

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

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17 **Conflict of Interest**

18 There are no relevant conflicts of interest.

19

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33

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.

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

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

58

### 59 **Keywords**

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

62

### 63 **Introduction**

64 Although some health-related conditions may not be life-threatening, their effects may produce  
65 durable life-changing and debilitating experiences for patients. One such symptom is tinnitus, in  
66 which individuals hear sounds in their ears or head that do not originate from the environment.  
67 Various conditions are associated with developing tinnitus, including ear disorders (Kostev et al.,  
68 2019), exposure to loud noise, presence of a hearing loss and increasing age (Kim et al., 2015).  
69 Tinnitus is highly prevalent, with an estimated 10-15% of the adult population reporting hearing

70 tinnitus (McCormack et al., 2016). Reactions to tinnitus can greatly vary between individuals  
71 (Beukes et al., 2020a). Although tinnitus is not bothersome for the majority of individuals, there  
72 are millions of individual who find it distressing, resulting in activity limitations and  
73 participation restrictions (Manchaiah, et al., 2018a). For those with chronic distressing tinnitus,  
74 there are various management strategies that can address quality-of-life issues, coping with  
75 tinnitus effects, that that foster individuals' habituation to the tinnitus sensation Audiologists  
76 often employ strategies that include directed counselling, sound enrichment, and when indicated  
77 by hearing loss, the fitting of hearing aids (Zenner, et al., 2017). In addition to these strategies,  
78 however, the strongest evidence-based approach found helpful for addressing negative reactions  
79 and behaviors towards tinnitus is a psychological approach known as Cognitive Behavioral  
80 Therapy (CBT). Numerous clinical trials and systematic reviews have indicated the efficacy of  
81 CBT in tinnitus management (see systematic reviews by Fuller et al., 2020 and Landry et al.,  
82 2020). CBT is recommended in most practice guidelines including those provided by the  
83 American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) (Tunkel, et al.,  
84 2014; Fuller, et al., 2017). Despite these recommendations, CBT is seldomly provided to those  
85 with tinnitus in the U.S. and the world at large. For instance, a large-scale epidemiological study  
86 (n=75,764) in the U.S. showed that CBT was discussed with only 0.2% of patients, whereas the  
87 use of medication, for which supporting evidence was weakest, was discussed with 46% of  
88 patients (Bhatt, Lin, & Bhattacharyya, 2016). Several barriers limit accessible CBT interventions  
89 for tinnitus. These include medicolegal obstacles, such psychologists not being allowed to  
90 practice across states. Boundaries between disciplines may reduce the number of clinicians  
91 willing to employ strategies for which they are not licensed, few psychologists routinely provide  
92 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

116 tinnitus therapies provided in the US, such as Tinnitus Retraining Therapy (TRT) (Jastreboff &  
117 Jastreboff, 2000) and Progressive Tinnitus Management (Henry, Zaugg, Myers, & Kendall,  
118 2010), are generally provided in an in-person format, although Henry et al (2019a) recently  
119 published a trial delivering PTM via telephone presentation. Acceptance of an internet-based  
120 format is thus not known within the US. It is also not known whether those undertaking such an  
121 intervention would engage sufficiently or whether they would engage at all with any self-help  
122 intervention. It is furthermore not known if a psychological approach will be accepted by  
123 audiologists, as the emphasis of most audiologic tinnitus management programs is on sound  
124 therapy and fitting devices (Henry et al., 2019b; Tyler et al., 2020).

125

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

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

134

## 135 **Method**

### 136 **Study Design**

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

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

#### 149 **Study Population**

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

159

160 *Inclusion criteria:*

- 161 ■ 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 ( $\geq 15$ ) 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

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

186 ■ Any participants with a score of 15 or more on the PHQ-9 or indicated self-harm on question  
187 10 received a phone consultation from a clinical psychologist on the research team. This call  
188 ensured that they were under care elsewhere or necessary resources and/or referral were  
189 provided.

190

### 191 **Intervention**

192 The ICBT intervention content was based on a CBT self-help program originally developed in  
193 Swedish (Andersson & Viktor, 2004) and translated into German (Weise et al., 2016) and  
194 English (Abbott, et al., 2009). The intervention was then adapted into an 8-week interactive e-  
195 learning version suitable for a UK population (Beukes, et al., 2016). For the purposes of this pilot  
196 investigation, the program employed additional linguistic and cultural adaptations to ensure  
197 suitability for a US population (Beukes, et al., 2019). These adaptations included ensuring  
198 accessibility of the intervention, such as confirming readability at below the recommended 6<sup>th</sup>-  
199 grade level. The ICBT platform was enhanced further with the addition of a module on  
200 mindfulness and adding videos for all modules discussing techniques. As reported herein, the  
201 ICBT program employed 22 modules with worksheets and quizzes as outlined in Beukes et al.  
202 (2021a).

203

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

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

208

### 209 **Audiologist Guidance**

210 Guidance was provided to support individuals who participated in the intervention. The study  
211 design included monitoring progress, monitoring weekly scores, providing feedback on  
212 worksheets completed, outlining the content of new modules, and answering questions.  
213 Participants who enrolled, but displayed minimal activity on the platform, were contacted using  
214 an encrypted 2-way messaging system within the ePlatform to encourage engagement and discuss  
215 possible barriers. Although psychologists have traditionally guided CBT interventions, tinnitus  
216 management is generally delivered by Audiologists (Henry et al., 2019b). To maintain consistency  
217 with the standard clinical approach to tinnitus management, an experienced Audiologist provided  
218 patient support. This approach was shown to be feasible in previous trials in the UK (Beuke et al.,  
219 2018a, b). If required further support was available from a specialist tinnitus audiologist or a  
220 licensed CBT therapist.

