**Understanding user reactions and interactions with an Internet-based intervention for tinnitus self-management: Mixed-methods evaluation**

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Running Head: Evaluation of an internet intervention tinnitus

# Abstract

**Purpose:** Internet-based interventions have the potential to reduce the disparity in access to psychological therapy that people with tinnitus currently experience. One example is the Tinnitus E-Programme, which although freely available online, has not yet been formally evaluated. The purpose of this study was to evaluate past, current, and new users’ reactions and interactions with the Tinnitus E-Programme.

**Method:** Study 1 used an online survey to gather past and current users’ reactions to, and interactions with, the intervention (*n*=27). Study 2 used interviews and a relaxation log to assess how new users implemented the skills they learned into their everyday lives (*n*=13).

**Results:** Generally, users expressed positive views of the intervention content and design features. Users particularly valued the education about tinnitus and its management, and relaxation skills training, and use of these components was high. In contrast, user reactions to self-monitoring tools, an online support forum, and therapist support were mixed, and use was lower. Implementation was limited by instances of poor usability and accessibility, user engagement, and adherence to relaxation goals. Users’ perceptions of the interventions credibility and relevance, and beliefs regarding a negative impact on their tinnitus influenced engagement. Users in both studies identified several benefits gained, including functional and emotional management; self-efficacy for managing and coping with tinnitus; understanding tinnitus and its management; social support; and acceptance of tinnitus.

**Conclusions:** Findings suggest that the intervention was acceptable to its target group but also highlighted some areas for improvement. These findings will be used to inform further optimization work.

**Keywords:** tinnitus; internet interventions; acceptability; self-help; mixed methods.

**Word count:** 9859

# Introduction

Tinnitus is defined as conscious perception of a sound without any corresponding external stimulus. Prevalence estimates range from 12-30% of the adult population (McCormack, Edmondson-Jones, Somerset, & Hall, 2016) and prevalence in people with hearing loss is as high as 70-85% (Axelsson & Ringdahl, 1989; Davis & El Refaie, 2000; Meikle & Taylor-Walsh, 1984). About 20% of people with tinnitus experience symptoms that negatively affect their quality of life and require clinical intervention. Symptoms include sleep disturbances, hearing difficulties, difficulties with concentration, social isolation, and emotional difficulties such as anxiety, depression, irritation, or stress (Davis & El Refaie, 2000). There is currently no effective treatment for tinnitus; therefore, various management strategies are applied. They focus mainly on reduction of tinnitus percept with sound therapy, and/or reduction of negative emotional reaction to tinnitus with cognitive behavior therapy (CBT) or counselling. Currently, access to psychological therapies is reserved for those with the greatest need (Gander, Hoare, Collins, Smith, & Hall, 2011; Hoare, Gander, Collins, Smith, & Hall, 2012; Nyenhuis, Golm, & Kröner-Herwig, 2013).

Self-help interventions, delivered via the internet or books, have the potential to improve access to self-management and psychological therapy for people with tinnitus. Trials evaluating the impact of these interventions on reducing tinnitus distress and depression in this group have shown promising findings (Greenwell, Sereda, Coulson, El Refaie, & Hoare, 2016; Nyenhuis et al., 2013). In the UK, two internet-based interventions for tinnitus have been developed. This article focuses on the Tinnitus E-Programme, which was developed by a hearing therapist/psychotherapist and made freely available online in 2009[[1]](#footnote-1). It aimed to support tinnitus self-management through education about tinnitus and psychological support (relaxation and brief cognitive restructuring skills training) (Greenwell, Featherstone, & Hoare, 2015). Hearing professionals in the UK were aware of the intervention and referred patients to it (Smith et al., 2018). One advantage of this intervention was that it was primarily self-guided, meaning it could be delivered at scale with minimal resource use and was suitable for delivery in a primary care setting. In the UK, although many tinnitus patients are referred to audiological services, only a third are referred to therapeutic interventions and many are discharged, or return, to primary care (McFerran, Hoare, Carr, Ray, & Stockdale, 2018).

A preliminary within-groups evaluation with 23 users carried out by the intervention developer demonstrated that the intervention led to reductions in tinnitus distress (as measured using the Tinnitus Handicap Inventory (THI; Newman, Jacobson, & Spitzer, 1996)). Eighty seven percent of users achieved reductions of at least one severity category and 52% moved more than one category (‘Severe’ to ‘Mild’ or ‘Moderate’ to ‘No tinnitus distress’) (Featherstone, 2012). At the time of study, the intervention had reasonably high usage (the website was visited by approximately 1600 people per month; Vistaprint estimate). Although this preliminary data provides proof of concept, the intervention had not yet undergone any formal or independent evaluation.

More recently, a guided (using audiological support) internet-based CBT intervention for tinnitus has been developed and evaluated. A recent randomized controlled trial demonstrated that participation in the intervention led to significantly greater improvements in tinnitus distress, comorbidities, and quality of life, when compared to a weekly monitoring control group (Beukes, Baguley, Allen, Manchaiah, & Andersson, 2018). One limitation of this intervention is that it is relatively resource-intensive, requiring input from trained audiologists of at least 10 minutes per participant per week.

The Medical Research Council guidance on developing and evaluating complex interventions (Craig et al., 2008) recommends carrying out adequate development and piloting work prior to a definitive randomized controlled trial. Without this, interventions are likely to be weaker and difficult to evaluate (Craig et al., 2008). When evaluating interventions, a useful first step is to test the intervention on small samples for feasibility and acceptability among target users (O’Cathain et al., 2019). The person-based approach to intervention development emphasizes the importance of using iterative in-depth qualitative research to understand and accommodate the views of the target group who will use the intervention (Yardley, Morrison, Bradbury, & Muller, 2015). Moreover, qualitative methods can be helpful for exploring relatively unknown mechanisms of impact and unanticipated intervention outcomes (Grant, Treweek, Dreischulte, Foy, & Guthrie, 2013).

Previous exploratory evaluations of similar interventions (Beukes, Manchaiah, Baguley, Allen, & Andersson, 2018; Beukes, Manchaiah, Davies, et al., 2018) have solely recruited people who are using the intervention as part of a research study, ﻿which reduces the findings’ external validity and relevance to real-world practice (Bennett & Glasgow, 2009; Glasgow, 2007; Glasgow, Lichtenstein, & Marcus, 2003). This study explored the perspectives of two different populations: new users who used the Tinnitus-Eprogramme for the purposes of this research; and past and current users who used the intervention for their own purposes outside of a research context.

## Aims and objectives

Development of the study aims and objectives was guided by the Medical Research Council’s guidance on evaluation of complex interventions (Moore et al., 2014). The aim of this study was to explore past, current, and new users’ reactions to and interactions with the Tinnitus E-Programme. Specifically, we aimed to gain a better understanding of potential outcomes of the intervention and processes by which these were achieved, and identify any implementation (i.e. what is delivered in practice) or contextual (or pre-existing external) factors that may strengthen or impede its delivery and functioning.

The study objectives were to understand:

1. The acceptability and usability of the intervention;
2. How users engage with the intervention;
3. Users’ perceptions of the processes and outcomes of the intervention; and
4. User enactment of the relaxation skills learned in the intervention.

In line with a person-based approach, the findings of this research will be used to further optimize the acceptability and feasibility of the intervention (Yardley et al., 2015), thus maximizing its chances for success in a definitive outcomes evaluation (O’Cathain et al., 2019).

# Methods

## The Intervention

The Tinnitus E-Programme is a ten-week Internet-based self-management intervention for tinnitus (Greenwell et al., 2015). The intervention is free to access without registration. The self-management components (Taylor et al., 2014) of the intervention are: (1) downloadable information resources to provide education about tinnitus and its management; (2) training/rehearsal for psychological strategies, including relaxation and brief cognitive restructuring skills training; (3) online discussion forum to provide social support from peers and lay and professional moderators; (4) self-monitoring of tinnitus distress using the THI; and (5) information about available resources, including book references and hyperlinks to other websites or services.

