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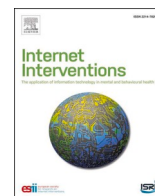
Dismantling internet-based cognitive behavioral therapy for tinnitus. The contribution of applied relaxation: A randomized controlled trial

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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 heterogeneous tinnitus subgroups respond differently to ICBT.

Aims: This dismantling study aimed to explore the contribution of applied relaxation within 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 reduction 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 employing strategies to improve compliance and engagement are required. The intervention's effectiveness increased with initial 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 severity. Larger samples are needed to confirm this.

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 intervention elements contribute to overall 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; Tay et al., 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; Tunkel 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 and Kaldo, 2004) and a systematic review affirmed the efficacy of ICBT for tinnitus (see Beukes et al., 2019).

ICBT is generally presented as a comprehensive, multi-dimensional 8-week intervention, resources and costs for intervention delivery cost may be prohibitie. 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 and Kim, 2018; Manzoni et al., 2008), and thus applied relaxation may serve as an integral part of tinnitus therapy. Relaxation therapies for tinnitus 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 et al. (1995) 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.

2. 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 no 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 https://clinicaltrials.gov/ct2/show/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 and Consort-EHEALTH Group, 2011) as found in Appendix 1.

2.3. 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) for use in waiting rooms and throughout the community. Those interested were directed to the study website (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 reporting 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; and undergoing 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, participants completed 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 groups.

i. 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).
ii. Due to numerous participants scoring below 25 and requesting help with their tinnitus, those with less than a significant level of tinnitus distress (<25 on the TFI) were included as a separate subgroup (i.e., low tinnitus severity group).
iii. 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 app for 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., submittedA). 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 and 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 min a day practicing the suggested exercises and completing worksheets to monitor their progress.

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 et al., 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, c, submittedB).

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	Program outline
	Tinnitus overview	Tinnitus overview
2	Deep relaxation	Deep relaxation
	Positive imagery	Positive imagery
	Sound enrichment	
3	Deep breathing	Deep breathing
	Views on tinnitus	
	Sleep guidelines	
4	Entire body relaxation	Entire body relaxation
	Shifting focus	
	Improving focus	
5	Frequent relaxation	Frequent relaxation
	Thought Patterns	
	Increasing sound tolerance	
6	Relaxing when stressed or upset	Relaxing when stressed or upset
	Challenging thoughts	
	Listening tips	
7	Relaxation routine	Being mindful
	Listening to tinnitus	
8	Being Mindful	Relaxation routine
	Summary	
	Future planning	
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

2.8.2. 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 et al., 1999) indicated symptoms of depression.
- The Insomnia Severity Index (ISI; Bastien et al., 2001) assessed the presence of insomnia.
- The Tinnitus Cognitions Questionnaire (TCQ; Wilson and 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 0.05. 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). The secondary study outcome were changes in the 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 and 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.

