Unification of treatments and interventions for tinnitus patients

Proposal No.: 848261

Deliverable D3.4

UNITI Health socio-economic impact analysis

Deliverable No. D12 – WP3

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Contents

1 Introduction

1.1 Purpose and scope

The current document is the main outcome of UNITI "Task 3.5 Health socio-economic impact model and analysis". Task 3.5 scope is twofold: firstly, to report on the socio-economic impact factors of tinnitus to health care and society in Europe and secondly to evaluate the cost effectivenessof the UNITI treatment and intervention in terms of cost quality-adjusted life-year (QALY). As a consequence, in this study will try to calculate the socio-economic costs of tinnitus and estimate the socio-economic value of the UNITI treatments and interventions. Therefore, the overall objective is the generation of improved knowledge that will lead to better diagnostic predictions that can potentially lead to reduced costs and improve life-expectance.

This document reports on the progress and status of Task 3.5. According to UNITI GA, Task 3.5 ends on M21 (September 2021). A systematic literature review on the healthcare and societal costs of tinnitus was completed and is already published. The results of this review were used to design a questionnaire for an empirical evaluation with the participants in the UNITI RCT trial. The result of this empirical study will be reported in final report in project month 39.

From the early stages of the project and specifically for this task a UNITI working group on "healthcare and societal costs of tinnitus" has been established comprised of experts from partners VIL (Ilias Trochidis, Kyriaki Karydou), MIL (Alessandra Lugo, Carlotta Jarach, Elisa Borroni, Silvano Gallus) and UHREG (Winfried Schlee, Stefan Schoisswohl). The working group is meeting regularly (once a month) to discuss the status and progress of the current study and to define the next steps.

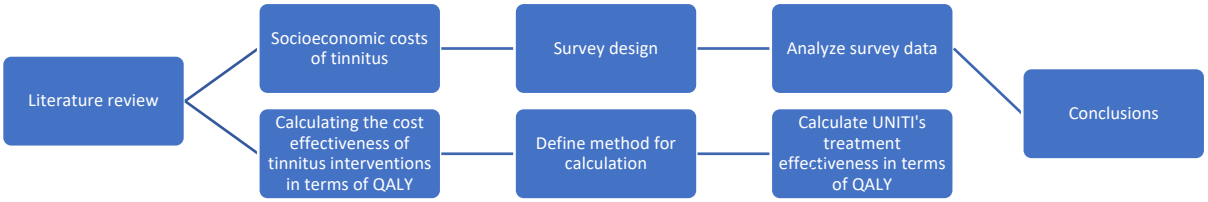
The following methodology for the execution of this task followed by the working group:

1. A systematic literature review has been conducted aiming at reporting the current state of play regarding the socioeconomic burden of tinnitus on the healthcare system as well as the society, showing a significant gap on the literature regarding this topic. The systematic review was summarized in a manuscript and is already published (Trochidis et al. 2021, https://www.mdpi.com/1660-4601/18/13/6881).
2. Aiming at tackling this issue and bearing in mind the objectives of this task, a study has been designed by developing a survey questionnaire to be distributed to the

tinnitus patients with the objective to calculate the socioeconomic costs of tinnitus in Europe.

3. Regarding the calculation of the cost effectiveness of the UNITI treatment, the relevant methodology is under development. Different methodologies are being taken into account and analysed based on the article of Newman & Sandridge (2012) [13] for identifying the best course of action for calculating the cost effectiveness of the UNITI treatment in terms of QALY.

Graph 1: Study methodology



The next steps are:

1. Run the survey
2. Match and analyse the relevant available data found in the national registries regarding the costs of the tinnitus treatments and the doctor visits with the ones gathered from the survey
3. Define and run the methodology for calculating the cost effectiveness of the UNITI treatment

1.2 Relation to other WPs & tasks

The present deliverable “D3.4 UNITI Health socioeconomic impact analysis” is part of the “Task 3.5 Health socio-economic impact model and analysis” under “WP3 Analysis of existing data”. This deliverable is interlinked with “WP4 Harmonization of technical solutions”, “WP5 Intelligent data analysis”, “WP6 Genetics”, “WP7 Randomized Clinical Trial” as it aims to use the knowledge gained from these WPs in order to assess to what extent the treatment developed under the UNITI project is a sustainable and cost-efficient solution. In parallel, it interlinks also with “WP8 Dissemination, Communication and Exploitation” as it will assist on

providing data about the sustainability of the UNITI outcomes and more specifically for the importance of a tool like the UNITI DSS.

