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## Tackling Tinnitus – The Time Is Now

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Tinnitus is a non-curable, invisible and debilitating hearing disorder that can take on many different forms – ringing, hissing, buzzing, and even the sound of crickets. Almost everyone has experienced brief periods of mild tinnitus, but for many, this sound can be permanent. Over 360,000 Canadians report suffering from chronic tinnitus, and almost half of those are severely affected.<sup>1</sup> In the US, over 16 million tinnitus sufferers seek treatment every year.<sup>2</sup> Tinnitus is the number one disability claim for US veterans<sup>3</sup> and has also become the top disability claim for current and former male RCMP members.<sup>4</sup> This persistent sound can have a serious impact on quality of life; leading to sleep deprivation, depression, anxiety, and even suicide. What adds to the challenges faced by tinnitus sufferers is a lack of knowledge, support and options available to them. Unfortunately, there are currently too few health care professionals providing services to tinnitus sufferers who are seeking ways to manage their tinnitus. Unfortunately, the phrase “learn to live with it” is still heard far too often by those that seek help for tinnitus.

Health care professionals who incline to offer patients an option or strategy to deal with tinnitus are confronted with the variability inherent to this disorder.<sup>5</sup> The cause of tinnitus can vary, although people who experience tinnitus have usually first developed hearing loss due to ageing or from exposure to loud noise that caused peripheral auditory damage. In fact, the number of tinnitus sufferers that develop the constant ringing due to hearing loss may be even higher than thought, as some tinnitus sufferers only appear to have *normal* hearing when thresholds at frequencies below 8 kHz are measured. Less frequently, tinnitus may also occur after a head or neck injury, or due to the presence of an acoustic neuroma. Certain medications may also contribute to the development of tinnitus through effects on hair cells in the inner ear or via mechanisms that are not yet well understood.<sup>6</sup> This variety in cause has been the first part of the challenge in developing a “cure” or effective treatment for tinnitus. However, even for the largest group of tinnitus sufferers (those who may develop tinnitus due to hearing damage), effective treatments have been hard to come by.

## Brain Plasticity and Tinnitus

A wealth of research has gone into understanding the mechanisms of tinnitus due to the increased concern in our ageing and noise exposed society through the support of organizations such as the Tinnitus Research Institute, the American Tinnitus Association and even the US Department of Defense. This research has helped us to understand not only why and how this phantom percept can develop, but also sheds light on why it may sound like a hiss for one person and a high pitched tone for another.<sup>7</sup> In addition, neuroscientists have shown connections between the limbic system (where emotions are processed) and the auditory system; it is not uncommon for tinnitus to increase during times of stress or negative emotions.<sup>5</sup> As such, the effective tinnitus treatment strategies should be enjoyable and positive, and should account for the variability in what tinnitus sounds like for each patient.

While there may be a wide range of causes, an important underlying factor for the development of tinnitus is brain plasticity.<sup>5,7</sup> This property allows the brain to change and adapt, and it is essential to how we learn. Unfortunately, in some cases, such as with hearing loss, the auditory part of the brain may be altered as brain plasticity tries to compensate for the abnormal auditory inputs. This response leads to changes in brain activity in the auditory system (e.g., the auditory cortex) that can create a phantom percept: tinnitus. As such, while tinnitus may begin a problem at the auditory periphery, it persists because of changes throughout the auditory system. Treating tinnitus may require addressing both the initiator (e.g., hearing loss) and the driver (changes in the auditory brain).

## Existing Treatment Options for Tinnitus

Some tinnitus sufferers have experienced relief through hearing aids, but studies indicate that such benefits are limited to those with low-frequency tinnitus.<sup>8</sup> For those with a tinnitus pitch above 5–6 kHz or those with a hissing or buzzing tinnitus, the benefits of hearing aids are more limited or even nonexistent. This makes sense from a neuroscience point of view, as the hearing aid will typically not be making up for hearing loss at frequencies above 6–8 kHz; this prevents any possible effects on tinnitus types that are caused by changes to higher frequency regions in the auditory system. While hearing aids are essential to improving the lives of the hearing impaired, they are not typically the best option for tinnitus; especially when used alone.

