Welcome back everyone. And welcome to the final session, afternoon session, for the DCoE Summit TBI track. This session, session T3004, Interdisciplinary Telephone-Based Tinnitus Intervention For Military Members and Veterans with TBI.

I am Dr. Scott Livingston, and it's my pleasure to introduce our presenters for our first session this afternoon, Dr. Tara Zaugg and Dr. Kathleen Carlson. Dr. Zaugg is a Research Audiologist at the National Center for Rehabilitative Auditory Research at the VA Portland Healthcare System. And Dr. Carl is the Core Investigator for Health Services Research and Development Center to Improve Veteran Involvement in Care, also at the VA Portland Healthcare System.

This presentation will discuss recommendations for the use of a standardized interdisciplinary approach for tinnitus management, a unique approach offering audiology and behavioral healthcare for tinnitus.

The presenters will also discuss results of a randomized control trial and efficacy study among telephone-based tinnitus management.

Please join me in welcoming Dr. Zaugg and Dr. Carlson.

Hi, thank you. So this is Kathleen Carlson and you may know we're experiencing some technical difficulties in Portland. You see Dr. Schmidt on the screen and she's on the East Coast and it's all wired in, and Tara Zaugg is over trying to get her webcam working in a different offices with a different computer.

So I had planned anyway to start us off with the initial slides of the presentation, and then hand it over to Caroline and Tara. And so I'm hoping that she'll be up and running, Tara will be ready to take it away by the time I get to that part.

So, let's see, next slide, please. Okay. So this is the disclosures. The views that we express today are ours and ours alone and don't necessarily reflect those of the VA or the U.S. government. We have no relevant financial relationships to disclose. We don't intend to promote any off-label commercial products and we're really just describing a program today based on a 20-year program of research -- there she is -- and we do intend to promote this program, but it's freely available and open access to everyone, and we really just want to describe the program in hopes that people will pick it up and add it to their toolbox for addressing tinnitus among veterans with TBI.

Okay, next slide. Next -- thank you. Okay, so just to kind of lay the groundwork, we're here in Portland at the National Center for Rehabilitative Auditory research, or NCRAR. And this is a VA-funded rehabilitation research center of excellence funded since 1997. And it's focused on hearing and auditory impairment, so dedicated to the discovery and delivery of cutting-edge solutions to auditory system impairment. And we do research as well as training and outreach.

In the bottom right-hand corner you see a plug for our biennial conference, which is happening next week, and it's focused on hearing loss as a public health concern. So we have lots of things going on in this large center. We have about 25 Ph.D. level investigators and lots and lots of research staff, including audiologists, engineers, statisticians, and data managers.

And we get funding from lots of different research funders, but primarily from VA's rehabilitation, research and development service. Next slide, please.

This is just a picture of the big group of NCRAR researchers. On top of one of our research buildings, and you see the Portland VA Medical Center in back of us. Next slide, please.

So we did want to kick this off with a couple of polling questions, just to get to know our audience a little bit better, so indulge us here. First, we wanted to know what your primary role is as a healthcare provider.
And at this point, moderators, I’m not sure how long to hold off for, what to do. There’s an awkward silence.

Dr. Zaugg, (sic) you can go ahead and continue with your presentation, and then we’ll come back to the responses to that polling question.

Great, okay. Hopefully, Kathleen and Caroline are seeing the responses in the chat box group, the chat box there. Now I’m figuring out how this is working. Thank you so much, everyone, for typing those in.

Out second question is what environment do you typically provide healthcare services in. Perfect. Okay. Awesome. Military, (inaudible) facilities and VA. Thank you so much.

So while I’m kind of an overarching tinnitus bullet side, you’ll hear a lot more about tinnitus as we move along. So I was going to just touch on a couple points about prevalence of tinnitus. So tinnitus (technical difficulty) is often -- also called tinnitus, is the sensation of ringing, buzzing, hissing or other sounds in the ears or head in the absence of an acoustic stimulus. So probably everyone in this presentation has experienced tinnitus during their life, maybe not as severe or debilitating as some may experience it.

The prevalence in the U.S. population has been estimated to be between 10 and 15%. And this was a summary of studies that happened and we presented back in 2004. And in their analysis, looking at the National Health Interview Survey data, which assessed the prevalence of tinnitus for three or four months across respondents to the NHIS, the prevalence ranged from 10 to 15%, depending on the age of the respondents.

So they found that the prevalence of tinnitus increased with age and was also highly associated with hearing loss which -- both of which are probably associated with high levels of noise exposure or a lifetime history of noise exposure.