1.3 Structure of the deliverable

The structure of the present deliverable is the following: **Section 1** describes the outcomes of the systematic review on healthcare and societal costs of tinnitus that was conducted as part of this study. The review shows a gap in the knowledge about the economic burden of tinnitus on healthcare systems, patients and society. **Section 2** presents the questionnaire that has been developed that will be distributed to tinnitus patients and will assist in calculating the socioeconomic costs of tinnitus across Europe. Finally, **Section 3** presents the conclusions and the next steps of the present study.

2 Review on socio-economic impact factors of tinnitus to health care and society

2.1 Introduction

Tinnitus which consists of the continuous perception of a phantom sound in the ears or head in the absence of a corresponding external stimulus [1,2], remains a scientific and clinical enigma of immensely high prevalence and socio-economic burden [3]. So far, the cause of the symptoms cannot be explained by conventional medical or psychiatric diagnosis [4].

Tinnitus can occur in all ages, in various frequencies, intensity and duration scales, whereas annoyance caused to the patients varies from totally absent to tinnitus-related suicidal tendency. It is estimated that more than 10% of the population are affected by tinnitus.

The most common ways of treating tinnitus are [5]:

1. Counselling or cognitive therapy
2. Using hearing aid amplification
3. Using hearing aids or sound generators for masking the tinnitus percept
4. Combination of education, counselling and sound therapy based on a neurophysiological model of tinnitus.

Despite the availability of these treatment options, none of them can fully eliminate the tinnitus perception and given that there is not a standardized treatment procedure, tinnitus perception can lead potentially to a high health care and societal cost including the patients themselves. Taking into consideration the abovementioned issues and the high spread of tinnitus among the general population it is of utmost importance to understand the exact economic burden of

tinnitus. For the purposes of this document, we conducted a systematic review to collect information on both direct (medical and non-medical costs) and indirect costs (including societal costs, such as work loss and reduced productivity) for tinnitus management from the available scientific literature. This will allow us to describe the costs for the healthcare system and tinnitus patients under the current practice. The results of this systematic review will help us understand and evaluate the extent of evidence currently available on the financial burden of tinnitus and identify potential gaps to direct future research.

2.2 Systematic review on Healthcare and Societal Costs of tinnitus

In this section we present the materials and methods that were used to conduct a systematic review on healthcare and societal costs of tinnitus. More details about this study are presented in [6], a study conducted in the context of the UNITI project.

The following scientific databases were considered to conduct the systematic literature search: PubMed/MEDLINE, Embase and the Cochrane Database of Systematic Reviews (CDSR). A search on Google Scholar was also performed in order to identify relevant articles published in scientific journals not indexed in those databases. In addition, the databases of the World Health Organization (WHO), Eurostat and the Organisation for Economic Co-operation and Development (OECD) were consulted to retrieve possible additional relevant information about direct and indirect costs associated with tinnitus and related quality-adjusted life years. The search strategy was designed for PubMed and then adapted for use in the other databases. Search terms included terms for the condition and the considered outcome (i.e., “tinnitus AND (economic OR costs OR market OR “Cost of Illness” OR QALY)). We did not apply any restriction on publication time, considering all scientific articles published in English before the search date. Articles published in a language other than English were excluded from the review. Reference lists of other reviews were also checked to identify other potentially relevant publications.

On 1 April 2021, we applied the search strategy. Overall, through PubMed, 137 publications were identified, with an additional 14 on Embase, 28 on CDSR and 170 publications on Google Scholar. Excluding duplicates, we obtained a total of 273 publications. Out of 273 identified publications, 26 were included after the first screening of titles and abstracts. Of these, only five articles met the eligibility criteria (in order to be eligible, studies had to provide data on direct or indirect costs due to the management of tinnitus disability in human subjects) and

were included in the systematic review. Those studies were conducted in the United States of America (USA), the Netherlands and the United Kingdom (UK).

