Project Plan

Feasibility and validity of a portable automated rapid testing (PART) device to evaluate central auditory dysfunction in the school-aged population

Specific Objective: To collect feasibility and validity pilot data on psychoacoustic measures of speech in noise, spectrotemporal coding and auditory scene analysis using a portable automated rapid test device (PART) in the school-aged population. This exploratory data, on a battery of digital adaptive tests, has a potential for telehealth auditory processing assessments in the schools, administered by multidisciplinary team members. This data would be pilot work for a larger study that would associate performance on these tests with reported difficulties, as well as developing normative values for a school-aged population.

Significance

In recent years, the scope of Auditory Processing Disorder (APD) has broadened due to greater recognition of auditory phenomena that are both peripherally (Saxena et al., 2015) and centrally (Gallun & Lee, 2014) mediated. However, there still exists a wide gap between modern theories of central auditory dysfunction and the clinical tests used to diagnose deficits associated with this dysfunction. The diagnosis of APD is elusive as defined by AAA and ASHA guidance and commonly presents with comorbidities of academic, attention and learning difficulties in the school-aged population (AAA 2010, ASHA 2005). Unfortunately, assessing and diagnosing APD has underlying barriers, including but not limited to lengthy test batteries, validity of measures, accessibility and professional community acceptance.

The SCAN-3 is an example of a commonly used, age-normed APD test battery (Keith 2009). The test battery is administered via a CD, over 45 minutes (not including breaks), usually with audiologic equipment (audiometer & transducers, sound booth), and pen & pencil scoring. Each aspect may be considered a technical limitation of the test battery and is not unique to the SCAN. In addition to these technical issues and the specialized clinical knowledge required, there is ongoing controversy in the field as to the best test to use and the proper interpretation of the results of APD tests. In a recent study (Moore et al 2018) researchers at the Cincinnati Children's hospital performed a retrospective review of 1,113 patients (aged 5-19 yrs) whom underwent Central Auditory Processing Evaluations (CAPE) between the years 2009-2014. The study noted that a diagnosis of APD, based on the current guidelines, was neither realistic nor appropriate, given the current tests (SCAN) and clinical judgements by the audiologists administering the CAPEs. One of the limitations was raw-score ceiling effects on many of the CAPE tests administered. Another limitation, identified in the study, is the difficulty of distinguishing APD from attention and language disorders, relevant comorbidities of this

population. These technical and training requirements result in limited access to professionals who can administer and interpret lengthy APD evaluations.

A currently funded NIH R01, awarded to the Principal Investigator Frederick Gallun, PhD at the Oregon Health and Science University (OHSU) is investigating the reliability of a portable automated rapid testing (PART) device for auditory processing. This digital platform is freely available, can be calibrated using standard hardware, runs on multiple platforms, including the iPad, and contains a set of clinically viable tests for central auditory dysfunction that have been established in the laboratory to reveal variations in processing ability in an adult population. The data collected in this pilot will help to determine if the tests implemented on this platform are 1) feasible for school-aged children, 2) the degree to which they are influenced by mild to moderate hearing loss, and, thus, 3) whether it is likely that they can be used to provide a valid set of measures used as normative values for this population. If successful, this study would provide data to support a larger study that could implement more rigorous tests of validity and reliability and establish normative values as a function of age and hearing loss (as measured by the audiogram), as well as establishing the degree to which these measures covary with comorbidities such as disorders of attention and language.

There is a recognized need to develop a concise battery of adaptive tests that are well validated, normed, and relevant to the school-aged problems reported by parents, educators and students (DeBonis, 2015). This project is an initial step in a modern delivery approach to assess auditory processing abilities in school-aged children, addressing the limitations related to assessment and accessibility. The PART device, has the potential to increase access to testing, decrease test time, and provide more precise referrals. The theoretical and practical application of the PART device, with digital and adaptive test measures to assess central auditory processing functions, is monumental for the school-aged population and invaluable to multidisciplinary teams in the education system.

