

Audiologist-supported Internet-based Cognitive Behavioral Therapy for Tinnitus in the United States: A Pilot Trial

Eldré W. Beukes,^{1,2} Gerhard Andersson,^{3,4} Marc Fagelson,^{5,6} & Vinaya Manchaiah^{1,7}

1. Department of Speech and Hearing Sciences, Lamar University, Beaumont, Texas, USA

2. Department of Vision and Hearing Sciences, Anglia Ruskin University, Cambridge, UK

3. Department of Behavioral Sciences and Learning, Linköping University, Linköping, Sweden

4. Department of Clinical Neuroscience, Division of Psychiatry, Karolinska Institute, Stockholm, Sweden

5. Department of Audiology and Speech-Language Pathology, East Tennessee State University, Johnson City, Tennessee, USA

6. Audiological Rehabilitation Laboratory, Auditory Vestibular Research Enhancement Award Program, Veterans Affairs Medical Center, Mountain Home, Tennessee, USA

7. Department of Speech and Hearing, School of Allied Health Sciences, Manipal University, Manipal, Karnataka, India

Conflict of Interest

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24 **Address for Correspondence**

25 Eldré Beukes, PhD

26 Department of Speech and Hearing Sciences,

27 P.O. Box: 10076, Lamar University,

28 Beaumont, Texas 77710, USA

29 E-Mail: ebeukes@lamar.edu

30 Tel: +1 (409) 880 8977

31 Fax: +1 (409) 880 2265

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34 **Abstract**

35 **Background:** Patients often report that living with a condition such as tinnitus can be debilitating,
36 worrying, and frustrating. Efficient ways to foster management strategies for individuals with
37 tinnitus and promoting tinnitus self-efficacy are needed. Internet-based cognitive behavioral
38 therapy (ICBT) for tinnitus shows promise as an evidence-based intervention in Europe, but is not
39 available in the United States (US). The aim of this pilot study was to evaluate the feasibility of an
40 ICBT intervention for tinnitus in the US.

41 **Method:** This study reports the Phase 1 trial intended to support implementation of a larger
42 randomized clinical trial (RCT) comparing ICBT to a weekly monitoring group. As a pilot study,
43 a single-group pre-post test design was used to determine outcome potential, recruitment strategy,
44 retention, and adherence rates of ICBT for tinnitus. The primary outcome was a change in tinnitus
45 distress. Secondary outcome measures included measures of anxiety, depression, insomnia,
46 tinnitus cognitions, hearing-related difficulties, and quality of life.

Results: Of the 42 screened participants, 9 did not meet the inclusion criteria and 6 withdrew. There were 27 participants who completed the intervention, with a mean age of 55.48 (± 9.9) years. Feasibility was established, as a large pre-post test effect size of $d = 1.6$ was found for tinnitus severity. Large pre-post test effect sizes were also found for tinnitus cognitions and hearing-related effects and a medium effect was found for insomnia, and quality of life. Treatment adherence varied with a retention rate of 85% ($n = 23$) at post-intervention assessment and 67% ($n = 18$) for the follow-up assessment.

Conclusions: This pilot study supported the feasibility of ICBT for tinnitus in the US. Ways of improving intervention retention and recruitment rates need to be explored in future ICBT studies. Protocol refinements that were identified will be implemented prior to further RCT's to investigate the efficacy of ICBT for tinnitus in the US.

Keywords

Tinnitus, Internet intervention, cognitive behavioral therapy, Tinnitus treatment, e-Health, Teleaudiology, digital therapeutics

Introduction

Although some health-related conditions may not be life-threatening, their effects may produce durable life-changing and debilitating experiences for patients. One such symptom is tinnitus, in which individuals hear sounds in their ears or head that do not originate from the environment. Various conditions are associated with developing tinnitus, including ear disorders (Kostev et al., 2019), exposure to loud noise, presence of a hearing loss and increasing age (Kim et al., 2015). Tinnitus is highly prevalent, with an estimated 10-15% of the adult population reporting hearing

tinnitus (McCormack et al., 2016). Reactions to tinnitus can greatly vary between individuals (Beukes et al., 2020a). Although tinnitus is not bothersome for the majority of individuals, there are millions of individual who find it distressing, resulting in activity limitations and participation restrictions (Manchaiah, et al., 2018a). For those with chronic distressing tinnitus, there are various management strategies that can address quality-of-life issues, coping with tinnitus effects, that that foster individuals' habituation to the tinnitus sensation Audiologists often employ strategies that include directed counselling, sound enrichment, and when indicated by hearing loss, the fitting of hearing aids (Zenner, et al., 2017). In addition to these strategies, however, the strongest evidence-based approach found helpful for addressing negative reactions and behaviors towards tinnitus is a psychological approach known as Cognitive Behavioral Therapy (CBT). Numerous clinical trials and systematic reviews have indicated the efficacy of CBT in tinnitus management (see systematic reviews by Fuller et al., 2020 and Landry et al., 2020). CBT is recommended in most practice guidelines including those provided by the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) (Tunkel, et al., 2014; Fuller, et al., 2017). Despite these recommendations, CBT is seldomly provided to those with tinnitus in the U.S. and the world at large. For instance, a large-scale epidemiological study (n=75,764) in the U.S. showed that CBT was discussed with only 0.2% of patients, whereas the use of medication, for which supporting evidence was weakest, was discussed with 46% of patients (Bhatt, Lin, & Bhattacharyya, 2016). Several barriers limit accessible CBT interventions for tinnitus. These include medicolegal obstacles, such psychologists not being allowed to practice across states. Boundaries between disciplines may reduce the number of clinicians willing to employ strategies for which they are not licensed, few psychologists routinely provide CBT for patients with bothersome tinnitus, and indeed, a limited number of audiologists

93 routinely deliver tinnitus services (Planey, 2019) despite the great need among the clinical
94 population. Although audiologists are generally involved in the management of tinnitus, their
95 primary training is not the use of psychological interventions, and this lack is expressed in the
96 US and most other countries. Although additional training may be obtained, the required
97 resources are not always available to clinical audiologists. Nevertheless, audiologists routinely
98 rely upon tenets of CBT in their counseling when fitting hearing aids, offering falls prevention
99 strategies, and when working with families of patients who receive cochlear implants. Many
100 audiologists focus tinnitus management around sound enrichment and information counselling
101 approaches (Henry et al., 2019) despite familiarity with potentially helpful elements of CBT.
102

