Tinnitus Retraining Therapy

by
WCB Evidence Based Practice Group
Dr. Craig W. Martin, Senior Medical Advisor

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Tinnitus Retraining Therapy

Background

Tinnitus Retraining Therapy (TRT) is one form of potential treatment being offered to patients with chronic subjective tinnitus. Recently, a number of publications in clinical journals and the mainstream media has hailed TRT as a breakthrough in the treatment of chronic subjective tinnitus\(^1\,^2\). At present and in selected cases, the Workers' Compensation Board of BC (WCB of BC) also offers TRT as one method of treating chronic tinnitus among injured workers.

In May 2003, the Evidence Based Practice Group (EBPG) was approached by the Hearing Loss Department at the WCB of BC to investigate the effectiveness of TRT in treating chronic subjective tinnitus and to comment on the Tinnitus Project Report developed by the Hearing Loss Department. Thus, these are the objectives of this paper.

Tinnitus

The word tinnitus comes from the Latin word *tinnre* which means to ring or tinkle\(^3\). The history of attempts to treat this disorder goes back to ancient Egypt\(^4\). The Ebers papyrus (± 2500 BC) includes significant details regarding the treatment for 'a bewitched ear'. Assyrian clay tablets (± 7 BC) also described tinnitus, differentiating it into 3 types (singing, whispering and speaking), each with its own specific treatment. Descriptions of tinnitus continued through time with examples found in the Roman, Byzantine, Medieval and Renaissance literature. In his letter to a friend in 1801, Beethoven described his experience with tinnitus stating, "only my ears whistle and buzz continuously day and night. I can say I am living a wretched life"\(^3\).

Tinnitus is a very common and yet, still poorly understood disorder\(^5\,^6\). The National Hearing Study, conducted in the UK in 1985, reveals that about a third of all adults reported having had tinnitus at some time; 10%-15% of adults reported prolonged spontaneous tinnitus following loud noise or oto-toxic drugs exposure; about 5% reported troublesome and annoying tinnitus that affected their ability to get to sleep and 0.5% - 1% of adults reported tinnitus of such severity that they noted significant adverse effects on their quality of life\(^7\).

A population-based study conducted in the Blue Mountains area of New South Wales, Australia, revealed the prevalence of tinnitus to be 30.3% among adults aged 55 - 90 years old. 67% of these with tinnitus reported their tinnitus to be extremely annoying. However, only 37% had sought professional help and only 6% had received any treatment\(^8\).

A population study in Sweden reported that 14.2% of the adults experienced tinnitus 'often' or 'always'\(^4\). While population studies conducted in 5 cities in Italy reported that 14.5% of the population experienced prolonged, 'spontaneous' tinnitus\(^4\).
In the United States much of what is known about the prevalence of tinnitus comes from government agencies and their health surveys. The most current one is the 1996 National Center for Health Statistics survey on chronic diseases\(^{3,5}\). The survey reveals that the overall prevalence of tinnitus was 3%. The survey also shows that the prevalence was 1% among those aged 45 or younger and 9% for those aged 65 years or older\(^{3,5}\).

In Canada, it is estimated that more than 360,000 (> 1.16%) Canadians have tinnitus in an annoying form\(^{9,10}\). Of these, 150,000 find that the tinnitus seriously impairs their quality of life\(^{9,10}\).

A large and well analyzed study conducted by the Hearing Section of the WCB of BC in 1984 showed that the prevalence of tinnitus among noise exposed workers in BC was 6.6%\(^{11}\). The study showed that the prevalence of tinnitus was neither gender nor age associated. The prevalence of tinnitus among noise exposed workers in BC was found to be associated with hearing thresholds.

In an attempt to study the natural history of tinnitus, Andersson et al\(^{12}\) followed 146 tinnitus patients for an average of 4.9 years. About half of these patients were given cognitive behavioral therapy and half did not. The authors found that, regardless of their treatment, tolerance of tinnitus increased overtime, suggesting overall habituation to tinnitus. Further, regardless of their treatment, overall patients perceived that their tinnitus severity remained unchanged over time.

Currently, there are many definitions of tinnitus without any universally accepted classification system\(^{13}\). Perhaps the simple and most useful one is that of tinnitus being the conscious experience of a sound that originates in the head or neck, and without voluntary origin obvious to that person. Thus, tinnitus refers to the perception of sound in the absence of external stimuli. Patients usually describe these perceptions as ringing, buzzing, roaring, and chirping or similar to the sound of steam escaping.

Within various tinnitus classification systems available, perhaps the differentiation between subjective and objective tinnitus is the simplest and most practical one\(^{6}\). Subjective tinnitus is heard only by the patient, while objective tinnitus can be heard by the patient and the examiner. This is an important distinction since objective tinnitus usually has an identifiable acoustic source, such as a carotid bruit. Objective tinnitus is also called vibratory or extrinsic or pseudo-tinnitus. Subjective tinnitus is more common than objective tinnitus and usually is idiopathic. Subjective tinnitus is also called non-auditory tinnitus.

Tinnitus, which is sensory-neural in origin, does not have a clear physiological explanation\(^{14,15}\). It may be caused by abnormalities of the cochlea, cochlear nerve, ascending auditory pathway or auditory cortex. Many theories on the origin of tinnitus have been proposed. These theories generally involve hyperactive hair cells or nerve fibers activated by a chemical imbalance across cell membrane or decoupling of stereocilia.

In 1993, a neurophysiologic model of tinnitus was developed by Jastreboff based on his animal studies\(^{15}\). Jastreboff and Hazell\(^{15}\) proposed that tinnitus is the result of the interaction of a number of subsystems in the nervous system, with auditory pathways playing a role in the development and appearance of tinnitus as sound perception. In this theory, the limbic system is responsible for the...
development of tinnitus annoyance. The perception of tinnitus provides negative reinforcement which enhances the perception of tinnitus and the perception of time the person is aware of its presence\(^{(16)}\). This model has led to the development of tinnitus retraining therapy (TRT).

**Tinnitus Retraining Therapy (TRT)**

One method of tinnitus treatment that has received worldwide recognition during the last decade is TRT. The conceptual basis of TRT was first described in 1990 as a method of tinnitus treatment based on a neurophysiological model of tinnitus developed by Pawel Jastreboff, a neurophysiologist, and JWP Hazell, an otolaryngologist\(^{(17)}\). This neurophysiologic model suggests tinnitus is more than an auditory nervous system 'problem' and may involve the limbic and autonomic nervous systems\(^{(18,19)}\).

The Neurophysiologic model

According to the neurophysiologic model of tinnitus, the treatment of tinnitus should focus mainly on the limbic and autonomic nervous systems. Only secondary attention is given to the tinnitus sensation itself. The central auditory nervous system processes environmental sounds by identifying, sorting and routing their associated neural signals. Some of the sounds activate emotions (limbic system) and/or cause behavioral reactions (autonomic nervous system). These kinds of sounds thus carry an emotional 'meaning' to the listener, likely due to previous association of such sounds with a significant emotional reaction. The rules of learning and conditioning that apply to external sounds also apply to the tinnitus signal or component. If an individual's tinnitus becomes associated with an emotional response, any future perception of the tinnitus is likely to activate the same response. It is suggested that the emotional response therefore further increases the likelihood of paying attention to the tinnitus, thus creating a vicious, self perpetuating circle\(^{(18)}\).

The central auditory nervous system receives and processes an almost constant stream of acoustic information. The brain must determine, in real time, which of the environmental sounds, if any, will receive the listener's attention. Neural signals that are associated with pertinent auditory information are transmitted to the auditory cortex. On the other hand, less important signals are terminated prior to reaching consciousness. This routing of signals is controlled by patterns of memory that recall consequences that are associated with each of the stimuli. Signals that are normally blocked from reaching consciousness have undergone habituation. Subconscious pattern recognition of habituated signals function to identify the signals as unimportant and consequently unnecessary for receiving conscious attention. Novel stimuli or stimuli that are recognized as important will bypass this blocking mechanism to activate other brain centres\(^{(18)}\).
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Thus, the neurophysiologic model considers problematic tinnitus to be caused by an aberrant auditory signal that has been conditioned to cause activation of the limbic and or autonomic nervous systems. The aberrant signal must undergo specific conditioning procedures to be processed differently as a meaningless unimportant signal. It can be concluded that the ultimate goal of TRT is to retrain the brain to habituate to the tinnitus signal\(^{(18)}\). The audiological literature states that such retraining is entirely different from 'masking therapy' where the goal is one of masking the tinnitus signal up front\(^{(16)}\).

