GSA Webinar Series

Hearing- and Vision-Related Practical Strategies for Clinical Research With Older Adults During COVID-19 Pandemic

WEDNESDAY, JUNE 24, 2020
Webinar Panel

• Heather E. Whitson, MD, MHS, Associate Professor of Medicine (Geriatrics) and Ophthalmology, Duke University School of Medicine (Moderator)

• Nicholas S. Reed, AuD, Assistant Professor, Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health; Instructor of Audiology in the Department of Otolaryngology-Head and Neck Surgery at the Johns Hopkins School of Medicine.

• Bonnielin Swenor, MPH, PhD, Associate Professor, Wilmer Eye Institute, Johns Hopkins School of Medicine; Associate Professor of Epidemiology, Johns Hopkins Bloomberg School of Public Health

• Frank R. Lin, MD, PhD, Professor of Otolaryngology and Epidemiology; Director, Cochlear Center for Hearing and Public Health, Johns Hopkins Bloomberg School of Public Health

• Alan Stevens, PhD, Holleman-Rampy Centennial Chair in Gerontology & Director, Center for Applied Health Research at Baylor Scott & White Health; Professor, Texas A&M Health Science Center
Webinar Agenda

1. Importance of recognizing sensory loss and considerations for addressing it in research settings
2. Adaptation of the Aging and Cognitive Health Evaluation in Elders (ACHIEVE) Randomized Trial due to COVID-19
3. Adaptation of the Dementia Care Study due to COVID-19
4. Audience Question & Answer
Importance of Recognizing Sensory Loss and Considerations for Addressing It in Research Settings

Bonnielin Swenor, MPH, PhD, Associate Professor, Wilmer Eye Institute, Johns Hopkins School of Medicine

Nicholas S. Reed, AuD, Assistant Professor, Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health
Hearing Loss Prevalence

- Nationally representative data (NHANES 2001-2008)
- ~50% of all adults over 60 years of age have a hearing loss

Lin et al., Arch Int Med. 2011
Hearing Aid Use

- Nationally representative data (NHANES 2001-2006)
- Only 16.4% of older adults (>50 years) with hearing loss own and use a hearing aid
• Generally a clarity issue, not only volume

“You should go to the pharmacy before you get to your house.”
Vision Loss Prevalence

• 2.2 billion people are visually impaired or blind worldwide
  o 1/3 of the global population
  o ~14 million American adults
• Prevalence increases with age

Understanding Vision Loss
Understanding Vision Loss

- Vision is complex
- More than glasses or “blindness”
- Affects most aspects of daily life
# Sensory Loss Considerations: Technology

**VISION**
1. Magnification and contrast
2. Text to speech
3. Accessibility options
4. Guided technology

**HEARING**
1. Handheld amplifier / smartphone amplifier
2. Speech to text
3. Videoconferencing
4. Guided technology
Sensory Loss Considerations: Environment

- ENVIRONMENT
  - Lighting and glare
  - Noise
  - Whiteboards / pre-prepared placards
## Sensory Loss Considerations: Communication

<table>
<thead>
<tr>
<th>VISION</th>
<th>HEARING</th>
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<tbody>
<tr>
<td>1. Image description</td>
<td>1. Ensure attention</td>
</tr>
<tr>
<td>2. Introduce yourself</td>
<td>2. Facial visualizations (i.e., mouth)</td>
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<tr>
<td>3. Do not rely on gestures or facial expressions</td>
<td>3. Slow speech, don’t shout</td>
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<tr>
<td>4. Ask for feedback</td>
<td>4. Rephrase, don’t repeat</td>
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[Image: The Gerontological Society of America logo]
Sensory Loss Considerations

- All people improve communication from these tips

- Adults with Dual Sensory Impairment are especially vulnerable and benefit from redundancy
Adaptation of the Aging and Cognitive Health Evaluation in Elders (ACHIEVE) Randomized Trial due to COVID-19

Frank R. Lin, MD, PhD, Professor of Otolaryngology and Epidemiology; Director, Cochlear Center for Hearing and Public Health, Johns Hopkins Bloomberg School of Public Health
ACHIEVE: Study Overview

Primary question: Among 70-84 y.o. community-dwelling older adults with mild to moderate hearing loss (N=977), does provision of a hearing loss intervention compared to a successful aging education control intervention reduce rates of cognitive decline over 3 years of post-randomization follow-up?

