# Patient and public involvement in the development of user-friendly patient information sheets

Adele Horobin[1], Fred Higton[2], Najibah Mohamad[1,3], Deborah Hall[1,3]

[1] Nottingham Hearing Biomedical Research Unit; [2] Lay assessor for Nottingham Hearing Biomedical Research Unit; 3. Otology and Hearing group, Division of Clinical Neuroscience, School of Medicine, University of Nottingham.

**Nottingham Hearing Biomedical Research Unit**

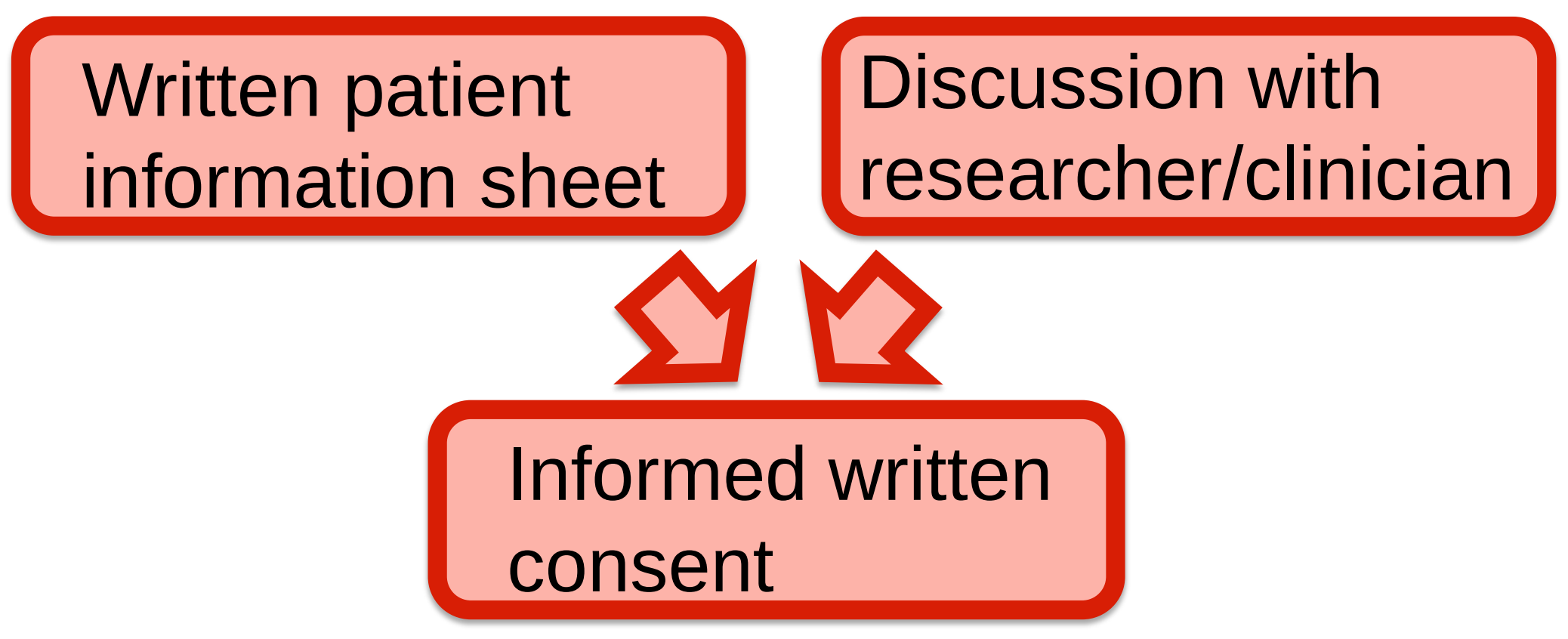
## 1. Patient information sheet – the problem

Some concern has been expressed about the safety of human volunteers in medical research. This includes how well researchers ensure that volunteers can give genuine informed consent.

Studies have shown that trial participants do not always fully understand the trial they have signed up to. Often, the patient information sheet is poorly written, poorly presented or too complex.

## 2. Patient information sheet & informed consent

The patient (or participant) information sheet plays a vital part in ensuring that volunteers can give informed consent before taking part in research.



Written patient information sheet

Discussion with researcher/clinician

Informed written consent

Informed consent to take part in research requires that all volunteers "should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him/her to make an understanding and enlightened decision" *(Nuremburg code, 1947)*.

