

Development and technical functionality of an Internet-based intervention for tinnitus in the UK



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ABSTRACT

Purpose: Creative approaches to improve access to evidence-based tinnitus treatments are required. The purpose of this study was to develop an Internet-based cognitive behavioural therapy (iCBT) intervention, for those experiencing tinnitus in the United Kingdom (UK). Furthermore, it aimed, through technical functionality testing, to identify specific aspects of the iCBT that require improving.

Method: An innovative iCBT intervention for treating tinnitus in the UK has been developed using a cognitive-behavioural theoretical framework. This iCBT was evaluated by two user groups during this developmental phase. Initially, five expert reviews evaluated the intervention, prior to evaluation by a group of 29 adults experiencing significant levels of tinnitus distress. Both groups evaluated iCBT in an independent measures design, using a specifically designed satisfaction outcome measure.

Results: Overall, similar ratings were given by the expert reviewers and adults with tinnitus, showing a high level of satisfaction regarding the content, suitability, presentation, usability and exercises provided in the intervention. The iCBT intervention has been refined following technical functionality testing.

Conclusions: Rigorous testing of the developed iCBT intervention has been undertaken. These evaluations provide confidence that further clinical trials can commence in the UK, to assess the feasibility and effectiveness of this iCBT intervention for tinnitus.

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1. Introduction

Technological advances are transforming healthcare provision (Harris, 2013). The implementation of these innovations is important, particularly for chronic conditions, as they place a substantial burden on health organisations (West, 2012). One such condition is tinnitus, described as “the conscious perception of unwanted subjective auditory sensations, in the absence of a corresponding external stimulus”

(McFadden, 1982). A cure for tinnitus is yet to be found, possibly due to its heterogeneous aetiology, varied clinical presentation and the limited understanding regarding its pathophysiology (Elgoyhen et al., 2015). Treating tinnitus remains challenging and exploring new interventions for tinnitus management is imperative (Hall et al., 2013).

An understanding of the impact of tinnitus is required prior to selecting possible intervention strategies. Tinnitus experiences are highly variable and not everyone with tinnitus is affected in the same way (Baguley et al., 2013). For some, experiencing tinnitus is a devastating medical symptom, leading to significant clinical problems (Belli et al., 2008). Many aspects of daily life are disrupted, leading to sleep and concentration difficulties, and indirect psychosocial effects, including hopelessness, anxiety and depression (Langguth, 2011). What adds to the tinnitus paradox is that tinnitus severity is not related to the loudness or character of tinnitus experienced, but rather to the psychological

Abbreviations: CBT, cognitive behavioural therapy; iCBT, Internet-based cognitive behavioural therapy; TFI, Tinnitus Functional Index; UK, United Kingdom.

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complaints thereof (Andersson, 2002). Tinnitus interventions targeting the tinnitus sound itself, are therefore less effective than psychological treatments which focus on improving functionality and minimising the effects tinnitus may have (Hoare et al., 2011). Psychological treatments, such as cognitive behavioural therapy (CBT), are the treatment with the most evidence of effectiveness in reducing tinnitus distress (see Hesser et al., 2011 for a systematic review). Despite positive outcomes, there is limited accessibility to CBT for tinnitus, largely due to a shortage of suitably trained clinicians (Hoare et al., 2015; McFerran and Baguley, 2009).

Andersson et al. (2002) utilised the Internet to overcome difficulties related to accessing CBT for tinnitus. They developed a guided self-help Internet-based cognitive behavioural therapy for tinnitus (iCBT). The recruitment, assessment and intervention were run via the Internet, over a six week period. The materials were text-based chapters to read together with weekly worksheets to complete. Results of the initial randomised control trial (RCT) with a waiting-list control group indicated a reduction in tinnitus-related distress and depression for those undergoing the intervention (Andersson et al., 2002). Following intervention improvements, a study run in Sweden indicated similar results to group-based CBT (Kaldo et al., 2008). A further study by Hesser et al. (2012) found both iCBT and Internet-delivered acceptance and commitment therapy to be effective when compared to a discussion forum control group. Furthermore, iCBT has been shown to be effective when implemented in regular clinics (Kaldo-Sandström et al., 2004; Kaldo et al., 2013).

Following the success of these studies iCBT has been subsequently translated into both English and German. Effectiveness of iCBT was indicated using the German version in studies performed using a German population (Nyenhuis et al., 2013; Jasper et al., 2014; Weise et al., 2016). In a study by Abbott et al. (2009) using the translated English iCBT version, no statistically significant benefit was found when compared to an information-only control programme (without CBT content) in Australia and attrition rates were high. This was partly due to a relatively low level of baseline tinnitus distress and possibly due to cultural differences not being considered. Cultural dissimilarities could include differences in attitudes towards text-based learning, on which the programme was based for the industrial population sample selected. It is, therefore, important to ensure that these interventions are adapted to account for cultural variances found in different populations.

