Sensory Integration of Auditory and Visual Cues in Diverse Contexts
Study Protocol
June 1st, 2020
NCT04479761

The same sample of adult participants (18 or older) will be recruited to study both specific aims. All participants will have normal or corrected to normal vision and no peripheral neuropathy or other neurological conditions. Control participants will be recruited from the NYU community, and registry of alumni, local fitness centers and local senior centers. The two patients' groups will be recruited from the Ear Institute of Mount Sinai.

Group 1: Unilateral peripheral vestibular hypofunction and normal hearing, e.g., vestibular neuritis. Potentially eligible participants with a functional complaint of head motion provoked instability or dizziness affecting their functional mobility and quality of life will be identified by key personnel and additional staff at the Ear Institute during their standard clinical evaluation. They will present with at least one positive finding indicating unilateral vestibular hypofunction on the following clinical tests: head thrust, subjective visual vertical and horizontal, post head shaking nystagmus, spontaneous and gaze holding nystagmus[84] in addition to a score of at least 16 (mild handicap) on the Dizziness Handicap Inventory (DHI).[71] Unilateral peripheral vestibular hypofunction will then be confirmed by the meeting at least one of the following diagnostic criteria:[2,85]

- 25% or above unilateral weakness on caloric testing[70];
- Low gain on vHIT <.8;[86]
- Ocular Vestibular evoked myogenic potential (oVemp) amplitude asymmetry greater than 34%;
- Cervical (cVemp) amplitude asymmetry greater than 40%.

Patients will be excluded if they are diagnosed with an unstable peripheral lesion, e.g., Meniere's Disease, Perilymphatic Fistula, Superior Canal Dehiscence, or Acoustic Neuroma.

Group 2: Acquired moderate/severe/ profound unilateral hearing loss no evidence of retrocochlear pathology on MRI and no active complaint of dizziness (DHI score < 16)[71] or imbalance.[72] Hearing loss will be defined as having an unaided pure-tone average (PTA) of hearing thresholds at 0.5, 1, 2, and 4 kHz in the affected ear > 40 dB HL and normal hearing in the contralateral ear. Normal hearing will be defined as an unaided PTA < 26dB HL (0.5–4 kHz) bilaterally. This is considered healthy hearing according to the World Health Organization.[20,73] For those above 65 years of age, symmetric age-related hearing loss (ARHL) in the mild hearing loss range, specifically an unaided PTA < 40 dB (0.5-4KHz) will be included.[74] Given that ARHL has been reported to affect 67% of adults over the age of 70 and 80% of adults over the age of 85[75,76], this criterion will allow for a better representation of the aging population. We will adjust for the presence of ARHL in the statistical analysis.

Exclusion criteria for all groups will include a medical diagnosis of peripheral neuropathy; lack of protective sensation based on the Semmes-Weinstein 5.07 Monofilament Test;[87] visual impairment above 20/63 (NYS Department of Motor Vehicle cutoff for driving) on the Early Treatment Diabetic Retinopathy Study (ETDRS) Acuity Test that cannot be corrected with lenses; conductive hearing loss or air bone gap; pregnancy; any neurological condition interfering with balance or walking (e.g. multiple sclerosis, Parkinson's disease, stroke); acute musculoskeletal pain at time of testing; currently seeking medical care for another orthopaedic condition; and inability to read an informed consent in English. Control participants will be excluded for any positive finding on the vestibular diagnostic testing or history of vestibular symptoms (dizziness, vertigo).

The following procedures will be done:

Diagnostic Session (Ear Institute, could be split into 2): First, we will obtain a written informed consent. Then participants will complete a short demographic questionnaire noting age, gender, height, weight, ethnicity and race, as well as confirming the absence of exclusion criteria from self-reported medical history. Next participants will go through vestibular and auditory testing done by an audiologist at the Ear Institute. These tests are part of a standard battery for patients with vestibular complaints and include:

Videonystagmography (VNG): The VNG caloric test requires the participant to wear goggles that allow careful monitoring of eye movement in response to hot and cold air placed in the ear canal.

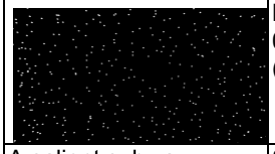
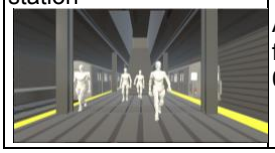
Audiogram: The participant wears headphones and is asked to identify sounds at different frequencies and repeat simple words.

Video Head Impulse Test (vHIT): The vHIT requires the participant to wear special goggles and focus on a target on the wall. The examiner will move that participant's head right, left, up, down and diagonal while he/she keeps their eyes on the target.

The session is expected to take 2 hours.

Postural Control session (NYU Physical Therapy Department, Arthur J. Nelson Jr., Human Performance Laboratory, could be split into 2): Participants will complete 4 self-reported questionnaires as described under 'materials' below (they can complete it at home prior to the session as well if they prefer). The participants will be wearing a virtual reality headset (HTC Vive) and bluetooth-connected headphones (Bose). They will complete a series of standing tasks while observing a virtual display and listening to sounds. They will be asked to stand with their feed hips-width apart. The variations of visuals and sounds are explained in Table 1 below. All conditions will be randomized. Sounds will be displayed at the highest level that is comfortable to the participant. Scenes are 60 seconds long. We have a total of 12 combinations: 2 environments (stars, subway) X 2 visuals (moving, static) X 3 sounds (moving, none, static) and each combination will be repeated 3 times for a net testing time of 36 minutes. Including rest breaks, total testing time is expected to take no longer than 2 hours could be completed over 2 sessions. For aim 1, we will assess the significance of contrasts between no sounds / dynamic sounds for the different visual conditions and groups. For aim 2, the same will be done for contrast between no sounds / static sounds.

Table 1. Protocol for the 2 specific aims.

The environment	Visuals	Sounds
An abstract display of star wall 	Static stars Moving stars: 0.2 Hz, 0.032m, Anterior-Posterior (AP)	No sound Static White Noise Moving Sound: white noise circling around the participant
A salient subway station 	Static avatars and train Avatars are moving from front and back at a speed of 0.71–2.45m/s, flow of trains	No sound Static White Noise Detailed natural environmental sounds with high density of footsteps and train sounds

The following materials will be collected:

Diagnsotic Outcomes:

1. Caloric testing: Unilateral weakness percentage
3. Audiogram: decibel hearing threshold across various frequencies (pure-tone average).
4. vHIT: Vestibulo-Ocular Reflex Gain

Self-reported Questionnaires:

1. The Dizziness Handicap Inventory (DHI): Designed to identify difficulties that a patient may be experiencing because of his/ her dizziness.[45] We will record the total score as well as scores on the Functional, Physical, and Emotional sub-scales.

2. The Activities-Specific Balance Confidence (ABC): A subjective scale where subjects are asked to rate their balance confidence from 0-100% performing 16 different tasks.[45]
3. The Speech, Spatial and Quality of Hearing 12-item Scale (SSQ12): A valid, short version of the original SSQ which provides insights day-to-day hearing loss impact.[79]
4. The Simulator Sickness Questionnaire: This 15-item questionnaire will be administered as a structured interview every rest break to monitor participants' symptoms.[80] The number of none, slight, moderate or severe symptoms will be recorded.

Physical Outcomes:

Center of Pressure position in the anterior-posterior and medio-lateral directions will be recorded at 100 Hz from a laboratory force platform that is embedded in the floor under the participants' feet. Directional Path, and sway area will be calculated in a custom-designed Matlab software.