'That's just how I am': a qualitative interview study to identify factors influencing engagement with a digital intervention for tinnitus self-management

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Objectives. To explore users' reactions to and expectations of the Tinnitus E-Programme 2.0, a digital cognitive behavioural intervention for tinnitus, and to identify contextual factors and mechanisms of action that may influence user engagement with the intervention.

Design. Qualitative interview study.

Methods. Think-aloud and semi-structured interviews were carried out with 19 people with tinnitus. Interviews explored participants' views of the intervention's information and advice, its wider intervention goals (e.g. behaviour change, self-management), and factors that may strengthen or impede users' engagement. Data were analysed using inductive thematic analysis, and findings were used to develop a conceptual model of user engagement with the intervention.

Results. Generally, participants expressed positive views of the intervention, its intervention components, and its design features. Identified contextual factors included pre-existing attitudes, beliefs, skills, and knowledge (e.g. perceptions of tinnitus symptom severity, openness to tinnitus management, and psychological techniques); previous experience of tinnitus management; and characteristics of the condition (e.g. heterogeneous nature of tinnitus, stage in healthcare journey). These contextual factors were hypothesized to influence engagement through four mechanisms of action: motivation to

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change tinnitus-related attitudes and behaviour; perceived personal relevance of the intervention; expectations of benefit; and appeal of the intervention techniques.

Conclusions. This study demonstrated the acceptability of the Tinnitus E-Programme 2.0 amongst its target group, while highlighting potential areas for improvement in future intervention modifications. Our findings identified contextual factors that others developing interventions for tinnitus or cognitive behavioural interventions may wish to consider.

Statement of contribution

What is already known on this subject?

- Tinnitus is a prevalent condition that can significantly affect an individual's quality of life and lead to high levels of emotional distress.
- People with tinnitus currently have limited access to psychological support. Digital interventions could provide a relatively low-cost way of improving access to such support.
- Engagement with digital interventions is hypothesized to moderate intervention outcomes.

What does this study add?

- It demonstrates the acceptability of a digital intervention for people with tinnitus.
- A model of user engagement explains how the intervention might work across different contexts.
- It highlights contextual factors that might moderate intervention outcomes for tinnitus.

Background

Tinnitus (often described as ringing in the ears) is a prevalent condition, affecting an estimated 12–30% of the population (McCormack, Edmondson-Jones, Somerset, & Hall, 2016). It can significantly affect an individual's quality of life, leading to sleep disturbances, hearing difficulties, difficulties with concentration, disruption to work activities, social life, and relationships, and emotional difficulties such as anxiety, depression, and irritation (Marks, Smith, & McKenna, 2019; Watts et al., 2018). In the absence of a cure, tinnitus management focuses on reducing tinnitus symptom severity. This typically involves reducing the tinnitus percept through sound therapy (e.g. wearable sound generators, hearing aids) and/or reducing the negative emotional impact of tinnitus through education or psychological therapy (e.g. cognitive behaviour therapy [CBT], client-centred counselling) (Cima et al., 2019). Of these options, psychological therapy has the strongest evidence base (Fuller et al., 2020). However, access to psychological therapies is limited and is reserved for those most in need (McFerran, Hoare, Carr, Ray, & Stockdale, 2018). Digital interventions may provide a relatively low-cost way of improving access to psychological support.

The Tinnitus E-Programme 2.0 is a digital cognitive behavioural intervention to improve tinnitus symptom severity. Since its inception, the intervention has undergone optimization work using theory-, evidence-, and person-based approaches to intervention development (Band et al., 2017; Greenwell et al., 2018). Guidelines for developing complex interventions recommend creating a 'programme theory' for an intervention and refining the theory throughout the development process (O'Cathain et al., 2019). Programme theories describe how an intervention is expected to lead to its effects (mechanisms of action), the key intervention components (in terms of content and delivery), and how these interact with contextual factors (e.g. population, setting) (Funnell & Rogers, 2011). A logic model (visual representation of the programme theory)

was created for the Tinnitus E-Programme 2.0 to illustrate the key intervention components, hypothesized mechanisms of action, and intended intervention outcomes.

Users' 'engagement' with digital interventions has been hypothesized to moderate the intervention's influence on its mechanisms of action. Perski, Blandford, West, and Michie (2017) defined engagement with digital interventions in terms of (1) the extent (e.g. amount, frequency, duration, depth) of usage of the intervention; and (2) a subjective experience characterized by attention, interest, and affect. Yardley et al. (2016) extends this definition to include engagement with wider intervention goals, such as behaviour change or self-management, and the factors that strengthen or impede users' abilities to achieve these goals. In their conceptual framework, Perski et al. (2017) argued that engagement with a digital intervention is influenced by the content and delivery of the intervention, and the context and the behaviour that the intervention is targeting. Context may include aspects of the population (including user demographics or pre-existing attitudes, knowledge, skills) and the setting (including the social and physical environments of the user). Understanding context is important for explaining how an intervention works and how it might work with different individuals and in different circumstances.

