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Technical Report

Pre-market version of a commercially available hearing instrument with a tinnitus sound generator: feasibility of evaluation in a clinical trial

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Abstract

Objective: This report considers feasibility of conducting a UK trial of combination devices for tinnitus, using data from the study which evaluated different listener programmes available within the pre-market version of Oticon Alta with Tinnitus Sound Generator. *Design*: Open and closed questions addressed the following feasibility issues: (1) Participant recruitment; (2) Device acceptability; (3) Programme preferences in different self-nominated listening situations; (4) Usability; (5) Compliance; (6) Adverse events. *Study sample*: Eight current combination hearing aid users (all males) aged between 62–72 years (mean age 67.25 years, SD = 3.8). *Results*: All eight participants reported the physical aspects and noise options on the experimental device to be acceptable. Programmes with amplification and masking features were equally preferred over the basic amplification-only programme. Individual preferences for the different programme options varied widely, both across participants and across listening situations. *Conclusions*: A set of recommendations for future trials were formulated which calls for more ''real world'' trial design rather than tightly controlling the fitting procedure.

Key Words: Tinnitus; combination device; hearing aid; sound therapy; feasibility; clinical trials

Introduction

Sound therapy (hearing aids or sound generators) is a core component of many tinnitus management programmes (Hobson et al, 2012). Potential mechanisms of benefit include making tinnitus less noticeable, promoting habituation, distracting attention from tinnitus and promoting neuroplastic changes (Bentler & Tyler, 1987; Vernon & Meikle, 2000; Tyler, 2006; Newman & Sandridge, 2012).

Technological improvements have enabled the prescription of open fit, digital hearing aids for people with mild hearing loss and tinnitus. Sound generators and hearing aids cannot be worn at the same time and so combination hearing aids might be a preferable option in these situations. These are henceforth called combination devices. Combination devices provide both amplification and sound generation, and new generations now offer the same amplification features as their 'standard' hearing aid counterparts (Henry et al, 2004).

Several authors have formulated candidacy and fitting recommendations for tinnitus sound therapy. However, those recommendations are variable, mainly depending on which management programme the authors follow (Bentler & Tyler, 1987; Tyler et al, 1992; Vernon & Meikle, 2000; Henry et al. 2005; Sweetow & Sabes, 2010). As a result, current tinnitus management guidelines lack clear recommendations about candidature and prescription options for combination devices, including the acoustic features of the masking sound (Department of Health, 2009; Tunkel et al, 2014). Perhaps the only explicit recommendation is the Tinnitus Research Initiative algorithm, which recommends combination devices ''for intrusive tinnitus where hearing aids alone are ineffective'' (Biesinger et al., 2011). But this is not evidence based nor does it advise on hearing loss characteristics or device prescription options.

With respect to device prescription options, current combination devices offer a wide choice of noise types (Hoare et al, 2013, 2014). Broadband noise options (white, pink, red or brown noise) are ''standard'' on most of the devices, with additional options to modulate the sound or to apply low- or high-bandpass filtering. Several manufacturers offer individualised broadband noise options

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that are shaped according to an individual's audiogram and/or tinnitus pitch to improve audibility of the sounds and provide broad frequency activation (Baguley et al, 1997; Searchfield et al, 2002). In studies investigating the efficacy of combination devices for tinnitus, little attention is paid to the acceptability of the sounds despite acceptability being vital for listening comfort and promoting sustained device usage (Tyler, 2006; Henry et al, 2008; Hoare et al, 2013). The present study was originally designed to evaluate experience of a pre-market version of the Oticon Alta with Tinnitus Sound Generator (thereafter called the ''intervention device''), compared to participants' existing combination device. Here, we consider the feasibility of trialling this device in terms of its: (1) Acceptability; (2) Programme preferences in different self-nominated listening situations; (3) Usability; (4) Compliance; (5) Adverse events.

Methods

Study site/funding

The study was conducted at the National Institute for Health Research (NIHR) Nottingham Hearing Biomedical Research Unit and funded by Oticon A/S. This study was approved by the NHS Health Research Authority Nottingham Research Ethics Committee 1 (Reference Number: 13/EM/0269) on 23 July 2013. The Sponsor was Nottingham University Hospitals NHS Trust.

