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Effectiveness of Guided Internet-Based Cognitive Behavioral Therapy vs Face-to-Face Clinical Care for Treatment of Tinnitus

A Randomized Clinical Trial

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IMPORTANCE Accessible clinical care is not always available to individuals with distressing tinnitus. Internet-based cognitive behavioral therapy has the potential to increase access to evidence-based services that manage tinnitus. Research comparing the effectiveness of this internet-based intervention with face-to-face care is required.

OBJECTIVE To evaluate whether an internet-based cognitive behavioral therapy intervention is at least as effective as established individualized face-to-face clinical care in reducing tinnitus distress and tinnitus-related difficulties.

DESIGN, SETTING, AND PARTICIPANTS A randomized, multicenter, 2-arm parallel group, noninferiority trial with 2-month follow-up was performed between October 4, 2016, and July 14, 2017. Invited to participate were 374 adults based in the United Kingdom who had been referred to their local tinnitus clinics because of bothersome tinnitus. The experimental group received the internet-based intervention online, and the active control group underwent the usual face-to-face tinnitus care at 1 of 3 UK-based National Health Service hospitals. Participants were randomly assigned (1:1) to either intervention using variable permuted block sizes of 4 and 6. Of 92 participants who were randomized (46 each in the experimental and control groups), 88 participants completed the assessment immediately after intervention and 74 participants completed the follow-up assessment.

INTERVENTIONS Participants were randomized to receive either 8 weeks of guided internet-based cognitive behavioral therapy or a mean of 2 to 3 individualized face-to-face appointments in a tinnitus clinic.

MAIN OUTCOMES AND MEASURES The primary outcome was a change in tinnitus distress (assessed by the Tinnitus Functional Index). Secondary assessment measures were included for insomnia, anxiety, depression, hearing disability, hyperacusis, cognitive failures, and satisfaction with life.

RESULTS Of 92 patients overall, 55 (60%) were men with a mean (SD) age of 52.96 (12.07) years and mean (SD) tinnitus duration of 6.54 (9.25) years. The between-group difference in the Tinnitus Functional Index scores after intervention were 5.18 (95% CI, −4.17 to 14.53) at the initial assessment and 5.52 (95% CI, −4.60 to 15.61) at follow-up; both differences were within the noninferiority margin of 13 points for the lower 95% CI. For the secondary outcomes, only outcomes for insomnia fell outside the noninferiority margin, both after intervention and at follow-up, favoring internet-based cognitive behavioral therapy.

CONCLUSIONS AND RELEVANCE This is the first trial, to our knowledge, to compare an internet-based intervention with standard individualized face-to-face care for tinnitus. It revealed that both interventions are equally effective for reducing tinnitus distress and most tinnitus-related difficulties.

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Supplemental content

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Tinnitus, described as the conscious perception of unwanted sounds in the absence of a corresponding external acoustic stimulus,[1] is a prevalent complaint and one of the most distressing audiologic symptoms.[2] Because no cure has been identified, managing tinnitus remains challenging and costly. The estimated health care cost of tinnitus is $660 per patient per year in the United States,[3] with an annual health care cost of £750 million (US $965 million) and resulting societal cost of £2.7 billion (US $3.5 billion) per year in the United Kingdom.[4] Tinnitus clinics are not always readily accessible because of service and geographic constraints.[5,6] Moreover, although various tinnitus management approaches exist, evidence for their efficacy is scarce.[7] To date, cognitive behavioral therapy (CBT), has the most evidence of efficacy in reducing tinnitus distress.[8] Despite positive outcomes, there is limited accessibility to CBT for tinnitus, largely because of a shortage of suitably trained clinicians.[5] To improve access to evidence-based tinnitus care, an internet-based cognitive behavioral therapy intervention (iCBT) for tinnitus was pioneered in Sweden.[9] An iCBT intervention aimed at a UK population was adapted[10] from previous versions of the Swedish program. Both feasibility[11] and efficacy[12] of the UK version of iCBT have been indicated. It is, however, not known how outcomes for tinnitus using iCBT compare with those of the individualized face-to-face (F2F) care that is typically provided in the United Kingdom. Previous study comparisons with iCBT used group-based CBT (GCBT) as the active control group.[13-15]

The primary aim of this study was to evaluate whether iCBT for managing tinnitus is at least as effective as established F2F care in reducing tinnitus severity. The secondary objective was to compare the effects of these interventions for tinnitus-related difficulties, such as insomnia, depression, and anxiety. An additional objective was to assess the stability of the results 2 months after undertaking the intervention. The study hypothesis was that iCBT is not inferior to F2F care for managing tinnitus.