Quantitative studies of tinnitus digital interventions have identified several factors associated with intervention outcomes. These include the number of tinnitus treatments undergone previously (Kaldo-Sandström, Larsen, & Andersson, 2004), stage of change (i.e. readiness to change behaviour and attitudes in relation to tinnitus; Kaldo, Richards, & Andersson, 2006), belief in intervention efficacy, and self-reported ratings of tinnitus loudness (Rheker, Andersson, & Weise, 2015). In their study of tinnitus support groups, Pryce, Moutela, Bunker, and Shaw (2019) identified several contextual factors that either facilitated or obstructed the creation of social support through these groups, including the meeting structure, leadership style and preferences, and information-led or experience-led focus. Evaluations of an audiologist-supported digital tinnitus intervention identified potential barriers to engagement including time-restrictions, poor health, and low-self motivation (Beukes, Manchaiah, Baguley, Manchaiah, Baguley, Allen, & Andersson, 2018; Beukes, Manchaiah, Davies, et al., 2018). Our mixed-methods evaluation of an earlier version of the Tinnitus E-Programme (Tinnitus E-Programme 1.0) identified additional barriers to engagement with the intervention, including perceived need for the intervention and concerns that the intervention would make tinnitus worse, and barriers to enactment of the intervention behaviours, including lack of time and forgetting to practice relaxation (Greenwell, Sereda, Coulson, & Hoare, 2019). We need a better understanding of the wider contextual factors that may influence engagement with tinnitus digital interventions and the mechanisms by which these contextual factors exert this influence.

The current study aimed to explore users' reactions to and expectations of the Tinnitus E-Programme 2.0, to identify contextual factors that may influence user engagement with the intervention. Findings will be used to refine the intervention's programme theory by hypothesizing how these contextual factors may influence engagement with the intervention.

Methods

Design

A qualitative study using think-aloud and semi-structured interviews with people with tinnitus. Think-aloud interviews were used to ask participants to share their immediate reactions to the intervention in the presence of a researcher and to identify aspects of the

intervention content or design that may negatively impact a users' engagement with the intervention (Yardley, Ainsworth, Ainsworth, Arden-Close, & Muller, 2015). The semi-structured interviews further explored users views of the intervention and potential contextual factors influencing user engagement. This research was conducted from a critical realist perspective (Bhaskar, 2008). This perspective claims that reality exists independent of those who observe it, but that our experiences and knowledge of reality are subjective. This research had ethical approval from the University of Nottingham Research Ethics Committee (Reference Number: Q11122014 SoM NIHR RHA QEST).

Intervention

The Tinnitus E-Programme 2.0 is a self-guided digital cognitive behavioural intervention to improve tinnitus symptom severity. It provides education about tinnitus to help people develop realistic illness beliefs; cognitive skills training (e.g. cognitive restructuring) to develop effective and adaptive ways of thinking and feeling; and relaxation skills training to support people to develop a regular relaxation practice to reduce their physiological arousal and emotional distress. Cognitive behavioural models of tinnitus have argued that negative thinking, tinnitus beliefs, and physiological arousal are key determinants of tinnitus symptom severity (McKenna, Handscomb, Hoare, & Hall, 2014). Moreover, research has shown that CBT that focuses on tackling negative thoughts, group education, and relaxation therapy can improve tinnitus symptom severity (Fuller et al., 2020).

Table 1 provides an overview of the intervention content, including aims, self-management components, and individual techniques.

The optimized version, which is the focus of this study, has been informed by a current evidence base that includes the findings from a mixed-methods evaluation of the original intervention (Greenwell et al., 2019) and a quantitative systematic review of self-help interventions for tinnitus (Greenwell, Sereda, Coulson, El Refaie, & Hoare, 2016).

As part of the optimization process, guiding principles were created that consisted of intervention design objectives that addressed the key issues, needs and challenges of the target group, and the key intervention features that will achieve these objectives (Appendix 1). We also drew upon Yardley et al.'s common person-based guiding principles that are important for maximizing acceptability and engagement with digital interventions (Yardley, Morrison, Morrison, Bradbury, & Muller, 2015).[1] and the somatosensory amplification theory[2] (van Ravenzwaaij et al.., 2010).

A logic model was created to illustrate the intervention's programme theory, specifically outlining how the intervention's components are hypothesized to impact on intervention processes and mediators to affect the intervention outcome (Figure 1). For this study, the concept of engagement has been added to demonstrate how it may moderate the intervention's influence on its mechanisms of action. The intervention was created using LifeGuide, the open-source software for creating and testing digital interventions.

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[1] The signal filter theory suggests that, in healthy people, the brain successfully blocks any 'sensory noise' (i.e. tinnitus signals). This theory argues that people with tinnitus have 'faulty filtering' that allows this noise to pass through (i.e. tinnitus is experienced).

[2] The somatosensory amplification theory of tinnitus suggests that when patients experience a physical sensation (i.e. tinnitus), they perceive it as a threat, and subsequently focus their attention on it (van Ravenzwaaij et al., 2010). This can lead them to attribute certain beliefs or thoughts to this sensation, which can subsequently lead to an amplification of people's perception of the physical signals, thus setting up a vicious (or 'tinnitus') cycle. This explanation also included a description of the 'autonomic response' to explain how our bodies physiologically react to potential threats in our environment.