We know that tinnitus can greatly impact functioning and quality of life, so it’s oftentimes associated with sleep disorders, with depression, with anxiety, attention and focus problems, mentally problems, self-reported low quality of life, even suicidal ideation. But it’s really important to be able to address tinnitus in this population.

Among veterans we know that tinnitus (technical difficulty) is even more prevalent that in the general U.S. population, so Bob Fulmer and Jim Henry and other collaborators here at NCRAR published a paper looking at another population-based survey called NHANES. They used data from 1999 through 2006, and the assessment of tinnitus in this population was whether or not they experienced chronic tinnitus, quote, unquote, almost all the time. So maybe a little bit more severe level of tinnitus than the NHIS was affecting.

So in NHANES’ data, they found that in the U.S. general population, about 5% endorsed experiencing tinnitus almost all the time, whereas 12% of those who were military veterans reported experiencing tinnitus all the time.

In the VA system of care, we’re quite aware of the fact that tinnitus is the most prevalent service-connected disability for veterans, and this has been ongoing since 2007.

And you can flip to the next slide, please. So this just depicts the study increase in the number of service-connected disability awards for veterans from 1994 through 2013. So in the last reported fiscal year of 2013, we had over 1.1 million veterans who were service-connected for a disability related to tinnitus. And that was 135,000 new tinnitus disability awards in a one-year time period alone.

All right, so we’re now on day three of a really rich series of presentations on TBI, so I won’t go into the detail here. The point that I wanted to make about traumatic brain injury is its relatively high prevalence in the newest generation of veterans returning from OEF or OIF/OND and other related conflicts.
And also the prevalence of comorbidities in those who are diagnosed with TBI. So in the VA, we know that somewhere between nine and 11% are receiving diagnoses for TBI, and among those, comorbid paid and mental health disorders are the rule, rather than the exception. So this is important to consider when considering tinnitus as part of an overall constellation of symptoms and disorders that are going on in violence with TBI. Next slide, please.

So tinnitus is strongly associated with traumatic brain injury. In fact, in the Hoffmann and Reed paper from 2004 where they summarized studies up to that point, they reported that it was age and head trauma that was most strongly associated with the onset of tinnitus. And we see this to be true in the most recent population of veterans where studies published up through 2014 that reported on veterans with TBI and also reported prevalence of tinnitus, that prevalence ranged from 34% to 76% across studies. So relatively high in this newest population.

And this can occur because tinnitus can be a direct consequence of the event that causes the TBI, which may be the case in blasts, where the blast wave causes damage to the peripheral auditory system, but it may also be a symptom of the physiological damage to the brain in the TBI, so maybe central auditory system damage. It could also occur as a side effect of medications that are often used to treat sequelae of TBI, and it could also just independent of the TBI event, so tinnitus is relatively prevalent, TBI is relatively prevalent, we may just be coming across veterans who have both TBI and tinnitus that aren’t related to the same event.

No matter what, no matter how it occurs, the management of tinnitus, and especially chronic bothersome tinnitus in veterans with TBI is critical, so being able to provide services to veterans with comorbidities and who may also be experiencing TBI-related symptoms, like cognitive or mentally symptoms is important for the population. Next slide, please.

So we’re on slide 11 now, for those who are following along. And I’m going to hand over to Tara to take over from here. Thank you so much.

All right. So I’m really pleased to have the opportunity to talk to you a little bit about our team. I consider myself to be really fortunate to work with the group of people I work with where a group of people with a lot of different strengths and we’re all really committed to improving the quality of life of veterans.

Jim Henry is the only member of our team that's been around for more than 20 years, so he's been doing tinnitus research for more than 20 years. I joined forces with him about 15 years ago, and somewhere in the range of five to ten years ago, Carolina Schmidt, who you’ll hear from later today, joined us as we were recognizing a true need for collaboration with mental health folks.

So the tinnitus population is, I think, a somewhat misunderstood population. Medical professionals are trained to address medical conditions that need to be addressed associated with tinnitus, which doesn't really come up very often. Occasionally, but not too much. Audiologists are trained to screen for medical conditions that need to be addressed, but beyond that tend to not have much training on what to do with people who have chronic, long-term bothersome tinnitus.

And even mental health professionals, they often have the skills to help people improve quality of life, but don’t realize that they can provide to a population of people who have tinnitus. So it's been kind of an interesting adventure as a team figuring out what it seems like people with tinnitus need and also helping the various professionals who can be helpful understand what they need.