Key Points

Question Is undertaking an internet-based cognitive behavioral therapy program as effective as undergoing individualized face-to-face clinical care in reducing distress from tinnitus?

Findings In this randomized, multicenter, noninferiority clinical trial of 92 adults, internet-based cognitive behavioral therapy for tinnitus led to outcomes similar to those of individualized face-to-face clinical care for tinnitus.

Meaning Internet-based cognitive behavioral therapy has shown potential as an evidence-based intervention that could increase access to managing tinnitus care.

Methods

Trial Design and Participants

A randomized, multicenter, 2-arm parallel group, noninferiority trial with a sequential adaptive design and 2-month follow-up was performed between October 4, 2016, and July 14, 2017, to compare the clinical effectiveness of iCBT with the usual F2F tinnitus care. The recruitment and treatment sites for the control group were 3 hospitals in eastern England: Norfolk and Norwich University Hospitals National Health Service Foundation Trust (Norwich), Milton Keynes University Hospital National Health Service Foundation Trust (Milton Keynes), and Hinchingbrooke Health Care National Health Service Trust (Huntingdon). Eligibility criteria included age of 18 years or older, regular computer and internet access, no report of any major medical or psychiatric disorder, and not undergoing any tinnitus treatment. Participants were examined clinically (hearing test, ear examination, and case history of symptoms) and had been referred to the local tinnitus clinic by an audiologist and/or an ear, nose, and throat specialist. Because this was an effectiveness trial, the study was not advertised. Nurses and ear, nose, and throat specialists shared details of the study with patients who met the inclusion criteria. Ethical approval was granted by the East of England-Cambridge South Research Ethics Committee and Health Research Authority. Individuals who wanted to participate provided informed consent online. The study protocol is detailed in the Supplement; no changes were made to the protocol after the trial commenced.

Interventions

The guided iCBT and F2F intervention groups received information about managing tinnitus from an audiology professional. Participants were provided with hearing aids or combination devices regardless of group allocation.

Guided iCBT Intervention

The iCBT intervention content was based on a CBT self-help program originally developed in the Swedish language[9] and adapted into an 8-week, interactive e-learning version consisting of 16 recommended modules and 5 optional modules for a UK population.[10,16] To monitor progress and provide feedback on completed worksheets, a minimum of 10 minutes of asynchronous audiologist guidance using an encrypted 2-way messaging system was provided.

F2F Intervention

The F2F group received tinnitus information counseling which was generally used for the management of tinnitus in the United Kingdom. The initial appointment (60 minutes) was used to provide explanations about tinnitus and some basic management strategies. Patients received additional strategies for tinnitus management, including sleep hygiene, relaxation strategies, and negative thought analysis, during follow-up appointments.

Randomization and Masking

Participants were randomly assigned (1:1) by an independent researcher to either treatment arm using a randomization sequence generated by computer algorithm and variable randomly permuted block sizes of 4 and 6. To prevent a delay in providing the interventions, an adaptive design was used to sequentially allocate groups of participants as they were recruited. Participants were stratified using the Tinnitus Func-

tional Index (TFI) for tinnitus severity (score, ≤50, indicating lower severity, or >50, indicating greater severity).[17] A masked design in this context was not feasible. Allocation to the treatment arms was known to the participants and the clinicians. To minimize bias, the data analysis was masked in terms of group allocation.

Outcomes

Data were collected online at baseline (T_0), immediately after undertaking the (T_1), and at 2-month follow-up (T_2). A demographic questionnaire was used to establish health-related and tinnitus-specific information.