221

### 222 **Outcome Measures**

#### 223 ***Primary Outcome Measure***

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

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

231

### 232 ***Secondary Outcome Measures***

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

243

244 [Insert Table 1 around here]

245

### 246 ***Weekly Monitoring During the Intervention***

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

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

255

### 256 **Intervention Variables**

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

264

### 265 **Questionnaire Administration**

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

273

274

## 275 **Data Analysis**

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

286

## 287 ***Effect Sizes and Statistical Modelling***

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

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

299

### 300 *Sample Characteristics*

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

305

## 306 **Results**

### 307 **Participant Characteristics**

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

311

312 [Insert Figure 1 around here]

313

314 [Insert Table 2 around here]

315

316 [Insert Table 3 around here]

317 **Primary Outcome Result**

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

323

324 [Insert Figure 2 around here]

325

326 **Secondary Outcome Results**

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

329

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

336

337 **Weekly Monitoring**

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

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

345

346 [Insert Figure 3 around here]

347

### 348 **Retention, Adherence and Engagement**

349 The completion rate for the post-intervention was 85% and for the follow-up outcome measures  
350 67%. Participant engagement with the intervention was highly variable. During the 8-week  
351 intervention, the average number of logins was 20 (SD: 17). An average of 12 (SD: 8) modules  
352 were read by participants. During the course of the intervention, participants sent an average  
353 of 5 (SD: 5) messages during the course of the intervention and received an average of 17  
354 messages from the audiologist.

355

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

359

### 360 **Intervention Satisfaction**

361 An average score of 50/75 (67%) was obtained for the post-intervention satisfaction  
362 questionnaire with most questions scoring an average of 3 to 3.5 out of 5 for questions such  
363 as suitability of the information, ease of navigation, and benefit of the topics. When  
364 answering the open-ended question, participants explained that some of the video captioning  
365 was difficult to read and that there were too many worksheets. They felt that more time was  
366 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

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

398

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

410

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

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

419

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

425

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

436

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

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

450

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

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

469

470 Due to the evidence supporting the use of both ICBT and CBT for tinnitus (Fuller et al.,  
471 2020; Landry et al., 2020), further ways of delivering these interventions should be sought.  
472 Although formulation driven CBT for specific psychological difficulties or conditions should  
473 always be provided by a CBT licensed psychologist, guided CBT self-help interventions may  
474 be assisted by other professionals, and indeed, tenets of CBT are routinely practiced by  
475 audiologists with regard to audiological rehabilitation and falls prevention. Previous studies  
476 for other health conditions have indicated that the level of qualification and experience of the  
477 professional providing guidance does not appear to affect treatment efficacy (Baumeister et  
478 al., 2014). Outcomes have, for instance, been comparable using a psychologist versus a  
479 technical assistant for depression (Titov et al., 2010), social phobia  
480 (Titov et al., 2009) and anxiety (Robinson et al., 2010). Likewise, no significant difference in  
481 outcomes was found when comparing guidance by a psychologist versus a student  
482 psychologist for social anxiety (Andersson, Carlbring & Furmark, 2012). Similarly, no  
483 difference was found when comparing guidance between psychologists with and without  
484 specialist training for anxiety (Johnston et al., 2011). Outcomes have, for instance, been  
485 comparable using a psychologist versus a technical assistant for depression (Titov et al.,  
486 2010), social phobia. Favorable outcomes were obtained using an audiologist instead of a  
487 psychologist for ICBT for tinnitus in the UK population (e.g., Beukes et al., 2018a,b, 2019).  
488 Equipping audiologists to deliver or guide psychological interventions such as CBT should  
489 be prioritized during audiology training programs and continued professional development  
490 opportunities. The importance of available remotely accessible tinnitus interventions have

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

493

494 Overall intervention satisfaction was lower than that reported for ICBT when presented in the  
495 UK (Beukes et al., 2018c, d). This was surprising as great efforts were made to ensure that  
496 the intervention was culturally and linguistically suitable for this population (Beukes, et al.,  
497 2020b; Manchaiah et al., 2020a). Suggestions made by participants in the free text should be  
498 implemented to see if satisfaction can be improved. Public involvement in planning and  
499 implementing subsequent research phases should consider the factors important to  
500 participants (Staniszewska, et al., 2019). Numerous other CBT interventions for tinnitus have  
501 been developed (e.g., Aazh, 2020; Schmidt et al., 2018) and increasing evidence for their  
502 effects are shown in reducing tinnitus distress and associated problems such as insomnia  
503 (e.g., Curtis et al., 2020). Evaluating the components of each to ensure the most suitable  
504 intervention is delivered should be investigated with the goal of improving patient outcomes.

505

### 506 **Limitations**

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

514

### 515 **Conclusions**

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

527

## 528 **References**

- 529 Aazh, H. (2020). Free Internet-based Cognitive Behavioral Therapy (iCBT) for  
530 Tinnitus. *Hearing Review*, 1-6.
- 531 Abbott, J. M., Kaldo, V., Klein, B., Austin, D., Hamilton, C., Piterman, L., & Andersson, G.  
532 (2009). A cluster randomised controlled trial of an Internet-based intervention  
533 program for tinnitus distress in an industrial setting. *Cognitive Behaviour Therapy*,  
534 38(3), 162-173. <http://doi:10.1080/16506070902763174>
- 535 Andersson, G., Carlbring, P., Furmark, T., on behalf of the S.O.F.I.E. Research Group.  
536 (2012). Therapist experience and knowledge acquisition in internet-delivered CBT for social  
537 anxiety disorder: A randomized controlled trial. *PloS One*, 7(5), e37411. [http://doi:](http://doi:10.1371/journal.pone.0037411)  
538 [10.1371/journal.pone.0037411](http://doi:10.1371/journal.pone.0037411)
- 539 Andersson, G., & Kaldo, V. (2004). Internet-based cognitive behavioral therapy for tinnitus.  
540 *Journal of Clinical Psychology*, 60(2), 171-178. <https://doi.org/10.1002/jclp.10243>

