Research Protocol

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Physiotherapy Section

High- versus Low-intensity Functional Training on Cognition, Balance, and Functional Ability in Individuals with Cognitive Impairment: A Protocol for a Randomised Clinical Trial

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ABSTRACT

Introduction: Cognitive impairment significantly reduces functional independence in older adults, increasing the risk of falls, disability, and poor quality of life. Cognitive and motor functions are closely linked, with deficits in attention, executive function, and memory adversely affecting balance, gait, and physical performance. Exercise interventions, particularly functional training approaches like High-Intensity Functional Training (HIFT) and Low-Intensity Functional Training (LIFT), have shown promise in addressing both cognitive and motor impairments.

Need of the study: Although exercise is beneficial for cognitive impairment, comparative evidence on training intensity remains limited. LIFT is commonly used for its safety and feasibility, but may yield modest cognitive-motor improvements. HIFT, involving higher-intensity, multi-joint movements may offer greater neuromuscular and cognitive benefits. However, direct comparisons between HIFT and LIFT in cognitively impaired individuals are lacking. Therefore, this study aims to determine the most effective intervention for improving cognitive-motor performance and functional outcomes.

Aim: To evaluate and compare the effectiveness of HIFT and LIFT in improving cognition, balance, and functional ability in individuals with cognitive impairment.

Materials and Methods: A randomised clinical trial will be conducted at TDTR DAV Institute of Physiotherapy and Rehabilitation, Yamunanagar, from January 2026 to December 2027. 28 individuals with cognitive impairments according to Montreal Cognitive Assessment (MoCA) scores: 17-24, both male and female, aged 55-75 years, Borg Rating of Perceived Exertion ≤13, Resting Blood Pressure <160/100 mmHg will be recruited via criterion-based purposive sampling. Participants will be randomly allocated into two groups: Group-A will receive HIFT, whereas Group-B will receive LIFT for eight weeks, three times/week. Cognition, balance, and functional ability will be evaluated at baseline, at the end of the 4th week and post-intervention by the MoCA, Berg Balance Scale, and the Functional Independence Measure (FIM), respectively. For normally distributed data, repeated measures ANOVA will be used for within-group analysis and the independent t-test for between-group analysis and for non-normally distributed, the Friedman test will be used for within-group analysis and the Mann-Whitney U test for between-group analysis. The p-value of <0.05 is considered statistically significant.

Keywords: Aged, Cognitive dysfunction, Exercise therapy, Functional status, Postural balance

INTRODUCTION

The worldwide prevalence of cognitive impairment in people aged 50 years and older is more than 15% [1]. A study on 956 rural community-dwelling adults of either sex in Punjab, North India, found the 8.8 % prevalence of cognitive impairment [2]. A review of 19 studies reported that the prevalence of falls among older adults in India ranged from 14% to 53% [3]. A study shows that slow gait and MCI are related, and concurrently associated with falls in elderly people [4]. Cognitive impairment can cause disability and dependency in individuals and deterioration of functional capacity [5]. Importantly, this decline often constitutes the early stages of a continuous process, leading to the inability to effectively carry out activities of daily living [6]. Thus, maintenance of cognitive and functional independence is essential, as cognitive impairment and dependencies of activities of daily living emerged as the strongest predictors of nursing home admission [7]. Although it is becoming increasingly apparent that functional capacity and cognitive function are interrelated [8], interventional evidence in cognitively impaired populations remains limited.

The HIFT is characterised by constantly varied high-intensity functional exercises that involve movements with body weight and/or external resistance [9]. HIFT has been proposed to be equal or advantageous to continuous endurance training in terms of physiologic results and in enjoyment [10]. Vigorous intensity exercise that has the greatest effects on acute levels of circulating Brain-Derived Neurotrophic Factor (BDNF) and corticospinal excitability [11]. Furthermore, it improves neural plasticity of the hippocampus, facilitates inhibitory control and its underlying neuro-electrical activation, and improves brain activation during memory retrieval [12]. One of the most popular forms of exercise for enhancing cognitive function is aerobic exercise, especially low-intensity exercise [13]. Typical low-intensity exercises include light walking, stretching, lifting hand weights, sit-ups, and push-ups against the wall. Low-intensity aerobic exercise leads to an increase in BDNF resulting from the signalling of myokines which are produced from muscles during exercise. Increasing BDNF levels resulting from aerobic exercise may result in improvements in cognitive and executive functions. Second, aerobic exercise reduces inflammatory cytokine levels, which are important predictors of MCI progression, and enhances physical fitness in older persons with MCI, which is linked to higher levels of BDNF and lower levels of inflammatory cytokines, leading to improved cognitive functions [14]. Although extensive research highlights the global rise in the ageing population and the associated cognitive and motor decline, exercising at moderate-to-vigorous intensities is recommended over lighter intensities for cardiovascular, muscular, and neuromotor benefits in healthy young and old adults [15].