Primary Assessment Measure

The primary outcome was a change in tinnitus distress between the groups. The TFI[17] was selected to measure tinnitus distress because of its validation for assessing intervention responsiveness. In addition, the Tinnitus Handicap Index[18] was administered for comparison because this is the most common tinnitus assessment measure used within clinics globally.[19] Both questionnaires consist of 25 items, scored on a scale of 0 to 100, with the lower scores indicating less distress.

Secondary Assessment Measures

The following secondary measures were incorporated to assess commonly reported tinnitus-related difficulties: (1) the Insomnia Severity Index[20] assessed the presence of insomnia; (2) the Generalized Anxiety Disorder-7[21] assessed symptoms of generalized anxiety disorder; (3) the Patient Health Questionnaire-9[22] indicated symptoms of depression; (4) the Hearing Handicap Inventory for Adults-Screening version[23] assessed difficulty in hearing; (5) the Hyperacusis Questionnaire[24] assessed the presence of reduced tolerance to everyday sounds; (6) the Cognitive Failures Questionnaire[25] assessed cognitive functions; and (7) the Satisfaction with Life Scales[26] assessed life satisfaction. In addition, participants were monitored weekly using the Tinnitus Handicap Inventory-Screening version.[27]

Statistical Analysis

The CONSORT guidelines for noninferiority randomized clinical trials were followed.[28] Statistical analyses were performed using SPSS, version 23.0 (SPSS Inc).

Sample Size

Sample size calculations were performed using the SampSize app[29] for noninferiority parallel groups. Power was 90%; α was 0.025; and the estimated SD was 17 points, as indicated by the preceding efficacy trial.[12] The noninferiority margin was set to 13 points, as indicated during the validation of the TFI[17] to be a clinically significant change in scores. Thus, 39 participants were required for each arm. Each intervention arm was assigned 46 participants to allow for possible dropouts, which were estimated to be between 10% to 20% by the previous effectiveness trials.[30,31]

Group Comparisons

Both intention-to-treat and per-protocol results were analyzed. Participants were categorized as per protocol if they completed the assessment measures after intervention at the time under investigation (T_1 or T_2). Because there were no differences in the results, the per-protocol results were reported, in accordance with current guidelines for noninferiority trials.[28]

Compared with F2F care for tinnitus distress, noninferiority of iCBT was established if the lower limit of the 2-sided, 95% CI for the mean TFI difference between these 2 interventions was smaller than the noninferiority margin of 13 points. For the secondary assessment measures, noninferiority was established if a marginal between-group effect size of Cohen d < 0.20 was found.

Mixed 2 × 3 analyses of variance were carried out for repeated measures with the between-subject factor of group (iCBT and F2F) and within-subject factor of time (T_0, T_1, and T_2) for each assessment measure. A Greenhouse-Geisser correction for nonsphericity was applied. For significant group by time interactions, the main effects were followed up by Bonferroni-corrected post hoc testing. Effect sizes after intervention and follow-up were calculated, with Cohen d = 0.20-0.49 representing small effect sizes; Cohen d = 0.5-0.79, medium effect sizes; and Cohen d 0.80, large effect sizes.[32] A subanalysis was performed by comparing effect sizes in each group with and without amplification to determine the effect of amplification.

The Reliable Change Index[33] was used to determine clinical significance. The criteria were calculated to be a 21-point difference score, using the means (SDs) at baseline, means after intervention, and the test-retest reliability coefficient of 0.8 for the TFI.[17]

Monitoring Intervention Effects Between T_0 and T_1

A mixed 2 × 8 analysis of variance for repeated measures was used to compare the weekly Tinnitus Handicap Inventory-Screening scores with the within-subject factor of time (weeks 1-8) and between-subject factor of each group (iCBT and F2F). The main effects were followed up by Bonferroni-corrected post hoc testing.

