Study protocol:

Title of Project: **Internet-based cognitive behaviour therapy for adults with tinnitus in the United Kingdom**

Trial registration: ClinicalTrials.gov; NCT02370810, date 05/03/2015

Ethical approval: Research Ethics Committee (REC) of Anglia Ruskin University (FST/FREP/14/478)

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INTRODUCTION

Tinnitus is one of the most distressing and debilitating hearing-related symptoms.[1] Unwanted sounds, such as ringing or buzzing are experienced, in the absence of a concurrent external sound source.[2] It is highly prevalent, affecting between 10-15% of adults in the UK, with an increased prevalence in older adults.[3]

Despite much research, medical treatments are usually ineffective at reducing tinnitus and a cure remains to be found.[4] Tinnitus is therefore managed as a chronic condition, thereby adding strain on current healthcare systems.[5] For some, experiencing tinnitus can result in a complex set of complaints.[6] As there is a strong relationship between tinnitus and hearing difficulties, this adds to the distress experienced.[7] In addition to the possible adverse effects on daily life, such as the impact on sleep, mood and concentration, there may also be a number of indirect psychological and psychosocial effects, including depression and anxiety.[8] These concurrent physical and psychological effects add to the healthcare burden, as further input may be required from various health professionals.[9]

When it comes to tinnitus management strategies, there is a low evidence-base for many practices.[10] Good Practice Guidelines for tinnitus management were set by the Department of Health in the UK in 2009.[11] Hoare and colleagues,[12] found poor guideline adherence, unequal access to care, lack of standardization and limited use of psychological interventions for tinnitus. Innovative ways of addressing these issues in the UK are therefore required.

Cognitive Behavioural Therapy (CBT) is a technique, which reduces the distress associated with tinnitus,[13] and is one of the tinnitus treatment options with the most evidence of effectiveness.[14] It has been shown to add to the efficacy of Audiology/ENT approaches to treatment.[15] It is however, rarely offered in clinical practice,[16] particularly in the UK.[17] This is largely due to a shortage of those with appropriate CBT training, such as Psychologists who are audiologically literate, and willing to manage tinnitus.[18]

To provide an accessible evidence-based tinnitus treatment, an internet-based, CBT intervention (iCBT) was developed by Andersson and colleagues,[19] and results of their initial Randomized Control Trial (RCT) showed promising effects. Following intervention improvements, further studies, run in Sweden and Germany, indicated similar results to face-

to-face group CBT.[20,21] A further RCT in Australia by Abbott and colleagues,[22] found results of iCBT did not show any statistically significant benefit over a information-only control program (without CBT content). In addition, the attrition rate was higher in the iCBT group. This poses questions regarding whether the structure and presentation of the intervention requires updating to improve overall outcomes. If iCBT for tinnitus distress was feasible in the UK it may bridge a gap for those who have not been able to access appropriate tinnitus services. It could furthermore reduce the burden on the healthcare system for those who do not require supra-specialist support.

A study to determine whether iCBT could be a suitable intervention is therefore of value. The aim of this study is to further our knowledge of the feasibility and effectiveness of iCBT for tinnitus management in the UK. This research is timely and in line with two of the tinnitus research priorities recommended by the James Lind Alliance,[4] namely: research investigating which management strategies are more effective than the usual model of audiological care in improving outcomes for people with tinnitus and research determining whether CBT, delivered by audiology professionals, is effective for people with tinnitus.

The research objectives for this study are therefore as follows:

1. To establish the feasibility of using iCBT for tinnitus distress, as an intervention for adults with tinnitus in the UK
2. To evaluate the effectiveness of iCBT for tinnitus distress in reducing the impact associated with tinnitus for adults in the UK.
3. To ascertain predictors of outcome for whom this iCBT intervention is a suitable intervention
4. To determine the longer term effects of iCBT, 12 months post-intervention