In particular, two studies were conducted in the USA: a cross-sectional study from 2011, analyzing a sample of 692 tinnitus patients, estimated that the annual average tinnitus-related costs per patient for clinical visits were EUR 564 (standard deviation, SD: EUR 1186) [7]; a cohort study evaluated the treatment costs during a 1-year period of follow-up of 56 tinnitus patients, treated either with sound generators or the Neuromonics Tinnitus Treatment. Treatment costs were EUR 1388 for sound generators and EUR 3725 for the Neuromonics Tinnitus Treatment [8].

A cross-sectional study from the Netherlands provided direct and indirect annual mean costs per patient. Total annual mean healthcare costs added up to EUR 1544, patient and family costs to EUR 69 and costs due to productivity loss to EUR 3702 [4]. This study reported higher costs for patients with severe compared to moderate and mild tinnitus. In particular, healthcare costs were EUR 767, EUR 1329 and EUR 2218 for patients with mild, moderate and severe tinnitus, respectively. The corresponding estimates for patients and family costs were EUR 31, EUR 61 and EUR 115, and those due to productivity loss were EUR 1222, EUR 4781 and EUR 5105. A randomized controlled trial (RCT) from the Netherlands conducted in 2007–2011 on 492 tinnitus patients estimated annual mean direct and indirect costs per patient divided by usual care (UC) and specialized care (SC). The study provided healthcare costs (UC: EUR 3300; SC: EUR 3429), patient and family costs (UC: EUR 115; SC: EUR 90) and costs due to a loss of productivity (UC: EUR 2565; SC: EUR 2764). Thus, estimates for the total annual costs (i.e., the sum of the three categories mentioned above) were EUR 5980 for UC and EUR 6283 for SC [9]. The last eligible included study was a cohort study conducted in the UK, estimating mean annual direct costs expressed as healthcare costs only. The mean annual total healthcare costs were EUR 1938 [5]. Indirect costs and patient and family costs were not provided in this publication.

2.3 Discussion

This is the first systematic review [6] summarizing direct and indirect costs for tinnitus management in the current practice, based on the published scientific literature. Our systematic review follows the guidelines for systematic reviews (PROSPERO - International prospective register of systematic reviews - No: CRD42020180438). Although there is a wide consensus among scientific and clinical professionals that tinnitus is associated with high

direct and indirect healthcare costs, our systematic review identified only five studies that calculated costs for tinnitus management [4, 9, 5, 7, 8], with only three of them reporting overall estimates of societal or healthcare costs [4, 9,10].

Cost categories

One aspect that emerged from most studies in the scientific literature and other relevant databases was the lack of comprehensive and detailed information on tinnitus costs, except for two studies from the Netherlands. Cost categories ideally include both direct costs (direct medical and non-medical costs) and indirect costs, including societal costs (e.g., work loss, worker replacement, reduced productivity from illness and disease, family costs and financial estimation of the impact on quality of life) [5, 11]. This systematic review identified only two studies, both from the Netherlands, providing a detailed description of direct costs (healthcare, patient and family costs) and indirect costs (due to productivity losses) [4]. Two additional studies provided only a portion of the overall picture of costs, showing total healthcare costs [10] and costs for clinical visits [4].

Country differences

In our systematic review, two of the studies reporting information on the economic burden of tinnitus were conducted in the US [7, 8], two in the Netherlands [4,9] and one in the UK [5]. Therefore, it is evident that data on healthcare and societal costs of tinnitus come from a very limited portion of countries worldwide. The current scientific literature does not permit comparison among countries, since complete information on total annual average costs for tinnitus patients comes from the Netherlands only [4,9]. To our knowledge, no cross-border study comparing cost data in different countries, applying the same methodology for calculating tinnitus costs, is available. This type of study would allow investigating the impact of different healthcare systems, therapy procedures, treatment availability and countries' economic indicators on tinnitus-related costs.

However, an attempt for a broad estimation of the total costs in the EU could pursue the following path: The first step would be to broadly translate expenses to the average income of these countries and then consider the average EU income. The second step would be to extend these estimates to the whole EU, taking into account that various epidemiological studies estimated a prevalence of tinnitus exceeding 10%, which means that at least 30 million people in the EU live with tinnitus.

Additionally, comparisons between countries on the costs of various treatments for tinnitus management are lacking in the current literature. For future health economic evaluations of treatments for disabling tinnitus, consensus on a set of standardized and homogenous evaluative tools is of high importance, in order to facilitate cross-country and cross-study comparisons.

