Study Protocol and Statistical Analysis Plan

Study Title: Internet-based cognitive behavioral therapy for tinnitus in the United States: A randomized controlled trial protocol

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Background: Tinnitus, characterized by the perception of sound in the absence of an external stimulus, is one example of such a condition. Managing tinnitus is notoriously challenging as there is often not a curable medical cause. The intervention with strongest research evidence is cognitive behavioral therapy (CBT) for tinnitus. CBT is psychological intervention addressing unhelpful thought patterns and emotional reactions caused by tinnitus (Andersson, 2002). 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 (Bhatt et al., 2016; Henry et al., 2019).

To overcome this barrier, an Internet-based CBT for tinnitus (ICBT; Andersson et al. 2002) has been developed. The efficacy of ICBT has been indicated in nine clinical trials across mainland Europe and the UK (for review see Beukes et al., 2019). No clinical trials,

Study Objectives:

1. To evaluate the efficacy of audiologist-delivered ICBT in reducing tinnitus distress compared with weekly monitoring of tinnitus in the US.
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 will be that patients with tinnitus would experience greater reduction of tinnitus distress and comorbidities after receiving ICBT compared to patients receiving weekly monitoring.

Study Design

A prospective two-arm delayed intervention efficacy trial with a 2-month follow-up is planned.

Randomization

Participants will be randomized to the ***Experimental Group*** and received the ICBT intervention for 8-weeks, or the ***Control Group*** whose participants will be monitored weekly during this 8-week period. During the first phase the experimental group will completed the intervention. Following this both groups will complete T1 (post-treatment) outcome measures. During the second phase, the control group will receive the same ICBT intervention, after which both groups will complete T2 (2 month follow-up) 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.

Study Population

Study eligibility

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 will be determined by a two-stage process as follows:
- An online screening questionnaire, which includes demographic information, health and mental health-related questions, and standardized outcome measures as shown in Table 1.
- A telephone interview during which the researcher will recheck eligibility, and provided the opportunity for potential participants to ask any questions related to the study. The study procedures will be explained, and motivational interviewing will be done to encourage participants to commit and engage in the intervention.
- Participants with a score of 15 or more on the PHQ-9 or indicated self-harm on question 10 will receive a phone consultation from a clinical psychologist on the research team. This call will ensure that they are under care elsewhere or necessary resources and/or referrals can be provided.

Recruitment Strategy

Recruited will involve many 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 will involve the use of social media (e.g., Facebook and Twitter). Flyers and posters will be distributed to local communities and put up in clinic waiting rooms. Professionals such as audiologists and otolaryngologists in the state of Texas will be notified about the study and provided with leaflets to distribute to suitable patients. Those interested will be directed to the study website (www.tacklingtinnitus.org) where they can read more about the study and register their interest in study participation. Following registration, they will be invited to complete the screening questionnaire. They will be informed of their right to withdraw without penalty at any stage of the process.

Sample Size, Power and Attrition

Sample size estimation will be calculated using G*Power version 3.1.6 (Faul et al., 2007) and based on achieving a 13-point clinically meaning change between baseline and post-intervention using the primary assessment measure, the TFI. Pilot data (Beukes et al., Submitted) 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 will be fewer than the 58 participants suggested using data from previous RCTs of this intervention, (Beukes et al., 2018) we selected 58 per group. In addition, sample size will be inflated to account for missing data, estimated to be 20% from the US phase I trial data (Beukes et al., 2021b). The aim will be thus to recruit 146 participants with 73 in each arm (calculated as 58/0.8).

Randomization

Participants meeting the inclusion criteria will be 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 are pre-stratified for language (English and Spanish).