In practice this means that people should be given information which allows them to understand exactly what the research involves for them before they agree to take part. This includes any harms and benefits.

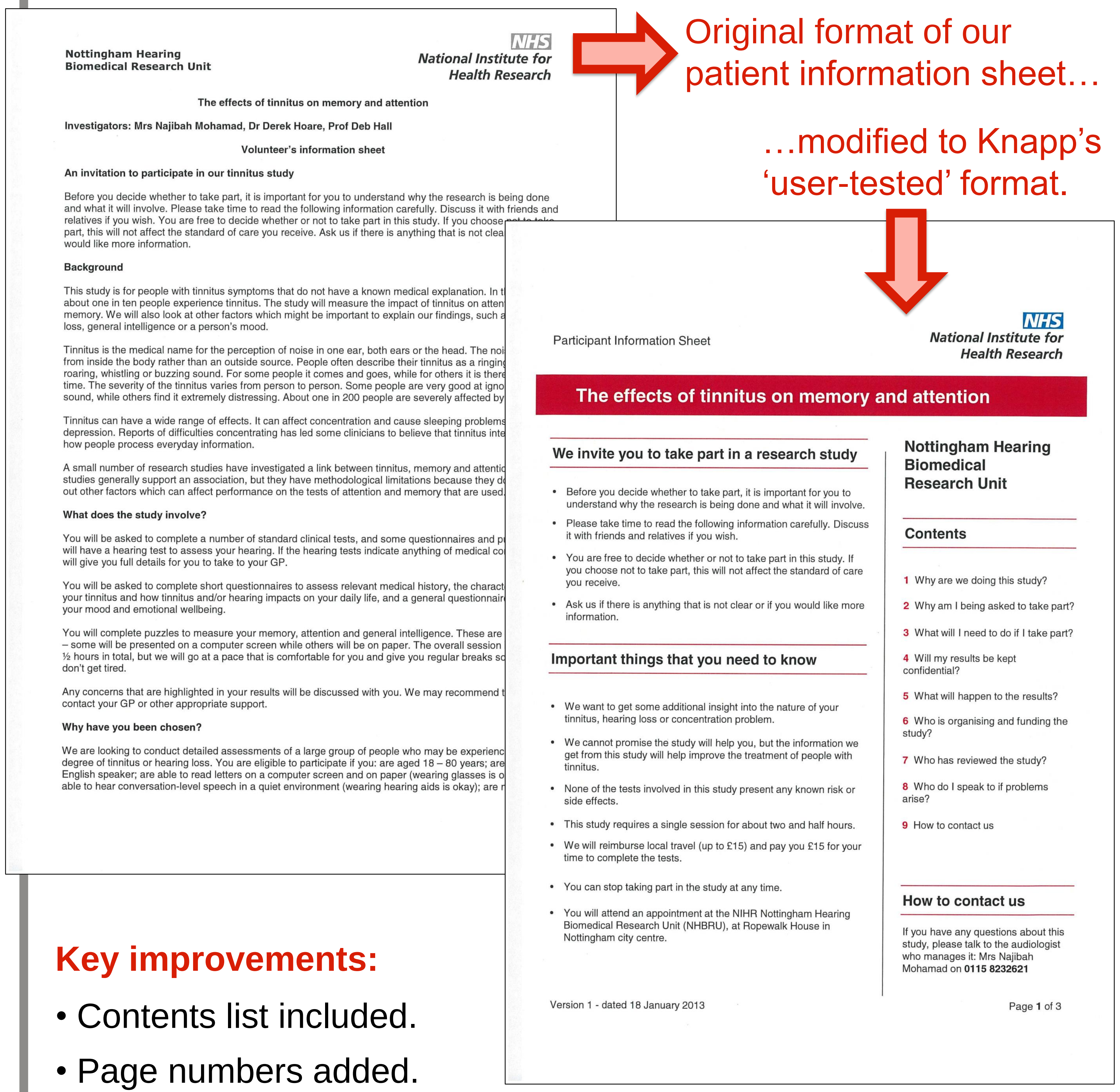
*The Nuremberg Code was developed following the Nuremberg trials of Nazi war criminals. The trials revealed the horrific experiments conducted on prison camp inmates by Nazi doctors. The Code forms the basis for all rules regarding human experiments.*

Photo cc Marion Doss

## 3. Improving the patient information sheet

Knapp and colleagues (2011)* developed a patient information sheet, based on 'performance-based user testing' (how well people pick up on and understand key points in the information).

