Internet-based Cognitive Behavioral Therapy for tinnitus in Spanish: A global feasibility trial

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Abstract

Objective: Internet-based cognitive behavioral therapy (ICBT) for tinnitus is an evidence-based intervention, but only available in a few languages. To increase accessibility, ICBT was translated into Spanish. This study's objective was to determine the feasibility of ICBT for Spanish speakers.

Design: A single-group pretest posttest design was used. Compliance, engagement, acceptance and outcome feasibility were measured.

Study Sample: 46 Spanish-speakers with tinnitus were screened. There were 32 participants meeting the eligibility criteria, with a mean age of 47 (± 11) years. Of these 91% were Hispanic or Latino with 66% living in Spain and 34% living in South America.

Results: Outcome feasibility was established, as a large pre-posttest within-group effect size of *d* = 0.90 was found for tinnitus severity. Large pre-posttest effect sizes were also present for the secondary outcomes of anxiety and depression with a medium effect for insomnia, health-related quality of life, and tinnitus cognitions. Intervention engagement and compliance were not optimal although no participants withdrew. Intervention acceptance rates indicated scope for improvement.

Conclusions: ICBT for Spanish communities appears to be feasible. A randomized controlled trial is required to further investigate the effects and identify ways of improving engagement and attracting Spanish speakers from different countries.

Introduction

Goals have been set by the United Nations to achieve universal healthcare coverage to ensure healthy lives and promote well-being (World Health Organization, 2019). Achieving these goals thus requires creative ways of increasing accessibility using sustainable systems. One approach has been providing Internet interventions due to the advantage they offer in improving accessibility utilizing fewer resources. Adoption of such interventions have escalated during the COVID-19 pandemic to enable continued healthcare when in-person appointments were not possible (Wind et al., 2020). These interventions have been widely applied for a range of healthcare needs and internet based cognitive behavioral therapy (ICBT) has improved access to cognitive behavioral therapy (CBT) for a range of psychiatric and somatic disorders, including tinnitus (Andersson et al., 2019).

Tinnitus is the perception of sound in the absence of an external sound source. It is a prevalent condition with prevalence estimates ranging between 5-43% of the adult population (e.g., McCormack et al., 2016) with an incidence of around 0.5-1% per annum (e.g., Stohler et al., 2019). Although various conditions are associated with tinnitus, including a history of hypertension and osteoarthritis, the greatest risk factors include hearing loss and loud noise exposure (Kim et al., 2015). Tinnitus is often associated with additional difficulties such as insomnia, anxiety, and depression (Salazar et al., 2018). Although there are several management

strategies, CBT is the strategy with the most evidence of effectiveness in reducing tinnitus distress. (Fuller et al., 2020; Landry et al., 2020). Unfortunately, it is seldomly provided to those with tinnitus due to a lack of professionals with expertise in providing CBT for tinnitus (Bhatt, Lin, & Bhattacharyya, 2016).

To increase accessibility, ICBT for tinnitus was developed in Swedish (Andersson and Kaldo, 2004), and later translated into English and German. Its efficacy has been demonstrated in nine randomized controlled trials (RCTs) in Europe indicating a moderate effect size for both tinnitus distress and insomnia and improvements for anxiety, depression, and quality of life (Beukes et al., 2019). Recent studies also show its efficacy in the US population (Beukes et al., 2021c, 2021d, 2021e) but has not yet been routinely offered in many other countries.

Spanish is spoken by approximately 580 million people across the globe and is the largest non-English language spoken in the US according to the 2017 census (US Census Bureau, 2017). In spite of it being one of the most common languages spoken world-wide, few studies on tinnitus have focused on Spanish-speaking people. Although a few Internet-based studies in Spanish are emerging for other health-related interventions, (e.g., Botella et al., 2010; Oromendia et al., 2015; Vallejo et al., 2015) none exist for tinnitus. Interventions that are conducted in a person's native language are twice as effective as those delivered only in English (Griner & Smith, 2006).

To support the World Health Organization health promotion initiatives (World Health Organization, 2019), ICBT for tinnitus was translated into Spanish to make it linguistically accessible to Spanish communities (Beukes, et al., 2020a; Manchaiah et al., 2020a). What is not known, is whether Spanish speakers will be willing to use ICBT as a management approach for addressing problematic tinnitus. Public attitudes toward internet interventions are variable and

acceptability of such interventions can be obscured by misinformation regarding their effectiveness (Apolinário-Hagen et al., 2018). If ICBT is not well understood, it may affect the uptake of this intervention. It is thus important to establish ease of recruitment within the Spanish population (Cunningham et al., 2011).

The aim of the present study was to determine the feasibility of delivering ICBT in Spanish. The specific objectives were to investigate whether Spanish speakers were willing to use ICBT as a management approach by investigating the recruitment, compliance, engagement, acceptance feasibility. Outcome feasibility of using ICBT in Spanish to reduce tinnitus distress and tinnitus associated problems was furthermore assessed.

Materials and methods

Study Design

A single-group pretest-posttest design was used to determine the feasibility of ICBT for Spanish-speaking communities as an essential pre-requisite to prepare for larger scale RCTs (Campbell et al., 2000). This study was intended to be an initial small-scale study (n =30) without a control group. Ethical approval was obtained from the Institutional Review Board at Lamar University, Beaumont, Texas, USA (IRB-FY20-200). To ensure that best practice was followed, the Transparent Reporting of Evaluations with Nonrandomized Designs checklist (Des Jarlais, Lyles, Crepaz, & Trend Group, 2004) was used. The study protocol was pre-registered at ClinicalTrials.gov (NCT04335929).

