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The Effectiveness of Unguided Internet-Based Cognitive Behavioral Therapy for Tinnitus for Patients with Tinnitus Alone or Combined with Hyperacusis and/or Misophonia: A Preliminary Analysis

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Conflict of Interest: HA is the developer and owner of the iCBT(T) program. No conflicting interests are declared for the other authors.

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Abstract:

Background: In the UK, audiologist-delivered cognitive behavioral therapy (CBT) is a key intervention to alleviate the distress caused by tinnitus and its comorbid hyperacusis. However, the availability of face-to-face CBT is limited, and such therapy involves significant costs. CBT provided via the internet provides a potential solution to improve access to CBT for tinnitus.

Purpose: The aim was to perform a preliminary assessment of the effect of a specific program of non-guided internet-based CBT for tinnitus, denoted iCBT(T), in alleviating the problems caused by tinnitus alone or tinnitus combined with hyperacusis.

Research Design: This was a retrospective cross-sectional study.

Study Sample: The data for 28 people with tinnitus who completed the iCBT(T) program and answered a series of questions about their tinnitus and hearing status were included in the study. Twelve patients reported also having hyperacusis (including five also with misophonia).

Data collection and analysis: The iCBT(T) program has seven self-help modules. Anonymous data were collected retrospectively from patients' answers to the questions in the iCBT(T) initial and final assessment modules. Questionnaires administered within the iCBT(T) program were: 4C Tinnitus Management Questionnaire (4C), Screening for Anxiety and Depression in Tinnitus (SAD-T), and the CBT Effectiveness Questionnaire (CBT-EQ).

Results: Responses to the 4C showed a significant improvement from pre- to post-treatment, with a medium effect size. The mean improvement was similar for those with and without hyperacusis. Responses to the SAD-T questionnaire also showed a significant improvement from pre- to post-treatment with a medium effect size. The improvement was significantly greater for participants with tinnitus alone than for participants who also had hyperacusis. For both the 4C and the SAD-T, the improvements were not significantly related to age or gender. Participants' views of the effectiveness of the iCBT(T) program were assessed using the CBT-EQ. The mean score was 50 out of a maximum of 80, indicating moderately high effectiveness. CBT-EQ scores did not differ for those with and without hyperacusis.

Conclusions: Based on this preliminary analysis, the iCBT(T) program showed promising result in improving the ability to manage tinnitus and decreasing symptoms of anxiety and depression. Future studies with larger samples and control group(s) are required to further assess various aspects of this program.

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The Effectiveness of Unguided Internet-Based Cognitive Behavioral Therapy for Tinnitus for Patients with Tinnitus Alone or Combined with Hyperacusis and/or Misophonia: A Preliminary Analysis

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Abstract

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Results: Responses to the 4C showed a significant improvement from pre- to post-treatment, with a medium effect size. The mean improvement was similar for those with and without hyperacusis. Responses to the SAD-T questionnaire also showed a significant improvement from pre- to post-treatment with a medium effect size. The improvement was significantly greater for participants with tinnitus alone than for participants who also had hyperacusis. For both the 4C and the SAD-T, the improvements were not significantly related to age or gender. Participants' views of the effectiveness of the iCBT(T) program were assessed using the CBT-EQ. The mean score was 50 out of a maximum of 80, indicating moderately high effectiveness. CBT-EQ scores did not differ for those with and without hyperacusis.

Conclusions: Based on this preliminary analysis, the iCBT(T) program showed promising result in improving the ability to manage tinnitus and decreasing symptoms of anxiety and depression. Future studies with larger samples and control group(s) are required to further assess various aspects of this program.

Tinnitus is the perception of sound without any acoustic stimulus external to the body. It can significantly affect the sufferer's mental health, and up to 60% of patients seeking help for their tinnitus show symptoms of anxiety and mood disorders (1). Hyperacusis is the perception of certain everyday sounds, such as domestic noise or noise in public places, as too loud or painful (2). Misophonia is the perception of certain sounds produced by human beings or animals, such as eating and breathing noises, as disgusting or offensive (3, 4).

Hyperacusis and misophonia often lead to intolerance of certain day-to-day sounds and cause significant distress and impairment in the sufferers' social, occupational, recreational, and other activities (5, 6). Tinnitus, hyperacusis and misophonia sometimes co-occur. Twelve percent or more of patients with misophonia also suffer from tinnitus (7, 8). Hyperacusis is present for about 40% of patients with moderately severe tinnitus and for up to 80% of those with severe tinnitus (9, 10).

In the UK, audiologist-delivered cognitive behavioral therapy (CBT) is a key intervention to alleviate the distress caused by tinnitus and its comorbid hyperacusis and misophonia (11-16). CBT is often delivered over 6 to 14 face-to-face individual sessions. However, the availability of face-to-face therapy under the UK National Health Service is limited, and such therapy involves significant costs. In many developing countries, tinnitus therapy is not available or is unaffordable. Even in developed countries, tinnitus therapy may not be covered by health insurance (15). CBT provided via the internet (iCBT) provides a potential solution to these issues.