- 541 Andersson, G., Strömgren, T., Ström, L., & Lyttkens, L. (2002). Randomized controlled trial  
542 of Internet-based cognitive behavior therapy for distress associated with tinnitus.  
543 *Psychosomatic Medicine*, *64*(5), 810-816.  
544 <http://doi:10.1097/01.psy.0000031577.42041.f8>
- 545 Baumeister, H., Reichler, L., Munzinger, M., & Lin, J. (2014). The impact of guidance on  
546 Internet-based mental health interventions—A systematic review. *internet*  
547 *Interventions*, *1*(4), 205-215. <https://doi.org/10.1016/j.invent.2014.08.003>
- 548 Barrera, M., Castro, F. G., Strycker, L. A., & Toobert, D. J. (2013). Cultural adaptations of  
549 behavioral health interventions: A progress report. *Journal of Consulting and Clinical*  
550 *Psychology*, *81*(2), 196-205. <http://doi:10.1037/a0027085>
- 551 Bastien, C. H., Vallières, A., & Morin, C. M. (2001). Validation of the Insomnia Severity  
552 Index as an outcome measure for insomnia research. *Sleep Medicine*, *2*(4), 297-307.  
553 [http://doi:10.1016/s1389-9457\(00\)00065-4](http://doi:10.1016/s1389-9457(00)00065-4)
- 554 Beukes, E. W., Vlaescu, G., Manchaiah, V., Baguley, D. M., Allen, P. M., Kaldo, V., &  
555 Andersson, G. (2016). Development and technical functionality of an Internet-based  
556 intervention for tinnitus in the UK. *Internet Interventions*, *6*, 6-15.  
557 <http://doi:10.1016/j.invent.2016.08.002>
- 558 Beukes, E. W., Allen, P. M., Manchaiah, V., Baguley, D. M., & Andersson, G. (2017).  
559 Internet-based intervention for tinnitus: Outcome of a single-group open trial.  
560 *American Academy of Audiology*, *12*(4), 340-351. <http://doi:10.3766/jaaa.16055>
- 561 Beukes, E. W., Baguley, D. M., Allen, P. M., Manchaiah, V., & Andersson, G. (2018a).  
562 Audiologist-guided Internet-based cognitive behavior therapy for adults with tinnitus  
563 in the United Kingdom: A randomized controlled trial. *Ear and Hearing*, *39*(3), 423-  
564 433. <http://doi:10.1097/AUD.0000000000000505>

- 565 Beukes, E. W., Andersson, G., Allen, P. M., Manchaiah, V., & Baguley, D. M. (2018b).  
566 Effectiveness of guided Internet-based cognitive behavioral therapy vs face-to-face  
567 clinical care for treatment of tinnitus: A randomized clinical trial. *JAMA*  
568 *Otolaryngology–Head & Neck Surgery*, *144*(12), 1126-1133.  
569 <http://doi:10.1001/jamaoto.2018.2238>
- 570 Beukes, E. W., Manchaiah, V., Baguley, D. M., Allen, P. M., & Andersson, G. (2018c).  
571 Process evaluation of Internet-based cognitive behavioural therapy for adults with  
572 tinnitus in the context of a randomised control trial. *International Journal of*  
573 *Audiology*, *57*(2), 98-109. <http://doi:10.1080/14992027.2017.1384858>
- 574 Beukes, E. W., Manchaiah, V., Davies, A., Allen, P. M., Baguley, D. M., & Andersson, G.  
575 (2018d). Participants' experiences of an Internet-based cognitive behavioural therapy  
576 intervention for tinnitus. *International journal of audiology*, *57*(12), 947–954.  
577 <https://doi.org/10.1080/14992027.2018.1514538>
- 578 Beukes, E. W., Manchaiah, V., Allen, P. M., Baguley, D. M., & Andersson, G. (2019).  
579 Internet-based interventions for adults with hearing loss, tinnitus, and vestibular  
580 disorders: A systematic review and meta-analysis. *Trends in Hearing*, *23*, [http://doi:](http://doi:10.1177/2331216519851749)  
581 [10.1177/2331216519851749](http://doi:10.1177/2331216519851749).
- 582 Beukes, E. W., Manchaiah, V., Allen, P. M., Andersson, G., & Baguley, D. (2020a).  
583 Exploring tinnitus heterogeneity. *Progress in Brain Research*.  
584 <https://doi.org/10.1016/bs.pbr.2020.05.022>
- 585 Beukes, E. W., Fagelson, M., Aronson, E. P., Munoz, M. F., Andersson, G., & Manchaiah, V.  
586 (2020b). Readability following cultural and linguistic adaptation of an Internet-based  
587 intervention for tinnitus for use in the United States. *American Journal of Audiology*,  
588 *29*(2), 97-109. [https://doi.org/10.1044/2019\\_AJA-19-00014](https://doi.org/10.1044/2019_AJA-19-00014).
- 589 Beukes, E. W., Baguley, D. M., Jacquemin, L., Lourenco, M., Allen, P. M., Onozuka, J.,

