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Background

A feasibility study asks can something be done? Should it be done?, and if so, How? Feasibility studies consider issues such as timing, participant burden, response rates, and testing logistics.

We are investigating the feasibility of creating a tinnitus biobank to better understand what underlies tinnitus distress. The study addressed the following questions:

- Are people with tinnitus willing to provide data to a tinnitus biobank?
- What data should be collected and how?
- Do participants find the selected tests acceptable?
- How much time is needed to collect the desired data?
- Will participants attend an appointment in a laboratory and/or in a mobile testing unit located in a public space?

Methods

The research took place (a) in a laboratory at Manchester Centre for Audiology and Deafness (ManCAD) and (b) in a mobile testing unit (van) at location around Greater Manchester.

Laboratory-based testing

Participants (n=50)

- Tinnitus as reported on the tinnitus screener¹
- Mean age: 60.1yr. (SD = 10.5), range: 41-79
- Normal hearing to profound hearing loss
- Recruited via ManCAD's research participant database, and social media

Test battery

Pre appointment

- **Online questionnaires:** Demographics, Tinnitus-specific case history¹⁴, tinnitus severity^{2,3,4}

In lab (testing was conducted for a max of 3 hr.)

- Case history: Tinnitus and medical, measured height, weight, questionnaire based on the Noise Exposure Structured Interview¹³
- Hearing assessment: Otoscopy, tympanometry, PTA with extended high frequency testing (EHF), DPOAEs, Uncomfortable loudness levels, digits in noise test
- Tinnitus severity questionnaires³⁻⁶
- Tinnitus percept: loudness and pitch matching, minimum masking level (MML), residual inhibition (RI)
- Sound sensitivity questionnaires^{6,7}
- Mental health and wellbeing questionnaires¹⁰⁻¹²
- Ratings of annoyance, boredom, fatigue, difficulty, and confidence during tests

Results

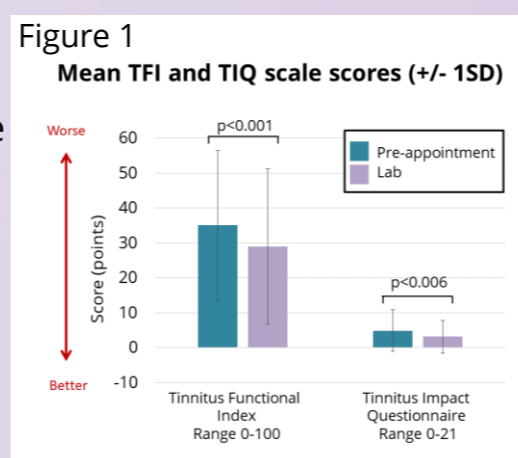
1. Willingness to take part

>90% of participants attended their scheduled appointment, and >90% completed their pre-appointment questionnaires.

2. What data should be collected and how?

Comparison of pre-appointment and lab-based questionnaire scores

Figure 1 shows mean pre-appointment and lab-based questionnaire scores. Reported tinnitus was statistically more severe pre-appointment, but the differences are not clinically meaningful



We conclude questionnaires can be completed in advance of an in-person appointment.

Independence of questionnaire scores

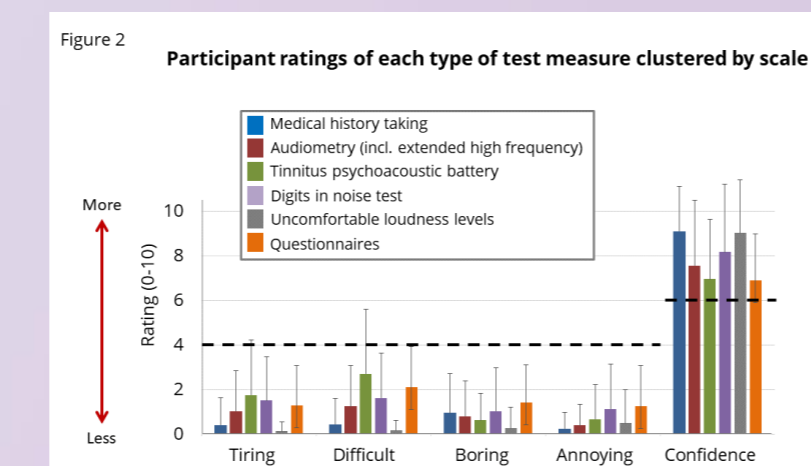
Strongly correlated measures are assessing the same underlying construct. Intercorrelations between questionnaires score here were:

- Tinnitus questionnaires: Range $r=0.763$ to $r=0.914$
- Sound sensitivity questionnaires: $r=0.567$ to $r=0.574$
- Mental health and wellbeing questionnaires: $r=0.272$ to $r=0.919$

We conclude some questionnaires can be omitted because they assess the same construct.

