2

Research Leading to PTM

In 2005, audiologic tinnitus management (ATM) was published as a comprehensive protocol for the management of tinnitus by audiologists (J. A. Henry, Zaugg, & Schechter, 2005a, 2005b). ATM was modified and expanded upon to create five hierarchical levels of clinical management, at which point the name was changed to "progressive" ATM (PATM) (J. A. Henry, Zaugg, Myers, & Schechter, 2008a, 2008b). PATM now is under revision to incorporate components of cognitive-behavioral therapy (CBT) to address psychological aspects of tinnitus (J. A. Henry, Zaugg, Myers, Kendall, & Turbin, 2009). As PATM is evolving to become inherently interdisciplinary, use of the word "audiologic" to describe the protocol no longer is appropriate. For that reason, the name was shortened to progressive tinnitus management (PTM).

The need for a *progressive* approach to tinnitus management became apparent as a result of conducting our series of controlled clinical studies. The PTM methodology evolved largely as a result of these experiences. Additional influences for PTM came from clinical experiences with patients and from consultation with experts from different disciplines whose insights in particular shaped the PTM patient education. PTM is designed to address the needs of all patients who complain about tinnitus while having minimal impact on clinical resources.

Prospective, controlled clinical studies are essential to evaluate and document the efficacy of tinnitus interventions. We have completed three studies and two are underway—both of which involve PTM. Conducting these studies required the development of highly specified protocols to ensure consistent performance of the various interventions. In addition, procedures were developed to efficiently screen and evaluate candidates to determine if they met study inclusion criteria, which differed for each study. Conducting these studies not only provided efficacy data, but also identified procedures that were most efficient for clinical application. Each of these studies and the insights gained from them are described below.

First Study

Our first study evaluated the relative efficacies of tinnitus masking (TM) and tinnitus retraining therapy (TRT) (J. A. Henry, Schechter, et al., 2006a, 2006b). For the study protocol, each of these methods involved the use of ear-level devices (hearing aids, noise generators, combination instruments) and intervention appointments at 0, 3, 6, 12, and 18 months. Only persons with very problematic tinnitus would warrant such rigorous, long-term clinical procedures. Therefore, it was necessary to carefully evaluate study candidates to determine their eligibility for receiving one of the interventions.

Advertising resulted in about 800 callers who expressed interest in participating. This level of response greatly exceeded our capacity to conduct a full clinical evaluation of each candidate. We therefore devised a three-stage screening protocol. For stage 1, a brief series of questions were administered to callers to establish that they experienced chronic tinnitus and that the tinnitus was so problematic that 18 months of intervention seemed justified. If so, they were invited for a hearing and tinnitus assessment (stage 2). Of the 800 callers, 171 (21%) received the stage 2 assessment. Following the assessment, those who qualified met with one of the tinnitus specialists (stage 3) to discuss results and to ensure a full understanding of all study requirements. Of the 171 who received the stage 3 assessment, 123 qualified and agreed to participate —representing only 15% of the original 800 callers.

Study outcomes were based on the Tinnitus Handicap Inventory (THI) (C. W. Newman, Jacobson, & Spitzer, 1996; C. W. Newman, Sandridge, & Jacobson, 1998). Overall, both TM and TRT cohorts showed significant improvement on the THI, with TRT providing greater benefit at 12 and 18 months (J. A. Henry, Schechter, et al., 2006a, 2006b).

Lessons Learned from First Study

The first study showed that both TM and TRT, when conducted in a tightly controlled manner, could provide significant benefit to a large majority of individuals with severely bothersome tinnitus. Both methods utilize broadband noise as therapeutic sound, but the application and purpose of the sound differ substantially between methods (J. A. Henry, Schechter, Nagler, & Fausti, 2002). With TM, sound is used to achieve an immediate sense of relief. "Immediate relief" is irrelevant with TRT because the objective of TRT is to create contrast reduction between tinnitus and the acoustic environment to promote habituation (P. J. Jastreboff, 2004). Our study provided evidence that these different clinical objectives largely were achieved for the two methods. Thus, a major lesson learned from this study was that sound can be used in different ways to accomplish different therapeutic objectives. The use of therapeutic sound with PTM expands on this concept to provide patients with an understanding of many different ways that sound can be used for tinnitus management. By understanding these different strategies for using sound, patients learn to use sound in a targeted manner to address any situation in which tinnitus is problematic.

