

1 **Features, functionality, and acceptability of Internet-based cognitive**  
2 **behavioral therapy for tinnitus in the United States**

3

4 **Vinaya Manchaiah,<sup>1,2</sup> George Vlaescu,<sup>3</sup> Srinivas Varadaraj,<sup>4</sup> Elizabeth Parks Aronson,<sup>5</sup>**  
5 **Marc A. Fagelson,<sup>6,7</sup> Maria F. Munoz,<sup>1</sup> Gerhard Andersson<sup>3,8</sup> & Eldré W. Beukes<sup>1,9</sup>**

6

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

8 2. Department of Speech and Hearing, School of Allied Health Sciences, Manipal,  
9 Karnataka, India

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

12 4. Information Technology Services and Support, Lamar University, Beaumont, Texas,  
13 USA

14 5. Department of Psychology, Lamar University, Beaumont, Texas, USA

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

17 7. Audiologic Rehabilitation Laboratory, Auditory Vestibular Research Enhancement  
18 Award Program, Veterans Affairs Medical Center, Mountain Home, Tennessee, USA

19 8. Department of Clinical Neuroscience, Division of Psychiatry, Karolinska Institute,  
20 Stockholm, Sweden

21 9. Department of Vision and Hearing Sciences, School of Psychology and Sport Science,  
22 Anglia Ruskin University, Cambridge, United Kingdom

23

24 **Corresponding author:** Dr. Vinaya Manchaiah  
25 **Communication address:** Department of Speech and Hearing Sciences,  
26 Lamar University, Beaumont, Texas 77710, USA  
27 **Email:** [vinaya.manchaiah@lamar.edu](mailto:vinaya.manchaiah@lamar.edu)  
28 **Tel:** +1 (409) 880 8927  
29 **Fax:** +1 (409) 880 2265

30

### 31 **Conflict of Interest**

32 None to declare.

33

### 34 **Funding**

35 This work was funded by the National Institute on Deafness and Communication Disorders  
36 (NIDCD) of the National Institute of Health (NIH) under the award number R21DC017214.

37

### 38 **Abstract**

39 **Objective:** Although tinnitus is one of the most commonly reported symptoms in the general  
40 population, patients with bothersome tinnitus are challenged by issues related to accessibility of  
41 care and intervention options that lack strong evidence to support their use. Therefore, creative  
42 ways of delivering evidence-based interventions are necessary. Internet-based Cognitive  
43 Behavioral Therapy (ICBT) demonstrates potential as a means of delivering this support, but is  
44 not currently available in the US. This paper discusses the adaptation of an ICBT intervention,  
45 originally used in Sweden, Germany and in the UK, for delivery in the US. The aim of this study  
46 was to (a) modify the web platform's features to suit a US population; (b) adapt its functionality

47 to comply with regulatory aspects, and (c) evaluate the credibility and acceptability of the ICBT  
48 intervention from the perspective of healthcare professionals and patients with bothersome  
49 tinnitus.

50 **Materials/Method:** Initially the iTerapi ePlatform developed in Sweden was adopted for use in  
51 the US. Functional adaptations followed to ensure the platform's functional and security features  
52 complied with both institutional and governmental regulations, and that it was suitable for a US  
53 population. Following these adaptations, credibility and acceptance of the materials were  
54 evaluated by both healthcare professionals (n = 11) and patients with bothersome tinnitus (n = 8).

55 **Results:** Software safety and compliance regulatory assessments were met. Healthcare  
56 professionals and patients reported favorable acceptance and satisfaction ratings regarding the  
57 content, suitability, presentation, usability and exercises provided in the ICBT platform.

58 Modifications to the features and functionality of the platform were made according to user  
59 feedback.

60 **Conclusions:** Ensuring that the ePlatform employed the appropriate features and functionalities  
61 for the intended population was essential to developing the Internet-based interventions. The  
62 favorable user evaluations indicated that the intervention materials were appropriate for the  
63 tinnitus population in the US.

64

## 65 **Key Words**

66 eHealth, Internet interventions, Teleaudiology, Telerehabilitation, Tinnitus, Cognitive behavioral  
67 therapy

68

69

## 70 **Introduction**

71 Various chronic conditions require both medical interventions and self-management to reduce  
72 negative consequences and to improve quality of life for individuals living with these conditions  
73 (Grady & Gough, 2014). Tinnitus is one such chronic symptom for which there is no known  
74 cure. The focus of tinnitus management may be medical, such as the use of pharmaceuticals;  
75 audiological, which emphasizes sound enrichment; or psychological, which may include CBT.  
76 Indeed, the approach with the most evidence of effectiveness in reducing tinnitus distress at  
77 present is the use of cognitive behavioral therapy (CBT; Hesser, Weise, Westin, & Andersson,  
78 2011; Hoare et al. 2011). Its effectiveness is attributed to CBT's focus on facilitating accurate  
79 interpretations of the tinnitus event, as well as enhancing various coping strategies, thereby  
80 helping individuals manage their reactions to tinnitus (Andersson, 2002; Cima, Andersson,  
81 Schmidt, & Henry, 2014; Henry & Wilson, 2001).

82

83 Often patients with bothersome tinnitus do not have access to such evidence-based interventions.  
84 As a result, they may develop negative reactions to and behaviors associated with hearing  
85 tinnitus, which can lead to additional difficulties such as associated anxiety, isolation, depression  
86 and insomnia (Beukes et al., 2017; Martz & Henry, 2016). Therefore, it is essential for those  
87 with chronic tinnitus to have access to interventions that promote positive coping behaviors and  
88 teach strategies for self-management of tinnitus. Historically, the majority of tinnitus  
89 interventions were delivered using face-to-face care (Thompson et al., 2017). To increase the  
90 reach of these interventions, Internet-based provision of CBT (known as ICBT) was tested, with  
91 success, in several countries including Sweden, Germany, and the UK (Andersson et al., 2002;  
92 Beukes et al., 2017, 2018; Weise et al., 2016). Such interventions promoted self-management in

93 patients with bothersome tinnitus and were delivered with and without the support of clinicians.  
94 A systematic review and meta-analysis (Beukes et al. 2019) identified that tinnitus Internet-  
95 interventions were effective interventions in reducing tinnitus distress and other associated  
96 difficulties (e.g., anxiety, depression, insomnia). Results are commensurate with those from face-  
97 to-face clinical care (Beukes et al., 2018). Such results indicate the potential of digital  
98 technologies to provide evidence-based care for individuals with bothersome tinnitus when  
99 provision of tinnitus therapies is limited.

100

101 Despite the strong evidence base regarding CBT for tinnitus, CBT is rarely provided to patients.

102 A large-scale epidemiological survey (n = 75,764) in the US suggests that nearly half of the  
103 individuals (49.4%) with tinnitus discuss their tinnitus with their physicians (Bhatt et al., 2016).

104 The study results suggest that medication, which has the weakest evidence-base for tinnitus  
105 management, is the most frequently recommended management option (i.e., 45.5%) and CBT,  
106 which has the most evidence for tinnitus management is the least recommended management  
107 option (i.e., 0.2%). This may be partly associated with the lack of provision of tinnitus CBT  
108 interventions in the US, a finding that reinforces the great need for accessible evidence-based  
109 tinnitus interventions for the US population. An ICBT intervention may well serve this  
110 population due to the large geographical area and low audiologist/patient ratio in certain regions.  
111 Although ICBT is available, its most recent application for patients with tinnitus is adapted for a  
112 UK population (Beukes et al. 2016); modifications of such an intervention would be required to  
113 ensure its suitability for use in the US. Modifications should ensure security regulations are met  
114 and that the intervention is appropriate for the population of interest. Adaptations can include  
115 language and terminology used in the intervention as well as the features and functionality of the

116 ePlatform used when delivering the intervention. The intervention also must comply with the  
117 institutional, local, regional (state) and national regulations (e.g., Health Insurance Portability  
118 and Accountability Act; HIPAA).

119

120 The aim of this present study was to adapt ICBT to ensure the platform and its implementation  
121 met regulatory standards in the US. A further aim was to evaluate the credibility and  
122 acceptability of the ICBT program from the perspective of healthcare professionals and patients  
123 with bothersome tinnitus. Confirming acceptability was required before undertaking clinical  
124 trials investigating the efficacy of such an intervention.

