Long-term Efficacy of Audiologist-Guided Internet-Based Cognitive Behaviour Therapy for Tinnitus

Eldré W. Beukes,[1] Peter M. Allen,[1,2] David M. Baguley,[1,3,4] Vinaya Manchaiah [5,6,7] and Gerhard Andersson,[8,9]

1. Department of Vision and Hearing Sciences, Anglia Ruskin University, Cambridge, United Kingdom
2. Vision and Eye Research Unit, Anglia Ruskin University, Cambridge, United Kingdom
3. National Institute for Health Research, Nottingham Biomedical Research Centre, Ropewalk House, 113 The Ropewalk, Nottingham, United Kingdom
4. Otology and Hearing Group, Division of Clinical Neuroscience, School of Medicine, University of Nottingham, Nottingham, United Kingdom
5. Department of Speech and Hearing Sciences, Lamar University, Beaumont, Texas, USA
6. Audiology India, Mysore, Karnataka, India
7. Department of Speech and Hearing, School of Allied Health Sciences, Manipal University, Karnataka, India
8. Department of Behavioural Sciences and Learning, Linköping University, Linköping, Sweden
9. Department of Clinical Neuroscience, Division of Psychiatry, Karolinska Institute, Stockholm, Sweden

Address for correspondence:

Eldré W. Beukes, Department of Vision and Hearing Sciences, Faculty of Science and Technology, Anglia Ruskin University, Cambridge CB1 1PT, UK. E-mail: eldre.beukes@anglia.ac.uk; Telephone: +44 (0)1223-698847. Fax: +44 (0)1223 695056.

Keywords: Tinnitus, tinnitus intervention, Internet-intervention, cognitive behavioural therapy, long-term outcomes, unwanted effects

Conflicts of Interest and Source of Funding: Anglia Ruskin, Lamar and Linköping Universities and National Institute for Health Research, Nottingham, supported the undertaking of this study but the views expressed are those of the authors and not of these institutions. The research was conducted without external funding. No conflicts of interest are declared.

Abbreviations

CBT: Cognitive Behavioural Therapy

CFQ: Cognitive Failures Questionnaire

GAD-7: Generalized Anxiety Disorder

GP: General Practitioner

HHIA-S: Hearing Handicap Inventory for Adults - Screening

HQ: Hyperacusis Questionnaire

ITT: Intention-to-treat

NHS: National Health System

iCBT: Guided Internet-based Cognitive Behavioural Therapy Intervention

ISI: Insomnia Severity Index

PHQ-9: Patient Health Questionnaire

RCI: Reliable Change Index

SPSS: Statistical Package for Social Sciences

SWLS: Satisfaction with Life Scales

TFI: Tinnitus Functional Index

THI-S: Tinnitus Handicap Inventory - Screening

UK: United Kingdom

ABSTRACT

Purpose The purpose of this study was to investigate the long-term outcomes 1 year after undertaking an audiologist-guided Internet-based cognitive behavioural therapy (iCBT) intervention for tinnitus. Secondary aims were to identify any predictors of outcome and whether there were any unwanted events related to undertaking iCBT for tinnitus.

Method Participants who had previously undertaken a randomised iCBT efficacy trial for tinnitus were invited to participate. 104 participants, out of the 146 who were initially randomized for the efficacy trial, completed the 1-year post-intervention assessment measures.

The primary outcome was a change in tinnitus distress as assessed by the Tinnitus Functional Index. Secondary assessment measures were included for insomnia, anxiety, depression, hearing handicap, hyperacusis, cognitive failures and satisfaction with life. An intention-to-treat analysis using repeated measures analysis of variance and hierarchical multiple regression was used for statistical analysis. Unwanted effects were categorized according to the unwanted events checklist.

Results Undertaking iCBT for tinnitus led to significant improvements 1-year post-intervention for tinnitus and related difficulties e.g. insomnia, anxiety, depression, hearing handicap, hyperacusis and life satisfaction. The best predictors of improving tinnitus severity at 1-year post-intervention were greater baseline tinnitus severity scores, reading more of the modules and higher satisfaction with the intervention. Unwanted events were reported by 11% of participants and were more likely to be reported by females than by males. These events were related to worsening of symptoms, the emergence of new symptoms, negative wellbeing and prolongation of treatment.

Conclusions The clinical benefits of audiologist-guided iCBT for tinnitus and tinnitus-related difficulties were sustained 1 year post-intervention. Predictors of outcome indicated that the intervention is applicable to a wide range of participants regardless of their demographic backgrounds. Attempts should be made to minimise unwanted events in subsequent trials.

INTRODUCTION

Innovative ways of providing sustainable cost and clinically effective ways of managing chronic healthcare conditions are required (West, 2012). One such chronic condition is tinnitus, defined as the conscious perception of unwanted subjective auditory sensations in the absence of a related external stimulus (Baguley, McFerran, & Hall, 2013). It is one of the most distressing and debilitating audiological symptoms (Cima, Vlaeyen, Maes, Joore, & Anteunis, 2011). It is a prevalent complaint with 10–30% of the adult population reporting tinnitus across the globe, for example, Korea (Kim et al., 2015), New Zealand (Wu, Searchfield, Exeter, & Lee, 2015) Nigeria (Lasisi, Abiona, & Gureje, 2010), the UK (Davis & Rafaie, 2000; Dawes et al., 2014) and the United States of America (USA; (Bhatt, Lin, & Bhattacharyya, 2016; Shargorodsky, Curhan, & Farwell, 2010). As no cure has been identified to eliminate tinnitus, interventions are directed towards alleviating or managing the accompanying symptoms, making the tinnitus less intrusive or distressing (Langguth, Kreuzer, Kleinjung, & De Ridder, 2013). Although various management strategies have evolved, many lack empirical support (Martinez-Devesa, Perera, Theodoulou, & Waddell, 2010a). Psychological interventions, such as cognitive behavioural therapy (CBT), currently have the most evidence of efficacy in reducing tinnitus distress (Cima, Andersson, Schmidt, & Henry, 2014; Hesser, Weise, Westin, & Andersson, 2011; Martinez-Devesa, Perera, Theodoulou, & Waddell, 2010b). Despite the known efficacy of CBT in reducing tinnitus-related distress and the fact that it is one of the most researched tinnitus management interventions, it is rarely offered in clinical practice (Gander, Hoare, Collins, Smith, & Hall, 2011; Hall et al., 2011; Hoare, Broomhead, Stockdale, & Kennedy, 2015). This is largely due to the associated costs and a shortage of suitably trained psychologists and psychotherapists (Andersson, 2015; Hall et al., 2011; McFerran & Baguley, 2009). Tinnitus services are also not consistently available and are particularly sparse in remote geographical regions (Hoare

et al., 2015). In addition, they are costly. An economic evaluation of the healthcare cost of tinnitus management in the UK in 2017 indicated that the annual cost of tinnitus interventions was £750 million in total, or £717 per tinnitus patient (Stockdale et al., 2017). This is equivalent to 0.6% of the annual UK National healthcare spending. It is not only healthcare costs that need to be considered. The annual societal costs related to tinnitus were estimated to be £2.7 billion per year in the UK (Stockdale et al., 2017), although higher costs have been quoted, for example, €6.8 billion in the Netherlands (Maes et al., 2013). Moreover, the prevalence of tinnitus is predicted to increase due to factors such as an increase in life expectancy and recreational noise exposure, which is a known risk factor for developing tinnitus (Martinez, Wallenhorst, McFerran, & Hall, 2015). This will place further financial constraints on already pressurized healthcare systems (Smith, McKeon, Blunt, & Edwards, 2014). Innovative planning is required to meet these additional demands and address existing challenges faced with regards to the provision of tinnitus services.

Technological advances can assist innovations in healthcare. One example is the use of telehealth for patient diagnosis, treatment, and prevention of health-related conditions (Michie, Yardley, West, Patrick, & Greaves, 2017). They have the potential to improve access to care, reduce costs and improve the patient experience for numerous health-related conditions (Polisena, Coyle, Coyle, & McGill, 2009). Considering the difficulties accessing CBT for tinnitus together with the potential of telehealth, an Internet-delivered cognitive behavioural therapy (iCBT) intervention for tinnitus was developed (Andersson, Strömgren, Ström, & Lyttkens, 2002). The addition of iCBT for tinnitus distress could complement existing tinnitus pathways by providing a more cost-effective, evidence-based, accessible, comprehensive and standardized intervention. Efficacy of iCBT for tinnitus provided has been indicated (Hedges g = 0.60), largely evaluated in Sweden and Germany (Andersson, 2015). Outcomes have been

maintained up to one year after completing guided iCBT for tinnitus (Hesser et al., 2012; Kaldo et al., 2008; Weise, Kleinstauber, & Andersson, 2016).

Due to the limited provision of CBT for tinnitus within the UK, a comprehensive, user-friendly iCBT intervention tailored for a UK population was designed (Beukes et al., 2016). Better outcomes are reported for guided mental health interventions (Baumeister, Reichler, Munzinger, & Lin, 2014; Richards & Richardson, 2012). For Internet-based tinnitus interventions, the evidence for the benefit of guidance is inconclusive. A systematic review and meta-analysis on the efficacy of self-help interventions in tinnitus found that tinnitus distress and depressiveness were not influenced by the presence of therapists (Nyenhuis, Golm, & Kröner-Herwig, 2013). For the present study, a guided intervention was selected for this study to obtain further information regarding outcomes obtainable with such a guided intervention.

