

# PARTICIPATION INFORMATION SHEET

## Tackling tinnitus: An Internet-based intervention for tinnitus

### INTRODUCTION

You are being offered the opportunity to participate in a research study, due to having tinnitus. This information sheet is designed to help you decide whether you would like to take part. Please take the time to read the information and discuss it with friends, relatives, your GP or the study team, if you wish. Our contact details are on the last page if you would like any further information. This application has been reviewed by the Cambridge South Research Ethics Committee, under the REC reference number: 16/EE/0148. The IRAS project identification number is 195565.

### WHAT IS THIS RESEARCH ABOUT?

Experiencing tinnitus can be very bothersome and interfere with many aspects of daily life. Although there is no cure for tinnitus, research has identified strategies that can help people better manage their tinnitus. Research has also shown that many people with tinnitus, are not always able to access tinnitus services. To provide additional support to individuals with tinnitus, the Tackling Tinnitus programme was developed. This is an Internet-based intervention for tinnitus, which can be compared to an e-learning programme. The information provided is similar to that received at a tinnitus clinic, but the delivery of the information is different. Instead of going to a clinic to receive information about tinnitus, you receive it online. This research is designed to evaluate the effectiveness of this programme, by comparing it to services offered within three NHS Audiology departments, namely Norfolk and Norwich Universities Hospitals, Milton Keynes University Hospital, and Hinchingsbrooke Health Care NHS Trust.

### WHO IS ELIGIBLE TO TAKE PART?

To partake, you need to be 18 years or over and attend one of the hospitals involved in this study. You will require access to a computer and the internet and be able to read and type in English. You should not be undergoing any other tinnitus therapy or have any major medical or psychiatric conditions which may hamper your ability to partake in the programme.

## DO I HAVE TO TAKE PART?

Your participation is voluntary and it is your decision whether you want to participate. If you choose not to take part, you will still receive an appointment to go to the tinnitus clinic at your hospital.

If you would prefer another form of support, there are some options in the table below:

Other support	Description	Contact details
British Tinnitus Association (BTA)	A charity supporting those experiencing tinnitus by providing impartial advice	Tel: 08000180527 <a href="http://www.tinnitus.org.uk/">http://www.tinnitus.org.uk/</a>
Support Forum	Discuss your tinnitus with others that experience tinnitus	<a href="http://www.tinnitus.org.uk/bta-forum">http://www.tinnitus.org.uk/bta-forum</a>
Local tinnitus support groups	Regular educational meetings for those experiencing tinnitus	<a href="http://www.tinnitus.org.uk/groups">http://www.tinnitus.org.uk/groups</a>
BTA shop	Equipment that may help	<a href="http://tinnitus.org.uk/bta-shop">http://tinnitus.org.uk/bta-shop</a>

You are also entitled to withdraw from the study at any time. Your anonymised data collected prior to this point will still be used during statistical analysis unless you ask for all your data to be removed from the analysis.