Rationale for TRT

The rationale for treatment with TRT is based entirely on the neurophysiologic model of tinnitus as summarized in the previous section\(^{(18-20)}\). The goal of the therapy is to induce habituation to the patient's tinnitus. This goal is addressed using two strategies\(^{(18,19)}\). The first strategy is to remove any negative thought or fears that may be associated with tinnitus perception. This first goal is accomplished through directive counseling which consists of a structured program of patient education with a view to eliminating or at least decreasing the patient’s reaction to any perceived tinnitus. The counseling and education delivered to the patients is designed to mitigate any fears and concerns associated with tinnitus.

The second strategy is to remove the tinnitus from conscious perception. TRT proponents suggest that the second strategy can only be accomplished after successful implementation of the first strategy. The strategy to remove tinnitus from conscious perception is done through 'sound' therapy. In TRT, sound therapy uses constant low levels of background sound ('white noise generator') to reduce the detectability of tinnitus at the subconscious level. This reduced detectability is said to have to be maintained for one to two years to achieve retraining of the tinnitus signal processing mechanism\(^{(18,19)}\).

When both of these strategies are successful, the tinnitus signal will be habituated from negative reactions (i.e. limbic and sympathetic portions of the autonomic nervous systems) and from conscious perception (i.e. cortical association areas)\(^{(19)}\).

The habituation method relies heavily on brain plasticity and the ability of the brain to learn and re-learn. As such, drugs that impair brain plasticity or reduce the brains ability to learn (such as in benzodiazepines use which is commonly prescribed to patient with tinnitus) are contra-indicated in TRT\(^{(19)}\).

Not all TRT patients will be given both the directive counseling and sound therapy\(^{(20)}\). Based on the medical and audiological evaluation results, at the end of the TRT initial interview, each patient is categorized into one of five categories depending on the impact of tinnitus, the level of hearing loss and the existence of hyperacusis. The category in which the patient is placed determines the type of TRT treatment the patient will receive. The patient category, criteria for the category and type of TRT treatment is summarized in Table 1\(^{(19,20)}\), below. It should be noted that patients can change categories
during treatment. The patient may then require a different type of sound therapy and may be given different, category specific, directive counseling.

Table 1. Patient category number, category criteria and type of TRT treatment.

<table>
<thead>
<tr>
<th>Patient category number</th>
<th>Criteria for the category</th>
<th>Type of TRT treatment</th>
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<tbody>
<tr>
<td>0</td>
<td>Tinnitus is a minimal problem. The tinnitus is weak, &lt; 2 months or short lasting. Patient doesn't have significant hearing loss or hyperacusis</td>
<td>Basic directive counseling + sound therapy w/o the need for wearable sound generators or hearing aids. Requires fewer follow-ups.</td>
</tr>
<tr>
<td>1</td>
<td>Tinnitus is a significant problem/bothersome. Without associated significant hearing loss or hyperacusis</td>
<td>Directive counseling and sound therapy which includes tabletop sound machine and a wearable sound generator which is set at 'mixing' or blending point.</td>
</tr>
<tr>
<td>2</td>
<td>Hearing loss and tinnitus a significant subjective problem. Without hyperacusis nor prolonged worsening of symptoms after sound exposure.</td>
<td>Directive counseling and combination instruments (hearing aids and sound generator)</td>
</tr>
<tr>
<td>3</td>
<td>Hyperacusis is a significant problem. Tinnitus or hearing difficulties irrelevant. Prolonged worsening of tinnitus or hyperacusis after sound exposure is not present</td>
<td>Directive counseling and wearable sound generator or combination instruments.</td>
</tr>
<tr>
<td>4</td>
<td>Hyperacusis as dominant complaint, shows worsening of tinnitus or hyperacusis following exposure to sound.</td>
<td>Relatively uncommon, most difficult to treat, slow response to treatment. Directive counseling + sound generator.</td>
</tr>
</tbody>
</table>

With regard to patient category, category criteria and type of TRT treatment (Table 1), the EBPG failed to identify any published literature on the criteria of minimal or significant tinnitus (scoring based on the interview questions, medical and audiological tests?), on neither the conduct/content of directive counseling nor the number of follow-ups required within each patient category. This lack of high level, peer reviewed literature is worrisome.

It should be noted that the distinction in TRT between directive counseling and cognitive therapy has been criticized\(^\text{[17,21]}\). Jastreboff and Hazell\(^\text{[15]}\) stated that ‘the modification in the processing of the tinnitus signal is achieved by utilizing methods of cognitive therapy with highly specific and directive counselling’. Cognitive therapy, including cognitive behavioural therapy, is one of the most extensively researched psychological treatments, particularly as a treatment for depression. Wilson et al\(^\text{[21]}\) and Kroener-Herwig\(^\text{[17]}\) et al argue that the description of cognitive therapy in TRT differs from standard cognitive therapy in two significant ways i.e. it is described as ‘directive’ and it is given 4 - 6 times over an 18 month period. The authors\(^\text{[17,21]}\) stated that cognitive therapy, which is developed by Aaron T. Beck in the late 1960s, refers to the analysis and modification of behaviours, beliefs, attitudes and attributions and that cognitive therapy is a collaborative
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approach, rather than directive (directive therapy is described by Jastreboff and Hazell\(^{(15)}\) as a one way communication in which the patient is given information regarding the nature of the problem, its likely course over time, its connection with hearing loss and its responsiveness to treatment). In contrast, the collaborative approach, used in standard cognitive therapy, is one where the patient and therapist identify dysfunctional thoughts and develop hypotheses which can be tested in relation to these thoughts. The therapist helps the patient to challenge the validity of the thoughts as a description of themselves, the world or future events. Cognitive therapy is usually implemented intensively over a relatively brief time, usually 8-12 weekly sessions.

Materials and Methods

1. Literature review
   
   Literature searches were undertaken on medical literature databases including PubMed, Cochrane Library, ACP Journal Club, Clinical Evidence, Bandolier, the US Agency for Healthcare Research and Quality and the NHS Centre for Reviews and Dissemination at the University of York.; websites of members of the International Network of Agencies for Health Technologies Assessment (including Canada, the US, Great Britain, New Zealand, Australia, Sweden and Denmark); websites of BC, Alberta and the Quebec Office of Health Technology Assessment; websites of other WCBs in Canada (including Yukon and Northwest Territories, Alberta, Saskatchewan, Manitoba, Nova Scotia, Newfoundland, PEI, Quebec and Ontario) and in the US (Washington State, Colorado, California and Oregon); private health insurance companies (including Aetna, Blue Cross - Blue Shields, Humana, Permanente Medical group, Tuft and Western Health Advantage); websites of tinnitus associations including those in the US, the UK, Canada and the US Department of Veterans Affairs. The searched was done up to December 2, 2003.

   The searches were undertaken in two steps:
   
   1) The first search was done in order to identify published systematic review, randomized/controlled trials or any other study designs (including case-series/reports) on TRT. This search was done by employing a combination of medical subject heading and keywords of; (tinnitus) and (tinnitus retraining therapy or tinnitus retraining treatment or retraining therapy or habituation therapy)

   2) The second search was undertaken in order to identify available reviews (systematic or non-systematic) on the subject of the available treatment for chronic subjective tinnitus. This search was done by employing a combination of medical subject heading and keywords of; (tinnitus or chronic tinnitus or subjective tinnitus) and (treatment or therapy).
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- **Inclusion criteria**: publications were selected for critical review if they involved human subjects. There was no restriction placed on the year of publication. Publications were restricted to those where at least the abstract was available in English.
- **Exclusion criteria**: the publications were excluded if the methodology used to evaluate the quality of the primary studies were not apparent.
- The EBPG did not search commercial databases (such as Dialog®) that contain publication of conference abstract/proceedings under the assumption that these abstracts will be published in full in the peer-reviewed journal subsequent to its presentation in conferences. This particular limitation maybe important with regard to the 1999 and 2002 International Tinnitus Conference on which several abstracts on the outcome of TRT were presented. The EBPG was not able to find the full publication of these abstracts in the subsequent years. However, these studies were quoted in recent articles on the outcome of TRT.
- Appendix 1 provides the interpretation of level of evidence as adopted by the EBPG at the WCB of BC.

