Author's response to reviews

Title: Munster tinnitus randomized controlled clinical trial-2013 based on Tailor-Made Notched Music Treatment (TMNMT)

Authors:

Christo Pantev (pantev@uni-muenster.de)
Claudia Rudack (rudackc@ukmuenster.de)
Alwina Stein (alwinastein@uni-muenster.de)
Robert Wunderlich (robert.wunderlich@uni-muenster.de)
Alva Engell (a.engell@uni-muenster.de)
Pia Lau (pia.lau@uni-muenster.de)
Andreas Wollbrink (a.wollbrink@uni-muenster.de)
Alex Shaykevich (ashayk1@yahoo.com)

Version: 2 Date: 18 July 2013

Author's response to reviews: see over
Dear Editor of BMC Neurology,

This is a study protocol focused on sensory treatment of tonal tinnitus. Taking into account the neuroscientific view that tinnitus is a result of hyper-activity and hyper-synchrony of auditory neurons owing the lack of inhibition, we assume that removal of the tinnitus frequency components from a broadband auditory stimulus will cause the brain to reorganize around the tonotopic regions coding the tinnitus frequency. Based on this assumption a novel treatment for tonal tinnitus - tailor-made notched music training (TMNMT) has been introduced and it will be tested in this clinical trial on a large number of tinnitus patients.

The submitted trial protocol characterizes a Randomized Control Trial (RCT) in parallel group design, which is the gold standard for evaluating the efficacy of a treatment intervention and will be performed in a double-blinded manner in order to control for non-specific and placebo effects. The choice of the intervention we are going to apply is based on two “proof of concept” studies in humans and on a recent animal study. However, the study protocol represents the first randomized controlled trial applying the TMNMT on a larger number of patients with tonal tinnitus. Thus the data obtained in this clinical trial will verify more securely and reliably the effectiveness of the TMNMT, which is completely non-invasive and low-cost treatment approach on tonal tinnitus. So, we believe that the outcome of this clinical trial will be of general interest in the field of neural plasticity and tinnitus treatment, a research field of great importance for neuroscience in which BMC Neurology is revealing an essential interest. Taken into account that 5-15% of the people in Western societies suffer from chronic tinnitus and from the tinnitus-generated effects in their quality of life, we believe that the expected results of the trial will be very important for testing and estimating the value of this new and original tinnitus treatment, and the open access character of the BMC Neurology seems to be especially suitable for their dissemination. Therefore we would like to ask you to consider this article for publication as clinical trial protocol, which we have already registered as controlled trial: ISRCTN04840953.

Sincerely yours on behalf of all my co-authors
Prof. Dr. Christo Pantev