With PTM, the basic strategies of using therapeutic sound with TM and TRT have been retained. However, the terminology and descriptions used with patients have been changed. These changes were designed to simplify the concepts for patients—to avoid misconceptions (such as thinking that the purpose of "masking" is to make the tinnitus inaudible) and to reduce confusion (such as trying to understand how specifically to achieve the "mixing point" with TRT). With PTM, use of sound to provide "immediate relief" is referred to as "soothing sound." Soothing sound can be used whenever patients wish to reduce stress or tension associated with tinnitus. Using sound to create "contrast reduction" is referred to as "background sound." Patients are advised to use background at all times as a passive-listening strategy to pay less attention to their tinnitus. Patients receiving PTM education learn to distinguish between the different applications of sound and to select different applications to accomplish different purposes.

For any clinical trial, it is necessary to determine if a candidate's condition warrants the intervention being offered. Our unexpectedly high volume of

callers made it immediately evident that methodology was needed to provide efficient screening of individuals who claim to have a problem with tinnitus. In Chapter 3 we discuss how the large majority of people who experience tinnitus are not bothered by it. Many individuals with nonbothersome tinnitus, however, respond to announcements about tinnitus trials—even if the announcement states clearly that the study is for persons who are *bothered* by tinnitus. We needed methodology to query these callers to quickly assess the nature and severity of their tinnitus. It was particularly important to determine if a caller's complaint was due more to a hearing problem than to the tinnitus itself (J. A. Henry, Zaugg, et al., 2005a; Zaugg, Schechter, Fausti, & J. A. Henry, 2002). We have since developed and refined screening techniques to differentiate hearing problems from tinnitus problems. Most importantly, we developed the Tinnitus and Hearing Survey that now is the essential tool used with PTM for this purpose (see Chapter 5).

Second Study

The purpose of our second study was to determine the potential benefit of group education as intervention for bothersome tinnitus (J. A. Henry, Loovis, et al., 2007). The educational curriculum was an adaptation of the structured TRT counseling protocol. Participants attended four weekly 1.5-hour classes. Two control groups consisted of a "tinnitus support group" and a no-intervention group. The support group, also involving four weekly 1.5-hour meetings, was led by a facilitator who encouraged positive discussion about tinnitus but did not provide education. Veterans with bothersome tinnitus (n = 269) were randomized into one of the three groups. Outcomes were assessed at baseline and at 1, 6, and 12 months. Overall results revealed that group education provided significant improvement on the Tinnitus Severity Index (R. M. Johnson, 1998) from baseline through 12 months (p <.001). Neither of the control groups showed significant improvement from baseline to any of the follow-up time points.

Lessons Learned from Second Study

This study tested the effectiveness of a unique protocol of group education for tinnitus. Importantly, although participants did not receive an audiologic evaluation, 93% of the participants responded "sometimes," "usually," or "always" in response to the questionnaire item "Do you experience hearing difficulty?" In response to another item ("Does your tinnitus make it more difficult for you to hear?"), 83% responded "sometimes," "usually," or "always" (an additional 8% were "unsure"). In Chapters 3 and 5 we discuss the concern that many patients who complain about tinnitus mostly are bothered by hearing difficulties. Thus, when patients seek services for their tinnitus they may really need a hearing assessment and possibly hearing aids. Not addressing these participants' audiologic needs undoubtedly reduced the effectiveness of the group education. This insight confirmed the need to conduct a hearing evaluation and fit hearing aids if necessary as the first stage of management for tinnitus. For this reason, the Level 2 Audiologic Evaluation is the first stage of management with PTM, and includes a hearing evaluation and questionnaires to differentiate hearing problems from tinnitus-specific problems.