There are several different approaches to iCBT. However, they mostly use an internet platform similar to that for online educational training courses and utilize a mix of educational videos and audio recordings, text, puzzles, games, and assignments for participants to complete (17, 18). The contents are often developed based on existing self-help materials or on methods that are used in face-to-face therapy sessions, modified for delivery in a self-help format. A recent meta-analysis that reviewed nine randomized controlled trials (RCT) of iCBT for tinnitus reported that iCBT led to a medium overall effect size (ES) in reducing tinnitus-related distress, with Cohen's $d = 0.50$ (95% confidence interval, CI: 0.37–0.63) over studies using both passive and active control groups (19).

There are several guided and unguided iCBT approaches that have been used for treating people with bothersome tinnitus, with varied success (19). Participants who use guided iCBT benefit from additional support from a clinician or therapist who can encourage them and help them to engage with the program as well as answering questions. Unguided iCBT does not involve additional support from a therapist, and it appears to be somewhat less effective than guided iCBT (19). However, unguided iCBT is less costly and therefore has the potential to be scaled up and used when face-to-face therapy is not easily accessible.

Several studies have reported that patients who have tinnitus combined with hyperacusis or misophonia exhibit a more severe impact of their tinnitus and more marked symptoms of

anxiety and depression than those with tinnitus alone (1, 8, 20, 21). Therefore, it is not clear if iCBT for tinnitus is as effective for patients with comorbid hyperacusis and/or misophonia as for patients with tinnitus alone.

This study assessed of a specific unguided iCBT program for tinnitus with seven self-help modules. Hereafter, the program is designated as iCBT(T). The program was developed by the first author in 2020, with input from the third and fourth authors (22). The aims of this study were: (1) to perform a preliminary assessment of the effectiveness of the iCBT(T) by retrospectively comparing pre- and post-treatment scores on self-report questionnaires that were integrated into the program; (2) to assess participant's views about the effectiveness of the iCBT(T) program; and (3) to perform a preliminary comparison of the effectiveness of the iCBT(T) program for participants with tinnitus alone and for those with tinnitus combined with hyperacusis or misophonia.

Method

Ethics

All participants agreed that their anonymized data could be used for service improvement and research purposes. The study was approved by the University of Surrey ethics committee (Project ID: FHMS 21-22 147 EGA).

Study Design and Participants

This was an exploratory study with a retrospective cross-sectional design using anonymized data from 28 consecutive participants who completed the iCBT(T) program between October and December 2020. The participants were self-selected rather than being recruited by the authors. Presumably, the participants found the program via internet search or were directed to the iCBT(T) website by audiologists who were aware of the program. Anonymized data collection was built into the program in order to create personalized reports for the participants and to assess their feedback about the effectiveness of the iCBT(T) program. The preliminary assessment of the effectiveness of the iCBT(T) program in this study was evaluated using these data. Anonymous demographic data about the participants, characteristics of their tinnitus, ear and hearing history, and the outcomes of their self-report questionnaires were imported from their answers to the questions in the iCBT(T) initial and

final assessment modules.

The Content of the iCBT(T) Program

The iCBT(T) program (version 1.1, 2020) has seven modules that were designed based on a specialized CBT program for tinnitus management that has been used for over a decade by audiologists in the UK and elsewhere (11-14, 16, 23). Table 1 gives details of the content and objectives of each module. Participants are advised to start from the first module (Assessment) and go on to completing the other modules in order. The amount of time needed for each module ranges from 45 to 90 minutes. Participants are informed that they need to allocate time to complete assignments between modules. The suggested interval between each of the first six modules is 3-4 days. This is intended to allow time to practice specific exercises between each module. The final assessment (module 7) needs to be completed one month after completing the iCBT(T) program. The iCBT(T) program is self-explanatory and does not require any intervention from a therapist. Figure 1 illustrates the structure of the program. Audiologists or therapists also can choose to guide their patients in completing the modules if required, changing the program to guided iCBT. However, the data included in this study are for a cohort of participants who completed iCBT(T) without guidance from a therapist.

****insert Table 1 and Figure 1 here****

For internet therapy programs, especially those for which a therapist or clinician is not providing additional support and guidance, it is important to use strategies to increase each participant's engagement and willingness to persist. This can be facilitated by persuasive system design, which is a framework proposed by Oinas-Kukkonen and Harjumaa (24). It includes 28 recommendations for making the design of an internet therapy program more persuasive and engaging. Examples of such principles are reducing complex behavior into simple tasks, personalized content, offering praise, reminders, and visually attractive design. Some of the persuasive system design principles are utilized in the iCBT(T) program and these are listed in Table 2.

****insert table 2 here****

Self-report Questionnaires

All questionnaires described here were integral parts of the iCBT(T) program and were not chosen for the purpose of this study. The data collected using these questionnaires were analyzed retrospectively. In what follows we describe the questionnaires and the reasons why they were included in the iCBT(T) program.

There can be significant differences between paper and electronic versions of a given questionnaire (25, 26). Therefore, it is recommended to re-measure the reliability of a questionnaire when it is used in different format (27). In this study, Cronbach's alpha was estimated for each of the online versions of the questionnaires incorporated in the iCBT(T) program.