In the UK, self-help methods for tinnitus management are advocated in the Good Practice Guidelines for tinnitus management (DOH, 2009). Self-help is promoted as a means of increasing an individual's knowledge of tinnitus and helpful information is freely available through tinnitus charities, support groups, and general practitioners. In addition, the Internet has been used in the UK to serve those experiencing tinnitus, by means of online tinnitus support groups and forums. Although there are no national Internet-based interventions, there is an Internet-delivered unguided tinnitus Programme (www.Tinnitusprogramme.org), developed by a hearing therapist. It consists of education, psychoeducation, relaxation and attentional-focus exercises running over 6 weeks, followed by a 4 week maintenance period (Greenwell et al., 2015). Since its inception in 2009, it has not been widely used, which may be linked to the fact that this intervention has never been formally evaluated, although a protocol to evaluate this intervention has been proposed (Greenwell et al., 2016).

What is clearly limited in the UK is CBT support, guided self-help and evidence-based Internet interventions for people with troublesome tinnitus. The additional treatment option of guided iCBT for tinnitus distress in the UK would complement existing tinnitus pathways and self-help information by providing an evidence-based, accessible, comprehensive and standardised intervention. As health-care in the UK is largely face-to-face, an Internet intervention would need to be specifically designed to be appealing and overcome potential barriers to usage. It would also be imperative to ensure that the intervention is

functioning well at a technical level and determine end user satisfaction prior to undertaking further clinical trials (Haynes, 1999).

This study aimed to address the need for an evidence-based iCBT intervention for tinnitus distress, specifically for a UK population. The specific objectives were as follows:

- i) Development of an Internet-based intervention for tinnitus adapted specifically for a UK population
- ii) Identifying technical functionality concerns that may cause barriers to the usability of iCBT in the UK
- iii) Evaluating the intervention in terms of content, presentation, suitability and materials provided

2. Method

2.1. Ethical considerations

The Faculty of Science and Technology Research Ethics Panel (FREP) of Anglia Ruskin University (FST/FREP/14/478) granted ethical approval for this study. The research was conducted in accordance with the tenets of the Declaration of Helsinki.

2.2. Development process

As tinnitus is best treated within a multidisciplinary team (Cima et al., 2009), a multi-professional collaboration, with a broad skill set, consisting of the authors of this paper, was formed to guide this intervention. Including professionals involved in developing the original iCBT intervention in Sweden was considered imperative. GA and VK's expertise from the original iCBT development was utilised together with their clinical proficiency in providing psychological interventions. Moreover, it was important to have Clinical Audiologists involved. DB and EB fulfilled this roll and their knowledge of the pathophysiology of tinnitus and tinnitus therapy was incorporated. VM and PA added proficiency in both quantitative and qualitative research methods as well as experience in the running of clinical trials. GV's expertise in web-design and Internet-intervention delivery was key to the successful development of this intervention.

Guidance on developing complex interventions was followed (Craig et al., 2008). The fundamental premise was based on proven conceptual models. The Internet was chosen as the delivery method, as overall studies using CBT delivered via the Internet show promise as an effective and cost-efficient treatment option to reduce tinnitus distress (e.g. Hesser et al., 2012; Kaldo et al., 2008, 2013; Nyenhuis et al., 2013; Jasper et al., 2014; Weise et al., 2016). Internet-based CBT interventions have also been shown to be effective for a range of conditions, including anxiety, mood disorders, headache, insomnia, and somatic problems such as chronic pain (see meta-analysis and systematic reviews by Cuijpers et al., 2008; Arberg et al., 2014; van Beugen et al., 2014).

The theoretical model by Ritterband et al. (2009) was used to guide the development of this intervention. The key features known to add to the effectiveness of Internet interventions, such as those found by Andersson et al. (2009), were considered and the following eight principles were selected for the design of this intervention:

2.2.1. Evidence-based content

There are various approaches to tinnitus management that are currently in use. The objective was to present only evidence-based, informative, accurate and interesting content within the intervention.

2.2.2. Comprehensiveness

Andersson et al. (2009) reported that for maximum effectiveness an Internet intervention must be comprehensive. The intent was, therefore, to maximise behavioural change by offering various techniques within a comprehensive intervention that focuses on addressing the physical, emotional and daily effects of experiencing tinnitus. Key CBT

techniques such as negative automatic thought analysis, cognitive restructuring, imagery, applied relaxation, exposure techniques, sleep hygiene and concentration management (Andersson, 2002) were deemed important to include. In addition, incorporating key Audiological approaches to the treatment of tinnitus such as the use of sound enrichment, hearing tactics and advice for sound sensitivity (DOH, 2009) would ensure a fully comprehensive intervention.

2.2.3. Interactive approach

The main sources of information for those with tinnitus in the UK are provided passively and in the written form, so an interactive approach, to differentiate this intervention from others, was considered essential. In order to address the use of different learning styles a variety of materials, such as videos, quizzes, diagrams, and pictures would all be used (Cassidy, 2004).

2.2.4. Guided support

Many people with tinnitus connect electronically, as is seen with the increasing UK specific online tinnitus forums. Guided Internet interventions are more effective and have higher compliance rates, than information-only interventions (see Baumeister et al., 2014 for a systematic review). Incorporating a secure messaging system was therefore considered an essential element of this intervention to enable therapeutic interactions.

