Cover Letter for Clinical Trial Registration

Official Title: Effects of a Powered Hip Exoskeleton on Dual-Task Performance in Older Adults Following Adaptation Under Physical and Mental Fatigue

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Study Protocol

Background:

Dual-task walking performance, which is highly associated with fall risk, is more compromised in older adults because they ambulate with greater prefrontal resource demands. With the growing development of power exoskeleton devices, power exoskeletons can provide mechanical assistance and support weak muscle power. It also alters joint proprioceptive input and the original motor programs. More executive cognitive resources may be required to adjust to using a power exoskeleton device.

One of the primary applications of a powered exoskeleton is to provide assistance during fatigue. Muscle fatigue and mental fatigue were characterized in the previous study. Since there is a possibility of increased cognitive load when using a power exoskeleton, it is critical to investigate how adaptation to use alters dual-task performance and how exoskeleton use influences dual-task performance under muscle and mental fatigue conditions.

Therefore, this study aims to investigate: (1) whether adaptation training would alter dual task performance or cortical modulation for older adults, (2) how a powered hip exoskeleton device alters dual task performance and cortical modulation for older adults under muscle and mental fatigue conditions.

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

The first section compares pre- and post-adaptation to the powered hip exoskeleton device. The second section compares performance with and without an exoskeleton under either muscle or mental fatigue conditions.

Methodology protocols: Healthy older adults 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

住 to record gait performance. Participants will be instructed to walk at a self-selected comfortable speed along a 40-meter walkway under all conditions. Two experimental factors will be examined: exoskeleton condition and dual-task condition:

Exoskeleton Conditions:

1. Walking without power hip exoskeleton device
2. Walking with powered hip exoskeleton device

Dual-task conditions

1. Single-task walking
2. Cognitive dual-task walking (auditory Stroop task)

Experimental sessions:

1. Compare pre and post adaptation training
2. Compare exoskeleton and no exoskeleton conditions during either muscle or mental fatigue.

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.

Statistical Analysis Plan:

To analyze gait parameters, a repeated-measures ANOVA will be used to examine the effects of task condition and exoskeleton 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 exoskeleton. 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 exoskeleton and no-exoskeleton 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 exoskeleton 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 exoskeleton 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 $p < 0.05$.