In the early days of our research when I first came on board about 15 years ago, what we were mostly doing was carrying out research with methods of intervention for tinnitus that already existed. So we spent a lot of time with tinnitus retraining therapy and masking therapy. We had really close relationships with the folks who developed both of those methods. We also became very familiar with (inaudible) and other methods of intervention for tinnitus.
And we spent a lot of time with veterans who had bothersome tinnitus using those methods of intervention. There is one study where we followed -- it was over 170 veterans for 18 months, providing associative long-term intervention.

So we really started learning a lot about the interventions that existed and also how people reacted to them and we started forming a lot of our own opinions and recognizing that there were pieces of all of the methods that were really great and there were some pieces of the methods that didn't seem to resonate or caused little regularly occurring trouble spots.

And so we also started thinking -- recognizing that there were some people who seemed better suited to one method than they did to another and we were thinking wouldn't it be nice if we could expose people to all these different coping skills and let them run with whatever resonated for them. And that line of thinking is really what led up to the existence of Progressive Tinnitus Management, which is mostly what we're going to talk to you about today.

The big picture for PTM, so Progressive Tinnitus Management, I'll usually refer to it as PTM, it's a manualized program. So we developed a bunch of materials that were intended to be used by mental health providers and audiologists who don't have a lot of experience working with people who have bothersome tinnitus, and we made the model really flexible. We came up with a framework for how we think it makes the most sense to carry out in a clinical setting, but we recognize that the needs and limitations of clinics vary and the needs of individuals vary. So it's really flexible. There are lots of tools there that can be used in lots of different ways.

And the whole idea is to provide, give providers the resources they need to provide effective assistance to people who are really bothered by the tinnitus.

This method continues to evolve as we learn, so it -- the kind of early concept of PTM came about about ten years ago, but it's really evolved in pretty meaningful ways since then, including adding several components of cognitive behavioral therapy, Caroline Schmidt helped us do that. And it continues to evolve.

At the bottom of this slide you'll see a little link there and that links to the National Center for Rehabilitative Auditory Research’s website where we have a ton of PTM materials that are available from the website.

So, as I already explained, PTM is a structured approach to offering services for tinnitus. It's multidisciplinary. So early on we were kind of an audiology only show and recognized pretty quickly that once we started establishing relationships with people who were very bothered by the tinnitus, that it was really essential that we get mental health involved, so eventually then we added on the mental health folks.

And the rule for -- kind of the big picture for the role the audiologist plays is to screen for medical conditions, address hearing needs -- most people who have tinnitus also have hearing loss -- and education and use of sound for tinnitus. So people who have tinnitus will often intuitively recognize that sounds can be helpful, but sometimes the go-to is to try to find the sound that will cover up or mask completely mask the tinnitus and that usually doesn't play out very well. Kind of a more nuanced expectation is required for successful use of sound for tinnitus.

And then the role of mental health provider is to screen for mental health conditions and teach coping skills based on cognitive behavioral therapy. So PTM has been endorsed by the essential office since 2009.

And this is kind of an overall flow chart, so at the very bottom in the big box you can see some basic guidelines to help providers. It was really designed for non-audiology providers to figure out do I need to
refer to audiology, do I need to refer to ENT, is this something that's really like an urgent ENT issue or is this something that requires an urgent mental health referral?

Most of the information in these boxes audiologists will be familiar with, but people outside of the world of audiology often don't know how to make appropriate referrals, where people need to go. And so this gives just some basic information. It can also be used as a way, if there's a healthcare facility that has a PTM program set up, this can be used as a way of letting people know that there's a health -- that there's a system set up to help people who have tinnitus to kind of easily spread the word along with some basic information.

So at the very bottom is this referral level where we provide a lot of guidance for how do you refer somebody if they're telling you that they have tinnitus. And if you move up to level two, it's the Level Two Audiologic Evaluation and the Level Two Audiologic Evaluation looks pretty much like a standard audiologic evaluation, but requires the addition of a survey, one little survey that helps patients pull apart hearing issues from tinnitus issues, so patients kind of tend to mix those two together, but the interventions that help for hearing problems are very different than the interventions that help for tinnitus problems, so you have to kind of help them sort through those two separate issues, which they usually view as one, and then looking at just the tinnitus issues, ask people do you want help with just these, with the fact that tinnitus keeps you from sleeping, keeps you from being able to concentrate on reading, things like that.