Results

Participant Characteristics and Attrition

Among 374 adults who had been referred to their local tinnitus clinics because of bothersome tinnitus, the baseline assessment measures were completed by 92 participants who met the eligibility criteria (**Figure 1**). Of the 92 patients, 55 (60%) were men with a mean (SD) age of 52.96 (12.07) years and mean (SD) tinnitus duration of 6.54 (9.25) years. Hearing aids were fitted before or during the trial to 38 of 92 participants (41%), with 19 participants from each group. The groups were well matched; there were no clinically meaningful imbalances between the groups at baseline (**Table 1** and **Table 2**). No participants withdrew participation during the study, and no adverse events were reported. Assessment measures were completed by 88 of 92 participants (96%) at T_1, and by 74 of 92 participants (80%) at T_2, with no group differences.

Effectiveness of iCBT vs F2F for Tinnitus Distress

The within-group effect sizes of the iCBT and F2F groups for both tinnitus assessment measures (TFI and Tinnitus Handicap Index) were large at T_1 and T_2 (Table 2).

For the iCBT group, the mean (SD) TFI scores at T_1 were 27.13 (21.21) points lower than baseline. The mean (SD) TFI scores at T_2 were 32.16 (20.45) points lower than baseline.

For the F2F group, the mean (SD) TFI scores at T_1 were 21.69 (22.86) points lower and, at T_2, were 24.06 (21.98) points lower compared with baseline.

The magnitude of the between-group difference was 5.18 points (95% CI, -4.17 to 14.53) at T_1 and 5.52 points at T_2 (95% CI, -4.60 to 15.61), favoring the iCBT group. The between-group difference (T_0-T_1 and T_0-T_2) in TFI scores fell within the noninferiority margin of 13 points for the lower 95% CI of both per-protocol and intention-to-treat analyses. Similar results were obtained for the Tinnitus Handicap Index (**Figure 2**).

There were no significant differences in the range of difference scores before and after intervention between the 2 groups ($F_{1,9}$ = 0.008, P = .93). A clinically significant improvement was achieved by 25 of 44 participants (57%) in the iCBT group and 18 of 44 (41%) in the F2F group at T_1 and by 20 of 37 (54%) in the iCBT group and 17 of 37 (46%) in the F2F group at T_2. At T_1, 23 of 44 (52%) from the iCBT group and 15 of 44 (34%) from the F2F group had a clinically significant improvement and TFI scores below the level of requiring intervention (score <25). There were no significant differences in tinnitus distress after intervention when comparing only those using or not using hearing aids ($F_{2,57}$ = 1.20, P = .23).

Monitoring Intervention Effects Between T_0 and T_1

The iCBT group had greater weekly reductions in tinnitus distress (**Figure 3**), as evidenced by the significant between-group effects (time by group interaction: $F_{7,524}$ = 2.80, P = .04) and effect size (Cohen d = 0.57). Follow-up analysis indicated that tinnitus distress was significantly lower in the iCBT group from weeks 4 to 8, compared with the F2F group.

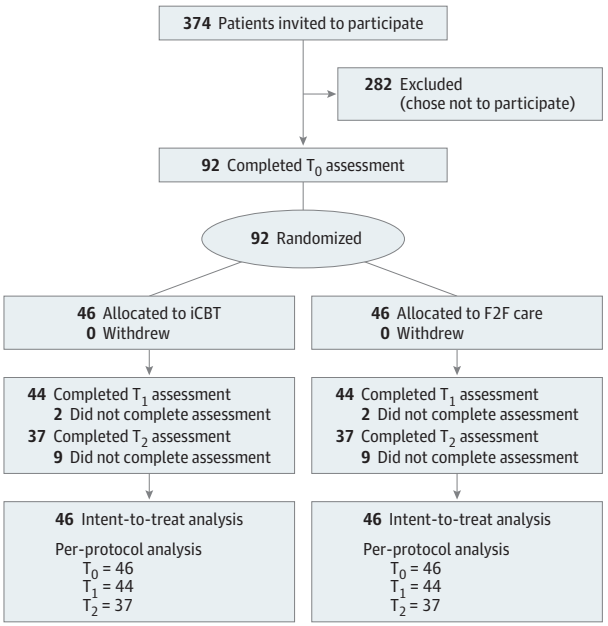
Effectiveness of iCBT vs F2F for Tinnitus-Related Difficulties