Methods and Procedures

Project Design

This is a prospective study design. Data will be collected at the Multnomah Educational Service District Administrative offices, where audiology services are located.

Personnel

1. Audiologist/Co-Investigator: Keri O. Bennett, AuD., CCC-A. Dr. Bennett is an Educational Audiologist at Multnomah Educational Service District (MESD). Under the mentorship and guidance of Dr. Gallun, she will be responsible for study design, recruitment, data collection as well as database maintenance and integrity at MESD. She will be responsible for the dissemination of the results of the study.

2. Mentor/Co-Investigator: Frederick J. Gallun, PhD, is a Research Investigator at the NCRAR and an Associate Professor in the Department of Otolaryngology and the Neuroscience Graduate Program at OHSU. Dr. Gallun's background is in psychoacoustics and cognitive psychology, with an emphasis on computational models based on functional and neurophysiological descriptions of the auditory system. His research focuses on understanding the skills and abilities necessary for listening in complex environments, including the role of auditory memory and attention, the challenges presented by aging and hearing loss, and the benefits of binaural hearing. His research interests also include the study of the relationships between simple and complex stimuli, and intensity perception and amplitude modulation sensitivity. He will provide mentorship in all aspects of this research proposal including design, implementation, and interpretation and dissemination of the work.

Instrumentation

1. Portable Automated Rapid Testing (PART): is a platform that features a range of built-in assessments of auditory processing, runs on an iPad (or other computer), and is connected to a pair of calibrated headphones.
2. PART software assessments: include tests of temporal, spectral, and spectrotemporal processing, binaural function, detection of targets in competition, and auditory scene analysis.
3. ECLiPS questionnaire.

Subjects & Recruitment

50 students of school-age (5 to 19) will be recruited for participation. Students, accompanied by a parent or legal guardian, who visit the MESD audiology clinic and complete a comprehensive audiologic evaluation will be asked to participate in the study, post clinical evaluation. All non-English speaking families will be accompanied by a language interpreter supplied by the student's school and the consent/assent process will be conducted via the language interpreter. No participants unable to assent will be recruited.

Inclusion Criteria:

1. Age 5 to 19 years
2. No greater than a moderate (55 dB HL) hearing loss
3. Able to complete study procedures

Measurement Technique

All participants will have been screened for inclusion based on a comprehensive audiologic evaluation at MESD. If hearing thresholds are determined to be within the normal limits up to a moderate (55 dB HL) hearing loss, the student will

be asked to participate in the pilot study and consent and assent will then be obtained. The consent and assent form will be thoroughly explained and a copy provided to the subject and parent/legal guardian to read and review.

Test Measures: Participants will be seated in a comfortable chair, at a desk, in a sound treated booth or quiet location. The iPad will be placed on the desk or can be hand held by the participants. Headphones, similar to those used in routine audiologic testing, will be placed on the participants ears. These headphones are calibrated for use with PART. The participants will be instructed and familiarized with the use of a touch screen device. Up to three tests will be administered. Tests will measure sensitivity to spectral and temporal cues as well as the ability to detect signals and understand speech in competing acoustical environments. These tests were developed in Dr. Gallun's lab and are targeted at the abilities measured in currently available APD tests, without confounds of attention and language/vocabulary (Lelo de Larrea-Mancera et al., 2020). All stimuli will be presented at comfortable levels (always below 95 dB SPL and usually in the range 60-85 dB). When PART is ready to begin presenting trials, the listener will touch the screen to initiate the experimental session. Trials consist of a sound presentation, followed by a response from the listener (e.g., virtual button push on iPad touch screen), a feedback signal or other indication that the response was either registered or represented a "correct" response, and then the initiation of the next trial. Each trial typically requires about 2-3 seconds, depending on how rapidly the subject makes a response, and there is usually at least a second between the end of one trial and the initiation of the next. Trials continue until a stopping criterion is reached (e.g., number of trials). The experiment is mostly self-paced by the subject, and the subject can take a break at any time. Testing time may vary based on age and ability of each participant, but is expected to average between 15 to 30 minutes.