Information resources cover the mechanisms of tinnitus, stress and its management, attention focus, and negative thinking. Several behavior change techniques are used to promote relaxation behavior (e.g. goal setting, behavioral practice/rehearsal). Intervention content is delivered over six weekly sessions, followed by a four-week maintenance period where participants continue with the set daily relaxation goals. A recommended intervention structure is given; however, users have free choice regarding which components they access and in what order they access them. Table 1 outlines this weekly structure and the content provided in each week.

\*\*\*INSERT TABLE 1 ABOUT HERE\*\*\*

The intervention was primarily self-guided, but an intervention email address was provided so users could email the therapist if they wished. Users were encouraged to email their completed THI to the intervention therapist at the beginning and end of the ten weeks, but this was not mandatory, and users were not given feedback on their THI results. No other instructions on when to contact the therapist and topics to contact them about were given. The online discussion forum was moderated by health professionals (hearing therapists, audiologists) and lay people with tinnitus. Moderators provided forum users with information and emotional support where appropriate. The intervention content is described in detail in Greenwell et al. (2015).

## Overarching Design

The protocol for this research (Greenwell, Sereda, Coulson, & Hoare, 2016) is summarized here. Two parallel mixed-methods studies were carried out with two different populations. This design allowed triangulation of research data and methods to generate and compare complementary perspectives and contexts. The intention was to use both qualitative and quantitative research methods and more than one study population to provide a more complete, in-depth, and valid understanding of the phenomenon than if only one method or population was used (Creswell & Plano Clark, 2011; Torrance, 2012). A diagrammatical representation of the overall study design can be found in Appendix 1. This study was approved by the University of Nottingham Research Ethics Committee (Reference Number: Q11122014 SoM NIHR RHA QEST) and was sponsored by the University of Nottingham.

## Participants

The inclusion criteria for both studies were: (1) adults aged 18 years and over, (2) ability to read English, and (3) access and ability to use the Internet.

## Study 1: Online Survey with Current and Past Users

### Design

A data-validation variant of a convergent parallel mixed methods design was adopted (Creswell & Plano Clark, 2011). Open (i.e. qualitative) and closed (i.e. quantitative) questions were used in the online survey, and then the qualitative data used to validate and elaborate on the quantitative data. The online survey is reported according to the CHERRIES checklist (Eysenbach, 2004).

### Recruitment

In addition to the inclusion criteria outlined in the participants section, participants in this study were also required to have visited the Tinnitus E-Programme website or used the intervention. Using convenience sampling, past and current intervention users were invited to take part in an online survey hosted on SurveyMonkey©. Advertisements were posted on the Tinnitus E-Programme website and online support forum, and via social media and the British Tinnitus Association. Advertisements included a direct link to the survey or a dedicated page on the Tinnitus E-Programme website. All participants were given a participant information sheet that detailed the purpose of the study, the length of time required to complete the survey, who the investigator and the research team were, and which data were stored, where, and for how long. The research team sent email invitations to 97 people who had registered with the intervention website or online support forum at the time of recruitment. Twelve of these email addresses were no longer valid. Reminder emails were sent two months later to those with valid email addresses. No incentives were offered to complete the survey. The survey was launched in February 2015 and closed in June 2016, once 50 participants were recruited.

### Online Survey

The initial survey design was informed by relevant literature and the comprehensive intervention description developed previously (Greenwell et al., 2015). To maximize the acceptability and face validity of the survey, feedback was sought from a public and patient involvement (PPI) panel at a face-to-face focus group. The panel comprised 4 people with tinnitus and/or hearing loss and a voluntary sector representative from the British Tinnitus Association with experience in writing communication materials for people with tinnitus. The final online survey was also piloted with three users of the Tinnitus E-Programme. More detail on survey development and the findings of this pilot is provided in Greenwell, Sereda, Coulson, and Hoare (2016). Initially, the survey was restricted so that only one submission per computer was allowed. However, it became clear that some participants were reaching the survey before they had made the decision to engage with the intervention, which was not anticipated. The survey was subsequently modified to include a disqualifier question to identify those who have not yet used the intervention, but intended to do so in the future, and multiple submissions per computer was permitted. These participants were asked to return to the survey once they had completed the intervention and use a security word they provided at the beginning of the survey, so they could be identified as a duplicate participant on their return (See Appendix 2 for survey).

The online survey was open to anyone who accessed the publicly available survey link and anonymous (i.e. no personal data or IP addresses were collected) to encourage participation. It was voluntary for visitors of the Tinnitus E-Programme. Adaptive questioning (i.e. survey questions were conditionally displayed depending on how previous questions were answered) was used so that participants only viewed the questions that were relevant to them. Depending on their answers, participants were presented with seven to 18 screen pages of questions in the online survey. To avoid excessive page scrolling and encourage survey completion, there were one to five questions per page and questions with rating scales had no more than seven items. Participant responses were saved as they progressed through the survey so incomplete data could be accessed. Previous answers could be modified by clicking on the back button.

### Analysis

Answers to closed questions were analyzed using descriptive statistics. Users who did not provide data on their intervention usage (i.e. did not answer question 11: ‘Did you use the Tinnitus E-Programme’) or indicated that they had not used the intervention but intended to do so in the future were excluded. Answers to open questions were analyzed using inductive thematic analysis (Braun & Clarke, 2006) and QSR’s NVivo v10 qualitative data analysis software (see Greenwell, Sereda, Coulson, & Hoare (2016) for details). This integration was carried out by KG and reviewed and agreed by the co-authors.

## Study 2: Retrospective Interviews and Relaxation Log with New Users

### Design

An adapted version of an embedded mixed methods design was used (Creswell & Plano Clark, 2011) in which the data collection and analysis for the qualitative and quantitative data were embedded within an overall qualitative research design. As such, the quantitative relaxation log data played a secondary and supportive role to the qualitative data.

### Recruitment

In addition to the inclusion criteria outlined in the participants section, participants in this study were required to have self-reported tinnitus, reside in the United Kingdom, and have not previously used the Tinnitus E-Programme. A purposive sample was recruited from the department’s research database via email invitation using maximum variation sampling (Polkinghorne, 2005). After consenting, participants were sent a hyperlink to the Tinnitus E-Programme and asked to notify the researcher once they started using the intervention. Recruitment ceased once data saturation was reached for the interviews; ﻿that is, when no new themes are emerging (Patton, 1990). On study completion, participants were given a free copy of three CBT workbooks that are usually available at a cost from the Tinnitus E-Programme (i.e. not part of the free intervention).

### Interviews

Interviews were organized 6-8 weeks after participants’ start date. The interview guide (Appendix 3) was reviewed by the PPI panel and piloted with a previous user of the intervention (Greenwell, Sereda, Coulson, & Hoare, 2016). Participants were sent sample interview questions to encourage transparency with the interview process and improve recall (Coulson, 2015). Interviews were carried out by KG between April and November 2015 and lasted 26-81 minutes each. KG was not involved in the development of the Tinnitus E-Programme, but was involved in further development and evaluation work, which may have introduced biases into the interview. The audio from the interviews was recorded and transcribed and email text was saved.

### Relaxation Log

Users were set daily goals for each of two relaxation exercises. A secure online relaxation log was created for each participant. Users were required to answer:

1. Did you practice the mind calming breathing exercise three or more times today? (Goal 1)
2. Did you practice any of the 30-minute relaxation exercises today? (Goal 2)
3. Did you use any other parts of the Tinnitus E-Programme today? If yes, please write which parts. If no, please write “no.”

There was also a free-text comments box for each day. At the end of week ten, participants were asked: “Did you practice the recommended relaxation exercises every day? If not, could you tell us about some of the things that made it difficult to do so?” Participants had the option of either completing their log online or completing a paper copy.

### Analysis

The interview data and open-question responses from the relaxation logs were analyzed together using the same inductive thematic analysis strategy as in Study 1. Quantitative relaxation log data were analyzed using descriptive statistics. Results from the relaxation logs are reported alongside the qualitative themes. This integration was carried out by KG and then reviewed and agreed by three other coders.

