

**Internet-based intervention for tinnitus: Outcome of a
single-group open trial**

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Internet-based intervention for tinnitus: Outcome of a single-group open trial

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Abstract

Background: Managing chronic tinnitus is challenging and innovative ways to address the resulting health-care burden are required. Internet-based cognitive behavioural therapy (iCBT) for tinnitus shows promise as a cost-effective treatment option. The feasibility and effectiveness of iCBT in the United Kingdom (UK) are yet to be explored. Furthermore, it is not known if iCBT can be supported by an Audiologist rather than a Psychologist.

Purpose: This study aimed to determine the feasibility of guided iCBT using Audiological support on tinnitus distress and tinnitus related comorbidities. Furthermore, it aimed to establish the feasibility of iCBT for tinnitus distress in the UK, by determining recruitment, attrition and compliance rates. Lastly it aimed to identify which aspects of the protocol require refinement for subsequent clinical trials.

Research Design: A single-group open trial design was implemented. This study would serve as a pre-requisite study, to identify barriers, prior to undertaking effectiveness trials.

Study Sample: Participants consisted of 37 adults (18 males, 19 females), with an age range of between 50-59 years. The mean pre-intervention tinnitus severity rating was 56.15 (SD 18.35) which is categorised as “severe tinnitus” as measured by the Tinnitus Functional Index. Five participants withdrew during the study and 29 of the remaining participants completed the post-intervention questionnaire.

Intervention: The guided iCBT intervention ran over an eight-week period and consisted of 16 obligatory modules and 5 optional modules. The intervention was designed to be interactive, interesting and stimulating. A key element was the provision of support from an Audiologist throughout the programme.

Data Collection and Analysis: Online questionnaires were used throughout the study. These were administered at baseline and post-intervention to determine attrition and compliance rates and to facilitate sample size estimates for further clinical trials. Outcome measures for

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2
3 tinnitus severity, hearing handicap, insomnia, cognitive functioning, hyperacusis, anxiety,
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5 depression and life satisfaction were used to investigate the effects of iCBT with
6
7 Audiological support. In addition, a weekly questionnaire was incorporated to monitor
8
9 change in tinnitus distress while undertaking the intervention.
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11
12 **Results:** Feasibility was established using an Audiologist to support this guided iCBT
13
14 intervention, as a significant change post-intervention was found for tinnitus severity, as
15
16 measured by the Tinnitus Functional Index and the Tinnitus Handicap Inventory screening
17
18 version. The attrition rate was 22% and compliance was variable. Although these results were
19
20 based on a small sample, they provide encouraging evidence for the feasibility of delivering
21
22 iCBT treatment for tinnitus symptoms with Audiology support in the UK.
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25 **Conclusions:** An internet-based intervention of tinnitus appears to be feasible in the UK
26
27 when using Audiological support. Randomised controlled trials to further investigate the
28
29 effectiveness of iCBT for tinnitus in the UK are required.
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31

32 33 34 **Keywords**

35
36 Tinnitus, tinnitus treatment, e-Health, internet-intervention, cognitive behavioural therapy
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40 41 **Abbreviations**

42
43 CBT: Cognitive Behavioural Therapy
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45 CFQ: Cognitive Failures Questionnaire
46
47 CONSORT: Consolidated Standards of Reporting Trials
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49 CSQ-8: Client satisfaction questionnaire
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51 DMC: Data monitoring committee
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53 GAD-7: Generalized anxiety Disorder
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55 HCPC: Health and Care Professions Council
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57 HHIA-S: Hearing Handicap Inventory for Adults - Screening Version
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59 HQ: Hyperacusis Questionnaire
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iCBT: Internet-based Cognitive Behavioural Therapy Intervention
ISI: Insomnia Severity Index
PHQ-9: Patient Health Questionnaire

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3 RCT: Randomized Control Trial
4 RCI: Reliable Change Index
5 SPIRIT: Standard Protocol Items, Recommendations for Interventional Trials
6 SPSS: Statistical Package for Social Sciences
7 SWLS: Satisfaction with Life Scales
8 TFI: Tinnitus Functional Index
9 THI-S: Tinnitus Handicap Inventory - Screening Version
10 UK: United Kingdom
11 WCI: Weekly check-in control group
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16 **Introduction**

