Article title: Internet-Based Cognitive Behavioural Therapy (ICBT) as an effective treatment alternative to tinnitus management: An Empirical Research

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Preprint statement: This article is a preprint and has not been peer-reviewed, under consideration and submitted to ScienceOpen Preprints for open peer review.

DOI: 10.14293/S2199-1006.1.SOR-.PPOBIPJ.v1

Preprint first posted online: 16 June 2022

Keywords: tinnitus, icbt, cbt, telemedicine, teleaudiology
Internet-Based Cognitive Behavioural Therapy (ICBT) as an effective treatment alternative to tinnitus management- An Empirical Research.

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Abstract:

Introduction- Tinnitus is a type of chronic hearing disorder often described as ringing in the ears. With the global pandemic in 2020, a shift was observed to telemedicine. Cost-effectiveness aside, Internet-based Cognitive Behavioral Therapy (ICBT) has gained popularity as a convenient and accessible alternative to face-to-face treatments. However, its usage has yet to gain traction in Indonesia.

Objectives- To determine the effectiveness of ICBT and its possibility to be used as a feasible audiologist-guided intervention tool. This study is targeted at existing tinnitus patients who have yet to receive any form of intervention previously.

Method- Thirty-six patients were chosen from the existing pool of patients diagnosed with tinnitus by Ear Nose and Throat (ENT) practitioners. Their baseline tinnitus perception and QOL measures were determined using the Tinnitus Reaction Questionnaire (TRQ), the Tinnitus Functional Index (TFI), and the Tinnitus Handicap Inventory (THI). These patients were subjected to ICBT. A post-intervention measurement was taken at the 3-months and 6-months mark respectively.

This Randomized Control Trial (RCT) seeks to determine the effectiveness of ICBT in improving the overall QOL of patients and to find out how effective ICBT is in alleviating tinnitus-associated distresses.

Results & Conclusion- The effectiveness of ICBT was established in this study in alleviating tinnitus-related distress in patients and contributing to overall improvement of patient QOL and other negative tinnitus-related effects. The results were consistent throughout the 6 months of this study. Results suggest that patients experienced greater relief from tinnitus-linked comorbidities and better QOL improvement vis-à-vis the baseline results.

Keywords: tinnitus, icbt, cbt, telemedicine, teleaudiology
Acknowledgements

The author would like to express his gratitude to the parties that make this research possible.

His wife, Cheryl for the support throughout the transitioning journey from a Captain, to a Manager, finding his calling as a clinical audiologist. You have brought out the best in me and I am blessed to have you in my life.

RSUD Raja Ahmad Tabib Hospital, Tanjung Pinang, Indonesia Ear Nose and Throat Department for their guidance and mentorship, Epiphany Hearing and Audiological Consultancy for believing in me and providing me the opportunity to practice and render hearing health screening and early intervention in rural areas of Indonesia. The management team of Epiphany Hearing and Audiological Consultancy for their kind support and entrusting me to roll out the ICBT program.

Special Thanks to

School of Advanced Education, Research and Accreditation (SAERA)’s faculty for their support and high-quality training that has made me the clinician that I am today.

Ad Maiorem Dei Gloriam
Abstract

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<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Introduction</td>
<td>1</td>
</tr>
<tr>
<td>2.0 Literature Review</td>
<td>3</td>
</tr>
<tr>
<td>2.1 How is Tinnitus Developed</td>
<td>3</td>
</tr>
<tr>
<td>2.1.1 Physical Damage</td>
<td>3</td>
</tr>
<tr>
<td>2.1.2 Medication</td>
<td>3</td>
</tr>
<tr>
<td>2.1.3 Meniere's Disease</td>
<td>4</td>
</tr>
<tr>
<td>2.1.4 Eustachian Tube Dysfunction (ETD)</td>
<td>4</td>
</tr>
<tr>
<td>2.1.5 Otosclerosis</td>
<td>4</td>
</tr>
<tr>
<td>2.1.6 Temporomandibular Joint Disorders (TMJ) and Muscle Spasms</td>
<td>4</td>
</tr>
<tr>
<td>2.1.7 Tumors</td>
<td>5</td>
</tr>
<tr>
<td>2.1.8 Blood Vessel Disorders</td>
<td>5</td>
</tr>
<tr>
<td>2.1.9 Noise Exposure</td>
<td>5</td>
</tr>
<tr>
<td>2.2 Tinnitus Comorbidities</td>
<td>6</td>
</tr>
<tr>
<td>2.3 Existing Tinnitus Intervention Methods</td>
<td>6</td>
</tr>
<tr>
<td>2.4 Tinnitus Management</td>
<td>7</td>
</tr>
<tr>
<td>2.4.1 Alternative Medicine and Therapies</td>
<td>7</td>
</tr>
<tr>
<td>2.4.2 Electromagnetic Stimulations</td>
<td>7</td>
</tr>
<tr>
<td>2.4.3 Sound-based Clinical interventions</td>
<td>8</td>
</tr>
<tr>
<td>2.4.4 Neuronomical Tinnitus Treatment (NTT)</td>
<td>9</td>
</tr>
<tr>
<td>2.4.5 Acoustic Coordinated Reset Neuromodulation (CR)</td>
<td>10</td>
</tr>
<tr>
<td>2.4.6 Mindfulness-Based Stress Reduction (MBSR)</td>
<td>10</td>
</tr>
</tbody>
</table>
2.4.7 Acceptance and Commitment Therapy (ACT) ............................................. 10
2.4.8 Cognitive Behavioural Therapy (CBT) ....................................................... 11
2.4.9 Doing Nothing ......................................................................................... 11
2.5 Gap Analysis of Existing Tinnitus Management Model in Indonesia ....... 12
  2.5.1 Limitations in Digital Literacy ................................................................. 12
  2.5.2 Lack of Access to Hearing Care Professionals in the Country ............... 13
  2.5.3 Lack of Integration of Alternative Tinnitus Intervention Methodologies in
       Existing Medical Workflow ........................................................................ 13
  2.5.4 The Costs Associated with Tinnitus Treatment ....................................... 14
2.6 Overcoming Barriers .................................................................................. 15
3.0 Research Methodology .............................................................................. 15
  3.1 Study Design ............................................................................................. 15
  3.2 Patient Recruitment and Enrolment Process ............................................ 16
  3.3 Condition Measurement and Assessment .................................................. 17
  3.4 Intervention Outline for I₀, I₁, and I₂ ....................................................... 17
  3.5 ICBT Workflow for I₁ (Intervention group) .............................................. 18
  3.6 Statistical Analysis in this Study ................................................................. 19
  3.7 Establishing the Non-Inferiority Margin (Δ) for Clinical Significance ....... 19
  3.8 Calculating the Sample Size ..................................................................... 19
  3.9 Determining Clinical Significance ............................................................. 20
4.0 Results ........................................................................................................ 21
  4.1 Participant Data......................................................................................... 21
4.2 Attrition

4.3 Efficacy of ICBT I₁ and I₂ in comparison to Baseline I₀

5.0 Discussion

6.0 Conclusion

7.0 References
1. Introduction

Tinnitus is a type of hearing disorder that occurs from the patient’s brain and not from an external source. Tinnitus appears as a form of auditory sensation that is not to be confused with auditory hallucinations, which is usually related to psychosis (Traynor, 2018). It can be described as "ringing in the ears." Some of the common sounds that can be heard in this condition include buzzing, grinding, and humming, hissing, whistling (NHS Scotland, 2021).

