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

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Presenter: Victoria Sanchez, AuD, PhD

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Partner: OticonMedical

- [Vicky] Okay, I see that the recording has started, so welcome everyone. I am Vicky Sanchez and it is both an honor and a pleasure to present today on behalf of Oticon Medical Sound Matters lecture series. I am an Assistant Professor in the Department of Otolaryngology at the University of South Florida. USF labels me as a clinician scientist as I provide clinical services, seeing patients in our division of audiology a few times per week and the rest of the time is dedicated to academic and research responsibilities. Today I present some of our collaborative work coming from our Auditory Rehabilitation and Clinical Trials Laboratory or more easily referred to as the ARCT Lab. Our ARCT Lab focuses on a variety of auditory disorders and interventions. And with that brief introduction, I want to also thank all of you for joining in today and let's get started. Starting with our learning outcomes, after this course you should be able to summarize the observed associations between hearing loss and cognition from available epidemiological research, describe the need for current trials currently underway to determine if hearing intervention can mediate cognitive decline and also identify at least two outcomes that can be utilized to assess benefit from hearing intervention and audiological clinical practice.

So to move on to our presentation outline, first we will discuss the prevalence of dementia, followed by the review of some epidemiological research indicating the association between hearing loss, poor health outcomes and cognitive decline. We will also review clinical trials evaluating the influence of hearing intervention on cognition and quality of life. Following that, we will summarize what is known and also discuss briefly what implications of these current studies will have on the landscape of the future hearing healthcare. Hopefully there'll be plenty of time after that for some questions and discussion. So to start with dementia prevalence, what I show here is the World Alzheimer's Report from 2015 which indicates that dementia is a worldwide problem. This map shows the estimated number of people living with dementia in the world and these numbers are increasing. In fact, every three seconds, a patient is

diagnosed with dementia. In 2015, there was 46.8 millions of patients with dementia and that number will almost double every 20 years. Much of the increase will take place in low and middle income countries, which might be more easily seen in this figure here. So this figure is representing on the Y axis people by the millions across time and what we can see here is that there will be a dramatic growth in millions across the years, with an increase in the number of people living with dementia, more so in the low and middle-income countries but also in the high-income countries. And with this increase in dementia prevalence, there will also be an increase in hospitalization, depression, morbidity and mortality. There will be a significant increase in burden related to caregivers, both family member caregivers and systematic. There will also be a significant burden on the financial system. So talking about financial burden of dementia, I will show this figure here also from the World Alzheimer's Report. Currently there's over one trillion dollars spent on dementia. In the US, the yearly monetary cost per person that was attributable to dementia was estimated as over $55,000. So that is per patient with dementia, $55,000 per year. Now this number is increasing as well, with an estimated amount reaching two trillion dollars by 2030 and that's just 10 years away. And because there's an increase in dementia, a lot of that is related to also our aging population that's increasing.

Shown here is a metaphor used to describe the population aging, known as the Silver Tsunami. So being based out of Florida and being a beach goer, it is somewhat funny to giggle at the idea of a crashing wave of grandmas and grandpas but when we think about the actual impact of our aging population, there's nothing to joke about. According to the US Census Bureau, the US is an aging nation and for the first time in US history, around 2030, older adults are projected to outnumber children. Today there are more than 46 million older adults aged 65 and older living in the US and by 2050, the number is expected to grow to almost 90 million. Now on top of that, our aging adults experience the higher risk of chronic disease. In fact, 60% of older adults manage two or more chronic conditions. As we all might be aware of, hearing loss is a

chronic condition. So let's move on to some hearing loss prevalence statistics too. Now across the world, 5% of the world's population has a significant hearing loss and by 2050, the number of people suffering from hearing loss could increase to 12.5%. Now maybe that's not so surprising, considering the aging population statistics that we just discovered. The prevalence of hearing loss nearly doubles with every age decade, which is shown here in the figure represented by the blue bars. As you go on from decades, the 50s to the 60s to the 70s and so forth, there's nearly a doubling effect on that blue bar. And in fact, there are about two out of every three adults that are 70 years or older has a clinical-significant hearing loss. Also on this figure is hearing aid use related to that prevalence data, which shows less than 20% of these individuals use a hearing aid and in fact globally, the global production of hearing aid meets less than 10% of the global need. So on top of an increasing prevalence of dementia and increasing prevalence of hearing loss, there's also a burden not only related to dementia costs but an economic burden related to hearing loss too. It's estimated the cost of unrelated hearing loss amounts to 750 billion per year, worldwide.