2.2.5. User-friendly

Andersson et al. (2009) found that user-friendly Internet interventions have a higher chance of success. Minimising technological barriers to treatment access was considered imperative. Moreover, ensuring that information was clear, straightforward to read, and all features were easily accessible was a priority. This would increase the application of the intervention to a wider range of demographical groups that experience tinnitus.

2.2.6. Appearance

As those with tinnitus often have co-morbidities such as anxiety, it was considered important to organise the layout and colour scheme to produce a calming effect on users. Further aspirations were to select an attractive and visually stimulating appearance whilst ensuring that information presentation did not overwhelm participants.

2.2.7. Facilitating participation

A key component to behavioural change is enabling patients to be actively involved in their own treatment, which in turn facilitates patients deriving more benefit from the treatment (James, 2013). Encouraging active involvement by supporting engagement with the intervention, both when reading the materials and in practising the techniques, was essential.

2.2.8. Tailoring

Due to the heterogeneous nature of tinnitus, a tailored intervention which has the flexibility to address an individual's unique needs and preferences in a patient-centred approach (Kreuter et al., 1999) is more suitable than a purely standardised intervention. Tailored interventions have demonstrated increased benefits compared to non-tailored interventions in promoting various behavioural changes such as targeting physical activity, dietary behaviours and promoting undertaking screening (Kroeze et al., 2006; Richards et al., 2007; Sohl and Moyer, 2007). Following positive outcomes of previous tailored interventions, tailoring aspects such as personal treatment goals, receiving individualised weekly feedback and inclusion of both optional and obligatory modules were also incorporated into subsequent revisions of the original iCBT intervention for tinnitus to improve outcomes and attrition rates (Kaldo et al., 2007).

2.3. Technical functionality testing of the intervention

2.3.1. Research design

An independent-measures research design was used to evaluate the developed intervention in terms of suitability, content, usability, presentation, and exercises provided. To ensure that the intervention was of a high standard and appropriate to those with tinnitus, two groups, namely an expert reviewers group and group of adults with tinnitus were involved in the evaluation of the intervention. Initially the intervention was evaluated by the expert reviewers and refined prior to evaluation by adults with tinnitus group. Both professionals and the general public were thus involved in the intervention from the outset. Participants were provided login information and full access to the intervention, including the quizzes and worksheets. The purpose of the evaluation was explained and participants had a two-month period to complete the intervention evaluation.

2.3.2. Participants

2.3.2.1. Expert reviewers group. Ten experts with an established background in tinnitus management from both a clinical perspective and supportive background were individually selected and invited to evaluate the intervention. Eight clinical professionals treating tinnitus patients in National Health Care Hospitals in the East of England, namely Specialised Audiologists and Hearing Rehabilitationists were approached, as involving practitioners enables translation of practice to research (Glasgow et al., 1999). Two committee members from an established tinnitus patient support group based in the East of England were also invited to obtain a varied level of expertise.

The iCBT intervention evaluation questionnaire was completed by five expert reviewers, consisting of two Specialised Audiologists, one Hearing Rehabilitationist and two members of the tinnitus support group (2 males, 3 females). This yielded a 50% response rate, which is low, but reflects the heavy workload that clinicians experience.

2.3.2.2. Adults with tinnitus group. To ensure that those with varying levels of tinnitus distress evaluated the iCBT, the study was advertised UK-wide at tinnitus support groups, hearing and tinnitus charities and forums and in Audiology Departments. Those with troublesome tinnitus lasting for at least a three month period that has caused significant levels of distress were invited to register for the study on the study website (www.tacklingtinnitus.co.uk version 2).

Participants' eligibility for the study was as follows:

Inclusion criteria:

- Adults, aged 18 years and over, living in the UK, with the ability to read and type in English
- Access to a computer, the Internet and the ability to email
- Experiencing significant levels of tinnitus distress for a period of at least three months
- Tinnitus severity score indicating the need for tinnitus care (26 or above on the Tinnitus Functional Index (TFI; Meikle et al., 2012)). Permission was obtained to use the questionnaire and it was delivered online.

Exclusion criteria:

- Reporting any major medical or psychiatric conditions which would make partaking in the study difficult
- Reporting pulsatile, objective or unilateral tinnitus, which have not been investigated medically or tinnitus still under medical investigation
- Tinnitus as a consequence of a medical disorder
- Currently undergoing any tinnitus therapy

There were 44 adults with tinnitus who registered for the study. Of those who registered, 37 completed the screening questionnaire and were invited to participate. There were 29 adults who completed the iCBT intervention evaluation questionnaire, leading to a response rate of 65.9% of those who initially registered. Group characteristics are shown in Table 1. The group was equally matched for gender (14 males, 15 females) and there was a wide age range (18 to 80 years) with the majority being between 40 and 80 years old. There were no exclusions, as everyone fulfilled the inclusion criteria. The average tinnitus severity score was 58 out of 100 ($SD = 18.08$), indicating a severe level of tinnitus within this group. The majority of participants had tinnitus for between 1 and 5 years (45%), although tinnitus duration varied greatly between 3 months to more than 10 years. There were 72% participants who reported a co-existing hearing loss. This group was consequently familiar with the challenges that the typical combination of both hearing loss and tinnitus presents. They were well read and around half of the group had underwent previous tinnitus treatments. This group, therefore, had the appropriate background characteristics to evaluate the intervention. Suggestions made by the expert reviewers were incorporated prior to the adults with tinnitus evaluating the intervention. This included simplifying the login process and vocabulary used, including more questions in the frequently asked questions sections at the end of each module and adding subtitles to the videos.

