

# Outcomes of Clinical Trial: Tinnitus Masking versus Tinnitus Retraining Therapy

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## Abstract

A controlled clinical study was conducted to evaluate prospectively the clinical efficacy of tinnitus masking (TM) and tinnitus retraining therapy (TRT) in military veterans having clinically significant tinnitus. Qualifying patients were placed into the two groups in an alternating manner (to avoid selection bias), and treatment was administered at 0, 3, 6, 12, and 18 months. Outcomes of treatment were evaluated using three self-administered tinnitus questionnaires (Tinnitus Handicap Inventory, Tinnitus Handicap Questionnaire, Tinnitus Severity Index) and the verbally administered TRT interview forms. Findings are presented from the three written questionnaires, and from two of the interview questions (percentage time aware of, and annoyed by, tinnitus). Outcomes were analyzed on an intent-to-treat basis, using a multilevel modeling approach. Of the 123 patients enrolled, 118 were included in the analysis. Both groups showed significant declines (improvements) on these measures, with the TRT decline being significantly greater than for TM. The greater declines in TRT compared to TM occurred most strongly in patients who began treatment with a “very big” tinnitus problem. When patients began treatment with a “moderate” tinnitus problem, the benefits of TRT compared to TM were more modest.

**Key Words:** Clinical trial, hearing disorders, military veterans, rehabilitation, tinnitus

**Abbreviations:** GHI = General Hearing Instruments; HLM = Hierarchical Linear Modeling; MLM = multilevel modeling; MML = minimum masking level; PVAMC = Portland Veterans Affairs Medical Center; THI = Tinnitus Handicap Inventory; THQ = Tinnitus Handicap Questionnaire; TISI = Tinnitus-Impact Screening Interview; TM = tinnitus masking; TRT = tinnitus retraining therapy; VA = Veterans Affairs; VHA = Veterans Health Administration

## Sumario

Se condujo un estudio clínico controlado para evaluar prospectivamente la eficacia clínica del enmascaramiento del acúfeno (TM) y de la terapia de reentrenamiento para acúfenos (TRT) en militares veteranos con acúfenos

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clínicamente significativos. Los pacientes fueron colocados en los dos grupos en una forma alternante (para evitar un sesgo de selección) y el tratamiento de administró a los 0, 3, 6, 12 y 18 meses. Los resultados del tratamiento se evaluaron utilizando tres cuestionarios auto-administrados sobre el acúfeno (el Inventario de Impedimento con Acúfeno, el Cuestionario de Impedimento con Acúfeno, y el Índice de Severidad del Acúfeno) y las fórmulas de entrevista de TRT administradas verbalmente. Se presentan los hallazgos de los tres cuestionarios escritos y de dos de las preguntas de la entrevista (porcentaje de tiempo conciente del acúfeno y porcentaje de tiempo de molestia por el acúfeno). Los resultados fueron analizados de acuerdo al intento de tratar, con un enfoque de modelaje multinivel. De los 123 pacientes involucrados, 118 fueron incluidos en el análisis. Ambos grupos mostraron una disminución significativa (mejorías) en estas mediciones, con una declinación para el TRT significativamente mayor que para el TM. La mayor disminución del TRT comparado con el TM ocurrió con mayor énfasis en aquellos pacientes que iniciaron con un problema de acúfeno “muy grande”. Cuando los pacientes iniciaron tratamiento con un problema moderado, los beneficios comparativos de estas terapias fueron más modestos.

**Palabras Clave:** Estudio clínico, trastornos auditivos, militares veteranos, rehabilitación, acúfeno

**Abreviaturas:** GHI = General Hearing Instruments; HLM = modelaje lineal jerárquico; MLM = modelaje multinivel; MML = nivel mínimo de enmascaramiento; PVAMC = Centro Médico de Asuntos de Veteranos de Portland; THI = Inventario de Impedimento con Acúfeno; THQ = Cuestionario de Impedimento con Acúfeno; TISI = Entrevista de Tamizaje sobre el Impacto del Acúfeno; TM = enmascaramiento del acúfeno; TRT = terapia de reentrenamiento para acúfenos; VA = Asuntos de veteranos; VHA = Administración de Salud de Veteranos.

**S**ubjective tinnitus is the sensation of hearing a sound that exists only inside the head. Persistent sensorineural tinnitus is experienced by millions of people in this country and is symptomatic of auditory system pathology. Exposure to loud noise can cause tinnitus and hearing loss (Axelsson and Barrenas, 1992; Penner and Bilger, 1995). Noise exposure is common in the military; thus, tinnitus is a particular concern for veterans. Tinnitus has become increasingly problematic both for veterans and for the Veterans Health Administration (VHA). Statistics provided by Veterans Affairs (VA) Office of Policy, Planning and Preparedness reveal that over 289,000 veterans with service-connected tinnitus received a total of over \$345 million in 2004 for their tinnitus disability compensation (Henry et al, 2004). These amounts represent a one-year increase of \$60 million for over 46,000 veterans who received a new tinnitus service connection. In 2001 tinnitus was the most common new

disability for veterans (Veterans Benefits Administration Annual Report, 2001).

Direct effects of problematic tinnitus include cognitive, emotional, and sleep disorders—all of which can impact performance of everyday activities (Erlandsson et al, 1992; Tyler, 1993; Axelsson, 1998). Veterans with tinnitus may report any or all of these disabling conditions, which vary considerably in severity. Veterans with more severe effects require structured, individualized treatment, which is not presently available at most VA medical centers (VAMCs) (Henry et al, 2004). Because of the VHA's emphasis on evidence-based clinical practice (e.g., VHA Directive 2002-039), any new implementation of treatment for tinnitus will require compelling research evidence. Dobie (1999, 2002, 2004) reviewed the randomized clinical trials that have assessed the efficacy of various treatments for tinnitus. He concluded that none of these studies showed a reduction or elimination of

tinnitus sensation more than placebo, nor did they demonstrate replicable, long-term benefit in tinnitus impact compared to placebo. Surprisingly, there were no randomized clinical trials to report for two widely used methods of tinnitus treatment: tinnitus masking (TM) and tinnitus retraining therapy (TRT).

TM and TRT have been used for many years in tinnitus clinics around the world. These two methods differ significantly with regard to both their rationale for treatment and their specific treatment protocols. Implementation of treatment with these techniques is accomplished most efficiently by audiologists who have received the proper training. A number of studies have reported good results with these methods (reviewed in Henry et al, 2002b). Most of these studies, however, were retrospective reports of clinical data.

VA is committed to implementing nationally developed, evidence-based practice guidelines to improve health-care outcomes and efficiency in the veteran patient population (Management Decision and Research Center, Department of Veterans Affairs, 1998; Feussner, 1998). For veterans with tinnitus, the present need is for evidence demonstrating the efficacy of implementable methods of tinnitus treatment. In response to this need, we have conducted a controlled clinical trial to evaluate the efficacy of TM and TRT in veterans.

## METHODS

### Design Overview

A two-group by five-time-period repeated measures experimental design was used to evaluate the effectiveness of the two treatment conditions, TM and TRT, in improving five patient outcomes reflecting tinnitus difficulty: the Tinnitus Handicap Inventory (THI), Tinnitus Handicap Questionnaire (THQ), Tinnitus Severity Index (TSI), and percentage ratings of awareness of tinnitus (AWARE) and annoyance by tinnitus (ANNOY). A multilevel modeling approach was used to analyze trajectories of 118 patients, of the 123 who were enrolled in the study, on each outcome over an 18-month period after study entry (Raudenbush and Bryk, 2002). In addition to estimating the

average patient trajectory in terms of baseline (intercept) and rate of change (linear slope) on each outcome, significant variation in patient intercepts and slopes was predicted by seven predictor variables including treatment condition, three baseline patient characteristics (hearing loss, duration of tinnitus, extent of tinnitus problem), and interaction of treatment condition with each patient characteristic.

### Recruitment of Patients

Recruitment of patients involved a three-stage process to ensure that only veterans with clinically significant tinnitus (i.e., a tinnitus condition warranting 18 months of individualized treatment) were enrolled into the study: (1) telephone screening; (2) baseline questionnaires and audiologic assessment; and (3) an appointment with a tinnitus specialist. Most of the veterans who inquired about the study responded to an advertisement placed in the local newspaper. Some veterans responded to a poster placed at the Portland Veterans Affairs Medical Center (PVAMC) Audiology Clinic, or were referred from the clinic. The use of human subjects for this research purpose was approved by the Institutional Review Board Committee at the PVAMC. Each participant signed an informed consent form prior to study enrollment.

Interested veterans were screened over the telephone using the Tinnitus-Impact Screening Interview (TISI, see Appendix A) that we developed to rapidly assess tinnitus severity (Henry et al, 2004). The TISI contains six questions that were derived from the TRT initial interview (Jastreboff and Jastreboff, 1999; Henry et al, 2003) and from the Tinnitus Severity Index (Meikle et al, 1995). (Note: the present version of the TISI is revised from what is shown in Appendix 1.) Telephone screening was performed primarily by the study audiologist (T. Zaugg), with some assistance by other staff who were trained for this purpose. If both the interviewer and the veteran felt that the tinnitus was so severe as to warrant long-term treatment, the veteran was scheduled for an evaluation appointment with the study audiologist.

At the evaluation appointment, candidates first signed informed consent. They then underwent audiologic and tinnitus testing, and answered questions from the

TRT initial interview (all performed by the study audiologist). This appointment served as a second “filter” to determine if the veteran’s condition warranted long-term treatment. If the study audiologist considered the condition to be sufficiently severe, and if the veteran was willing to comply with the study protocol, then the veteran was assigned to either the TM group or the TRT group. The first qualifying patient was placed into a treatment group by random selection. Each subsequent qualifying patient was placed by alternating between groups. This alternating approach to group assignment ensured that there was no group-selection bias for individual patients.

Following group assignment, patients were scheduled for an appointment with their respective treatment specialist to review the questionnaire and testing data and to discuss the specifics of the treatment protocol. This appointment served as the third and final stage of screening. Continuation in the study was contingent on the patient and the specialist reaching agreement regarding the treatment plan and the requirements to fulfill the study’s objectives.

Over 800 veterans were screened initially by telephone, of whom 171 were scheduled for an initial evaluation. During the second and third stages of screening, 48 of these 171 veterans were excluded from the study. There were, therefore, 123 veterans enrolled into treatment, including 59 (53 males and 6 females) in the TM group and 64 (all males) in the TRT group. (There were different group sizes because more veterans were excluded from the TM group than from the TRT group during the third stage of screening, i.e., after being assigned to a group but prior to initiating treatment. Also, the alternating group assignment method resulted in all six of the qualifying females being placed in the TM group.) Mean ages for the patients were 61.0 years ( $sd = 9.6$ ) for the TM group and 58.7 years ( $sd = 10.5$ ) for the TRT group. An independent samples  $t$ -test to compare mean ages between groups found no significant difference ( $p = 0.20$ ).

## Procedures

All clinical activities for this study were conducted at the PVAMC Audiology Clinic. The study audiologist performed audiologic and tinnitus testing, collected and checked the

patients’ written questionnaires, and administered the TRT interviews (to all patients in both groups). Treatment was performed by M. Schechter for TM and by J. Henry for TRT.

In a recent article (Henry et al, 2002b), the rationale and procedures for performing TM and TRT were described in detail consistent with the protocols of, respectively, J. Vernon and P. Jastreboff—founders of the two techniques. These individuals served as consultants for this project, and the procedures adhered closely to their recommendations. Both methods utilized specific variations of both counseling and sound therapy. Importantly, the 18-month treatment schedule was based on the schedule normally utilized with TRT. Thus, TM treatment, which is most typically accomplished in a single session, was extended to include return visits on the same schedule as for TRT. This modification to the TM protocol ensured that all patients were treated on the same time schedule.