Guidance in previous iCBT for tinnitus studies was provided by clinical psychologists, due to their expertise in provision of CBT. As guidance from psychologists would not be feasible in a UK context where tinnitus is largely treated within the audiology community (McFerran & Baguley, 2009), an audiologist was selected to guide the intervention. Feasibility of audiology-guided iCBT in the UK was indicated (Beukes, Allen, Manchaiah, Baguley, & Andersson, 2017a), and efficacy was established when compared with weekly monitoring (Beukes, Manchaiah, Baguley, Allen, & Andersson, 2017; Beukes, Baguley, Allen, Manchaiah, & Andersson, 2017). Before such an intervention is accepted as credible further evaluation of its efficacy and effectiveness are required. The long-term outcomes of audiologist-guided iCBT are not known. Therefore,

investigating whether intervention effects are maintained 1-year post-intervention for audiologist-guided iCBT for a UK population is important. The results will hopefully influence future evidence-based management of tinnitus.

Moreover, to date, there are no established predictors of outcomes for guided iCBT interventions (Andersson, 2016). Continued searches for moderators and mediators of outcome should be undertaken as these may help to triage participants to the most appropriate intervention route. There is also the possibility of unwanted events from such an intervention. Unwanted events are defined as all events of negative quality occurring alongside interventions but not intended by the intervention (Linden, 2013). The incidence of these events does not imply a causal relationship between the intervention and do not necessarily influence intervention outcomes. Circumstances unrelated to treatment such as personal or vocational issues may contribute.

As information to date on iCBT for tinnitus has been primarily focused on examining effectiveness, little is known about the occurrence or characteristics of unwanted events in these trials. It is important to establish whether tinnitus may worsen in some participants or if participants encounter adverse events when undertaking such an Internet-based intervention in order to address these in future interventions (Boettcher, Rozental, Andersson, & Carlbring, 2014). Unwanted effects may include a deterioration instead of an improvement in outcome following undertaking an intervention. An individual patient data meta-analysis of 29 clinical trials of iCBT (n = 2866) indicated that 5.8% of participants in intervention groups and 17.4% of those in control conditions showed a deterioration in outcome following receiving iCBT (Rozental, Magnusson, Boettcher, Andersson, & Carlbring, 2017).

The purpose of this study was to investigate the long-term outcomes 1 year after undertaking an audiologist-guided iCBT intervention for tinnitus. The hypothesis was that the reduction of tinnitus distress and tinnitus-related difficulties established would be sustained 1 year post-intervention. Further aims were to identify any predictors of outcome, and to establish whether there were any unwanted events related to undertaking iCBT for tinnitus.

METHOD

Study Design

An efficacy randomized control trial with a delayed intervention group preceded this study investigating the long-term effects of this intervention. The iCBT experimental group received the iCBT intervention for 8 weeks (n = 73), while the weekly check-in group were monitored weekly (n = 73). This monitoring involved the weekly completing of 10 questions from the Tinnitus Handicap Inventory Screening version questionnaire online (Newman, Jacobson, & Spitzer, 1996).

Once the experimental group completed the intervention the control group underwent the same iCBT intervention. As both groups undertook the same intervention, a repeated-measures single group analysis was conducted for the present study.

This study was registered on the clinical trials database: NCT02370810 on 05/03/2015. To ensure best practice was followed the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) checklist (Des Jarlais, Lyles, Crepaz, & TREND Group, 2004) was used to

report this trial. For the full study protocol, see Beukes et al. (2015). There were no changes to the methods or assessment measures used after the trial commenced.

Ethical Considerations

The central electronic online data capturing system was held at Linköping University (Sweden) and complied with a high level of data security to safeguard confidentiality (Vlaescu et al. 2015). Ethical approval was granted by the Faculty Research Ethics Panel of Anglia Ruskin University (FST/FREP/14/478). The trial was conducted in accordance with good clinical practice together with the ethical principles of the Declaration of Helsinki.

Study Population

Sample size estimation for the original efficacy trial indicated that 58 participants were required for each group (1:1 allocation ratio), to achieve a clinically relevant change using the main outcome measure with a two-sided significance level of 0.05, effect size of 0.5 and 80% power (G*Power version 3.1.6; Faul et al. 2007). To account for possible dropouts, 73 participants were recruited to each group using a range of strategies such as newspaper and magazine articles, social media and tinnitus support forums and groups.

Participants, therefore, represent a research instead of a clinical tinnitus population. To undertake the intervention, participants had to meet the original eligibility criteria for the randomized control trial (Beukes, Manchaiah, Allen, Baguley, & Andersson, 2015) of being 18 years or older, living in the UK and having experienced tinnitus for a minimum of 3 months. Their tinnitus severity, assessed by the Tinnitus Functional Index (Meikle et al., 2012), had to indicate the need for intervention (score > 25), and no major mental or medical disorder could be present.

All participants assigned to either the experimental or the control group in the efficacy trial, except for those who withdrew during the study, were invited to partake in the present study (n = 139). All 146 of the original participants randomised were included in the IIT analysis.

Intervention

The study intervention was Internet-based to provide a standardized intervention that could be easily accessible. It was created on the Iterapi (https://www.iterapi.se/) purpose-built web-based platform (Vlaescu, Carlbring, Lunner, & Andersson, 2015; Vlaescu, Alasjö, Miloff, Carlbring, & Andersson, 2016). To access the intervention a link with instructions and login information was emailed to participants. Those that had not accessed the link were contacted to offer assistance. To ensure the intervention encouraged engagement (such as reading the materials and completing quizzes and worksheets), the design was visually stimulating and interactive (Beukes et al., 2016). Due to the efficacy of CBT for tinnitus (Hesser et al., 2011), CBT principles based on a self-help programme originally developed by Andersson and Kaldo (2004) were incorporated. There were 16 recommended modules and five optional modules which were delivered over 8 weeks. Each week two recommended modules were released. During weeks 2 to 6 an additional optional module was released. A message was sent to introduce the new modules on their release. If participants were unable to complete the modules they were able to request additional time before receiving the next set of modules.

. Recommended modules included CBT content such as applied relaxation, thought analysis, cognitive restructuring, imagery and exposure techniques. Optional modules were available to add an element of tailoring, and participants could choose whether or not to do these modules. They included strategies for insomnia, hearing difficulties, hyperacusis, concentration and the use of sound enrichment.

Intervention Guidance

Asynchronous audiologist-guidance using an encrypted two-way messaging system was provided during the intervention. Guidance included monitoring progress, providing feedback on worksheets completed, sending encouraging messages to those who have not accessed the intervention for a few days and answering queries participants had. A minimum of 10 minutes of guidance per week per participant was provided, with additional time given if required. There were no restrictions on the number of messages that participants could send to the audiologist. Some participants who were not engaged made limited use of the messaging system. The audiologist was trained to Masters Level in Audiology, was registered with the Health and Care Professions Council, and had experience in managing tinnitus patients together with a suitable understanding of CBT principles but no formal CBT training. Supervision was provided by a clinical psychologist who was specialised in providing tinnitus interventions.

Assessment Measures

Data collection was online throughout the trial. Assessment measures were integrated into the intervention platform and participants were sent a message when they were required to complete them. The assessment timeline was as follows: T_0: baseline; T_1: post-intervention assessment; T_2: follow-up assessment and T_3: at 1 year post-intervention follow-up (see Figure 1). The T_3 assessment measures were collected at different time

points for each group to ensure that 12 months had passed post-intervention for each group (initially taken for the experimental group and taken for the control group two months later). To minimise attrition, encouraging reminders were provided throughout for participants who had not completed questionnaires or worksheets on time. Three reminders were automatically and electronically sent on the three consecutive days following the release of the questionnaire. A further reminder was sent out 1 and 2 weeks later.

The following assessment measures were selected:

Demographical Information

A demographic questionnaire was used to obtain information related to gender, age, tinnitus duration, previous tinnitus treatments (such as audiological, complementary approaches, medical) and hearing aid use.

Primary Assessment Measure

The Tinnitus Functional Index (TFI; Meikle et al. 2012) was selected as the primary assessment measure to measure tinnitus distress due to its validation for assessing intervention responsiveness. The TFI has acceptable psychometric properties with an internal consistency of .80 and intra-class reliability of .91 for a UK research population (Fackrell, Hall, Barry, & Hoare, 2016). It is a 25-item questionnaire, scored on a scale of 0–100. Scores less than 25 indicate mild tinnitus, with no need for intervention, whereas scores ranging from 25–50 signify significant tinnitus and the possible need for intervention. A score of 50 or greater demonstrates more severe tinnitus and indicates the need for more intensive intervention.

A reduction in TFI scores shows improvement in tinnitus distress. Meikle et al. (2012) reported that meaningful changes occur when scores are reduced by 13 points or more whereas the smallest detectable change score of 22.4 is proposed by (Fackrell et al., 2016) for a UK research population.