Table 1. Outline of intervention content, including intervention aims, self-management components, module names, and individual techniques

Intervention aims	Self-management component to address these aims	Individual techniques
To develop realistic tinnitus-related illness beliefs	Education about tinnitus	• Provide information that targets specific illness cognitions (e.g. causes, timeline, curability/controllability) • Provide lay-friendly explanations of adaptive models of illness explaining how tinnitus is created and maintained in the brain.
To develop effective and adaptive ways of thinking and feeling	Cognitive skills training	• Monitoring thoughts • Thought record • Cognitive defusion • Cognitive restructuring (challenging thoughts and beliefs) • Gratitude diary
To reduce physiological arousal and emotional distress	Relaxation skills training	• Breathing exercise • Muscle relaxation • Guided relaxation • Relaxation challenge
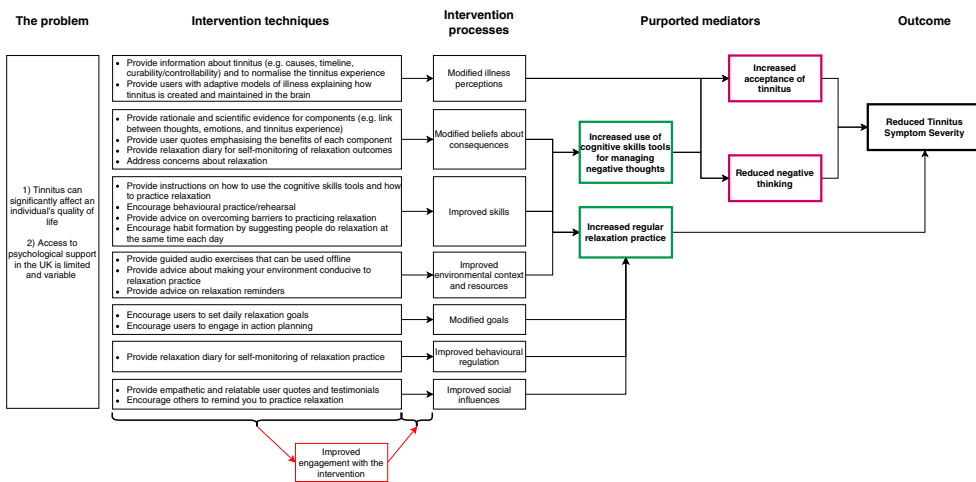
Figure 1. Logic model of the intervention components, mechanisms, and intended outcomes of the Tinnitus E-Programme 2.0. Items in red have been added for this paper.

Sampling and recruitment

Adults (aged 18 years and over) were selected from the National Institute for Health Research (NIHR) Nottingham Biomedical Research Centre (BRC) research database if they had self-reported tinnitus and resided in the UK. Participants self-selected, based on their judgement of whether they met the following criteria: (1) ability to read English; (2) ability to use a computer; and (3) have not used the Tinnitus E-Programme 1.0. Maximum variation sampling (Polkinghorne, 2005) was used to recruit participants covering a wide range of ages and tinnitus durations, and a balance of males and females.

Three rounds of email invitations, together with a participant information sheet, were sent to selected database members ($n = 230$) by a member of the research team. The first round targeted those at the older and younger ends of the age range, while subsequent rounds targeted demographics that were under-represented in the current sample (i.e. females, those with different types of tinnitus, those who had tinnitus for less than 5 years). It was decided a priori that recruitment would cease once data saturation was reached (i.e. no new codes were emerging) and each page had been viewed by at least three people. It was judged that data saturation was reached after 15 interviews, but there were still some intervention pages that had not reached their minimum number of views. Four additional interviews were carried out until this criterion was met.

From the 45 people who volunteered to take part, 23 participants were not recruited, as they were too similar to those in the current sample or contacted the author once data saturation had been reached, and three interested participants later dropped out due to competing work commitments, or personal and family illness. On average, five participants viewed each of the intervention pages and 5–10 participants viewed each module. Participants received £10 for taking part and local travel expenses up to £15 were reimbursed. Informed consent was obtained from participants prior to the interview.

Participants

The final sample included 19 people: 10 males and nine females. The age range was 42–73 years (Mean = 58 years) and the tinnitus duration was 1–25 years (Mean = 9 years). Most participants had high levels of education (i.e. undergraduate level or higher) and used computers and the Internet daily. Participant characteristics are detailed in Table 2.

Data collection

KG (a female health psychologist who was a PhD student at the time of data collection) carried out the interviews between March and May 2016. She led on the development of the Tinnitus E-Programme 2.0. The researcher knew two of the participants, as they had previously been involved in Public and Patient Involvement activities for the Tinnitus E-Programme 1.0 evaluation study. Participants were aware that the interviewer had been involved in the development of the intervention and they were encouraged to provide honest and critical feedback so that the intervention could be optimized for future users.

Interviews were carried out at the NIHR Nottingham BRC. A person-based approach think-aloud protocol was used to focus on participants' views of the information and advice provided by the intervention, the wider intervention goals (e.g. behaviour change, self-management), and the factors that strengthen or impede users' engagement with these goals (Yardley et al., 2013, 2016). In early interviews, participants had freedom regarding what pages they viewed. Later interviews became more directive, with participants being asked to view specific sections that had not been looked at by many participants previously.

Following the think-aloud interview, some semi-structured interview questions were asked about the intervention as a whole. These questions further explored satisfaction, usability, relevance, and times when the intervention would be helpful. Appendix 2 provides a copy of the interview topic guide. The think-aloud interview procedure was piloted with a member of research staff not involved in the project to test the computer setup and interview timings. The interview topic guide was not piloted, but feedback on the topic guide was gained from the first participant who did not suggest any changes.

Interviews lasted between 67 and 96 minutes, were audio-recorded, and transcribed verbatim. Modifications to the intervention were only made in between interviews to resolve major navigational issues that prevented participants from using the intervention effectively or to correct minor problems that could be resolved quickly (e.g. typographical errors).

