The TinMan study: feasibility trial of a psychologically informed, audiologist-delivered, manualised intervention for tinnitus

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The TinMan study: feasibility trial of a psychologically informed, audiologist-delivered, manualised intervention for tinnitus

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Abstract

Objective: To develop a manualised psychological treatment for tinnitus that could enhance audiologist usual care, and to test feasibility of evaluating it in a randomised controlled trial.

Design: Feasibility trial, random allocation of patients to manualised treatment or treatment as usual, and mixed-methods evaluation.

Study sample: Senior audiologists, and adults with chronic tinnitus.

Results: Recruitment reached 63% after 6 months (feasibility pre-defined as 65%). Only nine patients (47%) were retained for the duration of the trial. Patients reported that the treatment was acceptable and helped reassure them about their tinnitus. Audiologists reported mixed feelings about the kinds of techniques that are presented to them as 'psychologically informed'. Audiologists also reported lacking confidence because the training they had was brief, and stated that more formal supervision would have been helpful to check adherence to the treatment manual.

Conclusions: The study indicate potential barriers to audiologist use of the manual, and that a clinical trial of the intervention is not yet feasible. However, positive indications from outcome measures suggest that further development work would be worthwhile. Refinements to the manual are indicated, and training and supervision arrangements to better support audiologists to use the intervention in the clinic are required.

Trial Registration:ISRCTN13059163.

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Keywords: Tinnitus, Audiology, Psychological intervention, Randomised controlled trial (RCT), Manual

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Background

Tinnitus involves the perception of sound in the absence of any acoustic stimuli (Davis & El Refaie, 2000), and is often associated with insomnia, hearing problems, depression, and anxiety (Tyler & Baker, 1983; Pinto et al., 2014). Cognitive behaviour therapy (CBT) has been trialled extensively, but evidence is largely limited to clinical trials where a psychologist delivered it (Fuller et al., 2020; Hesser et al., 2011; Hoare et al., 2011). Some studies have additionally included multiple disciplines such as clinical physicists in audiology, who deliver elements of care that are informed by psychology (e.g. Cima et al., 2012). In the UK most tinnitus care is delivered by audiologists. However, there is no standard protocol for tinnitus management and various approaches to assessment and treatment are used (Hoare et al., 2015). Most audiology departments offer management of hearing loss, use of sound generators, and patient education. Only some departments have access to psychologists (Gander et al., 2011) and there is no evidence for the effectiveness of psychological interventions when delivered by audiologists (Hoare et al., 2011). If audiologists were to use a psychologically informed treatment approach, this could lead to improved outcomes and a more cost-effective service (Stockdale et al., 2017; Wan Suhailah et al., 2015).

The Department of Health (now the Department of Health and Social Care) (2009) recommends that audiologists provide psychological therapies where psychologists are not available. Furthermore, patients and clinicians agree that whether CBT delivered by audiologists is an effective treatment for tinnitus is a priority research question (Hall et al., 2013). To that end, and in accordance with Medical Research Council (MRC) recommendations for developing and evaluating complex interventions (Craig et al., 2008), we took a phased approach to developing an audiologist delivered intervention that was 'psychologically informed'. To begin with, components of psychological therapies for

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tinnitus were catalogued in a scoping review (Thompson et al., 2017). The primary aim of that scoping review was to catalogue components of psychological therapies which have been used or tested by psychologists in a format that would inform the development of a standardised audiologist-delivered psychological intervention. Twenty-five 'themes' of components were identified including tinnitus education, psychoeducation, evaluation, treatment rationale, treatment planning, problem solving, behavioural intervention, thought identification, thought challenging, worry time, emotions, social comparison, interpersonal skills, self-concept, lifestyle advice, acceptance and defusion, mindfulness, attention, relaxation, sleep, sound enrichment, comorbidity, treatment reflection, relapse prevention, and common therapeutic skills.

In the second development stage, consensus on which therapy components audiologists should deliver as part of their usual care was derived in a three-round Delphi survey of patients who have experienced tinnitus counselling or psychological therapy, and specialist audiologists, hearing therapists, and psychologists, who had significant experience of using counselling or psychotherapeutic techniques for tinnitus (Thompson et al., 2018). The Delphi survey included all those components identified in the scoping review (Thompson et al., 2017) and any additional components identified by our experts during the first round of the survey. Components that typically reached consensus for inclusion were common therapeutic skills such as Socratic questioning and active listening, which are common to different therapeutic modalities, rather than specific techniques such as graded exposure therapy or cognitive restructuring, which are unique to a cognitive behavioural orientation. There was clear consensus also to use a psychological model of tinnitus rather than a neurophysiological model in patient education.

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Here we report the next stage of this work. The aims were to (1) manualise a low-intensity audiologist-delivered psychologically informed intervention for tinnitus, and (2) evaluate feasibility of delivering and evaluating the manualised intervention. The intervention was delivered by NHS audiologists with prior experience in tinnitus management. The study primarily considered feasibility of a clinical trial of the manualised intervention in terms of the likely patient population, willingness of patients to receive/engage with the manualised treatment, willingness of audiologists to recruit and randomise tinnitus patients to a trial, and willingness of patients to be randomised. Secondary objectives considered qualitative judgements on the acceptability of the intervention from audiologist and patient perspectives, and the likely completeness of selected outcome measures in a randomised controlled trial (RCT). It was our aim to embed good practice in patient and public involvement at all stages.

Methods

The protocol for this work has previously been published (Taylor et al., 2017), and is summarised here.

Development of the manual

Manual development commenced with a one-day reference group meeting involving steering group and study team members (patients, audiologists, hearing therapists, psychologists, and researchers) to decide on which components to include, and how to incorporate them into a manualised care protocol. It was agreed at this meeting that a working framework for the manual would comprise the following sections: Rationale, Assessment, Education, Treatment Planning/Goal Setting, Management/Self-Management, and Relapse Prevention. All 76 components for which consensus for inclusion was reached in the Delphi survey (Thompson et al., 2018) were first considered for allocation under these headings. This was followed by a

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discussion on whether any of the 84 components for which consensus was not reached should be included (no component reached consensus to absolutely exclude) and if so, under which headings they would be written into the manual. Decisions were based on (1) level of agreement from the Delphi survey, (2) whether components had a good evidence-base, theoretical cohesiveness, and, (3) what could realistically be included in a brief low-intensity intervention delivered by audiologists given resource limitations and time-limited training. Individual members of the team drafted specific sections of the manual in accordance with their areas of expertise and according to consensus opinion on what features are typical of a 'good' treatment manual (McCulloch & McMurran, 2007). The manual was then reviewed and amended to reflect a 'whole' in terms of style, coherence, and theory.

The final manual included nine sections (see Supplemental Information 1 for the overview contained in the manual) detailing background and overview of the manual, assessment through a standardised interview, the rationale for psychologically informed treatment, collaborative goal setting and treatment planning, tinnitus education, management/self-management strategies, relapse prevention, a bibliography containing references related to the intervention and further reading for the audiologist or patient, and appendices containing materials used for training purposes. An accompanying 'toolkit' (listed in Supplemental Information 2) of questionnaires, worksheets, and information leaflets was collated to support use of the manual.

Feasibility trial

Ethical approval for the feasibility trial was granted by North West - Preston Research Ethics Committee (reference: 16/NM/0047). The trial involved random allocation of tinnitus patients who received psychologically informed treatment from an audiologist trained in the

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use of the manual, or treatment as usual (TAU) from an audiologist who was not trained in or aware of the content of the treatment manual (Figure 1). Patients were randomised using the randomisation function in Microsoft Excel such that patients allocated to the greatest five random numbers per site were allocated to TAU. A member of the research department not involved in the trial performed randomisation. There was no blinding (to allocation) of the researchers who collected or analysed the qualitative or quantitative data.

INSERT FIGURE 1 ABOUT HERE

Trial sites and training

Patients were recruited at three sites, audiology/Ear, Nose and Throat (ENT) services situated in (1) Nottingham University Hospitals NHS Trust, (2) Sherwood Forest Hospitals NHS Foundation Trust, and (3) Derby Hospitals NHS Foundation Trust. The audiologists delivering the psychological tinnitus intervention and TAU at each site were senior audiologists with several years of experience of managing tinnitus. A 2-day workshop was developed by AC and DF to train audiologists to deliver the manual. Training was designed to be interactive by using a constructive alignment approach (Biggs, 2003). AC developed lesson plans using the Race lecturer toolkit (Race, 2014) including learning outcomes for each session; resources needed to deliver the session; and the structure, content and method of delivery. One senior audiologist from each site received training in the use of the manual during the workshop. Learning was assessed using the Teach-back technique (Meyer et al., 2010).

Participants

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The recruitment method targeted people with tinnitus attending each participating site for an audiology assessment appointment as part of the NHS standard care. Following consultation with six NHS audiology sites, it was estimated that on average recruitment of two eligible patients per month per site was readily achievable. We therefore conservatively estimated feasibility of a trial to reflect this and requested each site to recruit and randomise up to ten patients within a 6 month period. For inclusion, patients were required to (1) be adults aged 18 and over, (2) have intellectual/cognitive capacity to provide informed consent, (3) have sufficient mobility to attend clinics, (4) score ≥ 25 on the Tinnitus Functional Index (TFI; Meikle et al., 2012), and (5) be willing to complete questionnaires and a semi-structured interview about their experiences of taking part in the trial. Patients were excluded if they (1) had tinnitus with a medically treatable origin, (2) were unable to communicate in English, (3) had comorbid conditions (e.g. dementia) which meant they were unable to give informed consent, or (4) had participated in other tinnitus management research between consenting and the start of the intervention. No exclusions were made because of previous experience with psychological services or medications taken. All patients were enrolled at or before their first visit to audiology with a primary complaint of tinnitus.

A member of the research team (JAT) was responsible for recruitment at Site 1. At Site 2 and Site 3, the local PI was delegated responsibility for recruitment, with infrastructure support provided by the National Institute for Health Research (NIHR) Clinical Research Network. JAT regularly monitored recruitment at Sites 2 and 3 and maintained regular email contact with the local PIs to offer support where recruitment rate was lower than required. However, no additional support was requested during the trial.

Intervention

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Psychologically informed treatment was delivered according to the treatment manual. This involved an average of 2.75 sessions (range = 1-3) delivered one-to-one by an audiologist who attended the training workshop.

Control

Patients allocated to the control condition received TAU from an audiologist not trained in psychological therapy and who had not received training in the manualised intervention. TAU typically involved management of hearing loss, education and advice, lasting an average of 1.5 sessions (range = 1-2).

Outcomes

Feasibility of a powered RCT was predefined as (1) a recruitment efficiency of at least 10% of those screened, (2) recruitment of at least 65% of the overall target sample size, (3) retention of 80% of patients who were randomised, (4) completion of 80% for the primary outcome questionnaires, and (5) patient and clinician compliance to the manualised tinnitus counselling.

