Understanding User Reactions and Interactions with an Internet-Based Intervention for Tinnitus Self-Management: Mixed-Methods Process Evaluation

Abstract

**Background:** Tinnitus is a common symptom that can affect an individual’s quality of life, requiring psychological support that is not readily accessible. Internet-based interventions have the potential to reduce the disparity in access to psychological support that people with tinnitus currently experience. One example is the Tinnitus E-Programme, which was developed in the UK to support self-management in people with tinnitus. Although freely available online, it had not been formally evaluated.

**Objective:** To carry out a process evaluation to explore past, current, and new users’ reactions and interactions with the Tinnitus E-Programme.
**Methods:** 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 explore this aim with new users and assess how well they were able to implement the skills they learned during the intervention in their everyday lives \((n=13)\). Findings were triangulated to develop an in-depth understanding of the intervention’s mechanisms of impact and identify any implementation or contextual factors that strengthen or impede its delivery and functioning.

**Results:** Generally, users expressed positive views of the Tinnitus E-Programme content and design features. Users particularly valued the education about tinnitus and its management, and relaxation skills training, whereas reactions and usage of the self-monitoring tools, online support forum, and therapist support were mixed. Implementation was limited by instances of poor usability and accessibility, user engagement, and adherence to relaxation goals. Users’ perceptions of the intervention’s credibility and relevance, and beliefs regarding the intervention’s negative impact on their tinnitus influenced their engagement with the intervention. Users in both studies identified several benefits gained from the intervention, 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 acceptability was high among the target group but also highlighted some areas for improvement. These findings will be used to inform further development work.

**Keywords:** tinnitus; health; internet; program acceptability; mixed methods; process evaluation

**Word count:** 6911
Introduction

Background

Tinnitus is defined as conscious perception of a sound without any corresponding external stimulus. It is a major problem affecting 12-30% of adult population [1], with prevalence in people with hearing loss being as high as 70-85% [2–4]. 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 [4].

There is currently no effective treatment for subjective 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 [5–7].

Self-help interventions, delivered via the internet or books, have the potential to improve access to self-management and psychological support for people with tinnitus. Trials evaluating the impact of these interventions on reducing tinnitus distress and depression in this group have shown promising findings [8,9]. In the UK, the Tinnitus E-Programme was developed to support tinnitus self-management. Although freely available online since 2009, there is little understanding of how the intervention is used, how it works, the circumstances in which it works best, and whom it works best for. This study will carry out the first process evaluation of the Tinnitus E-Programme to develop an in-depth understanding of the intervention’s mechanisms of impact and identify any implementation or contextual factors that strengthen or impede its delivery and functioning [10]. It will offer insights into the users’ perspective on internet-based interventions for tinnitus, which has previously received little attention. Such insights are vital for maximizing intervention acceptability, feasibility, and user engagement [11,12]. Moreover, qualitative methods can be helpful for exploring relatively unknown mechanisms of impact and unanticipated intervention outcomes [13].

Aims and objectives

To explore past, current, and new users’ reactions to and interactions with the Tinnitus E-Programme. The objectives were to explore:

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.

Methods

The Intervention

The Tinnitus E-Programme [14] is a ten-week Internet-based self-management intervention for tinnitus. The intervention was developed by a hearing therapist/psychotherapist and it is free to access without registration. The self-management components [15] 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 Tinnitus Handicap Inventory [THI; 15]; 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 (eg, goal setting, behavioral practice/rehearsal). Intervention content is delivered over six weekly sessions, followed by a 4-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.

Overarching Design

The protocol for this research [17] is summarized here. Two parallel mixed-methods studies were carried out with two different populations. Findings were triangulated in an overall interpretation. A diagrammatical representation of the overall study design can be found in Multimedia 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.
Study 1: Online Survey with Current and Past Users

Design

A data-validation variant of a convergent parallel mixed methods design was adopted [18]. Open (ie, qualitative) and closed (ie, quantitative) questions were used in the online survey, and then the qualitative data used to validate and elaborate on the quantitative data.

Participants

The inclusion criteria were: (1) adults aged 18 years and over, (2) ability to read English, (3) access and ability to use the Internet, and (4) have visited the Tinnitus E-Programme website or used the intervention.