### Overall Interpretation

The various perspectives elicited from the two studies were triangulated. For this, we followed a conceptualization of triangulation in which researchers combine different perspectives when studying a phenomenon (Flick, Garms-Homolová, Herrmann, Kuck, & Röhnsch, 2012). These perspectives may be derived from using different methods (e.g. quantitative and qualitative data), or studying several study populations (e.g. patients, professionals). In this study, we triangulated the perspectives of the two different populations experiencing the Tinnitus E-Programme (i.e. current/past real-world users, and new users and research participants), and the perspectives provided by the two different methods (i.e. qualitative and quantitative) in each study. The overall interpretation was carried out by the KG and then reviewed and agreed by co-authors. It is reported in the discussion section of this manuscript.

# Results

## Study 1: Online survey with current and past users

### Participants

Fifty people consented to the survey from which data from 27 participants (25 with tinnitus; two health professionals; Table 2) were analyzed. Of the 50 participants who consented, thirteen participants were excluded as they identified themselves as future intervention users and ten because they provided incomplete data. Four participants in the final sample did not complete the entire survey. The overall completion rate (﻿ratio of users who finished the survey/users who agreed to participate) was 62% (*n*=23).

\*\*\*INSERT TABLE 2 ABOUT HERE\*\*\*

### Quantitative findings

#### How participants used the intervention

Most participants found the intervention using a search engine (Table 3). The two health professionals found the intervention using a search engine and through another health professional. Eleven participants used the complete intervention, ten used some (including the two health professionals), one used only the forum, and six did not use the intervention. Participants with tinnitus who used ‘some’ of the intervention reported using at least some of the information leaflets and relaxation exercises. Most participants had used the THI, whereas under a half of participants had joined the forum and read posts. Half of these people had posted on the forum and most reported that they no longer use the forum. Long-term usage of the intervention was mixed, with some participants still using the intervention on a regular basis, while others reported not visiting the intervention since their initial use and did not intend to use it in the future.

\*\*\*INSERT TABLE 3 ABOUT HERE\*\*\*

#### Satisfaction with the intervention

Users reported that the intervention was easy to use and a trustworthy source of support, instructions were clear, and the intervention’s time requirement was achievable (Table 4). One third of users disagreed that the intervention website was visually attractive. Eighteen of the 20 (90%) intervention and forum users, including the two health professionals, reported that the intervention had helped them.

\*\*\*INSERT TABLE 4 ABOUT HERE\*\*\*

#### Views on self-management components

Users rated the information resources easy to understand and most reported that they were relevant to them (Table 5). Most users found the information resources, relaxation exercises and THI helpful. However, views on the online support forum were mixed. Seventy-eight percent (*n*=14) of tinnitus users (*n*=18) rated the relaxation goals as achievable.

\*\*\*INSERT TABLE 5 ABOUT HERE\*\*\*

### Qualitative findings

Four themes emerged from the data.

#### Theme 1: Acceptability of the self-management components

The qualitative data identified some negative views of the information resources. Some commented that they already knew a lot of the information, the resources were not authoritative or relevant to those with profound hearing loss and hyperacusis, or essential information about the process of habituation was lacking. The qualitative data also provided insights into some of the mixed views people held regarding the online support forum. One user expressed positive views of the forum: *“The support forum is a positive environment in which help can be provided and sufferers do not feel so alone”* (P2, forum user with tinnitus, UK). A few users (3/21) decided not to join the forum or stopped using it because they perceived the forum posts as negative or believed the forum would, or had, a negative impact on their tinnitus and emotional well-being.

I don’t use the forum now as it is mostly people who are in the acute distress who post there and I find reading such posts now increases my own tinnitus for a day or so. (P1, female user with tinnitus, Australia)

#### Theme 2: Motivations for accessing the intervention

Users with tinnitus accessed the intervention when they were either experiencing high levels of tinnitus distress or struggling to manage their tinnitus. Some users accessed the intervention to gain support in managing their tinnitus or provide support to others. Some of these users were motivated by a perceived lack of support from health professionals, long waiting lists to see those professionals, and inadequacies of the health services in their country.

In my country there is very limited help for tinnitus sufferers. There are literally no support groups, no hearing therapists, and ENT specialists have no time to dwell on a problem they do not know how to treat. (P14, female user with tinnitus, Czech Republic)

Some users accessed the intervention following a referral from a health professional or used it during, and in between, the one-to-one therapeutic sessions provided by the intervention therapist. The two health professionals described how they used the intervention to extend, or complement, the health services they provide. They used the intervention to organize the goals of their therapeutic work or, for what one user called “progressive self-management”. However, one health professional emphasized that the intervention should not be used without health professional support: “*clients reported that the programme supported the face to face clinical support but did not replace it*” (P19, female user, UK).

#### Theme 3: Factors influencing engagement with the intervention

Several facilitators to engaging with the intervention were identified. Users valued that the intervention was easy to access, was provided free of charge, and could be started immediately.

As a long term tinnitus sufferer, who has spent tons of time and money in an attempt to find a relief, I appreciate an attempt on behalf of professionals to provide FREE help and support to anyone, anywhere and at any time. (P14, female user with tinnitus, Czech Republic)

Users who had contact with the intervention therapist valued this optional therapist support and perceived the intervention as an extension of her service for those who are unable to attend face-to-face appointments: *“For those who are unable to visit her [the intervention therapist] in person, the [Tinnitus] e programme is an extension of her expertise and provides support and care in a wholly appropriate way, allowing the user to self-help in a controlled manner”* (P13, male user with tinnitus, UK).

Users generally perceived the intervention as trustworthy and appreciated that the intervention was not-for-profit, had worked for others, and delivered the important elements of professional tinnitus therapy. Users’ perceptions of credibility were further facilitated by their generally positive evaluations of the intervention developer’s expertise and experience as a therapist and the fact that the intervention had been recommended by their health professional. In contrast, lack of credibility was also a barrier, with some users identifying factors that negatively influenced their perceptions of credibility, mainly concerns that the intervention was no longer active, its *“confrontational”* style, unengaging appearance, and lack of novelty.

*Recently I have stopped directing people to the site as the first page seems a little confrontational and implies the site is so longer supported.* (P19, health professional user, UK)

*The website design was not too inviting...it looked a little unprofessional and uninteresting.* (P21, male non-user with tinnitus, Finland).

Other barriers to engagement included lack of time (especially for those in employment) and ability to practice relaxation.

#### Theme 4: Gaining benefit

As highlighted by the quantitative findings, many users reported gaining benefit from the intervention, with some claiming it to be “*absolutely essential*” and “*a lifesaver*”. Users reported reductions in the intrusiveness of tinnitus, which helped them gain control over their tinnitus and their lives: *“I stopped focusing on the noise so much. It changed my perception of it. I felt power over it. It was like I could lower the volume, even though I really can't”* (P16, user with tinnitus, UK).

Users reported that the intervention helped them to deal with the worry, distress, upset, and isolation they experience because of tinnitus. Some explained how the intervention provided hope that their tinnitus will get better, that there is help available, and that they will be able to cope with or manage their tinnitus: *“I can’t speak highly enough about how this programme helped me. It took me from upset and distressed about tinnitus to, 'okay I can cope'. It’s not a major”* (P3, female user with tinnitus, New Zealand). Relaxation exercises also helped with sleep for some users. The information resources and forum helped some to learn about tinnitus and learn potentially useful methods of tinnitus management from others.

Two users indicated that the intervention had not helped, citing poor presentation, an inability to offer any long-term relief, and lack of specificity: *“[The intervention is] too generic and not specific enough to my particular issue*” (P10, male user with tinnitus, New Zealand).

## Study 2: Retrospective interviews and relaxation log with new users

### Participants

Twenty-four people consented to take part in the study. Six participants did not start the intervention. A further five participants started but did not complete it, citing personal or family illness, increase in tinnitus severity, lack of time, or technical issues with their computer. Thirteen people completed retrospective interviews (six females and seven males). The mean age was 54 years (range 22-79 years) and all participants were White British. Nine had tinnitus for more than ten years, two for 2-5 years, and two for 6-12 months. Five interviews were carried out over the phone, three in person at the research department, three via video chat, one at a participants’ place of work, and one via email.

