

Randomised controlled trial of community based speech and language therapy in preschool children

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Abstract

Objective To compare routine speech and language therapy in preschool children with delayed speech and language against 12 months of "watchful waiting."

Design Pragmatic randomised controlled trial.

Setting 16 community clinics in Bristol.

Participants 159 preschool children with appreciable speech or language difficulties who fulfilled criteria for admission to speech and language therapy.

Main outcome measures Four quantitative measures of speech and language, assessed at 6 and 12 months; a binary variable indicating improvement, by 12 months, on the trial entry criterion.

Results Improvement in auditory comprehension was significant in favour of therapy (adjusted difference in means 4.1, 95% confidence interval 0.5 to 7.6; $P=0.025$). No significant differences were observed for expressive language (1.4, -2.1 to 4.8; $P=0.44$); phonology error rate (-4.4, -12.0 to 3.3; $P=0.26$); language development (0.1, -0.4 to 0.6; $P=0.73$); or improvement on entry criterion (odds ratio 1.3, 0.67 to 2.4; $P=0.46$). At the end of the trial, 70% of all children still had substantial speech and language deficits.

Conclusions This study provides little evidence for the effectiveness of speech and language therapy compared with watchful waiting over 12 months. Providers of speech and language therapy should reconsider the appropriateness, timing, nature, and intensity of such therapy in preschool children. Continued research into more specific provision to subgroups of children is also needed to identify better treatment methods. The lack of resolution of difficulties for most of the children suggests that further research is needed to identify effective ways of helping this population of children.

Introduction

Of the impairments presenting in early childhood, speech or language delay may be the most common.¹ At any one time a fifth of parents in Britain are concerned about their young child's language development.² Although there has been a shift to providing early intervention for these children, this has not been based on research evidence. Yet provision of therapy to children is estimated to consume 70% of the NHS budget for speech and language therapy in the United Kingdom.²

A systematic review has shown short term efficacy of speech and language therapy for young children in an experimental environment.³ No clear evidence exists, however, on the long term effectiveness of therapy in the context of service provision or on the natural course of early speech and language delays. In particular, the longer term course of early difficulties seems to vary for different groups of children. Some studies have suggested that 40% to 60% of children with only expressive language delay outgrow their dif-

ficulties⁴⁻⁵; others have shown that those with a range of language problems have more persistent linguistic, literacy, and social difficulties.⁶⁻⁸

We investigated in a pragmatic randomised controlled trial the effectiveness of speech and language therapy for preschool children as delivered in community clinics.

Subjects and methods

Subject selection and baseline assessment

We considered for inclusion all children presenting to 16 NHS community clinics from December 1995 to March 1998. Box 1 shows the selection criteria; box 2 shows the three clinical criteria. Local research ethics committees for the three participating healthcare trusts gave approval for the trial; informed parental consent was obtained by therapists.

Baseline assessments were performed before randomisation and included the preschool language scale⁹ to determine auditory comprehension and expressive language scores (age standardised); phonological analysis of 22 words, yielding a percentage error rate¹⁰; a 30 minute audiotaped sample of the child's spontaneous verbal output scored from 0 to 10 on the Bristol language development scales¹¹; and the daily living, socialisation, and motor skills domains of the Vineland adaptive behaviour scales (age standardised).¹² Other measures of overall functioning were attention levels (range 1-6),¹³ symbolic play (range 1-5),¹⁴ and the therapy outcome measures tool (range 0-5).¹⁵ We also collected data from parents.¹⁶

Assignment

Eligible children were randomised to receive therapy or to "watchful waiting." Randomisation was stratified by the 16 clinics and by the three clinical criteria (general language, expressive language, and phonology). The sequence of random numbers was generated before the trial independently of the therapists. The allocation was implemented by the therapists opening sealed opaque envelopes in the presence of the parents.

Children randomised to the therapy group received the one-to-one speech and language therapy routinely offered by the therapist. Parents of children in the watchful waiting group could request therapy at any time. All children in the study were reassessed by the research therapists after 12 months.

Blinding

The same assessments were used at 6 and 12 months as at baseline, with the exception of the Bristol language development scales and the Vineland scales, which were measured only at 12 months. Assessors were blind to previous results, and every attempt was made to maintain blindness in terms of allocation.