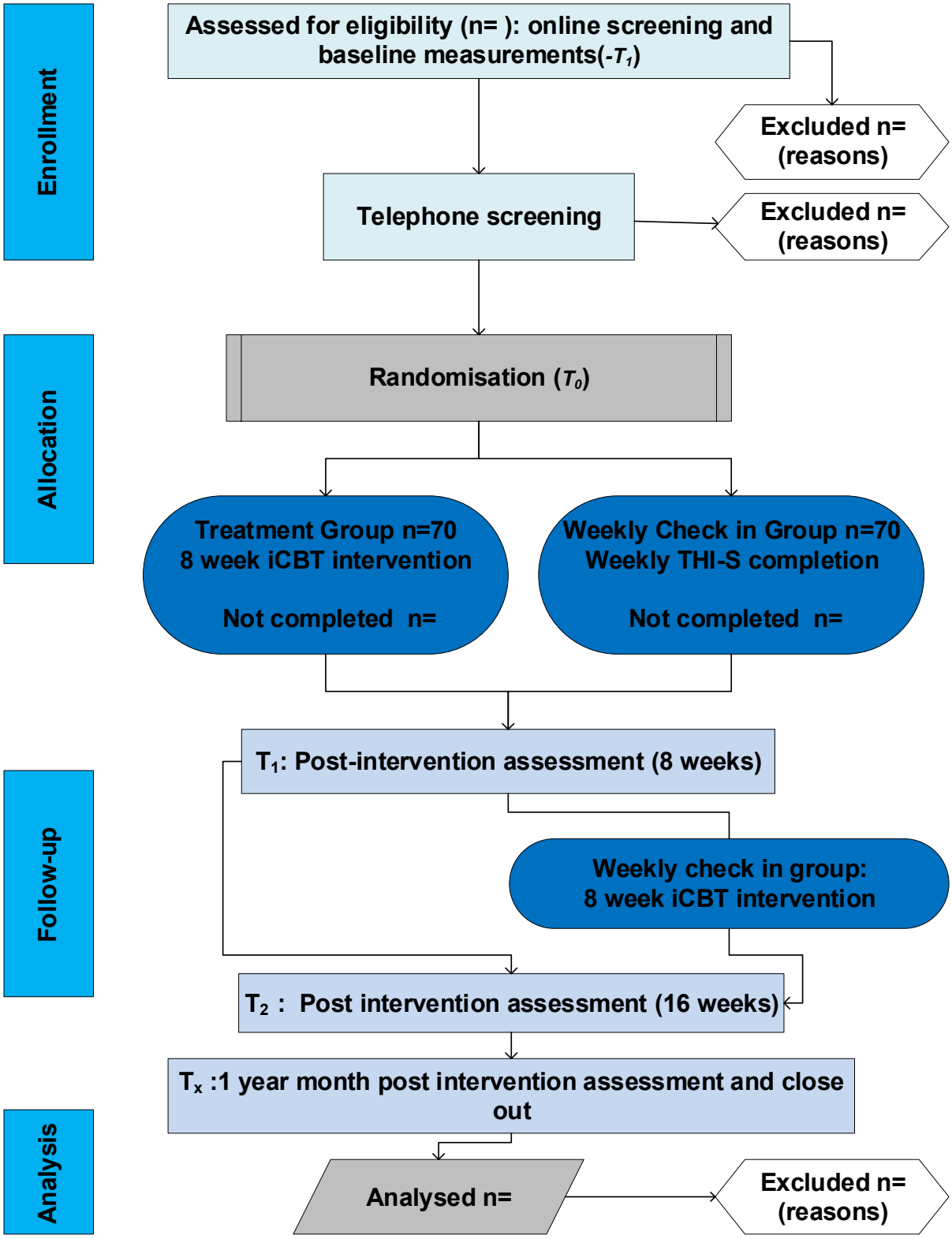
METHODS

Study design

This will be an internet-based study run in the UK. This intervention study will be implemented as a two-armed RCT, with a one-year follow-up, to evaluate the effectiveness iCBT on tinnitus distress. An effectiveness trial has been selected, to increase the extent to which the study results can be generalised and be used to identify for which subgroups of tinnitus sufferers this is a suitable intervention. A delayed treatment design using a weekly check-in control (WCI) group will be used, as shown in Figure 1. The objective is to test the superiority of the

intervention, with the hypothesis that the treatment group will perform better than the weekly check-in group. These groups will be followed prospectively for 1 year, to establish the long-term effectiveness of the intervention programme.

