

AWARD NUMBER: W81XWH-19-1-0367

TITLE: Towards Development of a Mobile Assessment and Differential Diagnosis of Auditory Dysfunction: Hidden Hearing Loss and Central Auditory Processing Disorders

PRINCIPAL INVESTIGATOR: Dr. Michelle Molis

CONTRACTING ORGANIZATION: OREGON HEALTH & SCIENCE UNIVERSITY
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| 14. ABSTRACT: The purpose of this study is to develop a screening tool to identify Veterans with hearing problems that are not detected by standard clinical hearing tests. Development of an objective and simple-to-administer test of speech understanding that is sensitive to subtle impairments in the auditory system would provide VA audiologists with evidence-based guidance for assessing the communication difficulties of Veterans without significant threshold shifts who nevertheless report increased listening effort or difficulty in challenging listening situations. This will be done by comparing an individual's performance on a test called Time Compressed Digits (TCD) with their self-reported hearing difficulties, as measured by the Speech, Spatial and Qualities of Hearing Scale (SSQ-12), to determine if this test is a good reflection of hearing abilities in everyday life. Additionally, based on auditory behavioral and electrophysiological assessment, a statistical model will be developed to predict deficits in outer hair cell function, synaptic/neuronal function, central auditory proce | | | | | | | | | |
| 15. SUBJECT TERMS NONE LISTED | | | | | | | | | |
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1. INTRODUCTION: *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

The purpose of this study is to develop a screening tool to identify Veterans with hearing problems that are not detected by standard clinical hearing tests. Development of an objective and simple-to-administer test of speech understanding that is sensitive to subtle impairments in the auditory system would provide VA audiologists with evidence-based guidance for assessing the communication difficulties of Veterans without significant threshold shifts who nevertheless report increased listening effort or difficulty in challenging listening situations. This will be done by comparing an individual's performance on a test called Time Compressed Digits (TCD) with their self-reported hearing difficulties, as measured by the Speech, Spatial and Qualities of Hearing Scale (SSQ-12), to determine if this test is a good reflection of hearing abilities in everyday life. Additionally, based on auditory behavioral and electrophysiological assessment, a statistical model will be developed to predict deficits in outer hair cell function, synaptic/neuronal function, central auditory processing, and working memory based on an individual's age and their performance on the TCD task.

2. KEYWORDS: *Provide a brief list of keywords (limit to 20 words).*

hearing loss, sensorineural; hearing loss, central; speech understanding; hidden hearing loss; Veterans; hearing difficulties; synaptopathy; central auditory processing; working memory

3. ACCOMPLISHMENTS: *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

The **long-term objective** of this research is development of an auditory screening tool for identification of suprathreshold auditory deficits that will also provide an initial differential diagnosis of the type of auditory dysfunction in order to guide follow-up assessment. The **short-term objective** of this proposal is to examine the utility of a recently developed test measure called Time Compressed Digits (TCD) to reveal auditory dysfunction by examining relationships between performance on the TCD, self-reported hearing difficulties, and laboratory assessments of hidden hearing loss (HHL) and auditory processing disorders (APD).

Specific Aim 1: Determine how performance on the TCD test corresponds to Veterans' self-reported difficulties with hearing in everyday life as measured by the 12-item version of the Speech, Spatial and Qualities of Hearing Scale (SSQ12).

Specific Aim 2: Develop a statistical model to predict deficits in outer hair cell (OHC) function, synaptic/neuronal function, central auditory processing, and working memory based on an individual's age and their performance on the TCD task.

| | Timeline Months | % Completion |
|---|----------------------------|-------------------------|
| Major Task 1: Prepare for subject recruitment and testing | | |
| Subtask 1: IRB Approval | 1-3 | 100 |
| Subtask 2: HRPO Approval | 1-3 | 100 |
| Subtask 3: Purchase test materials and supplies | 1-3 | 80* |
| Subtask 4: Purchase equipment and computer | 1-3 | 70* |
| Subtask 5: Set up IHS system | 4 | 100 |
| Subtask 6: Hire Research Assistant (RA) | 1 | 100 |
| Subtask 7: Modify TCD computer program | 4 | 80* |
| Milestone(s) Achieved: Approvals obtained, purchases competed, lab set up completed, RA hired and added to IRB, TCD program modified to present specified test conditions | 5 | 90* |
| Major Task 2: Data collection | | |
| Subtask 1: Recruit subjects (10-11 per month) | 6-36 | 0* |
| Subtask 2: Test subjects | 6-36 | 0* |
| Subtask 3: Monitor recruitment and data collection | 6-36 | 0* |
| Milestone(s) Achieved: 300 subjects recruited and tested; adjustments made to recruitment methods as needed | 6-36 | 0* |
| * Note: Further explanation regarding delays in % completion is provided in section 5 Changes/Problems. | | |