2. **Hearing Loss Department Tinnitus Project Report.**
   - In April 2003, the EBPG received the Tinnitus Project Report from the manager of the Hearing Loss Department at the WCB of BC.
   - The EBPG reviewed this report and was asked to provide critical comments on methodological quality of the program evaluation and outcome of TRT.

**Results.**

**Systematic review of TRT.**

- **Report on published systematic reviews (Level 1 evidence).**
  Leal and Milne from the Wessex Institute for Health Research and Development at the University of Southampton did a narrative/qualitative systematic review on the effectiveness of TRT in 1998\(^{22}\).
  
  The authors searched various databases, including Medline (1993-September 1997), HealthSTAR (1975-September 1997), Embase (1980-August 1997), Cochrane Library (issue 3, 1997), GEARS (issue 2, 1997), NEED (Web), Best Evidence (1997), PsycLit (1990-September 1996), ASSIA (1992-1996) and CINAHL. The authors also searched current clinical trials within the National Research Register, undertook personal communication with staff at the British Tinnitus Association and the Royal National Institute for Deaf People as well as searching the internet at [www.tinnitus.org](http://www.tinnitus.org).
  
  *Inclusion criteria*: retraining therapy that was defined as a comprehensive approach to the management of tinnitus, involving psychological, prosthetic (and behavioural) components.
  
  *Exclusion criteria*: study which only evaluated one component of TRT.
The authors found 2 articles (abstracts, published in the Proceedings of the 5th International Tinnitus Seminar) that fulfilled the inclusion criteria. These are described below.

Sheldrake et al(in 22) reported a case series involving 149 tinnitus distressed patients who attended a private tinnitus centre in London. The range of duration of attendance was 7 months to 15 years. Data was collected retrospectively using a non-validated self report questionnaire administered by interview. 96% of patients reported improvement in awareness of tinnitus at the end of treatment. 28 (19.6%) of the improved patients experienced periods of time when tinnitus was totally absent. The mean (± standard error) duration of symptom free periods was 10.5 ± 4.5 days. This study has been criticized due to the lack of controls, unclear patient selection, recall bias, un-reported drop out rate and a lack of description of the TRT method being used.

McKinney et al(in 22) reported on a similar group of patients with tinnitus attending a National Health Services referral centre in London. Participants were divided into three groups, including those who received directive counseling only, those who received directive counseling + noise generator and those who received directive counseling + hearing aids. Measurements of tinnitus habituation (audiometric testing and self administered questionnaire) were done prior to treatment, and at 1, 2, 6 and 12 months of treatment. At 12 months of treatment, improvements in self rated scores for tinnitus annoyance, effect of the quality of life and tinnitus loudness were reported but were not significantly different across the 3 groups of treatment. At 12 months of treatment the participants reported a 20% reduction in tinnitus awareness. The hearing aid group showed the greatest overall change, while the noise generator group showed the least. This study has been criticized on the basis that this was a study on the effect of directive counseling. Further criticism includes the lack of information on the number of the total available population and the drop outs/loss to follow-up patients.

In this 1998 published systematic review(22), Leal and Milne stated that the effectiveness of TRT in treating tinnitus had not been evaluated in any randomized controlled trials. Based on the available published case series, the authors concluded that there was no evidence to suggest that TRT was effective in treating patients with debilitating tinnitus.

- Case series reports (Level 3-4 evidence).

The search conducted by the EBPG on the various databases failed to identify any published randomized/controlled trials of TRT. Twelve published case series (4 were non-English publication with abstracts in English) on TRT or modified TRT were identified and retrieved. These studies are summarized and presented in Table 2.

The 12 case series reported in Table 2 show improvement in tinnitus (measured by different criteria) by about 55% - 90% during varying periods of clinical follow-up (immediate to 28 months). However, these studies reported in Table 2 suffer from various methodological problems mainly due to lack of
controls, non-blinded assessment and the high possibility of selection bias being introduced. Further, these studies employed various standards and non-standards Jastreboff's TRT treatments and used different, non-validated criteria for outcome measurements. As such, based on these case series, it can be concluded that there is lack of evidence on the effectiveness of TRT in treating chronic subjective tinnitus.

- **Randomized controlled trial reports (Level 1 evidence).**

  The search conducted by the EBPG on the various databases failed to identify any published randomized/controlled trials of TRT.

  Through personal communication, the EBPG was able to identify and obtain, perhaps, the only randomized controlled trial (RCT)\(^{(43)}\) on TRT conducted and presented to date (Appendix 2). A pilot RCT study to investigate the clinical efficacy of tinnitus masking and TRT has been conducted by Henry and Schechter\(^{(35)}\) from the US Department of Veterans Affairs in Portland, OR. The authors screened 124 out of 800 veterans with tinnitus to be randomized into either masking or TRT (Jastreboff method\(^{(19)}\)). Both interventions were given for 18 months. Interventions were given by 'experts' (*no treatment protocols were given*) and outcome data was collected by an audiologist at 3, 6, 12 and 18 months (*blinding was not mentioned in this presentation note*). The outcome measures included the Tinnitus Severity Index, Tinnitus Handicap Questionnaire, Tinnitus Handicap Inventory (these 3 questionnaires have been validated) and TRT interview forms which included tinnitus awareness, annoyance, impact on quality of life and magnitude of tinnitus as a 'problem'.

  111 patients completed 18 months of treatment according to their protocol. At 18 months, patients in TRT had significantly lower Tinnitus Severity Index, Tinnitus Handicap Inventory, Tinnitus Handicap Questionnaire, as well as a lower mean percentage of tinnitus awareness, tinnitus annoyance, impact on quality of life and tinnitus being perceived as a 'problem' compared to patients treated with masking. At 18 months 87% of those in TRT was classified as 'improved' compared to 58% on masking (*no criteria was given for 'improved').

  The authors concluded that:

  - Both masking and TRT were effective for the majority of veterans with severe tinnitus
  - TRT might have greater efficacy over a 12-18 month treatment period
  - Findings were not definitive and the study needs to be replicated and expanded

  It should be noted that the authors did not provide any information on whether data was analyzed by employing the 'intention to treat' principal or not. Further, it should be noted that the veteran population is distinctive in the high number of patients with sudden hearing loss secondary to explosion or gunfire. These hearing loss patients due to blast trauma or other military
noise exposures shared a common scenario of permanent hearing loss with chronic, residual tinnitus. Thus, the generalizability of this study toward injured workers at the WCB of BC needs to be interpreted with caution.

Thus, the only available RCT on TRT has not provided definitive evidence on the effectiveness of TRT in treating chronic subjective tinnitus.

Other treatment(s) for chronic subjective tinnitus.

The pathophysiology of tinnitus remains unclear, as such the types of treatment being offered to treat tinnitus are extremely varied, including those of mainstream or alternative medicines\(^{(37)}\).

Dobie conducted a narrative/qualitative systematic review (evidence level 1) based on published clinical trails of treatment for tinnitus\(^{(38)}\). The inclusion criteria were any randomized controlled trial treatment for patients with tinnitus. The exclusion criteria were those studies with tinnitus as a side effect of treatment, studies limited to single otological or neurological disorder (including Meniere's disease, vertebrobasilar insufficiency, acute acoustic trauma), studies employing 'waiting list' as placebo treatment and studies on intravenous lidocaine. He searched Medline (1966-1998) and old medline (prior to 1966). Dobie was able to identify 69 RCTs. In this review he identified various methodological flaws in these published RCT, including incorrect statistical analysis, incomplete reporting, potential confounders due to differing intensity of physician interaction, lack of or compromising of blinding, high drop-out rates, lack of intention to treat analysis, inadequate implementation of intervention and most of all, a lack of consensus regarding outcome measurements. Six RCTs using Tocainide showed inconsistent results; two RCTs on iontophoresis of lidocaine did not show any difference in outcome between treatment groups; four RCTs on carbamazepine use suggested no benefit; two RCTs on amino-oxy-acetic-acid showed inconsistent results. The smaller trial (n = 10) showed benefit, while the larger trial (n = 132) reported no benefit. Four RCTs on benzodiazepine use in the treatment of tinnitus showed inconsistent results and three RCTs on tricyclic antidepressant therapy showed inconsistent results. There were two RCTs on ginkgo treatment that suggested that the treatment response was no different than that of placebo Six RCT studies on sound masking devices showed inconsistent results. Three RCTs on electrical stimulation showed no benefit and three RCTs on magnetic stimulation, 2 RCTs on ultrasound, five RCTs on biofeedback and three RCTs on hypnosis showed inconsistent results. The six RCTs on acupuncture that Dobie reviewed showed no statistically significant difference. There were fourteen RCTs - on miscellaneous drugs, including amylobarbitone, GABA agonist, lamotrigine and others - none of these were shown to have a benefit over those of placebo.

