# Dismantling internet-based cognitive behavioral therapy for tinnitus. The contribution of applied relaxation: A randomized controlled trial

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# Highlights

* This is the first study to dismantle the effects of internet-based cognitive behavioral therapy (ICBT) for tinnitus
* Intervention effects of applied relaxation were compared with results for full ICBT
* To identify if outcomes differ for tinnitus subgroups, three tinnitus subgroups were compared
* Differential effects depending on tinnitus subgroups were not identified for the subgroups selected

# Abstract

**Background:** Internet-based cognitive behavioral therapy (ICBT) for tinnitus is an evidence-based intervention. The components of ICBT for tinnitus have, however, not been dismantled and thus the effectiveness of the different therapeutic components is unknown. It is, furthermore, not known if tinnitus subgroups with different clinical profiles respond differently to ICBT.

**Aims:** This dismantling study aimed to explore the contribution of applied relaxation within internet-based cognitive behavioral therapy (ICBT) for reducing tinnitus distress and comorbidities associated with tinnitus. A secondary aim was to assess whether outcomes varied for three tinnitus subgroups, namely those with significant tinnitus severity, those with low tinnitus severity, and those with significant depression.

**Methods:** A parallel randomized controlled trial design (n = 126) was used to compare audiologist-guided applied relaxation with the full ICBT intervention.Recruitment was online and via the intervention platform. Assessments were completed at four-time points including a 2-month follow-up period. The primary outcome was tinnitus severity as measured by the Tinnitus Functional Index. Secondary outcomes were included for anxiety, depression, insomnia, negative tinnitus cognitions, health-related quality of life, hearing disability, and hyperacusis. Treatment engagement variables including the number of logins, number of modules opened, and the number of messages sent. Both an intention-to-treat analysis and completer’s only analysis were undertaken.

**Results:** Engagement was low which compromised results as the full intervention was undertaken by few participants. Both the ICBT and applied relaxation resulted in large improvements of tinnitus severity (within-group effect sizes *d* = 0.87 and 0.68, respectively for completers only analysis), which were maintained, or further improved at follow-up. These reductions in tinnitus distress were greater for the ICBT group, with a small effect size differences (between-group *d* = 0.15 in favor of ICBT for completers only analysis). Tinnitus distress decreased the most at post-intervention for those with significant depression at baseline. Both ICBT and applied relaxation contributed to significant reductions on most secondary outcome measures, with no group differences, except for a greater reduction of hyperacusis in the ICBT group.

**Conclusion:** Due to poor compliance partly attributed to the COVID-19 pandemic results were compromised. Further studies with stronger protocols are required. The intervention’s effectivness increased with intital level of tinnitus distress; those with the highest scores at intake experienced the most substantial changes on the outcome measures. This may suggest tailoring of interventions according to tinnitus serverity. Larger samples are needed to confirm this.

**Key Words**

Tinnitus, Internet intervention, Digital therapeutics, Telehealth, Cognitive behavioral therapy, Applied relaxation

# 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: Internet-based Cognitive Behavioural Therapy Intervention

ISI: Insomnia Severity Index

PHQ-9: Patient Health Questionnaire

RCI: Reliable Change Index

TFI: Tinnitus Functional Index

US: United States

1. **Introduction**

Interventions provided for chronic health conditions are often complex and lengthy and can burden healthcare systems (Reed et al., 2019). Identifying components within these interventions that are critical for behavior change can help the delivery of cost-effective interventions. Dismantling treatment components of complex interventions can also refine the understanding of how treatment works and lead to improved efficacy. Cognitive behavioral therapy (CBT) is an evidence-based intervention applicable for a wide range of difficulties (e.g. López-López et al., 2019; Tray, Subramaniam, & Oei., 2019). It is the intervention with the most evidence of effectiveness for tinnitus (Fuller et al., 2020; Landry et al., 2020), defined as the sensation of sound in the absence of an external sound source. Due to its proven effectiveness, CBT is advocated in multiple tinnitus clinical guidelines across the globe (Cima et al., 2019; Fuller et al., 2017; Trunkel et al., 2014). Despite these recommendations, accessibility to CBT for tinnitus is costly and limited due to a shortage of healthcare providers with the expertise to provide CBT for tinnitus (Bhatt et al., 2016; Henry et al., 2019). Different protocols, such as a stepped-care approach (Cima et al., 2012) or CBT self-help approaches (Kaldo et al., 2007) have been proposed to address the lack of CBT- related resources. A guided internet-based CBT intervention for tinnitus (ICBT; Andersson et al. 2002) was developed as a bridge between in-person care and self-help. This approach enabled both support on-demand from a professional in addition to a structured self-help program (Andersson & Kaldo, 2004) and a systematic review affirmed the efficacy of ICBT for tinnitus (see Beukes et al., 2019).

ICBT is generally presented in an 8-week intervention, thus a comprehensive intervention but this length adds to the intervention delivery costs. CBT therapies consist of various components. In a scoping review, 25 component themes were included within psychological therapies for tinnitus, including tinnitus education, problem-solving, thought identification, thought challenging, lifestyle advice, relaxation, sound enrichment, treatment reflection (Thompson et al., 2017). In an attempt to improve outcomes for ICBT, Beukes et al. (2018a) investigated which specific components of the CBT intervention participants found most helpful. Interestingly, applied relaxation, which comprised a substantial part of the intervention originally developed in Sweden (Scott et al., 1985), was rated higher than any other aspect. Applied relaxation has proven effectiveness for various disorders associated with tinnitus, such as anxiety (Kim & Kim, 2018; Manzoni et al., 2008), and thus applied relaxation may serve as an integral part of tinnitus therapy. Relaxation therapies for tinntius have used a range of methodologies with varied outcomes. Biesinger et al. (2010) reported Qigong, a mindful exercise and active relaxation, reduced tinnitus severity. Small scale studies comparing CBT and relaxation have found variable results, and for example, Davies, McKenna, and Hallam (1993) were unable to conclude the efficacy of relaxation, whereas Tavakoli et al. (2019) reported both treatments effective in reducing tinnitus distress. The efficacy of ICBT for tinnitus has generally be compared with other therapies such as ACT (Hesser et al., 2012), usual care (Beukes et al., 2018b), but not specifically with applied relaxation in isolation. A study dismantling the effects of applied relaxation within CBT is thus required.

A further factor affecting tinnitus intervention delivery is the highly heterogeneous nature of tinnitus (Cederroth et al., 2019), evidenced by a range of perceptions and reactions to these sounds (Manning et al., 2019). For some individuals, tinnitus is not a single symptom, as it co-occurs with, and can be exacerbated by multiple conditions including anxiety, depression, insomnia, hearing loss, sound sensitivity, and reduced cognitive functioning (Clarke et al., 2020; Salazar et al., 2019; Trevis et al., 2018). This variability complicates tinnitus management approaches (Zenner et al. 2017). The heterogeneous presentation of tinnitus indicates that there are tinnitus subgroups, but there are no universally accepted subgroups or established guidelines for tailoring tinnitus management for different subgroups (van den Berge et al., 2017).