The benefit observed for the education group was sustained for 12 months, contrasting with results from a similar trial (J. L. Henry & P. H. Wilson, 1996). In that trial, significant improvement was observed on the Tinnitus Reaction Questionnaire for the education group immediately following the intervention, but which dissipated by 12 months. A major difference between the two education groups was that in our study the education group received focused instruction on using constant low-level background sound to facilitate habituation to tinnitus. It may be conjectured that the participants applied this information, thus facilitating the sustained benefit. Using constant background sound is a major instructional point with the PTM education and counseling.

Of the approximately 750 callers who were screened, 269 (36%) were enrolled. Thus, although all participants were offered the four education classes (those in the control groups could attend

the classes after completing the study), 64% of the callers declined the opportunity to receive the education. Most callers indicated that their tinnitus was not enough of a problem to warrant attending the classes. This again speaks to the need to provide a hierarchy of clinical services so as to tailor services to the individual and to avoid providing more services than are necessary.

Additional insights gained from this study include: (a) a typical noneducational tinnitus support group does not seem to benefit the participants (thus, any group meetings for patients should include an appropriate educational component); and (b) individuals who are bothered by tinnitus but do not receive clinical services seem to stay at the same level with regard to how they are affected by their tinnitus (the fact that they don't seem to improve over a period of a year suggests that these individuals should receive clinical services). Most importantly, this study showed clear benefit of providing education in a group setting, which led to the development of PTM Level 3 Group Education (J. A. Henry, Zaugg, Myers, Kendall, et al., 2009).

Third Study

The first study evaluated the methods of TM and TRT to determine their efficacy for veterans who are severely bothered by tinnitus. Benefit was evident, but each method was conducted by an expert in the respective intervention. This third study was designed to determine if audiologists who are not tinnitus experts can provide effective intervention with TM and TRT. The study was conducted at four VA hospitals (Bay Pines, Florida; Portland, Oregon; San Diego, California; and Seattle, Washington). At each site, 36–38 veterans with clinically significant tinnitus (total $n = 148$) were recruited and randomized to TRT, TM, or a control group that received generic tinnitus counseling (i.e., nothing specific to TM or TRT) and hearing aids (if needed). Participants in all three groups received an initial evaluation and attended counseling appointments at 0, 3, 6, 12, and 18 months. Analyses revealed that each of the three groups showed significant improvement (based on mean index scores from the Tinnitus Handicap Inventory), with no significant differences between groups (publication in preparation).

Lessons Learned from Third Study

It was unexpected that the control group had outcomes comparable to TM and TRT. Although intended as a nonspecific-therapy control group, the counseling developed for this group was effective and subsequently published as part of the method referred to as audiologic tinnitus management (ATM) (J. A. Henry, Zaugg, et al., 2005b). The ATM counseling focused on how to use sound and sound-delivery devices to reduce the impact of tinnitus, which was the precursor to the counseling we have since developed for PTM. For PTM, these basic concepts have been refined and organized into a systematic description of the different ways that sound can be used to manage tinnitus. Thus, an insight from the third study was that a single approach to using sound may be too restrictive for addressing all of the different situations when tinnitus is problematic for patients. With PTM, patients are instructed in depth about the different uses of therapeutic sound to empower them to determine *on their own* how to use sound in a specific manner whenever their tinnitus is bothersome (J. A. Henry, Zaugg, Myers, Kendall, et al., 2009).

As a result of developing the "generic" counseling for the control group, we devised a third strategy for using therapeutic sound (in addition to using "soothing sound" and "background sound" as described under "Lessons Learned from First Study" above). The third strategy was to use sound for attention diversion, by listening to anything that would engage the mind for a sustained period. For PTM, this third strategy is referred to as using "interesting sound" with the purpose of focusing conscious attention away from the tinnitus and onto the target sound. Furthermore, the counseling created for the control group led to our development of numerous concepts, techniques, and tools for using therapeutic sound that now are described in the PTM self-help workbook and as part of the PTM educational counseling.