This study design is described using the Standard Protocol Items, Recommendations for Interventional Trials (SPIRIT) checklist.[23,24] and has been registered with Clinical Trials.gov: NCT02370810, date 05/03/2015



Study groups

There will be two study groups. The ***Test Group*** will receive the eight-week long iCBT treatment following baseline measurements and allocation (after T_0). The weekly check-in ***Control Group*** will be monitored during the active treatment phase by means of the Tinnitus

Handicap Inventory- Screening Version.[25] but will have no other contact or involvement in the study during this period. The control group will undergo the same iCBT intervention once the treatment group finishes the programme (after T_1).

Inclusion Criteria

A clinical evaluation prior to partaking in the study is desirable, to rule out the presence of a serious auditory pathology or associated psychological problem, which may be related to having tinnitus.[26] If there are any concerns, a letter will be provided for participants to take to their General Practitioner, for further management.

Participant's eligibility for the study is as follows:

i) Aged 18 years and over living in the UK
ii) The ability to read and type in English
iii) No barriers to using a computer (e.g. significant fine motor control or visual problems)
iv) Internet and e-mail access, and the ability to use these
v) Commitment to completing the programme
vi) Completion of the online screening and outcome questionnaires
vii) Agreeing to participate in either group and be randomized to one of these groups
viii) Understanding and working towards the end goal of reducing the impact and distress of tinnitus, although the strength of the tinnitus may remain the same
ix) Be available for 12 months after starting the study to complete a 1 year follow-up questionnaire
x) Suffering with tinnitus for a minimum period of 3 months
xi) Tinnitus outcome measure scores indicating the need for tinnitus care (26 or above on the Tinnitus Functional Index)[27]

Exclusion Criteria

i) Reporting any major medical or psychiatric conditions
ii) Reporting pulsatile, objective or unilateral tinnitus, which have not been investigated medically
iii) Tinnitus as a consequence of a medical disorder, still under investigation
iv) Undergoing any tinnitus therapy concurrently to partaking in this study

A two-staged selection procedure will be followed:

i) An online screening questionnaire, which includes health and mental health related questions

ii) A telephone interview, during which the researcher will re-check eligibility and provide the opportunity for potential participants to ask any questions related to the study.

Recruitment

Recruitment will be UK wide, using as many different forms as possible to achieve adequate participant enrolment. Information about the study will be advertised at tinnitus and hearing-related support groups and charities, in their newsletters and drop in centres. It will furthermore be advertised in Audiology Departments and by using social media. Talks to professionals, such as ENT Consultants and Audiologists, will also be given to introduce the study and aid recruitment. Those interested can obtain information and register interest on the study website.

Sample size

Sample size estimation was calculated using Power and Sample Size Programme, version 3.1.2 and based on achieving a clinically relevant change of 13 points (std dev 24.7) in the main outcome measure to be used for this study; the Tinnitus Functional Index.[27] This indicated 30 participants were required per group; with an allocation ratio of 1:1, to achieve a two-sided significance level of 0.05 and effect size of 0.8. As these calculations are based on a fairly new outcome measure and there may be dropouts, an additional 40 participants will be added, to ensure enough valid data to draw conclusions from. Therefore, 70 participants will be assigned to the experimental group, and 70 participants to the control group. This is roughly in line with the sample sizes used in similar studies.

Allocation

Participants will be randomly assigned to either control or experimental group with a 1:1 allocation using a computer generated randomization schedule (http://www.randomizer.org/) by an independent researcher. To prevent an unequal distribution among groups, participants will be pre-stratified on the factors of age (<= 60 or >60 year) and Tinnitus severity (TFI <= 50 or >50). Furthermore, block randomization, with blocks of four, will be applied to ensure equal groups sizes within each stratum.

Following allocation participants will be contacted by telephone, to provide the opportunity to discuss the aspects of the study and answer any questions. This initial contact has been found to be valuable to ensure participants are motivated to complete the treatment.[20]

Intervention

The intervention to be followed, is built on an internet-based CBT self-help programme (iCBT) for reducing tinnitus distress developed by Andersson and colleagues.[19] It incorporates a combination of a cognitive rational,[28] and a learning theory approach.[29] The original intervention was largely text based. The present authors have redesigned and modified the intervention content and presentation, to have an interactive e-learning version, as shown in Figure 2. This will ensure the intervention is visually stimulating, engaging and responsive to participant's progress.