For our own patient information sheets, we have adopted a similar format of presentation that Knapp and colleagues (2011)* recommended.



Original format of our patient information sheet…

**Nottingham Hearing**
**Biomedical Research Unit**

**The effects of tinnitus on memory and attention**

**Investigators: Mrs Najibah Mohamad, Dr Derek Hoare, Prof Deb Hall**

**Volunteer's information sheet**

**An invitation to participate in our tinnitus study**

Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. You are free to decide whether or not to take part in this study. If you choose
part, this will not affect the standard of care you receive. Ask us if there is anything that is not clea
would like more information.

**Background**

This study is for people with tinnitus symptoms that do not have a known medical explanation. In t
about one in ten people experience tinnitus. The study will measure the impact of tinnitus on atten
memory. We will also look at other factors which might be important to explain our findings, such a
loss, general intelligence or a person's mood.

Tinnitus is the medical name for the perception of noise in one ear, both ears or the head. The noi
from inside the body rather than an outside source. People often describe their tinnitus as a ringing
roaring, whistling or buzzing sound. For some people it comes and goes, while for others it is there
time. The severity of the tinnitus varies from person to person. Some people are very good at igno
sound, while others find it extremely distressing. About one in 200 people are severely affected by

Tinnitus can have a wide range of effects. It can affect concentration and cause sleeping problems
depression. Reports of difficulties concentrating has led some clinicians to believe that tinnitus inte
how people process everyday information.

A small number of research studies have investigated a link between tinnitus, memory and attentic
studies generally support an association, but they have methodological limitations because they d
out other factors which can affect performance on the tests of attention and memory that are used.

**What does the study involve?**

You will be asked to complete a number of standard clinical tests, and some questionnaires and p
will have a hearing test to assess your hearing. If the hearing tests indicate anything of medical co
will give you full details for you to take to your GP.

You will be asked to complete short questionnaires to assess relevant medical history, the charact
your tinnitus and how tinnitus and/or hearing impacts on your daily life, and a general questionnair
your mood and emotional wellbeing.

You will complete puzzles to measure your memory, attention and general intelligence. These are
– some will be presented on a computer screen while others will be on paper. The overall session
½ hours in total, but we will go at a pace that is comfortable for you and give you regular breaks s
don't get tired.

Any concerns that are highlighted in your results will be discussed with you. We may recommend t
contact your GP or other appropriate support.

**Why have you been chosen?**

We are looking to conduct detailed assessments of a large group of people who may be experienc
degree of tinnitus or hearing loss. You are eligible to participate if you: are aged 18 – 80 years; are
English speaker; are able to read letters on a computer screen and on paper (wearing glasses is o
able to hear conversation-level speech in a quiet environment (wearing hearing aids is okay); are r

…modified to Knapp's 'user-tested' format.

Participant Information Sheet

**The effects of tinnitus on memory and attention**

**We invite you to take part in a research study**

- Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve.
- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish.
- You are free to decide whether or not to take part in this study. If you choose not to take part, this will not affect the standard of care you receive.
- Ask us if there is anything that is not clear or if you would like more information.

**Important things that you need to know**

- We want to get some additional insight into the nature of your tinnitus, hearing loss or concentration problem.
- We cannot promise the study will help you, but the information we get from this study will help improve the treatment of people with tinnitus.
- None of the tests involved in this study present any known risk or side effects.
- This study requires a single session for about two and half hours.
- We will reimburse local travel (up to £15) and pay you £15 for your time to complete the tests.
- You can stop taking part in the study at any time.
- You will attend an appointment at the NIHR Nottingham Hearing Biomedical Research Unit (NHBRU), at Ropewalk House in Nottingham city centre.

**Nottingham Hearing Biomedical Research Unit**

**Contents**

**How to contact us**

If you have any questions about this study, please talk to the audiologist who manages it: Mrs Najibah Mohamad on **0115 8232621**

Version 1 - dated 18 January 2013

Page **1** of 3

**Key improvements:**

- Contents list included.
- Page numbers added.
- Headline section on front page, summarising key points.
- Use of clear sub-headings and bullet point lists.
- Greater prominence to contact names and telephone numbers.
- Splitting of text into two columns and use of colour.