Secondary Assessment Measures

To assess intervention effects on tinnitus-related difficulties the following secondary assessment measures were included:

i) The Insomnia Severity Index (ISI; Bastien et al. 2001) assessed the presence of insomnia, as sleep difficulties are prevalent amongst those with tinnitus (Crönlein et al. 2016). This 7 item questionnaire is scored between 0–28 and has an acceptable internal consistency of .74 (Bastien et al. 2001).

ii) The Generalised Anxiety Disorder-7 (GAD-7; Spitzer et al. 2006) quantified the level of anxiety, as the prevalence of anxiety is high in those with severe tinnitus (Pinto et al. 2014). This 7 item questionnaire is scored between 0-21 and has an internal consistency of .89 (Lowe et al. 2006).

iii) The Patient Health Questionnaire-9 (PHQ-9; Spitzer et al. 1999) indicated symptoms of depression, as depression amongst those with severe tinnitus is often reported (Pinto et al. 2014). Scoring is between 0–28 on this 9 item questionnaire with an internal consistency of .83 (Spitzer et al. 1999).

iv) The Hearing Handicap Inventory for Adults Screening version (HHIA-S; Newman et al. 1991) assessed difficulty hearing, which in this context may be related to the penetrating nature of tinnitus or the presence of hearing loss, commonly found in those with tinnitus

(Langguth et al. 2017). This measure consists of 10 items, scored between 0–40 with an internal consistency of .93 (Newman et al. 1991).

v) The Hyperacusis Questionnaire (HQ; Khalfa et al. 2002) was administered to assess the presence of reduced tolerance of everyday sounds, otherwise known as hyperacusis, as there is a large overlap in the prevalence of tinnitus and hyperacusis (Schecklmann et al. 2014). This 14-item questionnaire is scored between 0–42 and has an internal consistency of .88 (Fackrell et al., 2015).

vi) The Cognitive Failures Questionnaire (CFQ; Broadbent et al. 1982) was administered to assess cognitive functions, as tinnitus may impact the control of attention leading to cognitive slips and errors in task completion (Tegg-Quinn et al. 2016). This 25-item questionnaire is scored between 0–100 and with an internal consistency of .89 (Broadbent et al. 1982).

vii) The Satisfaction with Life Scales (SWLS; Diener et al. 1985) was administered as a quality of life measure assessing global life satisfaction as opposed to quality of life measures often related to self-care and mobility. Scoring is between 0-35 for 5 items and has an internal consistency of 0.87 (Dienter et al. 1985).

Assessment measures were used with permission of the copyright holders, and agreements were established for those that are not freely available to use, such as the TFI and ISI. A low score signifies fewer problems than a high score and a reduction in score indicates improvement for all these measures except for the SWLS. For the SWLS a higher score shows more life satisfaction than a lower score and an increase in score reveals improved life satisfaction.

Intervention Variables

To assess intervention variables data logging was recorded of the number of logins, the number of modules read, and the number of messages sent during the intervention. As assessing intervention satisfaction was important a standardized satisfaction questionnaire was sought. As an appropriate measure was not found, one was designed. Although it was not standardized it provided the opportunity to collect information regarding participant's views on the presentation, content, usability, and information provided on a 1–5 point Likert scale (see Appendix 1). The overall score for the 15 questions asked was used to determine intervention satisfaction (higher scores indicating more satisfaction). This questionnaire was piloted during the feasibility study (Beukes, Allen, Manchaiah, Baguley, & Andersson, 2017)

Unwanted Events

Recommendations from leading experts in the field of Internet interventions for measuring unwanted events (Rozental et al., 2014) were followed. These included using both quantitative and qualitative methods. Pre and post intervention data were compared to identify no response or deterioration in outcomes, and dropout rates were recorded. As recommended, probing for unwanted effects was undertaken by asking an open-ended question. Additional follow up questions deemed to provide important information were included as follows:

- Did you experience any unwanted effects/events associated with the Internet intervention you undertook? (yes/no)
- If yes, please list all the unwanted affects you experienced associated with undertaking this intervention (open question)
- What was the negative impact of the event/s at the time of the event? (select on a 5 point Likert scale from a range of minimal to very severe)

- What is the negative impact of the event/s at present? (i.e. 1 year post-intervention (select on a 5-point Likert scale from a range of minimal to very severe)

Data Analysis

The Statistical Package for Social Sciences (SPSS) version 23.0 was used for statistical analysis (Armonk, 2011). For all analyses, a two-tailed significance level of <0.05 was considered statistically significant. For purposes of data analysis, results at T_1 were not used, as not all the participants (the original control group) had not undertaken the intervention at this point. To evaluate the long-term outcomes, the pooled results from T_0, T_2 and T_3 were used for data analysis.

The primary study outcome was a change in TFI score at 1 year post-intervention (T_3). Secondary study outcomes were changes in the scores of secondary assessment measures at T_3. A difference in scores between T_2–T_3 was used to assess long-term stability of intervention effects.

Missing Data Analysis

An intention-to-treat (ITT) paradigm was used, as this analysis is less susceptible to bias than complete case analysis techniques. Missing value analysis was conducted to determine how to account for missing data. Little's missing completely at random test (Little, 1988), indicated that data were likely to be MCAR (missing completely at random, $\chi^2(67) = 77.73$, $p = 0.17$). This suggested that missing values were likely to be randomly distributed across all observations and there was no systematic pattern to the missing data. Missing data could thus, be imputed through the multiple imputation procedure offered by SPSS using the Markov Chain Monte Carlo method which uses five imputation runs (Asendorpf et al., 2014). All

pre-intervention assessment measure results were used as predictors. Results obtained by averaging the five imputation runs (pooled results) were used where available. For some of the statistics, a pooling algorithm was not available. When this was the case, the first imputed set of results was reported.

Sample Characteristics

Descriptive statistics including gender, age, tinnitus duration, hearing aid use, previous treatment, tinnitus severity and intervention engagement (number of logins, worksheets completed and modules read) were used to describe the sample characteristics for the participants completing the 1 year post-intervention outcomes and the original trial cohort.

Significance Testing

Repeated measures ANOVA with the independent variable of time [T_0, T_2 (after both groups completed the intervention), T_3], was carried out to compare the assessment measure results across the three time points. The main effects were followed up by Bonferroni-corrected post-hoc testing.

Effect Sizes

Effect sizes at post-intervention were calculated by dividing the mean in pre and one- year post-intervention means by the pooled standard deviations. 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).

Clinically Significant Change

A statistical significance of differences in group means is the standard analysis of clinical trials. Supplementing these results with an evaluation to determine whether the change in score is clinically meaningful, is an indicator of the value of the intervention. The Reliable Change Index (RCI; Jacobson & Truax, 1991) was used to determine clinical significance.

For the primary outcome measure the RCI was calculated using the baseline standard deviation and means, 1 year post-intervention means, and a test-retest reliability coefficient of 0.78 for the TFI, as reported in the TFI validation study (Meikle et al., 2012). For the secondary assessment measures, the Chronbach's alpha was used where test-retest reliability coefficient were not available. Individual's mean difference scores between T_0–T_3 were also evaluated against the RCI criterion for each assessment measure.

Outcome Predictors

Hierarchical multiple regression analysis was performed to investigate the ability of baseline clinical, intervention and demographic variables to predict improvement in FTI scores 1 year post-intervention (T_0–T_3 difference scores). The dependent variable was the TFI difference score (continuous variable). For the sample size (n = 146), the model could accommodate the most likely 10 predicators of outcome. The independent variables selected were three blocks of variables: baseline clinical (baseline scores for the TFI, GAD-7, PHQ-9), intervention (satisfaction with the intervention, modules read) and demographic (age, tinnitus duration, previous tinnitus treatment received, hearing aid use). The assumptions of homogeneity of variance and linearity were tested and the distribution of the data was assessed.

Unwanted Events

Unwanted events, reported in an open format question, were coded according to the checklist for unwanted events and adverse treatment reactions (Linden, 2013). Two raters independently coded the events (EB & GA). Unwanted events were catergorised as either a lack of clear treatment results, prolongation of treatment, non-compliance, emergence of new symptoms, negative wellbeing, strains in relationships, or stigmatization. Both raters judged how related these events were to the intervention using the UE-ATR categories of either unrelated, probably unrelated, possibly related, probably related or related. The inter-rater reliability for the categorization was calculated using Cohen's Kappa (Cohen, 1960). The kappa-coefficient indicated substantial agreement (100%) between the two raters (K = 1.0).

To assess if there were any group differences between those reporting unwanted events and those not reporting unwanted events, independent sample t-tests for continuous variables and Chi-square tests for categorical variables were used. Levene's test for equality of variances was performed to assess for equality of variances.

RESULTS

Participant Characteristics

All participants who undertook the iCBT intervention, except 7 who withdrew, were invited to complete the 1 year post-assessment intervention questionnaire (n = 139). Of these 104 (76%) completed the questionnaire. They consisted of 50 from the original experimental group and 54 from

the control group as seen in Figure 1. Completion rates were not significantly different between these groups, with 68% from the experimental group and 74% from the control group completing the 1 year assessment [$\chi^2(85) = 89.31$, $p = 0.35$].

From the cohort completing the long-term outcomes, the mean age was 58.30 (SD: 12:48). As found at baseline (see Table 1), a higher proportion of the participants were male (56%) whereas 44% were female [$\chi^2(85) = 93.19$, $p = 0.26$]. No significant baseline differences in terms of age, gender, employment status, level of education, tinnitus severity, insomnia, anxiety or depression were found between those who completed the assessment measures and those who choose not to complete them.