These reports come from the World Health Organization or WHO. Hearing loss causes significant annual costs, including costs of educational supports, loss of productivity and societal costs and of course health sector costs but these are excluding the costs of actual devices too. In the United States to be specific, estimates of economic cost of loss of productivity varied from 1.8 to 194 billion and direct medical costs ranged from 3.3 to 12.8 billion, so significant amount of money related to hearing loss too. Now what we might see in our clinic on a daily basis is the negative health consequences associated with 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 and an increased risk of falls. On top of that, what brings us here today is that with an increase in hearing loss, there's also known relationship with an accelerated cognitive decline and dementia. Let's go ahead and look at that much

closer now. So here's some work presented in JAMA in 1989 and what we're seeing here is severity of hearing loss in its relation to increased risk of developing dementia. And what we see here with a mild loss all the way to a moderate, severe loss, there is a dose-dependent response, meaning that the more hearing loss, the more likelihood or an increased risk of developing dementia. Now many other studies and epidemiological data sets have found the same, such as cross-sectional studies from the NHANES, represented US population as well as the HealthABC study, which was a prospective, population-based study and the Baltimore Longitudinal Study of Aging. The figure I'm showing here is from that Baltimore Longitudinal Study, published by Lin and colleagues in 2011 and what this figure here is actually showing is your ability to stay dementia free. So on the Y axis is the probability of remaining dementia free across time on the X axis. Now if you look at the very top line, this is a representative of the population that had normal hearing and they stayed relatively dementia free. But as hearing loss increased from mild to moderate to severe, there was a two to almost five increased risk of developing dementia. Now let's think a little bit more about what those epidemiological studies are actually telling us because they cannot tell us a cause and effect or a causation.

But they can help us start to think about what might be going on to lead to the observations in those studies. So if we were to think about what could be leading the associated observations that we're seeing and we're looking at hearing loss compared to cognitive and physical functioning, one explanation might be that there's a common pathological process. Meaning that there's something that's happening to our older adults as they age that's also influencing the hearing in their cognitive and physical functioning. An example of this would be a overall inflammatory increase or a microvascular disease. Now, the other idea is that hearing loss may be influencing cognitive load and cognitive load might be influencing the cognitive and physical functioning. On top of that, hearing loss is known to alter and change brain structure and functioning and that might have an negative influence on cognitive and physical

functioning or hearing loss is known to be related to decrease in social isolation. Having someone having hearing loss makes them withdraw from social activities and that social isolation could be negatively influencing cognitive and physical functioning. So these are what's referred to as possible, mechanistic pathways relating hearing loss and cognition and physical functioning. But we do not known these are true yet and we do not know the cause and effect of the data that we're seeing in our epidemiological studies. So a brief summary of just what we've kind of covered so far. We see a high prevalence of dementia and it's growing, hearing loss is highly prevalent in older adults and has been associated with adverse health outcomes, there's an association between hearing loss and cognition and all of this is a significant, public health concern. There is money flying out the window to cover these associations and costs and based on what we know, where can we go to help tip the scale and be able to provide appropriate care for our aging population? Well one thing to look at is a recent report in the Lancet. The Lancet is a prestigious medical journal and in 2017, the Lancet's Commission on Dementia Prevention and Intervention Care provided the following information about ways to possibly reduce the rate of dementia. And what this figure is showing is the likelihood of developing dementia across someone's timeline. Now 2\3 of dementia risk was identified to be purely genetic, however 1/3 of dementia cases may be preventable through modifiable lifestyle factors.