Intervention

The ICBT program was based on a CBT self-help program originally developed in Swedish (Andersson & Kaldo, 2004). The written chapters were later redeveloped by Beukes et al. (2016) into an online English version which contained interactive elements in including quizzes, worksheets, and videos. The intervention contains 22 modules, with 2-3 modules being released weekly over an 8-week period. CBT principles such as goal setting, active participation, and addressing relapse prevention were integral to the intervention. A holistic approach to tinnitus management was provided by including other aspects such as sound enrichment and mindfulness together with CBT strategies. The intervention has 16 recommended modules including applied relaxation, thought analysis, cognitive restructuring, imagery and exposure to tinnitus, as outlined in Beukes et al. (2021a). The intervention also provides strategies to address problematic tinnitus situations, identified by Beukes et al., (2018a), in the optional modules, such as difficulty sleeping, concentrating, hearing, being in quite situations, and sound sensitivity. In this study the intervention was translated into Spanish, ensuring readability at below the recommended 6th-grade level (Beukes, et al., 2020a). The expert videos provided in the intervention were presented in Spanish voice over together with Spanish subtitles. The intervention platform was housed at Lamar University, US and complied with the required data security and encrypted communications (Manchaiah et al., 2020b).

On-demand Support

On-support guidance was offered to participants (Rheker, Andersson, & Weise, 2015). There was an encrypted two-way messaging system enabling participants to ask questions about the program. These messages were monitored by a Spanish-speaking doctoral audiology student who responded

in Spanish. If required, further support was available from an audiologist specializing in tinnitus or a licensed CBT therapist.

Outcome Measures

The primary outcome was tinnitus distress as measured by the Tinnitus Functional Index (TFI) (Meikle et al., 2012). Secondary outcomes included measures of anxiety, depression, insomnia, tinnitus cognitions, hearing-related difficulties, and health-related quality of life. Spanish translations (Manchaiah et al., 2020a) of all outcome measures were used as shown in Table 1.

In order to monitor participant's tinnitus distress while undertaking the intervention, the screening version of the Tinnitus Handicap Inventory (THI-S; Newman et al, 2008) was completed weekly during the course of the 8-week intervention. If scores increased by more than 10 points between two consecutive weeks, the participant was contacted to discuss presenting difficulties. Participants were also monitored weekly by a newly developed Tinnitus Qualities Questionnaire (TQQ; Beukes et al., 2021a). The TQQ measures psychoacoustic tinnitus qualities such as pitch, loudness, and the number of tones heard.

Online questionnaires were used throughout the study. All the measures were completed pre- and post-intervention, and at two-month follow-up. Three electronic reminders were sent to participants who had not completed questionnaires.

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

Outcome Measures: Assessed at Baseline (T0), Post-intervention (T1) and 2-months Follow-up (T2)	**Spanish Translated version**	**Internal consistency**	**Range of scores**	**Levels of significance**
Tinnitus Functional Index (TFI; Meikle et al, 2012)	Obtained from authors of the original English scale with a user agreement.	.8	0-100	>25= mild 26-50= significant 50+ =severe
Generalized Anxiety Disorder (GAD-7, Spitzer, Kroenke, Williams, et al., 2006)	Obtained from the website: https://www.phqscreeners.com/	.89	0-21	0-4= minimal anxiety 5-9= mild anxiety 10-14= moderate anxiety 15-21= severe anxiety
Patient Health Questionnaire (PHQ-9; Spitzer, Kroenke, Williams, 1999)	Obtained from the website: https://www.phqscreeners.com/	.83	0-27	5-9=mild depression 10-14=moderate 15-19=moderately severe 20-18= severe depression

Insomnia Severity Index (ISI; Bastien, Vallières, & Morin, 2001)	Obtained from the website with a user agreement: https://eprovide.mapi-trust.org/instruments/insomnia-severity-index.	.74	0-28	0–7 = Not clinically significant 8–14 = Subthreshold insomnia 15–21 = Clinical insomnia (moderate severity) 22–28 = Clinical insomnia (severe degree)
EQ-5D-5L (Herdman, et al., 2011)	Obtained from their website with a user agreement: https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/.	.7-.85	0-15	Measures 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/ depression
EQ-5D-5L Visual Analogue Scale (VAS) (Herdman, et al., 2011)		.7-.85	0-100	VAS for overall health. Higher scores indicated improved health
Tinnitus and Hearing Survey (THS; Henry, et al., 2015)	Manchaiah et al., 2020b	.86-.94		Subscale for Tinnitus: 0-16 Hearing: 0-16 Sound tolerance: 0-8

Tinnitus Cognitions Questionnaire (TCQ; Wilson & Henry, 1998)	Manchaiah et al., 2020b	.91	0-104	Higher scores indicate a greater tendency to engage in negative cognitions in response to tinnitus
Tinnitus Handicap Inventory-Screening (THI-S) (Newman, Sandridge, & Bolek, 2008)	Questions were taken from the translated THI full Spanish version with the author, C Newmans's permission.	.93	0-40	>6 tinnitus handicap
Tinnitus Qualities Questionnaire (TQQ; Beukes, Andersson, Manchaiah, & Kaldo, 2021)	Translated: Manchaiah et al., 2020b; not validated	Not assessed	0-100	Higher scores indicate more bothersome aspects of tinnitus (loudness, number of tones heard)
Intervention satisfaction (Beukes, et al., 2016)	Translated during intervention development (Beukes et al., 2020a).	Not assessed	0-75	Higher scores indicate more intervention satisfaction

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Intervention Compliance and Engagement Variables

Intervention adherence was assessed by determining retention rates and questionnaire completion rates. Intervention engagement was assessed by the number of logins, the number of modules read, and the number of messages sent during the intervention. Intervention satisfaction was measured using the Acceptability and Satisfaction Questionnaire (Beukes et al., 2016) by collecting participants' views regarding the presentation, content, usability, and information in the intervention using a 0–5-point Likert Scale with a maximum score of 75 points. Messages written and free text responses in the outcome questionnaire were used to identify any adverse effects.