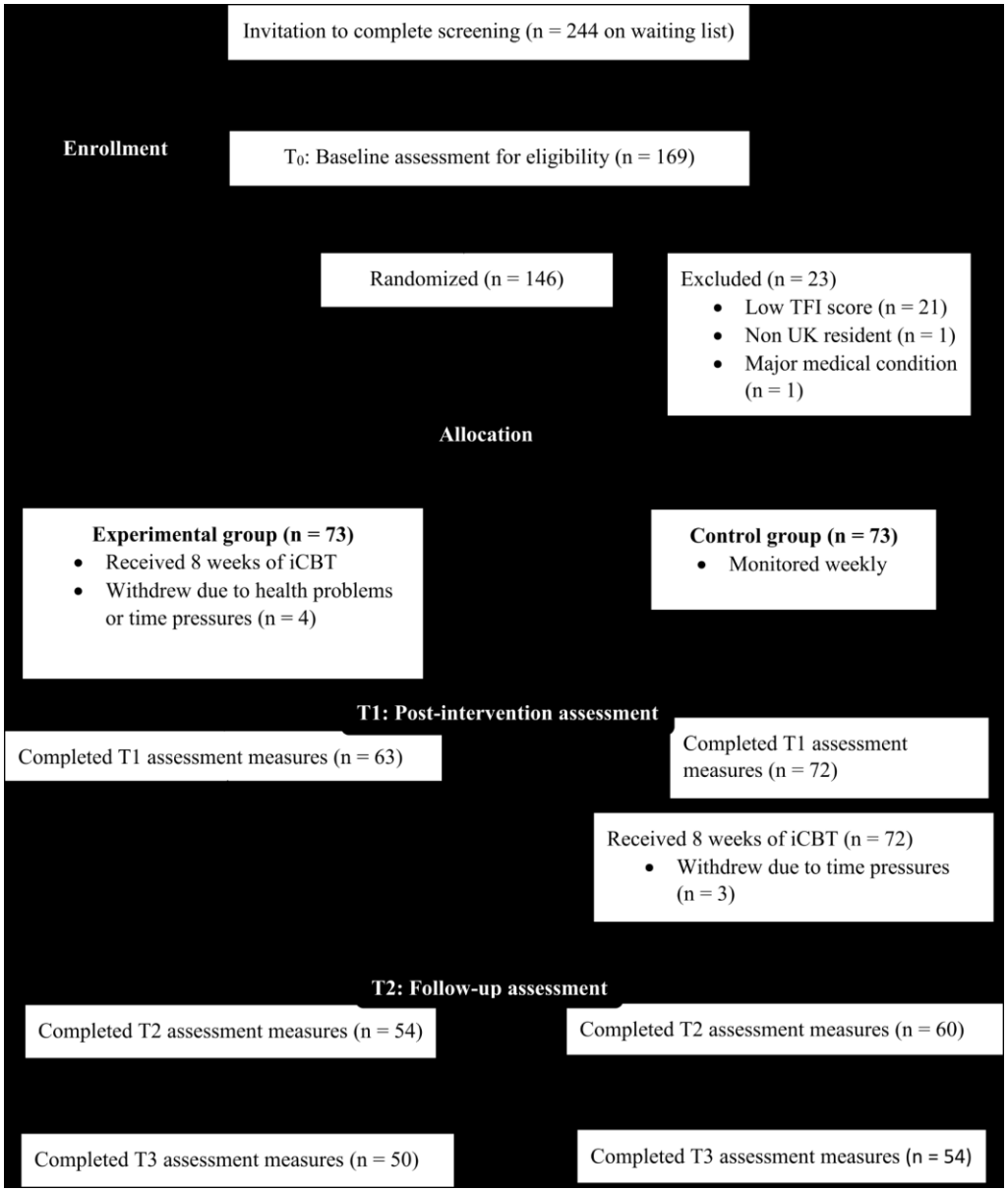
Invitation to complete screening (n = 244 on waiting list)
Enrollment
T0: Baseline assessment for eligibility (n = 169)
Randomized (n = 146)
Excluded (n = 23)
Low TFI score (n = 21)
Non UK resident (n = 1)
Major medical condition (n = 1)
Allocation
Experimental group (n = 73)
Received 8 weeks of iCBT
Withdrew due to health problems or time pressures (n = 4)
Control group (n = 73)
Monitored weekly
T1: Post-intervention assessment
Completed T1 assessment measures (n = 63)
Completed T1 assessment measures (n = 72)
Received 8 weeks of iCBT (n = 72)
Withdrew due to time pressures (n = 3)
T2: Follow-up assessment
Completed T2 assessment measures (n = 54)
Completed T2 assessment measures (n = 60)
Completed T3 assessment measures (n = 50)
Completed T3 assessment measures (n = 54)

Figure 1

Table 1: Baseline demographical and clinical characteristics of the participants

Category	**Description**	**Original trial cohort at T_0 (n = 146)**	**Participants completing outcomes at T_3 (n = 104)**	**Participants reporting unwanted effects (n = 11)**	**Differences between those reporting and not reporting unwanted effects**
Gender	Male	83 (56.9%)	58 (55.7%)	2 (18.2%)	χ^2 (1) = 6.88, p = 0.011*
	Female	63 (43.2%)	46 (44.2%)	9 (81.8%)	
Age	Mean years (SD)	55.6 (SD: 12.9)	58.30 (SD: 12.48)	60.4 (SD 5.12)	t(29.71) = -1.18, p = 0.248
	Range	22–83 years	23–84 years	53–67 years	
Tinnitus duration	Mean years (SD)	11.7 (SD: 11.9)	12.02 (SD: 10.69)	7.3 (SD 5.9)	t(102) = 2.09, p = 0.545
	Range	4 months–56 years	4 months– 50 years	4 months–20 years	
Using hearing aids	No	92 (63.0%)	67 (64.4%)	10 (90.9%)	t(102) = 1.92, p = 0.58
	Yes	54 (37.0%)	37 (35.6%)	1 (9.1%)	

Previous tinnitus treatment at baseline (1 year previously)	No Yes	112 (76.7%) 34 (23.3%)	83 (79.8%) 21 (20.2%)	2 (18.2%) 9 (81.8%)	χ^2 (1) = 0.04, p = 848
TFI score at baseline (1 year previously)		59.49 (SD: 18.4)	59.29 (SD: 17.43)	54.87 (SD: 19.87)	$t(102) = 0.90$, $p = 0.372$
Satisfaction with the intervention rating	Rating out of 100		84.97 (SD: 15.75)	86.67 (SD: 16.95)	$t(102) = -0.37$, $p = 0.711$
No of modules read during the intervention	Read out of 21		15.47 (SD 6.15)	18.36 (SD 3.04)	$t(102) = -1.64$, $p = 0.105$
No of logins	Mean		27.92 (SD 20.54)	33.09 (SD 17.52)	$t(102) = -0.85$, $p = 0.396$

Long-Term Effects for Tinnitus Distress

Differences between the TFI means were not constant over time. The T_3 mean improved by 22.70 points (SD 22.85) when compared to the pre-intervention mean (T_0). This difference was statistically significant (Cohen's d = 1.04), as seen in Table 2. This was a clinically significant change for 46% of the ITT sample (n = 146), using the reliable change criterion of 22.66 in TFI score**.** There were no significant differences in the scores between T_2–T_3 indicating that scores had been maintained 1 year post-intervention, as seen in Figure 2. There was one participant who had no change in score and 20 (14%) out of the ITT sample who had a deterioration in score (average 8.37 points, SD: 6.70). Comparison of the magnitude of the change between T_0–T_2 and T_0–T_3 is shown in Figure 3.

Table 2 Within-group comparisons of the assessment measures over time.

Measure	**Mean score at each time point (Standard deviation)**	**F-Statistic repeated measures ANOVA**	***Bonferroni Post Hoc Testing*** **Mean difference ± Standard error, *p* value**	**Cohen's *d* (95% CI)**

	T_0	T_2	T_3	T_0–T_2–T_3	T_0–T_2	T_0–T_3	T_2–T_3	T_0–T_3
TFI	59.49 (18.40)	38.17 (24.58)	36.79 (24.84)	F = 589.81 p = 0.001*	21.29 ± 0.77, p = 0.001*	22.07 ± 0.79, p = 0.001*	1.38 ± 0.49, p = 1.00	1.04 (0.69–1.38)
ISI	12.94 (7.03)	9.01 (6.93)	9.05 (6.99)	F = 182.55, p = 0.001*	3.93 ± 0.19, p = 0.001*	3.89 ± 0.23, p = 0.001*	-0.04 ± 0.17, p = 0.47	0.55 (0.22–0.88)
GAD-7	7.42 (5.52)	5.55 (4.90)	6.00 (5.53)	F = 55.75, p = 0.001*	1.87 ± 0.19, p = 0.001*	1.42 ± 0.22, p = 0.001*	-0.45 ± 0.13, p = 0.002*	0.32 (0.01–0.65)

PHQ-9	7.99 (5.66)	5.88 (5.23)	6.74 (6.08)	F = 79.52, p = 0.001*	2.09 ± 0.17, p = 0.001*	1.24 ± 0.20, p = 0.001*	-0.86 ± 0.13, p = 0.001*	0.21 (-0.11–0.54)
HHIA-S	17.84 (11.41)	14.62 (10.52)	16.83 (10.85)	F = 58.29, p = 0.006*	3.22 ± 0.29, p = 0.001*	1.02 ± 0.35, p = 0.013*	2.21 ± -0.26, p = 0.001*	0.09 (-0.23–0.41)
HQ	19.22 (8.48)	16.92 (9.04)	18.19 (9.67)	F = 41.63, p = 0.001*	2.30 ± 0.24, p = 0.001*	1.03 ± 0.30, p = 0.002*	-1.26 ± 0.19, p = 0.001*	0.11 (-0.21–0.44)
CFQ	40.63 (15.92)	39.96 (16.97)	42.36 (18.43)	F = 15.69, p = 0.001*	0.67 ± 0.45, p = 0.411*	-1.73 ± 0.54, p = 0.004*	-2.40 ± 0.31, p = 0.001*	-0.10 (-0.42–0.22)

