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Interventions for mild to moderate permanent childhood hearing impairments identified by neonatal hearing screening

Submission date 25/04/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/04/2003	**Overall study status** Completed	
Last Edited 24/07/2012	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol
Not provided at time of registration

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 98/39/02

Study information

Scientific Title

Study objectives
1. To determine by a prospective, longitudinal clinical trial the effectiveness and cost effectiveness of habilitation, including amplification, for children with mild to moderate hearing impairment.
2. To assess the appropriateness of earlier rather than later amplification in this group of children by randomly varying the age at which amplification is introduced into the habilitation. Major outcomes include acceptance, benefit and use of amplification, development of speech, language and communication, quality of life and quality of family life including social, emotional and behavioural aspects.
3. To determine the most cost-effective target criteria for the UK national universal neonatal hearing screening programme.

Strand 1: Qualitative workshops to determine
i. An agreed set of principles for the development of protocols for the clinical trial
ii. Current practice and beliefs of professionals and parents to refine the range of clinical equipoise necessary for an RCT in this area
iii. The best recruitment strategies for districts and families
iv. The best ways to provide family support using health and education services
v. Ways of minimising family anxiety about early screening and intervention
vi. Optimum early initial amplification fitting strategies and fine tuning procedures.
Strand 2: A clinical trial of intervention for mild to moderately hearing impaired children identified by neonatal screening with randomised allocation to groups 1-3 based on the age at which hearing aids are fitted (1=6 months, 2=11-13 months, 3=17-19 months) compared with comparison groups 4-6 (4=mild to moderate hearing impaired detected at 24-36 months, 5=moderate hearing impaired children detected and aided early, 6=normal hearing). The trial will be carried out at children's hearing services in UK districts using targeted or universal neonatal hearing screening.

Details of this study can also be found at: http://www.hta.ac.uk/project/1238.asp

Please note that, as of 17 January 2008, the start and end date of this trial have been updated from 1 April 2000 and 1 April 2005 to 1 April 2001 and 31 October 2007, respectively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Longitudinal clinical trial

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Ear, nose and throat diseases

Interventions
An intervention package for children with mild to moderate hearing impairment will be assessed for appropriateness, effectiveness and cost effectiveness. The package has two components:
i. Quality family support, including personal support and an information package on hearing loss and language development (in written and video form)
ii. Appropriate amplification at an age that is randomly assigned in the region of clinical equipoise.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The societal costs (direct and indirect) associated with the different interventions will be estimated together with the associated benefits in terms of quality of life (including quality of family life and detailed behavioural and emotional aspects of development). The major outcomes assessed on 4 occasions (ages 9-12, 15-18, 21-24 months and final visit) will be (i) compliance with amplification, (ii) expressive and receptive speech and language (iii) QoL for child and family and (iv) behavioural and emotional measures. Costs will be estimated in a similar way to those in our present studies assessing outcomes in UK children who have had a cochlear implant or a hearing aid.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/04/2001

Completion date
31/10/2007

Eligibility

Key inclusion criteria

Children identified with permanent mild or moderate hearing impairment by neonatal screening.

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
Not provided at time of registration.

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/04/2001

Date of final enrolment
31/10/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Institute of Hearing Research
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Sponsor information

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Sponsor type
Government

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ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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