## *Counseling for TRT*

The patients treated with TRT received structured educational counseling (Jastreboff, 2000; Jastreboff and Hazell, 2004). The TRT counseling protocol is modeled at the semiannual TRT training seminars that are conducted by P. Jastreboff. The TRT counseling protocol used in this study was based on the protocol as presented at the TRT seminars, including the use of patient counseling materials (diagrams, charts, etc.). The purpose of the counseling is to “demystify” the tinnitus by explaining mechanisms that underlie tinnitus and its annoyance. The basis of TRT counseling is P. Jastreboff’s “neurophysiological model,” which describes tinnitus from the standpoint of a neural signal and how the signal causes emotional and stress reactions. Patients are also explained the rationale and importance of “sound therapy,” that is, maintaining an “enriched” environment of nonannoying sounds to maximize treatment effects. Successful counseling removes negative associations with the tinnitus, which is necessary to facilitate habituation to the annoyance caused by the tinnitus (Jastreboff and Hazell, 1998). The TRT counseling amounts to a “teaching session.” The initial session requires about one hour, with

subsequent sessions requiring progressively less time to cover essentially the same material.

### ***Counseling for TM***

The structured and repeated counseling for TRT contrasts with the informal counseling approach that is characteristic of treatment with TM. Because of its informal and unstructured nature, a specific counseling protocol for TM has not been described in the literature. The TM specialist for the present study, however, has described in general terms the counseling points that are consistent with a TM approach (Schechter and Henry, 2002). TM patients receive counseling that focuses mainly on effective use of sound for providing a sense of immediate relief from the tinnitus. Depending on the patient's particular set of tinnitus-related problems, counseling can also include (1) providing reassurance to allay fears concerning the potential health/psychological ramifications of their tinnitus; (2) basic principles for preventing exacerbation of their tinnitus; (3) hearing loss and its relation to tinnitus; and (4) reducing stress in their lives. It needs to be emphasized that counseling for TM is variable, both in terms of content and duration, and is provided to a patient in accordance with the patient's particular complaints. Thus, although patients in both of the treatment groups received counseling, the TRT counseling was structured and repeated during every session while the TM counseling was informal and variable.

### ***Sound Therapy for TRT***

Sound therapy is considered an adjunct to the structured counseling that is used with TRT. The sound therapy protocol is intended to modify auditory processing at *subconscious* levels so that neural changes facilitated by sound therapy will promote habituation to the tinnitus perception. The counseling must be successful in removing negative thoughts about tinnitus in order for habituation to take place (Jastreboff and Hazell, 1998). Thus, hierarchically, counseling is the most critical aspect of TRT, without which sound therapy cannot be effective. The concepts of sound therapy are incorporated into the TRT counseling protocol. Patients are instructed to "enrich" their sound

environment at all times with comfortable, nonannoying types of background sound. Treatment with TRT thus always includes sound therapy, with or without the use of ear-level devices (Jastreboff, 2000; Jastreboff and Jastreboff, 2000). For patients who require long-term treatment with TRT, bilateral ear-level devices are normally recommended. All patients in the present study received ear-level devices.

Ear-level devices used for TRT are basically the same as for TM, except that only certain models of sound generators and combination instruments are approved for use with TRT. "Approved" means that P. Jastreboff has determined that the devices meet certain performance criteria, including stability of the wideband noise, precision volume adjustment at low levels, and open-ear configurations (Jastreboff, 1994; Jastreboff et al, 1996). Models provided by General Hearing Instruments (GHI, New Orleans, LA) meet these criteria, and only GHI sound generators and combination instruments were used for the TRT patients in this study. Hearing aids can also be used for sound therapy with TRT if amplification needs cannot be met with the combination instruments.

Patients in the TRT group who used sound generators or combination instruments were instructed to adjust the output of their devices to a level below the "mixing" or "blending" point, and always below any level that would cause annoyance. The mixing point was described to patients as the point at which the sound and the tinnitus just start to mix, or blend, together. Below the mixing point the tinnitus can be heard distinctly. It is a premise of TRT that above the mixing point, the tinnitus percept changes, and this must not occur because patients cannot habituate to their "usual" tinnitus if the tinnitus percept is changed during sound therapy (Jastreboff and Hazell, 2004). The patients were asked to "set and forget" their devices (i.e., to not readjust them during the day) and to wear them at least eight hours per day. They were told that they should not expect improvement within the first 3 to 6 months but that gradual improvement (i.e., habituation) should be noticed beyond this initial period.

### ***Sound Therapy for TM***

TM employs wearable ear-level devices,

which can include any brand/model of (1) tinnitus masker (sound generator), (2) hearing aid, and (3) tinnitus masker/hearing aid combination instrument. Each of these three types of devices has been termed a “masker” when used primarily to treat tinnitus with the TM approach (Vernon, 1988). The purpose of maskers is to provide immediate relief from tinnitus, either by completely covering the patient’s tinnitus (“complete masking”) or by reducing the perceived loudness of the tinnitus (“partial masking”) (Vernon et al, 1990). Vernon (pers. comm.) has also pointed out that maskers serve to alter the intrusiveness or disturbing sound quality (pitch) of some tinnitus sounds. As an adjunct to therapy, other means of attaining relief are recommended to some patients, using nonwearable devices such as bedside maskers, specially recorded masking tapes and CDs, and “sound pillows.”

Selection of ear-level devices for the TM group was made on the basis of the results of trial use of in-clinic stock devices and patient feedback from trial use. The clinician worked with the patient to make the selection, but the patient ultimately selected which device he or she felt was most effective and acceptable in providing some level of relief. Amplification was the first option attempted if the patient was an appropriate hearing aid candidate. After trial use of the hearing aids in a variety of conditions, the patient would provide feedback as to its effectiveness as a masker.

The next trial would typically include use of a combination instrument for assessing the effectiveness of both amplification and masking. The hearing aid would be set to a comfortable level, and noise would be introduced to determine if the combination of amplification plus noise was a better option than amplification alone. (Frequently, less noise is needed in combination with amplification.) Many patients who were marginal hearing-aid candidates (i.e., for whom benefit from hearing aids was equivocal) were given the opportunity to try combination instruments as well.

Patients who had normal hearing levels were given the opportunity to try a variety of tinnitus maskers with in-clinic adjustment of the filter potentiometers to determine the most acceptable type of noise. A sound booth is not representative of typical acoustic environments and could bias against fitting

of devices that may perform more effectively in everyday listening conditions. Therefore, these devices were tested both in a sound booth and in areas where there was a reasonable level of ambient noise.

TM patients were always carefully instructed about the trade-off between complete masking and tolerable levels of noise, and that they should use no more noise than necessary. For the TM approach, the level of adequate stimulation (from the masker) is essentially chosen by the patient. Complete masking is the ideal choice if this can be accomplished with a well-tolerated level of noise.

Patients were not required to wear the devices consistently throughout the day; however, overall sound stimulation and sound enrichment with other devices (radio, CD player, tabletop sound generator, etc.) were encouraged. If patients felt that tinnitus was not bothersome on a particular day, they were free to not wear the maskers. This is a distinct difference from the TRT approach for which continual use of ear-level devices is required.

### ***Ear-Level Devices Worn by Patients***

Table 1 shows the numbers of the different types of ear-level devices used by all of the 123 patients. For some patients, the devices were changed during treatment. Table 1 thus shows numbers for devices that were fitted initially, and for the final device configurations. The different ear-level devices include different makes and models of hearing aids, sound generators, and combination instruments (as described above). The sound generators and combination instruments presented various spectra of wideband noise having a high-frequency emphasis. The acoustic spectrum and the acoustic level of the noise within the external auditory meatus, of any given listener, was affected by the impedance of the trapped volume of air, by the size and the length of vents to the atmosphere, and by masker filter setting on the devices.

In the TM group, all fittings were bilateral, except for six of the patients who were fitted unilaterally: two with a single tinnitus masker (sound generator), and four with a single combination instrument. All six of the TM patients who were fitted unilaterally had bothersome tinnitus in one

**Table 1. Numbers of Patients Wearing Different Ear-Level Devices for Each of the Two Treatment Groups**

Ear-Level Devices	Initial Fitting		Final Configuration	
	TM	TRT	TM	TRT
Bilateral Hearing Aids	11	22	12	18
Bilateral Sound Generators	2	39	2	32
Bilateral Combination Instruments	39	1	38	12
Unilateral Sound Generator	2	0	2	0
Unilateral Combination Instrument	4	0	4	0
Sound Generator and Hearing Aid	0	2	0	2
BICROS Hearing Aid	1	0	0	0
CROS Hearing Aid	0	0	1	0
<b>TOTAL</b>	<b>59</b>	<b>64</b>	<b>59</b>	<b>64</b>

*Note:* Numbers are shown separately for the initial fittings and for the final configurations of devices (differences resulting from device changes during treatment).

ear, while the other ear had no tinnitus or mild occasional tinnitus. The ear with bothersome tinnitus was fitted with a masker or a combination instrument to provide relief from tinnitus and/or to aid with communication. These patients had normal or near-normal hearing in the ear with no tinnitus (or mild occasional tinnitus), and so a hearing aid would have been inappropriate in that ear. In addition, one patient (the only one with an anacusic ear) was fitted with a BICROS hearing aid, which was later changed to a CROS aid to reduce the occlusion effect.

Bilateral fittings for the TM patients included 11 patients fitted with hearing aids, two with tinnitus maskers, and 39 with combination instruments. All but one set of the tinnitus maskers were Starkey Corp. (Eden Prairie, MN) model TM1s. One TM patient was fitted with a set of tinnitus maskers (Tranquils) from GHI. Combination instruments were either Starkey TMCs or TMLs. Hearing aids were various makes and models. Forty-seven of the 59 TM patients were provided with devices capable of producing masking noise.

For the TRT group, 39 of the patients were fitted initially with sound generators, one with combination instruments, and 22 with hearing aids. Two of the TRT patients were fitted with a sound generator in one ear and a hearing aid in the other ear. Combination instruments that were eventually fitted to 12 of the TRT patients were GHI Harmony (custom fit), which were not available at the start of the study but

which became available toward the end of the patient recruitment period. One TRT patient was fitted with a Harmony combination instrument initially, and 11 were refitted when the devices became available. Of the 11 who were refitted with combination instruments, eight were fitted initially with sound generators, and three were fitted initially with hearing aids.

Sound generators used for TRT were either GHI Tranquil (custom fit) or Simply Tranquil (noncustom fit) models. The custom Tranquil sound generators were fitted initially to 17 of the TRT patients. Of those 17, three were switched to combination instruments. Noncustom Simply Tranquils were fitted initially to 22 of the TRT patients. Of those 22, one switched to bilateral hearing aids, nine switched to custom Tranquils, five switched to combination instruments, and the remaining seven continued to use the Simply Tranquils. It should be noted that the noncustom Simply Tranquil sound generators have not been formally endorsed for use with TRT.

Further details concerning the ear-level devices used by the study patients are beyond the scope of this article. A forthcoming publication will focus on specific differences in device use between groups, and how these differences might have influenced outcomes of treatment.

### **Baseline Questionnaires**

Prior to attending their first appointment, patients were mailed a packet

of self-administered questionnaires. The questionnaires included comprehensive medical, noise, and tinnitus histories that are similar to those used at the Oregon Tinnitus Clinic (Johnson, 1998). Since there is no universally accepted tinnitus outcomes instrument, three instruments were utilized: Tinnitus Handicap Inventory (THI) (Newman et al, 1996; Newman et al, 1998), Tinnitus Handicap Questionnaire (THQ) (Kuk et al, 1990; Tyler, 1993), and Tinnitus Severity Index (TSI) (Meikle et al, 1995). These particular instruments were selected because they have each been validated for use with tinnitus patients. Also, of the many tinnitus instruments available, they are the most often used and cited. Patients in this study provided their completed baseline questionnaires to the study audiologist at the initial evaluation appointment.