To seek ways of improving outcomes of ICBT, the aim of this study was twofold. Firstly, to dismantle the whole ICBT package against applied relaxation only. Secondly, to assess the intervention effects across different tinnitus subgroups. To our knowledge, this is the first ICBT trial to investigate the components of ICBT for tinnitus that are most meaningful and compare tinnitus subgroups.

# Material and Methods

**2.1 Trial Design**

A randomized, prospective 2-arm intervention dismantling trial with a 2-month follow-up was undertaken online between May and October 2020 to compare the effects of applied relaxation with full ICBT for tinnitus. Participants were randomized to the full ICBT intervention or applied relaxation. During Phase I (8 weeks) the ICBT group was provided the full CBT intervention and the applied relaxation group received the applied relaxation sections. During Phase II (4 weeks), the applied relaxation group was provided the remaining CBT components. This study design, therefore, provided the opportunity to evaluate the intervention effects in two independent groups at three different time points. No adverse effects were reported and there were no technical or privacy breaches and hence no requirement to stop the study until completion. There was significant intervention downtime, and there were no changes to the protocol, intervention, or study outcomes after the study commenced. The trial data is freely available on the Figshare data repository.

**2.2 Ethics and Preregistration**

This RCT was pre-registered at Clinical Trials.gov: clinical trial NCT04335812 where the protocol is available. Ethical approval was obtained from the Institutional Review Board at Lamar University, Beaumont, Texas, US (IRB-FY20-200). Online informed consent was required to participate. The study was conducted and reported according to the Consolidated Standards of Reporting Trials (CONSORT) eHealth guidelines (Eysenbach & Consort-EHEALTH Group, 2011) as found in Appendix 1.There were no changes to the methods or assessment measures used after the trial commenced. No harms or unintended effects were reported.

* 1. **Recruitment Strategy**

The participants were recruited from the general public using a range of strategies, including promoting the study via tinnitus support groups and the American Tinnitus Association (ATA) between 1 April to 4 May 2020. Further recruitment strategies included the use of social media (e.g., Facebook and Twitter), and also distributing flyers and posters to local health clinics (i.e., primary care physician, audiology, ENT) and communities and put up in clinic waiting rooms. Those interested were directed to the study website ([www.tacklingtinnitus.org](http://www.tacklingtinnitus.org)) where they could read more about the study, the university hosting the study, the research team, and how they could register interest in partaking in the study. Following registration, an online screening questionnaire (i.e., baseline assessment at T0) was completed. Participants were informed of their right to withdraw at any stage without penalty.

**2.4 Study Population**

The eligibility *inclusion criteria included*: adults, aged 18 years and over; living in the US;

the ability to read and type in English; access to a computer, the internet and the ability to email; experiencing tinnitus for a minimum period of three months; any configuration of hearing levels (normal or any degree of hearing loss) and any use of hearing devices (using or not using hearing aids); and participants were included if they described a need for a tinnitus intervention and not based on their tinnitus outcome scores.

*The exclusion criteria were r*eporting pulsatile, objective, or unilateral tinnitus, which had not been investigated medically or tinnitus still under medical investigation; reporting any major medical condition or treatment that would prevent undertaking this intervention; andundergoing any tinnitus therapy concurrent with participation in this study.

Participants were required to provide online consent to participate. Eligibility was determined by a two-stage process. Firstly, participantscompleted an online screening questionnaire, which included demographic information, health and mental health-related questions, and standardized outcome measures.After this, a telephone interview was conducted 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.Any participants with a score of 15 or more on the Patient Health Questionnaire–9 (PHQ-9) or indicated self-harm on question 10 received an additional phone consultation from a clinical psychologist on the research team. This call ensured that their depression was being managed and that they had the required resources and were not in any danger of self-harm. If the psychologist was assured that their depression was well managed they were eligible to participate in the study.

Participants meeting the inclusion criteria were divided into three subgroups.

1. Those with significant levels of tinnitus distress with scores of 25 or above on the Tinnitus Functional Index (TFI) which was used to measure tinnitus severity (i.e., high tinnitus severity group).
2. Due to numerous participants scoring below 25 and requesting help with their tinnitus, those with low tinnitus severity (<25 on the TFI) were included as a separate subgroup (i.e., low tinnitus severity group).
3. Those with high depression scores > 10 on the PHQ-9 or those answering positively for question 10, were added as a further subgroup (i.e., significant depression group).

**2.5 Sample Size, Power, and Attrition**

Sample size calculations were performed using the SampSize appfor superiority parallel groups. Power was 90%; α was 0.025; and the estimated SD was 20 points, as indicated by the preceding pilot trial (Beukes et al., submitted). The mean difference was set to 13 points, as indicated during the validation of the TFI (Meikle et al., 2012) to be a clinically significant change in scores. Thus, 51 participants were required for each arm. To ensure sufficient power, calculations for the larger sample were followed with the aim of recruiting 63 participants per arm to inflate for possible missing data.

**2.6 Randomization**

Participants meeting the inclusion criteria were randomly assigned in the ratio of 1:1 after being stratified for tinnitus (<25 or ≥25 on the TFI) and depression (<10 or ≥10 on the PHQ) and enrolled to either the ICBT or applied relaxation group using a computer-generated randomization scheduled by an independent research assistant in blocks of varying sizes. Participants and investigators could not be blinded to group allocation due to the nature of the intervention. The researchers were however blinded during data analysis. Participants were informed of their group allocation and when the intervention would commence by the principal investigator.

**2.7 Intervention**

The study employed a structured intervention based on a CBT for tinnitus program (Andersson & Kaldo, 2004; Beukes et al., 2021). This intervention was originally developed in Sweden (Andersson et al., 2002), and was later adapted into an interactive e-learning version for a UK population (Beukes, et al., 2016). To ensure suitability for a US population, the intervention was further modified with linguistic and cultural adaptions, such as lowering the readability to below the recommended 6th English reading grade level, (Beukes et al., 2020a; Manchaiah et al., 2020b). The full program consists of 22 modules with explanatory videos, weekly homework assignments, worksheets and quizzes (Beukes et al., 2021). The intervention platform (Vlaescu et al., 2016) was housed in the US at Lamar University to comply with the needed data protection regulations. Prior to this trial, acceptability and functionality of this intervention for a US population were ensured (Manchaiah, et al., 2020a) and the intervention was piloted for a US population (Beukes et al. submittedA). Guidance was provided by an audiologist throughout the intervention. This included introducing the module content, monitoring progress, providing feedback on worksheets completed, outlining the content of new modules, answering questions, and encouraging questionnaire completion. Participants who were not engaging were contacted (messages/ text/ phone) to encourage engagement and discuss possible barriers, and an encrypted 2-way messaging system within the ePlatform was used to communicate with participants. Although psychologists have traditionally guided CBT interventions, tinnitus management is generally delivered by audiologists (Henry et al., 2019). Thus, an audiologist provided guidance to participants to maintain consistency with previous English trials using this intervention (Beukes et al., 2018c, SubmittedB).