103 Due to the efficacy and effectiveness of CBT for tinnitus, there is growing interest among
104 practitioners specializing in the care of patients with bothersome tinnitus to increase access to
105 CBT using creative approaches. One such approach is the development of an Internet-based CBT
106 intervention for tinnitus (ICBT; Andersson, Strömberg, Ström, & Lyttkens, 2002). ICBT was
107 used in Europe and its efficacy demonstrated in nine randomized clinical trials (RCTs) indicating
108 a moderate effect size for both tinnitus distress and insomnia and improvements for anxiety,
109 depression, and quality of life (Beukes, Manchaiah, Allen, Baguley, & Andersson, 2019).
110 Unfortunately, ICBT for tinnitus is not yet routinely offered in the US. The availability of an
111 additional self-help tinnitus intervention, such as ICBT, could improve the accessibility of
112 tinnitus care. Prior to identifying if ICBT may be a suitable approach for a US population, its
113 feasibility first needs to be established. Healthcare and medicolegal practices differ in the US to
114 Europe, where psychologists are for instance not allowed to practice across states. Feasibility for
115 a US population cannot be assumed, as ICBT would be an unfamiliar treatment approach. Most

tinnitus therapies provided in the US, such as Tinnitus Retraining Therapy (TRT) (Jastreboff & Jastreboff, 2000) and Progressive Tinnitus Management (Henry, Zaugg, Myers, & Kendall, 2010), are generally provided in an in-person format, although Henry et al (2019a) recently published a trial delivering PTM via telephone presentation. Acceptance of an internet-based format is thus not known within the US. It is also not known whether those undertaking such an intervention would engage sufficiently or whether they would engage at all with any self-help intervention. It is furthermore not known if a psychological approach will be accepted by audiologists, as the emphasis of most audiology tinnitus management programs is on sound therapy and fitting devices (Henry et al., 2019b; Tyler et al., 2020).

To identify the feasibility of ICBT in the US, a pilot study was undertaken prior to implementing a larger RCT (Leon, Davis, & Kraemer, 2012). In addition we also evaluated outcomes of ICBT. The aim of this study was to run a small-scale pilot study to investigate the feasibility of a full scale RCT in the US population. The research questions were:

- i) Do the outcomes obtained from ICBT for tinnitus indicate that a full-scaled study should be conducted?
- ii) Is the protocol feasible in a US population in terms of recruitment potential, retention rates, intervention compliance, and engagement?

Method

Study Design

This study provided the Phase 1 trial of a larger RCT. Phase I trials are intended to focus on establishing safety of trial, adverse effects, and information on outcomes by involving small

numbers or participants (Mahan, 2014). A single-group pre-post-test design was used to determine the feasibility of ICBT in the USA and identify any adverse effects. On recommendation from the funding body, this was to be an initial small scale study (n =30) without a control group to test the protocol prior to allocating resources to a larger scale study (n = 150). Phase I trials are an important initial part of clinical trials designs for complex interventions (Campbell et al. 2000). Ethical approval was obtained from the Institutional Review Board at Lamar University, Beaumont, Texas, USA (IRB-FY17-209). To ensure that best practice was followed, the Transparent Reporting of Evaluations with Nonrandomized Designs checklist (Des Jarlais, Lyles, Crepaz, & Trend Group, 2004) was used to report this trial. An independent data monitoring committee monitored the running of the trial.

Study Population

To comply with the US government's health promotion initiative requiring health care be linguistically and culturally accessible (U.S Department of Health and Human Services, 2010), all the study materials were made available in both English and Spanish (Beukes, et al., 2019; Manchaiah et al., 2020a). A range of strategies were used to disseminate information, including social media, flyers, emails, forums, and newsletters, which were distributed to local communities and put up in clinic waiting rooms. Professionals such as audiologists and otolaryngologists serving those with tinnitus in southeast Texas were also notified about the study. Those interested were directed to the study website where they could read more about the study and register interest in partaking in the study. Study eligibility was determined as follows:

Inclusion criteria:

- Adults, aged 18 years and over, living in Texas in the US.

- 162 ▪ The ability to read and type in English or Spanish.
- 163 ▪ Access to a computer, the internet and the ability to email.
- 164 ▪ Experiencing tinnitus for a minimum period of three months.
- 165 ▪ A tinnitus severity score of 25 or greater on the TFI indicating the need for an intervention.
- 166 ▪ Any configuration of hearing levels (normal or any degree of hearing loss) and any use of
- 167 hearing devices (using or not using hearing aids)

168

169 *Exclusion criteria:*

- 170 ▪ Indication of significant depression (≥ 15) on the Patient Health Questionnaire (PHQ-9).
- 171 ▪ Indications of self-harm thoughts or intent, answering affirmingly on Question 10 of the
- 172 Patient Health Questionnaire (PHQ-9; Spitzer, Kroenke, Williams, 1999) completed during
- 173 the screening procedure
- 174 ▪ Reporting any major medical or psychiatric conditions.
- 175 ▪ Reporting pulsatile, objective or unilateral tinnitus, which has not been investigated medically
- 176 or tinnitus still under medical investigation.
- 177 ▪ Undergoing any tinnitus therapy concurrent with participation in this study.

178

179 Eligibility was determined by an initial assessment as follows:

- 180 ▪ An online screening questionnaire, which included demographic information, health and
- 181 mental health-related questions, and standardized outcome measures as shown in Table 1.
- 182 ▪ A telephone interview during which the researcher rechecked eligibility, and provided the
- 183 opportunity for potential participants to ask any questions related to the study. The study

procedures were explained, and motivational interviewing was done to encourage participants to commit and engage in the intervention.

- Any participants with a score of 15 or more on the PHQ-9 or indicated self-harm on question 10 received a phone consultation from a clinical psychologist on the research team. This call ensured that they were under care elsewhere or necessary resources and/or referral were provided.

Intervention

The ICBT intervention content was based on a CBT self-help program originally developed in Swedish (Andersson & Viktor, 2004) and translated into German (Weise et al., 2016) and English (Abbott, et al., 2009). The intervention was then adapted into an 8-week interactive e-learning version suitable for a UK population (Beukes, et al., 2016). For the purposes of this pilot investigation, the program employed additional linguistic and cultural adaptations to ensure suitability for a US population (Beukes, et al., 2019). These adaptations included ensuring accessibility of the intervention, such as confirming readability at below the recommended 6th-grade level. The ICBT platform was enhanced further with the addition of a module on mindfulness and adding videos for all modules discussing techniques. As reported herein, the ICBT program employed 22 modules with worksheets and quizzes as outlined in Beukes et al. (2021a).