### Relaxation log

Nine participants submitted their relaxation log. On average, users met 46% of the daily goals for the breathing exercises and 38% for guided relaxation exercises (Table 6).

\*\*\*INSERT TABLE 6 ABOUT HERE\*\*\*

### Qualitative findings

Six themes emerged from the data.

#### Theme 1: Intervention expectations and motivations

In general, users’ expectations were in line with the intervention aim. Users expected that the intervention would lead to a reduction in tinnitus intrusiveness and they would gain relief from it. However, a minority still hoped for a difference in the sound they perceive. Other expectations included learning a new technique or ways to deal with their tinnitus, learning to relax more, and understanding why they have tinnitus and its causes. Users were aware that the intervention required a personal time commitment to engage with the intervention and its techniques. Other motivations included altruistic reasons (i.e. to help others through research), and interest and curiosity about the intervention.

#### Theme 2: Acceptability of the self-management components

*Education about tinnitus and its management:* Acceptability of this component was high, with users commenting that the information about tinnitus was informative, clear, and easy to read and understand. Users found the technical and scientific nature of the information enjoyable and interesting. A few users (2/13) explained that they already knew a lot of the information and felt that some of the information was basic or common sense. One user did not relate to the theories of tinnitus described in the intervention, disagreeing with the suggestion that one’s experience of tinnitus is influenced by how you perceive and react to it.

[The] theory that the tinnitus is perceived as a threat by the brain and therefore we concentrate on it...find this one more difficult to accept. It’s a loud noise to me, but not sure I find it as an alert-type noise, hence a threat etc. (P27, 47, had tinnitus for 10+ years, email interview)

Two users (2/13) found certain ideas, such as whispering a nonsense word to block out intrusive thoughts or worries, going to another room temporarily if you are struggling to sleep, to be impractical or unhelpful.

*Training/rehearsal for psychological strategies:* Most users had previous experience of practicing relaxation and understood its relevance for tinnitus. As such, this component was used and valued by most users. Users valued the breathing exercises, as they were brief, easy, and could be practiced anywhere and without anyone noticing. People also liked the guided relaxation exercises, but reported they were more difficult to do daily. The verbal instructions in the guided relaxation audios received mixed views, with some believing the guidance helped them to do the relaxation for longer, and others finding the voice distracting and annoying. Despite differences in time commitment and user preferences, adherence to the relaxation goals for the breathing (46%) and guided (38%) relaxation exercises was similar (Table 6). Most users felt that, although they were not always able to meet the daily relaxation goals, they were achievable and realistic. However, a minority of users (2/13) suggested reducing the duration or frequency of the relaxation goals and one user was unclear about why it was important to adhere to the 30-minute relaxation goals.

A few users (2/13) were less positive about the relaxation component of the intervention because of lack of time and patience to practice relaxation, and a belief that the relaxation was not specific to their tinnitus. P33 was “*not a great believer in relaxation therapy*” and commented that his *“lifestyle does not promote or lend itself to periods of quiet reflection/relaxation*”. He therefore did not achieve any of the relaxation goals and reported not gaining any benefit from the intervention. Some users (3/13) preferred other types of relaxation exercises or ways of relaxing such as meditation, positive imagery, playing a musical instrument, or engaging in physical activity: *“I hadn't got half an hour to sit around and listen [to the guided relaxation]...I'd rather practice the piano”* (P33, 65, had tinnitus for 10+ years).

Several users (3/13) found the brief cognitive restructuring helpful and understood the relevance of negative thinking to tinnitus. One user, who had a previous experience with CBT, perceived the negative thoughts component as limited and superficial, especially for those more distressed by their tinnitus.

*Monitoring of condition and feedback to the patient*: Some users (5/13) did not complete the THI because they were not aware of it or could not find it on the website. Some users (3/13) felt the THI was easy to complete, while others (3/13) found the rating scale, the item responses, and some of the questions difficult to use or interpret.

I tend to disagree on some of the questions...let's read one to you...“Because of your tinnitus, do you feel you have a terrible disease?” It, it isn't a disease. It is a physical problem, that's created by your brain, and it's not a disease that you can eradicate. So it's just a question I think is irrelevant. (P28, 73, had tinnitus for 10+ years)

For a few users (2/13), the scores obtained on the THI were inconsistent with how they perceived their own tinnitus severity: *“I was a bit surprised that I was only classed as moderate...I class myself as a bit worse than that”* (P24, 64, had tinnitus for 10+ years).

Users saw potential benefits of using a self-monitoring tool such as the THI, allowing them to gain feedback on their progress towards their tinnitus-related goals, and a sense of achievement and confidence that the intervention was beneficial. Users also suggested other methods of monitoring progress such as face-to-face interview, or a journal. A few users (2/13) questioned the motivations behind the THI: *“‘Am I doing this [the THI] for my benefit or for the benefit of the programme?’...It felt like it was more for [the intervention developer’s] benefit”* (P25, 40, had tinnitus for 10+ years).

*Social support:* About one third of users reported joining the forum, however none reported posting. Reasons for not using the forum included concerns about internet safety (e.g. the forum included some spam posts), doubts about the trustworthiness of the information provided in the posts, difficulty of use, and forgetting to use it. Some participants (4/13) did not like talking to other people with tinnitus because it made their tinnitus worse, they disliked talking to people they could not see, or they perceived the posts as negative.

Talking about it [tinnitus] with other people, I didn't really feel comfortable with that...because you are talking about it [tinnitus], it gets worse...I want to just be my own person and be able to deal with it on my own and not let it take control of my life. (P29, 33, had tinnitus for 2-5 years)

#### Theme 3: Acceptability of the design features

This theme described users’ views on four intervention design features.

*User autonomy:* Some users who previously attended group-based interventions explained how they preferred the self-guided approach because it was more convenient, less pressured, and meant they did not have to talk about their tinnitus with others.

I didn’t feel under any pressure...I could do it [the relaxation] when I wanted and how I wanted. (P21, 70, had tinnitus for 10+ years)

I didn't have to talk about it [tinnitus]…And that is what I preferred really. (P29, 33, had tinnitus for 2-5 years)

One user highlighted advantages and disadvantages of the lack of therapist contact.

On the one hand, by being checked up on, then it increases your likelihood of following the process and doing it properly. The downside to it is that as it feels a bit like, kind of, [the] teacher's watching you. (P25, 40, had tinnitus for 10+ years)

A few users suggested introducing contact from a therapist or automatic emails to remind them what week they are on and provide encouragement, or having a face-to-face interview with someone to explore how you are feeling about your tinnitus at the beginning and end of the intervention. Although users had an option to contact the intervention therapist, none of them reported doing so, and some did not know they could do this.

*Credibility:* Users’ perceptions of the intervention’s credibility were influenced by their perceptions of the intervention’s professional presentation and trustworthiness, and the extent to which the intervention could convince them that it would be beneficial. While some felt that the intervention’s presentation was professional, others held the opposite opinion and suggested improvements to its appearance. Some users disliked that the intervention had not been updated recently and others suggested introducing new material after the ten weeks to keep them engaged. Features that increased the intervention credibility included its institutional branding, being targeted at people with tinnitus, and the description of the intervention developer’s tinnitus expertise and altruistic motivations. It was important for users to understand the rationale and evidence-base behind the various components of the intervention, with some users feeling that that the current rationale provided was insufficient. Two users felt that the intervention was too simplistic, did not offer anything new, or did not allow them to explore their own tinnitus experience in detail: *“My first impression was, ‘Is that it?’ It didn't seem particularly profound or extensive. It was just a very bare couple of pages to read”* (P33, 65, had tinnitus for 10+ years).

