

Process evaluation of Internet-based cognitive behavioural therapy for adults with tinnitus in the context of a randomised control trial

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Abstract (200 words max)

Objective: The research objectives were to identify processes that could facilitate or hinder clinical implementation of an Internet-based cognitive behavioural therapy intervention for tinnitus in the UK. This was done by exploring the research context, the intervention components and the factors that contributed to the outcomes obtained.

Design: This study investigated eight processes including the recruitment strategies, reach, research context, treatment dose delivered and received, implementation fidelity, barriers to implementation and effectiveness of the intervention.

Study sample: Of the 169 registered participants, 146 were randomly assigned to the experimental or control groups (23 excluded). The mean age was 55.57 years with a mean tinnitus duration of 11.63 years.

Results: The research context included varying demographical backgrounds, significant levels of tinnitus distress and those underserved with evidence-based interventions. The full intervention was delivered although dosage received indicated that not all modules and worksheets were completed. Intervention components such as the relaxation programme, interest and readability facilitated significant post-intervention outcomes. Barriers hampering intervention application included time pressures and low self-motivation.

Conclusions: The intervention is comprehensive and applicable to a wide demographical and clinical context. Further work to address the current barriers and maximise potential is required.

Keywords

Process evaluation; satisfaction; clinical trial; tinnitus; tinnitus treatment; Internet-intervention

Abbreviations

iCBT: Internet-based cognitive behavioural therapy for tinnitus (iCBT)

RCT: Randomised control trial

SD: Standard deviation

THI-S: Tinnitus Handicap Inventory- Screening version

UK: United Kingdom

WCI: Weekly check-in control group

Introduction

Providing effective and cost-effective prevention campaigns and treatment routes is at the heart of healthcare (Wanless, 2004). Offering the level of care required is not always achieved due to various barriers preventing delivery of appropriate interventions (Sung et al., 2003; Grol, 2001). One such barrier is the poor translation of health-related research into clinical practices and policies (Grol, 2001). This lag leads to discrepancies in evidence-based practice and to the public failing to benefit optimally from advances in health care (Grimshaw et al., 2012). This gap can be narrowed by ensuring suitable methodologies are followed that include the various phases of intervention development and evaluation. This will promote understanding of the expected outcomes (Craig et al., 2008). Of importance is examining the underlying process than have contributed to the specific outcomes obtained and the context under which these outcomes were obtained (Grant et al., 2013). This provides insights into the contexts in which interventions can produce certain outcomes and when tailoring may be required for different contexts (Moore et al., 2015). A holistic approach is required to interpret the results from outcome measures to identify factors that could facilitate or hamper the application of interventions (Saunders et al., 2005). Process evaluation models can provide such a framework for evaluating an intervention's potential for successful dissemination (Manchaiah et al., 2014).

Process evaluation models for public health interventions and research have gradually developed since the 1960's and have become more complex since the beginning of the century (Steckler et al., 2002). These models provide a framework for organising conceptual thinking about key process components. The three models that have been widely used in healthcare interventions include the five dimensions of the Reach, Efficacy, Adoption, Implementation and Maintenance framework (RE-AIM; Glasgow et al., 1999; Dzewaltowski

et al., 2004), the 11 components by Baranowski and Stables (2000) and the seven key components suggested by Linnan and Steckler (2002). Although each model is unique, there is some overlap. The RE-AIM model includes i) Reach, investigating the extent to which the intervention was received by the targeted group; ii) Effectiveness, related to the impact of the intervention as measured by the selected outcome measures; iii) Adoption, associated with delivering the intervention; iv) Implementation, investigating whether the protocol was followed as planned and looks at the delivery of the intervention; v) Maintenance, related to the degree the intervention and results and involvement can be sustained over time. The components suggested by Baranowski and Stables covered i) recruitment procedures; ii) maintenance; iii) the specific context; iv) resources required; v) implementation of the programme; vi) reach; vii) barriers encountered; viii) exposure to the intervention; ix) initial use; x) continued use; and xi) contamination related to the extent to which additional treatments were received. Linnan and Steckler selected i) context; ii) reach; iii) dose delivered related to the intended intervention components to be provided; iv) dose received indicating engagement with the intervention on an individual level; v) fidelity investigating the extent to which the intervention was delivered as planned; vi) implementation; and vii) recruitment.