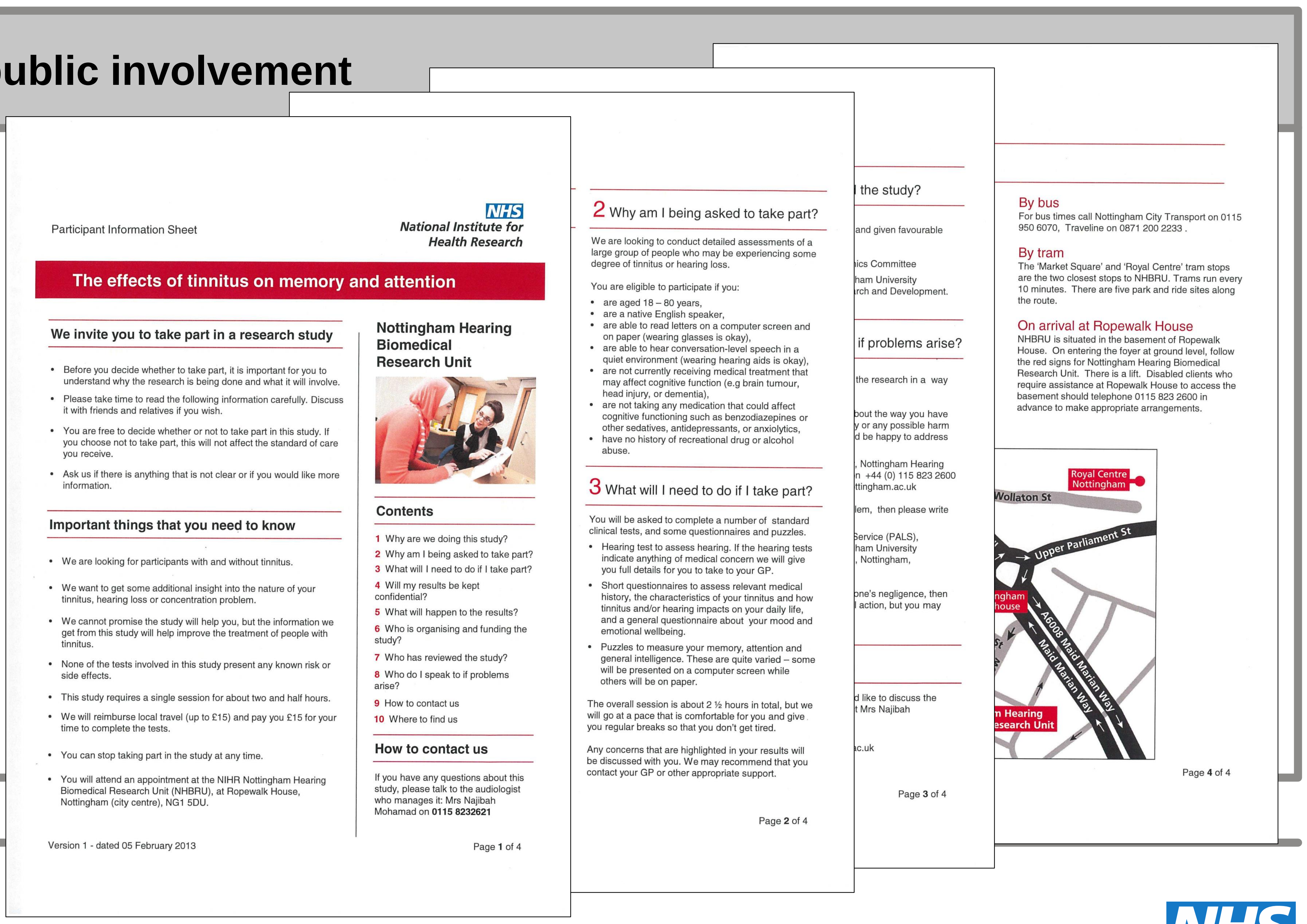
* Knapp P, Raynor DK, Silcock J, Parkinson B (2011) Can user testing of a clinical trial patient information sheet make it fit-for-purpose? – a randomized controlled trial. BMC Medicine 9: 89

## 4. Further improvements through local public involvement

We asked three members of the public to review the content and format of our modified patient information sheet. Their advice resulted in key changes. These changes could be applied to anybody's patient information sheet:

- Including a relevant photo to make the front page look more approachable.
- Including a map, directions, full address and travel advice to help volunteers get to our premises.