Waddel and Canter\(^{(40)}\) summarized up-dated evidence on the effectiveness of available treatments for tinnitus (evidence level 1). The authors concluded that there was no significant difference between active treatment, including ginkgo biloba, tocainide and tricyclic antidepressant and placebo. Further, the authors concluded that there was insufficient evidence attesting to the beneficial effect of a number of treatments, including acupuncture, anti-epileptic medications, baclofen,
benzodiazepines, cinnarizine, electromagnetic stimulation, hyperbaric oxygen, hypnosis, lower power laser, nicotinamide, tinnitus masking devices, and zinc. Based on two systematic reviews of psychotherapy in the treatment of tinnitus, the authors stated that there was limited evidence that psychotherapy might improve symptom scores of people with chronic tinnitus. However, the authors cautioned that due to the weaknesses of the methods used in the reviews as well, the methodology employed in the primary studies that were included in the review, the effects of psychotherapy in treating tinnitus remained unclear.

Seidman and Babu did a non-systematic review (evidence level 4) on complementary and alternative medicine treatments being used to treat tinnitus. The review included the used of herbs such as ginkgo, black cohosh, ligustrum, mullein, pulsatilla and St John’s Wort, vitamins and minerals such as Mg, Ca, K, Zn, Mg, Cu, Se, vitamin B_{12}, β-carotene, vitamin C, Vitamin E and niacin. However, to date, there is no evidence on the effectiveness of these treatment modalities in treating tinnitus.

In its frequently asked questions portion of its website, the Tinnitus Association of Canada\(^{(9)}\) states that acupuncture, homeopathic tincture, craniosacral manipulation, naturopathy, chiropractic, nutritional supplements, Chinese herbs, shiatsu massage and ear candling do not help in treating tinnitus (evidence level 4).

**Who is paying for TRT?**

Based on a search conducted on their respective web sites (the search was done in August 2003 and repeated in December 12, 2003), the EBPG failed to collect any information on the payment status of tinnitus retraining therapy from the all the provincial and territorial WCBs in Canada as well as the WCB of Colorado State and Washington State Department of Labor and Industries in the US.

Private insurance companies, including Aetna\(^{(41)}\) and Blue Cross of California\(^{(42)}\), stated in their policy that TRT is considered investigational/not medically necessary. As such, these companies do not provide reimbursement for TRT.

**The Hearing Loss Department Tinnitus Project Report.**

In April 2003, the EBPG received a report on WCB Tinnitus Retraining Therapy prepared by the Hearing Loss Department (Appendix 2). Since July 2000, the WCB of BC has been providing TRT for injured workers with severe tinnitus. In BC, there are four service providers that were formally trained in TRT and have been authorized to treat WCB tinnitus patients (2 in Vancouver, 1 in Kelowna and 1 in Victoria).

Since July 2000 to 2002, 33 injured workers with tinnitus have been treated with TRT (as of March 2003, 14 more clients were waiting for approval for TRT). In the report, the cost and cost control measurements in place regarding TRT treatment was presented, in different formats. The WCB audiologists make candidacy recommendations for TRT referral or not. However, it was not reported the criteria being used for such referrals. The costs presented were the direct cost of
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TRT treatment only (i.e. the cost of counseling and devices used). However, these are not the only cost incurred by the WCB of BC. Further, it was noted there was a large variation in terms of cost of counseling and devices between the four approved TRT providers.

It should be commended that some providers have employed literature validated and reported outcome measurement tools such as the Tinnitus Handicap Inventory. However, the application of such validated outcome measurement tools appears inconsistent both within and between providers.

As of July 2002, 6/32 (18.75%) TRT patients have been discharged from the program, two (33.3%) 'successfully' completed the program and four (66.7%) were discharged due to lack of progress. The success cases showed 30% - 62% improvement in their, presumably, THI score. The authors of this report also mention the influence of pension benefits and litigation in the patient's THI scores across time. With regard to 'success' rate, it appears the WCB patients demonstrate lower rates than what is reported in the literature (between 50% - 80% in case series and the only RCT available). It is, however, important to note the low number of patients treated to date.

Recognizing the lack of convincing evidence from the literature on the efficacy of TRT in treating patients with tinnitus, and being aware of the varying components within each providers 'treatment regime' (including inadequate or a lack of appropriate outcome measurement tools), it is recommended that a more formal 'study' be put in place. While the specifics of such a study will need to be debated, one would also want to ensure that the 'providers' do indeed deliver similar, measurable treatments and that all outcome measurement tools are validated and used consistently.

Summary and Recommendations.

- Tinnitus is a phantom auditory perception which can be potentially debilitating. It is a common otologic symptom and yet still poorly understood. At present the underlining pathophysiology of tinnitus remains unclear.
- Tinnitus presents an enormous challenge for clinicians to treat. Various ways of treating tinnitus have been tried, none of them providing a cure. Some of these treatments, such as cognitive-behavioral therapy and tinnitus masking, may provide relief of the symptoms. However, the results of these treatments are still inconclusive due to the quality of published research on the subjects (Evidence level 1).
- Tinnitus Retraining Therapy was developed by Jastreboff and Hazell in early 1990s based on the neurophysiological model of tinnitus developed by Jastreboff in late 1980s. Currently, there are many centres in the world claiming to treat tinnitus patients according to the TRT method developed by Jastreboff and Hazell. However, based on the published literature, it seems that there are significant variations in how the Jastreboff and Hazell model is applied across these centres.
Most of published literature on the effectiveness of TRT would be classified as case series/case reports (Evidence level 4). The authors of these case series claimed a success rate of between 50% - 80%. From a critical appraisal standpoint the evidence provided from this research is inconclusive due to the unavailability of controls, unclear patient selection criteria, the variability of TRT methods being implemented and the variability in the criteria of treatment outcomes being employed.

The only available randomized controlled trial (Evidence level 1) on the effectiveness of TRT has been conducted and presented by researchers at the National Center for Rehabilitative Auditory Research, the Departments of Veterans Affairs, Portland, OR (the full article is in preparation for submission). At 18 months, 87% of patients in TRT programs had significant improvement compared to 58% among those using tinnitus masking therapy. However, caution has been noted by the researchers in interpreting the outcomes of this research due to the fact that this is the first and only RCT study and has not been replicated by others. It should be noted that the US Department of Veterans Affairs serves a distinctive population, therefore, the generalizability of this research and its implications to the WCB of BC injured workers population needs to be examined further.

It is suggested that:
- The Hearing Loss Department together with the EBPG conduct a formal study on the effectiveness of TRT and other treatment modalities being offered to treat subjective chronic tinnitus.
- In the case that a formal evaluation can not be undertaken, it is recommended that the WCB:
  - undertake a more in-depth and inclusive cost analysis on TRT from the WCB of BC perspective
  - investigate the cause of variation in the services being provided by the four different providers
  - should ensure that validated outcome measurement tools, such as the Tinnitus Handicap Inventory, should be chosen and applied toward every TRT patients in order to provide analyzable data from all providers
  - investigate why, to date, the WCB of BC successful outcome rates are lower than that reported in the literature
## Table 2. Summary of the available published research (case series, level 4 evidence) on TRT

<table>
<thead>
<tr>
<th>Ref*</th>
<th>No. of patients</th>
<th>Intervention</th>
<th>Outcome measures</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
</table>
| 23   | - > 100 subjects out of > 500 patients  
- inclusion criteria must either under treatment for ≥ 6 months or that ≥ 6 months has passed since initial evaluation & consultation  
± 40% of patients had an element of hyperacusis | - TRT as described by Jastreboff  
- 63% received noise generator, 16% had hearing aids and 21% received counseling alone | Questionnaire on tinnitus habituation, effect of tinnitus on patient’s life, level of tinnitus induced annoyance | Significant improvement:  
- 83% among noise generator group  
- 18% among counseling alone  
- 70% among hearing aids group | - no information on non-selected patients nor patients who did not finish the study  
- unclear description and non-validated outcome measurement tool  
- no clear definition of 'significant' improvement  
- unclear follow-up period |
| 24   | - abstract only (German study)  
- did not specify number of patients  
- 3 years recruitment  
- 1 year follow-up reported | - partial vs. complete masking (did not specify further)  
- partial masking is being treated as comparable to TRT | - Goebel & Hiller modified Hallam's Tinnitus Questionnaire | After 1 year treatment:  
- 20% - 30% tinnitus remission  
- 50% - 60% significant reduction | - somewhat modified from the original, described TRT as consisting of 4 strategies  
- no information on number of patient nor patient selection criteria  
- no clear definition on 'significant reduction' |
Table 2. Summary of the available published research (case series, level 4 evidence) on TRT (continued)