17
18 Experiencing tinnitus can lead to adverse consequences such as insomnia, anxiety, and
19 depression, which may negatively affect relationships and the ability to work (Langguth,
20 2011). Despite extensive research, a cure for tinnitus is still to be found (Henry et al, 2014).
21
22 Managing tinnitus and its comorbidities places a burden on health care systems (Maes et al,
23 2013) and has significant health economic cost implications (Martinez et al, 2015). There are
24 added concerns that health organisations will be under-resourced in the future, especially
25 considering that the incidence of significant tinnitus has been increasing over the last 10 years
26 (Martinez et al, 2015). A further concern regarding tinnitus management in the United
27 Kingdom (UK) is that many who experience tinnitus remain without access to tinnitus
28 treatment as they are not always referred for treatment by their General Practitioner (El-
29 Shunnar et al, 2011). For those that are referred, both the structure and provision of tinnitus
30 services throughout the UK is variable, leading to inequality in tinnitus care (Hoare et al,
31 2015). Cognitive behavioural therapy (CBT), a psychological intervention aimed at altering
32 maladaptive responses to tinnitus through behavioural modifications, has the most evidence
33 of effectiveness at reducing tinnitus distress (Hesser et al, 2011). Despite positive outcomes
34 associated with the use of CBT for tinnitus, there remains limited accessibility, largely due to
35 a shortage of trained clinicians to provide CBT for tinnitus (Baguley et al, 2013). There are
36 thus various obstacles to effectively manage tinnitus in the UK.
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5 One potential solution to overcome current barriers is using the Internet to deliver treatment.
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7 Numerous studies have shown promise using Internet-based interventions in various fields
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9 such as pain, psychological conditions and health problems (Andersson, 2014). An advantage
10
11 of Internet interventions is having materials to refer to in written form, which serves to aid
12
13 information retention. This is beneficial, as information recall can be poor when provided
14
15 verbally in clinics (Reese and Smith, 2006). An internet-based system also enables patients to
16
17 be actively involved in their own treatment, which in turn leads to them deriving more benefit
18
19 from the treatment (James, 2013). Further benefits include facilitating adjustment behaviours,
20
21 providing an easily accessible clinician, as well as complementary information sources that
22
23 can be absorbed at a pace that suits patient needs, in the comfort of their own homes
24
25 (Andersson and Titov, 2014). It could provide accessible treatment to those who are in
26
27 remote geographical areas. There may, however, be barriers such as poor computer skills or
28
29 lack of Internet availability. Encouragingly, it is estimated that 87.9% of people in the UK
30
31 have Internet access (Office of National Statistics, 2016), and so hopefully these barriers
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33 should decrease over time.
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40 Internet-based CBT for tinnitus (iCBT) has been studied in Sweden, Germany and Australia
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42 (e.g. Andersson et al, 2002; Kaldo et al, 2008; Abbott et al, 2009; Nyenhuis et al, 2013;
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44 Jasper et al, 2014; Weise et al, 2016). A meta-analysis of internet-delivered CBT for tinnitus
45
46 showed that it is an effective form of intervention for both reducing tinnitus distress and
47
48 associated depression (Andersson, 2015). These trials have been developed and supported by
49
50 experienced Clinical Psychologists, who are accustomed to applying CBT techniques to
51
52 address psychological distress, anxiety, depression and insomnia that often co-occur with
53
54 tinnitus. Audiologists, on the other hand, play a significant role in most models of tinnitus
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3 healthcare provision, particularly in the UK (Henry et al, 2005). The advantages of having the
4
5 Audiological community deliver tinnitus treatment include their understanding of the
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7 auditory system, using their expertise to address comorbidities such as hearing handicap and
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9 hyperacusis that often co-occur with tinnitus (Nelson and Chen, 2004), as well as
10
11 incorporating their skill in counselling potentially anxious patients presenting with hearing-
12
13 related or balance disorders (Searchfield and Baguley, 2011). Audiologists are, however,
14
15 traditionally not trained explicitly in CBT techniques unless additional training is undertaken.
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17 This lack of experience applying CBT techniques may affect the way support is offered to
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19 those undertaking an iCBT intervention. In the UK context, delivering iCBT via an
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21 Audiologist would be optimal, but providing this form of support for an iCBT intervention
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23 needs to be established. To date, previous research has not determined whether delivering
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25 iCBT for tinnitus by a non-Psychological professional is feasible.
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32 The efficacy and feasibility in terms of recruitment, attrition, and compliance of iCBT in the
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34 UK are yet to be explored. Moreover, applying the same iCBT programme that has been used
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36 in previous trials, would not account for cultural differences. Therefore, iCBT, suitable for a
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38 UK population was developed using a format that may be more appealing to a UK
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40 population. The iCBT programme used in Europe was based on downloadable text-based
41
42 information and worksheets developed by Andersson and Kado (2004). This text has been
43
44 simplified and the presentation has been modified by adding videos, diagrams, and quizzes,
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46 to ensure it is appealing, interactive and responsive to mobile devices (Beukes et al, 2016). A
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48 feasibility study was considered an important pre-requisite to identify barriers and guide
49
50 planning of [randomised controlled trials](#), as suggested by the Medical Research Council
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52 framework for the evaluation of complex interventions (Campbell et al, 2000).
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3 The specific objectives of this study were determining the feasibility of guided iCBT using
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5 Audiological support on tinnitus distress and tinnitus related comorbidities. Additionally, the
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7 study aimed to establish the feasibility of iCBT for tinnitus in the UK, by determining
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9 recruitment, attrition and compliance rates. Lastly an aim was to refine this iCBT intervention
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11 and the protocol for implementation during subsequent randomised control trials.
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14 15 16 **Method**

17 18 *Design*

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20 A single-group open trial design was implemented to evaluate the feasibility of iCBT prior to
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22 undertaking an effectiveness study. The same protocol as for the effectiveness trial was
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24 followed, without including a control group and long-term evaluation (see Beukes et al, 2015
25
26 for this protocol). The CONSORT-eHealth guidelines were used (Eysenbach et al, 2011).
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32 33 *Recruitment*

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35 Recruitment was UK-wide, using a variety of approaches. Recruitment strategies
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37 incorporated social media, flyers, emails, forums, and newsletters, which were distributed to
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39 tinnitus charities, tinnitus support groups, tinnitus forums and Audiology departments for a
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41 two-month period prior to the study commencing. Those interested were directed to the study
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43 website (www.tacklingtinnitus.co.uk version 3) where they could read more about the study
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45 and register interest in partaking in the study.
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49 50 *Participants*

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52 Participant's eligibility for the study was as follows:

53 54 *Inclusion criteria:*

- Adults, aged 18 years and over, living in the UK, with the ability to read and type in English;
- Access to a computer, the internet and the ability to email
- Suffering from tinnitus for a minimum period of three months

Exclusion criteria:

- Reporting any major medical or psychiatric conditions
- Reporting pulsatile, objective or unilateral tinnitus, which have not been investigated medically or tinnitus still under medical investigation
- Tinnitus as a consequence of a medical disorder
- Undergoing any tinnitus therapy concurrent to participation in this study.

Participants who had registered on the study website were invited to participate (n=44). Of those invited, 37 provided online consent, completed the online questionnaire and were eligible to participate. Participants with a range of TFI scores were included, including two who had scores below 26, which is considered to be “mild” tinnitus. The reason for this was to assess what criteria should be set for the TFI in subsequent clinical trials.