And so it doesn't require much at the level of audiologic evaluation, other than sorting out those two issues and finding out if people want help. It's not a lot, but that alone sends a really big and important message to people who have tinnitus, and the message is there's something we can do to help you if this is bugging you. There's something we can do to help improve your quality of life, and I think that's a big deal. We talked to lots and lots of people who have tinnitus who've been told by healthcare providers of a variety of strengths that nothing can be done and it's sometimes a really devastating thing for people to hear, particularly if it's coming from a healthcare provider.

And so it is often true that there is nothing that can be done medically to get rid of the tinnitus or there's nothing that needs to be done about a health condition relating to the tinnitus, but what's also true that people often don't hear when they really need to is that there are lot of things that can be done to improve quality of life with tinnitus.

So even if that's the only message you're giving us, that's a really important and good one. If people say - let's see. So another thing that that little survey screen's for is problems not tolerating sound, which is another thing that crops up for people who have tinnitus. So if the person has a big sound-tolerance problem and that needs to be addressed, we have a bunch of materials developed to guide clinicians through the process of helping people with a sound tolerance problem and educating them on how to not make it worse and also how to make it better.

Once you've dealt with the sound-tolerance problem, which our experience has been that it's fairly unusual that people really need to have a lot of help dealing with a sound-tolerance problem. Sometimes it does need to be addressed; it usually doesn't. Because once you make it through level two, Audiologic Evaluation, you really define the problem and find out if they want help with it.

The next step is level three. So level three, skills, education, and this is where you begin teaching coping skills for tinnitus. And some of the coping skills are taught by audiologists, and these are all kind of sound-based coping skills and I'll talk to you more about that later in the presentation, what exactly that looks like and what that means.

And also the other crucial piece of the skills education is teaching coping skills based on cognitive behavioral therapy. Often this is done in a group setting. It seems to be a pretty efficient way to help
people acquire the coping skills they need. It can be done -- if education isn't an option, it can be done one on one, it can be done on the phone, it can be done in a lot of different ways.

So once you’ve taught the skills, our experience has been that the vast majority of people don’t need anything beyond that. There’s a really small percentage of people who need more beyond that and when that’s the case, then you move up to level four, interdisciplinary evaluation, where the one-on-one evaluation with both an audiologist and a mental health provider, just to try to get a bigger, more solid understanding of their individual situation and all the pieces that are contributing to their experience with tinnitus.

And where you end with the interdisciplinary evaluation is learning does it make sense to move on to one-on-one individualized approach with the mental health provider, does it make sense to move on to one-on-one individualized support with an audiologist. And it could be with one or both providers, whatever makes the most sense as you figure things out in level four evaluation. But, like I said, it's really unusual, actually, for people to need to go to level four and five. Most people have been taken care of -- these are rough numbers, 90, 95% of people (inaudible) have mostly been around 95% of people have their needs taken care of at level three.

All right, so that's the big picture, that's the flow chart for PTMS, so what's happening with progressive tinnitus management. So let's talk a little bit about the evidence based for traditional PTM, what I just described to you, traditional PTM, it's the cumulative result of 20-plus years of tinnitus research, and I’ve already given you some background on that.

The initial development took place as part of a grant that we carried out between 2006 and 2009. And really what we were developing were a lot of the support materials and we were, at that point, still just focused on using sound. We hadn't added the cognitive behavioral therapy potion yet.

So we developed this and tried it out with a bunch of veterans in Tamps, Florida actually. But in 2010 we recognized that cognitive behavioral therapy is the method that has the largest evidence base for helping people with tinnitus, so we wanted to add components of cognitive behavioral therapy and we connected with Caroline Schmidt, who's going to talk to you soon. And she helped us incorporate some concepts of cognitive behavioral therapy into PTM.

Let's spend a little bit of time talking about the American Academy of Audiology practice guidelines. So the very recently -- so just in 2014, the American Academy of Otolaryngology Head Neck Surgery Foundation got pretty serious about developing guidelines for working with people who have tinnitus. And they really have done the most -- so they convened a group of people, it was mostly otolaryngologists, there were three audiologists involved, once of them was Jim Henry, and they did a thorough literature review looking at what's out there for research support, for what's helpful for people who have tinnitus and convened a lot of people. Like I said, mostly otolaryngologists, to talk through what makes the most sense in terms of guidelines for care for people who have tinnitus.

And PTM -- these AAO guidelines were developed after PTM was developed, but PTM actually falls pretty -- is in line with the AAO guidelines, as you'll see in just a moment.

