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Cost-effectiveness of screening for permanent hearing loss in children at school entry

Submission date
25/04/2012

Recruitment status
No longer recruiting

Registration date
27/04/2012

Overall study status
Completed

Last Edited
23/03/2017

Condition category
Ear, Nose and Throat

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This study asks questions about the screening programme to identify permanent hearing loss in children when they start primary school; is it necessary, is the cost of such a screen appropriate for the outcomes achieved i.e. the number of children identified by this method compared with a system with no screen; and if it is to be done, which of two different ways of doing the screen is better?
These questions are very relevant as previous research has shown that the number of children identified by this screen around age 5 is low, perhaps only 1 child in every 3000 children tested. This is because all newborn babies are offered hearing screening at birth and there is a good system in place to respond to professional and parental concerns at any age so children who have a hearing impairment are very likely to be identified before they reach school age.
The aims of this project are evaluation of the diagnostic accuracy of hearing screening tests and the cost-effectiveness of screening for hearing impairment at school entry. We propose a series of five related studies.

Who can participate?
Study 1:
1. Case children aged 4-6 years with a confirmed permanent hearing loss
2. Control children aged 4-6 years with no identified hearing loss
Study 2:
All children aged 4 years or older referred to the 2nd tier audiology service in Cambridgeshire from October 2007 to June 2014
Study 3:
All children referred to the Nottingham Audiology Service as a result of failing the school entry hearing screen, and their parents
Study 4:
All children in the reception classes of participating schools in Nottinghamshire

What does the study involve?
Study 1 will look at which of two different ways of doing the screen is more accurate in correctly identifying children with and without a hearing loss. We will recruit 80 children in the East Midlands, aged 4-6 years, who have a known permanent hearing loss, assessed and documented

by pure tone audiometry (PTA) and invite them to undergo 2 screening tests either at home or in research facilities in Nottingham. A second group of children aged 4-6 with no identified hearing loss will be recruited from local schools and invited to attend the research facilities to have their hearing assessed by 2 screening methods and by PTA.
Study 2 will ask whether having a screen is more effective than not having one. There has been no routine school entry screen since 1997 in parts of Cambridgeshire. We will collect data on age, level and probable cause of hearing loss, referral route and number and type of assessments and interventions for all children 4 years old and above who have been referred to the audiology service since October 2007.
Study 3 will collect the same information for all children referred over one year to the Nottingham Audiology service as a result of failing the routine school screen. To look at what it means for children and families referred by the screen and subsequently confirmed to have a hearing loss (true positives) or not (false positives), we will ask families to complete questionnaires. Another important issue is the impact of a child passing the screen but later being found to have a hearing loss. We will address this by reviewing the existing records.
In study 4 we will measure the resources used and practical implications of using the 2 screening methods in real-life situations in schools.
Study 5 will use the data collected and information from previous research to look at the cost-effectiveness of all aspects of the screening programme and make recommendations for its future use.
The research team includes both NHS staff contributing clinical knowledge and university staff contributing research and methodological expertise.

What are the possible benefits and risks of participating?
If any child in study 1 is found to have a previously unknown hearing loss they will be offered a referral for a full assessment of their hearing. All children taking part in studies 3 and 4 will receive the routine care they would normally receive.
There are no risks to any of the children or their families taking part in these studies.

Where is the study run from?
Study 1: Hearing-impaired children are recruited from 14 hosptials in England and non-hearing-impaired children recruited from 51 schools in Nottingham and Nottinghamshire (UK)
Study 2 and 3: Cambridge (UK)
Study 4: Seven schools in Nottingham (UK)

When is the study starting and how long is it expected to run for?
July 2012 to February 2016

Who is funding the study?
National Institute for Health Research, Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Mara Ozolins

Contact information

Type(s)
Scientific

Contact name
Dr Mara Ozolins

Contact details
National Biomedical Research Unit in Hearing (NBRUH)
Ropewalk House
113 The Ropewalk
Nottingham
United Kingdom
NG1 5DU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA: 10/63/03

