RESEARCH PROTOCOL OUTLINE

Title of Project: Enhancing Postural Control in Older Adults by Increasing Somatosensory Contribution

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Abstract
Falls in older adults pose significant health risks due to age-related decline in the somatosensory system, leading to compromised gait and postural control. This study aims to investigate the efficacy of a novel sensory "re-weighting" intervention using dynamic balance training with restricted vision to enhance somatosensory input contribution to postural control during walking in older adults.

We propose a 2-week intervention involving adults over 65 years old. Participants will undergo dynamic balance training on an movable platform (stabilometer) with either restricted or full vision. The primary objective is to facilitate sensory re-weighting, hypothesizing that restricted vision training will increase somatosensory input utilization for postural control. Pre- and post-training assessments will measure postural control during gait initiation under a dual-task condition. We hypothesize that the restricted vision group will demonstrate:

1. Improved postural control, indicated by increased center of pressure displacement during gait initiation.
2. Improved ability to utilize somatosensory input during a balance task.

This study is the first to examine the effects of vision-restricted balance training on postural control in older adults. Our proposed 2-week dynamic training focused on re-weighting of sensory input for balance control will open new opportunities to further improve the efficacy and efficiency of balance training in older adults. The findings will inform future research on balance training with manipulated visual parameters and underlying neural mechanisms of sensory re-weighting benefits.

A. Specific Aims

Aim 1: Determine the effect of dynamic balance training with restricted vision on postural control during gait initiation under a dual-task condition.

Hypothesis 1: Balance training with restricted vision, compared to full vision, will lead to improved postural control as indicated by increased center of pressure displacement during gait initiation under a dual-task condition

Aim 2: Determine the effect of dynamic balance training with restricted vision on the ability to utilize somatosensory input during balance tasks.

Hypothesis 2: Balance training with restricted vision, compared to full vision, will lead to improved utilization of somatosensory input during balance tasks, as indicated by greater time in balance while standing with eyes-closed on firm surface condition.

B. Background and Significance

Falls in older adults are particularly concerning due to the high rate of both fatal and/or non-fatal injuries, such as hip fractures and traumatic brain injuries.[1] The somatosensory system, involved in 50% of all sensory inputs dedicated to maintaining adequate balance control, undergoes age-related changes that compromise gait and postural control in older adults.[2] Previous studies have shown that reduced sensitivity, acuity and integration of proprioception[2] and cutaneous sensation[3] are associated with the deteriorated postural control in older adults. To compensate for this decline in somatosensory input, older adults develop alternative motor strategies that rely heavily on visual input during activities of daily living and other more balance-challenging tasks.[4] It has been suggested that these motor strategies are less “automatic” and require more focused cognitive resources. This is consequential given that less attentional reserve is available to these individuals to perform a secondary task, e.g. walking while holding

a cup, talking to others, performing a cognitive task or reacting to an unexpected event that may cause a fall during walking. Somatosensory input plays a critical role in motor control and motor learning, and is considered a significant factor in facilitating automaticity of gait.[5] A rehabilitation intervention to facilitate the use of somatosensory input for balance control is critical to a successful rehabilitation program targeting fall prevention in older adults.

Our long-term goal is to develop an effective intervention to re-distribute sensory inputs to improve postural control in older adults during walking. ***We propose to employ a sensory "re-weighting" intervention using dynamic balance training with restricted (i.e., blocked) vision to increase the demand for somatosensory input during postural control and walking.*** Sensory "re-weighting", a process to re-distribute the contribution of sensory resources among vision, somatosensory, and vestibular inputs, occurs when the environmental conditions change or the selection of sensory inputs change. A previous report has suggested that eliminating vision increases the contribution of somatosensory inputs to postural control by more than 35% in theoretical neural modeling. Greater sensorimotor cortex involvement has also been reported when young adults walked with restricted vision compared to an "eyes-open" condition.[6] We believe, that older adults with degraded somatosensory contribution to postural control will benefit using a similar paradigm through balance training under restricted vision. We anticipate they will develop motor strategies that enhance the use of somatosensory input, achieving adequate postural control and improved automaticity during walking. Previous studies have restricted vision to enhance postural control and skilled motor performance by increasing the contribution of somatosensory input (i.e. "sensory re-weighting") during motor learning in healthy young adults.[7] Additionally, walking and balance training with "eyes-closed" have demonstrated greater improvement in gait stability, balance, and proprioception compared to training under "eyes-open" conditions in individuals with stroke.[8] However, a missing piece in the current literature on balance training in older adults is the extent to which motor learning with restricted vision will impact critical postural control and the ability to utilize somatosensory input in balance tasks.

