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Research Report

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

James M. Boyle[†], Elspeth McCartney[‡], Anne O'Hare[§] and John Forbes[¶]

†Psychology and, ‡Department of Educational and Professional Studies, Division of Speech and Language Therapy, University of Strathclyde, Glasgow, UK

§Department of Reproductive and Developmental Medicine and, ¶Public Health Sciences Section, Division of Community Health Sciences, University of Edinburgh, Edinburgh, UK

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Abstract

Background: Many school-age children with language impairments are enrolled in mainstream schools and receive indirect language therapy, but there have been, to the authors' knowledge, no previous controlled studies comparing the outcomes and costs of direct and indirect intervention delivered by qualified therapists and therapy assistants, and each delivery mode offered to children individually or in groups.
Aims: To investigate the relative effectiveness of indirect and direct intervention therapy modes delivered individually or in groups for children with primary language impairment.
Methods & Procedures: A multi-centre randomized controlled trial investigated 161 children with primary language impairment aged 6–11 years randomized to a usual-therapy control group or to direct individual, indirect individual, direct group or indirect group therapy modes. Intervention was delivered three times a week for 30–40-min sessions in mainstream schools over 15 weeks. Language performance was assessed at baseline, post-therapy and at 12 months. Cost analysis was based on salary and travel costs for intervention modes and usual therapy.

Address correspondence to: James Martin Boyle, Psychology, University of Strathclyde, Graham Hills Building, 40 George Street, Glasgow G1 1QE, UK; e-mail: j.boyle@strath.ac.uk

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Outcomes & Results: Compared with controls, children receiving project therapy made short-term improvements in expressive (p=0.031), but not receptive, language immediately following intervention. Children with specific expressive language delay were more likely to show improvement than those with mixed receptive–expressive difficulties. The four project therapy modes did not differ on primary language outcomes (all p-values>0.392) and there were no further improvements evident at follow-up. Indirect group therapy was the least costly mode, with direct individual therapy the most costly.
Conclusions & Implications: Intervention in this age group can be effective for expressive language and can be delivered equally effectively though speech and language therapy assistants and to children in groups.

Keywords: speech and language therapy, randomized control trial (RCT), developmental language impairment, expressive language, receptive language.

What this paper adds

What is already known on the subject

Speech and language therapy in the UK is delivered via direct individual, direct group, indirect individual and indirect group modes, including via speech and language therapist assistants. Professional bodies have published guidelines on competencies and on the roles that may be allocated to assistants, but there have been to the authors' knowledge no previous controlled studies comparing the outcomes and costs of intervention delivered by speech and language therapists versus speech and language therapist assistants. This omission is problematic in view of the increasing importance of support workers in providing services to children.

What this study adds

The paper reports the findings from a large-scale, blinded, randomized controlled trial of language therapy for primary school-aged children in the UK with well-defined presenting problems, outcomes based upon age-controlled standardized assessments, 12-month follow-up, a manualized, replicable intervention, and an economic evaluation. The findings reveal that the four modes did not differ significantly on language outcomes (all p-values>0.392), but children receiving research therapy made significant gains in expressive language post-therapy relative to a control group receiving on-going community-based therapy (p<0.05), indicating the efficacy of indirect and group modes of language therapy. Indirect group therapy was the least costly mode, with direct individual therapy the most costly.

Introduction

Speech and language delays that cannot be accounted for by non-verbal ability, behavioural or emotional problems, hearing or neurological impairments are the most common neurodevelopmental problems of childhood, affecting some 6% of children (Law *et al.* 2000a). Studies indicate that 30–60% of children with primary language impairment (LI) may experience adverse effects upon school achievement or social, emotional or behaviour problems (Young *et al.* 2002, Rutter *et al.* 1992).

However, while long-term sequelae are likely where problems persist to 5.5 years and beyond (Bishop and Adams 1990, Haynes and Naidoo 1991, Stothard *et al.* 1998), LI is subject to high rates of spontaneous remission of up to 60% in the pre-school years (Law *et al.* 2000a). This uncertainty regarding the longer-term case status of pre-school children with LI poses problems for cost–benefit analyses of the effects of LI and treatment outcomes (Law *et al.* 1998). As a population with clearer case status, children of school-age with marked and persistent LI provide a more stable basis for estimating the both the benefits and economic costs of intervention (Dickson *et al.* 2008) and are the focus of this study.

Speech and language therapy in the UK is delivered in a variety of modes (Department for Children, Schools and Families (DCSF) 2008) with marked heterogeneity of service delivery (Lindsay *et al.* 2008). Many school-age children in the UK with LI are enrolled in mainstream schools, in line with principles of social inclusion (Department for Education and Employment (DfEE) 1997). An earlier national survey showed a predominance of speech and language therapy services in the UK using indirect, consultative approaches (Law *et al.* 2000b).

The research reported here was a response to a commission by the National Institute for Health Research Health Technology Assessment Programme to provide purchasers with information regarding the relative benefits of providing children with LI with language therapy delivered directly by a SLT or indirectly by an SLT assistant (SLTA) to children individually or in groups. The Royal College of Speech and Language Therapists (RCSLT) (1996) uses the term 'assistant' to cover all support workers who do not hold SLT professional qualifications and who work under the direction of a qualified clinician who retains duty of care. Programmes at further education level are being developed for support workers across the UK but no statutory qualification exists. Further increases in the ratio of SLTs to SLTAs are anticipated across the UK.

This mode of service delivery is used internationally to enhance the frequency and intensity of service offered to clients, and to allocate limited resources cost-effectively. Professional bodies have published guidelines on competencies and on the roles that may be allocated to assistants (American Speech–Language–Hearing Association (ASHA) 2007, Canadian Association of Speech–Language Pathologists and Audiologists (CASLPA) 2007, RCSLT 2006, Speech Pathology Association of Australia (SPAA) 2001), but there have been to our knowledge no previous controlled studies comparing the outcomes and costs of intervention delivered by SLTs versus SLTAs. This omission is problematic in view of the increasing importance of support workers in providing services to children.

Potential benefits of working with children with LI in groups have been identified in regard to the efficiency of service delivery (Gains and Smith 1995, Law *et al.* 2000b) and to increasing the children's opportunities for social exchange, increased peer support with resulting increased self-esteem, and the prevention of over-dependence on adults (Marvin 1998).

