

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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Sex

All

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**

United Kingdom

England

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)

Funder(s)

Funder type

Government

Funder Name

NHS Executive South West (UK)

Results and Publications

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
Results article	results	01/07/2003		Yes	No
Other publications	evaluation of multimethod approach	01/11/2002		Yes	No