
TINNITUS TODAY

To Promote Relief, Help Prevent, and Find Cures for Tinnitus

Vol. 44, No. 2, Summer 2019

The Beauty and Dangers of **Music**

**Understanding Why
People Are Drawn to
Loud Music**

**Famous Musicians
with Tinnitus**

**Tinnitus Retraining
Therapy Findings**

Tinnitus Tools

- **Internet Music and Radio
for Tuning Out Tinnitus**
- **High-Fidelity Earplugs
that Maintain Sound
Quality**



Table of Contents

Vol. 44, No. 2, Summer 2019

SPECIAL FEATURES

4 | Why Do We Like Listening to Loud Music?

11 | Michael Santucci, Hearing Conservationist for America's Music Legends



13 | Musicians Should Invest In Custom-Fit High-Fidelity Earplugs

14 | The Dangers of Loud Music: Let's Turn the Volume Down



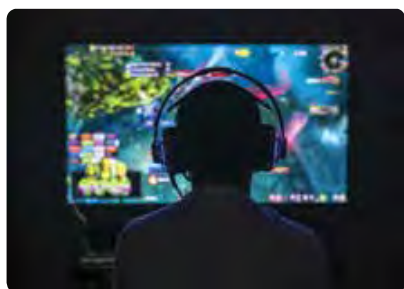
26 | Dangerous Decibels: The Drive to Educate and Change Listening Behavior

38 | Music Therapy to Heal the Mind and Emotions

SCIENCE & RESEARCH NEWS

17 | Most People Prefer Music at Lower Volumes

24 | Neurofeedback to Alter Brain Waves Associated With Negative Tinnitus



34 | Tinnitus Retraining Therapy Trial Demonstrates the Importance of Counseling and Sound Enrichment

36 | Does Tinnitus Retraining Therapy Improve Quality of Life?

41 | Gender Association of Tinnitus and Suicide Attempts

TINNITUS TOOLS & RESOURCES

21 | Be Ear-Responsible: High-Fidelity Earplugs for Safer Quality Sound



42 | An Endless Variety of Music and Sounds

44 | Support Group Locations

46 | Spotlight on Patient Providers

PERSONAL STORIES

6 | Music Was Magic Until the Ringing Began



22 | One Loud Night Too Many

33 | How Tinnitus Changed My Life



YOUR HEALTH

9 | A Musician's Exposure to Loud Music: A Case Study



19 | Auditory Injury is Permanent, so Wear Earplugs

31 | What Noise Level Is Safe?



TRIBUTE

43 | ATA Board of Directors Tribute

Tinnitus Retraining Therapy Trial Demonstrates the Importance of Counseling and Sound Enrichment

The Tinnitus Retraining Therapy Trial (TRTT), conducted at multiple sites between August 2011 and June 2017, is the first and only phase III trial of tinnitus retraining therapy (TRT) or of any tinnitus treatment to date. The American Tinnitus Association had the opportunity to ask Craig Formby, PhD, one of the principal researchers and Study Chair for the TRTT, about this groundbreaking research on the efficacy of one of the leading treatments for bothersome tinnitus.

Joy Onozuka (JO): *Why was the TRTT important?*

Craig Formby (CF): Since the 1990s, tinnitus retraining therapy (TRT) has been a prominent and influential—but controversial—habituation-based treatment protocol for alleviating the negative emotional reactions to and the awareness of debilitating tinnitus. TRT had not previously been vetted adequately in a definitive

phase III trial, which was the primary purpose of the TRTT.

The TRTT was a multisite randomized placebo-controlled phase III trial that was designed to assess the efficacy of TRT versus standard of care (SoC) over 18 months of treatment and follow-up. The SoC control was a patient-centered counseling protocol. SoC was based

on surveys of ongoing military care for tinnitus together with elements of current recommended best practice professional care guidelines.

The secondary objectives of the trial were to establish the contributions of TRT counseling and sound therapy components. The latter, with the aid of a short-acting sound generator placebo control,

“Our findings suggest that if a tinnitus patient is treated by a clinician providing quality care of the kind administered in our trial by a professional who demonstrates empathy for the patient and his or her condition, then the patient’s quality of life with respect to the tinnitus problem can be expected to improve meaningfully with treatment.”

also allowed for a comparison of the efficacy of the sound generators versus that of enriched environmental sound. Enriched environmental sound was routinely encouraged for use across all participants in the study.

Findings (see summary on page 39 for greater detail)

The main findings, after 18 months of follow-up, consistently revealed that all three treatment groups improved significantly. Specifically, the distressing effects of the tinnitus were reduced significantly relative to baseline pretreatment measures, with no meaningful differences in the treatment effects across the three groups of participants as assessed by the primary outcome measure, the Tinnitus Questionnaire, or by any of the key secondary outcome

indices, including the Tinnitus Functional Index and the Tinnitus Handicap Inventory.


Our findings suggest that if a tinnitus patient is treated by a clinician providing quality care of the kind administered in our trial by a professional who demonstrates empathy for the patient and his or her condition, then the patient's quality of life with respect to the tinnitus problem can be expected to improve meaningfully with treatment. The use of sound generators in TRT for tinnitus patients with unaided functionally adequate hearing sensitivity may not be necessary if enriched environmental sound is used routinely by these patients.

[However,] some of our analyses suggest the treatment response

dynamics achieved when patients used sound generators in TRT were expedited when compared with the treatment dynamics for either SoC or partial TRT using placebo sound generators. That is, TRT achieved its full treatment effect within slightly fewer than six months, whereas either of the other treatments required 10 to 12 months to achieve their full treatment effects. Future research should explore this finding



Craig Formby, PhD

in greater detail, which if it holds true suggests that the use of sound generators may be important for expediting treatment by TRT. 