These lifestyle factors include managing diabetes, obesity, smoking and hearing loss. And in fact, hearing loss was the largest found modifiable risk factor in both mid and late life. And this is very interesting to have a possible modifying factor in both mid and late life and since this report came out, there's a few other epidemiological studies that have looked at this midlife modifiable factor, such as a Danish group, over almost a million Danish men were evaluated and midlife hearing loss was associated with an increased rate of dementia if that hearing loss was diagnosed before the age of 60. Similarly, in a Taiwanese-patient population, they looked at over 8000 patients with hearing loss, represented in this figure by the black line, compared to an age-matched,

sex-matched cohort of individuals with no hearing loss, represented by the gold line here. And what they found is dementia-incident rate in the hearing loss group was significantly higher than the normal hearing group. The group with hearing loss aged 45 to 65 was associated with the highest risk of dementia. So these are two additional epidemiological studies highlighting the importance of looking at modifying hearing loss in that midlife area. So the epidemiological data is growing and the evidence is strong, with hearing loss independently associated with a two to five fold increase of incident dementia, accelerated cognitive decline on cognitive assessments, accelerated whole brain and lateral, temporal lobe atrophy. And what's shown here is also from that Lancet report, which shows across studies, there is a consistent report of a 1.9 increased risk of dementia with hearing loss. So altogether, the evidence is continuing to grow and continuing to be very strong.

Now if you're interested in knowing more about these epidemiological studies and how to interpret them and what they can tell us, then I would probably want to invite you to check out another Audiology Online series from two of my colleagues that I collaborate with at Johns Hopkins University. Both Dr. Frank Lin and Dr. Jennifer Deal really dig deeply into these types of studies as well as the mechanistic pathways that we briefly referred to. But I would like to spend the remainder of my time focusing on hearing intervention and what we know about that and how it relates to cognitive decline and dementia. So what about hearing intervention do we know? So we know, for sure, that hearing intervention is related to and can be proved to improve communication, improve speech recognition and listening ability, improve quality of life and leads to outcomes related to listening effort, better listening effort outcomes, memory and other cognitive outcomes. So knowing that hearing intervention can have those positive influences, if we think back of those pathways that we discussed earlier, then it's not too farfetched to think about if we treated hearing loss, that we could possibly have an influence on cognitive load. We could have an influence because hearing intervention has shown to have improvements or changes in brain and structure function. And with

hearing intervention, we may reduce socialization allowing patients with hearing loss to get back into those social gatherings. All of which might have an influence on cognitive and physical functioning. However, it's important to note that although some unaided versus aided experiments, as well as cross-sectional cohort studies have reported either improved cognition or slower rates of cognitive decline with hearing aids, there are many studies that have not found a significant effect here. So the information that we have in our research is not clear. And that's mainly driven by the fact that determining the role of hearing intervention in attenuating cognitive decline in dementia and observational studies is just not possible. Now there's many reasons why we cannot do that. For example, in these observational studies, the individuals choosing the use of hearing aids differ substantially from those who do not. It is likely that maybe in your own clinics you might see that some patients choose to pursue hearing intervention and some do not and there's probably differences among those patients and there's also differences among these big observational data sets of those who choose hearing aids and those who do not.

On top of that, the actual hearing intervention that might be selected by these patients in these observational studies is really not known. We don't know the types of devices, how often they were worn or any of the educational-supports counseling that they may have received related to that hearing intervention. So we can't really describe the hearing interventions selected and therefore make any predictions of how that affects the outcomes in these observational studies. There're several other limitations in the current literature, which include small sample sizes, the use of retrospective design, the use of self-reported hearing aid use instead of actually measuring the amount the hearing aids were used as well as self-reported hearing loss, instead of actually measuring hearing loss. So there's some studies, epidemiological studies that describe hearing loss just by a questionnaire. Do you have hearing loss, yes or no versus actually measuring the hearing loss. Now there's plenty of other studies that also measure hearing loss but the type, degree and configuration of that hearing loss are