Study information

Scientific Title
The diagnostic accuracy of hearing tests and cost-effectiveness of school entry hearing screening programmes

Study objectives
Study aims:
1. To determine and compare the diagnostic accuracy of two methods for screening for the identification of permanent hearing impairment at or around school entry i.e. pure tone sweep audiometry across 4 frequencies and 1 level, and the HearCheck pure tone screen with 2 fixed frequencies and 3 levels
2. For a service with a routinely applied school entry hearing screen (SES) and a service with no SES, to compare the yield, referral age and route through assessment to intervention for permanent childhood hearing impairment and to measure the costs of referrals
3. To evaluate the effectiveness and cost effectiveness of screening for hearing impairment relative to no implementation of a universal screen at school entry through an economic model
4. To explore the impact for the child and the family of a positive result from a screen (both true and false positives) resulting in referral for further assessment
5. To determine the resource costs in implementing the two alternative screening methods in primary schools
6. To develop an existing SES economic model and synthesise the findings of studies 1-4 in order to provide robust estimates of key parameters in the economic model. In particular the yield and nature of hearing loss detected in a system with no SES; the yield, consequences and costs of screen positive individuals in an SES system; and the costs of setting up an SES system

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - Staffordshire, 21/08/2012, ref: 12/WM/0195

Study design
Observational: case-control study (study 1), retrospective and prospective cohort studies (study 2&3), practical implementation (study 4), health economic modelling (study 5)

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Other

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Permanent sensorinerual or conductive hearing loss

Interventions
Study 1 will look at which of two different ways of doing the screen is more accurate in correctly identifying children with and without a hearing loss. Given the small numbers, it would need a very long and expensive study to do this in a prospective randomised control trial. We propose therefore to conduct this part of the research as a case-control study, simply assessing the accuracy of the two tests. We will recruit 80 children in the East Midlands, aged 4-6 years, who have a known permanent hearing loss, assessed and documented by pure tone audiometry (PTA, the gold standard) and invite them to undergo two screening tests either at home or in research facilities in Nottingham. A second group of children aged 4-6 with no identified hearing loss will be recruited from local schools and invited to attend the research facilities to have their hearing assessed by 2 screening methods and by PTA. Recruitment will occur in school terms from October 2012 to July 2014 and children will be invited fo rassessment in the School holidays over the same period.

Study 2 will ask whether having a screen is more effective than not having one. There has been no routine school entry screen since 1997 in parts of Cambridgeshire. We will collect data on age, level and probable cause of hearing loss, referral route and number and type of assessments and interventions for all children 4 years old and above who have been referred to the audiology service since October 2007. Anonymised data will be analysed retrospectively for data collected from October 2007 to June 2012 and prospectively for data collected from July 2012 to June 2014.

Study 3 will collect the same information for all children referred over the period September 2012 to December 2013 to the Nottingham Audiology service as a result of failing the routine school screen. To look at what it means for children and families referred by the screen and subsequently confirmed to have a hearing loss (true positives) or not (false positives), we will ask families to complete questionnaires. Another important issue is the impact of a child passing

the screen but later being found to have a hearing loss. We will address this by reviewing the existing literature.

In study 4 we will measure the resources used and practical implications of using the 2 screening methods in real-life situations in schools between November 2012 and June 2013.

Study 5 will use the data collected and information from previous research to look at the cost-effectiveness of all aspects of the screening programme and make recommendations for its future use.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Study 1:
For both screening tests will be a pass or refer as defined by the protocol compared with the result of the gold-standard pure-tone audiogram which provides a measure of hearing level on the decibel scale.

Study 2
Age of referral

Study 3
Age at referral and the costs both to the service and the families of referral through to definitive identification of hearing loss or discharge

Study 4
The mean cost per child of implementing each of the two test technologies. Costs will include the staff type, grade and time taken in conducting the test plus the cost of the equipment. For the purposes of this study we will assume that all other things between the two tests are equal i. e. travel time of screening to visit the school, set up time to organise the children etc.