As for the first study, this third study required participants who were so bothered by their tinnitus that rigorous, long-term intervention was warranted. Screening methods that we developed as a result of the first and second studies were used with the third study to ensure that only qualified veterans were enrolled from the 505 candidates. Prior to completing all of the appointments, however, many participants realized that the intervention they had received was sufficient and that no further services were needed (30% of the participants dropped out of the study—most for this reason). Although it was gratifying to observe early therapeutic success, it was clear that a *progressive* approach was needed to provide services only to the degree necessary to meet individual needs. This progressive approach is a hallmark concept for PTM—patients undergo a series of short-term clinical interventions that can, if necessary, lead to Level 5 Individualized Support.

A comprehensive tinnitus assessment protocol was developed for use with all participants in this study. The protocol was published as one of the two ATM companion articles (J. A. Henry, Zaugg, et al., 2005a), and included: (a) a structured interview to identify problematic aspects of tinnitus; (b) a tinnitus psychoacoustic assessment; and (c) in-clinic trials to determine the potential benefit of ear-level noise generators and combination instruments. The protocol has since been refined for the PTM Level 4 Interdisciplinary Evaluation, and some components have been adapted for use during the Level 2 Audiologic Evaluation (J. A. Henry et al., 2008b).

Conducting this study required training 12 audiologists at four VA hospitals. The training was provided via the VA videoconferencing (V-Tel) system. Each study audiologist received about six hours of V-Tel training supplemented by a procedures manual. This training likely was inadequate for audiologists to perform methodology that normally requires much more training and considerable experience to attain a high level of proficiency. It was evident that any future tinnitus trials would require much more intensive training. For our pilot PTM study (described immediately below), we developed an extensive online training course as well as numerous clinical tools to facilitate all aspects of implementing the protocol.

Fourth Study

The fourth study currently is nearing completion at the James A. Haley Veterans' Hospital in Tampa, Florida. This study was designed to develop PTM and to evaluate its clinical efficacy in a pilot study to compare it to "usual care." Usual care (UC) involves services that are typical of what is provided at VA audiology clinics, that is, an audiologic examination, hearing aids if needed, and some minimal counseling specific to tinnitus. For this study, UC participants can receive ear-level noise generators or combination instruments if deemed necessary by the audiologist.

Development of the PTM implementation materials was a substantial undertaking requiring two years of continuous effort. Insights gained from our previous trials were applied to the PTM protocol. Five hierarchical levels of PTM were defined and detailed clinical procedures were developed for each level. A new counseling protocol was developed that incorporated principles of patient education and health literacy to ensure that the materials were accessible to as many patients as possible (J. A. Henry, Zaugg, Myers, Kendall, et al., 2009). An online, 18-module training course was developed for audiologists and numerous materials were developed for audiologists and patients. Major educational materials were developed to implement the protocol at the different levels.

As of November 2009, 221 clinical patients were enrolled by telephone in this study—109 were randomized to UC and 112 to PTM. Of these 221 patients, 21 who were randomized to UC, and 26 randomized to PTM, were excluded from study participation because they did not show up, called to be removed, or had a diagnosed psychotic disorder, dementia, or serious health concern. After excluding these 47 patients, 86 PTM patients and 88 UC patients attended an initial appointment and completed questionnaires. Of the 86 PTM patients, 23 attended at least one of the Level 3 Group Education sessions. Following Level 3, four patients attended a Level 4 evaluation. Only one PTM patient felt it was necessary to receive Level 5 Individualized Support. Of the 88 UC patients,

36 attended only the evaluation appointment and 52 attended a second appointment to receive hearing aids. As the study is still in progress, analyses of outcomes are not yet possible to determine how well patients do at the different levels of PTM.