4C Tinnitus Management Questionnaire

The 4C questionnaire was chosen for use in the iCBT(T) program because, in addition to being a validated measure of how well an individual is coping with their tinnitus (28), the 4C is intended to motivate the participant in engaging with the therapy process by encouraging them to think about how they can become more confident in managing their day-to-day life events despite having tinnitus. Unlike other commonly used tinnitus questionnaires, the 4C is focused on the individual's ability to manage the problem. For example, instead of asking "How often did your tinnitus make it difficult to fall asleep or stay asleep?" which is a question from the Tinnitus Functional Index (TFI) (29), the 4C asks "How confident are you that you are able to rest and relax, even with tinnitus?". Instead of asking "Does your tinnitus make it difficult to enjoy life?", which is a question from the Tinnitus Handicap Inventory (THI) (30), the 4C asks "How confident are you that you can enjoy your life fully, even with tinnitus?". The change in focus from the problem to the individual's ability to manage the problem can help the patient to assess their strengths and weaknesses and to think about how to develop more confidence in dealing with the problem (31, 32). The 4C questionnaire is partly consistent with the Self-Efficacy for Tinnitus Management Questionnaire (SETMQ, (Smith & Fagelson 2011), which also focuses on assessing a participant's confidence in their ability to control their reaction to their tinnitus and to implement tinnitus management strategies. However, the 4C has only 4 items compared to 40 items in the SETMQ. The 4C is

designed to be used for CBT intervention (28), while the SETMQ has items that are not relevant to CBT and are related to the use of masking and sound-generating devices.

The 4C asks participants to select a number based on how they feel now for each question (28). The 4C items are: (1) How confident are you that you are able to carry out your day-to-day tasks, even with tinnitus? (2) How confident are you that you are able to rest and relax, even with tinnitus? (3) How confident are you that you can enjoy your life fully, even with tinnitus? (4) How confident are you that you can do all the above without using any avoidance behavior? The response choice range is from 0 to 10. 0 means “Not confident at all” and 10 means “Very confident”. To calculate the overall score for the 4C questionnaire, the sum of the scores for the first three questions (Q1-Q3) is multiplied by the score for the fourth question (Q4). Then the result is divided by 3. The highest possible score is 100, so the total score can be regarded as a percentage. 4C scores between 57 percent and 100 percent indicate a high level of confidence. Scores between 52 percent and 57 percent indicate a fair degree of confidence, scores between 37 percent and 52 percent indicate slight confidence, and scores between 0 and 37 percent indicate low confidence. Cronbach's alpha for the 4C questionnaire in pen and paper format is 0.91 (28).

Screening for Anxiety and Depression in Tinnitus (SAD-T)

The SAD-T contains four items that match those for the physical health questionnaire (PHQ-4; 33). Each item is rated on a four-point scale. Two items relate to experiences of anxiety and two relate to experiences of depression. The overall score ranges from 0 to 12. Scores ≥ 4 indicate symptoms of anxiety and/or depression. Cronbach's alpha for the SAD-T in pen and paper format is 0.91 (34). This questionnaire was used in the iCBT(T) program in order to identify participants who might benefit from further psychological evaluations and to make such a recommendation in their assessment reports for modules one and seven.

CBT Effectiveness Questionnaire (CBT-EQ)

The CBT-EQ has eight questions asking about the effectiveness of the iCBT(T) program and its components, as judged by the participant. This questionnaire was included in the iCBT(T) program to provide a measure of the effectiveness of the program and each of its components from the participant's perspective. Seeking users' feedback is common for most clinical services (35).

The pen and paper version of the CBT-EQ has been used in a study evaluating patients' perspectives about the effectiveness of face-to-face CBT for tinnitus management (11). For each question, the participant is asked to choose a number between 0 and 10. The total score ranges from 0 to 80. The questions are:

1) How effective was iCBT in helping you manage your tinnitus? Number 0 is "Not effective at all" and number 10 is "Very effective".

2) Are you able to manage your tinnitus differently compared to before you started the iCBT? Number 0 is "No" and number 10 is "Yes, a lot".

Please rate the effectiveness of each of the iCBT modules in helping you manage your tinnitus? Number 0 is "Not effective at all" and number 10 is "Very effective".

3) Doing a "Behavioral Experiment" and reflecting on its outcome.

4) Filling in the "Diary of Thoughts" and reflecting on them.

5) Completing the Assessment & 4C questions.

6) Learning about Positive Psychology.

7) General learning about CBT for tinnitus.

8) Learning how to challenge your negative thoughts.

Other Questions

Other questions that were included in the iCBT(T) program are shown in Table 1. Participant's answers to these questions were needed to develop their module one assessment report. They responded by selecting among a range of response options. The questions were related to: whether they had hearing difficulties, hyperacusis and misophonia; when the tinnitus started relative to when they started the iCBT(T) program; where the tinnitus appeared to be located; what the tinnitus sounded like; and what the likely cause of the tinnitus was.

Analysis

Descriptive statistics, medians, means, standard deviations (SD), and 95% CIs of the scores for the self-report questionnaires are reported. The reliability of the 4C, SAD-T and CBT-EQ

questionnaires were re-assessed using Cronbach's alpha (36), which is a standard measure of reliability. To be considered as reliable, the value of alpha was required to be greater than 0.7.