Recruitment

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. Email invitations were sent 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. Sample sizes for similar descriptive online survey studies have been between 50-249 individuals [19–23]. Therefore, a sample size of 50 was deemed acceptable. 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 [24]. It was improved with feedback from a public and patient involvement (PPI) panel and tested for acceptability and face validity with past users [17]. 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. These participants were asked to return to the survey once they had completed the intervention (See Multimedia Appendix 2 for final survey).
Analysis

Answers to closed questions were analyzed using descriptive statistics. Users who did not provide data on their intervention usage, 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 [25] and QSR’s NVivo v10 qualitative data analysis software (see [17] for details). Quantitative findings that did not fit under the identified qualitative themes were reported as additional themes. 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 [18] 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.

Participants

The inclusion criteria were: (1) adults aged 18 years and over, (2) ability to read English, (3) access and ability to use the Internet, (4) self-reported tinnitus, (5) reside in the United Kingdom, and (6) not previously used the Tinnitus E-Programme.

Recruitment

A purposive sample of 24 people was recruited from the department’s research database via email invitation using maximum variation sampling [26]. 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 [27]. On study completion, participants were given a free copy of the three Tinnitus E-Programme CBT workbooks.

Interviews

Interviews were organized 6-8 weeks after participants’ start date. The interview guide (Multimedia Appendix 3) was reviewed by the PPI panel and piloted with a previous user of the intervention [17]. Participants were sent sample interview questions to encourage transparency with the interview process and improve recall [28]. Interviews were carried out by KG between April and November 2015 and lasted 26-81 minutes each. 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. 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 findings from the two studies were summarized and triangulated. The overall interpretation was carried out by the KG and then reviewed and agreed by co-authors.

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 1) were analyzed. Thirteen participants were excluded as they identified themselves as future intervention users and ten because they provided incomplete data. Only one participant in the final sample did not complete the entire survey (overall completion rate = 70%; n=26).
<table>
<thead>
<tr>
<th>Variable</th>
<th>n (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (n=27)</strong></td>
<td></td>
</tr>
<tr>
<td>18-24</td>
<td>1 (4)</td>
</tr>
<tr>
<td>25-34</td>
<td>5 (19)</td>
</tr>
<tr>
<td>35-44</td>
<td>3 (11)</td>
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<tr>
<td>45-54</td>
<td>5 (19)</td>
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<tr>
<td>55-64</td>
<td>8 (30)</td>
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<tr>
<td>65-74</td>
<td>5 (19)</td>
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<tr>
<td><strong>Gender (n=27)</strong></td>
<td></td>
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<tr>
<td>Female</td>
<td>14 (52)</td>
</tr>
<tr>
<td>Male</td>
<td>13 (48)</td>
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<tr>
<td><strong>Country (n=27)</strong></td>
<td></td>
</tr>
<tr>
<td>Argentina</td>
<td>1 (4)</td>
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<td>Australia</td>
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<td>Austria</td>
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<td>Canada</td>
<td>1 (4)</td>
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<td>Czech Republic</td>
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<td>Finland</td>
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<tr>
<td>India</td>
<td>1 (4)</td>
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<tr>
<td>Ireland</td>
<td>1 (4)</td>
</tr>
<tr>
<td>New Zealand</td>
<td>2 (7)</td>
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<tr>
<td>Portugal</td>
<td>1 (4)</td>
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<tr>
<td>Slovenia</td>
<td>1 (4)</td>
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<tr>
<td>Spain</td>
<td>1 (4)</td>
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<tr>
<td>United Kingdom</td>
<td>13 (48)</td>
</tr>
<tr>
<td>United States</td>
<td>1 (4)</td>
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<tr>
<td><strong>English as first language (n=27)</strong></td>
<td></td>
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<tr>
<td>Yes</td>
<td>20 (74)</td>
</tr>
<tr>
<td>No</td>
<td>7 (26)</td>
</tr>
<tr>
<td><strong>Do you have tinnitus? (n=27)</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>25 (93)</td>
</tr>
<tr>
<td>No, I have never had tinnitus</td>
<td>2 (7)</td>
</tr>
<tr>
<td><strong>Tinnitus Duration (n=25)</strong></td>
<td></td>
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<tr>
<td>&lt; 6 months</td>
<td>4 (16)</td>
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<tr>
<td>1-5 years</td>
<td>9 (36)</td>
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<tr>
<td>5-10 years</td>
<td>5 (20)</td>
</tr>
<tr>
<td>10+ years</td>
<td>7 (28)</td>
</tr>
<tr>
<td><strong>What have you used to help you manage your tinnitus? (n=25)</strong></td>
<td></td>
</tr>
<tr>
<td>Sound therapy</td>
<td>16 (64)</td>
</tr>
<tr>
<td>Relaxation</td>
<td>19 (76)</td>
</tr>
<tr>
<td>Counselling or other psychological therapy</td>
<td>9 (36)</td>
</tr>
<tr>
<td>Tinnitus retraining therapy</td>
<td>5 (20)</td>
</tr>
<tr>
<td>Medication</td>
<td>11 (44)</td>
</tr>
<tr>
<td>Seeking out information about tinnitus:</td>
<td></td>
</tr>
<tr>
<td>• from health professionals</td>
<td>17 (68)</td>
</tr>
<tr>
<td>• online</td>
<td>23 (92)</td>
</tr>
<tr>
<td>• from books</td>
<td>10 (40)</td>
</tr>
<tr>
<td>• from other people with tinnitus</td>
<td>16 (64)</td>
</tr>
</tbody>
</table>
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 organisation 10 (40)
Other b 2 (8)