Lessons Learned from Fourth Study

A major goal of this project was to learn about the process of putting the PTM protocol into clinical practice. To do so we conducted several formative evaluations. (A formative evaluation is "a rigorous assessment process designed to identify potential and actual influences on the progress and effectiveness of implementation efforts" [Stetler et al., 2006].) The results have been applied to our current research with PTM.

Online Course for Clinicians

An early, central element of implementing the PTM protocol is clinician education via an online course. The Chief of Audiology at the Tampa VA hospital made time available for each clinician to complete the 18-module course. All study audiologists completed the course and responded to embedded questions. These responses were compiled and analyzed to identify how to improve the course.

The online course currently is being revised and updated, and we are working with VA Employee Education System to make the course available via the VA Learning Management System (LMS). This course should become available for use by VA audiologists shortly after the publication of this handbook. We also will attempt to make the course available to non-VA audiologists.

When the online course becomes functional, an additional need will be to develop a program that simulates a clinical practicum for audiologists who have received the PTM training. To address this need, future plans include development of a "virtual clinic" to computer-simulate patients receiving clinical services with PTM. The program will depict patients with a variety of clinical presentations and clinicians will be challenged to make appropriate decisions to provide optimal care.

Conference Calls Held with PTM Audiologists

During these calls with clinicians and the study team, semistructured discussions addressed the acceptance and general satisfaction with the protocol as well as any difficulties performing each level of PTM care. Notes from these calls were compiled and reviewed to identify any barriers or facilitators to the management of tinnitus using PTM. We are adapting the program to be responsive to the feedback received from these calls.

Clinical Implementation of PTM

By collecting formative data during the implementation of PTM in the Tampa VA Audiology Clinic, we learned that preplanning for some of the activities could improve the implementation process. For example, prior to starting the program, administrators should know that (a) the PTM audiologists will require release time to complete the Web-course; (b) the audiologists will be working with psychologists, which will require preplanning with the psychology section of the hospital; (c) patients being seen for tinnitus will need hearing evaluations and may need ear-level devices; and (d) the PTM protocol necessitates access by audiologists to a meeting room for the Level 3 workshops. We also recommend holding regular calls or meetings with audiologists who are beginning to use the protocol to address barriers that may arise as they put PTM into practice. Valuable information can be identified and acted on to improve fidelity to protocol.

Patients in this pilot study were all veterans at the Tampa VA hospital who complained of bothersome tinnitus. As all of the patients in the PTM cohort were offered tinnitus services beyond Level 2 Audiologic Evaluation, it is clear that the majority of these patients either chose not to receive higher-level services or it was too difficult for them to attend the additional visits that were required to participate in the Level 3 workshops. We will look carefully at the data to determine if patients' perceptions of adequate care following Level 2 are accurate. We now are more strongly advising patients to attend Level 3 Group Education to ensure that each patient who is bothered by tinnitus receives the edu-

cation that is essential to learn basic self-management skills. We also provided patients in the PTM cohort the self-help workbook at the end of Level 2. We now are recommending that the workbook not be provided to patients until they attend their first Level 3 workshop (see Chapters 3 and 5).

Finally, only a few patients in the PTM cohort required services beyond Level 3. With the addition of CBT to the Level 3 protocol, the effectiveness of the Level 3 workshops is expected to be substantially improved, which should ensure that very few patients will require Level 4 and 5 services.

Fifth Study

This is an observational pilot study currently being conducted to assess an adaptation of the PTM methodology for use with veterans and active military who have experienced traumatic brain injury (TBI) and also have bothersome tinnitus. As these individuals are located all over the country, we developed a home-based telehealth method. The procedures are conducted over the telephone, and intervention materials and questionnaires are delivered via the mail/FedEx. The study includes three cohorts (all with bothersome tinnitus): (a) probable mild TBI history; (b) moderate or severe TBI; and (c) no TBI.

