INFORMED CONSENT FORM

Study Title: UNITI (UNification of treatments and Interventions for TInnitus Patients) – BIG online study

Study Code: UNITI-BIG

Site: online

Study Team:

Prof. Dr. Berthold Langguth (physician)

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Dear study participant,

thank you very much for your interest in participating in this online study, which will investigate the relationship between tinnitus characteristics, app usage behaviour and effectiveness of the app-based intervention including acoustic therapy and structured counseling for tinnitus. Please read carefully through this Informed Consent Form (ICF) which has two parts.

- **Information Sheet** - for information on the progress of the study
- **Certificate of Consent** – to accept if you agree to take part

If you have any questions or difficulties understanding the following information, please do not hesitate to contact us by mail.

PART 1: INFORMATION SHEET – UNITI-BIG

You are being asked to participate in this clinical research study. Before you decide whether to participate, it is important that you understand why this study is conducted, what is expected of you as a participant, the potential benefits, risks and inconveniences

involved, and how your information and data will be used. Please read this information carefully and if you have any questions, please ask the study team. Before you make a decision regarding your participation, you are welcome to consult with others, such as your family doctor, family and friends. If you do not understand parts of the information presented to you, you are welcome to ask the study team to explain them to you. Should you have questions later, please do not hesitate to contact the study team by mail. The contact details of the respective contact persons are listed at the end of this document.

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1. WHAT IS THE PURPOSE OF THE STUDY?

Tinnitus is the perception of noise or ringing without the presence of an external source of sound. It is a very common problem and many people are suffering from this condition. Although much progress has been made, there is currently no curative treatment for tinnitus available. However, there are treatments alleviating tinnitus symptoms and improving life quality (tinnitus management). Nevertheless, many affected people do not receive any treatment. Related reasons are long waiting times for medical and psychotherapeutic treatments and a lack of accessibility in rural regions. One solution to this problem could be the provision of therapies through digital applications via computer or smartphone. Therefore, we have developed an app providing already established tinnitus therapies (structured counselling and acoustic therapy) via smartphone. We want to make this available to as many sufferers as possible and at the same time collect data on tinnitus characteristics, usage behaviour, quality, acceptance and therapeutic benefit of the app-based therapy. We will analyse these variables for possible correlations in order to gain knowledge about which individual factors benefit from digital therapy, among others.

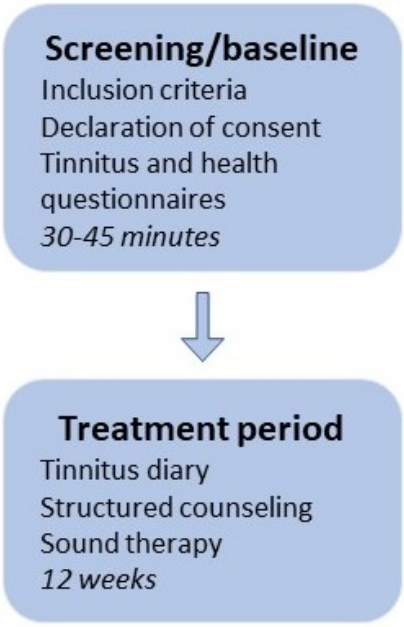
2. DO I HAVE TO TAKE PART?

Your participation in the study is entirely voluntary. You decide whether you want to participate or not. If you decide to participate, you are free to cancel your participation at any time and without giving reasons. However, if you decide to withdraw from the study, we ask you to inform the study team. This will in no way affect your medical care in the future.

3. PROCEDURE OF THE STUDY OR WHAT WILL HAPPEN IF I DECIDE TO TAKE PART?

The study is conducted online, which means you can do everything from home with a working internet connection via your computer and smartphone.

Figure 1 – Flow chart study procedure



Screening and baseline assessment

Study procedures

As part of the screening, a few questions will be asked to clarify whether you are suitable to take part in the study. You can find the link to the screening on our website (https://uniti.tinnitusresearch.net/index.php/study/big-online-study).

If you are eligible, you will be enrolled in the study and then sent directly to the baseline measurement.

As part of the baseline measurement, the study team will

- ask you to accept the informed consent online.
- ask you to fill in some health- and treatment-related questionnaires online.
- ask you to fill in some tinnitus specific questionnaires online.

Treatment Period

The treatment period will last 12 weeks. During the treatment period you will receive daily sessions of acoustic therapy and structured counselling via the app, in addition to completing the tinnitus diary.