The groups accessed the intervention via a secure login, each group accessing different elements of the intervention along with different schedules as seen in Table 1. Both groups were asked to spend around 10 minutes a day practicing the suggested exercises and completing worksheets to monitor their progress.

**Table 1. The Intervention schedule for each group**

|  |  |  |
| --- | --- | --- |
| **Week** | **ICBT group schedule** | **Applied relaxation group schedule** |
| **Phase I** | **22 modules** | **10 modules** |
| 1 | Program outline  Tinnitus overview | Program outline  Tinnitus overview |
| 2 | Deep relaxation  Positive imagery  Sound enrichment | Deep relaxation  Positive imagery |
| 3 | Deep breathing  Views on tinnitus  Sleep guidelines | Deep breathing |
| 4 | Entire body relaxation  Shifting focus  Improving focus | Entire body relaxation |
| 5 | Frequent relaxation  Thought Patterns  Increasing sound tolerance | Frequent relaxation |
| 6 | Relaxing when stressed or upset  Challenging thoughts  Listening tips | Relaxing when stressed or upset |
| 7 | Relaxation routine  Listening to tinnitus | Being mindful |
| 8 | Summary  Future planning | Relaxation routine |
| **Phase II** | | |
| 9 | N/A | Views on tinnitus  Thought patterns  Sound enrichment |
| 10 | N/A | Sleep guidelines  Challenging thoughts  Improving focus |
| 11 | N/A | Shifting focus  Listening to tinnitus  Increasing sound tolerance |
| 12 | N/A | Listening tips  Summary  Future planning |

**2.8 Outcome Measures**

Data were collected online at baseline (T0); after the ICBT group completed the full ICBT intervention and the applied relaxation group completed only the relaxation part (T1); for the applied relaxation group after they completed the full ICBT intervention and compared the T1 results for the ICBT group (T2); and at 2-month post-intervention for both groups (T3).

A demographic questionnaire was used to establish health-related and tinnitus-specific information at baseline (T0). A series of primary and secondary outcome measures were administered at baseline as well as during post-intervention. Although not all measures are validated for online use, results should be comparable as equivalent psychometric properties have been previously reported (Thorén, Andersson, and Lunner, 2012).

***2.8.1 Primary Outcome Measure***

The primary outcome measure was tinnitus severity as measured by the TFI (Meikle et al., 2012). 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 similar trials in the UK and the US (Beukes et al., 2017, 2018b, 2018c, submittedB).

***2.8.2 Secondary Outcome Measures***

The following secondary measures were incorporated to assess commonly reported

tinnitus-related difficulties:

* The Generalized Anxiety Disorder–7 (GAD-7; Spitzer et al., 2006) assessed symptoms of generalized anxiety disorder.
* The PHQ-9 (Spitzer, Kroenke, Williams, 1999) indicated symptoms of depression.
* The Insomnia Severity Index (ISI; Bastien, Vallières, & Morin, 2001) assessed the presence of insomnia.
* The Tinnitus Cognitions Questionnaire (TCQ; Wilson & Henry, 1998) was used to measure negative tinnitus cognitions.
* The EQ-5D-5L (Herdman et al., 2011) measured general health-related quality of life.
* The Tinnitus and Hearing Survey (THS; Henry et al., 2015) was used as a short measure to identify participants’ tinnitus severity, hearing disability, and hyperacusis.

**2.9 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 opened, and the number of messages sent during the intervention.

**2.10 Data Analysis**

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. For transparency, both an intention-to-treat approach including all participants, and a completers-only analysis was undertaken for comparison purposes. For the intention-to-treat model, an imputation analysis was undertaken. Missing data were handled through multiple imputations using the Markov Chain Monte Carlo approach.The analysis thus included all participants at each time point.

The primary study outcome was a change in TFI score between groups at post-intervention (T1). Secondary study outcomes were changes in secondary outcomes between groups at T1. According to recommendations for statistical analysis of internet interventions (Hesser, 2015) effect sizes, Linear Mixed Effects Models (LMM), and the Reliable Change Index (RCI) was used to assess the outcomes. Changes from baseline to post-intervention were compared within and between groups using the standardized mean differences (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).

The LMM, which provided unbiased results in the presence of missing data (using all available data) was applied to analyze the intervention effect accounting for the repeated measurements. An unstructured repeated effect 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 are presented. As a sensitivity analysis, baseline tinnitus severity was initially added as a covariate. As it had no significant effect on the results, it was removed from the model. Subgroup analysis was performed for the three pre-defined subgroups to compare outcomes between them.

The RCI (Jacobson & Truax, 1991) was used as a standardized way 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 (26.00), and a test-retest reliability coefficient of 0.78, and as reported in the validation study (Meikle et al., 2012).

***2.10.1 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 mean and standard deviation were reported for each outcome measure at each time point. Descriptive statistics were also used to assess the sample and intervention engagement including the number of logins and modules opened. A Chi-square test of independence was used to identify group differences regarding engagement and compliance rates.

1. **Results**

**3.1 Participant Characteristics**

A total of 126 screened participants met the eligibility criteria and were randomly assigned to the ICBT (n = 63) and applied relaxation groups (n = 63) as seen in Figure 1. There was no estimated difference in baseline tinnitus severity between the groups (*p* = .92). Of the total sample, 51% were female and 49% male with a mean age of 57 (SD: 12) years and most participants (91%) indicated that they were frequent computer and internet users (Table 2). The groups were well matched although there were more females in the ICBT group (59%) compared with 40% in the applied relaxation group and the duration of tinnitus was shorter in the ICBT group (10 years) compared with 15 years for the applied relaxation group. To assess the effect of tinnitus subgroups, participants were subdivided into three groups:

* High depression group: Those with high depression scores (i.e., above 15) or indicating a positive response to question 10 of suicidal inclination in PHQ-9: 49/126 (39%).
* High tinnitus severity group: Participants with TFI scores of 25 or greater indicating the need for a clinical intervention: 45/126 (36%).
* Low tinnitus severity group: Those with low TFI scores below 25 identifying that they needed help with their tinnitus: 32/126 (25%).

This intervention commenced in May 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, which could directly impact on the trial.

