Internet-based audiologist-guided cognitive behavioral therapy for tinnitus in the United States: A randomized controlled trial

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Abstract

Background

Tinnitus is a symptom that can be very distressing due to hearing sounds not related to any external sound source. Managing tinnitus is notoriously difficult and access to evidence-based care is limited. Cognitive Behavioral Therapy is the tinnitus management strategy with the most evidence of effectiveness, but is rarely offered to those distressed by tinnitus. Provision of Internet-based cognitive behavioral therapy (ICBT) for tinnitus overcomes accessibility barriers, but is not at this time readily available in the US.

Objectives

The aim of this study was to investigate the efficacy of ICBT compared with weekly monitoring for the management of tinnitus in i) reducing tinnitus distress; ii) reducing tinnitus-related comorbidities including tinnitus cognitions, insomnia, anxiety, and depression and iii) assessing the stability of the intervention effects two-months post intervention.

Methods

A two-arm randomized clinical trial comparing audiologist-guided ICBT (n = 79) against a weekly monitoring group (n =79) with a 2-month follow-up assessed the efficacy of ICBT. Eligibility included adults seeking help for bothersome tinnitus. Recruitment was online using an open-access website. Participants were randomized with a 1:1 allocation but blinding was not possible. The study was undertaken online by English or Spanish speakers. The primary outcome was a change in tinnitus distress as measured by the Tinnitus Functional Index. Secondary outcome measures included measures of anxiety, depression, insomnia, tinnitus cognitions, hearing-related difficulties, and quality of life.

Results

ICBT led to a greater reduction in tinnitus distress (mean: 36.57, SD: 22:00) compared with weekly monitoring (mean: 46.31, SD: 20.63) with an effect size of d = 0.46 [0.14 to 0.77] using an intention-to-treat analysis. For the secondary outcomes there was a greater reduction in negative tinnitus cognitions and insomnia. There results remained stable over the 2-month follow-up period. No important adverse events were reported. There were 10 (16%) participants who withdraw, with low overall compliance rates for questionnaire completion of 72% (107 participants) at T1, 57% (91 participants) at T2 and 42% (62 participants) at T3.

Conclusions

This study is the first to evaluate and indicate the efficacy of audiologist-delivered ICBT in reducing tinnitus distress for a US population. It was also the first study to offer ICBT in Spanish to accommodate the large Hispanic population in the US. The results have been encouraging and further work is indicated in view of making such an intervention applicable to a wider population. Further work is required to improve compliance and attract more Spanish speakers.

Trial registration:

Clinical Trials.gov: clinical trial NCT04004260. Registered on 2 July 2019.

Keywords

Tinnitus; Cognitive Behavior Therapy; Internet-Intervention; Web-Based Intervention, Randomized Controlled Trial; Telehealth; Teleaudiology; eHealth

Introduction

Tinnitus, characterized by the perception of sound in the absence of an external stimulus, is one example of such a condition. It is highly prevalent with at least 10% of American's experiencing some form of tinnitus, of which a proportion have chronic burdensome or debilitating tinnitus [1]. Bothersome tinnitus causes various functional impairments in sleep, concentration, cognitive performance and thought processing [2-3]. It is also associated with an increased risk of psychological difficulties such as anxiety, depression and reduced quality

of life [4-5]. This may result in participant restrictions and activity limitations [6-7]. Due to the negative impact of tinnitus, those distressed by their tinnitus require interventions to help them cope with the tinnitus.

Managing tinnitus is, however, notoriously challenging as there is often not a curable medical cause [8]. When comorbid problems such as hearing loss accompany tinnitus, hearing aids and sound-therapy may reduce tinnitus severity [8]. Although these interventions may reduce the tinnitus percept, they do not always alter negative reactions to tinnitus. Psychological intervention changing reactions to tinnitus have effectively helped reducing tinnitus distress [9]. The intervention with strongest research evidence according to the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) tinnitus practice guidelines [10-12] and several systematic reviews [9,13], is cognitive behavioral therapy (CBT) for tinnitus. CBT is psychological intervention addressing unhelpful thought patterns and emotional reactions caused by tinnitus [14]. Despite the evidence base, accessibility to CBT for tinnitus is limited due to a dearth of healthcare providers with the knowledge and expertise to provide CBT to this population [15-16].

Prior work

To overcome this barrier, an Internet-based CBT for tinnitus (ICBT) [17] has been developed. This intervention was originally developed in Sweden [18] and was later translated to German [19] and English [20] and was provided with psychological guidance. To further increase accessibility, ICBT for tinnitus has been adapted to be delivered by audiologists [21] with some training to handle the CBT elements without compromising outcomes [22-27]. The efficacy of ICBT has been indicated in nine clinical trials across mainland Europe and the UK (for a review see 28). No clinical trials, however, determined the effects of ICBT in the US. An evidence-based, standardized approach, such as ICBT, is desirable, as tinnitus provision varies substantially across clinics and providers [16].

Study Rationale

To address this need, ICBT was adapted for a US population to improve cultural and linguistic suitability [29]. It was furthermore translated into Spanish to serve the large Spanish-speaking population in the US, and functionality and acceptability testing was undertaken [30]. ICBT for tinnitus in the US was evaluated within a clinical trial framework to evaluate complex intervention [31]. A small (N=28) Phase I trial was undertaken in the US [32] indicating feasibility. A larger randomised clinical trial (RCT) is, however, needed to determine efficacy for a US population. Efficacy cannot be assumed due to many differences regarding healthcare provision in the US and Europe. In the US, Tinnitus interventions include Tinnitus Retraining Therapy (TRT) [33] and Progressive Tinnitus Management (PTM) [34] with limited provision of CBT for tinnitus. It is also not known if a psychological approach will be acceptable due to the large emphasis of most tinnitus management programs on sound therapy and the fitting of devices [35]. The fee structure for healthcare in the US is also very different to largely free of charge healthcare in the UK, as it is generally paid for out of pocket, and clinicians have great difficulty receiving payment for non-diagnostic appointments such as tinnitus counselling.. Prior to the COVID-19 pandemic, healthcare was also generally provided in-person face-to-face. Hence the uptake for a remote intervention is uncertain but has now become a more urgent matter. These factors may all be potential barriers or facilitators for ICBT in the US.

This RCT set out to explore the effects of ICBT in the US with the following aims:

1. To evaluate the efficacy of audiologist-delivered ICBT in reducing tinnitus distress compared with weekly monitoring of tinnitus.
2. To ascertain the efficacy of ICBT in reducing comorbidities associated with tinnitus.
3. To assess the stability of ICBT intervention effects 2-months post-intervention.

The hypothesis was that patients with tinnitus would experience greater reduction of tinnitus distress and comorbidities after receiving ICBT compared to patients receiving weekly monitoring.

Methods

Trial Design

A prospective two-arm delayed intervention efficacy trial with a 2-month follow-up was implemented. As an efficacy trial, an active comparator was not included. Participants were randomized with a 1:1 allocation ratio to the ***Experimental Group*** to receive the ICBT intervention for 8-weeks, or the ***Control Group*** whose participants were monitored weekly during this 8-week period. During the first phase the experimental group completed the intervention. Following this both groups completed T1 outcome measures. During the second phase, the control group underwent the same ICBT intervention, after which both groups were invited to complete T2 outcomes. This study design, therefore, provided the opportunity to evaluate the intervention effects in two independent groups at three time points as shown in Figure 1.

Ethics and Preregistration

This RCT and protocol was pre-registered at Clinical Trials.gov: clinical trial NCT04004260 on 2 July 2019. Ethical approval was obtained from the Institutional Review Board at Lamar University, Beaumont, Texas, US (IRB-FY17-209). The study was conducted and reported according to the Consolidated Standards of Reporting Trials (CONSORT) EHealth guidelines [36] (see multimedia appendix 1: CONSORT_E_Health Checklist). An independent data monitoring committee monitored the running of the trial. There were no changes to the methods or trial outcomes used after the trial commenced. Participants were closely monitored for any harms. No harms or unintended effects were reported.

Participants

The study was undertaken online and no clinical visits were required. Study eligibility was as follows:

Inclusion criteria:

- Adults, aged 18 years and over, living in Texas in the US;
- The ability to read and type in English or Spanish;
- Access to a computer, the internet and able to email;
- Experiencing tinnitus for a minimum period of three months and
- A tinnitus severity score of 25 or greater on the Tinnitus Functional Index (TFI) indicating the need for an intervention.

Exclusion criteria:

- Indication of significant depression (≥ 15) on the Patient Health Questionnaire (PHQ-9);
- Indications of self-harm thoughts or intent, answering affirming on Question 10 of the PHQ-9 questionnaire;
- Reporting any medical or psychiatric conditions that could interfere with the treatment;
- Reporting pulsatile, objective or unilateral tinnitus, which has not been investigated medically or tinnitus still under medical investigation; and
- Undergoing any tinnitus therapy concurrent with participation in this study.