The Cohen d within-group effect sizes (Table 2) for the Insomnia Severity Index were medium to large for both groups. They were medium for the General Anxiety Disorder-7 and Patient Health Questionnaire-9 (except at T_2 for the iCBT group, where a large difference occurred). They were small for the other assessment measures. The T_1 between-group effect sizes for the secondary assessment measures were within the noninferiority margin (Cohen d 0.20) for anxiety, depression, hearing disability, hyperacusis, and life satisfaction (Table 2). They were outside this margin, favoring the iCBT group for insomnia and cognitive failures. At T_2 between-group effect sizes were outside this margin for insomnia, hearing handicap, and depression, again favoring the iCBT group.

Treatment Adherence and Clinician Resources

Participants in the F2F group received a mean (SD) of 2.28 (1.10) appointments (mean treatment duration of 137 minutes) with a maximum of 5 appointments. Seven individuals did not attend their appointment. Those in the iCBT group read a mean

Figure 1. CONSORT Study Profile



F2F indicates face-to-face intervention; iCBT, internet-based cognitive behavioral therapy; T_0, time before intervention; T_1, time after intervention; and T_2, time at 2-month follow-up.

Table 1. Participant Characteristics

Characteristic	Intervention		Overall (N = 92)
	iCBT (n = 46)	F2F (n = 46)	
Sex, No. (%)			
Male	29 (63)	26 (57)	55 (60)
Female	17 (37)	20 (43)	37 (40)
Age, mean (SD) [range], y	50.65 (12.19) [26-79]	55.26 (11.62) [29-76]	52.96 (12.07) [26-79]
Tinnitus duration, mean (SD) [range], y	5.23 (9.01) [0.4-40]	7.85 (9.62) [0.4-50]	6.54 (9.25) [0.4-50]
Hearing aids, No. (%)			
Not using	27 (59)	27 (59)	54 (59)
Using	19 (41)	19 (41)	38 (41)

Abbreviations: F2F, face-to-face; iCBT, internet-based cognitive behavioral therapy.

Table 2. Group Comparisons Before and After Intervention and at 2-Month Follow-Up

