Pilot Study Protocol: Auditory Contributions to Postural Steadiness in OlderAdults With and Without Hearing LossLaCorey Cunningham, SPT

Introduction

Falls affect over 25% of older adults each year, leading to adverse outcomes such as bone fractures, head injuries, hospitalizations, increased healthcare costs, and even death.¹ It is commonly accepted that balance is maintained by a complex process that integrates sensory information from the visual, proprioceptive, and vestibular systems in order to control postural steadiness.² These systems naturally deteriorate with age and create deficits in balance that increases susceptibility to falls and limits independence in community-dwelling older adults. However, preliminary evidence suggests that the auditory system may also play a role in sustaining balance, and thus qualifying hearing impairment as a potential falls risk to be further investigated.³ For every 10dB of hearing loss, the odds of annual falls increase by 3.8% for community-dwelling older adults.⁴ Furthermore, older adults with hearing impairment above 25dB are at an 1.4 times increased risk of falls when compared to those with better hearing acuity.³ There is low-quality evidence demonstrating this potential relationship between hearing impairment and increased risk of falls in this population. These studies suggest that auditory input contributes to postural steadiness^{5–7} and that hearing aid use may improve balance in older adults with bilateral hearing loss, ^{8–10} but the statistical significance of the results are often inconsistent.¹¹ Therefore, there is a need to further explore the auditory contributions to balance and the potential mechanisms responsible for this association.

Objectives

This pilot study will contribute to the existing evidence investigating the association between hearing loss and increased risk of falls in community-dwelling older adults by providing additional insight into why this may occur. The objective of this study is to examine whether static balance function is influenced by the audibility of sound in community-dwelling older adults with and without hearing impairments. Between group and within group comparisons of alterations of static balance function, measured by a force platformed under different sound conditions, will be made to test our theory that acoustical spatial reference cues are used to control postural steadiness. Therefore, we hypothesize that postural stability will be enhanced under audible sound conditions, while static balance performance under inaudible sound conditions will demonstrate increased postural sway. When comparing normal hearing (NH) and hearing loss (HL) groups of older adults, we expect to see a significant difference in balance performance when sound is only audible to the NH group.

Methods

1. Participants

This pilot study will compare two groups community-dwelling older adults (total N=30) with and without identified hearing loss to compare changes in postural stability under various sound conditions using force posturography. The study will take place in a laboratory of the Division of Physical Therapy at The University of North Carolina at Chapel Hill. The protocol will be reviewed and approved by the Institutional Review Board (IRB) and will be in compliance with HIPPA regulations. All participants will sign an informed consent form approved by the Biomedical IRB prior to participation in the study. Participants will be recruited from the UNC Hearing and Communication Center and divided into groups based on data from their most recent audiogram.

1.1 Eligibility

Participants for the pilot study must be 65 years or older in order to remain consistent with most research on older adults and falls.^{1,8} *Inclusion criteria* includes recent audiogram data, symmetric audiometric thresholds across the ears, normal conductive mechanisms as verified by a tympanogram within normal limits, and a score of 26 or above on the Montreal Cognitive Assessment. Participants will be excluded from the study if any of the following are indicated: cognitive impairments,¹² neurological or vestibular conditions,^{3,8,11} peripheral neuropathy,¹³ or any lower extremity conditions or pain that limits stance or ambulation.^{8,9} Additional exclusion criteria include interaural differences exceeding 10 dB for any frequency.

1.2 Screening

Participants will be screened using a questionnaire that assesses hearing difficulties, history of falls, medical conditions or diagnoses, and cognitive impairments. An example of this questionnaire can be seen in **Appendix A**. Participants will also be given a Montreal Cognitive Assessment prior to participation in the study and must receive a normative value of 26 out of 40 points.¹⁴ Both of these measures can be performed in person or remotely via telephone conversation.

