Direct versus indirect and individual versus group modes of language therapy for children with primary language impairment: principal outcomes from a randomized controlled trial and economic evaluation
Boyle JM, McCartney E, O'Hare A, Forbes J

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
This study examined the clinical and economic impact of school-based therapy, delivered individually or in groups, by therapists or assistants, for children aged six to 11 years, who had language impairment. The authors concluded that the four therapy modes were equally effective for primary language outcomes, but group therapy delivered by assistants was cheapest. The methods of the clinical part of the study were robust and the conclusions from the cost-consequences analysis appear to be valid.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
This study examined the clinical and economic impact of school-based therapy, delivered individually or to groups, by therapists or assistants, for children aged six to 11 years, who had primary language impairment.

Interventions
The four interventions were direct individual therapy, indirect individual therapy, direct group therapy, and indirect group therapy. These were compared with the usual care, which was community-based, with consultations at school. The intervention was delivered three times a week, in 30 to 40 minute sessions, in mainstream schools, for 15 weeks. Direct therapy was delivered by a speech and language therapist, while indirect therapy was delivered by a speech and language therapy assistant.

Location/setting
UK/community (school).

Methods
Analytical approach:
The analysis was based on a single study with a one-year time horizon. The authors stated that the perspective of the UK National Health Service (NHS) was adopted.

Effectiveness data:
The clinical analysis was based on a prospective, large-scale, blinded, randomised controlled trial (RCT) of 163 children attending mainstream primary schools in Scotland. There were 32 children in the control group and 34 received direct individual therapy, 31 received direct group therapy, 33 received indirect individual therapy, and 33 received indirect group therapy. Two children did not meet the intelligence quotient criterion and were excluded (one from control and one from the indirect group). The inclusion and exclusion criteria were reported in detail, the length of follow-up was 12 months, and an intention-to-treat analysis was conducted. The primary endpoints were the standard scores from the Clinical Evaluation of Language Fundamentals - third edition UK (CELF-3 UK) receptive and expressive subscales and these were assessed at baseline, after approximately six months, and at one year follow-up.

Monetary benefit and utility valuations:
Not considered.
Measure of benefit:
No summary benefit measure was used. The primary outcome measures were changes in the CELF-3<sup>UK</sup> receptive and expressive scores.

Cost data:
The economic analysis included salary and travel costs. The salaries of personnel delivering the therapy were based on the hourly NHS salaries for therapists and assistants. The travel costs for children were calculated using city licensed taxi tariffs for a return journey from the primary school to the therapy location. The travel costs for therapists and assistants were based on the estimated return distance between the city centre and the therapy location. Similar methods were used to calculate the costs for the control group. All costs were in UK pounds sterling (£), for the fiscal year 2004 to 2005, and bootstrapping techniques were used to calculate the average costs.

Analysis of uncertainty:
Not investigated.

Results
The unadjusted CELF-3<sup>UK</sup> receptive score changed from 76.00 at baseline to 76.19 at one year for the control group; from 72.91 to 75.06 for direct individual; from 73.74 to 76.77 for direct group; from 73.09 to 76.64 for indirect individual; and from 72.44 to 75.97 for indirect group therapy. The unadjusted CELF-3<sup>UK</sup> expressive score changed from 70.16 at baseline to 71.81 at one year for the control group; from 67.82 to 71.68 for direct individual; from 68.23 to 74.00 for direct group; from 67.55 to 71.36 for indirect individual; and from 69.78 to 72.97 for indirect group therapy.

No statistically significant difference was observed between treatment groups in these clinical endpoints. There was a statistically significant improvement in the four options pooled together, compared with the control group, at approximately six months follow-up, but this was not statistically significant at one year (there was a trend for a better outcome with the interventions).

The average cost per child was £786 across all therapy modes, with a maximum of £1,144 for direct individual therapy and a minimum of £493 for indirect group therapy. The mean cost in the control group was £181 per child. The cost differences between groups were statistically significant.

The difference in mean costs between indirect (assistant-led) individual and group modes was £407. There was a difference of £517 in favour of group therapy compared with individual therapy. There was a difference of £152 in favour of assistant-led compared with therapist-led treatment.

Authors' conclusions
The authors concluded that the four therapy modes were equally effective for primary language outcomes, but assistant-led group therapy was the cheapest.

CRD commentary
Interventions:
The selection of the comparators was appropriate as the proposed therapy modes were compared against the usual care in the authors' setting. The authors justified their selection of the four modes of therapy, which were defined using published recommendations and previous studies.

Effectiveness/benefits:
A RCT is usually considered to be a valid source of evidence because of its methodological strengths. The randomisation procedure should limit any selection bias and detailed inclusion and exclusion criteria were reported. Power calculations were carried out to ensure that the number of participants was appropriate for capturing the differences in the primary endpoints, between groups. The clinical outcomes were evaluated by qualified speech and language therapists, who were blind to therapy allocation. The selection of the two primary language outcome measures was explained and they appear to have been appropriately chosen for their relevance and their internal consistency. Suitable statistical analyses were used to account for missing data at follow-up.
Costs:
The categories of costs reflected the viewpoint adopted. The resource use was based on detailed data from the RCT, but it was not reported separately from the unit costs, which were from standard UK sources. Appropriate statistical analyses were carried out to assess the significance of the differences in total costs. Regression analyses were also conducted, where necessary. The price year was reported and discounting was not necessary. The economic analysis appears to have been satisfactorily conducted.

Analysis and results:
The study results were clearly reported. The clinical and economic outcomes were not synthesised and a cost-consequences analysis was carried out. No sensitivity analysis was carried out to assess the uncertainty. The authors stated that their results were not easily generalisable to other educational or health systems, due to possible differences in the intensity of programmes and in resource use.

Concluding remarks:
The methods of the clinical part of the study were robust and the authors’ conclusions appear to be valid.

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