Qualitative analysis

Transcripts were analysed using inductive thematic analysis (Braun & Clarke, 2006) and QSR's NVivo 10. KG generated initial codes from the data and developed a coding manual that listed all codes, including descriptions and example quotes from the text (Joffe & Yardley, 2004). At least one other coder (MS, DH; both tinnitus researchers and members of the intervention development group) independently applied the coding manual to approximately 50% sample of transcripts (10 transcripts) to clarify ambiguous codes, remove duplicate codes, and identify data that did not fit the coding scheme. Coding was compared and discussed between coders and subsequent modifications made to the coding manual. Disconfirming case analysis (Yardley, 2007) was used to proactively identify data that did not fit with the identified themes. Participant quotes were used in the final write-up to illustrate the themes and pseudonyms were used to refer to participants.

Table 2. Participant characteristics

Demographic characteristic	Frequency (percentage)
Gender	
Female	9 (47.4)
Male	10 (52.6)
Ethnic group	
White British	18 (94.7)
Black British	1 (5.3)
Tinnitus duration	
0-9 years	13 (68.4)
10-19 years	1 (5.3)
20 + years	5 (26.3)
Computer use	
Daily	16 (84.2)
Weekly	2 (10.5)
Occasionally	1 (5.3)
Internet use	
Daily	18 (94.7)
Weekly	1 (5.3)
Employment status	
Employed Full-Time	7 (36.8)
Employed Part-Time/Self-employed Part-time	1 (5.3)
Self-Employed Full-Time	2 (10.5)
Retired	8 (42.1)
Unemployed due to illness	1 (5.3)
Education level	
Level 1	2 (10.5)
Level 2	1 (5.3)
Level 3	3 (15.8)
Level 4+	13 (68.4)

Note. Key: Level 1 = 4 O-Levels, GCSE's grade D-G, Foundation Diploma, Foundation Learning or equivalent; Level 2 = GCSE's grades A*-C, Higher Diploma, BTEC First Diploma or equivalent; Level 3 = A & AS Level, Advanced/Progressive Diploma, Advanced Apprenticeship, BTEC National Diploma or equivalent; Level 4+ = BTEC level 4, HNC, Certificate of Higher Education, Professional qualification, Foundation Degree, NVQ Level 4-5, Honours Degree (BA, BSc), Higher Degree (MA, PhD, PGCE), or equivalent.

Once thematic analysis was complete, we reviewed key findings to identify factors that may have influenced user engagement with the intervention and developed a model of user engagement. The final model and interpretations were reviewed and agreed by all co-authors.

Findings

Themes

Appeal of the intervention content

Generally, users expressed positive views about the intervention content. Specifically, the educational component was highly appealing to users, who had a strong desire for

information. On the other hand, users' views about relaxation and cognitive therapy components were more mixed. Some users expressed positive views about these components and their associated techniques and believed that they were helpful for managing tinnitus.

> Just looking at that [the thought record] and making you think about it is very positive because it does make you think. A lot of things happen where my tinnitus isn't involved. . .and it is not all negative. (Avril, tinnitus for 10 years)

> Relaxation is top of my agenda. . .I think it's a real way to go forward with tinnitus. (Sally, tinnitus for 4 years)

In contrast, some users associated practicing formal relaxation techniques and the cognitive defusion technique with other calming complementary therapy activities that did not appeal to them, such as Pilates, massage, and meditation. Users acknowledged the value of relaxation, but preferred more everyday ways of relaxing such as having a bath or watching TV.

> I've not really been one for relaxation. . .it's just not me. . .I don't go in for massages or anything like that. . .but that's just how I am. . .you see I quite like my bath that relaxes me and sit and read a book or watch the telly, switch off. (Helen, tinnitus for 8 years)

It can be argued that such negative views represented a pre-existing dislike of these types of techniques, rather than a dissatisfaction with the specific intervention techniques. When justifying their dislike of these techniques, participants used phrases such as *'that's just how I am'* and *'it's just not me'*. This suggests that these users did not identify themselves as someone who would use these techniques, which were perceived as being less relevant for men or more suitable for those who subscribed to more alternative therapies.

> I'm a standard bloke [man], you know, I watch sport on television and that relaxes me. But I know there are other people who. . . find meditation relaxing. I personally don't. (Richard, tinnitus for 20 years)

> I'm not a big fan of sort of, new age, crystal therapy, and stuff like that, you know. . .I'm more of a practical, this heals this, type person, rather than "Sit and think about your breathing", all that, you know. It probably works, I'm just saying, initially, to me, I just start to think, "What a load of [poppy]cock [nonsense]." (Brian, tinnitus for 2 years)

From the quotes above, it could also be argued that some participants expressed doubts regarding the effectiveness or medical credibility of these techniques.

Other factors influencing the appeal of the individual cognitive therapy techniques for users included how well the techniques fit with their personality (e.g. optimistic) or way of thinking (e.g. positive thinker), and the familiarity or novelty of the technique.