still not well defined. So all of these are limiting factors for our ability to determining the role of hearing intervention within these observational studies. Now there are some relatively new studies that are looking at the influence of hearing intervention, such as the group of individuals out of Australia who recently published a report where they followed 99 adults aged 60 to 84. They followed these individuals for 18 months with well controlled hearing aid use, so meaning that the hearing intervention that was utilized in this study was well defined, the same devices and they made sure that the participants were utilizing the devices as prescribed. At the end of the 18 months, this study reported that there were improved speech perception, self-reported listening disability and quality of life and they also said that there was no decline in the cognitive battery that was measured at that 18 month.

There was also a report of an improved executive function. So all of those are great things, however this study did not have any randomization or a control group, really limiting our ability to generalize these results. Now there was one randomized control trial that included cognition as an outcome. This was back in 1990 and it was from a patient sample population from the Veterans Affairs. So 192 veterans were randomized to either obtain hearing intervention or to wait four months, they were put on a waiting list. Now at the end of the four months, the two groups were compared for outcomes and in the group that received the hearing intervention, there were reports of improved communicative and emotional function and there was also reports of improved cognition using only a cognitive screener. Although this is a great finding, these results were never confirmed in a trial with a larger representative cohort, using current hearing rehabilitation strategies or technologies. As we all know, hearing technology has changed significantly since 1990. And there has been no reports since then on evaluating cognition with a longer follow up. In order to really determine the use of hearing intervention to reduce risk or cognitive decline would require a longterm follow up, as cognitive decline happens over many years and not just a short, four months timeframe. So that leads us to the question that needs to be answered still. The

question of whether treating hearing loss could delay cognitive and physical decline or dementia, this still remains unknown. In fact, there has never been a randomized control trial of treating hearing loss to explore the effects of reducing the risk of cognitive decline and dementia. And so developing such evidence requires a multiphase process and what I'm showing here with these colorful circles is a figure from the NIH Mind And Body Framework. And what these circles represent are the different processes required to develop strong evidence. Starting from the left-hand side in the orange, yellow and green circles are the studies that would be required to start up the evaluation of an intervention and the effects of that intervention. In the blue circle highlights the need for an efficacy study with appropriate comparisons. There's a need for efficacy trials to test the clinical benefit of an intervention when delivered in settings optimized to detect an effect. So this would include in settings with the best trained providers, specific enrollment criteria of the participants that enrolled in the study, extensive follow up and a precise study protocol. So these are all the phases that would need to be required and in order to generate the evidence relating to hearing loss intervention and cognition.

So now I get to introduce the study that has been designed to do so. The study I'm referring to is the Aging and Cognitive Health Evaluation in Elders or what's referred to as the ACHIEVE Randomized Control Trial. The ACHIEVE trial has taken on this big, exciting task of determining if hearing intervention could potentially reduce the rate of cognitive decline. And this group picture here shows the huge, teamwork effort that is required to handle such study. I do want to highlight the two colleagues on the upper right, Dr. Terry Chisolm and Dr. Michelle Arnold that are with me here at USF and at USF, we've been responsible for designing the hearing intervention that is utilized in this clinical trial. Down in the lower left is Dr. Frank Lin. He's an otologist and epidemiologist from Johns Hopkins and he's our principle investigator of this study and leading the efforts, along with his Co-principle Investigator, Dr. Josef Coresh, who's also an investigator in the ARIC Study. ARIC stands for the Atherosclerosis Risk In

Communities, it's a neurocognitive study. So what's really unique about this ACHIEVE clinical trial is that we have embedded it within an ongoing longitudinal observational study. So the ACHIEVE trial is happening within the ARIC trial. An ARIC Trial has over 16,000 adults that have been followed for over 25 years. So these ARIC participants, we know so much about them for over 25 years and they are at that point where they're starting to have age-related hearing loss and it's a perfect time to ask the question if hearing intervention could have an influence on these participants. Like I mentioned, the ARIC Study is happening in the nation. It happens at four different clinical sites. One site is in Mississippi, the others are in North Carolina, Maryland and Minnesota. And to go in a little bit more details about the ACHIEVE Randomized Control Trial, here's a conception of the trail itself, conceptional model. The aim of ACHIEVE is to determine the effects of best practice hearing intervention.