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

1) Major activities: The first two quarters of the study were spent accomplishing the first major task of preparing for participant recruitment and testing. Activities included developing and finalizing the test protocol and test procedures, piloting test measures. Substantial time was spent cleaning and setting up lab spaces along with ordering the electrophysiology (EP) test system and calibrating and piloting test stimuli needed for the enhanced audiometric portion of tests. Much of the second quarter was spent selecting and hiring a new research assistant. Local IRB documents were approved and a Data Access Request Tracker (DART) request was submitted and approved to receive contact information of potentially eligible Veterans from the VA Corporate Data Warehouse (CDW) for recruitment purposes. Revisions to the protocol and data collection forms and their IRB approval occurred as appropriate. Q3 and Q4 have been spent pre-screening eligible candidates. Research staff have reviewed the CPRS records of over 4200 Veterans for pre-screening purposes. In addition, HRPO documents were approved.

2) Specific objectives: Begin to address Aims 1 and 2 through participant recruitment, enrollment and testing, and statistical model development.

3) Significant results: All study questionnaires were generated in the Research Electronic Data Capture (REDCap) system. Databases have been developed in Access for participant tracking and data entry purposes. Participant pre-screening began in Quarter 3. This time-consuming task involves reviewing an individual's entire electronic medical record to determine if there are any obvious factors that would disqualify an individual. Our hope is that will decrease our in-person screen failure rate.

| | |
|----------------------|------|
| Total Pre-Screened | 4281 |
| Potential Candidates | 2884 |
| May Not Qualify | 224 |
| Does Not Qualify | 1166 |

4) Other achievements:
Nothing to report.

Due to the COVID-19 pandemic, an administrative hold was placed on the study by the local review board in March 2020. Therefore, the Q3/Q4 goals pertaining to participant recruitment, testing and monitoring of data collection have not been met. Additional details may be found in section 5 (Changes/Problems) of the report.

What opportunities for training and professional development has the project provided?

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased

knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Study staff have participated in online and in-person Python courses to learn ways in which to write programs to make repetitive study tasks and data analyses more efficient.

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to report.

What do you plan to do during the next reporting period to accomplish the goals?

If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

As soon as we receive guidance from ORD to resume in-person research activities, we will work diligently to recruit, enroll, and test Veteran participants. Once we have collected enough data, we will begin to address how performance on the TCD test determine how corresponds to Veterans' self-reported difficulties with hearing. It is likely that once we do resume research, will be operating on a limited status. Therefore, we hope to focus on Specific Aim 1 at the beginning of Year 2. As our operational status expands, we will expand our efforts in developing the statistical model, which will incorporate indirect measures of cochlear/synaptic function (DPOAEs, ABR wave I amplitude, and wideband acoustic reflexes), central auditory processing, and working memory.

4. **IMPACT:** *Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

The goal of this research is to develop a test of speech understanding that can be administered using mobile computing devices or remotely via the Internet. The development of a test of this kind will extend our ability to screen and diagnose hearing problems outside of a clinical setting and reduce the length and/or frequency of in-person clinical assessment and treatment.

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to report.

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report.

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to report.

5. **CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are*

significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Initially we had planned to conduct study sessions over multiple visits to the Portland VA. However, due to scheduling and loss to follow-up challenges often encountered with the younger Veteran population, we have changed the wording on some of our documents to emphasize that multiple tests sessions may be completed in fewer visits, or even one visit, to the Portland VA if preferred and feasible.

In addition, while changes have not yet been implemented, we have begun to brainstorm changes in approach that may need to occur in order to mitigate any future slowdowns associated with COVID-19.

Actual or anticipated problems or delays and actions or plans to resolve them

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Due to administrative, IRB, and HRPO delays, the starting period to recruit, enroll, and test participants was delayed. In addition, the same week we received HRPO approval to start activities, our facility issued an administrative hold on all non-critical, in-person research activities. In order to decrease any additional testing delay, we have been spending a lot of time pre-screening potential participants so that we can focus on recruitment and data collection as soon as we can resume testing.