Research evidence from intervention studies

There are few controlled studies of the efficacy of treatment for children with speech and language delay (Law *et al.* 2004). A search of the four major databases relevant to the study (*Medline*, *PsyInfo*, *ERIC*, and *Linguistics and Language Behaviour*

Abstracts) and of unpublished research was carried out and identified five controlled studies providing evidence of the efficacy of both direct and indirect and group and individual approaches to intervention within the 6–11 years age range (for details, see McCartney *et al.* 2004).

However, there have been no direct comparisons between these therapy modes and although there is evidence indicating that direct and indirect approaches to therapy yield comparable outcomes for expressive language (McCartney *et al.* 2004), there is a dearth of data regarding outcomes for other areas of language within the 6–11 years age group, most notably receptive language.

We evaluated modes of service delivery for this population ensuring treatment fidelity in line with the UK Medical Research Council (MRC) Guidelines for Complex Interventions (MRC 2000) by means of an RCT to determine how direct individual therapy (SLT working individually with a child), indirect individual therapy (SLTA working individually with a child), direct group therapy (SLT working with a small group of children) and indirect group therapy (SLTA working with a small group of children) compare regarding language outcomes for school-age children with persistent primary receptive and/or expressive language impairment relative to a comparison group of children receiving their current model and level of SLT service, mainly via a consultancy approach in their school. We also investigated whether there are long-term benefits for such children from their therapy at 12 months' follow-up.

Method

Design

Following MRC (2000), we utilized RCT methodology with participants randomized to control and intervention modes to eliminate the effects of selection bias. All assessments post-baseline were carried out by SLTs not otherwise connected to the project to eliminate any bias resulting from the expectations of the research team.

Participants

Participants were 161 children with LI attending mainstream primary schools in Scotland (in Glasgow and surrounding areas, or Edinburgh). The pupils were eligible if aged 6–11 years with receptive and/or expressive language scores $\leqslant 1.25$ standard deviation (SD) on the Clinical Evaluation of Language Fundamentals (CELF-3^{UK}) (Semel *et al.* 2000); non-verbal IQ$>$75 on the Wechsler Abbreviated Scale of Intelligence (WASI) (Wechsler 1999); no reported hearing loss; no moderate/severe articulation, phonology or dysfluency problems or otherwise requiring specialist SLT skills; and with informed parent and child consent. The criterion for severity of LI is supported by Tomblin *et al.* (1997), and the inclusion criterion for non-verbal IQ by Plante (1998).

Participants were referred by their local SLT or paediatrician. All were known to SLT services. With 130 randomized to the four research intervention conditions and 31 to the control group, power of 0.80, two-sided tests, and standardized between-group differences in post-intervention scores (i.e. where effect size equals mean post-intervention scores for the groups receiving project therapy minus mean

post-intervention scores for the control group, divided by the pooled standard deviation for the two groups) (Cohen 1988), a main treatment effect of d=+0.56 could be detected between those receiving research intervention relative to controls to determine whether children of this age group, if treated by intensive school-based therapy, make better progress than children who have their usual level of care. With regard to the comparisons between the four research modes, a main effect of d=+0.50 could be detected with power of 0.80.

Intervention

As a Phase III RCT (MRC 2000), the trial aimed to compare fully defined validated intervention to an appropriate alternative, in this case the children's on-going language therapy. In line with Carroll (1997), the manualized intervention developed for the trial specified structural aspects, boundaries of treatment, goals and processes of therapy, and active ingredients of the interventions (McCartney *et al.* 2004). The main areas of language intervention relevant to school-age children were comprehension monitoring, vocabulary, grammar and narrative. The evidence-base for intervention in these areas was identified in the literature searches noted above. The language therapy in the manual (McCartney 2007) was based upon controlled studies on vocabulary development by Hyde-Wright (1993) and on the effectiveness of group-based service delivery by Johnson and Thomas (1995); and upon a cohort study on comprehension monitoring by Johnson (2001), case studies on vocabulary development (Lewis and Speake 1997), grammar (Bryan 1997, Fey and Proctor-Williams 2000), and narrative (Shanks 2000). The therapies were therefore considered to reflect research findings and current UK SLT practice for school-aged children with LI but also reflect the relative paucity of controlled studies for this age group.

Each child received intervention over 15 consecutive weeks in the period August 2001 to June 2002, undertaking three 30–40-min sessions per week. This level of input was based upon the meta-analysis carried out by Law *et al.* (1998), specifically, the median number of hours of therapist time from RCT and quasi-experimental studies, some 20 hours, associated with a overall effect size of +0.97 for expressive language, the largest data set available. The number of sessions per week was also informed by a controlled study of indirect language intervention with small groups of children which indicated that three sessions per week led to more effective outcomes than two sessions (Boyle *et al.* 1995).

Direct therapy was delivered by five qualified SLTs, indirect by five SLTAs under their direction. SLTAs were experienced in working with children and undertook in-service training from the research team; a recognized training course for SLTAs (ELKLAN 2005); observed local SLTAs, and trained on baseline assessments. Individual research intervention took place in the child's school; some children randomized to group mode were transported by taxi to a different school. Control children maintained their ongoing therapy regime.

Outcome measures

Standard scores (mean=100, SD=15) from the CELF-3^{UK}-R (receptive) and CELF-3^{UK}-E (expressive) subscales of the CELF-3^{UK} (Semel *et al.* 2000) were the

primary language outcome measures. These two UK-standardized subscales have high levels of internal consistency reliability (ranging from 0.85 to 0.91 for the receptive and expressive composite scores across the 6–11 years age group) and construct validity ranging from 0.64 to 0.73 (based upon intercorrelations between the receptive and expressive composite scores, again across the 6–11 years age range). The CELF-3^{UK}-R is a composite of three sub-tests measuring understanding of grammar, ability to follow verbal instructions and semantic relationships, and the CELF-3^{UK}-E is a composite of the ability to form and produce meaningful and grammatically correct sentences. All outcome measures were ascertained blind. Pre-intervention standard scores on a secondary outcome measure, the British Picture Vocabulary Scale – Second Edition (BPVS-II) (Dunn *et al.* 1997), a norm-referenced test of receptive vocabulary with good levels of internal consistency ranging from 0.81 to 0.89 for the 6–11 years age range were also combined with the CELF-3^{UK}-R to form a more general composite measure of receptive language ability.