*Percentages are reported without decimal points so may not always add up to 100%. Only the variables with responses are reported.
*Included changing diet (i.e. cutting out caffeine), hyperbaric oxygen therapy, and dietary supplements (eg, ginkgo biloba)

**Themes**

Two themes (Themes 1 and 2) were created to report the quantitative findings (Multimedia Appendix 4) and four (Themes 3-6) were identified in the qualitative thematic analysis.

**Theme 1: How participants used the intervention**

Participants found the intervention using a search engine \((n=20)\); through health professional recommendation \((n=2)\); word of mouth \((n=2)\); or through other methods \((n=3)\), including a tinnitus online support forum, or contact with the intervention therapist. Eleven participants used the complete intervention, ten used some, one used only the forum, and five 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. All but two users reported completing the THI (the remaining users could not remember whether they used it). Ten users joined the forum and read posts, but only five had posted. Seven forum users reported that they no longer use the forum and three use it occasionally. Of those users with tinnitus, seven reported using the intervention in the last six months, two seven months-1 year ago, and nine over a year ago (one participant did not provide answer). Eight users with tinnitus had not revisited the intervention since their initial use; six used at least some of the intervention regularly, and four used at least some of the intervention occasionally (one participant did not provide an answer). Of those who had not used the intervention since their first use, five reported that they would not use it again and three reported that they would.

**Theme 2: Satisfaction with the intervention**

All 18 users reported the website was easy to use, and that it was clear how much time they were expected to spend on the intervention and the order in which they should complete the intervention. Seventeen users reported that it was clear which tasks they had to complete, that the intervention’s time requirement was achievable, and that the intervention was a trustworthy source of support. One third of users disagreed that the intervention website was
The website design was not too inviting...it looked a little unprofessional and uninteresting” (P21, non-user with tinnitus, Finland).

Theme 3: Acceptability of the self-management components

All users rated the information resources easy to understand and all but one user ($n=17$) reported that the information leaflets were relevant to them and were helpful. In contrast, 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. All but one user with tinnitus found the relaxation exercises helpful and 78% ($n=18$) believed the relaxation goals were achievable. Most users (81%; $n=13$) who completed the THI found it helpful. Views on the online support forum were mixed; with 60% ($n=6$) of users finding it helpful: 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). Several users 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, user with tinnitus, UK)

Theme 4: 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. 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. 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 5: Factors influencing engagement with the intervention**

Users valued that the intervention was easy to access, was provided free of charge, and could be started immediately. 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. 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 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, some users identified 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 no longer supported” (P19, health professional user, UK). Other barriers to engagement included lack of time (especially for those in employment) and ability to practice relaxation.

**Theme 6: Gaining benefit**

Eighteen of the 20 intervention and forum users reported that the intervention had helped them, 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, 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, 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.

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 2).

Table 2 Number and percentage of relaxation goals met for each user

<table>
<thead>
<tr>
<th>User</th>
<th>Goal 1: Breathing exercise goals met</th>
<th>Goal 2: Guided relaxation goals met</th>
<th>Total goals met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>P22</td>
<td>14 (50)</td>
<td>6 (21)</td>
<td>20 (36)</td>
</tr>
<tr>
<td>P24</td>
<td>28 (100)</td>
<td>24 (86)</td>
<td>52 (93)</td>
</tr>
<tr>
<td>P26</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>P28</td>
<td>21 (75)</td>
<td>0</td>
<td>21 (38)</td>
</tr>
<tr>
<td>P29</td>
<td>9 (32)</td>
<td>10 (36)</td>
<td>19 (34)</td>
</tr>
<tr>
<td>P31</td>
<td>2 (7)</td>
<td>24 (86)</td>
<td>26 (46)</td>
</tr>
</tbody>
</table>
The thematic analysis identified six themes.