2.3.3. Outcome measure

The programme evaluation instrument was an anonymous satisfaction questionnaire presented online. Although standardised satisfaction questionnaires, such as the Client Satisfaction Questionnaire (Attkisson and Zwick, 1982) were considered, their use for this specific

Table 1
Demographic characteristics of the adults with tinnitus group.

Demographical information	Number (%)
Gender	Male: 14 (48.3%) Female: 15 (51.7%)
Age ranges	18–29 years: 1 (3.4%) 30–39 years: 0 (0%) 40–49 years: 8 (27.6%) 50–59 years: 4 (13.8%) 60–69 years: 12 (41.4%) 70–79 years: 3 (10.3%) 80 years: 1 (3.4%)
Highest educational level	School: 6 (20.7%) College/vocational training: 8 (27.6%) Undergraduate degree: 12 (41.4%) Postgraduate degree: 3 (10.3%)
Employment	Manager/professional: 9 (31.0%) Skilled tradesman/technical: 4 (13.8%) Homemaker/service occupation: 2 (6.9%) Retired: 12 (41.4%) Unemployed: 2 (6.9%)
Tinnitus Functional Index average	58.1 out of 100 ($SD 18.08$)
Tinnitus duration	3–12 months: 2 (6.9%) 1–5 years: 13 (44.8%) 5–10 years: 5 (17.2%) More than 10 years: 9 (31.0%)
Location of tinnitus	Both ears: 15 (51.7%) Right ear: 3 (10.3%) Left ear: 6 (20.7%) Head/unsure: 5 (17.2%)
How often tinnitus is heard	All of the time: 17 (58.6%) Most of the time: 11 (37.9%) Without hearing aids: 1 (3.4%)
Tinnitus characteristics	High pitched: 13 (44.8%) Low pitched: 6 (20.7%) Pulsating: 6 (20.7%) Clicking: 4 (13.8%)
Seen a GP/ENT regarding tinnitus	28 (96.6%)
Hearing loss reported	21 (72.4%)
Hearing aids used	10 (34.5%)
Previous tinnitus treatments received	14 (48.3%)
Read up about tinnitus	27 (93.1%)

intervention was inappropriate. A satisfaction outcome measure was consequently designed to consider the suitability, content, usability, presentation and exercises on the platform. The questionnaire consisted of 15 five-point Likert-type scaled questions. The scale was from low to high, with “1” representing strongly disagree and “5” representing strongly agree. Four additional open-ended questions were posed regarding what the best aspects of the intervention were, how much time was spent on each module, what required attention and any suggestions for further development.

2.4. Data analysis

The Statistical Package for Social Sciences (SPSS) version 23.0 was used for statistical analysis. Descriptive statistics were used to evaluate the sample characteristics. Independent sample t-tests were used to compare usability evaluation of expert reviewers and participants. A p -value of <0.05 was considered statistically significant. Levene's test for Equality of variances was performed to determine the variances in the two groups.

3. Results

3.1. The developed iCBT intervention

This iCBT intervention for tinnitus was developed in-house, at the Department of Behavioural Sciences and Learning at Linköping University, Sweden. This system complies with a high level of data security, to protect user privacy and confidentiality (Vlaescu et al., 2015). The design is furthermore responsive to various mobile devices in order to assure a similar experience to all users on all platforms.

All the principles aimed for have been incorporated, as described below.

3.1.1. Evidence-based content

CBT principles form the evidence-base for the intervention, as these have the most evidence of effectiveness in minimising the effects of tinnitus (Hesser et al., 2011). The CBT self-help programme, designed by Kaldo et al. (2007), specifically for tinnitus was selected, due to its strong theoretical base. The programme combines a cognitive rationale (Henry and Wilson, 2001) and a learning theory approach (Hallam et al., 1984). Audiological principles found from clinical experience and research to be effective for tinnitus (e.g. Jastreboff, 2007), such as sound enrichment, hearing tactics and advice for sound sensitivity, furthermore informed the theoretical base. Various resources were used to ensure that the content was accurate and tailored to those with tinnitus.

