

Hearing Intervention & Cognition: Review of the Evidence and Current Trials

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Learning Outcomes

After this course learners will be able to...

- Summarize the observed associations between hearing loss and cognition from available epidemiology research.
- Describe the need for the current clinical trials underway to determine if hearing intervention can mediate cognitive decline.
- Identify at least two (2) outcomes that can be utilized to assess the perceived benefits of hearing intervention in audiological clinical practice.



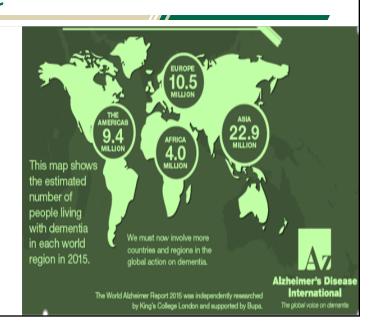
Presentation Outline

- 1. Prevalence of Dementia
- 2. Review of epidemiological research indicating the association between hearing loss, poor health outcomes, and cognitive decline
- 3. Review of clinical trials evaluating the influence of hearing intervention on cognition and quality of life
- 4. Summary of what is known and what implications current studies will have on the landscape of hearing healthcare
- 5. Discussion and Questions?

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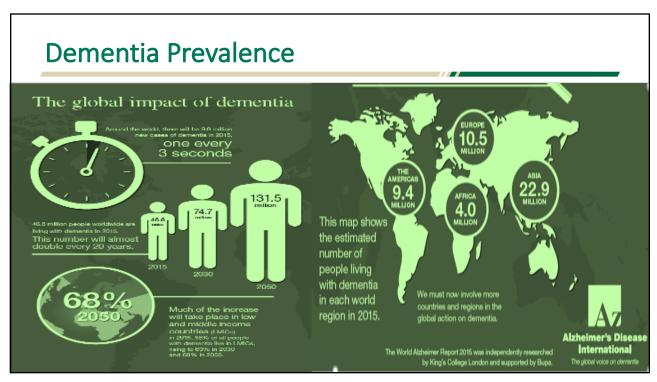
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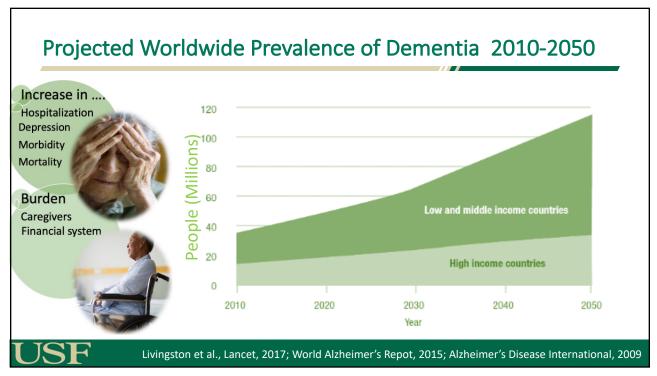
Dementia Prevalence

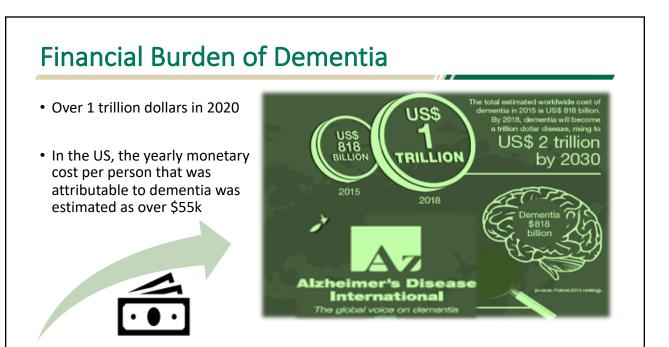


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World Alzheimer's Repot, 2015; Hurd et al., N Engl J Med, 2013; Alzheimer's Disease International, 2009

Aging Population

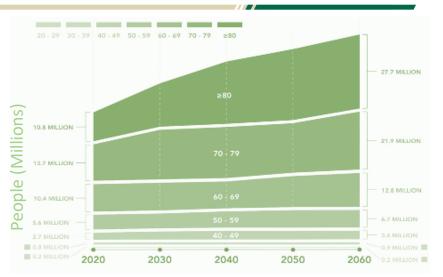
• Silver tsunami!