[Insert Figure 1 here]

**Table 2. Demographical characteristics of the participants**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Category | Description | ICBT group  (n = 63) | IRA group  (n = 63) | Overall (n = 126) |
| Gender | Male  Female | 26 (41%)  37 (59%) | 38 (60%)  25 (40%) | 64 (51%)  62 (49%) |
| Age | Mean years(SD)  Range | 55 (13)  25–79 years | 57 (13)  26–81 years | 56 (13)  25–81 years |
| Tinnitus duration | Mean years (SD)  Range | 10 (11)  8 months to 52 years | 15 (14)  3 months to 60 years | 12 (12)  3 months to 60 years |
| Ethnicity | Hispanic/ Latino  Not-Hispanic/ Latino | 4 (6%)  59 (94%) | 4 (6%)  59 (94%) | 8 (6%)  118 (94%) |
| 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  3 (5%)  56 (89%)  3 (5%) | 0  0  1 (1%)  0  2 (3%)  58 (93%)  2 (3%) | 0  0  2 (1%)  0  5 (4%)  114 (91%)  5 (4%) |
| Highest educational level | High School  College/ vocational training  University degree | 5 (8%)  18 (29%)  40 (63%) | 5 (8%)  20 (32%)  38 (60%) | 10 (8%)  38 (30%)  78 (62%) |
| Employment | Entry-level or unskilled work  Skilled or professional  Retired  Not working | 0  33 (52%)  26 (41%)  4 (6%) | 3 (5%)  36 (57%)  17 (27%)  7 (11%) | 3 (2%)  69 (55%)  43 (34%)  11 (9%) |
| All professionals seen | Primary Care Physician  ENT Physician  Audiologist | 25 (40%)  38 (60%)  38 (60%) | 31 (49%)  32 (51%)  41 (65%) | 56 (44%)  70 (56%)  79 (63%) |
| Veterans  Duration in the military service | Number  Service duration mean (SD; range) in years | 7 (11%)  14 (11; 2–32) | 9 (14%)  4 (2; 1.5–8) | 16 (13%)  8 (9; 1.5–32) |
| Ease of using a computer | Limited skills  Basic skills  Frequent user | 2 (3%)  5 (8%)  56 (89%) | 1 (2%)  3 (5%)  59 (94%) | 3 (2%)  8 (6%)  115 (91%) |

**3.2 Retention, Compliance, and Engagement**

Overall compliance for completing the outcome measures was low with 32 to 50% completion rates for the ICBT group and 37 to 47% completion for the applied relaxation group (Figure 2). There were no significant between-group completion rates [*X*2 = (3, N = 159) = .46, *p* = .79]. Due to this low compliance, the sample size of 51 was not achieved at post intervention. Thus, the study was underpowered which needs to be considered during result interpretation.

Intervention engagement was low but varied considerably among participants, although there were no significant differences between the ICBT and applied relaxation groups [*X* 2 = (1, N = 190) = 0.53, *p* = .77] as seen in Figure 2. On average 70% of the ICBT group and 65% of the applied relaxation group logged into the platform; 60% from the ICBT group and 55% of the applied relaxation group opened at least one module, and 28% from the ICBT group and 34% from the applied relaxation group sent at least one message.

When comparing the subgroups (see Figure 2), it was seen that that engagement varied as those with TFI scores > 25 were the most engaged and those with low TFI scores < 25 were the least engaged, although these differences were not significantly different between groups (logins *p* = .71; modules *p* = .10, messages *p* = .71).

[Insert Figure 2 here]

* 1. **Dismantling the Effects of Applied Relaxation Compared with ICBT in Reducing Tinnitus Severity**

Both groups showed a significant reduction in tinnitus severity over time with large within-group effect sizes for both analysis protocols (Table 3, Figure 3). At post-intervention (T1) the within-group effect size was greater for the ICBT group (*d* = 0.87 for completers analysis) compared to the applied relaxation group (*d* = 0.68 for completers analysis) with no between-group difference (*d* = 0.15, CI -0.37 to 0.66 for completers analysis). The test of fixed effects (Table 4) indicated that only the intercept and slope revealed significant changes in tinnitus severity. The estimated difference in tinnitus severity was not significant between the groups at any time point. The model indicated an estimated baseline to 2-month follow-up mean difference of 24 points (CI: 18 to 30) after undertaking the intervention with an estimated TFI score of 25 at follow-up (CI: 23 to 27).

There was considerable individual variability resulting in large standard deviations. This resulted in a large reliable change criterion of 33.80 required to achieve clinical significance. This criterion was met or exceeded by 20 (32%) of the ICBT group and 17 (27%) from the applied relaxation group at T1 (after the ICBT group had access to the full CBT and the applied relaxation group had only the relaxation components). At 2 month follow-up, this criterion was met or exceeded by 19 (30%) from the ICBT group and 17 (27%) from the applied relaxation group.

As a comparison, when using a criterion of 13 point difference in scores as suggested by Meikle et al. (2012) to represent a meaningful difference across TFI administrations, 37 (59%) of the ICBT group and 35 (56%) of the applied relaxation group experienced a significant change in tinnitus effects at T1. At 2 month follow-up, the change was observed for 41 (65%) from the ICBT group and 39 (62%) from the applied relaxation group.

Similar to the results of the primary outcome, the THS tinnitus secondary measure indicated a medium effect size for both groups. Although this was larger for the ICBT group (*d* = 0.82 for completers analysis) compared with the applied relaxation group (*d* = 0.61 for completers analysis), there were no between-group differences (*d* = 0.12; CI: -0.41 to 0.65 for completers analysis). As for the TFI, the test of fixed effects (Table 4) indicated that only the intercept and slope had significant effects on the changes in tinnitus severity.

[Insert Figure 3 here]

**3.4 Comparison of Changes in Tinnitus Severity for Each Subgroup**

Tinnitus severity changed significantly between sub-groups over time as seen in Figure 4. The Test of Fixed effects indicated significant intercept, time, group, and time-by-group interactions (all *p* < .001\*) as tinnitus severity decreased for those with high depression and for those with tinnitus severity above 25 points, whereas tinnitus severity increased compared with their baseline scores for those with low tinnitus severity (under 25 points), possibly due to regression to the mean effects.

[Insert Figure 4 here]

