Amplification With Hearing Aids for Patients With Tinnitus and Co-existing Hearing Loss

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Workshop aims

Provide and discuss -

• The existing research evidence base for clinical effectiveness of amplification with hearing aids for tinnitus – Cochrane review

• The clinical consensus among expert clinicians on when tinnitus patients benefit from hearing-aid fitting – Delphi review

Ask -

• What kind of trial on hearing aids for tinnitus would be feasible in your clinical setting?
## Intervention – Hearing aids

### QUESTIONS

**Participants** - consider patients with mild hearing loss and bothersome tinnitus -

In 1 month how many tinnitus patients do you see who might be eligible to take part in a trial?  

What proportion of these patients would be willing to be randomised to different interventions?  

**Control** – which control intervention would you be happy to prescribe as part of a trial?

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
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<tbody>
<tr>
<td>A placebo hearing aid (0 dB gain)</td>
<td></td>
<td></td>
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<tr>
<td>Placement on a 3 month waiting list</td>
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<tr>
<td>Placement on a 6 month waiting list</td>
<td></td>
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<tr>
<td>Sound generator</td>
<td></td>
<td></td>
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<tr>
<td>Education only</td>
<td></td>
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</table>

**Outcome measures** – which outcome measures would you be happy to use in your clinic to support a clinical trial?

**Questionnaire measures of**

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
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<tbody>
<tr>
<td>Tinnitus handicap</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hearing handicap</td>
<td></td>
<td></td>
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<tr>
<td>Quality of Life</td>
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</table>

**Psychoacoustic measures of**

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
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<tbody>
<tr>
<td>Tinnitus Pitch</td>
<td></td>
<td></td>
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<tr>
<td>Tinnitus loudness</td>
<td></td>
<td></td>
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<tr>
<td>Minimum masking levels</td>
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**Patient interviews**

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**Study design** - Would you be willing to randomly allocate patients who were suitable for a trial irrespective of:

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<tr>
<td>Hearing handicap</td>
<td></td>
<td></td>
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<tr>
<td>Age</td>
<td></td>
<td></td>
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<tr>
<td>Gender</td>
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</table>
Our research approach

Systematic Review

Delphi Review
Consensus on hearing aid fitting candidature and practice for mild hearing loss, with and without tinnitus

Randomised Controlled Trial
that will determine whether those with bothersome tinnitus but mild hearing loss should or should not routinely be offered a hearing aid

- specification of inclusion and exclusion criteria, design of the RCT and baseline measurements should be defined based on current practice,
- no guidelines,
- 47% of hearing professionals use different criteria (Hoare et al. 2012).
Cochrane review - background

**Systematic review:** identify, appraise, select and synthesise all high quality research evidence relevant to that question

**Hearing aids for tinnitus:**

- in tinnitus management since the 1940’s (*Saltzman 1947*),
- amplify external sounds so may help mask tinnitus,
- improve communication which may reduce stress and anxiety often associated with tinnitus,
- improve tinnitus symptoms by reducing or reversing tinnitus-related changes in brain activity,
- amplification may refocus attention on alternative auditory stimuli that are unrelated to tinnitus sound,
- supplemented with education and advice, is the primary intervention for someone who has tinnitus and aidable hearing loss (*Hoare et al., 2012*).
Review objective

To evaluate the effects of hearing aids on tinnitus in adults with co-morbid hearing loss

- **Self-reported tinnitus severity**
- Anxiety, depression, quality of life, coping
- Perceptual characteristics of tinnitus
- Tinnitus related brain activity

Randomised and non-randomised controlled trials only (high level evidence)
The evidence

RCT, NRCT level evidence – only one study, comparing hearing aids and sound generators in patients with normal thresholds at 2 kHz, and moderate or greater loss at 4 kHz

Parazzini 2011

EFFECT SIZE

Favours sound generators

Favours hearing aid

Parazzini 2011

100.0 % 0.0 [-0.41, 0.41 ]
Lower level evidence – outside the acceptable range of a Cochrane review

Hearing aids versus no device: patient choice, retrospective study

EFFECT SIZE

- Favoring no device
- Favoring hearing aid

Folmer (2006)
Searchfield (2010)
Delphi review

To identify which factors hearing professionals believe are important for making decisions about fitting hearing aids for patients with mild hearing loss and tinnitus or hearing loss alone.