- 590 Stockdale, D., Kaldo, V., Andersson, G., & Manchaiah, V. (2020c). Changes in  
591 Tinnitus Experiences During the COVID-19 Pandemic. *Frontiers in public health*, 8,  
592 592878. <https://doi.org/10.3389/fpubh.2020.592878>
- 593 Beukes, E., Andersson, G., Manchaiah, V., & Kaldo, V. (2021a). *Cognitive behavioral*  
594 *therapy for tinnitus*. San Diego, USA: Plural Publishing Inc.
- 595 Beukes, E.W., Onozuka, J., Brazell, T., Manchaiah, V. (2021b). Coping with tinnitus during  
596 the COVID-19 pandemic. *American Journal of Audiology*. In press
- 597 Beukes, E.W., Andersson, G., Fagelson, M.A., & Manchaiah, V. Internet-based audiologist-  
598 guided Internet-based cognitive behavioral therapy for tinnitus in the United States: A  
599 randomized controlled trial. *JMIR Preprints*. <https://preprints.jmir.org/preprint/27584>
- 600 Bhatt, J. M., Lin, H. W., & Bhattacharya, N. (2016). Prevalence, severity, exposures, and  
601 treatment patterns of tinnitus in the United States. *JAMA Otolaryngology Head and*  
602 *Neck Surgery*, 142(10), 959-965. <http://doi:10.1001/jamaoto.2016.1700>
- 603 Campbell, M., Fitzpatrick, R., Haines, A., Kinmonth, A. L., Sandercock, P., Spiegelhalter,  
604 D., & Tyrer, P. (2000). Framework for design and evaluation of complex  
605 interventions to improve health. *Bmj*, 321(7262), 694-696.  
606 <https://doi.org/10.1136/bmj.321.7262.694>
- 607 Carman, K. L., Dardess, P., Maurer, M., Shoshanna, S., Adams, K., Bechtel, C., & Sweeney,  
608 J. (2013). Patient and family engagement: A framework for understanding the  
609 elements and developing interventions and policies. *Health Affairs*, 32(2), 223-231.  
610 <http://doi:10.1377/hlthaff.2012.1133>
- 611 Cohen, J. (1992). A power primer. *Psychological Bulletin*, 112(1), 155-159.  
612 <http://doi:10.1037//0033-2909.112.1.155>.
- 613 Curtis, F., Lapidou, D., Bridle, C., Law, G. R., Durrant, S., Rodriguez, A., ... &

- 614 Siriwardena, A. N. (2020). Effects of Cognitive Behavioural Therapy on insomnia in  
615 adults with tinnitus: systematic review and meta-analysis of randomised controlled  
616 trials. *Sleep Medicine Reviews*, 101405. <https://doi.org/10.1016/j.smr.2020.101405>
- 617 Des Jarlais, D. C., Lyles, C., Crepaz, N., & TREND Group. (2004). Improving the reporting  
618 quality of nonrandomized evaluations of behavioral and public health interventions:  
619 The TREND statement. *American Journal of Public Health*, 94(3), 361-366.  
620 <http://doi:10.2105/ajph.94.3.361>
- 621 Fuller, T., Cima, R., Langguth, B., Mazurek, B., Vlaeyen, J., & Hoare, D. (2020). Cognitive  
622 behavioural therapy for tinnitus. *Cochrane Database of Systematic Reviews*.  
623 <http://doi:10.1002/14651858.CD012614.pub2>.
- 624 Fuller, T., Haider, H., Kikidis, D., Lapira, A., Mazurek, B., Norena, A., Rabau, S., Lardinois,  
625 R., Cederroth, C. R., Edvall, N. K., Brueggemann, P. G., Rosing, S. N., Kapandais, A.,  
626 Lungaard, D., Hoare, D. J., & Cima, R. F. F. (2017). Different teams, same  
627 conclusions? A systematic review of existing clinical guidelines for the assessment  
628 and treatment of tinnitus in adults. *Frontiers in Psychology*, 8,  
629 206. <https://doi.org/10.3389/fpsyg.2017.00206>
- 630 Hall, D., Láinez, M., Newman, C., Sanchez, T., Egler, M., Tennigkeit, F., Koch, M., &  
631 Langguth, B. (2011). Treatment options for subjective tinnitus: Self reports from a  
632 sample of general practitioners and ENT physicians within Europe and the USA.  
633 *BMC Health Services Research*, 11(302), <https://doi.org/10.1186/1472-6963-11-302>.
- 634 Handscomb, L., Hall, D., Shorter, G., & Hoare, D. (2017). Positive and negative thinking in  
635 tinnitus: Factor structure of the Tinnitus Cognitions Questionnaire. *Ear and Hearing*,  
636 38(1), 126-132. <http://doi:10.1097/AUD.0000000000000365>
- 637 Hawthorne, K., Robles, Y., Canning-John, R., & Edwards, A. G. (2010). Culturally  
638 appropriate health education for Type 2 diabetes in ethnic minority groups: A

- 639 systematic and narrative review of randomized controlled trials. *Diabetic Medicine*,  
640 27(6), 613-623. <http://doi:10.1111/j.1464-5491.2010.02954.x>
- 641 Henry, J. A., Griest, S., Zaugg, T. L., Thielman, E., Kaelin, C., Galvez, G., & Carlson, K. F.  
642 (2015). Tinnitus and Hearing Survey: A screening tool to differentiate bothersome  
643 tinnitus from hearing difficulties. *American Journal of Audiology*, 24(1), 66-77.  
644 [http://doi:10.1044/2014\\_AJA-14-0042](http://doi:10.1044/2014_AJA-14-0042)
- 645 Henry, J., Griest, S., Thielman, E., McMillan, G., Kaelin, C., & Carlson, K., F. (2016).  
646 Tinnitus functional index: development, validation, outcomes research, and clinical  
647 application. *Hearing Research*, 334, 58-64. <http://doi:10.1016/j.heares.2015.06.004>
- 648 Henry, J. A., Thielman, E. J., Zaugg, T. L., Kaelin, C., McMillan, G. P., Schmidt, C. J.,  
649 Myers, P. J., & Carlson, K. F. (2019). Telephone-Based Progressive Tinnitus  
650 Management for Persons With and Without Traumatic Brain Injury: A Randomized  
651 Controlled Trial. *Ear and Hearing*, 40(2), 227–242.  
652 <https://doi.org/10.1097/AUD.0000000000000609>
- 653 Henry, J., Piskosz, M., Norena, A., & Fournier, P. (2019). Audiologists and tinnitus.  
654 *American Journal of Audiology*, 28(4), 1059-1064.  
655 [https://doi.org/10.1044/2019\\_AJA-19-0070](https://doi.org/10.1044/2019_AJA-19-0070)
- 657 Henry, J., Zaugg, T., Myers, P., & Kendall, C. (2010). *Progressive tinnitus management:*  
658 *Clinical handbook for audiologists*. Long Beach, CA: VA Employee Education  
659 System.
- 660 Herdman, M., Gudex, C., Lloyd, A., Janssen, M., Kind, P., Parkin, D., Bonsel, G., & Badia,  
661 X. (2011). Development and preliminary testing of the new five-level version of EQ-  
662 5D (EQ-5D-5L). *Quality of Life REsearch*, 22(7), 1727-1736.  
663 <http://doi:10.1007/s11136-011-9903-x>