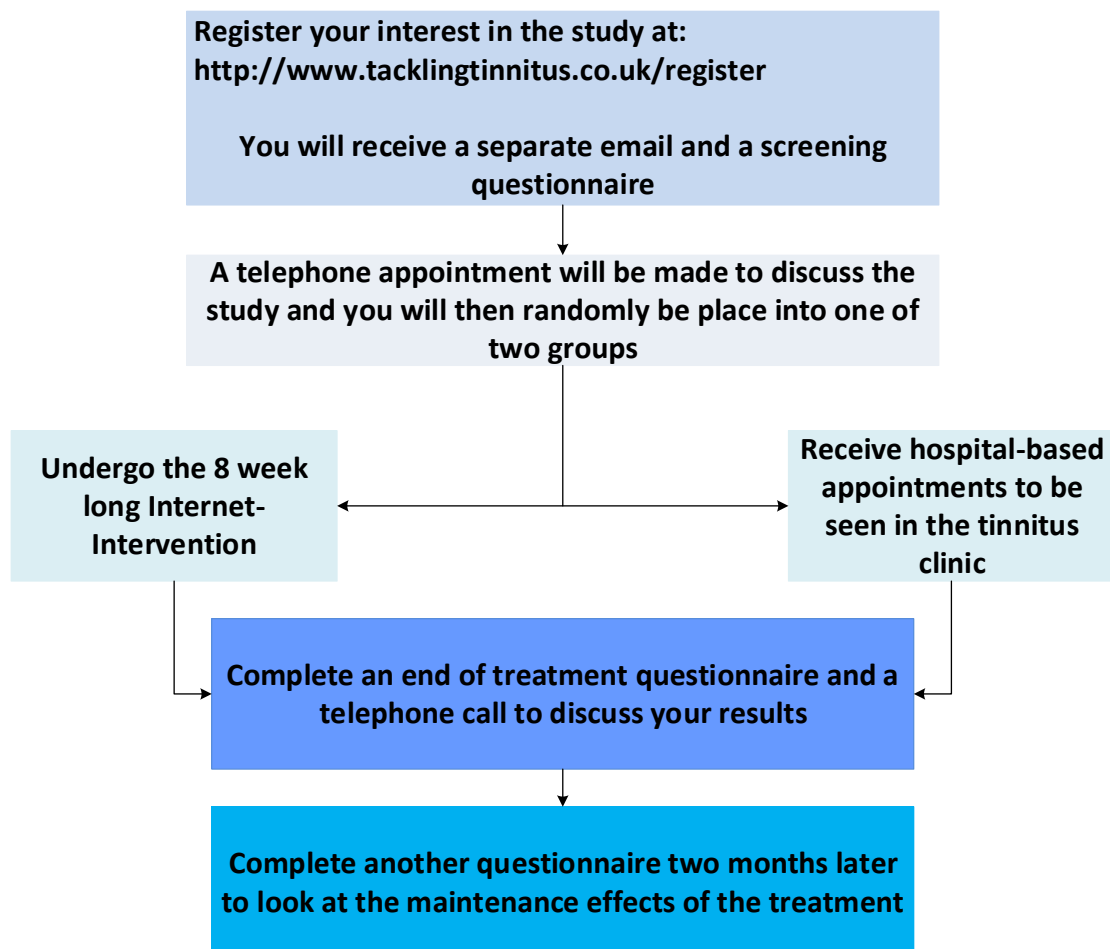
## WHAT ARE THE POSSIBLE BENEFITS OF PARTAKING?

By partaking in this research you will receive a wealth of information about tinnitus and how to manage it. You will be given strategies regarding how to reduce the impact of tinnitus by a qualified Audiologist. Following the study, you will also have access to the treatment stream you were not allocated to.

## WHAT WILL HAPPEN IF I TAKE PART?

If you are interested in participating, you need to register for the study online, by logging onto <http://www.tacklingtinnitus.co.uk/register> and provide consent to partake.

A summary of what the research involves is shown and discussed on the next few pages.



- To find out more about your tinnitus and the effects your tinnitus may have, you will be asked to complete an online screening questionnaire. An example of this is shown on the next page and should take no more than 30 minutes to do.

**\* Do you hear the sounds in time with your pulse or heart beat?**

Yes  
 No

**\* Has the tinnitus sound changed over time?**

Yes  
 No

**\* ...If so please describe:**

- A 10 minute telephone appointment will be made to ensure you are clear on what the research involves and provide the opportunity for you to ask any questions. If you are eligible you will be invited to partake in the study. You can decide if you want to go ahead or not. If you do not fit eligibility, the reasons will be discussed with you and you will receive help for your tinnitus on the standard hospital pathway in the tinnitus clinic.
- If you decide to participate your GP will be notified of your participation. If it is apparent that you require any further help with additional difficulties such as anxiety or depression, this will be discussed with you and your GP may be notified.
- You will be placed by chance (randomly) into one of two groups and be told which group you have been allocated to.
- If you are allocated to receive hospital-based treatment, you will be sent an appointment, during which you will be provided with information about tinnitus and management strategies. These may include sound enrichment advice, sleep management advice, and relaxation advice. A follow-up appointment may be booked.
- If you are allocated to receive internet-based treatment, you will be sent details to login to the website, where you will read about suggested strategies to try. An Audiologist will support you through a messaging system and by telephone as required. The internet programme lasts 8 weeks and includes videos, worksheets, and easily readable information. An example is shown on the next page.

- Relaxation: Step 1 >
- 1. Importance of relaxation >
- 2. Deep relaxation >
- 3. What you require >
- 4. How >
- 5. Demonstration >
- 6. Further help >

## What you require

For this relaxation step you need to think *where* and *when* you can practise using the following as a guide.

### 1. Where to practise deep relaxation

Select somewhere peaceful where you will not be disturbed. Places may include:

- Your bedroom
- The living room
- The kitchen
- The study
- Your garden



### 2. When

You will require two opportunities each day this week to relax for 10-15 minutes.

Ensure you select times when your phone can be switched off and you will not be disturbed.