125

## 126 **Method**

### 127 **Study Design**

128 This study design was comprised of three phases: (I) to identify the key features of the  
129 intervention to include for a US population, (II) to adapt the ePlatform to comply with US  
130 institutional and governmental regulations, and (III) to obtain end-user credibility and  
131 acceptability ratings regarding the intervention and the ePlatform. Ethical approval (IRB-FY17-  
132 209) was obtained from the Institutional Review Board at Lamar University, Beaumont, Texas,  
133 USA.

134

### 135 **Participants**

136 Purposeful sampling was used to recruit participants for each phase according to their expertise  
137 and suitability as follows:

- 138       ▪ **Phase I:** Tinnitus practitioners and researchers were approached to be part of a steering  
139       group. The purpose of this steering group was to identify the features and functions of the  
140       ePlatform from a user-centric perspective to address its appropriateness for the US  
141       population. The group consisted of two psychologists and three audiologists working  
142       with patients with tinnitus and two patients with bothersome tinnitus. Physicians were not  
143       included in the expert group as they were unlikely to be involved in the psychological  
144       therapies and might not be familiar with the use of CBT for patients with bothersome  
145       tinnitus.
- 146       ▪ **Phase II:** Two software engineers with expertise in security features were assigned to be  
147       involved in adjusting the ePlatform features to ensure compliance with regulations.
- 148       ▪ **Phase III:** Healthcare professionals (n = 20 invited) and patients with bothersome  
149       tinnitus (n = 15 invited) were asked to evaluate the credibility and acceptance of the  
150       materials. To ensure a range of views, the healthcare professionals recruited included  
151       audiologists, psychologists, tinnitus researchers, and tinnitus support workers. To ensure  
152       different cultural views were included, both Spanish and English professionals and  
153       patients with tinnitus were approached.

154

### 155 **Phase I: Identification of Key Features and Functionalities of ICBT**

156 Identifying the most appropriate theoretical base and specific intervention for this study was  
157 initially undertaken by considering the various programs available in the US. The ICBT  
158 intervention selected for use for a US population was that originally developed for a Swedish  
159 population (Andersson et al., 2002) and later updated by Andersson and Kaldo-Sandström (2003)  
160 and Kaldo et al. (2007), to address the growing evidence backing this program (e.g., Weise et al.

161 2016, Beukes et al., 2018). The program was furthermore available in multiple languages having  
162 already been translated to English (Abbott, et al., 2009) and German (Jasper, et al., 2014).  
163 Additional updates were implemented, such as adapting the English version into a more  
164 interactive version (Beukes, et al., 2016). However, in order to ensure its suitability to US  
165 population, the program required further modifications. Adaptations were based on intervention  
166 design principles outlined by Beukes et al. (2016), including:

- 167     ▪ Involving a multi-disciplinary team in deciding the content.
- 168     ▪ Updating the evidence-based content of the program to ensure its relevance.
- 169     ▪ Ensuring the comprehensiveness of materials provided, including tailored materials to  
170         suit individual patient needs.
- 171     ▪ Incorporating interactive elements to encourage user engagement, facilitate participation,  
172         promote self-management, enhance self-efficacy and initiate behavior change.
- 173     ▪ Ensuring a user-friendly, uncluttered design to minimize technological barriers that might  
174         increase anxiety.
- 175     ▪ Incorporating a user centric approach by accommodating different learning styles and  
176         cultural adaptations for a US population. These included adding more video explanations  
177         and instructions and sharing relevant additional resources such as smartphone  
178         applications.

179

## 180 **Phase II: ePlatform Adaptation**

181 Initially, the most appropriate ePlatform for this study had to be identified requiring features and  
182 functionalities of various platforms be considered and compared. The ePlatform “iTerapi,”  
183 originally developed in Sweden, was selected for this project as its specific features(see Beukes



184 et al. 2016) and security measures best met the needs for this project (see Vlaescu et al. 2016).  
185 Furthermore, this platform was well tested and used in more than 100 behavior intervention trials  
186 across the globe.

187

188 Following selection, the platform required adaptation to ensure that the security components  
189 complied with both institutional and governmental regulations and met the regulations outlined  
190 by the HIPAA of 1996. HIPAA compliance requires implementation of three types of  
191 safeguards: (1) administrative, (2) physical, and (3) technical. Finally, functional modifications  
192 were made to customize the platform features for a US tinnitus population.

193

### 194 **Phase III: User Credibility and Acceptability Evaluation**

195 The study design for this phase consisted of an independent-measures research design that  
196 established user evaluation of the ICBT content and iTerapi platform. The main goal of this step  
197 was to determine whether the treatment materials and the ePlatform were appropriate for the US  
198 tinnitus population from the perspectives of patients and healthcare professionals whose  
199 practices included tinnitus management. Study participants were recruited using a mixture of  
200 purposeful and convenience sampling methods. Participants who volunteered and consented  
201 were provided full access to the intervention and its interactive elements. 35 participants (20  
202 healthcare professionals and 15 patients with bothersome tinnitus) who were recruited from the  
203 Lamar University Audiology Clinic and also via the American Tinnitus Association (ATA). No  
204 specific criteria were used(?) in recruiting patients with tinnitus, although efforts were made to  
205 recruit healthcare professionals with different background and work experience in the area of  
206 tinnitus management. Only 26 of the 35 invited responded to the email, agreed to participate in

207 the study and were given access to the ICBT program. However, only 19 participants (11  
208 healthcare professionals and 8 patients with bothersome tinnitus) examined the intervention  
209 materials and completed the questionnaires.

210  
211 Access to all the modules was provided at the same time. Brief instructions were provided  
212 regarding the intervention tasks and expectations from the study participants. They were  
213 instructed to familiarize themselves with the ICBT program and the iTerapi ePlatform and spend  
214 as much time as possible evaluating the program features. Participants had a two-month period to  
215 complete the intervention evaluation. The evaluation was a 15-item questionnaire which was  
216 developed by Beukes et al. (2016) to specifically evaluate online interventions. This measure  
217 was designed to consider the suitability, content, usability, presentation, and exercises offered by  
218 online interventions. The response scale included a five-point Likert-scale, with low to high  
219 rating, upon which “1” represented strongly disagree and “5” represented strongly agree. In  
220 addition, four open-ended questions were posed regarding the best aspects of the intervention,  
221 how much time was spent on each module, what elements required attention, and participant  
222 suggestions for further development. Completing the questions was optional for all participants.

223

#### 224 **Data Analysis**

225 Statistical analysis was conducted using IBM SPSS Software Version 24.0. The descriptive  
226 statistics were used to identify sample characteristics such as gender and age. Continuous  
227 variables were summarized with means and standard deviations. Categorical variables were  
228 described using frequencies and percentages. When ordinal data (the individual Likert scale  
229 questions) were present, the median was reported. When the scores from questions were

230 combined (total scores) the mean scores were reported. The distribution of the data was assessed  
231 using the Shapiro Wilk test and normality plots. As the assumption of normality was violated,  
232 Mann-Whitney U test was used to compare usability ratings of health professionals and patientst  
233 with bothersome tinnitus. A  $p$ -value of 0.05 was considered statistically significant.

234  
235 Analysis of the free text responses was undertaken using a thematic analysis framework (Clarke,  
236 Braun, & Hayfield, 2015). Individual statements were coded and similar codes were grouped into  
237 themes. The coverage was calculated by counting the number of times the theme appeared in  
238 relation to the total number of free text comments (with a maximum ratio of 1.0). To verify the  
239 themes selected, the coverage of each theme was identified to ensure it was substantial enough to  
240 be reported. Themes with a low coverage (below 0.1) were excluded due to lack of sufficient  
241 relevance to be reported. The coverage of that theme (the number of times the codes associated  
242 with that theme appeared in the free text comments) was calculated with a maximum possible  
243 coverage value being 1.0 (all free text comments are grouped within this one theme). Themes  
244 with a coverage below 0.1 suggest lack of sufficient relevance are not reported.