**Table 3. Outcome measures at each time point comparing completers-only and imputation analysis**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Outcome measure and** | **Group allocation** | **T0: Pre-treatment (baseline)** | **Analysis protocol** | **T1: Post ICBT for ICBT group and relaxation for relaxation group** | **T2: Post full ICBT treatment for both groups** | **T3: 2-month follow-up for both groups** | **Within-group**  **Cohen’s *d* (95% confidence intervals) at T1** | **Between-group Cohen’s *d* (95% confidence intervals)** |
| **Tinnitus Functional Index (TFI)** | ICBT group | 50.52 (26.65) | Completers analysis | 28.95 (20.75) | 28.95 (20.75) | 27.16 (20.78) | 0.87 [0.41 to 1.31] | **Completers analysis**  At T1: 0.15 [-0.37 to 0.66]  At T2: 0.08 [-0.43 to 0.59]  At T3: -0.19 [-0.79 to 0.43] |
| Imputation analysis | 28.89 (14.56) | 29.46 (14.61) | 26.94 (11.86) | 1.10 [0.63 to 1.37] |
| Applied relaxation group | 48.70 (25.51) | Completers analysis | 32.13 (21.38) | 30.66 (23.45) | 23.81 (9.87) | 0.68 [0.22 to  1.13] | **Imputation analysis**  At T1: 0.19 [-0.16 to 0.54]  At T2: 0.07 [0.28 to 0.42]  At T3: -0.29 [-0.64 to 0.07] |
| Imputation analysis | 31.62 (14.52) | 30.54 (16.17) | 23.81 (9.87) | 0.82 [0.45 to 1.18] |
| **Anxiety (GAD-7)** | ICBT group | 9.19 (6.39) | Completers analysis | 4.48 (4.17) | 4.48 (4.17) | 4.68 (4.75) | 0.81 [0.35 to 1.26] | **Completers analysis**  At T1: 0.15 [-0.37 to 0.67]  At T2: 0.08 [-0.49 to 0.64]  At T3: -0.23 [-0.83 to 0.39] |
| Imputation analysis | 4.51 (3.16) | 4.58 (3.19) | 4.67 (3.33) | 0.93 [0.56 to 1.29] |
| Applied relaxation group | 7.75 (6.77) | Completers analysis | 5.21 (5.62) | 4.86 (5.84) | 3.70 (3.88) | 0.39 [-0.21 to 0.84] | **Imputation analysis**  At T1: 0.20 [-0.15 to 0.55]  At T2: 0.02 [-0.33 to 0.37]  At T3: -0.29 [-0.64 to 0.07] |
| Imputation analysis | 5.23 (4.02) | 4.65 (4.21) | 3.79 (2.80) | 0.45 [0.10 to 0.80] |
| **Depression (PHQ-9)** | ICBT group | 9.10 (7.14) | Completers analysis | 4.32 (3.95) | 4.32 (3.95) | 4.12 (4.40) | 0.75 [0.29 to 1.21] | **Completers analysis**  At T1: 0.14 [-0.38 to 0.67]  At T2: 0.15 [-0.38 to 0.37]  At T3: 0.34 [-0.21 to 0.90] |
|  | Imputation analysis | 4.50 (2.87) | 4.29 (2.94) | 3.80 (2.81) | 0.85 [0.48 to 1.2] |
| Applied relaxation group | 9.17 (7.12) | Completers analysis | 4.96 (5.07) | 5.04 (5.70) | 3.35 (4.17) | 0.64 [0.19 to 1.10] | **Imputation analysis** At T1: 0.20 [-0.15 to 0.55]  At T2: 0.15 [-0.20 to 0.50]  At T3: -0.08 [-0.43 to 0.27] |
| Imputation analysis | 5.16 (3.79) | 4.89 (4.08) | 3.58 (2.95) | 0.70 [0.18 to 0.34] |
| **Insomnia (ISI)** | ICBT group | 12.25 (7.70) | Completers analysis | 7.46 (5.80) | 7.46 (5.80) | 6.33 (6.08) | 0.67 [0.22 to 1.12] | **Completers analysis**  At T1: 0.24 [-0.29 to 0.76]  At T2: 0.17 [-0.36 to 0.69]  At T3: 0.15 [-0.50 to 0.80] |
| Imputation analysis | 7.81 (4.33) | 7.47 (4.11) | 5.87 (3.58) | 0.71 [0.35 to 1.01] |
| Applied relaxation group | 11.90 (7.45) | Completers analysis | 8.93 (6.50) | 8.43 (5.93) | 7.13 (5.00) | 0.41 [-0.04 to 0.86] | **Imputation analysis**  At T1: 0.27 [-0.08 to 0.62]  **At T2: 0.45 [0.13 to 0.76]\***  At T3: 0.00 [-0.31 to 0.31] |
| Imputation analysis | 9.03 (4.71) | 8.51 (4.40) | 6.90 (3.31) | 0.46 [0.10 to 0.81] |
| **Health-related quality of life (EQ-5D-5L)** | ICBT group | 8.22 (3.17) | Completers analysis | 7.11 (1.95) | 7.11 (1.95) | 6.67 (1.63) | 0.39 [-0.07 to 0.84] | **Completers analysis**  At T1: 0.26 [-0.27 to 0.79]  At T2: 0.33 [-0.20 to 0.87]  At T3: 0.39 [-0.27 to 1.05] |
| Imputation analysis | 7.26 (1.52) | 7.08 (1.65) | 6.78 (1.18) | 0.39 [0.03 to 0.74] |
| Applied relaxation group | 8.41 (3.16) | Completers analysis | 7.71 (2.55) | 8.11 (3.73) | 7.65 (2.93) | 0.17 [-0.28 to 0.62] | **Imputation analysis**  At T1: 0.25 [-0.11 to 0.60]  At T2: 0.10 [-0.21 to 0.42]  At T3: 0.05 [-0.27 to 0.36] |
| Imputation analysis | 7.70 (2.01) | 7.89 (2.69) | 7.52 (2.18) | 0.27 [-0.08 to 0.62] |
| **Health-related quality of life (EQ-5D-5L) VAS scores** | ICBT group | 75.43 (15.92) | Completers analysis | 78.15 (17.51) | 78.15 (17.51) | 85.87 (6.91) | 0.17 [-0.29 to 0.62] | **Completers analysis**  At T1: -0.10 [-0.63 to 0.43]  At T2: 0.10 [-0.43 to 0.63]  **At T3: 0.78 [0.11 to 1.45]** |
| Imputation analysis | 77.94 (11.68) | 77.98 (11.78) | 86.17 (4.18) | 0.18 [-0.17 to 0.53] |
| Applied relaxation group | 72.59 (17.00) | Completers analysis | 79.71 (12.14) | 76.43 (15.79) | 78.22 (11.29) | 0.45 [0.00 to 0.90] | **Imputation analysis**  At T1: -0.19 [-0.53 to 0.17]  At T2: 0.23 [-0.09 to 0.54]  At T3: -0.15 [-0.46 to 0.16] |
| Imputation analysis | 79.83 (8.36) | 76.72 (10.83) | 77.96 (7.24) | 0.54 [0.18 to 0.89] |
| **Tinnitus score from THS** | ICBT group | 6.29 (5.70) | Completers analysis | 2.85 (2.66) | 2.85 (2.66) | 2.07 (2.12) | 0.82 [0.35 to 1.29] | **Completers analysis**  At T1: 0.12 [-0.41 to 0.65]  At T2: 0.16 [-0.37 to 0.69]  At T3: 0.25 [-0.40 to 0.90] |
|  |  | Imputation analysis | 3.03 (2.03) | 2.99 (2.05) | 1.92 (1.48) | 0.76 [0.40 to 1.12] |
| Applied relaxation group | 5.79 (4.55) | Completers analysis | 3.21 (3.32) | 3.36 (3.68) | 2.78 (3.19) | 0.61 [0.16 to 1.07] | **Imputation analysis**  At T1: 0.27 [-0.08 to 0.62]  At T2: 0.24 [-0.07 to 0.55]  At T3: -0.06 [-0.37 to 0.25] |
| Imputation analysis | 3.69 (2.80) | 3.46 (2.82) | 2.87 (2.24) | 0.56 [0.20 to 0.91] |
| **Hearing disability (THS)** | ICBT group | 5.94 (5.06) | Completers analysis | 4.59 (4.01) | 4.59 (4.01) | 3.13 (2.36) | 0.29 [-0.17 to 0.05] | **Completers analysis**  At T1: -0.22 [-0.75 to 0.31]  At T2: 0.03 [-0.50 to 0.56]  At T3: 0.48 [-0.18 to 1.14] |
| Imputation analysis | 4.58 (3.07) | 4.76 (2.98) | 3.08 (1.61) | 0.32 [-0.03 to 0.67] |
| Applied relaxation group | 6.19 (4.84) | Completers analysis | 3.75 (3.70) | 4.71 (4.32) | 4.65 (3.59) | 0.54 [0.09 to 0.99] | **Imputation analysis**  At T1: -0.30 [-0.65 to 0.05]  At T2: 0.28 [-0.03 to 0.59]  At T3: -0.11 [-0.42 to 0.20] |
|  |  | Imputation analysis | 3.69 (2.80) | 4.63 (3.21) | 4.25 (2.57) | 0.63 [0.27 to 0.99] |
| **Hyperacusis (THS)** | ICBT group | 1.22 (1.30) | Completers analysis | .67 (1.07) | .67 (1.07) | .47 (.74) | 0.44 [-0.01 to 0.90] | **Completers analysis**  At T1: 0.27 [-0.27 to 0.80]  At T2: 0.25 [-0.28 to 0.78]  At T3: 0.46 [-0.20 to 1.12] |
| Imputation analysis | .77 (.93) | .8 (.92) | .61 (.69) | 0.4 [0.04 to 0.75] |
| Applied relaxation group | 1.17 (1.40) | Completers analysis | 1.00 (1.39) | .96 (1.23) | .91 (1.08) | 0.06 [-0.38 to 0.51 | **Imputation analysis**  **At T1: 0.37 [0.01 to 0.72]\***  At T2: 0.23 [-0.12 to 0.58]  **At T3: 0.45 [0.09 to 0.80]\*** |
| Imputation analysis | 1.17 (1.23) | 1.02 (.98) | .99 (.97) | 0.00 [-0.35 to 0.35] |
| **Tinnitus cognitions (TCQ)** | ICBT group | 42.52 (18.58) | Completers analysis | 27.26 (20.17) | 27.26 (20.17) | 23.07 (17.54) | 0.80 [0.33 to 1.27] | **Completers analysis**  At T1: 0.18 [-0.35 to 0.71]  At T2: 0.09 [-0.44 to 0.617]  At T3: 0.14 [-0.52 to 0.79] |
|  |  | Imputation analysis | 26.95 (13.45) | 27.46 (13.45) | 23.66 (9.19) | 0.96 [0.59 to 1.32] |
| Applied relaxation group | 44.67 (20.43) | Completers analysis | 30.96 (20.03) | 28.93 (17.81) | 25.30 (15.84) | 0.67 [0.22 to 1.13] | **Imputation analysis**  At T1: 0.30 [-0.05 to 0.65]  At T2: 0.25 [-0.06 to 0.56]  At T3: -0.03 [-0.34 to 0.28] |
|  |  | Imputation analysis | 31.01 (13.49) | 28.91 (12.12) | 26.05 (10.10) | 0.79 [0.42 to 1.15] |