**Some ideas are:**

- After meals
- Before going to bed
- When waking up
- During your lunch break
- After work



### 3. Requirements

Initially you are going to learn this relaxation technique while sitting on a chair

**Select the chair using the following guidelines:**

## HOW WILL MY PROGRESS BE MONITORED?

- While partaking you will be asked to keep a record of your activities and reflect on your experiences
- You will be sent 10 questions on a weekly basis, which should take less than three minutes to complete
- After receiving your treatment, your progress will be evaluated by an online questionnaire, which should take less than 20 minutes to complete

- To determine the longer-term effects, there will be another online questionnaire two months after completing the treatment. This should take no longer than 15 minutes to complete.

## WILL MY EXPENSES BE PAID?

If you are allocated to be in the hospital treatment group, your travel expenses to and from the hospital during the treatment phase will be covered. This will include any car parking charges.

## WHAT ARE THE POSSIBLE RISKS INVOLVED IN TAKING PART?

### **Are there risks to my confidentiality?**

No, as all the information collected for the research will be kept confidential. Your personal information will only be available to a few members of the research team and the NHS Hospital you attend. This will be destroyed after the study results have been published. All data analysis will also be done using study codes and not using any identifiable information.

### **Will my data be safely stored?**

All information provided by participants will be saved safely at Linköping University, Sweden at the address <https://www.iterapi.se/sites/tinnitusuk>. The reason that the web portal holding the data is in Sweden is due to Linköping University being world leaders in internet interventions. The servers are located in a locked room and all data will be stored encrypted and require passwords to access.

### **What if I run into unforeseen difficulties?**

You are able to contact the researcher through a messaging system at any time or by telephone and assistance will then be provided. Due to the range of expertise from multidisciplinary fields of the research team, including Psychological and Audiological, the team will try to efficiently deal with any difficulties you may experience during the intervention.

## WHAT IF I WANT TO FILE A COMPLAINT?

If you have any enquiries or concerns, please feel free to contact any of the researchers on the team, so that these concerns can be addressed. If your concerns are not dealt with, patient advice and liaison services (PALS) have been introduced to ensure that any concerns regarding your NHS experiences are dealt with appropriately. Contact details to raise concerns are found in the table below.

Organisation	Contact email address	Telephone
Norfolk and Norwich University Hospital PALS services	pals@nnuh.nhs.uk	01603 289036
Milton Keynes University Hospital NHS Foundation Trust PALS services	PALS@mkhospital.nhs.uk	01908 243633
Hinchingbrooke Health Care Trust PALS services	hch-tr.pals@nhs.net	01480 428964
Anglia Ruskin University Complaints services	Jennifer.Powell@anglia.ac.uk	01245 683730

## HOW WILL THE INFORMATION I PROVIDE BE USED?

All data collected during the study may be published in a report, journal or presented at a conference but only in the group or anonymised format. It will also be used in a Ph.D. thesis. The results of the study will also be made available to those who participate.

## WHO IS INVOLVED IN THE RESEARCH?

The research is being carried out by Anglia Ruskin University and Linköping University in Sweden and is supported by a multidisciplinary team as shown below:

ROLE	NAME
Principle Investigator and Audiologist for the Internet intervention	Eldré Beukes (registered Clinical Scientist and Ph.D. researcher)

Advisory Team	Dr. David Baguley (Tinnitus Specialist) and Prof. Gerhard Andersson (Clinical Psychologist) Dr. Vinaya Manchaiah and Prof. Peter Allen (Researchers)
Hearing therapists/ Audiologists at Norfolk and Norwich University Hospitals NHS Foundation Trust	Claire Gatenby, Samantha Nutt, and Alexandra Ryan
Audiologists at Hinchingsbrooke Health Care NHS Trust	Corinne Bailey, Julie Lloyd and Emma King
Audiologist at Milton Keynes, University Hospital NHS Foundation Trust	Rachel Robinson
IT System administrator	George Vlaescu
Research assistants	Alice Davies and Kaneez Sham

## HOW DO I GET FURTHER INFORMATION ABOUT THIS STUDY?

WHERE	HOW
Study website	See <a href="http://www.tacklingtinnitus.co.uk">www.tacklingtinnitus.co.uk</a>
Contacting the research team e-mail	e-mail: <a href="mailto:tinnitusuk@anglia.ac.uk">tinnitusuk@anglia.ac.uk</a> Telephone: 01223-698847
Independent advice	Contact the research team and they will put you in touch with a member of the <u>public-patient involvement group</u> for this study

Thank you for reading this leaflet and considering taking part in the Tackling Tinnitus Study