Assessments

Aspects that were assessed included attrition rates and compliance in completing outcome questionnaires. Table 1 provides details of all the questionnaires used to determine the feasibility of iCBT with Audiological support, on the effect of iCBT on tinnitus and its comorbidities. Online questionnaires were used throughout the study. Psychometric properties have been established for this format for some of the questionnaires used, e.g. the GAD-7 and PHQ-9 (van Ballegooijen et al, 2016). Although psychometric properties have

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3 not been established for online use for all the questionnaires, previous research has found
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5 comparable results in terms of psychometric properties between computer and paper
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7 questionnaire delivery (Thoren et al, 2012). All the measures were completed pre- and post-
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9 intervention.

14 **Pre-intervention assessments**

16 The initial assessment consisted of an eligibility screening questionnaire and relevant self-
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18 reported outcome measures, related to areas which may be affected by tinnitus. Outcome
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20 measures for tinnitus severity, hearing handicap, insomnia, cognitive functioning,
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22 hyperacusis, anxiety, depression and life satisfaction were thus selected, as seen in Table 1.
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24 The TFI was selected as the main outcome measure, over more established tinnitus outcome
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26 measures, as it has been specifically developed to measure tinnitus severity and assess
27
28 responsiveness to treatment (Meikle et al, 2012). Although further validations are still
29
30 required, the TFI is increasingly being used internationally and is being validated for these
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32 purposes (see Henry et al, 2014; Rabau et al, 2014; Fackrell et al, 2015). As a secondary
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34 tinnitus measure, the screening version of the Tinnitus Handicap Inventory (THI) was used,
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36 as scores are comparable ($r=0.9$) with the full version of the THI (Newman et al, 2008).
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43 All instruments were used with the permissions of the copyright holders, and agreements
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45 were set up for those that are not freely available to use, such as the TFI and ISI.
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49 A two-staged selection procedure was followed:

- 51 I. An online screening questionnaire, which included health and mental health-related
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53 questions and standardised outcome measures as shown in Table 1.
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3 II. A telephone interview during which the researcher rechecked eligibility, and provided
4 the opportunity for potential participants to ask any questions related to the study.
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9 10 **Assessments during the intervention**

11 Throughout the programme, participants were monitored weekly by means of the Tinnitus
12 Handicap Inventory, Screening version (THI-S), which consists of a 10-item questionnaire
13 (Newman et al, 2008).
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18 19 20 21 **Post-intervention assessments**

22 Following completion of the eight-week iCBT intervention, the same outcome measures were
23 administered, again in the form of an online questionnaire. A telephonic interview was
24 scheduled to discuss progress and provide the opportunity for participants to discuss their
25 experiences undertaking the intervention. Reminders and encouragement were provided
26 throughout for participants who had not completed questionnaires or worksheets on time.
27 There were three reminders that were automatically and electronically sent on the three
28 consecutive days following the release of the questionnaire. Further reminders were sent if
29 required to a maximum of seven, as well as a reminder phone call, over a period of three
30 weeks.
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45 46 **Intervention**

47 An interactive intervention was developed using a cognitive-behavioural theoretical
48 framework, based on a CBT self-help programme by Andersson and Kaldo (2004). This
49 intervention includes key CBT techniques, such as negative automatic thought analysis,
50 cognitive restructuring, imagery and exposure techniques. It applies the principles of CBT
51 such as goal setting, structure, active participation relapse prevention and a set time-frame for
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3 the therapy (Beck, 2011). Audiological principles found to be effective for tinnitus such as
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5 sound enrichment; hearing tactics and advice for sound sensitivity were also included. The
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7 content of the intervention was tailored to include both obligatory and optional modules, as
8
9 shown in Table 2. A responsive web-based treatment platform was designed in-house at
10
11 Linköping University, Sweden, complying with a high level of data security and encrypted
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13 communications (Vlaescu et al, 2015). Key principles to maximise effectiveness, compliance,
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15 and retention rates were incorporated, as recommended by Dziura et al. (2013). The treatment
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17 format included a mixture of videos, quizzes, diagrams, pictures, worksheets and solutions to
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19 common problems, all provided free of charge for participants to work through online. There
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21 was also the option of downloading or printing the content and worksheets for those who
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23 preferred to read offline and/or read a printed version of the content. There were, therefore,
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25 various ways in which participants could access the information to suit different preferences.
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27 Participants were encouraged to record the effectiveness of techniques practised, using online
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29 worksheets provided for this purpose. These worksheets were tailored to the nature of the
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31 particular module and provided the opportunity for participants to indicate how they
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33 approached techniques, how effective these techniques were and in which situations they
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35 were practised.
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43 **Therapist**

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45 A key element of this intervention was ensuring it was guided, whereby participants had
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47 access to a clinician throughout the programme. To maintain consistency with the standard
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49 approach of tinnitus therapy being delivered within the audiology community in the UK, an
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51 experienced Audiological Scientist, registered with the Health and Care Professions Council
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53 (HCPC), and appropriately trained to Masters Level in Audiology, undertook the role of
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55 supporting the participants. The therapist was experienced in managing tinnitus patients in a
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3 clinical setting and had a suitable understanding of CBT principles. Supervision was provided
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5 by a Clinical Psychologist (specialised in tinnitus treatment) throughout the intervention. The
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7 therapist's role was to conduct the telephonic interviews, introduce weekly modules, provide
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9 feedback, answer queries, provide guidance, support and encourage engagement. This
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11 feedback was provided using an encrypted messaging system within the intervention and by
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13 telephone when required. Having Audiology support for an iCBT intervention is unique to
14
15 this study, as Psychologists have guided participants in previous studies.
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20 21 **Ethical considerations**