Recruitment

We aimed to recruit Spanish speakers from across the globe without any geographical barriers. To recruit Spanish speakers, a range of strategies were used to disseminate information, including social media (Facebook and Twitter), emails, and forums. A short storyline 2-minute video was also made in Spanish in aid of explaining the study and was available on the study website and shared on social media. The main recruitment period was between 1 March to 20 April 2020. This timing was unfortunate as it was during the onset of the COVID-19 pandemic. Those interested were directed to the study website, where all the information was available to read in Spanish regarding what the study entailed and how to register. Study eligibility was determined as follows:

- Spanish speakers, adults, aged 18 years and over from any location. It was not explicitly stated, but it was assumed that Spanish was the first language or their preferred language of those interested in the intervention.
- Access to a computer, the internet, and the ability to email.

- Experiencing tinnitus for a minimum period of three months.
- A score of 25 or greater on the TFI indicating the need for an intervention.
- Not undertaking any other therapies or interventions that may interfere with the current study.
- Not presenting with any serious health conditions that may prevent undertaking the intervention.

Data Analysis

Statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) version 26.0. The study outcomes of interest were retention, feasibility, and effect size at post-intervention. For all analyses, the goal of this pilot was to estimate the pre-post-test effect size for all primary and secondary outcomes; however, 2-sided *p*-values using alpha = 0.05 were also reported. As missing outcome data can affect the results validity various approaches were followed. Initially missing data were handled through multiple imputation using the Markov Chain Monte Carlo approach due to a non-significant result for the assumption of missing data Little's MCAR test (X^2 = 17.50 (24) = .83). This analysis used all participants originally included in the trial. This approach relies on the data being completely missing at random. As this cannot be ascertained due to the large amount of missing data, a completer's only analysis was also done as a sensitivity analysis. Including only those completing the intervention also has limitations as it is likely that a non-random subset of this sample completed the outcomes, possibly those who were more motivated or received more treatment benefits, thus increasing the risk of bias in the estimates of the outcome effects. The data that support the findings of this study are openly available in Figshare at http://doi.org/10.6084/m9.figshare.13718896.

Effect Sizes and Statistical Modelling

Effect sizes (Cohen's *d*) at post-intervention were calculated by dividing the differences in pre- and post-intervention means by the pooled standard deviations. The reliable change index (RCI) (Jacobson & Truax, 1991) was used as a means of calculating clinical significance of the changes on the TFI. This was calculated using the mean pretest posttest score difference, the pre-intervention standard deviation, and a test-retest reliability coefficient of 0.78 as reported in the validation study (Meikle et al, 2012). Finally, linear mixed models (LMM) using maximum likelihood with random intercept for participants were used to account for repeated measures and incorporate all available data points in the analysis. The models were used to determine the effect of the pre-intervention scores on follow-up scores. The LMM induced a scaled identity covariance structure. Bonferroni-corrected pairwise post hoc tests were applied to determine which timepoints were significantly different, for each variable.

Sample Characteristics

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

Results

Recruitment Feasibility

Recruitment of Spanish speakers was possible from different countries, although only 46 participants were screened during the recruitment timeframe. Of these, 3 did not meet the inclusion criteria due to low scores on the TFI (below 25/100) and 11 were unable to do the intervention during the given timeframe (Figure 1). The demographic profile of the remaining 32 participants completing the intervention is shown in Table 2. The majority lived in Spain (69%), while the others (31%) were living in South America. Of the participants 91% were Hispanic or Latino. The average age of the participants was 47 years (SD: 11 years).

Google analytics indicated that the recruitment page was viewed in both English and Spanish by most users from the United States (78%), followed by Spain (6%), Mexico (3%), Argentina (2%), Chile (1%) and Columbia and Peru (0.5%) each. There was regional representation within the country of Spain with the majority of views from Madrid, Valencia, Seville, and Barcelona. The study website information pages were available in both English and Spanish. During the recruitment period, the Spanish pages were viewed by 285 Spanish speakers. The views lasted for an average of 2 minutes with an average of 3 of the 8 recruitment pages being viewed.

Table 2: Demographic characteristics of the participants (n=32)

DEMOGRAPHICAL INFORMATION	**Mean (SD) or number (%)**
Gender	Female 17 (53%) Male 15 (47%)

Average age	46.63 ± 11.0 years Range 23-63 years
Country	Spain or other European Country: 22 (69%) South America: 10 (31%)
Tinnitus duration	6.0±8.09 years
Ethnicity	Hispanic or Latino: 29 (91%) Not-Hispanic or Latino: 3 (9%)
Race	White: 26 (81%) More than one race: 3 (9%) American Indian/ Alaskan Native: 2 (6%) Pacific Islander: 1 (3%)
Professionals seen	Primary Care Physician 13 (41%) ENT Physician: 23 (72%) Audiologist: 18 (56%) Neurologist: 1 (3%) None: 3 (9%)
Highest educational level	Less than high school: 2 (6%) High School: 6 (19%) College/ vocational training: 5 (16%) University degree 19 (59%)
Employment	Skilled or professional: 24 (75%) Retired: 3 (9%) No working: 5 (16%)

Internet Use	Basic skills: 11 (34%) Frequent user: 21 (66%)

Compliance Feasibility

No participants withdrew during the study. The number of participants completing the outcome measures were reduced as the trial progressed with a post-intervention completion rate of 69% (n=22) and follow-up completion rate of 50% (n=16) as seen in Figure 1. There were no adverse effects or harms reported. There were no participants whose THI-S score increased by more than 10 points when monitored weekly.