Eligibility was determined by a two-stage process as follows:

- An online screening questionnaire, which included demographic information, health and mental health-related questions, and standardized outcome measures as shown in Table 1.
- A telephone interview during which the researcher rechecked eligibility, and provided the opportunity for potential participants to ask any questions related to the study. The study procedures were explained, and motivational interviewing was done to encourage participants to commit and engage in the intervention.
- Participants not meeting the inclusion criteria were participants with a score of 15 or more on the PHQ-9 or indicated self-harm on question 10 received a phone consultation from a clinical psychologist on the research team. This call ensured that they were under care elsewhere or necessary resources and/or referral were provided.

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

Dimension	Outcome Measures	Internal consistency	Range of scores	Levels of significance	Timeframe measured
Primary outcome measure					
Tinnitus distress	Tinnitus Functional Index (TFI; 42)	.97	0-100 A reduction of scores indicates improvement	>25= mild (no need for intervention) 26-50= significant (possible need for intervention) 50+ =severe (need for a more intense intervention)	T0 T1 T2 T3 (control only)
					T0 T1 T2 T3 (control only)
Secondary outcome measures					
Generalized Anxiety	Generalized Anxiety Disorder (GAD-7, 44)	.89	0-21 A reduction of scores indicates improvement	0-4= minimal anxiety 5-9= mild anxiety 10-14= moderate anxiety 5-21= severe anxiety	T0 T1 T2 T3 (control only)
Depression	Patient Health Questionnai	.83	0-27	5-9=mild depression 10-14=moderate	T0 T1 T2

	re (PHQ-9; 45)		A reduction of scores indicates improvement	15-19=moderately severe 20-18= severe depression	T3 (control only)
Insomnia	Insomnia Severity Index (ISI; 46)	.74	0-28 A reduction of scores indicates improvement	0–7 = Not clinically s 8–14 = Subthreshold 15–21 = Clinical insc (moderate severity) 22–28 = Clinical insc (severe degree)	T0 T1 T2 T3 (control only)
Tinnitus Cognitions	Tinnitus Cognitions Questionnaire (TCQ; 47)	.91	0-104 A reduction of scores indicates improvement	Higher scores indicate a greater tendency to engage in negative cognitions in response to tinnitus	T0 T1 T2 T3 (control only)
Health-related quality of life	EQ-5D-5L (48)	.7-.85	0-15 A reduction of scores indicates improvement	Measures 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/ depression	T0 T1 T2 T3 (control only)
Health-related quality of life	EQ-5D-5L Visual Analogue Scale (VAS; 48)	.7-.85	0-100 Higher scores indicates improved health	VAS for overall health.	T0 T1 T2 T3 (control only)
Short measure for tinnitus, hearing disability and hyperacusis	Tinnitus and Hearing Survey (THS; 49)	.86-.94	Subscale for Tinnitus: 0-16 Hearing: 0-16 Sound tolerance: 0-8		T0 T1 T2 T3 (control only)
Weekly monitoring					
Screening of tinnitus severity	Tinnitus Handicap Inventory-Screening (THI-S) (Newman, Sandridge, & Bolek, 2008)	.93	0-40 A reduction of scores indicates improvement	>6 tinnitus handicap	Weekly while undertaking the 8-week intervention
Tinnitus percept	Tinnitus Qualities Questionnaire (TQQ; Beukes,	Not assessed	0-100 A reduction of scores indicates improvement	Designed to determine whether tinnitus qualities such as loudness, pitch, the number of tones heard and so	Weekly while undertaking the 8-week intervention

	Andersson, Manchaiah, & Kaldo, 2021)			forth improves while undertaking an intervention. Higher scores indicate more bothersome aspects of tinnitus are present.	

T0= preintervention; T1= 8 weeks after the experimental group started the intervention, prior to the control group starting; T2=8 weeks after the experimental group complete the intervention and at post-intervention for the control group

Recruitment Strategy

In line with the US government's health promotion initiative to make health care linguistically and culturally accessible [37], all the study materials were available in both English and Spanish and were also written at or below the 6th English reading grade level [29,38]. The participants were mostly recruited from the general public using a range of strategies including a television broadcast, promoting the study via tinnitus support groups in Texas and the American Tinnitus Association (ATA), and contracting the company "TrialFacts" to boost recruitment. Further recruitment strategies included use of social media (e.g. Facebook and Twitter), flyers and posters which were distributed to local communities and put up in clinic waiting rooms. Professionals such as audiologists and otolaryngologists in the state of Texas were also notified about the study and provided with leaflets to distribute to suitable patients. Recruitment was online from an open access website between 17 February to 30 March 2020. Those interested were directed to the study website where there was detailed information about the study, the study team, and register their interest in study participation. Informed consent was provided online, confirming understanding of how data would be used, to be randomized, the length of the trial, the commitment expected and being contacted for follow-up data collection. Following registration they were invited to complete the online screening demographic and outcome questionnaire. They were informed of their right to withdraw without penalty at any stage of the process.

Sample Size, Power and Attrition

Sample size estimation was calculated using G*Power version 3.1.6 [39] and based on achieving a 13-point clinically meaning change between baseline and post-intervention using the primary assessment measure, the TFI. Pilot data [32] indicated 26 participants per group

with a 1:1 allocation to achieve 80% power to detect a between-group mean standardized difference effect size of $d = 0.50$ (a moderate effect size). As this was fewer than the 58 participants suggested using data from a UK-based ICBT RCTs, [23] we selected 58 per group. In addition, sample size was inflated to account for missing data, estimated to be 20% from the US phase I trial data [32]. The aim was thus to recruit 146 participants with 73 in each arm (calculated as 58/0.8).

Randomization

Participants meeting the inclusion criteria were randomly assigned in the ratio of 1:1 and enrolled to either the experimental or control group using a computer-generated randomization scheduled by an independent research assistant in blocks of varying sizes after participants were pre-stratified for language (English and Spanish). Participants and investigators could not be blinded to group allocation due to the nature of the intervention. Participants were informed immediately after randomization when the intervention would commence by the principal investigator, but not explicitly to which group they were assigned.

Patient Public Partnership (PPI)

A PPI was established to include two individuals with tinnitus who had piloted the ICBT intervention, two audiologists, two researchers. Meetings were held via video conferencing. The aim of the PPI was to guide the study processes and input into the research strategy to boost recruitment and other elements of the study to ensure high compliance and engagement.

Intervention

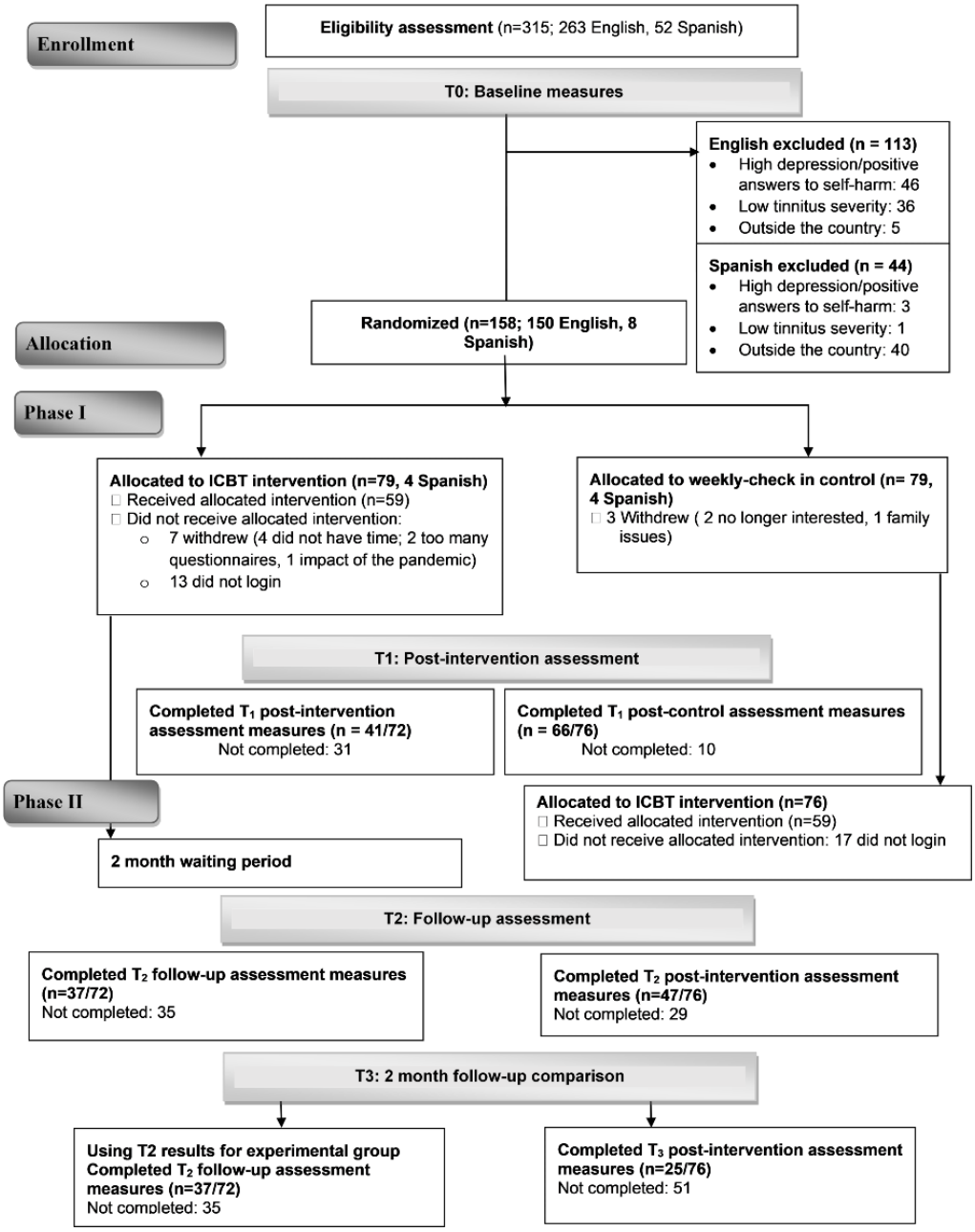
The ICBT intervention content was based on a CBT self-help program originally developed in Swedish [18] and later adapted and translated in English [20]. The intervention was subsequently transformed into an 8-week interactive e-learning version suitable for a UK population [40] and then adapted linguistically and culturally to ensure suitability for a US population [29]. These adaptions prioritized accessibility of the intervention, such as lowering the readability to below the recommended 6th-grade level, as more than half the US adult population have low literacy skills [41]. The intervention was augmented by a module on mindfulness and more videos. The ICBT platform version 1 in the US application consisted of 22 modules with worksheets and quizzes [see 21,29 for more details]. Participants require an internet connection to access the materials and email correspondence regarding the intervention.

