

# Short scientific report – STSM at the Tinnitus Center in Rome (Italy)

TINNET COST Action (BM1306)

STSM - Multidisciplinary Approach To Diagnose and Treat Subtypes of Tinnitus

WG 1 Clinical: Establishment of a standard for patient assessment and characterization

## Background and purpose of the mission

The **participants** of the STSM were

- Tinnitus Center Rome, Italy: Prof. Alberto Eibenstein, Dr. Alessandra Fioretti, Dr. Eleonora Natalini, Dr. Theodoros Varakliotis, and Dr. Sara Cisternino
- Medical University of Innsbruck, Austria: Mag. David Riedl
- National and Kapodistrian University of Athens, Greece: Dr. Dimitris Kikidis

Furthermore Dr. Roland Moschèn (Medical University of Innsbruck) attended the STSM and Dr. Federica Tortorella (Tinnitus Center Rome) introduced the Hyperacusis Scale or Khalfa's screening questionnaire (7 items).

### **Purpose of the mission:**

The main purposes of the mission were

- To discuss and plan the validation of the Italian "Chronic Tinnitus Acceptance Questionnaire" (CTAQ-I)
- The reinforcement of the scientific collaboration between the Tinnitus Center (Rome, Italy), the Medical University Innsbruck (Austria) and the National and Kapodistrian University of Athens (Greece)

## Description of the work carried out during the mission

In the STSM at the Tinnitus Center in Rome the **work plan** included three areas:

1. Validation of the Italian "Chronic Tinnitus Acceptance Questionnaire" (CTAQ-I).
2. Comparison between the ENT and psychological approach to different subtypes of tinnitus patients.
3. Indications for Tomatis method (Carmela Stillitano).

While area 1 included mostly scientific discussion and planning, area 2 and 3 focused on the exchange of clinical experience.

The mission lasted between February 16<sup>th</sup> and February 21<sup>st</sup>. The agenda included daily sessions in the morning as well as in the afternoon at different locations.

The **content** of the daily sessions were:

- New patients: Two morning sessions included the medical and psychological assessment of new patients at the Tinnitus Center. Medical assessment included an educational parts as

well as audiological (degree of hearing loss, tinnitus pitch match) and otolaryngological examination. The psychological assessment included a psychological interview and psychological tests. The aim of the assessment was to evaluate the best possible treatment from a multi-disciplinary perspective for the individual patient.

- Control patients: These sessions were follow-up examination for patients who already were examined at the Tinnitus Center earlier and who have been included in some kind of treatment (e.g. sound therapy, counseling, psychotherapy, Tomatis method, etc.). The aim of these sessions was to evaluate how helpful the interventions were for the patients and whether further treatment was necessary.
- Sound Therapy and Tomatis Method: These sessions showed how patients were treated with sound therapy respectively the Tomatis Method at the Tinnitus Center.
  - Indications for the Tomatis method are: chronic tinnitus (>6 months), previously treated successfully, significant psychological component (THI>36, anxiety, depression, panic attacks, sleep disorders, etc.).
  - Exclusion criteria: age > 70 years, Ménière's disease, otosclerosis, cholesteatoma, chronic otitis, pulsatile tinnitus.
- Mindfulness: Two sessions included presentations on mindfulness for the participants and patients from the clinic. Two different approaches were presented: the “Mindfulness-Based Stress Reduction” (MBSR) following the approach by Kabat-Zinn and the “Psychosomatic Mindfulness”, a more traditional approach to mindfulness.
- Clinical cases: some especially challenging and interesting cases of the new-/and control-patients were discussed in a multi-professional team
- Research planning:
  - Sessions included discussion on possible multi-center research with a focus on the evaluation of the CTAQ-I. Specific problems were discussed and concrete solutions were planned
  - A separate discussion was held on the (psychometrical) instruments used in the assessment of patients with tinnitus in Innsbruck, Rome and Athens.
  - Recent findings and yet unpublished work of the different institutions were presented and critically discussed.
- Tinnitus Congress: The approach to the psychological treatment and the result of an outcome-study were presented at the Congress on tinnitus (Ordine degli psicologi del Lazio) on Saturday, 21<sup>st</sup>.