For each of the three questionnaires, higher scores indicate greater perceived tinnitus handicap. The THI has 25 items, and response choices are “no” (0 points), “sometimes” (2 points), and “yes” (4 points). The index score can thus range from 0 to 100. The THI has been documented for internal consistency reliability (Cronbach’s  $\alpha = .93$ ) and test-retest stability ( $r = .92$ ) (Newman et al, 1998). The THQ has 27 items, each providing response choices between 0 (“strongly disagree”) and 100 (“strongly agree”) for a total possible maximum score of 2700. The THQ has been documented for internal consistency reliability (Cronbach’s  $\alpha = .95$ ) (Kuk et al, 1990) and test-retest reliability ( $r = .89$ ) (Newman et al, 1995). The THI and THQ each provide three subscales, but only the total index scores were utilized for this analysis. The TSI is a 12-item instrument that provides five response choices for each question (“never” = 0, “rarely” = 1, “sometimes” = 2, “usually” = 3, “always” = 4) with a possible index-score range of 0 to 48. It has been shown to have a Cronbach’s  $\alpha$  of .92 (Meikle et al, 1995) and test-retest reliability of .88 (Henry et al, 2005b).

### ***TRT Initial and Follow-Up Interviews***

Administration of the TRT initial interview is essential for any patient being assessed for treatment with TRT (Jastreboff and Jastreboff, 1999; Jastreboff and Hazell, 2004). The TRT follow-up interview is similar

to the TRT initial interview, but is revised to evaluate specifically outcomes of treatment. For this study it was determined that the TRT interviews would be administered to patients in both the TRT and TM groups for two reasons: (1) administering the interviews required significant time, and patient contact time needed to be equalized between groups as much as possible; and (2) to enable intergroup comparison of the interview outcome data. Each of the TRT interview forms was modified for use with this project to ensure consistent administration (Henry et al, 2003). Instructions to patients and the interview questions were scripted, and a closed set of response choices was provided for most questions. The study audiologist administered all of the interviews for both treatment groups. The initial interview required 30–60 minutes to complete, and the follow-up interview required 20–40 minutes.

Two of the interview questions were used as outcomes for the data analysis: “What percent of your total awake time, over the last month, have you been aware of your tinnitus?” (AWARE) and “What percent of your total awake time, over the last month, were you annoyed by your tinnitus?” (ANNOY). Patient responses for each of these questions were obtained using a scale of 0% to 100%.

### ***Baseline Audiometric and Tinnitus Evaluation***

Patients received a complete audiometric and tinnitus evaluation at their initial appointment with the study audiologist. The audiologic assessment was performed following completion of the TRT initial interview, and included otoscopy, pure tone and speech audiometry, immittance measures, and loudness discomfort levels (LDLs) at .5, 1, 2, 3, 4, 6, and 8 kHz. Audiometric testing was carried out with calibrated equipment in a conventional sound-treated booth meeting established standards. Mean hearing thresholds for each treatment group are shown in Table 2. The tinnitus evaluation included tinnitus loudness and pitch matching, minimum masking levels, and residual inhibition testing (Henry, 2004). Equipment for tinnitus testing was custom built by the computer engineer (R. Ellingson) who has built different versions of these systems for our research. The tinnitus evaluation was consistent with a protocol

**Table 2. Mean Audiometric Hearing Thresholds, in dB HL, for the Patients Enrolled in This Study**

Frequency (Hz)	Tinnitus Masking				Tinnitus Retraining Therapy			
	Left ear		Right ear		Left ear		Right ear	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
250	19.0	13.3	19.2	15.9	19.2	13.6	17.6	9.6
500	19.9	13.6	19.4	18.8	20.2	13.9	18.3	11.7
1,000	21.8	14.3	21.9	17.5	21.6	14.4	20.8	13.7
2,000	33.1	23.2	32.3	25.6	28.1	22.5	24.9	20.0
3,000	48.6	23.9	45.8	28.5	45.4	25.2	41.2	22.8
4,000	58.5	21.4	55.3	25.8	55.0	23.3	51.0	22.1
6,000	64.3	23.0	62.9	26.7	62.7	22.3	56.4	24.0
8,000	63.3	20.2	64.8	23.4	62.9	25.6	58.7	24.3

described previously (Henry et al, 2002a), except for the addition of residual inhibition testing. Space constraints do not allow a complete description of the audiologic and tinnitus testing, nor of the data resulting from those tests. This information will be provided in a publication that is in preparation.

### ***Initial Appointment with Tinnitus Specialist***

Following the initial evaluation with the study audiologist, patients were scheduled for an initial appointment with their respective tinnitus specialist. The tinnitus specialist reviewed the questionnaire and testing data and discussed the treatment protocol with the patient. For patients who entered treatment, ear-level devices were selected and earmold impressions were made to order custom devices. Patients were scheduled for an appointment approximately one month later for device fitting and initial counseling (i.e., the first treatment appointment). Patients were also referred to an otolaryngologist for a medical evaluation and to receive medical clearance to wear the ear-level devices.

Results of the tinnitus psychoacoustic assessment have no bearing on the treatment protocol for TRT. These measurements are important, however, for selecting ear-level devices for treatment with TM. The MML (minimum masking level) is a particularly important measurement for the TM approach, since it can serve as a predictor of success with application of maskers (Schechter and Henry, 2002). Because of the importance of this measurement, the tinnitus specialist for TM made more precise measures in 1 dB steps (as opposed to the 5 dB steps used by

the study audiologist). The repeated MML test often resulted in a different measurement value; thus, the residual inhibition test, which was based on this value, was also repeated.

### ***First Treatment Appointment***

At the initial treatment appointment, ear-level devices were fitted, and treatment-specific counseling was administered. When amplification was used, real ear testing was performed routinely at the time of the fitting to verify target gain settings.

### ***Continuing Treatment Appointments***

Continuing treatment appointments were scheduled at 3, 6, 12, and 18 months after the first treatment appointment. Approximately two weeks prior to each treatment visit, patients were mailed a packet of questionnaires that included an abbreviated version of the medical, noise, and tinnitus histories questionnaire, and the THI, THQ, and TSI. At each appointment, the study audiologist: (1) checked the written questionnaires for completeness; (2) administered the TRT follow-up interview (Henry et al, 2003); and (3) performed audiologic and tinnitus testing (audiologic and tinnitus testing were not performed at the 3-month visit). The treatment specialist then met with the patient to check the performance and proper usage of the ear-level devices, and to administer counseling as described above.

### ***Data Analysis***

Many studies that focus on change in tinnitus outcomes have been limited by cross-

sectional and pretest-posttest designs using methods such as repeated measures ANOVA. These studies have generally met Guyatt et al's (1993) minimal criteria for properly conducting randomized clinical trials (Dobie, 2004). There are, however, numerous design issues that have limited the knowledge gained from these studies. In many cases, dropouts have not been handled on an intent-to-treat basis, which is now generally agreed to be a requirement of statistical analysis for outcome studies. Repeated measures ANOVA assumes that all of the patients can be summarized by the same mean profile over time and any individual variation is characterized as error.

Alternatively, innovative approaches such as multilevel modeling (MLM) capitalize on multiple times of measurement to explicitly examine (1) individual trajectories of tinnitus outcomes over time (both the average trajectory and the individual variation around this average trajectory); (2) reliability estimates of change in tinnitus outcomes; (3) the correlation between baseline and rate of change in tinnitus outcomes; and (4) predictors of change in tinnitus outcomes. The individual patient becomes his or her own reference, and thus, rate of change is more informative and relative.

MLM is considered hierarchical as it involves data that vary at two levels: within individuals (level 1) and between individuals (level 2). At level 1, each individual's change is represented by an individual trajectory captured by a set of unique growth parameters: intercept and slope. These latent growth parameters are corrected for measurement error. At level 2, these latent parameters become outcome variables to be explained by a set of individual-level variables.

MLM provides a powerful and flexible framework for analyzing individual change. The key statistical advantage above other methods is that it controls for the dependencies among the repeated measurements. The key design advantage is that it allows for differences in the number of times of measurement across individuals when random "missingness" exists. This is possible as the multiple observations over time are considered nested within the individual. For a more detailed discussion of multilevel modeling and its applications see Raudenbush and Bryk (2002).

## **Outcome Measures**

Of the five outcome measures analyzed, three had a potential range of 0 to 100 (THI, AWARE, and ANNOY). For a fourth outcome, the THQ, we used an average score of the 27 THQ items rather than the usual total THQ score, in order for the potential range of the THQ to be from 0 to 100, the same as the range of the THI, AWARE, and ANNOY outcomes. The fifth outcome, the TSI, had a potential range of 0 to 48.

## **Predictors**

Seven predictors were used. One predictor was treatment condition, TM (coded 0) and TRT (coded 1). The other six predictors were three baseline patient characteristics and the interaction of each characteristic with treatment condition.

"Hearing loss" was measured using the first unrotated factor from a principal components factor analysis of seven right-ear and seven left-ear hearing levels (.25, .5, 1, 2, 3, 4, and 8 kHz) from audiologic testing. The first unrotated factor, representing extent of hearing loss, explained 58% of the variance in the principal components analysis and its z-score form ( $M = 0.0$ ;  $sd = 1.0$ ) was used in the MLM analysis.

"Duration of tinnitus" was the self-reported length of time the patient had tinnitus and was coded into three categories for analysis: -1 (0–10 years), 0 (11–20 years), or 1 ( $\geq 21$  years). The percentages of TM patients in the three respective duration categories were 32%, 18%, and 51%; the percentages of TRT patients, respectively, were 28%, 15%, and 57%. The distribution of duration did not differ by group,  $\chi^2(2, N = 118) = 0.51, p = .78$ .

"Extent of tinnitus problem" was a self-report item in which patients rated the extent of their tinnitus problem; responses were coded -1 (moderate problem), 0 (big problem), or 1 (very big problem). The percentages of TM patients in the three respective problem categories were 28%, 51%, and 21%; the percentages of TRT patients, respectively, were 30%, 46%, and 25%. The distribution of tinnitus problem at baseline did not differ by group,  $\chi^2(2, N = 118) = 0.33, p = .85$ .

Three interaction terms were computed for use in the analysis: treatment X hearing loss, treatment X duration, and treatment X

extent of tinnitus problem. The dichotomous variable for treatment condition (TM = 0, TRT = 1) was multiplied by each of the three patient characteristics (z-score for hearing loss; -1, 0, 1 for duration; -1, 0, 1 for extent of tinnitus problem) to obtain the interaction term predictors.

**Overall MLM Analysis**

We used a two-level MLM approach to determine the extent to which variation in patient trajectories on each of five outcomes over an 18-month period could be explained by treatment condition and the other six predictors. The HLM (Hierarchical Linear Modeling) software Version 6.0 was used (Raudenbush et al, 2004). Underlying an MLM approach in analyzing treatment effectiveness is the assumption that a treatment condition does not necessarily have a uniform effect on all patients but that treatment effectiveness can vary across patients. Using HLM we estimated each patient's individual trajectory (baseline and linear slope) on each of the five outcomes (THI, THQ, TSI, AWARE, ANNOY) over 18 months after entering treatment. Then, for each outcome, we estimated the average trajectory across all patients. If there was significant variation around the average baseline and average slope, we examined the extent to which seven predictors explained

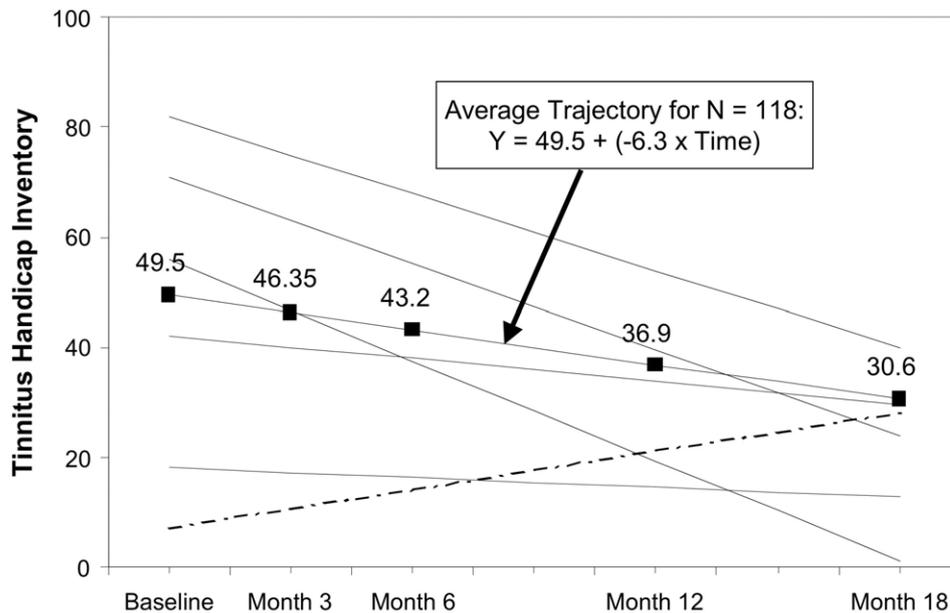
such variation.