So there was a 23-member committee; there was an exhaustive search of peer-reviewed literature to identify the appropriate randomized control trials and we think it's reasonable to consider these AAO guidelines as a standard that guides evaluated-based clinical services for tinnitus management.

This is an overview of their recommendation. So they came up with six recommendations for things they think should be done for all people who have tinnitus; three recommendations for things they don’t think should be done, that you should refrain from doing. Two things that they consider to be optional and there's one thing that they think -- they just had no recommendation.
So let's just quickly walk through them. One, clinicians should perform a history and physical exam to identify conditions that might be treatable. Perform comprehensive audiologic exam for patients with tinnitus that's unilateral, chronic or associated with hearing difficulties. Distinguish patients with chronic tinnitus from -- patients with chronic tinnitus from those with bothersome tinnitus of recent onset. So is this something that's been a long-term, ongoing problem for them or is this something that just came up.

And they think that the AAO guidelines say that all patients should be educated about treatment options, hearing aid evaluation if there's a hearing loss, if hearing loss is part of the picture, and cognitive behavioral therapy.

There are some things they recommend against based on the research. They recommend against antidepressants, anticonvulsants, anxiolytics or intratympanic medication for routine treatment of patients with persistent bothersome tinnitus, there are things that aren't the first go-to things, these are. Ginkgo biloba, melatonin, zinc, or other dietary supplements for treating patients and they recommend against transcranial magnetic stimulations for routine treatment of patients with persistent bothersome tinnitus. Things they consider to be optional, an initial comprehension of audiologic exam and they also consider to be optional sound therapy for patients with bothersome tinnitus. And they had no recommendations regarding the effect of acupuncture in patients with persistent bothersome tinnitus.

Overall, I think these are excellent guidelines to follow. The one thing that doesn't exactly line up with how I've seen things play out -- so AAO, the American Academy of Otolaryngologists, are saying that anybody who reports tinnitus should have an otolaryngology exam. I've done some clinic work and in VA audiology clinics and audiologists are trained to know when to refer people for a medical evaluation by an otolaryngologist. And with the veteran population anyway, it's really, really common for there to be tinnitus, but it's pretty clear why they have it. There's a good reason for it to be there and there aren't any other signs of pathology that needs to be addressed.

And, honestly, our otolaryngologists could be kind of irritated with us if we referred absolutely everyone who reported tinnitus. In some settings that's really not practical and we haven't seen that be problematic, so in practice we don’t refer everyone to otolaryngology. And keep in mind this is coming from a perspective of an audiologist, I'm an audiologist. I do actually think that -- so they consider an audiology exam to be optional. I think that really anyone who reports tinnitus should have an audiologic exam. Most people with tinnitus also have hearing loss. Sometimes it can be just a hearing problem. That takes care of everything. Sometimes they are calling it a tinnitus problem when it's really a hearing problem. And audiologists are really the only ones who are fully qualified to figure out kind of the difference between those two and if -- and they are the most qualified to provide the rehab type stuff for hearing problems.

All right. So a little while ago I walked you through kind of the traditional PTM flow chart. The way PTM is usually conducted is in a clinic. It requires specialized training for clinicians, so both audiologists and mental health providers need some special training. There's no standardized training program that exists.

Level two of PTM is done by audiologists and levels three through five are a collaborative effort between mental health and audiology and patients attend multiple in-person meetings. So sometimes that's great, but sometimes that's a tricky thing.

So some things that we were noticing was that a lot of the stuff that -- not regular audiology, so the level two of PTM is really mostly traditional audiology with a questionnaire added in to figure out if people need help specifically for tinnitus. All the skills education that happens after that is something that really doesn't have to happen in person. As the current state of affairs, certainly within the VA and definitely within the civilian population is that a lot of people who have problematic tinnitus just don’t have access to somebody who knows how to help them with it. And we are realizing that really the parts that are specific to teaching people coping skills could potentially be done over the phone.
So we started exploring that option, telephone-based PTM. So it's a novel approach to providing services to people with tinnitus. It can -- it may facilitate participation among those of limited access to VA or DoD Medical Centers. Level two is still done in the clinic, but it doesn't require any special training. It's just regular audiology combined with a survey.

Levels three through five are conducted over the telephone and they do require special training, but you can have a small number of people who can disseminate that information, that skills training anywhere they can reach somebody over the phone.