SWLS	16.54 (6.14)	18.42 (6.19)	21.46 (8.46)	$F = 319.18$, $p = 0.001$*	1.88 ± 0.18, $p = 0.001$*	4.93 ± 0.23, $p = 0.001$*	3.05 ± 0.18, $p = 0.001$*	0.67 (0.33–1.00)

***** Significance at $p < 0.05$

Acronyms: *T_0: pre-intervention, T_1: post-intervention, T_2: follow-up, TFI: Tinnitus Functional Index, ISI: Insomnia Severity Index, GAD: Generalised Anxiety Disorder, PHQ: Patient Health Questionnaire, HHIA-s: Hearing Handicap Inventory for Adults-screening version, HQ: Hyperacusis Questionnaire, CFQ: Cognitive Failures Questionnaire, SWLS: Satisfaction with Life Scale*

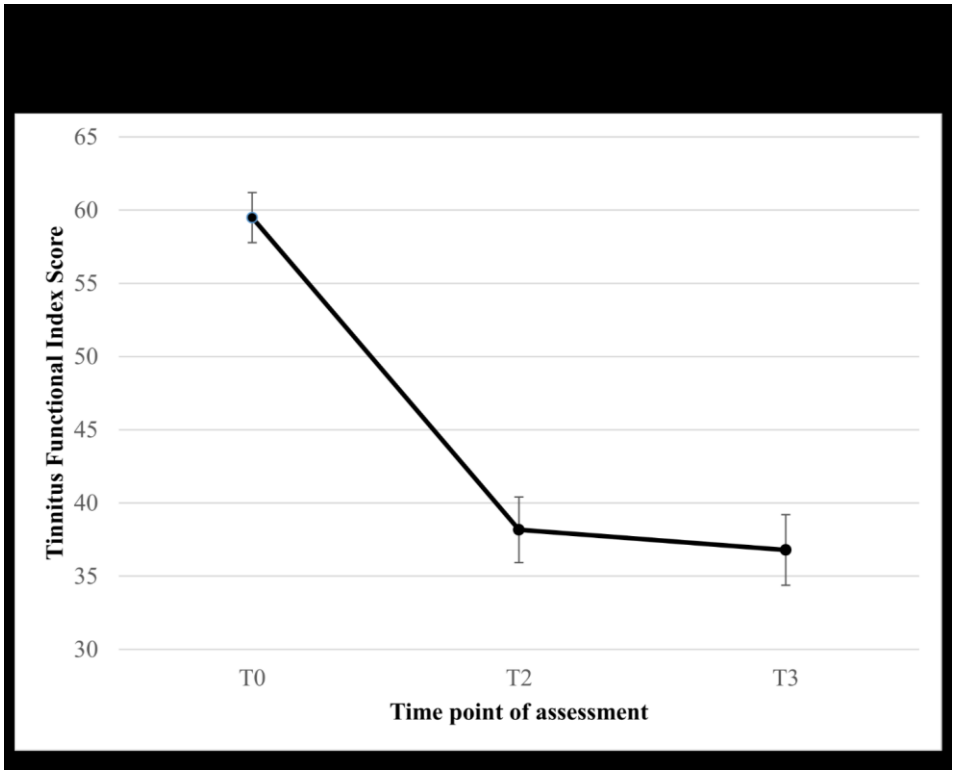

Figure 2

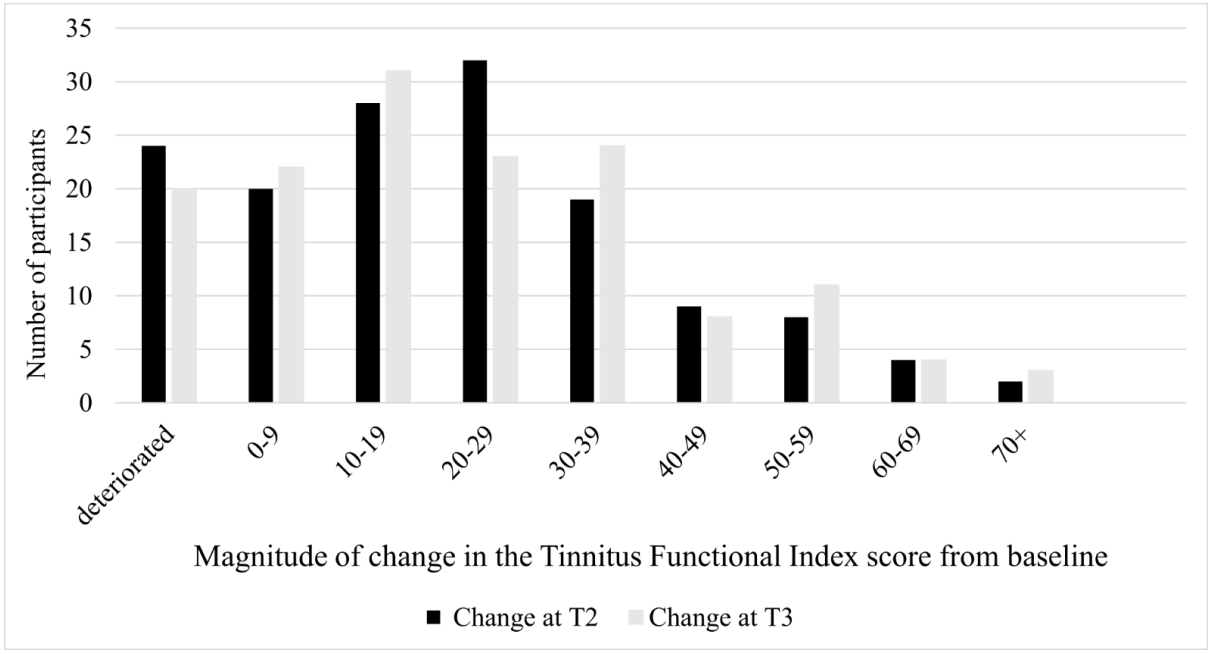

Figure 3

Long-Term Effects for Tinnitus-related Difficulties

Differences between the secondary assessment measures were not constant. These had all improved significantly over time, except for the CFQ, in which scores were significantly worse

at T_3 (scores increased). Figure 4 shows the magnitude of change from baseline (T_0) to post-intervention (T_2) and 1 year post-intervention (T_3) for the various assessment measures. The magnitude of T_0-T_3 change was greatest in assessment measures associated with life satisfaction, insomnia and anxiety with less change for the other variables. The T_2–T_3 were maintained for the ISI, improved for the SWLS and had deteriorated for the other secondary measures.

Clinical significance for the secondary assessment measures using the ITT data were not reached by many participants, as expected with the small effect sizes seen in Table 2. Clinical significance (score change >9.63) was reached by 14% for the ISI. For the GAD-7, it was attained by 22% (score change of >5.07). Clinical significance for the PHQ-9 was reached by 14% (score change of >6.02). It was attained by 20% for the HHIA and 4% for the HQ (score change of >8.83 and >14.83 respectively). Clinical significance for the CFQ was 8% and 14% for the SWLS (score change of >15.03 and >6.13 respectively).