Impact of Patients' and Tinnitus Characteristics (e.g., Severity) on Costs

Only one study conducted in the Netherlands investigated the impact of tinnitus severity on costs, showing that the more disabled patients had significantly higher healthcare costs compared to patients with mild to moderate complaints [4]. In fact, patients with severe tinnitus disability had more contacts with the GP, medical specialists—including ENT specialists and neurologists—and other healthcare professionals such as psychologists, social workers and clinical physicists in audiology [4]. This study also found that productivity losses were higher for moderate and severe tinnitus patients, compared to the mild group. At the same time, no differences regarding out-of-pocket costs were observed across the three groups [4]. The same study identified other relevant predictors for both higher healthcare and societal costs, besides tinnitus severity. These included younger age, shorter duration of tinnitus (less than 1 year) and higher scores of depression, while sex, level of education, health-related quality of life and anxiety did not impact costs [4]. No information on the effect of other possibly relevant socio-demographic, economic and clinical characteristics is available in the current scientific literature. Including these predictors in other populations [5] might provide insight into the effect of socio-demographic and economic parameters, such as family and personal socio-economic status, and tinnitus-related characteristics on costs.

Future perspectives

This systematic review found only a few studies dealing with the economic burden of tinnitus, none of which were published in recent years (2018–2021). Thus, it is important to be able to make some updated and validated statements about the economic impact of tinnitus on the individual and society. Future studies are needed to provide new detailed data on the healthcare and societal costs for tinnitus. Such studies are useful today because of their implications for health policy (e.g., determining priorities by reporting tinnitus cases that require special help, evaluating the efficacy of treatments, allocating appropriate funds for research and development of tinnitus treatments). The framework for calculating tinnitus costs must include data from various countries and must consider individual-level characteristics of tinnitus patients (e.g., sex, age, income, concomitant comorbidities) and of the symptom itself

(e.g., tinnitus onset, duration, severity) that could determine higher costs for tinnitus management. At the same time, information on costs per quality-adjusted life years (QALY) is scant in the literature. The UNITI project and more specifically Task 3.5, provides the opportunity to add to the gaps in knowledge on the economic burden of tinnitus.

For the purposes of this study, the cost analysis methodology of the studies from the Netherlands [4,19] will be adopted and applied, and patient and tinnitus-specific characteristics relevant to tinnitus costs will be collected on all patients entering the RCT. The UNITI consortium has committed to performing a comprehensive health economic evaluation, including an analysis of cross-country differences. To this end, the present study aims at filling this literature gap by calculating the socioeconomic burden of tinnitus across Europe. For doing so, a survey has been developed aiming to be distributed to tinnitus patients in Europe. Section 3 describes the questionnaire.

3 UNITI socioeconomic impact assessment Questionnaire

For calculating the health care and societal costs associated with tinnitus, the specific UNITI working group worked from January 2021 to develop this survey questionnaire (see full questionnaire in the annex of the present document). The team was meeting approximately once a month for the development of the questionnaire following the [4] study methodology. As a consequence, costs have been divided into 3 main components as it is normally done in similar cost of illness studies:

1. Medical/health care costs
2. Patients and family's costs
3. Indirect costs

In particular, a self-administered cost questionnaire including 44 questions divided into 7 sections with a recall period of 12 months has been developed. Several updates have been made including the incorporation of the feedback received from 3 English speaking tinnitus patients, the UNITI's RCT group and tinnitus experts members of UNITI consortium.

The core survey has been developed in English and will be translated in 6 languages, Greek, Spanish, Italian, Swedish, German, Dutch. The approximate time needed for the completion of the study is 20 minutes. The survey is estimated to run approximately one year for gathering sufficient input from tinnitus patients (From October 2021 until September 2022). The questionnaire has two versions: 1. Web based and the conventional paper/pencil version. The

survey will be administered to individuals that have participated in the UNITI's clinical trials as well as patients affiliated with a tinnitus association in Europe. Participants have the chance to indicate if they participated to the UNITI's clinical trials by clicking the relevant box. UNITI's clinical trials participants were asked to skip 12 questions of the questionnaire as they responded to those in a previous study conducted within the UNITI project.