Measure, Group	Intervention, Mean (SD)			Group Comparison, *P* Value[a]			Between-Group Effect Sizes[b]		Within-Group Effect Sizes	
	Before, T_0	After, T_1	2-mo Follow-up, T_2	Time by Group Interaction	Within-Group Time Effect	Between-Group Effect	T_1 Cohen *d* (95% CI)	T_2 Cohen *d* (95% CI)	T_0-T_1 Cohen *d* (95% CI)	T_0-T_2 Cohen *d* (95% CI)
TFI										
iCBT	55.01 (21.58)	27.88 (20.84)	22.85 (19.26)	.36	<.001[a]	.072	0.30 (-0.12 to 0.72)	0.45 (-0.01 to 0.91)	1.28 (0.81 to 1.72)	1.56 (1.06 to 2.04)
F2F	56.57 (20.61)	34.88 (24.91)	32.51 (23.28)						0.95 (0.51 to 1.38)	1.10 (0.63 to 1.56)
THI										
iCBT	44.57 (23.40)	22.33 (19.63)	17.78 (14.77)	.38	<.001[a]	.022[a]	0.32 (-0.11 to 0.73)	0.33 (-0.13 to 0.79)	1.08 (0.63 to 1.51)	1.28 (0.80 to 1.74)
F2F	47.13 (20.31)	28.74 (20.07)	27.11 (21.62)						0.96 (0.55 to 1.38)	1.05 (0.58 to 1.50)
ISI										
iCBT	11.43 (6.36)	6.71 (6.20)	5.69 (4.64)	.33	<.001[a]	.002[a]	0.46 (0.03 to 0.88)	0.74 (0.26 to 1.20)	0.75 (0.32 to 1.17)	1.01 (0.55 to 1.46)
F2F	13.65 (6.62)	9.55 (6.15)	10.03 (6.88)						0.65 (0.21 to 1.06)	0.54 (0.09 to 0.97)
GAD-7										
iCBT	6.43 (5.64)	3.45 (3.66)	3.33 (3.21)	.56	<.001[a]	.67	-0.06 (-0.36 to 0.48)	-0.03 (-0.49 to 0.42)	0.62 (0.20 to 1.04)	0.66 (0.21 to 1.09)
F2F	6.78 (5.54)	3.33 (3.78)	3.42 (3.60)						0.72 (0.29 to 1.14)	0.70 (0.25 to 1.14)
PHQ-9										
iCBT	6.50 (5.48)	3.67 (3.64)	2.78 (3.02)	.55	<.001[a]	.042	-0.03 (-0.42 to 0.49)	0.57 (0.10 to 1.03)	0.61 (0.18 to 1.02)	0.82 (0.36 to 1.26)
F2F	7.98 (6.05)	4.19 (4.08)	4.97 (4.54)						0.73 (0.30 to 1.15)	0.55 (0.11 to 0.99)
HHIA-S										
iCBT	11.74 (10.66)	10.10 (10.82)	9.11 (11.59)	.98	.006[a]	.23	-0.19 (-0.23 to 0.61)	0.27 (-0.19 to 0.73)	0.15 (-0.26 to 0.57)	0.24 (-0.20 to 0.67)
F2F	14.30 (11.58)	12.14 (10.71)	12.00 (9.56)						0.19 (-0.22 to 0.61)	0.21 (-0.22 to 0.65)
HQ										
iCBT	15.65 (9.06)	12.24 (7.61)	12.51 (9.01)	.94	<.001[a]	.68	0.16 (-0.26 to 0.57)	-0.05 (-0.40 to 0.51)	0.41 (-0.01 to 0.82)	0.35 (-0.09 to 0.78)
F2F	16.54 (7.42)	13.40 (7.29)	12.94 (7.51)						0.43 (0.01 to 0.84)	0.48 (0.04 to 0.92)
CFQ										
iCBT	34.93 (14.38)	30.83 (12.14)	30.06 (12.89)	.91	.009[a]	.32	0.29 (-0.23 to 0.61)	-0.18 (-0.28 to 0.64)	0.31 (-0.11 to 0.72)	0.35 (-0.08 to 0.79)
F2F	39.65 (19.31)	35.56 (19.23)	33.06 (19.24)						0.21 (-0.20 to 0.62)	0.34 (-0.10 to 0.77)
SWLS										
iCBT	18.70 (5.73)	20.10 (4.96)	21.00 (5.05)	.44	.04[a]	.61	0.01 (-0.41 to 0.43)	0.10 (-0.36 to 0.56)	0.26 (-0.16 to 0.67)	0.43 (0.00 to 0.84)
F2F	19.48 (5.54)	20.05 (5.61)	20.50 (4.95)						0.10 (-0.31 to 0.51)	0.19 (-0.24 to 0.62)

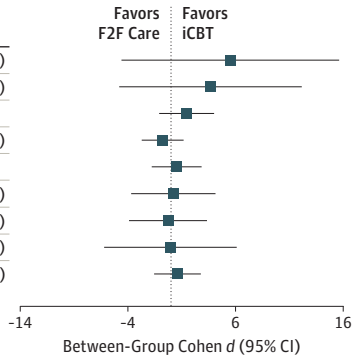
Abbreviations: CFQ, Cognitive Failures Questionnaire; F2F, face-to-face intervention; GAD-7, Generalized Anxiety Disorder-7; HHIA-S, Hearing Handicap Inventory for Adults-Screening version; HQ, Hyperacusis Questionnaire; iCBT, internet-based cognitive behavioral therapy intervention; ISI, Insomnia Severity Index; PHQ-9, Patient Health Questionnaire-9; SWLS, Satisfaction With Life Scales; TFI, Tinnitus Functional Index; THI, Tinnitus Handicap Index.