245

## 246 **Results**

### 247 **Phase I: ICBT Key Feature Identification**

248 Adaptations of the program were identified by consulting the multi-disciplinary team. The  
249 following modifications were made:

250

251 *Updating the evidence-based content:* A new module on “mindfulness meditation” was added  
252 due to the emerging evidence-base supporting this as an effective method of managing tinnitus

253 (McKenna, Marks, & Vogt, 2018). Additional sections such as ‘research focus’ segments were  
254 added to share research evidence with participants to improve participant motivation.

255

256 ***Ensuring the comprehensiveness and tailoring the materials to suit individual needs:*** The  
257 multi-disciplinary team included experts in tinnitus management who went through the program,  
258 modified the content for comprehensiveness, and identified instances in which tailoring was  
259 required. The final program consisted of 22 modules, of which five were optional (Table 1). It  
260 was determined that running the program over an 8-week period should provide adequate time  
261 for participants to explore the broad range of topics. Modules were carefully organized in a  
262 logical order that started with an overview, followed by simple and important concepts,  
263 subsequently introducing strategies the participants could work through on their own.

264 <Table 1 near here>

265

266 ***Adding interactive elements:*** The ICBT modules included text, images, videos, and exercises  
267 that encouraged user engagement as they ensured an interactive intervention was offered. The  
268 ICBT content and exercises were modified to facilitate behavior change in the novel population,  
269 and were based on the COM-B model (Michie et al., 2011; Thompson et al., 2018). The  
270 worksheets were also revised, for example, one change added a worksheet that would serve as a  
271 record for daily practice, instead of different worksheets for different practice exercises. To  
272 promote behavioral change, a section on goal setting and monitoring for the program was  
273 included. In addition, a short survey to evaluate the most relevant modules for each user were  
274 also included.

275

276 ***Minimizing technological barriers:*** To ensure the intervention enabled behavior change and was  
277 not a barrier, possible technological barriers were identified. Ease of navigation was prioritized  
278 by incorporating user-friendly features; worksheets and processes were simplified. The design  
279 which had the calming background and used in the UK was selected. Images most appropriate  
280 for a US population were included such as photos of familiar US landscapes. Technological  
281 barriers were further reduced by simplifying the language that was used to ensure it was below  
282 the 6<sup>th</sup> reading grade level (Beukes et al., 2020). Figures 1-3 provide examples of the  
283 intervention layout and worksheets.

284 <Figure 1 near here>

285 <Figure 2 near here>

286 <Figure 3 near here>

287

288 ***Incorporating a user centric approach:*** To accommodate this specific population, cultural and  
289 linguistic adaptations were made by using word substitutions, changing examples and modifying  
290 the spelling of certain words (see Beukes et al., 2020). When making cultural adaptations, it was  
291 necessary to consider aspects relevant to the general population as well as the population of  
292 interest (i.e., tinnitus patients) to ensure that the intervention was appropriate for the targeted  
293 culture (Heim & Kohrt, 2019). For this intervention cultural adaptations included matching the  
294 materials with the ethnic, cultural and social context of the population. Adaptations included  
295 modifying the language and examples used to support compatibility with the US cultural  
296 expectations and meanings (for more details see – Beukes et al., 2020). Spelling and use of  
297 words that were unfamiliar or less commonly used in the US were modified to support  
298 participant engagement. In addition, intervention materials and outcome measures were

299 translated into Spanish and cross-checked to improve accessibility for the Spanish-speaking  
300 population (Beukes et al., 2020; Manchaiah et al., 2020). To accommodate auditory and visual  
301 learners, video explanations were added to each module. In addition, an animated video was also  
302 added to the study home pages to encourage engagement for those who preferred obtaining  
303 information about the study visually. This video included information about the study purpose  
304 and intervention design in a way that was easily understandable for the general population.

305

## 306 **Phase II: ePlatform Adaptation**

### 307 *Security Feature Modifications*

308 To ensure the ePlatform was compliant with HIPAA regulations and functionally suitable for a  
309 US population, the following steps were undertaken: First, the location of the ePlatform required  
310 consideration. The iTerapi ePlatform software is installed at the Linköping University server, and  
311 provides international researchers access to software to run their clinical trials, but under the U.S.  
312 law (i.e., HIPAA), health care providers and their business associates are legally accountable for  
313 securing the privacy of patient data. Hence, it was deemed appropriate to store the study data  
314 within the U.S. institution leading the study. In order to achieve this, special permission was  
315 required to have a copy of the iTerapi software installed on the Lamar University server. A  
316 software licensing agreement was established between Linköping University (Sweden) and  
317 Lamar University (US). The agreement was reviewed by the researchers, the IT team, and legal  
318 departments at both universities.

319

320 The next step was to ensure the iTerapi ePlatform met institutional and governmental compliance  
321 specifications for use in the US. The platform was selected due to its superior inbuilt security

322 features as detailed by Vlaescu et al. (2016). These features were assessed and modified where  
323 required by assessing compliance against HIPAA specifications, and assessing the physical  
324 infrastructure and the software systems as follows:

- 325     ▪ ***Administrative safeguarding:*** IT-technicians at the University ensured that the hardware  
326         equipment (servers and network) was constantly running. Redundancy was implemented  
327         by having multiple hardware backups to ensure continuity if one system failed. Full  
328         software backups were created daily, stored in a different building from the live servers,  
329         and were encrypted with a key that only two administrators could access.
- 330     ▪ ***Physical safeguarding:*** Physical safeguarding was ensured by storing the data within the  
331         Lamar University data center infrastructure. The Lamar University data center maintains  
332         the data with standard IT physical security controls and restricts access to only authorized  
333         personnel. The data in the server are fully encrypted and two levels of encrypted backups  
334         are stored elsewhere within the University in separate locations. Moreover, another  
335         backup copy is stored in a geographically separate location.
- 336     ▪ ***Technical safeguarding:*** The information in the database was encrypted using AES-256  
337         algorithms. This ensured that a relationship between the encrypted data on the platform  
338         and individual users was not possible by simply accessing the database. Moreover, the  
339         workstations of therapists were secured with malware and encryption software.

340

### 341 ***Functional Modifications***

342 The most appropriate features of the platform were sought for the study participants. In-depth  
343 discussions between the selected team of experts identified the features and functions of the  
344 ePlatform from a user centric perspective to ensure its appropriateness for the US population. For

345 instance, although there was the option of adding an open discussion forum, in which  
346 participants could interact, this feature was not activated. The omission was intended to prevent  
347 the possibility of negative thoughts or comments from one participant triggering negative  
348 thoughts in other participants. Mixed reactions to such an online forum were reported from users  
349 undertaking a Tinnitus E-Program (Greenwell et al., 2018).

350  
351 Table 2 provides details of features and functions selected for the US population. The ePlatform  
352 was accessed via the public page (Tackling Tinnitus, 2020) by both study participants and  
353 therapists. While the information in the public page was accessible to anyone, the access to  
354 intervention and other facilities were only available to study participants who completed the  
355 screening process and were enrolled in the study. Study participants accessed specific features,  
356 whereas the therapist (or administrator) had their own set of additional features. Figure 4  
357 provides an example of a progress bar graph regarding weekly tinnitus distress.

358 <Table 2 near here>

359 <Figure 4 near here>

360

### 361 **Phase III: User Credibility and Acceptability Evaluation**

#### 362 *Study Participants*

363 Credibility and acceptance of the materials were evaluated by both healthcare professionals (n =  
364 11) and patients with bothersome tinnitus (n = 8). Table 3 provides the demographic details of  
365 study participants.

366

367 <Table 3 near here>



368

369 ***Credibility and Acceptance Ratings***

370 Figure 5 shows the credibility and acceptance ratings of professionals and patients with  
371 bothersome tinnitus regarding the ICBT for English and Spanish language materials. The  
372 average ratings on the full-scale and sub-scales typically were approximately 3.5 on a 5-point  
373 scale suggesting a favorable rating towards ICBT. Table 4 provides the median credibility and  
374 acceptance ratings for individual items. *Appropriate module length* element received the lowest  
375 median rating (i.e., 2.5 to 3), whereas the elements *straightforward to use*, *suitable level of*  
376 *information*, *interesting materials*, *easy to read*, *suitable for those with tinnitus*, and *beneficial*  
377 *topics covered* received the highest median rating (i.e., 4). All three items in the exercise section  
378 received lower median ratings compared to other section. Moreover, closer examination of the  
379 responses suggested that the professionals who had more substantial experience of working with  
380 the tinnitus population evaluated the components of the intervention more favorably with ratings  
381 4 or 4.5 in a 5-point scale in most elements. We did not record how much time the study  
382 participants spent evaluating the ICBT program; doing so could have provided some additional  
383 insights.