Participants have the chance to agree to participate in our study and subsequently agree with our principles on data usage which are following the general GDPR principles, by checking the relevant box in the beginning of the questionnaire. Below, a brief presentation of the questions included in the questionnaire per section is presented.

The **first section** of the questionnaire gathered data on sociodemographic characteristics of the patients including age, gender, education and economic status as well as the exposure of the participant to loud noises. The definition of a loud noise was included in the questionnaire to avoid any misunderstanding.

The **second section** focused on assessing the participants' overall hearing condition. The questions included in this part, have been tested and verified via the ESIT Q questionnaire.

The **third section** focused on data gathering the participants' tinnitus diagnosis and characteristics. In this part, questions related to the frequency and severity of tinnitus were asked along with information regarding the specialist that diagnosed the patients with the tinnitus disability. Last but not least, in the third part, information on comorbid conditions and data on family's hearing condition were collected via participants' self-report.

The **fourth section** focused on the treatment the participants' followed due to tinnitus and the respective costs. Participants were asked to record the frequency of visits to various health care professionals occurring over the 12 months for tinnitus treatment. Participants could choose from various types of health care providers. Furthermore, they could indicate the type of treatment they received and to report on any other activity that might have followed such as attending a sports club as a part of the tinnitus treatment. Finally, the participants were provided with a list of medications commonly used because of tinnitus as well as they asked to indicate if they used any hearing aid. The associated costs for all the above visits and treatments were asked to be reported.

The **fifth section** gathered data on participants indirect costs aiming at exploring the effect of tinnitus to the participants working life. Participants had to indicate if they had any paid job

within the past 12 months, the frequency of reporting sick this time period and the effect of tinnitus in their productivity and concentration level.

The **sixth section** explored the impact of COVID-19 on the participants tinnitus-related treatment/doctor visits. In particular, the participants had to indicate if their treatment/doctor visits were increased or decreased during COVID-19.

The **seventh section** focused on gathering participants interests on participating in a follow-up study in the future.

4 Conclusions and next steps

The next step for the continuation of this study is running the survey for approximately a year. Then, the relevant available data found in the national registries regarding the costs of the tinnitus treatments and the doctor visits will be gathered, matched with the ones gathered from the survey and analyzed further for concluding the study. In parallel, for calculating the cost effectiveness of the UNITI treatment in terms of QALY the definition of the relevant methodology will be realized and run.

The results of this study will be made available upon the project's completion for utilizing the relevant data from the RCT participants.

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6 Annex I: UNITI Questionnaire

Introduction:

Dear participant, with this survey we hope to gain insight in the financial burden to the individual, as well as to society, associated with suffering from tinnitus with the final aim to obtain an estimate of the health care costs associated with tinnitus. Tinnitus is the repeated or constant perception of a sound in one or both ears (or head) which nobody else hears nor originates from a sound source in the environment. Oftentimes a ringing or buzzing sound is reported. From now this point onwards we will use the term tinnitus, which can mean any sound you hear repeatedly or constantly in your ears (in the head). We would like to kindly ask you to reply to the questions below as accurately as possible. Your answers will be stored safely and anonymously following the General Data Protection Regulation (GDPR) rules.

The approximate time to complete this questionnaire is estimated to 20 minutes.

Acknowledgements: This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme, Grant Agreement Number 848261

☐ I Agree to participate in the study

☐ I Agree with the UNITI data privacy policy

1. **Have you participated in the UNITI clinical trials?**

   ☐ Yes (if yes, questions 2 to 6, 11 to 14 and 16 until 18 shall be skipped)

   ☐ No

In Part A, we will ask you a few demographic questions. Please remember that our study is fully anonymized, and the data collection follows the GDPR principles.

Part A – Individual characteristics

2. **Age (in years)**: .....
3. **Gender:**

   ☐ Male

☐ Female

☐ Non-binary

☐ I prefer not to mention

4. **What is your height? ...** cm
5. **What is your weight? ...** kg
6. **Level of education:**

☐ No school
☐ Primary (elementary school)
☐ Lower secondary (middle school)
☐ Upper secondary (high school)
☐ University or higher degree

7. **Approximate annual personal income, compared to the average in your country:**

☐ Below average
☐ Average
☐ Above average
☐ Prefer not to mention

8. **Country of residence:** …….
9. **Occupation**:

☐Employed

☐Self-Employed

☐Not employed
☐Retired
☐Disabled, not able to work

10. **Are/were you exposed to occupational noise*?**

Occupational noise is the amount of acoustic energy received by an employee's auditory system when working in industry. An example can be the exposure to loud sounds/high noise levels

☐ Yes, if yes, please indicate the average number of working days per week…..