The intervention platform was transferred from Sweden and housed in the US (Lamar University) to comply with the needed US data protection regulations. Prior to this feasibility trial, acceptability and functionality of this intervention for a US population were first ensured [30].

Both groups received the same intervention, only the timings regarding receiving the intervention varied. The control group received the experimental intervention 8 weeks after the experimental group commenced the program. The intervention was 8 weeks long. Participants were asked to read the modules weekly and ideally spend 10 minutes each day practicing the suggested strategies.

Audiology Guidance

Guidance was provided to support participants while undertaking the intervention. This included monitoring progress, monitoring weekly scores, providing feedback on worksheets completed, outlining the content of new modules, and answering questions. Participants who did not engage were contacted to support participation and to discuss possible barriers. An encrypted 2-way messaging system within the ePlatform was used to communicate with a minimum guidance time of 10 minutes per participant. Although psychologists have traditionally provided CBT interventions, tinnitus management is generally delivered by audiologists [16]. Thus audiologists provided guidance to participants in a manner consistent with the previous English trials [22-24] using this intervention, to ensure standardization of the intervention approach. Support to the Spanish participants was provided by a Doctor of Audiology (AuD) student with clinical experience whose first language was Spanish using a handbook that was developed by the lead English speaking audiologist.



Outcome Measures

Primary Outcome Measure

The primary outcome measure was tinnitus severity as measured by the Tinnitus Functional Index (TFI) [42]. A meaningful change was defined to occurs when scores are reduced by 13 points or more [42]. The TFI has been translated into more than 15 languages and been validated for several populations including Chinese, Dutch, Swedish and German [43]. It was selected over other tinnitus questionnaires as it was specifically developed to measure

tinnitus severity and assess responsiveness to treatment and for comparison purposes with previous trials [22-25].

Secondary Outcome Measures

Secondary outcome measures assessed anxiety [44], depression [45], insomnia [46], tinnitus cognitions, [47], general health-related quality of life [48], and a short measure of hearing-related difficulties [49], as shown in Table 1. All questionnaires were used with the required permissions and agreements were set up for those that are not freely available to use. For Spanish speakers, validated Spanish translated versions were used. Where these were unavailable, validated translations were undertaken [38].

Weekly Monitoring of Tinnitus During the Active Intervention Period

Throughout the program, participant's tinnitus was monitored weekly by means of the Tinnitus Handicap Inventory, Screening version (THI-S). The THI-S consists of a 10-item questionnaire and scores are comparable (r =.90) with the full version of the THI [50]. The weekly scores were also used to detect possible adverse effects. If scores increased by more than 10 points between two consecutive weeks, this was noted as an adverse effect. Those indicating adverse effects were contacted to address the identified problems. Participants were also monitored by a newly developed Tinnitus Qualities Questionnaire (TQQ) [21]. The TQQ measures tinnitus qualities such as pitch, loudness, and the number of tones heard. The scores of TQQ can range between 0 to 100 with higher scores indicating more problematic tinnitus.

Intervention Variables

Intervention compliance was assessed by determining retention rates and compliance in completing outcome questionnaires. Intervention engagement was assessed by the number of logins, the number of modules read, and the number of messages sent during the intervention. Adverse effects were monitored by 1) Direct questioning in the outcome questionnaire regarding the presence of adverse effects 2) Adverse effects written in messages or worksheets 3) An increase of 10 points or more during weekly monitoring using the THI-S questionnaire.

Questionnaire Administration

Online questionnaires were used throughout the study for both groups. Although not all measures are validated for online use, results should be comparable as equivalent psychometric properties have been reported [51]. All the measures were completed at

baseline, T1 (post-intervention for experimental group), T2 (post-intervention for the control group and at two-month follow-up for the experimental group). To have a measure of the control group 2 months post intervention, participants completed further outcome measures at T3. For data analysis purposes the T3 results for the control group and those at T2 for the experimental group were compared in order to assess the invention effect at same experimental time point for both groups (i.e., 2 months post intervention). To maximize retention, 3 electronic reminders were sent to participants who had not completed questionnaires, on the 3 consecutive days after the release of the questionnaire. A further reminder was sent out via email and text message. If questionnaires were still not completed participants were telephoned to encourage questionnaire completion. Participants were also phoned after completing the intervention to discuss the progress they had made and share their questionnaire results.

Statistical Analysis Plan

Statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) version 26.0. All statistical tests were 2-tailed with an alpha set to .05. To account for missing data from participants not completing the post-intervention or follow-up intervention analysis an imputation analysis was undertaken. As the data were missing at random, missing data were handled through multiple imputation using the *Markov Chain Monte Carlo* approach due to the ability to reduce bias even when the proportion of missing data is large [52, 53] For comparison, a complete case analysis was also performed by analyzing only the completed questionnaire data without imputing missing data. As there were substantial differences, statistical analysis using the imputed data are reported in the results section as a more accurate unbiased account of the findings.

The primary study outcome was a change in TFI score between the groups at post-intervention (T1). A difference in scores between T1–T2 for the experimental group was used to assess the stability of intervention effects. Effect sizes, linear mixed effects models, and the reliable change index were used to assess the primary and secondary outcomes. *Changes from baseline to post-intervention were compared within and between groups using the pre-post-test effect size (Cohen's d) for all primary and secondary outcomes using the observed data. Effect sizes of* d *= 0.20 represent small effect sizes; those of* d *= 0.50, medium effect sizes; and those equal or greater than* d *= 0.80, large effect sizes* [54].

A Linear Mixed Model (LMM), which provided unbiased results in the presence of missing data (using all available data), was applied to analyze the intervention effect over time for each outcome measure. An unstructured-repeated effects and identify-random effects covariance structure provided the best model fit based on the Akaike's Information Criterion (AIC). Time was treated as a repeated and fixed effect. Restricted maximum likelihood estimation was applied. The Type III *F* test sums of squares from the LMM was calculated. As a sensitivity analysis, baseline tinnitus severity was initially added as a covariate, but as it had no significant effect on the results it was removed from the model.

Another model was run to test the differences during the course of the 8 weeks intervention for the weekly tinnitus outcome measures. Post hoc time comparison were carried out in the case of significant group differences to assess at which time points these differences occurred. In addition to statistical significant, clinical significance is also reported. A 13 point difference is recommended by the original developers of the TFI [42] to indicate a meaningful change in scores. To handle study variability, the reliable change index (RCI) [55] is recommended as a means of calculating clinical significance for the TFI as the

primary outcome. This was calculated using the mean pretest-posttest score difference, the pretreatment standard deviation (17.49), and a test-retest reliability coefficient of 0.78, and as reported in the validation study

Sample Characteristics

Descriptive statistics including gender, age, ethnicity, race, tinnitus duration, hearing aid use, and professionals consulted, ease of computer use, veteran status, education and employment status were used to describe the sample. The means and standard deviations were reported for each outcome measure at each time point. Descriptive statistics were also used to describe the sample and intervention engagement including the number of logins and modules read. A Chi square test of independence was used to identify group differences regarding engagement and compliance rates.