3.1.2. Comprehensiveness

The iCBT was designed to incorporate pre-treatment, treatment and assessment components all on the same website, as shown in Fig. 1. Pre-treatment information was available for anyone to read. Treatment and assessment components were secured, requiring users to login. The intervention covers a broad and comprehensive spectrum, consisting of 21 modules, following the version developed by Kaldo et al. (2007). There were fifteen CBT modules, of which six focused on relaxation. In addition, there were three modules based on audiological principles and three targeting aspects of daily life. A progressive relaxation programme, together with techniques such as positive imagery, was included to deal with the physical aspects of tinnitus and promote behavioural change. To target the emotional aspects of tinnitus and transform unhelpful thought patterns, CBT principles such as cognitive restructuring, exposure and reinterpretation were included. Individual modules were organised into a clear structure, including an overview, explanation and rational, step-by-step instructions and further help section, covering possible difficulties that may have been experienced.

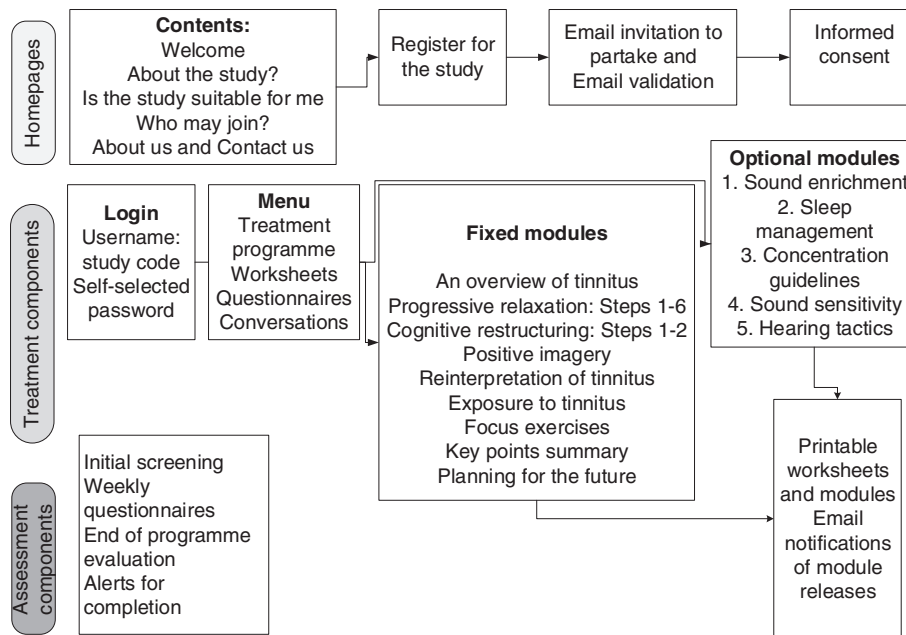


Fig. 1. Outline of the components used for iCBT for tinnitus.

3.1.3. Interactive approach

A variety of learning methods were combined into the intervention e.g. supporting text with images and diagrams. Thirteen videos were included, either demonstrating techniques or providing expert opinions and explanations. There were 15 quizzes asking questions such as 'how many people do you think have tinnitus, select A, B, C or D'. There were also 50 worksheets with questions to think about such as 'how do you view your tinnitus?'

3.1.4. Guided support

A secure encrypted messaging system was incorporated to enable an assigned therapist and participants to freely communicate. Participants could ask questions about the techniques or difficulties they were experiencing and the clinician provided further advice, support, motivation, feedback and encouragement as required. Providing a guided Internet-support system further differentiated this programme from any information only programmes.

3.1.5. User-friendly

The content was generally presented using bullet points to keep it simple and clear.

The first module included navigation instructions to explain the site layout e.g. what to find under the menu icon. An option to print and download information was also incorporated to provide off-line use of the programme. Information provided was proof read, and Fletcher reading ease scores and Flesch-Kincaid grade level ensured that high levels of reading ability were not required (between 60–70 and 7 respectively).

3.1.6. Appearance

The website appearance was carefully designed to ensure that it did not appear cluttered and had a calming effect. The background was white for ease of reading with a theme colour of blue, due to the calming effect thereof. Attractive and visually stimulating diagrams and pictures were selected to enhance the appearance of the intervention. An example is given in Fig. 2.

3.1.7. Facilitating participation

Facilitating active involvement in the intervention was enabled by including worksheets which acted as diaries. Participants noted the effectiveness of the techniques used and could review these worksheets to look at their progress over time. The assigned therapist could view these diaries and provide feedback accordingly. Assessment components were included to encourage reflection on progress and to promote behavioural change.

3.1.8. Tailoring

In line with the version of the iCBT programme developed by Kaldo et al. (2007), a tailoring procedure was incorporated. Sixteen modules were recommended for all users, together with five optional modules. The optional modules addressed life areas that may be affected due to tinnitus, for certain individuals. These included strategies for sleep management, hearing tactics, concentration management, sound sensitivity and the use of sound enrichment. In addition participants could define their own treatment goals and would receive individualised feedback on work done or on a weekly basis.

This development was not without difficulties, and some alternative ways of delivering this material were experimented with before the final version was established. The usability of the worksheets, quizzes, and diaries was taken into consideration across various client browsers whilst maintaining ease of navigation inside the modules.