Furthermore, although aerobic exercises like HIFT, LIFT and cognitive-motor interventions have shown promise in improving cognitive functions, comparative and longitudinal studies assessing their specific impact on cognition, functional ability and fall prevention in the elderly are lacking, especially in the Indian context. There is a need to explore integrated, accessible interventions that can enhance both cognitive and motor performance in aging populations. This study aims to evaluate and compare the effectiveness of HIFT and LIFT in improving cognition, balance, and functional ability in individuals with cognitive impairment.

REVIEW OF LITERATURE

Cognitive impairment in older adults is frequently accompanied by balance deficits, gait disturbances, and reduced functional independence [16]. Exercise interventions are increasingly recommended as non-pharmacological strategies to enhance neuroplasticity and functional recovery [17]. However, the optimal intensity of functional training required to maximise both cognitive and physical outcomes remains uncertain.

Rivas-Campo Y et al., conducted a randomised controlled trial involving 169 older adults with mild cognitive impairment, demonstrating that 12 weeks of HIFT significantly improved gait and balance ($p<0.001$) and independence in daily, instrumental, and advanced activities ($p\leq0.003$). Improvements in functional capacity were independent of age, sex, BMI, cognition, and health status. The study's strengths include its large sample size and rigorous statistical analysis. However, cognitive outcomes were not comprehensively examined, limiting conclusions regarding the cognitive benefits of high-intensity protocols [9].

Krootnark K et al., conducted a single-blind randomised controlled trial of 90 older adults who reported significant cognitive improvements following three months of low-intensity aerobic and resistance exercise compared with controls. Improvements were observed in global cognition and executive function measures, with sustained effects at follow-up. Although this study provided valuable evidence for cognitive enhancement through exercise, it focused primarily on cognitive outcomes and did not comprehensively assess balance or functional performance [14].

Sanders LMJ et al., conducted an assessor-blinded randomised trial in 91 individuals with dementia, comparing a 24-week program of low- to high-intensity walking and lower-limb training with flexibility and recreational activities. Outcomes assessed up to 36 weeks showed no significant improvements in physical or cognitive functions, and the genetic factor Apolipoprotein E (ApoE4) did not influence results. Despite its randomised design, moderate adherence and reliance mainly on walking-based exercise may have limited its effectiveness, highlighting the need for more structured and progressive exercise programs [18].

De Diego-Moreno M et al., conducted a randomised study of young adults, both (HIFT, >85% HRmax) and moderate-intensity continuous training (MICT, 70-80% HRmax) performed for 30 minutes resulted in significant within-group improvements. In the Stroop Test, HIFT improved fastest response time (MD=-1.14, $p<0.01$, d=0.9), mean response time (MD=-2.16, $p<0.01$, d=0.66), and number of correct answers (MD=1.08, $p<0.05$), while MICT showed similar improvements (FRT: MD=-1.79; MRT: MD=-3.07, $p<0.01$; NCA: MD=1.54, $p<0.05$); no changes were observed in the control group. However, no significant between-group differences were found, and the focus on young, healthy individuals limits generalisability, highlighting a gap in understanding the comparative effects of exercise modalities in older adults with cognitive impairment [19].