**Estimating Patient Trajectories at Level 1**

At level 1 of HLM, for each patient, ordinary least squares (OLS) estimates of baseline and rate of change every six months (linear slope) for each of the five outcomes were derived where time of assessment (0, 3, 6, 12, and 18 months) was centered at zero, and therefore coded as 0, 0.5, 1, 2, and 3, respectively. The questions to be answered at level 1 were:

1. What is the average trajectory (baseline and slope) of patients on the tinnitus outcomes over the 18 months after entering treatment? The average baseline and slope are referred to as the level-1 fixed effects.
2. Is there significant variation around the average trajectory, above and beyond what would be expected by chance? Variation around the average intercept and average slope are referred to as level-1 random effects. If there had been no significant variation around the growth parameters, we would not have gone on to a level-2 model where we examined predictors of variation in individual patient trajectories.

For illustration purposes, in Figure 1,



**Figure 1.** Average THI trajectory for the overall sample and individual trajectories for six patients. The trajectory with a dashed line indicates a patient whose THI scores increased (worsened).

we have shown the average THI trajectory,  $Y = 49.5 + (-6.3 \times \text{Time})$ , and individual THI trajectories for six patients. As shown, five of six patients declined on the THI, reflecting improvement, but one patient (with the dashed line) worsened and had increases on the THI. Of these six patients, their starting places (baseline) differed as did their rate of change (slope), with some changing rapidly and others changing more slowly. It is these variations in baseline and slope that we were interested in predicting.

### ***Predicting Variation in Patient Trajectories at Level 2***

At level 2 of HLM, predictors of significant variation in patient trajectories for each outcome were examined. The questions of main interest at level 2 were:

1. To what extent does receiving TM versus TRT explain variation in patient trajectories around the average trajectory for each outcome?
2. To what extent do three baseline patient characteristics—hearing loss, duration of tinnitus, and perceived problem due to tinnitus—and the interaction between the treatment condition and each of these characteristics explain variation in patient trajectories around the average trajectory for each outcome?

### ***Rationale for Predictors***

Treatment condition, TM versus TRT, was the predictor of main interest. Although we did not hypothesize directional differences between TM and TRT on patient trajectories, comparison of effectiveness of the two treatment conditions was the main goal of the study.

We used hearing loss and duration of tinnitus, including their interactions with treatment condition, as predictors of patient trajectories because we wanted to explore the extent to which they were associated with baseline levels of the tinnitus outcomes and to evaluate whether TM or TRT was differentially effective, depending on the level of a patient's hearing loss or duration of tinnitus. We selected extent of tinnitus problem as a predictor of variation in patient trajectories, because we thought it could serve

as a common baseline measure of tinnitus difficulty across all the outcomes, rather than using each outcome's baseline score as a covariate. We hypothesized that extent of tinnitus problem would be positively associated with variation in patient baseline. In addition, because patients with more tinnitus difficulty have more room to change as a result of treatment, we expected a bigger improvement (larger slope) in patients starting out worse (i.e., patients with a "very big" tinnitus problem) compared to patients with a "big" or "moderate" tinnitus problem. Finally, although we did not hypothesize an interaction between treatment condition and extent of tinnitus problem, we were interested in whether TM or TRT was differentially effective, depending on whether patients started treatment at very big, big, or moderate levels on the extent of tinnitus problem.

### ***Sample Attrition and Missing Data***

Of the 123 patients who entered the study, five were missing data on one or more of the predictor variables and were therefore removed from the sample, resulting in a final sample of 118 patients for the MLM analyses ( $n = 57$  for TM,  $n = 61$  for TRT). When patients do not have complete data on predictor variables, they are dropped from the HLM analysis.

One advantage of MLM is that missing data over time in the outcome variables (level-1 missingness) can be addressed if the data are assumed to be missing at random. HLM uses maximum likelihood to estimate parameter values based on all existing data across waves of measurement and data at level 2. Maximum likelihood is an iterative process that uses all available information in the data to obtain unbiased parameter estimates that have been adjusted for missingness (Schafer and Graham, 2002). In the current study, random missingness occurred, in part because the THI and THQ were added as outcome measures after 13 and 29 patients, respectively, had begun the study; however, these patients were administered the THI and THQ at later data collection periods. Further, at the 3-month follow-up period, the different outcome measures were not completed by between 17 and 57 patients. Finally, not all patients participated at each follow-up period. See Table 3, which indicates the number of patients who have data for each

**Table 3. Outcome Variables: Means, Standard Deviations, and Ranges**

Outcome Variable	Baseline n = 118	3 Months n = 101	6 Months n = 110	12 Months n = 108	18 Months n = 107
<i>Tinnitus Handicap Inventory (THI)</i>					
n	105	61	94	101	106
M	52.54	47.27	41.01	35.48	30.97
SD	22.41	24.92	25.34	23.47	24.73
Range	12.0–98.0	6.0–100.0	6.0–100.0	0.0–98.0	0.0–100.0
<i>Tinnitus Handicap Questionnaire (THQ)</i>					
n	89	62	95	101	106
M	56.22	51.18	45.54	39.95	36.39
SD	21.02	22.51	23.35	22.57	22.56
Range	16.1–97.0	8.0–93.5	6.3–96.3	3.7–94.4	0.0–92.6
<i>Tinnitus Severity Index (TSI)</i>					
n	118	97	107	104	107
M	28.28	25.16	23.79	20.96	19.21
SD	8.72	8.86	9.05	9.92	10.87
Range	8.7–48.0	1.3–48.0	5.1–48.0	1.3–48.0	2.0–46.7
<i>Percent Awake Time Aware of Tinnitus (AWARE)</i>					
n	117	101	110	108	107
M	72.51	63.47	52.13	38.37	24.38
SD	22.78	28.42	30.13	28.72	22.55
Range	6.5–100.0	2.5–100.0	0.0–100.0	0.0–80.0	1.0–100.0
<i>Percent Awake Time Annoyed by Tinnitus (ANNOY)</i>					
n	116	101	110	108	107
M	51.12	35.39	31.31	21.20	14.50
SD	28.20	27.06	27.68	24.60	18.53
Range	1.0–100.00	0.0–100.0	0.0–100.0	0.0–100.0	0.0–80.0

outcome at each data collection period.

Outcome data were reasonably complete. Of the 118 patients, 46 had complete data on all five outcomes at all five data collection periods, resulting in 25 usable scores for each patient. Another 62 patients had 15 to 24 usable outcome scores of the 25 possible. Only three of the 118 patients had baseline data only, with one score on each of the five outcomes; the remaining 10 patients had 10 to 14 of the possible 25 outcome scores. Data were most complete for three outcomes—TSI, AWARE, and ANNOY—with 72% to 76% of the patients having outcome scores for all five periods.

## RESULTS

Descriptive statistics for the five outcomes at all five time points are presented in Table 3. Descriptive statistics for the predictor variables are presented in Table 4. The intercorrelations among the treatment condition and the three baseline predictors (hearing loss, duration of tinnitus, and extent of tinnitus problem) were low, ranging from  $-.09$  to  $.24$ . At baseline, three outcome variables (THI, THQ, and TSI) were highly

intercorrelated ( $r = .76$  to  $.78$ ), and two other outcome variables (AWARE and ANNOY) had a moderately high correlation ( $r = .60$ ). At baseline, the correlations of ANNOY with THI, THQ, and TSI were modest ( $r = .34$  to  $.36$ ,  $p < .05$ ), and AWARE was not significantly correlated with THI, THQ, or TSI ( $r = .11$  to  $.20$ ).

### Level-1 Models: Average Trajectory over Time and Variation around the Average

As shown under the Fixed Effects columns in Table 5, both the baseline and linear slope for each of the outcomes were significantly different from zero. Using the THI as an example, on average, the level of tinnitus handicap for the patients at baseline was 49.50, and the rate of change was  $-6.29$  THI points every six months, or nearly 19 THI points decline across the 18 months. The average THI trajectory is shown in Figure 1.

Using the percent Awake Time Aware of Tinnitus (AWARE) as another example, on average, the level of AWARE for the patients at baseline was 71.24, and the rate of change was  $-16.05$  AWARE points every six months, or more than 48 AWARE points decline across

**Table 4. Predictor Variables: Means, Standard Deviations, and Ranges (n = 118)**

Simple Predictors		Interaction Variables: Treatment X Baseline Characteristics	
<i>TM (0) v. TRT (1)</i>			
M	0.52		
SD	0.50		
Range	0–1		
Hearing Loss		Treatment X Hearing Loss Interaction	
M	0.01		-0.04
SD	1.00		0.69
Range	-1.81–3.37		-1.68–3.37
Duration of Tinnitus		Treatment X Duration of Tinnitus Interaction	
M	0.25		0.15
SD	0.89		0.65
Range	-1–+1		-1–+1
Extent of Tinnitus Problem		Treatment X Extent of Tinnitus Problem Interaction	
M	-0.06		-0.03
SD	0.72		0.53
Range	-1–+1		-1–+1

the 18 months. Similar interpretations of baseline and 6-month rate of change can be made to describe the average trajectory for THQ, TSI, and ANNOY. Over 18 months, the average patient declined about 18 THQ points from a baseline of 54, declined about 8 TSI points from a baseline of 27, and declined about 34 ANNOY points from a baseline of 46.

One advantage of MLM over traditional methods of analyzing change is that the true correlation between baseline and rate of

change can be estimated. The correlations between baseline and rate of change in tinnitus outcomes were -.36 for THI, -.21 for THQ, .01 for TSI, -.34 for AWARE, and -.84 for ANNOY. The magnitude of the correlation for ANNOY was large and indicates that patients who reported higher annoyance from tinnitus at baseline were the ones who showed the greatest declines in annoyance; change in annoyance can be predicted very well from initial annoyance status. The

**Table 5. Results of HLM Level-1 Models of Fixed and Random Effects for the Five Outcomes**

Outcome	Fixed Effects			Random Effects		
	B Unstandardized	SE	Variance	df	$\chi^2$	Reliability of Growth Parameters
<i>Tinnitus Handicap Inventory (THI)</i>						
Intercept	49.50**	2.13	459.45	113	952.29**	.85
Linear slope	-6.29**	0.73	42.60	113	348.20**	.64
<i>Tinnitus Handicap Questionnaire (THQ)</i>						
Intercept	53.87**	1.94	313.92	107	520.86**	.72
Linear slope	-6.01**	0.78	35.05	107	239.51**	.50
<i>Tinnitus Severity Index (TSI)</i>						
Intercept	27.27**	0.73	48.52	114	482.49**	.78
Linear slope	-2.76**	0.31	5.61	114	244.54**	.51
<i>Percent Awake Time Aware of Tinnitus (AWARE)</i>						
Intercept	71.24**	2.17	361.93	114	329.50**	.65
Linear slope	-16.05**	0.91	27.21	114	170.22**	.26
<i>Percent Awake Time Annoyed by Tinnitus (ANNOY)</i>						
Intercept	45.65**	2.29	433.83	114	370.89**	.70
Linear slope	-11.18**	0.80	10.40	114	140.93*	.14

\* $p < .05$  \*\* $p < .001$

correlations between baseline and rate of change for THI, THQ, and AWARE were modest, and there was no relationship indicated between baseline and rate of change for TSI.