Paired *t*-tests were used to compare pre- and post-treatment scores for the 4C and SAD-T questionnaires. Welch's *t*-tests (37) for unequal samples were used to compare the changes in 4C and SAD-T scores and the scores for the CBT-EQ between patients with and without hyperacusis and/or misophonia, between males and females and between patients with a duration of tinnitus ≤ 1 month versus ≥ 6 months prior to enrolling in the iCBT(T) program.

For ordinal data (i.e., categories of participants with abnormal SAD-T scores), Wilcoxon matched-pairs signed-ranks tests were used to compare the medians of the variables before and after treatment. Pearson correlation was used to assess factors related to changes in 4C and SAD-T scores (before and after treatment) as well as the CBT-EQ total scores (after treatment).

ES values, Cohen's *d*, were used to assess the changes in 4C and SAD-T scores pre- and post-treatment. These were calculated using equation 8 of Morris and DeShon (38). This takes into account the correlation between pre- and post-treatment scores that occurs in a within-subjects design. The resulting ES values are called "corrected" ES values. ES values between 0.2 and 0.5 are considered as small, those between 0.5 and 0.8 as medium, and those above 0.8 as large (39). The *p*-value required for statistical significance was set at $p < 0.05$. The Stata program (version 13) (40) was used for statistical analyses.

Results

Characteristics of the Participants

All 28 participants reported having bothersome tinnitus. Their average age was 52 years (SD = 16.5 years, range 18 to 75 years) and 17 were male. Based on their responses to questions 10 and 11 listed in Table 1, twelve participants reported experiencing hyperacusis and five reported misophonia. All participants who reported misophonia also reported hyperacusis. Eighteen participants reported having some hearing difficulties in addition to their tinnitus.

The following are the numbers of participants who reported hearing their tinnitus in the specified location(s): two outside their head; sixteen in both ears; two in one ear only; three in the back of their head as well as in both ears; one in the back of their head as well as in their right ear; two in the front of their head in addition to both ears; one in the front of their head

only; and one in the front and back of their head.

None of the participants reported discharge from their ears. Three participants reported ear pain and three reported balance problems. Twenty-three participants reported that their tinnitus started six months or more prior to starting the iCBT(T) program. For the remaining five participants, the onsets of tinnitus relative to starting the iCBT(T) program were: one month for one participant, one week for two participants and in the last 24 hours for two participants. Participants were asked to select the likely cause of their tinnitus from several options. They were allowed to choose more than one option. The number of participants selecting each cause of tinnitus was sixteen for stress, eight for loud noise, eight for infections, six for drugs, five for ear wax, and one for an accident. Eight selected miscellaneous other causes, and nine reported that they did not know what might have caused their tinnitus.

Participants were asked to select from various options what their tinnitus sounded like. They were allowed to choose as many options as they liked. Twenty participants described their tinnitus as a high-pitched sound, nine as a hissing noise, eight as white noise, seven as buzzing, seven as ringing, five as a whistle, five as a pulsing sound, two as a humming noise, two as a heartbeat, one as clicks, one as beeps, and one as a plane taking off. Three participants did not find a description that matched their tinnitus and selected the option “others”.

Depending on their responses, some participants were recommended to see their healthcare providers. The criteria used to generate a recommendation to seek medical help are summarized in Table 1, in the initial “Assessment” module.

Sixteen participants had symptoms of anxiety and depression based on their scores for the SAD-T. They received a recommendation to discuss their mood with their healthcare provider and explore the possibility of being referred for psychological support (if they had not done that already). They were also given information about general mental health support organizations in the UK, USA and Australia and were given the contact details of those organizations.

Reliability of the Questionnaires Used in the iCBT(T) Program

Cronbach's alpha was 0.98 for the CBT-EQ, 0.88 for the 4C, and 0.91 for SAD-T, indicating good internal consistency for all three questionnaires in online format, as used in the iCBT(T) program.

Pre- and Post-Treatment Comparison

Table 3 shows the mean pre-and post-treatment scores for the 4C and SAD-T across all participants. Corrected ES values were medium in size and were significant for both questionnaires. The differences between pre-and post-treatment in 4C scores were not significantly correlated with age ($r = 0.26$, $p = 0.18$) or with pre-treatment SAD-T scores ($r = -0.16$, $p = 0.42$). Similarly, the differences between pre-and post-treatment in SAD-T scores were not significantly correlated with age or pre-treatment 4C scores ($r = 0.09$, $p = 0.63$; $r = -0.22$, $p = 0.26$, respectively). There was no significant difference in the change in 4C and SAD-T scores between men and women ($p = 0.1$ and 0.2 , respectively).

The number of participants who had scores ≥ 4 for the SAD-T, indicating symptoms of anxiety and depression, reduced from sixteen before treatment to nine after treatment, and a Wilcoxon signed-rank test showed that this difference was significant ($Z = -2.11$, $p = 0.034$).

****insert Table 3 here****

The change in SAD-T score was on average 2.5 points larger (95% CI: 0.35 to 4.6) for the sixteen participants with tinnitus alone than for the twelve who had tinnitus combined with hyperacusis, and this difference was significant ($p = 0.024$).

