

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

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

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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

SO16 6YD

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?
Results article	results	01/01/2016		Yes	No
Results article	results	24/02/2018		Yes	No
HRA research summary			28/06/2023	No	No