[Insert Figure 1 here]

Engagement Feasibility

Participant engagement with the intervention was highly variable. All participants logged in at least once and completed at least 1 worksheet. The average number of logins was 12 (SD: 8), with an average of 13 (SD: 8) modules (mode of 22) of the full 22 modules that were opened by participants (Figure 1). Module 1 was opened by 31 (97%) participants whereas the later modules were opened by fewer participants, with the lowest for the optional module on listening tips opened by 12 (38%) of the participants (Figure 2). Very few participants asked questions during the intervention, sending an average of 1 (±3) message. Engagement decreased during the course of the intervention with fewer worksheets being completed as time commenced.

[Insert Figure 2 here]

Outcome Feasibility

Feasibility to Reduce Tinnitus Distress

A significant large effect (d = 0.93 imputation analysis; d = 0.85 completers analysis) was observed for the change in tinnitus distress at post-intervention (see Table 3). This change further improved at the 2-month follow-up (d = 1.06 imputation analysis; d = 0.95 completers analysis). The reliable change index indicated a pre-post score difference of 19.30 on the TFI would be a clinically significant change. This was obtained by 14/32 (44%) at both T1 and T2 for the imputation data and 8/22 (36%) at T1 and 6/16 (50%) at T2 for the completers only data .

Overall, there was a weekly reduction in tinnitus distress (THI-S) and tinnitus qualities (TQQ), as seen in Figure 3. This reduction was only significant for the TQQ [$F(7,7.80) = 3.45$, p = .002*], but not for the THI-S [$F(7,63.33) = 2.16$, p = .05*]. Pairwise comparison of the THI-S scores in week 1 to subsequent weeks of the intervention displayed significant differences between week 1 and weeks 5 to 8 ($p < .05$).

[Insert Figure 3 around here]

Table 3: Pre, post, and 2-month follow-up intervention comparisons for the various outcome measures using an imputation analysis.

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

Outcome measure	**Mean (SD) [range]**			**Effect size, Cohen's *d* (95% confidence intervals for**		**Linear Mixed Model**	***Pairwise comparison:* *M*ean difference, (SE)**		
	T0 (baseline)	**T1 (post-intervention)**	**T2 (2 month follow-up)**	**T0-T1**	**T0-T2**	**Type III test of fixed effects**	***T0-T1***	***T0-T2***	***T1-T2***
TFI Imputed analysis	61.06 (19.03) [29-96]	41.76 (22.50) [3-100]	40.89 (19.08) [2-99]	0.93 (0.40-1.43)	1.06 (0.52 to 1.57)	*F* (2,31.000) = 16.634, *p* < .001	*19.30 (SE: 3.60); p < .001*	29.48 (SE: 4.30), *p < .001*	.87 (SE: 3.07), *p = 1.00*
Completers analysis	61.06 (19.03) [29-96]	41.78 (27.02) [3-100]	40.38 (26.65) [2-99]	0.85 (0.29 to 1.41)	0.95 (0.3 to 1.39)	*F* (2,67) = 6.193, *p* = .003	*19.28 (SE: 6.53); p = .013*	*20.69 (SE: 7.21); p = .012*	*1.41 (SE: 7.74); p = 1.00*
GAD-7 Imputed analysis	10.25 (5.32) [0-20]	5.11 (3.75) [0-21]	5.71 (3.97) [0-17]	1.12 (0.58 to 1.63)	0.97 (0.44 to 1.47)	*F* (2,31.000) = 13.538, *p* < .001	5.04 (SE: .97), *p* < .001	4.44 (SE: 1.0), *p* < .001	-.60 (SE: .55), *p* = .89
Completers analysis	10.25 (5.32) [0-20]	5.23 (4.24) [0-21]	5.62 (5.40) [0-17]	1.02 (0.43 to 1.58)	0.85 (0.32 to 1.48)	*F* (2,67) = 7.969, *p* < .001	*5.02 (SE: 1.41); p = .002*	*4.63 (SE: 1.56); p = .012*	*-.40 (SE: 1.67); p = 1.00*