Ethical approvals

Directorates of relevant education departments gave approval and the ethics committees of the relevant National Health Service (NHS) Trusts and of the Strathclyde University Psychology Department granted ethical approval. A Data Monitoring and Ethics Committee monitored progress. The study is registered: International Standard Randomized Control Trial Number ISRCTN94684735.

Procedures

Non-verbal IQ and language assessments were undertaken by the research team under the supervision of the first author before the start of intervention (T1). Language assessments post-intervention (T2) and 12 months post-intervention (T3) were carried out by qualified SLTs blind to therapy mode and not otherwise involved with the study. After informed, written parent and child consent was obtained, eligible children were allocated to mode stratified by city, using random number sequences generated by a statistical consultant via numerically sequenced, sealed envelopes opened by a project secretary.

Statistical methods

T1, T2 and T3 scores on CELF-3^{UK}-R and CELF-3^{UK}-E for direct versus indirect and group versus individual main effects were analysed using analyses of covariance (ANCOVAs) ($\alpha=0.05$), using T1 scores as a covariate. Analyses were on the basis of intention to treat (ITT), and protocol analyses. The ITT analyses here are based upon all of the outcomes from eligible children randomized to conditions irrespective of whether they participated in the intervention programme or whether post-baseline measures are available. Accordingly, missing post-intervention scores for language outcomes were replaced by their pre-intervention baseline equivalents, or T2 scores where available, in the case of T3. This is a conservative approach which minimizes any bias that can arise from participants withdrawing or dropping out of the study by assuming no change in children's post-baseline scores. In

contrast, the protocol analyses were of outcomes for the children for whom post-baseline measures are available.

There was missing data for eleven children in total. Nine were withdrawn by their parents after randomization, and a further two were withdrawn from the 12 months' follow-up assessment having participated in the previous two assessments. The procedures used to deal with the missing data which resulted were as follows.

Four missing T1 pre-intervention BPVS-II scores where children failed to cooperate with the task were imputed by means of Expectation Maximization (SPSS for Windows, Release 13).

Missing post-intervention scores for all language outcome measures at both T2 and T3 for nine children who were withdrawn from the study (three children in the control group, three in the direct group therapy group, and three in the indirect group therapy mode) were replaced by their pre-intervention baseline equivalents.

Finally, missing language outcome scores at the T3 12 months' follow-up for a further two children (twins who were both randomized to indirect individual therapy) were replaced by their T2 post-intervention equivalents.

AMOS 6.0 software (Arbuckle 2005) was used to analyse direct and indirect effects of combined intervention. Specific covariance terms were included in the AMOS model only where evidenced by significant correlations between variables.

Resource use and costs

Salary and travel costs of delivering each therapy mode were estimated. In the UK, SLTs are employees of the NHS. Salary costs were applied to the recorded time therapist and assistants spent preparing and delivering sessions including travel time between intervention locations; end costs were based on NHS salaries (2004/2005) calculated on an hourly basis at the midpoint of the annual gross pay scale for a therapist (UK=£30 270) and assistant (UK=£14 280). Travel costs for children were calculated using city licensed taxi tariffs applied to the cost of a return journey by taxi from primary schools to therapy locations for each session attended. The cost of transport of SLTs and assistants was based on the estimated return journey distance from city centres to therapy locations. We used a comparable method for estimating the costs of providing services in the community for children allocated to the control group.

The full sample method was used to summarize the cumulative distribution of within trial total (therapy and travel) costs arising from the time of randomization to follow-up at T2 using arithmetic mean costs observed for all children. Confidence intervals for estimated untransformed arithmetic mean costs were estimated analytically and empirically using bootstrapping techniques utilizing re-sampling to correct for bias to check for the adequacy of the assumptions made regarding the normality of the cost distributions.

Role of the funding source

The funding source had no involvement in the study design, collection, analysis, or interpretation of data or writing of the report.

Results

Recruitment

A total of 260 children were referred, 145 from Glasgow and surrounding areas and 115 from Edinburgh. A total of 65 parents did not return consent forms, and 195 children were assessed for eligibility. The flow of participants is shown in figure 1.