1.3 Assessment

An on-site assessment will be provided to ensure safe participation and eligibility prior to beginning the study. A student physical therapist will assess balance via the MiniBEST outcome measure (reliable for identifying falls in healthy older adults)¹⁵ and a 10-second tandem stance (inability to complete indicates falls risk).¹⁶ Additionally, the physical therapy student will assess ankle dorsiflexion range of motion and lower extremity sensation due to their strong associations with postural sway in older adults.¹⁷ If a participant presents with less than 10 degrees of dorsiflexion range of motion (i.e. bringing toes up towards the sky) or present with plantarflexion contracture (i.e. reduced ability to dorsiflex due to shortening of associated soft tissues), then specific measurements will be taken with a goniometer and documented. Lower extremity sensation will be assessed using a 5.07 monofilament and any evidence of peripheral neuropathy will also be documented. Identified impairments will not exclude the participants from the study but will be noted in order to increase the generalizability of results. In order determine foot dominance for the study, participants will be asked "If you were to kick a ball, which foot would you use?" Patient characteristics from the screening and evaluation will be included as exampled by the table in Appendix B. The research team is comprised of a physical therapist and physical therapy student, a clinical audiologist/professor in the Division of Speech and Hearing, a professor within the department of the Otolaryngology-Head and Neck Surgery and an undergraduate research assistant.

2. Study Design

Participants will be recruited into two groups—normal hearing (NH) and hearing loss group (HL)—based on results from most recent audiogram. Participants with hearing loss will perform in the study without the use of hearing aids. Postural stability will be objectively assessed by three trials of 30-second static balance performance on a force platform under various auditory conditions, in order to be consistent with similar studies.⁷⁻⁹ To standardize the standing position, all participants will stand barefoot on the force platform in semi-tandem stance position, with the dominant foot placed anterior to the non-dominant foot. As previously mentioned, foot dominance will be established prior to beginning the study based on kicking preference. Participants will be instructed to rest their arms naturally at their sides and remain as still as possible while maintaining this stance. They will also be blindfolded to eliminate visual cues and the well-known contributions of the visual system in maintaining static balance² and to increase the challenge of balance performance.

Each participants will complete three trials for each of the three auditory conditions—1) no sound (enforced by use of earplugs and headphones), 2) sound audible only to the normal hearing older adults, and 3) sound audible to both the normal hearing- and hearing-impaired groups of older adults. There will be randomization to the order of administration of the different auditory stimuli for each participant. Auditory input will be administered from four surround sound speakers located anteroposterior and mediolateral to the subjects. Audiologists will predetermine the selected frequencies, which will be standardized based on the average baseline characteristics of the audiogram results for each group. To ensure participant safety and prevent the chance of falls, a physical therapist or qualified research assistant will stand close by and guard the patient (without contact) in the event that the patient loses balance. A seated rest break will be required for one minute between each trial and three minutes between each sound condition.

The study will consist of 9 total trials (3 trials for each of the three conditions) and the 3-dimentional components of the single equivalent force generated through each participant's feet to the surface of the force platform will be measured and recorded. Postural steadiness will be indicated by the calculations of changes

in the location or point of application of this force, known as the center of pressure (COP). Since differences in body dimensions between the participants may cause variations in COP parameters, we will use the foot length of the participants as a covariate. We will evaluate mean velocity as the main parameter of COP due to its sensitivity for differentiating age-related changes.¹⁸

3. Statistical Analysis

The average value of the center of pressure (COP) mean velocity will be calculated from the 3 trials for each auditory condition and reported for every participant. Due to the mixed between- and within-subject design of this study, a 2 x 3 analysis of covariance (ANOVA) will be used to compare the main and interaction effects of the groups (NH and HL) and the auditory conditions (no sound, audible to NH, and audible to all) on the COP mean velocities.

Discussion

Participants will be recruited from an audiology faculty clinic with access to recent audiogram data to increase the feasibility of the study and reduce the time commitment of the older adult participants. Formal audiometric testing yields an audiogram, or a graph depicting the pure-tone average (PTA) that describes the measured hearing threshold (in decibel hearing loss dBHL) at a given sound frequency (Hz).¹⁹ The data from the audiogram is used to categorize the type (i.e. conductive, sensorineural, or mixed), degree (i.e. mild, moderate, severe), and configuration (i.e. describing frequency, laterality of loss, symmetry of hearing impairment, progressive or sudden, fluctuating or stable, etc.) of hearing loss.²⁰ For reference, The National Institute on Deafness and Other Communication Disorders (NIDCD) describes *normal* PTA at 25dB HL or less, *functionally hearing impaired* at 40dB HL, and *severely impaired* if greater than 70dB HL.¹⁹