[a] Indicates statistical significance at $P < .05$.

[b] For the difference in scores between baseline and T1 or T2.

Figure 2. Mean Between-Group Difference in Scores Between Baseline and Follow-up for Each Assessment Measure

Assessment Measure	Between-Group Effect Size, Cohen *d* (95% CI)
Tinnitus Functional Index	0.45 (-0.01 to 0.91)
Tinnitus Handicap Inventory	0.33 (-0.13 to 0.79)
Insomnia Severity Index	0.74 (0.26 to 1.20)
Generalized Anxiety Disorder-7	-0.03 (-0.49 to 0.42)
Patient Health Questionnaire-9	0.57 (0.10 to 1.03)
Hearing Handicap Inventory for Adults-Screening	0.27 (-0.19 to 0.73)
Hyperacusis Questionnaire	-0.05 (-0.40 to 0.51)
Cognitive Failures Questionnaire	-0.18 (-0.28 to 0.64)
Satisfaction With Life Scales	0.10 (-0.36 to 0.56)



F2F indicates face-to-face intervention; iCBT, internet-based cognitive behavioral therapy intervention.

(SD) of 13 (8) modules of the 21 modules, and 17 of 46 participants (37%) completed all the modules. Users sent a mean (SD) of 7 (10) messages, and the audiologist sent a mean (SD) of 20 (11) messages per iCBT participant (corresponding to 64 minutes contact time per participant during the intervention period). When time spent was divided by the mean TFI score change (iCBT, 64/27.13 = 2.36; F2F, 137/21.69 = 6.32), iCBT was 2.68 times as time-effective as F2F when only taking the audiologist's time into account.

Discussion

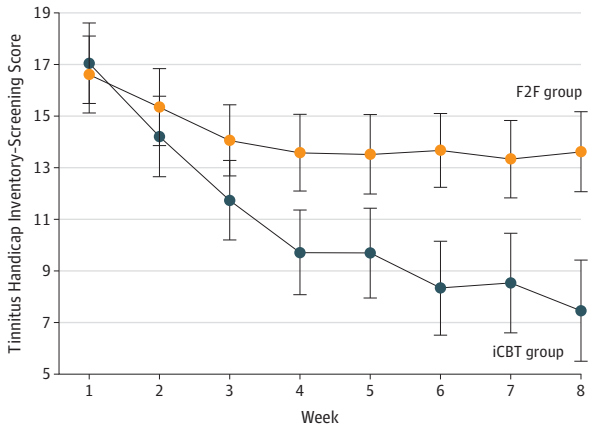
Effectiveness of iCBT vs F2F Care for Tinnitus

To our knowledge, this is the first randomized clinical trial to compare the effectiveness of iCBT for tinnitus with that of standard F2F clinical care in a clinical population. The results indicate that the interventions are equally effective and within the boundaries of noninferiority for reducing tinnitus distress. The present trial is unique because it compared iCBT with individualized F2F clinical care instead of GCBT, which was used in previous efficacy studies. Those previous studies found no significant group differences between iCBT and GCBT.[13,15]

During the monitoring of groups weekly for the first 8 weeks of the active treatment phase, tinnitus distress in the iCBT group was rated significantly lower than that of the F2F group from week 4 onward. This was possibly because of the differences in the intensive weekly input for the iCBT group compared with longer follow-up periods for the F2F group.

There were 2 previous nonrandomized iCBT studies for tinnitus effectiveness at the Uppsala Clinic in Sweden. The within-group effect sizes were smaller than those in the present study (Cohen *d* = 0.56[30] and Cohen *d* = 0.58).[31] In the present study, a clinically significant improvement was achieved by 57% at T_1 and 54% at T_2 for the iCBT group compared with 41% at T_1 and 46% at T_2 for the F2F group. This is higher than the 27%[13] and 38%[31] reaching clinical significance in some previous studies. Differences in the ways of calculating clinical significance (50% reduction in scores vs using Reliable Change Index criteria) may have contributed to these discrepancies.

