Tinnitus COST Action BM1306: an international standard for outcome measurements in clinical trials of tinnitus

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**Reason for the TINNET COST Action**

Tinnitus is a common condition that is characterised by sounds in the ears or head. Over 70 million people in Europe experience tinnitus, and for 7 million it creates a debilitating condition.

In spite of its enormous socioeconomic relevance, research funding is limited. There are no standards for clinical management and treatments typically have low evidence levels.

One of the problems is the heterogeneity of tinnitus. Both in experimental (pre-clinical) research and in clinical trials, many of the reported findings cannot be replicated. Many clinical trials fail to demonstrate a significant benefit, even if individual patients may improve.

The European Union has approved funding for a TINNET COST Action (2014-2018) to create a pan-European tinnitus research network.

The overall aim is to better understand the heterogeneity of the condition.

**TINNET COST Action strategy**

The TINNET strategy is to standardise and coordinate clinical, neuroimaging and genetic assessment of tinnitus patients and to aggregate data in a large-scale database in order to identify tinnitus subtypes and their neurobiological underpinnings. There are five working groups (WG):

- WG1: Defining clinical assessments of tinnitus patients according to common standards
- WG2: Managing data in a central database and identifying subtype candidates via meta-analysis.
- WG3: Developing standards for neuroimaging studies and probing the neurobiological entity of the defined subtypes by large-scale analyses of neuroimaging data.
- WG4: Identifying the involvement of genetic factors in the pathogenesis of the different subtypes of tinnitus
- WG5: Developing standards for outcome measurements in clinical trials and to facilitate central database management.

This poster summarises the aims of Working Group 5 (WG5).

**Activities planned so far**

- **May 2014**: WG5 introductory group meeting in Berlin
  
  Meeting held during the International Tinnitus Seminar in Berlin
  
  Purpose: Invite new participants and establish contacts with EU charities that support people with tinnitus

- **Nov 2014**: WG5 Workshop in Amsterdam
  
  "Agreed Standards for Measurement : An International Perspective."
  
  Purpose: Introduce a range of ongoing research activities on evaluating tinnitus questionnaires (Ms Kathryn Fackrell), WHO ICF core set for hearing loss (Prof Sophia Kramer), the COSMIN initiative (Dr Caroline Tenwee), and the HOME initiative (Prof Phyllis Spuls)

- **Nov 2014**: WG5 Management group in Amsterdam
  
  Purpose: Agree first steps on i) how to develop a consensus about core outcome domains, ii) whether the consensus should be limited to controlled trials or extended to clinical recordkeeping (e.g. as in the HOME initiative, Schmitt et al. Journal of Investigative Dermatology 2011, 131: 623-30).

**Year 1**

**Ongoing**

- Initiate and conduct a web-based Delphi survey to first map out what clinicians and patients consider to be important core outcome domains for adults with tinnitus.

- Publish a discussion paper and invitation (e.g. as in the WHO ICF core set for hearing loss, Damermark et al. International Journal of Audiology 2010, 49: 256-62).

- **May 2015**: Dissemination in Istanbul
  
  12th Congress of the European Federation of Audiological Societies. An overview presentation about the TINNET COST Action.

- **January 2016**: Dissemination in UK
  

**Year 2**

**Short Term Scientific Missions (STSMs)**

**What are they?** Funded placements (5-90 days) with a leading tinnitus research team.

**Who can apply?** Clinicians, graduate students or early-career researchers are encouraged to apply especially if they want to actively engage with the rest of the TINNET network, and further afield.

**STSM opportunities in WG5:**

1. Developing expertise in systematic review methodology and strengthening European collaboration across TINNET. Systematic reviews are important for identifying, without bias, what outcome measurement tools have been so far used in randomized controlled trials of therapeutic interventions for tinnitus. This STSM would enable the visiting clinician or researcher to initiate and conduct the search strategy, record filters and data extraction for a systematic review to define what outcome measures have been used hitherto by our community.

2. Developing expertise in Delphi survey methodology and strengthening European collaboration across TINNET. Delphi surveys provide a well-established methodology for developing consensus-based sets of core outcome domains. An outcome domain is a distinct aspect of tinnitus, such as sleep or quality of life, and typically each outcome domain can be measured by different instruments or scales. This STSM would enable the visiting clinician or researcher to initiate and conduct a key phase of a planned Delphi survey.

For further details speak to Deborah Hall at this meeting (or email)

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