Process evaluation is particularly important for complex interventions, often required for chronic conditions, which place substantial strains on health-care systems worldwide (Andersson, 2016). One such chronic condition is tinnitus, which is highly prevalent, with figures found between 10-15% in the UK (Davis & Rafaie 2000). There are concerns that the prevalence of tinnitus is on the rise secondary to an increase in noise and music exposure, which is one of the greatest risk factors for developing tinnitus (Martinez et al., 2015). Although there are various recommended treatment approaches for tinnitus including patient

education, sound therapy and using hearing aids, research supporting the efficacy of many of these interventions is hampered by poor methodologies (Landgrebe et al., 2012). The intervention with the most evidence at present for efficacy in reducing tinnitus distress is cognitive behavioural therapy (CBT; Hesser et al., 2011; Grewal et al., 2014). Despite this evidence, there is limited provision of CBT in clinical practice, largely due to a shortage of trained professionals to provide CBT for tinnitus (Gander et al., 2011). To increase access to CBT for tinnitus, a guided Internet-based intervention (iCBT) for tinnitus was developed for the UK (Beukes et al., 2016), following the model used in Sweden (Andersson et al., 2002), and Germany (Weise et al., 2016). Unique to this intervention was that it was guided by an Audiologist, whereas Clinical Psychologists have guided previous interventions. It was then tested for feasibility and piloted (Beukes et al., 2017a). A randomised control trial (RCT) has been conducted, indicating the efficacy of this intervention for both tinnitus distress and problems related to experiencing tinnitus. Results were also maintained two months post-intervention for the experimental group. (Beukes et al., accepted). Further evaluations are underway comparing the iCBT treatment to that of standard clinical care (Beukes et al. 2017b). If this intervention is indeed to be implemented as a credible intervention, more insight is required to gain knowledge of the factors facilitating and hampering its application (Saunders et al., 2005). Determining the amount of iCBT treatment required for positive change is for instance still unknown. To build an evidence-base that informs policy, understanding the intervention context influences outcomes is vital (Craig et al. 2008). Integrating the process evaluation information with the outcome data can maximise result interpretation and aid in maximising the effectiveness of the intervention (Moore et al., 2015).

Despite the relevance of process evaluation to evaluate new interventions, the only comprehensive process evaluation to date in the field of Audiology is that of Gussenhoven et al., (2015), in which a vocational enablement protocol was evaluated for employees with hearing difficulties in clinical practice. They used the framework outlined by Linnan and Steckler (2002) and this research drew inspiration from that study. The aim of this research is gaining insight into factors that could facilitate or hinder application of an Internet-based intervention for tinnitus when guided by an Audiologist by exploring:

1. The research context and how this affected the intervention coverage
2. The delivery of the intervention components provided and how participants engaged with these
3. Factors that contributed to the outcomes obtained

Methods

Study design

Process evaluation was run parallel to a randomised control trial, with a two-month follow-up to evaluate the efficacy of iCBT (Beukes et al. 2015). The experimental group received treatment for 8 weeks, while the control group were monitored weekly by means of the Tinnitus Handicap Inventory- Screening Version (THI-S; Newman, Sandridge & Bolek, 2008). Once the experimental group had completed treatment, the control group underwent the same intervention. Once the experimental group completed the intervention, the control group undertook the same intervention. This allowed for intervention effects to be evaluated between and within groups at two different time points for two independent groups.

Ethical considerations

Ethical approval was granted by the Faculty Research Ethics Panel of Anglia Ruskin University (FST/FREP/14/478) and the study was registered with Clinical Trials.gov: NCT02370810, date 05/03/2015. It was conducted in accordance with good clinical practice together with the ethical principles of the Declaration of Helsinki. A protocol was in place to ensure the security of participants' confidentiality when using the web-portal, complying with the following UK legislation: The Data Protection Act of 1998 and The Privacy and Electronic Communications (EC Directive) Regulations (Riach, 2003).

Participants

There were 244 participants who registered interest in undertaking this intervention in an RCT trial format on the study website (www.tacklingtinnitus.co.uk). Of those 169 (69.3%) completed the initial screening questionnaire. Eligibility for the study was determined in a two-stage process. Initially, participants completed the baseline measurements online. Following completion, a telephonic screening was arranged, to ensure participants fulfilled the study requirements. Inclusion criteria was that they needed to be aged 18 or over and living in the UK. They required computer and the internet access. They had to have experienced tinnitus for a minimum duration of three months and have a score of 26 or above on the Tinnitus Functional Index suggesting the need for tinnitus care (Meikle et al., 2012). The exclusion criteria was reporting any major medical, psychiatric or mental disorder which may hamper commitment to the programme, or tinnitus as a consequence of a medical disorder still under investigation.

Of those who complete the screening questionnaire, 23 were excluded, mainly due to tinnitus severity scores being below that indicating clinical intervention. The remaining 146 were

stratified for tinnitus severity and age and randomly assigned to the experimental (n=73) and the control groups (n=73) as seen in Figure 1.