So within the model, on the left-hand side, we see the intervention, which is best-practices hearing treatments and we assume that best-practice hearing intervention is going to have a direct influence on receiving audibility of speech and environmental sounds and hopefully enhance verbal communication in social engagements. Now the primary outcome of this trial is rates of cognitive decline and we also will be evaluating this best-practice hearing intervention on a variety of secondary outcomes as well. The secondary outcomes include evaluating health-related quality of life, social and leisure activities, daily functioning, mobility and a longitudinal brain atrophy study using structured MRI. This study is designed to investigate those mechanistic pathways we discussed earlier. And so we will be looking at if hearing intervention has an influence on those pathways and how they potentially might influence cognitive functioning and physical functioning. So you've seen these colorful circles in our past slide and so what I want to do is kind of go through the different stages of what has happened in the ACHIEVE Trail design all the way to where we're at today. So in a timeline shown here, it's starting back in 2014, funded by the National Institute of Health, we received funding to conduct a

clinical-trial planning grant. It is exactly as it sounds, it is funding to plan a clinical trial. And during that process, we completed the development of the protocols and the manualized interventions and we completed a feasibility study. The manuscript that you see on the right-hand side here really details all of those processes out and it was just recently published in Ear and Hearing. After completing the feasibility study, there was also a pilot study that was completed. So not only did we evaluate the intervention, we then evaluated if it could be adapted at a different location and the manuscript that is shown here describes those results. So following these activities from 2014 to 2016, the full grant was submitted to the National Institute of Health and the National Institute of Aging decided to fund our study. Which leads us to 2017 when the trial started. What you see here, the manuscript on the right for those who may be interested, describes the detailed protocol or the methodology that is used in the clinical trial. And what you also see here is a little bit of what has happened since the start of the trial. From 2017 to 2018, recruitment started and we successfully recruited 977 healthy, cognitively normal, community-dwelling adults aged 70 to 84 years old, all with untreated, mild to moderate hearing loss.

We are in the midst of the follow up stage right now, meaning that we are following all of these participants for three years and we will have results in year 2022, so we do have to wait a good amount of time. But I want to describe the interventions that are being evaluated in this clinical trial. So the 977 participants were randomized to either receive a successful aging intervention, which is our active control intervention and those participants will receive time with the interventionists where they cover topics related to successful aging and receive successful aging strategies. The other half of the cohort is randomized to receive the best-practice manualized hearing intervention and I do wanna go through that in detail. So shown here are the components of the ACHIEVE Hearing Intervention and we're gonna walk through the components one by one starting with the comprehensive evaluation in educational counseling. So during the first intervention phase, the participants received a comprehensive evaluation

including otoscopy, tympanometry, pure-tone audiometry, word recognition in quiet as well as word recognition in noise in a soundfield environment using the QuickSIN Test. Following the evaluation, participants moved on to receive individualized goals and the purpose of this is to really target participant-specific communication needs and foster realistic expectations. So when setting these goals, the participants were asked to create important goals for themselves following the guidelines from the Client Oriented Scale of Improvement or commonly known at the COSI. And the goals must be specific and prioritized for each participant. Setting these goals is really important because that then set the stage for the rest of the intervention. Next was the sensory management of the hearing loss, which is centered around amplification.

