Cover letter for Clinical Trail Registration

Official Title: The effect of ankle foot orthosis influences the prefrontal load in stroke patients during dual task walking.

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Study Protocol

Background: Foot drop is a common gait impairment in individuals with stroke. Clinically, ankle–foot orthoses (AFOs) are frequently prescribed to provide ankle stability and support during the swing phase of gait. Previous studies have shown that AFO use can improve gait symmetry, increase walking speed, and reduce oxygen consumption during walking. The ability to walk while performing concurrent tasks is essential for individuals with stroke to function safely in community environments. Functional near-infrared spectroscopy (fNIRS) can be used to measure changes in oxygenated hemoglobin (HbO) concentration in the prefrontal cortex, reflecting cognitive workload during walking tasks. Carbon-fiber AFOs can store and release elastic energy during the gait cycle, assisting push-off and improving walking efficiency. Previous studies have shown that walking with carbon-fiber AFOs can increase walking speed and reduce oxygen consumption. However, whether carbon-fiber AFOs reduce prefrontal cortical workload during dual-task walking in individuals with stroke remains unclear. Therefore, this study **aims** to investigate the effects of carbon-fiber AFOs on dual-task performance and prefrontal cortical activation during dual-task walking in individuals with stroke.

Design: A repeated-measures design will be adopted with two AFO conditions (with AFO and without AFO) and three walking task conditions (single-task walking, cognitive dual-task walking, and motor dual-task walking).

Methodology protocols: Participants with stroke will complete the Mini-Mental State Examination (MMSE) to confirm cognitive eligibility, provide demographic information, and will sign the informed consent form. Functional near-infrared spectroscopy (fNIRS) sensors will be placed on the participant's forehead and secured using an elastic headband. Inertial sensors will be attached to the dorsum of both feet to record gait performance. An additional inertial sensor will be attached to the center of the tray to assess tray stability. Participants will be instructed to walk at a self-selected comfortable speed along a 13-m walkway under all conditions. Two experimental factors will be examined: AFO condition and dual-task condition: Participants will wear their own athletic shoes during all walking trials.

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AFO Conditions:

1. Walking without an carbon-fiber ankle-foot orthosis (AFO)
2. Walking with a carbon-fiber AFO

Dual-task conditions

1. Single-task walking
2. Cognitive dual-task walking (auditory Stroop task)
3. Motor dual-task walking (carrying a tray with the non-paretic hand)

During the cognitive dual-task condition, participants will wear a wireless Bluetooth headset and will perform an auditory Stroop task while walking. Participants will be instructed to respond based on the pitch of the auditory stimulus rather than its semantic meaning. For example, when hearing the word "low" presented in a high pitch, participants will respond "high." All verbal responses will be recorded. Accuracy (correct response rate) and reaction time will be measured. During the motor dual-task condition, participants will be asked to walk while carrying a tray with three wooden blocks stacked on top of each other using their non-paretic hand. The number of blocks that fall from the tray will be recorded. The number of blocks that fall from the tray will be recorded. Each experimental condition will be repeated for five trials, and rest periods will be provided between trials to minimize fatigue.

Statistical Analysis Plan:

Since it is difficult to directly compare the motor and cognitive dual-task walking conditions, the analysis will be conducted separately for each dual-task condition.

To analyze gait parameters, a repeated-measures ANOVA will be used to examine the effects of task condition and AFO use. In addition, dual-task cost (DTC) will also be calculated for each gait parameter to quantify the relative change in performance during dual-task walking. Hotelling's T^2 test may be used to compare the dual-task cost of multiple gait variables between walking with and without an AFO. To evaluate secondary task performance, Hotelling's T^2 test will be used to examine the dual-task cost of correct response rate and reaction time between the AFO and no-AFO conditions. To examine changes in oxyhemoglobin(HbO) concentration in the prefrontal cortex, a repeated-measures ANOVA will be conducted at the subject level to test the effects of task and AFO use. If variability in participants' mobility function is observed, a linear mixed model will be applied to control for accounting for inter individual difference and to evaluate the effects of task and AFO use at the trial level. All statistical analyses will be performed using IBM SPSS Statistics (version 19.0), and the level of statistical significance will be set at $p < 0.05$.

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