Main inclusion criteria

- Mild-to-moderate sensorineural hearing loss not using hearing aids
- Vision testing with MN Vision Near Vision Card (20/63 or better ➔ 14 pt font at 16 inches)
- 70-84 years, community dwelling
- No cognitive impairment
ACHIEVE: Study Overview

Study visits

• Baseline visit and randomization (Jan 2018 – Oct 2019)
• 4 study intervention visits (Jan 2018 – Feb 2020)
• Semiannual visits for 3 years (July 2018 – present)

Study outcomes

• **Primary outcomes**: Global and domain-specific cognitive function measured with a comprehensive neurocog battery (1 hour)
• **Secondary outcomes**: Adjudicated dementia/MCI diagnoses, depression, communicative and social function, physical functioning, accelerometry, falls, hospitalizations, brain MRI (~2-3 hours)
ACHIEVE: Prior to COVID-19

- Conducted in person at established field sites
- Staff trained to work with older adults
- Participants instructed to bring and use sensory aids
- Prior to neurocognitive testing at all visits, “Ensuring Speech Understanding” test
- Participants not provided with portable amplifier or similar systems → Psychometric testing conditions have to be transferable to real-world situations for the participant
- Site workload: ~8-10 visits/week
ACHIEVE: COVID-19 Contingency Planning

Mid-March to Early April

• Mid-March → All sites suspended in-person clinic visits for participants

• Contingency planning priorities
  o Participant safety
  o Research integrity
    1. Maintaining engagement
    2. Delivering interventions
    3. Prioritized data collection
ACHIEVE: COVID-19 Contingency Planning

Mid-March to Early April

• Convening of CARE committee

• Postcard mailer sent to all participants

• COVID-19 guidance document for staff on how to discuss concerns

• Planning for mailing of cloth face mask with study logo to all study participants
### ACHIEVE: Immediate Short-Term Actions

*In April, memo released on standardized procedures providing guidance on:*

<table>
<thead>
<tr>
<th>Conversion to phone-based visits</th>
<th>Delivery of hearing and successful aging education treatments</th>
<th>Cognitive screener: standardization of phone delivery</th>
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<tbody>
<tr>
<td>Response cue cards and other materials mailed or on study website</td>
<td>Messaging about continuation of study</td>
<td>Handling questions about COVID-19</td>
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</table>
ACHIEVE: Medium-Term Actions

Mid-April to June

Adapting QC procedures
- Track missed visits, missing data, consistency of data collection

Pilot testing a phone-based neurocog protocol
- Goal to implement full neurocognitive protocol via telephone

Planning for enhanced retention efforts
- Additional calls from audiologists and successful aging educators
ACHIEVE: Long-Term Actions

May to December

Assuming resumption to full ‘normality’ won’t be until 2022 or later, planning for:

• Indefinite continuation of phone visits

• Testing feasibility of mailing pre-configured tablets to participants to allow for consistent videoconferencing – www.grandpad.net

• Possible home visits by study staff for Year 3 visits and potentially other visits as well
Adaptation of the Dementia Care (D-Care) Study Supporting Individuals and Caregivers due to COVID-19

Alan Stevens, PhD, Holleman-Rampy Centennial Chair in Gerontology & Director, Center for Applied Health Research at Baylor Scott & White Health; Professor, Texas A&M Health Science Center
COMPARATIVE EFFECTIVENESS OF HEALTH SYSTEM-BASED VERSUS COMMUNITY-BASED DEMENTIA CARE /
A PRAGMATIC TRIAL OF THE EFFECTIVENESS AND COST-EFFECTIVENESS OF DEMENTIA CARE

DAVID B. REUBEN, MD, PRINCIPAL INVESTIGATOR

CO-I’S AND SITE PI’S: DAVID BASS, PHD; THOMAS GILL, MD; LEE JENNINGS, MD;
MAYA LICHTENSTEIN, MD; PETER PEDUZZI, PHD; ALAN STEVENS, PHD; ELENA VOLPI, MD; JEFFREY
WILLIAMSON, MD