PHQ-9 Imputed analysis	11.25 (7.02) [0-27]	4.97 (5.01) [0-27]	6.25 (6.29) [0-26]	1.03 (0.50 to 1.54)	0.75 (0.23 to 1.25)	*F* (2,31) = 16.37, *p* < .001	6.28 (SE: 1.16), *p* < .001	5.00 (SE: 1.46), *p* = .005	-1.28 (SE: .84), *p* = .41
Completers analysis	11.25 (7.02) [0-27]	5.41 (SD: 5.82) [0-27]	6.13 (8.55) [0-26]	0.89 (0.31 to 1.44)	0.68 (0.05 to 1.28)	*F* (2,67) = 5.41, *p* = .007	*5.84 (SE: 1.95); p = .012*	*5.13 (SE: 2.16); p = .062*	*-.72 (SE: 2.32); p = 1.00*
ISI Imputed analysis	14.97 (6.60) [3-27]	10.96 (6.21) [0-28]	9.79 (5.69) [1-28]	0.63 (0.12 to 1.12)	0.84 (0.32 to 1.34)	*F* (2,31.000) = 8.37, *p* < .001	4.01 (SE: 1.06), *p* = .002	5.18 (SE: 1.35), *p* = .002	1.17 (SE: .94), *p* = .68
Completers analysis	14.97 (6.60) [3-27]	10.55 (7.11) [0-28]	9.38 (7.71) [1-28]	0.65 (0.08 to 1.20)	0.83 (0.19 to 1.43)	*F* (2,67) = 4.39, *p* = .016	*4.42 (SE: 1.95); p = .078*	*5.59 (SE: 2.15); p = .034*	*1.17 (SE: 2.31); p = 1.00*
EQ-5D-5L Imputed analysis	8.94 (2.81) [5-18]	7.58 (2.26) [5-15]	7.16 (1.41) [5-11]	0.53 (0.03 to 1.03)	0.80 (0.28 to 1.30)	*F* (2,31.000) = 6.16, *p* = .006	1.36 (SE: .59), *p* = .08	1.78 (SE: .52), *p* = .005	-.42 (SE: .37), *p* = .81
Completers analysis	8.94 (2.81) [5-18]	7.45 (2.60) [5-15]	7.00 (1.59) [5-11]	0.55 (-0.01 to 1.09)	0.78 (0.15 to 1.39)	*F* (2,67) = 4.005, *p* = .023	*1.48 (SE: .79); p = .110*	*1.48 (SE: .79); p = .110*	*-.46 (SE: .83); p = 1.00*
EQ-5D-5L VAS Imputed analysis	67.03 (16.94) [20-90]	73.20 (12.23) [40-95]	77.29 (10.87) [40-90]	0.42 (0.08 to 0.91)	0.72 (0.21 to 1.22)	*F* (2,31) = 6.52, *p* = .004	6.17 (SE: 2.71), *p* = .09	10.25 (SE: 2.88), *p* = .004	4.08 (SE: 1.96), *p* = .14

Completers analysis	67.03 (16.94) [20-90]	73.64 (14.65) [40-95]	76.75 (15.33) [40-90]	0.41 (0.14 to 0.95)	0.59 (0.03 to 1.19)	*F* (2,67) = 2.33, *p* = .105	NA	NA	NA
THS: Tinnitus Imputed analysis	8.06 (3.60) [0-16]	5.14 (3.40) [0-16]	4.63 (3.39) [0-16]	0.83 (0.31 to 1.33)	0.98 (0.45 to 1.49)	*F* (2,31) = 13.93, *p* < .001	2.92 (SE: 0.62), *p* < .001	3.43 (SE: .68), *p* < .001	-.51 (SE: 0.51), *p* = .92
Completers analysis	8.06 (3.60) [0-16]	4.64 (3.75) [0-16]	4.44 (4.35) [0-16]	0.92 (0.3 to 1.48)	0.94 (0.29 TO 1.55)	*F* (2,67) = 7.32, *p* = .001	*3.63 (SE: 1.17); p = .009*	*3.43 (SE: 1.06); p = .006*	*.20 (SE: 1.26); p = 1.00*
THS: Hearing Imputed analysis	5.34 (4.29) [0-13]	5.57 (3.50) [0-16]	3.85 (3.28) [0-15]	-0.06 (-0.55 to 0.43)	0.39 (0.11 to 0.88)	*F* (2,31) = 4.37, *p* = .412	NA	NA	NA
Completers analysis	5.34 (4.29) [0-13]	5.55 (4.06) [0-16]	3.94 (4.40) [0-15]	-0.05 (-0.59 to 0.49)	0.32 (-0.29 to 0.92)	*F* (2,67) = .78, *p* = .465	NA	NA	NA
THS: Sound tolerance Imputed analysis	1.72 (1.28) [0-4]	1.56 (1.39) [0-4]	1.03 (0.99) [0-4]	0.12 (-0.37 to 0.61)	0.60 (0.09 to 1.10)	*F* (2,31) = 3.26, *p* = .052	NA	NA	NA

Completers analysis	1.72 (1.28) [0-4]	1.50 (1.47) [0-4]	1.13 (1.09) [0-4]	0.16 (-0.38 to 0.70)	0.48 (-0.13 to 1.08)	F (2,67) = 1.11, p = .336	NA	NA	NA
TCQ Imputed analysis	52.56 (13.18) [27-89]	38.42 (20.53) [1-100]	37.47 (16.81) [5-96]	0.60 (0.09 to 1.09)	1.00 (0.47 to 1.51)	F (2,31.000) = 14.54, p < .001	14.14 (SE: 3.20), p < .001	15.10 (SE: 2.88), p < .001	-.96 (SE: 2.50), p = 1.00
Completers analysis	52.56 (13.18) [27-89]	38.55 (24.57) [1-100]	37.06 (23.53) [5-96]	0.75 (0.18 to 1.30)	0.86 (0.28 to 1.41)	F (2,67) = 4.76, p = .01	*14.02 (SE: 5.50); p = .039*	*15.50 (SE: 6.08); p = .039*	*1.48 (SE: 6.52); p = 1.00*

Acronyms: TFI: Tinnitus Functional Index; ISI= Insomnia Severity Index; GAD-7= Generalized Anxiety Disorder-7; PHQ-9= Patient Health Questionnarie-9; VAS= Visual Analogue Scale of the EQ-5D-5L, THS= Tinnitus and Hearing Survey; TCQ= Tinnitus Cognitions Questionnaire. T0 = baseline; T1 = post-intervention; T2 = Follow-up. *Significance at $p < 0.05$

Feasibility to Reduce Problems Associated with Tinnitus

At post-intervention, a large effect was found for anxiety (d = 1.12 imputation analysis; d =1.02 for completers analysis), depression (d = 1.03 imputation analysis; d =0.89 for completers analysis), and the secondary tinnitus outcome measure measured by the THS (d = 0.83 for imputation analysis; d =92 for completers analysis). Medium effects were present for insomnia (d = 0.63 imputation analysis; d =65 for completers analysis), health-related quality of life (d = 0.53 imputation analysis; d =55 for completers analysis), and tinnitus cognitions (d = 0.60 imputation analysis; d =75 for completers analysis). There were no significant improvements on the visual analogue rating scales for quality of life, hearing disability, and hyperacusis at post-intervention. At follow-up, further improvements were evident for all outcomes except for anxiety and depression (See Table 3).