> [The technique that] would appeal to me it is my somewhere between letting my thoughts go [cognitive defusion] and positive thinking [gratitude diaries]. We already know I am positive thinking, so I will go to letting my thoughts go and see what that says. . . letting my thoughts go is better than challenging negative thoughts because I don't have a lot of negative thoughts. (Avril, tinnitus for 10 years)

> Well I think it [the monitoring your thoughts technique] can be quite helpful. . . I've started to
> engage with that, having done the mindfulness course. (Ron, tinnitus for 25 years)

Across all of the self-management components, users specifically liked content that normalized tinnitus (e.g. knowing there are others with tinnitus), made them feel less isolated (e.g. user quotes), and portrayed a positive image of tinnitus self-management (i.e. there are things that you can do that will help you to manage your tinnitus). In contrast, users disliked content, such as the cognitive restructuring technique, that reminded them how bad their tinnitus was or disrupted their positive mind-set: *'I want to think and head positively. And I know the negative situations, I've lived with them and I do live with them, you know, with regards to tinnitus'* (Ron, tinnitus for 25 years). Disconfirming case analysis identified one user who expressed negative reactions to this normalization content. Janice felt comforted by the fact that there are lots of people with tinnitus; however, this fact also highlighted how she may not be coping as well as others: *'I look. . .and I think, "Well, all these people have tinnitus but they're just getting on with life, and you're the only one who's, sort of, freaking out about it."'* (Janice, tinnitus for 4 years).

Expectations of benefit

The intervention explained to users that the aim was to support people to manage their tinnitus and reduce the impact that it has on their everyday lives. Generally, users valued these aims and they were consistent with their expectations of such an intervention, considering that there is no 'cure' for tinnitus. Conversely, some users were less convinced about the personal value of these aims because the intervention did not seek to change their tinnitus, they did not see how the intervention components could help, or they were not convinced that anything could help them with their tinnitus.

> Because my tinnitus is there anyway, so it doesn't matter what I think about it I can't change it. (Dorothy, tinnitus for 2.5 years).

> I feel sceptical because nobody so far has come up with anything that helps me. . .and I feel that people have rejected me. . .only two months ago. . . [I] was told "Go away and learn to live with it." (Alan, tinnitus for 6 years)

A few users questioned whether tinnitus should be *'managed'* at all or just *'ignored'*. These users were concerned that the act of focusing on their tinnitus, specifically through reading about tinnitus, is counter-productive. Janice (tinnitus for 4 years) expressed such concerns, but also explained how she found that ignoring her tinnitus was not easy when it was bad:

> *Janice::* Some people say that you shouldn't really focus on your tinnitus much and actually doing this [the intervention] may be a bad thing. . .By kind of managing it. The best thing maybe is to forget about it and keep busy.
> *Interviewer::* Mhm. And how do you feel about that advice?
> *Janice::* Well, I mean well at the moment it's [tinnitus] quite bad and I seem to be, I can't help myself. I want to find out everything that I can find out about it.

Some users questioned the value of the cognitive skills training techniques that encouraged people to become more aware of, or deal with, their negative thoughts, with

some believing this to be counter-productive. Users were concerned that these techniques might make them dwell on their negative thoughts or become more aware of their tinnitus, which is what they tried to avoid: *'I think it [the "thought record" technique] would make me become more aware of it [tinnitus], and the less I think about it, the less I'm made conscious of it, then the the better off I am'* (Graeme, tinnitus for 22 years).

Relating to the educational content and advice

Generally, users related to, or agreed with, the educational content and advice provided in the intervention, including the description of the tinnitus sensation (e.g. typical sounds, ear locations) and possible tinnitus risk factors (e.g. loud noise exposure). Most users related to the explanations of how tinnitus was created and maintained in the brain. For example, some had personally experienced an amplification of their tinnitus in response to stress or focussing on their tinnitus.

> I relate to that very much (Laughter) because. . .the more stress you get, the louder it gets, the more stressed you become. . .It's difficult to get yourself out of that cycle sometimes. (Ben, tinnitus for 23 years)

In contrast, disconfirming case analysis identified that some users did not relate to or disagreed with some aspects of these explanations. Two of the eight users who viewed the mechanisms of tinnitus content commented how the signal filter theory explanation was different to what they believed or had been told previously by an audiologist, that is, that their tinnitus was caused by damage to their hearing system. Some users did not perceive a link between their tinnitus and feelings of stress or emotions. That is, they reported that their tinnitus did not become worse when they were stressed, or they did not perceive their tinnitus as a threat.

> I don't understand why it [tinnitus] would want to attach an emotional label to a high-pitched whine. I don't feel the slightest bit emotionally connected to mine [Laughter]. Some, emotions never come into it. (Brian, tinnitus for 2 years)

> I just think of it [tinnitus] as annoyance. . .And I wish it'd stop. Yes, so I don't see it as a threat, but I see it as a very substantial discomfort that is ruining my life. (Alan, tinnitus for 6 years)

Although Alan did not perceive his tinnitus as a threat, the above quote demonstrates that he still perceived his tinnitus negatively. Therefore, it may be that it is the extreme language, rather than meaning behind the world 'threat', that prevented him from relating to the explanation of the tinnitus cycle. Two users did not relate to the explanation of the tinnitus cycle whereby worsening tinnitus leads to increasing stress, which further worsens the tinnitus, as this implies the experience was never-ending and tinnitus only becomes louder over time.