Tinnitus sufferers have tried many alternative therapies but often to no avail. Some have heard of success stories involving the use of certain vitamins, minerals, herbal preparations, or even a change in diet, but often did not experience personal success in treating tinnitus using such options. Unfortunately, no studies to date have been able to associate such treatments to any real benefits. While much of the existing research have been dedicated to helping us understand tinnitus and its etiological underpinnings, there are currently very few treatments that are clinically validated. Of the few that conducted clinical studies to evaluate the effectiveness, most did not use rigorous clinical methods such as controlling for placebo effects or double-blinding to ensure the integrity of the data and to eliminate any sources of bias. Tinnitus sufferers who access such treatments often do not experience relief from their tinnitus. As a result, tinnitus sufferers often experience confusion, frustration, a loss of hope, and skepticism after having invested time and money on available treatment

options.

Sound therapies are one method that has previously been shown to reduce the severity of tinnitus. While not all sound therapies have gone through rigorous clinical testing, they have far greater traction and adoption in the tinnitus community. There are two types of sound therapy approaches: (1) maskers that are intended to block out the tinnitus and have the patient learn to ignore their tinnitus, and (2) sound therapies that utilize the same brain plasticity that is thought to be causing the tinnitus for the purpose of reducing it. Both approaches can be delivered via electronic devices that can produce sound. There has been an increase in tinnitus maskers that are built into hearing aids. These built-in maskers generate different sounds including white noise and random tones. Unfortunately, due to their design, hearing aids are still limited to providing masking at frequencies below 8 kHz.

## Adopting a Personally Customized Approach to Treat Tinnitus

Due to the large variability in tinnitus, a one-size-fits-all approach (as offered by maskers) will have limited benefits. Indeed, there is evidence that being able to customize a sound therapy (e.g., using the tinnitus pitch or hearing loss profile), will provide greater benefits<sup>7,8</sup> for tinnitus sufferers. Given the evidence supporting this line of thinking and the limitations of existing tinnitus management options, we were driven to develop and rigorously test an enjoyable, personalized sound therapy that has potential to provide lasting relief to tinnitus sufferers.

This tinnitus treatment we developed makes use of software that customizes a music-based therapy for each individual tinnitus sufferer. The software achieves this by incorporating a computational model of the “tinnitus brain.” This model captures changes in the auditory brain which may be causing the tinnitus.<sup>5,7</sup> We do this by taking into account the individual’s audiogram and a pitch match of their tinnitus, which generates a tinnitus profile unique to him or her. The software then uses the model to predict how each music track can be altered spectrally to reduce tinnitus for that specific tinnitus profile. Delivering the treatment using headphones that could produce high frequencies (above 10–12 kHz) was an integral part of treatment effectiveness. With such headphones, the treatment could work by taking advantage of the same kind of brain plasticity that may contribute to the person's tinnitus in the first place without being limited by a lack of high-frequency sounds.<sup>8</sup> By incorporating the latest tinnitus research into our software, we developed a treatment approach that provides greater promise in treating tinnitus than existing treatments with a one-size-fits-all approach.

## Customized Music-based Therapy Reports Relief from Tinnitus in just 3 Months

As an initial test of our treatment, we first conducted a small pilot study to see if there were measurable benefits within 3 to 6 months of using this therapy. While we did not inform participants of whether they would receive a treatment or unaltered music, every participant in fact received a treatment. Participants reported a drop in scores on the Tinnitus Handicap Inventory (THI) within 3 months of using their personalized sound therapy for about 2 hours a day. THI is a psychometrically robust and validated questionnaire that assesses the impact of tinnitus on daily living and the degree of distress suffered by the tinnitus patient. Furthermore, we saw increased benefits after 6 months of treatment use (Figure 1). This data suggested that our treatment may be engaging brain plasticity in a

positive manner, thereby gradually reducing tinnitus over time. Armed with this information, we designed a more rigorous trial that is very uncommon among research in tinnitus therapies.