Inclusion and exclusion criteria

We recruited experienced combination device users (6 months/6 h a day minimum use) who perceived benefit from both amplification and sound generation. Exclusion criteria were pulsatile tinnitus, Ménière's disease, temporomandibular joint disorder related to tinnitus, intermittent tinnitus, reduced sound level tolerance (score >28 on Hyperacusis Questionnaire, Khalfa et al, 2002), amplification users <6 months or long-term amplification users with audiological adjustments within last 1 month, using Zen tones on the existing digital combination device, and taking part in another trial during the last 30 days before study start. Use of Zen tones was excluded because this masking sound forms one component of Zen Therapy, in addition to counselling and relaxation. It is not a fair comparator to a standard combination device sound therapy.

Intervention device

The intervention device was a Pre-Market version of Oticon Alta with a Tinnitus Sound Generator, receiver-in-the-ear digital combination hearing aid. Four programmes were available and active (Table 1). In programme 4, the device offered the choice of three novel nature sounds that resembled the sound of the ocean but differed in the underlying noise spectrum (white, pink and red). Other fitting options included parameters for the masker noise. In particular, the device provided ''white'', ''pink'' and ''red'' broadband masking noise options as described by manufacturer, with minimum and maximum settings for the masker sound level. Additional parameters for shaping the noise included three options for frequency cut-off (modified with the trimmers) and several options for the modulation (both speed and depth) of the masking noise (tranquil with the least modulation, mild, spirited and bustling with the clearly audible modulation).

Table 1. Programmes available on the intervention device.

Programmes	
Programme 1	Amplification
	Manual volume control for adjusting the level of amplification
Programme 2	Amplification
	Masking noise (white/pink/brown, unmodulated or modulated, non-filtered or bandpassed)
	Manual volume control for adjusting the level of masking noise
Programme 3	Amplification
	Masking noise (white/pink/brown, unmodulated or modulated, non-filtered or bandpassed)
	Automatic level steering for adjusting the level of masking noise
Programme 4	Amplification
	Ocean sounds (three options)
	Manual volume control for adjusting the level of the nature sound

The device also contained a ''streamer'' which was a compact Bluetooth device that acted as a gateway between the combination device and external sound sources. The streamer could also be used as a remote control for adjusting the volume of amplification or masking noise as well as changing programmes. Use of the streamer was optional.

Device fitting

The intervention device was programmed by a qualified audiologist (JD), according to manufacturer's standard clinical protocol and programming software. Training on device fitting was provided by one of the manufacturer's audiologists. Amplification was matched to the participant's existing device using real ear measurements (REM), adhering where possible to UK professional guidelines (British Society of Audiology & British Academy of Audiology, 2007). As we did not have access to each participant's computer-based clinical hearing aid settings, this was achieved by first measuring the in-situ ''aided gain'' of the participant's existing device using a 65 dB modulated speech noise. This measure then became the ''target'' response curve to which the intervention device was fine tuned to match. In all cases, we were able to closely match the aided gain of the intervention device with each participant's own device to within ±5 dB.

Participants selected the standard masker noise (white, pink, brown) that most resembled that of their existing device. Loudness was subjectively matched to their existing masker noise. A nature sound was chosen according to preference (i.e. the most pleasant and most resembling an ocean sound).

Each participant received the manufacturer's written instructions for the intervention device and a spare set of batteries. Participants were instructed to wear the device for at least 6 h/day and try the device in all situations that they nominated as those where alleviating their tinnitus was important for them (see Results).

Procedure

Participants were encouraged to use the intervention device exclusively for a two-week period. During that time, they were instructed to try all the four programme options in different listening situations. After two weeks, participants returned the intervention device and went back to using their own device.

Table 2. Characteristics of the 8 enrolled participants.