This includes the selection of appropriate level of hearing aid technology, electroacoustic analysis evaluation of these devices across the entire timeframe of the study as well as verification of the devices on-ear using real-ear measurements. In addition to on-ear hearing aids, there was also the use of a hearing assistive technology. Now the hearing assistive technology selection was based on the patient's performance of the QuickSIN as well as their hearing loss, their COSI goals and their participant history and preferences. Now if a participant had a COSI goal that was not being met with just purely their hearing aids alone, they would be encouraged to utilize these HATs to help reach their COSI goal settings. Now you probably noticed and as we go through these different components on each level, there is education, counseling and self management. Now the education, counseling and self management was standardized completely throughout this entire trial, meaning that we provided the same materials and utilized the same materials on all participants. But we also encouraged the expertise of our audiologists that were delivering this intervention as well to help support all the needs of the participants. Some of the standardized materials that were used were focused on this, what we refer to as a toolkit for self management. The toolkit for self management was developed, the idea to teach adult hearing aid users about their hearing loss, support new hearing aid users by providing

strategies based on their goals, their individualized goals. So this is very customized to specific needs of all of our participants. The topics include understanding in noise, communication strategies, telephone and television support, meetings and crowds, places of worship, hearing assistive technologies and all of these materials were developed to be understood by persons of a variety of health literacy backgrounds and to also incorporate inclusive and racially-diverse images. On top of these written materials, we also had a medial set of materials as well to help with education and self management. The video-based materials are from the C2Hear Reusable Learning Objects or the RLOs and these are short video clips, about two to seven minutes, that were originally developed in Nottingham University in England. So they originally developed with a British English but we were able to Americanize them with American English and these videos cover a variety of common topics and issues that hearing aid users experience. So altogether, the hearing intervention that I have described so far is pretty extensive and with complex interventions, we also need intervention fidelity and what I mean by intervention fidelity is the ongoing assessment, monitoring and enhancement of the reliability and internal validity of a study.

Meaning that we have to carefully watch the intervention to make sure that it is provided as we would hope it was intended to. Intervention fidelity is key in multi-site clinical trials to ensure consistency across sites and to make sure that there's adherence to the study protocol. The ACHIEVE clinical trial has an extensive intervention fidelity process where we monitor all of our sites, the audiologists delivering the intervention and the participants receiving the interventions. So the intervention that I've described so far, it's heavily weighted with the majority of the intervention happening in about eight to 12 weeks. About the end of that 12-weeks time, the majority of the participants are consistently using their intervention, are comfortable with the intervention and so then they enter what's referred to as the post-intervention phase. And during this post-intervention phase, all participants can receive any support required if they have any broken hearing aids or if things change in

their life and they need additional supports but there are also all the participants are brought in every six months for booster sessions to continue to improve their use and utilization of the intervention and also collect outcomes. So for every six months for three years, our participants are coming into the center for booster sessions of the intervention as well as outcome measures. And what I'm showing here is a really busy chart with all the outcomes that are collected in the ACHIEVE clinical trial. Now this is placed here just purely as a joke because obviously this is way too small to see but the idea is to show you that there is an extensive amount of outcomes that are being measured throughout this entire three-year process with all of our participants. If we were to look at the outcomes and categorize them, we have outcomes related to generic outcomes, that are just talking about general good health as well as disease specific outcomes in this trial. We have disease-specific outcomes for cognition, both objective and subjective and hearing-specific outcomes that are both objective and subjective. And I do want to remind everyone that the primary outcome of this trial is an objective measure of cognition known as a neurocognitive battery, it's a subset of validated tests to determine small changes in cognition.

But unfortunately due to time, we won't be able to go through all of these outcomes but I do wanna spend a good amount of time on the hearing outcomes as it was important to obtain the hearing outcomes throughout the entire portion of the study. So the hearing outcomes that were obtained from the start of the intervention, that's going to continue to obtain to the end of the three years, include both objective and subjective outcomes. The objective outcomes include data logging, that are being able to obtain from the software. We're able to show use of hearing aids, both daily average use as well as the scenarios, the listening scenarios that are processed by the hearing aid as well. We are also able to collect aided, soundfield speech and noise performance utilizing the QuickSIN. Now this objective measures of using and benefiting from the hearing intervention complement nicely with the subjective measures or what's referred to as the patient's perception of their intervention. So the