We have sought to widen the use of this style of information sheet. In 2014, The Collaboration for Leadership in Applied Health Research and Care (CLAHRC) in the East Midlands adopted our patient information sheet template.



Participant Information Sheet

**The effects of tinnitus on memory and attention**

**We invite you to take part in a research study**

- Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve.
- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish.
- You are free to decide whether or not to take part in this study. If you choose not to take part, this will not affect the standard of care you receive.
- Ask us if there is anything that is not clear or if you would like more information.

**Important things that you need to know**

- We are looking for participants with and without tinnitus.
- We want to get some additional insight into the nature of your tinnitus, hearing loss or concentration problem.
- We cannot promise the study will help you, but the information we get from this study will help improve the treatment of people with tinnitus.
- None of the tests involved in this study present any known risk or side effects.
- This study requires a single session for about two and half hours.
- We will reimburse local travel (up to £15) and pay you £15 for your time to complete the tests.
- You can stop taking part in the study at any time.
- You will attend an appointment at the NIHR Nottingham Hearing Biomedical Research Unit (NHBRU), at Ropewalk House, Nottingham (city centre), NG1 5DU.

**Nottingham Hearing Biomedical Research Unit**

**Contents**

**How to contact us**

If you have any questions about this study, please talk to the audiologist who manages it: Mrs Najibah Mohamad on **0115 8232621**

Version 1 - dated 05 February 2013

Page **1** of 4

**2 Why am I being asked to take part?**

We are looking to conduct detailed assessments of a large group of people who may be experiencing some degree of tinnitus or hearing loss.

You are eligible to participate if you:

- are aged 18 – 80 years,
- are a native English speaker,
- are able to read letters on a computer screen and on paper (wearing glasses is okay),
- are able to hear conversation-level speech in a quiet environment (wearing hearing aids is okay),
- are not currently receiving medical treatment that may affect cognitive function (e.g brain tumour, head injury, or dementia),
- are not taking any medication that could affect cognitive functioning such as benzodiazepines or other sedatives, antidepressants, or anxiolytics,
- have no history of recreational drug or alcohol abuse.

**3 What will I need to do if I take part?**

You will be asked to complete a number of standard clinical tests, and some questionnaires and puzzles.

- Hearing test to assess hearing. If the hearing tests indicate anything of medical concern we will give you full details for you to take to your GP.
- Short questionnaires to assess relevant medical history, the characteristics of your tinnitus and how tinnitus and/or hearing impacts on your daily life, and a general questionnaire about your mood and emotional wellbeing.
- Puzzles to measure your memory, attention and general intelligence. These are quite varied – some will be presented on a computer screen while others will be on paper.

The overall session is about 2 ½ hours in total, but we will go at a pace that is comfortable for you and give you regular breaks so that you don't get tired.

Any concerns that are highlighted in your results will be discussed with you. We may recommend that you contact your GP or other appropriate support.

Page **2** of 4

l the study?
and given favourable
ics Committee
ham University
rch and Development.
if problems arise?
the research in a way
bout the way you have
y or any possible harm
d be happy to address
, Nottingham Hearing
n +44 (0) 115 823 2600
ttingham.ac.uk
lem, then please write
Service (PALS),
ham University
, Nottingham,
one's negligence, then
l action, but you may
d like to discuss the
t Mrs Najibah
ac.uk

Page **3** of 4

By bus
For bus times call Nottingham City Transport on 0115 950 6070, Traveline on 0871 200 2233 .

By tram
The 'Market Square' and 'Royal Centre' tram stops are the two closest stops to NHBRU. Trams run every 10 minutes. There are five park and ride sites along the route.

On arrival at Ropewalk House
NHBRU is situated in the basement of Ropewalk House. On entering the foyer at ground level, follow the red signs for Nottingham Hearing Biomedical Research Unit. There is a lift. Disabled clients who require assistance at Ropewalk House to access the basement should telephone 0115 823 2600 in advance to make appropriate arrangements.

Page **4** of 4

**Dr Adele Horobin** adele.horobin@nottingham.ac.uk

Our thanks go to the members of the public who reviewed our modified patient information sheet.