For each outcome there was significant variation in the baseline and slope to be explained in a level-2 model, as shown in Table 5 by the  $\chi^2$  test results under the Random Effects columns. Reliability coefficients, which indicate the proportion of variance in the OLS estimates of baseline and slope that is true variance, provided further evidence that systematic variance existed in the level-1 baseline and slope coefficients to be explained at level 2. In examining the reliability of the growth parameters in the last column of Table 4, we concluded that reliability of the baseline estimates was very high for all five outcomes. The reliability of the slope was very high for the THI, THQ, and TSI but quite low for AWARE (reliability = .26) and below generally acceptable levels for ANNOY (reliability = .14).

Due to the low reliability for the ANNOY linear slope (14% systematic or true variance) and the fact that the individual variation around the average ANNOY slope was almost nonsignificant ( $p = .045$ ), we did not proceed with level-2 analysis of ANNOY. Instead, we felt a more appropriate analysis of change in ANNOY should occur at the group level through repeated measures analysis of variance (ANOVA). Thus, at the end of this "Results" section, we report ANOVA results comparing TM and TRT across 0, 6, 12, and 18 months; the 3-month ANNOY scores were not included in order to minimize missing data.

### **Level-2 Models: Explaining Variation in Patient Trajectories**

#### ***Overall Level-2 Models***

The seven predictors were entered into a level-2 model to examine their association with interindividual differences in the baseline and linear slope (6-month rate of change) in each outcome. As shown in Table 6, the seven predictors explained large amounts of variance (38.9% to 43.4%) in the baseline for THI, THQ, and TSI, but a relatively small amount of variance (13.9%) in the baseline for AWARE. Very large

amounts of variance (46.0% to 63.3%) in the linear slopes were explained for THI, THQ, and TSI, with a modest amount of variance (14.3%) in the linear slopes explained for AWARE.

### ***Explaining Variation in THI, THQ, and TSI Trajectories***

Examination of the predictors of the baseline showed that extent of tinnitus problem was the predictor most strongly associated with the baseline, as hypothesized. Controlling for all other predictors, the unstandardized coefficients indicate that for each one-unit increase in extent of tinnitus problem from -1 to 0 (moderate problem to big problem) and from 0 to +1 (big problem to very big problem), the THI baseline was 14.53 points higher, the THQ baseline was 12.96 points higher, and the TSI baseline was 4.57 points higher. Duration of tinnitus was also a significant predictor of variation in patient baselines for the THQ and TSI, indicating that longer duration of tinnitus was associated with more tinnitus difficulty at baseline. Specifically, for each one-unit increase in tinnitus duration, from -1 to 0 (0–10 years to 11–20 years) and from 0 to +1 (11–20 years to 20+ years), the THQ baseline was 5.50 points higher and the TSI baseline was 2.17 points higher. Other important findings were that the TM and TRT groups were not significantly different at baseline on the THI, THQ, or TSI, suggesting that assignment to treatment conditions resulted in roughly comparable groups.

There were three significant unstandardized coefficients for rate of 6-month linear change: (1) the intercept for linear slope (i.e., the value of the slope when all predictors are 0); (2) TM versus TRT; and (3) treatment X extent of tinnitus problem interaction. Generally, as shown by these unstandardized coefficients in Table 6, TM patients exhibited a significant 6-month rate of decline on each outcome (-3.83 on THI; -2.65 on THQ; -1.37 on TSI), but TRT patients exhibited these declines plus an additional significant 6-month rate of decline (-5.99 on THI; -7.49 on THQ; -3.03 on TSI), which translates into 6-month declines of -9.82, -10.14, and -4.4 on THI, THQ, and TSI, respectively, for TRT patients.

The nature of the significant treatment X extent of problem interaction is displayed

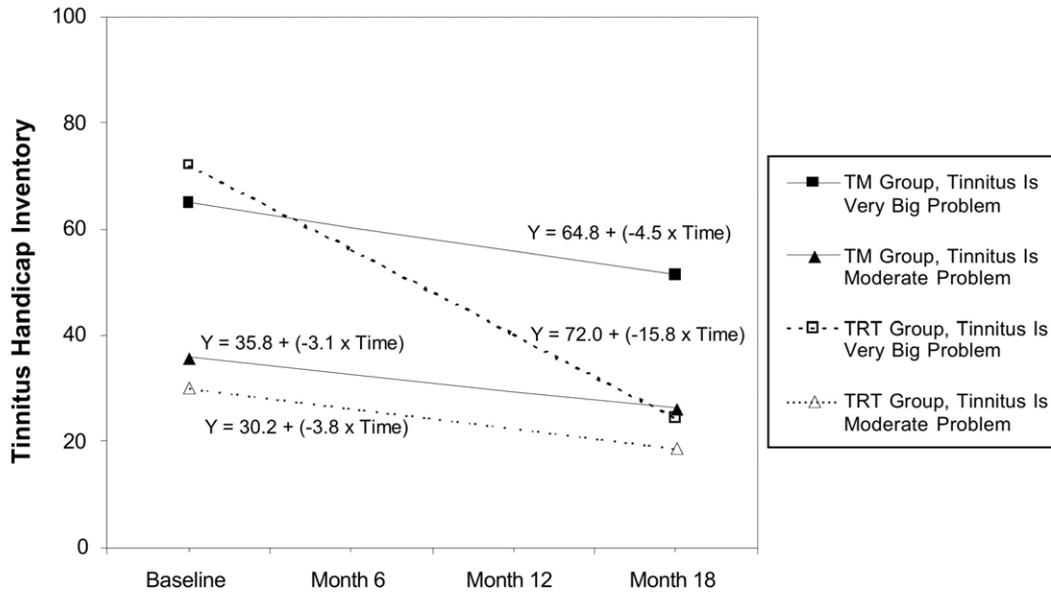
**Table 6. Parameter Estimates and Associated Standard Errors from the Level-2 Model of the Effects of the Predictors on Baseline and Linear Change in Tinnitus Handicap, Severity, and Awareness**

	Baseline		Rate of 6-Month Linear Change (Slope)			
	Unstandardized B	SE	Variance Explained	Unstandardized B	SE	Variance Explained
<i>Tinnitus Handicap Inventory (THI)</i>						
Intercept	50.29**	2.57		-3.83**	0.96	
TM vs. TRT	0.78	3.64		-5.99**	1.34	
Hearing Loss	-2.38	2.47		0.47	0.89	
Duration	4.20	2.90		1.50	1.09	
Extent of Problem	14.53**	3.58		-0.69	1.29	
Tx X Hearing Loss	0.50	3.63		0.12	1.31	
Tx X Duration	-5.30	4.10		-0.56	1.51	
Tx X Extent of Problem	6.39	5.00	38.9%	-5.32**	1.83	46.0%
<i>Tinnitus Handicap Questionnaire (THQ)</i>						
Intercept	52.07**	2.34		-2.65**	0.98	
TM vs. TRT	5.08	3.36		-7.49**	1.38	
Hearing Loss	-0.89	2.32		0.69	0.94	
Duration	5.50*	2.70		0.92	1.15	
Extent of Problem	12.96**	3.21		0.42	1.30	
Tx X Hearing Loss	0.24	3.36		0.12	1.36	
Tx X Duration	-7.03	3.83		0.56	1.58	
Tx X Extent of Problem	2.95	4.50	43.4%	-4.95**	1.85	56.7%
<i>Tinnitus Severity Index (TSI)</i>						
Intercept	27.21**	0.89		-1.37**	0.38	
TM vs. TRT	0.34	1.27		-3.03**	0.53	
Hearing Loss	-1.67	0.86		0.84	0.36	
Duration	2.17*	1.01		0.43	0.43	
Extent of Problem	4.57**	1.24		0.13	0.51	
Tx X Hearing Loss	0.81	1.26		-0.66	0.53	
Tx X Duration	-1.95	1.42		-0.05	0.60	
Tx X Extent of Problem	2.45	1.72	42.3%	-1.98**	0.72	63.3%
<i>Percent Awake Time Aware of Tinnitus (AWARE)</i>						
Intercept	72.17**	3.07		-14.16**	1.34	
TM vs. TRT	-3.41	4.35		-3.97*	1.88	
Hearing Loss	-3.74	2.99		0.16	1.29	
Duration	9.00*	3.46		0.80	1.52	
Extent of Problem	5.66	4.30		-0.74	1.83	
Tx X Hearing Loss	1.67	4.37		-0.36	1.88	
Tx X Duration	-6.94	4.88		0.78	2.10	
Tx X Extent of Problem	-1.28	5.94	13.9%	-0.58	2.54	14.3%

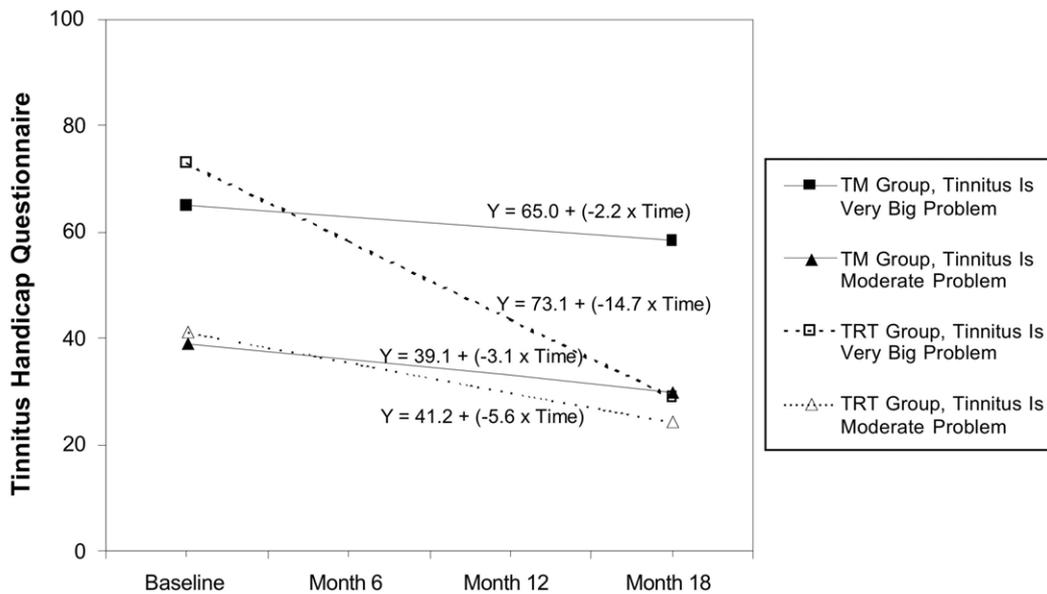
\* $p < .05$  \*\* $p < .001$ 

in Figures 2, 3, and 4 for THI, THQ, and TSI, respectively. In each figure, four prototypical trajectories of the outcome are plotted. Two trajectories are for TM patients who began treatment with either a very big or a moderate tinnitus problem; the other two trajectories are for TRT patients who began treatment with either a very big or a moderate tinnitus problem. In the trajectories, hearing loss and duration of tinnitus are controlled for, with trajectories computed for patients with average hearing loss ( $z = 0$ ) and the median duration of tinnitus (11 to 20 years, coded as 0). The most prominent pattern in these figures is that for patients who began treatment with a very big tinnitus