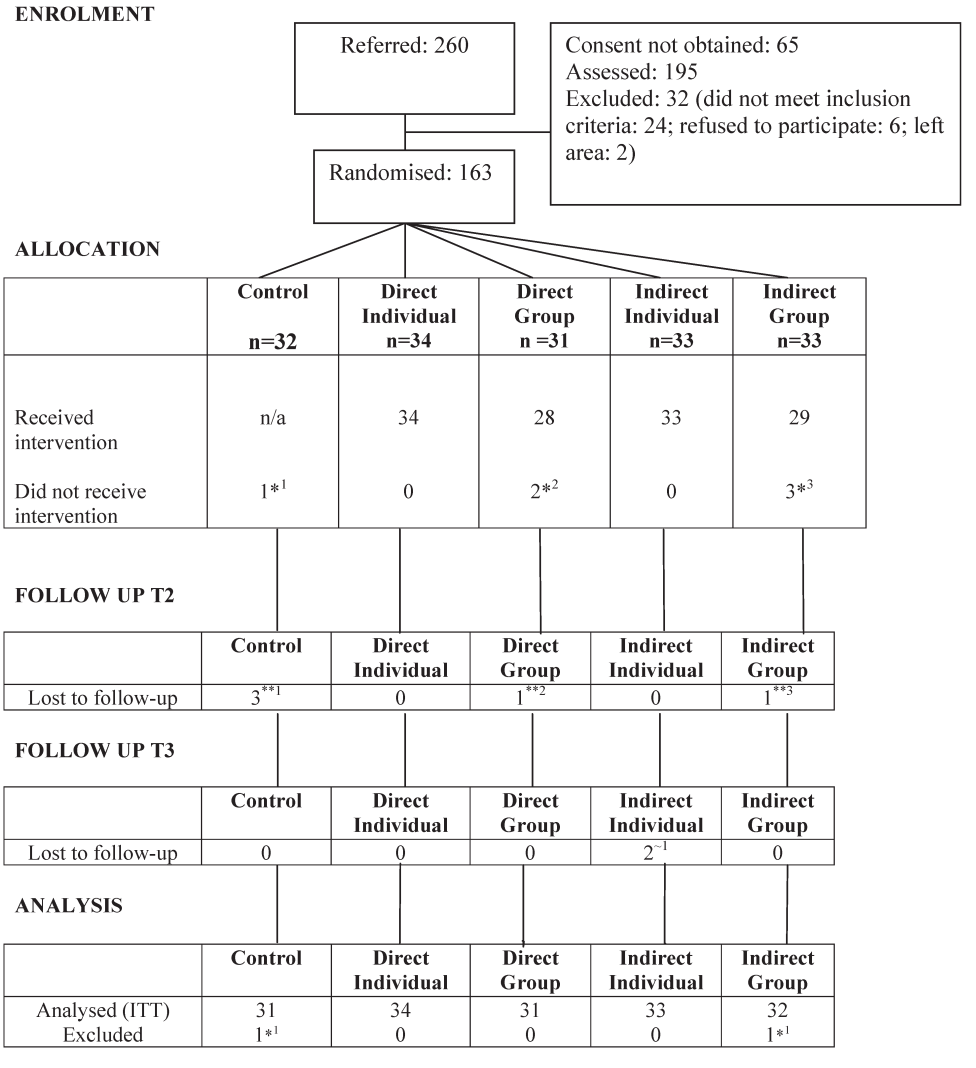

Figure 1. Flow of participants through the trial: *[1]one child was randomized with IQ=75, one point too low; *[2]two children could not be grouped due to age (they were offered limited individual therapy as part of a duty of care but not further included in the study); *[3]two children could not be grouped due to age (they were offered limited individual therapy as part of a duty of care but not further included in the study); one child was randomized with IQ=75, one point too low; **[1]two children were withdrawn from T2 assessments by their parents and one child left the area; **[2]one child was withdrawn from T2 assessment by its parent; **[3]one child was withdrawn from T2 assessment by its parent; and ~[1]two siblings were withdrawn by their parent from follow-up assessments.

Two children randomized were excluded from analysis as their WASI scores were 1 point below the eligibility criterion, yielding a final sample of 161.

Number of therapy sessions

Research intervention could reach a maximum of forty-five 30–40-min sessions over the 15-week period. The mean number of sessions achieved per child was 38.12 (SD=5.28, range=13–45). A total of 63% of children attended 40 or more sessions. Control children undertaking their usual therapy were allocated contacts by their local community SLT services, uninfluenced by the research team. They received very varied amounts of intervention. Between T1 and T2 many control children had little or no contact with an SLT or SLTA, although they may have received ongoing consultancy approaches through their schools. Their average number of contacts with an SLT/A over the course of T1 to T2 was 8.11 (SD=13.38, range=0–59).

Between T2 and T3, no child received therapy from the project. Overall, 152 children randomized were available for follow-up. A total of 36 of the children (five from the control group, ten from the direct individual group, nine from the direct group mode, nine from the indirect individual group and three from the indirect group mode) did not receive any therapy over the T2–T3 period, and one child entered a language unit. The remaining 115 children received a mean of 6.26 contacts (SD=5.34, range=1–26).

Test/re-test intervals

Details of the test/re-test intervals are shown in table 1. The average T1–T2 interval was 6.59 months (SD=1.76, range=2–12 months) and there were significant differences between the project therapy groups in regard to this ($F_{(4,\ 151)}=4.15$, $p<0.003$), the largest being 1.74 months between the control group and the indirect group mode. Bonferroni-adjusted multiple comparisons of the between-condition T1–T2 intervals revealed a consistent underlying pattern. There were no significant differences between the control group and the direct individual and indirect individual conditions (all p-values>0.05) in test/re-test interval, but the interval was significantly shorter in the case of the control group than in the direct group and

Table 1. Details of the mean test/re-test intervals by therapy mode

	Control (n=28)	Direct individual (n=34)	Direct group (n=28)	Indirect individual (n=33)	Indirect group (n=29)
T1–T2					
Mean test/re-test interval (completed months)	5.75	6.35	6.96	6.48	7.49
SD	1.88	1.20	2.28	1.18	1.80
Range	2–9	5–9	3–12	5–12	3–12
T2–T3					
Mean test/re-test interval (completed months)	12.14	12	12	12.13	12.03
SD	0.36	0.25	0.47	0.34	0.33
Range	12–13	11–13	10–13	12–13	11–13

indirect group conditions (all p-values<0.05). Further, the test/re-test interval for the direct individual condition was also significantly shorter than that for the indirect group mode ($p<0.05$). However, there were no between-group differences in the T2–T3 follow-up period (overall mean=12.06 months, SD=0.35, range=10–13 months) ($F_{(4,\ 145)}=1.18$, $p=0.322$).

Language outcome measures

Table 2 shows means and standard deviations for primary language outcome measures and BPVS-II and WASI scores for the 161 participants for each therapy mode for T1–T3. Missing data at T2 and T3 were replaced by their T1 or T2 equivalents, as appropriate. All of the participants began the study with marked problems in expressive language. A total of 75 participants had expressive primary impairment (E-LI), with receptive language above the tenth percentile indexed on an equally weighted composite of CELF-3^{UK}-R and the BPVS-II at T1 (standard score=82 or more). The remaining 86 had mixed receptive–expressive impairment (RE-LI), with delay in both language domains (all scores less than the tenth percentile).

As table 3 reveals, ANOVAs confirmed the five modes showed equivalent scores at baseline for chronological age, WASI and all language measures ($p>0.076$). Significantly more males than females participated (115 versus 46, $\chi^2_{(\text{d.f.}=4)}=13.20$, $p=0.01$) with no significant differences in the proportions of males to females in the direct individual, indirect individual or indirect group modes ($\chi^2_{(\text{d.f.}=2)}=0.93$, $p=0.637$), but significantly fewer females in control and direct group modes than in the other three modes combined ($\chi^2_{(\text{d.f.}=1)}=7.01$, $p=0.008$).