384

385 Mann-Whitney  $U$  tests suggested no statistically significant difference between ratings by both  
386 participant groups for overall scale ( $U = 42, p = 0.87$ ) nor the five sub-scales including suitability  
387 ( $U = 42, p = 0.89$ ), content ( $U = 39, p = 0.7$ ), usability ( $U = 38, p = 0.6$ ), presentation ( $U = 43, p$   
388  $= 0.93$ ), and exercises ( $U = 37, p = 0.55$ ).

389 **<Figure 5 near here>**390 **<Table 4 near here>**

391

392 *Perceptions of the Intervention*

393 The optional open-ended questions were examined to identify response patterns. Two  
394 overarching themes were identified: aspects of the program that were beneficial, or those that  
395 were seen as barriers. The program was identified as beneficial as it was informative, had a range  
396 of relevant and usable materials, and provided varied presentation of materials as shown in Table  
397 5. The barriers identified included the functional aspects (i.e., issues with ePlatform interface),  
398 language and module length. Sometimes conflicting ideas were reported. For example, some in  
399 the patient group identified that the information could be simplified whereas professionals  
400 suggested that more complex information about neuroanatomy should be added. Additionally,  
401 some participants in each group reported that the modules were too long and numerous, while  
402 other participants suggested additional modules be included. Some of the professionals also  
403 wanted a greater emphasis on sound enrichment rather than the focus of the materials being on  
404 CBT. When comparing the responses from the English and Spanish participants, coverage was  
405 similar except for the barrier of language. For this aspect the English language coverage was 0.1  
406 and the Spanish coverage was 0.5. A few Spanish participants reported that the language used in  
407 the intervention was too(?) complex to understand.

408 &lt;Table 5 near here&gt;

409

410 **Discussion**

411 In the last decade, reports of various teleaudiological services in the literature range from  
412 diagnosis to rehabilitation (for review see – Beukes et al., 2019; Paglialonga et al. 2028; Tao et  
413 al., 2018). The initial efforts in teleaudiology focus predominantly on screening and diagnostic

414 solutions, although there is now a move towards use of eHealth approaches to management and  
415 rehabilitation. Internet-based interventions allow individuals with hearing-related conditions to  
416 practice condition management by learning and mastering various coping strategies. ICBT for  
417 tinnitus demonstrates as effectiveness in the UK population (Beukes et al., 2017, 2018), .  
418 however, there remains a need to adapt such evidence-based programs to other populations such  
419 as that in the US. This study's focus on the adaptation process, in terms of deciding the features  
420 and functionality and ensuring the ePlatform meets US regulatory standards, also provides  
421 credibility and acceptability ratings of the adapted platform.

422

423 In retrospect, the ePlatform adaptation process was much more time consuming than anticipated.  
424 Time delays were due primarily to the software licensing agreement between the institutions  
425 required before using the software in a local server. Ensuring the study met the HIPAA  
426 requirements was also challenging. Clearly, systems and processes may slow down the  
427 adaptation of evidence-based interventions across cultures and/or countries, thereby hampering  
428 the initiation, sustainability, and scaling up of such digital interventions. Such important  
429 adaptation processes would benefit from clearer delineation of the digital ecosystem across  
430 countries that include social, political, economic, legal, and ethical contexts (Labrique et al.,  
431 2018).

432

433 The cultural and contextual adaptation of evidence-based health interventions are necessary  
434 before evaluating the efficacy, effectiveness, and cost-effectiveness for different populations  
435 (Castro, Barrera, & Holleran Steiker, 2010; Lal et al., 2018; Michie et al., 2017). In this study, an  
436 expert steering group was consulted and ensured the features and functions of the ICBT program

437 were appropriate for patients with bothersome tinnitus in the US. Moreover, extensive revisions  
438 were made to the intervention to ensure cultural and linguistic adaptation (Beukes et al., 2020).  
439 These adaptations were associated with favorable acceptability ratings of ICBT by health  
440 professionals and adults with tinnitus. However, acceptability ratings for many items were lower  
441 than the ratings of ICBT interventions in the UK, which were generally more than 4 on a 5-point  
442 scale (Beukes et al., 2016). These differences could be attributed at least in part to cultural  
443 differences and variances in the healthcare system. The professional group's ratings were  
444 influenced by their perspective that this CBT intervention should include more sound-based  
445 materials and more complex neuroanatomical explanations. Conversely, patients wanted certain  
446 modules to be simplified. These contrasting views were difficult to reconcile. However, all  
447 elements in the exercise section received lower median ratings compared to other sections, which  
448 may suggest need for improving these elements. It could also have been hard for participants  
449 relate to these elements and provide appropriate ratings as the intervention was not actively  
450 followed as such. The exercises thus did not have as much value as they would to someone  
451 working with the intervention on a daily basis. Moreover, Spanish participants made several  
452 comments about difficulties understanding the intervention materials due to the level of  
453 complexity in modules' language. Considering the user feedback in questionnaire ratings and  
454 free-text comments, further adaptations were made to the ePlatform and also ICBT program in  
455 terms of content, length of the chapters, and language complexity in the Spanish version. Efforts  
456 were made to make the exercises simpler and more relevant each module. The appropriateness of  
457 these changes, as well as the adequacy of cultural adaptations related to the way tinnitus is  
458 perceived across cultures, requires testing during subsequent clinical trials. (Heim & Kohrt,  
459 2019).

460  
461 A recent study in the UK suggested that patients have high acceptability of audiologist-delivered  
462 face-to-face CBT program (Aazh, Bryant, and Moore, 2019). High acceptability was also noted  
463 in the ICBT trials in the UK (Beukes et al., 2016). Hence, continued monitoring to evaluate the  
464 acceptance and satisfaction of ICBT will take place during the planned clinical trials in the US.  
465 We anticipate a higher acceptance rating in further evaluations as a result of the implemented  
466 changes. Such changes would be important to improve credibility ratings of the intervention  
467 before widespread use. Realistic expectations of the intervention should be provided prior to  
468 patients undertaking the program. As those with tinnitus represent a heterogeneous population,  
469 different users may also prefer certain elements of the program. When evaluating perceptions of  
470 a Tinnitus E-Program, Greenwell et al. (2018) identified that users valued the content and skills  
471 training more than the self-monitoring tools, online support forum and therapist support. The  
472 themes identified from participant experience undertaking ICBT in the UK were similar in terms  
473 of the benefit of the program being due to its informative nature of the material and the  
474 convenient access thereto (Beukes, Manchaiah, Davies, et al. 2018). Conversely, some  
475 participants also found the length too long. Overall, the user evaluations of ICBT in the current  
476 study were positive, and comparable to user evaluations of previous studies from the UK  
477 (Beukes et al., 2016; Greenwell et al., 2018).

478

### 479 **Study Limitations**

480 The study has a few limitations. First, the expert steering group only included five healthcare  
481 professionals who were based in the southern part of the US. A more representative group of  
482 professionals from across the US would have provided more in-depth suggestions and feedback

483 in cultural and linguistic adaptation. Second, the study sample included in user evaluations were  
484 predominantly from the same ethnic and educational backgrounds (white and highly educated).  
485 Hence, the study results provide a preliminary understanding and are not necessarily  
486 generalizable. Further studies should be undertaken with a participants from different cultural  
487 groups.

488

## 489 **Conclusions**

490 Due to the rise of digital therapeutics in healthcare, we expect that there will be more clinicians  
491 and researchers adapting evidence-based health interventions from other cultures and/or  
492 countries. We believe that the framework presented this paper could aid those who are interested  
493 in such work. Moreover, the features and functionalities of Internet-interventions discussed in  
494 this manuscript could also be of interest to wider stakeholders including the patient organizations  
495 (e.g., ATA) and technology companies involved in the development of digital therapeutics.