Results

Participant Characteristics

A total of 158 adults of the 315 participants screened met the eligibility criteria and were randomly assigned to the experimental (n = 79) and control groups (n = 79) as seen in Figure 1. Eight (4 in each group) of the 158 participants were Spanish speakers who completed the Spanish version of the ICBT program. Of the total sample 51% (80 participants) were female and 49% (78 participants) male with a mean age of 57 (SD: 12) years for the full sample. The groups were well matched and there were no clinically meaningful differences as seen in Table 2. Most participants (91%, 144 participants) indicated that they were frequent computer and internet users. There were no functionality failures regarding the intervention during the trial. This trial commenced at the end of March 2020. This timing was unfortunate

as it coincided with the peak of the COVID-19 pandemic. Some participants reported became ill, struggling to adjust emotionally, or finding the required lifestyle changes difficult.

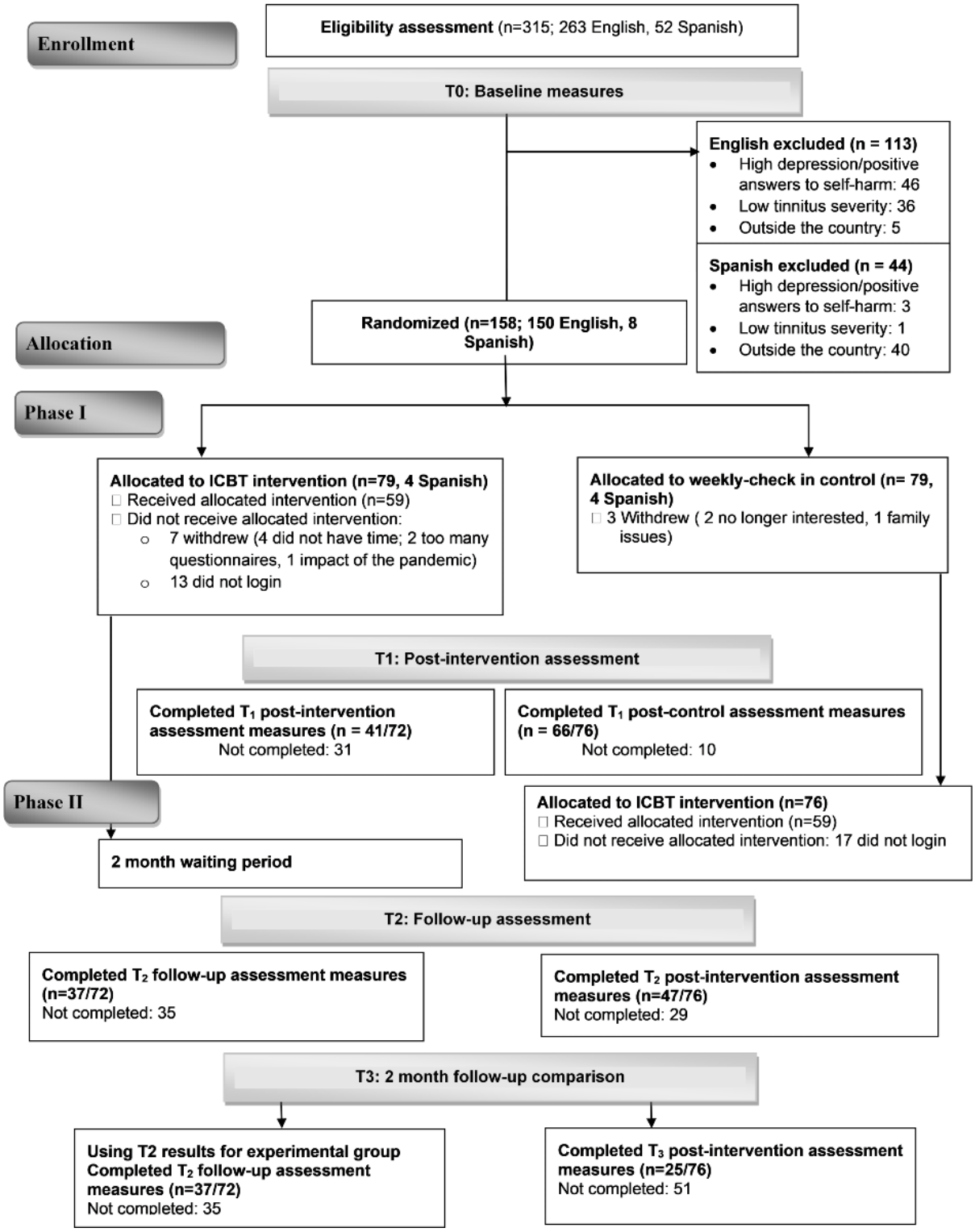


Figure 1. The Consolidated Standards of Reporting Trials (CONSORT) Flow diagram.

Table 2. Demographical characteristics of the participants

Category	Description	Experimental group (n = 79)	Control group (n = 79)	Overall (n = 158)
Gender	Male Female	40 (51%) 39 (49%)	38 (48%) 41 (52%)	78 (49%) 80 (51%)
Age	Mean years (SD) Range	56 (13) 19–76years	58 (11) 29–84years	57 (12) 19–84 years
Tinnitus duration	Mean years (SD) Range	15 (16) 4 months to 70 years	12 (12) 3 months to 58 years	14 (14) 3 months to 70 years
Ethnicity	Hispanic/ Latino Not-Hispanic/ Latino	9 (13%) 70 (87%)	11 (14%) 68 (86%)	20 (13%) 138 (87%)
Race	American Indian / Alaska Native Asian Native Hawaiian or Pacific Islanders Black or African American White More than One Race	0 0 1 (1%) 0 2 (2.5%) 74 (94%) 2 (2.5%)	0 0 0 0 2 (2.5%) 74 (94%) 3 (3.5%)	0 0 1 (0.5%) 0 4 (2.5%) 148 (94%) 5 (3%)
Highest educational level	High School College/ vocational training University degree	11 (14%) 22 (28%) 46 (58%)	10 (13%) 31 (39%) 38 (48%)	21 (13%) 53 (34%) 84 (53%)
Employment	Skilled or professional Retired Not working	55 (69%) 22 (28% 2 (3%)	41 (52%) 30 (38%) 8 (10%)	96 (61%) 52 (33%) 10 (6%)
All professionals seen	Primary Care Physician ENT Physician Audiologist	41 (52%) 33 (42%) 36 (46%)	44 (56%) 36 (46%) 39 (49%)	85 (54%) 69 (44%) 75 (47%)
Veterans Duration in the military service	Number Service duration mean in years Service duration range in years	8 8 (3) 2–10	11 8 (6) 2–23	19 8 (5) 2–23
Ease of using a computer	Basic skills Frequent user	7 72	7 72	14 (9%) 144 (91%)

Retention, Compliance, Engagement and adverse effects

Overall compliance for completing the outcome measures was low with 57% (41 participants) and 51% (37 participants) completion rate at T1 and T2 respectively for the experimental group (Figure 1). Although compliance was greater in the control group with 87% (66 participants) and 62% (47 participants) completion at T1 and T2 there was only 33% (25 participants) completion for the control group at T3 resulting in a significant difference between-group completion rate (χ^2 = (3, N = 411) = 7.98, P = .046) at T3 with lower completion by the control group, as seen in Figure 2.

The reporting of adverse effects were low. During the intervention period, only 1 (0.6%) participant had an increase of more than 10 points on the THI-S questionnaire. On finding out more, this was related to a particularly stressful deadline for work under difficult circumstances during the COVID-19 pandemic. There was only 1 (0.6%) participant who reported an adverse effect on the outcome questionnaire, explaining that initially their tinnitus was more bothersome due to all the focus on tinnitus at the start of the intervention. There were no serious adverse events such as privacy breaches or major technical problems.

Intervention engagement was low but varied considerably among participants. To identify if group allocation contributed, engagement between groups were compared while each group was actively involved with the intervention. No significant group differences were, however, identified (χ^2 = (1, N = 273) = 0.13, P = .93) as seen in Figure 2. On average 82% of the experimental group (59/ 72 participants) and 77% (59/ 76 participants) of the control group logged into the platform; 74% (53/ 72 participants) from the experimental group and 75% (57/ 72 participants) of the control group read at least one module and 32% (23/ 72

participants) from the experimental group and 29% (23/ 76 participants) from the control group sent at least one message.

