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TITLE: Toward 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 and Science University - Portland

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

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6. AUTHOR(S)

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5e. TASK NUMBER

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

VA Portland Health Care System – NCRAR
3710 SW US Veterans Hospital Road
Portland, OR 97239

With a subcontract to:
Oregon Health & Science University (OHSU)

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Development Command
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13. SUPPLEMENTARY NOTES

14. ABSTRACT

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). The proposed research will test Veterans separated from the military within the previous five years with no more than a mild hearing loss as a preliminary step toward further test development in both active-duty and clinical populations. Performance on the TCD task will be related to self-reported difficulties with hearing in everyday life as measured by the Speech, Spatial and Qualities of Hearing Scale (SSQ-12). 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. 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 difficultly in challenging listening situations.

15. SUBJECT TERMS
hearing; hearing disorders, hearing loss, sensorineural; hearing loss, central

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
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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 difficultly 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	95*
Subtask 4: Purchase equipment and computer	1-3	90*
Subtask 5: Set up IHS system	4	100
Subtask 6: Hire Research Assistant (RA)	1	100
Subtask 7: Modify TCD computer program	4	100
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	97*
Major Task 2: Data collection		
Subtask 1: Recruit subjects (10-11 per month)	6-36	40*
Subtask 2: Test subjects	6-36	70*
Subtask 3: Monitor recruitment and data collection	6-36	70*
Milestone(s) Achieved: 300 subjects recruited and tested; adjustments made to recruitment methods as needed	6-36	30*
Major Task 3: Data analyses		
Subtask 1: Quarterly interim data analyses on validation subjects to update prediction model	6-36	0*
Subtask 2: Annual report of prediction model and evaluation of test predictive utility	6-36	0*

* Note: COVID-19 related delays. 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: In Y3, research staff sent over 650 recruitment letters and made over 1500 follow-up phone calls to Veterans previously identified as potential candidates through the pre-screening process. Of the 112 individuals screened over the phone, 67 were eligible for in-person screening. Participant testing began in Y2Q2. Efforts are ongoing to collect TCD data from currently enrolled participants. We have begun to analyze all other data collected from Y3. This has yielded a sample of individuals with varying self-reported hearing ability so that relationships between hearing ability and TCD can be explored.

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

3) Significant results: Subject testing began in Quarter 2. To date 92 individuals have been consented and 77 individuals (61 males) have enrolled in the study. We have scheduled ~ 200 and completed around 125 testing visits resulting in the following data set:

ABR	APD	LENS-Q	N-Back/ Corsi	OAE	Questionnaires	Stroop	TCD	WBR
59	66	69	60	62	77	64	61	67

The discrepancy between the number of scheduled and number of completed visits is due to participants cancelling, rescheduling, or not showing up for appointments. Please see the Changes/Problems section for more details.

Ultimately, Bayesian statistics will be used 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.

4) Other achievements:
Nothing to 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.

The project was not intended to provide training or professional development opportunities for the field in general.

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.

We will continue with best efforts to recruit, enroll, and test Veteran participants and will analyze and report findings on all available data. Once we have collected sufficient data, we will begin to address how performance on the TCD test corresponds to Veterans' self-reported difficulties with hearing with statistical model development that investigates the relationship among indirect measures of outer hair cell (OHC) function (otoacoustic emissions), synaptic/neuronal function (auditory brainstem response and wideband acoustic reflexes), central auditory processing, and working memory (Stroop, N-Back, Corsi blocks) to determine speech processing ability.

4. **IMPACT:** D*escribe 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.

The findings of this project are likely to impact the health and well-being of the general population through the development of a test that can be used to screen and monitor the speech understanding of the aging population. Once the initial statistical model is developed, it can be evaluated and modified for application to older individuals with greater degrees of hearing loss.

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.*

Many hearing aid companies are developing methods to estimate hearing ability remotely. The COVID-19 pandemic has highlighted the importance for telehealth and developing remote test measures.

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.*

Although many Service members with suprathreshold auditory dysfunction will experience little difficulty understanding speech in favorable communication situations, they will experience greater difficulty communicating in challenging listening environments such as in combat training or on the battlefield. It would be difficult to recreate a communication setting that is as complex and challenging as a real-life operational environment for the purposes of auditory testing. However, increasing the demands of listening tasks and simulating high-pressure communication situations can be achieved with the presentation of time-compressed signals.

Better methods of monitoring hearing changes in military service members that extend beyond pure tone thresholds are required so that auditory damage can be detected early, and appropriate preventative measures taken to minimize additional dysfunction. No forward operations screening for suprathreshold auditory function currently exists. A brief version of TCD test that could be used as a screener and a more comprehensive version that could serve as a differential diagnosis assessment could help assess whether a Service Member's hearing capability is sufficient to perform assignment duties.

Use of the test could be expanded to other environments where noise can severely impact speech understanding ability (e.g. hospital wards, manufacturing plants, etc) to help create a metric for when breaks need to be implemented or if certain pieces of noise-generating equipment need to be sound treated or re-engineered to reduce decibel output.

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.

Nothing to report.

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.

Until April of 2020, Portland VA research was adhering to the CDC guidelines recommendation of only bringing in individuals who were not at higher risk for severe disease from COVID. In addition, in order to adhere to COVID guidelines on time-out periods and number of individuals in the facility, NCRAR had implemented a restricted patient testing schedule in which studies are only allowed to test individuals on pre-determined days.

While we were off to a good start at the beginning of Quarter 2, recruitment and enrollment efforts slowed during Quarter 3. However, Quarter 4 was more successful. In general, enrollment still proves to be more challenging across all studies at NCRAR. Several individuals have expressed hesitation at coming in for testing due to COVID-19. Out of those who have expressed interest and were scheduled for a screening visit, many cancel and reschedule appointments or do not show up for their appointments. In the past, we often posted flyers around local universities and attended Veteran outreach events. However, many of these avenues are no longer an option due to COVID. Revisions were made to recruit individuals through the GovDelivery listserv. However, we have received very few responses to the thousands of emails that have been sent out to individuals on the list. In general, there has been slow down in recruitment. We feel as though COVID has shifted the priorities of many people and individuals express no longer having the interest or availability to participate.

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. This may include testing at community-based outreach centers, phone consenting, and/or tablet-based testing.

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. We will also continue to offer the option of weekend and/or evening testing if warranted. We have also implemented a study completion bonus of $50 to help incentivize the completion of all study visits.

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 delays in participant testing, we have not utilized all of the participant payment funds allocated for Year 3.

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: Dr. Molis has aided in the development in a Python-based version of the TCD program.

Name:	Serena Dann
Project Role:	Research Audiologist
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	7.2

Study contribution: In addition to the continuation of work completed in previous quarters, Dr. Dann has completed work in the areas of participant recruitment and enrollment, data collection, organization and analysis.

Name: Melissa Frederick
Project Role: Research Audiologist
Researcher Identifier (e.g. ORCID ID): n/a
Nearest person month worked: 4
Study contribution: Dr. Frederick has completed work in the areas of participant recruitment and enrollment, data collection, organization and analysis.

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: Dr. Bramhall has aided in the development in a Python-based version of the ABR scoring program used to analyze study ABR data.

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: Dr. Papesh has aided in the development in a Python-based version of the TCD program.

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 participant recruitment and scheduling.

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.