496

## 497 **Acknowledgements**

498 We would like to American Tinnitus Association (ATA) for helping in finding the study  
499 participants.

500

## 501 **References**

502 Aazh, H., Bryant, C., Moore, B.C.J (2019). Patients' Perspectives About the Acceptability and  
503 Effectiveness of Audiologist-Delivered Cognitive Behavioral Therapy for Tinnitus and/or  
504 Hyperacusis Rehabilitation. *American Journal of Audiology*, 28(4), 973-985.  
505 [https://doi.org/10.1044/2019\\_AJA-19-0045](https://doi.org/10.1044/2019_AJA-19-0045)

- 506
- 507 Abbott, J. M., Kaldo, V., Klein, B., Austin, D., Hamilton, C., Piterman, L., & Andersson, G.  
508 (2009). A cluster randomised controlled trial of an Internet-based intervention program for  
509 tinnitus distress in an industrial setting. *Cognitive Behaviour Therapy*, 38, 162-173.
- 510
- 511 Andersson, G. (2002). Psychological aspects of tinnitus and the application of cognitive-  
512 behavioral therapy. *Clinical Psychology Review*, 22, 977-990.
- 513
- 514 Andersson, G., and V. Kaldo-Sandstrom. (2003). Treating Tinnitus via the Internet. *CME*  
515 *Journal Otorhinolaryngology, Head and Neck Surgery*, 7, 38–40.
- 516
- 517 Andersson, G., Stromgren, T., Strom, L., & Lyttkens, L. (2002). Randomized controlled trial of  
518 internet-based cognitive behavior therapy for distress associated with tinnitus. *Psychosomatic*  
519 *Medicine*, 64(5), 810–816.
- 520
- 521 Beukes, E. W., Vlaescu, G., Manchaiah, V., Baguley, D. M., Allen, P. M., Kaldo, V., &  
522 Andersson, G. (2016). Development and technical functionality of an Internet-based intervention  
523 for tinnitus in the UK. *Internet Interventions*, 6, 6-15.  
524 <https://doi.org/10.1016/j.invent.2016.08.002>
- 525
- 526 Beukes, E. W., Baguley, D. M., Allen, P. M., Manchaiah, V., & Andersson, G. (2017).  
527 Audiologist-guided internet-based cognitive behavior therapy for adults with tinnitus in the

- 528 United Kingdom: A randomized controlled trial. *Ear and Hearing*, 39(3), 423–433.  
529 <https://doi.org/10.1097/AUD.0000000000000505>  
530
- 531 Beukes, E. W., Andersson, G., Allen, P. M., Manchaiah, V., & Baguley, D. M. (2018).  
532 Effectiveness of guided internet-based cognitive behavioural therapy vs face-to-face clinical care  
533 for treatment of tinnitus. A randomized clinical trial. *JAMA Otolaryngology–Head & Neck*  
534 *Surgery*, 144(12), 1126-1133. <https://doi.org/10.1001/jamaoto.2018.2238>  
535
- 536 Beukes, E. W., Manchaiah, V., Allen, P. M., Baguley, D. M., & Andersson, G. (2019). Internet-  
537 based interventions for adults with hearing loss, tinnitus, and vestibular disorders: A systematic  
538 review and meta-analysis. *Trends in Hearing*, 23. <https://doi.org/10.1177/2331216519851749>  
539
- 540 Beukes, E. W., Manchaiah, V., Davies, A. S., Allen, P. M., Baguley, D. M., & Andersson, G.  
541 (2018). Participants’ experiences of an Internet-based cognitive behavioural therapy intervention  
542 for tinnitus. *International Journal of Audiology*, 57(12), 947-954.  
543
- 544 Beukes, E.W., Manchaiah, V., Fagelson, M.A., Aronson, E.P., Munoz, M.F., & Andersson, G.  
545 (2020). Readability following cultural and linguistic adaptations of an Internet-based  
546 Intervention for Tinnitus for use in the United States. *American Journal of Audiology*, Published  
547 Online.  
548
- 549 Beukes, E. W., V. Manchaiah, G. Andersson, P. M. Allen, P. M. Terlizzi, and D.  
550 M. Baguley. (2018). Situationally influenced tinnitus coping strategies: A mixed methods



- 551 approach. *Disability and Rehabilitation*, 40(24):2884-2894.  
552 <https://doi.org/10.1080/09638288.2017.1362708>  
553
- 554 Bhatt, J. M., Lin, H. W. & Bhattacharyya, N. (2016). Prevalence, severity, exposures, and  
555 treatment patterns of tinnitus in the United States. *JAMA Otolaryngol. Neck Surg*, 92697, 1–7.  
556
- 557 Castro, F. P., Barrera, M., & Holleran Steiker, L. K. (2010). Issues and challenges in the design  
558 of culturally adapted evidence-based interventions. *Annual Review of Clinical Psychology*, 6,  
559 213-239.  
560
- 561 Cima, R. F. F., Andersson, G., Schmidt, C., & Henry, J. A. (2014). Cognitive-behavioral therapy  
562 for tinnitus: A review of literature. *Journal of the American Academy of Audiology*, 25, 29-61.  
563
- 564 Clarke, V., Braun, V., & Hayfield, N. (2015). Thematic analysis. *Qualitative psychology: A*  
565 *Practical Guide to Research Methods*, 222-248.  
566
- 567 Grady, P. A., & Gough, L. L. (2014). Self-management: a comprehensive approach to  
568 management of chronic conditions. *American Journal of Public Health*, 104(8), e25–e31.  
569 <https://doi.org/10.2105/AJPH.2014.302041>  
570
- 571 Greenwell, K., Sereda, M., Coulson, N. S., & Hoare, D. J. (2019). Understanding user reactions  
572 and interactions with an Internet-based intervention for tinnitus self-management: Mixed-  
573 methods evaluation. *American Journal of Audiology*, 28(3), 697-713.

574

575 Heim, E., & Kohrt, B. A. (2019). Cultural adaptation of scalable psychological interventions: A  
576 new conceptual framework. *Clinical Psychology in Europe*, 1(4), 1-22.

577 <https://doi.org/10.32872/cpe.v1i4.37679>

578

579 Henry, J.L. & Wilson, P.H. (2001). *Tinnitus: A Self-Management Guide for the Ringing in Your*  
580 *Ears*. Allyn and Bacon: Boston, MA, USA.

581

582 Hesser H, Weise C, Westin VZ, Andersson G. (2011). A systematic review and meta-analysis of  
583 randomized controlled trials of cognitive-behavioral therapy for tinnitus distress. *Clin Psychol*  
584 *Rev*, 31(4), 545-553.

585

586 Hoare, D. J., Kowalkowski, V. L., Kang, S., & Hall, D. A. (2011). Systematic review and meta-  
587 analyses of randomized controlled trials examining tinnitus management. *The*

588 *Laryngoscope*, 121(7), 1555-1564. <https://doi.org/10.1002/lary.21825>

589

590 Jasper, J., Weise, C., Schweda, I., Andersson, G., Hiller, W., & Kleinstäuber, M. (2014).

591 Internet-based guided self-help versus group cognitive behavioral therapy for chronic tinnitus: A  
592 randomized controlled trial. *Psychotherapy and Psychosomatics*, 234-246.

593

594 Kaldo, V., S. Cars, M. Rahnert, H. C. Larsen, and G. Andersson. (2007). Use of a Self-help Book  
595 with Weekly Therapist Contact to Reduce Tinnitus Distress: a Randomized Controlled Trial.

596 *Journal of Psychosomatic Research*, 63, 195–202.

597

598 Labrique A, Vasudevan L, Weiss W, Wilson K. (2018). Establishing standards to evaluate the  
599 impact of integrating digital health into health systems. *Glob Health Sci Pract*, 6(1), S5–17.

600

601 Lal S, Gleeson J, Malla A, Rivard L, Joober R, Chandrasena R, et al. (2018). Cultural and  
602 Contextual Adaptation of an eHealth Intervention for Youth Receiving Services for First-  
603 Episode Psychosis: Adaptation Framework and Protocol for Horyzons-Canada Phase 1. *JMIR*  
604 *Res Protoc*, 7(4), e100.