### **Learning Experience**

During the STSM I learned a lot about the use of mindfulness-based interventions, both from a theoretical and a practical perspective. Since we have a lot of experience using CBT group therapy we discussed how to boost benefits of a group therapy approach, but also what difficulties come along with such an approach: e.g. I was surprised to hear that the Tinnitus Center had problems to get enough patients for a group, while we have been offering two groups a year for several years in a way smaller city. We tried to figure out reasons for this discrepancy and how to consider crucial factors of group therapy, especially in the context of the interventional study (see below).

We also discussed the different approaches of psychological assessment used in Innsbruck and Rome: while we focus on comorbid psychiatric problems (e.g. depression, anxiety, somatization,...), interpersonal problems and quality of life, the psychological approach of the Tinnitus Center includes a broad assessment of personality disorders as well as coping possibilities.

Furthermore I learned about the structure of the Tinnitus Center (Rome) and the concept of multi-disciplinary tinnitus treatment in Rome, respectively Italy.

## **Main results**

The two main results of the mission were

1. The concrete planning of the evaluation of the Italian “Chronic Tinnitus Acceptance Questionnaire” (CTAQ-I). Furthermore the possibility to also translate and evaluate the CTAQ to Greek was discussed.
2. Planning of several possible multi-center research projects between Innsbruck, Rome and Athens

### **1. Validation of the Italian “Chronic Tinnitus Acceptance Questionnaire” (CTAQ-I)**

#### **Procedure**

Data collection is proposed as part of a multicenter study in outpatient facilities (and / or stationary) of Otolaryngology in Italy.

#### **Participants**

Patients with acute (< 6 months) or chronic (> 6 months) tinnitus, in the context of ambulatory care and / or hospital. Relevant data and doctors will be reported in a CRF (Case-Report-Form) or TSCH. Inclusion criteria: ENT examination, age over 18 years, knowledge (fluid) of the Italian language.

#### **Start and duration of the study**

Start possibly within the year. The duration is oriented to the time required to administer the questionnaire to n=120 patients.

#### **Method**

##### *Instruments*

- Tinnitus Sample Case History (TSCH)
- Medical data
- Demographics
- Psychometric Questionnaires:
  - CTAQ-I 20 items
  - Tinnitus Handicap Inventory (THI)
  - Mini-Tinnitus Questionnaire (TQ-12)
  - Hospital Anxiety and Depression Scale (HADS)
  - BSI
  - SF36

##### *Statistical approach*

- Description of psychometric properties
- Internal consistency measured using Cronbach's alpha coefficient
- Spearman correlations and independent sample t-test to evaluate the validity
- Factor analysis

## **2. Further research cooperation**

We discussed several possibilities for further research cooperation. We started to make a detailed plan for two particular studies. I want to point out that, although we had a very productive week and worked on a lot of details on the research projects, the concepts are still in progress and might be adapted.

### *a. Mindfulness-Based Stress Reduction (MBSR) vs. Acceptance and Commitment Therapy (ACT) in the treatment of tinnitus: A randomized controlled trial*

**Rationale:** Acceptance and Commitment Therapy was found to reduce tinnitus distress in a group of normal hearing tinnitus patients. The treatment effect sizes were comparable to Cognitive Behavioral Therapy (CBT) and even better than the Tinnitus Retraining Therapy (TRT). Mindfulness-Based Stress Reduction Therapy was found to be beneficial in different types of chronic diseases and is hypothesized to be beneficial for patients with chronic tinnitus.

**Objectives:** Compare a treatment of MBSR to ACT to assess the mediating role of tinnitus acceptance as well as meta-emotions.