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23 The Faculty of Science and Technology Research Ethics Panel (FREP) of Anglia Ruskin
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25 University (FST/FREP/14/478) granted ethical approval for this study. The research was
26
27 conducted in accordance with the tenets of the Declaration of Helsinki. Participation was
28
29 voluntary and all participants provided informed consent online. A full explanation of every
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31 step of the study was provided and participants were able to withdraw at any stage without
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33 penalty. A protocol was established to ensure the security of participants' confidentiality
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35 when using the web-portal, complying with European guidelines for Internet studies.
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37 Participants' data were anonymised and unique reference codes used.
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43 44 **Data Analysis**

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46 The Statistical Package for Social Sciences (SPSS) version 20.0 was used for statistical
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48 analysis. An intention-to-treat paradigm for analysis was followed, by which statistical
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50 analysis was performed on everyone allocated to the treatment programme, and not only
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52 those who complete the treatment programme. Missing data analysis was performed using
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54 Little's MCAR test to determine the best method to use for missing data analysis (Little,
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56 1988). In addition, data would also be analysed for completers only. If there was no
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3 difference in results, intention-to-treat data was reported. Paired sample *t*-tests were used to
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5 compare pre- and post-treatment scores with a significance level of 0.05. Effect sizes
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7 (Cohen's *d*) were calculated by dividing the differences in pre- and post- intervention means
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9 by the pooled standard deviations.

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11 Partial correlations were performed, to determine the relationship between post-treatment
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13 scores while controlling the effects of additional variables. There were six variables
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15 considered, namely initial TFI score, level of education, employment type, tinnitus duration,
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17 age, and gender. During each correlation, five variables were partialled out.

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23 The reliable change index (RCI; Jacobson and Truax, 1991) was used as a means of
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25 calculating clinical significance for the TFI. This was calculated using the pretreatment
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27 standard deviation, and a test-retest reliability coefficient of 0.78, as reported in the validation
28
29 study (Meikle et al, 2012). The internal data monitoring committee had access to the data and
30
31 ensured correct interpretation and analysis thereof.

32 33 34 35 36 **Results**

37 38 **Participant Characteristics**

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40 The demographic profile of the participants (Table 3) demonstrated that a range of
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42 participants with different educational and employment backgrounds, as well as varying
43
44 tinnitus experiences were drawn to the study. Participants were spread across the UK, with
45
46 the majority based in England and a few in Wales, Scotland, and Northern Ireland.

47 48 49 50 **Participant flow**

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52 Figure 1 shows the study profile. Of the 37 participants who started the study, two developed
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54 major health complaints and were given the option to transfer to a subsequent study to
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3 provide time for recuperation. A further three withdrew, one due to login and navigation
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5 difficulties and two as they no longer required the intervention. One of the participants that
6
7 withdrew had a low initial TFI score of 24 and felt that his tinnitus was not significant
8
9 enough to require this level of support. Those that completed the intervention (n=32) together
10
11 with the three that withdrew were invited to complete the post-treatment questionnaire
12
13 (n=35). Of these, 29 completed the post-treatment questionnaire, yielding a completion rate
14
15 of 82.9%. The attrition rate included five who withdrew and four who did not complete the
16
17 post-intervention questionnaires, leading to a rate of 22% during the study. The extent to
18
19 which participants actively engaged and interacted with the resources provided by this iCBT
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21 intervention was highly variable. An average of 14.8 of the modules were read with an
22
23 average login of 19.7 times during the intervention. Participants completed an average of
24
25 74% of the worksheets.
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32 The therapist spent at least 10 minutes at the end of each week providing written feedback to
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34 each participant on the work done. Written feedback was also provided during the week as
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36 and when worksheets were completed. *The therapist reported that using written therapeutic
37
38 input was an effective way of supporting participants.* There were 413 tailored messages to
39
40 individual participants (12.9 per user, of the 32 who completed), with a minimum of one
41
42 message per week. These messages added encouragement to maintain involvement and
43
44 provided feedback on worksheets completed. Group e-mails were sent on a weekly basis to
45
46 introduce the new modules. For those that were not logging on, the therapist telephoned them
47
48 to find out if they could be assisted. In many cases participants who were not engaging
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50 explained this was due to a bout of ill health or lack of time. All written and telephone
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52 contact was approached in a professional, constructive and motivating way. This format
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54 appeared to work well and participants valued the guided feedback.
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Statistical analysis

Missing data was missing “completely at random” ($\chi^2 = 12.37$, $DF = 9$, $p = 0.19$), demonstrating that there was no relationship between missing and observed data. Due to this random distribution, imputing missing values was undertaken, using the Markov Chain Monte Carlo approach. Results were compared to per protocol results. As there were no differences when comparing results of completers only or using intention-to-treat data, the latter’s pooled results will be reported. The mean pre- and post-treatment scores, the level of significance and statistical results for the various outcome measures used are shown in Table 4.

For both tinnitus questionnaires, there was a significant improvement post-intervention, underlined with a large effect size for the change in TFI score. Further analysis of the subcategories of the TFI indicated that there was a significant change in all eight categories of the TFI. There was a mean difference of 19.04 in the pre-post scores for the TFI. The RCI indicated a change of 23.86 in the TFI score was required post-intervention to be considered clinically significant. This was reached by 38% of participants (n=14).

The pre-treatment scores for many of the secondary outcome measures were below the level of clinical significance. Post-treatment improvements would, therefore, be unlikely. Only the ISI showed a significant change post-intervention, with the mean severity changing from “subthreshold significance” to “non-significant” results. This change represented a large-sized effect. No significant changes were found for questionnaires related to hearing handicap, hyperacusis, satisfaction with life, anxiety, depression and cognitive failures.

Possible outcome predictors

Partial correlations were calculated to determine which pre-intervention factors may be correlated to the post-treatment TFI score, whilst controlling for the effects of additional variables. There was a significant positive correlation between pre- and post-intervention TFI scores [$r(31) = .533, p = 0.001$]. No correlation was found between post-intervention TFI outcome and level of education, employment status, duration of having tinnitus, age or gender. The only factor, therefore, possibly predicting greater post-treatment outcome, is higher pre-treatment TFI scores, although further randomised controlled trials with larger sample sizes are required to validate this finding.