*Ten-week structure:* Generally, users liked the ten week structure. Users liked the breakdown of the content into different stages, which made the intervention well-structured, manageable and methodical, gave users a sense of progression, and helped them to be disciplined in the use of the intervention. Views regarding the duration and intensity of the intervention differed, with some users preferring it was shorter or more condensed, and others feeling the timings of the content should be more spaced out.

Having a week between each one [session] didn’t seem quite as long enough to get used to whatever it was asking or to properly take it in. (P31, 22, had tinnitus for 6 months – 1 year)

Why it takes ten weeks, I've no idea. I could've done that in a week. I could've done it in a day actually. (P33, 65, had tinnitus for 10+ years)

As users were free to access intervention materials from any of the weeks, users did not necessarily follow the consecutive weekly structure. Some users liked the intervention’s flexibility and being able to use it when they wanted. Most reported that they planned to use the intervention beyond the ten weeks, and the relaxation exercises in particular.

*Online and offline use:* Users who decided to print the information or save pdfs did so because they found it easier to read and understand printed text over text on a screen, or so that they could revisit the information without being online. People who transferred the audio to CD or portable MP3 player appreciated the ability to use the guided relaxation audio in a comfortable and convenient location (e.g. lying on bed or during a walk). A few users chose to access the intervention and its materials solely online due to cost of printing or effort of downloading the materials.

#### Theme 4: Factors influencing engagement with the intervention

This theme described users’ views on the factors that discouraged or motivated them to engage with the intervention.

*Usability and accessibility:* Some participants found the intervention easy to use and follow, user-friendly, and clear, which are factors that facilitated engagement. Most users however, encountered usability issues that made the intervention confusing and difficult to navigate. These factors were barriers to engagement as they resulted in users missing out or not using some components. Parts of the interventions were not accessible for two people with more severe hearing losses, as they could not hear or understand the speech in the audio recordings. This barrier was significant enough to prevent these users from achieving their relaxation goals. Those users suggested introducing visual relaxation such as music with calming imagery, breathing exercises, or visualization relaxations.

*Perceived need:* Users’ motivation for engaging with the intervention was influenced by their perceived need, which was a facilitator to engagement. Some felt the intervention was aimed at those with more severe tinnitus and explained how they would be more likely to engage with the intervention or certain components if their tinnitus severity increased.

[The intervention is] more for people who…suffer more. (P33, 65, had tinnitus for 10+ years)

If it [tinnitus] got really bad, like worse, then I probably would join [the forum]. (P34, 40, had tinnitus for 2-5 years)

Experiencing improvement from the intervention also led one person to temporarily disengage from the intervention, believing they no longer needed to use it. Those with higher perceived levels of tinnitus distress and stress were more likely to engage with the intervention or its components: *“Yeah, I thought, ‘This [the intervention] is what I’m looking for’. Because at that time, my tinnitus was incredibly bad”* (P23, 70, had tinnitus for 10+ years). On the other hand, high tinnitus severity was also a barrier for some users who withdrew or delayed their participation in the research because their tinnitus was too severe.

*Beliefs regarding the intervention’s negative impact on tinnitus:* Some users were concerned that engaging with the intervention or its components might negatively affect their tinnitus. Specifically, these beliefs acted as a barrier for some, preventing them from engaging with the support forum, relaxation exercises, and written information: *“I’ve [heard] that the more you focus on it [tinnitus] the worse it is. So reading the [information] material to me is focusing on it too much...So I don't”* (P34, 40, had tinnitus for 2-5 years).

*External barriers:* Users also identified external barriers that prevented them from engaging with the intervention, including lack of time and illness unrelated to tinnitus.

#### Theme 5: Factors influencing enactment of relaxation skills

Availability of a comfortable and quiet environment away from interruptions and distractions facilitated users’ enactment of the relaxation exercises. Fatigue acted as both a barrier and facilitator. Some found it more difficult to practice relaxation whilst tired, whereas others were more likely to practice relaxation during this time or after a busy day as this was when their tinnitus was worst. Some users found that they would fall asleep during their relaxation. For some, this was helpful as they often had difficulties sleeping, whereas for others the interruption was frustrating and prevented them from feeling the full effects of the relaxation. Lack of time and forgetting were also barriers to engagement. Several users found the study’s relaxation log useful for prompting practice and one user set an alarm on his phone as a reminder.

#### Theme 6: Gaining benefit

Users reported that the intervention gave them the confidence and tools to manage and cope with their tinnitus. The information resources enabled users to develop a better understanding of tinnitus and its management, specifically the role of negative thoughts and stress, strategies that can help their tinnitus, and why these strategies help. Users reported that the relaxation exercises had improved their ability to relax and sleep. Participants reported feeling calmed, focused, and energized following the relaxation, which helped them deal with both their tinnitus and general life stress: *“I don't think I am as uptight...in the last six weeks. I know I can re-focus my mind by doing the breathing exercises”* (P29, 33, had tinnitus for 2-5 years).

Many users reported that the intervention reduced the intrusiveness of their tinnitus including reducing how much they have noticed their tinnitus, were bothered by it, or could tolerate it. This benefit was mainly attributed to the relaxation exercises, which provided distraction from tinnitus, masked it, or reduced how often they thought about it. Users reported how the intervention helped them to normalize and accept their tinnitus. Many found it comforting to know that there were other people with tinnitus, which made them feel less alone.

One of the things what I did find interesting reading the forum, was the amount of people what’s very similar to meself (sic)...I know I’m not on me own…it made you think that you’re more normal. (P24, 64, had tinnitus for 10+ years)

Completing the THI was helpful for gaining feedback on tinnitus severity. For some, this made them realize that their tinnitus was not as bad as they thought or provided reassurance that their tinnitus was not ‘severe’. In contrast, one person highlighted that being categorized as having ‘mild’ tinnitus may make people worry that their tinnitus may get worse in the future. One user explained how the THI questions helped to normalize her tinnitus experience.

The questions that they [the THI] asked were quite well related to how you feel when you’ve got tinnitus...it also made me think, well, I’m not the only person here that’s suffering like this. (P23, 40, had tinnitus for 10+ years)

For a minority, this normalization and acceptance process involved challenging their negative thoughts about tinnitus or adopting a more positive mind-set: “[The intervention] made me more positive rather than negative about things” (P22, 70, had tinnitus for 10+ years).

# Discussion

Overall, users in both studies expressed positive views about the intervention and its various self-management components and identified several actual or potential benefits. Users reported that the intervention was easy to use and a trustworthy source of support, the instructions were clear, and the intervention’s time requirement was achievable. However, some users felt that the presentation of the intervention website could be improved, encountered usability issues or difficulties performing certain exercises. Taken together, the findings suggest that the Tinnitus E-Programme is acceptable to its target group. However, further improvements are needed before additional evaluation work can be carried out.

Users expressed positive views about the intervention’s educational content and training in relaxation and cognitive restructuring, and usage of these components were high. These components were also rated as beneficial by users of an internet-based CBT intervention for tinnitus (Beukes, Manchaiah, Baguley, et al., 2018; Beukes, Manchaiah, Davies, et al., 2018). Although this intervention was generally well-received, some participants felt the intervention provided too much information or found the intervention content difficult to understand. Such difficulties were not reported in the current study, however, a few users believed they already knew some of the information or felt some of the information was basic or common sense.

Users in the current study perceived the THI as useful because it allowed them to gain feedback on their progress towards their tinnitus-related goals, and a sense of achievement and confidence that the intervention was beneficial. However, users encountered difficulties with its response scale, confusion over the scoring and feedback system, and difficulty interpreting some of the items. A future option is to provide more user-friendly tools that allow users to set and regularly review their own intervention goals (e.g. to learn more about tinnitus, to reduce the stress caused by tinnitus). Such tools have been used in other unguided interventions (Kaldo, Cars, Rahnert, Larsen, & Andersson, 2007). Providing persuasive information (e.g. a rationale and scientific evidence) on the value of the intervention and its components could also help convince users that the intervention will be beneficial (Yardley et al., 2015).