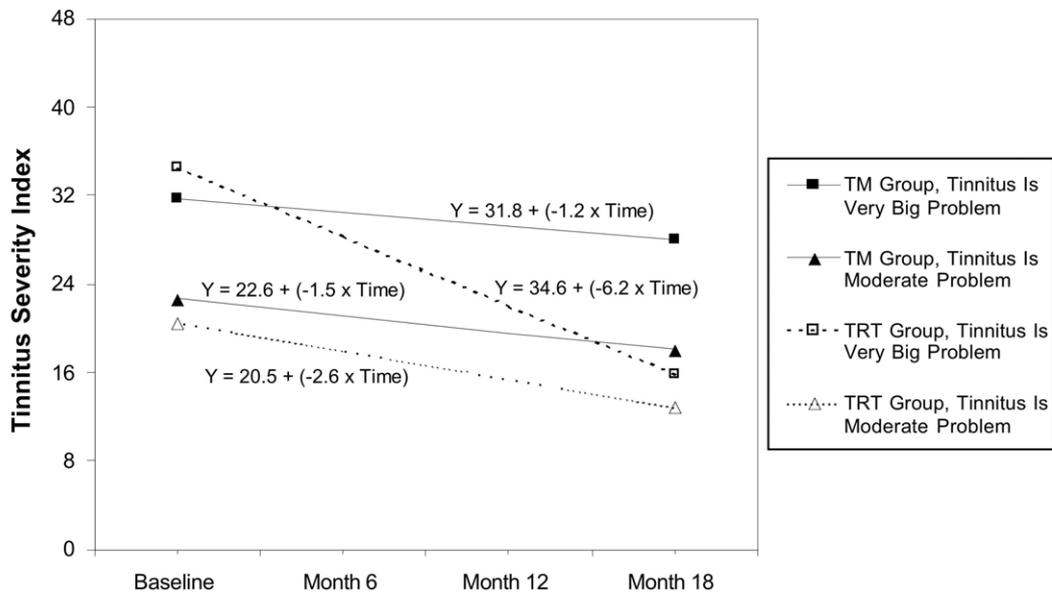
problem, those receiving TRT exhibited 6-month declines of -15.8, -14.7, and -6.2 on THI, THQ, and TSI, respectively, compared to 6-month declines of -4.5, -2.2, and -1.2 for patients receiving TM. For patients who began treatment with a moderate tinnitus problem, those receiving TRT exhibited declines of -3.8, -5.6, and -2.6 on THI, THQ, and TSI, respectively, compared to 6-month declines of -3.1, -3.1, and -1.5 for patients receiving TM. The declines on the outcomes were much larger for TRT compared to TM for patients who began treatment with a very big tinnitus problem, whereas the benefits of TRT over TM were more modest for patients who began treatment with a



**Figure 2.** Treatment X tinnitus problem interaction for the THI outcome. Shown are four THI trajectories across 18 months. Two trajectories are for TM patients who began treatment with either a very big or a moderate tinnitus problem; the other two trajectories are for TRT patients who began treatment with either a very big or a moderate tinnitus problem. Hearing loss and duration of tinnitus are controlled for, with trajectories computed for patients with average hearing loss ( $z = 0$ ) and the median duration of tinnitus (11 to 20 years, coded as 0).



**Figure 3.** Treatment X tinnitus problem interaction for the THQ outcome. Shown are four THQ trajectories across 18 months. Two trajectories are for TM patients who began treatment with either a very big or a moderate tinnitus problem; the other two trajectories are for TRT patients who began treatment with either a very big or a moderate tinnitus problem. Hearing loss and duration of tinnitus are controlled for, with trajectories computed for patients with average hearing loss ( $z = 0$ ) and the median duration of tinnitus (11 to 20 years, coded as 0).



**Figure 4.** Treatment X tinnitus problem interaction for the TSI outcome. Shown are four TSI trajectories across 18 months. Two trajectories are for TM patients who began treatment with either a very big or a moderate tinnitus problem; the other two trajectories are for TRT patients who began treatment with either a very big or a moderate tinnitus problem. Hearing loss and duration of tinnitus are controlled for, with trajectories computed for patients with average hearing loss ( $z = 0$ ) and the median duration of tinnitus (11 to 20 years, coded as 0).

moderate tinnitus problem.

Also of note was the lack of significant association of duration of tinnitus and hearing loss with rate of change on the THI, THQ, and TSI. Further, as shown by the nonsignificant treatment X duration and treatment X hearing loss interaction terms, the effectiveness of TM and TRT did not differ depending on the patient's duration of tinnitus or hearing loss.

### ***Explaining Variation in AWARE Trajectories***

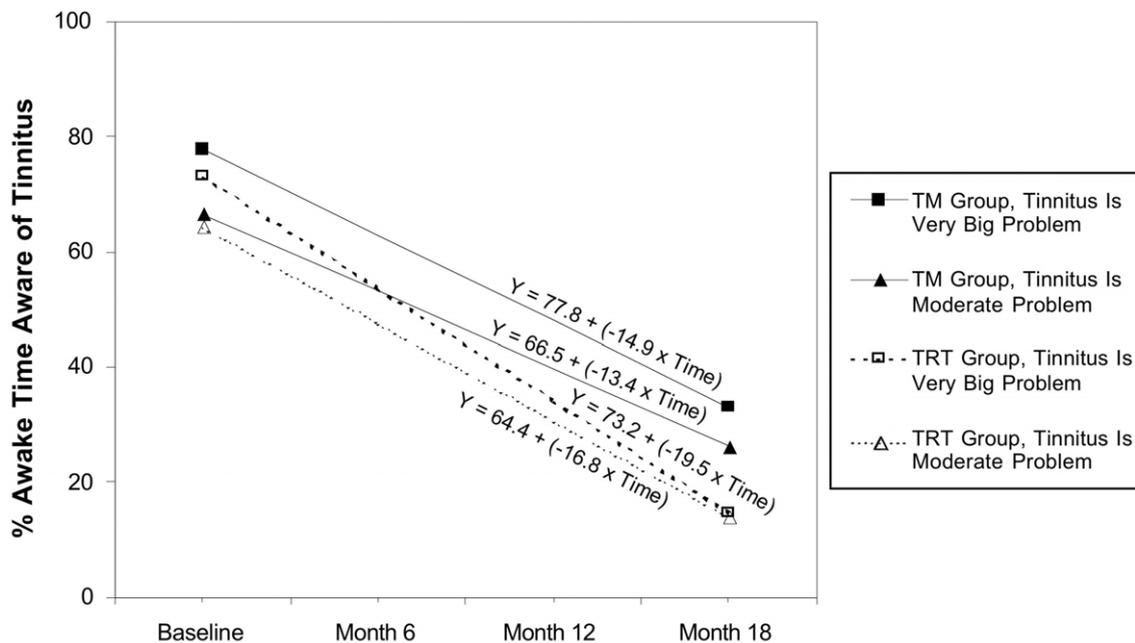
Only duration of tinnitus explained variation in the AWARE baseline. Controlling for other predictors in the model, the unstandardized coefficients show that for each one-unit increase in duration of tinnitus, the AWARE baseline was 9.0 points higher. There were two significant unstandardized coefficients for rate of 6-month linear change: (1) intercept for linear slope (i.e., the value of the slope when all predictors are 0); and (2) TM vs. TRT. On average, as shown by the unstandardized coefficients in Table 6, TM patients exhibited a significant 6-month rate of decline on AWARE (-14.16), and TRT patients

exhibited this decline plus an additional significant -3.97 points in 6-month rate of decline. Although the treatment X extent of problem interaction was not significant for AWARE, for illustration purposes and comparison with Figures 2, 3, and 4, four prototypical trajectories of AWARE are plotted in Figure 5. The most noticeable feature in Figure 5 is that the four trajectories have similar slopes, with the slope for the TRT patients with a very big problem ( $B = -19.5$ ) being 1.3 times larger than the slope for the TM patients with a very big problem ( $B = -14.9$ ).

To conclude, the level-2 models with seven predictors for THI, THQ, TSI, and AWARE were a significantly better fit than an unconditional model with no predictors (THI,  $\chi^2 = 77.49$ ,  $df = 14$ ,  $p < .001$ ; THQ,  $\chi^2 = 76.11$ ,  $df = 14$ ,  $p < .001$ ; TSI,  $\chi^2 = 90.85$ ,  $df = 14$ ,  $p < .001$ ; AWARE,  $\chi^2 = 29.30$ ,  $df = 14$ ,  $p < .01$ ).

### **Repeated Measures ANOVA for ANNOY**

A 2 X 4 repeated measures ANOVA for  $n = 101$  patients with complete ANNOY data revealed significant main effects ( $p = .001$ ) for treatment group,  $F(1, 99) = 11.80$  and time,



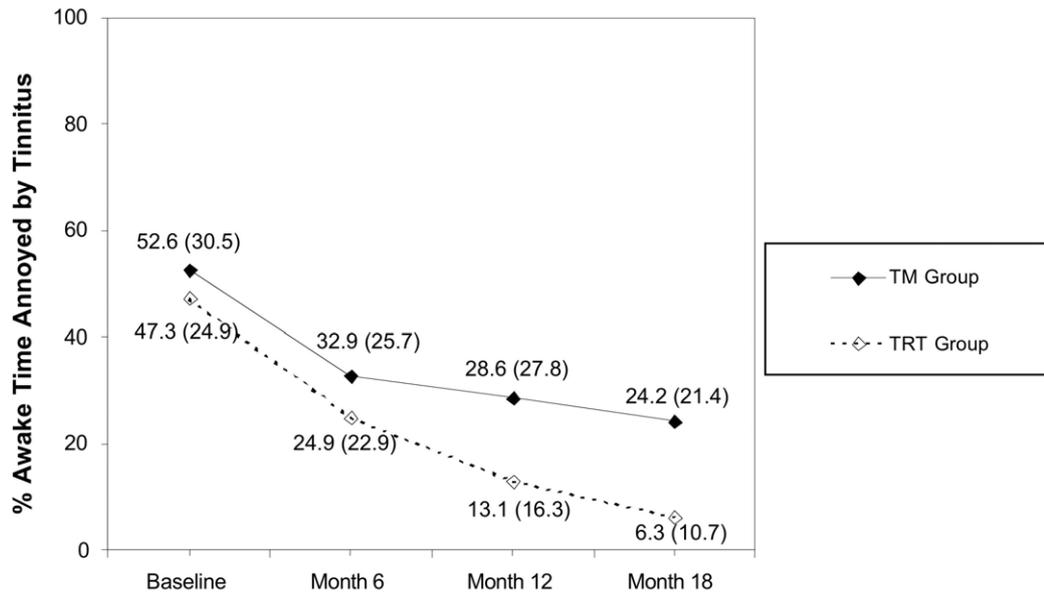
**Figure 5.** Treatment X tinnitus problem interaction for the AWARE outcome. (Note: The treatment X tinnitus problem interaction was not significant,  $p > .05$ .) Shown are four AWARE trajectories across 18 months. Two trajectories are for TM patients who began treatment with either a very big or a moderate tinnitus problem; the other two trajectories are for TRT patients who began treatment with either a very big or a moderate tinnitus problem. Hearing loss and duration of tinnitus are controlled for, with trajectories computed for patients with average hearing loss ( $z = 0$ ) and the median duration of tinnitus (11 to 20 years, coded as 0).

$F(3, 297) = 71.57$ , as well as a significant group X time interaction,  $F(3, 297) = 2.79$ ,  $p = .041$  (see Fig. 6). Generally, we expected to see declines in ANNOY over time. Therefore, after obtaining the significant F test for the interaction, we computed a priori comparisons using the Bonferroni adjustment for multiple tests to see if ANNOY scores were declining differently for each group. Simple effects tests comparing mean changes over time for each group separately showed that within-group change on the ANNOY outcome over time was different for TM compared to TRT. The TM Group showed a large and significant decline of 19.7 points in ANNOY from Month 0 to Month 6 ( $p < .001$ ); however, the 4.3-point decline in ANNOY from Month 6 to Month 12 and the 4.4-point decline from Month 12 to Month 18 were not significant ( $p = .40$  and  $.50$ , respectively); however, the 8.7-point decline from Month 6 to Month 18 was significant ( $p = .03$ ). Similar to the TM Group, the mean ANNOY score for the TRT Group showed a large and significant decline of 22.4 points from Month 0 to Month 6 ( $p < .001$ ). Unlike the TM Group, the TRT group showed continued significant declines from Months 6 to 12 (11.8-point decline,  $p = .002$ ) and Months 12 to 18

(6.8-point decline,  $p = .002$ ). Over the entire 18-month period, the annoyance from tinnitus declined 28.3 points in TM patients, on average, compared to TRT patients whose decline averaged 41.0 points. So, the overall picture is that both the TM and TRT patients showed improvement over time, but the TRT patients continued to show greater improvement after Month 6, compared to TM.