Participant	Age (years)	Global THI score (0–100)	Tinnitus duration (years)	Tinnitus laterality	Tinnitus description
1	63	66	10	Unilateral, left ear and left side of the head	High-pitched whistle
2	66	58	20	Bilateral, worse in the right ear	Whistling
3	67	42	7	Unilateral, left ear	Hissing
4	71	68	2	Unilateral, right ear	Hissing
5	66	38	7	Unilateral, left ear	Buzzing
6	72	24	3	Bilateral, worse in left ear	Hissing
7	62	36	2	Bilateral, worse in the left ear	White noise (right ear) and high-frequency fluctuating tone (right ear)
8	71	36	14	Unilateral, left ear and left side of the head	White noise and whistling

Participants kept their existing devices for the entire duration of the study.

Measures

Authors' own questionnaires collected information about acceptability and preferences of different masker sound options and patient and audiologist's perspectives of device usability. These comprised a mix of open and closed questions (Appendix 1).

Twelve questions (2.1–2.12) explored the acceptability in terms of the physical aspects of the device, the programme options (masker sound options), and the listening experience. Questions covered the appearance of the device, its comfort to wear, sound quality, speech intelligibility, listening comfort and overall hearing ability, masker sound options and level steering.

Two questions (1.5 and 1.6) explored patient preferences in the different self-nominated listening situations. The first asked which programme they preferred to use in which self-nominated situation where alleviating tinnitus was perceived to be important. The second question asked how much that programme helped with their tinnitus.

To provide information on device usability questions 3.1–3.5 asked about ease of using the device including putting it on and taking it off, changing programmes, changing volume of the noise, changing batteries.

Adverse events were reported to a member of the study team and were addressed according to the Sponsor's Standard Operating Procedure. An adverse event could be a marked worsening of tinnitus.

As a measure of compliance, participants were asked to confirm that they had used the intervention device for at least 6 h/day.

Results

Characteristics of the included participants

Eight males were enrolled. All had unilateral ($n = 5$) or bilateral ($n = 3$) chronic subjective tinnitus (mean duration = 8.2 years, SD = 6.4) aged between 62–72 years (mean = 67.25, SD = 3.8). Tinnitus severity measured by the Tinnitus Handicap Inventory varied between 24 and 68 points (mean = 46, SD = 16). Two participants described their tinnitus as whistling, three as hissing, one as buzzing and two had two sounds (white noise and whistling).

Participants all had an aidable hearing loss. Five had high-frequency hearing loss in both ears and three had an asymmetric hearing loss, according to national audiometric procedures (British Society of Audiology, 2011). Six received free combination devices through the NHS, and two paid through an independent sector clinic. Characteristics of participants are summarised in Table 2.

Participant recruitment

The recruitment target was 10 existing combination device users. A range of advertising sources were targeted including British Tinnitus Association members database, website and magazine, national tinnitus events, network of tinnitus self-help groups across East Midlands, Nottingham Hearing BRU database of 1000 people interested in research participation, and a number of local audiology sites.

Over 10 months, 34 participants were screened and eight of those enrolled onto the study. A large number of screen fails were from those device users who reported unsatisfactory benefit for their tinnitus ($n = 7$) and 12 existing users of conventional hearing aids (amplification only) wanted to try a combination device. After two months without enrolling a single eligible participant, a decision was made to terminate the study early.

Acceptability

In general, participants reported the physical aspects of the intervention device to be acceptable. They liked the fact that the device was small and not very noticeable. Participants reported that the device was comfortable and very often they ''forgot it was there''.

Table 3 summarises participants' experiences with different noise options and amplification component of the device. The majority of participants agreed that the ocean sound resembled a real ocean and that it was pleasant to listen to. Only one participant did not find that option helpful at all as he found the modulation of the sound distracting and sometimes irritating. One participant commented that for him it resembled more ''gusts of wind'', another one indicated that for him it did not sound exactly like an ocean but he could understand why it is called that. One participant commented that it sounded similar to his CDs of waves on a beach, which he used when he went to bed.

Some participants described why the novel ocean sounds were acceptable: ''(...) the sound of waves breaking on the shore, are very calming'', ''(Ocean sound) does not mask tinnitus but provides the distraction (...) when I wanted to distract myself from listening to my tinnitus'' and ''It is useful to have a variation from white noise''.

Table 3. Participants' experiences with the intervention device and different noise options.