- seeks consensus among experts through consultation using a series of iterative questionnaires,
- has been successfully applied to solve problems in many healthcare settings, including defining the best clinical practice, research priorities and service planning (Powell, 2003; Avery et al., 2005),
- experts taking part in the study bring a wide range of expertise and experience to the decision-making process,
- the study gathered the opinions of experts based all over the country in a relatively time efficient and cost effective way.
Delphi review

We identified two groups of factors:

- Consensus among audiologists (defined as ≥70% agreement)
- Variable opinions and clinical practices.

42 UK hearing professionals agreed to take part in the study.
29 responded to the Round 1 survey and formed our final expert panel.
28 completed all three Rounds.

We identified two groups of factors:
- Consensus among audiologists (defined as ≥70% agreement)
- Variable opinions and clinical practices.
## Factors to consider when fitting HAs for mild hearing loss alone

<table>
<thead>
<tr>
<th>Factors</th>
<th>Agreement (%)</th>
<th>Number of experts that rated this factor as top five</th>
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<tbody>
<tr>
<td>Patient reported hearing difficulties</td>
<td>100</td>
<td>26 (93%)</td>
</tr>
<tr>
<td>Motivation of patient to wear hearing aid(s)</td>
<td>100</td>
<td>23 (82%)</td>
</tr>
<tr>
<td>Patient self-reported impact of hearing loss on quality of life</td>
<td>100</td>
<td>18 (64%)</td>
</tr>
<tr>
<td>Degree of hearing loss</td>
<td>100</td>
<td>14 (50%)</td>
</tr>
<tr>
<td>Realistic patient expectations</td>
<td>92</td>
<td>14 (50%)</td>
</tr>
<tr>
<td>Health of ears (e.g. infections etc.)</td>
<td>96</td>
<td>9 (32%)</td>
</tr>
<tr>
<td>Shape of the audiogram</td>
<td>96</td>
<td>9 (32%)</td>
</tr>
<tr>
<td>Speech discrimination and comprehension in quiet and background noise</td>
<td>77</td>
<td>5 (18%)</td>
</tr>
<tr>
<td>General ability to hear in quiet settings and in background noise</td>
<td>81</td>
<td>5 (18%)</td>
</tr>
<tr>
<td>Hyperacusis/reduced sound level tolerance</td>
<td>81</td>
<td>4 (14%)</td>
</tr>
<tr>
<td>Manual dexterity/manipulation difficulties</td>
<td>100</td>
<td>0</td>
</tr>
</tbody>
</table>

- Importance rankings revealed that patient-centred criteria, such as patient reported hearing difficulties, had higher priority over objective measures when fitting HAs for mild hearing loss without bothersome tinnitus.
Factors to consider when fitting HAs for mild hearing loss with TI

- For patients with mild hearing loss and bothersome TI clinicians would offer HAs even if patient does not report hearing difficulties (82%).

- Inclusion criterion for RCT: presence of bothersome TI even without hearing difficulties.
Audiometric criteria for fitting HAs with and without TI

- Majority of the panel (75%) agreed that they would offer hearing aid(s) only if patient has a 4-frequency pure-tone average (PTA) worse than 20 dB at least in one ear.

- Inclusion criterion for RCT: 4-frequency pure-tone average (PTA) worse than 20 dB at least in one ear.

- Inclusion criterion for RCT: 4-frequency pure-tone average (PTA) worse than 20 dB at least in one ear.
Use of questionnaire scores when deciding candidature for fitting HAs in patients with and without TI

- COSI and GHABP do not provide much more information than conversation with the patient and history taking.
- COSI and GHABP help outline difficulties or can be a good starting point for the discussion.
- Clinicians are aware that THI questionnaire is not appropriate to use as an outcome measure.
- TFI is fairly new and not many clinicians are familiar with it.
- Questionnaire scores will not be part of inclusion criteria for RCT.
Clinicians generally agreed that unilateral fitting of hearing aid in patients with mild hearing loss and bothersome tinnitus is not appropriate even if patient has unilateral tinnitus.

Clinical observations pointed to the possibility that monaural aiding can shift the tinnitus perception to the unaided ear (75%).

RCT: participants with tinnitus will be fitted with bilateral HAs.
• RCT: the assessments for which consensus was reached will be used to verify HAs fitting.
Research team

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