C. Preliminary Studies/Progress Report

The Principal Investigator (PI) has more than 15 years of experience with conducting and publishing research studies involving various measurements of human movement in healthy controls, older adults and individuals with neuromusculoskeletal impairment, such as amputation or diabetes related neuropathy[9,10]. This experience is critical for an understanding and conducting the procedures and instrumentation proposed in this study, including motion analysis[11] and electromyography[12].

D. Research Design and Methods (What, When, How, Where)

General study design

The study will be carried out and completed at the Center for Human Performance Measurement, Room 3020 in the Allied Health Building. We propose this study that will employ a 2-week intervention to test the hypotheses that restricted vision during balance training improves postural control and increases the contribution of somatosensory input. Aim 1 will examine the effect of the interventions on postural control during gait initiation under a dual-task condition, by comparing the results of the restricted vision (no-V) group and full vision (full-V) group. Aim 2 will examine the effect of the interventions on the utilization of somatosensory input during balance tasks, as evaluated by the Modified Clinical Test of Sensory Interaction in Balance (CTSIB-M).

Recruitment. The recruitment will occur through direct contact, phone call, email list server, flyers posted on campus, local senior health and wellness centers, website, and social media. Two Co-Is, Drs. Bobbette Miller and Andriy Yabluchanski have extensive experience in recruiting older adults in the Oklahoma metro area. We will recruit 24-30 participants for the study.

Participants. All participants will sign written informed consent before their participation. The inclusion criteria are: 1) age 65 and above, 2) able to walk continuously for at least 10 min without assistive device, 2) have normal or corrected-to-normal vision. The exclusion criteria are: 1) neurological conditions such

as stroke, Parkinson's disease, multiple sclerosis, brain tumor that significantly affect balance task and walking, 2) known peripheral neuropathy that influence sensation, 3) known vestibular dysfunction, 4) known cognitive impairments, 4) self-reported pain or musculoskeletal conditions that will significantly affect balance task and walking. **Prior to enrolling in the study, the general purpose, procedures, and potential risks of the study will be explained to the potential participant and consent secured.** Participants will be allocated to the no-V or the full-V group using a computerized random generator. The statistician will develop a randomization schedule and will issue it to the researchers before patient recruitment. Participants will be assigned to intervention groups using a block randomization scenario to keep the two groups even.

Baseline assessment. Demographic information will be collected in the 1st visit. Participants will complete questionnaires to record demographics and quantify physical activity level, quality of life, and psychological characteristics. Clinical outcomes regarding balance ability and proprioception assessment will also be performed. The information, surveys, and clinical outcomes collected at baseline assessments are listed in Table 1. **Instrumentation.** A stabilometer (Lafayette Instrument, Lafayette, IN, USA, Fig. 1) will be used for the training of the dynamic balance task. Outcome measures will be recorded in a motion analysis lab using force plates (AMTI, Watertown, MA, USA) for the center of pressure trajectory displacements. **Intervention protocol.** The experiment will take place over a 3-week period including screening and pre-intervention testing (1st visit, within 2 hours), six dynamic balance training sessions (2nd to 7th visits, 40-50 min each training), and post-intervention testing (8th visit, within 2 hours). The six training sessions will be accomplished in 2 weeks. **The dynamic balance training.** The 2 weeks dynamic balance training involves standing and maintaining balance on a stabilometer, which consists of a platform (1.3m long by 1.4m wide) connected to a single axis that allows bidirectional sway (Lafayette Instrument Co.; Fig. 2). The maximum angular deviation of the platform is 18°. A safety harness may be provided to prevent falls but does not provide support during the performance of the task. Participants are required to maintain balance with feet in a medio-lateral orientation while standing on the balance board. A potentiometer monitors the sway angle of the platform. An integrated timer measures time in balance, which is defined as when the platform angle is within ± 5° of horizontal. The participants will be encouraged to maintain the platform in horizontal for as long as possible within a 30 s trial. Participants assigned to no-V group will perform the task with blind-fold.