**Table 4: Random intercept mixed model results using results from the imputation data comparing the full ICBT group and applied relaxation group. Significant results (*p* < .05) in bold and end with a \*.**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Outcome predictor** | **Type III Test of Fixed Effects** | | | | | | | | | |
|  | **Tinnitus** | **Anxiety** | **Depression** | **Insomnia** | **EQ-5D-5L** | **EQ-5D-VAS** | **THS\_**  **Tinnitus** | **Hearing disability** | **Hyperacusis** | **Tinnitus cognitions** |
| Intercept: for completers analysis | *F*(1,135.889) = 279.812, *p* < .001\* | *F*(1,137.907) = 137.540, *p* < .001\* | *F*(1,136.156) = 128.012, *p* < .001\* | *F*(1,139.383) = 212.545, *p* < .001\* | *F*(1,137.975) = 815.462, *p* < .001\* | *F*(1,145.346) = 2805.553, *p* < .001\* | *F*(1,139.395) = 126.098, *p* < .001\* | *F*(1,139.287) = 121.851, *p* < .001\* | *F*(1,139.838) = 71.98, *p* < .001\* | *F*(1,142.865) = 393.356, *p* < .001\* |
| Intercept: for imputation analysis | *F*(1,124.012) = 835.955, *p* < .001\* | *F*(1,124.000) = 377.647, *p* < .001\* | *F*(1,124.000) = 418.560, *p* < .001\* | *F*(1,123.990) = 720.264, *p* < .001\* | *F*(1,123.990) = 2806.009, *p* < .001\* | *F*(1,60.25) = 2806.009, *p* < .001\* | *F*(1,124.000) = 426.713, *p* < .001\* | *F*(1,47.591) = 426.496, *p* < .001\* | *F*(1,124.000) = 245.99, *p* < .001\* | *F*(1,124.012) = 1221.930, *p* < .001\* |
| Time  for completers analysis | *F*(3,107.066) = 46.678, *p* < .001\* | *F*(3, 106.911) = 19.855., *p* < .001\* | *F*(3,100.176) = 23.756, *p* < 0.001\* | *F*(3,98.976) = 21.03, *p* < .001\* | *F*(3,97.074) = 1.701, *p* = .188 | *F*(3,104.490) = 4.168, *p* < .018\* | *F*(3,98.310) = 24.398, *p* < .001\* | *F*(3,99.996) = 11.573, *p* < .001\* | *F*(3,105.055) = 2.41, *p* = .10 | *F*(3,111.560) = 20.436, *p* < .001\* |
| Time: for imputation analysis | *F*(3,124.001) = 40.45, *p* < .001\* | *F*(3, 124) = 20.29, *p* < .001\* | *F*(3,124.000) = 23.93, *p* < 0.001\* | *F*(3,124.000) = 5.82, *p* = .001\* | *F*(3,124.000) = 14.33, *p* < .001\* | *F*(3,113.433) = 14.19, *p* < .001\* | *F*(3,124.000) = 28.58, *p* < .001\* | *F*(3,83.812) = 13.83, *p* < .001\* | *F*(3,124.000) = 3.46, *p* = .02\* | *F*(3,124.000) = 38.92, *p* < .001\* |
| Group  for completers analysis | *F*(1,135.889) = .234, *p* = .629 | *F*(1, 124.000) = .006, *p* = .936 | *F*(1,136.156) = .04, *p* = .84 | *F*(1,139.383) = .979, *p* = .32 | *F*(1,137.975) = .108 *p* = .897 | *F*(1,145.346) = .207, *p* = .65 | *F*(1,139395) = .388, *p* = .53 | *F*(1,139.838) = 1.01, *p* = .317 | *F*(1,139.838) = 1.01, *p* = .317 | *F*(1,142.865) = .966, *p* = .327 |
| Group: for imputation analysis | *F*(1,124.012) = .02, *p* = .90 | *F*(1, 124.000) = .45, *p* = .50 | *F*(1,124.000) = .26, *p* = .61 | *F*(1,123.990) = 3.59, *p* = .06 | *F*(1,156.000) = .13, *p* = .72 | *F*(1,60.238) = 2.72, *p* = .10 | *F*(1,124.000) = .42, *p* = .52 | *F*(1,47.59) = .05, *p* = .83 | *F*(1,124.000) = 3.80, *p* = .05 | *F*(1,124.012) = 1.95, *p* = .17 |
| Time\*Group  for completers analysis | *F*(3,107.066) = 1.599, *p* = .207 | *F*(3, 106.911) = 3.086, *p* = .05\* | *F*(3,100.176) = .233, *p* = .793 | *F*(3,98.976) = 2.811, *p* = .065 | *F*(3,98.976) = 2.811, *p* = .065 | *F*(3,104.90) = ..579, *p* < .562 | *F*(3,98.310) = 1.95, *p* = .15 | *F*(3,105.055) = 1.355, *p* = .262 | *F*(3,105.0055) = 1.355, *p* = .262 | *F*(3,111.560) = .119, *p* = .888 |
| Time\*Group  : for imputation analysis | *F*(3,124.001) = 2.25, *p* = .09 | *F*(3, 124.000) = 3.05, *p* = .03\* | *F*(3,124.000) = .77, *p* = .52 | *F*(3,124.000) = .66, *p* = .58 | *F*(3,156) = .19, *p* = .90 | *F*(3,113.435) = .10.17, *p* < .001\* | *F*(3,124.000) = 1.95, *p* = .13 | *F*(3,83.812) = 4.67, *p* = .005\* | *F*(3,124.000) = 1.164, *p* = .33 | *F*(3,124.000) = .86, *p* = .466 |