Study procedures

After answering all questionnaires of the baseline assessment, you will automatically receive information about the app installation and treatment phase (Important: The app only works on smartphones with an iOS or Android operating system). A video will introduce you to the app usage. You will also receive personal login details with which you

can log in to the app and start the treatment. From this day on, you are invited to complete one unit of structured counseling (TinEdu) and acoustic therapy (ShadesofNoise) every day. At the same time, you are asked to fill out the tinnitus diary in the app every evening. The diary questions you about your tinnitus and how you are currently feeling. As the information you provide in the diary is very important for our research, the app will remind you to fill in the diary every day at 7:30 pm. It is advisable to fill in the diary at a similar time every day so that your data is comparable. The treatment phase lasts 12 weeks, during you can expect to spend 20-30 minutes a day.

4. WHAT DO I HAVE TO DO?

If you agree to take part in this study, you must complete the baseline questionnaires described above as well as fill in the tinnitus diary daily. You should also complete one session of the TinEdu counseling module each day and use the ShadesofNoise acoustic therapy daily.

5. WHAT ARE THE POSSIBLE SIDE EFFECTS, RISKS AND DISCOMFORTS OF TAKING PART?

It is not expected that you will have more side effects than those you might experience from current clinical practice.

As with any tinnitus investigation there is a possibility of a slight increase of tinnitus since you will pay more attention to your tinnitus. If you experience a severe long-term deterioration of your tinnitus, please inform the study team and do not quit the treatment by yourself.

In order to get as much information about you and your tinnitus as possible, you will be asked to complete many different questionnaires. This can sometimes be very time-consuming and demanding. But we are well aware of this and trying to find a good balance for any participant.

6. HOW WILL I BENEFIT FROM TAKING PART?

It is hoped that the new treatment will help you with your tinnitus suffering, but this cannot be guaranteed. Information from this study may help researchers understand tinnitus and develop new tests and treatments to help other patients with this condition.

7. WHAT IF NEW INFORMATION BECOMES AVAILABLE?

If important new information on the study treatment becomes available we will publish it on the study homepage (https://uniti.tinnitusresearch.net/index.php/study/big-online-study) and via our Tinnitus Science Channel (http://www.tinnitus.science/).

8. WHAT ARE THE COSTS OF TAKING PART?

There are no costs for you if you take part. You will receive the treatment at no cost and there will be no charges for tests or procedures. You will not be paid for being in this study. After completion of the study you are allowed to continue using the app.

9. HOW WILL MY PERSONAL DATA BE USED AND PROTECTED?

No personal data is collected. Therefore, the tinnitus and health-related data we collect from you is **anonymous**. This means that they cannot be traced back to you personally.

Results of the questionnaires mentioned in the section "Procedure of the study or what will happen if I decide to take part" are study-relevant data that will be stored in an international tinnitus database in anonymised form according to the EU data security and privacy settings. All collected data will be treated strictly confidential within the legal framework.

The study information from this study must be kept for at least 10 years (§ 13 GCP-V). The results will be used to learn about tinnitus and different treatment methods. They can also be used to answer other questions including the safety of treatment.

The results of this study will be published, for example, in medical journals or online, but you will not be mentioned in a way that would allow the public to find out who you are. Researchers, such as those from other companies and universities, may ask to use information from this study, including your information, for other medical, health or scientific research. Researchers may combine the results from this study with results from other studies. Any disclosure of study data for scientific purposes will only be made in an anonymous form, i.e. no conclusions can be drawn about you as an individual, and in accordance with this document. You have the right to object to the use of your data for this additional research for reasons specific to you. If you wish to object to such use, please contact the study team with you App-ID.

Your coded study data information will not be sent outside the European Economic Area (EEA).

If you would like a copy of the Binding Corporate Rules, please contact the study team first. You can also contact the responsible data protection officer:

Contact details: datenschutzbeauftragter@ur.de

If you are not satisfied with the answers you receive, or in the event of violations, you have the right to complain to the relevant supervisory authority:

Der Bayerische Landesbeauftragte für den Datenschutz (Bavarian State Commissioner for Data Protection)
Postfach 22 12 19
80502 München
poststelle@datenschutz-bayern.de
https://www.datenschutz-bayern.de/

10. WHOM SHOULD I CONTACT IF I NEED MORE INFORMATION OR HELP?

If you have any questions or need clarifications for this study or in case of any side effects, feel free to contact one of the study team whose contact details are on the first page of this document.

You have the right to ask questions at any time about the potential risks of this study. **Your participation in this study is voluntary and can be revoked at any time during the study period without giving reasons and without serious disadvantages for you.**