[Insert figure 1 approximately here]

The Intervention

The iCBT intervention incorporated CBT principles, as these presently have the most robust evidence of effectiveness in minimising the effects of tinnitus (Hesser et al., 2011). The programme originally designed by Andersson et al. (2002) and later updated by Andersson and Kaldo-Sandström, (2003) and Kaldo et al. (2007), was selected due to its strong theoretical base. It was translated into English for a study in Australia (Abbott et al., 2009). It was then developed specifically for a UK population by Beukes et al. (2016) to include interactive elements such as quizzes, videos, diagrams and accommodate different learning styles. It ran over an 8-week period and covered a broad and comprehensive spectrum, consisting of 21 modules, of which five were optional as outlined in Table 1. There were three optional modules based on audiological principles (sound enrichment, hearing difficulties, sound sensitivity) and two targeting aspects of daily life often affected by having tinnitus (sleep and concentration difficulties). A progressive relaxation programme, together with techniques such as positive imagery were included to deal with the physical aspects of tinnitus and promote behavioural change (Andersson & Kaldo, 2006). To target the emotional aspects of tinnitus and transform unhelpful thought patterns, CBT principles such as cognitive restructuring, exposure and reinterpretation were included. Individual modules were organised into a clear structure, including an overview, explanation and rational, step-by-step instructions and further help section, covering possible difficulties that may have been experienced with each of the techniques suggested.

Process evaluation parameters

The parameters used were selected from the three models widely applied to intervention delivery, namely the RE-AIM model (Glasgow et al., 1999), those by Baranowski & Stables, (2000) and the framework by Linnan and Steckler (2002). The following processes were selected to cover a broad spectrum and address the specific research objectives of this study:

Processes related to the research context included:

Recruitment: related to the procedures used to approach and attract participants to participate in the study. It investigates the effectiveness of these recruitment strategies in creating awareness of the trial in the targeted population.

Reach: was defined as the characteristics of those that partook in the study and how well they represented the target population of those with distressing tinnitus who were underserved with evidence-based interventions

Context: was connected to the social, demographical and socio-economic characteristic of the participants that may affect generalisability of the outcomes

Processes related to the intervention delivery involved:

Amount of treatment (dose) delivered: this is defined as intervention components actually provided to participants. The content of the intervention is investigated and the nature of the guided-intervention and how this may influence outcomes.

Amount of treatment (dose) received: this refers to the extent in which participant's engaged and adhered to the intervention.

Processes related to the outcomes obtained were:

Implementation fidelity: this is defined as the degree to which the protocol was carried out as intended. Intervention fidelity can be a moderator of the relationship between interventions and their intended outcomes, and is therefore important to investigate (Dusenbury et al., 2003).

Barriers to implementation: this process investigates the processes that were considered as barriers that may affect implementation of this intervention

Facilitation of effectiveness: was related to effectiveness of the intervention from the participant's perspectives. It was related back to the context of the outcome data. It also involved determining which elements had the most impact on obtaining effectiveness.

Data collected for process evaluation indicators

Data collection was multifaceted and consisted of different measures at different time points as outlined below:

Reviewing processes related to the research context:

Recruitment processes: Google analytics were used to evaluate the recruitment processes by monitoring the traffic on the recruitment website and examine trends related to who was interested in the intervention.

Reach: A demographic questionnaire was used to determine the demographical profile of the participants and included questions regarding tinnitus duration, previous medical examinations related to tinnitus and previous tinnitus treatments. This questionnaire was completed at registration for the trial.

Context: the following self-reported questionnaires were used to determine the research context:

- 1) The Tinnitus Functional Index consisting of 25 items scored on a scale of 0-100 (TFI; Meikle et al. 2012) was selected to measure tinnitus distress.
- 2) The Insomnia Severity Index comprising of seven questions, scored between 0-28 (ISI; Bastien et al. 2001) was used to determine the presence of insomnia
- 3) The Generalised Anxiety Disorder made up of seven items, scored between 0-21 (GAD-7; Spitzer et al. 2006) was selected to quantify the level of anxiety.
- 4) The Patient Health Questionnaire (PHQ-9; Spitzer et al. 1999) was chosen to establish the presence of depression. The nine items are scored between 0-28.
- 5) The Hearing Handicap Inventory for Adults-Screening version (HHIA-S; Newman et al. 1991) was also administered to assess difficulty hearing. The 10 items are scored between 0-40.
- 6) Commitment and motivation ratings were used to rate how committed and motivated participants were to the programme on a scale of 1-10 at the start of the intervention with “1” representing not committed and not motivated and ‘10’ representing very committed and very motivated.

Reviewing processes related to the intervention delivery

Treatment dose delivered: the programme contents, the number of messages sent and the influence of the characteristics of the health professional guiding the intervention.

Treatment dose received: data logging from the intervention website was used to logs the system usage such as the number of times participants accessed the intervention, which modules were read and how many worksheets they completed. The number of messages sent by participants was also recorded.

To compare dose received with tinnitus distress, tinnitus distress was measured weekly by means of the Tinnitus Handicap Inventory-screening (Newman et al, 2008).

