

A randomised controlled trial of speech and language therapy (SLT) for pre-school children

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/02/2010	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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
C/PHYSDIS/02/05-10-94/ENDERBY/D

Study information

Scientific Title

Study objectives

To compare the progress made by children during a 12 month period of watchful waiting with that made by the children who had immediate access to therapy.

The study will recruit 372 subjects, standardised speech and language tests will assist to stratify the subjects in order to examine the outcomes of different sub-groups. A taped speech and language sample will be analysed blind to test the validity of the findings on the standardised procedures.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 15/01/10 (see publication):

Local research ethics committees for the three participating healthcare trusts gave approval for the trial

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Behavioural disorders

Interventions

1. Children received conventional Speech and Language Therapy provided in the community clinics
2. Watchful waiting - i.e. no therapy

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Four quantitative measures of speech and language assessed at 6 and 12 months; a binary variable indicating improvement, by 12 months on the entry criterion

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/05/1995

Completion date

31/07/1999

Eligibility

Key inclusion criteria

159 pre-school children with significant speech and/or language difficulties who fulfilled entry criteria for admission to Speech and Language Therapy and whose parents consented for them to participate.

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

159

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/05/1995

Date of final enrolment

31/07/1999

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Frenchay SLT Research Unit
Bristol
United Kingdom
BS16 1LE

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
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+44 (0)20 7307 2622
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Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive South West (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results on parents views	01/07/2000		Yes	No
Results article	results	14/10/2000		Yes	No
Results article	results of parent views	01/10/2001		Yes	No
Results article	results on scale to measure parent views	01/10/2001		Yes	No
Other publications	evaluation of multimethod approach	01/11/2002		Yes	No
Results article	results	01/07/2003		Yes	No