- 664 Jacobson, N. S., & Truax, P. (1991). Clinical significance: A statistical approach to defining  
665 meaningful change in psychotherapy research. *Journal of Consulting and Clinical*  
666 *Psychology*, 59(1), 12-19. <http://doi:10.1037//0022-006x.59.1.12>
- 667 Jasper, J., Weise, C., Conrad, I., Andersson, G., Hiller, W., & Kleinstäuber, M. (2014).  
668 Internet-based guided self-help versus group cognitive behavioral therapy for chronic  
669 tinnitus: A randomized controlled trial. *Psychotherapy and Psychosomatics*, 83(4),  
670 234-246. [http://doi: 10.1159/000360705](http://doi:10.1159/000360705)
- 671 Jastreboff, P. J., & Jastreboff, M. M. (2000). Tinnitus Retraining Therapy (TRT) as a method  
672 for treatment of tinnitus and hyperacusis patients. *Journal of the American Academy*  
673 *of Audiology*, 11(3), 162-177.
- 674 Johnston, L., Titov, N., Andrews, G., Spence, J., & Dear, B. F. (2011). A RCT of a  
675 transdiagnostic internet-delivered treatment for three anxiety disorders: Examination  
676 of support roles and disorder-specific outcomes. *PLoS One*, 6(11), e28079. doi:  
677 [10.1371/journal.pone.0028079](http://doi.org/10.1371/journal.pone.0028079)
- 678 Kim, H. J., Lee, H. J., An, S. Y., Sim, S., Park, B., Kim, S. W., Lee, J. S., Hong, S. K., &  
679 Choi, H. G. (2015). Analysis of the prevalence and associated risk factors of tinnitus in  
680 adults. *PLoS one*, 10(5), e0127578. <https://doi.org/10.1371/journal.pone.0127577>
- 681 Kostev, K., Alymova, S., Kössl, M., & Jacob, L. (2019). Risk Factors for Tinnitus in 37,692  
682 Patients Followed in General Practices in Germany. *Otology & neurotology : official*  
683 *publication of the American Otological Society, American Neurotology Society [and]*  
684 *European Academy of Otology and Neurotology*, 40(4), 436–440.  
685 <https://doi.org/10.1097/MAO.0000000000002161>
- 686 Landry, E. C., Sandoval, X. C. R., Simeone, C. N., Tidball, G., Lea, J., & Westerberg, B. D.  
687 (2020). Systematic review and network meta-analysis of cognitive and/or behavioral

- 688 therapies (CBT) for tinnitus. *Otology & Neurotology*, 41(2), 153-166. [http://doi:](http://doi:10.1097/MAO.0000000000002472)  
689 10.1097/MAO.0000000000002472
- 690 Leon, A. C., Davis, L. L., & Kraemer, H. C. (2012). The role and interpretation of pilot  
691 studies in clinical research. *Journal of Psychiatric Research*, 45(5), 626-629.  
692 <http://doi:10.1016/j.jpsychires.2010.10.008>
- 693 Levkoff, S., & Sanchez, H. (2003). Lessons learned about minority recruitment and retention  
694 from the centers on minority aging and health promotion. *The Gerontologist*, 43(1),  
695 18-26. <http://doi:10.1093/geront/43.1.18>
- 696 Mahan, V. L. (2014). Clinical trial phases. *International Journal of Clinical Medicine*, 5(21),  
697 1374. <http://doi:10.4236/ijcm.2014.521175>
- 698 Manchaiah, V., Beukes, E., Granberg, S., Durisala, N., Baguley, D., Allen, P., & Andersson,  
699 G. (2018a). Problems and life effects experienced by tinnitus research study  
700 volunteers: An exploratory study using the ICF classification. *Journal of the*  
701 *American Academy of Audiology*, 29(10), 936-947. <http://doi:10.3766/jaaa.17094>
- 702 Manchaiah, V., Vlaescu, G., Varadaraj, S., Aronson, E. P., Fagelson, M., Munoz, M. F.,  
703 Andersson, G., & Beukes, E. W. (2020a). Features, functionality, and acceptability of  
704 Internet-based cognitive behavioral therapy for tinnitus in the United States. *American*  
705 *Journal of Audiology*, 1-15.
- 706 Manchaiah, V., Muñoz, M. F., Hatfield, E., Fagelson, M. A., Parks Aronson, E., Andersson,  
707 G., & Beukes, E. (2020b). Translation and adaptation of three English tinnitus patient-  
708 reported outcome measures to Spanish. *International Journal of Audiology*, 59(7), 1-  
709 6. <http://doi:10.1080/14992027.2020.1717006>
- 710 McCormack, A., Edmondson-Jones, M., Somerset, S., & Hall, D. (2016). A systematic  
711 review of the reporting of tinnitus prevalence and severity. *Hearing research*, 337, 70–79.  
712 <https://doi.org/10.1016/j.heares.2016.05.009>