In this study, we decided to use static posturography to objectively measure postural steadiness in community dwelling older adults. *Static posturography* is the measurement of postural stability, or the postural control system's ability to maintain balance in a static position during quiet stance.¹⁸ It is often measured by force platforms which detect the vertical and horizontal reaction forces from the individual's feet during quiet stance and quantifies the postural sway in a given timeframe using various center-of-pressure (COP) measures.¹⁸ Therefore, optimal postural stability is reflected through minimal amplitude of COP oscillations or reduced postural sway.¹⁸ Since postural stability is a function of the visual, somatosensory, and vestibular systems, it is often measured in both eyes-open and eyes-closed conditions to account for the visual role in maintaining static balance.¹⁸ However, in this study will eliminate visual input to emphasize the hypothesized auditory relationship with balance.

Similar studies examining postural stability in older adults have utilized various stance positions, including feet apart, feet together (referred to as Romberg), semi-tandem, and tandem stance.^{8–11,21} In semi-tandem stance, one foot is placed in the arch of the other so that the big toe is touching the opposite foot.¹⁶ Conversely, the tandem stance progresses to one foot being placed directly in front of the other so that the heel and toe are touching.¹⁶ For our pilot study, we decided on semi-tandem stance in order to make it feasible for each participant to obtain at least 30 seconds of COP measurements without losing balance or taking an additional step. Although most studies utilize Romberg or tandem stance, we wanted a test that was less likely to have a ceiling effect, (i.e. Romberg test in the study by Rumalla et al)⁸ and would not exclude those at risk of falls, as indicated by the inability to sustain tandem stance for 10 seconds.¹⁶ One study demonstrates the progression in challenge amongst these stance positions, as postural sway increased by 25% when using semi-tandem stance.²² Additionally, sway can increase by 50% when closing eyes compared to open, further justifying our use of blind folding to increase the challenge of the balance task.

Multiple COP parameters have been reported in literature and balance studies to describe or compare postural stability during quiet stance; including but not limited to *mean velocity* (speed), *mean distance* (displacement or *total path length*), *mean frequency*, *sway area*, *root mean square difference*, and *standard deviation velocity*.^{18,23,24} Most

of these measures are reported in both mediolateral (ML) and anteroposterior (AP) directional components; however, mediolateral sway is a distinguishable factor associated with falls in older adults.^{18,24,25} Additionally, *COP displacement* (or path length) and COP velocity results (in both eyes-open and eyes-closed conditions) are significantly higher in older adults with history of falls²⁶ and are "arithmetically related,"^{18,24,25} which justifies its use for assessing falls risk in older adults. Furthermore, evidence supports the use of mean velocity as a COP parameter due to its sensitivity in differentiating age-related changes and differences in postural stability between the closed-eye and open-eye conditions in both younger and older adults.^{18,25} However, *sway area*, which describes the "area enclosed by the COP path per unit of time," is also sensitive in differentiating between open-eyed and closed-eyes conditions in this population.¹⁸ Therefore, when performing Romberg stance or tandem stance, changes in *sway area, path length*, or *mean velocity* are often reported in evidence.²⁶

Upon consulting with a statistician, we calculated a 0.80 power at p<0.05 indicating a need of 30 subjects per group. We suspect that our study will be underpowered, which led to the decision to begin as a feasibility study to test our methodology and to collect preliminary data for determining the effect size for a larger study. We hypothesized that the biggest between group differences would be observed for the auditory condition that is only audible to the normal hearing group. For simplicity purposes of this pilot, we selected the difference between group means of this condition to calculate power for simplicity purposes of this pilot.

Conclusion

Literature review on the auditory contributions to postural steadiness in community-dwelling older adults yields low-quality evidence that vary in methodology, outcomes, and study characteristics—such as type of auditory stimuli, visual conditions, balance assessment, testing conditions, and participant characteristics—making it difficult to standardize and generalize the results.³ The studies often have small sample sizes, differ on the type of balance assessments implemented, and are also inconsistent on the type of parameters reported. Furthermore, there is a lack of high-quality evidence that intentionally explores the proposed mechanism of spatial localization specifically in older adults with and without hearing impairment.³ This would suggest that auditory input is utilized as a point sound source and that postural steadiness is maintained by orienting to these external cues.³ Therefore, we propose a pilot study with minimal factors—one standardized balance test, eliminated visual input, three auditory conditions, and an evidence-based COP parameter—to test the methodology and to ensure the feasibility of the study. We aim to build on this research to produce a higher-powered study that will advance our understanding of why community-dwelling older adults with hearing loss are at an increased risk of falling.