3.2. Technical functionality testing

3.2.1. Participant engagement

The expert group and the adults with tinnitus group engaged with all aspects of the programme as seen in Table 2, indicating that the intervention underwent sufficient usability testing.

3.2.2. Difficulties encountered

To allow an initial login to the website, login information was sent via participants' e-mail addresses. Some of the emails sent from the platform did not reach recipients with certain email accounts. Tactics were put in place to counter this. This included changing the programme name from Conquering Tinnitus to Tackling Tinnitus, as this change of wording was potentially less likely to be analysed as spam

1. Where to practise deep relaxation

Select somewhere peaceful where you will not be disturbed. Places may include:

- Your bedroom
- The living room
- The kitchen
- The study
- Your garden



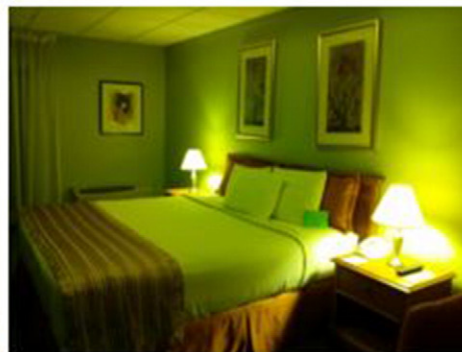
2. When

You will require two opportunities each day this week to relax for 10-15 minutes.

Ensure you select times when your phone can be switched off and you will not be disturbed.

Some ideas are:

- After meals
- Before going to bed
- When waking up
- During your lunch break
- After work



3. Requirements

Initially you are going to learn this relaxation technique while sitting on a chair

Select the chair using the following guidelines:

Fig. 2. Example of the developed intervention.

Table 2
Expert and adults with tinnitus' engagement in the intervention.

	Expert group (n = 5) Total (per reviewer)	Adults with tinnitus (n = 29) Total (per participant)
Logins	24 (M = 4.8)	572 (M = 19.7)
Modules read	90 (M = 18)	475 (M = 14.8)
Worksheets completed	23 (M = 4.6)	1184 (M = 40.8)
Messages sent	8 (M = 1.6)	119 (M = 4.1)

by email systems. In addition, the initial login requiring a high-security password was difficult for some users, despite onscreen instructions.

3.3. Satisfaction evaluations

The expert reviewers and adults with tinnitus completed online evaluations using a five point Likert scale to evaluate the intervention for suitability, content, usability, presentation, and exercises, as seen in Fig. 3. Mean comparison scores are shown in Table 3. Overall, the intervention was highly rated, with an average score of 4.31 (SD = 0.75) out of 5 (range 3 to 5) as seen in Fig. 3. The rating for each question is shown in Fig. 4, indicating comparative ratings between the two user groups. The areas with the lowest rating were those associated with the worksheets provided.

On average expert reviewers' and adults with tinnitus' ratings for the different questions asked were not significantly different, as seen in Table 3. The overall expert reviews mean rating for iCBT was 4.45 (SD = 0.33), and the overall the tinnitus user participant rating was 4.29 (SD = 0.28). The only significant difference found was for how informative the materials were, which the expert reviewers rated significantly higher than the participant group.

3.3.1. Suggestions made by the expert reviewers group

One aspect commented on by the experts was simplifying the vocabulary, by replacing words such as internalised and diminish. Furthermore, they suggested additional questions for the frequently asked questions sections and recommended adding subtitles to the videos. These suggestions were implemented prior to the adults with tinnitus evaluating the intervention.

3.3.2. Suggestions made by the adults with tinnitus

The participants remarked that the weekly questionnaire options of 'yes, sometimes, no' were too general, and a questionnaire with more defined options would be preferred. In addition, they found that the screening questionnaire categories were too broad, for example, instead of the options for duration of tinnitus, participants would have preferred

open-ended questions. A further suggestion was to personalise messages, instead of anonymising these.

4. Discussion

In this paper, the development and technical functionality evaluations of an Internet-based intervention for tinnitus as adapted for a UK population are described. This intervention was tested for usability and evaluated to refine it prior to implementation in clinical trials.

4.1. Development of iCBT for tinnitus

An iCBT intervention was developed following guidance on the development of complex interventions (Craig et al., 2008). Important theoretical principles have been incorporated into every aspect of the intervention. The strength of the design is the multi-disciplinary collaboration at each phase of development. The final version is comprehensive, attractive, easy to navigate and interactive. A high level of adaptability has been incorporated into the design to ensure that it can be revised and altered if further refinements are required. As experiences of tinnitus are heterogeneous, the intervention is tailored, enabling participants to select optional modules that would be of benefit. The intervention has been designed to enable users to engage with the content visually. This can reinforce information retention, which is known to be poor for information obtained during clinical appointments (Doherty and Desjardins, 2012). As evidence suggests that some form of minimal therapeutic support is required for Internet-interventions to work (Baumeister et al., 2014), a secure encrypted communications messaging system is utilised.