The intervention consists of fixed and optional modules, covered over a period of 8 weeks, as shown in Table 1. The modules contain a mixture of information, videos, quizzes, diagrams, suggested techniques to apply to daily life, worksheets to keep track of progress, solutions for common problems and downloadable information.

The iCBT intervention will be delivered on a secure web platform, for which participants will receive password protected login information.

Table 1: The components of the iCBT intervention

Week	Module	Explanation	Application
1	About this treatment	Introduction to the modules	Reading
	Tinnitus overview	In depth information	Quizzes
2	Relaxation: step 1	Deep relaxation	10-15 min, twice/day
	Identifying negative thoughts	The link between thoughts and feelings	Writing down thoughts
	*Sound enrichment	Using background sounds	Applying external sounds
3	Relaxation: step 2	Diaphragmatic breathing	5-7 min, twice/day
	Cognitive restructuring	Analysing thoughts	Writing down situation, thoughts, feelings
	*Sleep guidelines	Various Techniques	Chose and apply techniques

4	Relaxation: step 3	Entire body relaxation	2-3 min, twice/day
	Positive imagery	Use to enhance relaxation	Twice/day after relaxation
	*Concentration tips	Techniques discussed	Engage in mentally engaging activities
5	Relaxation: step 4	Rapid relaxation	20-60 sec, 5-10 times/day
	Focus exercises	Mindful awareness	Twice/day after relaxation
	*Sensitivity to sound	Gradual exposure	Listen to non-damaging, non-annoying sounds
6	Relaxation: step 5	Rapid relaxation in more difficult situations	30-60 sec, 10-15 times/day
	Reinterpretation of tinnitus	Change negative tinnitus associations	Writing about tinnitus thoughts
	* Hearing tactics	Communication advice	Follow advice
7	Relaxation: step 6	Making relaxation part of daily routines and habits	Rapid relaxation 10-20 times/day
	Exposure to tinnitus	Decrease negative emotions and avoidance of tinnitus	Actively listen to tinnitus for 5-10 min, once/day, after relaxation
8	Key points summary	Highlighting key concepts	Online quiz
	Future planning	Maintenance and relapse prevention	Making a plan to use tools in daily life

Optional modules are marked with an *

Monitoring progress

Participants will be minimally guided via a secure online messaging system. This therapeutic alliance will allow for feedback and assistance if participants have any difficulties and has shown better outcomes than internet interventions without this communication.[30] The clinician will contact any participants who have not completed their weekly progress worksheets to ensure they are assisted as required. In these worksheets, participants record details about when, where, and for how long they practiced the suggested techniques and how effective these techniques were.

As tinnitus therapy is largely delivered by the audiology community in the UK, an experienced Audiological Scientist, registered with the Health Professions Council, will therefore undertake the role of supporting the participants, to maintain consistency with the standard approach. Support will however be provided by a Psychologist, with experience in iCBT interventions and a protocol for dealing with different situations will be used.

Assessment

The assessment battery will consist of a screening eligibility questionnaire and relevant self-reported outcome measures, related to areas which may be affected by tinnitus. Outcome measures for tinnitus severity, hearing handicap, insomnia, cognitive functioning, hyperacusis, anxiety, depression and life satisfaction were therefore selected. Careful consideration was given to ensure each questionnaire was as brief as possible and had good psychometric properties as seen in Table 2. The outcomes were furthermore selected to be aligned with the International Classification of Functioning, Disability and Health (ICF)[31] framework on the domains of activity limitation and participation restriction.

The assessment battery and outcome measures will include:

1. *Eligibility screening:* A range of demographic, tinnitus specific and health related questions will be asked to determine demographic variability and study eligibility. Open-ended questions asking about positive and negative experiences related to having tinnitus will also be incorporated.

2. *The main outcome measures:* The Tinnitus Functional Index (TFI), has been selected to determine tinnitus severity, as it is validated for assessing responsiveness to treatment both for scaling the severity and negative impact of tinnitus and for measuring treatment-related changes in tinnitus.[27] The TFI was specifically designed to measure the effectiveness of interventions, a feature lacking in previous tinnitus outcome measures.[32] Due to its validation for assessing treatment responsiveness, it was chosen above some other more established questionnaires, such as the Tinnitus Handicap Inventory.[33]

3. *Secondary outcome measures:*

   3.1 The Tinnitus Handicap Inventory -Screening Version (THI-S),[25] will be used as a concise outcome measure, particularly to monitor tinnitus handicap on a weekly basis during the active treatment phase.