It is anticipated that once we do have permission to resume testing, it will be under limited operational status. We are brainstorming ways to streamline the test procedures and develop alternate test methods which are more conducive to remote/mobile/or out-of-the booth testing. For example, we are exploring ways to develop a tablet-friendly version of the TCD and working memory tasks and are investigating ways in which may be able to utilize portable audiometers to test hearing in outdoor environments.

Because we are working with a younger participant population, we anticipate many individuals may cancel and reschedule appointments or not show up for their appointments. Participants in this age range tend to be part of the workforce or seeking employment, making it difficult for them to prioritize study participation. We plan on emphasizing our ability to complete multiple test sessions in one day to decrease the scheduling burden. In addition, we are considering offering the option of weekend and/or evening testing if warranted.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Due to the administrative hold and our inability to test participants, we have not utilized any of the participant payment funds in Year 1. In addition, certain supply and equipment purchases have been postponed due to reduced staff availability at our grant administration site (OHSU) and due to our decision to have more concrete information on when testing may resume prior to proceeding with the purchases to help us determine if any quantities or purchasing decisions need to be altered.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. PRODUCTS: *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

• **Publications, conference papers, and presentations**

Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume; year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report.

Books or other non-periodical, one-time publications. Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

Nothing to report.

Other publications, conference papers and presentations. Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.

Nothing to report.

- **Website(s) or other Internet site(s)**

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to report.

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to report.

- **Inventions, patent applications, and/or licenses**

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report.

• **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- data or databases;
- physical collections;
- audio or video products;
- software;
- models;
- educational aids or curricula;
- instruments or equipment;
- research material (e.g., Germplasm; cell lines, DNA probes, animal models);
- clinical interventions;
- new business creation; and
- other.

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate “no change”.

Example:

Name: Mary Smith
Project Role: Graduate Student
Researcher Identifier (e.g. ORCID ID): 1234567
Nearest person month worked: 5

Contribution to Project: Ms. Smith has performed work in the area of combined error-control and constrained coding.

Funding Support: The Ford Foundation (Complete only if the funding support is provided from other than this award.)

Name: Michelle Molis
Project Role: Principal Investigator
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 6.4
Study contribution: no change

Name: Serena Dann
Project Role: Research Audiologist
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 12
Study contribution: In addition to the continuation of work completed in previous quarters, Dr. Dann has completed work in the area of participant pre-screening and recruitment database preparation.

Name: Melissa Frederick
Project Role: Research Audiologist
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 4
Study contribution: Dr. Frederick organized incoming data needed for participant recruitment and has performed work in the areas of participant pre-screening and COVID study assessment paperwork required for the local IRB.

Name: Naomi Bramhall
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 1.2 (no charge to grant)
Study contribution: no change

Name: Melissa Papesh
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 1.2 (no charge to grant)
Study contribution: no change

Name: Gregory Sebastian
Project Role: Research Assistant
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 12
Study contribution: Mr. Sebastian assisted in the piloting of study tests and has performed work in the area of participant pre-screening.

Commented [DS(1): Not sure if you want to leave your study contribution as “no change” or if you want to add a few sentences about your contributions over the past year.

| | |
|--|------------------|
| Name: | Garnett McMillan |
| Project Role: | Biostatistician |
| Researcher Identifier (e.g. ORCID ID): | n/a |
| Nearest person month worked: | 1.8 |
| Study contribution: | no change |
| Name: | Samuel Gordon |
| Project Role: | Engineer |
| Researcher Identifier (e.g. ORCID ID): | n/a |
| Nearest person month worked: | 1.8 |
| Study contribution: | no change |

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to report.

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:

Organization Name:

Location of Organization: (if foreign location list country)

Partner’s contribution to the project (identify one or more)

- Financial support;
- In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);
- Facilities (e.g., project staff use the partner’s facilities for project activities);
- Collaboration (e.g., partner’s staff work with project staff on the project);

- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Organization Name: Oregon Health Sciences University (OHSU)

Location of Organization: Portland, Oregon

Partner's contribution to the project:

- Financial distribution
- Purchasing
- Grant administration
- Joint IRB oversight with VA Portland HCS

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.*

9. **APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*