Weekly monitoring

The THI-s was used to monitor change in tinnitus distress while undertaking the intervention, on a weekly basis. Some participants omitted to complete this weekly questionnaire some weeks (up to $n=12$), despite reminders. Overall there was a reduction in tinnitus handicap over time as seen in Figure 2. Comparing the results on a week-by-week basis, there was a significant difference found for the results of the THI-s between weeks 5 to 6 [$t = 2.37(25) = 0.003$] using paired sample t-tests. When comparing the beginning weeks of the intervention to the final weekly score of the THI-s, there were significant differences between weeks 1 through to 5, compared to week 8. This indicates that there needs to be a six-week time frame of intervention in order to start having a positive effect.

Satisfaction ratings

Participants rated their satisfaction of the intervention on a 1-5 Likert scale. Overall ratings were high with a rating of 85.8% (mean score of 4.29 (SD=0.28)). Feedback, on the whole, was positive, with comments such as “Thanks so much to you and the team, it is so great to

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3 be doing something positive and taking control rather than just grinning and bearing my
4
5 tinnitus which I had been doing until now.” During post-intervention phone calls participants
6
7 shared how they valued having had the opportunity to participate and how much the
8
9 intervention has helped.
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11 12 13 14 15 **Sample size calculations for further clinical trials**

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18 From these results, sample size requirements can be established for further clinical trials.
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20 Calculations indicated that 19 participants are required per group, based on achieving a
21
22 significant **between-group** change of 19.04 points at a significance level of 0.05 and effect
23
24 size of 0.9, when using G*Power version 3.1.6. **Additional participants will, however, need to**
25
26 **be recruited to account for possible drop-outs. This will ensure that the required power is**
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28 **achieved.**
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33 34 **Discussion**

35 36 **Feasibility of iCBT in the UK**

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38 The aim of this study was to evaluate the feasibility of an Internet-based CBT treatment for
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40 tinnitus in the UK, using Audiologist support in an open trial design with 37 participants.
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42 This study forms an essential pre-requisite prior to undertaking large scale RCTs. When using
43
44 an Audiologist to support iCBT, tinnitus severity was lowered as measured by all subscales
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46 of two tinnitus outcome measures. The Audiologist’s field of expertise was considered an
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48 advantage in addressing both tinnitus and hearing related concerns often contributing to the
49
50 tinnitus. Although not directly comparable, the effect size indicated in this study is in line
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52 with that of similar open trials using an iCBT paradigm by Kaldo-Sandström et al (2004) and
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54 Kaldo et al (2013) who obtained medium effect sizes (Cohen’s $d = 0.56$ and 0.58
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3 respectively) when using the Tinnitus Reaction Questionnaire (Wilson et al, 1991). Using an
4 Audiologist instead of a Psychotherapist, therefore, appears feasible. Previous internet-based
5 studies for depression, anxiety and social phobia have found comparable results, regardless of
6 whether the therapist was a clinician or a technical assistant (Robinson et al, 2010; Titov et al,
7 2009 and Titov et al, 2010).
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16 The RCI indicated that a difference of 23.96 for the TFI scores was required to be considered
17 a clinically significant change. In this study, only 38% of participants achieved this. This RCI
18 value is similar to the meaningful difference found by Fackrell et al, (2015) studying a group
19 of research volunteers, although it differs from the 13 point difference indicated by Meikle et
20 al (2012) studying a clinical population. This may be partly due to the population for our
21 study and the Fackrell study both including research volunteers.
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32 As tinnitus may be associated with various comorbidities, secondary outcome measures for
33 hearing disability, anxiety, depression, insomnia, quality of life, cognitive failures and
34 hyperacusis were included in this study. Results indicate an effect only on the ISI. There were
35 no treatment effects seen on the outcome measures for hearing handicap, depression, anxiety,
36 cognitive failures, hyperacusis, and satisfaction with life. Possible contributing factors may
37 be related to the pre-treatment scores being low for these outcome measures and therefore
38 unlikely to show a change post-intervention. This may in part be secondary to the feasibility
39 study sample size, and a larger sample may be required before concrete conclusions can be
40 drawn. A further explanation may be that the Audiologist may not have the expertise of a
41 Psychologist at clarifying psychological concepts such as cognitive restructuring, and the
42 approach may have differed. Further controlled trials are required to fully investigate the
43 effects of the intervention on these secondary outcome measures. Participants were monitored
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3 on a weekly basis. Results indicated that it takes about 6 weeks of iCBT before reductions in
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5 tinnitus severity are experienced.
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10 In terms of recruitment feasibility, take-up rates for the study were low. Musiat et al (2014)
11 found that perceptions in the UK of computerised interventions were poor as more
12 acceptance was found for face-to-face interventions. Acceptance rates appear to be higher
13 where a culture of internet intervention is more established. For instance, Kaldo et al (2004)
14 found that an internet programme for tinnitus was rated as acceptable as individual or group
15 therapy. To improve recruitment rates, working on the public perceptions of such
16 interventions within the UK will be required.
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25 One concern about internet-delivered treatments is the possibility of a high dropout rate,
26 especially in unguided interventions without therapist support (Eysenbach, 2005). In previous
27 iCBT studies for tinnitus, attrition rates have varied greatly, between 5-57%, with the largest
28 being due to methodological shortcomings in a study in Australia by Abbott et al (2009).
29 Attrition rates for the present study fell within the middle of this range at 22%, however, the
30 within-group design may have inflated these. Attrition rates within this region are on par with
31 that found for traditional group-based CBT treatments for tinnitus (Kaldo et al, 2008), which
32 is encouraging. Ensuring post-intervention questionnaire completion should be a key element
33 in improving attrition in further trials. Arranging appointments for post-intervention
34 telephone interviews may also improve these rates. Overall these attrition rates indicate the
35 feasibility of iCBT within the UK and an effectiveness trial is warranted.
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51 In terms of compliance, there was variability of engagement in the programme. Despite
52 regular therapeutic encouragement, some participants struggled to engage with the
53 intervention. Barriers to engagement included time constraints, work pressures, and poor
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3 health. Bendelin et al (2011) reported that a key factor to successful outcomes with internet
4 interventions is for participants to take responsibility and identify the link between their
5 efforts and the resulting success. Donkin and Glozier (2012) investigated what influences
6 persistence in online interventions. They found those that persisted could identify with the
7 programme, were intrinsically motivated due to values about task completion and being able
8 to see improvements and a sense of feeling in control. Although protocols were followed to
9 mimic interventions provided with Psychotherapist support, it is possible that feedback from
10 an Audiologist, as opposed to a Psychotherapist, may have contributed to the variability in
11 engagement. Exploring and comparing the nature of this feedback is therefore of importance.
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24 25 **Refining the protocol for further clinical trials**

