

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

**Submission date**

23/01/2004

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

23/01/2004

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

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**

Frenchay SLT Research Unit

Frenchay Hospital

Frenchay Park Road

Bristol

United Kingdom

BS16 1LE

+44 (0)117 9701212 x2294

sue@speech-therapy.org.uk

## 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  
SW1A 2NL  
+44 (0)20 7307 2622  
dhmail@doh.gsi.org.uk

### **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?
<a href="#">Results article</a>	results on parents views	01/07/2000		Yes	No
<a href="#">Results article</a>	results	14/10/2000		Yes	No
<a href="#">Results article</a>	results of parent views	01/10/2001		Yes	No
<a href="#">Results article</a>	results on scale to measure parent views	01/10/2001		Yes	No
<a href="#">Other publications</a>	evaluation of multimethod approach	01/11/2002		Yes	No
<a href="#">Results article</a>	results	01/07/2003		Yes	No