Table 2. Unadjusted means and standard deviation (SDs) for primary language outcome measures, receptive vocabulary and non-verbal IQ (standard scores, mean=100, SD=15) for therapy modes: T1–T3

	Mean baseline scores (SD) at T1				Mean scores (SD) at T2		Mean scores (SD) at T3	
Outcome measure	(BPVS-II)	(WASI)	CELF-3^{UK}-R	CELF-3^{UK}-E	CELF-3^{UK}-R	CELF-3^{UK}-E	CELF-3^{UK}-R	CELF-3^{UK}-E
Therapy mode: control (n=31)	85.45 (7.37)	90.94 (10.13)	76.00 (10.01)	70.16 (4.57)	77.03 (10.00)	70.84 (5.96)	76.19 (11.36)	71.81 (6.05)
Direct individual (n=34)	86.00 (7.98)	89.65 (9.45)	72.91 (9.64)	67.82 (4.27)	75.91 (10.08)	72.59 (9.01)	75.06 (8.36)	71.68 (8.80)
Direct group (n=31)	85.13 (9.22)	90.97 (13.12)	73.74 (8.10)	68.23 (4.45)	76.55 (10.81)	71.87 (6.45)	76.77 (9.91)	74.00 (8.50)
Indirect individual (n=33)	86.00 (8.56)	90.24 (12.23)	73.09 (8.24)	67.55 (4.05)	74.15 (9.03)	71.24 (6.95)	76.64 (10.65)	71.36 (6.08)
Indirect group (n=32)	87.03 (10.82)	89.09 (11.98)	72.44 (9.26)	69.78 (5.42)	75.22 (8.59)	72.34 (7.75)	75.97 (11.91)	72.97 (9.63)

BPVS-II=British Picture Vocabulary (Second Edition).
CELF-3^{UK}-R/E/Total=Clinical Evaluation of Language Fundamentals.
WASI=Wechsler Abbreviated Scale of Intelligence.

Table 3. Gender balance and pre-intervention scores across therapy modes

Variable/ measure	Control (n=31)	Direct: individual therapy (n=34)	Direct: group therapy (n=31)	Indirect: individual therapy (n=33)	Indirect: group therapy (n=32)	Significance levels
Gender						$\chi^2_{(d.f.=4)}=13.20$, $p=0.01$
Male	27	23	27	20	18	
Female	4	11	4	13	14	
Mean CA (months)	97.23	91.85	92.74	96.57	95.87	$F_{(4, 156)}=0.64$, $p=0.365$
SD	15.30	16.19	16.18	20.38	16.82	
Range	74–137	72–126	72–135	72–135	72–131	
Mean WASI NVIQ	90.94	89.65	90.97	90.24	89.09	$F_{(4, 156)}=0.16$, $p=0.958$
SD	10.13	9.45	13.12	12.23	11.98	
Range	76–121	76–121	76–132	76–124	77–123	
Mean BPVS-II SS	85.32	86.00	85.10	86.28	87.06	$F_{(4, 150)}=0.23$, $p=0.932$
SD	7.75	7.98	9.37	8.54	11.00	
Range	67–98	65–108	60–106	67–102	64–112	
Mean CELF-3^{UK}-R	76.00	72.91	73.74	73.09	72.44	$F_{(4, 156)}=0.75$, $p=0.560$
SD	10.01	9.64	8.10	8.24	9.26	
Range	64–99	64–104	64–90	64–98	64–101	
Mean CELF-3^{UK}-E	70.16	67.82	68.23	67.55	69.78	$F_{(4, 156)}=2.16$, $p=0.076$
SD	4.57	4.27	4.45	4.05	5.42	
Range	64–79	64–77	64–80	64–77	64–81	

ANOVAs revealed no differences amongst modes in the number of project therapy sessions delivered ($F_{(3, 120)}<1$), but small, consistent between-group differences in test/re-test intervals ($F_{(3, 120)}=2.84$, $p=0.041$), with the re-test period one month longer on average in group therapy modes.

The first analyses compared the main effects of individual versus group and direct versus indirect research therapy. A series of 2 × 2 ANCOVAs were carried out with the T2 score as dependent variable and the corresponding T1 score as a covariate and also with the T3 score as a dependent variable and the corresponding T2 score as a covariate.

Table 4 shows no significant differences between direct/indirect therapy or individual/group therapy on CELF-3^{UK}-R or CELF-3^{UK}-E scores at either T2 (all F-values<1, all p-values>0.392) or T3 (all F-values<2.46, all p-values>0.119). Therefore, while some participants made sizeable shifts in their adjusted scores at T2 and T3, these were not systematically associated with any specific mode and Cohen's *ds* for each main effect at T2 and T3 with adjustment for the corresponding covariate were all $\leqslant +0.15$, as shown in table 5.

Assuming a power of 0.80, some 699 participants per mode would be required to detect between-mode differences of this order at conventional levels of statistical significance. It is therefore unlikely that sample size here masked clinically significant effects (Gillam *et al.* 2001).

Outcomes at T2 and T3 for the 124 eligible children randomized to research therapy with no imputed scores were analysed with T1–T2 test intervals as an

Table 4. Results from ANCOVAs of the effects of direct versus indirect and individual versus group language therapy upon post-intervention and follow-up primary language scores[a]

Therapy mode	Outcome measure	F (1, 126)	p	ε^2	Adjusted mean difference[b]	95% confidence interval (CI) for difference
Direct versus indirect therapy	CELF-3^{UK}-R T2	0.739	0.392	0.004	+1.247	−1.62/+4.12
	CELF-3^{UK}-R T3	0.868	0.353	0.005	−1.377	−4.30/+1.55
	CELF-3^{UK}-E T2	0.584	0.446	0.004	+0.919	−1.46/+3.30
	CELF-3^{UK}-E T3	0.092	0.762	0.000	+0.356	−1.96/+2.67
Individual versus group therapy	CELF-3^{UK}-R T2	0.306	0.581	0.002	−0.803	−3.67/+2.07
	CELF-3^{UK}-R T3	0.000	0.999	0.000	+0.001	−2.92/+2.92
	CELF-3^{UK}-E T2	0.423	0.517	0.003	+0.789	−1.61/+3.19
	CELF-3^{UK}-E T3	2.459	0.119	0.012	−1.837	−4.16/+0.48

[a]Analyses incorporated the corresponding T1 measure as a covariate in the T2 analyses and the T2 measure as covariate in the T3 analyses.
[b]A positive value denotes a change in favour of direct or individual therapy respectively, while a negative value indicates change in favour of indirect or group therapy.