3.2 As there is a strong relationship between tinnitus and hearing difficulties,[7] the Hearing Handicap Inventory for Adults-Screening Version (HHIA-S),[34] will be administered to quantify perceived hearing handicap. It includes both emotional and social/situational subscales.

3.3 As sleep disturbances are commonly associated with tinnitus,[35] the Insomnia Severity Index (ISI)[36] will be included. This questionnaire assesses the nature, severity, and impact of insomnia by assessing sleep duration, sleep quality, the negative impact on daily functioning and psychological well-being.

3.4 As having tinnitus may disrupt cognitive functioning,[37] the Cognitive Failures questionnaire (CFQ)[38] will be included. It was designed to assess proneness to committing cognitive slips and errors in the completion of everyday tasks such as failures in perception, memory, and motor function.

3.5 As there is a high comorbidity of hyperacusis (a reduced tolerance of everyday sounds)[39] in those with tinnitus,[40] the Hyperacusis Questionnaire[41] will be administered. Although further work on the structure of this questionnaire is required to establish its reliability for measuring hyperacusis in the tinnitus research population, the scores obtained will be useful to compare pre and post-intervention changes.

3.6 As anxiety and depression are common comorbid conditions in individuals with tinnitus,[6] the Patient Health Questionnaire (PHQ-9),[42] to measure depression severity and the Generalised Anxiety Disorder (GAD-7),[43] to assess anxiety severity will be administered.

3.7 To include a measure of quality of life, the Satisfaction with Life Scales,[44] assessing global life satisfaction will be used. For the purpose of this study, it was felt that the questions in this scale were more appropriate than those of longer quality of life measures, which include areas of mobility and self-care, which are not directly targeted by this study.

Permission has been obtained to use the questionnaires, for which it is required, such as the TFI.

Table 2: Known psychometric properties of the questionnaires to be administered at some point during the study

Measure and validation reference	Items	Scale used	Internal consistency (Cronbach's alpha)
Tinnitus Functional Index[27]	25	1-10	0.97
Tinnitus Handicap Inventory-Screening[25]	10	1-3	0.87
Hearing Handicap Inventory: Screening[34]	10	1-3	0.93
Insomnia Severity Index[36]	7	0-4	0.74
Cognitive Failures Questionnaire[38]	25	0-4	0.89
Hyperacusis Questionnaire[41]	14	0-4	0.66-0.68
Patient Health Questionnaire[42]	9	0-3	0.83
Generalised Anxiety Disorder[45]	7	0-3	0.89
Satisfaction with Life Scales[44]	5	1-7	0.87

Questionnaire delivery

The format of the questionnaire delivery will remain consistent throughout the study using online questionnaires. Not all questionnaires to be used have been validated for internet use. Previous research has found comparable results in terms of psychometric properties between computer and paper questionnaire delivery, with high test-retest reliability and completion rate on the internet.[46,47] See Table 3 for the schedule of outcome measure delivery.

Process Evaluation

An intervention, such as iCBT is known as a 'complex intervention' as it combines different components but does not involve drugs or surgical procedures.[48] To fully investigate the different aspects of this complex intervention, we will be exploring the processes involved in implementing the iCBT intervention, as shown in Figure 3, in parallel to the iCBT study. By integrating this process evaluation information with the outcome data, we will maximise our ability to interpret the results and the effectiveness of the intervention.[49]

We will be combining components from three evaluation models, namely the Reach, Efficacy, Adoption, Implementation and Maintenance (RE-AIM model);[50,51] and those of Linnan and Steckler,[52] as well as those of Baranowski and Stables.[53] The following eight components have been selected:

1. *Recruitment:* procedures used to approach and attract participants.
2. *Reach:* the extent to which the targeted population were drawn to the study and were willing to be involved in this intervention study.

3. *Context:* characteristics of the participants that affect the iCBT intervention including social, demographical, socio-economic factors.
4. *Dose delivered:* The number of modules and component included in this iCBT intervention.
5. *Dose received:* The extent to which participants actively engage and interact with the resources provided by this iCBT intervention.
6. *Effectiveness:* examining both the positive and negative consequences of the intervention, as well as factors that may positively or negatively influence the effectiveness of the intervention from the participant's perspective.
7. *Maintenance:* keeping participants involved in this iCBT intervention and data collection.
8. *Fidelity*: The extent to which the intervention was implemented as planned.