Reviewing processes related to the outcomes obtained

Implementation fidelity: comparison of the actual programme to the protocol described in Beukes et al., (2015)

Barriers to implementation: A post-intervention satisfaction questionnaire designed for this particular intervention was used to determine barriers regarding the suitability, content, usability, presentation and exercises on the intervention. The questionnaire consisted of 15 questions. A five-point Likert-scale scale was used with “1” representing strongly disagree and “5” representing strongly agree. This was completed by each group independently after they completed the intervention.

Open-ended questions were furthermore used to offer the opportunity for participants to add any positive or negative comments and any suggestions regarding the iCBT intervention.

Processes that facilitated efficacy

A benefit questionnaire to rate the usefulness of each module undertaking on a five-point Likert-scale questionnaire was used. This scale was from low to high with “1” representing not useful and “5” representing very useful. These ratings were compared between groups. Self-reported assessment measures collected pre and post-intervention and at a 2 months follow-up to determine the context of participants, efficacy and maintenance of the scores.

Data Analysis

The Statistical Package for Social Sciences version 23.0 was used for statistical analysis. Descriptive statistics were used to evaluate the sample characteristics. Scores for the assessment measures were converted to scores out of 100 for comparison purposes between assessment measures. Baseline group differences were analysed using independent sampled *t*-tests for continuous variables and Chi-Squared tests for categorical variables. Outcomes related to the satisfaction of the intervention and the specific components were rated on a 5-point Likert scale were analysed using descriptive statistics. Independent sample *t*-tests were used to compare satisfaction of intervention between the experimental and control groups. A *p*-value of <0.05 was considered statistically significant.

Results

Recruitment procedures

A comprehensive study website was designed for recruitment purposes with sections related to the intervention, what happens during the study, who the study is suitable for, and contact details. There was a link on the website to register for the study. Those registered were invited to complete the screening questionnaire once the study commenced. To improve press coverage, a press release was written which gave information about tinnitus, the study and how to register. It was published in newspapers, and magazines (e.g., Mature Times, People's Friend, Musicians Union bulletin, New Scientist, National Federation of Occupational Pensioners Magazine, and Cambridge News). For those that may look up clinical trial, information was available on websites notifying people of clinical trials. To target those who use the internet, twitter, forums and facebook was used.

Google analytics indicated that there were around 2,300 sessions from 1,003 users on the recruitment website during the recruitment period. Although the majority of the views were from the UK, there were views from other countries, which may have been linked to the trial being registered on clinicaltrials.gov and therefore easily located worldwide. The most views were on the day the recruitment went live with 908 page views. The average session duration was 10 minutes, indicating that those interested, thoroughly considered the information presented about the study. The majority of the visitors (59%) returned to the recruitment pages. The main locations of those visiting the website were London, Southampton, Manchester, Hastings and Birmingham. The main pages searched on the recruitment website were 'who may join,' 'about the programme' and 'what happens during the study.' The recruitment strategies was successful at creating enough interest in the trial recruiting the required number of participants according to sample size calculations for this particular trial.

Reach

Participants were spread across the UK, although the majority were based in England, as seen in Figure 2.

[Figure 2 near here]

The intended population of those that had already had a medical examination due to tinnitus was evident as 92.3% had seen their General practitioner and 68.0% had been referred to an Otology specialist. It was also found that the greater part were underserved with tinnitus intervention as 77.5% had not had access to previous interventions. Of those that had had treatment, this included, Audiological treatment (n=20), tinnitus retraining therapy (n=3) medical interventions (n=6), Psychological treatments (n=3), complementary therapies (n=2).

The majority (89.3%) were not attending tinnitus support groups and therefore not receiving additional tinnitus support. The reach, therefore, included participants across the UK that had been clinically examined to exclude medical causes for their tinnitus. They had not had access to services that provided management strategies for their tinnitus.

The context of the RCT participants

The social, demographical and socio-economic characteristics of the 146 participants who participated in the trial are shown in Table 2. There were no significant differences for any demographical or clinical variables between the groups at baseline that may have created bias.

[Table 2 near here]

A good range of ages were represented in the study (24-83 years) with a mean of 55.57 years (SD: 12.86). The mean tinnitus severity score was 59.49 (SD: 18.40) on the Tinnitus Functional Index (Meikle et al., 2012). The range of scores was 24.40 to 97.20. There were 21 (12.4%) participants excluded due to TFI scores below the recommended level of clinical significance of 26 that required clinical intervention (Meikle et al., 2012). The majority have severe tinnitus (63.01%). Those undertaking the intervention therefore had tinnitus that was at least significantly distressing.

The mean anxiety score on the Generalised Anxiety Disorder (Spitzer et al., 2006) was 7.39 (SD: 5.56) indicating mild anxiety. The majority of participants had either minimal (36.30%) or mild anxiety (32.88%) There were less participants with moderate (n=28) or severe anxiety (n= 17). A similar pattern was found for the mean depression score on the patient health

questionnaire (Spitzer et al., 1999) with a score of 7.99 (SD: 5.72). The majority had mild depression (67.12%). The Insomnia Severity Index (Bastien et al., 2001) indicated that the majority of participants had subthreshold insomnia (32.19%) or moderate insomnia (28.77%). Self-reported hearing disability indicated that the majority (43.84%) had 50% probability of hearing disability, with 36.99% using hearing aids.