<table>
<thead>
<tr>
<th>Ref*</th>
<th>No. of patients</th>
<th>Intervention</th>
<th>Outcome measures</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
</table>
| 25   | - all type of patient category in TRT (as described in Table 1)  
- median first-last visit 20.7 months (mean 27.7 months)  
- 483 patients were treated, 224 (46.4%) received full TRT (number of patients at the last visit who had outcome measurement reported) | - TRT as described by Jastreboff and Hazell (Table 1) | - percentage awareness of tinnitus over the previous week during waking hours  
- percentage of the time it causes distress / annoyance  
- no. of life factors affected, incl. concentration, quiet recreational activities, sleep, work, social, sport or family activities.  
- Jastreboff's 40% rule for criteria of treatment success. Incl. 40% improvement in annoyance and awareness OR 40% improvement in annoyance or awareness + improvement/facilitation of one life factor | - 83.7% successful treatment at the last visit | - no selection criteria  
- non-validated outcome measurement  
- possible selection bias due to large percentage of patients not having outcome measurement reported |
| 26   | - 'almost 1000' patients treated with TRT  
- treatment duration 18-24 months  
- no of patients completed treatment, drop outs and those who provided outcome measurements are not stated | - TRT based on neurophysiological model  
- no clear description of treatment method | - it is not clear what is being used to measure 'improvement of tinnitus' or 'liberation of tinnitus' | - 80% of patients who completed therapy reported significant improvement or liberation of tinnitus | - patient selection criteria, duration of follow-up and criteria for treatment success are not stated  
- non-validated outcome measurement tool |

* reference number.
Table 2. Summary of the available published research (case series, level 4 evidence) on TRT (continued)

<table>
<thead>
<tr>
<th>Ref*</th>
<th>No. of patients</th>
<th>Intervention</th>
<th>Outcome measures</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>27</td>
<td>- the program does not participate with insurance company, thus patients have to pay themselves - 152 consecutive patients treated at the University of Maryland Tinnitus Center for at least 6 months - 129 (84.9%) received directive counseling and instrumentation - did not specify duration of treatment, study period, nor total no. of patient enrolled</td>
<td>- full TRT treatment as described by Jastreboff and Jastreboff (19)</td>
<td>- 3 parameters measured i.e. is the patient performing activities that were prevented or interfered previously, is there a change in the level of annoyance of tinnitus when it is perceived and is there a change in the % of time when patient is aware of the tinnitus. - definition of treatment success: positive change of at least 20% in at least 2 of the above parameters</td>
<td>- 81.4% (105 patients) of those received directive counseling and instrumentation showed significant improvement - did not report those who presumably only received directive counselling</td>
<td>- unclear patient selection criteria for TRT and study participation - non-validated outcome measurement tool</td>
</tr>
</tbody>
</table>

* reference number.
Table 2. Summary of the available published research (case series, level 4 evidence) on TRT (continued)

<table>
<thead>
<tr>
<th>Ref*</th>
<th>No. of patients</th>
<th>Intervention</th>
<th>Outcome measures</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
</table>
| 28   | - this is an extension/update of the University of Maryland study (22)  
- 263 patients were able to be contacted; 90.1% received directive counseling and TRT; 9.9% received only 1 time counseling and no instrument and was considered do not have had TRT  
- did not specify total number of patients at baseline  
- did not report those unable to be contacted  
- did not specify duration of follow-up | - full TRT treatment as described by Jastreboff and Jastreboff (19) | Significant improvement is defined as:  
- at least 1 activity previously prevented/interfered with is no longer affected or all activities who improvement  
- tinnitus awareness, the impact of tinnitus on life and tinnitus annoyance is decreased by at least 20%  
- evaluation was performed after at least 6 months of treatment and is repeated at least once with the last assessment performed not later than 3 years after initiation of treatment; and  
- an improvement in > 1 category. If there is improvement only in 1 category, then the patient is classified as showing no improvement | - Of 263 patients, 75% improved significantly as defined in the outcome criteria.  
- of 237 patients who also received instruments, 80% reported significant improvement as defined  
- 163 patients who also had hyperacusis showed 'higher rate' of improvement | - unclear patient selection criteria for TRT treatment  
- non-validated outcome measurement  
- did not take into account missing patients  
- overlap with Reference no. 27. |
| 30   | - 108 out of 516 patients  
- all 108 had been treated for about 12 months  
- patients consisted of 38 category 0, 30 category 1 and 40 category 2 (patient category as described by Jastreboff and Jastreboff (19)) | - full TRT treatment as described by Jastreboff and Jastreboff (19) | Same as Reference no. 29 | - Overall the average significant improvement across different patient categories was 80.6%  
- significant improvement was observed on 78.9% of category 0 patient; 73% of category 1 patient and 87.5% of category 2 patient | - overlap with Reference no. 29  
- unclear patient selection criteria for TRT treatment  
- non-study participation  
- non-validated outcome measurement |

* reference number.
Table 2. Summary of the available published research (case series, level 4 evidence) on TRT (continued)

<table>
<thead>
<tr>
<th>Ref*</th>
<th>No. of patients</th>
<th>Intervention</th>
<th>Outcome measures</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
</table>
| 29   | - 100 out of 516 patients registered at the clinic  
- 100 consist of 20 on each patient category as described by Jastreboff and Jastreboff (19)  
- patient treated for at least 10 months and no longer than 1 year | - full TRT treatment as described by Jastreboff and Jastreboff (19) | - Significant improvement is defined as the decrease of at least 3 of the parameters by a minimum of 20% and the liberation of at least 1 of the everyday life activities previously impaired by tinnitus &/or hyperacusis  
- parameters include the impact of tinnitus and hyperacusis on various everyday life activities; % of time of awake during which they are aware of tinnitus;  
degree of annoyance evaluated by the patient on the scale from 0 - 10; the impact of tinnitus and or hyperacusis on the life of the patient on the scale from 0 - 10; the intensity of tinnitus on the scale from 0 - 10; intensification of tinnitus after exposure to loud sounds of long duration | - Overall the average significant improvement across different patient categories was 71%  
- significant improvement was observed on 90% of category 0 patient; 80% of category 1 patient; 70% of category 2 patient; 55% of category 3 patient and 60% of category 4 patient. | - unclear patient selection criteria for TRT treatment nor study participation  
- non-validated outcome measurement |
| 31   | - abstract only (German study)  
- 1841 patients, study period 1994-2000  
- treatment lasted 5-6 weeks | - retraining and habituation program with addition of intensive psychotherapeutic evaluation and stabilization, and relaxation technique | - data was collected 6 months post-treatment  
- Goebel and Hiller's German translation of Hallam Tinnitus Questionnaire (TQ) | - 90% showed, on average 13 points improvement in the TQ right after therapy.  
-did not report outcome at 6 months follow-up | - did not specify total number of tinnitus patients seen during study period  
- did not specify criteria of patient selection into treatment nor selection into study |

* reference number.
Table 2. Summary of the available published research (case series, level 4 evidence) on TRT (continued)

