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

Submission date	Recruitment status  No longer recruiting	Prospectively registered		
23/01/2004		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/01/2004	Completed	[X] Results		
<b>Last Edited</b> 10/02/2010	Condition category  Mental and Behavioural Disorders	[] Individual participant data		

## Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Prof Sue Roulstone

#### Contact details

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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

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### 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 artic	e results on parents views	01/07/2000	Yes	No
Results artic	<u>e</u> results	14/10/2000	Yes	No
Results artic	e results of parent views	01/10/2001	Yes	No
Results artic	e results on scale to measure parent views	01/10/2001	Yes	No
Results artic	<u>e</u> results	01/07/2003	Yes	No
Other public	ations evaluation of multimethod approach	01/11/2002	Yes	No