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Aging Population

- Silver tsunami!
- Switching to more older adults than younger
- In 2012, 60% of older adults managed 2 or more chronic conditions.

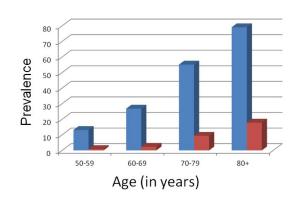


Colby et al., U.S. Census Bureau, 2014; Ward et al.; Prev Chronic Dis, 2014

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Prevalence of Hearing Loss

Figure 1 Prevalence of hearing loss & hearing aid use in the United States



- 5% of the world's population has disabling hearing loss
- By 2050, the number of people suffering from hearing loss could increase to 12.5%
- Prevalence of hearing loss nearly doubles with every age decade
- 2 of every 3 adults 70 years or older has a clinically-significant hearing loss
- <20% of these individuals use a hearing aid
- Global production of hearing aids meets less than 10% of the global need

WHO, 2017; Lin Arch Intern Med. 2011; Lin J Gerontol A Biol Sci Med Sci. 2011; Chien & Lin, Arch Intern Med. 2012

Economic Burden of Hearing Loss

- Estimated costs of unaddressed hearing loss amounts to \$750 billion per year worldwide.
- Hearing Loss causes immense annual costs including costs of educational support, loss of productivity, and societal costs, and health sector costs (excluding devices)
- In the United States, estimates of the economic cost of lost productivity varied from \$1.8 to \$194 billion, and direct medical costs ranged from \$3.3 to \$12.8 billion.



GLOBAL COSTS OF UNADDRESSED HEARING LOSS AND COST-EFFECTIVENESS OF INTERVENTIONS Executive Summary



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WHO, 2017; Huddle et al. JAMA-OTO, 2017

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Effects of Untreated Hearing Loss

Hearing Loss in older adults results in an increased likelihood of....

- · Decreased quality of life
- · Social isolation
- Depression
- · Poor mental health
- · Decreased self-sufficiency in Activities of Daily Living
- · Hospitalization
- Reduced walking speed
- · Increased risk of falls
 - ... Accelerated cognitive decline and dementia







(National Council on Aging, 1999; Carabellese et al., JAGS, 1993; Li et al., Gait & Posture 2012; Lin et al. Arch Int Med 2012; Genther et al, JAMA, 2013)



Epidemiologic Analyses

Table 5.—Risk of Dementia at Various Levels of Hearing Loss

Hearing Loss, dB	Adjusted Odds Ratio*	95% Confidence Interval
Mild (20-29)	1.5	0.4-5.4
Moderate (30-39)	2.2	0.6-7.8
Moderate/severe (≥40)	4.1	1.1-15.8

^{*}Odds ratio was adjusted for family history of dementia, depression diagnosis, number of prescription medications, and source of primary care. Reference odds ratio for normal hearing (<20-dB loss) is 1.0. Trend of increasing risk of dementia for increasing level of hearing loss is statistically significant (*P*<.05).