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27 An intervention such as this may be a useful supplement for standard clinical tinnitus care in
28 the UK. As such it is essential to determine for which populations of those with tinnitus this
29 may be a suitable intervention. Besides the initial pre-intervention TFI score, there were no
30 significant predictors of post-treatment TFI scores, for educational level, employment status,
31 tinnitus duration, age or gender. Inconclusive results have been found regarding
32 characteristics that may affect outcomes for internet interventions, and previous studies have
33 also suggested that gender, age, educational level, and computing skills do not affect the
34 outcome (Andersson et al, 2009).
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47 From the present study, it appears as though initial TFI scores may be an important factor in
48 determining the outcome, although results require verification with larger samples. This is in
49 line with findings that significant levels of tinnitus distress are required to serve as motivation
50 to complete CBT programmes (Kaldo et al, 2013). This has implications for the inclusion
51 criteria. If severity is mild, participants may not feel the need to commit to such a
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3 programme. A score of 26 or higher was suggested by Meikle et al, (2012) to be indicative of
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5 tinnitus **requiring clinical intervention**. Of the two participants with TFI scores lower than 26,
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7 one withdrew, expressing that their tinnitus was not severe enough to undergo an
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9 intervention. The other participant continued to participate and found great benefit from the
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11 study. However, for this participant, post-treatment scores were higher than his baseline
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13 scores. Due to his positive experience of the intervention, this was attributed to having filled
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15 in his initial questionnaire in a guarded manner. From this experience, we suggest that a
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17 telephone interview should be used to help decide whether initial scores were too guarded.
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19 The inclusion criteria of TFI score of 26 or higher would be recommended for further trials.
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22 It is important to reach the intended population of those with significant levels of tinnitus
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24 who are not well supported. As the recruitment was largely through tinnitus support group
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26 networks, most of those who participated have tried various therapies in the past, which
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28 would have influenced their impressions of interventions. There are many who have tinnitus
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30 and have not received much intervention, and these people need to be targeted with wider
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32 recruitment strategies.
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38 **Strengths and limitations of the study**

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40 This study is of preparatory value for future iCBT controlled trials in the UK. Using an
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42 adapted intervention specifically for a UK population was a strength of the study. Keeping in
43
44 line with current tinnitus management in the UK, using an Audiologist to deliver the
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46 treatment, was a further advantage. Further strengths lie in the comprehensive nature of the
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48 study, investigating the effects of the intervention on tinnitus and relating to areas that may be
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50 affected by tinnitus.
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3 There were, however, some limitations which need to be considered for the planned
4 randomised control trial. Baseline measurement may not have been stable, as test-retest
5 effects were not accounted for. Furthermore, no control group was present, placebo effects
6 cannot be discounted, and need to be considered during result interpretation. For the initial
7 assessment demographical questions were not specific enough as questions related to age and
8 tinnitus duration were categorised into broad groups. This questionnaire needs to be adjusted
9 to ensure more accurate information is obtained during future studies. The recruitment
10 strategy also requires improving to reach the target population of those with distressing
11 tinnitus that are not well supported. This may be achieved by having a wider recruitment
12 strategy by advertising in health magazines, local newspapers, and various Internet forums.
13 Lastly, to improve attrition, scheduling post-intervention phone calls, should be introduced,
14 as this may also serve as a motivator to encourage post-intervention questionnaire
15 completion. One important aspect of feasibility that was not explored was participant's
16 willingness to be randomised. Exploring this aspect will be important during future
17 randomised control trials.
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39 **Future directions**

40 This study has provided encouraging results which need to be further explored in a
41 randomised control trial. More research is required to determine the effect of the therapist
42 variable (i.e. Psychotherapist versus Audiological Professional) on treatment outcomes. The
43 longer term effects of this intervention as well as participants' experiences with this
44 intervention, should be established.
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51 **Conclusions**

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3 The use of an internet-based intervention for tinnitus in a UK population has been shown to
4 be feasible. This study has been of value to identify sample size, possible barriers and refine
5 the protocol for subsequent [randomised controlled trials](#). Further research should focus on
6 [effectiveness trials](#).
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11 12 13 14 **List of figure legends**

15 Figure 1: Study profile

16
17 Figure 2: Weekly check-in scores over the eight-week treatment period
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20 21 **List of table legends**

22 Table 1: Study outcome measures used pre- and post-intervention

23 Table 2: Components involved in the intervention

24 Table 3: Demographics characteristics of the participants

25 Table 4: Pre- and post-intervention comparisons for the various outcome measures [using](#)
26 [corrected values from the intention-to-treat data](#)
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36 37 **Acknowledgements**

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39 study. We would also like to thank Linköping University for hosting the web portal and their
40 webmaster, George Vlaescu, for technical assistance provided.
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47 48 **Author's contributions**