3. 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 Fig. 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:
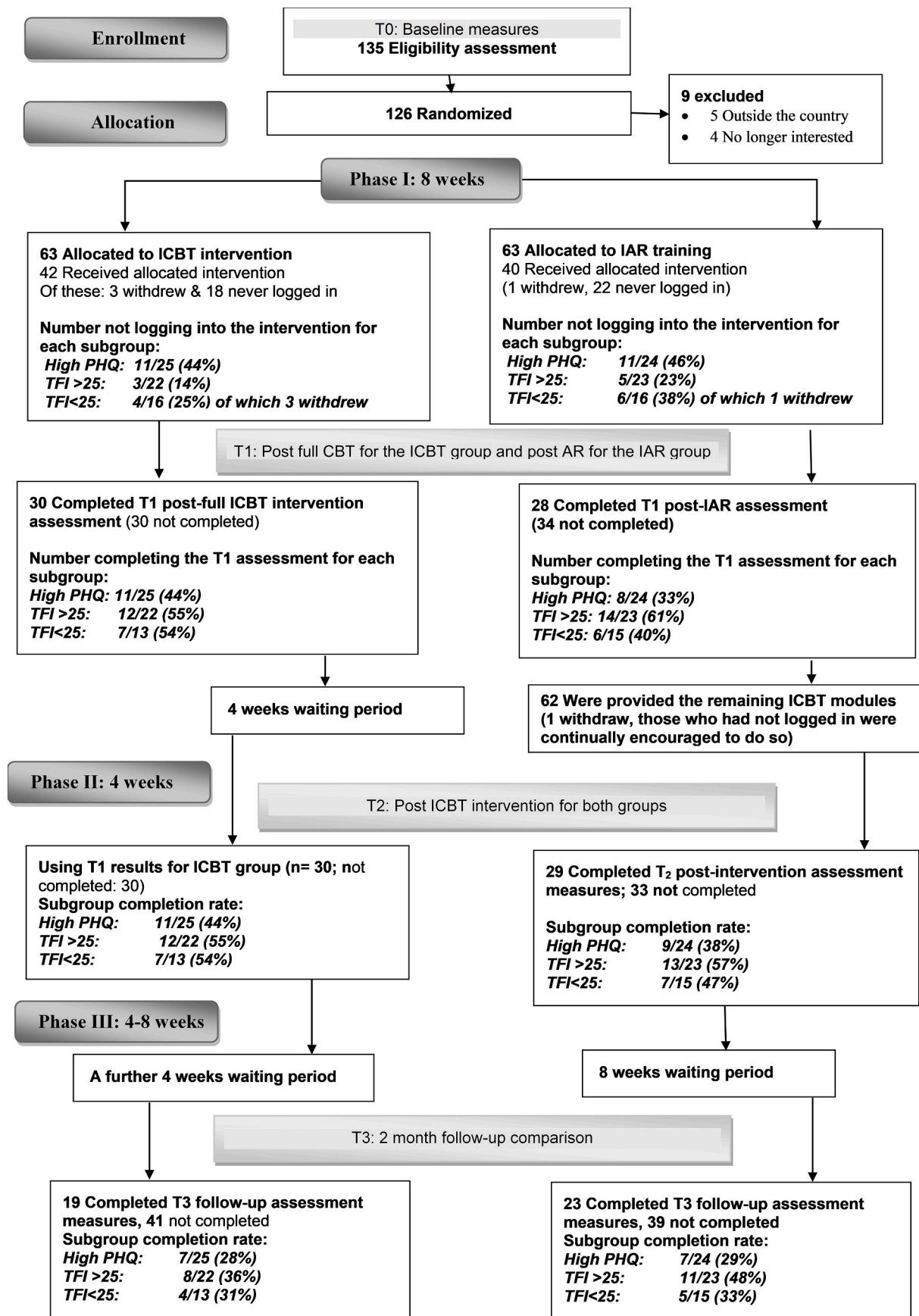
Enrollment

T0: Baseline measures
135 Eligibility assessment

↓

Allocation

126 Randomized

→

9 excluded
- 5 Outside the country
- 4 No longer interested

Phase I: 8 weeks

63 Allocated to ICBT intervention
42 Received allocated intervention
Of these: 3 withdrew & 18 never logged in

Number not logging into the intervention for each subgroup:
High PHQ: 11/25 (44%)
TFI >25:   3/22 (14%)
TFI<25:   4/16 (25%) of which 3 withdrew

63 Allocated to IAR training
40 Received allocated intervention
(1 withdrew, 22 never logged in)

Number not logging into the intervention for each subgroup:
High PHQ: 11/24 (46%)
TFI >25:   5/23 (23%)
TFI<25:   6/16 (38%) of which 1 withdrew

T1: Post full CBT for the ICBT group and post AR for the IAR group

30 Completed T1 post-full ICBT intervention assessment (30 not completed)

Number completing the T1 assessment for each subgroup:
High PHQ: 11/25 (44%)
TFI >25:   12/22 (55%)
TFI<25:   7/13 (54%)

28 Completed T1 post-IAR assessment (34 not completed)

Number completing the T1 assessment for each subgroup:
High PHQ: 8/24 (33%)
TFI >25: 14/23 (61%)
TFI<25: 6/15 (40%)

4 weeks waiting period

62 Were provided the remaining ICBT modules (1 withdraw, those who had not logged in were continually encouraged to do so)

Phase II: 4 weeks

T2: Post ICBT intervention for both groups

Using T1 results for ICBT group (n= 30; not completed: 30)
Subgroup completion rate:
High PHQ: 11/25 (44%)
TFI >25:   12/22 (55%)
TFI<25:   7/13 (54%)

29 Completed T2 post-intervention assessment measures; 33 not completed

Subgroup completion rate:
High PHQ: 9/24 (38%)
TFI >25:   13/23 (57%)
TFI<25:   7/15 (47%)

Phase III: 4-8 weeks

A further 4 weeks waiting period

8 weeks waiting period

T3: 2 month follow-up comparison

19 Completed T3 follow-up assessment measures, 41 not completed
Subgroup completion rate:
High PHQ: 7/25 (28%)
TFI >25:   8/22 (36%)
TFI<25:   4/13 (31%)

23 Completed T3 follow-up assessment measures, 39 not completed
Subgroup completion rate:
High PHQ: 7/24 (29%)
TFI >25:   11/23 (48%)
TFI<25:   5/15 (33%)

Fig. 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.