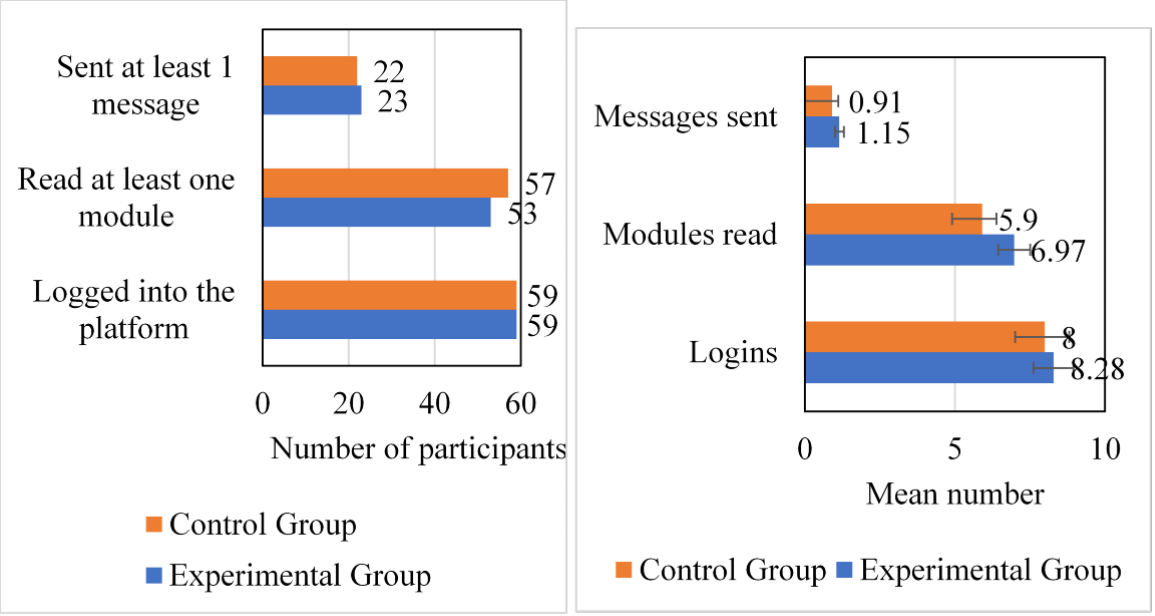


Figure 2. Intervention engagement.

Efficacy of ICBT in Reducing Tinnitus Distress Compared With Weekly Monitoring

Tinnitus severity between the treatment arms was not constant over time (Figure 3, Table 3). The mean difference indicated a great difference for the ICBT group with an effect size of *d* = 0.46 at T1. The test of fixed effects (Table 4) indicated that the intercept, slope and group by time interaction all had significant effects on the changes in tinnitus severity. There was no estimated difference in baseline tinnitus severity between the groups (*P* = .92). The post-treatment effect was much lower for the control group. After the experimental group underwent the treatment (T1) they had an estimated 10-point decrease in tinnitus severity (CI: 3 to 16; [*t*(156.00 = -2.88, *P* = .004]). After the control group also underwent the treatment (T2), there was a non-significant estimated difference of 5 points (CI: -2 to 11; [*t*(156.00) = -1.48, *P* = .14]). This may have been due to the initial large reduction (mean of 7.62 points) in scores during weekly monitoring despite not having the intervention.

The model indicated an estimated baseline to 2-month follow-up mean difference of 22 points (CI: 18 to 25) after undertaking the intervention with an estimated TFI score of 32 (baseline score was 54) at follow-up (CI: 30 to 34).

Comparison of the margin of score reduction between T0 and T1 is provided in Figure 4. It indicates that experimental group had a greater score reduction (between 20 to 50 points) due to the intervention with a maximum reduction of 88 points, compared with a maximum reduction of 44 points in the control group (with the majority between 0-9 points) who were only monitored weekly during this period.

Clinical significance was calculated using the reliable change index. The reliable change criterion was calculated to be 22.74 in TFI score. Using this value clinical significance was achieved by 45 (57%) participants in the experimental group and 12 (15%) from the control group at T1 (after the experimental group did the intervention). A clinically significant change was found for 40 (51%) of the experimental group at T2 (2 months post-intervention) and 30 (38%) of the control group (after the control group did the intervention) and 40 (48%) of the control group at their 2 month follow-up.

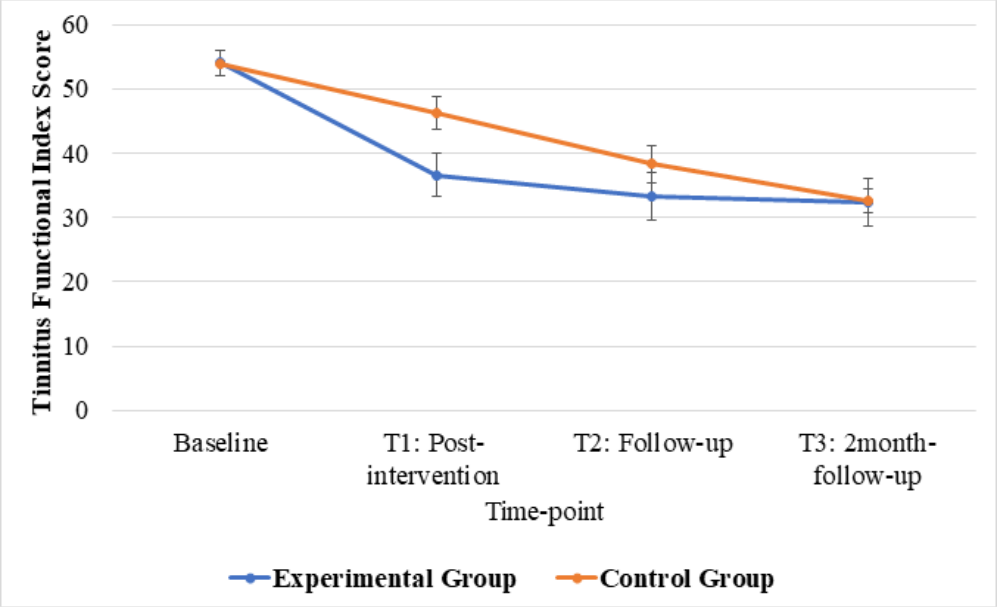
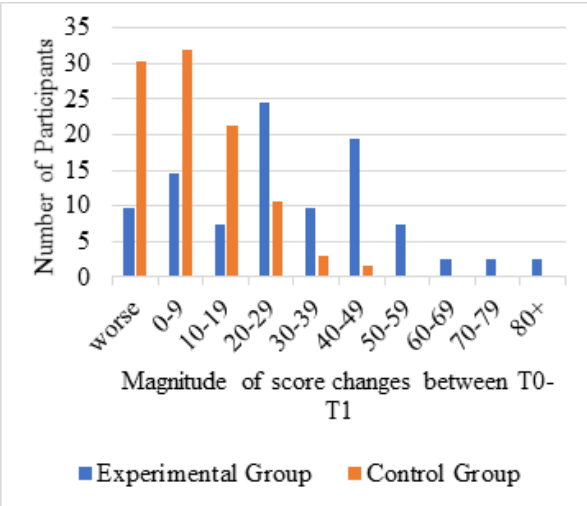


Figure 3. Change in Tinnitus Severity between groups over time. T1, only the experimental group had the intervention. T2, post intervention for the control group and 2 month follow-up for the experimental group, T3 is comparison of 2 month follow-up for both groups.



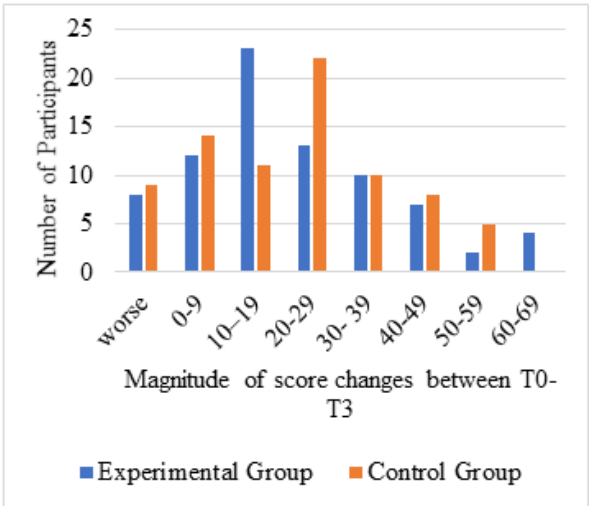


Figure 4a (to the left). Magnitude of FTI score changes between T0 to T1 after the experimental group underwent ICBT and the control group were monitored weekly and **Figure 4b (to the right).** Magnitude of these changes between T0 to T3 at 2 months follow-up after both groups undertook the full intervention.

