



Short term scientific mission announcement for Grant period 4 (May 2017-April 2018)

Title: Establishing Core Domain Sets for early-phase clinical trials of three intervention strategies to manage chronic subjective tinnitus in adults: Data analysis and reporting from Delphi reviews.

Host: National Institute for Health Research (NIHR) Nottingham Hearing Biomedical Research Unit, University of Nottingham, Nottingham, UK
<http://www.hearing.nihr.ac.uk/>

Supervisor: Prof Deborah Hall

Goal of the Short Term Scientific Mission: A major WG5 goal in year 4 is to advance the standards for clinical trials of interventions for tinnitus by developing an agreed list of elements that are critically important for determining whether a treatment has worked (Hall et al., 2015). At present, there is no consensus on what are the critically important domains of tinnitus that should be assessed to determine whether the responses to treatment are beneficial or not for patients. Our recent systematic review, examining 228 published clinical trials, indicated a wide range of measures for assessing benefit from a tinnitus intervention, with many trials assessing pharmacology (n = 66), sound therapy (n = 56) and psychological (n = 47) interventions (Hall et al., 2016). Different intervention strategies are aimed at alleviating different outcome domains of tinnitus. For example, psychological interventions are intended to reduce emotional distress, whilst sound-based interventions aim to reduce loudness. If all clinical trials for each of these three interventions used and reported results for the same set of agreed outcomes, they could be compared and combined.

WG5 is currently working on three Delphi surveys which are expected to be launched in February 2017 and completed by end of July 2017. The Delphi process will generate a list of domains agreed across expert stakeholder groups for what should be assessed when assessing the effect of pharmacological, sound-based, and psychology-based interventions for tinnitus. The intervention-specific Core Domain Sets should be measured and reported in all clinical trials associated with the intervention type. Any outcome domains which are common across all three intervention-specific Core Domain Sets will be combined to create a common cross-cutting intervention Core Domain Set that should be measured and reported in every clinical trial of tinnitus. Adoption of the WG5 actions across different tinnitus groups and countries would support data collection in a central database in order to enable further meta-analysis of patient responses to specific treatment options.

This STSM will deliver data analysis and dissemination activities relating to three Delphi surveys that will establish Core Domain Sets for early-phase clinical trials of pharmacological, sound-based and psychology-based intervention strategies to manage chronic subjective tinnitus in adults. Specifically, the STSM includes analysis of a secondary objective for the Delphi reviews: to identify the strengths and limitations of our study-design strategies for recruiting and for reducing attrition of expert stakeholder participants. To achieve this, we will collect participant reflections on the Delphi survey process and use open text questions to capture feedback on the experience of being a participant.

Relevant TINNET publications:

Hall et al., 2015 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4409939/>

Hall et al., 2016 <https://www.ncbi.nlm.nih.gov/pubmed/27250987>

What we can offer to the grantee: Our research team is dedicated to tinnitus and our passion is to create reliable knowledge that can underpin evidence-based practice for people with tinnitus. The team includes Prof Deborah Hall, Dr Kathryn Fackrell, Dr Derek Hoare and Dr Magdalene Sereda, and we currently also have numerous PhD students, a statistician, research assistant and research administrator. We have expertise in Delphi surveys, systematic reviews and psychometric validation of outcome instruments. We conduct carefully designed, randomized controlled trials that seek to provide rigorous and systematic evaluations of the audiological and psychological interventions that reflect most common clinical practice at the moment. We also evaluate novel management strategies that the clinical profession judges are likely to benefit tinnitus management. In particular we want to encourage open debate on the validity of outcome instruments for tinnitus and we've recently published a critical review of some frequently used measures:

https://www.novapublishers.com/catalog/product_info.php?products_id=50204

As Chair of the 'outcomes' working group within TINNET, I am interested in how we can best establish standards for outcome measurements in clinical trials to enable data collection of treatment results in the central database. This is important for establishing a standard for the performance of clinical trials in tinnitus.

The anticipated output is a short publication reporting recruitment and retention strategies for Delphi surveys in this growing field of Core Domain Sets. The publication will report findings from qualitative data analyses of open text data. The successful STSM applicant will be a co-author on this publication based on their input generated during the STSM period.

Requirements of the grantee:

This Short Term Scientific Mission would be ideal for a Psychology student wishing to gain more experience in tinnitus, research methods and qualitative data analysis. We particularly encourage applications from people working outside the UK, with a good working knowledge of the English language. Active engagement with the rest of the TINNET network, and further afield, will be encouraged.

Duration: This mission is available for up to 6 weeks between 3rd July and 29th September 2017.

How to get in contact with the STSM supervisor: Email deborah.hall@nottingham.ac.uk

How to apply for the STSM

Please contact Prof Deborah Hall in the first instance. If both parties agree, please request an application form from Susanne Staudinger Susanne.Staudinger@medbo.de, and 'cc' malgorzata.wrzosek@amu.edu.pl.

After completion of the STSM the grantee is required to submit a scientific report (3-4 pages) on the visit within 30 days after end of the stay. Please submit the report to the STSM coordinator:

malgorzata.wrzosek@amu.edu.pl