

## **Brief description of the submitted scientific work by PD Dr. Stefan Schoisswohl for the research prize „Tinnitus & Hören“ of the Deutsche Stiftung Tinnitus und Hören Charité**

As part of the EU-funded multidisciplinary [UNITI-project \(Unification of Treatments and Interventions for Tinnitus Patients\)](#), the UNITI randomized controlled trial (RCT) was conducted in five clinical centers across four European countries (Leuven, Belgium; Berlin and Regensburg, Germany; Athens, Greece; and Granada, Spain). The UNITI-RCT represents the first large-scale, international, multi-center trial to systematically evaluate the efficacy of various established tinnitus treatments either alone or in combination. In detail, cognitive behavioral therapy (CBT), hearing aids, structured counselling and sound therapy were applied either as a single treatment or a combination of treatments (10 parallel treatment arms), in an international sample of tinnitus patients. This was the first systematic study to evaluate CBT, hearing aids, structured counselling and sound therapy within the same trial, allowing direct comparison between most established treatment strategies for tinnitus. Treatment procedures were based on recent guidelines and developed by a group of dedicated experts in the respective fields e.g. psychologists and/or psychotherapists for CBT and structured counselling or ENTs and/or audiologists for hearing aids and sound therapy. All treatment and assessment approaches were harmonized among study centers. A central innovation of the UNITI-RCT was the inclusion and evaluation of novel app-based interventions (structured counselling, sound therapy) with high potential accessibility and health-system integration.

A total of 461 patients with chronic subjective tinnitus were enrolled (combination treatment: 231; single treatment 230). All treatment arms led to an improvement in tinnitus-related distress. Symptom amelioration was stronger for combination than single treatment. Hearing aids in combination with structured counselling evoked the strongest improvement. Detailed analyses indicated that a combination did not yield an unambiguous synergistic benefit. Instead, the more effective intervention counterbalances the effect of a low-effectiveness treatment and elevates the clinical improvement up to a level comparable to the single high-effectiveness treatment.

For clinical practice, where it is unclear which treatments will help a specific patient, these results imply that a combination of treatment approaches can improve the chances of benefit.

The UNITI-RCT was characterized by a high degree of interdisciplinarity with experts from different professions working closely together (e.g., psychology, psychiatry, data science, audiology, otorhinolaryngology, computer science etc.) within a collaborative European

consortium. To the best of our knowledge, the UNITI-RCT provides the most detailed evaluation of tinnitus treatments so far. It's large scale, methodological rigor and innovative design make it a landmark study for the field. Rigorous randomization and stratification procedures, blinded statistical analyses, harmonized treatment protocols, and comprehensive outcome assessments ensured scientific robustness. A particular strength of the trial was the prior publication of the study protocol (Schoisswohl et al., 2021) and statistical analysis plan (Simoes et al., 2023) ensuring scientific rigor, transparency, and adherence to prespecified methodological standards. The recent acceptance in the reputable journal *Nature Communications* (Impact Factor: 15.7; Schoisswohl et al., in press) further highlights the scientific quality and importance of the study.

## References

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