The intervention platform was housed in the US to comply with mandated data protection regulations. Prior to this feasibility trial, acceptability and functionality of this intervention for a

US population were ensured; details regarding related features and functionality of the intervention were reported previously (Manchaiah, et al., 2020a).

Audiologist Guidance

Guidance was provided to support individuals who participated in the intervention. The study design included monitoring progress, monitoring weekly scores, providing feedback on worksheets completed, outlining the content of new modules, and answering questions. Participants who enrolled, but displayed minimal activity on the platform, were contacted using an encrypted 2-way messaging system within the ePlatform to encourage engagement and discuss possible barriers. Although psychologists have traditionally guided CBT interventions, tinnitus management is generally delivered by Audiologists (Henry et al., 2019b). To maintain consistency with the standard clinical approach to tinnitus management, an experienced Audiologist provided patient support. This approach was shown to be feasible in previous trials in the UK (Beuke et al., 2018a, b). If required further support was available from a specialist tinnitus audiologist or a licensed CBT therapist.

Outcome Measures

Primary Outcome Measure

Tinnitus severity as measured by the Tinnitus Functional Index (TFI) (Meikle et al., 2012) was selected as the primary measure to determine the outcome of ICBT in a pilot US population. The TFI was selected over other tinnitus questionnaires as it was specifically developed to measure tinnitus severity, assess responsiveness to treatment, and for the purpose of comparing results with similar trials in the UK (Beukes et al., 2017). It has been translated into more than 15

languages and been validated for numerous populations including Chinese, Dutch, Swedish and German (Henry et al., 2016).

Secondary Outcome Measures

Secondary outcomes included measures of anxiety, depression, insomnia, tinnitus cognitions, hearing-related difficulties, and health-related quality of life, as shown in Table 1. To reduce the number of questionnaires and questions to be answered, the Tinnitus and Hearing Survey, a 10-item questionnaire (THS; Henry, et al., 2015), was used to identify participant perceptions of hearing disability and hyperacusis. The section on tinnitus also served as a secondary tinnitus measure. The EQ-5D-5L (Herdman, et al., 2011) was selected to measure health-related quality of life. All questionnaires were used with the required permissions and agreements were set up for those that are not freely available to use. For Spanish speakers, validated Spanish translated versions were used. When these were unavailable, the investigators developed validated translations (Manchaiah, et al., 2020b).

[Insert Table 1 around here]

Weekly Monitoring During the Intervention

Throughout the program, participants were monitored weekly by means of the Tinnitus Handicap Inventory, Screening version (THI-S). The THI-S is a 10-item questionnaire and scores are comparable ($r=0.9$) with the full version of the THI (Newman et al, 2008). The weekly score comparison was used as an indication of adverse events. If scores increased by more than 10 points between two consecutive weeks, this was handed as an adverse effect. Those indicating adverse

effects were contacted to address the identified problems. Participants were also monitored by a newly developed Tinnitus Qualities Questionnaire (TQQ; Beukes et al., 2021a). The TQQ measures psychoacoustic tinnitus qualities such as pitch, loudness, and the number of tones heard.

Intervention Variables

Intervention adherence was assessed by determining retention rates and questionnaire completion rates. Intervention engagement was assessed by the number of logins, the number of modules read, and the number of messages sent during the intervention. Intervention satisfaction was measured by collecting participants' views regarding the presentation, content, usability, and information in the intervention using a 0-5 point Likert Scale with a maximum score of 75 points. Messages written and free text responses in the outcome questionnaire were used to identify any adverse effects.

Questionnaire Administration

Online questionnaires were used throughout the study. All the measures were completed pre- and post-intervention, and at two-month follow-up. To maximize retention, 3 electronic reminders were sent to participants who had not completed questionnaires, on the 3 consecutive days after the release of the questionnaire. A further reminder was sent out via email and text message. If questionnaires were still not completed participants were telephoned to encourage questionnaire completion. Participants were also phoned after completing the intervention to discuss the progress they had made and share their questionnaire results.

Data Analysis

Statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) version 26.0. The primary study outcomes of interest were retention, feasibility, and effect size at post-intervention. For all analyses, the goal of this pilot was to estimate the pre-post-test effect size for all primary and secondary outcomes; however 2-sided p -values using $\alpha = 0.05$ were also reported. For some outcome measures more than 15% of data were missing. To account for missing data from participants not completing the post-intervention or follow-up intervention analysis an imputation analysis was undertaken. Missing data were handled through multiple imputation using the *Markov Chain Monte Carlo* approach. In addition, a completers analysis was also performed by analyzing only the completed questionnaire data without imputing missing data. The data that support the findings of this study are openly available in Figshare .

Effect Sizes and Statistical Modelling

Effect sizes (Cohen's d) at post-intervention were calculated by dividing the differences in pre- and post-intervention means by the pooled standard deviations. The reliable change index (RCI) (Jacobson & Truax, 1991) was used as a means of calculating clinical significance for the TFI as the primary outcome. This was calculated using the mean pre-post test score difference, the pretreatment standard deviation, and a test-retest reliability coefficient of 0.78, and as reported in the validation study (Meikle et al, 2012). Finally, linear mixed models with random intercept for patient was used to account for repeated measures and incorporate all available data points in the analysis. The models were used to determine the effect of the pre-intervention scores on follow-up scores. The linear mixed model induces a compound symmetry covariance structure.

Bonferroni-corrected pairwise post hoc tests were applied to determine which timepoints were significantly different, for each variable.

Sample Characteristics

Descriptive statistics including gender, age, tinnitus duration, hearing aid use, and professionals consulted, were used to describe the sample. The mean and standard deviation were reported for each outcome measure at each time point. Descriptive statistics were also used to describe intervention adherence and engagement including the number of logins and modules read.

Results

Participant Characteristics

Of the 42 screened participants, 9 did not meet the inclusion criteria and 6 withdrew (Figure 1). The demographic profile of the remaining 27 participants completing the intervention is shown in Table 2. All participants selected to do the intervention in English, despite ethnicity type.