Table 5. Standardized effect sizes and 95% confidence intervals derived from one-way ANCOVAs for direct versus indirect and individual versus group language therapy for post-intervention T2 and T3 scores for ITT analyses

Therapy mode	Outcome measure	Adjusted standardized effect size (SES)[a]	95% confidence interval (CI) for SES
Direct versus indirect therapy	CELF-3^{UK}-R T2	+0.15	−0.20/+0.50
	CELF-3^{UK}-R T3	−0.004	−0.34/+0.34
	CELF-3^{UK}-E T2	+0.06	−0.29/+0.41
	CELF-3^{UK}-E T3	+0.01	−0.33/+0.35
	BPVS-T2[2]	−0.01	−0.35/+0.33
	BPVS-T3	+0.005	−0.35/+0.35
Individual versus group therapy	CELF-3^{UK}-R T2	−0.08	−0.43/+0.27
	CELF-3^{UK}-R T3[b]	−0.005	−0.34/+0.34
	CELF-3^{UK}-E T2[b]	−0.02	−0.36/+0.32
	CELF-3^{UK}-E T3	−0.02	−0.36/+0.32
	BPVS-T2	−0.10	−0.45/+0.25
	BPVS-T3	+0.01	−0.34/+0.36

[a]Cohen's *d* with adjustment for the effects of the covariate. A positive value denotes a change in favour of direct or individual therapy, respectively, while a negative value indicates change in favour of indirect or group therapy.
[b]The direction of effect from the one-way ANOVA is different from that in the 2 × 2 analysis.

additional covariate. No significant differences between direct/indirect therapy or individual/group therapy for any language outcome measure were observed (all F-values$<$3.00, all p-values$>$0.086). The systematic, but small, between-mode differences in T1–T2 test/re-test interval and also the number of sessions of community SLT received between T2 and T3 both failed to account for significant levels of variance (all F-values$<$1.254, all p-values$>$0.265 for test/re-test interval, and all F-values$<$3.15, all p-values$>$0.078 for number of community sessions).

Planned comparisons between the four modes of research intervention using one-way ANCOVAs failed to reach statistical significance using a Bonferroni-adjusted alpha of 0.0125 to correct for the number of comparisons.

In the light of concerns about the sensitivity of standardized language tests in regard to the detection of treatment effects (Dockrell and Law 2007), we carried out a further check on the data from the 111 children who received project therapy and whose CELF-3^{UK} subtests did not change from T1 to T2, thus controlling for possible effects of different sub-tests introduced at T2 for those children aged below 9 years at T1 but above 9 years at T2. The results confirmed that there were no significant main effects for direct/indirect or individual/group modes and no significant interaction (all F-values<1.746, all p-values>0.189).

2 × 2 ANCOVAs (treatment versus control × specific expressive language delay versus mixed receptive/expressive delay) with post-intervention scores at T2 as the dependent variable and the related pre-intervention score, child's chronological age at T1, and T1–T2 test/re-test interval as covariates for those who completed therapy programmes revealed no significant interactions between type of language delay and treatment/control for CELF-3^{UK}-R scores ($p=0.200$) but a significant interaction in the case of the CELF-3^{UK}-E scores ($F_{1,\ 144}=4.49$, $p=0.036$). Children with E-LI had an average treatment effect of some 4.89 standard score points more than those with RE-LI, whose scores showed no improvement relative to the control group. Interactions between treatment/control and chronological age as a covariate failed to reach statistical significance, indicating that the children's age did not affect response to treatment (all p-values>0.276).

As there were no significant differences in primary outcomes between the four project therapy modes, further comparisons were made between those children who received project intervention from any of the four therapy modes ($n=130$) and the children in the control group ($n=31$), to maximize the statistical power of the analyses. Regression weights for pathways linking research therapy (of whatever mode) versus control to primary language measures at T2 and T3 using maximum likelihood estimation from ANCOVAs carried out using AMOS 6.0 provided tests of the hypothesis that adjusted post-intervention scores would be higher for those who received project intervention. This approach allows the investigation of both direct and indirect statistical effects (Ullman 2001). A direct effect provides a measure of the impact of one variable upon another. In contrast, an indirect effect provides a measure of the extent to which one variable influences another through the effects of a second intervening variable. For example, it is possible that there might be an indirect effect of intervention upon T3 scores at follow-up, mediated through short-term improvements in scores at T2 resulting from research therapy.

The models for CELF-3^{UK}-R (RMSEA=0.067, TLI=0.946, SRMR=0.0505) and CELF-3^{UK}-E (RMSEA=0.067, TLI=0.935, SRMR=0.049) based on intention to treat both achieved satisfactory levels of fit (Ullman 2001). However, only the standardized regression weight between all research therapy versus control and adjusted CELF-3^{UK}-E scores achieved conventional levels of significance.

Figure 2 reveals a significant advantage of research intervention immediately post-intervention ($p=0.031$). Eligible children randomized to research therapy achieved mean adjusted T2 scores on the CELF-3^{UK}-E of 2.72 standard score points (95% confidence interval (CI)=+0.24/+5.20) more than the control group. This exceeds the 95% confidence interval for the standard error of measurement for the CELF-3^{UK}-E based upon internal consistency reliability, so