As participants from a large range of educational and vocational backgrounds were drawn to the study, with around 57% working and 43% being retired or unemployed. A range of professions were covered including technical, service, sales and administrative jobs. Education levels also ranged from school to masters degrees. Around half had been educated to high school or college level with the other half receiving vocational training or degree training.

Participants were asked to rate how committed they were to the programme on a scale of 1-10 at the start of the intervention. The mean rating was 9.39 (SD: 1.10). To fully benefit, participants had to be willing to try new techniques to learn to minimise the impact of tinnitus. Before starting they were asked to rate how willing they were to try new things on a scale of 1-10. The mean rating was 9.51 (SD: 1.06). They were therefore very motivated and willing to try new techniques before starting the programme

The context of the research was therefore participants with a wide range of demographic backgrounds. They had significant and severe levels of tinnitus with mild anxiety, depression and insomnia levels. The majority had 50% probability of hearing disability with just over a third had hearing aids. They appeared committed and willing to try the intervention prior to commencing.

Processes related to the intervention delivery*Amount of treatment (dose) delivered*

The intervention modules were released on a weekly basis over an eight-week period. Each week two recommended modules were released. Between weeks 3-7 there was an additional optional module that was released. Participants were instructed to engage with the modules and then practise the suggested techniques on a daily basis. To ensure that the intervention could be easily accessed the information can be read online, downloaded to read offline or printed. It was also accessible on a range of formats including computers (both PC and Mac), tablets and smart phones. To deliver the information to reach people with different learning styles the modules contained a mixture of short explanations, videos, step-by-step instructions, suggested techniques to apply to daily life, worksheets to keep track of progress as well as solutions for common problems.

The intervention was guided, and the quality of the delivery would therefore be partly affected by the nature of this guidance. To maintain consistency with the standard approach of tinnitus therapy being delivered within the audiology community in the UK, an experienced female Audiological Scientist, registered with the Health and Care Professions Council (HCPC), and appropriately trained to Masters Level in Audiology, undertook the role of supporting the participants. This health professional was experienced in managing tinnitus patients both in a clinical setting and online and had a suitable understanding of CBT principles but no formal CBT training. The guidance included conducting the telephone interviews, introducing weekly modules, providing feedback, answering queries, supporting and encouraging engagement. The recommended time guidelines of a minimum of 10 minutes per participant was applied to this study. The clinician was alerted every time participants completed a worksheet and they were then given feedback in the form of a written message. These messages provided advice

and further suggestions when required. The clinician sent 1,925 tailored messages (15.65 on average to each participant). The guidance was provided in an asynchronous manner most of the time using a secure encrypted messaging system. This enabled two-way communication between the health-professional and the participants. Synchronous guidance using telephone calls was provided with a minimum of an introduction telephone call and a summary telephone call to each participant. Additional calls were made as required during the intervention as required to encourage engagement or address particular difficulties. A comprehensive, guided, evidence-based intervention was therefore delivered in an accessible format with the recommended amount of guidance.

Amount of treatment (dose) received

The majority of participants were able to utilise the intervention. For those that withdrew, reasons given were generally that they were too busy or developed poor health. The extent to which participants actively engaged and interacted with the resources provided by this iCBT intervention were used to determine the doses received. There were 27 logins on average for those that completed the intervention. On average 74% of the intervention's modules (16 recommended and 5 optional) were read with an average of 15.61 modules read by participants. Initial modules were read most, and later modules and optional modules the least. Overall 41% worksheets were completed with an average of 20.59 worksheets completed per participant. A similar trend was seen with the modules read as more worksheets were completed for the initial modules and less of the later modules and optional modules. Participants were monitored weekly for tinnitus severity whilst the experimental group undertook the intervention (T0-T1). This indicated that from weeks 4 -8 the experimental group's tinnitus distress was rated significantly lower than that of the control group not undergoing the intervention. This trend is shown in Figure 3. Therefore, although

less modules and worksheets were completed as the intervention progresses, this may partly be due to an improvement in tinnitus related distress and therefore less need for the programme. Satisfaction of the module information for each week is also seen on Figure 3. This trend was more linear and did not appear to have an impact on the number of modules read or worksheets completed.

[Figures 3 near here]

Participants sent less messages than the therapist at 597 messages with an average of 4.85 per participant that completed the intervention. At the end of the intervention participants indicated that they spent an average of 22.38 (SD: 18.95) minutes per week going through the module content with ranges between 5-60 minutes reported. Some participants (~n=25) mentioned that it was difficult to fit in the work within the eight week period. For these participants, the time period was extended by a couple of weeks.