These processes will be monitored during the intervention, by reflecting on study procedures and participant's experiences. After undergoing the intervention, participant satisfaction will be established using a Likert scale and telephone interview.

Pilot study

All materials will be piloted prior to running the study. Both professionals and those with tinnitus will test all aspects of the platform. Likert scaled questionnaire will be administered, asking specific questions related to the suitability, usability, content and experiences with the intervention and questionnaires, together with open-ended questions. The aim will be to identify any hindrances regarding use of the platform and possible barriers to participation. If any major changes are required, the ethical committee and trial body will be notified.

Further feasibility measures will include the recruitment rates, retention of participants, compliance and acceptability of the intervention by participants. The feasibility of having an Audiological professional running the intervention under supervision, instead of a Psychologist will also be evaluated.

Data collection

All data will be collected online. Baseline data will be collected at pre-treatment ($-T_1$), prior to allocation. During the active phase of the intervention, the 10 questions on the THI-S[25] will be collected on a weekly basis. Data will then be collected at post-treatment (T_1) and after the control group completes the intervention (T_2). To determine long-term effectiveness of the intervention, data will again be collected 12 months (T_x) after the start of the intervention at close out, and this will end the study. The specific outcome measures for each collection point are shown in Table 3.

To improve attrition rates at follow-up, an e-mail will be sent to encourage participants to complete the questionnaires, with a maximum of three reminders. If they do not wish to further participate in the study, the reasons for their withdrawal will be recorded, where provided, by means of a post-treatment satisfaction questionnaire.

Table 3: Schedule of enrolment, interventions and assessment

STUDY PERIOD					
	Enrolment	**Allocation**	**Post-allocation**		**Close-out**
TIMEPOINT	***$-T_1$***	***T_0***	***T_1 (8 weeks)***	***T_2 (16 weeks)***	***T_x (1 year)***
ENROLMENT					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS					
Experimental group		←	→		
Control group			←	→	
ASSESSMENTS					
Tinnitus Functional Index	X		X	X	X
Tinnitus Handicap Inventory-Screening Version	X	X (weekly)	X	X	X
Hearing Handicap Inventory-Screening Version	X		X	X	X
Insomnia Severity Index	X		X	X	X
Cognitive Failures Questionnaire	X		X	X	X
Hyperacusis Questionnaire	X		X	X	X

Patient Health Questionnaire	X		X	X	X
Generalised Anxiety Disorder	X		X	X	X
Satisfaction with Life	X		X	X	X

Data Management

All participants will receive a non-traceable unique reference code to keep their identities blinded during the result analysis. All files used will be password protected. The researchers, statisticians and internal data monitoring committee (DMC), will have access to the final dataset. The DMC includes researchers who are independent to this study without competing interests. They will ensure accurate analysis and result interpretation.

Data Analysis

Data analysis will be in accordance with Consolidated Standards of Reporting Trials (CONSORT) guidelines for randomized clinical trials.[54] The Statistical Package for Social Sciences (SPSS) version 20.0 will be used and the data analyst will be blinded to the groups, to minimise bias. Results at post-treatment will be based on an intention-to-treat paradigm, in which incomplete data sets will be analysed using multiple imputation, offered by SPSS. For all analyses, a two-tailed significance level of < 0.05 will be considered statistically significant. The data will be analysed, using a general linear model repeated measures approach to look at the effects of the intervention and changes over time.

Qualitative content analysis with a positivist philosophical approach will be used to analyse the responses for open-ended questions.[55] Integrating different analysis methods will yield further insight into the study outcomes.[56]

The study results will be shared in peer reviewed publications by the present authors and presented at research conferences. A summary of the findings will be available to study participants, members of tinnitus support and tinnitus charity groups.

Ethical considerations

Ethical approval has been granted by the Research Ethics Committee (REC) of Anglia Ruskin University (FST/FREP/14/478). Participation is voluntary and all participants will provide

informed consent online. A full explanation of every step of the study and will given and participants will be able to withdraw at any stage without penalty.