Tinnitus is a chronic condition that has posed a major challenge to healthcare systems globally, as they face the burden of providing effective and timely treatment (Tunkel et al., 2014; McFerran et al., 2019). At the point of writing, there is no cure for tinnitus, and the treatment of this debilitating audiological ailment remains incredibly challenging and costly (McFerran et al., 2019; JHBI, 2022). It is estimated that tinnitus affects more than 10-15% of the general adult population, of which up to 5% of adults are suffering severely from this condition, having a great impact on the patients’ Quality of Life (QOL) (Trochidia et al., 2021). Daoud et al. (2021), had collated the financial burden of patients directly attributed to tinnitus. The annual healthcare cost associated with this condition is estimated to be USD$660/ patient in the United States of America (Goldstein et al., 2015), 1540 Euro/patient in the Netherlands (Mahes et al., 2013) and GBP 720 in the United Kingdom (Stockdale et al., 2017).

Due to the limited number of specialist services available for treating this condition, there are currently no established nor regulated guides for tinnitus treatments, and as a result, many individuals are not able to access effective treatment methods (McFerran et al., 2019; Daoud et al., 2021). Although there are various approaches available, the evidence supporting their efficacy remains to be explored (Cederroth et al., 2013; Langguth et al., 2019).

Despite the positive outcomes of Cognitive Behavioral Therapy (CBT) supported by several medical studies (Andersson, 2002; Baguley et al., 2013), this mode of therapy is still not widely available for treating tinnitus due to the lack of trained clinicians in Indonesia. This issue is expected to be resolved through the development of effective treatment methods that can be accessed through creative approaches in an attempt to reduce the comorbidities that are directly associated with tinnitus (Patterson & Balough, 2006; McFerran et al., 2019). With the global pandemic in 2020, healthcare systems are streamlined to focus on acute conditions and emergency responses. For largely rehabilitative-based audiological treatments such as tinnitus, a shift was observed to telemedicine (Aazh et al., 2021; Singh et al., 2021).

Aside from being more cost-effective, telemedicine has also gained popularity as a convenient and accessible alternative to face-to-face CBT treatments. Reduced
possibility of COVID-19 transmission aside, therapy through telemedicine has other added benefits such as time zone differences. For patients that have difficulties articulating verbally, ICBT provides a safe “haven” for patients to voice out their concerns and articulate their conditions. As a result, telemedicine can provide patients with a more personalized and cost-effective approach (Hailey et al., 2002).

A study conducted by Andersson et al. (2002). Suggested that ICBT is an effective intervention measure in improving the quality of life due to the alleviation of tinnitus-associated comorbidities. This was supported by clinical trials initiated by Ruwaard et al. (2012). Andersson (2015) conducted a follow-up study and revealed that an ICBT intervention was able to reduce the distress caused by tinnitus. The study noted that the ICBT intervention was able to reduce distress levels and improve the quality of care for those suffering from Tinnitus.

Despite the promising results of the study, worldwide adoption of ICBT as a tinnitus intervention tool remains in the infancy stage Jasper et al. (2014) as the successful implementation of telemedicine in a country depends on a myriad of factors such as technological framework, legal framework, financial status, and culture of the country (Al-Samarraie et al., 2020). This challenge to implement is even more so for developing nations like Indonesia that has a lacking a national level telemedicine policy and a statutory framework to govern this process as this may result in potential medical liability which is a huge deterrent to medical professionals. Combined with the poor info-communications framework, telemedicine solutions such as ICBT may form a large barrier to implementation (Oh et al., 2006).

This thesis encompasses a Randomized Control Trial (RCT) to determine the effectiveness of ICBT in improving the overall QOL of patients and to find out how effective ICBT is in alleviating tinnitus-associated distresses.

The hypothesis established in this study are as follow:

\[ H_1 = \text{Tinnitus patients will experience greater relief from tinnitus and better overall Quality of Life (QOL) upon receiving ICBT vs non-intervention.} \]

\[ H_0 = \text{There are no differences between ICBT and non-intervention in terms of the patients’ overall Quality of Life (QOL) and relief from tinnitus-related effects} \]
2.0 Literature Review

The goal of this review is to develop a deeper understanding of the various aspects of tinnitus - possible aetiologies, and existing treatment methods. It also explores the current literature on the treatment of this complex condition and identifies the corresponding treatment gaps that accentuate the need for ICBT. These findings will form the basis of the hypothesis.

2.1 How is Tinnitus Developed

The neurobiological nature of tinnitus development is a medical topic of great scientific interest for many years. According to Brummett, most cases of hearing loss or other disorders that involve the inner ear or the auditory nerve can be linked to tinnitus. Tinnitus can also exist without the peripheral auditory system (Brummett, 1980). Studies had suggested that tinnitus is a systemic problem originating from excitatory and inhibitory input imbalances that can happen along with the input of the auditory neurons (Kaltenbach, 2011).

People with an underlying condition such as hearing loss, or an ear injury are more prone to experiencing tinnitus (Baguley et al., 2013). Tinnitus is also associated with other chronic conditions such as diabetes, thyroid problems, and autoimmune disorders (JHBI, 2022).

2.1.1 Physical Damage

Studies have shown that hair cell damage could cause random electrical impulses to travel to your brain, causing tinnitus through a “leak”. Middle ear conditions such as otitis media, cerumen impaction, and foreign body lodgment in the external auditory meatus can be a probable cause as well (Bogle, 2022). Head or neck injuries can also affect the hearing nerve and the inner ear. These injuries can lead to the development of tinnitus, usually, such injuries cause unilateral tinnitus (Han et al., 2009).