Questionnaire: While the student is performing PART tasks, the parent or guardian will be asked to fill out the ECLiPS Parental-Report Measure designed to assess listening difficulties in children (Barry & Moore 2014). It is comprised of 37 items with five subfactors: (1) Speech and Auditory Processing (SAP), (2) Environmental & Auditory Sensitivity (EAS), (3) Language/Literacy/ Laterality (L/L/L), (4) Memory & Attention (M&A), and (5) Pragmatic & Social Skills (PSS). Parents indicate on a 5-point Likert scale, the extent to which they agree or disagree with each statement. Scores for items within each factor are averaged, and age- and gender-scaled scores are calculated.

Remuneration: Subjects will receive $25 for the experimental session, regardless of completion of the tasks.

Data analysis

Normative data have recently been made available for 150 undergraduates (mean age of 20 years) with normal hearing (Lelo de Larrea-Mancera et al., 2020). The same tests will be conducted in this study and the data analysis will parallel that study. Most importantly, the means and standard deviations of the thresholds obtained in each test will be compared

with those in the published study and will be used to estimate normative ranges for a younger population. In addition, linear mixed-models analysis will be used to determine the degree of similarity between the two data sets as a function both of age and of the specific tests administered. Similarity will be assessed in terms of the mean thresholds, the variability across participants, and the number of trials necessary to obtain threshold measurements. Regardless of the relationship with the previous study, statistical regression will be used to establish the degree to which age and/or hearing loss impact the expected values on each test (Jakien and Gallun, 2018). The resulting “normative functions” can be used to develop charts that provide normative values that take into account age and hearing thresholds of the child being tested.

Facilities and Resources

The staff audiologist, Dr. Bennett, at Multnomah Educational Service District (MESD) provides audiologic services to the public schools of Multnomah County, comprised of seven districts. Her primary focus is in the elementary schools and this covers roughly 120 elementary schools between the seven districts. Additionally, any aged student (middle and high school) in the component districts has access to her audiologic services both in the school or office setting. Participants will be recruited within these seven public school districts. Facilities and equipment available at MESD include a sound treated booth located at the MESD administrative offices in Portland, OR. The sound suite has a GSI audiostar extended high frequency audiometer (insert, supra-aural and circumaural transducers) with sound field and VRA capabilities. Additional equipment includes a portable MAICO MA-42 audiometer, GSI Corti otoacoustic emission device, and MAICO easyTymp immitance bridge. Data collection will be obtained using the PART and will be conducted in the sound treated booth or quiet location. PART device will be provided by Dr. Gallun’s lab.

Appendices

References

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Child Assent Form

IRB#_____
Protocol Approval Date:_____

TITLE: Name of the study. [*Use the same title as that on the IRQ.*]

PRINCIPAL INVESTIGATOR: [list name and degree(s)] (503) 494-####

CO-INVESTIGATORS: [list name and degree(s)] (503) 494-####
[list name and degree(s)] (503) 494-####
[list name and degree(s)] (503) 494-####

This research study was explained to me. I know how it may or may not help me. I also know that this study will help doctors learn more about (insert name of condition). To be sure that I know what is going to happen, the investigator will ask me the following:

1. To explain what I will do and what will happen in this study.

2. If I have any questions or want to know anything else about this study or (insert name of condition).

3. To explain some of the good and bad things that might happen to me if I enter this study.

I have thought about being a part of this study. I have asked and received answers to my questions. I agree to be in this study. I know that I don't have to agree to be in the study. Even though I agree to be in it now, I know I may feel differently later on and can ask to stop being in the study. I know that I may talk with my parents and/or doctor about not being in this study at any time.

Name/signature:_____ Date:_____