

# Effect of early intervention for permanent childhood hearing impairment on outcome at secondary school age

<b>Submission date</b> 22/03/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/03/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/04/2018	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

Effect of early intervention for permanent childhood hearing impairment on outcome at secondary school age: a non-randomised observational study

### Acronym

Hearing Outcomes in Teenagers

### Study objectives

A follow up study of teenagers with hearing impairment and a comparison group of normally hearing teenagers, who participated in the first phase of this research in 2002-2004. This study will explore the impact of screening for hearing impairment at birth, and early confirmation of hearing impairment, on speech, language, behavioural, social and educational outcomes in the teenagers with hearing impairment.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Southampton and South West Hampshire REC (A), 14th September, ref: 201010/H0502/71

### Study design

Non-randomised observational study

### Primary study design

Observational

### Secondary study design

Non randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Prevention

### Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Permanent childhood hearing impairment

### Interventions

The participants will complete questionnaires and standardised tests assessing their receptive and expressive language, reading comprehension and accuracy, non-verbal intelligence, quality of life, health, everyday behaviour, and theory of mind. This will be supplemented by

information from their parents regarding their adaptive behaviour, quality of life, health, everyday behaviour, speech, economic costs and demographic factors. A subset of participants will also provide information on their social functioning through a semi-structured interview. Outcomes on these measures for early- and late-identified deaf teenagers will be compared, and data from the previous phase of this research will be used to look at speech, language and literacy outcomes longitudinally.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Reading comprehension- Single testing session

**Secondary outcome measures**

Questionnaires and standardised tests to assess:

1. Receptive and expressive language
2. Quality of life, health, everyday behaviour and theory of mind

**Overall study start date**

01/02/2011

**Completion date**

01/08/2012

## Eligibility

**Key inclusion criteria**

1. Male & Female, upper age limit 18 years, lower age limit 13 years
2. One of the children with bilateral permanent childhood hearing impairment (PCHI) > 40 dB in the 1992-1997, Wessex and Greater London birth cohort of 157,000 that was previously invited to take part in the Hearing Outcomes Project
3. One of the comparison group of children with normal hearing from the same birth cohort who were previously invited to take part in the Hearing Outcomes Project

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

13 Years

**Upper age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 144; UK Sample Size: 144

**Key exclusion criteria**

1. Severe, active illness precluding participation in this project
2. A known post-natal cause of the PCHI (e.g. meningitis)

**Date of first enrolment**

01/02/2011

**Date of final enrolment**

01/08/2012

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Mailpoint 806**

Southampton

United Kingdom

SO16 6YD

## Sponsor information

**Organisation**

Southampton University Hospitals NHS Trust (UK)

**Sponsor details**

Tremona Road

Southampton

England

United Kingdom

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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/0485axj58>

# Funder(s)

## Funder type

Research council

## Funder Name

Wellcome Trust (UK) (grant ref:no:089251/Z/09/Z)

## Alternative Name(s)

## Funding Body Type

Private sector organisation

## Funding Body Subtype

International organizations

## Location

United Kingdom

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2016		Yes	No
<a href="#">Results article</a>	results	24/02/2018		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No