

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

Contact name

Mr James Boyle

Contact details

Department of Psychology

Graham Hills Building

40 George Street

Glasgow

United Kingdom

G1 1QE

+44 (0)141-548 2584

j.boyle@strath.ac.uk

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

G1 1QE

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House

Quarry Hill

Leeds

United Kingdom

LS2 7UE

+44 (0)1132 545 843

Sheila.Greener@doh.gsi.gov.uk

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