[Insert Figure 1 around here]

[Insert Table 2 around here]

[Insert Table 3 around here]

Primary Outcome Result

A significant, large effect size was observed for the change in tinnitus severity post-intervention (see Table 3). This change was maintained at 2-month follow-up as shown in Figure 2. The reliable change index indicated a pre-post score difference of 19.51 on the TFI would be a clinically significant change. This was obtained by 22/27 participants (81%) using imputation analysis and 16/23 (70%) of the participants using completers analysis.

[Insert Figure 2 around here]

Secondary Outcome Results

A large effect was found for tinnitus cognitions and medium effect for insomnia, hearing disability, and hyperacusis (see Table 3).

Due to excluding participants who presented with significant levels of depression, the pre-treatment scores, pre-intervention scores for depression and anxiety were below the level of clinical significance. Post-treatment improvements were not found for depression and were only found for anxiety using the imputation analysis protocol, but not for the completers' analysis. A significant effect for overall global quality of life score was found only for the imputation analysis but not for the quality of life visual analogue scale.

Weekly Monitoring

Overall, there was a reduction in tinnitus severity (for the THI-S, $F(7,175) = 2.92, p = .02^*$) and tinnitus qualities (TQQ, $F(7,175) = 3.45, p = .002^*$) over the 8 week intervention period using a linear mixed model, as seen in Figure 3. Pairwise comparison of the THI-S scores in week 1 to subsequent weeks of the intervention displayed significant differences between

weeks 1 and weeks 3 to 8 ($p < .01$). When comparing the TQQ scores in week 1 with subsequent weeks of the intervention, there were significant differences between weeks 1 and weeks 4 to 8 (All p 's $< .01$).

[Insert Figure 3 around here]

Retention, Adherence and Engagement

The completion rate for the post-intervention was 85% and for the follow-up outcome measures 67%. Participant engagement with the intervention was highly variable. During the 8-week intervention, the average number of logins was 20 (SD: 17). An average of 12 (SD: 8) modules were read by participants. During the course of the intervention, participants sent an average of 5 (SD: 5) messages during the course of the intervention and received an average of 17 messages from the audiologist.

All the participants completed at least the first modules' worksheets. For the initial modules, worksheets were generally completed by 16/27 (59%) and for the last modules by 10/27 (37%). Engagement thus decreased during the course of the intervention.

Intervention Satisfaction

An average score of 50/75 (67%) was obtained for the post-intervention satisfaction questionnaire with most questions scoring an average of 3 to 3.5 out of 5 for questions such as suitability of the information, ease of navigation, and benefit of the topics. When answering the open-ended question, participants explained that some of the video captioning was difficult to read and that there were too many worksheets. They felt that more time was needed for the intervention with one participant saying, "*I feel the time frame for the study*

367 *should be longer because the content is excellent but to master the techniques takes longer*
 368 *than the time given.”*

369

370 Participants also mentioned beneficial aspects of the platform, including the range of
 371 techniques provided: *“It was helpful learning about a number of techniques to help me cope.*
 372 *If one was difficult it didn't work for me, I could try something else”* and that it helped them
 373 accept the tinnitus: *“The most positive aspect of this intervention is that I've ACCEPTED my*
 374 *tinnitus. It isn't a negative and I don't dwell on it. I can comfortably own it, and talk about it*
 375 *with friends. I no longer do I feel that my tinnitus is invasive.”* They mentioned finding the
 376 materials helpful for example: *“The materials were informative, interesting, well-presented,*
 377 *and easy to consume. There were very clear instructions and tips for practicing the different*
 378 *techniques. I really liked the videos. Examples cited within the text helped me to expand the*
 379 *ways I could apply concepts and techniques to other parts of my life. The writing was factual*
 380 *yet engaging, and easy to apply to my own situation.”* The guidance was furthermore
 381 beneficial as explained: *“It was great to have a contact at any time with the audiologist when*
 382 *needed. The support was understanding, very positive and helpful throughout. It was a great*
 383 *experience.”*

384

385 **Discussion**

386 The primary objective of this pilot study was to investigate the feasibility of a full scale RCT
 387 regarding ICBT for tinnitus in the US. A pilot study is an essential pre-requisite before
 388 larger-scale RCT's are undertaken (Leon, Davis, & Kraemer, 2012).

389

390 The ICBT intervention reduced tinnitus severity significantly when assessed post-
 391 intervention and the improvements were maintained at 2 months follow-up. For the current

sample, 70% of participants indicated clinically significant changes at post-intervention. Although this outcome may reflect primarily the positive effects of patients receiving tinnitus care, versus no care, the lack of homogeneity in the findings suggests that the notion of providing care, on its own, cannot explain the results. The current results are encouraging and justify further RCTs. Indeed, the findings of this study are in accord with those of the ICBT feasibility trial in the UK (Beukes et al., 2017).

Tinnitus is often accompanied by various comorbidities, particularly co-occurring mental health conditions. To assess intervention effects on these comorbidities, outcome measures for anxiety, depression, insomnia, hearing-related difficulties, tinnitus cognitions, and health-related quality of life were included. The intervention provided a large effect size related to tinnitus cognitions indicating fewer negative cognitions were associated with tinnitus after completing the intervention. This outcome measure has not been used in previous ICBT trials but was recommended to use for tinnitus therapeutic research (Handscomb, Hall, Shorter, & Hoare, 2017). As negative thinking appears to be associated with more problematic tinnitus, intervention reducing such thought patterns are important (Handscomb et al., 2017). Further RCTs are needed to monitor whether and to what degree the ICBT intervention reduces negative tinnitus cognitions.

A medium effect size was found for insomnia, hearing disability, and hyperacusis. This result was encouraging; although significant improvements have been found for insomnia, they have not always been found for hearing disability and hyperacusis in previous trials (e.g., Beukes et al., 2018a,b). Although the intervention improved some comorbid conditions, effects were not significant for anxiety and depression. The exclusion of individuals with severe mental health conditions likely reduced the opportunity to observe an intervention

effect, however such affected individuals may form an important participant group in subsequent trials.

The intervention was offered through an 8 week period and from the weekly measures, it appeared as though a four-week time frame of intervention was sufficient to produce a positive effect, as we previously have reported (Beukes et al, 2018a). These results indicated the feasibility of ICBT in the US as a suitable intervention. Further RCTs would more conclusively determine the efficacy of this intervention.