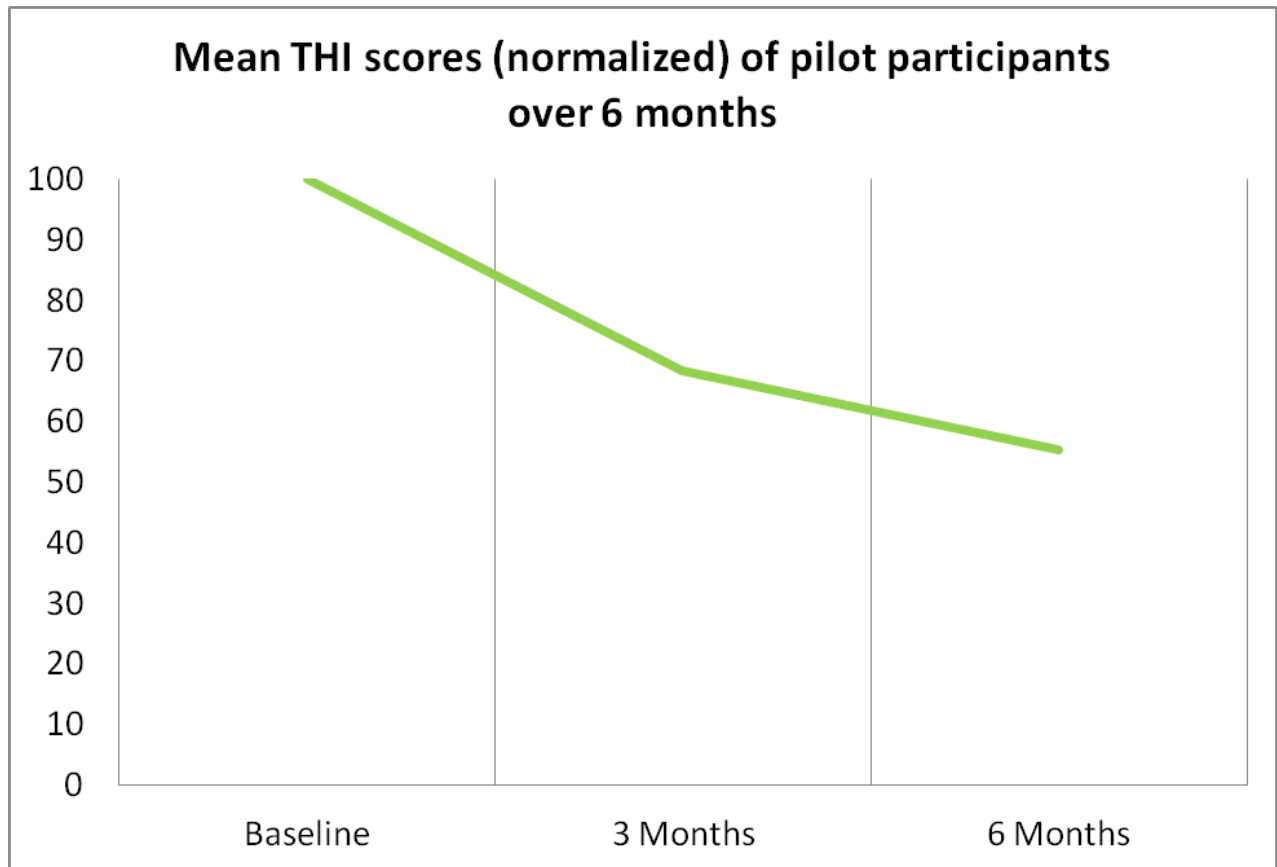


Figure 1. Data shows a drop in THI scores for participants in our pilot study.

## The Rigorous Clinical Trial

We conducted a randomized, double-blind, placebo-controlled trial investigating the effects of the customized music-based sound therapy for reducing tinnitus. Participants ( $N = 50$ ) who suffered from tinnitus were randomly allocated (with 1:1 ratio) to the treatment and placebo groups with assessments at baseline, 3, 6, and 12 months. The primary outcome was the differences in mean scores of the THI compared at four time intervals. Independent and paired samples t-tests were conducted to compare THI scores between and within groups, respectively.