<table>
<thead>
<tr>
<th>Ref*</th>
<th>No. of patients</th>
<th>Intervention</th>
<th>Outcome measures</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
</table>
| 32   | - abstract only (Polish study)  
- 150 patients were admitted to the Tinnitus Center in 2001, complete data were collected from 80 patients. | - TRT following Jastreboff | - not specified/reported | - the application of hearing aids bring immediate improvement in patient's self assessment of hearing & better tolerance towards tinnitus  
- all day wear of noise generator increased tolerance toward tinnitus  
- the efficacy of TRT depended on providing detailed information on the causes and mechanism of tinnitus | - this study did not report data on no. of significant improvement, quality of life nor other measurements  
- did not specify criteria of patient selection into treatment nor selection into study |
| 33   | - abstract only (Chinese study)  
- 225 patients → 117 were given TRT + drugs (TRT group) and 108 were given tinnitus masking + drugs (control group)  
- study period and treatment duration wasn't specified | - TRT which consisted of 4 strategies: tinnitus masking with low level & broadband noise; deep relaxation of the whole body; diversion of the attention to other things; psychological counseling & therapy.  
- participants were also given vasodilators, neurotrophic and sedative of similar dose and duration between the 2 treatment groups | - evaluation at 2, 6 and 12 months after the beginning of treatment  
- evaluation on whether the tinnitus was attenuated or disappear; whether patient's emotion, sleep and work were disturbed by tinnitus  
- no criteria for treatment success ('relief rate') | - the relief rate was 17%, 82% and 88% in the TRT group compared to 3%, 27% and 42% in the control group at 2, 6, and 12 months, respectively | - this was described as a controlled trial  
- the TRT being employed was not 'original' Jastreboff TRT  
- the use of sedative was against TRT theory  
- did not specify total number of tinnitus patients seen during study period  
- did not specify criteria of patient selection into treatment nor selection into study nor selection into treatment groups |

* reference number.
Table 2. Summary of the available published research (case series, level 4 evidence) on TRT (continued)

<table>
<thead>
<tr>
<th>Ref*</th>
<th>No. of patients</th>
<th>Intervention</th>
<th>Outcome measures</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
</table>
| 34   | - 32 patients attending the University of Maryland Tinnitus Center between October 1999 and January 2001 | - full TRT treatment as described by Jastreboff et al\(^{(23)}\) (same with Jastreboff and Jastreboff \(^{(19)}\)) | - the main purpose of this study is to validate Tinnitus Handicap Inventory (THI) measurement tool  
- THI consists of 3 domains i.e. emotional, functional and catastrophic  
- THI was administered at the initial visit and 6 months following treatment | - at 6 months following treatment, the total score, emotional, functional or catastrophic scores of the THI was about half their initial scores. | - did not specify total number of tinnitus patients seen during study period  
- did not specify criteria of patient selection into treatment nor selection into study |

* reference number.
References.


Other literature of interest.

   This article provides a non-systematic review on alternative medicine that is being used in the field of ENT medicine (including tinnitus). With regard to tinnitus, the article pointed out the effectiveness of ginkgo in treating tinnitus symptoms. The article also highlighted the evidence on the variation in the content of active ingredients in the commercially available supplements incl. ginkgo. However, a more scientifically rigorous review on the effectiveness of ginkgo in treating tinnitus concluded that the effectiveness of ginkgo in treating tinnitus is inconclusive due to the quality of published research on the subject.

   This is a systematic review on the effectiveness of ginkgo biloba for tinnitus. The authors concluded that overall the results of 5 randomized controlled trials with 621 participants included in the review were favourable to ginkgo as a treatment for tinnitus. However a firm conclusion about its efficacy was not possible due to the low quality of the published randomized controlled trials on the subject.

   This is a methodologically rigorous systematic review on the efficacy of acupuncture in treating chronic subjective tinnitus. There were 6 randomized controlled trials on 132 participants included in this review. Two un-blinded studies showed positive results, while four blinded studies showed no significant effect of acupuncture. The authors concluded that there was a strong placebo effect of acupuncture. As such, acupuncture has not been demonstrated to be efficacious as a treatment for tinnitus based on the evidence of rigorous randomized controlled trials.

   This is an article written by Jonathan Hazell, co-founder of TRT, in October 2002. The article provides a theoretical neurophysiological background of tinnitus and how TRT fits in. Interestingly, the article states that at present TRT is available in relatively few centres. It was estimated that in 2002, 800 professionals had attended TRT training courses around the world.

   This is one of the early papers published by the co-founder of TRT. This paper provides background on the neurophysiological aspect of tinnitus and how TRT fits in. This paper also describes a confusing aspect of TRT, namely the 'directive counselling'. The authors claimed that cognitive
therapy was sufficient alone in about 15% of cases. Directive counseling is claimed by the authors to be the most important part of TRT i.e. in the development of habituation toward tinnitus. Directive counseling itself can be argued as a 'rudimentary' form of cognitive therapy.

   Even though the title of the article is TRT in practice, it still does not provide a published protocol on TRT, however this article provides an outline of TRT according to Jastreboff and Hazell.

   This is the most recent single blinded small randomized controlled trial (n=37) using antidepressants in treating chronic subjective tinnitus. Despite the finding on the efficacy of amitriptyline over placebo in treating chronic tinnitus, the statistical analysis failed to take into account other factors that may affect the outcome of treatment. As such, the study does not provide conclusive evidence on the efficacy of amitriptyline in treating chronic tinnitus.

   It has been postulated that chronic subjective tinnitus suffers from a lack of zinc. This is the most recent small (n=41) non-blinded randomized controlled trial on the efficacy of zinc in treating chronic subjective tinnitus. Despite the finding on the efficacy of zinc over placebo in treating chronic tinnitus, the statistical analysis failed to take into account other factors that may affect the outcome of treatment. As such, the study does not provide conclusive evidence on the efficacy of zinc in treating chronic tinnitus.

   In an attempt to standardize the interview (data collection) process during TRT and in conjunction with research on the effectiveness of TRT that is being done at the Department of Veterans Affairs in Portland, Henry et al. developed these questionnaires that can be used either for research or clinical practice.

These are series of discussion on the efficacy/effectiveness of treatment on tinnitus. This discussion provides information on the understanding and
acceptance of evidence based medicine in the area of otology and neurotology.


There were 18 primary studies (RCTs, pre-post treatment designs and follow-up studies) included in this meta-analysis. The primary studies included cognitive/cognitive-behavioural therapy, relaxation, hypnosis, biofeedback, educational sessions and problem-solving. The authors found strong to moderate effects on tinnitus annoyance (with controlled trials having effect size almost double of pre-post or follow-up study design types). Low effect size was observed on the negative affect and sleep problems due to tinnitus. The authors concluded that psychological treatment was effective for tinnitus. However, the results of this study should be interpreted with caution due to the unavailability of standardized treatment outcome measurement in tinnitus, the grouping together of various psychological treatment method and the quality of the primary studies.


This book, written by the developers of TRT, will be published in early 2004. It is claimed to provide details on the essentials of TRT and a review of the literature to justify their claims together with a critique of other current therapeutic practices for tinnitus.
Appendix 1.

Workers' Compensation Board of BC - Evidence-based Practice group. Grades of quality of evidence *(adapted from 1,2,3,4)*.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Evidence from at least 1 properly randomized controlled trial (RCT) or systematic reviews of RCTs.</td>
</tr>
<tr>
<td>2</td>
<td>Evidence from well-designed controlled trials without randomization or systematic reviews of observational studies.</td>
</tr>
<tr>
<td>3</td>
<td>Evidence from well-designed cohort or case-control analytic studies, preferably from more than 1 centre or research group.</td>
</tr>
<tr>
<td>4</td>
<td>Evidence from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments could also be included here.</td>
</tr>
<tr>
<td>5</td>
<td>Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.</td>
</tr>
</tbody>
</table>

Reference.
Appendix 2.


BACKGROUND
The WCB Hearing Loss Department/Hearing Loss Claims initiated a Tinnitus Project circa July 2000. Under this project, clients with severe tinnitus accepted under a WCB claim have been approved for Tinnitus Retraining Therapy (TRT) under the following guidelines:

- Audiologists in WCB Hearing Loss Department make recommendations to claims about suitability of individual clients. Referrals to the audiologist have come from the client, claims officer, clinic, and doctor.
- Four service providers formally trained in TRT were authorized:
  - Glynnis Tidball, St. Paul’s Hospital Tinnitus Clinic (SPH); Vancouver
  - Carol Lau, Vancouver Tinnitus Centre (VTC); Vancouver
  - Jason Schmedge, Expert Hearing Solutions (Expert); Kelowna
  - Sue Schlatter, Island Hearing Services (IHS); Victoria

  (Note: Sue Schlatter no longer works in B.C.; therefore, there is currently no authorized service provider on Vancouver Island.)
- We have actively sought TRT providers in Prince George and other “unserved” areas of BC to no avail. 1 client is currently seen outside the province (included in report below) with 2 out of province referrals pending.