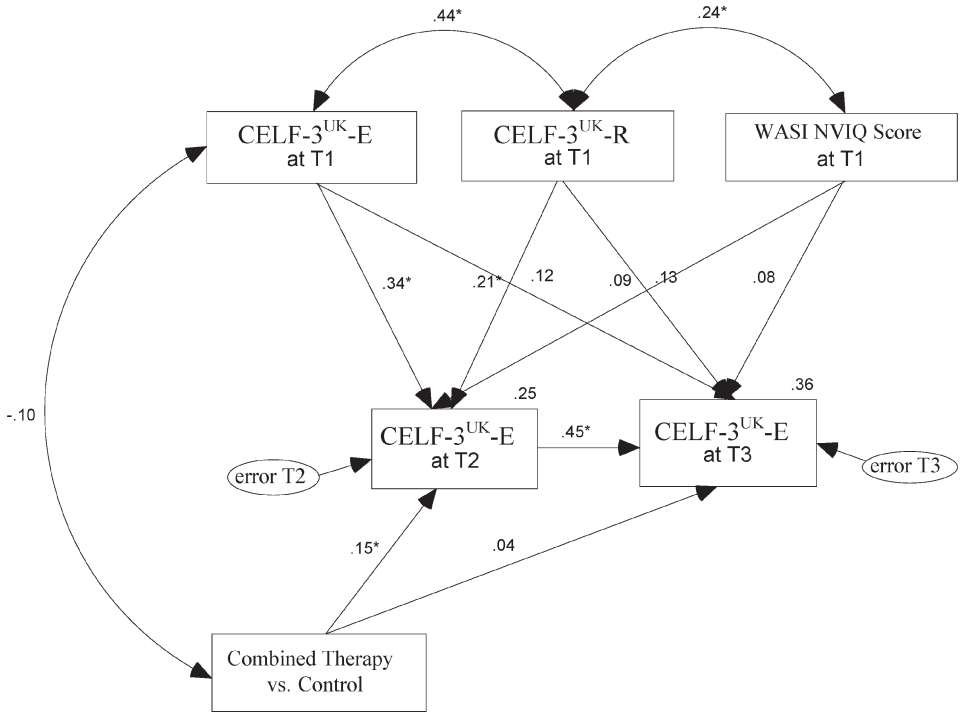

Figure 2. ANCOVA of post-intervention effects for CELF-3^{UK} expressive language outcomes: standardized regression weights from intention to treat analysis (n=161). RMSEA=root mean-square error of approximation (A measure of statistical goodness-of-fit, where a value of zero denotes exact fit and values of 0.08 or less indicate a reasonable error of approximation). TLI=Tucker–Lewis Index (A measure of statistical goodness-of-fit, where a value of 1.0 denotes an exact fit and values of 0.90–0.95 indicate acceptable levels of fit). SRMR=standardized root mean-square residual (A measure of statistical goodness-of-fit, which indicates that the model explains the average discrepancy between the sample observed and hypothesized correlation matrices to within 0.049. *p<0.05).

is unlikely to be due to measurement error. There was no significant direct statistical effect of research intervention upon T3 scores for expressive language at 12 months' follow-up, but a significant indirect statistical effect (p=0.044), equivalent to an adjusted mean score advantage of +1.32 (95% CI=+0.09/+2.60) for those receiving research therapy. Similar results were observed in the case of the protocol analysis, with only the regression weight for the direct effect of the four research therapy modes combined versus control for adjusted T2 scores for the CELF-3^{UK}-E achieving significance (p=0.050), an advantage of +2.65 standard score points in favour of research intervention. There was also a significant indirect effect (p=0.033) at T3 follow-up of +1.27 standard score

points in favour of research therapy, but this could be accounted for by measurement error (Gillam *et al.* 2001).

Those with higher receptive language scores at T1 made greater progress in expressive language at post-intervention T2 ($p=0.007$), though not at 12 months' follow-up ($p=0.085$). Non-verbal IQ at T1 was not a significant predictor of language outcomes at T2 or T3 for either the intention to treat or protocol analyses (all p-values>0.186).

Planned comparisons were carried out to compare the components of therapy with the control group to determine their relative effectiveness over the T1–T2 period. As the reduced sample size did not permit analysis using AMOS, one-way ANCOVAs were carried out, comparing the main effects of direct therapy versus control, indirect therapy versus control, individual therapy versus control for CELF-3^{UK}-E Scores at T2, with T1 scores as a covariate. Following the results from the AMOS models above, the WASI and the composite receptive language variable were included in the analyses to determine the moderating effects of non-verbal cognitive ability and E-LI (with higher receptive language scores) versus RE-LI (with lower receptive language scores). The T1–T2 test/re-test interval was also included in the protocol analyses. The results, including adjusted effect sizes, are shown in table 6.

Table 6. Results from ANCOVAs of adjusted scores at T2 for CELF expressive language scores for therapy mode versus control

Therapy mode	F (d.f.)	p	Adjusted mean difference (intervention – control) and effect size	95% confidence interval (CI) for difference
Intention to treat (ITT)				
Direct versus control	4.89 (1, 91)	0.029*	+3.060 $\varepsilon^2=0.051$ $d=+0.47$	+0.31/+5.81
Indirect versus control	2.14 (1, 91)	0.147	+1.960 $\varepsilon^2=0.017$ $d=+0.26$	−0.70/+4.62
Individual versus control	4.09 (1, 93)	0.046*	+2.955 $\varepsilon^2=0.042$ $d=+0.41$	+0.05/+5.86
Group versus control	2.83 (1, 89)	0.096	+2.120 $\varepsilon^2=0.031$ $d=+0.37$	−0.38/+4.62
Protocol analysis				
Direct versus control	4.02 (1, 84)	0.048*	+3.036 $\varepsilon^2=0.046$ $d=+0.43$	+0.03/+6.05
Indirect versus control	1.40 (1, 84)	0.241	+1.804 $\varepsilon^2=0.016$ $d=+0.26$	−1.23/+4.84
Individual versus control	2.67 (1, 89)	0.106	+2.560 $\varepsilon^2=0.029$ $d=+0.34$	−0.55/+5.67
Group versus control	2.828 (1, 79)	0.097	+2.451 $\varepsilon^2=0.035$ $d=+0.39$	−0.45/+5.35

With regard to covariates, both the CELF Expressive Language scores at T1 and the composite receptive language variable scores at T1 were significant in all analyses (all F-values$>$6.01, all p-values$<$0.02 and all F-values$>$4.33, all p-values$<$0.041, respectively). However, neither of the two other covariates explained significant levels of variance in any of the analyses (all F-values$<$2.43, all p-values$>$0.123 in the case of the WASI, and all F-values$<$1, all p-values$>$0.535, in the case of the T1–T2 test/re-test interval).

ε^2 statistics and Cohen's d effect sizes derived from them reveal sizeable effect sizes and in particular, adjusted mean differences relative to the control group of some three standard score points in favour of both direct therapy and individual therapy in the ITT analyses, and a difference of the same magnitude in the direction of direct therapy in the case of the protocol analysis. All of the other adjusted mean differences in the other comparisons favoured project intervention, and indeed exceeded +1.80, which represents a score increase outwith the upper-bound of the 95% confidence interval for the control group scores based upon the standard error of measurement of the CELF-3^{UK}-E based on internal consistency reliability. However, none of the comparisons met the requirements of a Bonferroni-adjusted alpha of 0.0125 to correct for the number of comparisons to ensure an overall Type I error rate of 0.05 for each.

Mean costs

The overall average cost per child, across all the research therapy modes, excluding those lost to T2 follow-up, was £786. The average total cost per child for the 15-week therapy duration was highest for children receiving individual therapy from an SLT, £1144. The lowest cost per child for the duration of the programme therapy was for indirect group therapy, £493. Children allocated to the control mode incurred average costs of only £181 reflecting their much lower level of contact with community-based services. ANOVAs show a significant difference in the average total cost across the four research therapy modes (α=0.05). The difference in mean total costs between therapist-led individual and group modes was £625 (95% CI=£517/£733). When assistant-led individual and group modes are compared the difference in mean total costs is £407 (95% CI=£326/£486). There is a difference in mean total costs of £517 (95% CI=£444/£590) in favour of group approaches compared with individual therapy. The average travel costs were also higher for children seen on an individual basis (£448 compared with £241 for groups). When modes led by therapists are compared with those led by assistants, the difference in mean total costs falls to £152 (95% CI=£38/£267). Further details of the economic analysis may be found in Dickson *et al.* (2008).

