

# A randomised controlled trial (RCT) and economic evaluation of direct versus indirect and individual versus group modes of speech and language therapy for children with primary language impairment

**Submission date**

25/04/2003

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

25/04/2003

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

01/04/2022

**Condition category**

Nervous System Diseases

☐ 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**

HTA 99/36/04

## **Study information**

### **Scientific Title**

A randomised controlled trial (RCT) and economic evaluation of direct versus indirect and individual versus group modes of speech and language therapy for children with primary language impairment

### **Study objectives**

1. To compare direct individual therapy (speech and language therapists working with children), indirect individual therapy (speech and language assistants working directly with children), direct group therapy (SLTs working with small groups of children) & indirect group therapy (SLAs working with small groups of children) with regard to the outcomes for school-age children with persistent primary receptive and/or expressive language impairment relative to a comparison group receiving current models and levels of SLT service.
2. To investigate the long-term benefits for such children from their therapy at 12 months follow-up.
3. To compare the four approaches in terms of cost.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **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**

Nervous system diseases: Other nervous system disease

### **Interventions**

1. Direct individual therapy (speech and language therapists [SLTs] working with children)
2. Indirect individual therapy (speech and language assistants [SLAs] working directly with children)
3. Direct group therapy (SLTs working with small groups of children)
4. Indirect group therapy (SLAs working with small groups of children)
5. Current models of standard care

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/04/2002

**Completion date**

30/06/2005

**Eligibility****Key inclusion criteria**

Children with language impairment

**Participant type(s)**

Patient

**Age group**

Child

**Sex**

Both

**Target number of participants**

Not provided at time of registration

**Total final enrolment**

161

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/04/2002

**Date of final enrolment**

30/06/2005

## **Locations**

**Countries of recruitment**

Scotland

United Kingdom

**Study participating centre****Department of Psychology**

Glasgow

United Kingdom

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## **Sponsor information**

**Organisation**

Department of Health (UK)

**Sponsor details**

Quarry House

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**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/en/index.htm>

**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**

Not provided at time of registration

**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>		01/07/2007		Yes	No
<a href="#">Results article</a>		01/11/2009	01/04/2022	Yes	No