Six questionnaire were completed at each time point. The TFI is a measure of tinnitus symptom severity over the last 2 weeks. It has 25 items (e.g. “Did you feel IN CONTROL in regard to your tinnitus?”), each with a 10-point scale. Scores are summed and divided by 2.5 to give a total possible score between 0 and 100. The eight factor TFI has very high internal consistency ($\alpha = 0.97$) (Meikle et al., 2012). It has excellent reliability, stability over time, and sensitivity to individual differences in tinnitus severity, although the auditory subscale (three items) may not contribute to the overall score (Fackrell et al., 2018).

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The Tinnitus Cognitions Questionnaire (TCQ; Wilson & Henry, 1998) consists of a series of statements preceded by the words "I think" or "I tell myself," (e.g., I think "if only the noise would go away"). The first 13 items refer to negative thoughts and the second 13 items refer to positive thoughts. Responses are marked on a five-point Likert scale from "never" = 0, to "very frequently" = 4. Positive items are reverse scored to give a total score from 0-104. The TCQ has a reliable two-factor structure and high internal consistency (α = 0.90) (Handscomb et al., 2017).

The Clinical Outcomes in Routine Evaluation - Outcome Measure (CORE-OM; Barkham et al., 2006) is a 34-item (four factor) measure of global distress. Respondents indicate how much each item (e.g. "I have felt optimistic about my future") has applied to them over the past week, using a 5-point Likert scale from "not at all" to "most or all of the time". The CORE-OM includes both positive and negative items (positive items being reverse scored) to give a total score from 0–136. Initial validation of this four factor questionnaire found it to have high internal consistency (α = 0.94) (Evans et al., 2002), although validation in a tinnitus population found that a three factor structure provided a better fit to the data (Handscomb et al., 2016).

The Health Utilities Index 15Q (HUI; Furlong et al., 2001) is a 15 item measure of health-related quality of life. Items are multiple choice with 5-6 rank-ordered response options. Decision tables of response combinations are used to determine the health-state level for each domain within the questionnaire, and then using the tables and a scoring algorithm, utility scores for all attributes of health and an overall health-related quality of life score is determined. Overall scores range from -0.36 –1.00, where 0 = "death" and 1 = "perfect health". Estimates of the reliability of the HUI vary considerably (Busija et al., 2011).

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The Working Alliance Inventory (WAI; Horvath & Greenberg, 1989) provides a measure of the quality of alliance within counselling. It contains 36 items (e.g. "I was worried about the outcome of the sessions") scored on a Likert scale from 1 (Never) to 7 (Always). The WAI contains both positive and negative items, with negative items being reversed scored, giving a possible range of scores from 36 to 252. Reliability of the three WAI scale scores appear to be high ($\alpha = 0.92$, 0.92, and 0.89 respectively) although two subscales ("Tasks" and "Goals") were very highly correlated ($r = .92$).

The Client Service Receipt Inventory (CSRI; Beecham & Knapp, 2001) is an adaptable form used to collect information on the whole range of services and supports study participants may use. It contains items such as "Please list any use of inpatients hospital services over the last three months".

After randomisation, and in advance of their first audiology appointment, patients completed the baseline study questionnaires. Questionnaires were completed again immediately at the end of treatment and at follow-up or 6 months after the commencement of treatment (excluding the CSRI which was only completed at follow-up). In practice, some 6-month follow-up questionnaires were completed before the end of treatment. Patients received one reminder (telephone or email) to complete the follow-up questionnaires if they had not been returned within 2 weeks of their due date.

Treatment fidelity

Treatment fidelity required that treatment components were all consistency administered according to the manual. Audiologists recorded administration of treatment components in a

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case report form held for each patient, and took part in semi-structured interviews after the last patient had completed their treatment. Interviews were used to determine which components of the manualised care they thought worked well, why, and which components were not useful. Patients involved in the intervention group also took part in semi-structured interviews to discuss their experiences of the intervention. JAT or DMT conducted interviews approximately 4 weeks after the last patient appointment. Clinician interviews were conducted after discharge of their final patient. Interviews were audio-recorded, transcribed verbatim and analysed using a thematic analysis approach (Braun & Clarke, 2006). DMT, DMW, and two patient representative members of the lead centre's Patient and Public Involvement (PPI) panel conducted analysis of the qualitative data.

Deviations from protocol

We had originally planned that public research partners trained in interview techniques would conduct patient interviews. However, this ultimately proved unworkable due to the Sponsor's stipulation that they would need formal registration as volunteers with the NHS Trust for this activity. The process for this, involving application and interviews, was deemed too time consuming to be accommodated within the study timeline. We had also originally planned to discuss emerging themes in two focus groups with audiologists and patients, to ensure that the themes and any identified barriers and facilitators to treatment implementation and maintenance of self-management were accurately representative of patient and audiologist experience. However, given the unanticipated length of the treatment process at sites, there was insufficient time for this to be included within the funding period.

Results

Demographic and clinical characteristics

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Nineteen patients were recruited to the trial and randomised to manualised care (n = 11) or TAU (n = 8). Demographic characteristics are reported in Table 1. Mean baseline TFI score was 67.08 (SD=23.644). Seven patients scored 25-50 on the TFI, scores interpreted as tinnitus being a significant problem with a possible need for treatment (Henry et al., 2014). Eleven patients scored above 50, interpreted as tinnitus severe enough to qualify for treatment that is more intensive. Demographic data were missing for one patient.

INSERT TABLE 1 ABOUT HERE

Feasibility outcomes

Participant flow is presented in Figure 1, and feasibility outcomes are presented in Table 2. Patients were screened from September 2016 to April 2017 (maximum six months from first screen at each site). At Site 1, all 10 participants were recruited within a 3 month period; at Site 2 three patients were recruited within a 3 month period, two of whom were recruited on the same day); at Site 3 six patients were recruited within a 7 week period, five of whom were recruited within the same week).

Six-month follow-up occurred from April to September 2017. Recruitment efficiency of those screened surpassed the feasibility target at Site 1 where 10 eligible patients were enrolled from just 16 patients screened (63%), while the target was one enrolment for every 10 patients screened (10%). Recruitment efficiency was also met at Site 2, where 24 patients were screened and three patients were recruited (13%). This difference in recruitment efficiency is in part a consequence of different patient pathways; at Site 1 all patients were referred by their GP to ENT, and from ENT onto audiology. At Site 2 some patients were referred directly to audiology by their GP. Indeed 10 of the 24 patients screened at Site 2

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were assessed by the audiologist as requiring referral to ENT or psychiatry and therefore not eligible for the trial. Also at Site 2, one recruited patient failed to attend any further appointments, and three patients screened as eligible declined to participate due to the time commitments involved and geographical distance between home and the audiology service. Site 3 did not return their screening records so we were unable to assess feasibility.

INSERT TABLE 2 ABOUT HERE

Nineteen patients were recruited and consented to take part in the study; representing a total recruitment of 63% (feasibility target was 65%). Site 1 surpassed the target for feasibility with 100% recruitment. Site 2 recruited three patients (30%) and Site 3 recruited six (60%).

Nine out of 19 patients were retained in the trial until the end of treatment, representing a retention rate of 47% (feasibility criterion was 80%). Reasons for discontinuation included spontaneous remission (n = 1), identification of Alzheimer's disease (n = 1), trial site error in allocating patients to treatment arms (n = 1), loss to follow-up (n = 2), declined to participate further (n = 1), or commenced other treatment (n = 3).

Effectiveness outcomes

Completeness of questionnaire data is given in Table 2, and descriptive statistics are presented in Table 3. TFI, TCQ, TCQ negative thoughts subscale, and CORE-OM scores decreased between baseline and the end of treatment. TFI scores continued to decrease between the end of treatment and 6-month-follow-up, whereas TCQ and CORE-OM scores were maintained between the end of treatment and 6-month follow-up. TFI emotional distress subscale scores increased between baseline and the end of treatment, but decreased below baseline by 6-month-follow up. Patients and audiologists' scores on the WAI task, bond, and

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goal subscales all increased between baseline and end of treatment. No adverse events or adverse reactions were recorded during the trial.

INSERT TABLE 3 ABOUT HERE

Treatment fidelity and experience

Six themes emerged from thematic analysis of interview transcripts: (1) acceptability of and fidelity to treatment components, (2) factors affecting fidelity, (3) refining treatment components, (4) factors affecting feasibility of wider implementation of treatment, (5) training and supervision, and (6) measurement of tinnitus outcomes.

(1) Acceptability of and fidelity to treatment components.

Patients and audiologists use, acceptance of, and fidelity to the treatment components varied. All audiologists reported that they actively promoted physical activity, and patients reported that they engaged in physical activity during the trial, despite it temporarily increasing awareness of tinnitus. Other components were not used consistently, e.g. one audiologist and one patient (from different sites) stated that they did not formally set any goals for treatment, thereby deviating from the treatment protocol:

> *"We didn't set any formal goals, it was just a case of, I would go away and see… whether it's got any worse or whether it got any better and in actual fact it's stayed about the same." (Patient 2).*

Another audiologist explained that goal setting can be challenging without first engaging in tinnitus education to explain to the patient that they cannot cure their tinnitus:

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"... I find the preliminary bit of goal setting a bit difficult because you've got to start by saying, 'we can't cure your tinnitus, so with that in your mind, what would you like to do?'" (Audiologist 3).