**3.5 Dismantling the Effects of Applied Relaxation Compared with ICBT on Secondary Outcome Measures**

Results varied slightly depending on the analysis protocol. Overall, both groups showed significant reductions in all secondary outcome measures with no between-group differences. For all outcomes measured at T1, the ICBT group showed greater improvements, except for the health-related quality of life VAS scores and hearing disability outcome for which the applied relaxation group showed greater improvements. From the test of fixed effects, there were no main effects for any outcome measures, except for anxiety (*p* = 0.05) during the completers only analysis (Table 4) due to the cross-over in scores seen between groups at different time-points.

Effect sizes varied slightly depending on the protocol. For the completers only analysis, the within-group effect size at T1 for anxiety (*d* = 0.81) and tinnitus cognitions (*d* = 0.80) were large for the ICBT group. A medium-sized within-group effect sizes were found for the ICBT group for depression (*d* = 0.75), insomnia (*d* = 0.67) and in the applied relaxation group for depression (*d* = 0.64), hearing disability (*d =* 0.54) and for tinnitus cognition (*d* = 0.67).

For the health-related quality of life general score, there was a small within-group effect for both groups. After both groups completed the full intervention, these improvements remained.

**3.6 Stability of the ICBT Intervention Effects for Both Groups**

At 2-months post-intervention follow-up, there were further reductions in tinnitus severity for both groups as noted in the TFI and THS scores. Although scores indicated slightly more improvements for the applied relaxation group, these differences were not statistically significant except for the VAS scores from the health-related quality of life measure (*d* = 0.78 at T3). They may indicate that with time further improvements may occur. There were also further reductions for both groups for all the secondary outcomes at 2-month follow-up except for anxiety in the ICBT group, where scores were slightly higher than at post-treatment. Overall, these results show that the outcomes of ICBT and applied relaxation were maintained at 2-month follow-up.

# Discussion

To improve outcomes of ICBT for tinnitus, this study aimed to identify which components of ICBT contribute to positive outcomes by dismantling applied relaxation which is a part of ICBT. Moreover, to assess intervention effects on tinnitus subgroups, three tinnitus subgroups were compared, based on levels of tinnitus severity and levels of depression. The main findings are discussed below.

**4.1 Dismantling the Effects of Applied Relaxation Compared with ICBT**

***4.1.1 Effects on Tinnitus Distress***

To dismantle the components of ICBT for tinnitus, the full ICBT program was compared with only the applied relaxation components. From the results of this preliminary study, it was found that although the full ICBT group improved more than the applied relaxation group, both interventions significantly reduced tinnitus severity with no group differences.

These results do, however, need to be considered within the context of this study. Unfortunately, engagement was particularly low, which may have biased these results. 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.

Due to this low engagement, the participants randomized to the ICBT group did not access the full ICBT intervention. This may partly explain why applied relaxation and ICBT did not produce different outcomes. Those in the ICBT group may have only worked with the first modules, which focus on applied relaxation. This is likely as a mean of only 6.38 modules were opened during the 8 weeks by the ICBT group and a mean of 6.59 modules by the applied relaxation group over the 12-weeks. Thus, a true comparison cannot be established by this data as neither group fully completed the full modules they were scheduled to do. It is furthermore not possible to determine how much participant’s practice and engaged with the materials. Further trials should identify ways of recording how much was actually done for each module. Due to the possible tendency not to access all of the modules, the ordering of the ICBT modules may play an important role in reducing tinnitus effects. By first learning to achieve relaxation, participants may be more able to attempt more complex CBT strategies, such as cognitive restructuring, reinterpreting tinnitus, and listening to tinnitus. Further work is thus required to untangle the role of the different CBT components ensuring that participants engage with and undertake the intervention assigned to them. This is particularly important considering that there is some evidence to suggest patients with tinnitus may improve over time even without provision of an intervention (Phillips et al., 2018). Results are, however, not dissimilar to previous dismantling and mantling studies of CBT for depression (Dimidjian et al., 2006), anxiety (Newman et al., 2011) and panic disorder (Schmidt et al., 2000) indicating that adding or removing components theorized to be critical does not always change outcomes.

Clinical trials comparing applied relaxation against CBT have sometimes observed greater effects for the CBT arm, thus indicating the low engagement in this trial may have contributed to the differences found for this study. For example, when comparing mindfulness-based cognitive therapy (MBCT) or mindfulness meditation, and relaxation training, it was found that although both approaches significantly reduced tinnitus, MBCT led to a significantly greater reduction in tinnitus severity than (Arif et al., 2017; McKenna et al., 2018). Considering these results collectively, it is still important to provide a comprehensive CBT intervention for those with significant tinnitus.

***4.1 2 Effects on Tinnitus Comorbidities***

During this study, the effects of ICBT and applied relaxation on associated difficulties with tinnitus were also investigated. Overall, both interventions significantly reduced problems associated with tinnitus. For the majority of the secondary outcomes, greater improvements were found for the ICBT group, although there were no significant group differences. The two outcome measures that indicated larger effects for the applied relaxation group compared with the ICBT group were for the health-related quality of life VAS scale and hearing disability, which will need further investigating.

For the completers only analysis, larger effect sizes were seen for the ICBT group for anxiety, depression and tinnitus cognitions, a medium effect for insomnia and small effect for the other measures. For the applied relaxation group there was a medium effect for depression, tinnitus cognitions and hearing disability, and small effects for the other outcomes. Regarding reducing anxiety at T1, the ICBT group showed a much larger within-group effect (*d* = 0.81), compared with a small effect in the applied relaxation group (*d* = 0.39). Although this was not a significant difference, it appeared that the CBT elements were more helpful in reducing anxiety than applied relaxation alone. Similar results were reported for other disorders such as generalized anxiety disorder (e.g., Donegar & Dugas, 2012) and post-traumatic stress disorder (e.g., Hinton et al., 2011) that have indicated that although both treatments are effective, CBT improved outcomes more than applied muscle relaxation. For reducing insomnia, the ICBT group again showed a larger within-group effect (*d* = 0.67) compared with the applied relaxation group (*d* = 0.41). These results need further investigating in studies where there is more engagement.

