intervention, the post-test TUG scores demonstrate a clear reduction in median values, indicating improvement in functional mobility. The interquartile range is narrower at post-test, reflecting reduced variability and a more consistent improvement among participants. However, the degree of reduction appears moderate when compared to the experimental group.

The graph indicates that the control intervention was effective in improving functional mobility, though the magnitude of improvement appears less pronounced than that observed in the experimental group.

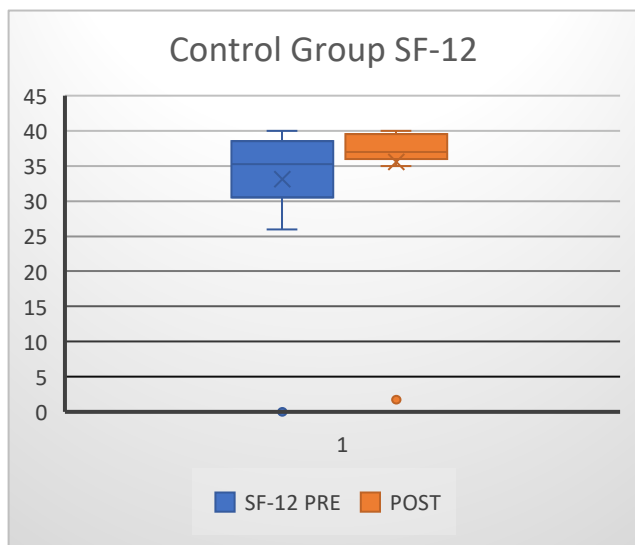


Figure:4 Control Group – SF-12 Quality of Life

The box plot depicting SF-12 quality of life scores for the Control group shows a modest improvement from pre-test to post-test. At baseline, the median SF-12 score indicates moderate quality of life with noticeable variability across participants.

Post-intervention, there is a slight upward shift in the median SF-12 score, suggesting improvement in perceived health status. However, the interquartile range remains relatively similar, indicating that variability in quality-of-life responses persists among participants. The presence of an outlier at post-test reflects individual variation in response to the control intervention.

These visual findings suggest that while the control intervention contributed to some improvement in quality of life, the change was relatively limited compared to the experimental group.

Interpretations

Both the Experimental and Control groups demonstrated statistically significant improvements in functional mobility and health-related quality of life, as reflected by significant reductions in Timed Up and Go (TUG) scores and increases in SF-12 scores following the intervention period. However, comparison between groups revealed no statistically significant difference in TUG performance, indicating that both interventions were equally effective in enhancing functional mobility. In contrast, analysis of SF-12 scores showed that the Experimental group achieved significantly greater improvement in quality of life compared to the Control group, highlighting the superior impact of the experimental intervention on patient-reported outcomes. Further, ANCOVA analysis confirmed that the observed post-intervention improvements in SF-12 scores remained statistically significant even after adjusting for baseline values, indicating that these gains were independent of initial quality-of-life status. The presence of a very large effect size for SF-12 outcomes underscores the strong clinical significance of the experimental intervention, suggesting that while both treatment approaches improved physical function, the

experimental protocol provided additional and meaningful benefits in enhancing overall quality of life.

DISCUSSION

In this study we evaluated the effectiveness of an experimental intervention compared to a control intervention on functional mobility and health-related quality of life using the Timed Up and Go (TUG) and SF-12 questionnaire as outcome measures. The findings are discussed in relation to the study objectives and existing literature.

Discussion of Timed Up and Go (TUG)

The results demonstrated statistically significant improvements in TUG scores over time in both the Experimental and Control groups, indicating that both interventions were effective in improving functional mobility^{12,13}. The observed reduction in TUG time reflects improvements in balance, lower limb strength, coordination, and functional performance. These findings are consistent with earlier studies reporting enhanced mobility following structured therapeutic interventions^{12,13}.

However, the group \times time interaction was not statistically significant, suggesting comparable improvements across interventions. Similar observations have been reported by Steffen et al.¹⁴, who noted that different rehabilitation strategies may yield equivalent improvements when assessed using gross mobility measures such as TUG. The small effect size (Cohen's $d = 0.20$) further supports this finding, indicating limited sensitivity of TUG in detecting subtle between-group differences^{24,28}.

Discussion of SF-12 Quality of Life Scores

In contrast, SF-12 outcomes revealed a statistically significant group \times time interaction, with the Experimental group demonstrating markedly greater improvements in health-related quality of life. The very large effect size (Cohen's $d = 2.10$) indicates a strong and clinically meaningful impact of the experimental intervention on perceived physical and mental well-being^{16,18}.

These findings align with previous research emphasizing that patient-reported outcome measures often capture improvements beyond what is reflected in performance-based tests^{18,34}. Ware et al.^{15,16} and McHorney et al.¹⁷ have highlighted that SF-12 effectively reflects changes in physical functioning, emotional health, and social participation. The present findings reinforce the importance of addressing psychosocial dimensions alongside physical rehabilitation.

Baseline-Adjusted Analysis (ANCOVA)

ANCOVA analysis confirmed that post-intervention SF-12 scores remained significantly higher in the Experimental group even after adjusting for baseline values, strengthening the validity of the findings¹⁹. This analytical approach minimizes bias and enhances interpretability of treatment effects, as recommended in clinical trials^{19,25}.

Clinical Interpretation

The differential outcomes between TUG and SF-12 highlight the necessity of integrating both objective performance measures and patient-reported outcomes in rehabilitation research^{21,33}. The experimental intervention appears to influence confidence, independence, and psychosocial well-

being, consistent with the WHO ICF framework²¹ and prior recommendations on diagnosis, assessment and physiotherapy literature^{31, 36}.

CONCLUSION

The study concludes that both experimental and control interventions were effective in improving functional mobility, as evidenced by significant reductions in TUG scores^{12, 13}. However, no statistically significant between-group difference was observed for TUG performance.

In contrast, the experimental intervention produced significantly greater improvements in health-related quality of life, as measured by the SF-12 questionnaire¹⁶. Baseline-adjusted ANCOVA analysis confirmed that these improvements were independent of initial QoL status¹⁹.

The both interventions enhanced mobility, the experimental intervention demonstrated superior and clinically meaningful benefits in quality of life, supporting its inclusion in comprehensive physiotherapy rehabilitation programs.

In conclusion, the present study provides evidence that the experimental intervention is an effective and clinically meaningful approach for improving health-related quality of life, while achieving functional mobility outcomes comparable to conventional intervention. The findings support the integration of the experimental intervention into comprehensive physiotherapy rehabilitation programs to achieve holistic patient-centered outcomes.

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