Table 2
Demographical characteristics of the participants.

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

- 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 less than a significant level of tinnitus distress with scores below 25 on the TFI 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 have directly impacted on the trial.

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 (Fig. 1). There were no significant between-group completion rates [$X^2 = (3, N = 159) = 0.46, p = .79$]. 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 Fig. 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 Fig. 3), 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 $p = .71$).

3.3. 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
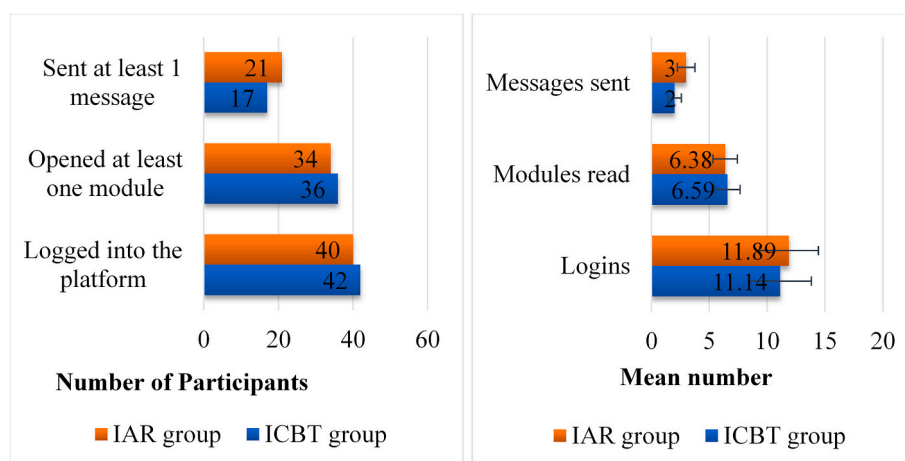

Fig. 2. Intervention engagement comparing messages sent, modules opened and number of logins between the Internet-based cognitive behavioral therapy (ICBT) and Internet-based applied relaxation (IAR) groups.
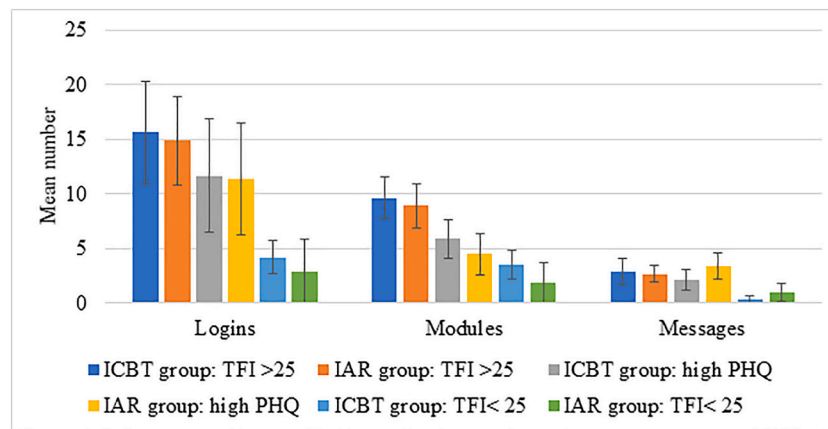
Fig. 3. Intervention engagement comparing messages sent, modules opened and number of logins compared between the subgroups of participants allocated to the Internet-based cognitive behavioral therapy (ICBT) and Internet-based applied relaxation (IAR) groups.

(Table 3, Fig. 4). 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.

3.4. Comparison of changes in tinnitus severity for each subgroup

Tinnitus severity changed significantly between sub-groups over time as seen in Fig. 5. 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.

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 ($p = .05$) 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.

4. 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.