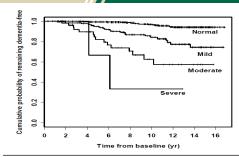
(Uhlmann, Larson, Rees, Koepsell & Duckert, JAMA 1989)

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Hearing Loss & Cognition/Dementia

Epidemiologic Analyses

- NHANES: National Health and Nutritional Examination Surveys
 - Cross-sectional, representative sample of U.S. population
- HealthABC: Health, Aging, & Body Composition Study
 - Prospective, population-based study of ~3000 adults 70 years and older
- BLSA: Baltimore Longitudinal Study of Aging
 - Ongoing prospective study of older adults since 1958;
 Dementia incidence in 639 adults followed for >10 years

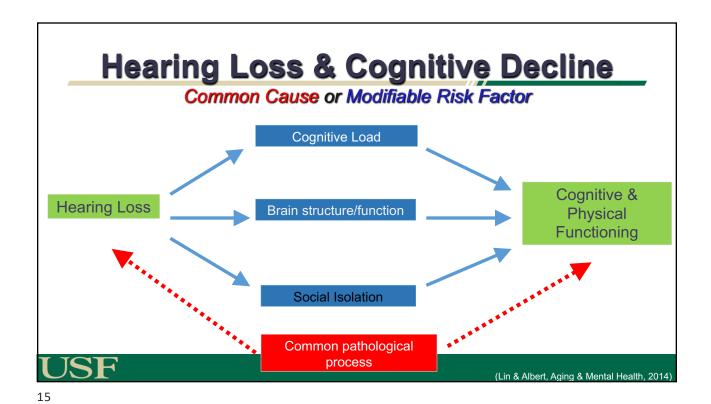


	<u>HR</u>	95% CI	<u>p</u>
Mild	1.89	1.00 – 3.58	0.05
Moderate	3.00	1.43 - 6.30	.004
Severe	4.94	1.09 – 22.4	.04

^a Adjusted for age, sex, race, education, DM, smoking, & hypertension

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Lin et al., Arch Neuro., 2011



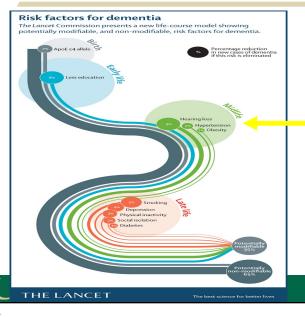
Summary: Dementia, Hearing, & Aging Population



- High prevalence of dementia
- Hearing Loss is highly prevalent in older adults and has been associated with adverse health outcomes
- Association between hearing loss and cognition
- Significant public health concern

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Lancet Commission on Dementia Prevention, Intervention & Care



- 1/3 of dementia cases may be preventable through modifiable lifestyle factors
- Managing diabetes, obesity, smoking, and hearing loss
- Hearing loss in mid & late life identified as the modifiable risk factor for dementia

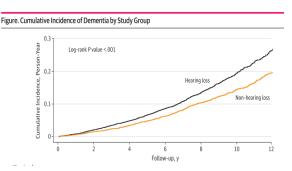
G. Livingston et al., Lancet, 19 July 2017

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Hearing Loss & Cognition/Dementia

Epidemiologic Analyses

- Danish Conscription Database & Danish Conscription Registry (DCD & DCR):
 - 942,567 Danish men
 - Midlife hearing loss was associated with an increased rate of dementia diagnosed before the age of 60 (Osler et al. 2019)
- National Health Insurance Research Database of Taiwan:
 - Dementia incidence rate in the hearing loss group was higher than the normal hearing group (Liu et al. 2019)
 - The group with hearing loss aged 45 to 64 was associated with the highest risk of dementia



The 8135 patients with hearing loss (HL group) were matched by sex, age, residence, and insurance premium with 8135 individuals without hearing loss (non-HL group).

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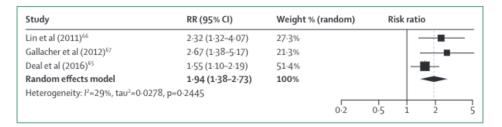
Osler et al 2019; Liu et al. 2019



Epidemiologic Analyses

Evidence is strong with hearing loss independently associated with:

- 2-5 fold increased risk of incident dementia
- · Accelerated cognitive decline on cognitive assessments (3MS and digit symbol test)
- Accelerated whole brain and lateral temporal lobe atrophy
- Across studies, consistent report of 1.9 increase in dementia risk



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Neurology 2012; Arch Neuro 2011; Arch Int Med 2013; Neurolmage, 2014; Livingston et al., Lancet, 2017

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Hearing Loss & Cognition/Dementia Want More Details? AudiologyOnline! Hearing Loss & Aging: A Public Health Perspective Want I See the second of the sec

How about hearing intervention and Cognition/Dementia?