The protocol feasibility for ICBT delivered to a US population was investigated during this pilot study. Participant analysis indicated that although different ethnic groups were recruited, no participants selected to do the intervention in Spanish. They explained that they preferred health-related materials to be in English as they perceived translated versions as less accurate. Further work on effective recruitment strategies to attract Spanish speakers will be needed. Recruitment through word of mouth, building rapport and trust, and personalizing the benefits of participation were suggested to support recruitment of Hispanic and Latino research participants (Sha et al., 2017). Recognizing cultural differences and building trust within Hispanic communities prior to recruitment should be emphasized to support larger trials (Levkoff & Sanchez, 2003).

The overall retention rate of 82% was consistent with that of the previous ICBT for tinnitus studies with rates between 57-95% (Beukes et al., 2019). These rates were particularly high for earlier studies (e.g., Abbott et al., 2009; Andersson et al., 2002) and have increased with improvements made in later studies. Those who withdrew in the present study indicated the decision was due to time constraints. One person's withdrawal was attributed to the

assessment burden of the intervention. Subsequent trials should further highlight the time demands and provide motivational interviewing at the screening stage to encourage intervention engagement and compliance. Completion for the follow-up questionnaire was only 67%, despite numerous reminders. Although more needs to be done to improve these retention rates, the present rates indicate the feasibility of ICBT within the US, and an effectiveness trial is warranted. Understanding factors contributing to retention in intervention studies is important and undertaking a process evaluation may be helpful to identify strategies to enhance participation (Beukes et al., 2018c).

Intervention engagement was variable. Despite regular therapeutic encouragement, some participants found it difficult to consistently engage with the intervention. Barriers to engagement included time constraints, family and work pressures. An unexpected additional barrier was identified: some participants had previously completed tinnitus retraining therapy, and as part of that protocol, the patients were encouraged to use sound enrichment for at least 8 hours a day. Recall that during the course of the ICBT intervention, participants were asked to not only rely on sound enrichment but also try the other strategies. This approach was very difficult for some participants, who were in the habit of using sound enrichment exclusively, for many years in some cases. Further trials should consider this possible barrier and offer additional instructions for those patients who indicate at intake adherence to a previously-recommended sound therapy regimen. As ICBT is largely a self-help therapeutic approach, it is not going to suit all individuals with tinnitus. For some, progress may be more reasonable if patients receive clinical sessions from a professional, either individually or in a group context. Individuals not progressing or engaging should be directed to other forms of care. ICBT may also not be the most appropriate treatment for those with other serious health conditions which may make it difficult to work on an

intervention independently. Although ICBT has the potential to reach more individuals, it will not suit everyone, and a range of approaches should be available to these people.

Due to the evidence supporting the use of both ICBT and CBT for tinnitus (Fuller et al., 2020; Landry et al., 2020), further ways of delivering these interventions should be sought. Although formulation driven CBT for specific psychological difficulties or conditions should always be provided by a CBT licensed psychologist, guided CBT self-help interventions may be assisted by other professionals, and indeed, tenets of CBT are routinely practiced by audiologists with regard to audiological rehabilitation and falls prevention. Previous studies for other health conditions have indicated that the level of qualification and experience of the professional providing guidance does not appear to affect treatment efficacy (Baumeister et al., 2014). Outcomes have, for instance, been comparable using a psychologist versus a technical assistant for depression (Titov et al., 2010), social phobia (Titov et al., 2009) and anxiety (Robinson et al., 2010). Likewise, no significant difference in outcomes was found when comparing guidance by a psychologist versus a student psychologist for social anxiety (Andersson, Carlbring & Furmark, 2012). Similarly, no difference was found when comparing guidance between psychologists with and without specialist training for anxiety (Johnston et al., 2011). Outcomes have, for instance, been comparable using a psychologist versus a technical assistant for depression (Titov et al., 2010), social phobia. Favorable outcomes were obtained using an audiologist instead of a psychologist for ICBT for tinnitus in the UK population (e.g., Beukes et al., 2018a,b, 2019). Equipping audiologists to deliver or guide psychological interventions such as CBT should be prioritized during audiology training programs and continued professional development opportunities. The importance of available remotely accessible tinnitus interventions have

been highlighted during the tinnitus pandemic, and ways of delivering these should be sought (Beukes et al., 2020c, 2021b).

Overall intervention satisfaction was lower than that reported for ICBT when presented in the UK (Beukes et al., 2018c, d). This was surprising as great efforts were made to ensure that the intervention was culturally and linguistically suitable for this population (Beukes, et al., 2020b; Manchaiah et al., 2020a). Suggestions made by participants in the free text should be implemented to see if satisfaction can be improved. Public involvement in planning and implementing subsequent research phases should consider the factors important to participants (Staniszewska, et al., 2019). Numerous other CBT interventions for tinnitus have been developed (e.g., Aazh, 2020; Schmidt et al., 2018) and increasing evidence for their effects are shown in reducing tinnitus distress and associated problems such as insomnia (e.g., Curtis et al., 2020). Evaluating the components of each to ensure the most suitable intervention is delivered should be investigated with the goal of improving patient outcomes.

Limitations

The results of this study need to be considered in the context of this study. This study represents a pilot investigation to identify the feasibility of ICBT in the US, and the results were not intended to evaluate the efficacy of ICBT as no control group was included and only a small sample was studied. The placebo effect may be present which could elevate findings and need to be considered during result interpretation. Although the results were maintained at 2 months post-intervention, further studies are required to assess whether they are maintained long term. These results could be further explored in a RCT.

Conclusions

Tinnitus is a prevalent condition that can be very debilitating. Ways of increasing access to standardized evidence-based interventions for tinnitus are required. Together with the urgent need to improve access to evidence-based tinnitus interventions, the COVID-19 pandemic has highlighted the need for evidence-based teleaudiology approaches to overcome limited in-person contact. Due to the importance of such remote intervention tools being highlighted during the COVID-19 pandemic, some barriers to implementing internet-interventions may be addressed. ICBT has the potential to reduce the debilitating effects of tinnitus, but is not available in the US. An ICBT intervention was adapted linguistically and culturally for a US population, but its efficacy in an RCT remains unknown. This pilot study has indicated the feasibility of ICBT for tinnitus in the US. The results have been encouraging and further RCTs should be undertaken (Beukes et al., submitted).