Reactions to the intervention design features

Overall, users found the intervention content and instructions for the various self-management techniques to be clear, concise, and easy to understand. Users felt the intervention was easy to use, intuitive, and flowed well; and they liked the page layout and design, specifically that there was not too much information on each page. Users

particularly valued content designed to improve their confidence in the intervention and its individual techniques and enhance their understanding of why the techniques are important. This included layperson summaries of the evidence for each intervention module; user stories or quotes highlighting intervention benefits; and a relaxation diary that allowed users to measure the immediate benefit they gained from practicing relaxation. Some users wanted more detail on who the users were in the user quotes and stories (e.g. their tinnitus duration, age), which was important for judging their authenticity and how similar these users were to them. Generally, users felt that the seven-week time-commitment was manageable and liked that weekly content was broken down in stages and could be completed flexibly at times that suited, rather than consecutively for seven weeks.

Right people, right time

When assessing the personal relevance of the intervention, users considered how well they were already managing their tinnitus or how much their tinnitus currently affected their everyday lives. Users who felt that the intervention held little relevance for them believed that the intervention was more suitable for those who had more severe tinnitus or were less able to cope with their tinnitus.

> With such a mild base level as I call it...I don't feel I need to go and search out a cure or searching out a management technique. But with, for people with, much higher levels of discomfort, then absolutely this should be very early on in their recognition that they've...got a problem. (Richard, tinnitus for 20 years)

> I think it would help people who were fragile minded, and felt a real need for it, people depressed, I suppose, yeah, people temperamentally not as, not as strong as, as obviously I am (Graeme, tinnitus for 22 years)

Similarly, users explained how they would be more likely to engage with and commit time to, the intervention and its individual modules if, or when, their tinnitus caused distress or they were struggling to cope. On the other hand, Janice questioned whether the intervention would be too upsetting for people like her who perceive their tinnitus to be severe.

When considering the relevance of each intervention component, users reflected on the extent to which they experienced high levels of stress (relaxation skills training) and negative thoughts (cognitive skills training), as well as how well they already understood tinnitus (education about tinnitus) and were aware of, and able to manage, their negative thoughts (cognitive skills training).

> [Learning relaxation skills] to me would be a bonus. Because I don't relax. (Nick, tinnitus for 1 year)

> I don't know actually, whether they [the aims of the intervention] would be [helpful], because I'm pretty much like that anyway, I'm sort of fairly chilled out, I don't have unhelpful thoughts...it [tinnitus] doesn't sort of, you know, impact on me life very much. (Brian, tinnitus for 2 years)

Some users who found the intervention less relevant were still keen to access it in the hope that it contained new content that would help them to manage their tinnitus even better.

Some users felt that, although people with tinnitus may be more in need of support at times of crisis, they may not be willing to engage with the intervention during this time. Specifically, when in crisis, people with tinnitus are looking for an immediate solution, which the intervention did not provide.

> In troublesome times, you need something that offers you a bit more kind of immediate relief. . .I wouldn't come to a written programme, I don't think, in those times. Because the anxiety around it makes it difficult to concentrate on something. (Avril, tinnitus for 10 years)

Ian (tinnitus for 4 years) explained how he would have been less willing to engage with the intervention during the early stages of tinnitus, when he was still looking for a cure and had not yet accepted his tinnitus.

> Maybe for the first couple of months. . .of having the thing [tinnitus], you're fighting. You're resisting what you've got to the point where you're not accepting it. . .I wouldn't have used it, at that time, I'd still be fighting against it and still be in denial.

Many believed that the intervention, in particular the educational components, should be offered early in their tinnitus journey to provide support during this worrying, confusing, and lonely period, and before tinnitus becomes a problem. Others felt it should be offered once tinnitus has become permanent and a diagnosis has been given in order to avoid the intervention being given incorrectly or unnecessarily (i.e. if the tinnitus is temporary). Some users believed that the intervention could be helpful at any time, even if you have had tinnitus for a long time, because you may learn something new or it may refresh your knowledge: *'To be perfectly honest I'm finding it helpful today, you know, 20 years in'* (Richard, tinnitus for 20 years). In contrast, others felt it would be less helpful if you have had tinnitus for a long time, once you have already learned to manage it.

Refining programme theory: Identifying factors that may influence user engagement

Across the findings, we identified several contextual factors and mechanisms of action that may influence user engagement with the Tinnitus E-Programme 2.0 (Figure 2). Contextual factors (present before viewing the intervention) included pre-existing attitudes, beliefs, skills, and knowledge (e.g. perceptions of tinnitus symptom severity); previous experience of tinnitus management; and characteristics of the condition (e.g. heterogeneous nature of tinnitus, stage in healthcare journey). We hypothesized that these contextual factors influenced engagement through four mechanisms of action (processes that could be influenced by these contextual factors and the intervention components). These were (1) motivation to change tinnitus-related attitudes and behaviour; (2) perceived personal relevance of the intervention; (3) expectations of benefit (i.e. the intervention and its techniques will lead to positive outcomes); and (4) appeal of the intervention techniques (i.e. willingness to engage with the specific techniques).

