

**Restoration of Spectral Resolution with Hearing-aid Amplification**

**NCT03850678**

**Study Protocol and Analysis Plan**

**March 13, 2019**

## **Brief Summary**

The objective of this study protocol is to determine the efficacy of using aided measures of spectral resolution to set the dynamic range of hearing with hearing-aid amplification. Measures of spectral resolution will be obtained, as will measures of speech recognition.

## **Significance/Purpose:**

Adults with hearing loss are more vulnerable to interference from background noise than adults with normal hearing. Despite the fact that the ability to extract speech information imbedded in background noise requires decoding differences in level across frequency (spectral information), few studies have addressed the extent to which we can provide spectral information to listeners with hearing loss. This fundamental gap in our knowledge prevents us from effectively addressing the systemic effects of hearing loss on communication, income, and ability to socialize with others. This work is a new application of established methods of characterizing spectral resolution to that of the most common device for rehabilitation of hearing loss—hearing-aid amplification. The proposed experiments will examine the degree to which access to spectral information can be restored to adults with hearing loss and the feasibility of utilizing this information to decrease interference from background noise. Aim 1 will delineate the impact of hearing-aid amplification on spectral decoding. Technology options that must be set by the clinician or hearing-aid manufacturer will be examined, including the frequency-specific gain, compressor speed, and number of compression channels. The proposed experiments will test the hypothesis that restoration of the lost dynamic range of hearing can support the encoding of spectral information. It is also hypothesized that the combination of technology options that best restore access to spectral information will differ across individuals and that these differences across individuals can be partially accounted for by an estimate of outer hair cell function. Aim 2 will determine the extent to which restoring access to spectral information supports speech recognition in background noise, under the guiding hypothesis that improving spectral resolution increases speech understanding. If it can be demonstrated that measures of spectral resolution with the provision of amplification are useful at delineating those who stand to benefit from different technology options, the knowledge gained could then be applied to the clinic to allow for clinicians to more successfully choose among different rehabilitation options.

## **Study Design**

### ***Data Collection Procedures:***

This study can be divided into 4 sections. For all four sections, the subject will sit in a sound attenuated booth.

### *Section 1 - Questionnaire and cognitive impairment screen*

At this time, each subject will complete a questionnaire that asks relevant questions about their medical and developmental history and educational level. Participants will be screened for a potential cognitive impairment using the Montreal Cognitive Assessment Basic (MOCA-B). The MOCA-B is a 10-minute cognitive screening tool to detect mild cognitive impairment. Participants are asked to perform tasks including connecting numbers and patterns on a sheet of paper, recalling words, naming of items, and simple math calculations. Participants with a score less than 26 will be informed of the test results and counseled to consult with their primary care physician. A screening for potential cognitive impairment is being implemented to limit the possible influence (i.e. confound) of cognitive impairment on our perceptual results.

### *Section 2 - Audiological test and hearing aid fitting*

Each subject will undergo a routine audiological examination. First an audiogram will be completed. The subject will hear a series of acoustic beeps. The subject's task is to indicate when he or she heard a beep. From this test we can determine the softest sounds that the subject can hear. This will be completed using an audiometer (sound presentation device) and earphones. The earphones will be attached to the subject. Each subject will be fitted for testing with hearing aids or a computer based hearing aid simulator. Tympanometry, a routine audiological test, will be completed.

### *Section 3 - Detection of Acoustic Information*

We will measure the ability of the subjects to detect small changes in the frequency of the signal. Via a touchscreen, the subject will indicate when he or she heard a change in the signal, from which a threshold is estimated. This measure is related to the perception of speech.

### *Section 4 - Speech Recognition*

Speech sounds will be presented at a variety of levels. The subject will repeat back the speech sounds that they heard and their spoken response will be scored.

#### ***Test Time:***

The audiological test and hearing aid fitting is anticipated to take 1 hour to complete. Section two is anticipated to take approximately 3 hours and section three approximately 2 hours. Participants with NH require less time; they are not fit with hearing aids and undergo fewer conditions. In addition to hearing status, the duration will depend on how quickly each subject completes the study and on whether a current audiological test can be used, thereby saving time. Consequently, we anticipate the study will take approximately 3-6

hours per subject. Generally subjects complete the study in 2-3 sessions scheduled over the course of a couple weeks.

***Recruitment:***

Recruitment will occur at the Barkley Speech, Language, and Hearing Clinic, Lincoln and surrounding community facilities that provide audiological or ear nose throat services, and through organizations with older individuals (e.g. OLLI at UNL). Participation will take place at the amplification and perception laboratory.

**Statistical Analysis:**

We plan to enroll 20 subjects with normal hearing and 40 subjects with sensorineural hearing loss (per experiment). While we plan to recruit the same subjects for each experiment, additional subjects will be recruited as needed. Additional subjects will be recruited for pilot testing and to account for attrition. We expect an effect size of 0.37 ( $np2$ ) or greater. Using G\*Power (v3.1) we estimated sample sizes necessary to detect an effect size of over 0.23 (power = 80%,  $\alpha = 0.05$ ). For Aim 1, planned comparisons to examine the effect of prescriptive procedure, compression speed, and number of compression channels on the sharpness of tuning measured will be conducted using an ANOVA or, if we find that the assumptions of the ANOVA to be violated, a linear mixed effect model. For Aim 2, planned comparisons to examine the effect of dynamic range of hearing (small, large) and tuning status (poor tuning, sharp tuning) on proportion correct will be conducted using an ANOVA or, if we find that the assumptions of the ANOVA to be violated, a linear mixed effect model. While results are not expected to differ by sex, differences by sex will be analyzed for all experiments. Other variables, such as age, degree of hearing loss, and working memory likely play a role in spectral resolution and speech recognition and will be considered as variables in our statistical models.