- Detailed written reports were required after the initial consultation and at appropriate intervals during treatment. Reports were to include:
  - Evaluation results
  - Progress/outcome measures
  - Recommendations

- Services and devices were to be billed under a WCB fee schedule for all tinnitus clients (XH and non-XH).
- Counselling fees were pre-authorized to an annual maximum of 8 hours ($960).

The following report provides an informal analysis of the WCB Tinnitus Retraining Therapy Program, including related costs. Recommendations for the TRT program are included.
CLIENT INFORMATION (2000-2002)

Since approx. July 2000 to 2002, 33 clients have participated in TRT. Files were unavailable for 1 client (at Review Board); therefore, data for 32 clients was reviewed.

<table>
<thead>
<tr>
<th>Year</th>
<th>XH</th>
<th>Non-XH</th>
<th>All claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000  (6 months)</td>
<td>2</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>2001</td>
<td>9</td>
<td>2</td>
<td>11</td>
</tr>
<tr>
<td>2002</td>
<td>6</td>
<td>7</td>
<td>13</td>
</tr>
<tr>
<td>Total</td>
<td>17</td>
<td>15</td>
<td>32</td>
</tr>
</tbody>
</table>

TRT pending as of March 2003

<table>
<thead>
<tr>
<th>Year</th>
<th>XH</th>
<th>Non-XH</th>
<th>All claims</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7</td>
<td>7</td>
<td>14</td>
</tr>
</tbody>
</table>

Comments: Table 1
- There are a small number of clients with tinnitus severe enough to be TRT candidates.
- TRT seems to be relatively evenly balanced between XH and non-XH claims.
- The number of clients entering TRT appears to be stable to slightly increasing. This is contrary to anecdotal reports that the numbers are “skyrocketing”.
- The number of non-XH clients referred suggests an awareness about TRT in WCB Claims Departments outside Hearing Loss Claims.

TRT PROGRAM COSTS

TRT uses a standardized treatment protocol which includes counselling sessions and environmental sound enrichment. As part of the environmental sound enrichment, TRT related devices may be required. These typically are either bedside sound generators (BSG) for nighttime use or ear-level devices (hearing aids, sound generators, or tinnitus instruments which are combination hearing aids + sound generator) for general use.

Cost control measures currently in place:
- Hearing Loss Department audiologists vet the claim file and make candidacy recommendations to claims prior to claims making a TRT referral.
- TRT services and devices are billed under a WCB fee schedule, with any ear-level devices billed as per the WCB Hearing Aid Program contract.
- Invoices are reviewed by the Hearing Aid Clerk. Any billing error or discrepancies are brought to an audiologist for review.
- Replacement requests (devices <5 years old) require pre-authorization as per the WCB Hearing Aid Program.
Tinnitus Retraining Therapy

- Tinnitus instruments (sound generation + amplification) which work effectively are relatively new on the market as of 2002. These are high cost devices with invoice cost significantly above the maximum invoice costs per aid allowed under the WCB Hearing Aid Program ($1,000 - $1,300). Since these devices may be essential for TRT success, they are approved on request on a case-by-case basis by audiologists after file review and discussion with services provider re potential alternatives. Typically these clients have already tried hearing aids or sound generators unsuccessfully.
- Whenever possible, clients are referred to the service provider closest to their geographical location.
- Since there are a limited number of service providers formally trained in TRT in limited geographical locations in the province, some travel costs are involved for assessment and treatment depending on where clients live. In order to minimize travel costs, service providers offer ongoing counselling via telephone as appropriate.

**Travel**
- 12 clients (38%) had travel costs (airplane tickets, etc.) in order to attend sessions.
- In addition, the majority of clients would have some related mileage costs.
- Since travel costs often are not specifically related to TRT treatment (clients sometimes seeing other medical practitioners at the same time), they were not included in the figures below. However, travel costs may be substantial for a few clients.

<table>
<thead>
<tr>
<th>Table 2: TRT Total Program Costs 2000 – 2002 (n=32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Counselling</td>
</tr>
<tr>
<td>Devices</td>
</tr>
<tr>
<td>Total</td>
</tr>
<tr>
<td>Average/client</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 3: Costs per Year of Treatment ($)</th>
</tr>
</thead>
</table>
| Year 1 (n=32) | Year 2 (n=18) | Year 3 (n=8) | *Year 4 (n=2)
| Counselling | $9,647       | $4,331       | $1,050     | $330       |
| Devices     | $34,290      | $7,908       | $3,793     | $0         |
| Total       | $43,937      | $12,239      | $4,843     | $330       |
| Average/client | $1,373      | $680         | $605       | $165       |

*2003 invoice costs for clients in program since 2000. To date treatment duration for these clients = 3.6 and 3.10 years.*
Table 4: Total 2002 TRT Costs (n=31*)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Counselling</td>
<td>$6,960</td>
</tr>
<tr>
<td>Devices</td>
<td>$20,618</td>
</tr>
<tr>
<td>Total:</td>
<td>$27,578</td>
</tr>
<tr>
<td>Average/client</td>
<td>$890</td>
</tr>
</tbody>
</table>

*1 client discharged before 2002

Table 5: Average 2002 TRT Costs per Client ($)

<table>
<thead>
<tr>
<th></th>
<th>All</th>
<th>SPH</th>
<th>VTC</th>
<th>Expert</th>
<th>IHS-Vict</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td># of Clients</td>
<td>n=31*</td>
<td>n=9</td>
<td>n=12</td>
<td>n=7</td>
<td>n=3</td>
<td>n=2</td>
</tr>
<tr>
<td>Counselling</td>
<td>$224</td>
<td>$317</td>
<td>$238</td>
<td>$120</td>
<td>$40</td>
<td>$330</td>
</tr>
<tr>
<td>Devices**</td>
<td>$665</td>
<td>$333***</td>
<td>$571</td>
<td>$1030</td>
<td>$859</td>
<td>$493</td>
</tr>
<tr>
<td>Average</td>
<td>$890</td>
<td>$650</td>
<td>$809</td>
<td>$1150</td>
<td>$899</td>
<td>$823</td>
</tr>
</tbody>
</table>

* Total n is not equal to sum of clinic n’s as 2 clients have been seen at >1 clinic
**“Devices” listed above includes the device and any associated fitting fees.
***SPH does not fit ear level devices; SPH devices total includes costs for devices fit by other clinics in cooperation with SPH recommendations.

Comments: Tables 2 – 5

- In 2000 and 2001, the Tinnitus Project was in its initial stages. It was felt that for 2002, annual cost information would be representative as a reference for future comparison. Therefore this year is analyzed above in more detail.
- The scientific literature on TRT suggests that TRT duration is typically 1-2 years. Devices are typically fit early in the treatment program. As a result, the costs are much higher in the earlier years of treatment.
- Most clients’ treatment has been within 1-2 years duration.
- All XH clients have noise-induced hearing loss. Many of the non-XH claims also have trauma related hearing loss. Therefore, in most cases devices (e.g. hearing aids) would be provided under their claim regardless of whether they were in TRT.
- Only 2 clients required replacement of initial devices with more appropriate tinnitus instruments once TRT commenced.
- TRT has been conducted by various service providers, 4 authorized in B.C. (SPH, VTC, Expert, IHS-Victoria). TRT has occasionally been provided by other service providers. This typically happens when non-XH clients are referred for service by claims staff unaware of the TRT program. Some clients also receive service out of province depending on their work/home location. Since all invoices come through Hearing Loss Claims, we are able to identify and track these clients.
- Average counselling costs per client for 2002 ($224) are well below the annual maximum of $960 (8 sessions pro-rated at $120 per hour) pre-authorized when TRT is approved under a claim.
Under the WCB Hearing Aid Program, an XH claim without tinnitus would receive coverage to a maximum $900 (unilateral) and $1800 (binaural) for a hearing fitting (device and fitting fee). Average TRT device related costs appear to be consistent with this figure. TRT devices do not appear to result in significantly higher costs than devices provided under a hearing loss claim without TRT, except when specialized tinnitus instruments are needed for TRT (n=2). There is no reason to expect tinnitus devices will need more frequent replacement than hearing aids in our regular program.

One service provider (Expert; IHS) appears to have higher device-related costs than average. This suggests more expensive devices are being fit than by other providers.

The limited number of clients makes a detailed statistical analysis difficult.

B.C. hearing aid service providers are aware that all WCB claims (XH and non-XH) must be billed according to the WCB contracted fee schedule. In the past, on the occasional non-XH claims, billings have been submitted which exceed provisions under the WCB hearing aid contract. These invoices have occasionally been paid in the absence of Hearing Loss Department audiologist input. For 2002 under the TRT Program, all invoices have been submitted per WCB fee guidelines.