☐ No

☐ Not sure

Thank you for completing Part A. Part B consists of general questions about your overall hearing condition. In particular, we will ask you a few questions on hearing issues and on the

sensation of noise in head or in one or both ears, which is a symptom that medical doctors call “tinnitus”

Part B – Overall hearing condition

11. Over the past year, have you had noises (such as ringing or buzzing) in your head or in one or both ears that last for more than five minutes at a time?

☐ Yes, most or all of the time

☐ Yes, a lot of the time

☐ Yes, some of the time

☐ No, not in the past year

☐ No, never

☐ Do not know/Prefer not to answer

12. Over the past year, how much did these noises in your head or ears worry, annoy or upset you when they were at their worst?

☐ Severely

☐ Moderately

☐ Slightly

☐ Not at all

☐ Do not know/Prefer not to answer

13. Over the past year, have you seen your family doctor or another healthcare professional for problems with noises in your head or ears?

☐ Yes, 5 or more visits

☐ Yes, 2 to 4 visits

☐ Yes, one visit

☐ No

☐ Do not know/Prefer not to answer

14. Do you currently have any other difficulty with your hearing, such as listening to speech in a noisy situation?

☐ Yes, cannot hear at all

☐ Yes, severe difficulty

☐ Yes, moderate difficulty

☐ Yes, slight difficulty

☐ No difficulty

☐ Do not know/Prefer not to answer

Thank you for completing Part B. Now, in Part C, we will ask you a few questions on "tinnitus"

Part C: Tinnitus diagnosis and characteristics

15. When did you start experiencing tinnitus?

…..Month ….Year

Never

16. How often do you experience tinnitus on average?

☐ Daily or almost daily

☐ Almost weekly

☐ Almost monthly

☐ Every few months

☐ Yearly

17. What best describes your tinnitus during a day?

☐ Constant: you can always or usually hear it in a quiet room

☐ Intermittent: "comes and goes", cannot always hear it in a quiet room

18. Where do you perceive your tinnitus?

☐ Right ear

☐ Left ear

☐ Both ears, worse in right

☐ Both ears, worse in left

☐ Both ears, equally

☐ Inside the head

☐ Other. Please specify

_____

☐ Do not know

19. Please indicate what bother you the most about the tinnitus perception, multiple answers are possible.

☐ Sense of loss of control over my body/feeling like I'm sick

☐ Intrusive tinnitus

☐ Inability to concentrate

☐ Sleep quality

☐ Ability to ignore

☐ Other, please specify

20. Have you been diagnosed with tinnitus?

☐ Yes

☐ No

21. When was the first time you have been diagnosed with tinnitus?

…..Month ….Year

22. Who diagnosed your tinnitus?

☐ General practitioner

☐ ENT

☐ Psychiatrist

☐ Psychologist

☐ Audiologist

☐ Other, please specify……

23. How severe were your tinnitus complaints when you noticed it in the beginning?

☐ 0= Not severe at all, tinnitus did not bother me at all, I lived my life as before

☐ 1= Not very severe, my tinnitus was only sometimes bothersome

☐ 2= Moderately severe, my tinnitus was often bothersome but not every day and/or not in all my daily activities

☐ 3=Severe, tinnitus bothered me most of the time, in almost all my daily activities

☐ 4= Very severe: Tinnitus was very bothersome all the time, it impacted my whole life, in everything I did

24. How severe would you rate your tinnitus now?

☐ 0= Not severe at all, tinnitus does not bother me at all, I live my life as before

☐ 1= Not very severe, my tinnitus is only sometimes bothersome

☐ 2= Moderately severe, my tinnitus is often bothersome but not every day, or not in all my daily activities

☐ 3=Severe, tinnitus bothers me most of the time, in almost all my daily activities

☐ 4=Very severe, tinnitus is very bothersome all the time, it impacts my whole life, in everything I do