## Recruitment and Randomization

Individuals were recruited from within and around Hamilton, Ontario via online announcements and audiology clinics. Applicants were initially interviewed via telephone to screen for all inclusion and exclusion criteria for the study in order to determine whether they qualified for on-site screening. The on-site screening, and characterization of participants' hearing thresholds and tinnitus profiles were conducted in a lab at McMaster University using a computer-based tinnitus assessment tool. Participants were randomly allocated to the treatment or placebo-control group. The assignment of the treatment or placebo music package was completed by a distributor site independent of the research

study site. Participants and research personnel were blinded to which music package the participants received.

## Clinical Testing and Treatment Design

Once the music package (MP3 player preloaded with assigned music tracks and headphones) was ready, participants were briefed on safe listening levels, and were instructed to complete a weekly log book to record their listening duration and frequency. The algorithms which modified the music provided to participants are built into proprietary software that was developed internally by Sound Options Tinnitus Treatments Inc. The modified and placebo music packages consisted of 4 hours of classical music.

### 3-Month Follow-Up

Participants were contacted to complete questionnaires (including THI) for the three-month assessment. A 30-minute individual phone interview with each participant was also conducted to explore their experiences with using the music package on a daily basis, and to further understand how the music package was affecting their tinnitus. At present, 27 participants have been interviewed to obtain the results presented here.

## Results

Demographic variables (age, sex, type of tinnitus) and baseline THI scores of placebo ( $n = 16$ ) and treatment ( $n = 11$ ) groups did not significantly differ from one another at the start of the study. At 3 months, participants in the treatment group reported significantly lower scores on the THI when compared to the placebo group ( $p < .05$ ). The treatment group also showed an 11-point drop in THI scores when comparing baseline and 3 months ( $p < .05$ ; please see Figure 2). THI scores for the placebo group comparing both time points were non-significant. Past studies have indicated that the minimum change in the THI score to be considered clinically significant is a drop of 6 to 7 points.<sup>9</sup> As such, the results of our clinical study suggest that tinnitus and its related symptoms can produce a clinically significant reduction in tinnitus within the first 3 months using the personalized music-based therapy.