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
			Imputation analysis	28.89 (14.56)	29.46 (14.61)	26.94 (11.86)	1.10 [0.63 to 1.37]	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]
	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
			Imputation analysis	31.62 (14.52)	30.54 (16.17)	23.81 (9.87)	0.82 [0.45 to 1.18]	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]
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
			Imputation analysis	4.51 (3.16)	4.58 (3.19)	4.67 (3.33)	0.93 [0.56 to 1.29]	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]
	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
			Imputation analysis	5.23 (4.02)	4.65 (4.21)	3.79 (2.80)	0.45 [0.10 to 0.80]	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]
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
			Imputation analysis	4.50 (2.87)	4.29 (2.94)	3.80 (2.81)	0.85 [0.48 to 1.2]	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]
	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]
			Imputation analysis	5.16 (3.79)	4.89 (4.08)	3.58 (2.95)	0.70 [0.18 to 0.34]	At T2: 0.15 [−0.20 to 0.50]
								At T3: −0.08 [−0.43 to 0.27]
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
			Imputation analysis	7.81 (4.33)	7.47 (4.11)	5.87 (3.58)	0.71 [0.35 to 1.01]	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]
	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
			Imputation analysis	9.03 (4.71)	8.51 (4.40)	6.90 (3.31)	0.46 [0.10 to 0.81]	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]
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
			Imputation analysis	7.26 (1.52)	7.08 (1.65)	6.78 (1.18)	0.39 [0.03 to 0.74]	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]

Table 3 (*continued*)

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)
	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
			Imputation analysis	7.70 (2.01)	7.89 (2.69)	7.52 (2.18)	0.27 [−0.08 to 0.62]	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]
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]
	Imputation analysis	77.94 (11.68)	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]	77.98 (11.78)	86.17 (4.18)	0.18 [−0.17 to 0.53]		
Imputation analysis	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
			79.83 (8.36)	76.72 (10.83)	77.96 (7.24)	0.54 [0.18 to 0.89]		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]
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
			Imputation analysis	3.03 (2.03)	2.99 (2.05)	1.92 (1.48)	0.76 [0.40 to 1.12]	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]
	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
			Imputation analysis	3.69 (2.80)	3.46 (2.82)	2.87 (2.24)	0.56 [0.20 to 0.91]	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]
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
			Imputation analysis	4.58 (3.07)	4.76 (2.98)	3.08 (1.61)	0.32 [−0.03 to 0.67]	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]
	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]
			Imputation analysis	3.69 (2.80)	4.63 (3.21)	4.25 (2.57)	0.63 [0.27 to 0.99]	At T2: 0.28 [−0.03 to 0.59] At T3: −0.11 [−0.42 to 0.20]
Hyperacusis (THS)	ICBT group	1.22 (1.30)	Completers analysis	0.67 (1.07)	0.67 (1.07)	0.47 (0.74)	0.44 [−0.01 to 0.90]	Completers analysis
			Imputation analysis	0.77 (0.93)	0.8 (0.92)	0.61 (0.69)	0.4 [0.04 to 0.75]	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]
	Applied relaxation group	1.17 (1.40)	Completers analysis	1.00 (1.39)	0.96 (1.23)	0.91 (1.08)	0.06 [−0.38 to 0.51	Imputation analysis
			Imputation analysis	1.17 (1.23)	1.02 (0.98)	0.99 (0.97)	0.00 [−0.35 to 0.35]	At T1: 0.37 [0.01 to 0.72]*

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Table 3 (*continued*)

| 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 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]	At T2: 0.23 [−0.12 to 0.58] At T3: 0.45 [0.09 to 0.80]*
			Imputation analysis	26.95 (13.45)	27.46 (13.45)	23.66 (9.19)	0.96 [0.59 to 1.32]	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]
	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]	
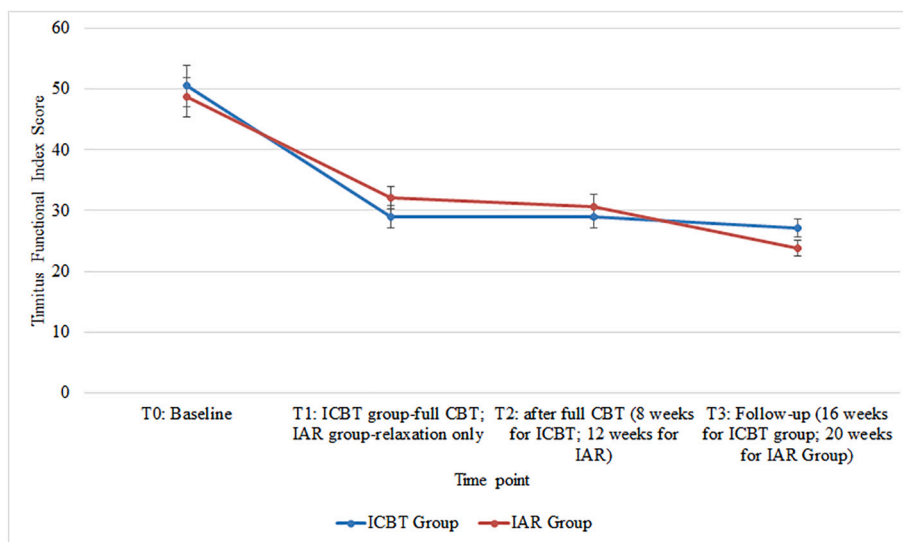
Fig. 4. Change in Tinnitus Severity between the ICBT group and applied relaxation group over time. At T1, the ICBT group had the full ICBT intervention without AR, and the applied relaxation group only the relaxation part. At T2 post intervention both groups had the full CBT program over 8 weeks for 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).