25. Do you suffer from any of the following illnesses or chronic physical or psychological complaints,?

☐ None
☐ Fibromyalgia
☐ Chronic low/back pain
☐ Irritable bowel syndrome
☐ Inflammatory rheumatic disorder
☐ Depression
☐ Migraines
☐ Allergies
☐ Asthma
☐ Headache
☐ Temporomandibular joint dysfunction (TMJ) disorder
☐ Vertigo
☐ Insomnia
☐ Hyperacusis
☐ Neck pain
☐ Ear pain
☐ Gastro-intestinal problems
☐ Sexual disfunction
☐ Other, please specify ……

26. How many first degree relatives do you have and how many of those do you know to have tinnitus and/or hearing loss?

First degree relatives
..... Brothers ..... Sisters .... Non-Binary
..... Sons ..... Daughters .... Non-Binary

First degree relatives with tinnitus or hearing loss
..... Father ……Mother
..... Brothers ..... Sisters .... Non-Binary
..... Sons ..... Daughters .... Non-Binary

Thank you for completing Part C. Now, in Part D we will ask you a few questions about any treatment you followed due to tinnitus and the respective costs. Here, we would like you to provide us with your most accurate estimations.

Part D: Direct medical and non-medical costs

27. When was the first and last time you received treatment because of tinnitus? You can indicate here the period you visited a caregiver for your treatment or the first time you used a hearing aid or had other form of treatment like the ones mentioned in Q31.

First time: …..Month ….Year … NA **Last time:** …..Month ….Year … NA

28. Do you still experience tinnitus?

☐Yes, more severely than the last time I received treatment
☐ Yes, less severely than the last time I received treatment
☐ Yes, with the same severity than the last time I received treatment
☐ No

29. If you received any treatment because of tinnitus within the past 12 months, how many appointments with a caregiver for your treatment you had and/or other form of treatment like the ones mentioned in Q31 did you have?

…….. number of appointments

30. For how many hours per week did you have an appointment relevant to your treatment within the past 12 months? (if you have had multiple appointments, enter an average otherwise enter 0)

_____ hours per week

31. Have you been in contact with any of the following caregivers because of tinnitus in the past 12 months? If yes, please indicate [a] the number of appointments in the past 12 months, [b] the average individual cost contribution per appointment, [c]

the means of transport you usually used for the visit(s) and [d] the number of times you were accompanied by one or more family member(s). Multiple answers are possible.

	Yes/No	**Indicate the number of appointment (in the past 12 months)**	**Average individual cost contribution per appointment (out-of-pocket costs) in local currency (You have to report the costs that were not covered by the health care system or by private insurance)**	**Means of transport (car, bicycle, on foot, public transport, other)**	**Were you accompanied by one or more family member(s)? If yes, indicate how many times (in numbers)**
General practitioner					
ENT					
Psychiatrist					
Psychologist					
Chiropractor					
Physiotherapist					
Social worker					
Company doctor					
Audiologist (in the hospital or in an audiology center)					
Other healthcare provider, please specify specialism: 1….					

2…					

32. Did you receive any treatments because of tinnitus in the past 12 months? Multiple answers are possible

	Yes/No	**Indicate the number of appointments (in the past 12 months)**	**Average individual cost contribution per appointment (out-of-pocket costs) in local currency (You have to report the costs that were not covered by the health care system or by private insurance)**	**Means of transport (car, bicycle, on foot, public transport, other)**
Magnetic stimulation				
Neurostimulation				
Repetitive Transcranial Magnetic Stimulation (rTMS or magnet therapy)				
Psychotherapy				
Counselling				
Sound stimulation				
Other treatment, please specify: 1…. 2….				

33. Have you undertaken other activities to reduce tinnitus? Multiple answers are possible

	Yes/No	**Indicate the frequency (number of times) in the past 12 months**	**Average individual cost contribution in local currency (Please**	**Means of transport (car, bicycle, on foot, public transport, other)**

			specify if personal costs are calculated per month or per session)	
Sports center / sports club membership				
Yoga / relaxation therapy				
Homeopathy				
Acupuncture				
Running				
Hiking				
Other, please specify: 1…. 2….				