subjective outcomes in this study include both the COSI goal attainment, so at the beginning of the intervention phase, the participants determine goals that they would want to accomplish and so we are constantly monitoring the ability to meet those goals. We also provided two questionnaires, the Hearing Handicap Inventory and the International Outcome Inventory and both of these questionnaires get out self-perceived benefits of the hearing intervention. Now as I mentioned, now generating the evidence to support hearing intervention as a possible mediating factor for cognitive decline is a multi-phase process. So we discussed a little bit about the developmental stages, going into the ACHIEVE study, the actual ACHIEVE study itself and provide its details on the intervention that is going to be evaluated in that trial but the question still remains, what could be next? Where do we go after the ACHIEVE trial? Or Post-ACHIEVE, if you wanna think about it that way.

So post-ACHIEVE, maybe it could be a telehealth approach, maybe we would be evaluating the hearing intervention with the same objectives but utilizing telehealth to help expand access and affordability of hearing healthcare. Of course telehealth is known to provide greater flexibility, lower costs and maybe even individualize plans because you might be presenting the telehealth intervention at their homes and in their own needs that they have. Currently at the University of South Florida, we are conducting pilot studies to evaluate the idea of using telehealth in some Post-ACHIEVE studies. Another idea is what about other patient populations in other hearing interventions? Now in the ACHIEVE trial, the majority of the participants have symmetrical, sensory neuro-hearing loss, all thought to be related to presbycusis or aging. But we know that there are other forms of hearing loss such as conductive losses and mixed losses and even single-sided deafness. And these types of hearing interventions may be recommended a different form of hearing intervention such as cochlear implants or ossesointegrated devices also referred to as OIDs. Shown here is a picture of an OID. So why would we potentially want to look at other patient populations and hearing interventions? Well, little is known about the hearing levels

and hearing configurations in the large epidemiological data sets that we first reviewed in this presentation. Hearing loss was defined in these studies using various methods and we really don't have a clear understanding of the configurations of the losses or the best interventions for those losses. So for example, if we were to evaluate patients that could potentially have benefit from an OID device, many of the same reported benefits that we see in traditional hearing aids are also known for patients who utilize an OID device, such as there has been shown results of improved access to sound, decrease in listening efforts, decrease in cognitive load, improved speech perception, quality of life and memory while using an OID device. So then it's therefore also not farfetched to think that these OID devices might have the same mechanistic pathways of hearing intervention and in the effect of cognitive function and physical function. So if you were interested in more details on OID devices themselves, the benefits of using an OID device and the possible candidacy of what type of patients would benefit from an OID device, I would recommend a few other lectures that were also within this Oticon Medical Sounds Matter series.

Both Dr. Jaclyn Renker and Dr. Rene Gifford have given great presentations on the candidacy for OID devices as well as improvements while utilizing these device. Due to time, we won't go onto those details but I do wanna share the idea of potentially starting a study which we're referring to as an observational comparative effective study to look at OID device use and cognition. Now the design of the study is an observational comparative effectiveness research. With that being said, it's going to be an observational study, meaning that we are going to invite patients who could potentially benefit from an OID device and follow them for the next several years. So for example, if someone has a conductive, mixed or single-sided deafness hearing loss, they could be recommended the use of an OID. And so we would be inviting them to participate in our observational comparative effectiveness research because some of these participants may decide to do nothing. They may not decide to move forward with the OID recommendation and the other participants may decide to move forward

with the OID recommendation and this is very similar to what happens in our typical clinics too. This is what's sometimes referred to as a preference study where our patients have to tell us their preference of what intervention they would move forward with. So what we would do is ask our individuals to present to our clinic, that could potentially benefit from an OID device and then follow them with extensive outcome measures. So therefore our primary object or purpose of this type of study is to evaluate the hearing and quality of life in cognition of these patients who could or do use an OID device. And shown here is another extensive table representing all the outcomes that would be selected. And again this is not for you to necessarily see or read but just to emphasize the study schedule and that participants would be asked to complete 11 study visits. And the outcomes that we decided to utilize in this upcoming study is very much related to all of the outcomes that are selected in the ACHIEVE clinical trial too.