2.1.2 Medication

Some medications can worsen the development of tinnitus. The higher the dose of these drugs, the louder the noise becomes. However, these effects usually go away when the medication stops (Bogle, 2022). Nonsteroidal anti-inflammatory drugs (NSAIDs) such as naproxen, ibuprofen, acetaminophen, and aspirin can cause the development of tinnitus (Risser et al., 2009). Certain antibiotics, diuretics, antidepressants, and cancer drugs can also make people develop this condition (Bogle, 2022).
2.1.3 Meniere’s Disease

Tinnitus can be an early sign of a condition known as Meniere’s Disease, a chronic condition that affects auditory and vestibular systems functionality in patients (Sajjadi & Paparella, 2008). Other symptoms of Meniere’s Disease include vertigo, and fullness of the ear (aural pressure) (Baguley et al., 2013).

2.1.4 Eustachian Tube Dysfunction (ETD)

The Eustachian tube is a narrow tube that is normally closed during chewing, swallowing, or yawning actions of individuals (Llewellyn, et al., 2014). ETD is a broad term referring to the inability of the ET to perform its intended function, which could be due to a myriad of factors. ETD plays a huge part in balance and hearing issues as well. Swelling of the mucosal layer of the said tube may cause otalgia, aural pressure, reduced hearing capacity, and tinnitus (Llewellyn et al., 2014). These symptoms may also surface when the patient’s eustachian tube is not able to open or close normally (Monsell & Harley, 1996).

2.1.5 Otosclerosis

Otosclerosis is a type of bone disease that affects the middle ear. One of the main causes of otosclerosis is when a bone in the middle ear gets stuck in place. This condition then stops the sound from traveling through the ear (Gristwood & Venables, 2003). Otosclerosis can also cause the bones to grow too slowly, which can cause hearing loss. Otosclerosis has the tendency to run in families (Gersdoff et al., 2000).

One of the most common symptoms of otosclerosis is hearing loss, which usually starts in one ear and gradually moves to the other. People with this condition usually notice that they can't hear low-pitched sounds or a whisper. Some people with this condition also experience other symptoms such as vestibular problems and tinnitus (Gersdoff et al., 2000).

2.1.6 Temporomandibular Joint Disorders (TMJ) and Muscle Spasms

The prevalence of chronic TMJs is usually observed in dentistry of up to 27% of the population as suggested by (Deng et al., 1995). These disorders can be caused by a TMJ injury. Other conditions such as arthritis and malocclusion can also affect the jaw muscles (Sharma et al., 2011; Chisnoiu et al., 2015).

The symptoms of a TMJ disorder include difficulty opening/ closing the jaw, pain, and popping noises when the jaw is moved. Tinnitus is also a common condition in patients with these conditions. It is estimated that 60% of patients with these disorders have this condition (Tuz et al., 2003; Edvall et al., 2019).
A number of studies conducted on the link between temporomandibular joint disorders and tinnitus have shown a significant relationship between the two conditions. These studies were presented in two systematic reviews (Edvall et al., 2019; Mottaghi et al., 2019).

The correlation between TMJ and tinnitus has been first suggested by (Costen, 1934). TMJ and muscle spasms are identified to be one of the possible causes of tinnitus as well.

Pains in the inner ear can trigger a feeling of fullness in the ear, which can cause hearing loss and worsen the condition of tinnitus. It can also be caused by a variety of neurological disorders (Kitsoulis et al., 2011; Buergers et al., 2014).

### 2.1.7 Tumors

Certain types of tumors, such as acoustic neuroma, can also cause tinnitus (Baguley et al., 2013). This is a benign tumor that affects the inner ear and controls hearing and balance. Other types of brain tumors such as vestibular schwannoma can also cause this condition.

### 2.1.8 Blood Vessel Disorders

A blood vessel disorder can affect blood flow through the affected blood vessels and cause tinnitus. Conditions such as aneurysms and arteriovenous malformations high blood pressure or atherosclerosis can cause these blood vessels to become more flexible (Hofmann et al., 2013).

### 2.1.9 Noise Exposure

Tinnitus’ direct relation to prolonged noise exposure has been reported as early as 1987 (LaMarte & Tyler, 1987). Early studies by Coles in 1984 had reported a 70% higher risk of developing tinnitus in workers subjected to prolonged noise compared to their non-exposed counterparts (Coles, 1984). Modern studies such as the one by (Fredriksson et al., 2015) reaffirmed a significant association between prolonged noise exposure and tinnitus development.
2.2 Tinnitus Comorbidities

Tinnitus patients in general suffer from a poorer Quality of Life (QOL) (Kennedy et al., 2004) due to other comorbidities such as reduced hearing capability, work absenteeism, sleep disturbance, and learning difficulty (Baguley et al., 2013). Tinnitus can also affect speech differentiation capabilities (Park et al., 2014) and sound localization (Gilles et al., 2016). Psycho-emotional factors such as anxiety and depression are also part of the identified comorbidities associated with tinnitus (Kim et al., 2017). It is therefore important to alleviate these comorbidities so that patients can experience an improved overall QOL.

2.3 Existing Tinnitus Intervention Methods

Despite medical technological advancement, treatment of this chronic condition remains elusive. Currently, there is no known cure that can completely eradicate tinnitus. However, there are multiple approaches that are available for patients to cope with it better.

Tinnitus can be treated with various types of medications and surgical procedures which can sometimes help reduce or remove the perception of the condition. Unfortunately, in some cases, tinnitus perception by the patients was aggravated instead of it being eradicated. While there are cases of tinnitus improvement after surgery (Ramsay et al., 1997), there are more cases that supported the worsening of tinnitus in up to 11% of patients (Glasgold & Altmann, 1966; Gersdorff et al., 2000; Bagger-Sjöbäck et al., 2015), tinnitus can still be triggered by certain types of surgical procedures, such as the auditory nerve section and the vestibular schwannoma resection (Trakolis et al., 2018).

In non-pathological cases, pharmacological treatment has been tried to treat the condition. It’s believed that these interventions can trigger a reduction in the neural activity that’s involved in the perception of tinnitus (Baguley et al., 2013).

A wide range of drugs, including antihistamines, vasodilators, and anti-depressants (Langguth et al., 2009; Elgoyhen & Langguth, 2010; Baldo et al., 2012), calcium antagonists, and benzodiazepines, have been tested on people with persistent tinnitus (Langguth et al., 2019). Unfortunately, these treatments have not been able to achieve consistent results. In some studies, the effects of these drugs on the condition were compared with those of a placebo. Tinnitus was also reduced in a double-blind study, but the results of the study did not differ between the two groups (Langguth et al., 2009).

Non-medical treatment alternatives are also commonly used to treat persistent tinnitus. They can help minimize or even eliminate the symptoms of the condition altogether (Baguley et al., 2013).
2.4 Tinnitus Management

The goal of non-medical treatment for tinnitus is to address the various aspects of the condition, such as its clinical, emotional, and cognitive aspects so that the patient can better live with this condition.