Clinical Implications

Although evidence suggests that community-dwelling older adults with hearing impairments experience a higher incidence of falls, increased risk of recurrent falls, and reduced postural stability,^{4,27,28} health professionals still structure interventions for falls prevention primarily around impairments to the motor, visual, somatosensory, and motor systems. However, results from this pilot study may add to existing evidence that supports the role of the auditory system and demonstrates how sound cues contribute to postural steadiness and control. This can provide novel clinical implications for health professionals, including physical therapists, working with older adults to detect and address hearing impairments during assessments and interventions for those at risk of falls. We can begin to advocate for falls screening within audiology clinics for older adults with hearing impairments. This can include inquiring the patient about their history of falls and/or referring to an appropriate health professional for a comprehensive falls-risk assessment. Furthermore, physical therapists can screen for hearing impairments (i.e. asking about hearing difficulties and/or hearing aid compliance), refer to audiologists, and/or include recommendations for strict adherence to hearing aid use both within and outside the clinical setting. Lastly, this new finding can foster unique collaborations between physical therapists and audiologists in the future in order to mitigate the risk of falls for community-dwelling older adults with hearing impairments.

Appendix:

A. Sample Participant Screening Questionnaire

- 1. Participant Demographics
 - a. Age:
 - b. DOB: _
 - c. Gender:
- 2. Hearing Abilities
 - a. Do you have any hearing difficulties?
 - b. Do you wear hearing aids?
 - c. If you wear hearing aids, how long have you worn them?
 - d. If you wear hearing aids, in which ears do you use them?
- 3. Musculoskeletal, Neurological, Vestibular, or Cognitive Conditions
 - a. Do you have any pain that interferes with your ability to walk?
 - b. If so, please describe:
 - c. Do you have any problems with your feet that would make it difficult for you to stand barefoot?
 - d. Have you been diagnosed with any neurological disorders, such as stroke, peripheral neuropathy, or Parkinson's disease?
 - e. Do you currently have any issues with dizziness?
 - f. Have you been diagnosed with any vestibular disorders, such as BPPV?
 - g. Do you have any issues with memory or following instructions?
- 4. Falls History
 - a. Any history of falls within the last year? A "fall" is described as coming to rest to ground or lower surface unintentionally?
 - b. If yes, how many?
 - c. What were the circumstances surrounding the fall(s)?
- 5. Feasibility
 - a. If selected for the study, would you have any difficulty coming to UNC for a single testing session?

B. Table 1: Sample Patient Baseline Characteristics

| <u>Characteristics</u> | <u>HL (N=15)</u> | <u>NH (N=15)</u> | <u>Total (N=30)</u> |
|------------------------|------------------|------------------|---------------------|
| Age (avg years) | | | |
| Gender | | | · |
| Male | | | |
| Female | | | |
| Hearing Impairment | | | |
| Yes | | | |
| No | | | |
| Bilateral HA Use | | | |
| Length of HA Use (mo) | | | |
| Cognitive Assessment | | | |
| MoCA Score | | | |
| Balance Assessment | | | |
| MiniBEST Score | | | |
| 10s Tandem Stance | | | |
| Evaluation | | | |
| L Ankle DF WNL | | | |
| R Ankle DF WNL | | | |
| LE Sensation WNL | | | |
| MSK Issues (Y) | | | |
| Neuro Disorders (Y) | | | |
| Memory Impairments (Y) | | | |
| Right Foot Dominant | | | |
| Falls History | | | |
| Fall in past year (Y) | | | |
| Number of Falls | | | |

Key: HA=hearing aid; MoCA=Montreal Cognitive Assessment; L/R=left/rigt; DF=dorsiflexion; WNL=within normal limits; mo= months; Y= years

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