All patients reported being reassured by receiving information about the causes, maintenance, and change in tinnitus over time, and for some patients, education was considered sufficient intervention. For many patients the cognitive behavioural model of tinnitus reflected their personal experiences of tinnitus. Patients and audiologists also commented that the model was understandable:

I think [the cognitive behavioural model is] quite a nice one because it's quite logical, the language that it uses is fairly easy, is nothing too sort of technical or too medical and you can [work] through [the manual] in a logical way." (Audiologist 2)

Relaxation was acceptable to audiologists although it was used sparingly and briefly in and outside of appointments. Patients mostly reported using relaxation to improve sleep. Patients and audiologists also highly valued the inclusion of education about sleep cycles in treatment. Patients in the trial did not use sleep diaries, sleep monitoring devices were favoured, although the principle of monitoring sleep to identify poor sleeping habits was maintained:

"No, I've been using [a fitness watch and not the sleep diary] because that records in quite reasonable detail the amount of sleep you've had." (Patient 1)

Cognitive techniques received mixed reviews. Some patients expressed an understanding of avoidance as a mechanism of tinnitus-related distress and recognised when they were engaging in avoidance behaviours:

"I avoided noisy environments. So, like if friends invited me round for a party, I always used to make excuses not to go..." (Patient 3)

Audiologists also demonstrated an understanding of safety behaviours such as avoidance. However, at least one felt unable to recognise avoidance consistently in various contexts:

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"Safety [avoidance] behaviours...seems very obvious when you read the words…. But then actually when the patient starts talking about the things that they do and their feelings and their attitudes and how they deal with things you don't necessarily think, 'that's a safety behaviour'." (Audiologist 1)

At least one audiologist found thought challenging prompts included in the treatment manual useful, but fidelity to the thought-challenging component varied, often limited to identifying negative thoughts without challenging them:

"I didn't use the thought record sheets. I used the unhelpful thinking styles [material], and patients do find this one quite useful and quite often they'll point out, 'yeah, that's me', and so that helps us to address some of these thoughts." (Audiologist 3)

When thought challenging was used, audiologists either considered the technique ineffective, or believed the benefit would only be short term:

"Most of the time [patients] don't [think of a more helpful realistic thought]. And I don't know whether that's because I'm not enabled enough or whether they just can't do it." (Audiologist 1)

The attention, monitoring and acceptance component of the manual was used in treatment but not consistently or as instructed in the manual. One audiologist introduced the concept of mindfulness, and two used metaphors when they thought it would be acceptable to patients. However, one patient reported their audiologist used metaphors as an imagination exercise rather than as an (intended) defusion technique:

"We didn't go through too many metaphors, obviously the metaphors of aligning the sounds of your tinnitus to natural sounds. We didn't talk about particular river banks." (Patient 1)

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Finally, relapse prevention was not addressed according to the manual. Patients remembered being advised to return if their symptoms worsened or if self-management using the techniques learned during the treatment were not effective:

> *"I don't think [the audiologist] did [share the relapse prevention handout] actually, no because I don't think we got on to that point actually." (Patient 1)*

(2) Factors affecting fidelity

Audiologists reported a lack of confidence in implementing treatment components including relaxation, acceptance-based components, and goal setting. One suggested that rigid use of the manual would impair the development of the therapeutic relationship, particularly for less experienced audiologists, and in contrast, another felt that the manual would help less experienced audiologists by providing a structure to follow. For one audiologist, confidence reportedly augmented with increasing experience during the trial:

> *"You're always a little bit nervous to start with. However, I found that after the first few appointments it's just flown. You develop your own pattern in appointments and I guess I developed a pattern very, very quickly and that's because it was very intense training…" (Audiologist 3)*

Patients sometimes resisted the use of treatment components such as thought challenging or mindfulness. Audiologists stated their patients would report not having enough time to engage with the treatment outside of appointments, or just believed that the treatment would be unsuccessful. Audiologists also considered some treatment components were within the scope of practice of psychologists or hearing therapists, but not theirs:

> *"To me [thought challenging] is a logical skill and I don't know that that's my leaning at all. To say to somebody, 'well that thought you are having there is very unhelpful'…if you're a psychologist you could do that. But I can't." (Audiologist 1)*

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(3) Refining treatment components

Patients and audiologists recommended changes to the manual. These included expanding the physical exercise component to include lifestyle advice on diet and alcohol.

> *"That's something that we do anyway so within the tinnitus therapy process we always talk about lifestyle choices. So, physical exercise comes into that but we also talk about things like diet, we might also talk about you know where patients are maybe drinking excessively." (Audiologist 3)*

> *"If they've taken up hobbies that have enabled them to be more distracted, sort of reinforcing those things and said, 'these are the things that you know are going to enable you in the long term to sort of ignore your tinnitus and live with it happily'." (Audiologist 2)*

One audiologist found that some patients' lack of motivation was a barrier to their engagement in the treatment and that a technique to improve motivation would be useful.

> *"It's like how can we break this down…what happens when you can't motivate a patient… how do you tackle somebody who is clearly giving you excuses…? Cause there's a harsh way which is, 'look, you're just giving lots of excuses.' But that's not the way to do it. That doesn't help anybody. But then is it up to us to go into maybe the deeper reasons why they're doing that, is it a confidence issue [for example], and it's that thing that's stopping that patient from getting better." (Audiologist 3)*

(4) Factors affecting feasibility of wider implementation of treatment

Audiologists unanimously agreed the treatment did not lengthen the amount of time spent with patients throughout their care. However, participation in the intervention arm of the trial affected the usual appointment structure. For example, the audiologists delayed hearing aid fitting to allow time to gather information about underlying mental health problems first.

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Audiologists also thought that reducing the time between appointments could increase treatment benefit:

> *" [reducing] follow-up [from] about 12 .. to...6 weeks after the initial appointment... works because patients either take on board everything you say or they struggle with it and if you've kind of let them go for three months you're almost back to square one sometimes." (Audiologist 1)*

However, concern was expressed that such changes to appointment structure might not be feasible in audiology services where resources are limited. Continuity of care, with patients seeing the same audiologist throughout their care was also considered beneficial:

> *".. some patients even though they are hearing aid patients, probably would benefit from being fitted by the tinnitus audiologist rather than an [other] audiologist because some of the reasoning behind why we're fitting the hearing aid has to be related to the tinnitus. And perhaps that was lost ..." (Audiologist 2)*

(5) Training and supervision

Audiologists were introduced to the manual across 2 days of training. Although audiologists valued the small group setting, the content of the 2 days was considered overwhelming. Audiologists involved in the trial suggested that it might not be feasible to implement this format outside of the trial for routine clinical practice:

> *"It was excellent, one-to-one with a group of experts, what else could you ask for? ...Feasibility-wise, would that work in practice? Probably not." (Audiologist 3)*

Some audiologists recommended role-play to improve the training to provide practice and feedback on techniques in a range of scenarios in order to help audiologists to understand how components of the manual would work in practice. All audiologists felt that formal

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supervision arrangement would be helpful to check adherence to the treatment manual. However, audiologists also noted the lack of supervision within audiology:

> *"In adult audiology, we work in a silo… we don't have anyone else except our colleagues to turn to, we don't have any formal supervision like you would if you were a therapist." (Audiologist 3)*

The potential for the treatment manual to be used as a training tool for inexperienced audiologists was raised repeatedly during interviews:

> *"I found [the manual] quite useful in terms of training somebody new to sort of say, 'do you want to delve a bit deeper, is there something in these questions that perhaps is relevant for the patient you've got sat in front of you?" (Audiologist 2)*

(6) Measurement of tinnitus outcomes

Patients and audiologists recognised that all the domains measured by the TFI and TCQ could be relevant to different patients, and no additional domains were identified as relevant that were not measured in the trial. The TFI was favoured as an assessment tool by patients and audiologists because of its broad coverage across tinnitus problem domains to enable identification of relevant treatment options. However, one audiologist highlighted that some patients conflate hearing loss and tinnitus when completing the TFI, which may limit its ability to distinguish between tinnitus-related and hearing-related distress. Audiologists were less familiar with the TCQ, although one appreciated it as a means to encourage patients to recognise and talk about their negative thoughts about tinnitus:

> *"Sometimes patients are quite reluctant to give [negative thoughts], some patients don't like feelings, but to get them to write it down and to score it, you get a bit more of an overview of about where they are and how severe really the tinnitus is and how much it is affecting them psychologically. So that again I've not used that one [TCQ]*

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routinely but I do think that one is one that I would probably use for those patients where I'm perhaps struggling to see how much is affecting them psychologically." (Audiologist 2)

Patients also welcomed the use of tinnitus questionnaires to monitor their improvement during treatment:

"It makes you start to realise how well you're doing and it gives you a chance to measure that…how bad it is or how you're managing really well." (Patient 2)

Patients and audiologists had different views on the difficulty of completing questionnaires. Whereas audiologists perceived questionnaires to be accessible, patients thought that support should be offered to complete any questionnaires:

"When you give a questionnaire like this and just give it to somebody – and I was put in another room to do it – I think there's an assumption made that everyone can do that task." (Patient 2)

Discussion

This study was the first to develop and assess feasibility of trialling an audiologist-delivered low intensity psychological intervention for tinnitus. Ultimately, we aimed to provide an evidenced-based, costed, manualised approach to tinnitus care that is attractive to commissioners and represents a flexible and accessible tinnitus treatment. The feasibility trial reported here determined that a manualised psychologically informed treatment was acceptable to patients and audiologists, but that it is not yet feasible to test in a multi-site effectiveness trial. Recruitment reached only 19 patients (63%) after 6 months, just short of the 65% target for feasibility, while average retention for the duration of the trial reached only nine patients (47%), very short of the 80% target for feasibility. Patient recruitment is acknowledged to be one of the most difficult and least predictable elements of a clinical trial.

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(Allen et al., 1998; Thoma et al., 2010; Sanchez et al., 2018). Here, performance varied across the three sites. The best in terms of recruitment efficiency and recruitment rate was Site 1, an audiology service based in a large teaching hospital where staff are supported to be research active. Having a large pool of potentially eligible patients to draw on, as well as engaging with audiologists who have previous experience in participating in RCTs, are known factors that can help to achieve study targets for hearing trials (Sanchez et al., 2018). In addition, a member of the research team was responsible for recruitment at Site 1, and did not have to contend with the same clinic demands as PIs at the other sites. That said, the pattern of recruitment would suggest all could have reached feasibility. Site 3 in particular recruited five patients (50% of target) within a single week, suggesting competing demands and/or a lack of engagement with the research, rather than low patient numbers, were barriers to recruitment at that site. In contrast, Site 1 performed poorest in terms of patient retention indicating that even experienced participating sites need a risk mitigation plan and regular trial monitoring. We would concur with the recommendations suggested by Sanchez et al. (2018) that a future RCT needs to ensure that it has sufficient resource to support a carefully specified plan to promote recruitment and retention of tinnitus patients. Furthermore, based on current findings, we would suggest that treatment fidelity could be improved and more accurately monitored by (1) including an audiologist familiarisation phase of treatment implementation before including patients in analyses, and (2) including direct in-session observation of a random selection of treatment sessions using standardised fidelity evaluation forms, based on the treatment manual.

From the Delphi survey (Thompson et al., 2018) we know that psychoeducation and common therapeutic skills are considered more important than specific CBT techniques in psychological tinnitus treatment. Patients and audiologists considered it essential to include

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psychoeducation and common therapeutic skills (aimed at informing the patient and conveying empathy) in psychological tinnitus treatment. Giving patients information about common cognitive distortions was considered essential, but cognitive restructuring was not. This pattern suggests that patients and audiologists understood the contribution of maladaptive behaviours and negative thoughts to bothersome tinnitus, but did not think that the audiologist's role should or could extend to managing patients' use of specific cognitive behavioural techniques. This issue was further highlighted in the current trial. Interviews revealed audiologists chose not to use certain psychological treatment components from the manual because (1) they lacked confidence in using them as training was brief and insufficient for them to learn how to implement them safely and effectively, (2) they thought patients do not want to record, monitor, and challenge specific negative thoughts and behaviours, and (3) they believed certain components would be ineffective. More work is therefore required to consider what audiologists can and want to deliver either within their current or a revised clinic and appointment structure, and what training and supervision arrangements need to be in place for these skills to be developed, used, and maintained throughout a clinical trial. Beyond feasibility and evaluation of effectiveness, it will also be essential to explore how the intervention can be implemented into routine clinical practice, which will involve further challenges such as organisational development, workplace cultures and individual barriers (De Silva, 2015).