Discussion

This study explored the reactions of people with tinnitus towards the Tinnitus E-Programme 2.0, a digital cognitive behavioural intervention for tinnitus. Generally, participants expressed positive views of the intervention, its intervention components,

Contextual factors   **Mechanisms of action**
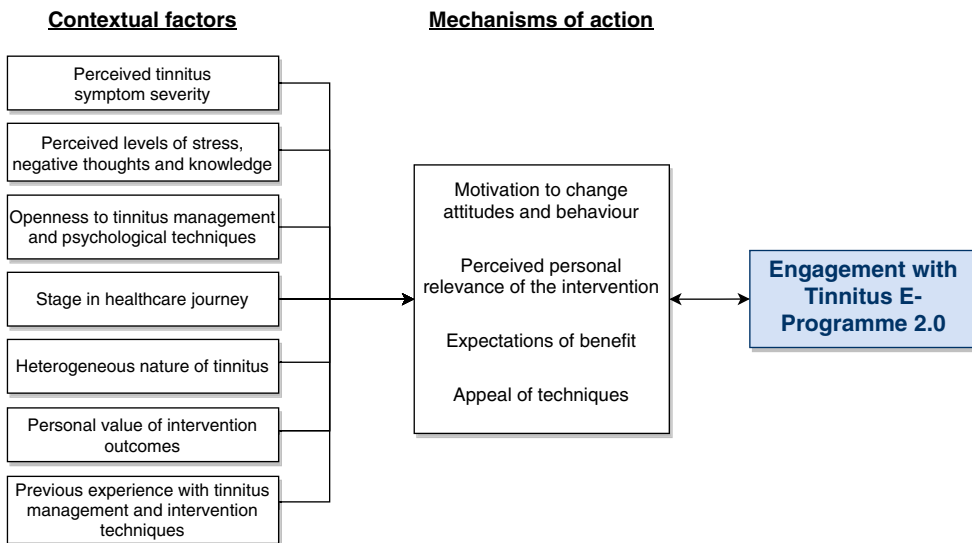
Figure 2. Model of engagement with the Tinnitus E-Programme 2.0.

and its design features, thus demonstrating acceptability amongst its target group. It also highlighted potential areas for improvement and issues to consider when implementing the intervention. This study also furthered our limited understanding of how contextual factors and mechanisms of action may influence user engagement with interventions for tinnitus. We identified contextual factors unique to tinnitus and/or cognitive behavioural interventions, including perceptions of tinnitus symptom severity, openness to tinnitus management and psychological techniques, and perceived value of intervention outcomes. Although psychological techniques that aim to reduce tinnitus-related distress have the strongest evidence base and are widely recommended to people with tinnitus, our research highlighted that not everyone with tinnitus may be ready and willing to engage in such techniques. Additionally, some users did not value the goals of self-management because they had not yet accepted their tinnitus as an incurable and potentially permanent condition, they believed that managing (rather than ignoring) tinnitus was counter-productive, or they believed that management was only helpful if it cured or changed the sound quality of their tinnitus.

Similar to our mixed-methods evaluation of the Tinnitus E-Programme 1.0 and other digital health interventions research (Greenwell et al., 2019; Arden-Close et al., 2013; Morrison et al., 2016), users' reactions to the Tinnitus E-Programme 2.0 were influenced by their perceptions of tinnitus severity. In line with its intended use within primary care, the intervention was perceived to be most relevant for those early in their tinnitus journey and those whose quality of life was impaired by tinnitus, but not those in crisis when a more immediate solution is needed. This mirrors the beliefs of tinnitus health professionals who believe that self-help interventions (e.g. digital interventions) are most suitable for motivated patients and those with mild tinnitus or mental health difficulties, and not suitable for those looking for a 'quick-fix' solution (S. Smith et al., 2018). Stage of change (i.e. readiness to change behaviour and attitudes in relation to

tinnitus; Kaldo et al., 2006) and beliefs that the intervention will be of benefit (Rheker et al., 2015) have been shown to be associated with tinnitus intervention outcomes. Our research provides a deeper understanding of these factors and how they may influence user engagement to ultimately affect tinnitus outcomes.

Generally, users expressed positive views of the intervention components. However, a minority of users were not open to the intervention's psychological techniques that are key in commonly used therapies (CBT, ACT), specifically, the relaxation and mindfulness techniques, instead preferring alternative ways of relaxing. Interestingly, the relaxation skills training component was well used and well received by users in our mixed-methods evaluation of an earlier version of this intervention (Greenwell et al., 2019). Possibly those users in the mixed-methods study expressed more positive views because, unlike the users in the current study, they had the opportunity to experience the relaxation techniques for themselves and were therefore more likely to be aware of their potential benefit. Users' motivation to engage in the relaxation skills training may improve once users become more familiar with this component. Future modifications of the intervention should aim to improve users' perceptions of credibility towards these formal techniques by strengthening the medical rationale and scientific evidence for their use. Behavioural activation techniques that encourage users to re-introduce or increase pleasant activities (e.g. reading, going for a walk) may provide alternative technique for those who dislike formal relaxation exercises. This component has been feasibly implemented in other self-help interventions for tinnitus (Greenwell, Sereda, Coulson, El Refaie, & Hoare, 2016).

User engagement was also influenced by the heterogeneous nature of tinnitus insofar as aetiology, clinical characteristics, and experiences of tinnitus vary between individuals (Baguley, McFerran, & Hall, 2013; Cederroth et al., 2019). Generally, users related to, or agreed with, the educational content and advice provided in the intervention, specifically the explanations of how tinnitus is created and maintained in the brain. A minority of users did not relate to some aspects of these explanations because they contradicted the explanations they had previously been given, or were incongruent with their own experience of tinnitus. Most of these issues can be addressed in future modifications of the intervention by adding in further explanation of how these models work (i.e. clarifying the role of the hearing system in these models or explaining how this model may differ for those with different tinnitus causes) or softening the language used (e.g. avoiding the word 'threat'). A minority of users did not perceive a link between their tinnitus and feelings of stress or emotions. This may be because these participants did not have particularly high levels of tinnitus-related distress or levels of stress. As this is a psychological intervention, we can assume that those experiencing tinnitus-related distress are more likely to benefit from this intervention. However, future iterations of the intervention should consider how the explanation might be adapted to avoid excluding these participants.