Acceptance Feasibility

No adverse effects were reported during the course of the intervention. An average score of 51/75 (68%) was obtained for the post-intervention satisfaction questionnaire with most questions scoring an average of 3 to 3.5 out of 5 for questions such as suitability of the information, ease of navigation, and benefit of the topics. When answering the open-ended question, participants explained that the intervention has helped them better manage the tinnitus saying: "*I've learned to deal with the tinnitus and control it. It has less of an impact on my life now as I am more capable of managing it*," and gain other perspectives with statements such as "*I see situations differently now and it has helped me control my mood."*

Some participants mentioned finding the new techniques helpful saying: "*I've learned new techniques of relaxation, to breathe and decrease tension I was carrying around*," and learning a lot from the program although it was online: "*you learn the same as if one had the professor in front of you teaching you, at least in my case, I took it as a course just like the ones I do in my profession."*

Discussion

Despite the efficacy of CBT for tinnitus (Fuller et al., 2020; Landry et al., 2020), it is not readily available. Provision of ICBT can improve accessibility, but there is no ICBT program available to Spanish speakers. The aim of the present study was to run a small-scale study to investigate the feasibility of ICBT in Spanish before implementing a larger RCT.

Recruitment Feasibility

On a small scale, recruitment from different countries was possible. The majority of participants represented a wide demographic from different regions in Spain (66%). The remaining 34% were from different regions in South America. It was encouraging to see that recruitment from more than one location was possible. It was also encouraging that 91% were Hispanic or Latino, indicating the potential to recruit these ethnic groups. Interestingly, the mean age at 47 years of those signing up for the intervention was lower than in other trials than that seen when pooling together previous trials with a mean of 51 years (Beukes et al., 2019). This may have been partly attributed to the recruitment strategy being mostly through social medial. This age group may have more regular internet access and be more engaged with social media. Furthermore, the mean tinnitus duration was also relatively low at 6 years, as it was previously reported in recent

trials being around 10-14 years (Beukes et al., 2021c, 2021d, 2021e). Asurprising result was the limited uptake of this intervention by the Spanish-speaking communities, although the reasons for this are unclear. One factor that could have contributed to recruitment difficulties was that the study was undertaken during the height of the COVID-19 pandemic during a time where day-to-day living was disrupted for most people and they may not have been actively seeking help for their tinnitus (Beukes et al., 2020b, 2021b). It could also be that ICBT as a management approach is not well understood and hence not pursued. Further recruitment strategies need to work at addressing these barriers.Although the recruitment target was reached, recruiting Spanish speakers was difficult and it required numerous campaigns, including contracting a company to boost recruitment. Further work on effective recruitment strategies to attract Spanish speakers will be needed prior to launching larger scale studies. Recruitment through word of mouth, building rapport and trust, and personalizing the benefits of participation have been suggested to support recruitment of Hispanic and Latino research participants (Sha et al., 2017). Recognizing cultural differences and building trust within Hispanic communities prior to recruitment should be emphasized when running larger trials (Levkoff & Sanchez, 2003). Intervention promotion through key individuals within Spanish-speaking communities may be helpful. Ways of strengthening confidence for the intervention are also required. Due to the difficulties encountered during recruitment it is suggested that subsequent trials should include Spanish-speaking public patient involvement with Spanish speakers representing different countries as this involvement may being wider suggestions to enhance recruitment and which recruitment strategies may work best (Staniszewska et al., 2017).

Compliance Feasibility

No participants actively withdrew during this study, which was reassuring. Retention rates have been variable when pooling previous ICBT trials with a mean of 86% (Beukes et al., 2019). Completion of the outcome measures was low at 69% post intervention and 50% at follow-up despite email reminders. Intervention completion rates are lower than past trials ranging between 57-95% (Beukes et al., 2019), but these lower rates are similar to recent trials (Beukes et al., 2021c, 2021d, 2021e). This may be partly attributed to the timing of the research during the COVID-19 pandemic. It is possible that the disruptions of the pandemic affected intervention engagement and completion of the outcome assessments.

Engagement Feasibility

Intervention engagement was variable. It was encouraging that all participants logged in at least once, read the initial modules, and completed the initial worksheets. On average around half of the intervention modules were opened, indicating that not all modules were read. This could partly contribute to the findings. This engagement did decrease during the course of the intervention. The COVID-19 pandemic may have partially contributed. It is likely that participants daily routines were disrupted, and they may have been doing more computer work than normal due to working from home. The participants may have wanted a break at the end of their day from their computers and therefore, were not as engaged as they may have been at a different timescale. There may also be cultural differences not accounted for affecting engagement.