- Hearing intervention
 - Improved communication
 - speech recognition, listening ability
 - · Improve quality of life
 - Listening effort, memory, and other cognitive outcomes



Although some unaided/aided experiments and cross-sectional cohort studies have reported either improved cognition or slower rate of cognitive decline with hearing aid use, others have found no significant effect.



Ferguson et al., Cochrane Database of Systematic Reviews, 2017; Dawes et al., Int J Audiol 2015

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Hearing Loss & Cognition/Dementia

Determining the role of hearing intervention in attenuating cognitive decline/dementia in observational studies is not possible.

- Individuals choosing to use hearing aids differ substantially from those who do not
- Hearing intervention cannot be determined from observational data
- Limitation in the current literature include:
 - small sample size
 - retrospective design
 - self-report hearing aid use
 - self-report hearing loss; and, type, degree, and configuration of hearing loss are not defined

Sarant et al., 2020

- 99 adults 60-84 years old, followed for 18 months with well controlled hearing aid usage
- Improved speech perception, self-reported listening disability and quality of life
- No decline in cognitive battery and improved executive function
- No control group or randomization



Sarant et al, J Clin Med, 2020



Mulrow et al., 1990

- Randomized Controlled Trial (RCT) of hearing treatment (n = 192 veterans)
- Outcomes measured at 4 months post-tx
- Reported improved communicative and emotional functioning
- Improved cognition (cognitive screener)

Results never confirmed in a trial with a larger representative cohort, using current hearing rehabilitative strategies/technologies, and evaluating cognition with longer follow-up (to observe for reduced risk of decline/incident dementia)



Mulrow et al Ann Intern Med 1990

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The question of whether treating hearing loss could delay cognitive/physical decline or dementia remains unknown

There has never been a randomized clinical trial of treating hearing loss to explore effects on reducing the risk of cognitive decline/dementia





Generating the Evidence: Multiphase Process



Efficacy Studies with **Appropriate** Comparison

- · Efficacy trial to test the clinical benefit of an intervention when delivered in a setting optimized to detect an effect
 - best-trained providers
 - · specific enrollment criteria
 - extensive follow-up
 - · precise study protocol

https://nccih.nih.gov/grants/mindbody/framework 25

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The <u>Aging and Cognitive Health Evaluation in Elders</u> (ACHIEVE RCT)











In partnership with Josef Coresh, MD PhD and the Atherosclerosis Risk in Communities-Neurocognitive Study (ARIC-NCS)



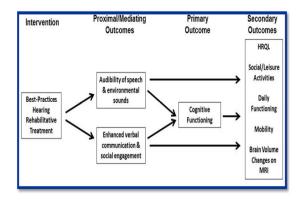
Clinicaltrials.gov Identifier: NCT03243422



ACHIEVE RCT: Rationale

- Aim of ACHIEVE is to determine the effects of best-practices hearing Intervention on:
 - Outcome measures
 - · Rates of cognitive decline
 - Health-related quality of life, social/leisure activities, daily functioning, mobility, and longitudinal brain atrophy on structural MRI.
 - To investigate the mechanistic pathways through which hearing rehabilitative intervention affects cognitive functioning

Figure 2. Conceptual Model for the Clinical Trial



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ACHIEVE Trial Design: Timeline & Overview of RCT

- Timeline
 - 2014-2016: RCT planning process (R34AG046548)
 - Feasibility study, development of protocol/manualized interventions, etc.