Overall, our findings provided support for the key intervention components and design features implemented in the Tinnitus E-Programme 2.0. Two key design features were new to this version; both of which were taken from the common guiding principles of the person-based approach. Firstly, we decided to offer users a choice of different cognitive and relaxation techniques. Users in the current study differed greatly regarding their preferences for these techniques, which provided support for this approach. Secondly, we added in design features that aimed to promote a positive emotional experience and sense of relatedness for users. In line with these objectives, users specifically liked content that normalized tinnitus (e.g. knowing there are others with

tinnitus), made them feel less isolated (e.g. user quotes), and portrayed a positive image of tinnitus self-management (i.e. there are things that you can do that will help you to manage your tinnitus).

Strengths and limitations

One strength of the current research is that it went beyond mere description of users' experiences, refining our programme theory and hypothesizing how the contextual factors may influence user engagement with a tinnitus digital intervention. Our findings provided support for previous models of engagement with digital interventions (Perski et al., 2017), while highlighting factors that are unique to interventions for tinnitus and/or cognitive behavioural interventions.

There are limitations of this study to consider. First, although attempts were made to recruit a diverse sample, users were generally older, White British, and highly educated (most at undergraduate level or higher). Many participants disclosed that they did not experience high levels of tinnitus distress. Participants were also recruited from a research database of people with tinnitus who have agreed to be contacted about research so were likely to be highly motivated. Future work would benefit from testing the intervention with a more diverse sample and including those have moderate to high levels of distress.

Second, participants shared their immediate reactions upon using the intervention in the presence of a researcher. Retrospective interviews whereby participants share their experiences of using the intervention over several weeks would provide further insight into contextual factors and mechanisms of change specific to engagement with the behavioural goals of the intervention (Short et al., 2018). Moreover, mediation and moderation analyses using quantitative self-report measures and objective system usage data would also allow the hypothesized relationships proposed in our model of engagement to be tested (Short et al., 2018).

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Conflict of interest

All authors declare no conflict of interest.

Author contributions

Kate Greenwell (Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Project administration; Visualization; Writing – original draft; Writing – review & editing) Magdalena Sereda (Conceptualization; Formal analysis; Funding acquisition; Methodology; Resources; Supervision; Writing – review & editing) Neil S. Coulson (Conceptualization; Formal analysis; Funding acquisition; Methodology; Supervision; Writing – review & editing) Adam W. A. Geraghty (Conceptualization; Formal

analysis; Funding acquisition; Methodology; Resources; Supervision; Writing – review & editing) Katherine Bradbury (Formal analysis; Writing – review & editing) Derek J. Hoare (Conceptualization; Formal analysis; Funding acquisition; Methodology; Resources; Supervision; Writing – review & editing).

Data availability statement

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Appendix 1:
Guiding Principles for the Tinnitus E-Programme 2.0

Intervention design objectives	Key features of the Tinnitus E-Programme 2.0
1. To normalize tinnitus	• Provide users with adaptive models of illness explaining how tinnitus is created and maintained in the brain, informed by theories of medically unexplained symptoms that have been used in practice to explain tinnitus to patients. • Provide information to normalize the experience of tinnitus (e.g. acknowledge how common tinnitus is, that you may not know what caused your tinnitus, that it is normal for tinnitus to vary, quotes from other people with tinnitus).
2. To support users to maintain a regular relaxation practice	• Facilitate behavioural habituation (e.g. 2-week relaxation challenge, suggest practicing relaxation at the same time each day, provide relaxation diary to log daily relaxation practice). • Provide advice on setting up relaxation reminders (e.g. set an alarm, put a marker somewhere eye catching), how to make your environment conducive to relaxation practice (e.g. avoid distractions and falling asleep, creating a comfortable environment), goal setting, and action planning. • Provide downloadable audio exercises for offline use.
3. To minimize the worsening of users' tinnitus sensation	• Address people's concerns about their tinnitus getting worse when engaging in the intervention (e.g. reassure users that a temporary increase in perceived loudness is normal when starting a relaxation practice). • Emphasize the aim to reduce the impact that tinnitus has on users' everyday lives, rather than reduce tinnitus loudness. • Recommend course structure reduced from 10 to 7 weeks. • Keep modules short and specify how long each one takes. • Provide offline materials that people can use without logging onto the intervention.
4. To ensure the intervention is accessible to those with hearing loss	• Provide written guided relaxation exercises for those with hearing loss.

Appendix 2:

Interview topic guide

The interviewer introduced the task by explaining that participants should say whatever they are thinking as they went through the intervention pages. Non-judgemental prompts were used to clarify the meaning of users' statements, understand why users made certain navigational decisions, and encourage the user to continue to comment when they were silent.

Example prompts:

- What are you thinking about now?
- How are you deciding where to go?
- What do you think of the information in this section?
- What are your thoughts about this page?
- Why did you choose to click on that?
- Can you tell me more about that?
- How helpful do you think this technique will be?

Questions asked during semi-structured interview:

- How easy to use was the programme?
- What did you like about the Tinnitus E-Programme? Why?
- What did you dislike about the Tinnitus E-Programme? Why?
- When do you think this programme would be helpful?
- When do you think that using this programme would not be helpful?
- How do you think the programme could be improved for future users?