**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 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. Some users 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)
Some users found certain advice, 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 2). 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 suggested reducing the duration or frequency of the relaxation goals and a few users were unclear about why it was important to adhere to the 30-minute relaxation goals.

Some users 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 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 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 did not complete the THI because they were not aware of it or could not find it on the website. Some users felt the THI
was easy to complete, while others 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 some users, 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. Some users 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 (eg, 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 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 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 (eg, 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. Most users however, encountered usability issues that made the
intervention confusing and difficult to navigate. This meant that some components were missed or not used. Parts of the interventions were not accessible for 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 two 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. 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 concerns prevented some users 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. 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...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).

**Key contrasting findings between Study 1 and 2**

There were some contrasting findings between the two studies. While participants rated the usability of the intervention highly in Study 1, Study 2 participants found the usability to be poor and the intervention difficult to navigate. Furthermore, THI usage appeared lower in Study 2. These differences may be explained by the therapist support received by some Study 1 users during the intervention. The therapist may have directed users to the THI, assisted them to overcome usability issues, and provided encouragement and support to use the intervention. Another explanation is that those completing the survey in Study 1 were likely to be highly motivated users who had a positive experience of the intervention, with those who encountered major usability issues being less likely to respond to the survey.

There were some subtle differences between the intervention benefits identified across the two studies (Table 3). 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. This could explain why ‘dealing with the emotional impact of tinnitus’ and ‘providing hope’ emerged as a prominent benefit in this study only. 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.

*Table 3 Comparison of ‘gaining benefit’ sub-themes between studies*

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<th>Benefits identified in Study 1</th>
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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

**Discussion**

**Principal Results and Practical Implications**

Overall, users in both studies demonstrated high levels of acceptability and satisfaction with the intervention, especially its educational content and training in relaxation and cognitive restructuring. Users perceived the THI as beneficial, but some 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 (eg, to learn more about tinnitus, to reduce the stress caused by tinnitus). Such tools have been used in other unguided interventions [29].

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 [21,30]. 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 [31,32].

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 [8,9]. Future trials of internet-based interventions for tinnitus should assess the impact of therapist or audiologist support on the user engagement and intervention outcomes.

Study 2 suggested that users experienced difficulties with meeting the daily relaxation goals and reported several barriers to this behavior. 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.

A belief that the intervention may make their tinnitus worse prevented some users from engaging in certain intervention components and is perhaps understandable given the evidence regarding the role of attention in the experience of tinnitus [33,34]. However, this worsening of symptoms is likely to be temporary and outweighed by long-term benefits. Future modifications to the intervention should acknowledge and address these concerns to maximize user engagement.

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 [35,36] and other long-term conditions [37]. The intervention may also lead to improvements in tinnitus intrusiveness, relaxation, emotional distress, and sleep. As such, outcome measures that capture functional (eg, intrusiveness, sleep, relaxation) and emotional (eg, distress) domains of tinnitus may best capture changes resulting from self-help interventions. The Tinnitus Functional Index [38] may be appropriate, however, the responsiveness of this measure for psychological or self-help interventions has not been tested.

Limitations

As registration is 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.

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 one’s behavior can act as a behavior change technique [39]. 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
This research demonstrated that the Tinnitus E-Programme was acceptable to its target users. However, its implementation was limited by instances of poor usability, user engagement, and adherence to behavioral goals. 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 [11]. 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 outcomes [10].

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Conflicts of interest
None declared.

Multimedia Appendix 1
Data collection, analysis, and interpretation for Study 1 and 2
Multimedia Appendix 2
Online survey for Study 1

Multimedia Appendix 3
Interview Guide for Study 2

Multimedia Appendix 4
How qualitative and quantitative findings were reported across the six themes identified in Study 1

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**Abbreviations**

CBT: Cognitive behavior therapy

NIHR: National Institute for Health Research

THI: Tinnitus handicap inventory

PPI: Public and patient involvement