**Methods:** Patients with chronic tinnitus will be randomized to the two groups. Baseline assessment will include an audiological and otolaryngological examination, tinnitus case history, and standardized psychological tests (for depression and anxiety, quality of life, tinnitus distress, tinnitus acceptance, and meta-emotions). Process measures will be conducted at half time of the therapy, including assessment of tinnitus acceptance and meta-emotions. Outcome measures will include the standardized tests from baseline and will be conducted at the end of the training and at a follow-up after six months.

Sample size will be sixty patients randomized on two treatment groups. At the end of the study the results of the two therapies will be compared and statistically analyzed with appropriate statistical analysis, such as linear mixed-effects models, reliable change index (RCI), and regression-based mediation analysis.

**Research motive:** The theoretical framework of acceptance and experiential avoidance has received growing attention in different areas of chronic diseases / conditions (e.g. pain, fatigue, type-II diabetes). Within the tinnitus clinic in Innsbruck we have been discussing the possibility and benefit of acceptance-based approaches for patients with chronic tinnitus for quite some time now. We found that patients who find their tinnitus unacceptable are more likely to avoid or reduce the experience. In accordance with the theory of experiential avoidance (Hayes et al. 2006), this behavior could intensify and increase the very sensation one is trying to control or avoid, creating a vicious circle of more avoidance and enlarged tinnitus distress. Therefore, patients might achieve better adjustment if the tinnitus would be approached rather than avoided. Our research has shown, that acceptance of tinnitus is very beneficial for people suffering from tinnitus distress. Within the Tinnitus Center in Rome recently very similar aspects have been discussed. Although recent research has shown some very promising results for acceptance- and mindfulness-based therapy for chronic tinnitus, so far only little research has been conducted on both therapeutic approaches. To our knowledge no study has compared the effectiveness of the two treatments yet.

The focus of our research project is therefore on one side caused by the recent theoretical and therapeutic development. On the other side it was also influenced by the coincidence that both the Tinnitus Center in Rome and the Tinnitus Clinic in Innsbruck were interested in researching acceptance- and mindfulness-based approaches for patients with chronic tinnitus.

*b. Acceptance in acute and chronic tinnitus – a multicenter-study*

Rationale: Acceptance of chronic tinnitus has been found to be an important factor to explain the amount of psychological distress due to tinnitus. In recent studies tinnitus acceptance was a significant mediator of tinnitus distress in cognitive behavioral therapy (CBT) and acceptance and commitment therapy (ACT). A strong focus on tinnitus and the “fight” against the tinnitus (which would be contrary to the concept of acceptance) are hypothesized to facilitate the chronification of the tinnitus. Only little research has been conducted on the influence of an accepting attitude toward the tinnitus in the early stage of the condition. In a RCT study Nyenhuis et al. (2013) pointed out that “that distress can be reduced as early as the acute stadium”. Since tinnitus acceptance plays such an important role in the treatment of chronic tinnitus, we hypothesized that it would also be influential on tinnitus distress in the early stages of the condition. If this was the case, focus on acceptance-based interventions already in the early stages would be warranted.

Objectives: Assess tinnitus acceptance in an early stage of the condition. Reassess the sample after six month to see if tinnitus acceptance in the early stage was found to mediate tinnitus distress after six month.

Methods: Patients with acute tinnitus onset will be assessed in the Tinnitus Center (Rome), Tinnitus Clinic (Innsbruck) and the National and Kapodistrian University (Athens) at baseline and after six month. Assessment at both points will include audiological and otolaryngological examination, tinnitus case history, and standardized psychological tests (for depression and anxiety, quality of life, tinnitus distress and tinnitus acceptance). The sample will be treated with standard treatment. Using post-hoc analysis we will divide the group in good-responders and bad-responders to see whether tinnitus acceptance can be understood as a good predictor of chronification.

**Other comment**

Apart from the very informative and well organized STSM I wanted to point out the hospitality of Dr. Fioretti and her team. Although we got a lot of work done in the week, they also managed to show me the most beautiful places in Rom, organized an evening in the theatre, introduced me to the Roman cuisine and helped me with everything I needed. I cannot emphasize enough how much I enjoyed the STSM.

Thank you very much for this great opportunity!