The mean changes in 4C and SAD-T scores for participants whose tinnitus started one month or less before starting the iCBT(T) program ($N=5$) were 33 (SD=25) and 4 (SD=2.5), respectively. These changes were larger than the changes for the participants whose tinnitus started six months or more before starting the iCBT(T) program ($N=23$), which were 13 (SD=28) for the 4C and 1.4 (SD=2.9) for the SAD-T, but the differences in change were not significant ($p = 0.16$ and 0.075 , respectively), possibly because of the small sample sizes.

Participants' Views About the Effectiveness of the iCBT(T) Program

The average total CBT-EQ score was 50 out of 80 (95% CI: 43 to 58). The average total CBT-EQ score for the twelve participants with tinnitus combined with hyperacusis was 52 (SD = 21). This did not differ significantly ($p = 0.77$) from the average score of 49.5 (SD = 19) for the sixteen participants who had tinnitus alone. There was no significant difference in total CBT-EQ scores between men and women ($p = 0.2$).

CBT-EQ total scores were not significantly correlated with age ($r = -0.23$, $p = 0.24$), pre-treatment 4C scores ($r = 0.27$, $p = 0.16$), or pre-treatment SAD-T scores ($r = -0.37$, $p = 0.055$). However, CBT-EQ total scores were significantly correlated with post-treatment 4C scores ($r = 0.66$, $p = 0.0001$) and post-treatment SAD-T scores ($r = -0.43$, $p = 0.02$).

For the question asking “How effective was iCBT in helping you manage your tinnitus?”, the median response was 6/10 (SD = 2.6). For the question asking “Are you able to manage your tinnitus differently compared to before you started the iCBT?”, the median response was 7/10 (SD = 3.0). The medians and SDs of responses to the questions asking for a rating of the effectiveness of each of the iCBT modules in helping them manage their tinnitus were: 6/10 (SD = 2.5) for the “Behavioral Experiment”, 6/10 (SD = 2.6) for the “Diary of Thoughts”, 5.5/10 (SD = 2.3) for the assessment module, 6/10 (SD = 2.5) for the “Positive Psychology” module, 7/10 (SD = 2.5) for general learning about CBT for tinnitus, and 7/10 (SD = 2.4) for learning how to challenge negative thoughts.

Discussion

The results of this study need to be interpreted bearing in mind its methodological limitations. The analysis was retrospective and hence was limited to data collected as an integral part of the iCBT(T) program. We do not know how many people started the program without finishing it. This may have led to selection bias, since the analysis was based only on participants who completed the program (41). It is possible that only those who perceived some initial benefit from the program chose to continue to completion. Future studies should explore the dropout rate from the iCBT(T) program, reasons for dropouts, how much time was spent on each module, and if the participants completed the assignments and adhered to the program.

The study lacked a control group. Therefore, it is difficult to assess the extent to which the measured improvements were produced specifically by the iCBT(T) as opposed to being a

more general effect of receiving treatment (placebo effect) (42). Studies with an RCT design are required to assess the efficacy of iCBT(T) for the management of tinnitus.

The study had a small sample size, so the lack of statistical significance for some of the analyses could reflect a type II error. Another limitation of this study is the fact it was conducted by the developer of the iCBT(T) program, although any biases introduced by this could not have influenced the responses of the participants. Future studies addressing these points and conducted independently of the developer of the iCBT(T) program are needed.

Clinicians involved with the treatment of tinnitus often wonder why many of their patients have been told that “nothing can be done” for their tinnitus. It is unfortunate that, despite the enormous progress in tinnitus management, there are still patients who develop a great level of stress and anxiety about their tinnitus because someone, often a healthcare provider, told them it is not curable. For many patients with tinnitus, the cost of management is a significant factor. In countries with insurance-based health system, tinnitus management is not covered by many insurance companies. The introduction of iCBT(T) is an important step in providing a non-invasive, supportive and affordable method of tinnitus management. The results showed that the iCBT(T) program for tinnitus had a medium ES for improving participants’ confidence in managing their tinnitus as measured via the 4C and a medium ES for reducing symptoms of anxiety and depression as measured via the SAD-T.

As noted above, part of these improvements may have been due to the “participation effect” (43, 44) or placebo effect. It is known that almost any acceptable intervention for tinnitus tends to result in a reduction in the severity of tinnitus as assessed using questionnaires. The magnitude of the participation effect can be estimated by comparing ES values in improving tinnitus distress for iCBT studies involving inactive (passive) control groups (e.g., being put on a waiting list) and studies involving active control groups (involving some plausible type of treatment other than iCBT); the participation effect is likely to influence the former but not the latter. In a meta-analysis of trials of iCBT, Beukes, Manchaiah (19) found mean ES values for reducing tinnitus distress of 0.59 for studies with inactive control groups and 0.32 for studies with active control groups. This suggests that the participation effect increased the ES by about 0.27. The corrected ES for improvement in tinnitus distress as measured by the change in 4C scores in the present study was 0.69, which is much larger than would be expected from the participation effect alone. Hence it seems likely that a substantial part of the beneficial effect of the iCBT(T) program found in the present study was not caused by the participation effect.