	Number of participants				
	Strongly agree	*Agree*	*Neutral*	*Disagree*	*Strongly disagree*
The ''ocean sound'' sounds like a real ocean.	2	3	3	–	–
The ''ocean sound'' is pleasant to listen to.	3	3	1	1	–
The noise sound is pleasant to listen to.	2	4	2	–	–
I am satisfied with the level steering option in Programme 3.	2	5	1	–	–
	Yes	*No*			
Sound quality is the same with the new and my existing device.	3	5 (better)			
Speech intelligibility is the same with the new and my existing device.	4	4 (better)			
Listening comfort is the same with the new and my existing device.	3	4 (better)			
Overall my hearing ability is the same with the new and my existing device.	3	5 (better)			

Table 4. Pattern of programme preferences used in different self-nominated situations. For a description of programmes see Table 1.

Programme number (1–4)	*Number of participants (max 8)*	*Situation*
1	1	Going out with family/social situation
		One to one conversation
2	6	Reading newspaper/book in quiet
		Working in the garden
		Concentrating on activity
		Watching television
		Driving
		One to one conversation
		Boys Brigade (noisy with a lot of people talking at the same time)
		Noisy work (construction)
		Pub
3	5	Household activities when other people are at the house
		Golf club (~30 people talking)
		Pub quizzes
		Reading newspaper
		Waking up in the morning (1st hour)
		Concentrating on activity
		Conversation with one or two people
4	5	Driving
		Reading/writing in quiet
		Gardening
		Concentrating on activity
		Pub
		Quiet situation (when occupied or not)
		On the train

The broadband masker was acceptable for all participants and was ''What they are used to'' and ''What they expected''.

Participants agreed unanimously that the listening experience provided by the intervention device was acceptable. Participants reported that ''listening comfort is better that my existing device and I found I can wear it for much longer periods because of the better sound quality'' and that it ''Felt more comfortable with the new device''.

Patient preferences in different self-nominated listening situations

A wide range of situations were self-nominated ranging from quiet activities (e.g. reading, gardening, working on a computer, working in office, doing nothing), through one-to-one conversations or watching television to very noisy environment and activities (e.g. social situations with a lot of people talking at the same time, pubs and restaurants, travelling on a train, noisy work environment). Each participant nominated both quiet and noisy situations as being important to alleviate their tinnitus. Choices were very individual and dependent on the style of living. Despite this variability all participants were able to find an option on the intervention devices that provided satisfactory relief from tinnitus for each of the self-nominated situations (Table 4).

Those programmes (Table 2) with amplification and masking features (2, 3 and 4) were equally preferred over the basic amplification-only programme (1). Programmes 2 and 3 using the ''standard'' broadband masker as well as Programme 4 using the

nature sound were chosen for the range of situations. What is most striking is that the individual preference for the different programme options varied widely across participants and listening situations. Seven out of the eight participants indicated a preference for one or another programme, depending which one was perceived to help relieve the tinnitus at the time. Four participants used two different programmes in the same listening situation, depending on which one seemed more comfortable.

Participants reported that choice of programmes gave them a sense of control over their tinnitus: ''It is good to have different noises, I feel more in control''. Participants also noted that having an alternative sound to the standard noise option allowed them to ''have a rest'' from constantly listening to the ''white noise'': ''It is nice to have variation from the white noise''.

Usability

No concerns regarding usability of the device were reported.

Compliance

All participants reported that they used the device at least 6 h/day for the whole 2-week duration and tried the device in all self-nominated situations. Participants reported that for majority of the self-nominated situations (36 out of 45), they used the intervention device all the time. Only one participant did not use the device at the end of the study in one of the self-nominated situations (going to the gym) as he was worried about damaging it.

Adverse events

No adverse events were reported and none of the participants returned to their current device during the two weeks.

Discussion

Although a recent British Tinnitus Association tinnitus service evaluation showed that 74% of UK audiology clinics can offer combination hearing aids (Hoare et al, 2015), the challenges that we faced in recruiting existing combination device users suggests that the numbers of wearers are small. Recruitment into a UK clinical trial would need to enrol either existing conventional hearing aid (amplification only) users or those who do not use any devices to manage their hearing loss and tinnitus.