Table 1. Baseline assessment

- Demographics: age, sex, body weight and height, history of fall
- Physical activity level: International Physical Activity Questionnaire
- Quality of life: Short Form 12 Health Status Questionnaire
- Clinical outcomes. Time Up & Go, time in seconds of stand on one leg, and Modified Clinical Test of Sensory Interaction in Balance (CTSIB-M)
- Laboratory testing. Details are described in Aim 1 Methods in the following pages

Fig. 2. The dynamic balance task – stabilometer training.

Aim 1 Method

Rationale. A critical component of gait, i.e. gait initiation, which is a destabilization process from static standing to continuous walking, provides an appropriate window to examine the integration of sensory and motor function. Compared to young adults, older adults demonstrate longer preparation time and reduced posterior displacement of center of pressure (CoP) trajectory as the individual prepares to accelerate the center of mass forward during gait initiation. Postural control during gait initiation are predictive of fall risk and have been used to examine the effects of selective interventions on sensorimotor integration during walking. This has direct clinical implications, as gait initiation is ecologically relevant to walking. **Instrumentation.** A force plate (AMTI, Watertown, MA, USA) will be used to capture the trajectory of the center of pressure during gait initiation. **Procedures.** Gait initiation will be performed at the pre-intervention and post-intervention testing. The participants will stand on a force plate with both legs, feet are should-width apart. The participant will be instructed to perform mathematic calculations (i.e. subtract seven consecutively from a three-digit number) and speak out the answers while standing on a force plate. The participants will be instructed to initiate walking while performing the cognitive tasks. They will be walking along a 7 m walk way as quickly as they safely can after a visual LED cue indicates the side of leg for gait initiation. The participant will be asked to continue walking for 3 m for one walking trial. **Data processing and analysis.** The posterior displacement of the center of pressure (CoP) will be measured by the displacement of the CoP trajectory from the initial CoP position to the maximum posterior position in the anterior-posterior direction (Fig 3). **Expected outcomes.** After 2 weeks of the dynamic balance training, we expect to see a greater increase in the posterior displacement of the CoP trajectory during gait initiation in the no-V group (Fig 4).

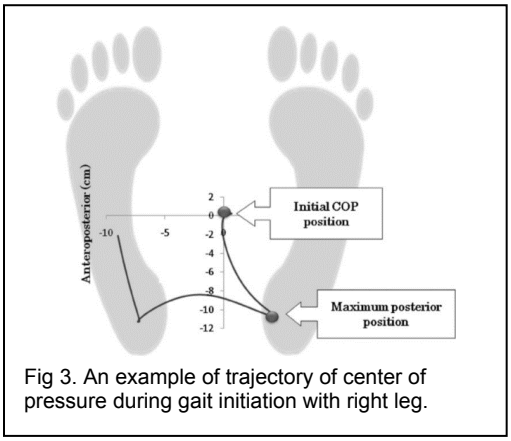

Fig 3. An example of trajectory of center of pressure during gait initiation with right leg.