Across both studies, views on the online forum were mixed and usage was low among new users. Reasons for low usage were similar to those found in other evaluations of online forums, including doubts about the trustworthiness of the information provided, perceived negativity of the forum posts, concerns regarding internet safety, and negative views of the forum platform (Coulson et al., 2016; Malik & Coulson, 2008). Unique to this population, some users were concerned that participation in the forum would make their tinnitus worse by focusing on it or highlighting people’s negative tinnitus experiences. As the forum may not be relevant to all users, it may be preferable to signpost people to online or face-to-face support forums, as an optional component of the intervention. Online support forums should be active and moderated to minimize users’ negative experiences (Attard & Coulson, 2012; Smedley & Coulson, 2017).

In Study 1, users who had contacted the therapist highlighted how important this form of support was. However, in Study 2, users’ views regarding the self-guided nature of the intervention were mixed, with some users preferring the user autonomy and convenience provided by the unguided intervention. When given the choice, none of these users reported contacting the intervention therapist. Recent systematic reviews on the added value of therapist-guidance in tinnitus self-help interventions have been inconclusive (Greenwell et al., 2016; Nyenhuis et al., 2013). Future trials of internet-based interventions for tinnitus should assess the impact of therapist or audiologist support on the user engagement and intervention outcomes.

The survey showed, in addition to use of the Tinnitus E-Programme, Study 1 users had at some time used various strategies to manage their tinnitus, most commonly relaxation and seeking information about tinnitus online. Other medical and face-to-face strategies, such as sound therapy, tinnitus retraining therapy, psychological therapies, and face-to-face support groups, were used to a lesser extent. Some Study 1 users were motivated to use the intervention by a perceived lack of support from health professionals, long waiting lists to see those professionals, and inadequacies of the health services in their country. Internet-based interventions like the Tinnitus E-Programme have the potential to provide support to those who do not have access to, or would prefer not to access, face-to-face support (Beukes, Manchaiah, Baguley, et al., 2018).

Study 2 suggested that users experienced difficulties with meeting the daily relaxation goals and reported several barriers to this behavior, including the availability of a quiet and comfortable relaxation environment away from distractions, fatigue, lack of time, and forgetting. Further behavior change techniques should be introduced to address any barriers and facilitators to enactment and, subsequently, improve user enactment of the relaxation goals. For example, offering advice on how to create a suitable environment for relaxation practice and make time to do relaxation, and reminders to facilitate daily practice. As there is no evidence on the optimal amount of daily relaxation practice, future iterations of the intervention could reduce the amount of recommended daily relaxation practice, but allow users to set their own relaxation goals.

Beukes, Manchaiah, Davies, et al. (2018) found that users of their guided internet-based CBT intervention were concerned that the intervention made their tinnitus worse. Similar beliefs were found in the current study and went so far as to prevent some users from engaging in certain intervention components. Such beliefs are understandable given the evidence regarding the role of attention in the experience of tinnitus (Rossiter, Stevens, & Walker, 2006; Stevens, Walker, Boyer, & Gallagher, 2007). However, this worsening of symptoms is likely to be temporary and outweighed by long-term benefits. Fear of tinnitus has been shown to be associated with tinnitus-related quality of life (Cima, Crombez, & Vlaeyen, 2011). These fears may lead people with tinnitus to engage in safety behaviors (i.e. behaviors people engage in to avoid the feared consequences of an event or situation, such as avoiding silence) that further maintain their fears and, subsequently, the associated tinnitus distress (Cima et al., 2011; McKenna, Handscomb, Hoare, & Hall, 2014). Avoiding interventions that are believed to exacerbate tinnitus may become one of these safety behaviors, unless these fears are addressed. Future modifications to the intervention should acknowledge and address these concerns (e.g. reassuring users that a temporary increase in perceived loudness is normal and remind them that the aim of the intervention is to reduce tinnitus distress not reduce loudness) to maximize user engagement.

The findings highlighted potential improvements to the intervention design, including improvements to the appearance and professionalism of the design and website navigation, and introducing suitable alternatives to the audio relaxation exercises for those with hearing loss (e.g. visual or written relaxation exercises). Users valued the intervention’s ten-week structure, however, some users commented that they would have preferred a different intensity and duration. To facilitate user autonomy (Yardley et al., 2015), it may be more appropriate to provide a recommended course structure, but allow users to choose which sections to use and when to start each section. Users should also be offered a choice of different relaxation techniques they can choose depending on preference, available time, accessibility needs, and context (e.g. at work).

Users in both studies identified several actual and potential benefits gained from the intervention that have been suggested as important for adjustment in people with tinnitus (Hesser, Westin, & Andersson, 2013; McKenna et al., 2014) and other long-term conditions (Moss-Morris, 2013). Users also reported similar benefits to those identified in other qualitative evaluations of internet-based tinnitus interventions, including improvements in tinnitus intrusiveness, relaxation, emotional distress, and sleep (Beukes, Manchaiah, Davies, et al., 2018). As such, outcome measures that capture functional (e.g. intrusiveness, sleep, relaxation) and emotional (e.g. distress) domains of tinnitus may best capture changes resulting from self-help interventions. The Tinnitus Functional Index (Meikle et al., 2012) may be appropriate and has been used to measure changes in tinnitus severity in randomized controlled trials of other internet-based interventions (Beukes, Baguley, Allen, et al., 2018).

## Bringing perspectives together

Using different research methods and populations in each study allowed us to confirm, disconfirm, or extend conclusions derived from one single perspective. In Study 1, the quantitative survey data from real-world users demonstrated that fewer people joined and participated in the online support group and users’ views on this component were mixed. The qualitative survey data extended these conclusions by providing insights into why these findings may have occurred (i.e. due to a belief that the forum would have a negative impact on their tinnitus and emotional well-being). The qualitative interviews in Study 2 further confirmed these findings around the online support group with new users who used the intervention as part of a research study. The in-depth interviews also allowed us to further explore these findings, generating evidence that numerous factors, including concerns about internet safety and difficulty of use, were reasons for poor engagement.

In both studies, users expressed positive views on the relaxation exercises. The quantitative data from the Study 1 survey demonstrated that most users rated the relaxation goals as achievable. Confirming this finding, most Study 2 interviewees also felt that the goals were achievable and realistic, with a minority suggesting reducing the duration or frequency of the relaxation goals. Study 2 furthered our understanding as it asked users to keep a relaxation log to assess adherence to the relaxation goals. This demonstrated that, although the goals were generally perceived as achievable, users could meet under half of the set goals, suggesting that there may be other barriers to adherence. The qualitative data from both studies extended these conclusions by providing insights into the barriers (e.g. fatigue, lack of time, forgetting) and facilitators (e.g. availability of a comfortable and quiet environment) to this behavior, and thus how adherence could be improved in the future.

Study 2 also allowed triangulation of qualitative and quantitative data at the single case level by enabling us to interpret individual users’ relaxation log data relative to their interview data (Flick et al., 2012). This enabled us to provide a direct link with users’ views on the relaxation component of the intervention and their subsequent adherence, thus providing some degree of validation of users’ accounts. Generally, users who expressed more negative views about the relaxation goals demonstrated poorer adherence to the relaxation goals, thus highlighting the importance of acceptance of the intervention components for behavior change.

There were also contrasting findings between Study 1 and 2. Usage of the THI varied between studies, appearing lower in the Study 2 users, compared to users in Study 1. Unlike Study 2 participants, Study 1 users had reported receiving support from the intervention therapist during the intervention. It is possible that the therapist may have directed users to the THI and provided encouragement and support to use it. Without this additional therapist guidance, users in Study 2 often encountered usability issues that caused them to overlook this component. While participants rated intervention usability highly in Study 1, Study 2 participants found the intervention difficult to navigate.