Patient Public Partnership (PPI)
A PPI will be established to include two individuals with tinnitus who had piloted the ICBT intervention, two audiologists, two researchers. Meetings will be held via video conferencing. The aim of the PPI will be 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 will be based on a CBT self-help program originally developed in Swedish (Andersson & Kaldo, 2004) and later adapted and translated in English (Abbott, et al., 2009). The intervention will be subsequently transformed into an 8-week interactive e-learning version suitable for a UK population (Beukes, et al., 2016) and then adapted linguistically and culturally to ensure suitability for a US population (Beukes, et al., 2020). 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 (Statistics, 2003). The intervention will be augmented by a module on mindfulness and more videos. The ICBT platform in the US application consisted of 22 modules with worksheets and quizzes (see Beukes et al., 2020; Beukes et al., 2021a for more details).

The intervention platform will be 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 will be first ensured (Manchaiah et al., 2020). Further details about the features, functionalities, and intervention components are presented in Manchaiah et al. (2020).

Both groups will received the same intervention, only the timings regarding receiving the intervention will vary. The control group will receive the experimental intervention 8 weeks after the experimental group commenced the program.

Audiology Guidance
Guidance will be provided to support participants while undertaking the intervention. This will include monitoring progress, monitoring weekly scores, providing feedback on worksheets completed, outlining the content of new modules, and answering questions.

Outcome Measures
Primary Outcome Measure
The primary outcome measure will be tinnitus severity as measured by the Tinnitus Functional Index (TFI; Meikle et al., 2012). The TFI has been translated into more than 15 languages and been validated for several populations including Chinese, Dutch, Swedish and German (Henry et al., 2016). It will be selected over other tinnitus questionnaires as it will be specifically developed to measure tinnitus severity and assess responsiveness to treatment and for comparison purposes with previous trials (e.g., Beukes et al., 2018). Meikle et al. (2012) reported that meaningful changes occur when scores are reduced by 13 points or more.

Secondary Outcome Measures
Secondary outcome measures will assess anxiety, depression, insomnia, tinnitus cognitions, hearing-related difficulties, and health-related quality of life, as shown in Table 1. To reduce the assessment load, the Tinnitus and Hearing Survey (THS; Henry, et al., 2015) will be used

to identify hearing disability and hyperacusis as it only includes 10 questions. The section on tinnitus also served as a secondary tinnitus measure. The EQ-5D-5L (Herdman, et al., 2011) will be selected to measure general health-related quality of life. All questionnaires will be used with the required permissions and agreements will be set up for those that are not freely available to use. For Spanish speakers, validated Spanish translated versions will be used. Where these will be unavailable, validated translations will be undertaken (Manchaiah, et al., 2020b).

Weekly Monitoring During the Intervention

Throughout the program, participants will be 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 (Newman et al, 2008). The weekly scores will be also used to detect possible adverse effects. If scores increased by more than 10 points between two consecutive weeks, this will be noted as an adverse effect. Those indicating adverse effects will be contacted to address the identified problems. Participants will be also monitored by a newly developed Tinnitus Qualities Questionnaire (TQQ; Beukes et al., 2021a). 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 will be assessed by determining retention rates and compliance in completing outcome questionnaires. Intervention engagement will be assessed by the number of logins, the number of modules read, and the number of messages sent during the intervention. Adverse effects will be 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 will be used throughout the study. All the measures will be 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 will be 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 will be sent to participants who had not completed questionnaires, on the 3 consecutive days after the release of the questionnaire. A further reminder will be sent out via email and text message. If questionnaires will be still not completed participants will be telephoned to encourage questionnaire completion. Participants will be also phoned after completing the intervention to discuss the progress they had made and share their questionnaire results.

Statistical Analysis Plan

Statistical analyses will be performed using the Statistical Package for Social Sciences (SPSS) version 26.0. All statistical tests will be 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 will be undertaken. Missing data will be handled through multiple imputation using the *Markov Chain Monte Carlo* approach (Jakobsen et al.,

2017). For comparison, a complete case analysis will be also performed by analyzing only the completed questionnaire data without imputing missing data. As there will be substantial differences, statistical analysis using the imputed data are reported in the results section.