***4.1.3 Stability of Results***

At 2-months follow-up there were further reductions in tinnitus severity for both groups from the TFI and THS scores. This measurement was 16 weeks after baseline for the ICBT group and 20 weeks post-baseline for the applied relaxation group. Scores were lower for the applied relaxation group, although these results were not significantly different between the groups. As this outcome was 4 weeks later for the applied relaxation group, it may indicate that further improvements over time are possible. There were also further reductions for both groups for all the secondary outcomes at 2-month follow-up except for anxiety in the CBT group, where scores were slightly higher than at post-treatment. These results show that the outcomes were maintained at 2 months follow up, as has been previously reported (Beukes et al., 2018c), although monitoring outcomes in the long-term is required (Beukes et al., 2018d).

**4.2 Subgroup Comparisons**

To identify ICBT intervention effects for tinnitus subgroups, three subgroups were compared. From this study, those with TFI scores indicating the need for a tinnitus intervention (scores of above 25) were the most engaged, and those with low TFI scores (below 25) the least. In addition, as anticipated, those with high depression were the group displaying the greatest amount of change following the intervention and again those with low TFI scores made the least progress.

***4.2.1 Low Tinnitus Severity Subgroup***

Due to a lack of a reliable objective measure of tinnitus severity, treatment success is generally determined by self-reported assessment measures. Due to the heterogeneity of tinnitus, there is no single measure that fully captures all tinnitus effects. When low scores are obtained on patient-reported outcome measures such scores do not necessarily confirm the patient considers tinnitus interventions as not required. Some people continue to seek help despite low TFI scores (e.g., Beukes et al., 2018b). Those with low TFI scores were thus included in this study. This led to some interesting findings. Firstly, the low- TFI participants were more likely to withdraw and less likely to finish the study. This may indicate that although the participants were open to the idea that some form of help could be beneficial, an 8-12-week intensive intervention was not the most appropriate form of help for this group. For those feeling they needed help, triaging to a lower intensity form of help (e.g., 1-3 weeks program), perhaps a smartphone application or informational counseling within a group session may be more appropriate (e.g., Searchfield et al., 2020).

The most surprising outcome was that assessment scores for the low tinnitus severity group increased instead of decreasing over time, possibly indicating a statistical effect of regression to the mean. It is also possible that the COVID-19 pandemic the increased participant anxiety levels and resulted in their tinnitus worsening, as was found in the general population during this period (Beukes et al., 2020b). It may also be that undergoing an intervention placed more awareness on tinnitus and its effects and this heightened awareness negatively influenced their tinnitus. Comparison of intervention effects for different levels of baseline tinnitus severity should be investigated for larger data sets. From these outcomes, it appears as though patients with low tinnitus severity scores at intake may be better severed with an approach that employs basic information, reassurance for the patient, and minimal help in tinnitus domains identified at intake (Henry et al., 2005).

***4.2.2 High Depression Subgroup***

A further interesting finding was that those with high depression scores had the best outcomes but were not as engaged as the regular group (TFI scores >25). Similar results have previously been reported, as engagement with homework activities, was lower for those with depression (32%) than those with anxiety (78%) from pooled studies (Kazantzis et al., 2017). This may indicate that a group of patients with depression would need more directive support to facilitate engagement. They may be more compliant with a non-self-help format. They may require fixed appointments with a professional to increase their motivation to engage and additional support to encourage engagement when undertaking self-help programs.

**4.3 Study Limitations and Future Directions**

The main drawback of the study was the low engagement and low compliance among participants. Many participants never logged into the ePlatform and did not access any treatment modules. These factors affect the generalizability of the study. Moreover, the treatment dosage received was not sufficient for either group, indicating that neither group undertook the full intervention assigned to them. Results are based on the intervention materials with which participants engaged and as such, results might be different if participants in all groups fully engaged in the program, thereby receiving the full treatment dosage. Compliance for completing the outcome measures was also low, although similar between the groups. Although participants were randomized there were some differences with regards to the gender allocation and tinnitus duration. Previously these factors were not identified as significant treatment variables to predict outcome (Beukes et al., 2018d), so were unlikely to have affected treatment outcomes. Process evaluations should be undertaken to aid of finding out how to improve engagement (Beukes et al., 2018a). Qualitative studies should be undertaken to find out how much they valued each component of ICBT. Further research is required to identify tinnitus subgroups and which intervention components are most useful for each subgroup (Beukes et al., 2020c).

**Conclusion**

This study represents one of the first dismantling evaluations of ICBT for tinnitus. Unfortunately, due to low compliance participants did not fully utilize the intervention. Drawing conclusions when the full CBT intervention was not accessed is thus not possible. Further studies are required to continue to further dismantle the relative contributions of CBT components to examine which components or combinations of components are superior for managing tinnitus effects. Protocols should be adjusted to improve compliance and engagement to ensure accurate group comparisons. Component network meta-analysis should also be applied to larger studies where various components of different therapies can be isolated and compared (Rücker et al., 2020). Interventions targetting tinnitus subgroups (e.g., those with higher or lower tinnitus distress) may furthermore target specific meeds and help to improve intervention outcomes.

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**Declarations of interests**

None

**Availability of data and materials**

The data that support the findings of this study are openly available in Figshare at http://doi.org/10.6084/m9.figshare.13679179

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**Figure legends**

**Figure 1.** The Consolidated Standards of Reporting Trials (Consort) Flow diagram outlining the Internet-based cognitive behavioral therapy (ICBT) and Internet-based applied relaxation (IAR) group pathways.

**Figure 2.** Intervention engagement comparing messages sent, modules opened and number of logins between the Internet-based cognitive behavioral therapy (ICBT) and Internet-based applied relaxation (IAR) groups.

**Figure 3.** Intervention engagement comparing messages sent, modules opened and number of logins compared between the subgroups of participants allocated to the Internet-based cognitive behavioral therapy (ICBT) and Internet-based applied relaxation (IAR) groups.

**Figure 4.** Change in Tinnitus Severity between the ICBT group and applied relaxation group over time. At T1, the ICBT group had the full ICBT intervention without AR, and the applied relaxation group only the relaxation part. At T2 post intervention both groups had the full CBT program over 8 weeks for the ICBT group and 12 weeks for the applied relaxation groups. T3 is comparison of 2 month follow-up for both groups (16 weeks post for the ICBT group and 20 weeks post for the applied relaxation group).

**Figure 5.** Change in Tinnitus Severity between sub-groups over time. T1, the ICBT group had the full CBT intervention, without applied relaxation, and the relaxation group only the relaxation part.

**Supplementary Materials File A**

Supplementary materials 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/](https://www.google.com/url?q=http://www.jmir.org/2011/4/e126/&sa=D&source=editors&ust=1611922028718000&usg=AFQjCNEmqvD8ZNLDqcdPNAZGKQHXzQsgoQ)doi: 10.2196/jmir.1923 PMID: 22209829

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