Secondary outcome measures
Study 2: The incidence of newly identified hearing loss in children, the referral route and aetiology of any hearing loss

Overall study start date
01/07/2012

Completion date
28/02/2015

Eligibility

Key inclusion criteria

Study 1:
1. Case children aged 4-6 years with a confirmed sensorineural or permanent conductive hearing loss either bilaterally (up to 60dB) or unilaterally (any level)
2. Control children aged 4-6 years with no identified hearing loss

Study 2:
All children aged 4 years or older referred to the 2nd tier audiology service in Cambridgeshire from October 2007 to June 2014

Study 3:
All children referred to the Nottingham Audiology Service as a result of failing the school entry hearing screen, and their parents

Study 4:
All children in the reception classes of participating schools in Nottinghamshire

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
6 Years

Sex
Both

Target number of participants
570

Key exclusion criteria
Children whose parents do not agree to the child taking part (Studies 1 and 4)

Date of first enrolment
19/02/2013

Date of final enrolment
14/08/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Children’s hearing assessment centre
Ropewalk House
113 The Ropewalk
Nottingham
United Kingdom
NG1 5DU

Study participating centre
Children's Audiology Clinic & Repair Centre
Hearing Support Service
Comet Way#
Coalville
Leicester
United Kingdom
LE67 3FS

Study participating centre
Sheffield Children’s Hospital
Western Bank
Sheffield
United Kingdom
S10 2TH

Study participating centre
Derbyshire Children’s Hospital
Children’s audiology
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Lincoln County Hosptial
Audiology
Greetwell Road
Lincoln
United Kingdom
LN2 5QY

Study participating centre
Special Needs Teaching Service
New Parks House
Pindar Road
Leicester
United Kingdom
LE3 9RN

Study participating centre
King's Treatment Centre
Children's audiology
Mansfield Road
Sutton in Ashfield
United Kingdom
NG17 4JL

Study participating centre
Chesterfield Royal Hospital
Children's Hearing Services
Calow
Chesterfield
United Kingdom
S44 5BL

Study participating centre
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Rotherham Hospital
Primary Ear Care Centre and Audiology Services
Moorgate Road
Rotherham
United Kingdom
S60 2UD

Study participating centre

Heartlands Hospital
ENT/Hearing Dept
Bordesley Green East
Birmingham
United Kingdom
B9 5SS

Study participating centre
Hinchingbrooke Hospital
Hinchingbrooke Park
Hinchingbrooke
Huntingdon
United Kingdom
PE29 6NT

Study participating centre
Birmingham Children's Hospital
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

Study participating centre
Doncaster Royal Infirmary
Paediatric Hearing Services, Children's Outpatients
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Parkdale Primary School
Parkdale Road
Carlton
Nottingham
United Kingdom
NG4 1BX

Study participating centre
Central Infant and Nursery School
Foxhill Road

Carlton
Nottingham
United Kingdom
NG4 1QS

Study participating centre
Westdale Infant School
Digby Avenue
Westdale Lane
Mapperley
Nottingham
United Kingdom
NG3 6ET

Study participating centre
Butlers Hill Infant and Nursery School
Broomhill Road
Hucknall
Nottingham
United Kingdom
NG15 6AJ

Study participating centre
Arnbrook Primary School
Bestwood Lodge Drive
Arnold
Nottingham
United Kingdom
NG5 8NE

Study participating centre
Sacred Heart Primary School
Southcliffe Road
Carlton
Nottingham
United Kingdom
NG4 1EQ

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
c/o Mr Paul Cartledge
Research Operations
Kings Meadow Campus
Lenton Lane
Nottingham
England
United Kingdom
NG7 2NR

Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment programme - HTA (UK) ref:10/63/03

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

The datasets generated during and/or analysed during the current study are available upon request from Prof. Chris Hyde (C.J.Hyde@exeter.ac.uk)

Intention to publish date
31/05/2016

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	01/05/2016		Yes	No