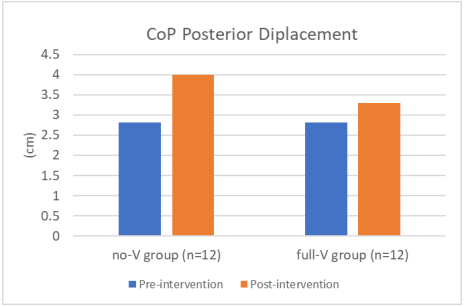

Fig 4. No-V group will show superior effect on postural control after intervention

Aim 2 Method

Rationale. The Modified Clinical Test for Sensory Interaction on Balance (CTSIB-M) is used clinically for balance analysis and to determine the dependence of the individual on all sensory systems (i.e. vision, vestibular and somatosensory) during balance tasks. The CTSIB-M has been shown to have excellent reliability in older adults and predictive to future fall incidenc. **Procedures.** To perform the CTSIB-M, the participants stands with their hands at their side with the goal to stand as steady as possible for 30 s, under four different conditions (i.e. stand on firm surface with eyes-open, stand on firm surface with eyes-closed, stand on compliant surface with eyes-open, stand on compliant surface with eyes-closed). We will collect three trials in each condition. Each trial will be timed with a stop watch, and the timer stops when the participant moves their arms, shows more than minimal body sway, and lose their balance or take a step. The test will be carried out on a force plate which will record the center of pressure trajectory for a secondary quantitative analysis regarding the amplitude of body sway. **Data processing and analysis.** The time in balance of the four conditions will be compared pre- and post- intervention using repeated measures ANOVA. **Expected outcomes.** We expect that the no-V group will show improved time in balance in the “stand on firm surface with eyes-closed” condition which focuses on to evaluate the contribution of somatosensory inputs during the standing balance task.

The participants can withdraw from the study any time without a negative impact on their health condition. The participants can see their movement signals after the testing and the outcome of the clinical measurements if they request.

Identifiers might be removed and the de-identified information may be used for future research without additional informed consent from the subject.

E. Inclusion / Exclusion Criteria

The **inclusion criteria** are:

1. age 65 and above
2. able to walk continuously for at least 10 min without assistive device
3. have normal or corrected-to-normal vision.

The **exclusion criteria** are:

1. neurological conditions such as stroke, Parkinson's disease, multiple sclerosis, brain tumor that significantly affect balance task and walking
2. known peripheral neuropathy that influence sensation
3. known vestibular dysfunction
4. known cognitive impairments
5. self-reported pain or musculoskeletal conditions that will significantly affect balance task and walking.
6. Drug use in the past 3 month.
7. At-risk drinker

The **early termination criteria are:** The procedures of this study are all non-invasive. However, the study will be terminated whenever the participant does not tolerate the procedures and refuse to continue. The cognitive impairment will be screened using The Mini Mental State Examination a score of 23 or lower out of 30 is indicative of cognitive impairment and the participant will be excluded. The drug and heavy alcohol use will be screened by the NIDA (National Institute of Drug Abuse) Quick screen v1.0. If the participants report any use of illegal drugs or prescription drug for nonmedical reasons in the past 3 month or is identified as an at-risk drinker (one or more days of heavy drinking in the past year), the participant will be excluded from the study.

F. Gender/Minority/Pediatric Inclusion for Research

We will recruit older adults based on our inclusion and exclusion criteria for our study. This will include women and minorities equally.

G. Recruitment and Enrollment

Participants will be recruited from the Oklahoma City metropolitan area through flyer and internet advertisement. Flyers will be distributed and posted at the campus, gym facilities specific for seniors, local hospitals, clinics. Internet advertisements will be delivered through email list and social media. Those who are interested in participating in the study will contact the PI or study staff for communication if they have any question. The general purpose, procedures, and potential risks of the study will be explained to the potential participant. They will have the opportunity to ask questions about the procedures of the experiment.

The eligibility for the study will be determined based on whether the potential participant fit the inclusion and exclusion criteria. The IRB approved consent form will be provided to the participant, and the participant will be given enough time to read the informed consent document. Study staff will answer any questions from the participant. If the potential subjects are willing to participate, they will then be required to give written consent for their participation and will receive a copy of their consent form. All subjects will be informed of their right to withdraw from the study at any time without any penalty or prejudice.

