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	Recruitment status No longer recruiting	Prospectively registered	
25/04/2003		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
25/04/2003	Completed	[X] 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

Contact name

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Additional identifiers

Protocol serial number 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

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

30/06/2005

Eligibility

Key inclusion criteria

Children with language impairment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

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

United Kingdom

Scotland

Study participating centre Department of Psychology

Glasgow

Sponsor information

Organisation

Department of Health (UK)

ROR

https://ror.org/03sbpja79

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

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?
Results article		01/07/2007		Yes	No
Results article		01/11/2009	01/04/2022	Yes	No