PCORI GRANT NUMBER: PCS-2017C1-6534
NIA GRANT NUMBER: 1 R01 AG061078-01
D-CARE Study: Objective

- Compare the effectiveness and cost-effectiveness of 3 unique approaches to supporting dementia care provided to families:
  
a) An evidence-based intervention provided by a community service organization (i.e., the Area Agency on Aging)

  b) An evidence-based intervention provided a health care system

  c) A nationally available telephone-based support program by the Alzheimer’s Association
D-CARE Study: Design

Using a pragmatic randomized clinical trial at 4 clinical trial sites representing a range of:

- Geographic regions
- Types of health care organizations
- Predominant payment systems

All study-related interactions with participants are conducted via telephone or telehealth.
# Retooling from In-Person to Telephone-Based Data Collection

## OBJECTIVE

1. Convert in-person written informed consent to telephone-based consent for both the person living with dementia (PWD) and the family caregiver.

2. Convert baseline interview of the PWD and family caregiver from in-person administration to telephone administration, (including standardized cognitive screening tool of the PWD and dementia caregiving-related questions).

3. Adapt one arm of the study from in-clinic care delivery to telehealth care delivery.

## PRIMARY TASKS

1. Identify and obtain central and local IRB approval for changes that support the objective.

2. Modify and pilot test the telephonic approach to obtaining informed consent and conducting interviews with PWD and family caregiver.

3. Modify data collection, data entry, and data flow structure of REDCap.
Challenges for Telephonic Administration of the Montreal Cognitive Assessment (MoCA)

Interviewers are challenged to:

1. Know basic contextual information about interviewee
2. Assess severity of cognitive and/or sensory impairment prior to phone calls
3. Notice nonverbal cues of agitation
4. Provide clear expression of the letters
5. Confirm that participant heard each item when repetition is supposed to be limited
6. Ensure a 5-minute delay between word recall and delayed recall
7. Deliver and score fluency of questions
Practical Strategies for Telephonic Administration of the MoCA

To do prior to the interview:

1. Provide copies of materials and branded paper by mail or email prior
2. Test the best method for fluency questions (tapping vs. clapping)

To do frequently during the interview:

1. Use participant’s name
2. Ask participant about willingness to continue or stop
3. Monitor engagement of the caregiver across the entire interview and have them refrain from helping the person with dementia

MoCA: Montreal Cognitive Assessment
Feedback From Family Caregivers Who Assisted With Pilot Test

<table>
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<tr>
<th>Enunciate and speak slower for hearing-impaired participants</th>
<th>Pause when listing words</th>
<th>Use visuals</th>
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<tr>
<td>Consider that participants will be using landline receiver</td>
<td>Be in a quiet place, without distractions</td>
<td>Frequently repeat interviewee names and encourage them</td>
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World Hearing Day and Sensory Interest Group

March 2020 Articles:
The Journals of Gerontology, Series A
The Journals of Gerontology, Series B
The Gerontologist
Innovation in Aging
Available at: https://medium.com/@OUPAcademic/world-hearing-day-2020-4c363a823b40

Sensory Health Interest Group
Convened by Bonnielin Swenor, bswenor@jhmi.edu
and Heather Whitson, heather.whitson@duke.edu
Question & Answer

• Thank you for joining us today!

• Please contact us with any questions:
  o Dr. Heather Whitson: heather.whitson@duke.edu
  o Dr. Bonnielin Swenor: bswenor@jhmi.edu
  o Dr. Nicholas Reed: nreed9@jhmi.edu
  o Dr. Frank Lin: flin1@jhmi.edu
  o Dr. Alan Stevens: Alan.Stevens@BSWHealth.org

• Archived recording of webinar on GSA’s YouTube channel
Webinar Evaluation

In an effort for continual improvement, we would like to hear your thoughts.

Please provide feedback by clicking the survey link at the end of the webinar.

Thank you again and we hope you enjoyed the program!