Participants were generally satisfied with device usability. Overall, all participants found the intervention device to be acceptable in terms of its physical aspects, choice of programme options (in particular the ocean sound) and the listening experience provided by the amplification. One important caveat is that we explicitly recruited successful existing combination device users so such high rates of acceptability might not be repeated in clinical research recruiting new users or there may be a period of adaptation to a new device and that period of adaptation/familiarisation needs to be accounted for in clinical trial design. Acceptability and the role of different sounds in providing tinnitus relief should be investigated alongside clinical efficacy. Qualitative data could provide insight on these issues.

Preferences for different noise options varied across different listening situations and across participants. Participants in our study also pointed to a different role of the various sound options. While broadband noise was the most effective masker, the sound of the ocean often did not mask tinnitus but rather provided distraction and/or aided relaxation. Participants received the same order of the sound programmes on the intervention devices and were explicitly instructed to try all the programmes in different listening situations. The order did not seem to inadvertently influence outcomes because all sound programmes were utilised in a range of situations. However, in a larger trial, one should consider randomising the order of the programmes to eliminate potential bias towards increased use of the first or second programme. To explore different patterns of use of different programmes and to monitor compliance with the intervention, data logging features should be utilised.

All participants expected their tinnitus to be masked. However, for the ocean sound that was not always the case. Instead its main mechanism of action appeared to be distracting attention or aiding relaxation. It is therefore worth considering adequate counselling of patients about the rationale behind the sound therapy and role of different types of sound in providing relief from tinnitus.

Rather than seeking to limit or restrict ''customised'' sound options, we would recommend a more ''real world'' trial design that allows for patient flexibility but includes qualitative data to examine which options were effective, for which participants and in what situations.

Conclusions

Given that the study protocol would need to be sufficiently flexible to cover individual needs and preferences of patients regarding amplification and tinnitus relief would seem to call for a more pragmatic trial design to assess effectiveness of combination devices for tinnitus. Qualitative data could inform understanding the utilisation of different options on the devices in the real world and the reasons behind those choices. The current study identified a number of feasibility issues to consider when designing future research on the effectiveness of combination hearing aids for tinnitus. Proposed recommendations are as follows:

(1) Consider recruiting existing conventional hearing aid (amplification only) users with tinnitus or those who do not use any devices to manage their hearing loss and tinnitus.
(2) Tailor the candidacy criteria and outcome measures to the intended mechanism of action of the sound used (e.g. relaxing, distracting, masking).
(3) Investigate the acceptability and role of different sounds in providing tinnitus relief, alongside efficacy.
(4) Accommodate individual needs and preferences through a flexible fitting protocol.
(5) Use data logging to monitor patterns of use for different programmes as well as to monitor compliance.
(6) Randomise the order of sound programmes to avoid potential bias.
(7) Explore common practices and seek consensus between clinics regarding fitting of combination devices, as well as rationale for different practices.

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Appendix 1

Questionnaires used for data collection

Questions assessing relief from tinnitus when using current and new device in nominated listening situations.

1.1 How bothersome is your tinnitus in that situation when you are not wearing your device?
0___N/A
1___Not at all
2___Only a little
3___A moderate amount
4___Quite a lot
5___Very much indeed

1.2 What feature on your current device are you using in that situation?
0___Amplification only
1___Amplification and sound generator
2___Sound generator only

1.3 In this situation, what proportion of the time do you wear your current device?
0___N/A
1___Never/Not at all
2___About ¼ of the time
3___About ½ of the time
4___About ¾ of the time
5___All the time

1.4 In this situation, how much does your current device help with your tinnitus?
0___N/A
1___No help at all
2___Device is some help
3___Device is quite helpful
4___Device is a great help
5___Can not hear my tinnitus

1.5 What feature on the new device did you tend to use in that situation?
0___N/A
1___P1- amplification only
2___P2- amplification with noise and volume control
3___P3- amplification with noise and level steering
4___P4- amplification with ocean sound

1.6 In this situation, what proportion of the time did you wear the new device?
0___N/A
1___Never/Not at all
2___About ¼ of the time
3___About ½ of the time
4___About ¾ of the time
5___All the time

1.7 In this situation, how much did the new device help with your tinnitus?
0___N/A
1___No help at all
2___Device was some help
3___Device was quite helpful
4___Device was a great help
5___Could not hear my tinnitus

1.8 In the above situation which of the two devices would you prefer to use?
Current device
New device

Questions about participant's personal experiences with the new device.