The Hearing Intervention for the Aging and Cognitive Health Evaluation in Elders Randomized Control Trial: Manualization and Feasibility Study

Victoria A. Sanchez, Michelle L. Arnold, Nicholas S. Reed, Preyanca H. Oree, Courtney R. Matthews, Ann Clock Eddins, Frank R. Lin, and Theresa H. Chisolm

Objective. The sook describes the development of a massilate beauty controlled beauty interesting in the Adapt and Copytine Install Evaluation in Biological Consistency in the Adapt and Copytine Install Evaluation in Biological Consistency of the Consistency of Consistency of Installation in Consistency of Installation in Consistency of Consist

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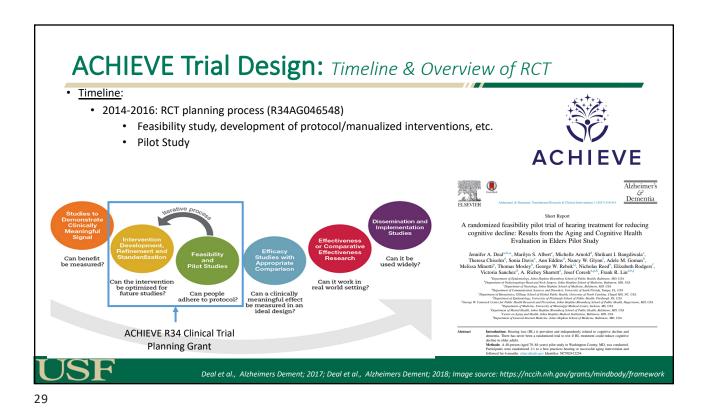
Design: Following published recommendations for manualized intervention development, an interaline process was used to define the AMEMEY-bearing intervention elements and create an inteller natural. The intervention was then delivered within the ACHIENE-Feesibility study using one-group pre-post design appropriate for assessing questions related to intellerentation. Participants were recruited from the Tampa. easibility study activities, results, and clinician and participant informa eedback.

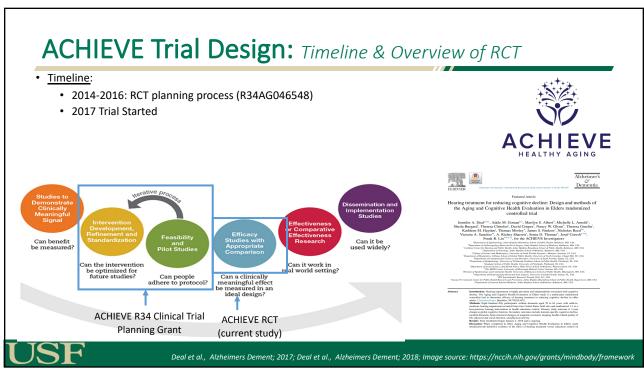
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Key words: Clinical trial, Feasibility, Hearing intervention, Manualizat

Sanchez et al., Ear&Hear 2020; Image source: https://nccih.nih.gov/grants/mindbody/framework

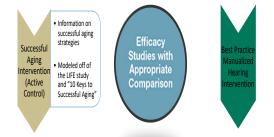






ACHIEVE Trial Design: Timeline & Overview of RCT

- Timeline:
 - 2014-2016: RCT planning process (R34AG046548)
 - · 2016 Trial grant submission
 - 2017-18 Recruitment at ARIC field sites
 - 2018-21 Follow-up
 - · 2022 Results



- <u>Participants</u>: Recruited 977 healthy, cognitively normal community-dwelling adults 70-84 years old with untreated mild-moderate HL
- <u>Intervention:</u> Randomization to best-practices hearing rehabilitative treatment vs. successful aging intervention control



Newmanet al., J Aging Health. 2010; https://nccih.nih.gov/grants/mindbody/framework

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ACHIEVE Hearing Intervention