32.1 Do you follow any special diet?

☐ Yes

☐ No

32.2 Do you use any supplements (i.e. vitamins A, B complex, D, E, K), zinc, magnesium, iron) to reduce tinnitus?

☐ Yes, daily

☐ Yes, Weekly

☐ Yes, monthly

☐ No

34. Have you used prescription drugs in the past 12 months because of tinnitus?

☐ No

☐ Yes, if yes, which prescription drugs did you use, how many packages did you purchase the past year and how much was your individual contribution (personal costs not covered by the National Health care System insurance) per package in local

currency (multiple answers possible), if it is fully covered by National Health care System or insurance please indicate 0 in the individual contribution per package:

☐Nitrazepam (e.g. Mogadon) .....number of packages purchased ….. individual contribution per package
☐Temazepam (e.g. Normison) .....number of packages purchased ….. individual contribution per package
☐Oxazepam (e.g. Seresta) .....number of packages purchased ….. individual contribution per package ☐Lormetazepam (e.g Loramet) .....number of packages purchased ….. individual contribution per package
☐Zolpidem (e.g Stilnoct) .....number of packages purchased ….. individual contribution per package
☐Alprazolam (e.g. Xanax) .....number of packages purchased ….. individual contribution per package
☐Lorazepam (e.g. Temesta) .....number of packages purchased ….. individual contribution per package
☐Diazepam (e.g. Valium) .....number of packages purchased ….. individual contribution per package
☐Other, namely
_____

35. Have you ever purchased a hearing aid (masker/noise generator - a hearing aid looking device, which makes a noise) due to tinnitus and/or hearing loss?

☐ Yes, due to tinnitus, namely _____Approximate individual purchase costs _____ Approximate maintenance costs (e.g. battery cost, repair cost, etc)_____

☐ Yes, due to hearing loss, namely _____ Approximate individual purchase costs _____ Approximate maintenance costs (e.g. battery cost, repair cost, etc)_____

☐ Yes, due to tinnitus and hearing loss, namely _____ Approximate individual purchase costs _____ Approximate maintenance costs (e.g. battery cost, repair cost, etc)_____

☐ No

36. If you have used other drugs or aids in the past 12 months from now, or have performed other activities specifically because of your tinnitus symptoms or to

ameliorate your tinnitus condition, you can describe them below. If there were costs involved, please write them down.

Activity / (tool) resource	Average individual contribution (not covered by the insurance or public health system) in local currency	Possible maintenance costs in local currency

Thank you for completing Part D. Now, in Part E we will ask you few questions regarding the effect of tinnitus into your working life. We would like you to provide us with your most accurate estimations.

Part E: Indirect costs

37. Did you have any paid job within the past 12 months?

☐ Yes

☐ No – go to question 40

38. Were you in sick leave due to tinnitus during the past 12 months?

☐ Yes

☐ no

39. How often were you on a sick leave due to tinnitus the past 12 months?

_____ times

40. Can you indicate the approximate duration of these absence periods in the past 12 months due to tinnitus?

Period 1: _____ days / months / year (cross out which does not apply)

Period 2:_____ days / months / year (cross out which does not apply)

Period 3:_____ days / months / year (cross out which does not apply)

Period 4:_____ days / months / year (cross out which does not apply)

41. During a normal working day and while you experience tinnitus can you indicate on average how much your concentration level is affected?

1	2	3	4	5	6	7	8	9	10
(Not at all)									(Completely)

42. During a normal working day and while you experience tinnitus can you indicate on average how much your productivity level is affected?

1	2	3	4	5	6	7	8	9	10
(Not at all)									(Completely)

Thank you for completing Part E. Our last part is focused on the impact of COVID-19 on your tinnitus-related treatment/doctor visits.

Part F: COVID-19

43. Overall, the COVID-19 pandemic and the restrictive measures put in place to reduce the virus spread:

☐ Reduced the number of treatments/doctor visits **related to tinnitus.**

☐ Slightly

☐ Moderately

☐ Highly

☐ Increased the number of treatments/doctor visits **related to tinnitus.**

☐ Slightly

☐ Moderately

☐ Highly

☐ Had no impact on the number of treatments/doctor visits **related to tinnitus**

Part G: Participation to future follow-up study

44. If you are willing and available to participate in a follow-up survey for this study in the future, we would be very grateful. Please write your e-mail address here, if you allow us to contact you again:.....