Similar issues are being faced in other areas. For example, there is emerging evidence that CBT-enhanced voice therapy for functional dysphonia leads to greater improvement in general well-being and distress (Miller, Deary, & Patterson, 2014), but as with the current study there are open questions about how clinicians should be trained and supervised and how cost-effective this approach may be. There are examples in other fields of how training

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might be achieved on a large scale. Richmond et al. (2016) evaluated feasibility of an online programme to train physiotherapists in the use of cognitive behavioural approaches to the management of non-specific low back pain. They found an internet-based approach to training to be equivalent to face-to-face group training in terms of retention of theoretical and procedural knowledge. However, clinicians who received the face-to-face training showed greater self-efficacy in delivering the assessment component of the therapy, were more satisfied with their training, and were more 'psychosocially' rather than 'biomedically' orientated after training, and by implication were more aligned with a cognitive behavioural approach. Regardless, uptake of the treatment approach after training was similar across both groups (about one third). Their conclusion, that there is a need to develop strategies for training and support to deliver treatments that use cognitive behavioural approaches, read relevant to all allied health professionals at this time. In the context of the current study, issues such as the acceptability and preference for different training formats will need to be explored.

Certain revisions to the TinMan study manual and training require consideration before it can be subjected to further feasibility testing. These include additional information about tinnitus and psychoeducation, including information about negative thought patterns and avoidant behaviours. An appreciation of patient preference and need with respect to psychological treatment components was also apparent in the current study. Specific cognitive behavioral techniques tend to purposefully engage patients in initially unwanted, though temporary, thoughts or emotional states. It is of importance to train audiologists in how to deal with these challenges and ultimately make use of the patient-states resulting from these approaches. The natural resistance and transferal of distress in both patients and audiologists when using these

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techniques needs to be adequately covered in training that balances informed patient choice and need.

Conclusion

What emerged most strongly from this study is that an audiologist-delivered low-intensity psychological intervention is an acceptable approach to tinnitus management, but even very experienced audiologists require more extensive training to 'upskill' in the use of psychological treatment components. Audiologists involved in delivering the psychological treatment reported that the amount of training was insufficient and lacked role-play and feedback from a supervisor to increase understanding of how to deliver the treatment effectively. This needs to be addressed before further testing. One potentially cost-effective means of training audiologists may be to develop reusable learning objects, e.g. including video recordings of role-play scenarios where an audiologist is using a set of psychological techniques from the manual. Once training is addressed, the treatment may progress to further feasibility testing. There has been recent discussion in the UK audiology community about some form of compulsory continual professional development or qualification in tinnitus care for practicing audiologists. The manual developed here, and the training resources that will support its use, could potentially meet this perceived need.

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Declaration of conflicts of interest

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Figure legends.

Figure 1. Feasibility trial flow chart

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Table 1. Baseline demographics

	Psychological treatment (SD)	Treatment as usual (SD)	Overall (SD)
Sex	3 female 7 male	3 female 5 male	6 female 12 male
Age	59 (10.989)	44 (18.330)	53 (16.092)
Baseline TFI	67.08 (23.644)	50.00 (23.849)	59.49 (23.644)

SD = Standard Deviation; TFI = Tinnitus Functional Index. Demographic data for one patient were not provided by trial site

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Table 2. Feasibility outcomes

	Site 1	Site 2	Site 3	Psychological treatment	TAU	Total
Recruitment efficiency of those screened	63%	12%	*	-	-	*
Recruitment relative to target	100%	30%	60%	73%	53%	63%
Retention of enrolled patients	30%	67%	67%	64%	25%	47%
Primary effectiveness outcome questionnaire received	100%	50%	0%	43%	50%	44%

TAU=Treatment as Usual; * = screening data not provided by sites; - = Not applicable. Note the each site had a recruitment target of 10 patients.

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Table 3. Questionnaire data

	Baseline		Post-treatment		6-month follow-up	
	Psychological treatment	TAU	Psychological treatment	TAU	Psychological treatment	TAU
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
TFI	67.08 (21.669)	50.00 (23.849)	26.53 (32.027)	8.80 (-)	22.48 (25.065)	10.40 (-)
TFI-E	59.00 (37.648)	38.75 (28.000)	25.56 (38.634)	0.00 (-)	15.56 (21.430)	3.33 (-)
TCQ	64.67 (24.378)	59.00 (56.569)	49.67 (12.097)	56.00 (-)	60.00 (-)	8.00 (-)
TCQ-N	46.17 (26.164)	48.50 (61.518)	32.67 (22.811)	36.00 (-)	54.00 (-)	3.00 (-)
CORE-OM	8.58 (7.425)	6.47 (4.575)	2.94 (2.080)	1.76 (-)	2.94 (2.080)	1.47 (-)
WAI-C Task	74.40 (7.162)	80.00 (4.243)	79.00 (6.928)	83.00 (-)		
WAI-C Bond	76.20 (8.843)	73.00 (15.556)	76.00 (6.928)	84.00 (-)		
WAI-C Goal	73.40 (7.369)	80.50 (3.536)	78.67 (9.238)	75.67 (7.234)		
WAI-T Task	38.75 (37.677)	6.00 (-)	75.00 (7.071)	50.67 (37.846)		
WAI-T Bond	74.50 (9.110)	84.00 (-)	77.50 (6.364)	72.00 (7.810)		
WAI-T Goal	62.50 (11.958)	54.00 (-)	73.00 (7.071)	54.00 (-)		

TAU = Treatment as usual; SD = Standard deviation; TFI = Tinnitus Functional Index; TFI-E = Tinnitus Functional Index-Emotion subscale; TCQ = Tinnitus Cognitions Questionnaire; TCQ-N = Tinnitus Cognitions Questionnaire-Negative subscale; CORE-OM = Clinical Outcomes in Routine Evaluation – Outcome Measure; WAI-C = Working Alliance Inventory-

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Background

Tinnitus involves the perception of sound in the absence of any acoustic stimuli (Davis & El Refaie, 2000), and is often associated with insomnia, hearing problems, depression, and anxiety (Tyler & Baker, 1983; Pinto et al., 2014). Cognitive behaviour therapy (CBT) has been trialled extensively, but evidence is largely limited to clinical trials where a psychologist delivered it (Fuller et al., 2020; Hesser et al., 2011; Hoare et al., 2011). Some studies have additionally included multiple disciplines such as clinical physicists in audiology, who deliver elements of care that are informed by psychology (e.g. Cima et al., 2012). In the UK most tinnitus care is delivered by audiologists. However, there is no standard protocol for tinnitus management and various approaches to assessment and treatment are used (Hoare et al., 2015). Most audiology departments offer management of hearing loss, use of sound generators, and patient education. Only some departments have access to psychologists (Gander et al., 2011) and there is no evidence for the effectiveness of psychological interventions when delivered by audiologists (Hoare et al., 2011). If audiologists were to use a psychologically informed treatment approach, this could lead to improved outcomes and a more cost-effective service (Stockdale et al., 2017; Wan Suhailah et al., 2015).

The Department of Health (now the Department of Health and Social Care) (2009) recommends that audiologists provide psychological therapies where psychologists are not available. Furthermore, patients and clinicians agree that whether CBT delivered by audiologists is an effective treatment for tinnitus is a priority research question (Hall et al., 2013). To that end, and in accordance with Medical Research Council (MRC) recommendations for developing and evaluating complex interventions (Craig et al., 2008), we took a phased approach to developing an audiologist delivered intervention that was 'psychologically informed'. To begin with, components of psychological therapies for

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tinnitus were catalogued in a scoping review (Thompson et al., 2017). The primary aim of that scoping review was to catalogue components of psychological therapies which have been used or tested by psychologists in a format that would inform the development of a standardised audiologist-delivered psychological intervention. Twenty-five 'themes' of components were identified including tinnitus education, psychoeducation, evaluation, treatment rationale, treatment planning, problem solving, behavioural intervention, thought identification, thought challenging, worry time, emotions, social comparison, interpersonal skills, self-concept, lifestyle advice, acceptance and defusion, mindfulness, attention, relaxation, sleep, sound enrichment, comorbidity, treatment reflection, relapse prevention, and common therapeutic skills.

In the second development stage, consensus on which therapy components audiologists should deliver as part of their usual care was derived in a three-round Delphi survey of patients who have experienced tinnitus counselling or psychological therapy, and specialist audiologists, hearing therapists, and psychologists, who had significant experience of using counselling or psychotherapeutic techniques for tinnitus (Thompson et al., 2018). The Delphi survey included all those components identified in the scoping review (Thompson et al., 2017) and any additional components identified by our experts during the first round of the survey. Components that typically reached consensus for inclusion were common therapeutic skills such as Socratic questioning and active listening, which are common to different therapeutic modalities, rather than specific techniques such as graded exposure therapy or cognitive restructuring, which are unique to a cognitive behavioural orientation. There was clear consensus also to use a psychological model of tinnitus rather than a neurophysiological model in patient education.

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Here we report the next stage of this work. The aims were to (1) manualise a low-intensity audiologist-delivered psychologically informed intervention for tinnitus, and (2) evaluate feasibility of delivering and evaluating the manualised intervention. The intervention was delivered by NHS audiologists with prior experience in tinnitus management. The study primarily considered feasibility of a clinical trial of the manualised intervention in terms of the likely patient population, willingness of patients to receive/engage with the manualised treatment, willingness of audiologists to recruit and randomise tinnitus patients to a trial, and willingness of patients to be randomised. Secondary objectives considered qualitative judgements on the acceptability of the intervention from audiologist and patient perspectives, and the likely completeness of selected outcome measures in a randomised controlled trial (RCT). It was our aim to embed good practice in patient and public involvement at all stages.

Methods

The protocol for this work has previously been published (Taylor et al., 2017), and is summarised here.

Development of the manual

Manual development commenced with a one-day reference group meeting involving steering group and study team members (patients, audiologists, hearing therapists, psychologists, and researchers) to decide on which components to include, and how to incorporate them into a manualised care protocol. It was agreed at this meeting that a working framework for the manual would comprise the following sections: Rationale, Assessment, Education, Treatment Planning/Goal Setting, Management/Self-Management, and Relapse Prevention. All 76 components for which consensus for inclusion was reached in the Delphi survey (Thompson et al., 2018) were first considered for allocation under these headings. This was followed by a

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discussion on whether any of the 84 components for which consensus was not reached should be included (no component reached consensus to absolutely exclude) and if so, under which headings they would be written into the manual. Decisions were based on (1) level of agreement from the Delphi survey, (2) whether components had a good evidence-base, theoretical cohesiveness, and, (3) what could realistically be included in a brief low-intensity intervention delivered by audiologists given resource limitations and time-limited training. Individual members of the team drafted specific sections of the manual in accordance with their areas of expertise and according to consensus opinion on what features are typical of a 'good' treatment manual (McCulloch & McMurran, 2007). The manual was then reviewed and amended to reflect a 'whole' in terms of style, coherence, and theory.