On average participants did not interact fully with all aspects of the intervention. Despite doses received being lower than dose delivered, significant positive post-intervention results were obtained. This is evident by the between-group effect size for the primary outcome measure for tinnitus distress being Cohen's $d = 0.76$ as measured following the experimental group undertaking the intervention (at T1: post-intervention) and prior to the control group commencing. Significant differences between groups were also found for many of the secondary assessment measures such as insomnia, depression, hyperacusis, cognitive failures and life satisfaction. The present dosage also led to significant within group changes were evident for all outcome measures following each group independently undertaking the intervention.

Processes related to the outcomes obtained

Implementation Fidelity

This intervention was delivered as planned. There were no changes to the methods or outcome measures used after trial commencement. This was partly due to methodology followed: initially the RCT study protocol was peer reviewed and amendments followed these recommendations. Further changes were incorporated after tinnitus professionals evaluated the programme in terms of functionality testing and suitability (see Beukes et al., 2016). A pilot study moreover identified shortcomings and the intervention and protocol was adapted accordingly (see Beukes et al., 2017a). Therefore the protocol and intervention had already been modified prior to the RCT commencing. The only modification was extending the treatment period by 2 weeks for those that were unable to complete the course within the given timeframe due to unforeseen circumstances.

Barriers to implementation

Participants that completed the intervention were asked to rate the programme in aid of determining where barriers to intervention usage existed. As these ratings were only given by those that completed the intervention, an element of bias was added. There was no statistically significant difference between the ratings of either group on any of these categories. Overall the intervention was rated highly, with a mean of above 4 out of 5 for most categories as indicated in Figure 4. The three areas with scores below 4 were motivation, worksheets and understandability of the intervention. These barriers can affect the application of this intervention. Motivation appeared to decrease for some participants as seen by the number of modules read and the worksheets completed for later parts of the intervention. Some of the worksheets with too many areas to complete e.g. date, effectiveness

rating, what was done, further comments could be simplified. The intervention content needs revision to improve understandability.

[Figure 4 near here]

A further barrier encountered was motivating participants to complete the end of intervention and follow-up questionnaires. Despite three automatic reminders as well as further personal reminders by the therapist to encourage completion only 85.62% completed the outcome measures post treatment, whilst 78.08% completed these at follow-up. Keeping some participants engaged during the intervention was also challenging. Messages were sent to those who were not engaging. If there was no response, a telephone call was made to them. Some participants found the lack of immediate results deterred them from continuing with the intervention. Weekly monitoring indicated that significant improvements were only found from about week 4 of the intervention. Some participants (n=25) mentioned that it was difficult to fit in the work within the eight week period. For these participants, the time period was extended by a couple of weeks. Self-motivation, family issues, new health problems and time-pressures were the main barriers to implementation identified.

Google analytics indicated that the majority of those looking at the recruitment website were aged 25 to 34 years (33.5%), and the least aged 55 to 64 years or over 65 years (both at 5.5%). Of interest is that those that chose to participate were generally older and a much smaller percentage of those aged below 35 years decided to participate. Of those that viewed the recruitment pages 54.1% were male and 45.9% were female. A slightly higher proportion of men joined the study (56.9%).

Facilitation of effectiveness

Following undertaking the intervention participants were asked to rate how beneficial different components within the intervention were. The results are indicated in Figure 5. The applied relaxation programme was rated the most beneficial, while the hearing tactics given was rated the least beneficial. These ratings were also reflected in some of the outcomes obtained. There was no significant group differences in hearing handicap directly following the experimental group undertaking the intervention $F(1,145)=2.06$; $p=0.154$ (Beukes et al. under review). It may be related to this information not being new to those with hearing aids that had seen an Audiologist in the past who may have provided these tactics. It could also be that participants could not relate the relevance of this module to their tinnitus or appreciate the possible benefit, and therefore choose not to do it. Outlining the advantages of the module will be important for future trials. Although sleep guidelines was not rated as high as some of the other modules there was a significant different post-intervention (Cohen's $d=0.55$). The impact of other modules such as the relaxation module may have contributed to this post-intervention effect. It may have been the combination between the modules contributed to improvements seen post-intervention on some outcome measures such as depression and quality of life.

[Figure 5 near here]

From open-ended questions it was evident that an Internet-intervention was valued by participant due to the ability to access help in the comfort of their own homes, without needing to be away from work for a hospital appointment. Furthermore, working at their own pace was an advantage. Participants also found it useful to access the information when they were out, such as on a train, due to the website being able to be viewed on mobile devices as well due to the responsive nature of the website design.