Table 3. Outcome measures at each time point

Outcome measure and Group allocation	T0: Pre-treatment at baseline	T1: Experimental group: post-intervention; Control group: post weekly monitoring	T2: Experimental group: follow-up for; Control group: post-treatment	T3: Experimental Group: repeated follow-up, not measured, Control group: follow-up	Between group Cohen's *d* (95% confidence intervals)
Primary Outcome; Mean (SD) **Tinnitus Functional Index**					
Experimental group	54.04 (17.85)	Completers: 29.44 (19.60) Imputation: 36.57 (22.00)	Completers: 25.10 (19.46) Imputation: 33.24 (22.00)	Completers: 25.10 (19.46) Imputation: 32.39 (14.70)	**At T1: 0.46 [0.14 to 0.77]** At T2: 0.23 [-0.09 to 0.54] At T3: 0.02 [-0.30 to 0.33]
Control group	53.93 (17.32)	Completers: 47.35 (21.25) Imputation: 46.31 (20.63)	Completers: 38.50 (21.36) Imputation: 38.25 (21.24)	Completers: 32.82 (26.80) Imputation: 32.57 (15.37)	
Secondary Outcomes; Mean (SD)					
Anxiety (GAD-7)					
Experimental group	5.97 (4.22)	Completers: 4.80 (4.84) Imputation: 5.67 (4.71)	Completers: 3.77 (4.65) Imputation: 4.63 (4.34)	Completers: 3.77 (4.65) Imputation: 5.07 (2.43)	At T1: 0.00 [-0.31 to 0.31] At T2: 0.00 [-0.31 to 0.31] At T3: 0.12 [-0.20 to 0.43]
Control group	5.23 (4.29)	Completers: 5.35 (4.59) Imputation: 5.68 (4.73)	Completers: 3.77 (3.52) Imputation: 4.62 (4.03)	Completers: 5.17 (5.58) Imputation: 5.43 (3.66)	
Depression (PHA-9)					
Experimental group	5.54 (4.17)	Completers: 4.41 (4.74) Imputation: 5.72 (4.93)	Completers: 3.17 (4.01) Imputation: 5.11 (4.86)	Completers: 3.17 (4.01) Imputation: 3.87 (2.01)	At T1: 0.07 [-0.24 to 0.38] At T2: 0.07 [-0.24 to 0.38] At T3: -0.004 [-0.35 to 0.28]
Control group	5.42 (4.10)	Completers: 5.91 (4.35) Imputation: 6.04 (4.23)	Completers: 4.20 (3.80) Imputation: 5.44 (4.03)	Completers: 3.70 (4.73) Imputation: 3.78 (2.96)	
Insomnia (ISI)					
Experimental group	10.18 (5.99)	Completers: 5.98 (4.80) Imputation: 7.97 (5.43)	Completers: 4.97 (5.00) Imputation: 6.70 (5.55)	Completers: 4.97 (5.00) Imputation: 5.67 (2.18)	**At T1: 0.34 [0.02 to 0.65]** **At T2: 0.45 [0.13 to 0.76]** At T3: 0.00 [-0.31 to 0.31]
Control group	9.92 (5.71)	Completers: 9.97 (6.39) Imputation: 9.97 (6.30)	Completers: 7.70 (5.56) Imputation: 8.24 (5.77)	Completers: 5.77 (6.24) Imputation: 5.81 (3.86)	

Health-related quality of life (EQ-5D-5L)					
Experimental group	7.44 (2.43)	Completers: 7.17 (2.05) Imputation: 7.38 (2.24)	Completers: 6.56 (1.52) Imputation: 6.72 (1.84)	Completers: 6.56 (1.52) Imputation: 6.88 (2.86)	At T1: 0.07 [-0.24 to 0.39] At T2: 0.10 [-0.21 to 0.42] At T3: 0.05 [-0.27 to 0.36]
Control group	7.42 (2.48)	Completers: 7.50 (2.37) Imputation: 7.55 (2.34)	Completers: 6.78 (1.62) Imputation: 6.91 (1.80)	Completers: 7.00 (2.25) Imputation: 7.00 (2.35)	
Health-related quality of life (EQ-5D-5L) VAS scores					
Experimental group	78.23 (13.14)	Completers: 79.68 (15.66) Imputation: 78.44 (14.83)	Completers: 80.79 (16.16) Imputation: 79.39 (14.40)	Completers: 80.79 (16.16) Imputation: 74.00 (15.56)	At T1: 0.14 [-0.17 to 0.45] At T2: 0.23 [-0.09 to 0.54] At T3: -0.15 [-0.46 to 0.16]
Control group	75.51 (13.96)	Completers: 76.02 (13.70) Imputation: 76.43 (13.63)	Completers: 78.52 (13.29) Imputation: 76.21 (13.78)	Completers: 78.05 (21.44) Imputation: 76.48 (17.51)	
Tinnitus score from THS					
Experimental group	5.80 (3.90)	Completers: 2.68 (2.47) Imputation: 3.34 (2.82)	Completers: 2.35 (3.40) Imputation: 2.73 (3.02)	Completers: 2.35 (3.40) Imputation: 3.75 (4.79)	**At T1: 0.64 [0.32 to 0.96]** At T2: 0.24 [-0.07 to 0.55] At T3: -0.06 [-0.37 to 0.25]
Control group	5.51 (3.52)	Completers: 5.31 (3.82) Imputation: 4.82 (4.02)	Completers: 3.46 (3.10) Imputation: 3.44 (2.86)	Completers: 2.86 (3.68) Imputation: 3.51 (3.50)	
Hearing disability (THS)					
Experimental group	6.89 (4.50)	Completers: 3.83 (3.65) Imputation: 5.00 (4.48)	Completers: 3.21 (3.20) Imputation: 4.80 (3.78)	Completers: 3.21 (3.20) Imputation: 4.29 (1.86)	**At T1: 0.34 [0.02 to 0.65]** At T2: 0.28 [-0.03 to 0.59] At T3: -0.11 [-0.42 to 0.20]
Control group	7.30 (4.79)	Completers: 7.29 (4.94) Imputation: 6.62 (5.15)	Completers: 6.46 (4.05) Imputation: 5.94 (4.28)	Completers: 4.14 (3.37) Imputation: 4.05 (2.38)	
Hyperacusis (THS)					
Experimental group	.87 (1.3)	Completers: .54 (.84) Imputation: .97 (1.02)	Completers: .47 (.79) Imputation: .81 (.77)	Completers: .47 (.79) Imputation: .82 (.71)	At T1: 0.09 [-0.22 to 0.40] At T2: 0.09 [-0.22 to 0.40] At T3: -0.006 [-0.38 to 0.25]
Control group	.80 (1.10)	Completers: 1.00 (1.30) Imputation: 1.07 (1.25)	Completers: .76 (1.14) Imputation: .89 (.98)	Completers: .64 (.90) Imputation: .77 (.83)	

Tinnitus cognitions (TCQ)					
Experimental group	39.63 (17.38)	Completers: 26.03 (15.58) Imputation: 34.17 (20.08)	Completers: 26.03 (16.80) Imputation: 29.60 (15.29)	Completers: 26.03 (16.80) Imputation: 32.29 (4.49)	**At T1: 0.46 [0.14 to 0.77]*** At T2: 0.25 [-0.06 to 0.56] At T3: -0.03 [-0.34 to 0.28]
Control group	37.95 (14.54)	Completers: 40.57 (15.72) Imputation: 42.43 (15.75)	Completers: 32.26 (15.54) Imputation: 33.53 (16.12)	Completers: 28.55 (17.00) Imputation: 32.06 (9.54)	

Efficacy of ICBT in Reducing Tinnitus Comorbidities Compared With Weekly Monitoring

Results from the secondary assessment measures between the treatment arms were not constant over time, except for hyperacusis and the VAS scores for the health-related quality of life (EQ-5D-5L) which did not have significant time effects (Table 4). At postintervention (T1), the experimental group had a significantly greater reduction in tinnitus cognition scores indicating a medium effect (rounded off to $d = 0.50$). The intercept, slope, and time by group interaction all revealed significant effects on the changes in tinnitus cognitions. Baseline tinnitus cognitions was not significantly different between the groups (p =.58). After doing the intervention (T1) the experimental group had an estimated 8-point decrease in tinnitus cognitions (CI 3 to 13; [$t(156) = -3.13$, $P = 0.002$]). After both groups undertook the intervention (T2) there was no significant estimated difference between the groups ($p = 0.08$). For tinnitus cognitions the model indicated an estimated baseline to 2-month follow-up mean difference of 7 points (CI: 3 to 11) after undertaking the intervention with an estimated score of 32 at follow-up (CI: 31 to 32).