Discussion

This is the first blinded, randomized trial of innovative complex language therapy for school-aged children in the UK with well-defined presenting problems, outcomes based upon age-controlled standardized assessments, 12-month follow-up, and a manualized, replicable intervention.

Since eligible children randomized to project intervention had significantly higher expressive scores at T2 compared with the control group and there was a

statistically significant indirect effect of therapy 12 months later, expressive language intervention appeared to be efficacious for school-age children with LI. The finding that the short-term benefits of research intervention reduced over time in the absence of further intensive therapy provides support for the view that blocks of intervention should be followed-up by 'booster' sessions to help maintain children's progress (Fey *et al.* 1997).

The absence of significant differences in receptive or expressive language outcomes between direct, indirect, individual or group therapy is consistent with results from controlled studies of younger children (Law *et al.* 2004), but here applies to older, school-age pupils whose persistent problems are less likely to 'catch up'. The findings thus demonstrate to parents that therapy can be delivered in these different modes without detriment to the child. Parents and teachers alike also reported functional benefits in areas such as the children's self-confidence, enthusiasm for learning, behaviour and literacy following research intervention (Boyle *et al.* 2007).

Children with E-LI made significantly greater score changes than those with RE-LI confirming recent reviews (Law *et al.* 2004). This study trialled only one intervention regime, based on the literature for school-age children, and cannot suggest what different intervention patterns might effect. Dockrell and Law (2007), for example, report that younger, pre-school children make progress in receptive language in response to short-term, intensive intervention. However, further studies with long-term follow-up are needed, contrasting varied lengths and intensities of intervention. There also remains a need to identify effective ways of managing and supporting children with RE-LI in view of the persistent nature of their difficulties, and a need to investigate models of integrative service delivery, for example partnership between SLTs and schools and the further involvement of class teachers, classroom assistants and parents/carers.

The relative lack of progress made by children randomly allocated to the usual therapy control mode, who had equivalent pre-intervention scores to those receiving project therapy, should be noted, together with the lack of progress of the cohort as a whole between T2 and T3. The difference in amount of contact with SLT services reported for this group of children outside project therapy may have translated into more limited language learning opportunities and resulting progress.

The within-trial cost analysis identified indirect therapy, particularly indirect group therapy as the least costly of the modes investigated, with direct individual therapy as the most costly option. However, these cost differences should not be over-interpreted as providing robust evidence of the cost effectiveness of different ways of providing therapy. The trial was not designed to demonstrate equivalence of the primary treatment effects. Hence, although the outcomes amongst the four research intervention modes did not achieve conventional levels of statistical significance, the lack of differences does not mean that the programmes can be analysed within a cost-minimization framework where efficacy is proven (or assumed) to be equivalent. Likewise, the absence of significant differences in the trial primary endpoints does not exclude the existence of treatment effects that could emerge in a larger investigation that could support a more definitive and reliable estimate of cost effectiveness.

Estimates were based on the pattern of resource use inherent in the trial design with allowance for how the different modes of therapy could be delivered in practical settings. These results should not be surprising given the differences in the

ratio of trained professional staff to children and differences in the cost of labour between different staff grades. Generalizing our central estimates of the relative cost of different therapy modes to other educational/health systems is possible but the precise differences we report in resource use need to be qualified by the level of programme intensity and other characteristic features of education and therapy services that may differ from those observed in the trial. Some elements of the programme could be varied in practice. We would not expect rigid replication of all modes studied and would caution against superimposing our findings in situations where local practices and resource constraints vary in material ways.

Conclusions

The T2 and T3 data from this study indicates that LI which persists into the school years is unlikely to resolve spontaneously. Further, those with more severe or more pervasive problems affecting both receptive language and expressive language are the least likely to show improvement. This poses problems both for the individuals concerned and their carers, and for the education and health services in the light of the research evidence which reveals the long-term adverse outcomes for those with LI.

The findings from this RCT indicate that intervention delivered three times a week for 30–40 min over a 15-week period can yield significant improvements in age-corrected standardized scores for expressive language, though not for receptive language. Direct modes provided less variable, hence more consistent, outcomes, but these were not significantly better than the outcomes from the other three modes. This supports the case for adoption of indirect modes of intervention delivered by trained SLTAs working under the direction of a qualified SLT, and also of group modes of intervention.

But by way of caveat, these findings are not generalizable to children whose LI includes severe phonological or articulatory difficulties. It may be that children with such speech problems may continue to require direct modes of therapy. Further, it would be problematic to generalize our findings to assistants who have not received appropriate training. In addition, although the use of standardized language tests, such as the CELF-3^{UK}, helps to minimize bias and enhances the replicability of findings across assessors, there are concerns that they do not discriminate sensitively at the extremes of their norms (Dockrell and Law 2007) should be noted. And finally, the use of time-limited RCT methodology restricted the results to a dosage approach rather than to completion of therapy programmes. Thus, while the findings are consistent with those elsewhere in the research literature, questions regarding the relationship between dose and treatment effects (e.g., would two sessions per week have delivered comparable outcomes, or four sessions a week better outcomes?) are unresolved.

The costs of providing intervention could be further reduced by means of delivering therapy where appropriate via groups formed within a school, to minimize travel costs, and via SLTAs. But the wider adoption of indirect approaches to intervention in this way may have considerable implications for the SLT profession, not least in changes in professional training programmes and in the training and regulation of assistants to reflect an increased shift in the focus of intervention from the child to the intermediary.

Implications for future research

The findings from this study highlight the need for further research into effective interventions for receptive language problems and also for investigations of the nature of the relationship between dose and treatment effect in both expressive and receptive language.

Finally, there is also a need for studies to identify the characteristics of children most likely to succeed with indirect intervention approaches, and to explore the effectiveness of models of integrative service delivery which involve school staff and parents/carers.

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ERRATUM

The iFirst version of this article published online ahead of print on 23 Dec 2008 contained an error on page 8. The connecting lines between "Follow up T3" and "Analysis" in figure 1 were misaligned. The corrected version is shown in this issue.