## DISCUSSION

This report provides an initial analysis of outcome data from a controlled clinical study that was conducted to compare the efficacy of two tinnitus treatment methods in U.S. military veterans. Veterans with clinically significant tinnitus received treatment with either TRT or TM for a period of 18 months. All patients who were enrolled in the study underwent the same three-stage screening process. The screening was designed to ensure that veterans were enrolled in the study only if they had tinnitus of sufficient severity to justify 18 months of individualized treatment. Patients in both groups were generally motivated to comply with the study protocol, resulting in a low attrition rate (about 10



**Figure 6.** Summary of TM (n = 48) and TRT (n = 53) mean profiles for the repeated measures ANOVA. Standard deviations are in parentheses.

percent—only 12 of the 123 patients enrolled were lost to attrition).

### Summary of Findings— Groups Combined

For both groups combined, the average patient entered treatment for tinnitus with an estimated baseline score around 50 on the THI and THQ and 27 on the TSI (which is just above midway on the TSI scale). The average patient reported awareness of his/her tinnitus about 71 percent of the time (“waking hours”) and annoyance by it 46 percent of the time. With each additional decade of having tinnitus, patients entered treatment with higher score levels on the THQ (5.50 points), TSI (2.17 points), and percent of Awake Time Aware of Tinnitus (AWARE) (9.00 percentage points). By the end of treatment, 18 months later, the average patient had declined 18 to 19 points on the THI and THQ and 8 points on the TSI, and was aware of his/her tinnitus 23% of the time and annoyed by it only 12% of the time.

### Summary of Findings— Groups Compared

To compare findings between groups, outcome data were analyzed on an intent-to-treat basis, using multilevel modeling (MLM)

analysis. The analysis revealed that both TM and TRT groups resulted in declines in tinnitus handicap and severity (THI, THQ, TSI), but the decline in TRT patients was considerably greater than the decline in TM patients. However, the greater declines in TRT compared to TM occurred most strongly in patients who began treatment with a “very big” tinnitus problem (as measured by a single baseline item on which patients rated their tinnitus problem as moderate, big, or very big). For these patients, the rate of improvement was considerably faster in TRT compared to TM. When patients began treatment with a moderate tinnitus problem, the benefits of TRT compared to TM were more modest.

On percentage awareness of tinnitus (AWARE), the advantage of TRT over TM was of a smaller magnitude: TM showed a big decline on AWARE (about 14 points every six months or 42 points over 18 months), with TRT adding an additional four-point decline every six months, for a total of 54 points decline over 18 months.

Repeated measures ANOVA was performed to evaluate outcomes of the percentage annoyance (ANNOY) of the patients’ tinnitus. The early improvement (first six months) in TM and TRT patients was fairly similar. Over the long run (6 to 18

months), however, TRT patients improved more than TM, although TM patients still improved modestly. Over the 18 months, ANNOY was reduced in TM patients by 26 percentage points, but it was reduced in TRT patients by an additional 14 percentage points for a total of 40 points.

### **Screening for Study Patients**

It has been observed that many individuals who experience chronic tinnitus are motivated to participate in any type of study concerning tinnitus. Most estimates of tinnitus prevalence, however, indicate that only about 20 percent of individuals who experience chronic tinnitus have a clinically significant condition that would warrant clinical intervention. For example, the American Tinnitus Association reports that approximately 40–50 million individuals in the United States experience chronic tinnitus (Davis and Refaie, 2000), but only 10–12 million of these seek professional help, and 2.5 million of these are debilitated by their tinnitus. Thus, for the present study, it was critical to screen for tinnitus severity the over 800 veterans who expressed interest in receiving treatment for their tinnitus.

Patient screening was a multistage process that started with initial contact over the telephone. The Tinnitus-Impact Screening Interview (Henry et al, 2004; and Appendix 1) was developed for the study as the first filter to ensure that patients had a tinnitus condition that warranted treatment. For screening purposes, the questions are short and concise with an emphasis on issues that would reflect the need for treatment. The study audiologist who conducted most of the telephone screening was trained to properly interpret veterans' responses to the questions and to make rapid decisions regarding their eligibility for study inclusion.

The screening process worked efficiently, as attested to by the relatively small number of veterans who did not feel the need to pursue treatment following the initial evaluation. Of the original 800 veterans who called about treatment, only 123 (15 percent) decided that they required treatment after screening. This information will be important to other VA medical centers as they implement clinical management programs for veterans with tinnitus. There is clearly a process that must be defined and documented

to categorize veterans according to their need for different levels of treatment. Based on our findings, it appears that about 85 percent of veterans with the complaint of tinnitus may only require some minimal information to acquire an understanding that their tinnitus does not pose a significant problem for them. This information can usually be conveyed over the telephone or during a brief appointment. We intend to follow up on these findings to develop a structured screening technique to appropriately respond to all veterans who report difficulties with chronic tinnitus.

### ***“Intervention” Provided at the Initial Appointment***

The initial evaluation, which was completed with 171 veterans, required about four hours to complete all testing and to administer the TRT initial interview. Although the study audiologist was not trained in tinnitus treatment techniques, she nonetheless could answer many of the veterans' questions about their test results and about tinnitus in general. The session was thus interactive, and the information provided to the veterans would equate to “educational counseling.” Results of audiologic testing provided information to explain any hearing difficulties. The tinnitus testing quantified the tinnitus perception and helped to provide answers to many questions about tinnitus. Administering the TRT initial interview involved up to an hour of interactive dialogue.

It has been our experience that uninformed patients are often confused about the differential effects of tinnitus, hearing loss, and sound tolerance. The initial interview is effective in clarifying these issues for patients (Henry et al, 2002a; Henry et al, 2003). Of the 171 veterans who completed the evaluation visit, 48 decided that they did not require any further treatment visits. Many of these 48 individuals came to the realization that their hearing loss was their primary problem and that it was not caused by their tinnitus. Moreover, their tinnitus was not enough of a problem to warrant any further action. As with the telephone screening, the initial evaluation thus provided all the intervention these patients needed to be satisfied that further tinnitus intervention was not necessary.

## Potential Confounding Variables

Although this was a prospective, controlled clinical trial, certain factors could have influenced the results.

### *Service Connection for Tinnitus*

Veterans who incur or aggravate a disease or injury during their military service can apply for a disability award from VA (see Henry et al, 2004). If the claim is approved, the veteran becomes “service connected” for the disabling condition with an assigned rating between 0 and 100 percent. A rating of at least 10 percent entitles the veteran to VA health-care services as well as monetary compensation that increases with the percent rating. A 0 percent rating provides health-care services only. Veterans can claim tinnitus as a service-connected disability, and approved awards are rated routinely at 10 percent. In our clinical trial, 38 (18 in TM and 20 in TRT) of the 123 veteran patients were service connected for tinnitus. Although this might be considered a potentially confounding variable, the disability award is not based on the severity of the condition but only on the presence of tinnitus that was incurred or aggravated during military service. Therefore, status of service connection should not have provided any incentive for veterans to either benefit or not benefit from treatment. In fact, outcomes between patients who were and were not service connected for tinnitus did not show any consistent differences across all outcome measures.

### *Types of Ear-Level Devices*

Although all patients were fitted with some type of ear-level devices, the devices used were different between groups. With respect to the sound generators and combination instruments, only General Hearing Instruments (GHI) devices were used with the TRT patients, and mostly Starkey devices were used with the TM patients. The TRT patients encountered numerous difficulties with their GHI devices (GHI has provided assurance that these problems have been remedied), especially with the noncustom sound generators that were eventually abandoned in favor of custom sound generators. The device problems that were encountered with the TRT patients

were resolved by the study audiologist. There were very few device problems for the TM patients, and these were handled by the TM specialist.

### *Use of Amplification with Ear-Level Devices*

An important distinction between the two treatment groups was the disparate use of ear-level amplification (hearing aids or combination instruments). In the TM group, 93 percent of the patients were fitted initially with amplification, compared to 36 percent of the TRT group (Table 1). For the TRT patients, sound stimulation solely with broadband noise was largely the preferred choice (61 percent of the TRT patients were fitted with bilateral sound generators—two patients were fitted with a hearing aid in one ear and a sound generator in the other). Amplification was clearly used much more often for the TM patients. One reason for this difference is that the TM specialist’s clinical experience has demonstrated that marginal hearing aid candidates (e.g., hearing thresholds of 25–35 dB HL at 3 kHz, and 40–45 dB HL at 4 kHz) with tinnitus often do well with the addition of high-frequency amplification. The use of sound generators alone was observed to frustrate these patients and to exacerbate their marginal hearing handicap.

### *Use of Wideband Noise*

Although some patients used hearing aids only, the majority of patients in each group were fitted with ear-level devices that produced wideband noise. Table 1 shows that, by the end of the 18-month treatment protocol, 46 patients (78%) in TM and 46 patients (72%) in TRT were using devices that produced wideband noise. As explained above (in Procedures), many differences existed between treatment groups regarding the prescribed use of the noise. Although patients received specific instructions as to how to utilize their devices, it cannot be known for certain exactly how the devices were used on a daily basis for each patient. The TM patients were allowed to use their devices in any manner that afforded the greatest tinnitus relief. It seems likely that some of these patients would have adjusted the noise output at a level “below the mixing point” as for the TRT patients. If the devices were adjusted this way and worn for

at least eight hours per day, then the device usage would have been the same as for the TRT patients. This issue points out the need for the development of technology to monitor device usage for each patient, with respect to both hours per day of use and output levels. The availability of such technology would enable investigation of these device-usage variables as factors affecting outcomes of treatment.

### ***Clinician Variables***

There was only one treatment specialist for each of the two treatment methods. These clinicians had in common their clinical certification as audiologists and their specialized expertise in the treatment of tinnitus. Any differences between clinicians, however, could have influenced outcomes. Unique characteristics of personality, attitude, and professional demeanor can affect a patient's perception of the quality of care received (Isenberg, 1998; Jensen et al, 2005). The TM specialist was a full-time clinician who provided clinical audiology services to five to seven patients per day. The TRT specialist was a full-time clinical researcher who only saw patients who were associated with his research (4–5 patients per week on average during this study). It is possible that such a difference in patient workload could have created differences in either the quality of service provided, the enthusiasm/energy level of the provider, or the manner in which the clinician was perceived by the patient.

### ***Clinical Contact Time***

Each patient's participation in this study involved at least seven clinical appointments over an 18-month period. The appointment schedule was the same for both groups, and all patients had about the same contact time with the study audiologist. The study audiologist reviewed the written questionnaires, administered the TRT interviews, and performed the audiometric and tinnitus assessments. Other aspects of the study, however, resulted in differences in the amount of patient-clinician contact time (see Table 7).

The structured TRT counseling was administered to patients by the TRT treatment specialist at every appointment (counseling time was generally shortened at later appointments as patients became more familiar with the concepts). Counseling for the TM patients was not structured, and these patients received counseling only as deemed necessary by the TM audiologist (and as time permitted). TM patients thus had less contact time with their treatment specialist than did the TRT patients. Between-groups differences in counseling time were most pronounced at the 3-, 6-, and 12-month appointments (Table 7). Some of this differential was offset by the added time required for the TM specialist to perform additional tinnitus tests and to select and fit devices.