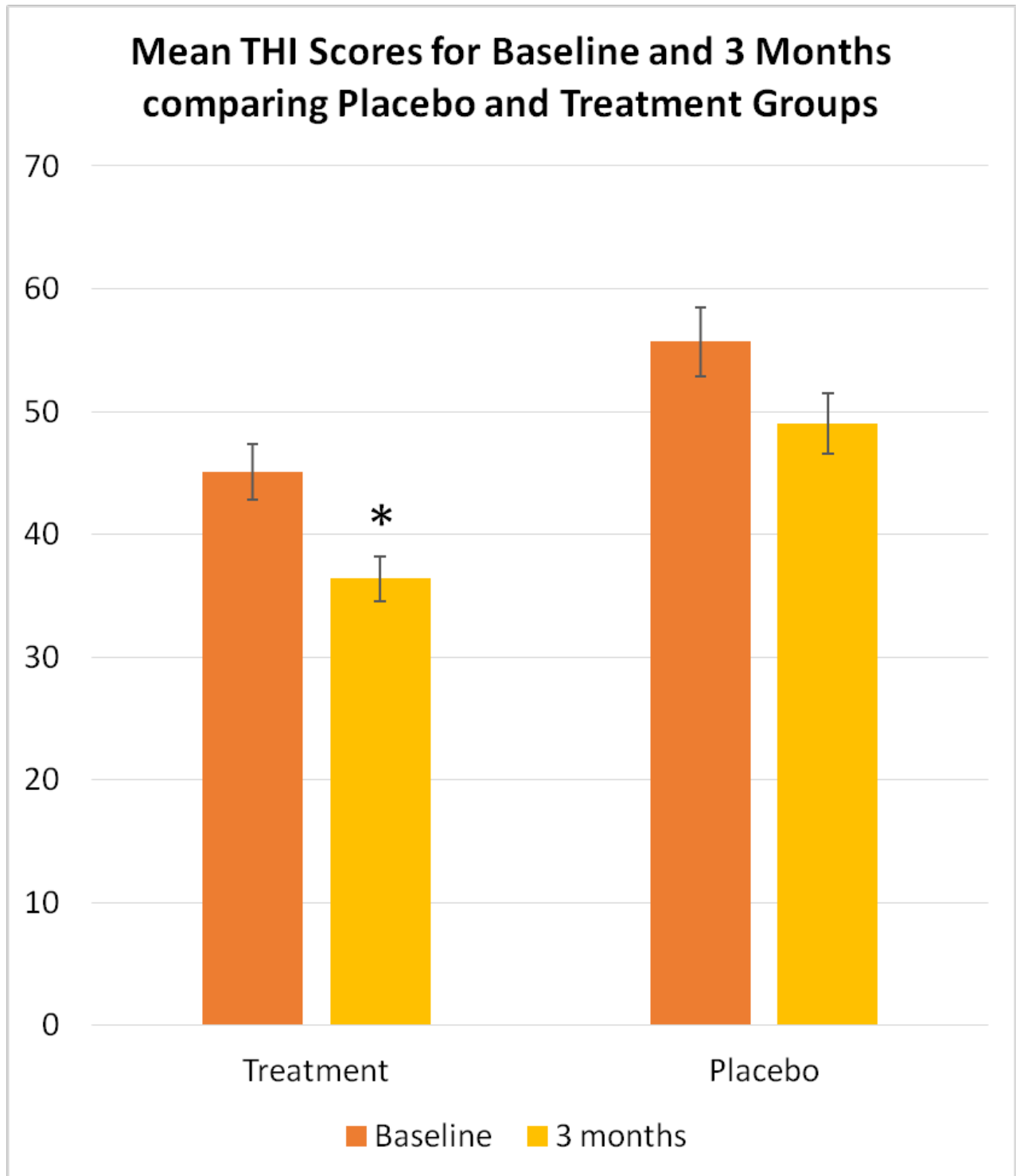


Figure 2. The graph illustrates the differences in mean THI scores at baseline and 3 months, comparing treatment and placebo groups using paired samples *t*-test. Statistically significant differences ( $p < .05$ ) are denoted using asterisk (\*).

### Future Directions

Additional three-month and six-month follow-ups with participants are currently underway. We are thrilled to observe the trends and the statistical findings that will unfold over the course of the study.

## Tackling Tinnitus: The Time Is Now

Tinnitus affects every layer of society, and there has been increasing support for awareness. Recently, musicians who are affected by tinnitus have come together to create awareness for the disorder. Artists including Chris Martin of Coldplay and Black Eyed Peas have created a compilation album to help raise funds towards finding a cure for tinnitus. In the United States, the Department of Defense has invested millions of dollars into investigations of tinnitus sound therapies. In addition, the American Tinnitus Association makes efforts to lobby the US government to provide support for tinnitus sufferers.

In Canada, the level of funding or engagement towards tackling the problem of tinnitus is comparably minimal. But with recent headlines about the effects of tinnitus on those in police forces<sup>2</sup> and frustration among veterans, this may change. Because of the progress made in tinnitus treatment and management research – including work done right here in Canada – the time is right to offer tinnitus sufferers effective options and the support they need. While many with tinnitus are not yet aware that there are ways to reduce or manage the constant ringing, hissing or buzzing in their ears, as more health care professionals make effective options available, word will spread. In time, tinnitus and its impact on quality of life can be reduced.

### About Sound Options Tinnitus Treatments Inc.

Sound Options Tinnitus Treatments Inc. addresses the need for an effective tinnitus treatment by offering a clinically validated, individually customized sound therapy. The sound therapy is based on leading neuroscience and tinnitus research that has been built into our software to produce a treatment that can be conveniently delivered via any music playing device. Sound Options is also heavily invested in community engagement. This includes educating and reaching out to seniors, veteran's groups, and police and firefighter associations, as these segments of our population are most affected by tinnitus. Sound Options is relentless about innovation and we are constantly seeking novel ways to help tinnitus sufferers. Our treatment has been designed with the tinnitus sufferer in mind: it is pleasantly effective, affordable, and individually customized.

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