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List of Tables

Table 1: Study outcome measures used pre-intervention, post-intervention and at 2-months follow-up

Table 1. Study outcome measures used pre-intervention, post-intervention and at 2-months follow-up

Outcome Measures	Internal consistency	Range of scores	Levels of significance	Assessment timeframe
Tinnitus Functional Index (TFI; Meikle et al, 2012)	.8	0-100	>25= mild 26-50= significant 50+ =severe	Pre, post and follow-up
Generalized Anxiety Disorder (GAD-7, Spitzer, Kroenke, Williams, et al., 2006)	.89	0-21	0-4= minimal anxiety 5-9= mild anxiety 10-14= moderate anxiety 15-21= severe anxiety	Pre, post and follow-up
Patient Health Questionnaire (PHQ-9; Spitzer, Kroenke, Williams, 1999)	.83	0-27	5-9=mild depression 10-14=moderate 15-19=moderately severe 20-18= severe depression	Pre, post and follow-up

Insomnia Severity Index (ISI; Bastien, Vallières, & Morin, 2001)	.74	0-28	0–7 = Not clinically significant 8–14 = Subthreshold insomnia 15–21 = Clinical insomnia (moderate severity) 22–28 = Clinical insomnia (severe degree)	Pre, post and follow-up
Tinnitus Cognitions Questionnaire (TCQ; Wilson & Henry, 1998)	.91	0-104	Higher scores indicate a greater tendency to engage in negative cognitions in response to tinnitus	Pre, post and follow-up
EQ-5D-5L (Herdman, et al., 2011)	.7-.85	0-15	Measures 5 dimensions: mobility, self- care, usual activities, pain/discomfort, and anxiety/ depression	Pre, post and follow-up
EQ-5D-5L Visual Analogue Scale (VAS) (Herdman, et al., 2011)	.7-.85	0-100	VAS for overall health. Higher scores indicated improved health	Pre, post and follow-up
Tinnitus and Hearing Survey (THS; Henry, et al., 2015)	.86-.94		Subscale for Tinnitus: 0-16 Hearing: 0-16 Sound tolerance: 0-8	Pre, post and follow-up
Weekly monitoring				

Tinnitus Handicap Inventory-Screening (THI-S) (Newman, Sandridge, & Bolek, 2008)	.93	0-40	>6 tinnitus handicap	Weekly while undertaking the 8-week intervention
Tinnitus Qualities Questionnaire (TQQ; Beukes, Andersson, Manchaiah, & Kaldo, 2021)	Not assessed	0-100	Designed to determine whether tinnitus qualities such as loudness, pitch, the number of tones heard and so forth improves while undertaking an intervention. Higher scores indicate more bothersome aspects of tinnitus are present.	Weekly while undertaking the 8-week intervention
Intervention satisfaction (Beukes, et al., 2016)	Not assessed	0-75	Higher scores indicate more intervention satisfaction	Post-intervention

Table 1. Study outcome measures used pre-intervention, post-intervention and at 2-months follow-up

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Patient Health Questionnaire (PHQ-9; Spitzer, Kroenke, Williams, 1999)	.83	0-27	5-9=mild depression 10-14=moderate 15-19=moderately severe 20-18= severe depression	Pre, post and follow-up
Insomnia Severity Index (ISI; Bastien, Vallières, & Morin, 2001)	.74	0-28	0–7 = Not clinically significant 8–14 = Subthreshold insomnia	Pre, post and follow-up

Table 2: Demographic characteristics of the participants**Table 2: Demographic characteristics of the participants (n =27)**

DEMOGRAPHICAL INFORMATION	Mean (SD) or number (%)
Gender	18 (67%) female 9 (33%) male
Average age	55.48 ± 9.9 years Range 34-71 years
Tinnitus duration	11.75±13.36 years
Ethnicity	Hispanic or Latino: 2 (7%) Not-Hispanic or Latino 25 (93%)
Race	White 26 (96%) More than one race 1 (4%)
All Professionals seen for tinnitus:	Primary Care Physician 19 (70%)

Note: for some individuals more than one professional was seen	ENT Physician: 23 (85%)
	Audiologist: 24 (89%)
	Neurologist: 3 (11%)
	None: 2 (7%)
Hearing aid use	Bilateral: 7 (26%)
	Unilateral 3 (11%)
	Hearing aids help mask the tinnitus: 4 (40%)
	Hearing aids don't mask the tinnitus: 6 (60%)
Highest educational level	School: 7 (22%)
	College/ vocational training: 10 (31%)
	Undergraduate degree 13 (41%)
	Postgraduate degree: 2 (6%)
Employment	Skilled or professional 21 (78%)
	Retired 6 (22%)

Table 3: Pre, post, and follow-up intervention comparisons for the various outcome measures

Table 3: Pre, post, and follow-up intervention comparisons for the various outcome measures. Results from both the completers and imputation analysis are provided for comparison.

Note: Multiple imputation using the *Markov Chain Monte Carlo* approach was used for imputation analysis. A decrease in scores indicates improvement for all outcomes except for the EQ-5D overall score, where an increase in scores indicates an improvement.

Outcome measure	Pre-Intervention Mean (SD) [range]	Analysis protocol	Post-Intervention Mean (SD)	Follow-up	Effect size, Cohen's <i>d</i> (95% confidence intervals for T0-T1)	Linear Mixed Model, Type III test of fixed effects (using all available data)	<i>T0-T1</i> Pairwise comparison: Mean difference, (SE) (significant *)	<i>T0-T2</i> Pairwise comparison: Mean difference, (SE) (significant *)	<i>T1-T2</i> Pairwise comparison: Mean difference, (SE) (significant *)
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TFI	58.4 (15.01) [24-90]	Completers analysis	29.98 (20.99) [2-86]	29.53 (21.55) [3-84]	1.60 (0.91- 2.23)	$F(2,43) = 34.42, p = .001^*$	28.04 (SE: 3.94); $p = .001^*$	29.48 (SE: 4.30), $p = .001^*$	1.44 (SE: 4.46), $p = 1.00$
		Imputation analysis	29.55 (19.36) [2-86]	29.71 (17.49)	1.76 (1.11- 2.36)				
GAD-7	7.15 (4.68) [1- 17]	Completers analysis	4.57 (4.02) [0- 14]	4.35 (2.42) [0-9]	0.58 (-0.02 to 1.16)	$F(2,39) = 7.07, p = .002^*$	2.74 (SE: .82), $p = .005^*$	2.68 (SE: .91), $p = .01^*$	-.07 (SE: .93), $p = 1.00$
		Imputation analysis	4.69 (3.75) [0- 14]	4.91 (2.43) [0-9]	0.58 (0.03 to 1.12)				
PHQ-9	6.00 (3.17) [0- 12]	Completers analysis	4.91 (3.94) [0- 14]	4.71 (2.78) [1-9]	0.30 (-0.28 to 0.89)	$F(2,39) = 1.99, p = .15$	N/A N/A		