The experimental group had a significantly greater reduction in insomnia scores at postintervention (T1) and follow-up (T2), although there was only a small effect ($d = 0.30$) at T1 and medium effect (rounded off $d = 0.50$) at T2. There was no significant group by time

interaction indicated by the test of fixed effects due to later improvements by the control group. Likewise, although the experimental group had a significantly greater reduction in hearing disability at T1, this was only a small effect *(d* = 0.3) without a significant group by time interaction due to later improvements by the control group.

Confirming the results of the primary outcome, the THS tinnitus secondary measure indicated that the experimental group had a significantly greater reduction in tinnitus (*d* = 0.60) with no significant difference at baseline or after the control group completed the intervention. The test of fixed effects results indicated that there was no significant time by group interaction for anxiety, depression, health related quality of life or hyperacusis outcome measures and no significant effect was seen.

Table 4: Random intercept mixed model results using results from the imputation data.

Outcome predictor	Intercept	Time	Group	Time*Group
Tinnitus	***F*(1,156.012) = 1364.769, *P* < .001***	***F*(3,156.000) = 77.21, *P* < .001***	*F*(1,156.012) = 2.80, *P* = .10	***F*(3,156.000) = 3.64, *P* = .01***
Anxiety	***F*(1,156.000) = 534.153, *P* < .001***	***F*(3, 156.000) = 4.74, *P* = .003***	*F*(1, 156.000) = .05, ***P*** = .83	*F*(3, 156.000) = .841, *P* = .47
Depression	***F*(1,155.992) = 489.593, *P* < .0***	***F*(3,156.000) = 12.250, *P* < 0.001***	*F*(1,155.992) = .05, *P* = .82	*F*(3,156.000) = .163, *P* = .92
Insomnia	***F*(1,156.000) = 637.397, *P* < .001***	***F*(3,156) = 42.064, *P* < .001***	*F*(1,156.000) = 1.81, *P* = .18	*F*(3,156) = 2.33, *P* = .08
EQ-5D-5L	***F*(1,156.000) = 2034.549, *P* < .001***	***F*(3,156) = 14.33, *P* < .001***	*F*(1,156.000) = .13, *P* = .72	*F*(3,156) = .19, *P* = .90
EQ-5D-5L VAS	***F*(1,156.000) = 8100.537, *P* < .001***	*F*(3,156.000) = 2.02, *P* = .11	*F*(1,156.000) = .64, *P* = .43	*F*(3,156.000) = 1.63, *P* = .19
THS: Tinnitus	***F*(1,156.000) = 294.231, *P* < .001**	***F*(3,156.000) = 38.850, *P* < .001***	*F*(1,156.000) = .750, *P* = .39	***F*(3,156.000) = 3.312, *P* = .02***
Hearing disability	***F*(1,155.975) = 526.930, *P* < .001***	***F*(3,156) = 21.511, *P* < .001***	*F*(1,155.975) = 2.24, *P* = .14	*F*(3,156) = 2.15, *P* = .10
Hyperacusis	***F*(1,156.000) = 247.016, *P* < .001***	*F*(3,156.00) = 2.51, *P* = .06	*F*(1,156.000) = 0.017, *p* = .895	*F*(3,156.000) = .410, *P* = .75
Tinnitus cognitions	***F*(1,155.984) = 1715.178, *P* < .001***	***F*(3,156.000) = 19.29, *P* < .001***	*F*(1,155.984) = 2.28, *P* = .13	***F*(3,156.000) = 4.15, *P* = .007***

Stability of ICBT Intervention Effects 2-months Post-intervention

At 2-months follow-up, the experimental group indicated further reduction in tinnitus severity and all other outcomes. There were no significant differences in scores between T1 and T2 for the experimental group, indicating that intervention effects were maintained 2-months post-intervention.

At 2-months follow-up, most of the secondary outcome measure scores were stable. There was however an increase in anxiety scores for both groups, an increase in negative tinnitus cognitions for the experimental group and as well as a decrease in health-related quality of life for the control group, although these differences were not statistically significant.

Comparison of Weekly Tinnitus Severity During the Active Intervention Period

Differences between the intervention arms were not constant across the 8-time points between T_0 and T_1 for both the THI-S and TQQ outcome measure scores. The experimental group had a greater weekly reduction in tinnitus distress, as evidenced by the significant group by time interaction for both the THI [F (7, 136.000) = 4.02; P = .04] and TQQ [F (7,136.000) = 2.55; P = .02], as well as a significant intercept and slope. Pairwise comparisons indicated significant differences between groups from weeks 5 for the TQQ and week 6 for the THIs, as the experimental group's (receiving ICBT) tinnitus distress was rated significantly lower than that of the control group (not undergoing ICBT). The maximum between group mean difference in scores was at week 8 with the experimental group having a THIS-S score of 3.5 (SE: 1.1) points lower and TQQ score of 8.72 (SE: 2.30) lower than that of the control group, as seen in Figure 5.

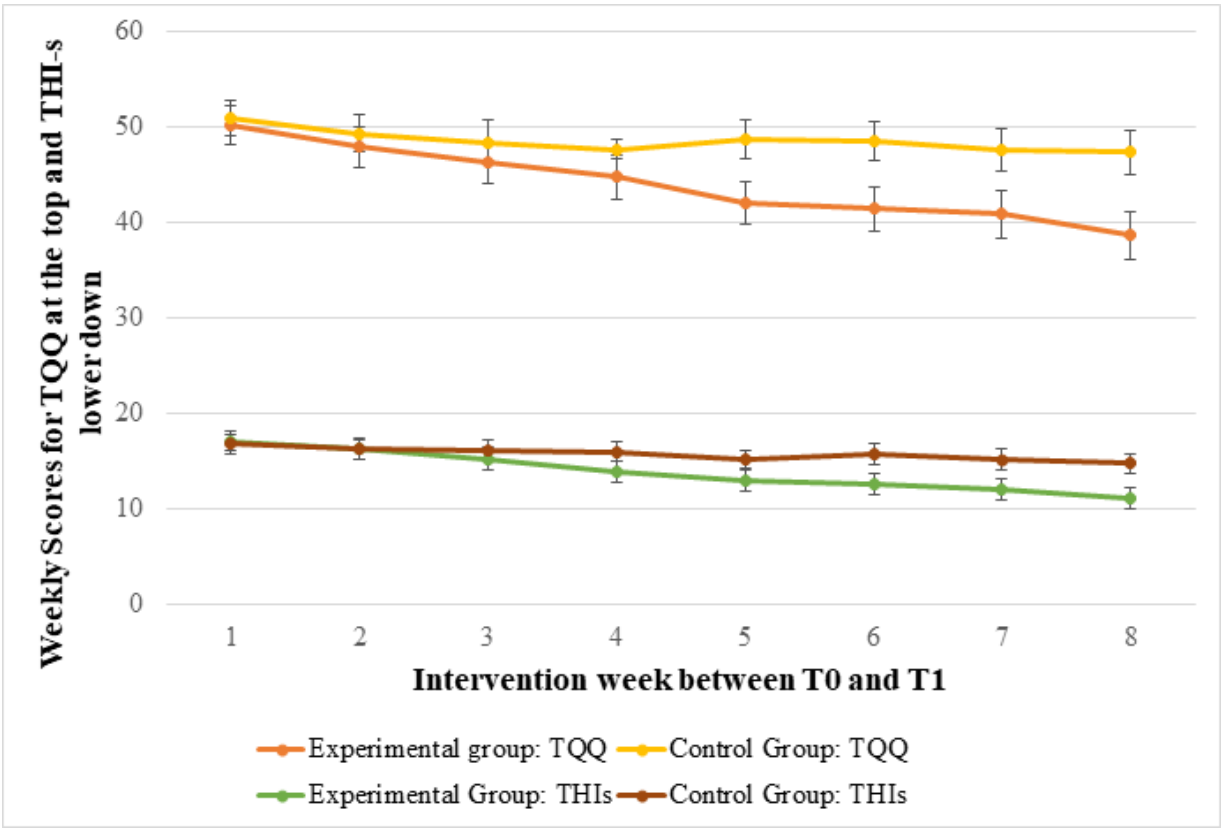


Figure 5. Weekly monitoring between the experimental and control group between T0 and T1.

Discussion

This study is the first to evaluate the efficacy of audiologist-delivered ICBT in reducing tinnitus distress for a US population. It was also the first study to offer ICBT in Spanish to accommodate the Hispanic population in the US. The study objectives were to evaluate the efficacy of audiologist-delivered ICBT in reducing tinnitus distress and in reducing comorbidities associated with tinnitus compared with weekly monitoring of tinnitus. It furthermore assessed the stability of the intervention effects, 2-months post-intervention.

Principal Results

Participating in the ICBT intervention led to significantly greater improvements in tinnitus distress and medium effect size, compared with weekly monitoring. This adds to the evidence-base regarding the feasibility of audiologist-guided ICBT, as indicated in the clinical trials in the UK using audiologist guidance [22-25]. These results are also in line with earlier ICBT trials for tinnitus indicating a pooled medium effect size (d = 0.59) [for a review see 28] with those from Europe using psychologist guidance.