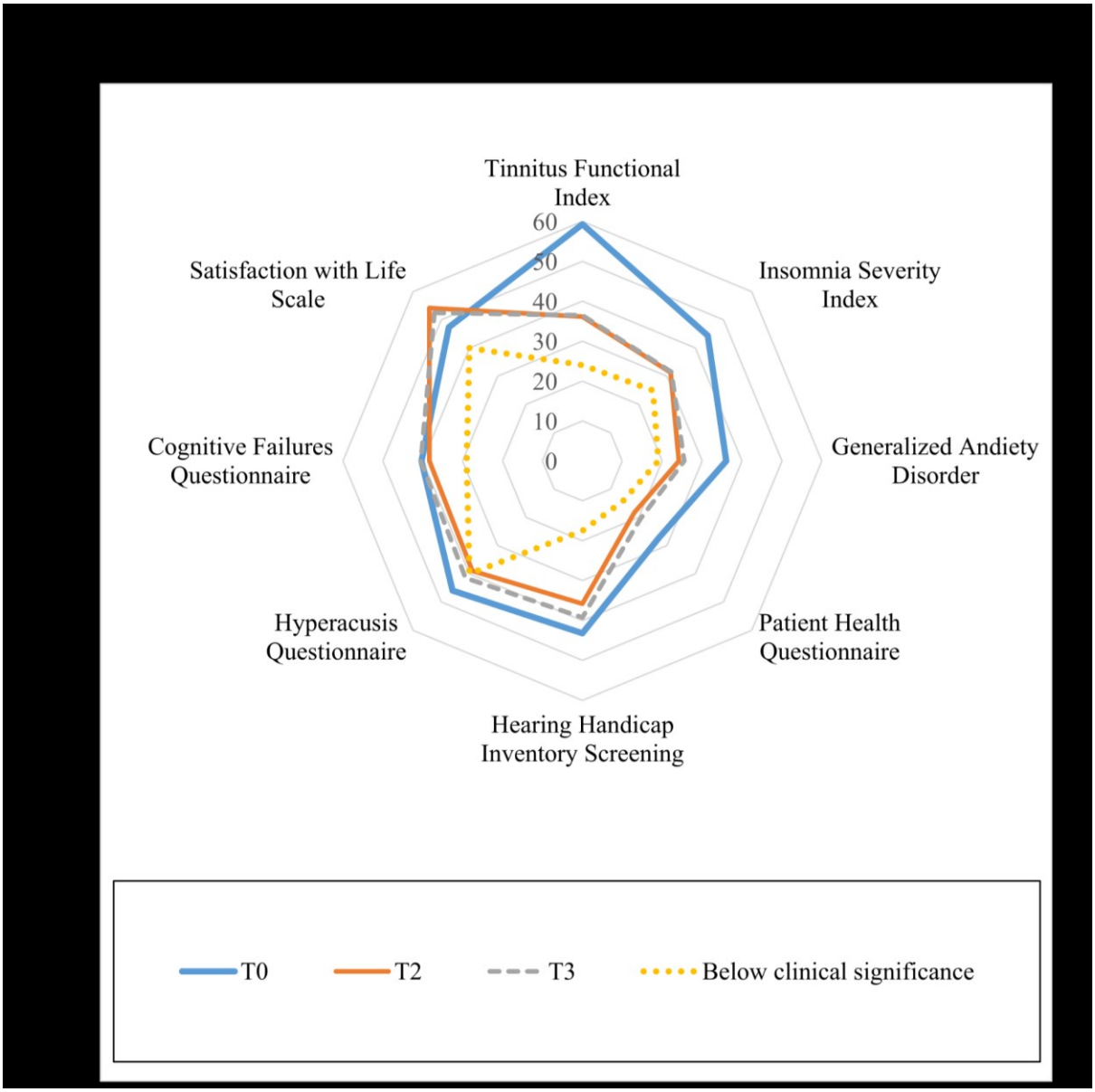

Figure 4

Predictor Variables

Hierarchical multiple regression analysis was carried out to investigate the ability of demographic, clinical and intervention variables to predict improvements in TFI score 1-year post-intervention (Table 3). The data met the assumptions of homogeneity of variance and the residuals were approximately normally distributed. There was no risk of multicollinearity, as indicated by the tolerance and VIF values. The model significantly improved the ability to predict the outcome variables [$F(6, 140) = 4.43$, $p = 0.001$] and explained 28% of the variance

in T_0–T_3 difference scores. The best predictors of greater improved TFI scores were baseline TFI scores (β = .31, p = 0.005) followed by intervention satisfaction (β =.27, p = 0.001) and then the number of modules read (β = .22, p = 0.01). There was a positive relationship between these variables and the difference in the T_0–T_3 TFI scores (increases in these variables increased the chance of greater TFI improvements).

Table 3: Hierarchical multiple regression results

Regression Step	***Variable***	***b***	***SE b***	***β***	***p***	***R***	***R^2***	**Variance**	***F***	***p***
Step 1	Constant	-13.28	12.01		.27	.45	.13	13%	4.76	0.001*
	Baseline TFI	.41	.14	.31	0.005*					
	Baseline ISI	.52	.35	.16	0.12					
	Baseline GAD-7	.71	.50	.17	0.15					
	Baseline PHQ-9	-.95	.61	-.22	0.12					
Step 2	Constant	-28.43	7.97		0.001*	.50	.25	25%	7.07	0.001*
	Satisfaction	.29	.09	.27	0.001*					
	Modules read	.70	.27	.22	0.01*					
Step 3	Constant	-13.28	12.01		0.27	.53	.28	28%	4.43	0.001*
	Age	-0.30	0.16	-.16	0.06					

Tinnitus duration	0.13	0.17	.06	0.44
Past tinnitus treatments received	-7.92	4.70	-.14	0.09
Wearing hearing aids	-0.48	1.47	-.03	0.75

Durbin-Watson Statistic = 1.95

Acronyms: *TFI: Tinnitus Functional Index; ISI: Insomnia Severity Index; GAD-7: Generalized Anxiety Disorder, PHQ-9: Patient Health Questionnaire*

Unwanted Events

There were 11 (11%) out of the 104 participants who reported unwanted events during the intervention period. There were 12 events in total, as one participant mentioned two unwanted events. These events were categorized to be 'related to the intervention' 82% of the time and 'probably related' to the intervention 18% of the time. The events were classified according to the UE-ART checklist (Linden, 2013) into the following four categories: worsening of symptoms, emergence of new symptoms, negative wellbeing and prolongation of treatment, as shown in Table 4. There were no significant differences in clinical or demographical characteristics between those reporting unwanted events and those not reporting them (Table 1), except that females were more likely than males to report unwanted events [χ^2 (1) = 6.88, p = 0.011].

Table 4 Unwanted events reported

Classification	Examples of reported unwanted effects	Number of meaning units	Severity during the intervention	Severity 1 year post-intervention
Worsening of symptoms	To begin with the process made me more aware of my tinnitus until I became better at controlling its impact	4	severe	mild
Emergence of new symptoms	I found the exercise where I had to tune into my tinnitus really difficult. It made me extremely anxious and panicky	3	severe	moderate
Negative well-being	I looked at the tinnitus in greater detail and became more aware of the limiting effect it has on me	3	moderate	moderate
Prolongation of treatment	It went on too long	2	moderate	moderate

DISCUSSION

The primary objective of this study was to evaluate the efficacy of audiologist-guided iCBT for tinnitus distress and tinnitus-associated difficulties up to 1 year post-intervention. Additional objectives were to identify predictors of outcome and to investigate the occurrence of unwanted events during the intervention period. This Discussion considers the results obtained for each objective.

Long-term Efficacy of iCBT

The benefit of audiologist-guided iCBT was sustained 1 year post-intervention for tinnitus and all related difficulties except for cognitive functioning. This could be attributed to concentration tips targeting cognitive functioning being an optional module and not read by all participants (read by 57%). It may also be that the CFQ was not an optimum assessment measure to measure the ability to concentrate and focus on mental activities as its focus is on cognitive failure in areas of perception, memory and motor function (Broadbent, Cooper, FitzGerald, & Parkes, 1982).

These findings are in line with previous iCBT for tinnitus studies also reporting stability of intervention effects up to 1 year post-intervention. Jasper et al. (2014) indicated stability of effects 6 months after completing iCBT for tinnitus severity, anxiety, depression, and insomnia in a German population. Kaldo et al. (2008) and Hesser et al. (2012), both using a Swedish population, and Weise et al. (2016) using a German population, reported stability (and improvements) of results 1 year after undertaking iCBT for tinnitus severity, anxiety, depression, but not for insomnia. Kaldo et al. (2008) compared 6 weeks of iCBT (n = 26) to those doing seven sessions of GCBT. They also found no significant changes from post-intervention to 1 year follow-up. In contrast to these studies and the present study, (Nyenhuis, Zastrutzki, Weise, Jäger, & Kröner-Herwig, 2013) reported a deterioration of results at 6-

month follow-up (d = 1.04 at T_1 to d = 0.66 at T_2 when using ITT analysis). This result may have been related to the difference in programme selected, as the CBT-oriented tinnitus coping training (Kröner-Herwig, Frenzel, Fritsche, Schilkowsky, & Esser, 2003) was used during this study whereas the other studies have been based on the CBT self-help programme for tinnitus developed by Andersson and Kaldo (2004).

More information is still required regarding the long-term efficacy of iCBT for tinnitus beyond 1 year post-intervention. Enduring effects up to 3 years post-iCBT have been indicated for conditions such as anxiety, depression, stress and fatigue (Andersson, Rozental, Shafran, & Carlbring, 2017).

Predictors of Outcome

Certain tinnitus patients may benefit more or less from iCBT (Kaldo-Sandström, Larsen, & Andersson, 2004). Identifying if specific patient variables can predict who many benefit from iCBT is therefore of importance. Demographic, clinical and intervention variables were investigated to aid identifying who was best suited for iCBT. Demographic variables did not predict outcome, indicating that iCBT is applicable to a wide range of participants, regardless of their demographical characteristics.

The best predictor of improvement in tinnitus severity was higher baseline TFI score. It is possible that the relationship between TFI score and improvement in tinnitus indicates a regression to the mean phenomenon, in that variables at extremes tend to be closer to the mean during follow-up measurements, letting natural data variation appear to be real change (Barnett, Van Der Pols, Jolieke C, & Dobson, 2004).

The next best predictors of improvement in tinnitus severity were higher intervention satisfaction and a higher number of modules read. Similar results were reported by Kaldo-Sandstrom, Larsen, & Andersson, (2004), who reported that intervention compliance, how

intensely participants worked at the intervention, and the number of messages sent were associated with outcome. Further identified trends were that patients referred from external routes and those undertaking previous treatments had better outcomes, which was not identified as a predictor by the present study. Kaldo-Sandstrom, Larsen, & Andersson used a clinical population, as opposed to a research population used in the present study, which could contribute to the difference in findings. Results from both this study and the present study suggest that positive intervention engagement contributes to improved outcomes. Identifying traits that promote engagement may, therefore, be important. It has been reported that personality traits such as openness and conscientiousness may suggest greater suitability for iCBT for tinnitus (Kleinstäuber, Weise, Andersson, & Probst, 2018). Moreover, higher scores for helplessness and lower scores for actively changing behaviours and attitudes and maintaining these behaviours and attitudes using the Tinnitus Stages of Change Questionnaire were associated with better outcomes for both group and Internet-based CBT for tinnitus (Kaldo, Richards, & Andersson, 2006). Furthermore, Langguth et al. (2007) found that agreeableness (competitive, self-centred, more susceptible to anger) was correlated with greater tinnitus distress. On the other had neuroticism (higher emotional responses such as anxiety, fear, anger, frustration) positively correlated with depressiveness. It may be that other factors, not investigated in the present study, may also predict outcome.