605

606 Martz E., Henry J. A. (2016). Coping with tinnitus. *J Rehabil Res Dev*, 53, 729–742.

607

608 Manchaiah, V, Munoz, M.F., Hatfield, E., Fagelson, M.A., Aronson, E.P., Andersson, G.,  
609 Beukes, E.W. (2020). Translation and adaptation of three English tinnitus patient-reported  
610 outcome measures to Spanish. *International Journal of Audiology*, Published Online.

611 <https://doi.org/10.1080/14992027.2020.1717006>

612

613 McKenna L, Marks EM, Vogt F. (2018). Mindfulness-Based Cognitive Therapy for Chronic  
614 Tinnitus: Evaluation of Benefits in a Large Sample of Patients Attending a Tinnitus Clinic. *Ear*  
615 *and Hearing*, 39, 359-366.

616

617 Michie S, van Stralen MM, West R. (2011). The behaviour change wheel: a new method for  
618 characterising and designing behaviour change interventions. *Implement Sci*, 6, 42.

619

- 620 Michie S, Yardley L, West R, Patrick K, Greaves F. (2017). Developing and evaluating digital  
621 interventions to promote behavior change in health and health care: recommendations resulting  
622 from an international workshop. *J Med Internet Res*, 19(6), e232  
623
- 624 Paglialonga, A., Cleveland Nielsen, A., Ingo, E., Barr, C. & Laplante-Lévesque, A. (2018).  
625 eHealth and the hearing aid adult patient journey: a state-of-the-art review. *BioMedical*  
626 *Engineering OnLine*, 17, 101.  
627
- 628 Tackling Tinnitus (2020). Tackling Tinnitus CBT program. Retrieved from:  
629 [www.tacklingtinnitus.org](http://www.tacklingtinnitus.org) (accessed on June 05, 2020).  
630
- 631 Tao, K. F., Brennan-Jones, C. G., Capobianco-Fava, D. M., Jayakody, D. M., Friedland, P. L.,  
632 Swanepoel, D. W., Eikelboom, R. H. (2018) Teleaudiology services for rehabilitation with  
633 hearing aids in adults: A systematic review. *Journal of Speech, Language, and Hearing*  
634 *Research*, 61(7), 1831–1849. [https://doi.org/10.1044/2018\\_JSLHR-H-16-0397](https://doi.org/10.1044/2018_JSLHR-H-16-0397)  
635
- 636 Thompson DM, Hall DA, Walker DM, Hoare DJ. (2017). Psychological therapy for people with  
637 tinnitus: a scoping review of treatment components. *Ear Hear*, 38:149–58.  
638
- 639 Thompson, L. M., Diaz-Artiga, A., Weinstein, J. R., & Handley, M. A. (2018). Designing a  
640 behavioral intervention using the COM-B model and the theoretical domains framework to  
641 promote gas stove use in rural Guatemala: A formative research study. *BMC Public Health*,  
642 18(1), 1–17. <http://doi.org/10.1186/s12889-018-5138-x>

643

644 Vlaescu G, Alasjö A, Miloff A, Carlbring P, Andersson G. (2016). Features and functionality of  
 645 the Iterapi platform for internet-based psychological treatment. *Internet Interventions*, 6,107-114.

646

647 Weise, C., Kleinstaubler, M., & Andersson, G. (2016). Internet delivered cognitive-behavior  
 648 therapy for tinnitus: A randomized controlled trial. *Psychosomatic Medicine*, 78(4), 501–510.

649 <http://doi.org/10.1097/PSY.0000000000000310>

Fixed modules / **Positive imagery** / 3. What images are best to use?



1. Outline >

2. What is a positive image? >

3. *What images are best to use?* >

4. Exploring images >

5. Expert opinion >

6. How >

7. Worksheet >

8. Technique guide >

9. Further help >

10. Key messages >

## What images are best to use?

The aim is to get one or two images that will be effective for you. It is good to think of places you know well.

Images that work well may be a beautiful waterfall, garden, or sparkling lake. They can be a forest, the seaside or a town you really like.

Select images that have a calming effect, without too much activity, but enough detail to actively explore the image.

The image should not remind you of problems, stress, work or your tinnitus.

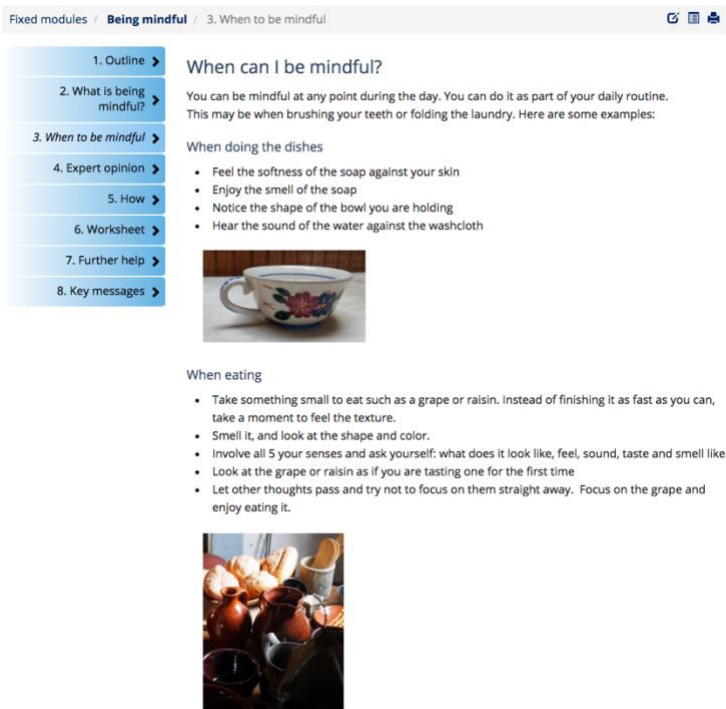


650

651

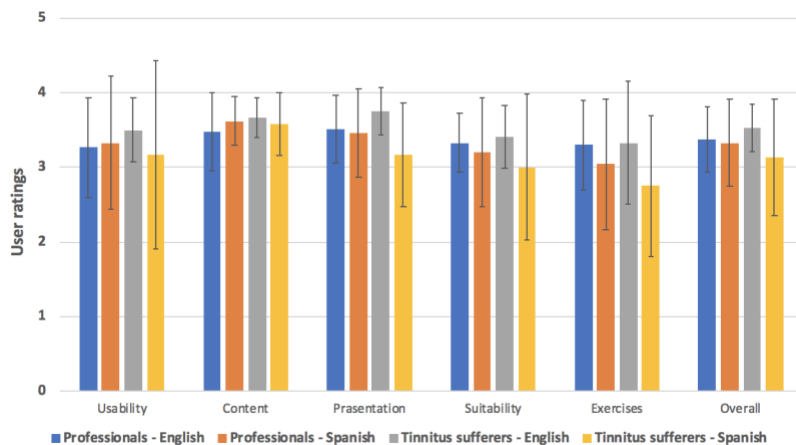
652

653 **Figure 1: Example of an ICBT intervention layout**



654

655 **Figure 2: Example of an ICBT intervention material**



656

657 **Figure 3: Example of a worksheet**

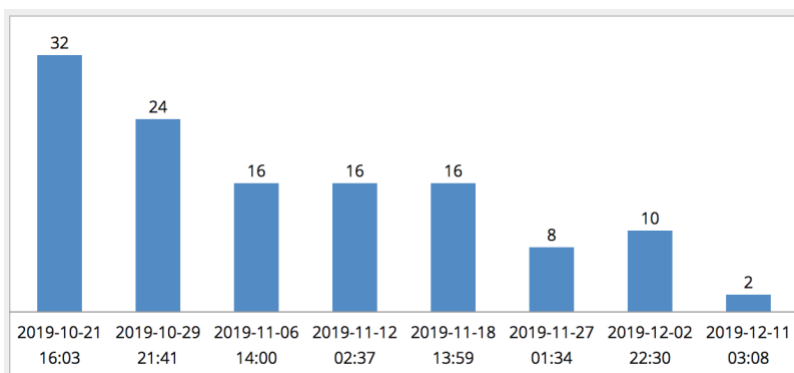
## Monitoring your progress

Complete the worksheet below. This will help you see your progress. It is good to have something to remind you of how much you have done. Here is an example