And that was purposely done because we have over seven years of experience from designing and running the ACHIEVE trial, taking on information learned in that timeframe and now spinning it into another study will help us accelerate the process of this study. Now you have to stay tuned. Unfortunately we don't have any results yet to share. The study will be starting hopefully this fall. Our timeline got pushed back a little bit because of COVID but as soon as it is safe for our practice as well as our participants, we will start to recruit individuals into this pilot study. Just wanna go through a few of the bullet points in summary. We have an aging population on our hand. There's a high prevalence of dementia, a high prevalence of hearing loss. There's a known association between hearing loss and cognition. We desperately need clinical trials to determine the mediating effect of hearing intervention on cognitive decline and dementia and we described two clinical trials that are taking on that process. We've described in detail the hearing intervention that is being utilized in the ACHIEVE clinical trial. And as a last bullet point here, I just wanna make a quick comment about what are some of the implications from these studies on the future of hearing healthcare.

Now we do believe that there will be substantial clinical, social and public health impact based on the findings of these studies. The implication to hearing healthcare policy and hearing healthcare reform could be very significant and it's very exciting to be a part of these studies in order to see the rigorous science lead to hopefully changes in our system to get better access and care for individuals with hearing loss. At the end here I just wanna say thank you so much for tuning in today and listening. We are right at the end of our time, pretty much and I do wanna make a statement about funding for these studies. The ACHIEVE clinical trial was funded by the NIH and devices were provided in kind by Sonova and Phonak. Now the OID and Cognition Comparative Effectiveness Pilot Study was funded by Oticon Medical through a donation to the ARCT Lab Foundation. So we thank them very much for their support in these very important clinical trials. As well as there's a list of acknowledgements of all of the key individuals who've supported the studies that we referred to today. At the very bottom is my email address.

For those of you who maybe need to jump off and move on to their clinics or the rest of their busy day, please feel free to email me any questions. You can also find our ARCT Lab both on Facebook and Instagram and Twitter using the handle @ARCTLab. So I will stop there. Thank you all and I'm happy to take any questions. Okay, there's a few here. First question I see, is obtaining a patient's perceived benefit from their hearing intervention can be attained through? When we were reviewing the different types of outcome measures that are found in the clinical trial as described, we talked about objective and subjective different outcomes and in order to obtain a patient's perceived benefit, you would be using a subjective outcome measure, such as the ones that we listed were for example the Hearing Inventory outcome and the HHIE. Gonna go onto the next question now. The next question is, what are the outcome measures and the current studies evaluating the influence of hearing intervention on cognition and quality of life? So we did review that figure that showed a variety of different outcome measures, the categories of them at least and then we dug in a little

bit deeper to the hearing intervention specific outcomes. And so those intervention outcomes included both objective and subjective outcomes. The next question I see here is, why is treatment fidelity and large multi-site clinical trials evaluating the influence of hearing intervention important? And it is important because we want to ensure that the hearing intervention or any intervention under investigation is being delivered as intended. So we wanna make sure that our participants are using the hearing intervention, utilizing the devices and the hearing assistive technologies and all of the support and make sure that utilization of the hearing intervention is consistent across all participants and all sites in order to have, at the end of the study, valid and reliable results. There is another question that's coming in. This question is, what is an example of an objective, disease-specific measure of hearing function? And to go back to the discussion about the different outcomes that are being utilized in the ACHIEVE study, an example of an objective, disease-specific measure of hearing function would include data logging, real-ear measures and speech and noise recognition, soundfield test measurements. Those would all be an examples of objective hearing-specific function measures. Very good questions. Not sure if there is anymore at the moment, I'll give a few more minutes. Again I thank everyone for their time. Really appreciate having you guys listen in on this exciting work. Again if there's any other questions that come up, feel free to reach out to me directly and thank you so very much.