- 713 Meikle, M. B., Henry, J. A., Griest, S. E., Stewart, B. J., Abrams, H. B., McArdle, R., Myers,  
714 P. J., Newman, C. W., Sandridge, S., Turk, D. C., Folmer, R. L., Frederick, E. J.,  
715 House, J. W., Jacobson, G. P., Kinney, S. E., Martin, W. H., Nagler, S. M.,  
716 Reich, G. E., Searchfield, G., . . . Vernon, J. A. (2012). The tinnitus functional index:  
717 development of a new clinical measure for chronic, intrusive tinnitus. *Ear and*  
718 *Hearing, 33*, 153-176 <http://doi:10.1097/AUD.0b013e31822f67c0>
- 719 Newman, C., Sandridge, S., & Bolek, L. (2008). Development and psychometric adequacy of  
720 the screening version of the tinnitus handicap inventory. *Otology & Neurotology,*  
721 *29(3)*, 276-281. <http://doi:10.1097/MAO.0b013e31816569c4>.
- 722 Planey, A. M. (2019). Audiologist availability and supply in the United States: A multi-scale  
723 spatial and political economic analysis. *Social Science & Medicine, 222(2)*, 216-  
724 224. <http://doi:10.1016/j.socscimed.2019.01.015>
- 725 Pretto, A., & Harrison, M. (2011). Family-centred approaches. In R. Seewald & A.M Tharpe  
726 (Eds). *Comprehensive hand-book of pediatric audiology*. (pp. 753-765). San Diego,  
727 CA: Plural Publishing.
- 728 Robinson, E., Titov, N., Andrews, G., McIntyre, K., Schwencke, G., & Solley, K. (2010).  
729 Internet treatment for generalized anxiety disorder: A randomized controlled trial  
730 comparing clinician vs. technician assistance. *PloS One, 5(6)*, e10942.
- 731 Schmidt, C.J., Kerns, R.D., Finkel, S., Michaelides, E., Henry, J.A. (2018). Cognitive  
732 Behavioral Therapy for Veterans With Tinnitus. *Fed Pract, 35(8)*:36-46. PMID:  
733 30766380; PMCID: PMC6263445.
- 734 Sha, M., McAvinchey, G., Quiroz, R., & Moncada, J. (2017). Successful techniques to recruit  
735 Hispanic and Latino research participants. *Survey Practice, 10(3)*, 2778.  
736 <https://doi.org/10.29115/SP-2017-0014>

- 737 Spitzer, R. L., Kroenke, K., & Williams, J. B. (1999). Validation and utility of a self-report  
738 version of PRIME-MD: the PHQ primary care study. *JAMA*, *282*(18), 1737-1744.  
739 <http://doi:10.1001/jama.282.18.1737>
- 740 Spitzer, R. L., Kroenke, K., Williams, J. B. W., & Löwe, B. (2006). A brief measure for  
741 assessing generalized anxiety disorder: The GAD-7. *Archives of Internal Medicine*,  
742 *166*(10), 1092-1097. [http://doi: 10.1001/archinte.166.10.1092](http://doi:10.1001/archinte.166.10.1092).
- 743 Staniszewska, S., Brett, J., Simera, I., Seers, K., Mockford, C., Goodlad, S., . . . Entwistle, A.  
744 (2019). GRIPP2 reporting checklists: Tools to improve reporting of patient and public  
745 involvement in research. *Research involvement and engagement*, *3*(1), 13.  
746 <https://pubmed.ncbi.nlm.nih.gov/28768629/>
- 747 Titov, N., Andrews, G., Davies, M., McIntyre, K., Robinson, E., & Solley, K. (2010).  
748 Internet treatment for depression: A randomized controlled trial comparing clinician  
749 vs. technician assistance. *PloS One*, *5*(6), e10939.
- 750 Titov, N., Andrews, G., Schwencke, G., Solley, K., Johnston, L., & Robinson, E. (2009). An  
751 RCT comparing effect of two types of support on severity of symptoms for people  
752 completing internet-based cognitive behaviour therapy for social phobia. *Australian  
753 and New Zealand Journal of Psychiatry*, *43*(10), 920-926.
- 754 Tunkel, D., Bauer, C., Sun, G., Rosenfeld, R., Chandrasekhar, S., Cunningham Jr, E., Archer,  
755 S. A., Blakley, B. W., Carter, J. M., Granieri, E. C., Henry, J. A., Hollingsworth, D.,  
756 Khan, F. A., Mitchell, S., Monfared, A., Newman, C. W., Omole, F. S., Phillips, C.  
757 D., Robinson, S. K., . . . Whamond, E. J. (2014). Clinical practice guideline: Tinnitus.  
758 *Otolaryngology–Head and Neck Surgery*, *151*(2\_Suppl), S1-S40.  
759 <http://doi:10.1177/0194599814545325>