DATE	How good I am at this before this session <i>Rate from 1-10 with 10 being very successful</i>	ACTIONS <i>e.g. deep relaxation</i>	COMMENTS <i>These may include when, where and for how long something was done. You can also note what you can do differently next time or change.</i>	How well this went <i>Rate from 1-10 with 10 being very successful</i>
1/1/19: AM	1	Deep relaxation	When waking I went to sit in the study. I forgot the sequence but did feel more relaxed for a short time. I need to read the sequence again. 11 min	2
1/1/19: PM	2	Deep relaxation	Before going to bed I did relaxation in the study. I remembered more of the sequence. It went too fast though. I need to be more peaceful before, during and after tensing and relaxing. I want to try a different setting tomorrow. 12 min	3
1/2/19: AM	3	Deep relaxation	I thought I would try a kitchen chair and do relaxation there this morning. I found the noises in the kitchen were more disturbing. I am beginning to experience the difference between tense and relaxed muscles. I need to try to practice for longer. 12 min	3
1/2/19: PM	3	Deep relaxation	As the kitchen was not ideal, I sat in a chair in my room. I spent a few minutes before and after tensing my muscles with my eyes closed, just relaxing. This helped. I am beginning to remember the full sequence. 15 min	4

658

659 **Figure 4: Example of a progress bar graph regarding weekly tinnitus distress** (Note:  
660 Tinnitus Handicap Inventory – Screening version was used for weekly monitoring. The scores  
661 can range from 0 to 40).



662

663 **Figure 5: Credibility and acceptance rating of health professionals and patients with**  
664 **bothersome tinnitus about the ICBT for English and Spanish language materials** (Note: The  
665 response scale included a 5-point Likert-scale, with 1 representing strongly disagree and 5  
666 representing strongly agree. Bars represent the mean. Error bars indicate SD).

667

668



669 **Tables**

670 **Table 1: The comprehensive nature of the ICBT intervention offered** (Note: The order of the  
 671 modules is designed to use prior learning to later modules, e.g. need to master deep relaxation  
 672 before being able to do quick relaxation).

673

Modules	Week	Content	Video	Short worksheets or quizzes	Intervention load	
					Reading time	Daily practicing
1	1	Program rationale and outline	1	3	15 mins	Setting goals
2	1	Tinnitus overview	1	4	15 mins	Reading the module
3	1	Deep relaxation	2	3	15 mins	Twice a day for 10-15 minutes
4	2	Positive imagery	1	5	10 mins	Twice a day for 5minutes
5	2	Deep breathing	1	5	10 mins	Twice a day for 5 minutes
6	3	Changing views	0	7	10 mins	Once a day for 5 minutes
7	3	Entire body relaxation	1	3	10 mins	Twice a day for 5 minutes
18	3	Sound enrichment*	1	2	10 mins	As required
8	4	Shifting focus	0	3	10 mins	4 times a day for 2 minutes
9	4	Frequent relaxation	1	3	10 mins	5-10 times 1-2 minutes
19	4	Sleep guidelines*	1	7	15 mins	Implement daily

10	5	Thinking patterns	0	4	15 mins	3 times a week for 10 minutes
11	5	Quick relaxation	1	3	10 mins	7-15 times a day for up to 1 minute
20	5	Improving focus*	1	2	10 mins	As required
12	6	Challenging thoughts	1	3	15 mins	4 times a week for 5 minutes
13	6	Relaxation routine	0	2	10 mins	Deep relaxation twice a week, Frequent relation 8 times a day, Rapid relaxation during, before or after difficult situations
21	6	Sound tolerance*	1	4	15 mins	As required, 1-2 minutes and increasing
14	7	Being mindful	1	2	10 mins	2-5 times a day during normal activities
22	7	Listening tips*	1	2	15 mins	As required
15	8	Listening to tinnitus	0	3	10 mins	Once a day
16	8	Key point summary	0	0	15 mins	Reading the module
17	8	Future planning	0	4	15 mins	Future plan

674 Note: \*=optional modules

675

676

677 **Table 2: ePlatform functionalities specific to ICBT program in the US**

678

Functionality	Rationale and description
<i>Functionalities for users</i>	
Public page	Public page serves as a gateway to the ePlatform (i.e., <a href="http://www.tacklingtinnitus.org">www.tacklingtinnitus.org</a> ). Both therapists and users can login to the ePlatform, but only through the public page. Anyone can access public page which provides detailed information about the program including the project aims, inclusion and exclusion criteria, reference to previous studies, and contact information. Moreover, the potential participants have the opportunity to either enroll into a waiting list (during inactive recruitment phase) or register for the study (during active recruitment phase). The webpage and ePlatform is fully responsive, transparently adapting to screen size and ensuring a fully-functional and rich user experience regardless of whether the platform is accessed using a desktop computer, mobile phone (smartphone) or tablet.
Treatment modules	Treatment modules (or chapters) consist of logically ordered web-pages with information presented in a variety of formats including text, images, and videos. The users also have access to PDF documents that they can download for offline use. Worksheets are also embedded within the treatment modules so that users can complete them while reading through the treatment modules. It is worth noting that a few modules (i.e., 2-3) are released each week so that users have specific, and different, modules to focus on each week. When modules are

	<p>read they are marked so that the user and therapist can identify which modules have been covered. Therapists can also use the “treatment module roadmap” function to pre-assign treatment modules to individual user or groups so that the specific modules are automatically released to users on the designated dates. Platform users may also review the usefulness of each module to determine which strategies they find most helpful and will continue to use. Figures 1 and 2 provide examples of a treatment module.</p>
Worksheets	<p>Users are provided exercises and homework to ensure that they are fully engaging themselves in the program and are practicing the strategies during daily life. In the current program, quizzes and worksheets are imbedded in the treatment modules. Daily practice can be completed on a worksheet that is linked to the individual modules but saves all the previous answers to enable users to monitor their progress on one worksheet. Figure 3 provides an example of a worksheet.</p>
Messaging system	<p>An encrypted messaging system is included to enable two-way communication between therapists and users. The users can communicate with the therapist to seek answers to their questions. Moreover, therapists can use this feature to follow-up with the users and to provide individualized feedback on their work. This function works somewhat like an email service.</p>
Questionnaires	<p>Users are requested to complete pre-treatment and post-treatment outcome measures and some weekly questionnaires. This enables monitoring of outcomes using self-reported outcome measures. A progress bar chart is provided to users as an opportunity to review their weekly scores to monitor</p>

	whether their tinnitus distress is decreasing during the 8-week period while the intervention is running
<b><i>Functionalities for therapist/administrator</i></b>	
User log	A user log that the therapist or administrator can access serves as a complete journal entry for each participant. The user logs include automatically recorded actions (e.g., login, module assignment, questionnaire completion, etc). The therapist can also make text journal entries on each user manually. For example, “user is enrolled in the study for treatment group”, “user passed the screening”, or “user did not answer the call”. These notes help therapist keep track of individual user progress and avoid making notes outside the ePlatform.
User list	A user list contains all users registered to the ePlatform with some key information such as user ID, roles assigned (e.g., user vs therapist), groups assigned (e.g., treatment vs control group), text notes, number of logins, and last login.
Groups	Groups functionality helps therapists to assign users to different groups (e.g., treatment group vs weekly-check in control group, excluded). Users can be added or removed from a group at any stage. Moreover, it is also possible to assign treatment modules, worksheets, or questionnaires to the group so that they are assigned to all individual users at the same time.
User hub	The user hub functionality provides all the details about the individual user in a single place. This include users’ demographic details, modules assigned and completed, questionnaires roadmap and completed questionnaires, worksheets