49 GA, VM, DB and PA conceived this study. GA developed the Swedish original iCBT
50 intervention for tinnitus together with Viktor Kaldo, EB developed this version for a UK
51 population, carried out the study, collected the data and drafted the manuscript. All authors
52 critically revised and approved the manuscript.
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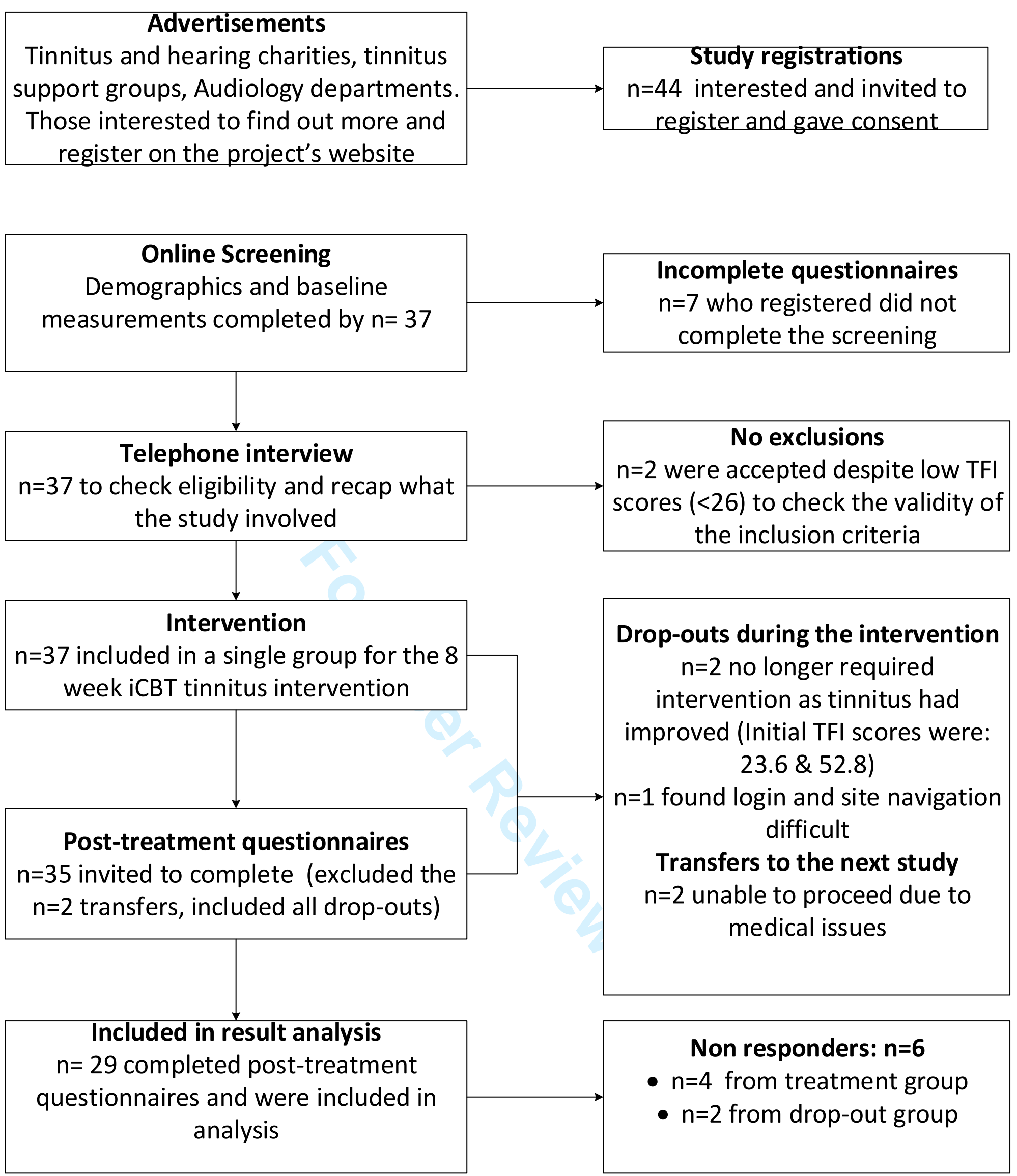
Recruitment

Enrolment

Treatment

Post-treatment

Analysis



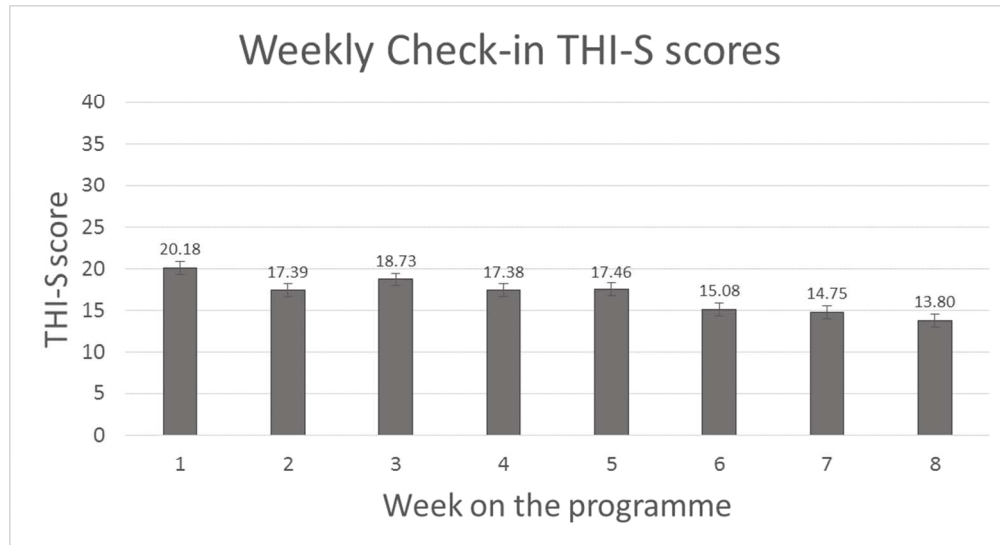


Figure 2: Weekly check-in scores over the eight-week treatment period
Overall there was a reduction