Stavrinou PS et al., conducted a cross-sectional observational study of 97 older individuals (age 80.6±8.2 years), with higher functional capacity, assessed through tests such as sit-to-stand, 6-minute walk, timed up-and-go, and handgrip strength, which was significantly associated with better global cognition and executive function ($p<0.05$). Mediation analysis further demonstrated that functional capacity partially mediated the relationship between age and cognitive outcomes (global cognition: β=-0.11, 95% CI -0.20 to -0.03; executive function: β=0.34, 95% CI 0.13 to 0.57). Additionally, greater functional capacity correlated with improved quality of life (r=0.32-0.41), reduced fatigue (r=0.23-0.37), and better sleep quality (r=0.23-0.24) ($p<0.05$). However, the cross-sectional design limits causal inference, highlighting a gap in interventional research to determine whether improving functional capacity can directly enhance cognitive and functional outcomes in older adults with cognitive impairment [20].

Collectively, existing literature suggests that high-intensity training may improve physical and functional outcomes, whereas low-intensity exercise appears beneficial for cognitive performance. However, direct comparisons of structured HIFT- versus LIFT within the same methodological framework are limited. Therefore, a clear gap exists regarding the optimal intensity of functional training for individuals with cognitive impairment. The present study addresses this gap by directly comparing HIFT and LIFT using comprehensive cognitive, balance, and functional assessments. Thus, the study aims to evaluate and compare the effectiveness of HIFT and LIFT in improving cognition, balance, and functional ability in individuals with cognitive impairment.

Primary objectives:

- To examine the effects of HIFT on cognitive, balance and functional ability in individuals with cognitive Impairment.
- To examine the effects of LIFT on cognitive, balance and functional ability in individuals with cognitive Impairment.

Secondary objectives:

- To compare the effects of HIFT vs LIFT on cognitive, balance and functional ability in individuals with cognitive impairment.

Null Hypothesis: There is no any significant difference in the effects of HIFT in comparison with LIFT on cognition, balance, and functional ability in individuals with cognitive impairment.

Alternate Hypothesis: There is a significant difference in the effects of HIFT in comparison with LIFT on cognition, balance, and functional ability in individuals with cognitive impairment.

MATERIALS AND METHODS

A randomised clinical trial, is conducted at Thakar Devi Takan Ram (TDTR) D.A.V. Institute of Physiotherapy and Rehabilitation, Yamunanagar, from January 2026 to December 2027. The Institutional Research Ethics Committee (IEC-2593) approved the study, and the trial was registered prospectively with reference number CTRI/2026/01/100466. Informed consent will be taken from participants or an assent form/guardian consent form will be taken from cognitively impaired.

Inclusion criteria: Participants included men and women aged 55-75 years with mild to moderate cognitive impairment (MoCA 17-24) [14,21], who had not engaged in any structured exercise program for at least four weeks and were not participating in additional physical activities. All participants were required to stand, walk, and perform sit-to-stand independently (with or without an assistive device), be able to safely participate in moderate to high-intensity activity with a Borg RPE ≤13 [14,22] after a six-minute walk or functional trial, and a resting blood pressure <160/100 mmHg, and show the ability to follow simple one- to two-step verbal instructions during screening.

Exclusion criteria: Participants were excluded if they had moderate to severe dementia, a history of stroke, or any other neurodegenerative condition; a history of psychiatric disorders requiring hospitalisation; uncontrolled cardiovascular disease; resting blood pressure above 160/100 mmHg; or severe musculoskeletal problems that limited mobility, such as recent fractures, severe osteoarthritis, or joint replacement within the past six months.

Sample size calculation: Sample size was calculated using the formula:

$$N=\lambda / (f^2 \times m \times \varepsilon)$$

Where, the following parameters were considered: effect size taken from a previous study [14] (f)=0.42, alpha error probability (α)=0.05, power kept at (1-β)=0.90, number of measurements taken as (m)=3, and nonsphericity correction (ε)=1 and non-centrality parameter (λ) kept at 11.6424.