	<p>completed, messages the participant has sent and received, user logs, and progress bars. Figure 4 provides an example of a progress bar graph regarding weekly tinnitus distress for an individual user.</p>
<p>Questionnaire roadmap</p>	<p>The questionnaire roadmap consists of a list of questionnaires and times at which they are assigned to participants. Therapists can activate the roadmap for a user or group and the ePlatform will automatically send out the questionnaires and reminders according to a roadmap timeline (e.g., every week in the case of a roadmap with weekly measurements). This feature allows full automation of questionnaire administration. Some important functionality features make the data collection and management of these responses user friendly. First, questionnaires can be automatically assigned to users (e.g. the screening questionnaire immediately after registration), or manually assigned by therapists during or after the treatment. The start date and the specific dates can also be pre-specified. Second, the ePlatform allows display of both the individual answers that a user has provided as well as a graphical representation of changes in pre-defined variables over time for that specific user. Third, reminder messages are sent automatically by the system to users who have not yet completed the questionnaires, usually the first three days following assignment, but this may be adjusted for each study. Finally, data can be conveniently exported into Excel files for direct use in external statistical programs (e.g., SPSS and R).</p>

681

682 **Table 3: Demographic details of study participants**

683

<b>Characteristic</b>	<b>Professionals (n = 11)</b>	<b>Patientst with bothersome tinnitus (n = 8)</b>
<b>Age in years (Mean/SD)</b>	42.9 (14.9)	30.9 (9.2)
<b>Gender (%)</b>		
▪ <b>Male</b>	36.4 (n = 4)	37.5 (n = 3)
▪ <b>Female</b>	63.6 (n = 7)	62.5 (n = 5)
<b>Language (%)</b>		
▪ English	72.7 (n = 8)	50 (n = 4)
▪ Spanish	27.3 (n = 3)	50 (n = 4)
<b>Ethnicity (%)</b>		
▪ Hispanic or Latino	36.4 (n = 4)	87.5 (n = 7)
▪ Non-Hispanic or Latino	63.6 (n = 7)	12.5 (n = 1)
<b>Race (%)</b>		
▪ American Indian/Alaska native	-	-
▪ Asian	-	12.5 (n = 1)
▪ Native Hawaiian or other pacific islander	-	-
▪ Black or African American	-	-
▪ White	72.7 (n = 8)	62.5 (n = 5)
▪ More than one race	27.3 (n = 3)	25 (n = 2)

<b>Education (%)</b>		
▪ Less than high school	-	-
▪ High school	-	-
▪ Some college but not degree	9.1 (n = 1)	25 (n = 2)
▪ A university degree	90.0 (n = 10)	75 (n = 6)
<b>Work (%)</b>		
▪ Entry level or unskilled work	-	12.5 (n = 1)
▪ Skilled or professional work	-	75 (n = 6)
▪ Retired	-	-
▪ Not working	-	12.5 (n = 1)
<b>Profession (%)</b>		
▪ Audiologists	63.6 (n = 7)	-
▪ Psychologists	18.2 (n = 2)	-
▪ Tinnitus Researcher	9.1 (n = 1)	-
▪ Tinnitus support worker	9.1 (n = 1)	-
<b>Users by language</b>		
▪ English	8 (72.7)	4 (50)
▪ Spanish	3 (27.3)	4 (50)
<b>Tinnitus duration in years (Mean/SD)</b>	-	10.2 (8.9)
<b>Duration in the profession in years (Mean/SD)</b>	14.7 (16.1)	-
<b>Ease of computer use (%)</b>		
▪ Find it hard	-	-
▪ Basic skills	18.2 (n = 2)	25 (n = 2)



▪ Frequent user	80.2 (n = 9)	75 (n = 6)
<b>Internet use (%)</b>		
▪ Communication such as email or chat	90.9 (n = 10)	100 (n = 8)
▪ Reading news	90.9 (n = 10)	87.5 (n = 7)
▪ Online shopping	90.9 (n = 10)	87.5 (n = 7)
▪ Watching videos	63.6 (n = 7)	87.5 (n = 7)
▪ Listening to music	45.5 (n = 5)	87.5 (n = 7)
▪ Searching for information	100 (n = 11)	87.5 (n = 7)

684

685

686

687 **Table 4: Median credibility and acceptability ratings of health professionals and patients**  
 688 **with bothersome tinnitus about the ICBT** (Note: The scores ranged from 1 to 5, with 1  
 689 representing strongly disagree and 5 representing strongly agree).  
 690

<b>Category</b>	<b>Healthcare professionals</b>	<b>Patients with bothersome tinnitus</b>
<b>Usability</b>		
Straightforward to use	4	4
Easy to navigate	3	3.5
Appropriate module length	3	2.5
<b>Content</b>		
Suitable level of information	4	4
Informative materials	3	4
Interesting materials	4	4
<b>Presentation</b>		
Content was well-structured	3	3
Suitable presentation	3	4
Easy to read	4	4
<b>Suitability</b>		
Suitable for those with tinnitus	4	4
Appropriate range of modules	3	3.5
Beneficial topics covered	4	4

<b>Exercises</b>		
Worksheet were appropriate	3	3.5
Clear instructions on how to practice	3	3.5
Motivation to do the exercises	3	2.5

691

692

693 **Table 5: Perceptions of aspects that were beneficial and barriers to undertaking the**  
 694 **program**  
 695

	<b>Examples from English participants</b>	<b>Examples from Spanish participants</b>
<b>Beneficial aspects</b>		
Informative	<p>“It is so informative using science-based information (Tinnitus patient)</p> <p>“There is a lot of helpful and appropriate information that is well written and presented using positive affirming language” (Professional)</p> <p><b>Coverage: 0.4</b></p>	<p>“I learned a lot about tinnitus” (Tinnitus patient)</p> <p>“The explanations were good to explain how the anguish caused by tinnitus is targeted” (Professional)</p> <p>“It was very useful. I learned new things that kept me wanting to be involved and read more” (Tinnitus patient)</p> <p><b>Coverage: 0.5</b></p>
Range of materials	<p>“Each module addressed a different topic which psychologically could help a patient realize their condition can be helped” (Professional).</p>	<p>“There were so many different strategies that patients can use to improve their tinnitus” (Professional)</p> <p><b>Coverage: 0.2</b></p>

	<p>“I loved how there were SO many different things to focus on. Many topics are covered” (Tinnitus patient).</p> <p>There were different sections to reinforce the materials. I liked the goals outlining the beginning of each module and the sections addressing possible challenges”</p> <p>(Professional)</p> <p>“Seeing the doctors discussing different aspects of tinnitus and its management was very helpful” (Tinnitus patient)</p> <p><b>Coverage 0.3</b></p>	
Presentation	<p>“The online format is perfect as I can do this in my own time” (Tinnitus patient)</p> <p>“ It is so well written using positive affirming language” (Professional)</p> <p>“The reader is kept engaged by videos that aid understanding of the text” (Tinnitus patient)</p>	<p>“I enjoyed the interaction and photos included” (Professional)</p> <p>“The videos were very useful! One of my favorite parts!” (Tinnitus patient)</p> <p><b>Coverage 0.3</b></p>

	<p>“I liked the numerous and varied examples that were provided in each section”</p> <p>(Professional)</p> <p><b>Coverage 0.5</b></p>	
<b>Barriers</b>		
Functional aspects	<p>“The size and positioning of the navigation buttons can be improved” (Professional)</p> <p>“There should be a next module button to click at the end of each module to take you to the next module” (Professional)</p> <p>“The subtitles on the videos- were sometimes difficult to read and blocked some of the visuals” (Tinnitus patient)</p> <p><b>Coverage 0.5</b></p>	
Language	<p>“Use a paragraph format more. I found the flow of reading difficult with the bullet points” (Professional)</p> <p><b>Coverage 0.1</b></p>	<p>“It was a little hard to read. There are some words that are difficult to understand”( Tinnitus patient)</p> <p>“The level of Spanish used is very advanced for the common Spanish</p>

		<p>speaker. No doubt the translations are accurate, but the vocabulary is too advanced” (Professional)</p> <p>“In some parts Spanish sounds very translated ... instead of being more natural” (Professional)</p> <p><b>Coverage 0.5</b></p>
Length	<p>“The first two modules were a bit of an information overload, but really great information” (Tinnitus patient)</p> <p><b>Coverage 0.1</b></p>	<p>“The modules are a bit long, but I understand that all this information is necessary” (Tinnitus patient)</p> <p><b>Coverage 0.1</b></p>

696

697

698

699

700

701

702

703