2.1 I like the appearance of the device.
Strongly agree – Agree – Neutral – Disagree – Strongly disagree
Please explain/give your comments

2.2 The device is comfortable to wear.
Strongly agree – Agree – Neutral – Disagree – Strongly disagree
Please explain/give your comments

2.3 The ''ocean sound'' sounds like a real ocean.
Strongly agree – Agree – Neutral – Disagree – Strongly disagree
Please explain/give your comments

(continued)

Continued

Questionnaires used for data collection	
2.4	The ''ocean sound'' is pleasant to listen to. Strongly agree – Agree – Neutral – Disagree – Strongly disagree Please explain/give your comments
2.5	The noise sound is pleasant to listen to. Strongly agree – Agree – Neutral – Disagree – Strongly disagree Please explain/give your comments
2.6	I am satisfied with the level steering option in Programme 3. Strongly agree – Agree– Neutral – Disagree – Strongly disagree Please explain/give your comments
2.7	Sound quality is the same with the new and my current device. Yes-No Please explain/give your comments
2.8	Speech intelligibility is the same with the new and my current device. Yes-No Please explain/give your comments
2.9	Listening comfort is the same with the new and my current device. Yes-No Please explain/give your comments
2.10	Loudness is the same with the new and my current device. Yes-No Please explain/give your comments
2.11	Feedback is the same with the new and my current device. Yes-No Please explain/give your comments
2.12	Overall my hearing ability is the same with the new and my current device. Yes-No Please explain/give your comments
2.13	The streamer is as good on the new device as it is on my current device. (Streamer users) The streamer adds value to the new device in comparison to my current device. (Streamer non-users) Yes-No Please explain/give your comments
Questions for participant about different aspects of usability of the new device.	
3.1	It is easy to put the device on. Strongly agree – Agree – Neutral – Disagree – Strongly disagree Please explain/give your comments
3.2	It is easy to take the device off. Strongly agree – Agree – Neutral – Disagree – Strongly disagree Please explain/give your comments
3.3	It is easy to change the programmes. Strongly agree – Agree – Neutral – Disagree – Strongly disagree Please explain/give your comments
3.4	It is easy to change the volume of the noise/ocean sound. Strongly agree – Agree – Neutral – Disagree – Strongly disagree Please explain/give your comments
3.5	It is easy to change the batteries. Strongly agree – Agree – Neutral – Disagree – Strongly disagree Please explain/give your comments
3.6	It is easy to use the streamer. Strongly agree – Agree – Neutral – Disagree – Strongly disagree Please explain/give your comments
Questions for audiologist performing the fitting about different aspects of usability of the new device.	
4.1	It is easy to fit the device. Strongly agree – Agree – Neutral –-Disagree – Strongly disagree Please explain/give your comments
4.2	The device provides enough flexibility. Strongly agree – Agree – Neutral – Disagree – Strongly disagree Please explain/give your comments
4.3	I did not have any problems to instruct the patient about the use of the single button. Strongly agree – Agree – Neutral – Disagree – Strongly disagree Please explain/give your comments

(continued)

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Questionnaires used for data collection	
4.4	I did not have any problems explaining level steering to the patient. Strongly agree – Agree – Neutral – Disagree – Strongly disagree Please explain/give your comments
4.5	I did not have any problems explaining the use of manual volume control to the patient. Strongly agree – Agree – Neutral – Disagree – Strongly disagree Please explain/give your comments
4.6	I did not have any problems to instruct the patient about the use of the streamer. Strongly agree – Agree – Neutral – Disagree – Strongly disagree Please explain/give your comments
4.7	I did not have any problems explaining different programmes to the patient. Strongly agree – Agree – Neutral – Disagree –Strongly disagree Please explain/give your comments
4.8	I did not have any problems choosing the right noise for the patient. Strongly agree – Agree – Neutral – Disagree – Strongly disagree Please explain/give your comments
4.9	I did not have any problems adjusting the level of the noise for the patient. Strongly agree – Agree – Neutral –-Disagree – Strongly disagree Please explain/give your comments