Comprehensive Evaluation & Educational Counseling



Individualized Goal Setting, Educational Counseling, & Self-Management



Sensory Management: Hearing Aids, Educational Counseling, & Self-Management

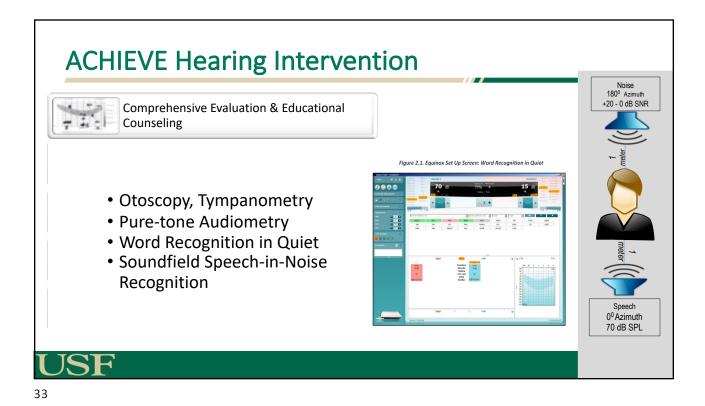


Hearing Assistive Technologies, Educational Counseling, & Self-Management



Outcomes Assessment

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Purpose: Target participantspecific communication needs and foster realistic expectations

- Must create **person-centered** goals for hearing intervention
 - Client Oriented Scale of Improvement (COSI)
- Goals must be **specific** and **prioritized** by the participant



Dillion et al., JAAA 1997





- Centered around Amplification:
 - Selection of appropriate level of hearing aid technology
 - Electroacoustic analysis
 - On-ear device verification





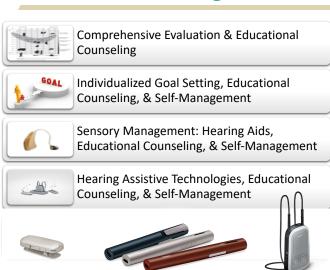




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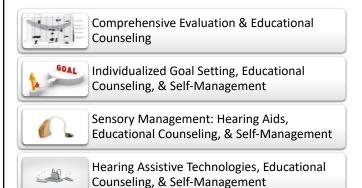
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ACHIEVE Hearing Intervention



- Hearing Assistive Technology
 - Selection of technology Based on QuickSIN, hearing loss, COSI goals, and participant history and preferences

ACHIEVE Hearing Intervention



Education, Counseling, Self-Management

 Orientation, counseling, and followup in ACHIEVE are standardized

....and of course! Our audiologists' expertise!

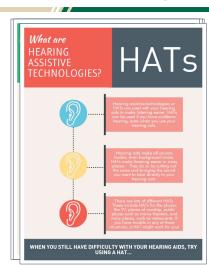
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ACHIEVE Hearing Intervention: Toolkit for Self-Management ©

Toolkit for Self-Management ©

- Teach adult hearing aid users about their hearing loss
- Support new hearing aid users by providing strategies based on their goals; Customized to a participant's specific goals for intervention
- · Topics include:
 - · Understanding in noise
 - Communication strategies
 - Telephone and television
 - Meetings & Crowds
 - · Places of worship
 - HATs
- Be understood by persons from a variety of health literacy backgrounds and incorporate inclusive, racially-diverse images





Arnold, M. L., Oree, P., Sanchez, V., Reed, N., & Chisolm, T. (2019). Development and formative assessment of the Hearing Loss Toolkit for Self-Management. Seminars in Hearing, 40(1), 49-67. doi: 10.1055/s-0038-1676783



ACHIEVE Hearing Intervention: C2Hear RLOs

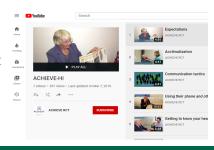
C2Hear Reusable Learning Objects (RLOs)

ACHIEVE-HI RCT YouTube

https://youtu.be/T85pTnv4614

- C2Hear RLOs Americanized
 - Nottingham University Biomedical Research Unit
 - Brief, 2-7 minute video clips
 - Cover a variety of common topics and issues for hearing aid users







Ferguson et al., Ear & Hear 2016; Oree et al, AAS Presentation 2018

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ACHIEVE Hearing Intervention: Fidelity & Post-Intervention