In order to provide the best possible care, guidelines for treating tinnitus have been established that involve direct counseling. New treatment options are being developed based on the increasing knowledge about the mechanisms of this condition. Some of these include the use of auditory stimulus (Jastreboff & Jastreboff, 2006), electrical, and magnetic waves (Han et al., 2009) which will be further elaborated in the following sections.

2.4.1 Alternative Medicine and Therapies

In addition, various complementary treatments such as acupuncture (Park et al., 2000) and mind-body therapies (Biesinger et al., 2010) are also being developed to treat this condition. These are expected to provide effective and safe ways to manage this condition (Birch et al., 2004).

Diet variation, vitamin supplementation, and herbal supplements were also used in the alleviation of tinnitus. However, its success lacks scientific support in its claim and though popular in Western countries, this mode of intervention is not accepted as a treatment alternative (Bauer, 2018).

2.4.2 Electromagnetic Stimulation

Repetitive Transcranial Magnetic Stimulation (rTMS) is a non-invasive treatment alternative to tinnitus to deliver electromagnetic pulses to the brain tissue directly and is known to cause the reduction of overly active neural hyperactivity in the neural cortex commonly used to treat patients with this condition (De Ridder et al., 2005; Kleinjung et al., 2005).

Although initial studies on the use of rTMS have shown promising results, they have also revealed mixed results. To improve the effectiveness of this therapy, researchers need to conduct further studies on the various aspects of its use. For instance, the ideal placement of the device, the frequency of its treatments, and the quality of the performed procedures are among the factors that researchers need to consider. A study by Goetz et al. (2015) argues that loud clicks during the procedure have the potential of damaging the patient’s auditory system if not handled adequately.
Transcranial Direct Current Stimulation (tDCS) treatment is carried out through a series of electrodes that are placed on the patient's scalp (Fregni et al., 2006; Vanneste et al., 2010). The goal of the therapy is to stimulate the brain's neural cortex and reduce the activity of the surrounding tissue. Depending on the electrical properties of the electrodes, the amount of electrical stimulation can vary (Vanneste et al., 2011). Although some studies show that this procedure can improve the quality of life for some patients, more clinical trials are needed to confirm its effectiveness (Shekhawat et al., 2014).

2.4.3 Sound-based Clinical interventions

In the field of sound-based clinical interventions, the use of sound can be used to change the perception of tinnitus (Langguth et al., 2013). Various sound-based interventions are commonly used in the treatment of tinnitus. They are designed to reduce the severity of the condition, promote control, and shift the focus from tinnitus (Kaldo-Sandström et al., 2004).

The neurophysiological mechanisms that underlie the effects of sound on the central auditory system are believed to be responsible for the development of plastic changes in the hearing system (Syka, 2002).

In 1976, Vernon first introduced sound therapy devices that were designed to mask the sounds of tinnitus by producing a more acceptable sound (Vernon, 1976, 1977). There are various sounds that can be suggested as a possible masking medium for tinnitus, such as music, nature sounds, and running water. Although there are reports of sound-based methods being used to treat the condition, there is currently no evidence supporting their effectiveness.

These days, the practice of partial masking has been replaced by sound enrichment. These devices can be used with table-top or ear-level sound generators (Hoare et al., 2014). Tinnitus can be treated with hearing aids, which were first used during the 1940s (Saltzman & Ersner, 1947). Through amplification, these devices reduce the contrast between the external and internal sounds, which helps minimize the salience of the condition (Surr et al., 1985; Del Bo & Ambrosetti, 2007).

These devices can also help people focus on the sounds that are different from the ones that are causing them to feel like they have a distinct sound (Vernon, 1977). They can also improve their hearing function and communication through the hearing prosthesis. In addition to reducing the effects of tinnitus, amplification can also help decrease the neuroplastic changes that occur in the central auditory system (Moffat et al., 2009).

There have also been several notable trials that have compared the effects of hearing aids and other combination devices, and some studies have suggested that they can
improve the quality of life for people with this condition (Trotter & Donaldson, 2008; Hoare et al., 2014).

Despite the various advantages of hearing aids, there is still not enough evidence supporting their effectiveness in treating tinnitus. This is because there are not enough clinical trials that have examined the extent of their effectiveness (Hoare et al., 2011). In addition to the lack of evidence supporting their effectiveness, other factors such as the complexity of the devices and the therapy are also contributing to the issue (Fuller et al., 2017).

Above which, there are limitations to the prescription of hearing aids to patients for tinnitus relief as well. Current guidelines only recommend the use of hearing aids for people with mild to moderate hearing loss, hence for patients who have no hearing loss, they are not recommended for the treatment (Fuller et al., 2017).

Although it is still not clear how effective cochlear implantation is, it is widely believed that it can reduce the percept of patients with severe or chronic hearing loss (Baguley & Atlas, 2007). Aside from the type of stimulation that can be used, other factors such as the duration of the procedure and the patient's overall health are also taken into account in the candidacy process (Quaranta et al., 2004). And due to its invasive nature, this option is usually recommended in extreme cases.

Another type of therapy that is commonly used for patients suffering from tinnitus on top of severe or chronic hearing loss is through a combination of sound therapy and directive counseling. This type of therapy, which is referred to as tinnitus-retraining therapy (TRT), was developed based on the neurophysiological model of the condition (Jastreboff et al., 1996).

Although there are currently no large-scale randomized controlled trials supporting the effectiveness of various components of TRT, a simplified version of this therapy was found to be of equivalent efficacy as compared to the traditional method (Westin et al., 2011). This suggests that the type of counseling and duration of the procedure don’t play a critical role in the outcome of the treatment (Dobie, 1999).

### 2.4.4 Neuronomic Tinnitus Treatment (NTT)

Various sound therapy methods are currently being developed for treating various conditions such as chronic hearing loss. One of these is Neuronomic Tinnitus Treatment (NTT), which is a sound-based therapy that uses modified music to desensitize the perception of tinnitus (Davis et al., 2007; Floretti et al., 2011).

A study conducted by Newman & Sandridge (2012) revealed the results of a comparison between ear-level sound generators and NTT and found the two methods similar in terms of outcomes. However, ear-level devices are considered the most cost-effective option when it comes to treating hearing loss.
2.4.5 Acoustic Coordinated Reset Neuromodulation (CR)

Acoustic coordination reset neuromodulation, which involves stimulating the brain’s neural synchrony system. It involves playing a sequence of tones that correspond to the pitch of the tinnitus pitch for several hours a day (Tass et al., 2012).

The goal of this therapy is to force the activation of the neurons in the brain that are involved in the asynchronous firing of neurons. Despite the growing popularity of sound therapy for treating chronic hearing loss, there is still a lot of doubt regarding its effectiveness (Wegger et al., 2017). Due to the lack of sufficient evidence supporting the use of sound-based interventions, many of these methods are not considered safe and effective. Although the lack of conclusive evidence regarding the effectiveness of sound therapy is not surprising, it should not be interpreted as evidence of a lack of confidence in the method.

2.4.6 Mindfulness-Based Stress Reduction (MBSR)

The use of MBSR in the management of tinnitus has been shown to be beneficial (Roland et al., 2015; Gans et al., 2014). According to the principles of mindfulness, people can practice being present in the moment and letting their feelings be as they are. This allows them to feel less threatened and lowers their impact (Gans et al., 2014; Arif et al., 2017). In addition to improving one's well-being, mindfulness has also been shown to reduce the impact of stress on the development and functioning of tinnitus (Gans et al., 2014) (Arif et al., 2017). The practice of mindful living can help reduce the effects of tinnitus.

Due to the similarities between relaxation and mindfulness, it has been suggested that both can be beneficial when it comes to treating tinnitus. In 2014, a study revealed that practicing mindfulness can improve the outcome of tinnitus patients (Gans et al., 2014).

2.4.7 Acceptance and Commitment Therapy (ACT)

The goal of ACT is to decrease avoidance behavior by increasing awareness of the various ways that thoughts and emotions can trigger distress (Westin et al., 2011). This method is similar to MBSR in that it focuses on the present moment and not on the past.

ACT should not be confused with Cognitive Behavioural Therapy (CBT). Unlike CBT, which focuses on the treatment of negative thoughts and emotions, the ACT focuses
on the acceptance of these concepts instead of trying to modify them. It has been shown that ACT can help people manage their health conditions.

There are various clinical trials that are evaluating the effectiveness of ACT in treating various conditions, such as tinnitus.

2.4.8 Cognitive Behavioural Therapy (CBT)

CBT can be used to treat various psychological conditions, such as anxiety and depression, as well as chronic pain and insomnia (Andersson, 2002). It can also be beneficial for people with other conditions that are related to the development and maintenance of tinnitus (Hesser et al., 2011). Due to the relationship between psychological distress and tinnitus, CBT has been used as a treatment approach for this condition for a long time (Scott et al., 1985; Hallam et al., 1988).

CBT is structured to provide a comprehensive treatment plan that includes a goal-setting exercise, and a variety of activities that are designed to support the participant. It can also be supported by a licensed psychologist.

Relaxation techniques are also used to reduce the arousal associated with stress. In addition, CBT can be used to overcome the fears and maladaptive thoughts that people have about hearing tinnitus (Andersson, 2002).

Although different components of CBT are commonly used by clinicians, the principles of this type of therapy are still the same. For instance, it utilizes sound enrichment techniques, which are based on the principles of audiology.

Over the years, various studies have been conducted on the use of CBT for treating the condition known as chronic hearing loss (Baguley et al., 2013). One of the studies revealed that this type of therapy can help reduce the distress experienced by those suffering from this condition (Andersson & Lytkens, 1999). Further studies have supported that CBT can also help improve the patients’ overall QOL for those suffering from this condition (Baguley et al., 2013).

These results support the idea that this type of therapy can help improve the daily functioning of individuals with this condition. This makes CBT an effective treatment for treating chronic Tinnitus, especially in patients with anxiety or depression (Martinez-Devesa et al., 2007).

2.4.9 Doing Nothing

Recent studies suggest that people with tinnitus does not encounter an aggravation of condition over time, and they can improve their QOL by doing nothing (Sourgen
& Ross, 1998; Andersson et al., 2001). This is in line with the results of meta-analyses that found similar results in controlled trials (Nondahl et al., 2010; Beukes et al., 2018).

Although this is good news for people with tinnitus, it varies with individuals. While there are cases of improvements doing nothing, medical assistance is still recommended. Especially for those who are experiencing distress due to their condition.

Of the above conventional strategies presented in this section, although challenged by the lack of consistent results, CBT is the most effective method of reducing distress.

Due to the complexity of the condition, it is not possible to implement a single discipline approach to treating it, and therefore no one-size-fits-all solutions to tinnitus treatment and management. Instead, focusing on the individual needs should be done in a multidisciplinary manner. This can be done through the development of treatment plans that involve the various disciplines of medicine, psychology, and neurosciences.

2.5 Gap Analysis of Existing Tinnitus Management Model in Indonesia

The main mode of tinnitus management is through the adoption of rehabilitation and CBT. The advantages of introducing CBT through internet means (ICBT) are introduced at the beginning of this paper. Although Covid-19 is an effective primer that hastened the overall implementation pace of ICBT, the barriers to implementing this system in a developing country like Indonesia remain high. The respective main challenges are discussed in the subsequent segments in this section.

2.5.1 Limitations in Digital Literacy

Despite increased digital literacy due to the improved educational level in Indonesia, digital literacy remained low on a country level (Harsono, 2022) and this may serve as a challenge to the success of ICBT implementation in the country, as ICBT requires a certain level of digital literacy and language competency level. Another challenge is due to the self-help nature of ICBT. Although audiologists guided this study, it is important for the patients to develop a sustainable habit and therefore empower individuals to have control of their tinnitus conditions. It is therefore important that the User Interface (UI) adopts good design, and have user-friendliness and good User Experience (UX) in mind.
2.5.2 Lack of Access to Hearing Care Professionals in the Country

The literature review so far shows us the importance of having a proper clinical care pathway for tinnitus patients with this condition. Unfortunately, they are not always available due to the various obstacles that prevent them from being delivered properly, especially in newly industrialized countries like Indonesia. Currently, there are various restrictions that prevent patients with tinnitus from receiving the appropriate care. These include the availability of evidence-based interventions, the cost associated with their delivery, and the lack of access to care.

Despite the availability of effective and proven medical services, such as audiological care, many people around the world do not have access to these services due to geographical location. Besides the lack of resources, other factors such as the poor infrastructure and the lack of trained professionals are also contributing to the low number of people with access to specialist care. The World Report on Hearing has reported that there is less than one ear, nose, and throat (ENT) specialist doctor per mission population and less than one audiologist per million population in 78% of low-income countries (WHO, 2021)

Due to the limited availability of specialist services, many people with tinnitus are unable to access effective interventions. This is especially true in remote areas. Even with the availability of free healthcare services, many people with this condition are still not able to receive the necessary treatment.

This problem can be further improved through the introduction of a multi-platform ICBT that is available on both laptops, as well as mobile devices that rely on mobile data (3G/4G). Indonesia’s internet penetration as of 2021 is 64% and its 4G coverage had achieved 90% in 2021 (Luthfia et al., 2021).

2.5.3 Lack of Integration of Alternative Tinnitus Intervention Methodologies in Existing Medical Workflow

The lack of a standardized approach to the management of tinnitus in Indonesia is a major barrier to the evaluation of this condition. There is currently no established procedure for the diagnosis and treatment of this. This is also reflected in the varying practice guidelines and resources available for the management of this condition.

Aside from its complexity, the severity of tinnitus may not be related to the frequency or characteristics of the sound itself. Instead, it is usually related to the psychological complaints that accompany this condition. Tinnitus interventions that are focused on improving the functionality of the ears are not as effective as those that are geared toward reducing the effects of this condition.
Currently, the most effective treatment for reducing distress associated with tinnitus is cognitive behavioral therapy (CBT) as supported by multiple clinical studies, establishing this mode of intervention with an improvement of QOL in patients (Baguley et al., 2013; Tunkel et al., 2014). Aside from audiological care, CBT can also help reduce the severity of the condition by providing a variety of psychological and behavioral interventions (Lewis et al., 2012; Baguley et al., 2013).

The use of self-help interventions has been shown to reduce the distress experienced by those with this condition (Nyenhuis et al., 2013).

### 2.5.4 The Costs Associated with Tinnitus Treatment

The cost-effectiveness of various interventions is a crucial factor that healthcare providers consider when planning for the provision of healthcare. A study revealed an average treatment cost of GBP 717 per patient per year (Stockdale et al., 2017), which is above the average health expenditure per capita of USD 120 (WHO, 2022) (The World Bank, 2022).

![Health expenditure per capita in Indonesia](Image Reference: (The World Bank, 2022))

The severity of the condition and the duration of the illness was also known to predict the higher societal costs associated with treating it. Among the other factors that were considered were the age of the respondents and their depression levels (Stockdale et al., 2017).

The increasing prevalence of this condition is also expected to place additional financial constraints on the healthcare systems. This issue is due to the lack of access to effective treatment options. In addition to this, the lack of coordination between health professionals is also expected to affect the quality of care.
2.6 Overcoming Barriers

The implementation of ICBT can greatly help improve the quality of healthcare and increase the outreach of tinnitus intervention due to its self-help nature. This type of treatment is typically done through a website that is designed to provide a prescriptive online program.

One of the main advantages of having an Internet-based treatment is that it can be more cost-effective than the usual face-to-face style CBT approach. This method can also be used by people who are unable to access the services through traditional means due to various factors such as time constraints and the stigma attached to seeing a therapist.

Another advantage of using an Internet-based treatment is that it can be more comfortable for people to access. This method can also help them retain the information they've learned. Learning can be facilitated by the ability to update information at any time.

One of the most important factors that can be considered when it comes to implementing an intervention is the ability to monitor the progress of the patient. This enables the healthcare professional to track the progress in real-time and empowers patients to manage their own condition at their own pace.

This thesis aims to provide an overview of the current state of research regarding the use of ICBT in treating patients with tinnitus in the Indonesian context. Due to the current lockdown within the country, as face-to-face treatment mediums are halted, it provided an opportunity to compare the efficacy of ICBT when implemented onto an existing group of tinnitus patients who had not been provided with any sort of treatment/ intervention prior.

3.0 Research Methodology

This chapter shall outline the research methodology undertaken in this clinical study.

3.1 Study Design

This study will adopt a randomized group, non-inferiority trial design conducted from 1 July 2021 to 6 May 2022. The research topic and methodology were first presented to the industrial collaboration company, Epiphany Hearing and Audiological Consultancy Pte Ltd, and the RSUD Raja Ahmad Tabib Hospital, Tanjung Pinang, Indonesia Ear Nose, and Throat Department, and were approved. The sampling size and the patient selection criteria were aligned with the
representatives as well.

On 3 July 2021, emergency measures were imposed by the state government for lockdown. All mediums of communication are via telephony, Microsoft Teams, WhatsApp®, and Short Message Service (SMS).

The aim of designing a non-inferiority trial is to prove statistically that a new intervention is not clinically worse-off than an active treatment control which in this case are patients that have yet to undergo any tinnitus intervention prior to this study. The experimental intervention was audiologist-guided ICBT. All patients are chosen from the same hospital in Indonesia.

Prior to the intervention rollout, all participants are briefed alongside their caretakers on the walkthrough of the program via Microsoft Teams on 13 September 2021. The participants are also briefed on the 3 questionnaires that they are required to fill in: The Tinnitus Functionality Index (TFI), Tinnitus Handicap Index (THI), and Tinnitus Reaction Questionnaire (TRQ).

The study groups will be split into 2 parts. The first portion, I₀ is the baseline measurement of the overall tinnitus conditions and their effect on their respective Quality of Life (QOL) by filling in the TFI, THI, and TRQ upon confirmation of their candidacy for this trial.

After the baseline was taken, the same group will be subjected to ICBT intervention. The group of patients will be invited to fill in the TFI, THI, and TRQ at the 3rd month (I₁), and 6th month (I₂) mark.

It was therefore established that I₀ is the active treatment control (before treatment intervention) and I₁ is audiologist-guided ICBT at intervention + 3 months, and I₂ is post-ICBT intervention +6 months.

3.2 Patient Recruitment and Enrolment Process

The selection of the candidates for this trial is solely by referral only. All participants are verified to have been diagnosed with tinnitus by a registered medical doctor or an audiologist holding certification recognized by the Republic of Indonesia. All treatment costs during the trial are free of charge. Each participant is reimbursed 50 USD (around 722,800 IDR) for their participation. There are no conflicting interests between the trial participants and the author of this thesis.

Participants who qualify are invited to undertake the baseline TFI test and allocation will be done in a staggered manner according to their TFI scores, age, gender, and tinnitus duration to ensure an equal distribution for both groups. All participants are aware of the intervention arm allocation.

The inclusion criteria for participants are as follow:
- A resident of the Republic of Indonesia, aged 18 and above
- Able to read and type in either Bahasa Indonesia or English
• Referred by ENT, any board-certified medical professional, or other hearing professionals holding certifications recognized by the Republic of Indonesia.
• TFI score of equal to 50 and above which suggests the need for tinnitus care (Meikle et al., 2012)

3.3 Condition Measurement and Assessment

The TFI, THI, and TRQ questionnaires are delivered via a Google Form that enables participants to rank their experiences via a Likert scale. Their responses are captured in real-time. The main language medium of the questionnaire is Bahasa Indonesia followed by English.

![TFI, THI, and TRQ Questionnaire in Bahasa Indonesia and English, delivered over Google Forms. Image Reproduced with permission from Epiphany Hearing and Audiological Consultancy Pte Ltd](image)

3.4 Intervention Outline for I₀, I₁, and I₂

Upon confirmation of their candidature for this study, the participants undertake the baseline TFI, THI and TRQ, and their results are captured as I₀. The same group will be subjected to an active intervention through ICBT for 6 months, supported by clinical audiologists. The TFI, THI, and TRQ scores were captured as I₁, at the 3rd and 6th month (I₂) after ICBT was introduced.

The audiologists chosen to guide the group were required to have prior clinical hours spent in managing tinnitus patients. The various modules in the ICBT, contains self-help resources and information about managing tinnitus. This information were briefed by the clinical audiologists attached to this study. If the patients run into any clarifications which are required, they can always drop an Instant Messaging (IM) note to the audiologist on duty.
The ICBT platform to be used is as shown in the figures below and is available on both Personal Computers (PC) and mobile platforms.

Figure 3. ICBT Platforms used in this study. Left is the PC compatible platform and the photo on the right is the mobile app equivalent. Image reproduced with permission from Epiphany Hearing and Audiological Consultancy Pte Ltd, Indonesia

3.5 ICBT Workflow for I1 (Intervention group)

The intervention actionable are detailed as below:
## 3.6 Statistical Analysis in this Study

This study follows the CONSORT guidelines for non-inferiority randomized clinical trials (Piaggio et al., 2012).

## 3.7 Establishing the Non-Inferiority Margin (Δ) for Clinical Significance

Upon a literature review of various clinical studies, it was found that there were no internationally established non-inferiority margin using TFI was established. Meikle et al. (2012) suggested that a 13 points reduction in the TFI index is deemed clinically significant. Meikle’s study was supported by Rabau et al. (2014). Similar studies regarding ICBT were conducted by Beukes et al. (2017) using the same measure. Henry et al. (2016), and the latest study by Frackrell et al. (2022) has also used the 13 points as the non-inferiority margin in their studies as well.

## 3.8 Calculating the Sample Size

The publicly available SampSize® application was used for the calculation of sample size.

---

**Figure 4. Actionables in the intervention group. Image Reference: Author’s own artwork**

<table>
<thead>
<tr>
<th>Intervention Description</th>
<th>Estimated Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Icebreaker between audiologist and patient</td>
<td>70 minutes</td>
</tr>
<tr>
<td>Patient Interview</td>
<td></td>
</tr>
<tr>
<td>Medical history walkthrough</td>
<td></td>
</tr>
<tr>
<td>Provide information about tinnitus and current available intervention measures</td>
<td></td>
</tr>
<tr>
<td>Runthrough ICBT modules using video</td>
<td></td>
</tr>
<tr>
<td>Question and answer session</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Kickoff demonstration</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Interview and follow up of general well being, review challenges and address challenges</td>
<td>60 minutes</td>
</tr>
<tr>
<td>Recap TFI, THI and TRQ questionnaires</td>
<td></td>
</tr>
<tr>
<td>Identifying triggers, negative thinking patterns and reprogramming</td>
<td></td>
</tr>
<tr>
<td>Mindfulness exercises and techniques</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Post intervention followup (3rd month)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Interview and follow up of general well being, review challenges and address challenges</td>
<td>60 minutes</td>
</tr>
<tr>
<td>Recap TFI, THI and TRQ questionnaires</td>
<td></td>
</tr>
<tr>
<td>Identifying triggers, negative thinking patterns and reprogramming</td>
<td></td>
</tr>
<tr>
<td>Mindfulness exercises and techniques</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Post intervention followup (6th month)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Interview and follow up of general well being, review challenges and address challenges</td>
<td>60 minutes</td>
</tr>
<tr>
<td>Recap TFI, THI and TRQ questionnaires</td>
<td></td>
</tr>
<tr>
<td>Identifying triggers, negative thinking patterns and reprogramming</td>
<td></td>
</tr>
<tr>
<td>Mindfulness exercises and techniques</td>
<td></td>
</tr>
</tbody>
</table>

*Throughout the process, audiologist is available upon demand through the Instant Messaging Function in the ICBT app. Response time is immediate from 0900-1800 Monday-Friday Indonesia Time, exclusive of public holiday. Post working hour replies will be made by next working day.*
size for non-inferiority parallel groups in this study

![Sampsize](image_url)

**Figure 5.** The parameters tabulated using the Sampsize application. Image reference: Artist's own artwork using the Sampsize platform.

An additional 6 participants were assigned to each group to factor for attrition.

3.9 Determining Clinical Significance

The goal of this study was to determine the clinical significance of the ICBT intervention compared to the pre- and post-ICBT intervention. Using a confidence interval method, the difference between the two interventions was analyzed to determine if there was an inferiority. If there is a difference of less than 13 points on the TFI it can be said that a non-inferiority has been established for the ICBT intervention.
4.0 Results

4.1 Participant Data

At the start of the recruitment, 90 adults were referred by the ENTs branch of the hospital. They were all found to be able to qualify for the trial. Upon determination of the sample size by online application Sampsize®, a minimum of 34 participants are required. 4 additional participants are invited to factor in for attrition (n=40).

The 40 participants took the baseline TFI, THI, and TRQ questionnaire, and 4 withdrew from the study due to personal matters. 36 remaining participants went ahead with the ICBT intervention as per the CONSORT diagram below.

Figure 6. CONSORT Diagram for the study. Image Reference: Author's own artwork derived from CONSORT 2010 Framework.

The average age of the 40 participants at baseline was 47.4 years of age (SD = 15.7), 25 (62.5%) are males and 15 are females (37.5%). Their overall age range was 23-74. Their tinnitus duration is on average 15.6 years (SD =12.8).

After attrition of 4 patients, the average of the remaining 36 participants was 47.3 years of age (SD = 16.09) with 64% male (23) male participants and 13 female (36%). The overall age range of the group is from 25-74, and on average the patients had been living with tinnitus for 16.25 years (SD = 12.88). The group is overall well-matched with a good spread of age and tinnitus duration. The ranges of TFI scores at t₀ were from 59-71 (SD = 4.77).
4.2 Attrition

Post-ICBT intervention at I₁ and I₂ reported no attrition in the 36 participants. All questionnaires at I₁ and I₂ are completed, with no group differences.

4.3 Efficacy of ICBT I₁ and I₂ in comparison to Baseline I₀

The within-group effect sizes for TFI, THI, and TRQ were large for both groups at both I₁ and I₂. At I₂ the TFI mean score had further reduced after 6 months of intervention, which tells us that the intervention is successful in reducing the tinnitus distress in patients. At I₁ the mean TFI scores are (M = 43.3, SD = 6.17) and I₂ the mean TFI scores were (M = 34 SD = 5.43). Which are 17.42 and 26.5 points lower respectively, compared with I₀. These mean differences are lower than the 13-point differences as per Meikle’s study.

<table>
<thead>
<tr>
<th>TFI</th>
<th>Before Intervention, I₀</th>
<th>3-month after intervention, I₁</th>
<th>6-month after intervention I₂</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>60.725</td>
<td>43.30556</td>
<td>34.22222</td>
</tr>
<tr>
<td>Std Dev</td>
<td>4.771644</td>
<td>6.172841</td>
<td>5.43066</td>
</tr>
<tr>
<td>Mean (I₀-I₁)</td>
<td>17.41944</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (I₀-I₂)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (I₁-I₂)</td>
<td>9.083333</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cohen’s Ds</td>
<td>0.578723</td>
<td>0.474381</td>
<td>0.542185</td>
</tr>
</tbody>
</table>

Figure 8. TFI Results Table. Post-intervention measures have discovered that the reduction in patient-reported tinnitus distress is clinically significant. Image from author’s own artwork

Similar results have been observed in THI. Based on the impairment ratings first established by (Newman et al., 1996), the overall tinnitus handicap index has dropped from 56.8 (moderate to severe) to 36.11 3-month post ICBT intervention and 35.27
6-month post ICBT intervention (mild). This corresponds to an impairment rating drop from 10 to 2 based on the framework established by the Australian Government Department of Veteran Affairs (CLIK, 2020).

![Tinnitus Handicap Questionnaire (THI)](image)

**Figure 9. THI Grading based on Newman’s study. Image Reference: (CLIK, 2020)**

<table>
<thead>
<tr>
<th>Impairment Ratings</th>
<th>Criteria</th>
<th>THI Score</th>
<th>Impact Guide</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIL</td>
<td>No tinnitus or occasional tinnitus.</td>
<td>0-16</td>
<td>None/light</td>
</tr>
<tr>
<td>TWO</td>
<td>Very mild tinnitus: not present every day.</td>
<td>18-36</td>
<td>Mild</td>
</tr>
<tr>
<td>FIVE</td>
<td>Tinnitus every day, but tolerable for much of the time.</td>
<td>38-56</td>
<td>Moderate</td>
</tr>
<tr>
<td>TEN</td>
<td>Severe tinnitus, e.g. of similar severity to that requiring a masking device, present every day.</td>
<td>58-76</td>
<td>Severe</td>
</tr>
<tr>
<td>FIFTEEN</td>
<td>Very severe tinnitus, present every day, causing distraction, loss of concentration and extreme discomfort, and regularly interfering with sleep.</td>
<td>78-100</td>
<td>Very severe/catastrophic</td>
</tr>
</tbody>
</table>

**Figure 10. THI grading has observed a decrease which signifies the success of ICBT intervention. Image from author’s own artwork.**

For TRQ, ICBT intervention’s mean score had also seen a difference from 74.8, which corresponds to a tinnitus impact rating of “severe” based on (Wilson et al., 1991) with an impairment rating of 10 to 46.639 3 months after the intervention and to 46.5 6 months after intervention, which corresponds to a tinnitus impact rating of moderate. ICBT intervention had reduced the impairment rating by 50%, from 10 to 2 based on the framework established by the Australian Government Department of Veteran Affairs (CLIK, 2020). This signifies a tremendous improvement in the patient’s overall QOL.
Figure 11. *TRQ Ratings based on (Wilson, Henry, Bowen, & Haralambous, 1991) study. Image Reference: (CLIK, 2020)*

<table>
<thead>
<tr>
<th>Impairment Ratings</th>
<th>Criteria</th>
<th>TRQ score</th>
<th>Impact Guide</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIL</td>
<td>No tinnitus or occasional tinnitus.</td>
<td>0-16</td>
<td>None/slight</td>
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<td>TWO</td>
<td>Very mild tinnitus: not present every day.</td>
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<tr>
<td>TEN</td>
<td>Severe tinnitus, e.g. of similar severity to that requiring a masking device, present every day.</td>
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<td>Severe</td>
</tr>
<tr>
<td>FIFTEEN</td>
<td>Very severe tinnitus, present every day, causing distraction, loss of concentration and extreme discomfort, and regularly interfering with sleep.</td>
<td>78-104</td>
<td>Very severe/catastrophic</td>
</tr>
</tbody>
</table>

Figure 12. *TRQ impairment grading has been halved, signifying an improvement in patients’ overall QOL. Image from author’s own artwork.*

The baseline comparison of questionnaire scores vs I₁ and I₂ are as shown in the chart below:
Figure 2. Mean TFI, THI and TRQ Scores vs Pre-intervention, I0. Image from author's own artwork.

The combined results of the 3 questionnaires at I1 and I2 have shown significant improvements from the baseline I0, before any form of tinnitus intervention. This proves that the null hypothesis, H0 is rejected, and Ha is accepted. It can be established therefore that Tinnitus patients will experience greater relief from tinnitus and better overall Quality of Life (QOL) upon receiving ICBT vs non-intervention.

5.0 Discussion

The thesis started as a feasibility study to ascertain whether ICBT’s clinical outcomes have any clinically significant difference when compared to its face-to-face CBT counterpart. However, due to the global pandemic as the public health framework transits to brace the impact to deal with the high covid-19 cases, allied health services such as hearing health takes a back seat. Chronic tinnitus patients are being neglected in the process. As the lockdown continues, the direction of the research transited into comparing the existing pre-intervention group versus ICBT.

With the success in this small trial, we can establish that thanks to ICBT, there is now a new alternative of treatment that patients can consider alleviating their tinnitus suffering and therefore improve their overall QOL.
The objective of this research was to propose the possibility of ICBT intervention as a possible solution to tinnitus management in Indonesia. Studies to ascertain the efficacy for such an intervention in this country has not been previously done.

Although it may not be possible to implement ICBT in rural areas in the near future, the mobile version of ICBT can prove to be an effective medium to ensure the inclusion of tinnitus treatment and care for the masses, so long as they have a 3G/4G connection.

6.0 Conclusion

The objective of this study was to explore the possibility of adopting ICBT for the management of tinnitus in Indonesia. Although evidence of its efficacy has not been studied in this country, the development of this intervention has been regarded as feasible. These include the feasibility of the intervention, the long-term effects of the intervention, and the effectiveness of the treatment which has been proven via this study.

The potential of ICBT for the treatment of tinnitus has been acknowledged as an effective and cost-effective method for reducing the burden of healthcare costs associated with the condition. It can also be recommended for certain individuals who are suffering from this condition. Having an additional intervention can also help individuals with limited access to care.

Although the possibility of ICBT as a plausible treatment method for tinnitus has been acknowledged, there are still several challenges still need to be addressed in order to develop a successful and cost-effective intervention. One of these is ensuring that the program is updated in line with the latest scientific developments. Another challenge that researchers will have to face is determining the factors that will help make the program more credible and acceptability among the various stakeholders.
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