

# Background noise

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This dissertation has addressed four major research questions. After a general introduction in chapter 1, we aimed to provide a state of the art review of clinical guidelines on assessment and treatment of tinnitus in chapter 2. Second, in chapter 3 we reviewed existing evidence from randomised controlled trials on the efficacy of Cognitive Behavioural Therapy (CBT) for Tinnitus. Third, in chapter 4 we examined the psychometric properties of a measure developed to assess fear of tinnitus (i.e., the Fear of Tinnitus Questionnaire) since fear and avoidance behaviours are predicted to be key factors in the onset and maintenance of tinnitus suffering. Finally, in chapter 5 we investigated whether a novel specialised stepped-care CBT treatment for tinnitus can be implemented in everyday clinical practice. Here, we present a summary and general discussion of the major implications from the studies that addressed these questions. We also discuss the major limitations and propose research questions to be addressed in the future.

## Summary of findings

To gain insight into the state of the art of existing clinical consensus and recommendations about assessment and treatment of disabling tinnitus in adults, a systematic review of clinical guidelines was performed and presented. As we expected sources to be scarce, we did not specify language or date limits on the literature search and ultimately included clinical guidelines from Denmark, Germany, Sweden, the Netherlands, and the United States in the review. We found that there was a high level of consistency between the guidelines with regard to the recommendations for assessment and treatment of tinnitus. Generally, the guidelines had similar principles in common but differed slightly on the specific methods or treatments recommended. For example, there was consistency in the recommendations for: audiometric assessment; physical examination; use of a validated questionnaire to assess tinnitus-related distress; and, referral to a psychologist when deemed required. Similarly, recommendations for CBT for individuals with disabling tinnitus, the use of hearing aids in instances of hearing loss, and recommendations against the use of medicines were also consistent across the included guidelines. There were however differences between the guidelines regarding recommending, or not, the use of imaging in assessment procedures and sound therapy as a form of treatment for tinnitus distress.

As the systematic review of clinical guidelines showed a consensus among existing guidelines recommending CBT to decrease suffering related to tinnitus, we subsequently addressed the question of whether or not CBT for tinnitus is effective and safe. In collaboration with Cochrane Ear Nose and Throat, we conducted a systematic review and meta-analysis of RCTs of CBT for tinnitus. We applied a broad definition of “CBT” (i.e., one including ACT and mindfulness as CBT), and following Cochrane’s strict guidelines for the conduct of a systematic review, included 28 trials. Twenty-three of these trials supplied data for the purposes of meta-analyses from which we concluded that CBT is likely to be safe and superior to: (a) wait-list control conditions/no treatment, (b) usual audiological care, and (c) “other” active experimental control/comparison treatments. Since only one trial compared CBT with Tinnitus Retraining Therapy (TRT), we

concluded that there was insufficient evidence to establish with any degree of certainty how CBT performed relative to TRT. From the included trials it was clear that there was considerable heterogeneity in the methodologies used (e.g., treatment protocols and outcome measures), and that 6- or 12-month follow-up data were scarce.

One of the prerequisites for improving the health care for individuals suffering from disabling tinnitus is the availability of tinnitus-specific assessment instruments. Therefore, we investigated the factor structure, reliability and validity of the Fear of Tinnitus Questionnaire (FTQ, Dutch version; Cima, Crombez, & Vlaeyen, 2011) in a sample of 588 participants recruited from Dutch patient-association websites on tinnitus and hearing loss. Based on exploratory and Bayesian confirmatory factor analyses, we found that a single- (*tinnitus-related fear*) and three-factor (*fear of future consequences of tinnitus*, *deterioration in tinnitus* and *somatic related fears*) Fear of Tinnitus models best fitted the data. We suggested that the three-factor model has greater utility for clinicians since its (potential) subscales reflect clinically relevant issues to address prior to treatment or during a CBT treatment. Furthermore, the analyses demonstrated: (a) that the FTQ had excellent test-retest reliability after a 2-week interval; (b) that FTQ added statistically significant amounts of variance to models predicting tinnitus-related distress and interference in daily life; and, (c) good convergent and concurrent validity. Despite the positive attributes of the FTQ, we recommended that additional research should be conducted to further test and establish norming data and the sensitivity of the measure to patients' changes following treatment. We also concluded that a version with increased response options would be an improvement to the FTQ.

Although the evidence suggests that CBT is safe and superior to other treatments for tinnitus distress, studies testing the effectiveness of CBT for tinnitus in real life contexts are rare. Therefore we conducted an uncontrolled pragmatic study of specialised stepped-care CBT for tinnitus as developed by Cima et al. (2012). The study involved 403 participants with chronic tinnitus. The main aim was to investigate whether the CBT protocol used by Cima et al. (2012) could be implemented under "everyday" conditions. We examined if adults suffering from chronic tinnitus showed improvements in quality of life over a 12-month period, and also examined predictors of favourable outcome. We collected data at baseline, and 3-, 8- and 12-months after baseline, as participants completed either a step 1 only or in case it was deemed clinically necessary, additionally a more intensive step 2. The study was carried out at an audiological rehabilitation centre in Eindhoven, the Netherlands. The primary outcome was health-related quality of life as measured by the Health Utilities Index III (HUI-III) at 12-months. Secondary outcome measures included self-reported levels of tinnitus-related- handicap, disability, affective distress, catastrophizing and fear. We used multilevel modelling (MLM) to examine effects and their predictors. Analyses revealed that, on average, participants improved by clinically meaningful amounts compared to baseline scores on all outcome measures, regardless of whether they received step 1 only, or an additional step 2. The observational study design prevented attributions of causality of improvement/change in participants to the treatment itself from being made, but did suggest that specialised CBT for tinnitus as described by Cima et al. (2012) can be implemented in other healthcare centres. Furthermore, the findings of this study, in addition to those of

## Chapter 6

Cima et al. (2012) and Maes et al. (2014), can be used to inform patients, policy makers, health authorities, and insurance companies in deciding whether to use this treatment for reducing tinnitus-related distress and improving health-related quality of life.