$$N=11.6424/((0.42)^2 \times 3 \times 1)$$

$$N=11.6424/0.5292=22$$

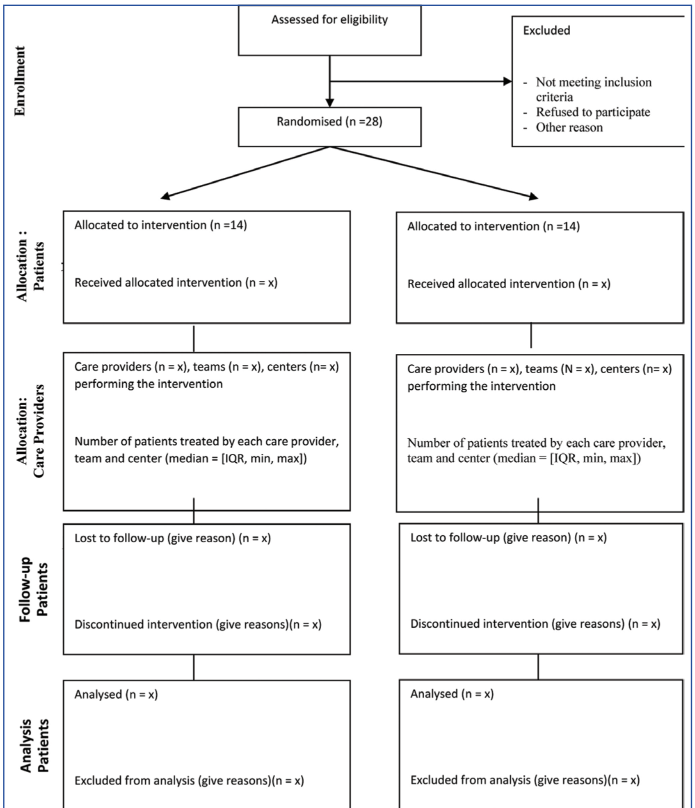
The calculated sample size was 22 participants. After keeping a 25% dropout rate, the final sample size was increased to 28 participants (14 per group).

Randomisation and allocation concealment: The random allocation sequence will be computer-generated using block randomisation with equal block sizes, without stratification. Allocation concealment will be ensured through sequentially numbered, opaque, sealed envelopes; then the sequence will be generated, participants will be enrolled and assigned to groups by the principal investigator.

Blinding: The study will be assessor-blinded (outcome assessor unaware of group allocation) and statistician-blinded to avoid any kind of biased responses to intervention.

Study Procedure

After participant recruitment, demographic characteristics (age and gender) and anthropometric measurements {height, weight, and Body Mass Index (BMI)} will be recorded. Participants will be randomly assigned to one of the two groups - Group A (HIFT) and Group B (LIFT) [Table/Fig-1]. Participation in the trial is voluntary, and participants will have the option to opt out. The trial will follow



[Table/Fig-1]: Consolidated Reports of Reporting Trials (CONSORT) flow diagram.

the Standard Protocol Items: Recommendation for Interventional Trials (SPIRIT) guidelines. Group-A will receive HIFT and Group-B will receive LIFT for eight weeks, three times/week [Table/Fig-2].

Component	HIFT Group	LIFT Group
Duration and frequency	8 weeks; 3 sessions/week; 45 min/session	8 weeks; 3 sessions/ week; 45 min/session
1. Warm-Up Phase (10 minutes)	**Joint mobility exercises** to prepare the musculoskeletal and cardiovascular systems for physical activity.	**Joint mobility exercises** to prepare the musculoskeletal and cardiovascular systems for physical activity.
2. Core Training Phase (25 minutes)	It will be divided into **four work intervals**, each lasting **4 minutes**. Exercises will be performed at 80–85% of maximum heart rate (HRmax) [9]. HRmax will be calculated using the formula HRmax=208 – (0.7×age) [18]. Each exercise will be performed for 30 seconds at a vigorous but controlled intensity corresponding to 15-17 on the Borg Rating of Perceived Exertion (6-20 scale), followed by 15 seconds of rest before repetition. All exercises will be supervised by a therapist to ensure correct technique and safety. Exercise will be discontinued immediately if participants develop chest pain, dizziness, excessive fatigue, shortness of breath, abnormal blood pressure response, or if heart rate exceeds the prescribed training range. Appropriate support and fall-prevention measures will be maintained throughout the session. The following exercises will be included: **Bicycle-like limb movements** from a seated position, **Wall push-ups** (standing position), **Chair squats**, **Ball throws against the wall** while performing **lateral and front lunges.** After each interval, active rest will be given for a total 2 min at 50-70% of the maximum heart rate, that include following activities: Lateral walking (30 sec), Heel raise (30 sec), Lateral and front upper limb raises (30 sec), Functional diagonal reach with trunk rotation (30 sec) **Monitoring:** Participants' heart rates will be continuously monitored using **pulse sensors**, worn on the wrist, to ensure adherence to the prescribed intensity zones.	Low intensity (≤ 13 on Borg scale) **a. Indoor walking-** 6 meters Set 1: 2 min with a rest period of 30 sec Set 2: 2 min with a rest period of 30 sec **b. March in place** Set 1- 2min with rest- 30 sec Set 2- 2min with rest- 30 sec **c. Step in a different direction** With the right leg and then with the left leg- forward, backwards, sideways 2 min each with right and left leg, rest 30 sec **d. March with arm movement** Set 1- 2min rest- 30 sec Set 2- 2 min rest-30 sec **e. Squat while stepping** With the right and left leg, step to the right/ left 10 times, then squat 2 min each with right and left leg, rest 30 sec
3. Cool-Down Phase (10 minutes)	**Muscle stretching, relaxation**, and **breathing exercises** to facilitate recovery and reduce muscle soreness	**Muscle stretching, relaxation**, and **breathing exercises** to facilitate recovery and reduce muscle soreness

