Revisiting the interpretation of a clinically meaningful treatment-related improvement in tinnitus using the Tinnitus Questionnaire (German version)

Helike Argstatter 1, Rajnikant L. Mehta 2,3, Deborah A Hall 2,3

1Deutsches Zentrum für Musiktherapieforschung (Viktor Dulger Institut) DZM e.V., 69123 Heidelberg, Germany
2National Institute for Health Research (NIHR) Nottingham Biomedical Research Centre, Nottingham UK
3Otology and Hearing group, Division of Clinical Neuroscience, School of Medicine, University of Nottingham, UK

Background

- Scores on a tinnitus questionnaire can vary each time it is completed by a patient. But how do we know whether or not these changes are meaningful?
- Clinical significance refers to whether the change is meaningful from a patient perspective.
- A minimal clinically meaningful difference (MCID) is the threshold for a change on a questionnaire score over which a patient or physician would consider that change to be meaningful and worthwhile.
- The concept of “clinical significance” is important for clinical practice and for clinical research because differences in scores on a tinnitus questionnaire, either between patient groups or over time, can be statistically significant without necessarily being clinically significant. In other words, there can be a statistically reliable change, but its too small to be meaningful to patients.
- The German version of the Tinnitus Questionnaire (TQ) is widely used across German-speaking nations, in both clinical practice and clinical research.
- But one big challenge is that investigators use very different estimates of the MCID for the TQ in German-speaking clinical populations, without any clear justification for their choice.
- There is probably no single MCID value for the TQ, so here we give evidence to support an informed choice.

Objectives

- We revisit the MCID for the TQ (German version).
- In contrast to earlier approaches for calculating an MCID for the TQ, we have applied statistical standards that take into account not only patient experience of clinical improvement, but also the test-retest reliability of the measurement.

Methods

- This was a retrospective analysis of 202 patients whom received the Heidelberg Neuro-Music-Therapy intervention at the DZM e.V. (German Center for Music Therapy Research) in Germany, from 2011 to 2016.
- Patients were not randomised and were not blinded to the treatment.
- The global TQ score is based on 42 of the 52 questions with a maximum score of 84, with higher values indicating greater symptom severity.
- Patients were also asked a Clinical Global Impression scale question about whether their tinnitus symptoms were changed by the music therapy (worsened, unaffected or improved) and if the change was ‘much better’, ‘slightly better’, ‘no change’, ‘slightly worse’ or ‘much worse’.

Conclusions

- From our observations, a change of at least 21 points would be needed for interpreting individual patients and in the context of non-randomised or unblinded studies when patients can select or know which intervention they have received.
- Previous estimates may be too optimistic because they have not accounted for measurement error or bias.