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Does Tinnitus Retraining Therapy Improve Quality of Life?



Summary by John A. Coverstone, AuD

Tinnitus retraining therapy (TRT)

was developed in the late 1980s by Pawel Jastreboff, who was studying tinnitus in animal models, and Jonathan Hazell, who pioneered the use of low-level broadband sound therapy for treatment of tinnitus. Jastreboff created the neurophysiological model of tinnitus, which describes the role of the limbic system (involved in emotional responses) and autonomic nervous system (responsible for many bodily functions) in the negative reactions to hearing tinnitus. To this model, Jastreboff and Hazell added principles of sound therapy to create TRT, which is a treatment protocol that includes counseling and sound therapy. TRT prescribes a specific method of counseling called directive counseling, in which the therapist provides advice and guidance to the patient's decisions. Sound therapy is often achieved with ear-level devices, usually in the form of sound generators, hearing aids, or a combination of the two instruments. Patients are also encouraged to keep some sort of sound in their environment at all times,

called an enriched sound environment. The purpose of sound therapy and enriched sound environments is to reduce the perception of the tinnitus sound and prevent tinnitus from ever being the only sound heard by the patient. Since its origin, TRT has been a fundamental tool of many providers of tinnitus care, and the underlying principles have been the basis for other treatment models developed over the years.

For the past decade, a group of academic civilian researchers has partnered with colleagues in military hospitals to create the Tinnitus Retraining Therapy Trial Research Group. They are investigating the efficacy of TRT and are assessing the separate contributions of sound therapy and counseling to TRT. In the most recent study, participants were randomly assigned to one of three treatment groups: TRT including counseling and sound therapy achieved with bilateral ear-level sound generators; partial TRT including counseling combined with short-acting "placebo" sound generators; and what the authors termed "standard of care," a patient-centered counseling approach based on surveys

of tinnitus treatment in the military and professional best practices.¹ All groups were encouraged to use enriched environmental sound throughout the day. By comparing the treatment results among the groups, the researchers' study design made possible the separation of the effects of sound therapy versus directive counseling, while comparing the efficacy of TRT with the standard-of-care treatment.

Baseline and treatment data were collected from August 4, 2011, to June 20, 2017, at six U.S. military hospitals. Participants had to have had tinnitus for at least one year, with medically or surgically treatable causes ruled out. None of the study participants had significant hearing loss, which otherwise might have confounded the utility of the sound generators. They also could not have had prior treatment within the past year and were required to have a baseline score of at least 40 on the Tinnitus Questionnaire, showing that tinnitus was having at least a moderately severe effect on their quality of life.

Participants enrolled in the standard and partial TRT groups were assigned to use bilateral sound generators

that were identical in appearance and initial operation. Those in the partial TRT group used sound generators that produced a constant low-level broadband output for the initial 40 minutes of operation, after which the output decreased by 1 dB every minute until becoming silent. Both researchers and participants were blinded as to whether participants had received standard sound therapy or placebo devices (called double-blinding). If the devices were checked by audiologists, the placebo sound generator output was restored to the initial volume level setting within approximately 3 seconds after removal from the ears. Counseling also reinforced the expectation that output from the sound generators would appear to decrease over time for both the standard and placebo TRT treatment groups.


All participants were counseled to maintain a sound-enriched environment throughout the day, meaning they were to avoid very quiet environments. This is a current strategy used in many treatment approaches to reduce the relative loudness of a patient's tinnitus. Audiologists were formally trained in TRT, and standardized protocols were

implemented to provide as close to identical treatment experiences as possible within and across hospitals. The study included 151 participants.

The Tinnitus Questionnaire was used as the primary outcome measure, and participants were assessed prior to treatment and at follow-up visits at three, six, 12, and 18 months after the initial treatment visit. Other assessments used included the Tinnitus Functional Index, Tinnitus Handicap Inventory, measures of depression, anxiety, and hearing handicap and a visual scale of tinnitus severity (similar to visual pain scales with faces depicting various states of distress, called a visual analog scale).

The overall results were similar across groups. Most importantly, all groups experienced significant improvement in rating their quality of life outcomes with tinnitus over the 18-month follow-up period. Change in questionnaire scores from baseline to 18-month follow-up revealed no meaningful differences among the treatment groups. That is, there was no meaningful difference in the changes in the quality of life measures when comparisons were made between groups receiving standard TRT and partial TRT, standard TRT and

standard of care, or partial TRT and standard of care.

There was no difference in treatment effects for sound therapy as prescribed by TRT versus partial TRT implemented with placebo sound therapy. This finding indicates that sound therapy from sound generators may not be necessary when TRT directive counseling is combined with an enriched sound environment, at least when treating tinnitus patients who have no greater than a mild hearing loss. This conclusion is further supported by the fact that the standard-of-care counseling approach had a similar effectiveness to the standard and partial TRT treatments. This study highlights the importance of counseling in tinnitus treatment and suggests that enriched environmental sound therapy in combination with counseling may be sufficient for achieving treatment success. Sound generators may be of lesser importance in the TRT treatment process for these individuals. 

1 Scherer, R. W., & Formby, C., for the Tinnitus Retraining Therapy Trial Research Group. (2019, May 23). Effect of tinnitus retraining therapy vs. standard of care on tinnitus-related quality of life. *JAMA Otolaryngology—Head & Neck Surgery*. Advance online publication. doi:10.1001/jamaoto.2019.0821

“Most importantly, all groups experienced significant improvement in rating their quality of life outcomes with tinnitus over the 18-month follow-up period.”