The final manual included nine sections (see Supplemental Information 1 for the overview contained in the manual) detailing background and overview of the manual, assessment through a standardised interview, the rationale for psychologically informed treatment, collaborative goal setting and treatment planning, tinnitus education, management/self-management strategies, relapse prevention, a bibliography containing references related to the intervention and further reading for the audiologist or patient, and appendices containing materials used for training purposes. An accompanying 'toolkit' (listed in Supplemental Information 2) of questionnaires, worksheets, and information leaflets was collated to support use of the manual.

Feasibility trial

Ethical approval for the feasibility trial was granted by North West - Preston Research Ethics Committee (reference: 16/NM/0047). The trial involved random allocation of tinnitus patients who received psychologically informed treatment from an audiologist trained in the

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use of the manual, or treatment as usual (TAU) from an audiologist who was not trained in or aware of the content of the treatment manual (Figure 1). Patients were randomised using the randomisation function in Microsoft Excel such that patients allocated to the greatest five random numbers per site were allocated to TAU. A member of the research department not involved in the trial performed randomisation. There was no blinding (to allocation) of the researchers who collected or analysed the qualitative or quantitative data.

INSERT FIGURE 1 ABOUT HERE

Trial sites and training

Patients were recruited at three sites, audiology/Ear, Nose and Throat (ENT) services situated in (1) Nottingham University Hospitals NHS Trust, (2) Sherwood Forest Hospitals NHS Foundation Trust, and (3) Derby Hospitals NHS Foundation Trust. The audiologists delivering the psychological tinnitus intervention and TAU at each site were senior audiologists with several years of experience of managing tinnitus. A 2-day workshop was developed by AC and DF to train audiologists to deliver the manual. Training was designed to be interactive by using a constructive alignment approach (Biggs, 2003). AC developed lesson plans using the Race lecturer toolkit (Race, 2014) including learning outcomes for each session; resources needed to deliver the session; and the structure, content and method of delivery. One senior audiologist from each site received training in the use of the manual during the workshop. Learning was assessed using the Teach-back technique (Meyer et al., 2010).

Participants

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The recruitment method targeted people with tinnitus attending each participating site for an audiology assessment appointment as part of the NHS standard care. Following consultation with six NHS audiology sites, it was estimated that on average recruitment of two eligible patients per month per site was readily achievable. We therefore conservatively estimated feasibility of a trial to reflect this and requested each site to recruit and randomise up to ten patients within a 6 month period. For inclusion, patients were required to (1) be adults aged 18 and over, (2) have intellectual/cognitive capacity to provide informed consent, (3) have sufficient mobility to attend clinics, (4) score ≥ 25 on the Tinnitus Functional Index (TFI; Meikle et al., 2012), and (5) be willing to complete questionnaires and a semi-structured interview about their experiences of taking part in the trial. Patients were excluded if they (1) had tinnitus with a medically treatable origin, (2) were unable to communicate in English, (3) had comorbid conditions (e.g. dementia) which meant they were unable to give informed consent, or (4) had participated in other tinnitus management research between consenting and the start of the intervention. No exclusions were made because of previous experience with psychological services or medications taken. All patients were enrolled at or before their first visit to audiology with a primary complaint of tinnitus.

A member of the research team (JAT) was responsible for recruitment at Site 1. At Site 2 and Site 3, the local PI was delegated responsibility for recruitment, with infrastructure support provided by the National Institute for Health Research (NIHR) Clinical Research Network. JAT regularly monitored recruitment at Sites 2 and 3 and maintained regular email contact with the local PIs to offer support where recruitment rate was lower than required. However, no additional support was requested during the trial.

Intervention

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Psychologically informed treatment was delivered according to the treatment manual. This involved an average of 2.75 sessions (range = 1-3) delivered one-to-one by an audiologist who attended the training workshop.

Control

Patients allocated to the control condition received TAU from an audiologist not trained in psychological therapy and who had not received training in the manualised intervention. TAU typically involved management of hearing loss, education and advice, lasting an average of 1.5 sessions (range = 1-2).

Outcomes

Feasibility of a powered RCT was predefined as (1) a recruitment efficiency of at least 10% of those screened, (2) recruitment of at least 65% of the overall target sample size, (3) retention of 80% of patients who were randomised, (4) completion of 80% for the primary outcome questionnaires, and (5) patient and clinician compliance to the manualised tinnitus counselling.

Six questionnaire were completed at each time point. The TFI is a measure of tinnitus symptom severity over the last 2 weeks. It has 25 items (e.g. “Did you feel IN CONTROL in regard to your tinnitus?”), each with a 10-point scale. Scores are summed and divided by 2.5 to give a total possible score between 0 and 100. The eight factor TFI has very high internal consistency ($\alpha = 0.97$) (Meikle et al., 2012). It has excellent reliability, stability over time, and sensitivity to individual differences in tinnitus severity, although the auditory subscale (three items) may not contribute to the overall score (Fackrell et al., 2018).

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The Tinnitus Cognitions Questionnaire (TCQ; Wilson & Henry, 1998) consists of a series of statements preceded by the words "I think" or "I tell myself," (e.g., I think "if only the noise would go away"). The first 13 items refer to negative thoughts and the second 13 items refer to positive thoughts. Responses are marked on a five-point Likert scale from "never" = 0, to "very frequently" = 4. Positive items are reverse scored to give a total score from 0-104. The TCQ has a reliable two-factor structure and high internal consistency (α = 0.90) (Handscomb et al., 2017).

The Clinical Outcomes in Routine Evaluation - Outcome Measure (CORE-OM; Barkham et al., 2006) is a 34-item (four factor) measure of global distress. Respondents indicate how much each item (e.g. "I have felt optimistic about my future") has applied to them over the past week, using a 5-point Likert scale from "not at all" to "most or all of the time". The CORE-OM includes both positive and negative items (positive items being reverse scored) to give a total score from 0–136. Initial validation of this four factor questionnaire found it to have high internal consistency (α = 0.94) (Evans et al., 2002), although validation in a tinnitus population found that a three factor structure provided a better fit to the data (Handscomb et al., 2016).

The Health Utilities Index 15Q (HUI; Furlong et al., 2001) is a 15 item measure of health-related quality of life. Items are multiple choice with 5-6 rank-ordered response options. Decision tables of response combinations are used to determine the health-state level for each domain within the questionnaire, and then using the tables and a scoring algorithm, utility scores for all attributes of health and an overall health-related quality of life score is determined. Overall scores range from -0.36 –1.00, where 0 = "death" and 1 = "perfect health". Estimates of the reliability of the HUI vary considerably (Busija et al., 2011).

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The Working Alliance Inventory (WAI; Horvath & Greenberg, 1989) provides a measure of the quality of alliance within counselling. It contains 36 items (e.g. "I was worried about the outcome of the sessions") scored on a Likert scale from 1 (Never) to 7 (Always). The WAI contains both positive and negative items, with negative items being reversed scored, giving a possible range of scores from 36 to 252. Reliability of the three WAI scale scores appear to be high ($\alpha = 0.92$, 0.92, and 0.89 respectively) although two subscales ("Tasks" and "Goals") were very highly correlated ($r = .92$).

The Client Service Receipt Inventory (CSRI; Beecham & Knapp, 2001) is an adaptable form used to collect information on the whole range of services and supports study participants may use. It contains items such as "Please list any use of inpatients hospital services over the last three months".

After randomisation, and in advance of their first audiology appointment, patients completed the baseline study questionnaires. Questionnaires were completed again immediately at the end of treatment and at follow-up or 6 months after the commencement of treatment (excluding the CSRI which was only completed at follow-up). In practice, some 6-month follow-up questionnaires were completed before the end of treatment. Patients received one reminder (telephone or email) to complete the follow-up questionnaires if they had not been returned within 2 weeks of their due date.

Treatment fidelity

Treatment fidelity required that treatment components were all consistency administered according to the manual. Audiologists recorded administration of treatment components in a

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case report form held for each patient, and took part in semi-structured interviews after the last patient had completed their treatment. Interviews were used to determine which components of the manualised care they thought worked well, why, and which components were not useful. Patients involved in the intervention group also took part in semi-structured interviews to discuss their experiences of the intervention. JAT or DMT conducted interviews approximately 4 weeks after the last patient appointment. Clinician interviews were conducted after discharge of their final patient. Interviews were audio-recorded, transcribed verbatim and analysed using a thematic analysis approach (Braun & Clarke, 2006). DMT, DMW, and two patient representative members of the lead centre's Patient and Public Involvement (PPI) panel conducted analysis of the qualitative data.

Deviations from protocol

We had originally planned that public research partners trained in interview techniques would conduct patient interviews. However, this ultimately proved unworkable due to the Sponsor's stipulation that they would need formal registration as volunteers with the NHS Trust for this activity. The process for this, involving application and interviews, was deemed too time consuming to be accommodated within the study timeline. We had also originally planned to discuss emerging themes in two focus groups with audiologists and patients, to ensure that the themes and any identified barriers and facilitators to treatment implementation and maintenance of self-management were accurately representative of patient and audiologist experience. However, given the unanticipated length of the treatment process at sites, there was insufficient time for this to be included within the funding period.

Results

Demographic and clinical characteristics

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Nineteen patients were recruited to the trial and randomised to manualised care (n = 11) or TAU (n = 8). Demographic characteristics are reported in Table 1. Mean baseline TFI score was 67.08 (SD=23.644). Seven patients scored 25-50 on the TFI, scores interpreted as tinnitus being a significant problem with a possible need for treatment (Henry et al., 2014). Eleven patients scored above 50, interpreted as tinnitus severe enough to qualify for treatment that is more intensive. Demographic data were missing for one patient.

INSERT TABLE 1 ABOUT HERE

Feasibility outcomes

Participant flow is presented in Figure 1, and feasibility outcomes are presented in Table 2. Patients were screened from September 2016 to April 2017 (maximum six months from first screen at each site). At Site 1, all 10 participants were recruited within a 3 month period; at Site 2 three patients were recruited within a 3 month period, two of whom were recruited on the same day); at Site 3 six patients were recruited within a 7 week period, five of whom were recruited within the same week).