		Imputation analysis	4.76 (3.71) [0-14]	4.52 (2.51) [1-9]	0.36 (-0.18 to 0.89)				
ISI	12.67 (6.50) [2-27]	Completers analysis	8.85 (6.02) [0-20] 7.04 (4.81)	11.53 (6.43) [1-23]	0.61 (-0.01 to 1.19)	$F(2,35) = 7.90, p = .001^*$	4.32 (SE: 1.09), $p = .001^*$	2.43 (SE: 1.16), $p = .13$	-1.90 (SE: 1.20), $p = .37$
		Imputation analysis	8.74 (5.35) [0-20]	10.69 (5.27) [1-23]	0.66 (-0.10 to 1.20)				
EQ-5D-5L	7.33 (1.94) [5-15]	Completers analysis	6.40 (1.19) [5-9]	6.53 (1.18) [5-9]	0.56 (-0.04 to 1.14)	$F(2,32) = 6.73, p = .004^*$.90 (SE: .26), $p = .005^*$.77 (SE: .28), $p = .03^*$	-.13 (SE: .30), $p = 1.00$
		Imputation analysis	6.57 (1.15) [5-9]	6.42 (1.01) [5-9]	0.46 (-0.13 to 1.04)				

EQ-5D-5L VAS	73.85 (16.03) [9-90]	Completers analysis	81.60 (7.50) [70-90]	80.94 (10.35) [50-90]	0.59 (-0.01 to 1.17)	$F(2, 18) = 2.63$, $p = .10$	<i>N/A</i>		
		Imputation analysis	80.71 (6.96) [70-90]	81.01 (8.42) [50-90]	0.56 (0.00 to 1.09)				
THS: Tinnitus	7.15 (4.13 [1-6])	Completers analysis	3.70 (4.47) [0-14]	3.69 (4.27) [0-16]	0.81 (0.19 to 1.39)	$F(2, 36) = 15.17$, $p = .001^*$	3.31 (SE: 0.68), $p = .001^*$	3.28 (SE: .74), $p = .001^*$	-0.03 (SE: 0.77), $p = 1.0$
		Imputation analysis	3.87 (3.91) [0-14]	3.61 (3.54) [0-16]	0.82 (0.25 to 1.36)				

THS: Hearing	7.04 (4.33) [0-16]	Completers analysis	4.05 (3.65) [0-12]	3.69 (3.30) [0-12]	0.74 (0.13) to 1.32)	$F(2,36) = 10.39, p = .001^*$	2.9 (SE: 0.76), $p = .002^*$	3.2 (SE: 0.82), $p = .001^*$.36 (SE: 0.85), $p = 1.0$
		Imputation analysis	4.32 (3.2) [0-12]	3.41 (2.86) [0-12]	0.71 (0.15) to 1.25)				
THS: Sound tolerance	1.33 (1.24) [0-4]	Completers analysis	0.60 (0.82) [0-3]	0.81 (0.98) [0-3]	0.67 (0.07) to 1.26)	$F(2,36) = 7.23, p = .002^*$.76 (SE: .21), $p = .002^*$.48 (SE: .23), $p = .11$	-.29 (SE: .23), $p = .66$
		Imputation analysis	0.61 (0.76) [0-3]	0.84 (0.89) [0-3]	0.70 (0.14) to 1.24)				
TCQ	41.7 (11.37) [22-62]	Completers analysis	29.65 (13.94) [11-57]	29.19 (13.11) [7-48]	1.76 (1.06) to 2.41)	$F(2,37) = 13.87, p = .001^*$	12.00 (SE: 2.63), $p = .001^*$	12.27 (SE: 2.86), $p = .001^*$	-.27 (SE: 2.97), $p = 1.0$

		Imputation analysis	29.47 (12.02) [11-57]	30.01 (10.37) [7-48)	1.05 (0.46 to 1.60)				
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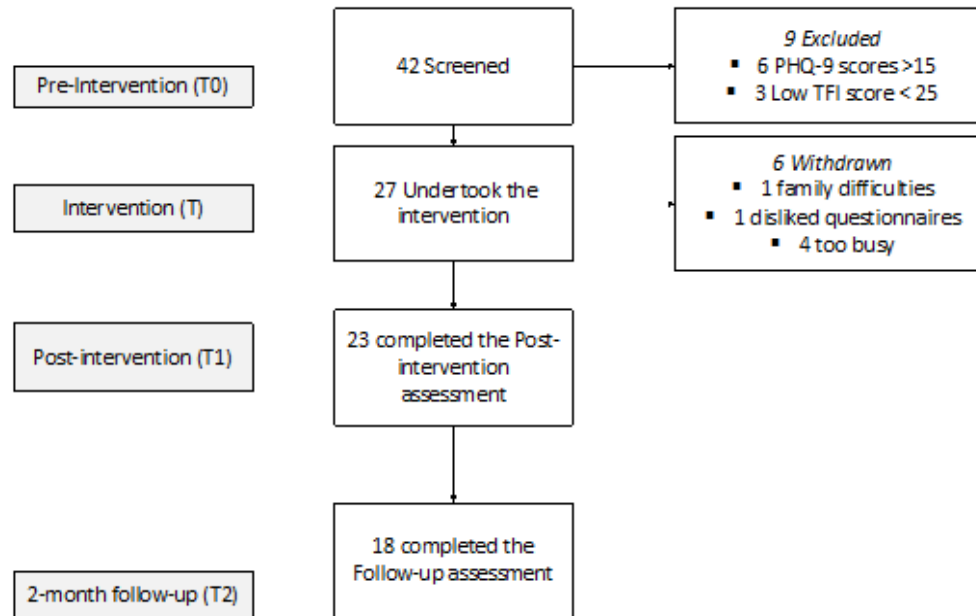
Acronyms: TFI: Tinnitus Functional Index; ISI= Insomnia Severity Index; GAD-7= Generalized Anxiety Disorder-7; PHQ-9= Patient

Health Questionnaire-9; EQ-5D; VAS= EuroQality of life measure, VAS= Visual analogue Scale; THS= Tinnitus Hearing Screener;

TCQ= Tinnitus Cognitions Questionnaire. *Significance at $p < 0.05$

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3 List of Figures



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5 **Figure 1:** Study profile