Interested callers are screened for tinnitus severity and probable TBI history. Callers who pass screening are sent the self-help workbook (2nd edition prepared specifically for this study) along with baseline questionnaires and the informed consent form. The research coordinator then conducts informed consent, assesses "capacity" (cognitive ability) for candidates to provide informed consent, and enrolls eligible candidates. Participants attend a telephone appointment with the study psychologist who conducts brief cognitive screening and teaches coping techniques for managing reactions to tinnitus based on CBT (J. L. Henry & P. H. Wilson, 2001). The next appointment is with the study audiologist who provides the PTM audiologic/sound-based counseling that normally is provided at Level 3 Group Education, but in a one-on-one format similar to Level 5 Individualized Support (J. A. Henry, Zaugg, Myers, Kendall, et al., 2009). Telephone appointments alternate between the psychologist and audiologist for 6 months (total of seven appointments).

As of November 2009, 172 individuals called about the study. Of these, 36 participants were enrolled, including 15 in the probable-mild TBI group, 10 in the moderate/severe TBI group, and 11 in the no-TBI group. Twelve-week outcome data are available for 23 participants, and 24-week outcome data are available for 16 participants. Preliminary results of the primary outcomes can be summarized as follows. On average, participants lowered their Baseline THI scores by 13.6 points at the 12-week evaluation, and by 21.7 points at 24 weeks. Because outcome data are incomplete, and because of the small numbers of participants, these data cannot yet be subjected to statistical comparisons.

Lessons Learned from Fifth Study

This project responds to the need to provide special clinical services for veterans and military personnel who have experienced TBI and also suffer from bothersome tinnitus. Because of the complications of TBI, it was necessary to include a neuropsychologist with expertise in TBI and a clinical psychologist with expertise in tinnitus management to assist in the design and implementation of the trial. These collaborators have made the necessary revisions to the PTM protocol so that it is appropriate for telephone-based administration to TBI patients. For example, the participants undergo a cognitive screen to determine their abilities to comprehend the counseling information and to follow through with the management recommendations.

Prior to the design and development of this study, it was obvious that psychological concerns were not adequately addressed by the PTM counseling. This was a shortcoming that is being addressed for the first time using the PTM protocol in this pilot study. The PTM protocol thus is evolving to include counseling that covers all aspects of using therapeutic sound as well as addressing psychological components of tinnitus. Several researchers

have conducted clinical trials that support CBT as an effective psychological method for managing tinnitus (Martinez Devesa, Waddell, Perera, & Theodoulou, 2007). Thus, CBT was incorporated into the PTM method. The components of CBT that are being used include training in behavioral modification (stress management via relaxation techniques and scheduling pleasant activities), as well as cognitive restructuring (step-by-step examination of changing thoughts to acquire a more positive attitude about tinnitus). Thus, abbreviated telephone-based CBT was developed to incorporate essential features of this psychotherapy.

The addition of CBT to the PTM protocol required expansion of the self-help workbook to include the new information. We developed a second edition of the workbook that is mailed to all participants in this pilot study (J. A. Henry, Zaugg, Myers, & Kendall, 2009). This new workbook also contains two DVDs that supplement the written material: (a) interactive video that guides patients through the material normally presented in PTM Level 3 Group Education; and (b) demonstrations of relaxation training exercises including deep breathing and imagery. We recently completed the third edition of the workbook based on feedback from subjects using it during this pilot study, which is being distributed to all VA audiologists and also is in publication for non-VA use (J. A. Henry, Zaugg, Myers, & Kendall, 2010a). The workbook contains a DVD and CD that were developed through VA Employee Education System.