The magnitude of the ES found here for the SAD-T is comparable to those found in controlled trials of various forms of iCBT in the management of mental illness and chronic conditions. For example, Mehta, Peynenburg (45) reviewed 25 RCTs that assessed the effects of iCBT on anxiety and depression symptoms for participants with various chronic conditions (tinnitus, fibromyalgia, pain, rheumatoid arthritis, cardiovascular disease, and diabetes). Their meta-analysis showed that iCBT resulted in significant improvements in anxiety and depression scores, with small to medium ES. It seems likely that reduction of the distress caused by tinnitus resulting from participation in the iCBT(T) program led to the observed reductions in anxiety and depression.

There was a non-significant trend for participants whose tinnitus started one month or less before commencing the iCBT(T) program to show greater improvements in their 4C and SAD-T scores than participants whose tinnitus started six months or more before commencing. This may partly reflect spontaneous recovery from tinnitus among those with a recent onset of tinnitus. Future studies should explore the effectiveness of the iCBT(T) program among participants with different durations of tinnitus, using a larger sample of participants.

The improvement in SAD-T score was on average 2.5 points larger (95% CI: 0.3 to 4.6) for the sixteen participants with tinnitus alone than for the twelve who had tinnitus combined with hyperacusis, and this difference was significant. It is possible that the smaller improvement for the participants who had tinnitus combined with hyperacusis was a consequence of the fact that the iCBT(T) program was specifically targeted at helping the participant to deal with their tinnitus. It is likely that the iCBT(T) program did not markedly reduce the distress caused by hyperacusis and/or misophonia, and hence was less effective in producing overall reductions in anxiety and depression. Another explanation is that we relied on the single questions that were used in the iCBT(T) assessment module to detect hyperacusis and misophonia. Although other researchers have also used single questions to diagnose hyperacusis and misophonia (10, 46), this is not ideal. To address this limitation, future studies should use validated measures to further explore the presence and severity of hyperacusis and misophonia and their relationships with treatment outcome.

The improvement in scores for the 4C and SAD-T questionnaires produced by participating in the iCBT(T) program was not significantly related to the gender or age of the participants. Similarly, ratings of the effectiveness of the iCBT(T) program obtained using the CBT-EQ questionnaire were not significantly related to gender or age. These outcomes suggest that the

iCBT(T) program seem to be equally effective for men and women and is effective regardless of age over the range 18-75 years.

CBT-EQ total scores were significantly correlated with post-treatment 4C scores ($r = 0.66$, $p = 0.0001$) and post-treatment SAD-T scores ($r = -0.43$, $p = 0.02$). In other words, the better the final outcome as measured by the 4C and SAD-T questionnaires, the higher were the ratings of effectiveness of the iCBT(T) program. This supports the convergent validity of the CBT-EQ questionnaire. The modules of the iCBT(T) program that were judged as most effective were “general learning about CBT for tinnitus” and “learning how to challenge negative thoughts”, both of which received median scores of 7/10. The module judged least effective was the assessment module, which received a median score of 5.5/10. This is not surprising since the assessment module is not primarily about therapy, although it is intended to allow participants to see that they have made progress.

Several of the persuasive system design principles were used in the development of the iCBT(T) program, as shown in Table 2. McCall, Hadjistavropoulos (47) reviewed 46 RCTs that used unguided iCBT for treatment of anxiety and depression symptoms. On average, the iCBT programs utilized about five of the persuasive design principles (the range was from 1 to 13). The meta-analysis showed that use of a greater number of persuasive design principles was associated with greater efficacy of iCBT for depression. Future studies should evaluate if inclusion of more of the persuasive design principles will improve the efficacy of iCBT(T).

The most frequent cause of tinnitus reported by the patients was stress. This may reflect the common observation that the distress caused by tinnitus becomes worse in stressful situations (48). It seems unlikely that tinnitus is directly caused by stress, but it may be the case that some participants first became aware of their tinnitus when they were in a stressful situation or were first bothered by their tinnitus when they were stressed.

Conclusions

This study had a small sample size, no control group, and the data collection was retrospective and hence limited to what was collected as an integral part of the iCBT(T) program. Therefore, the results need to be considered as exploratory and interpreted with caution. The results showed that the iCBT(T) program was moderately effective in improving the ability to manage tinnitus as measured via the 4C questionnaire and in decreasing symptoms of anxiety and depression as measured via the SAD-T. The ES reported here for

the iCBT(T) program are comparable to those found in controlled trials of various forms of iCBT in the management of mental illness and chronic conditions.

From the participant's perspective the modules of the iCBT(T) program that were judged as most effective, as measured via the CBT-EQ questionnaire, were "general learning about CBT for tinnitus" and "learning how to challenge negative thoughts", both of which received median scores of 7/10 (0 is "Not effective at all" and 10 is "Very effective").

Data Availability

The raw data will be made available on reasonable request to the corresponding author.

Conflict of Interest

HA is the developer and owner of the iCBT(T) program. No conflicting interests are declared for the other authors.