So the -- and there are some advantages to -- as we're developing our telephone-based PTM, we really had in mind the needs of people with traumatic brain injury. This is something we've really become kind of focused on, the needs of traumatic brain injury, and so there's some things about telephone-based PTM that are actually advantages for people who have traumatic brain injury.

So it allows for frequent and brief intervention to accommodate the needs of people with impaired memory, limited concentration, and other cognitive difficulties. So it doesn't have to be an appointment where they are driving all the way to the VA, you can just do short little -- short frequent check-ins a lot easier than you can do short frequent visits.

Appointments can be conducted from home, so they are in a comfortable and familiar environment. If they have a reminder system that they use at home, they can access that in their home environment as you're talking to them about the things that you want them to do, and there is no need to coordinate transportation.

And it only requires a telephone. So there is no complicated tele-health equipment. They don't have to get ahold of the equipment. They don't have to learn it. If they know how to use the phone, they have access to the care that they need for tinnitus.

Some other advantages. It's easily accessible by people who require these services, regardless of their location. When we think about the DoD, that seems like a pretty big advantage to be able to reach people anywhere in the world, as long as they have access to a telephone. And one especially advantageous thing about telephone-based PTM is that you can use a very small number of highly trained and experienced clinicians to provide services to a really large number of people.

And now I am going to hand things over to Caroline Schmidt.

Thanks, Tara. I’m going to take control now and make sure that you all can see and hear me okay. Maybe you can let me know via the chat if, for some reason, you can’t hear me okay. So, good. So it looks like everybody can hear me, so I’m going to take control of these slides as well and make sure I can do that yet.

So what I’m going to talk with you a little bit about is the study that we did, investigating the use and the efficacy of PTM delivered by telephone with veterans, military personnel and civilians. So we did the study, but before we did the study, we started with a pilot study which was funded from 2008 to 2010 and funded through R&D, the VA’s R&D.

And we looked at veterans who had head injuries versus those who did not. And what we did was we adapted the -- adapted PTM for telephone and we included 36 participants. We classified or categorized those veterans into three different categories of head injury. They were those with probable systematic mild TBI. We had those in the category of moderate to severe TBI and then we had a third group which was no symptomatic TBI.

And that's important because just because somebody said that they had a head injury a long time ago, we did not classify them into a head injury group unless they told us that they had current symptoms.
Now based on those symptoms and based on guidelines that we had in advance laid out, we were able to categorize them to these three groups. And for time sake, I'm going to move forward because we want to be able to get to questions.

That was our pilot study. And we had great results, so we moved on to a larger randomized control trial, which was funded from 2010 to 2015. That was funded through R&D, the VA R&D, and it was Tele-health Tinnitus Intervention For Patients with TBI, and we have now completed state (inaudible) for this study. Just recently, in fact, and are analyzing. So we've got a lot of our analyses done, but we still have a lot to go. So our results are preliminary.

We evaluated the efficacy of telephone-based PTM with 205 veterans, military personnel and civilians with tinnitus. And, again, we stratified the participants based on no TBI, mild TBI, and moderate to severe TBI.

We randomized after we stratified the groups and we decided -- we randomized into two sets. One group had -- immediately received PTM and the second group waited six months, and they were the wait-list control. So we administered the outcome questionnaire before they began receiving the intervention at six months.

And then we also used the tinnitus functional index, the TFI, which is the recent measure which is great for measuring change based on an intervention. And then the follow-up data were collected from 168 participants of those who were enrolled, so not all of them had follow-up yet, but, hopefully, we'll get all of those data completed. Actually, I think we've completed the data, but we have not completed the analyses.

And so the inclusion criteria were -- was all done by telephone. In fact, everybody was done by telephone. We did consenting by telephone. We disseminated the materials through the mail and we did all of the intervention by telephone. And veterans needed to have a clinically significant level of distress mode of tinnitus based on the tinnitus and hearing survey, which is the clinical measure, and we just wanted to have some basic -- wanted to make sure that they have at least the minimal significance in terms of their distress based on the THI.

They had to have a minimal score of a section on tinnitus of four. And to also demonstrate understanding of the requirements of the study based on questions, based on capacity to consent. We didn't want anybody to consent who didn't have the capacity to do so, especially considering the population. They had to have their hearing tested within the past year, two years, they had to be motivated and capable to participate and this was also where we assessed their risk to -- and their ability to consent in that way, because if they were actively having suicidal ideations, they weren't eligible for those studies, so at this point I did the -- most of the assessments to see if they had suicidal ideations, and if they did, then they weren't able to participate and then we referred them to the suicide crisis hotline and then we also checked in with them. We tried to connect them to local providers, either with their VA or at -- within the community, and then we -- if they were DoD -- I don't think this happened with DoD (inaudible), but if we had different procedures for that.