A protocol has been established to ensure the security of participant's confidentiality on the web-portal, complying with European guidelines for internet studies. Participant's data will be anonymised as unique reference codes will be used. Protocols to minimise the risks to participants and the researcher have been put in place. The data, together with any other spontaneously reported adverse events during the intervention will be reported. If any participants were identified as requiring additional support, a letter will be provided for them to take to their General Practitioner, so that this care can be arranged.

DISCUSSION

In this paper, the design of a study, to investigate the effectiveness and feasibility of an internet-based intervention for tinnitus in the UK, is outlined. The strength of the proposed methodology is the randomised design. A further strength is that not only the effects of the iCBT intervention, but also the process evaluation will be investigated, to fully determine the interventions feasibility and effectiveness.

This particular tinnitus intervention has been selected due to the numerous potential benefits it may have. It is a standardised treatment, in which each participant has access to the same materials. The researchers have however carefully considered how to improve on methods used in similar previous studies and built on these. The following improvements will be made during this study. Firstly, redesigning the module content and combining both CBT and audiology principles, thereby ensuring it is multidisciplinary in nature. Secondly, transforming the presentation of materials into an interactive e-learning version, which is visually stimulating may improve participant engagement. Thirdly, using a main outcome measure that is specifically designed for measuring intervention effects. Fourthly, assessing a range of outcomes to help identify for whom this intervention is most suited. Fifthly, enabling the intervention to be presented by an Audiologist instead of a Psychologist. Lastly, aiming for good participant retention by careful inclusion criteria and screening methods.

There are however potential barriers that can be forecasted for this study. Although according to the 2015 report from the Office of Statistics,[57] 86% of the population in Great Britain have

internet access, there is still a proportion who don't have access and will therefore not be able to partake in this study. Those without access may be older adults, which might impact the sample selected. There are also people with visual or motor disabilities who will be unable to use a computer effectively, and therefore may not be suitable for this intervention unless they have assistance. A further barrier is that participants will require motivation to complete the questionnaires and treatment modules. A limitation of the study design is that it is not possible to blind the researcher and participants during the intervention, as they will know in which group they have been placed. Bias will however be minimized by stratification and blinding during randomisation, and data analysis.

Feasibility and uptake of such an intervention will be determined by this study. It is however encouraging that other internet based studies, run within the UK, for other health related concerns,[58,59] have reported sufficient interest. Due to the multidisciplinary nature of the study, it furthermore has the prospect of determining the effects of the iCBT intervention not only on tinnitus outcomes, but also on the person globally, as various comorbid factors are being investigated.

The potential impact of this research is that it can change the way in which tinnitus services are delivered in the UK. If effective, iCBT may be suggested for certain tinnitus sufferers following their clinical examination. This will address differential clinical demands and reduce the number of tinnitus suffers needing face-to-face consultations. This may in turn diminish the current burden on the NHS healthcare and lead to a significant potential cost saving to the health service. It may also make treatment available to many who are unable to access speciality tinnitus services

If this intervention is feasible, future studies should focus on comparing iCBT to the usual tinnitus care in the UK. It is expected that the results of this study will become available early in 2017.

Figure legends

Figure 1: Flow chart of the study design
Figure 2: The modified iCBT intervention
Figure 3: The processes to be evaluated following the study

Abbreviations
CBT- Cognitive Behavioural Therapy
CFQ- Cognitive Failures Questionnaire
CONSORT- CONsolidated Standards of Reporting Trials
CSQ-8 - Client satisfaction questionnaire
DMC- data monitoring committee
DOH- Department of Health
GAD-7- Generalized anxiety Disorder
HFDTT- High Frequency Digit Triplet Test
HHIA-S – Hearing Handicap Inventory for Adults- Screening Version
HQ- Hyperacusis Questionnaire
iCBT- Internet based Cognitive Behavioural Therapy Intervention
ICF- International Classification of Functioning
ISI- Insomnia Severity Index
NHS- National Health System
PHQ-9 Patient Health Questionnaire
REC-Research Ethics Committee
RCT-Randomized Control Trial
SPIRIT-Standard Protocol Items, Recommendations for Interventional Trials
SPSS - Statistical Package for Social Sciences
SWLS- Satisfaction with Life Scales
TFI- Tinnitus Functional Index
THI-S- Tinnitus Handicap Inventory-Screening Version
UK – United Kingdom
WCI- weekly check-in control group

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