The consent procedures will be taken place in Center for Human Performance Measurement located in the College of Allied Health building where the experiment will be performed.

Non-English speaking participants will be asked to be accompanied by a family member or a friend who can translate the information for them during the visit.

To decrease participant coercion, the potential participants will be given sufficient time to review the consent. Study staff who obtain the consent does not has any authority over the potential participants nor a provider of any medical care over the potential participants.

H. Risks and Benefits

This study incurs no more than minimal risk to participants of our target population. This study involves common forms of physical activity, standing on a movable platform with appropriate safety precaution, walking at their comfortable walking speed, which should be familiar to the eligible participants to this study. From the testing, participants may experience mild skin irritations from the adhesives used to attach the reflective markers and electrodes, and chaffing from the safety harness. We expect this irritation to be transient. There is a very small chance of a cardiovascular event associated with the activities involved in the studies.

The participants will be monitored and guarded by the investigators when performing the walking trials. A safety harness with the capacity to support full body weight will be used during the balance training and walking trials to prevent injury from falling whenever it is needed. The adhesives used to contact the skin directly is made for such specific use to hold the markers and sensors on the skin with minimal skin irritation.

The participants will gain knowledge of their physical performance from the clinical balance outcome measure. The information may be beneficial to a person's health in general.

This study involves activities with minimal risk which is no larger than the risk in their daily life. The participants gain knowledge related to their physical performance from our procedures. Therefore, the risks are reasonable in relation to benefits.

If a participant reports depression or suicidal ideation, an action plan based on the Mental Health First Aid program will be executed. The Principle Investigator (Yo Shih, PhD) recently completed the training from the institute and will follow the five-step action plan during the conversation. The five steps include: 1) A – Approach, assess for risk of suicide or harm; 2) L – Listen nonjudgmentally, 3) G – Give reassurance and information, 4) E – Encourage appropriate professional help, 5) Encourage self-help and other support strategies. If the PI identifies a crisis situation where the participant is thinking about harming themselves or others, or is acting erratically, the research team will call 911 and tell the dispatcher that responders with specific training in mental health or crisis de-escalation are needed.

I. Statistical Methods

The changes of the outcome measures pre- and post- intervention including posterior displacement during gait initiation (Aim 1), the time in balance in CTSIB-M (Aim 2) will be compared between the no-V and full-V groups using repeated measures ANOVA. An unstructured covariance structure will be assumed for all models, unless model convergence fails. If model convergence fails, a simpler covariance structure (AR1 or compound symmetric) structure will be assumed. Differences in outcomes will be reported along with 95% confidence intervals. All statistical tests will be computed using SAS 9.4 (Cary NC) and assume a 5% chance of a type one error.

J. Data and Safety Monitoring Plan

Information/data collected will be reviewed monthly to monitor study progress, participant recruitment, data collection and analysis and fidelity checks. The regular meetings among the PI, Co-Investigators and study staffs will discuss:

1. Patient recruitment progress
2. Patient outcomes that require attention including but not limited to:
    a. Adverse events

   b. Unanticipated events
3. Outcome data - validity and reliability of each of the outcome measures being collected, and ways to improve it.
4. Policies and procedures of the study and any changes recommended or required
5. Supervision of all personnel
6. Data analysis up to that point in the study
7. Data management
8. Budget management
9. Gift card management

K. Confidentiality

All data will be coded by subject identification numbers, and no identifying information will be recorded on the digital files and data collection forms. Personal-identifying data will be stored in locked files and in password-protected computer to ensure confidentiality. Only the PI and the study staff that are processing these data will have access to the information. Data may be used for publication in peer-reviewed journals by any of the research team, but in its de-identified state. University IT Security requirements for research software development or use of mobile devices in research will be met. Any use of the Cloud and external data storage will meet university requirements.

L. Literature Cited

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