**PROGRESS/OUTCOME MEASURES 2000 - 2002**

There is no objective method available for measuring tinnitus. Tinnitus severity is based on patient self-report. Tinnitus loudness and pitch matching are sometimes conducted as part of a tinnitus assessment. However, it is well documented in the scientific literature that these are unstable measures which should not be used to confirm tinnitus existence or severity. Instead, other subjective patient-based outcome scales are typically used. The Tinnitus Handicap Inventory (THI) is a well-validated questionnaire which is widely used clinically and in research. Other subjective rating scales are also used. As of late 2002, the THI is included in the WCB Tinnitus Data Sheet completed by clients initiating a tinnitus claim. Therefore, initial THI data should be available for tinnitus clients in future.

<table>
<thead>
<tr>
<th></th>
<th>SPH</th>
<th>VTC</th>
<th>Expert</th>
<th>IHS-Victoria</th>
<th>Other (2 clinics)</th>
</tr>
</thead>
<tbody>
<tr>
<td>THI</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Sometimes</td>
<td>Yes</td>
</tr>
<tr>
<td>Other (e.g. rank/10)</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Sometimes</td>
<td>Yes</td>
</tr>
<tr>
<td>Included in Progress Reports</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Sometimes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Table 7: TRT Program Current Client Status

<table>
<thead>
<tr>
<th></th>
<th>All</th>
<th>XH</th>
<th>Non-XH</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Currently In Therapy</strong></td>
<td>26</td>
<td>11</td>
<td>16</td>
</tr>
<tr>
<td>Good Prognosis (Improving)</td>
<td>4/26</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Limited Prognosis (Not improving)</td>
<td>4/26</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>TRT Discharge: Success</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>TRT Discharge: Lack of Progress</td>
<td>4</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

Table 8: Treatment Outcome Summary

<table>
<thead>
<tr>
<th></th>
<th>Ongoing Therapy (n=26)</th>
<th>Discharged: Success (n=2)</th>
<th>Discharged: Lack of Progress (n=4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Hours of Counselling</td>
<td>3 hours (range=1-11)</td>
<td>7 hours</td>
<td>8 hours</td>
</tr>
<tr>
<td>Average Treatment Duration</td>
<td>16 months (range=3-42)</td>
<td>16 months</td>
<td>19 months</td>
</tr>
<tr>
<td>Average Improvement (THI)*</td>
<td>23% (range = -10-62)</td>
<td>40%</td>
<td>4%</td>
</tr>
<tr>
<td>Average Cost per Client</td>
<td>$1672</td>
<td>$1279</td>
<td>$3919</td>
</tr>
</tbody>
</table>

*A 20% THI improvement is considered significant in the scientific literature.

Table 9: Treatment Outcome versus Claim Type

<table>
<thead>
<tr>
<th></th>
<th>All Clients</th>
<th>XH</th>
<th>Non-XH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Treatment Duration</td>
<td>17 months (range=3-42)</td>
<td>16 months (range=3-35)</td>
<td>18 months (range=4-42)</td>
</tr>
<tr>
<td>Average Improvement (THI)*</td>
<td>20% (range = -10 to 62 )</td>
<td>34% (range=4-60)</td>
<td>11% (range = -10-62)</td>
</tr>
<tr>
<td>Average Cost per Client</td>
<td>$1907</td>
<td>$2113</td>
<td>$1672</td>
</tr>
</tbody>
</table>

*A 20% THI improvement is considered significant in the scientific literature.

Comments: Table 6 - 9

- There is no significant difference in average treatment duration for XH (1 year, 4 months) and non-XH (1 year, 6 months) claims.
- Only 4 out of 6 service providers are consistently including appropriate progress/outcome measures in reports. This will be addressed under recommendations.
- Some service providers sometimes include loudness/pitch matching information; however, this is not an appropriate progress/outcome measure as noted above.
- The overall trend is towards improvement in tinnitus, with significant improvement seen with XH claims.
Tinnitus Retraining Therapy

- The improvement in XH claims is very encouraging as it is well documented in the scientific literature that patients with a compensatory interest in their tinnitus (e.g. WCB claim) do not make the same gains as other patients. Service providers also note that there may be a discrepancy in the level of commitment or motivation of clients who receive TRT without charge (as WCB clients do) compared to those who pay for the service themselves.

- Non-XH claims (e.g. primarily head injury and other serious trauma) show much less improvement than noise-induced hearing loss related tinnitus. This could be related to brain injury cognitive and memory problems (e.g. short term memory loss) which can impact treatment efficacy. It could also be related to psychological disorders (e.g. anxiety/depression) arising from the trauma claim. Patients with psychological disorders do not make the same gains as other patients. Recent research suggests that patients with post traumatic stress disorder, sometimes seen with head injury clients, have tinnitus which is more severe and difficult to treat.

- Clients with limited prognosis = 4/27 (15%). We are unaware of comparative data in the literature to determine if this is consistent with similar client groups.

- Limited prognosis clients typically have issues related to financial or other gains which would impede TRT progress. (Note: when this is determined to be a significant factor at the initial TRT evaluation, the external service providers advise that the client is a poor candidate and TRT may not be recommended or approved.)

- In 3 of the limited prognosis cases, the clients are exploring claims related litigation (e.g. appeal process), tinnitus pension, and or tinnitus related wage loss/job change. Interestingly, 2 of these clients initially showed significant improvement in THI (28% and 36%). Once the compensation issues arose, their THI scores deteriorated (over 20%) to worse than their initial pre-treatment THI levels.

- In 1 case of limited prognosis, the client has untreated psychological problems which are impeding progress. A psychiatric referral has been recommended by the TRT provider.

- Service providers appear to be appropriately suspending or terminating treatment for clients when necessary.

- The “success” cases (significantly improved) showed 30 to 62% improvements. As reported by one service provider “the client and their family have repeatedly expressed their gratitude to WCB and the clinic for the assistance”.

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RECOMMENDATIONS

1. Continue the TRT program, with attention to several points as listed below.
2. Maintain current cost control measures including review of invoices.
3. Monitor potential cost differences between different service providers. Service providers which appear to have higher average costs can be further scrutinized at the discretion of the Hearing Loss Department audiologists (Action: audiologists on ongoing basis).
4. Continue to authorize tinnitus instruments on an individual case-by-case basis as appropriate, when these items are beyond the regular Hearing Aid Program scheduled amounts.
5. Maintain current referral process for XH and non-XH clients. Although TRT treatment for non-XH claims appears to be less successful overall, there is no way to predict which clients will benefit. It is recommended the current referral process should be maintained with XH and non-XH clients being considered as TRT candidates.
6. Some clients undergoing TRT have related psychological disorders. It would be most useful to have a designated WCB psychologist interested in tinnitus to consult on claims where psychological issues are affecting treatment. These claims are typically flagged by the service provider. The Audiology Unit and Hearing Loss Claims are unable to provide expertise in this area (Action: Frankie Lafayette).
7. Add new clinics to our list as new clinics with TRT-trained service providers are able to offer TRT. More accessibility throughout B.C. (e.g. Vancouver Island and Prince George region) would be very helpful for our clients. At present, we are aware of only 2 additional clinics, both in the Lower Mainland. (Action: audiologists on ongoing basis).
8. In reviewing both paper files and e-files for this report, it is apparent that in several cases, invoices have been scanned or placed onto files without being paid. Recommend service providers send all reports/invoices directly to “Tinnitus Project, Audiology Unit” so that reports/invoices can be dealt with appropriately and client status monitored on an ongoing basis. (Action: audiologists to follow-up with service providers).
9. Require appropriate standardized progress/outcome measures from all TRT providers (THI). (Action: service providers to include in reports on a regular basis).
10. Seek clarification from our providers on treatment duration and on criteria for treatment termination. Over time people in TRT may need only limited support in the form of counselling sessions (or check-ups) every 6-12 months. We need to know how long such limited support is likely to continue. (Action: audiologists to obtain input from service providers).
11. Seek TRT provider comments on this report and suggestions for the program (Action: audiologists to obtain input from service providers).
12. Develop a simple TRT Program client survey for input on client degree of satisfaction with this program (Action: audiologists with input from TRT providers).
If there are any questions regarding the contents of this report, please contact: