

Internet-based Cognitive Behavioural Therapy (ICBT) as an Effective Treatment Alternative to Tinnitus Management - An Empirical Research

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Received: June 16, 2022

Published: July 27, 2022

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Abstract

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 of this study is 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 and 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

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 [29]. 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 [21].

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 [18,31]. At the point of writing, there is no cure for tinnitus, and the treatment of this debilitating audiological ailment remains incredibly challenging and costly [15,18]. 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.* and Daoud., *et al.*

had collated the financial burden of patients directly attributed to tinnitus in his study in 2021 [10,30]. 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 [17] and GBP 720 in the United Kingdom [28].

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 [10,18]. Although there are various approaches available, the evidence supporting their efficacy remains to be explored [8,16].

Despite the positive outcomes of Cognitive Behavioral Therapy (CBT) supported by several medical studies [3,5], 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 [18,23]. 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 [1,27].

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 [12].

A study conducted by Andersson., *et al.* in 2002 suggested that ICBT is an effective intervention measure in improving the quality of life due to the alleviation of tinnitus-associated comorbidities [3]. This was supported by clinical trials initiated by Ruwaard., *et al.* (2012) [26]. Andersson conducted a follow-up study in 2015 and revealed that an ICBT intervention was able to reduce the distress caused by tinnitus [4]. The study noted that the ICBT intervention was able to reduce distress levels and improve the quality of care for those suffering from Tinnitus [4].

Despite the promising results of the study, worldwide adoption of ICBT as a tinnitus intervention tool remains in the infancy stage [14], 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 [2]. 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 [22].

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 = Tinnitus patients will experience greater relief from tinnitus and better overall Quality of Life (QOL) upon receiving ICBT vs non-intervention.
- H_0 = 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.

Materials and Methods

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, I_0 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 (I_1), and 6th month (I_2) mark.

It was therefore established that I_0 is the active treatment control (before treatment intervention) and I_1 is audiologist-guided ICBT at intervention + 3 months, and I_2 is post-ICBT intervention +6 months.

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 [19].

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.

Figure 1: 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.

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 2: 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.

ICBT workflow for I₁ (Intervention group)

The intervention actionable are detailed as below.

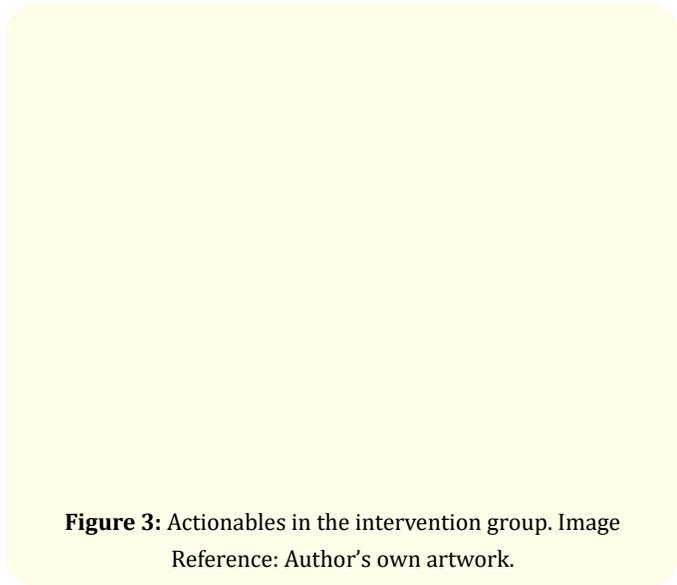


Figure 3: Actionables in the intervention group. Image Reference: Author's own artwork.

Statistical analysis in this study

This study follows the CONSORT guidelines for non-inferiority randomized clinical trials [24].

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.* study in 2012 suggested that a 13 points reduction in the TFI index is deemed clinically significant [19]. Meikle's study was supported by Rabau, *et al.* (2014) [25]. Similar studies regarding ICBT were conducted by Beukes, *et al.* in 2017 using the same measure [14], and the latest study by Frackrell, *et al.* in 2022 has also used the 13 points as the non-inferiority margin in their studies as well [11].

Calculating the sample size

The publicly available SampSize® application was used for the calculation of sample size for non-inferiority parallel groups in this study.

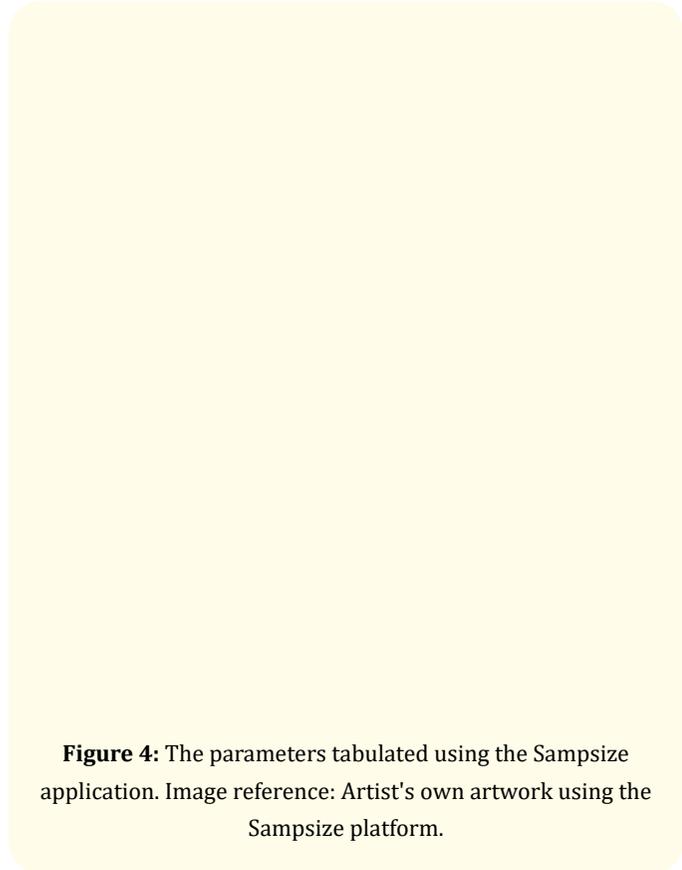


Figure 4: The parameters tabulated using the Sampsize application. Image reference: Artist's own artwork using the Sampsize platform.

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

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.

Results and Discussion

Results and discussion must illustrate and interpret the reliable results of the study.

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.

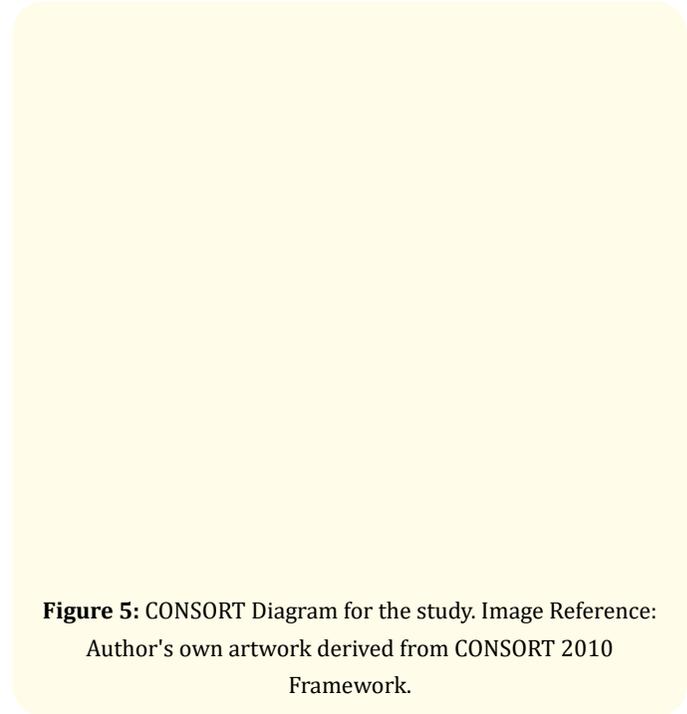


Figure 5: CONSORT Diagram for the study. Image Reference: Author's own artwork derived from CONSORT 2010 Framework.

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 I_0 were from 59-71 (SD = 4.77).

ICBT intervention Groups I1 and I2	
Sex	
Male	25 (62.5%)
Female	15 (37.5%)
Age	
Mean	47.33333
Std Dev	16.08904
Range	23-74
Tinnitus Duration	
Mean	16.25
Std Dev	12.87606
Range	1-45

Figure 6: Demographics of the intervention group. Image from author’s own artwork.

Attrition

Post-ICBT intervention at I_1 and I_2 reported no attrition in the 36 participants. All questionnaires at I_1 and I_2 are completed, with no group differences.

Efficacy of ICBT I_1 and I_2 in comparison to baseline I_0

The within-group effect sizes for TFI, THI, and TRQ were large for both groups at both I_1 and I_2 . At I_2 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 I_1 the mean TFI scores are (M = 43.3, SD = 6,17) and I_2 the mean TFI scores were (M = 34 SD = 5.43). Which are 17.42 and 26.5 points lower respectively, compared with I_0 . These mean differences are lower than the 13-point differences as per Meikle’s study.

Similar results have been observed in THI. Based on the impairment ratings first established by Newman., *et al.* in 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

TFI	Before Intervention, I_0	3-month after intervention, I_1	6-month after intervention I_2
Mean	60.725	43.30556	34.22222
Std Dev	4.771644	6.172841	5.43066
Mean (I0-I1)	17.41944		
Mean (I0-I2)			26.50278
Mean (I1-I2)			9.083333
Cohen’s Ds	0.578723	0.474381	0.542185

Figure 7: 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.

6-month post ICBT intervention (mild) [20]. This corresponds to an impairment rating drop from 10 to 2 based on the framework established by the Australian Government Department of Veteran Affairs [9].

Figure 8: THI Grading based on Newman’s study. Image Reference from CLIK in 2020 [9].

THI	Before Intervention, I_0	3-month after intervention, I_1	6-month after intervention I_2
Mean	56.8	36.11111	35.27778
Std Dev	11.35262	11.26252	8.742707
Mean (I0-I1)	20.68889		
Mean (I0-I2)			21.52222
Mean (I1-I2)			0.833333
Cohen’s Ds	0.29009	0.309176	0.399997

Figure 9: 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.* study in 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 [31]. 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 [9]. This signifies a tremendous improvement in the patient’s overall QOL.

The combined results of the 3 questionnaires at I_1 and I_2 have shown significant improvements from the baseline I_0 , before any form of tinnitus intervention. This proves that the null hypothesis, H_0 is rejected, and H_a 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.

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.

Acknowledgements

NIL.

Conflict of Interest

NIL.

Bibliography

1. Aazh H., et al. "Telehealth tinnitus therapy during the Covid-19 outbreak in the UK: Uptake and related factors". *International Journal of Audiology* 60.5 (2021): 322-327.
2. Al-Samarraie H., et al. "Telemedicine in Middle Eastern countries: Progress, barriers, and policy recommendations". *International Journal of Medical Informatics* 141 (2020): 104232.

Figure 10: TRQ Ratings based on the Wilson et al. study in 1991 [32]. Image Reference from CLIK in 2020 [23].

TRQ	Before Intervention, I0	3-month after intervention, I1	6-month after intervention I2
Mean	74.8	46.639	46.5
Std Dev	9.767	7.0676	7.0529
Mean (I0-I1)	28.161		
Mean (I0-I2)			28.3
Mean (I1-I2)	0.1389		
Cohen's Ds	0.4602	0.6688	0.6749

Figure 11: 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 I_1 and I_2 are as shown in the chart below.

Figure 12: Mean TFI, THI and TRQ Scores vs Pre-intervention, I0. Image from author’s own artwork.

3. Andersson G. "Psychological aspects of tinnitus and the application of cognitive-behavioral therapy". *Clinical Psychology Review* 22.7 (2002): 977-990.
4. Andersson G. "Clinician-supported internet-delivered psychological treatment of tinnitus". *American Journal of Audiology* 24.3 (2015): 299-301.
5. Baguley D., et al. "Tinnitus". *The Lancet* 382.9004 (2013): 1600-1607.
6. Beukes E., et al. "Audiologist-guided internet-based cognitive behavior therapy for adults with tinnitus in the united kingdom: a randomized controlled trial". *Ear and Hearing* 39.3 (2017): 423-433.
7. Beukes E., et al. "Situationally influenced tinnitus coping strategies: a mixed methods approach". *Disability and Rehabilitation* 40.24 (2018): 2884-2894.
8. Cederroth C., et al. "Hearing loss and tinnitus- are funders and industry listening?" *Nature Biotechnology* 31.11 (2013): 972-974.
9. CLIK. "The Consolidated Library of Information and Knowledge (CLIK)". Retrieved from Australian Government Department of Veterans' Affairs (2020).
10. Daoud E., et al. "The Utility of Economic Measures to Quantify the Burden of Tinnitus: A Scoping Review". *Pharmacoeconomics-Open* (2021): 1-12.
11. Frackrell K., et al. "Integrating Distribution-Based and Anchor-Based Techniques to Identify Minimal Important Change for the Tinnitus Functional Index (TFI) Questionnaire". *Brain Sciences* 12.6 (2022): 726.
12. Hailey D., et al. "Systematic review of evidence for the benefits of telemedicine". *Journal of Telemedicine and Telecare* 8 (2002): 1-7.
13. Henry J., et al. "Tinnitus Functional Index: Development, validation, outcomes research, and clinical application". *Hearing Research* 334 (2016): 58-64.
14. Jasper K., et al. "Internet-based guided self-help versus group cognitive behavioral therapy for chronic tinnitus: A randomized controlled trial". *Psychotherapy and Psychosomatics* 83.4 (2014): 234-246.
15. JHBI. "Why is there no cure for tinnitus?" Retrieved from Jacksonville Hearing and Balance Institute At Center One (2022).
16. Langguth B., et al. "Therapeutic approaches to the treatment of tinnitus". *Annual Review of Pharmacology and Toxicity* 59 (2019): 291-313.
17. Mahes I., et al. "Tinnitus: a cost study". *Ear and Hearing* 34.4 (2013): 508-514.
18. McFerran D., et al. "Why is there no cure for tinnitus?" *Frontiers in Neuroscience* (2019): 802.
19. Meikle M., et al. "The tinnitus functional index: development of a new clinical measure for chronic, intrusive tinnitus". *Ear and Hearing* 33.2 (2012): 153-176.
20. Newman C., et al. "Development of the tinnitus handicap inventory". *Archives of Otolaryngology-Head and Neck Surgery* 122.2 (1996): 143-148.
21. NHS Scotland. "Tinnitus". (2021).
22. Oh T., et al. "Telemedicine in Malaysia and Indonesia: The Importance, Opportunities And Challenges". *Journal of Mechanics in Medicine and Biology* 6.4 (2006): 337-348.
23. Patterson M and Balough B. "Review of pharmacological therapy for tinnitus". *International Tinnitus Journal* 12.2 (2006): 149.
24. Piaggio G., et al. "Reporting of noninferiority and equivalence randomized trials: extension of the CONSORT 2010 statement". *JAMA* 308.24 (2012): 2594-604.
25. Rabau S., et al. "Validation and translation of the Dutch tinnitus functional index". *B-ent* 10.4 (2014): 251-258.
26. Ruwaard J., et al. "The effectiveness of online cognitive behavioral treatment in routine clinical practice". *PLoS One* 7.7 (2012): e40089.
27. Singh A., et al. "A review of telemedicine applications in otorhinolaryngology: considerations during the coronavirus disease of 2019 pandemic". *The Laryngoscope* 131.4 (2021): 744-759.
28. Stockdale D., et al. "An economic evaluation of the healthcare cost of tinnitus management in the UK". *BMC Health Services Research* 17.1 (2017): 1-9.
29. Traynor RM. "Heard But Not Seen: innitus and Auditory Hallucinations" (2018).

30. Trochidia I, *et al.* "Systematic Review on Healthcare and Societal Costs of Tinnitus". *International Journal of Environmental Research and Public Health* 18.6881 (2021): 1-11.
31. Tunkel D., *et al.* "Clinical practice guideline: tinnitus". *Otolaryngology-head and Neck Surgery* 151.2 (2014): S1-S40.
32. Wilson P, *et al.* "Tinnitus reaction questionnaire: psychometric properties of a measure of distress associated with tinnitus". *Journal of Speech, Language and Hearing Research* 34.1 (1991): 197-201.