Six-month follow-up occurred from April to September 2017. Recruitment efficiency of those screened surpassed the feasibility target at Site 1 where 10 eligible patients were enrolled from just 16 patients screened (63%), while the target was one enrolment for every 10 patients screened (10%). Recruitment efficiency was also met at Site 2, where 24 patients were screened and three patients were recruited (13%). This difference in recruitment efficiency is in part a consequence of different patient pathways; at Site 1 all patients were referred by their GP to ENT, and from ENT onto audiology. At Site 2 some patients were referred directly to audiology by their GP. Indeed 10 of the 24 patients screened at Site 2

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were assessed by the audiologist as requiring referral to ENT or psychiatry and therefore not eligible for the trial. Also at Site 2, one recruited patient failed to attend any further appointments, and three patients screened as eligible declined to participate due to the time commitments involved and geographical distance between home and the audiology service. Site 3 did not return their screening records so we were unable to assess feasibility.

INSERT TABLE 2 ABOUT HERE

Nineteen patients were recruited and consented to take part in the study; representing a total recruitment of 63% (feasibility target was 65%). Site 1 surpassed the target for feasibility with 100% recruitment. Site 2 recruited three patients (30%) and Site 3 recruited six (60%).

Nine out of 19 patients were retained in the trial until the end of treatment, representing a retention rate of 47% (feasibility criterion was 80%). Reasons for discontinuation included spontaneous remission (n = 1), identification of Alzheimer's disease (n = 1), trial site error in allocating patients to treatment arms (n = 1), loss to follow-up (n = 2), declined to participate further (n = 1), or commenced other treatment (n = 3).

Effectiveness outcomes

Completeness of questionnaire data is given in Table 2, and descriptive statistics are presented in Table 3. TFI, TCQ, TCQ negative thoughts subscale, and CORE-OM scores decreased between baseline and the end of treatment. TFI scores continued to decrease between the end of treatment and 6-month-follow-up, whereas TCQ and CORE-OM scores were maintained between the end of treatment and 6-month follow-up. TFI emotional distress subscale scores increased between baseline and the end of treatment, but decreased below baseline by 6-month-follow up. Patients and audiologists' scores on the WAI task, bond, and

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goal subscales all increased between baseline and end of treatment. No adverse events or adverse reactions were recorded during the trial.

INSERT TABLE 3 ABOUT HERE

Treatment fidelity and experience

Six themes emerged from thematic analysis of interview transcripts: (1) acceptability of and fidelity to treatment components, (2) factors affecting fidelity, (3) refining treatment components, (4) factors affecting feasibility of wider implementation of treatment, (5) training and supervision, and (6) measurement of tinnitus outcomes.

(1) Acceptability of and fidelity to treatment components.

Patients and audiologists use, acceptance of, and fidelity to the treatment components varied. All audiologists reported that they actively promoted physical activity, and patients reported that they engaged in physical activity during the trial, despite it temporarily increasing awareness of tinnitus. Other components were not used consistently, e.g. one audiologist and one patient (from different sites) stated that they did not formally set any goals for treatment, thereby deviating from the treatment protocol:

> *"We didn't set any formal goals, it was just a case of, I would go away and see… whether it's got any worse or whether it got any better and in actual fact it's stayed about the same." (Patient 2).*

Another audiologist explained that goal setting can be challenging without first engaging in tinnitus education to explain to the patient that they cannot cure their tinnitus:

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"... I find the preliminary bit of goal setting a bit difficult because you've got to start by saying, 'we can't cure your tinnitus, so with that in your mind, what would you like to do?'" (Audiologist 3).

All patients reported being reassured by receiving information about the causes, maintenance, and change in tinnitus over time, and for some patients, education was considered sufficient intervention. For many patients the cognitive behavioural model of tinnitus reflected their personal experiences of tinnitus. Patients and audiologists also commented that the model was understandable:

I think [the cognitive behavioural model is] quite a nice one because it's quite logical, the language that it uses is fairly easy, is nothing too sort of technical or too medical and you can [work] through [the manual] in a logical way." (Audiologist 2)

Relaxation was acceptable to audiologists although it was used sparingly and briefly in and outside of appointments. Patients mostly reported using relaxation to improve sleep. Patients and audiologists also highly valued the inclusion of education about sleep cycles in treatment. Patients in the trial did not use sleep diaries, sleep monitoring devices were favoured, although the principle of monitoring sleep to identify poor sleeping habits was maintained:

"No, I've been using [a fitness watch and not the sleep diary] because that records in quite reasonable detail the amount of sleep you've had." (Patient 1)

Cognitive techniques received mixed reviews. Some patients expressed an understanding of avoidance as a mechanism of tinnitus-related distress and recognised when they were engaging in avoidance behaviours:

"I avoided noisy environments. So, like if friends invited me round for a party, I always used to make excuses not to go..." (Patient 3)

Audiologists also demonstrated an understanding of safety behaviours such as avoidance. However, at least one felt unable to recognise avoidance consistently in various contexts:

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"Safety [avoidance] behaviours...seems very obvious when you read the words…. But then actually when the patient starts talking about the things that they do and their feelings and their attitudes and how they deal with things you don't necessarily think, 'that's a safety behaviour'." (Audiologist 1)

At least one audiologist found thought challenging prompts included in the treatment manual useful, but fidelity to the thought-challenging component varied, often limited to identifying negative thoughts without challenging them:

"I didn't use the thought record sheets. I used the unhelpful thinking styles [material], and patients do find this one quite useful and quite often they'll point out, 'yeah, that's me', and so that helps us to address some of these thoughts." (Audiologist 3)

When thought challenging was used, audiologists either considered the technique ineffective, or believed the benefit would only be short term:

"Most of the time [patients] don't [think of a more helpful realistic thought]. And I don't know whether that's because I'm not enabled enough or whether they just can't do it." (Audiologist 1)

The attention, monitoring and acceptance component of the manual was used in treatment but not consistently or as instructed in the manual. One audiologist introduced the concept of mindfulness, and two used metaphors when they thought it would be acceptable to patients. However, one patient reported their audiologist used metaphors as an imagination exercise rather than as an (intended) defusion technique:

"We didn't go through too many metaphors, obviously the metaphors of aligning the sounds of your tinnitus to natural sounds. We didn't talk about particular river banks." (Patient 1)

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Finally, relapse prevention was not addressed according to the manual. Patients remembered being advised to return if their symptoms worsened or if self-management using the techniques learned during the treatment were not effective:

> *"I don't think [the audiologist] did [share the relapse prevention handout] actually, no because I don't think we got on to that point actually." (Patient 1)*

(2) Factors affecting fidelity

Audiologists reported a lack of confidence in implementing treatment components including relaxation, acceptance-based components, and goal setting. One suggested that rigid use of the manual would impair the development of the therapeutic relationship, particularly for less experienced audiologists, and in contrast, another felt that the manual would help less experienced audiologists by providing a structure to follow. For one audiologist, confidence reportedly augmented with increasing experience during the trial:

> *"You're always a little bit nervous to start with. However, I found that after the first few appointments it's just flown. You develop your own pattern in appointments and I guess I developed a pattern very, very quickly and that's because it was very intense training…" (Audiologist 3)*

Patients sometimes resisted the use of treatment components such as thought challenging or mindfulness. Audiologists stated their patients would report not having enough time to engage with the treatment outside of appointments, or just believed that the treatment would be unsuccessful. Audiologists also considered some treatment components were within the scope of practice of psychologists or hearing therapists, but not theirs:

> *"To me [thought challenging] is a logical skill and I don't know that that's my leaning at all. To say to somebody, 'well that thought you are having there is very unhelpful'…if you're a psychologist you could do that. But I can't." (Audiologist 1)*

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(3) Refining treatment components

Patients and audiologists recommended changes to the manual. These included expanding the physical exercise component to include lifestyle advice on diet and alcohol.

> *"That's something that we do anyway so within the tinnitus therapy process we always talk about lifestyle choices. So, physical exercise comes into that but we also talk about things like diet, we might also talk about you know where patients are maybe drinking excessively." (Audiologist 3)*

> *"If they've taken up hobbies that have enabled them to be more distracted, sort of reinforcing those things and said, 'these are the things that you know are going to enable you in the long term to sort of ignore your tinnitus and live with it happily'." (Audiologist 2)*

One audiologist found that some patients' lack of motivation was a barrier to their engagement in the treatment and that a technique to improve motivation would be useful.

> *"It's like how can we break this down…what happens when you can't motivate a patient… how do you tackle somebody who is clearly giving you excuses…? Cause there's a harsh way which is, 'look, you're just giving lots of excuses.' But that's not the way to do it. That doesn't help anybody. But then is it up to us to go into maybe the deeper reasons why they're doing that, is it a confidence issue [for example], and it's that thing that's stopping that patient from getting better." (Audiologist 3)*

(4) Factors affecting feasibility of wider implementation of treatment

Audiologists unanimously agreed the treatment did not lengthen the amount of time spent with patients throughout their care. However, participation in the intervention arm of the trial affected the usual appointment structure. For example, the audiologists delayed hearing aid fitting to allow time to gather information about underlying mental health problems first.

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Audiologists also thought that reducing the time between appointments could increase treatment benefit:

> *" [reducing] follow-up [from] about 12 .. to...6 weeks after the initial appointment... works because patients either take on board everything you say or they struggle with it and if you've kind of let them go for three months you're almost back to square one sometimes." (Audiologist 1)*

However, concern was expressed that such changes to appointment structure might not be feasible in audiology services where resources are limited. Continuity of care, with patients seeing the same audiologist throughout their care was also considered beneficial:

> *".. some patients even though they are hearing aid patients, probably would benefit from being fitted by the tinnitus audiologist rather than an [other] audiologist because some of the reasoning behind why we're fitting the hearing aid has to be related to the tinnitus. And perhaps that was lost ..." (Audiologist 2)*

(5) Training and supervision

Audiologists were introduced to the manual across 2 days of training. Although audiologists valued the small group setting, the content of the 2 days was considered overwhelming. Audiologists involved in the trial suggested that it might not be feasible to implement this format outside of the trial for routine clinical practice:

> *"It was excellent, one-to-one with a group of experts, what else could you ask for? ...Feasibility-wise, would that work in practice? Probably not." (Audiologist 3)*

Some audiologists recommended role-play to improve the training to provide practice and feedback on techniques in a range of scenarios in order to help audiologists to understand how components of the manual would work in practice. All audiologists felt that formal

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supervision arrangement would be helpful to check adherence to the treatment manual. However, audiologists also noted the lack of supervision within audiology:

> *"In adult audiology, we work in a silo… we don't have anyone else except our colleagues to turn to, we don't have any formal supervision like you would if you were a therapist." (Audiologist 3)*

The potential for the treatment manual to be used as a training tool for inexperienced audiologists was raised repeatedly during interviews:

> *"I found [the manual] quite useful in terms of training somebody new to sort of say, 'do you want to delve a bit deeper, is there something in these questions that perhaps is relevant for the patient you've got sat in front of you?" (Audiologist 2)*

(6) Measurement of tinnitus outcomes

Patients and audiologists recognised that all the domains measured by the TFI and TCQ could be relevant to different patients, and no additional domains were identified as relevant that were not measured in the trial. The TFI was favoured as an assessment tool by patients and audiologists because of its broad coverage across tinnitus problem domains to enable identification of relevant treatment options. However, one audiologist highlighted that some patients conflate hearing loss and tinnitus when completing the TFI, which may limit its ability to distinguish between tinnitus-related and hearing-related distress. Audiologists were less familiar with the TCQ, although one appreciated it as a means to encourage patients to recognise and talk about their negative thoughts about tinnitus:

> *"Sometimes patients are quite reluctant to give [negative thoughts], some patients don't like feelings, but to get them to write it down and to score it, you get a bit more of an overview of about where they are and how severe really the tinnitus is and how much it is affecting them psychologically. So that again I've not used that one [TCQ]*

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routinely but I do think that one is one that I would probably use for those patients where I'm perhaps struggling to see how much is affecting them psychologically." (Audiologist 2)

Patients also welcomed the use of tinnitus questionnaires to monitor their improvement during treatment:

"It makes you start to realise how well you're doing and it gives you a chance to measure that…how bad it is or how you're managing really well." (Patient 2)

Patients and audiologists had different views on the difficulty of completing questionnaires. Whereas audiologists perceived questionnaires to be accessible, patients thought that support should be offered to complete any questionnaires:

"When you give a questionnaire like this and just give it to somebody – and I was put in another room to do it – I think there's an assumption made that everyone can do that task." (Patient 2)

Discussion

This study was the first to develop and assess feasibility of trialling an audiologist-delivered low intensity psychological intervention for tinnitus. Ultimately, we aimed to provide an evidenced-based, costed, manualised approach to tinnitus care that is attractive to commissioners and represents a flexible and accessible tinnitus treatment. The feasibility trial reported here determined that a manualised psychologically informed treatment was acceptable to patients and audiologists, but that it is not yet feasible to test in a multi-site effectiveness trial. Recruitment reached only 19 patients (63%) after 6 months, just short of the 65% target for feasibility, while average retention for the duration of the trial reached only nine patients (47%), very short of the 80% target for feasibility. Patient recruitment is acknowledged to be one of the most difficult and least predictable elements of a clinical trial.

For Peer Review Only

(Allen et al., 1998; Thoma et al., 2010; Sanchez et al., 2018). Here, performance varied across the three sites. The best in terms of recruitment efficiency and recruitment rate was Site 1, an audiology service based in a large teaching hospital where staff are supported to be research active. Having a large pool of potentially eligible patients to draw on, as well as engaging with audiologists who have previous experience in participating in RCTs, are known factors that can help to achieve study targets for hearing trials (Sanchez et al., 2018). In addition, a member of the research team was responsible for recruitment at Site 1, and did not have to contend with the same clinic demands as PIs at the other sites. That said, the pattern of recruitment would suggest all could have reached feasibility. Site 3 in particular recruited five patients (50% of target) within a single week, suggesting competing demands and/or a lack of engagement with the research, rather than low patient numbers, were barriers to recruitment at that site. In contrast, Site 1 performed poorest in terms of patient retention indicating that even experienced participating sites need a risk mitigation plan and regular trial monitoring. We would concur with the recommendations suggested by Sanchez et al. (2018) that a future RCT needs to ensure that it has sufficient resource to support a carefully specified plan to promote recruitment and retention of tinnitus patients. Furthermore, based on current findings, we would suggest that treatment fidelity could be improved and more accurately monitored by (1) including an audiologist familiarisation phase of treatment implementation before including patients in analyses, and (2) including direct in-session observation of a random selection of treatment sessions using standardised fidelity evaluation forms, based on the treatment manual.

From the Delphi survey (Thompson et al., 2018) we know that psychoeducation and common therapeutic skills are considered more important than specific CBT techniques in psychological tinnitus treatment. Patients and audiologists considered it essential to include

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psychoeducation and common therapeutic skills (aimed at informing the patient and conveying empathy) in psychological tinnitus treatment. Giving patients information about common cognitive distortions was considered essential, but cognitive restructuring was not. This pattern suggests that patients and audiologists understood the contribution of maladaptive behaviours and negative thoughts to bothersome tinnitus, but did not think that the audiologist's role should or could extend to managing patients' use of specific cognitive behavioural techniques. This issue was further highlighted in the current trial. Interviews revealed audiologists chose not to use certain psychological treatment components from the manual because (1) they lacked confidence in using them as training was brief and insufficient for them to learn how to implement them safely and effectively, (2) they thought patients do not want to record, monitor, and challenge specific negative thoughts and behaviours, and (3) they believed certain components would be ineffective. More work is therefore required to consider what audiologists can and want to deliver either within their current or a revised clinic and appointment structure, and what training and supervision arrangements need to be in place for these skills to be developed, used, and maintained throughout a clinical trial. Beyond feasibility and evaluation of effectiveness, it will also be essential to explore how the intervention can be implemented into routine clinical practice, which will involve further challenges such as organisational development, workplace cultures and individual barriers (De Silva, 2015).

Similar issues are being faced in other areas. For example, there is emerging evidence that CBT-enhanced voice therapy for functional dysphonia leads to greater improvement in general well-being and distress (Miller, Deary, & Patterson, 2014), but as with the current study there are open questions about how clinicians should be trained and supervised and how cost-effective this approach may be. There are examples in other fields of how training

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might be achieved on a large scale. Richmond et al. (2016) evaluated feasibility of an online programme to train physiotherapists in the use of cognitive behavioural approaches to the management of non-specific low back pain. They found an internet-based approach to training to be equivalent to face-to-face group training in terms of retention of theoretical and procedural knowledge. However, clinicians who received the face-to-face training showed greater self-efficacy in delivering the assessment component of the therapy, were more satisfied with their training, and were more 'psychosocially' rather than 'biomedically' orientated after training, and by implication were more aligned with a cognitive behavioural approach. Regardless, uptake of the treatment approach after training was similar across both groups (about one third). Their conclusion, that there is a need to develop strategies for training and support to deliver treatments that use cognitive behavioural approaches, read relevant to all allied health professionals at this time. In the context of the current study, issues such as the acceptability and preference for different training formats will need to be explored.

Certain revisions to the TinMan study manual and training require consideration before it can be subjected to further feasibility testing. These include additional information about tinnitus and psychoeducation, including information about negative thought patterns and avoidant behaviours. An appreciation of patient preference and need with respect to psychological treatment components was also apparent in the current study. Specific cognitive behavioral techniques tend to purposefully engage patients in initially unwanted, though temporary, thoughts or emotional states. It is of importance to train audiologists in how to deal with these challenges and ultimately make use of the patient-states resulting from these approaches. The natural resistance and transferal of distress in both patients and audiologists when using these

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techniques needs to be adequately covered in training that balances informed patient choice and need.

Conclusion

What emerged most strongly from this study is that an audiologist-delivered low-intensity psychological intervention is an acceptable approach to tinnitus management, but even very experienced audiologists require more extensive training to 'upskill' in the use of psychological treatment components. Audiologists involved in delivering the psychological treatment reported that the amount of training was insufficient and lacked role-play and feedback from a supervisor to increase understanding of how to deliver the treatment effectively. This needs to be addressed before further testing. One potentially cost-effective means of training audiologists may be to develop reusable learning objects, e.g. including video recordings of role-play scenarios where an audiologist is using a set of psychological techniques from the manual. Once training is addressed, the treatment may progress to further feasibility testing. There has been recent discussion in the UK audiology community about some form of compulsory continual professional development or qualification in tinnitus care for practicing audiologists. The manual developed here, and the training resources that will support its use, could potentially meet this perceived need.

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For Peer Review Only

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Declaration of conflicts of interest

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Figure legends.

Figure 1. Feasibility trial flow chart

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Table 1. Baseline demographics

	Psychological treatment (SD)	Treatment as usual (SD)	Overall (SD)
Sex	3 female 7 male	3 female 5 male	6 female 12 male
Age	59 (10.989)	44 (18.330)	53 (16.092)
Baseline TFI	67.08 (23.644)	50.00 (23.849)	59.49 (23.644)

SD = Standard Deviation; TFI = Tinnitus Functional Index. Demographic data for one patient were not provided by trial site

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Table 2. Feasibility outcomes

	Site 1	Site 2	Site 3	Psychological treatment	TAU	Total
Recruitment efficiency of those screened	63%	12%	*	-	-	*
Recruitment relative to target	100%	30%	60%	73%	53%	63%
Retention of enrolled patients	30%	67%	67%	64%	25%	47%
Primary effectiveness outcome questionnaire received	100%	50%	0%	43%	50%	44%

TAU=Treatment as Usual; * = screening data not provided by sites; - = Not applicable. Note the each site had a recruitment target of 10 patients.

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Table 3. Questionnaire data

	Baseline		Post-treatment		6-month follow-up	
	Psychological treatment	TAU	Psychological treatment	TAU	Psychological treatment	TAU
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
TFI	67.08 (21.669)	50.00 (23.849)	26.53 (32.027)	8.80 (-)	22.48 (25.065)	10.40 (-)
TFI-E	59.00 (37.648)	38.75 (28.000)	25.56 (38.634)	0.00 (-)	15.56 (21.430)	3.33 (-)
TCQ	64.67 (24.378)	59.00 (56.569)	49.67 (12.097)	56.00 (-)	60.00 (-)	8.00 (-)
TCQ-N	46.17 (26.164)	48.50 (61.518)	32.67 (22.811)	36.00 (-)	54.00 (-)	3.00 (-)
CORE-OM	8.58 (7.425)	6.47 (4.575)	2.94 (2.080)	1.76 (-)	2.94 (2.080)	1.47 (-)
WAI-C Task	74.40 (7.162)	80.00 (4.243)	79.00 (6.928)	83.00 (-)		
WAI-C Bond	76.20 (8.843)	73.00 (15.556)	76.00 (6.928)	84.00 (-)		
WAI-C Goal	73.40 (7.369)	80.50 (3.536)	78.67 (9.238)	75.67 (7.234)		
WAI-T Task	38.75 (37.677)	6.00 (-)	75.00 (7.071)	50.67 (37.846)		
WAI-T Bond	74.50 (9.110)	84.00 (-)	77.50 (6.364)	72.00 (7.810)		
WAI-T Goal	62.50 (11.958)	54.00 (-)	73.00 (7.071)	54.00 (-)		