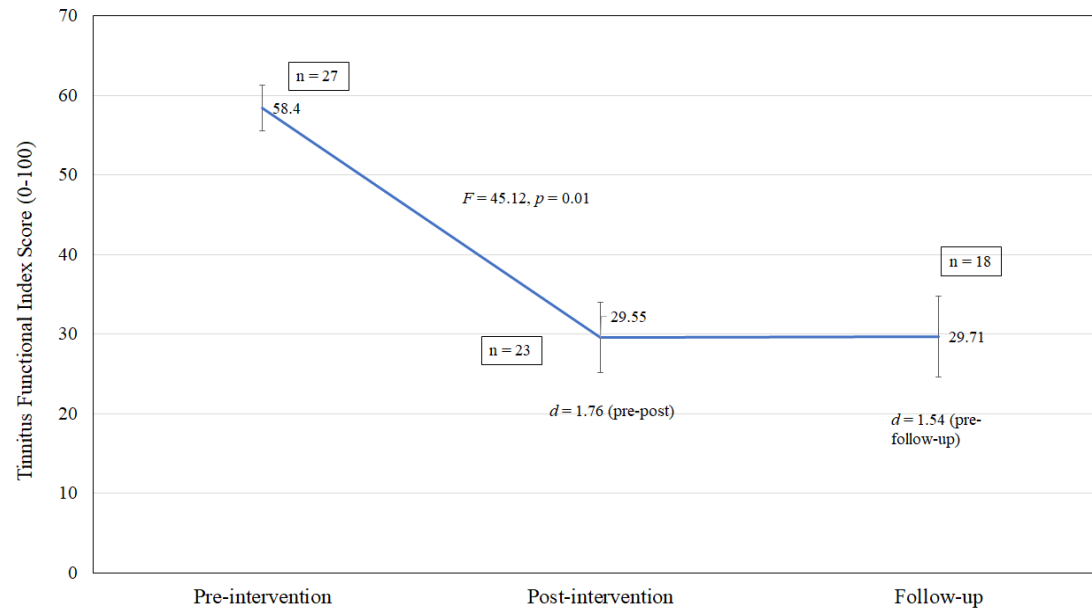


Figure 2: Change in tinnitus distress over time as measured by the Tinnitus Functional Index at Baseline, after the intervention and at 1-year post-intervention.

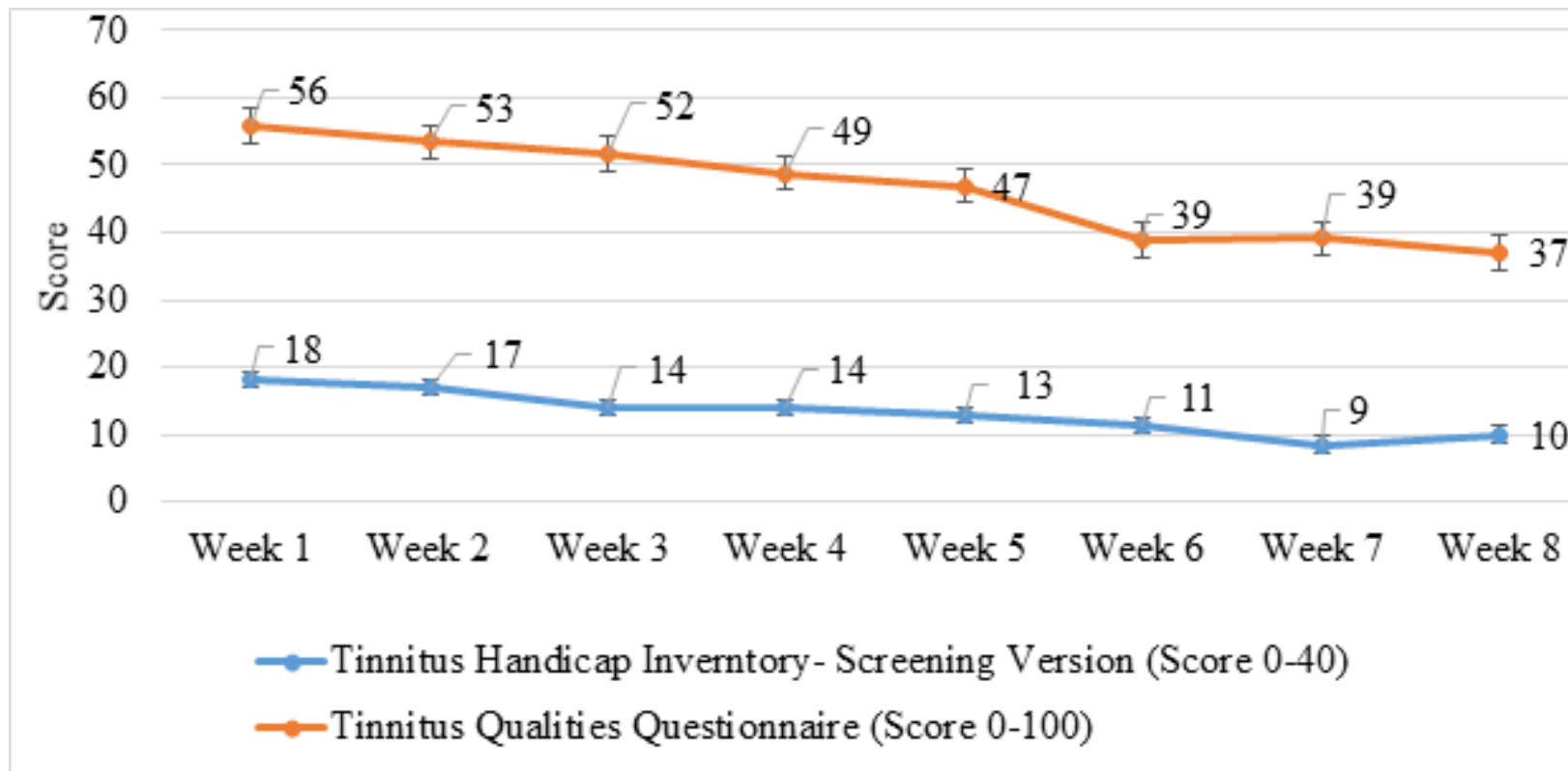


Figure 3: Change in Tinnitus severity and tinnitus qualities during the 8 weeks of the intervention

Data Availability

Data is available in Figshare at <http://doi.org/10.6084/m9.figshare.13678711>.