Intervention Fidelity

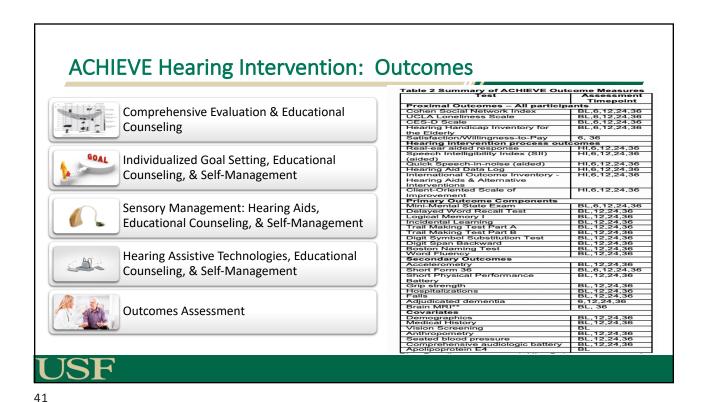
- The ongoing assessment, monitoring, and enhancement of the reliability and internal validity of a study
- Intervention fidelity is key in multi-site RCTs to ensure:
 - Consistency across sites
 - Adherence to study protocol

Post-Hearing Intervention

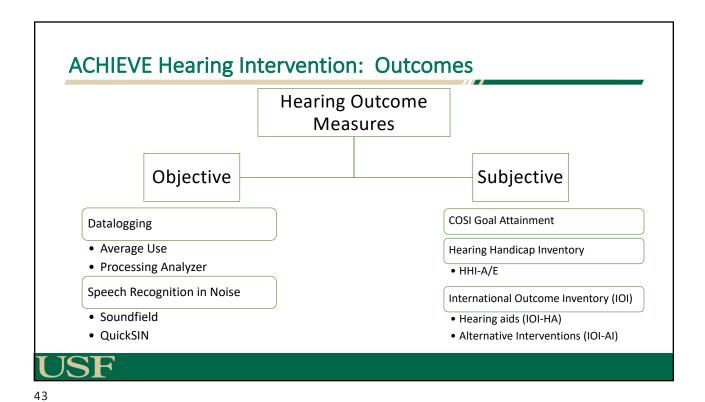
 Post-HI sessions take place at 6, 12, 18, 24, 30, and 36 months following the baseline audiologic evaluation







ACHIEVE Hearing Intervention: Outcomes Outcome Measures Disease Specific Generic Subjective Cognition Hearing Objective* Subjective Objective Subjective * Primary Outcome - Neurocognitive Battery



Generating the Evidence: Multiphase Process Dissemination and Implementation Studies Effectiveness or Comparative Can it be Can benefit and Pilot Studies used widely? Can the intervention Can it work in be optimized for future studies? real world setting? Can people Can a clinically meaningful effect be measured in an adhere to protocol? ideal design? What could be next? ACHIEVE R34 Clinical Trial ACHIEVE R01 (current study) **Planning Grant**

continued

Post-ACHIEVE, what could be next?

Telehealth Approach?

- Expand access and affordability of hearing health care
- Greater flexibility, Lower costs, Individualized plans (lifestyle/listening needs)
- Conducting eAudiology pilot study at USF with re-manualization



What about other patient populations? And, hearing interventions?

- · Conductive or Mixed hearing loss?
- Single-sided Deafness?
- Other hearing interventions
 - · Cochlear implants
 - · Ossesointegrated devices (OID)









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Why other patient populations & hearing interventions?