There are several potential interpretations of these differences. First, they may be explained by the provision of therapist guidance (e.g. to overcome usability issues). One user mentioned how the therapist sent her a CD of the relaxation audios when she was unable to transfer the MP3s onto a CD herself. Second, Study 1 users who encountered major usability issues may have been less likely to respond to the online survey. Third, the qualitative findings of Study 1 highlighted that users were motivated to engage with the intervention due to a perceived lack of support from health professionals, long waiting lists to see those professionals, and inadequacies of the health services in their country. Faced with no adequate alternative, these users may have been more likely to overlook any usability issues for an intervention. In contrast, Study 2 users were from a research population and were mainly motivated by curiosity and altruism. Some users felt their tinnitus distress was not severe enough to require the intervention and implied that they would not have engaged with the intervention, had they not been taking part in research. These different motivations meant that this group may have been less willing to work through usability issues and diligently work through all the intervention content. These interpretations suggest that the intervention in its current form is fit for use only if users are highly motivated and technical support is provided.

In Study 1, the quantitative survey data assessed the prevalence of benefits, while the qualitative survey data provided insights into how users benefited from the intervention (or why some users did not benefit). Both groups reported benefits in terms of reduced intrusiveness of tinnitus, learning about tinnitus and its management, improved relaxation and sleep, and reduced feelings of isolation. This suggests that some outcomes may be relevant, irrespective of context (i.e. real-world use vs research context). There were some subtle differences between the intervention benefits identified across the two studies (Table 7). First, the benefits identified in both studies incorporated a reduction in the intrusiveness of tinnitus. However, Study 1 extended this concept to ‘gaining control over your tinnitus and your life’. Second, Study 1 categorized discussions about tinnitus management as ‘providing hope’, whereas this was categorized as ‘gaining confidence in ability to manage, and cope with, tinnitus’ in Study 2. Finally, the benefit ‘dealing with the emotional impact of tinnitus’ was identified in Study 1, but not in Study 2.

\*\*\*INSERT TABLE 7 ABOUT HERE\*\*\*

One explanation for these observed differences may be that the participants in each study differed according to their needs from the intervention and level of pre-intervention distress. This explanation may be plausible since our participants in Study 1 engaged with the intervention following a particularly bad tinnitus experience and may have had higher levels of pre-intervention distress. In contrast, most Study 2 users were not highly distressed by their tinnitus and so they may have been less motivated and to engage with the intervention. By exploring these different perspectives, we have been able to demonstrate how outcomes might differ depending upon certain contextual factors, such as users’ motivations and tinnitus severity.

## Limitations

As registration was voluntary, there was no way of knowing how many people had previously used, or were currently using, the live intervention. This made it difficult to reliably estimate the sample size and assess external validity for Study 1. It was also impossible to track users who did not register, which meant that convenience sampling was the only feasible sampling method. This may have introduced a self-selection bias. It also resulted in a small sample size, which will reduce the external validity of the findings, making them less generalizable to the wider target group.

Some limitations may have led to an inflated mean adherence to the relaxation goals. First, 69% (*n*=9) of Study 2 participants completed their relaxation log, which meant that relaxation data was not available for all participants. It may be that those who failed to submit their log did so because they had stopped using the intervention after the first six weeks. Second, the practice of recording ones behavior can act as a behavior change technique (Michie et al., 2013). Therefore, adherence may be higher than would have been observed if the relaxation log were not used. In fact, some users noted that the relaxation log motivated and reminded them to practice relaxation. However, as the adherence data was secondary to the qualitative data, these limitations would not greatly influence the overall conclusions.

## Conclusions

The findings of this research are encouraging; suggesting that the Tinnitus E-Programme is acceptable to its target users. However, its implementation was limited by instances of poor usability, user engagement, and adherence to behavioral goals. Consistent with a person-based approach (Yardley et al., 2015), the findings of this mixed methods research will be used to develop an improved version of the intervention that will address any implementation issues to maximize user acceptability, engagement, and enactment. This intervention will then be further modified using iterative think-aloud methods in which researchers observe people using the intervention while saying their thoughts aloud. The understanding of the potential mechanisms of impact and benefits gained will also contribute towards the development of a logic model to explain how the intervention may lead to changes in outcome (Moore et al., 2014).

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# Tables

**Table 1 Intervention content across the 10-week Tinnitus E-Programme (reproduced from Greenwell et al. (2015))**

|  |  |
| --- | --- |
|  | **Intervention content** |
| **Week 1** | * Completion and self-scoring of Tinnitus Handicap Inventory (THI; portable document format [pdf] questionnaire)
* Mechanisms of tinnitus (pdf information)
* Three main aspects to the effective management of tinnitus (pdf information)
* Mind calming breathing exercise (pdf instructions)
* Prompt users to join and participate in online support group (webpage)
* Goal setting: Practice the mind calming breathing exercise at least 3 times a day throughout the 10-week program (webpage)
 |
| **Week 2** | * Effects of stress and how to manage it (pdf information)
* Relationship between human performance and physiological arousal (pdf instructions)
* Physiological relaxation exercise (pdf instructions)
* Guided Relaxation 1 (MP3 audio)
* Goal Setting: Practice ‘Guided Relaxation 1’ for 30 minutes every day during week 2 (webpage)
 |
| **Week 3** | * The ‘Three Levels of Hearing’ and its relationship to tinnitus (pdf information)
* Significance of sound in relation to behavior towards tinnitus (pdf information)
* Role of attention-focus and stress that relates to tinnitus distress (pdf information)
* Guided Relaxation 2 (MP3 audio)
* Goal Setting: Practice ‘Guided Relaxation 2’ for 30 minutes every day during week 3 (webpage)
 |
| **Week 4** | * Negative thinking and how it promotes intrusive distressing tinnitus (pdf information)
* How to identify negative thoughts, challenge those thoughts, and change them into positive thought (pdf information)
* Guided Relaxation 3 (MP3 audio)
* Goal Setting: Practice ‘Guided Relaxation 3’ for 30 minutes every day during week 4 (webpage)
 |
| **Week 5** | * Behavioral techniques on how to manage tinnitus (British Tinnitus Association pdf information)
* Guided Relaxation 4 (MP3 audio)
* Goal Setting: Practice ‘Guided Relaxation 4’ for 30 minutes every day during week 5 (webpage)
 |
| **Week 6** | * Prompt users to review information materials from week 1-5 (webpage)
* Goal Setting: Continue practicing the mind-calming breathing exercise for a minimum of 3 times each day and practicing relaxation for 30 minutes (by choosing one of the 30 minute recordings from weeks 2-5) each day (webpage)
 |
| **Week 7-10 (maintenance period)** | * Continue Goal Setting as per week 6 (webpage)
* Complete and self-score the THI at the end of Week 10 (pdf questionnaire)
 |

**Table 2. Participant characteristics for study 1**

|  |  |  |
| --- | --- | --- |
| **Variable** |  | ***n* (%)a** |
| **Age (n=27)** |  |
|  | 18-24 | 1 (4) |
|  | 25-34 | 5 (19) |
|  | 35-44 | 3 (11) |
|  | 45-54 | 5 (19) |
|  | 55-64 | 8 (30) |
|  | 65-74 | 5 (19) |
| **Gender (n=27)** |  |
|  | Female | 14 (52) |
|  | Male | 13 (48) |
| **Country (n=27)** |  |
|  | Argentina | 1 (4) |
|  | Australia | 1 (4) |
|  | Austria | 1 (4) |
|  | Canada | 1 (4) |
|  | Czech Republic | 1 (4) |
|  | Finland | 1 (4) |
|  | India | 1 (4) |
|  | Ireland | 1 (4) |
|  | New Zealand | 2 (7) |
|  | Portugal | 1 (4) |
|  | Slovenia | 1 (4) |
|  | Spain | 1 (4) |
|  | United Kingdom | 13 (48) |
|  | United States | 1 (4) |
| **English as first language (n=27)** |  |
|  | Yes  | 20 (74) |
|  | No | 7 (26) |
| **Do you have tinnitus? (n=27)** |  |
|  | Yes  | 25 (93) |
|  | No, I have never had tinnitus | 2 (7) |
| **Tinnitus Duration (n=25)** |  |
|  | < 6 months | 4 (16) |
|  | 1-5 years | 9 (36) |
|  | 5-10 years | 5 (20) |
|  | 10+ years | 7 (28) |
| **What have you used to help you manage your tinnitus? (n=25)** |  |
|  | Sound therapy | 16 (64) |
|  | Relaxation | 19 (76) |
|  | Counselling or other psychological therapy | 9 (36) |
|  | Tinnitus retraining therapy | 5 (20) |
|  | Medication | 11 (44) |
|  | Seeking out information about tinnitus: * from health professionals
 | 17 (68) |
|  | * online
 | 23 (92) |
|  | * from books
 | 10 (40) |
|  | * from other people with tinnitus
 | 16 (64) |
|  | Taking part in face-to-face tinnitus support groups | 2 (8) |
|  | Taking part in online tinnitus support groups | 16 (64) |
|  | Contacting a charity or non-profit organization | 10 (40) |
|  | Otherb | 2 (8) |

aPercentages are reported without decimal points so may not always add up to 100%. Only the variables with responses are reported.