Unwanted Events During the Intervention Period

Unwanted events following undertaking iCBT for tinnitus were investigated as empirical studies on the nature and frequency of unwanted events are scares in iCBT trials, and have not previously been investigated for iCBT for tinnitus (Boettcher et al., 2014). Unwanted events were reported by 11% of participants. This frequency is consistent with the 10% reported by a meta-analysis of previous non-tinnitus iCBT trials (Barak, Hen, Boniel-Nissim, & Shapira, 2008). The reported events were generally related, or probably related, to the intervention and

the severity thereof was described as moderate to severe. The most commonly mentioned unwanted event was that symptoms worsened (n = 4), as participants became more aware of their tinnitus during the initial parts of the intervention. Three participants also mentioned the emergence of new symptoms as the exposure techniques caused anxiety. By doing the intervention, three participants, came to fully realize the impact their tinnitus was having on them and this led to negative wellbeing. Two participants mentioned that the intervention was too prolonged. During a process evaluation of the trial, it was, however, found that the intervention time period was not long enough to complete all the information for around 17% of participants (Beukes et al., 2017). Identifying an optimal intervention period to suit all participants is one challenge surrounding such an intervention. As these particular unwanted events were only mentioned by a very small percentage of participants, these findings only provide indications of possible unwanted events. Further investigations are required to reach more concrete conclusions.

There may also be specific moderators associated with the reporting of unwanted events while undertaking such an intervention. In this trial, a significantly higher proportion (82%) reporting unwanted events were female ($p = 0.01$). It is possible that demographic characteristics not investigated in this study may be associated with unwanted events The possible unwanted events associated with this intervention, such as an initial deterioration of symptoms, negative wellbeing or emergence of new symptoms, should be disclosed in future trials. Moreover, providing some flexibility in the timings to complete the intervention should be provided.

Study Limitations

This study is not without limitations, which have implications for result interpretation. Due to the nature of the study design, randomisation was not obtainable to assess long-term outcomes. Furthermore, not all participants completed the post-intervention assessment measures, which could have resulted in treatment bias. The assessment measures selected may not have been optimal to identify intervention effects and this may have affected the results obtained.

Further Research

Further longitudinal studies would be of benefit to monitor outcomes to at least 3 years post-intervention for audiologist-guided iCBT. As identifying outcome variables will be useful for triaging participants, wider demographic and clinical variables should be searched for moderators and mediators of outcome. This may include factors such as helplessness, behaviour and/or attitude change and ability to maintain these behaviours. These factors were indicated to be predictors of outcome by Kaldo et al. (2006). Due to the importance of effective (i.e. sufficient) engagement in achieving the intended outcomes, ways of promoting such engagement is required (Yardley et al., 2016). Implementing qualitative research methods using semi-structured interviews to provide a more in-depth understanding of user's experiences with the intervention will provide further insights into wanted and unwanted intervention effects (Yardley et al., 2016). Further insights regarding unwanted events that need to be addressed or disclosed in future iCBT trials for tinnitus trials are required.

CONCLUSION

This study has demonstrated that the benefits of audiologist-guided iCBT are maintained 1 year post-intervention Few predictors of outcome could be identified, indicating the applicability of this study regardless of demographic and clinical profiles. This was the first study investigating

unwanted events from iCBT for tinnitus and knowledge of these effects can assist in improving future iCBT for tinnitus studies.

ACKNOWLEDGEMENTS

Portions of this paper were presented at the 3rd International Internet & Audiology Meeting, Louisville, KY, July 2017. The conference committee is thanked for providing a travel bursary for the first author to present this work at the conference. The authors wish to thank all participants and organizations that promoted and supported this study. We would also like to thank Linköping University for hosting the web portal and their webmaster, George Vlaescu, for the technical assistance provided.

List of Figures

List of Tables

Table 2 Within-group comparisons of the assessment measures over time

Table 3 Hierarchical multiple regression results

Table 4 Unwanted events

REFERENCES

Andersson, G. (2015). Clinician-supported internet-delivered psychological treatment of tinnitus. American Journal of Audiology, 24(3), 299-301.

Andersson, G. (2016). Internet-delivered psychological treatments. Annual Review of Clinical Psychology, 12, 157-179.

Andersson, G., Rozental, A., Shafran, R., & Carlbring, P. (2017). Long-term effects of internet-supported cognitive behaviour therapy. Expert Review of Neurotherapeutics, , 1-8.

Andersson, G., Strömgren, T., Ström, L., & Lyttkens, L. (2002). Randomized controlled trial of internet-based cognitive behavior therapy for distress associated with tinnitus. Psychosomatic Medicine, 64(5), 810-816.

Armonk, N. (2011). IBM SPSS statistics for windows.

Baguley, D., McFerran, D., & Hall, D. (2013). Tinnitus. The Lancet, 382(9904), 1600-1607.

Barak, A., Hen, L., Boniel-Nissim, M., & Shapira, N. (2008). A comprehensive review and a meta-analysis of the effectiveness of internet-based psychotherapeutic interventions. Journal of Technology in Human Services, 26(2-4), 109-160.

Barnett, A. G., Van Der Pols, Jolieke C, & Dobson, A. J. (2004). Regression to the mean: What it is and how to deal with it. International Journal of Epidemiology, 34(1), 215-220.

Baumeister, H., Reichler, L., Munzinger, M., & Lin, J. (2014). The impact of guidance on internet-based mental health interventions—A systematic review. Internet Interventions, 1(4), 205-215.

Beukes, E. W., Allen, P. M., Manchaiah, V., Baguley, D. M., & Andersson, G. (2017a). Internet-based intervention for tinnitus: Outcome of a single-group open trial. Journal of the American Academy of Audiology, 28(4), 340-351.

Beukes, E. W., Allen, P. M., Manchaiah, V., Baguley, D. M., & Andersson, G. (2017b). Internet-based intervention for tinnitus: Outcome of a single-group open trial. Journal of the American Academy of Audiology, 28(4), 340-351.

Beukes, E. W., Baguley, D. M., Allen, P. M., Manchaiah, V., & Andersson, G. (2017). Audiologist-guided internet-based cognitive behavior therapy for adults with tinnitus in the united kingdom: A randomized controlled trial. Ear and Hearing,

Beukes, E. W., Manchaiah, V., Baguley, D. M., Allen, P. M., & Andersson, G. (2017). Process evaluation of internet-based cognitive behavioural therapy for adults with tinnitus in the context of a randomised control trial. International Journal of Audiology, , 1-12.

Beukes, E. W., Vlaescu, G., Manchaiah, V., Baguley, D. M., Allen, P. M., Kaldo, V., & Andersson, G. (2016). Development and technical functionality of an internet-based intervention for tinnitus in the UK. Internet Interventions, 6, 6-15.

Beukes, E. W., Manchaiah, V., Allen, P. M., Baguley, D. M., & Andersson, G. (2015). Internet-based cognitive behavioural therapy for adults with tinnitus in the UK: Study protocol for

a randomised controlled trial. BMJ Open, 5(9), e008241-2015-008241. 10.1136/bmjopen-2015-008241 [doi]

Bhatt, J. M., Lin, H. W., & Bhattacharyya, N. (2016). Prevalence, severity, exposures, and treatment patterns of tinnitus in the united states. JAMA Otolaryngology–Head & Neck Surgery, 142(10), 959-965.

Boettcher, J., Rozental, A., Andersson, G., & Carlbring, P. (2014). Side effects in internet-based interventions for social anxiety disorder. Internet Interventions, 1(1), 3-11.

Broadbent, D. E., Cooper, P. F., FitzGerald, P., & Parkes, K. R. (1982). The cognitive failures questionnaire (CFQ) and its correlates. British Journal of Clinical Psychology, 21(1), 1-16.

Cima, R. F., Andersson, G., Schmidt, C. J., & Henry, J. A. (2014). Cognitive-behavioral treatments for tinnitus: A review of the literature. Journal of the American Academy of Audiology, 25(1), 29-61.

Cima, R. F., Vlaeyen, J. W., Maes, I. H., Joore, M. A., & Anteunis, L. J. (2011). Tinnitus interferes with daily life activities: A psychometric examination of the tinnitus disability index. Ear and Hearing, 32(5), 623-633. 10.1097/AUD.0b013e31820dd411 [doi]

Cohen, J. (1960). A coefficient of agreement for nominal scales. Educational and Psychological Measurement, 20(1), 37-46.

Cohen, J. (1992). A power primer. Psychological Bulletin, 112(1), 155.

Davis, A., & Rafaie, E. A. (2000). Epidemiology of tinnitus. Tinnitus Handbook, , 1-23.

Dawes, P., Fortnum, H., Moore, D. R., Emsley, R., Norman, P., Cruickshanks, K., . . . Munro, K. (2014). Hearing in middle age: A population snapshot of 40- to 69-year olds in the united kingdom. Ear and Hearing, 35(3), e44-51. 10.1097/AUD.0000000000000010 [doi]

Des Jarlais, D. C., Lyles, C., Crepaz, N., & TREND Group. (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. American Journal of Public Health, 94(3), 361-366.