4.2. Technical functionality of iCBT for tinnitus

The developed iCBT intervention was thoroughly tested by both expert reviewers and adults with significant tinnitus. Some initial technical difficulties were experienced as a few e-mails sent from the web platform were not accepted by certain e-mail accounts. Changes were required to ensure the smooth running of the intervention. Some users found the initial login difficult and needed assistance from the therapist. Often the on-screen instructions regarding the password requirements were not followed and participants did not always use their study user name to login. As login was challenging for some, this has been simplified as much as possible, without compromising security. It does appear as though there were more technical difficulties when compared to similar populations in Europe. Cultural differences for computer literacy, where previously evaluated, have been found to be variable (Pflug, 2011). Ensuring that clear instructions with initial

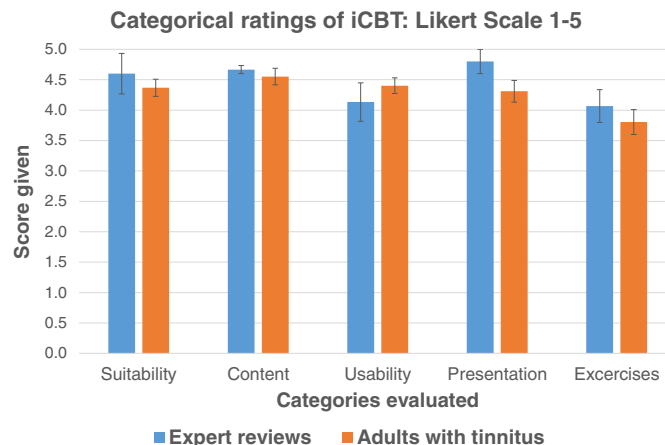


Fig. 3. Comparisons of the programme evaluation by the expert reviewers and adults with tinnitus for the main categories evaluated.

Table 3
Mean intervention ratings by the expert reviewers and the adults with tinnitus.

Category	Expert reviewers Mean (SD)	User participants Mean (SD)	Mean difference (95% CI)	t-test (statistical significance indicated by *)
<i>Usability</i>				
Straightforward to use	4.80 (0.45)	4.38 (0.78)	0.42 (−0.98 to 0.14)	$t(8.88) = -1.71; p = 0.122$
Easy to navigate	4.60 (0.89)	4.38 (0.73)	0.22 (−0.96 to 0.52)	$t(32) = -0.61; p = 0.548$
Appropriate module length	4.40 (0.89)	4.35 (0.77)	0.06 (−0.83 to 0.72)	$t(32) = -0.15; p = 0.886$
<i>Content</i>				
Suitable level of information	4.20 (0.84)	4.45 (0.78)	0.2483 (−0.53 to 1.03)	$t(32) = 0.649; p = 0.521$
Informative materials	5 (0.00)	4.57 (0.73)	0.41 (−0.69 to −0.14)	$t(28) = -3.04; p = 0.005^*$
Interesting materials	4.8 (0.45)	4.62 (0.68)	0.18 (−0.82 to 0.46)	$t(32) = -0.57; p = 0.570$
<i>Presentation</i>				
Content was well-structured	4.20 (0.84)	4.24 (0.79)	-0.04 (−0.74 to 0.82)	$t(32) = 0.11; p = 0.915$
Suitable presentation	4.2 (0.84)	4.35 (0.72)	-0.14 (−0.58 to 0.87)	$t(32) = 0.41; p = 0.687$
Easy to read	4.00 (1.00)	4.62 (0.56)	0.62 (−0.62 to 1.85)	$t(4.45) = 1.35; p = 0.241$
<i>Suitability</i>				
Suitable for those with tinnitus	4.80 (0.45)	4.28 (1.03)	0.52 (−1.12 to 0.07)	$t(13.13) = -1.89; p = 0.814$
Appropriate range of modules	4.80 (0.45)	4.38 (0.45)	0.42 (−0.98 to 0.14)	$t(9.52) = -1.67; p = 0.127$
Beneficial topics covered	4.80 (0.45)	4.28 (1.03)	0.52 (−1.12 to 0.07)	$t(13.13) = -1.89; p = 0.815$
<i>Exercises</i>				
Worksheets appropriateness	4.60 (0.55)	3.0 (1.08)	0.70 (−1.72 to 0.31)	$t(32) = -1.41; p = 0.168$
Clear instructions how to practice	4.00 (0.71)	4.14 (0.95)	0.14 (−0.78 to 1.05)	$t(32) = 0.31; p = 0.764$
Motivation to do the exercises	3.60 (0.55)	3.38 (1.27)	-0.22 (−1.40 to 0.96)	$t(32) = -0.38; p = 0.706$

login and navigation are thus of importance and should be provided prior to providing login details in further clinical trials.

4.3. Evaluation of iCBT for tinnitus

Five expert reviewers and 29 adults with tinnitus evaluated the intervention in terms of suitability, content, usability, presentation and exercises provided. On average, the intervention was well rated. Ratings between expert reviewers and adults with tinnitus were also not significantly different except for one subsection, namely how informative the materials were. Although both ratings were high, expert reviewers rated the intervention as significantly more informative than the adults with tinnitus did. This may be related to participants in the tinnitus user group being well read about tinnitus overall, and that around half had undergone previous tinnitus therapies. Prior knowledge probably contributed to not all the information presented being new.