bIncluded changing diet (i.e. cutting out caffeine), hyperbaric oxygen therapy, and dietary supplements (e.g. ginkgo biloba)

**Table 3 Participants’ interactions with the Tinnitus E-Programme**

|  |  |
| --- | --- |
| **Variable**  | ***n* (%)a** |
| ***All participants:*** |  |
| **How did you find out about the website? (n=27)** |  |
|  | Internet search engine | 20 (74) |
|  | Health professional | 2 (7) |
|  | Word of mouth | 2 (7) |
|  | Otherb | 3 (11) |
| **Did you use the TEP? (n=27)** |  |
|  | Yes, all of it | 11 (41) |
|  | Yes, some of it | 10 (37) |
|  | No | 6 (22) |
| ***Intervention and forum users:*** |  |
| **Did the programme help you? (n=20)** |  |
|  | Yes | 18 (90) |
|  | No | 2 (10) |
| **Did the forum help you? (n=1; forum only users)c** |  |
|  | Yes | 1 (100) |
| ***People with tinnitus:*** |  |
| **Did you join the support forum? (n=21)** |  |
|  | Yes | 10 (48) |
|  | No | 5 (24) |
|  | Cannot remember | 6 (29) |
| **Did you read the posts of others? (n=10; forum members only)** |  |
|  | Yes | 10 (100) |
| **Did you post anything yourself? (n=10; forum members only)** |  |
|  | Yes | 5 (50) |
|  | No | 3 (30) |
|  | Cannot remember | 2 (20) |
| **How do you use the forum now? (n=10; forum members only)** |  |
|  | I do not use it anymore | 7 (70) |
|  | I use it occasionally | 3 (30) |
| **How do you use the programme now? (n=18; users only)** |  |
|  | I have not used it since the first time I used it (and think I will not use it again in the future) | 5 (28) |
|  | I have not used it since the first time I used it (but think I will use it again in the future) | 3 (17) |
|  | I still use at least some of the programme regularly  | 6 (33) |
|  | I still use at least some of the programme occasionally | 4 (22) |
| **When was the last time you used any part of the programme? (n=18; users only)** |
|  | In the last 6 months | 7 (39) |
|  | 7 months-1 year ago | 2 (11) |
|  | More than 1 year ago | 9 (50) |
| ***Tinnitus users who reported using only some of the intervention:*** |  |
| **Did you read the information leaflets? (n=8)** |
|  | Yes, all weeks | 3 (38) |
|  | Yes, but only some of the leaflets | 5 (63) |
| **Did you do any of the relaxation exercises? (n=8)** |  |
|  | Yes, all relaxation exercises | 1 (13) |
|  | Yes, but only some of the exercises | 7 (88) |
| **Did you complete the THI? (n=8)** |  |
|  | Yes, at the beginning of the programme | 3 (38) |
|  | Yes, at the beginning AND end of the programme | 3 (38) |
|  | Cannot remember | 2 (25) |

**Key: a**Percentages for each variable are reported using one decimal point so may not always add up to 100%. Only the variables with responses are reported. bIncluding tinnitus online support forum and contact with the therapist; cThis question was only available to those who used the forum and not the main intervention. All other users were asked ‘Did the programme help you?’

**Table 4. Tinnitus users’ ratings of satisfaction with the intervention (n=18)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Variablea** | **Strongly Agree, n (%)** | **Agree, n (%)** | **Disagree, n (%)** |
| The website was easy to use | 8 (44) | 10 (56) | 0 |
| The website was visually attractive | 2 (11) | 10 (56) | 6 (33) |
| The programme was a trustworthy source of support for tinnitus | 11 (61) | 6 (33) | 1 (6) |
| It was clear from the website which tasks I had to complete | 11 (61) | 6 (33) | 1 (6) |
| It was clear how much of my time I needed to spend on the programme | 10 (56) | 8 (44) | 0 |
| The amount of time I needed to spend on the programme was achievable | 8 (44) | 9 (50) | 1 (6) |
| The order in which I needed to complete the tasks was clear | 9 (50) | 9 (50) | 0 |

aOnly the variables with responses are reported.

**Table 5. Tinnitus users’ ratings of intervention components**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Variable** | **n** | **Strongly Agree, n (%)** | **Agree, n (%)** | **Disagree, n (%)** | **Strongly Disagree, n (%)** | **Did not use, n (%)** |
| The information leaflets were easy to understand | 18 | 8 (44) | 10 (56) |  |  |  |
| The information leaflets were relevant to me | 18 | 8 (44) | 9 (50) | 1 (6) |  |  |
| The information leaflets were helpful | 18 | 9 (50) | 8 (44) | 1 (6) |  |  |
| The relaxation exercises were helpful | 18 | 9 (50) | 8 (44) | 1 (6) |  |  |
| The Tinnitus Handicap Inventory was helpful | 16 | 6 (38) | 7 (44) | 1 (6) | 1 (6) | 1 (6) |
| The forum was helpful | 10 | 3 (30) | 3 (30) | 2 (20) | 2 (20) |  |

**Table 6. Number and percentage of relaxation goals met for each user**

|  |  |  |  |
| --- | --- | --- | --- |
| **User** | **Goal 1: Breathing exercise goals met** ***n* (%)** | **Goal 2: Guided relaxation goals met*****n* (%)** | **Total goals met** ***n* (%)** |
| P22 | 14 (50) | 6 (21) | 20 (36) |
| P24 | 28 (100) | 24 (86) | 52 (93) |
| P26 | 0 | 0 | 0 |
| P28 | 21 (75) | 0 | 21 (38) |
| P29 | 9 (32) | 10 (36) | 19 (34) |
| P31 | 2 (7) | 24 (86) | 26 (46) |
| P32 | 25 (89) | 22 (79) | 47 (84) |
| P33 | 0 | 0 | 0 |
| P34 | 18 (64) | 11 (39) | 29 (52) |
| **Mean** | **117 (46)** | **97 (38)** | **214 (42)** |

**Note:** Percentages for the breathing exercises and guided relaxation are calculated by dividing the number of daily goals each user met over the 28 days by the total number of daily goals set by the intervention for each exercise (i.e. 28). The total goals met by each user was calculated by dividing the number of daily goals each user met over the 28 days by the total number of daily goals set by the intervention (i.e. 56, two goals each day).

**Table 7. Comparison of 'gaining benefit' sub-themes between studies**

|  |  |
| --- | --- |
| **Benefits identified in Study 1**  | **Benefits identified in Study 2** |
| Gaining control over your tinnitus and your life | Reduced intrusiveness of tinnitus  |
| Dealing with the emotional impact of tinnitus | - |
| Providing hope | Gaining confidence in ability to manage, and cope with, tinnitus |
| Reducing feelings of isolation | Normalizing and accepting tinnitus |
| Improved sleep | Improved ability to relax and sleep |
| Learning about tinnitus and its management | Learning about tinnitus and its management  |

**Key:** - = no comparable theme

1. Since the work reported in this article was completed the intervention provider has moved to a therapist-supported intervention model provided in private practice. [↑](#footnote-ref-1)