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# Postural control during dual-task walking

## Study Protocol and Statistical Analysis Plan

### 1. Background and Rationale

Alzheimer's disease (AD) is a progressive neurodegenerative disorder characterized by cognitive decline, impaired executive functions, and reduced ability to perform daily living activities. In addition to cognitive deficits, gait and motor dysfunctions are frequently observed in individuals with Alzheimer's disease, increasing the risk of falls and reducing functional independence. Dual-task training, which combines motor and cognitive exercises simultaneously, has recently been shown to enhance cognitive performance, executive functioning, and motor control in older adults and dementia populations. This study aims to evaluate the effects of a structured dual-task motor-cognitive training program on cognitive status, attention, executive functions, motor performance, and daily living activities in patients with mild-stage Alzheimer's disease.

## 2. Objectives

**Attention Level Assessments**

d2 Test of Attention: A widely used neuropsychological test evaluating visual attention and processing speed. Participants are asked to quickly and accurately mark target symbols (e.g., the letter “d” with two dashes) among distractors on a sheet consisting of similar letters and symbols (Zillmer & Brickenkamp, 1998). The validity and reliability of the test were demonstrated in a Turkish study by Çağlar & Koruç (2006).

Trail Making Test Part A (TMT-A): Assesses visual attention, processing speed, and psychological flexibility. The participant is required to connect numbered circles from 1 to 25 in order as quickly as possible (Reitan, 1956). Turkish validity studies have been conducted (Cangöz et al., 2009; Cangöz et al., 2013).

**Executive Function Assessments**

Stroop Test: Evaluates executive functions and attentional control. The participant must state the ink color of a word rather than reading the written word itself (e.g., the word “Blue” written in red ink should be answered as “red”) (Stroop, 1935). The Turkish version was validated by Karakaş et al. (1999).

Trail Making Test Part B (TMT-B): Used to assess executive functions, cognitive flexibility, and attention. The participant alternates between numbers and letters in sequence (1-A-2-B-3-C…) (Reitan, 1956). Turkish adaptation studies are available (Cangöz et al., 2009; Cangöz et al., 2013).

**Processing Speed Assessment**

Symbol Digit Modalities Test (SDMT): Measures processing speed and attention. Participants are presented with a key of symbol–digit pairings and asked to match as many symbols with their corresponding digits as possible within a set time (Smith, 1973).

**General Cognitive Function Assessment**

Montreal Cognitive Assessment (MoCA): Evaluates memory, attention, executive functions, and visuospatial skills. It is a standard and validated tool for monitoring cognitive status and comparing pre- and post-intervention performance in Alzheimer's patients (Nasreddine et al., 2005). The Turkish version was validated by Ozdilek & Kenangil (2014), showing high reliability for detecting mild cognitive impairment and dementia.

**Neurological Activity Indicators**

Functional Near-Infrared Spectroscopy (fNIRS): A non-invasive method to measure prefrontal cortex activation by monitoring oxygenated and deoxygenated hemoglobin levels (Dolu et al., 2015).

**Daily Living Activities Assessment**

Disability Assessment for Dementia (DAD): Developed to assess independence in activities of daily living among individuals with dementia. It evaluates both basic and instrumental activities of daily living, including self-care and social functioning (Gélinas, 1999). The Turkish version was validated by Tozlu et al. (2014), demonstrating high internal consistency (Cronbach's alpha) and test-retest reliability in patients with dementia, confirming its clinical utility.

**Dual Task Performance Assessment**

Dual Task Protocol: Participants will perform physical and cognitive tasks simultaneously. For example, during walking, they will be asked to complete word generation, simple arithmetic, or other attention-demanding tasks.

**Performance Measures:**

Walking speed and step count (measured using a metronome or gait analysis system).

Number of correct responses and error rate in the secondary cognitive task.

**Motor Function Assessments**

Gait Analysis System: Provides objective evaluation of walking dynamics using pressure sensors, motion capture systems, or accelerometers. Parameters such as walking speed, step length, balance, and postural control are measured. These parameters will be compared between single-task walking and dual-task walking (Muro-De-La-Herran et al., 2014).

Electromyography (EMG): Measures muscle electrical activity through surface electrodes, providing data on contraction duration, activation levels, and coordination (De Luca, 1997). EMG will be used to assess changes in motor control and muscle activation during dual-task training.

## 3. Study Design

This is a randomized controlled clinical trial with two parallel arms:
- Experimental Group: Dual-task motor-cognitive training.
- Control Group: Standard care (no intervention).

The intervention will last for 8 weeks, with training sessions conducted 3 times per week, each lasting 45 minutes.

## 4. Participants

Inclusion Criteria:

- Age ≥ 60 years
- Diagnosed with mild-stage Alzheimer's disease (DSM-5 or NINCDS-ADRDA criteria)
- MoCA score 10–25
- Ability to walk independently or with minimal assistance
- Adequate hearing and vision
- Physical and mental capacity to participate
- Signed informed consent

Exclusion Criteria:

- Advanced-stage Alzheimer's disease (MoCA <10)
- Neurological diseases affecting motor function (Parkinson's, stroke, MS)
- Severe hearing or visual impairment
- Psychiatric disorders (major depression, schizophrenia)
- Orthopedic or cardiopulmonary conditions preventing participation
- Participation in another rehab program in the last 3 months
- Recent unstable cognitive status due to medication changes

## 5. Outcome Measures

Primary Outcome:

• Montreal Cognitive Assessment (MoCA) – cognitive function assessment.

Secondary Outcomes:

• Attention: d2 Test, Trail Making Test A
• Executive Functions: Stroop Test, Trail Making Test B
• Processing Speed: Symbol Digit Modalities Test (SDMT)
• Motor Functions: Gait Analysis, EMG
• Neurological Activity: fNIRS,

• Daily Living Activities: Disability Assessment for Dementia (DAD)
• Dual-task performance parameters (walking speed, accuracy in secondary task)

## 6. Statistical Analysis Plan

Data will be analyzed using SPSS (version XX). Descriptive statistics (mean ± SD, frequency, percentage) will be presented for all variables. Normality of data distribution will be assessed using the Shapiro-Wilk test.

For normally distributed variables, paired-sample t-tests will be used for within-group comparisons, and independent-sample t-tests or repeated measures ANOVA for between-group comparisons. For non-normally distributed data, Wilcoxon signed-rank tests and Mann-Whitney U tests will be applied.

Effect sizes (Cohen's d or r) will be calculated to estimate the magnitude of intervention effects. The significance level will be set at $p < 0.05$. Intention-to-treat (ITT) analysis will be performed to handle missing data.

## 7. Sample Size Calculation

A priori power analysis (using G*Power software) with an expected medium effect size ($f = 0.25$), alpha = 0.05, and power = 0.80, indicated that a total of 52 participants (26 per group) are required. Considering a 15% dropout rate, the target sample size will be set at 60 participants.