The clinician guidance in this trial was designed as support on demand. Active guidance, checking in with participants more regularly and encouraging engagements, is likely to provide

better outcomes as this aspect has been highly valued in similar interventions (Beukes et al., 2018b), but requires more resources. A process evaluation may be helpful to identify the factors contributing to the retention and engagement rates and to identify what may improve these rates (Beukes et al., 2018c). Overcoming challenges may also involve adding further interactive designs and smart technologies (Kalle et al., 2018).

Outcome Feasibility

Following undertaking ICBT presented in Spanish, tinnitus distress was significantly reduced and large-effects were found. These improvements were maintained at the 2 month follow-up period. The findings are in agreement with previous feasibility trials in the UK and the US for English speakers (Beukes et al., 2017, 2021c, 2021d, 2021e). In the current sample, only 44% of participants indicated clinically significant changes at post-intervention, which is similar to the 38% for a pilot study in the UK (Beukes et al., 2017) but lower than that of a recent pilot trial in the US of 70% (Beukes et al., 2021c). This result needs to be confirmed in a larger clinical trial due to the single-group design and high drop-out rate in the present study. Further RCTs for Spanish-speaking communities are encouraged.

Tinnitus seldom occurs in isolation. It is often accompanied by various comorbidities, including hearing disability, hyperacusis, insomnia, and co-occurring mental health conditions. (e.g., Salazar et al., 2019; Trevis, McLachlan, & Wilson, 2018). The intervention content targeted these difficulties and outcome measures assessing intervention effects on these comorbidities were included. The intervention provided a large effect size related to reducing anxiety and depression which is encouraging. Medium effect sizes related to insomnia, health-related quality of life, and fewer negative tinnitus cognitions were furthermore identified. Again,

this is encouraging particularly as negative thinking appears to be associated with more problematic tinnitus, as interventions reducing such thought patterns are important (Handscomb, Hall, Shorter, & Hoare, 2017). An interesting finding was that the TQQ scores decreased. It is known that CBT can reduce tinnitus distress, but CBT does not specifically target a reduction of tinnitus loudness and other tinnitus qualities. Exploring this finding deserves further attention in future studies. Further RCTs are needed to establish the efficacy of this intervention against a control group and evaluate long-term outcomes (Beukes et al., 2018d). Exploration of the predictors of outcome deserves further attention in studies with larger sample sizes and longer follow-up time points.

Acceptance Feasibility

Overall, participants were satisfied with the intervention, although the rating of 68% is lower than reported for similar interventions (e.g., 86% for a pilot trial in the UK, Beukes et al., 2017, 2018d). This was unexpected due to the efforts made to ensure the intervention linguistically suitable for this population (Beukes, et al., 2020a; Manchaiah et al., 2020a,b). Those providing free text comments explained that the intervention had enabled them to control and manage the tinnitus. They valued the new techniques they had learned and found the information being presented online was as effective as if they were face to face. Public patient involvement from Spanish-speaking communities during the planning and implementation of subsequent research trials will be vital to gain insights regarding the factors important to Spanish participants (Staniszewska et al., 2019).

Study Limitations

The results of this study need to be considered in the context of this study. This study represents a feasibility trial of delivering ICBT in Spanish-speaking communities recruited across the globe with markedly different healthcare. The results were not intended to evaluate the efficacy of ICBT as no control group was included and only a small sample was studied. Moreover, the relatively low response rates at post intervention and follow-up may have inflated the results as those who were more motivated and gain more benefit may have been the participants completing the outcomes. Furthermore, placebo effects may be present which could elevate findings and need to be considered during result interpretation. Although the results were maintained at 2 months post-intervention, further studies are required to assess whether they are maintained long term. These results could be further explored in a controlled trial.

Conclusions

This trial supports the feasibility of ICBT for Spanish speakers. ICBT is a means of accessing evidence-based interventions, and the COVID-19 pandemic has furthermore highlighted the need for evidence-based eHealth approaches to overcome limited in-person contact and support available for individuals with tinnitus (Beukes et al., 2020b, 2021b). Further RCTs should be undertaken to establish efficacy offering ICBT to global communities on a larger scale.

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Disclosure statement

There are no relevant conflicts of interest.

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Data deposition

The data that support the findings of this study are openly available in Figshare at http://doi.org/10.6084/m9.figshare.13718896.

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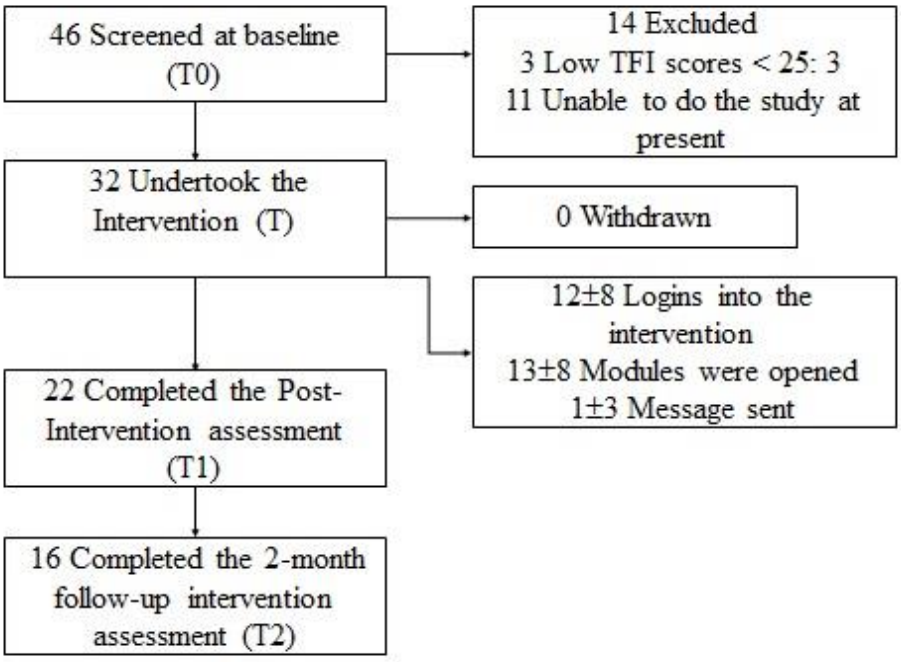