- Little is known about hearing levels in the large epidemiological datasets
 - Hearing loss is defined by various methods
 - Configurations of hearing losses are not well described
- Reported benefit from OIDs relate to similar reasons of why traditional hearing aids are important for age-related sensorineural hearing loss
 - Improved access to sound
 - Decrease in listening effort
 - Decrease cognitive load `
 - · Improved speech perception
 - · Improved quality of life
 - · Improved memory

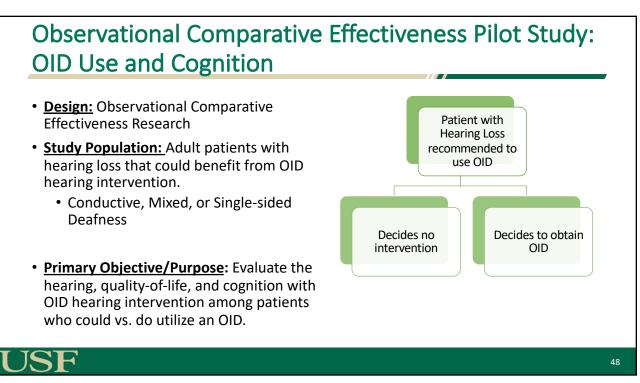




Pittman et al., Ear& Hearing, 2019; Lunner et al, Ear&Hearing. 2016

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OID Use and Cognition: Outcomes

• Study Schedule: Participants will be asked to complete a screening visit and up to 11 study visits.

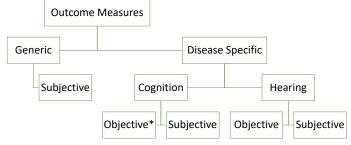
Asse	essment	Screeni	Baselin e		Intervention & Follow-Up Visits								
		Visit 0	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11
		(Day -31 to Day 0)	Day 0	W1-3	W3-5	W6-8	W8-10	6mo	12mo	18mo	24mo	30mo	36mo
				Α	В	С	D		Yr1		Yr2		Yr3
1.	Informed Consent	Х	Х										
1.	Demographics		Х										
1.	Health History Form		Х						Х		Х		Х
1.	Activities of Daily Living	X							Х		Х		X
1.	WRAT		Х										X
1.	Audiometric Assessment (SOC)	x							х		х		х
1.	Neurological Test Battery (Primary Outcome)		х					х	х	Х	Х	х	х
1.	Neurological Interview		Х					Х	Х	X	Х	Х	Х
1.	Questionnaires		Х					Х	Х	X	Х	Х	Х
1.	Adverse Event Assessment/Unanticipated problems		х					Х	Х		Х		Х
OID	Hearing Intervention Participants Only - All	Standard of C	are (SOC) F	rocedures	3.								
1.	Client-Oriented Scale of Improvement (SOC)		Х	Х	х	Х	х	х	х	Х	х	х	х
1.	Word Recognition in Quiet and Noise – Aided (SOC)			Х			х		х		х		х
1.	In-Situ Bone Conduction Audiometry (SOC)			Х				х	х	Х	х	х	х
1.	OID Data Log (SOC)				Х	Х	Х	х	Х	х	Х	х	Х
1.	International Outcome Inventory for Comprehensive Intervention (SOC)						Х	Х	х	х	х	х	х

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OID Use and Cognition: Outcomes

• Study Schedule: Participants will be asked to complete a screening visit and up to 11 study visits.

ACHIEVE Hearing Intervention: Outcomes



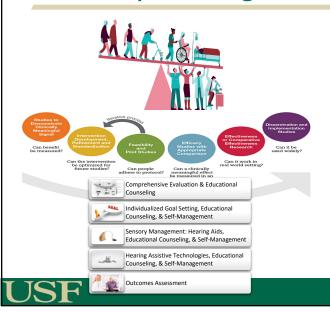
* Primary Outcome – Neurocognitive Battery

.... Stay tuned, study starting this fall!



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Summary: Hearing Intervention & Cognition



- The aging population
 - · High prevalence of dementia
 - · High prevalence of hearing loss
- Association between hearing loss and cognition
- Need clinical trials to determine the mediating effect of hearing intervention on cognitive decline and dementia
- Implications on healthcare policy and healthcare reform

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Acknowledgements

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This is the end of the presentation.... Thank you!

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Courtney Matthews - USF