And then we would follow up and make sure that those providers who we connected them with had the material so we could share it with them, the information and the patients can still get help for their tinnitus, even if they weren't in the study. And so then once they were included in the study and able to participate, then we did these intervention calls. So I had the initial talk with them before the intervention calls and then, you know, to assess TBI and also to assess risk. And then once we got to these intervention calls, there were four calls with the psychologist, and this would have been with me, and three calls with the audiologist, Tara and another gentleman, Dr. McDermott, Dan McDermott, also participated as the audiologist, the study audiologist.
And these occurred, these appointments occurred at one, two, three, four and five and three and six weeks and then three and six months. So weeks one through five ideally we liked them to be consecutive and then it was three months after the first initial call with us and then six months after that -- after the initial call with us was (inaudible).

So it was a pretty intense schedule, but we hope not too intensive. Each call was scheduled for about an hour and the intervention for the wait-list control was just delayed for six months, it was the same intervention. All participants received our PTM workbook by mail shortly before beginning the intervention.

The first appointment with the psychologist was also the first appointment of the intervention and what we did was explain the purpose of the call, give the basic principles and rationale for CBT, which is sort of typical for CBT is to offer that rationale. We would teach stress monitoring and relaxation skills and we would work collaboratively to set some goals -- oh, also and to offer attention diversion. We would also work collaboratively with the participants to set up some goals that they can work on between the sessions. And then we also would make a referral if wanted for mental health concerns if it became clear that they needed additional services, say, for a depression or anxiety.

This is the changing thoughts and feelings worksheet and there is an analogous type of worksheet that Dr. Zaugg is going to talk with you about in a minute, but we talked a little bit about the different coping skills, deep breathing, which is the relaxation technique that we offer; imagery, which is another relaxation exercise and then changing thoughts. There was a (inaudible) older worksheet.

Typically what we also do is have patients work with us on -- work to plan (inaudible) activities. So this worksheet is slightly old, so current one that we were using included how to get your mind off of your tinnitus by doing things you enjoy. And that's available on the website that Tara or, I guess, Kathleen gave earlier, one of them. It's the Portland, Oregon NCRAR website, where you can find lots of these materials and handouts.

I'm going to pass those to Tara who's going to talk with you about the second intervention call.

All right. Thank you, Caroline. I'm going to keep it really short, because we are really low on time, so the first call with the audiologist focuses around this worksheet right here where we teach people to focus on sounds as a soothing effect, sounds that are interesting enough to distract your attention and sounds that when they are in the background you just tend to notice your tinnitus less. And we are pretty careful not to suggest masking.

Another thing -- we only have five minutes left and we haven't gotten to the results. So I'm actually just going to fast-forward us to the results so you guys can take a look at the results we got as a result of the intervention.

We have a few slides that were intended to tell you a little bit more about what happens at the appointment, but we've just got five minutes, so . . .

It's a total of seven intervention appointments and then I'll let Caroline talk to you some more about the results.

Thanks, Tara. So let me just quickly go over the results of our study. We can quickly just see we had great results and the people in the immediate care group were doing much better at the six-months time point. That was the time point with the wait-listed who had not received the intervention. You can see that the overall change in mean among those participants in the immediate care group was 20.88. That's an improvement of 20 points on a 100-point scale, which is the TFI, and so that is the mean improvement score. Standard deviation was fairly wide in disbursement, which was 18.3.
The wait-list control group improved slightly, which was 1.31, with a standard deviation of 14.42, so you can see that the group containing telephone-based PTM during the first six months, significantly improved when compared to wait-list. So that's a strong endorsement, I think, of PTM by telephone.

Now looking at the next slide, which is looking at the specific groups, no TBI, mild TBI and severe TBI, there was an (inaudible) done by our analyses team and we can see that the immediate care group even did well compared to the wait-list group when you look at the stratified groups of TBI.

And also we found that there was no difference if you were just looking at the specific groups of TBIs if you just grouped them together, immediate care versus wait list control. So there was no difference in change from baseline to six months, depending on the TBI categories. It wasn't just that they were in that particular category, it was based on wait-list control versus six months -- I'm sorry, immediate care versus six months wait list.

And there was no evidence that the effect of telephone-based PTM is different for subjects with different categories. I think I mentioned that already.