The majority of participants had a reduction of between 20-50 points in their TFI scores, although there was a range of outcomes observed. There were improvements found in the control group after weekly monitoring, which have also previously been mentioned [56]. This may also be the effect of the control group knowing that they will be receiving an intervention and this expectation may have helped them manage better overall prior to receiving the actual intervention. This initial improvement did seem to affect the post-

intervention results, which were lower for the control group compared with the experimental group. When comparing the participants in each group on a weekly basis it was seen that experimental group had a greater reduction in tinnitus distress over the 8-week period. Significant differences were present from weeks 5 for the TQQ and week 6 for the THI. This was slightly later in the intervention than was found in the UK trial when comparing differences for the THI by week 4 [23]. After the control group undertook the intervention, they made similar significant improvements as those demonstrated by the experimental group and no significant differences were found between the groups. These results were maintained at two months follow-up for both groups, although the magnitude of reduction was more variable with the majority from the experimental group indicating a 10-19 point reduction and those from the control group a 20-29 point reduction in TFI scores. Further studies are required to assess whether they are maintained long-term (e.g., 1 year), as has been found by previous ICBT for tinnitus trials [17,25, 57-58].

More participants from the experimental group had a clinically significance (57%; 45 participants) after their treatment compared with 38% (30 participants) of the control group following their treatment. At two-month follow up, 51% (40 participants) and 48% (40 participants) respectively from each group achieved a clinically significant change in tinnitus distress. This was lower than for the pilot study [32] due to the reliable change criterion required being higher for the present study due to a larger baseline standard deviation. As the reliable change criterion was similar to the ICBT efficacy trial in the UK [23] comparable proportions of participants reached clinical significance in this study.

Secondary results

Experiencing tinnitus is accompanied by various comorbidities that may exacerbate the distress and negative emotional response to the perception. An important aspect of a tinnitus intervention is being able to address these challenging comorbidities. Undergoing ICBT resulted in a significantly greater reduction in negative tinnitus cognitions (d = 0.46) and insomnia (small effect). This finding is in line with the pooled results from previous ICBT studies also indicating a small effect (d = 0.42). This was the first ICBT for tinnitus study to include the tinnitus cognitions questionnaire (TCQ). The finding that this CBT intervention is able to reduce negative thought patterns associated with tinnitus is a positive finding and continued use of the TCQ is important as recommended by [59]. From the pooled results of ICBT studies, there has not been an effect for quality of life [28], similar to this study, but been a greater reduction in anxiety and depression, which was not found in this study. The reason may be related to the exclusion of individuals with severe mental health conditions, possibly reducing the opportunity to observe an intervention effect due to the low baseline scores. Broader inclusion criteria is necessary to ensure ICBT is provided to all those affected including those with mental health conditions as they seem to benefit from this as shown in previous studies [17, 19, 21-25, 57-58]. The pilot study also indicated an effect for hearing disability and hyperacusis [32] which was not seen in the present study. The content addressed in the modules providing hearing tactic strategies and advice on reducing sound sensitivity were in the optional modules, which were not read by many participants and this may have contributed to these results. Interestingly, changes were noted in TQQ suggesting that the ICBT may result in change in tinnitus perception (e.g., tinnitus pitch, loudness, number of sounds heard) in addition to reduction in tinnitus distress. However, these observations should be replicated in future studies in addition to possible biomarkers.

Comparison with Prior Work

The study participants characteristic were similar to those previously found from previous ICBT trials, however, the mean age was slightly higher at 57 years compared with a mean age of 51 years [28]. Despite extensive recruitment strategies and campaigns, following suggestions to support Hispanic and Latino research participants [60], only 8 participants selected to do the intervention in Spanish. Further efforts will be required to build trust within Hispanic communities prior to recruiting for subsequent trials [61].

Although study administration mimicked that that would be provided in a routine application, the overall completion rate of the post-treatment questionnaires was low across time points and groups, compared with that of previous ICBT for tinnitus studies [28]. Although there were only 10 participants (6%) who withdrew, many enrolled participants never logged into the intervention website. Moreover, not all the modules were read and very few messages were sent, indicating low intervention engagement. There could be numerous factors contributing to this finding. One may be the timing of this study taking place during the COVID-19 pandemic. Participants explained that they were on their computers all day doing zoom meetings due to having to stay at home. This may any additional computer work, such as this intervention difficult, due to them wanting a break from their computers. Some participants mentioned having contracted the COVID-19 virus, and even after recovering they remained fatigued, making intervention engagement difficult. Others found the lifestyle changes of working from home and juggling childcare difficult and some struggled emotionally. The COVID-19 pandemic is however unlikely to be the only reason for the poor engagement. Differences in compliance between the groups were also present. After receiving the intervention, compliance was lower in the experimental group and then lower for the control group at 2-month follow-up. This may have reflected the trial design that the control group had an additional assessment time-point and due to having already completing

assessments post-control and post intervention decided not to complete another assessment at two month follow-up. During the pilot study [32] lower engagement than noted earlier studies were noted. There may be cultural differences not accounted for. In contrast to the UK and many parts of mainland Europe, many people pay for healthcare via third-party reimbursements in the US. This ICBT intervention was offered free of charge. It may be that people undervalued this treatment as a free treatment that may be perceived as less effective than one requiring payment. The study also only recruited from the State of Texas, thus representing a very small minority of the US and may not represent the wider US population. Subsequent trials should be undertaken with a wider US population. A process evaluation may be helpful to identify the factors contributing to the retention and engagement rates and to identify what may improve theses [26]. Continued public involvement in planning and implementing subsequent research trials will be vital to gain insights regarding the factors important to participants [63].

Limitations

This study represents participants living in the state of Texas who do not present with severe mental health conditions, often associated with tinnitus. This may not present the typical tinnitus population and thus finding cannot readily be generalized to other populations. Despite recruitment efforts only 8 Spanish participants were recruited, similarly, the participants groups also contained low numbers of ethnic and racial minorities when compared to general population from this region. The study was furthermore done during the height of the COVID-19 pandemic, during a time where day-to-day living was disrupted for most people. Results may also have been different if a great proportion of participants were engaged and completed the outcome assessments.

Conclusions

Compounding the potentially debilitating nature of severe tinnitus, accessible, evidence-based interventions are still lacking. There is an urgent need to improve the availability of such interventions. 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 [63]. These results furthermore support the role of audiologist to guide such forms of tinnitus management. The results have been encouraging and further work is indicated in view of making such an intervention applicable to a wider population. Future work should consider enrolling heterogeneous tinnitus population to examine who are more suitable (or not) for ICBT program. In addition, a stepped approach (e.g., a brief intervention offered to all participants and a comprehensive intervention for more suitable patients following the brief intervention) should be examined in order to improve compliance and engagement.

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Conflicts of Interests

The authors declare that they have no competing interests

Availability of data and materials

Doi: 10.6084/m9.figshare.13646012

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Authors' contributions

VM obtained funding and licenses. GA provided the software. All authors contributed to the research design. Data collection, analysis and interpretation was by EB. EB drafted the manuscript. All authors read and approved the final manuscript.

Figure Headings

Figure 1. The Consolidated Standards of Reporting Trials (CONSORT) Flow diagram.

Figure 2. Intervention engagement.

Figure 3. Change in Tinnitus Severity between groups over time. T1, only the experimental group had the intervention. T2, post intervention for the control group and 2 month follow-up for the experimental group, T3 is comparison of 2 month follow-up for both groups.

Figure 4a (to the left). Magnitude of FTI score changes between T0 to T1 after the experimental group underwent ICBT and the control group were monitored weekly and **Figure 4b (to the right).** Magnitude of these changes between T0 to T3 at 2 months follow-up after both groups undertook the full intervention.

Figure 5. Weekly monitoring between the experimental and control group between T0 and T1.

Multimedia Appendix

Appendix 1: CONSORT E-Health checklist, Eysenbach G, CONSORT-EHEALTH Group CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health InterventionsJ Med Internet Res 2011;13(4):e126
URL: http://www.jmir.org/2011/4/e126/
doi: 10.2196/jmir.1923 PMID: 22209829

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Abbreviations

CBT: Cognitive Behavioural Therapy

CONSORT: Consolidated Standards of Reporting Trials

GAD-7: Generalized Anxiety Disorder

HHIA-S: Hearing Handicap Inventory for Adults - Screening

ICBT: Guided Internet-based Cognitive Behavioural Therapy Intervention

ISI: Insomnia Severity Index

PHQ-9: Patient Health Questionnaire

RCI: Reliable Change Index

SPSS: Statistical Package for Social Sciences

TFI: Tinnitus Functional Index

THI-S: Tinnitus Handicap Inventory - Screening

US: United States