Fackrell, K., Hall, D. A., Barry, J. G., & Hoare, D. J. (2016). Psychometric properties of the tinnitus functional index (TFI): Assessment in a UK research volunteer population. Hearing Research, 335, 220-235.

Gander, P. E., Hoare, D. J., Collins, L., Smith, S., & Hall, D. A. (2011). Tinnitus referral pathways within the national health service in england: A survey of their perceived effectiveness among audiology staff. BMC Health Services Research, 11, 162-6963-11-162. 10.1186/1472-6963-11-162 [doi]

Hall, D. A., Láinez, M. J., Newman, C. W., Sanchez, T. G., Egler, M., Tennigkeit, F., . . . Langguth, B. (2011). Treatment options for subjective tinnitus: Self reports from a sample of general practitioners and ENT physicians within europe and the USA. BMC Health Services Research, 11(1), 302.

Hesser, H., Weise, C., Westin, V. Z., & Andersson, G. (2011). A systematic review and meta-analysis of randomized controlled trials of cognitive–behavioral therapy for tinnitus distress. Clinical Psychology Review, 31(4), 545-553.

Hesser, H., Gustafsson, T., Lunden, C., Henrikson, O., Fattahi, K., Johnsson, E., . . . Andersson, G. (2012). A randomized controlled trial of internet-delivered cognitive behavior therapy

and acceptance and commitment therapy in the treatment of tinnitus. Journal of Consulting and Clinical Psychology, 80(4), 649-661. 10.1037/a0027021

Hoare, D. J., Broomhead, E., Stockdale, D., & Kennedy, V. (2015). Equity and person-centeredness in provision of tinnitus services in UK national health service audiology departments. European Journal for Person Centered Healthcare, 3(3), 318-326.

Kaldo, V., Levin, S., Widarsson, J., Buhrman, M., Larsen, H., & Andersson, G. (2008). Internet versus group cognitive-behavioral treatment of distress associated with tinnitus: A randomized controlled trial. Behavior Therapy, 39(4), 348-359.

Kaldo, V., Richards, J., & Andersson, G. (2006). Tinnitus stages of change questionnaire: Psychometric development and validation. Psychology, Health & Medicine, 11(4), 483-497.

Kaldo-Sandstrom, V., Larsen, H. C., & Andersson, G. (2004). Internet-based Cognitive—Behavioral self-help treatment of TinnitusClinical effectiveness and predictors of outcome. American Journal of Audiology, 13(2), 185-192.

Kaldo-Sandström, V., Larsen, H. C., & Andersson, G. (2004). Internet-based Cognitive—Behavioral self-help treatment of tinnitus: Clinical effectiveness and predictors of outcome. American Journal of Audiology, 13(2), 185-192.

Kim, H., Lee, H., An, S., Sim, S., Park, B., Kim, S. W., . . . Choi, H. G. (2015). Analysis of the prevalence and associated risk factors of tinnitus in adults. PloS One, 10(5), e0127578.

Kleinstäuber, M., Weise, C., Andersson, G., & Probst, T. (2018). Personality traits predict and moderate the outcome of internet-based cognitive behavioural therapy for chronic tinnitus. International Journal of Audiology, , 1-7.

Kröner-Herwig, B., Frenzel, A., Fritsche, G., Schilkowsky, G., & Esser, G. (2003). The management of chronic tinnitus: Comparison of an outpatient cognitive–behavioral group training to minimal-contact interventions. Journal of Psychosomatic Research, 54(4), 381-389.

Langguth, B., Kleinjung, T., Fischer, B., Hajak, G., Eichhammer, P., & Sand, P. (2007). Tinnitus severity, depression, and the big five personality traits. Progress in Brain Research, 166, 221-225.

Langguth, B., Kreuzer, P. M., Kleinjung, T., & De Ridder, D. (2013). Tinnitus: Causes and clinical management. The Lancet Neurology, 12(9), 920-930.

Lasisi, A. O., Abiona, T., & Gureje, O. (2010). Tinnitus in the elderly: Profile, correlates, and impact in the nigerian study of ageing. Otolaryngology-Head and Neck Surgery, 143(4), 510-515.

Linden, M. (2013). How to define, find and classify side effects in psychotherapy: From unwanted events to adverse treatment reactions. Clinical Psychology & Psychotherapy, 20(4), 286-296.

Martinez-Devesa, P., Perera, R., Theodoulou, M., & Waddell, A. (2010a). Cognitive behavioural therapy for tinnitus. The Cochrane Library,

Martinez-Devesa, P., Perera, R., Theodoulou, M., & Waddell, A. (2010b). Cognitive behavioural therapy for tinnitus. The Cochrane Library,

Martinez, C., Wallenhorst, C., McFerran, D., & Hall, D. A. (2015). Incidence rates of clinically significant tinnitus: 10-year trend from a cohort study in england. Ear and Hearing, 36(3), e69-75. 10.1097/AUD.0000000000000121 [doi]

McFerran, D., & Baguley, D. (2009). Is psychology really the best treatment for tinnitus? Clinical Otolaryngology, 34(2), 99-101.

Meikle, M. B., Henry, J. A., Griest, S. E., Stewart, B. J., Abrams, H. B., McArdle, R., . . . Vernon, J. A. (2012). The tinnitus functional index: Development of a new clinical measure for chronic, intrusive tinnitus. Ear and Hearing, 33(2), 153-176. 10.1097/AUD.0b013e31822f67c0 [doi]

Michie, S., Yardley, L., West, R., Patrick, K., & Greaves, F. (2017). Developing and evaluating digital interventions to promote behavior change in health and health care: Recommendations resulting from an international workshop. Journal of Medical Internet Research, 19(6), e232. 10.2196/jmir.7126 [doi]

Newman, C. W., Jacobson, G. P., & Spitzer, J. B. (1996). Development of the tinnitus handicap inventory. Archives of Otolaryngology–Head & Neck Surgery, 122(2), 143-148.

Nyenhuis, N., Golm, D., & Kröner-Herwig, B. (2013). A systematic review and meta-analysis on the efficacy of self-help interventions in tinnitus. Cognitive Behaviour Therapy, 42(2), 159-169.

Nyenhuis, N., Zastrutzki, S., Weise, C., Jäger, B., & Kröner-Herwig, B. (2013). The efficacy of minimal contact interventions for acute tinnitus: A randomised controlled study. Cognitive Behaviour Therapy, 42(2), 127-138.

Polisena, J., Coyle, D., Coyle, K., & McGill, S. (2009). Home telehealth for chronic disease management: A systematic review and an analysis of economic evaluations. International Journal of Technology Assessment in Health Care, 25(3), 339-349.

Richards, D., & Richardson, T. (2012). Computer-based psychological treatments for depression: A systematic review and meta-analysis. Clinical Psychology Review, 32(4), 329-342.

Rozental, A., Andersson, G., Boettcher, J., Ebert, D. D., Cuijpers, P., Knaevelsrud, C., . . . Carlbring, P. (2014). Consensus statement on defining and measuring negative effects of internet interventions. Internet Interventions, 1(1), 12-19.

Rozental, A., Boettcher, J., Andersson, G., Schmidt, B., & Carlbring, P. (2015). Negative effects of internet interventions: A qualitative content analysis of patients' experiences with treatments delivered online. Cognitive Behaviour Therapy, 44(3), 223-236.

Rozental, A., Magnusson, K., Boettcher, J., Andersson, G., & Carlbring, P. (2017). For better or worse: An individual patient data meta-analysis of deterioration among participants receiving internet-based cognitive behavior therapy. Journal of Consulting and Clinical Psychology, 85(2), 160.

Shargorodsky, J., Curhan, G. C., & Farwell, W. R. (2010). Prevalence and characteristics of tinnitus among US adults. The American Journal of Medicine, 123(8), 711-718.

Smith, P., McKeon, A., Blunt, I., & Edwards, N. (2014). NHS hospitals under pressure: Trends in acute activity up to 2022. London, UK: Nuffield Trust,

Stockdale, D., McFerran, D., Brazier, P., Pritchard, C., Kay, T., Dowrick, C., & Hoare, D. J. (2017). An economic evaluation of the healthcare cost of tinnitus management in the UK. BMC Health Services Research, 17(1), 577.

Vlaescu, G., Alasjö, A., Miloff, A., Carlbring, P., & Andersson, G. (2016). Features and functionality of the iterapi platform for internet-based psychological treatment. Internet Interventions, 6, 107-114.

Vlaescu, G., Carlbring, P., Lunner, T., & Andersson, G. (2015). An e-platform for rehabilitation of persons with hearing problems. American Journal of Audiology, 24(3), 271-275.

Weise, C., Kleinstauber, M., & Andersson, G. (2016). Internet-delivered cognitive-behavior therapy for tinnitus: A randomized controlled trial. Psychosomatic Medicine, 78(4), 501-510. 10.1097/PSY.0000000000000310 [doi]

West, D. (2012). How mobile devices are transforming healthcare. Issues in Technology Innovation, 18(1), 1-11.

Wu, B., Searchfield, G., Exeter, D., & Lee, A. (2015). Tinnitus prevalence in new zealand.

Yardley, L., Spring, B. J., Riper, H., Morrison, L. G., Crane, D. H., Curtis, K., . . . Blandford, A. (2016). Understanding and promoting effective engagement with digital behavior change interventions. American Journal of Preventive Medicine, 51(5), 833-842. S0749-3797(16)30243-4 [pii]