TAU = Treatment as usual; SD = Standard deviation; TFI = Tinnitus Functional Index; TFI-E = Tinnitus Functional Index-Emotion subscale; TCQ = Tinnitus Cognitions Questionnaire; TCQ-N = Tinnitus Cognitions Questionnaire-Negative subscale; CORE-OM = Clinical Outcomes in Routine Evaluation – Outcome Measure; WAI-C = Working Alliance Inventory-

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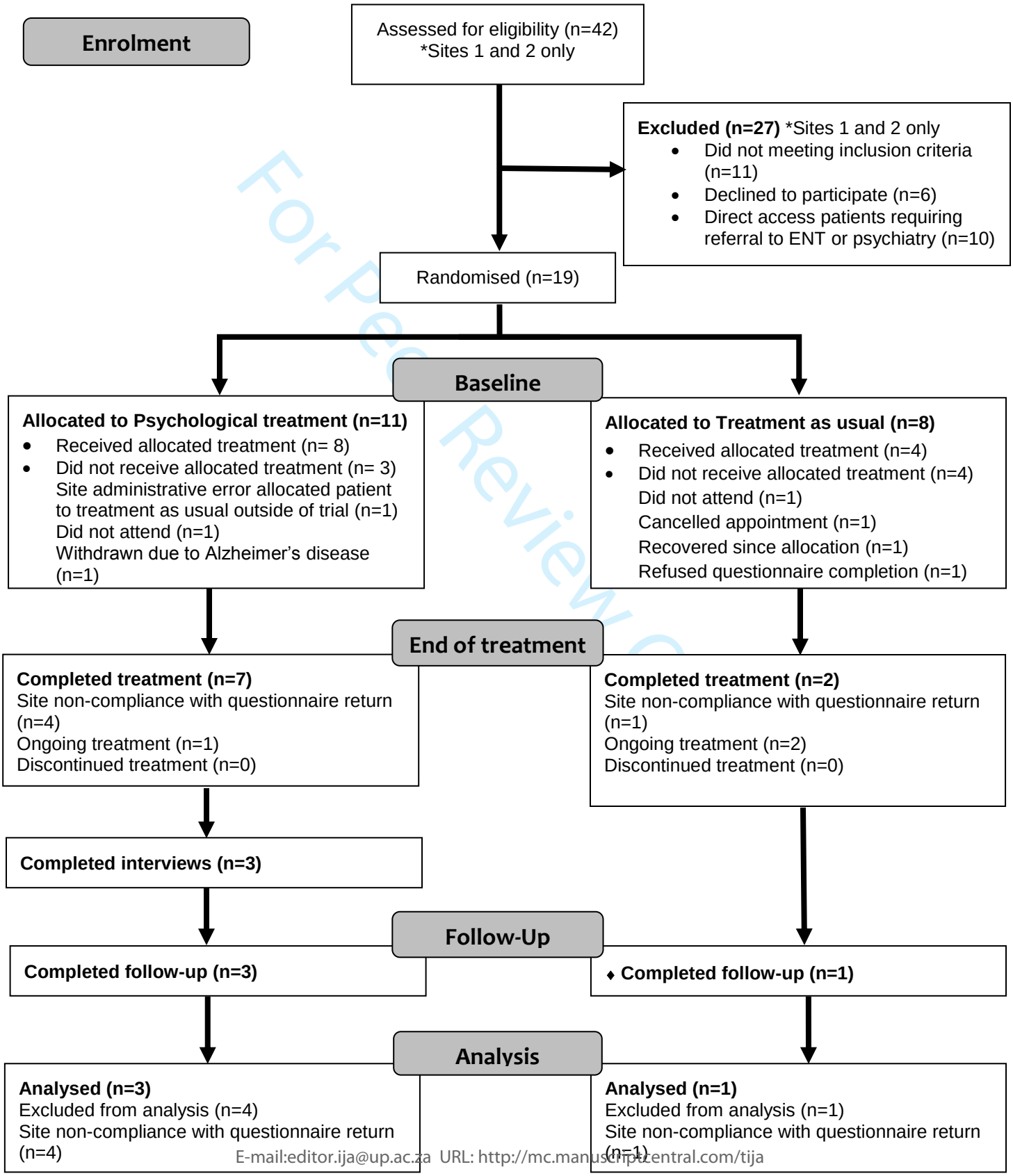

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Supplemental Information 1. OVERVIEW OF MANUAL

The materials in this manual are for delivery to NHS patients with intrusive tinnitus by an audiologist. It requires use of core counselling skills within the context of relationship building between audiologist and patient working in partnership with one another in a therapeutic alliance. Beginning with assessment, using the Relational Skills Model (more detail in **Appendices, Section 9**), the audiologist works in partnership with the patient through the following process:

PHASES OF RELATIONSHIP DEVELOPMENT	PROCESS	SKILLS
Setting up the relationship	Contacting/meeting the patient Getting to know the patient Communicating with & contracting with the patient	Initial core skills: Attending skills Active listening skills & contracting skills
Developing the relationship	Developing the relationship Problem identification & assessment	Additional core skills: Presence & communication of the core conditions Paraphrasing Summarising Identifying & reflecting feelings, content & meaning Asking questions
Working with the relationship	Challenging & creating new meaning, different possibilities & perspectives	Enhanced skills: The skill of challenging – Confronting Use of self-disclosure, immediacy & silence Clarifying Reassessing Probing Giving feedback & sharing information
The established relationship	Clarifying & focusing on likely changes Working collaboratively to make plans, set goals, & consider & evaluate possible strategies & directions	Intuitive & learned skills: Deeper empathy Focusing Use of metaphor & hunches Drawing together themes Clarifying & identifying goals Action planning
Maintaining and ending the relationship	Implementing & maintaining change Supporting self-management strategies	Embedding skills: Encouragement, support & affirmations Review, monitor, evaluate & facilitate ending Signposting/referring on

Midwinter R, Dixon J (2015) *Embedding Counselling and Communication Skills. A Relational Skills Model*. Routledge, Hove: p.3

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The process and skills used (more detail below) allow for the British Society of Audiology (BSA) Practice Guidance: Common Principles of Rehabilitation for Adults in Audiology Services to be fulfilled. These are:

- Identifying individual needs
- Setting joint goals
- Making shared informed decisions
- Supporting self-management

CORE COUNSELLING SKILLS

Attending and listening

- Active listening
- Listening with purpose and responding in such a way that patients are aware they have been heard and understood

Reflective skills

- *Restating* what you believe to be a significant word or phrase the patient has used
- *Paraphrasing* involves conveying the patient's core messages (facts and feelings) in your own words
- *Summarising* is offering the patient a précis of the information they have given you – not as a list of details and facts but as an organised overview of important themes or cluster of concerns

Reflective skills:

- Capture what a patient is telling you and repeat the message in your own words
- Are valuable for 'tracking' patients, since they impose minimal direction from the practitioner
- Enable the practitioner to communicate the core values, to clarify and to acknowledge the patient's experiences
- Build relationships that are supportive and challenging
- Are ideal information-gathering skills

Probing skills

- *Questioning* to facilitate exploration
- *Making statements* is a gentle form of probing. For example, instead of asking a patient, *"What did she do to upset you?"*, you might say, *"I'm not sure what she did to upset you"*. Statements tend to be less intrusive and controlling than questions

Probing skills:

- Tend to focus on what the practitioner wants to know and not necessarily on what the patient wants to tell
- Lead or direct patients
- Help to obtain information from the patient
- Influence direction of the exploration
- Increase practitioner control over process and content

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- Should be used with care because of the above, especially in the early stages

STRUCTURE OF MANUAL

As shown in the **Table of Contents (page 2),** the process of treatment comprises six broad sections:

- Patient assessment
- Rationale for psychologically informed treatment
- Goal setting and treatment planning
- Patient education
- Patient management/self-management (with eight sub sections)
- Relapse prevention

At the end of **Patient Assessment (Section 2)** there are recommendations about which elements of **Patient Education (Section 5)** and **Patient Management/Self-Management (Section 6)** to focus on dependent on individual needs. However, it is recommended that **Rapid Relaxation (Section 6.2)** should be a core (non-optional) element of Patient Management/Self-Management.

If it is agreed that the patient would benefit from psychologically informed treatment, it is important to discuss the **Rationale for Psychologically informed Treatment (Section 3)** with them prior to **Goal Setting and Treatment Planning (Section 4)**. Having worked through relevant elements of **Sections 5 and 6**, conclude the treatment with **Relapse Prevention (Section 7).**

The **Bibliography (Section 8)** contains references related to the intervention, training resources and further reading. The **Appendices (Section 9)** contain materials used to train audiologists in the use of the manual.

TOOLKIT OF RESOURCES

The manual is supported by a separate toolkit booklet (and electronic files) comprising resources to aid the delivery of tinnitus management and enable learning by the patient as s/he works through the process in partnership with the audiologist. Guidance for what resources to use and when to use them is highlighted in **red** throughout the manual. You are expected to print/photocopy specific resources from the toolkit as required for each patient.

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Supplemental Information 2. TOOLKIT OF RESOURCES

T1 TINNITUS FUNCTIONAL INDEX (& SCORING RUBRIC)
T2 TINNITUS CASE HISTORY QUESTIONNAIRE
T3 FORMULATION WORKSHEET (for Sections 3 and 6.3)
T4 BTA LEAFLET ALL ABOUT TINNITUS VER.1.4
T5 COGNITIVE MODEL OF TINNITUS PSYCHOLOGY TOOL
T6 STAGES OF CHANGE MODEL
T7 GOAL SETTING SHEET
T8 ACTION PLANNING SHEET
T9 GOAL SETTING & ACTION PLANNING PRACTICE FRAMEWORK
T10 WHAT KEEPS TINNITUS GOING PSYCHOLOGY TOOL
T11 WHAT CAUSES TINNITUS PSYCHOLOGY TOOL
T12 MEANING IN TINNITUS PSYCHOLOGY TOOL
T13 BTA LEAFLET TINNITUS AND STRESS VER.1.4
T14 RELAXATION TRAINING DIARY
T15 FEAR & AVOIDANCE EXAMPLE FORMULATION
T16 EXPOSURE WORKSHEET
T17 NEGATIVE THINKING EXAMPLE FORMULATION
T18 UNHELPFUL THINKING STYLES SHEET
T19 THOUGHT RECORD – BLANK COPY
T20 THOUGHT RECORD – EXAMPLE COPY
T21 PHYSICAL EXERCISE EXAMPLE FORMULATION
T22 PHYSICAL EXERCISE DIARY
T23 SLEEP CYCLES SHEET
T24 SLEEP DIARY
T25 BTA LEAFLET TAMING TINNITUS VER.1.3
T26 ACCEPTANCE IN METAPHORS SHEET
T27 MINDFULNESS: THREE SIMPLE WAYS TO GET PRESENT SHEET
T28 MY ‘MANAGING TINNITUS’ BLUEPRINT: MAKING A PLAN FOR WELLBEING

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