Additional Evidence Supporting PTM

Numerous studies have supported the use of therapeutic sound for tinnitus management. Evidence has been provided by these studies supporting the beneficial use of: (a) hearing aids (Del Bo & Ambrosetti, 2007; Folmer & Carroll, 2006; Saltzman & Ersner, 1947; Surr, Kolb, Cord, & Garrus, 1999; Surr, Montgomery, & Mueller, 1985; Trotter & Donaldson, 2008); (b) ear-level masking devices (Folmer & Carroll, 2006; Hazell et al., 1985; Schleuning, Johnson, & Vernon, 1980; Stephens & Corcoran, 1985); (c) TRT (Bartnik, Fabijanska, & Rogowski, 2001; Berry, Gold, Frederick, Gray, & Staecker, 2002; Herraiz, Hernandez, Plaza, & de los Santos, 2005; Herraiz, Hernandez, Toledano, & Aparicio, 2007); and (d) neuromonics tinnitus treatment (P. B. Davis, Paki, & Hanley, 2007). Our first clinical study (see First Study above) demonstrated that all types of ear-level devices (hearing aids, sound generators, and combination instruments) could be used effectively with both TM and TRT (J. A. Henry, Schechter, et al., 2006a, 2006b). Our third clinical study (see Third Study above) extended the first clinical trial and showed that TM, TRT, and a nonspecific control group all provide significant benefit to subjects. Folmer and Carroll (2006) evaluated 150 patients who attended a comprehensive tinnitus management clinic, including patients who (a) used hearing aids ($n = 50$); (b) used ear-level noise generators ($n = 50$); and (c) did not use ear-level devices ($n = 50$). Significant improvement was experienced by all three groups. Notably, the patients who used hearing aids and noise generators experienced significantly greater benefit than did the patients who did not receive devices.

As a whole, these many studies comprise a strong body of support for the efficacy of using therapeutic sound to manage tinnitus. It should be noted, however, that the evidence does not demonstrate that any one of these methods is superior to any other. Rather, it appears that any judicious use of sound seems to be helpful for managing tinnitus, and it may be that some methods are more helpful in certain situations and for certain patients. Clearly, research is needed that systematically evaluates the different parameters of sound to determine which parameters provide the greatest benefit and under what conditions. With PTM, the overriding philosophy is that therapeutic sound provides the greatest benefit when patients are informed about the different uses of sound for tinnitus management, and when patients learn how to develop, on their own, sound-management plans to address specific situations when their tinnitus is problematic. PTM utilizes procedures that encourage patients to incorporate good self-management practices.

CBT is an evidence-based and appropriate addition to PTM to address the psychological components of tinnitus distress that are so common with these patients. CBT is a type of psychother-

apy that targets specific thoughts, core beliefs, and negative appraisals of situations that are unconstructive (and may cause distress) while providing tools for implementing more adaptive behavioral and cognitive modifications (Beck, 1995; Sweetow, 2000). Martinez Devesa et al. (2007) conducted a meta-analysis of six randomized, controlled studies (285 participants) of CBT for tinnitus. They found significant improvement in quality of life (decrease of global tinnitus severity) for those receiving CBT compared to those who did not receive CBT.

Summary

The five levels of PTM provide a logical, sequential means of working collaboratively with a patient to best determine the patient's needs and to provide only the services that are needed. PTM patients receive only basic audiology services and tinnitus education (from an audiologist and a psychologist) through Level 3, which do not require a major commitment on the part of either the clinician or the patient. Included in the education are thorough explanations of the different ways that therapeutic sound and coping skills can be used to manage reactions to tinnitus. Patients are then taught how other sound-based methods use therapeutic sound. Patients should have this understanding before committing to an expensive and time-consuming clinical protocol. This also is the reason that fitting ear-level noise generators or combination instruments is not normally advocated until Level 4. Patients need to be fully informed before making such consequential decisions.

Tinnitus research has been conducted at the Portland VA Medical Center since 1995 (under the auspices of the NCRAR since 1997). In 1999 we began a series of clinical trials to evaluate different methods of tinnitus management, which provided the experience and data that led to development of the PTM model of care. The basic content of the PTM protocol (i.e., the levels of care) has been defined from the results of our years of research. The addition of CBT techniques to the PTM protocol addresses psychological aspects of tinnitus and thereby is expected to improve the effectiveness of PTM. The basic PTM protocol continues to provide a framework for "progressive" management for clinical expediency, but the clinical services provided now are of a more interdisciplinary nature.