TRT patients had many more problems with their ear-level devices than did the TM patients, especially during their first six months of treatment. The TRT patients required an average of 30 minutes to correct

**Table 7. Estimated Clinician Contact Time for Patients Who Completed This Study**

		Average Contact Time (hours)	
		TM	TRT
Appointment			
Baseline evaluation	Assessment and questionnaires (study audiologist)	4.00	4.00
Determine treatment plan	Device evaluation and earmold impressions (tinnitus specialist)	1.00	0.50
Initial treatment	Device fitting and counseling (tinnitus specialist)	1.50	1.50
3 month	Questionnaires (study audiologist)	0.75	0.75
	Treatment (tinnitus specialist)	0.33	1.00
6 month	Assessment and questionnaires (study audiologist)	1.75	1.75
	Treatment (tinnitus specialist)	0.33	0.75
12 month	Assessment and questionnaires (study audiologist)	1.75	1.75
	Treatment (tinnitus specialist)	0.33	0.75
18 month	Assessment and questionnaires (study audiologist)	1.75	1.75
	Treatment (tinnitus specialist)	0.33	0.50
Extra for device problems		0.15	0.50
TOTAL		13.97	15.50

device problems, while TM patients required less than ten minutes on average (Table 7). The device problems experienced by the TRT patients may have diminished their progress during the first six months. On the other hand, the additional contact time required to correct devices may have been an overall benefit to the TRT patients.

Considering all of these differences, the TM patients received an average of almost 14 hours of total clinician contact time while the TRT patients received about 15.5 hours. Stated another way, the TRT patients received approximately ten percent more “intensity of clinician interaction” than did the TM patients.

### ***Potential Sources of Systematic Error***

There are three potential sources of systematic error that could affect the validity of results: (1) observer bias, (2) subject bias, and/or (3) instrument bias (Hulley and Cummings, 1988; Johnson and Danhauer, 2002). Observer bias could affect the results if there was a consistent distortion in the collection, scoring, or reporting of the data. The potential for observer bias was minimized in this study by ensuring that all data were collected by the study audiologist who was not associated with either of the treatment methods. This individual had no previous tinnitus treatment experience and did not receive any specific training in TRT or TM for the duration of the study. The two treatment specialists were restricted to providing treatment only and were not involved in the data collection process. The TRT specialist was the study audiologist’s supervisor; thus, *unconscious* bias on the part of the study audiologist toward TRT was a possibility.

Subject bias refers to effects that can occur if study patients consistently distort their responses to outcome measures, either consciously or subconsciously (Johnson and Danhauer, 2002). The classic “Hawthorne” phenomenon (Roethlisberger and Dickson, 1939) suggests that patients may perform differently if they are aware that they are participating in an experiment. There is the potential that patients in the present study were affected by their knowledge of being involved in an experiment, which could have caused some of them to alter their responses to the outcome questions. This effect can be expanded to apply to any patient who is

receiving any form of treatment from professionals. Regardless of the method used, nonspecific therapeutic factors (e.g., effects of attention and positive expectancies) might occur as a function of the amount of contact time (“dose”) between the patient and a clinician who is perceived by the patient as being an “expert.” Isenberg (1998) has listed nonspecific effects that can influence results in outcomes studies. Those that are most germane to this study are the placebo effect (beneficial effect caused by positive expectation) and the “halo” effect (beneficial effect caused by manner, attention, and caring of clinician). These nonspecific benefits could have occurred for both groups in the present study, with potentially greater nonspecific benefit occurring for the TRT patients who received the greater amount of clinician contact time (Table 7).

Instrument bias refers to any measurement distortions that could take place as a result of faulty functioning of instruments used to measure outcome results. An example of instrument bias would be an audiometer that is out of calibration that would systematically alter all measurements obtained with the audiometer. The tinnitus questionnaires are subjective measurement instruments, and they might be subject to the same types of distortions. The use of multiple outcome instruments in the present study served to confirm the results that were obtained with any single instrument. Instrument bias was therefore not a confounding factor in this study.

### **Modification of Treatment Protocol for TM**

Treatment of tinnitus using the method of TM often involves only a single treatment appointment (Henry et al, 2002b). At the appointment, patients are fitted with ear-level devices and are instructed as to their proper use. Counseling is always provided, although a specific counseling protocol has not been described. Vernon (1987) advised clinicians who dispense maskers to contact their patients at six months and one year postfitting—to check on the proper use of maskers and to obtain information concerning treatment efficacy. TM patients are also encouraged to return to the clinic or to telephone the clinician, but only if necessary to resolve problems or to answer questions.

For the present study, patients in both groups attended ongoing treatment appointments on the same schedule: 3, 6, 12, and 18 months. This schedule was determined by the appointment schedule that is typically used with TRT. The usual TM protocol of a single treatment appointment was therefore modified so that all patients in this study received treatment on the same schedule.

### **Cost/Benefit Considerations**

It is of interest to clinicians to consider these results from a cost/benefit perspective. Cost in this case refers to hours of contact time since the monetary cost of ear-level devices is about equal for TM and TRT. The assessment of benefit can be based on any of the outcomes instruments. For illustrative purposes we will use the TSI since more TSI questionnaires were completed at each of the time points than for the other measures.

Using the TSI (which provides an index score between 0 and 48), the TM patients improved by an average of 4.6 points when they were first evaluated 3 months after initial treatment. Based on the contact time required to perform the evaluation and initial treatment for TM (6.5 hours—see Table 7), each hour of contact time resulted in a .7-point average improvement in the TSI (as measured at 3 months). This same computation done for the TRT patients shows a .4-point improvement in the TSI per contact hour following initial treatment. Cost/benefit assessed at 3 months thus shows an additional .3-point improvement per contact hour for the TM patients. When this analysis is done for 6 months, there is a .6-point average improvement, per contact hour, for both TM and TRT. Thus, cost/benefit is seen as equivalent for TM and TRT patients at 6 months. For 12 months, the average TSI improvement per contact hour for TM is .5, and .9 for TRT. By 18 months, the TSI improvement per contact hour for TM is .4, and 1.1 for TRT. Thus, there was a steady decrease in cost/benefit for TM compared to a steady improvement for TRT at the 12- and 18-month time points.

This cursory analysis suggests the possibility that cost/benefit is better in the short term for TM compared to TRT. There may be no difference in cost/benefit between groups after about 3 to 6 months of treatment.

If treatment is continued beyond 6 months, however, cost/benefit may improve incrementally for TRT compared to TM.

### **Outcome Instruments**

Ideally, there should be a standardized treatment-outcome instrument that would accurately and reliably reflect the severity of a patient's tinnitus condition, and that could be used to assess the efficacy of treatment over time. There are many instruments that have been developed for this purpose (mostly self-assessment questionnaires), but no single instrument has achieved universal acceptance. We chose to employ three documented and commonly used tinnitus outcome instruments, the Tinnitus Handicap Inventory (Newman et al, 1996; Newman et al, 1998), Tinnitus Handicap Questionnaire (Kuk et al, 1990; Tyler, 1993), and Tinnitus Severity Index (Meikle et al, 1995). The present report provides overall results of each instrument, revealing that these instruments functioned similarly in providing consistent global measures of tinnitus severity. In addition, use of the verbally administered TRT interview (Jastreboff and Jastreboff, 1999; Henry et al, 2003) was required for performing treatment with TRT. To enable a direct comparison of treatment outcomes using the TRT interview questions, the TRT interview was also used with the TM patients.

The completion of all four of these assessment instruments at each visit affords the opportunity to compare the instruments with regard to content, patient responses, and sensitivity. An important analysis will thus involve the detailed comparison of treatment outcomes from these different instruments that have each been developed independently. An in-depth analysis of these instruments and their relative outcomes from this study is presently underway, and a follow-up publication is planned to report results of that analysis.

### **Factors Associated with Problematic Tinnitus**

To improve clinical services for tinnitus management, it is important to understand the factors that dictate why so many people with permanent tinnitus seem to be

unaffected by it, while a relatively small percentage require clinical intervention. These factors most likely consist of some combination of personality traits, life circumstances, and characteristics of the tinnitus sound (Henry et al, 2005a). In the present study, we administered an extensive set of questionnaires at the initial visit to profile individuals with regard to personality and life-experience factors that could influence the impact of tinnitus on their lives. Additionally, each patient's tinnitus perception was carefully matched using sophisticated instrumentation and techniques. A comprehensive analysis will be conducted to determine how these different factors might be associated with different levels of treatment efficacy, and results of that analysis will be presented in a future publication.

## Conclusions

This prospective study involved a comparison of both TM and TRT in a controlled fashion and employing several outcome measurements to increase the validity of the findings. No prior study of this type has been conducted. The Veterans Health Administration is increasingly turning to evidence-based treatment methods (Feussner, 1998), and this study is expected to provide research evidence that will support the provision of effective treatment for tinnitus at VA medical centers.

1. The results of this study suggest that both TRT and TM are effective therapies for amelioration of tinnitus and may be more effective if patients are staged into different treatment groups. In particular, it appeared that (a) when patients have serious (high degrees of) difficulty with their tinnitus, they may benefit most from TRT, which will help them reach the (relatively) lowest levels of handicap and severity; (b) however, when the tinnitus difficulty being experienced is only moderate, TM may be a more efficient treatment because it is simpler and the appointments can be shorter, but it can still be nearly as effective as TRT for these patients.
2. Significant improvements for each of the treatment groups were noted,

but in varying degrees. Additionally, the time course of improvement appeared distinctly different. In general, for the TM group, most of the improvement was observed in the first 3 to 6 months of treatment and appeared to level off over the course of 18 months. For the TRT group, however, there appeared to be a steady improvement over time with the greatest level of improvement noted in the latter stages of treatment. This observation is in good agreement with the Jastreboff model, which predicts and asserts that benefit of TRT treatment should continue to increase over time. The present study showed that the TRT group showed substantial improvement between 12 and 18 months. The study protocol required that treatment end for all patients at 18 months; thus, it is unknown if further treatment might have produced further benefit. One clinical study has reported that patients treated with TRT continued to improve after the cessation of formal treatment, and that sustained benefit was observed after five years (Lux-Wellenhof and Hellweg, 2002).

3. Although longer duration of tinnitus was associated with higher THQ, TSI, and AWARE scores (reflecting greater tinnitus severity), at baseline, duration was not associated with improvement on these measures or with differential TM versus TRT treatment effectiveness. Likewise, the level of hearing loss was not associated with improvement or differential treatment effectiveness. Thus it appears that TM and TRT can be recommended, regardless of the patient's duration of tinnitus or hearing loss at the intake assessment.
4. There was good agreement between the written (self-administered) tinnitus instruments in assessing the initial and final degree of the tinnitus problem for our study patients. Results of individual questions from the TRT interview, however, did not provide the same level of agreement with the written questionnaires. Because the THI, THQ, and TSI were multiitem

measures, they may have been more sensitive than AWARE and ANNOY in detecting differential treatment effectiveness depending on the extent of a patient's tinnitus problem at baseline. The AWARE and ANNOY items from the TRT interviews, however, were very sensitive in detecting changes in the group as a whole.

5. This study is one of the first in tinnitus and audiology research to apply multilevel modeling to compare treatment groups and determine predictors of variation in patient trajectories. The many advantages that MLM affords may be ones that other researchers will want to consider.
6. One limitation of this study is that there was no control group that received comparable attention and time to determine if these nonspecific variables might account for similar improvements in outcome measurements. The study was also limited by having only two providers. At the present time there is a study underway at four VA medical centers to attempt to address these issues. The study will evaluate results of several providers who are administering TM, TRT, and "Audiologic Tinnitus Management" (standard audiologic care for tinnitus) (Henry et al, 2005c, 2005d).

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APPENDIX 1

TINNITUS-IMPACT SCREENING INTERVIEW

1. Do you have tinnitus that is constant? (i.e., it's usually or always there, whether you are consciously aware of it or not)  
YES                      NO
  
2. How much has tinnitus annoyed you, on average, over the last month? ("0" would be "not annoying at all"; "10" would be "as annoying as you can imagine.")  
0    1    2    3    4    5    6    7    8    9    10
  
3. How much did tinnitus affect or impact your life, on average, over the last month? ("0" would be "not at all"; "10" would be "as much as you can imagine.")  
0    1    2    3    4    5    6    7    8    9    10
  
4. Does tinnitus affect your sleep?                      Always/Often/Sometimes/Never
  
5. Does tinnitus affect your concentration? Always/Often/Sometimes/Never
  
6. If your tinnitus is a problem for you, what is the major reason your tinnitus is a problem?

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*Note:* The TISI has been revised since this version.