The primary study outcome will be a change in TFI score between the groups at post-intervention (T1). A difference in scores between T1–T2 for the experimental group will be used to assess the stability of intervention effects. According to recommendations for statistical analysis of internet interventions effect sizes, linear mixed effects models, and the reliable change index will be used to assess the primary and secondary outcomes (Hesser, 2015). Changes from baseline to post-intervention will be 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 (Cohen, 1992).

A Linear Mixed Model (LMM), which provides unbiased results in the presence of missing data (using all available data), will be 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 will be treated as a repeated and fixed effect. Restricted maximum likelihood estimation will be applied. The Type III *F* test sums of squares from the LMM will be calculated. As a sensitivity analysis, baseline tinnitus severity will be initially added as a covariate, but as it had no significant effect on the results it will be removed from the model.

Another model will be run to test the differences during the course of the 8 weeks intervention for the weekly outcome measures. Post hoc time comparison will be 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 will also reported. A 13 point difference is recommended by the original developers of the TFI (Meikle et al, 2012) to indicate a meaningful change in scores. To handle study variability, the reliable change index (RCI) (Jacobson & Truax, 1991) is recommended as a means of calculating clinical significance for the TFI as the primary outcome. This will be 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 will be used to describe the sample. The means and standard deviations will be reported for each outcome measure at each time point. Descriptive statistics will be also used to describe the sample and intervention engagement including the number of logins and modules read. A Chi square test of independence will be used to identify group differences regarding engagement and compliance rates.

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 : T0 (baseline)**	**Timeframe: T1**	**Timeframe: T2**	**Timefra me: T3**
Explanation						**Post-intervention for the experimental group; post weekly monitoring for the control group**	**2 month follow-up for experiment al group, postinterve ntion for the control group**	**2 month follow-up for the control group**
Tinnitus distress	Tinnitus Functional Index (TFI; Meikle et al, 2012)	.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)	Both groups	Both groups	Both groups	Control group only
					x	x	x	x
Generalized Anxiety	Generalized Anxiety Disorder (GAD-7, Spitzer, Kroenke, Williams, et al., 2006)	.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	x	x	x	x

Depression	Patient Health Questionnaire (PHQ-9; Spitzer, Kroenke, Williams, 1999)	.83	0-27 A reduction of scores indicates improvement	5-9=mild depression 10-14=moderate 15-19=moderately severe 20-18= severe depression	x	x	x	x
Insomnia	Insomnia Severity Index (ISI; Bastien, Vallières, & Morin, 2001)	.74	0-28 A reduction of scores indicates improvement	0–7 = Not clinically signi 8–14 = Subthreshold inso 15–21 = Clinical insomni (moderate severity) 22–28 = Clinical insomni (severe degree)	x	x	x	x
Tinnitus Cognitions	Tinnitus Cognitions Questionnaire (TCQ; Wilson & Henry, 1998)	.91	0-104 A reduction of scores indicates improvement	Higher scores indicate a greater tendency to engage in negative cognitions in response to tinnitus	x	x	x	x
Health-related quality of life	EQ-5D-5L (Herdman, et al., 2011)	.7-.85	0-15 A reduction of scores indicates improvement	Measures 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/ depression	x	x	x	x
Health-related quality of life	EQ-5D-5L Visual Analogue Scale	.7-.85	0-100 Higher scores indicates improved health	VAS for overall health.	x	x	x	x

	(VAS) (Herdman, et al., 2011)							
Short measure for tinnitus, hearing disability and hyperacusis	Tinnitus and Hearing Survey (THS; Henry, et al., 2015)	.86-.94	Subscale for Tinnitus: 0-16 Hearing: 0-16 Sound tolerance: 0-8		x	x	x	x
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, Andersson, Manchaiah, & Kaldo, 2021a)	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 forth improves while undertaking an intervention. Higher scores indicate more bothersome aspects of tinnitus are present.		Weekly while undertaking the 8-week intervention		

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.

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