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Figure 1. Flowchart illustrating the structure of the iCBT(T) program. The program comprises assessment and therapy modules. The program automatically develops email reports for users at different stages of the treatment. The typical structure of the therapy modules is shown under “iCBT Modules”. The two assessment modules are shown in boxes with gray coloring.

Table 1. Summary of the interventions provided in each iCBT(T) module.

Modules	Description
Assessment	<p>The assessment module comprised a list of questions about tinnitus, ear and hearing problems, and two short questionnaires: the 4C tinnitus management and the screening for anxiety and depression in tinnitus (SAD-T).</p> <p>After completing the assessment module, a report is developed automatically and sent to the email address that the participant provided. The report contains recommendations for further medical evaluations and/or psychological support (if indicated based on their answers to the questions). The criteria used to generate a recommendation for seeking medical help are described below. A recommendation to seek help from mental health professionals is generated when the SAD-T score is ≥ 4, indicating symptoms of anxiety and/or depression.</p> <p>The questions in the assessment module are listed below:</p> <p>Demographic questions</p> <p>Age and gender</p> <p>Tinnitus questions</p> <p>1- When did your tinnitus start?</p> <p><i>For this question, if the answer is less than 6 months, then the following recommendation is included in the report:</i></p> <p><i>“Given the relatively recent onset of your tinnitus, if you have not seen an Ear, Nose and Throat (ENT) specialist recently then we would recommend you to arrange an appointment with them in order to discuss the underlying cause(s) of your tinnitus.”</i></p> <p>2- What do you think caused your tinnitus?</p> <p>3- What does your tinnitus sound like?</p> <p><i>If the answer is clicks, pulsing, or heartbeat, then the following recommendation is included in the report:</i></p> <p><i>“Tinnitus that sounds like clicks, pulsing, or heartbeat may be related to problems associated with the muscles or blood vessels in the head and neck. If you have not seen an Ear, Nose and Throat (ENT) specialist recently then we recommend you to arrange an appointment with them in order to discuss the underlying cause(s) of your tinnitus.”</i></p> <p>4- Where is your tinnitus perceived?</p> <p><i>If the answer is in one ear only then the following recommendation is included in the report:</i></p> <p><i>“Tinnitus which is only perceived in one ear may be associated with some disorders of the auditory system. If you have not seen an Ear, Nose and Throat (ENT) specialist recently then we recommend you to arrange an appointment with them in order to discuss the underlying cause(s) of your tinnitus.”</i></p> <p>Ear and hearing questions</p> <p>5- Do you suffer from ear pain?</p> <p>6- Do you have any ear discharge?</p> <p>7- Do you have any balance problems?</p> <p>8- Do you feel that you have any hearing difficulties?</p> <p><i>If the answer to any of the above questions is “yes” then the following recommendation is included in the report:</i></p> <p><i>“If you have not seen an Ear, Nose and Throat (ENT) specialist recently then we recommend you to arrange an appointment with them in order to discuss your *the item(s) chosen from the above list*.”</i></p> <p>9- Do you have any medical conditions that might be relevant to your tinnitus?</p> <p><i>If the answer is “yes” then the following recommendation is included in the report:</i></p> <p><i>“If you have not seen a medical doctor about this relevant medical history then we recommend you to do so.”</i></p> <p>10- Do you have hyperacusis?</p> <p><i>Hyperacusis is intolerance of certain everyday sounds. The sounds may be</i></p>

	<p><i>perceived as uncomfortably loud, painful, frightening or annoying.</i></p> <p>11- Do you have misophonia?</p> <p><i>Misophonia is a strong emotional reaction to certain sounds, such as sounds created by chewing food, swallowing, tapping, breathing, lip smacking, nose sniffing, and other man-made noises.</i></p>
Introduction to CBT for tinnitus	<p>In this module, patients learn about CBT and its relevance to tinnitus distress.</p> <p>Objectives</p> <p>By the end of this session, the participant should be able to:</p> <ul style="list-style-type: none"> • Describe what tinnitus is. • Describe CBT and its relevance to tinnitus distress. • Apply a simple CBT model to tinnitus distress. • Differentiate between events, thoughts and emotions. • Create a CBT model explaining their own experience of tinnitus distress and describe how this model can be used in guiding their tinnitus management.
Behavioral experiment for tinnitus	<p>This module provides an opportunity to explore and challenge tinnitus-related negative thoughts by testing out different behaviours and how they influence any anxiety and negative emotions. This module has two sections. When section one has been completed, an email is sent to the participant with a link to section two.</p> <p>Objectives</p> <p>By the end of this session, participants should be able to:</p> <ul style="list-style-type: none"> • Describe what a behavioural experiment is. • Explore their irrational thoughts and predictions about tinnitus and its impact on them. • Analyse the link between automatic thoughts and emotions. • Differentiate between literal facts and thoughts. • Design a behavioural experiment to test the validity of their tinnitus-related thoughts. • Challenge their unhelpful thoughts. • Create some counter-statements (more helpful and rational thoughts). • Use the counter-statements in real life scenarios.
Challenge your negative thoughts	<p>In this module participants learn about common forms of cognitive distortions and develop the skills to identify errors of judgment in their own tinnitus-related thoughts.</p> <p>Objectives</p> <p>By the end of this module, participants should be able to:</p> <ul style="list-style-type: none"> • Describe the relationship between tinnitus, anxiety and negative thoughts. • Differentiate the levels of thoughts: automatic thoughts, rules of life and core beliefs. • Explain the mechanism by which tinnitus perception can lead to distress based on the level of thoughts. • List the 10 common forms of cognitive distortion. • Differentiate different forms of cognitive distortion. • Identify errors of judgment in their own tinnitus-related thoughts.
Diary of thoughts and feelings	<p>This module provides a tool for combining the different techniques that have been learned in the previous modules so as to identify and challenge negative automatic thoughts.</p> <p>Objectives</p> <p>By the end of this module, participants should be able to</p> <ul style="list-style-type: none"> • Identify tinnitus-related distress in their day-to-day life. • Distinguish between tinnitus-related distress and the distress caused by other underlying psycho-social and medical factors. • Explore and record what goes through their mind when they are bothered by their tinnitus. • Identify their thought distortions. • Identify and record their emotional reactions to tinnitus-related thoughts. • Develop a wide range of counter-statements that can substitute for tinnitus-related negative thoughts.
Positive psychology in	<p>The idea of this module is to use the power of positive psychology in generating</p>