[Table/Fig-2]: Exercise protocol of HIFT and LIFT group with duration and frequency.

Outcomes

Berg Balance Scale: The Berg Balance Scale is a 14-item clinical tool used to assess balance and fall risk in individuals, with each task scored from 0 to 4, and a maximum score of 56; higher scores indicate better balance, where scores of 41-56 suggest low fall risk, 21-40 moderate risk, and 0-20 high-risk. The relative intra-rater reliability of the Berg Balance Scale was high, with a pooled estimate of 0.98 (95% CI 0.97 to 0.99). Relative inter-rater reliability was also high, with a pooled estimate of 0.97 (95% CI 0.96 to 0.98) [23].

MoCA: The MoCA scale is a 30-point cognitive screening tool used to detect mild cognitive impairment by assessing functions such as memory, attention, language, and executive function. The MoCA is scored out of 30 points, with scores of 26-30 indicating normal cognition, scores below 26 suggesting possible cognitive impairment, and 1 point added for individuals with 12 or fewer years of education to adjust for educational background. The inter-rater reliability value was 0.96, and Cronbach's alpha was 0.79; the MoCA has an area under the curve value of 0.89. The Minimal Clinically Important Difference (MCID) for the MoCA in older adults is generally estimated to be between 1 and 2 points [24,25].

Functional Independence Measure (FIM): The FIM scale is a tool used to assess a person's level of independence in performing daily activities, especially in rehabilitation settings. The FIM scale evaluates functional ability in 18 items across motor and cognitive domains, each scored from 1 (total assistance) to 7 (complete independence), with a total score ranging from 18 to 126, where higher scores indicate greater independence. Scores between 18-60 indicate severe dependence, 61-90 suggest moderate dependence, 91-105 reflect mild dependence, and 106-126 represent functional independence. A study showed high test-retest reliability for 45 repeated FIM assessments for the motor (ICC=0.9) and cognitive subscales (ICC=0.8), as demonstrated [26].

A comprehensive patient assessment will be conducted using a detailed assessment form, which will include recording the patient's demographic information (Age, gender, BMI). Readings of the Berg Balance Scale, MoCA and FIM will be recorded in the 1st session (pre-treatment), at the end of the 4th week and at the end of the 8th week (post-treatment). All adverse events will be recorded and monitored throughout the study. Participants will be withdrawn in case of chest pain, excessive BP rise, dizziness, severe dyspnoea, cardiovascular instability, or falls during sessions. Exercise sessions will be supervised by trained personnel, and serious adverse events will be reported to the ethics committee.

STATISTICAL ANALYSIS

Data will be analysed using the Statistical Package for Social Sciences (SPSS) software version 26. Data normality will be assessed before analysis. For normally distributed data, repeated-measures Analysis of Variance (ANOVA) will be used for within-group comparisons and an independent t-test for between-group comparisons. For non-normally distributed continuous data, appropriate non-parametric or robust methods, such as aligned rank transform ANOVA/linear mixed models, will be used. Missing data will be handled using an intention-to-treat approach with appropriate imputation methods. The p-value of <0.05 is considered statistically significant.

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