3. Test acceptability

Figure 2 shows participants' acceptability ratings by measure type with ± 1 SD error bars.



No tests had mean burden scores of >4 ; all had a mean confidence scores of >6 .

We conclude all measures were acceptable to participants.

4. Time needed for data collection

Table 1 shows information about the time taken to complete each test measure.

| Test measure | | Timing min:sec | | | |
|-----------------------------|---------------------|----------------|-------|-----------------------|-----------------------|
| | | Mean | SD | 75 th %ile | 90 th %ile |
| Tinnitus | History | 09:47 | 04:26 | 11:30 | 16:06 |
| | TFI | 03:35 | 01:55 | 04:12 | 05:41 |
| | TIQ | 00:54 | 00:53 | 01:03 | 02:00 |
| | VAS | 00:49 | 00:30 | 00:56 | 01:27 |
| Sound sensitivity | HIQ | 02:28 | 01:29 | 03:28 | 04:52 |
| | SSIQ | 00:40 | 00:18 | 00:49 | 01:06 |
| | HQ | 01:36 | 00:32 | 01:49 | 02:36 |
| Mental health and wellbeing | Sleep | 03:59 | 01:33 | 05:14 | 06:32 |
| | Anxiety | 00:30 | 00:12 | 00:38 | 00:47 |
| | Depression | 00:53 | 00:23 | 01:08 | 01:29 |
| | COPE | 02:18 | 01:14 | 02:53 | 03:27 |
| Hearing | IPQ | 03:26 | 01:56 | 04:31 | 04:49 |
| | Otoscopy | 01:20 | 00:50 | 02:00 | 02:53 |
| | Tympanometry | 02:20 | 01:23 | 03:00 | 04:00 |
| | PTA (incl. EHF) | 17:39 | 17:40 | 16:30 | 27:17 |
| Tinnitus percept | ULL | 02:12 | 01:36 | 02:00 | 03:00 |
| | Pitch matching | 09:47 | 04:07 | 12:00 | 14:00 |
| | Loudness matching | 02:36 | 00:57 | 03:07 | 04:00 |
| | Residual inhibition | 04:11 | 01:55 | 05:00 | 06:06 |
| Min. masking level | | 04:28 | 01:30 | 05:00 | 07:00 |

If questionnaires are completed pre-appointment, then >75% of participants could complete the test battery within 70 minutes, and 95% complete the test battery within 100 minutes.

Mobile unit (van) testing

Method (ongoing)

- Tinnitus UK pre-arranges a location for testing, typically a supermarket car park.
- Participants register for the study, select a test location and appointment time. They then receive a link to complete the pre-appointment questionnaires.
- During the van appointment participants complete a medical history, hearing assessment and tinnitus percept measures.

Preliminary results

10 of 12 weeks of van testing have been completed

Appointments are taking about 1 hour to complete

Tinnitus UK has managed to arrange a testing location everyday

133 appointments have been scheduled, representing 64% of the 207 possible time slots (past and future).

73 appointments have been attended, there have been 12 no shows, 28 appointments were cancelled in advance by a participant and 8 appointments were cancelled by the research team. 16 of these cancelled appointments have been rebooked.



Summary

The data collected in the lab determined the battery used for mobile unit testing.

- Attendance at scheduled appointments has been acceptable indicating willingness to give data to a tinnitus biobank.
- The good agreement between pre-appointment and at-appointment questionnaire scores means questionnaires can be completed in advance, saving time during the appointment.
- No tests have been rated as burdensome

Tinnitus UK will use this data to decide on the next steps towards setting up a Tinnitus Biobank.

References

- ¹Henry et al., Am J Audiol. 2016;25(2):153-60. ²Meikle et al., Ear Hear. 2012, 33(2):153-76. ³Aazh et al., Int J Audiol. 2022;62(9):835-844. ⁴Raj-Koziak et al., Audiol Neurootol. 2018;23(4):229-237. ⁵Hallam. Polpres Press, 2008. ⁶Aazh et al., J Am Acad Audiol. 2022; 33(5):248-258. ⁷Buysse et al., Psychiatry Res. 1989;28(2):193-213. ⁸Kroenke et al., J Gen Intern Med. 2001; 16(9):606-13. ⁹Löwe et al., Med Care 2008; 46:266-274. ¹⁰Carver. Int J Behav Med. 1997;4(1):92-100; ¹¹Broadbent et al., J Psychosom Res. 2006; 60(6):631-7, ¹²Guest et al., Trends Hear. 2018 Jan-Dec;22: 2331216518803213 ¹³Genitsaridi et al., Hear Res. 2019;377:353-359

Acknowledgments

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