Figure 3. Weekly Tinnitus Handicap Inventory–Screening Scores for Each Group Across the First 8-Week Intervention Period Before and After Intervention



Error bars represent the SE of the mean. F2F indicates face-to-face intervention; iCBT indicates internet cognitive behavioral therapy.

Secondary intervention effects for both groups were largest for insomnia, followed by anxiety and depression. The combined results after intervention and 2-month follow-up indicated that the interventions are equally effective within the boundaries of noninferiority for tinnitus-related difficulties except for insomnia, which favored the iCBT group. In a preceding efficacy study by Beukes et al,[12] intervention effects were also greatest for insomnia. This result is of interest because previous meta-analyses[8,34] and a Cochrane review,[35] which were largely based on F2F interventions, failed to show the effectiveness of CBT for sleep problems in a population of patients with tinnitus. In the previous iCBT nonrandomized effectiveness trials,[30,31] significant before and after intervention within-group differences for insomnia, anxiety, and depression were found. Further work is required to identify how interventions for tinnitus can improve the results for tinnitus-related problems.

Both groups indicated stability of results at 2-month follow-up for tinnitus distress and the secondary assessment

measures. Stability of results have been reported for longer follow-up periods of 6 months[15] and 1 year,[13] when comparing iCBT with GCBT for tinnitus distress. Further studies with longer follow-up periods are required to establish the long-term effects of these interventions.

Intervention Adherence and Clinician Resources

Completion rates of assessment measures (96% at T_1 and 80% at T_2) were equal in both groups regardless of allocation. No demographic or clinical differences were identified between participants who completed assessment measures and those who did not complete these measures in the present study. This finding differed from that of Kaldo et al,[31] who found that younger participants were more likely to drop out of the study. Studies with larger sample sizes are required to further investigate these effects.

When assessing the resources required, iCBT was 2.68 times more time-effective than individualized F2F care when taking only clinician time into account (assuming equality of grading by the audiology professionals involved). Kaldo et al[13] reported that, compared with iCBT, the therapist time was twice as long for the GCBT sessions. These sessions included 7 participants per group attending 120-minute group sessions. Therefore, in terms of staff time, iCBT was 1.7 times more time-effective compared with GCBT. In contrast, Jasper and colleagues[15] found no difference in therapist time because more participants (10 participants) were included in each GCBT group, with shorter 90-minute sessions, whereas there was more therapist time for the iCBT group, with a mean of 14 minutes per week.

The present study focused on clinical effectiveness. More work is required to determine cost-effectiveness because this information is required by stakeholders.[4,36] A lexicon of assessment and outcome measures for telemental health has been developed as a resource for the evaluation of these services.[37] Evaluation metrics include treatment utilization, travel costs, stigma, anxiety, waiting times, training, and motivational readiness. Future research can use these domains to standardize approaches, to determine cost-effectiveness, and to provide a more comprehensive comparison of services.

Limitations

This trial had many challenges, such as difficulty recruiting a sufficient number of participants. After possibly following a long pathway before being able to obtain audiology and ear, nose, and throat services, some patients may have wanted to continue this pathway and not participate in a research study. Implementing more effective recruitment strategies will be required for future effectiveness trials. The low ratio of people participating in the study in comparison with those who were invited was a potential source of bias. In addition, the nonuniform nature of the clinical care received from the various study centers may have contributed to the variability. Interpretation of the data are limited to participants with similar demographic and clinical profiles, and further generalizability of the results to other populations is not possible without further systematic replication in other settings. Moreover, some of the outcome measures selected may not have been optimal for a population with tinnitus. Although the General Anxiety Disorder-7 can identify generalized anxiety disorder, other anxiety symptoms more specific to a population with tinnitus may be missed.

Conclusions

This study revealed that iCBT and F2F interventions are equally effective for reducing tinnitus distress and most tinnitus-related difficulties. Although further work is required to differentiate which patients are best suited for iCBT or F2F interventions and whether including low-intensity interventions would be cost-effective and clinically effective, this study adds to the evidence of effectiveness of iCBT for management of tinnitus.

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