- 760 Tyler, R., Perreau, A., Powers, T., Watts, A., Owen, R., Ji, H., & Mancini, P. (2020). Tinnitus  
761 sound therapy trial shows effectiveness for those with tinnitus. *Journal of the*  
762 *American Academy of Audiology*, 31(1), 6-16.
- 763 U.S Department of Health and Human Services. (2010). *Healthy People*. Washington, DC:  
764 U.S. Government Printing Office. Retrieved from:  
765 [https://www.cdc.gov/nchs/healthy\\_people/hp2010.htm](https://www.cdc.gov/nchs/healthy_people/hp2010.htm)
- 766 Weise, C., Kleinstäuber, M., & Andersson, G. (2016). Internet-Delivered Cognitive-Behavior  
767 Therapy for Tinnitus: A Randomized Controlled Trial. *Psychosomatic*  
768 *medicine*, 78(4), 501–510. <https://doi.org/10.1097/PSY.0000000000000310>
- 769 Wilson, P., & Henry, J. (1998). Tinnitus Cognitions Questionnaire: Development and  
770 psychometric properties of a measure of dysfunctional cognitions associated with  
771 tinnitus. *International Tinnitus Journal*, 4(1), 23-30.
- 772 Zenner, H.P., Delb, W., Kröner-Herwig, B., Jäger, B., Peroz, I., Hesse, G., Mazurek, B.,  
773 Goebel, G., Gerloff, C., Trollmann, R., Biesinger, E., Seidler, H., & Langguth, B.  
774 (2017). A multidisciplinary systematic review of the treatment for chronic idiopathic  
775 tinnitus. *European Archive of Otorhinolaryngology*, 274, 2079-2091.  
776 <http://doi:10.1007/s00405-016-4401-y>

777

## 778 **Acknowledgments**

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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

<b>Outcome Measures</b>	<b>Internal consistency</b>	<b>Range of scores</b>	<b>Levels of significance</b>	<b>Assessment timeframe</b>
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
<b>Weekly monitoring</b>				

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
<b>Intervention satisfaction</b> (Beukes, et al., 2016)	Not assessed	0-75	Higher scores indicate more intervention satisfaction	Post-intervention

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

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

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

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



<b>TFI</b>	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)				
<b>GAD-7</b>	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)				
<b>PHQ-9</b>	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)				
<b>ISI</b>	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)				
<b>EQ-5D-5L</b>	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)				

<b>EQ-5D-5L VAS</b>	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)	$F(2, 18) = 2.63,$ $p = .10$	N/A		
		Imputation analysis	80.71 (6.96) [70-90]	81.01 (8.42) [50-90]	0.56 (0.00 to 1.09)				
<b>THS: Tinnitus</b>	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)				

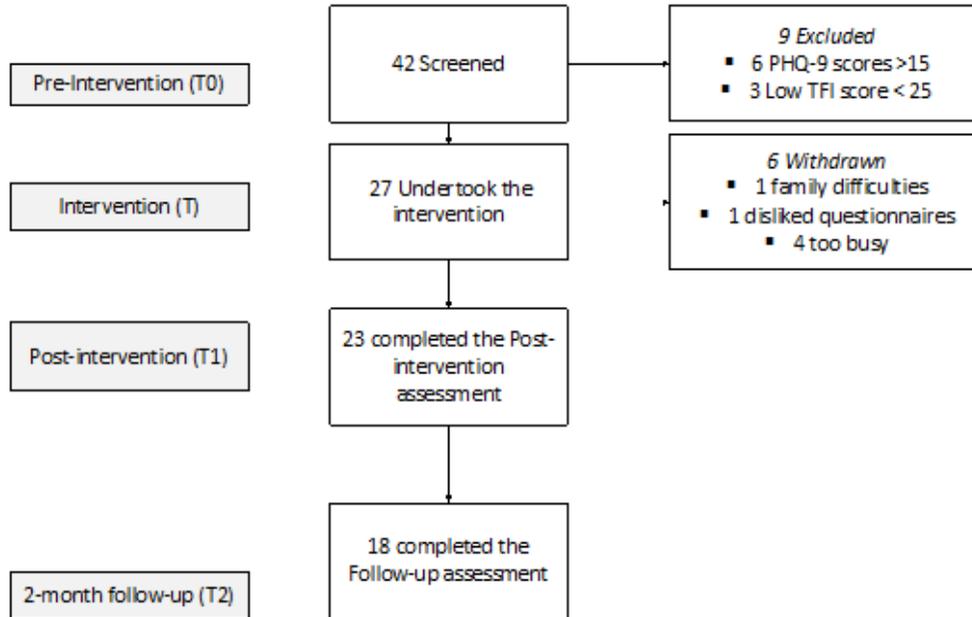
<b>THS: Hearing</b>	7.04 (4.33) [0-16]	Completers analysis	4.05 (3.65) [0-12]	3.69 (3.30) [0-12]	0.74 (0.13) to 1.32)	$F(2,36) = 10.39, p = .001^*$	2.9 (SE: 0.76), $p = .002^*$	3.2 (SE: 0.82), $p = .001^*$	.36 (SE: 0.85), $p = 1.0$
		Imputation analysis	4.32 (3.2) [0-12]	3.41 (2.86) [0-12]	0.71 (0.15) to 1.25)				
<b>THS: Sound tolerance</b>	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)				
<b>TCQ</b>	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= EuroQuality of life measure, VAS= Visual analogue Scale; THS= Tinnitus Hearing Screener; TCQ= Tinnitus Cognitions Questionnaire. \*Significance at  $p < 0.05$