The area in the intervention most poorly rated was that surrounding motivation to complete the worksheets. The worksheets were revised

to ensure that they are user-friendly. A shortcut to accessing the worksheets from the main menu was installed to enable participants to navigate more readily. Therapeutic encouragement during further trials would be important to increase motivation for completing the worksheets. Active involvement by completing the worksheets needs to be encouraged, as this is likely to lead to improved behavioural change (James, 2013).

4.4. Revising the intervention

Suggestions from the adults with tinnitus were implemented where possible into a revised version 3 of the programme: Tackling Tinnitus, January 2016. These included asking participants for their names so that personalised messages could be sent during correspondence. The vocabulary was simplified and subtitles were added to the videos. Additional frequently asked questions were added. The screening questionnaire was also adjusted to yield more specific results by having open responses for certain categories such as age and duration of tinnitus.

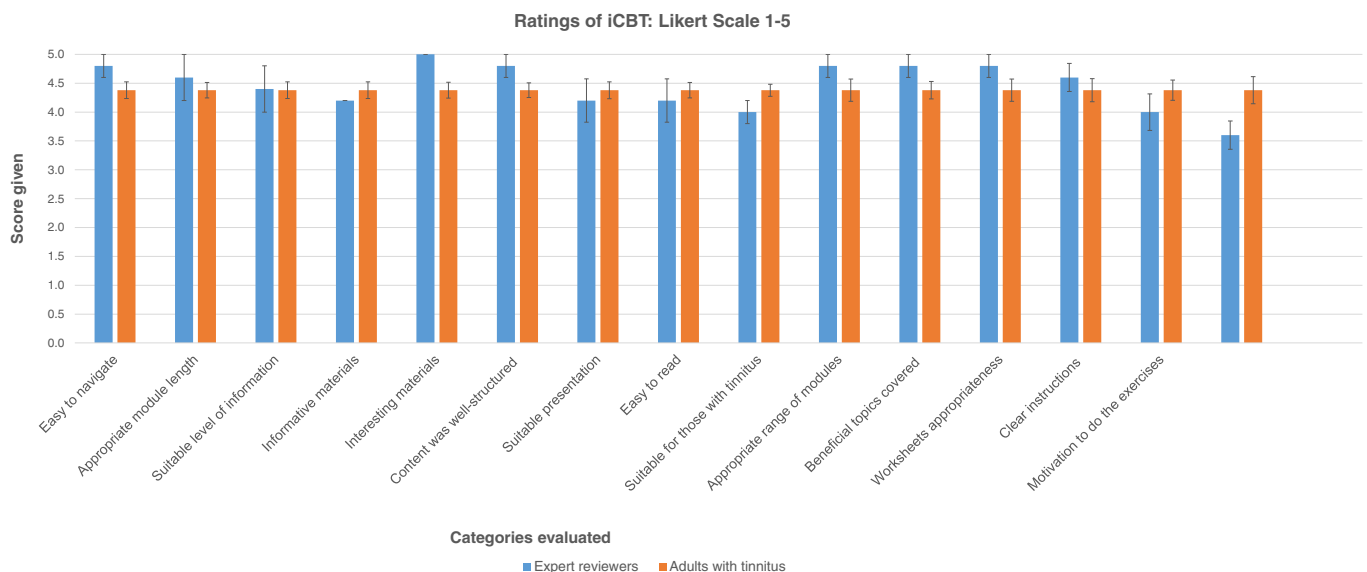


Fig. 4. Comparisons of the programme evaluation by the expert reviewers and the adults with tinnitus for the different subcategories evaluated.

Although the weekly questionnaire was not found to be specific enough, investigations indicated that it still remained the best option as alternative options were less specific or too long for a repetitive measure.

4.5. Study limitations

The sample size from the expert reviewers group could have been higher. Comparable ratings between the evaluations, however, suggest that sample size was sufficient. A standardised satisfaction outcome measure was not used, as one was not identified that was specific enough. Although this is a drawback, the designed outcome measure was very specific to this particular intervention.

5. Conclusions

A phased approach was undertaken in the development of iCBT for a UK population, following MRC guidance (Craig et al., 2008). The intervention is based on a sound theoretical base. Technical functionality testing identified problems which have been corrected in the revised version. Rigorous evaluations by both expert reviewers and adults with tinnitus showed high satisfaction regarding the content, suitability, presentation, usability and exercises provided in the intervention. These evaluations have provided confidence that the intervention is ready to be used and a protocol has been published to do so in a randomised control trial (Beukes et al., 2015).

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Author's contributions

GA, VM, DB and PA conceived this study. GA and VK developed the Swedish original iCBT intervention for tinnitus, EB developed this version for a UK population and GV was the web designer for the project. EB carried out the study, collected the data and drafted the manuscript. All authors critically revised and approved the manuscript.

Conflict of interest

None declared.

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