Maintenance of results (put efficacy in the context of the controlled trial)

Part of effectiveness is determining whether intervention effects can be maintained. This was evaluated in the experimental group two months post intervention. Figure 5 shows the change over time for all self-reported assessment measures, indicating a decrease in severity of scores for all assessment measures over time and improved life satisfaction. Significant differences (all $p < 0.05$) were found for tinnitus distress, insomnia, depression, hyperacusis, cognitive failures and life satisfaction between groups at post assessment after the experimental group had underwent the intervention. For all assessment measures there were significant changes within group for the experimental group and after this for the control group after they each undertook the intervention independently. One way repeated measures indicated that there was no significant difference (all $p > 0.05$) in the scores between the post-assessment and follow-up assessment, indicating that treatment effects were maintained over a 2 month period.

[Figure 5 near here]

Effectiveness was evident for tinnitus distress and also secondary outcome measures such as insomnia, depression, hyperacusis, cognitive failures and quality of life and these effects are maintained over a two month period. Process evaluation has indicated elements of the intervention that participants found most beneficial. Most of these were recommended modules. The optional modules were scored lower as expected due to the emphasis not being placed on these modules. It is important to evaluate effectiveness from participant's perspective. Obtaining high satisfaction from participants will add credibility to this

intervention. Integrating this information from outcome data and process evaluation adds perspective to the effectiveness of the intervention on different levels.

Discussion

Process evaluation was performed to identify aspects that could facilitate or hinder clinical implementation of an Internet-based cognitive behavioural therapy intervention for tinnitus in the UK. This was done by exploring the research context, the intervention components and the factors that contributed to the outcomes obtained.

The impact of the research context

The recruitment strategy had been expanded following the pilot study and was effective at recruiting the required sample size. Some people who registered for the trial did not pursue the intervention. This was related to the timing of the intervention not being convenient in most cases. Considering the high prevalence of tinnitus, recruitment strategies will need to be expanded if more individuals are to be made aware of this intervention if it were to be implemented.

The intended population of those with distressing tinnitus who were underserved with evidence-based tinnitus interventions were reached. The majority had not had previous tinnitus treatments and were not attending tinnitus support groups. A large proportion of these (68%) had been referred to an otology specialist. This percentage is higher than the estimated referral rates to specialist services of 37% by general practitioners (El-Shunner et al., 2011). Most participants had not undergone tinnitus interventions. Of those that had, the majority had had audiological treatments. Few had had psychological treatments which generally

cover CBT principles. The cognitive behavioural therapy aspect of the intervention may therefore have drawn some participants.

The aim was to ensure a spread of participants across the UK. Although participants covered a large range of England, there were fewer participants in more isolated parts of the UK, such as from Scotland or Wales. This could partly reflect the effect of the variation of availability of clinical tinnitus provision in the UK (Hoare et al. 2015). Strategies to improve the spread in areas not reached, needs consideration.

The context of this research indicated that the application of iCBT appears to be wide and encompass the full spectrum of different age groups, varying education levels and duration of having tinnitus. The intervention may need to be adjusted if applied in different contexts.

The impact of the intervention delivery

A comprehensive intervention was delivered. An Audiologist guided this intervention.

Previous studies in Europe investigating iCBT for tinnitus have used clinical psychologists who were either licensed CBT therapists, Clinical psychology trained to masters level, MSc students who had completed their clinical training including CBT training. Therapist have been both male and female. They received systematic training and supervision specifically for the iCBT intervention and were instructed on how to answer messages. Supervision was also provided. These studies have used a range of therapist and randomly assigned participants to therapist [i.e. six by Hesser et al. (2012), four therapist used by Weise et al. (2016) and Jasper et al. (2014); three by Kaldo et al. (2008)]. Although these therapist had a good understanding of CBT they had not always had previous experience seeing tinnitus patients. There were therefore large differences related to the therapist in this study compared

to those in previous studies in terms of training and experience. In comparison to the Audiologist, previous therapists had responsibility for less participants at any one time. Having one therapist could produce a consistent approach for all participants.

Therapeutic support improves engagement with Internet interventions (Kohl, Crutzen & de Vries, 2013). Efficacy trials to date have indicated that iCBT can reduce tinnitus distress using and audiologist in this context and in previous studies using clinical psychologists (e.g. Jasper et al., 2014; Weise, Kleinstaubler and Andersson, 2016). The exact effects of the health professional assigned is not yet known. Internet-based trials for depression, anxiety, and social phobia have found comparable results, regardless of whether a clinician or a technical assistant guided the intervention (Titov et al. 2009; Robinson et al. 2010; Titov et al. 2010). Outcomes obtained may be related to numerous factors and not only based on the qualification of the person guiding the intervention. Further studies directly comparing the effects using an audiologist versus a clinical psychologist are required. Outcomes of this trial on tinnitus distress (Cohen's $d = 0.69$) were comparable to those of previous iCBT controlled studies with pooled results of Hedges $g = 0.58$. The health professional providing the intervention does play a role, but this is not the only factor. An audiologist may not be as good at motivational techniques and may have contributed to some not engaging and dropping out. Direct comparison of Audiology-delivered versus Psychology-delivered interventions are required to draw firm conclusions.