tinnitus management	<p>realistic optimism, which is important for improving mental health.</p> <p>Objectives</p> <p>By the end of this module, participants should be able to</p> <ul style="list-style-type: none"> • Describe how acceptance can help them in managing their tinnitus. • List common human character strengths and virtues. • Identify their own character strengths and discuss how they can help them in accepting of tinnitus. • Use their character strengths in generating optimism and resilience.
Final assessment	<p>The final assessment module helps to (1) establish the progress each participant has made in tinnitus management, and (2) enhance their confidence and motivation in using CBT skills for tinnitus management.</p> <p>The SAD-T and 4C tinnitus management questionnaires are administered again in this module.</p> <p>Participants also complete a questionnaire exploring their views about the effectiveness of the iCBT(T) program.</p>

Table 2. Recommendations of the persuasive systems design framework (15 categories) used in the iCBT(T) program.

Categories	Description	How these are met in iCBT(T)
Reduction	A system that reduces complex behavior into simple tasks helps users perform the target behavior, and it may increase the benefit/cost ratio of a behavior.	Each module introduces one task. For example, developing a dairy for tinnitus-related thoughts or performing a behavioral experiment.
Tunneling	Using the system to guide users through a process or experience provides opportunities to persuade along the way.	Each module has an introductory video that guides the participant on what to do.
Personalization	A system that offers personalized content or services has a greater capability for persuasion.	The program takes into consideration the participant's answers to the questions. For example, the 4C module ask questions about the reasons for the choices and what can help them to make an improvement.
Self-monitoring	A system that keeps track of one's own performance or status supports the user in achieving goals.	Participants can monitor their progress by comparing the assessment and treatment progress reports.
Rehearsal	A system providing means with which to rehearse a behavior can enable people to change their attitudes or behavior in the real world.	The behavioral experiment module helps the participant to test the results of a change in a particular behavior.
Praise	By offering praise, a system can make users more open to persuasion.	The program acknowledges the correct answers in quizzes.
Reminders	If a system reminds users of their target behavior, the users will more likely achieve their goals.	After completing each module, a reminder is sent to the participant with a summary of the tasks that they need to complete before moving on to the next module.
Suggestion	Systems offering fitting suggestions will have greater persuasive powers.	The program gives examples and suggestions about how to analyze and modify tinnitus-related thoughts and behaviors.
Liking	A system that is visually attractive for its users is likely to be more persuasive.	Most pages in the program have images that are matched with the text.
Trustworthiness	A system that is viewed as trustworthy will have increased powers of persuasion.	The program is designed by a trusted source.
Expertise	A system that is viewed as incorporating expertise will have increased powers of	The program is designed by experts in tinnitus field.

Surface credibility	persuasion. People make initial assessments of the system credibility based on a firsthand inspection.	The program is designed based on audiologist-delivered CBT for tinnitus, which has been tested in several research studies and used for treating thousands of tinnitus participants in the UK and elsewhere in the world.
Real-world feel	A system that highlights people or organization behind its content or services will have more credibility.	The creator and collaborators of the program are introduced at the beginning of each module.
Authority	A system that leverages roles of authority will have enhanced powers of persuasion.	The program is designed by experts in tinnitus field.
Recognition	By offering public recognition for an individual or group, a system can increase the likelihood that a person/group will adopt a target behavior.	The program issues a certificate of completion after each module.

Table 3. Means (SDs) of scores for the 4C tinnitus management questionnaire and screening for anxiety and depression in tinnitus (SAD-T) before and after undertaking the iCBT(T) program. The *p* values and corrected effect sizes (ES) are also reported.

Questionnaire	Pre-treatment	Post-treatment	<i>p</i> value	Corrected ES
	Mean (SD)	Mean (SD)		
4C	24.4 (25)	41.0 (31.5)	0.004	-0.6
SAD-T	4.8 (3.9)	3.0 (3.5)	0.003	0.62