So basically we're happy with these results and happy that the intervention was useful by telephone and that it's useful both for people with no TBI and with TBI.

I'm going to hand this back over to Tara Zaugg who is going to finish up with the conclusions.

All right, we'll spend just a little bit of time on the conclusions and once we get to the end of this, we'll have another eight to ten minutes for questions.

So overall, tinnitus has increasing prevalence in the TBI population. We understand that tinnitus can result in a lower quality of life and it's become quite clear to us that intervention requires a multidisciplinary approach.

Now the most important takeaway message is that telephone-based PTM is an option for helping veterans and military service members with a history of TBI learn effective coping skills for bothersome tinnitus.

We've got numbers that support this and also we really have repeatedly been told by veterans that we've worked with that this is a meaningful way of approaching tinnitus and improving their quality of life.

So just a few acknowledgements. We're grateful to the many veterans and non-veteran participants in our research who contributed to the development of PTM. I'm just going to list here agencies that supported our work.

If you have any questions, feel free to contact us for more information. My email address is here and also James Henry's email address and if you're interested in picking up materials or if you just have questions for us, let us know and we'll be happy to help you.

All of our references listed out here and a little bit of information about receiving CE credits.

And now we'd like to open it up for questions.

Thank you very much, Dr. Zaugg and Dr. Carlson. We do have a few minutes for some questions. We'll start here with our live audience at DH HQ.

If there are any questions, if you could raise your hand and we'll get a mic to you.

Hi. (Inaudible) Adler (phonetic) from the DoD National Center for Tele-health and Technology. Excellent presentation. I just was really curious about whether you have -- I know this wasn't part of your formal investigation, but have you had any thoughts about integrating what you're doing with the VA's tele-
audiology intervention as a way of doing the hearing aid assessment and adjustment remotely so that you could further reduce the need for somebody to come in for live intervention?

That's something we really haven’t put a lot of thought into. Typically when we think about hearing aids for people who have bothersome tinnitus, we’re really focused on making for sure that people get hearing aids, that they get the help for hearing that they need.

And then -- so as many people are probably aware, but maybe some aren’t, a lot of hearing aids combine hearing aids along with a sound generator portion that's developed for people who have tinnitus and part of the skills education where we're teaching people about appropriate expectations from sound and kind of how to approach use of sound for tinnitus, that provides them with the education they need to figure out how to use the sound generator portion.

And I’ve never considered -- I’ve never really thought about advantages of making audiology tele-health services available specifically for people who have tinnitus. Off the top of my head, it seems like they’d have similar needs to anybody who needs to not come in for hearing aid services. But that's an interesting thing for us to consider, is how we might work with that network. I'm aware of it, but I really don't know a lot about it.

I’d like to just say something about what we’re doing in Connecticut. The hearing aid assessment is really considered level two anyway, and we don’t typically do an intervention at level two. And I think Tara was just talking a little bit about that. But we, in Connecticut, do work with our tele-hub team to provide services at our C-box. So we’re doing that by tele-health in Connecticut at any C-box. We aren't doing it in the home like this study was doing because we’re just not quite there yet in terms of providing that kind of service and there's a lot of things that we’re going to have to consider in terms of risk and other things once we launch this into the home, which I think is in the future.

So that's a very good question and I think that we have worked with some pockets of tele-health, in audiology, locally.

And we have time for one more question. I’m going to pose this question. It was submitted from a participant in our virtual audience. You mentioned focusing on sounds which distract from tinnitus. Can you offer a few other specific tips which may be beneficial for teaching patients?

Sure. Well, one of the distraction techniques that we mentioned was just planning cloaking activities, getting your mind off of your tinnitus. And that's just one of the many ways that patients can get distracted. What we hear from people all the time is that when I’m busy, I’m working, I’m, you know, doing this and doing that, doing things I enjoy, I don't notice my tinnitus. So it's like, great, let's work with that and help you get that more into your life. And sometimes it is the sound that helps distract people. We don’t quite know the mechanism of what sound is doing for managing tinnitus, and distraction might be a part of that element and that cloaking technique. So it's really whatever works for that person in taking an individualized approach to what works for that person in getting them distracted from their tinnitus. And so if it's, you know, listening to NPR that gets them distracted or if it's listening to music or if it's working, you know, getting whatever it is that works for that person, getting more of it and helping them really engage in those activities.

All right. That is, unfortunately, all the time we have for questions for this session. Please join me in thanking our speakers, Dr. Zaugg and Dr. Carlson.