Figure 1: Study profile

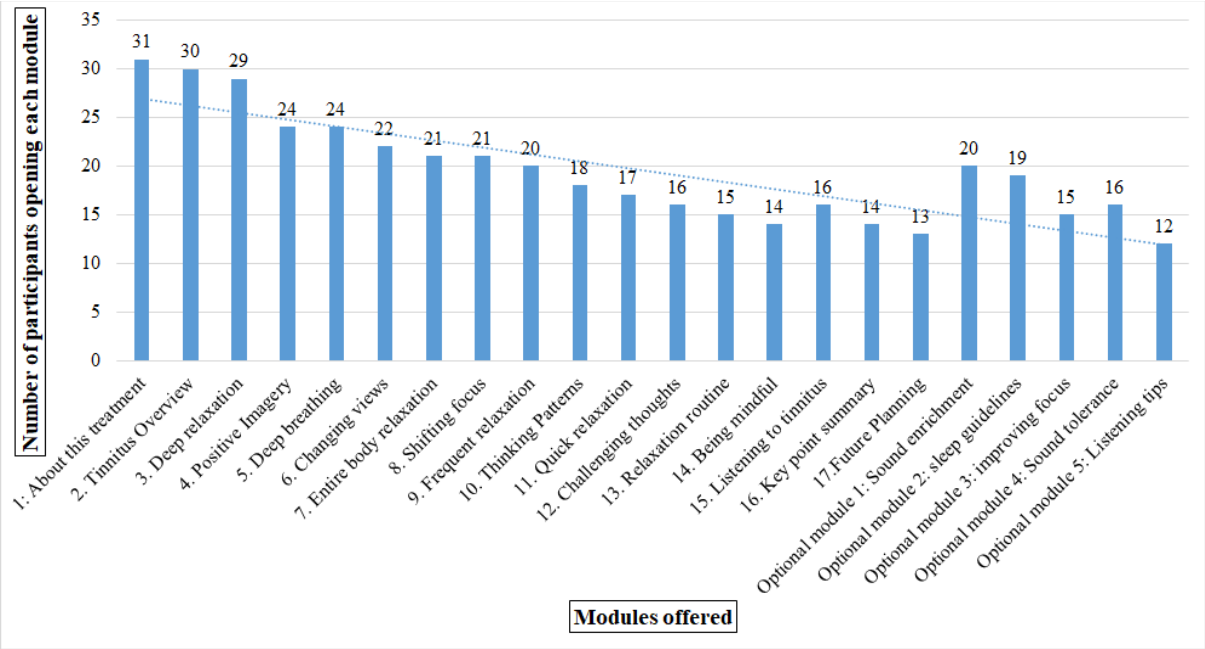

Figure 2. Number of participants opening each module.

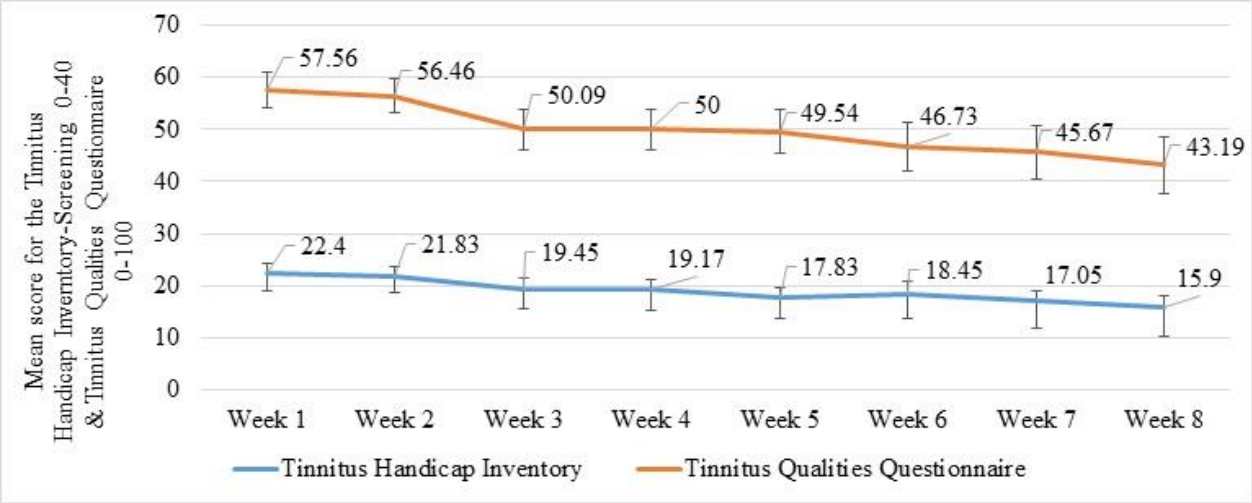

Figure 3: Change in Tinnitus distress measured by the Tinnitus Handicap Inventory-screening version and tinnitus qualities as measured by the Tinnitus Qualities Questionnaire during the 8 weeks of the intervention. Error bars represent standard error of the mean.