Although participants on average did not utilise the full scope of the intervention, undertaking the intervention led to a significant reduction in tinnitus and problems associated with tinnitus based on the results from outcome data. Additional tactics to improve engagement need to be considered.

Processes related to the outcomes obtained

Application was facilitated by preceding this trial by a feasibility study. This helped identify barriers that required improving and contributed to the efficacy of this intervention and enabled the RCT to run as planned and have good implementation fidelity. Participants indicated great satisfaction with, and benefit from, the intervention. The flexibility of access was an advantage as well as being able to learn more about managing their tinnitus. Although patients who access tinnitus services are well supported, there are many who do not have access to these services. El-Shunnar et al. (2011) reported that an estimated 750,000 people in England visited their GPs each year with tinnitus as the primary complaint. Of these only 37% were referred for specialist services, for which there was often a substantial wait. Hoare et al. (2015) highlights the need for accessible services to improve the ratio of those with distressing tinnitus receiving tinnitus care. Adding an intervention for tinnitus as an additional pathway could increase access to a comprehensive evidence-based intervention for tinnitus which could increase the percentage of people with distressing tinnitus who actually have access to a tinnitus intervention. Implementation requires fewer resources due to the intervention being provided via the Internet. Due to these benefits, it has been incorporated into regular clinical care in Sweden (Kaldo-Sandström, Larsen & Andersson, 2004, Kaldo et al., 2013). This will assist access to tinnitus care in the UK where there is a shortage of trained clinicians, as less clinical time and resources are required via this treatment route.

Some barriers to application were identified such as a smaller percentage of those that were younger ie aged 18-35 years participated. There were also less females participating. It may be related to the estimates that a slightly higher proportion of men experience tinnitus, although a higher proportion of women have a severe form of tinnitus (Seydel et al., 2013). It could also be that the flexibility and anonymous nature of this intervention suited males. Identifying factors deterring certain recipients, from participating is important.

Self-motivation is a requirement for such a self-help intervention and is a significant barrier. Ways of improving motivation is required. Improvements to simplify some of the worksheets is also needed as they were not as highly rated and can affect engagement with the intervention. Ensuring the understandability of the content is improve is also required to remove this barrier identified that may affect application of the intervention. Further barriers such as time-restrictions and poor-health resulted in not all participants being fully engaged in the intervention. Developing a shorter intervention with key principles is something that may be considered to target those who are unable to commit to an eight week programme. There are certain requirements such as a requiring access to a computer and internet connection. There are therefore certain individuals who will not be able to access this intervention. Having a range of suitable evidence-based interventions for those with distressing tinnitus is therefore important. It was found that over time engagement decreased but so did tinnitus severity. Improved tinnitus severity may have led to less reliance on the intervention over time. Some participants also mentioned finding the lack of initial results difficult, which decreased motivation. It was seen that significant results were evident from about half-way through the intervention. This should be highlighted to help encourage participants to push through initially.

Further research

To further understanding of the processes that may promote or hinder the delivery of this intervention additional longitudinal measuring of the patient journey through from considering undertaking the intervention to completion will be of value. Qualitative analysis of participant expectation and experiences (both positive and negative) will also be of value. This may provide valuable insights into factors that deter participants from undertaking the intervention. Evaluating the patient journey from the perspective of the spouse would add further insights into the application of such an intervention. Consideration to further tailor/shorten the intervention according to individual needs should be considered, to determine if this would make it more appealing to a younger population. Evidence of this intervention's efficacy together with the insights gained from process evaluation will build a strong case for translation from research to practice for this iCBT intervention for tinnitus in the UK.

Conclusion

This process evaluation has provided a broader understanding of the research context. The application has been viewed from both the perspective of the outcome data and participant perspectives, therefore maximising result interpretation. Ways of addressing barriers such as time-limitations and lower motivation levels which were found to limit engagement are required. This intervention has undergone various phases of development, feasibility, efficacy and process evaluation and has helped identify the outcomes that are possible under ideal contexts and processes that have contributed to the effectiveness of the intervention. This will be useful for future clinical applications of the intervention although continued process evaluation will be required if this intervention was to be adopted in a clinical setting.

The results of this process evaluation has aided identifying factors that can contribute to translating this research into clinical practice.

Funding and disclosure statement

The authors declare that they have no competing interests. Anglia Ruskin, Lamar and Linköping Universities and NIHR supported the undertaking of this study but the views expressed are those of the authors and not of these institutions.

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Table Legends

Table 1: An overview of the iCBT intervention

Table 2: The demographical and socio-economic characteristics of the participants

Figure Legends

Figure 1: Participant profile

Figure 2: The demographic location of the participants

Figure 3: Comparison of engagement, module rating and weekly tinnitus distress

Figure 4: Participation ratings of the intervention

Figure 5: Usefulness of specific modules within the intervention
(optional modules marked with a *)