Table 1. Study outcome measures used pre- and post-intervention

Outcome Measures delivered at enrolment and close out	Range of scores	Levels of significance
Tinnitus Functional Index (TFI; Meikle et al, 2012)	0-100	>25= mild 26-50= significant 50+ =severe
Tinnitus Handicap Inventory-Screening (THI-s; Newman et al, 2008)	0-40	>6 tinnitus handicap
Hearing Handicap Inventory-Screening (HHI-s; Newman et al, 1991)	0-40	0-8= 13% probability of HI, 10-24= 50% probability of mild-moderate HI 26-40= 84% probability
Insomnia Severity Index (ISI; Bastien et al, 2001)	0-28	0-7 = Not clinically significant 8-14 = Subthreshold insomnia 15-21 = Clinical insomnia (moderate severity) 22-28 = Clinical insomnia (severe degree)
Cognitive Failures Questionnaire (CFQ; Broadbent et al, 1982)	0-100	Higher scores indicate more difficulties
Hyperacusis Questionnaire (Hyper. Q; Vernon, 1987)	0-42	>28 strong hypersensitivity
Patient Health Questionnaire (PHQ-9; Spitzer et al, 1999)	0-28	5-9=mild depression 10-14=moderate 15-19=moderately severe 20-18= severe depression
Generalised Anxiety Disorder (GAD-7; Spitzer et al, 2006)	0-21	0-4= minimal anxiety 5-9= mild anxiety 10-14= moderate anxiety 15-21= severe anxiety
Satisfaction with Life Scales (SWLS; Diener et al, 1985)	0-35	0-9= Extremely dissatisfied 10-14= Dissatisfied 15-19= Below average

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	satisfaction
	20-24= Average satisfaction
	25-29= High satisfaction
	30-35= highly satisfied

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Table 2: Components involved in the intervention

Obligatory modules	Optional modules
▪ Intervention outline	▪ Sound enrichment
▪ Tinnitus overview	▪ Sleep guidelines
▪ Progressive relaxation in six phases	▪ Concentration tips
▪ Positive imagery	▪ Sensitivity to sound
▪ Reinterpretation of tinnitus	▪ Hearing tactics
▪ Focus exercise	
▪ Identifying negative thoughts	
▪ Cognitive restructuring	
▪ Exposure to tinnitus	
▪ Summary	
▪ Future planning	

Table 3: Demographic characteristics of the participants

DEMOGRAPHICAL INFORMATION	Mean (SD) or number (%)
Gender	18 (48.6%) male 19 (51.4%) female
Average Age Range	50-59 years (SD= 1.32) Range 18-80 years
Tinnitus duration	3-12 months: 4 (10.8%) 1-5 years: 16 (43.2%) 5-10 years: 6 (16.2%) 10+ years: 11 (29.7%)
Location of tinnitus	Both ears 17 (45.9%) Head/unsure: 7 (18.9%) Left ear: 7 (18.9%) Right ear: 6 (16.2%)
Frequency of tinnitus	Constant: 22 (59.5%) Most of the time: 14 (37.8%) Without hearing aids: 1 (2.7%)
Seen a GP/ ENT due to tinnitus	35 (94.6%)
Previous treatment for tinnitus received	16 (43.2%)
Read up about tinnitus	34 (91.9%)
Hearing loss reported	26 (70.3%)
Hearing aids used	10 (27%)
Highest Educational level	School: 11 (29.7%) College/ vocational training: 10 (27%)

	Undergraduate degree 14 (37.8%)
	Postgraduate degree: 2 (5.4%)
Employment	Manager/Professional: 10 (27%)
	Skilled tradesman/ technical: 5 (13.5%)
	Homemaker/Service occupation: 4 (10.8%)
	Retired 16 (43.2%)
	Unemployed: 16 (5.4%)
Working less due to tinnitus	Stopped working 8 (21.6%)
	Reduced hours: 1 (2.7%)

Table 4: Pre- and post-intervention comparisons for the various outcome measures using corrected values from the intention-to-treat data

Outcome measure	Pre-Intervention Mean (SD)	Post-Intervention Mean (SD)	Level of significance	Effect size, Cohen's <i>d</i>	<i>t</i> -test (significant *)
TFI	56.15 (18.35)	37.35 (19.49)	Pre: severe Post: significant	1.18	$t(36)=6.26; p = 0.001^*$
THI-S	22.49 (7.69)	13.55 (9.31)	Pre&Post: Tinnitus handicap	0.38	$t(36)=7.91; p = 0.001^*$
HHIA-S	15.14 (12.42)	12.87 (10.06)	Pre&Post: 50% probability of hearing handicap	0.06	$t(36)=1.32; p= 0.197$
GAD-7	7.59 (5.28)	5.56 (4.74)	Pre&Post: Mild anxiety	0.10	$t(36)=3.74 p=0.068$

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PHQ-9	7.35 (6.37)	5.68 (4.89)	Pre&Post: Mild depression	0.37	<i>t</i> (36)=1.73; <i>p</i> =0.085
ISI	11.73 (5.27)	7.04 (4.81)	Pre: subthreshold insomnia Post: no significant insomnia	1.20	<i>t</i> (36)=5.54; <i>p</i> = 0.001*
SWLS	16.12 (6.76)	17.45 (7.43)	Pre&Post: Below average satisfaction	0.28	<i>t</i> (36)=-1.22; <i>p</i> = 0.249
Hyper. Q	19.22 (10.06)	16.23 (9.68)	Pre&Post: Subthreshold hyperacusis	0.29	<i>t</i> (36)=1.71; <i>p</i> =0.103
CFQ	36.14 (15.22)	34.4 (15.04)	Pre&Post: Lower range of cognitive problems	0.16	<i>t</i> (36)=0.68; <i>p</i> =0.502

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