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 scheduling and the participants wanting time away 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 confident when attempting more complex CBT strategies, such as cognitive restructuring, reinterpreting tinnitus, and listening to tinnitus. Further

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, $p < .001$*	$F(3,98.976)$ = 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, $p < .001$*	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) = 0.234, $p =$ .629	$F(1, 124.000) =$ 0.006, $p =$ .936	F (1,136.156) = 0.04, $p =$ .84	F (1,139.383) = 0.979, $p =$ .32	F (1,137.975) = 0.108 $p =$ .897	F (1,145.346) = 0.207, $p =$ .65	F (1,139,395) = 0.388, $p =$ .53	F (1,139.838) = 1.01, $p =$ .317	$F(1,139.838)$ = 1.01, $p =$ .317	F (1,142.865) = 0.966, $p =$ .327
Group: for imputation analysis	F (1,124.012) = 0.02, $p =$ .90	$F(1, 124.000) =$ 0.45, $p = .50$	F (1,124.000) = 0.26, $p =$ .61	F (1,123.990) = 3.59, $p =$ .06	F (1,156.000) = 0.13, $p =$ .72	$F(1,60.238) =$ 2.72, $p =$ .10	F (1,124.000) = 0.42, $p =$ .52	$F(1,47.59) =$ 0.05, $p = .83$	$F(1,124.000)$ = 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) = 0.233, $p =$ .793	$F(3,98.976)$ = 2.811, $p =$ .065	$F(3,98.976)$ = 2.811, $p =$ .065	$F(3,104.90)$ = .0.579, $p <$ .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) = 0.119, $p =$ .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) = 0.77, $p =$ .52	F (3,124.000) = 0.66, $p =$ .58	$F(3,156) =$ 0.19, $p = .90$	F (3,113.435) = 0.10.17, $p < .001$*	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) = 0.86, $p =$ .466
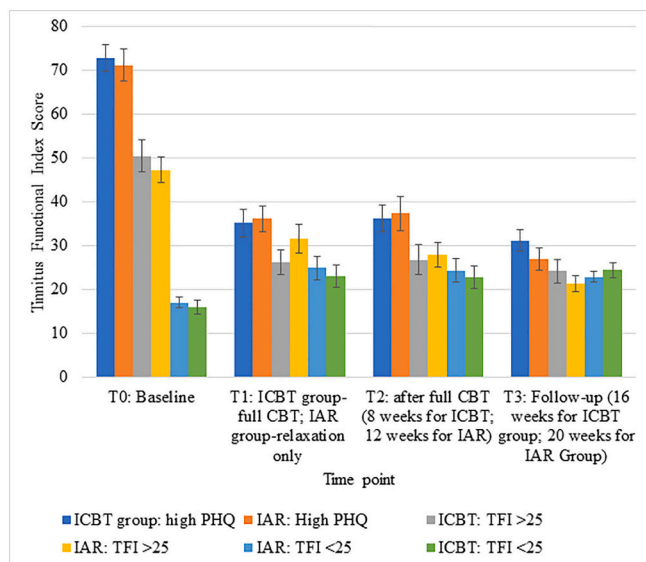
Fig. 5. Change in Tinnitus Severity between sub-groups over time. T1, the ICBT group had the full CBT intervention, without applied relaxation, and the relaxation group only the relaxation part.

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., Donegan and 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 group with significant tinnitus (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).

5. 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 generalizable 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 targeting tinnitus subgroups (e.g., those with higher or lower tinnitus distress) may furthermore target specific needs and help to improve intervention outcomes.

Availability of data and materials

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

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Declaration of competing interest

None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.invent.2021.100402.

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