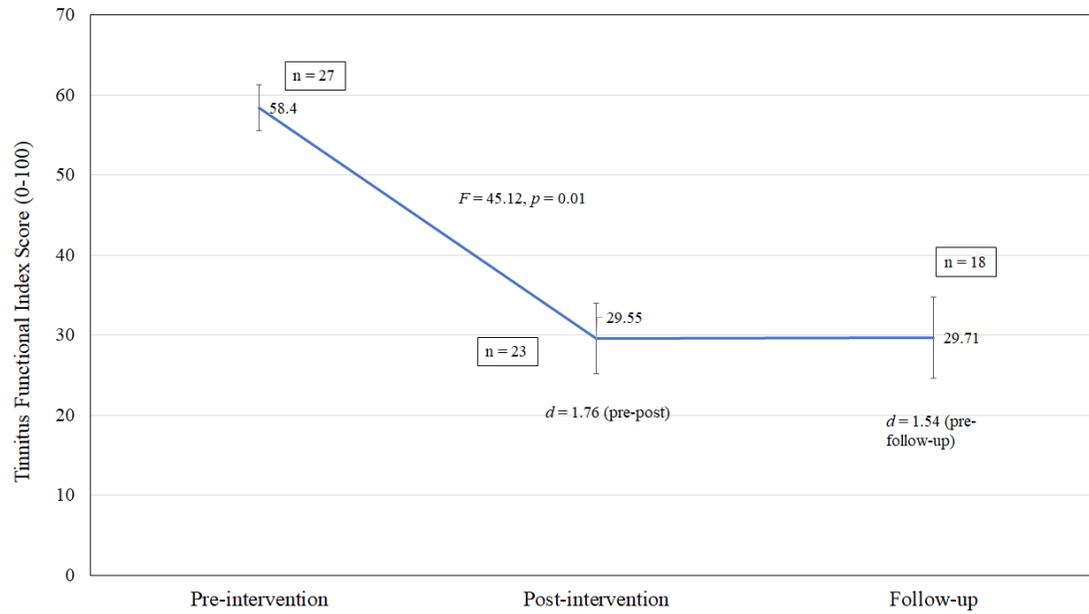
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### 3 List of Figures



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### 5 Figure 1: Study profile

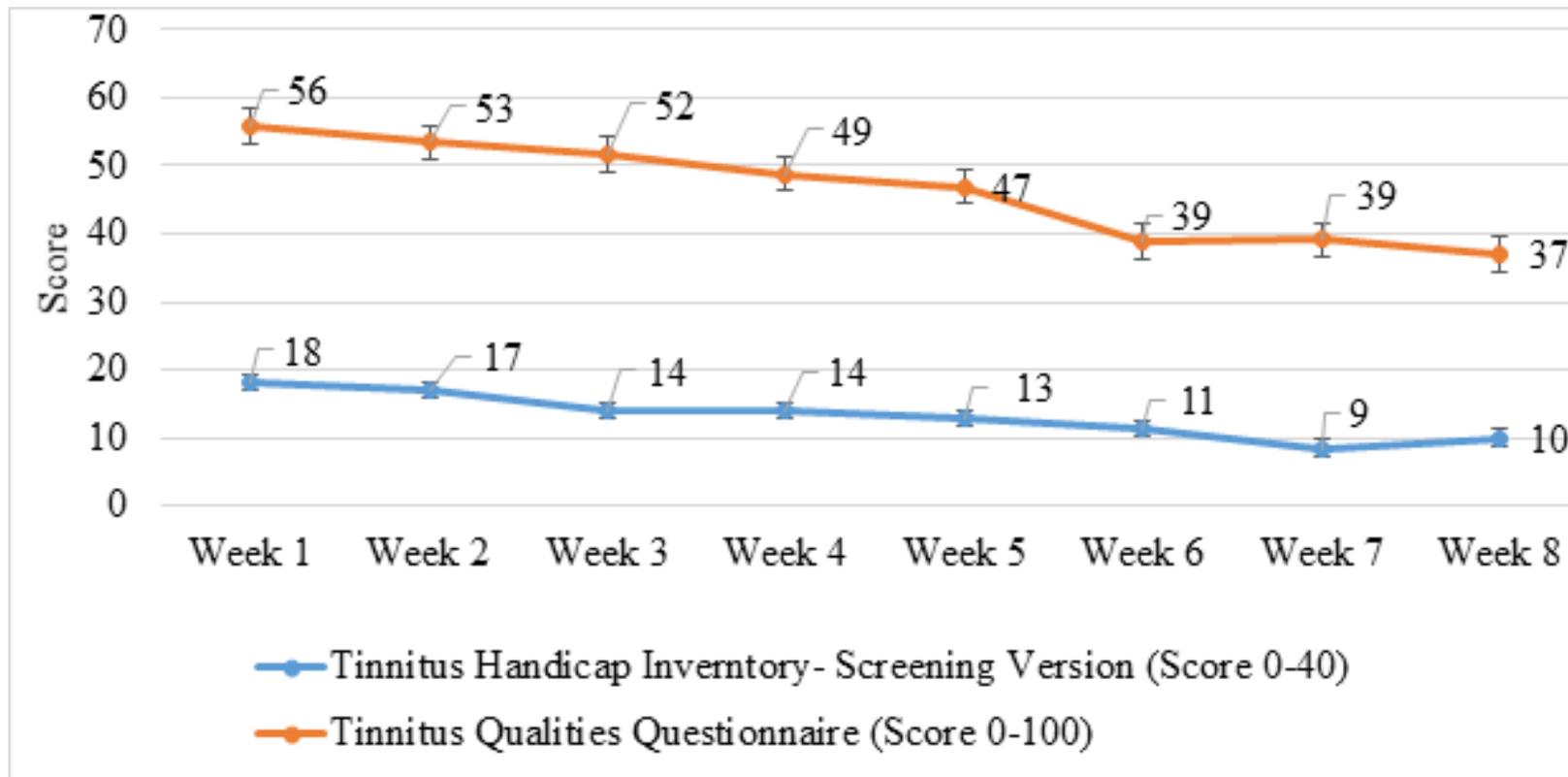


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7 **Figure 2:** Change in tinnitus distress over time as measured by the Tinnitus Functional Index at Baseline, after the intervention and at 1-year  
8 post-intervention.

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11  
 12 **Figure 3:** Change in Tinnitus severity and tinnitus qualities during the 8 weeks of the intervention

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14 Data Availability

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