Outcome measures

The five primary outcomes were auditory comprehension and expressive language scores, phonology error

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Box 1—General selection criteria

- Newly referred singleton children acquiring English in a monolingual home
- Aged under 3½ years at initial attendance for speech and language therapy assessment
- No diagnosis of severe learning difficulties or autism
- No oromotor deficits
- No primary diagnosis of dysfluency (stammering) or dysphonia (voice disorders)
- No siblings currently receiving speech and language therapy
- Children had to satisfy one of the clinical criteria (box 2)
- Be considered to have significant clinical difficulties by the speech and language therapist
- A “carer” had to attend sessions
- Parents had to give consent

rate, the score for the Bristol language development scales, and a binary variable indicating whether the child, by 12 months, had improved sufficiently on the single clinical measure on which he or she had entered the study to no longer satisfy that particular criterion. The 11 secondary outcomes were four therapy outcome measures¹⁵; attention and play ratings; the Vineland socialisation domain; three separate binary variables indicating improvement or no deterioration over 12 months in auditory comprehension, expressive language, and phonology; and a fourth binary variable reflecting whether, at the 12 month follow up, the child satisfied any of the clinical criteria (a reassessment of eligibility for the trial irrespective of the initial clinical criterion on which the child entered the trial).

Sample size considerations

A total of 146 to 166 children was needed to detect a 20% difference between the two arms (that is, 15% *v* 35%) at a two sided 5% significance level, for 80% to 85% power. This sample size range had 80% to 85% power to detect differences between the trial groups of 0.43 to 0.50 standard deviations for the continuous outcome measures.

Analysis

The trial arms were compared on an “intention to treat” basis. The continuous outcome measures were analysed by using simple or repeated measures analysis of covariance, with adjustment for the baseline assessment of the outcome measurement. The binary outcome measures were analysed by using χ^2 tests and logistic regression. In addition, for the two primary outcomes that were not age standardised (the Bristol

language development scales and the phonology error rate), the relevant regression models were repeated after adjustment for age. All analyses were performed with the SPSS statistical package (version 10.0), and a two sided 5% significance level was used throughout.

Results

In all, 507 children aged under 3½ years were referred to the participating speech and language therapy clinics, and 159 eligible children were subsequently randomised (figure). The children in both trial arms were closely similar for a broad range of baseline characteristics (table 1).

Therapy provided in the study tended to focus on several areas of language simultaneously. Therapy techniques included Derbyshire language scheme tasks, as well as everyday play and games used as contexts for modelling language for the child. Goals covered a wide range of language stages—for example, understanding and building single words, using narratives, and identifying consonants in words.

Although all of the observed comparisons for the primary outcome measures were in favour of the therapy group, only one was statistically significant—namely, auditory comprehension (table 2). For this outcome, the difference of 4.1 points corresponds to about 0.3 SD, with the upper confidence limit being about 0.5 SD.

For the 11 secondary outcomes none of the seven continuous variables was significant and all of the observed differences were very close to zero, with narrow confidence intervals in most cases. Of the four binary outcomes, however, two were significant, with a greater proportion of children in the therapy group improving their phonology and no longer satisfying the original eligibility criteria for the trial. Of the 71 children in the therapy group, 27 (38%) were no longer eligible by the end of the trial, compared with 19 (23%) of the 84 children followed up in the watchful waiting group. Overall, 109 (70%) children still satisfied the eligibility criteria at the 12 month follow up.

Discussion

This trial is by far the largest to date investigating the effectiveness of speech and language therapy in preschool children. Improvement in the therapy group was significant (compared with the watchful waiting group) for only one of the five primary outcomes—auditory comprehension. Moreover, the two secondary outcomes for which the results were significant measure different aspects. The two possible explanations are, firstly, that the statistically significant findings may simply be due to chance, and, secondly, that there may be a therapeutic benefit across a range of measures, with differential sensitivity resulting in only a small number of (different) outcomes yielding statistical significance. Table 2 supports this latter interpretation, given the direction of the estimates for the primary outcomes and that their confidence intervals generally include large effects in favour of the therapy group but rule out clinically significant differences in favour of the watchful waiting group. The sizeable minority of parents in the watchful waiting group who requested therapy at the 6 month follow up shows that

Box 2—Clinical criteria

General language group—a standardised score < 1.2 SD (standard deviation) below the mean on the auditory comprehension part of the preschool language scale⁹

Expressive language group—a standardised score > 1.2 SD below the mean on auditory comprehension but < 1.2 SD below the mean on the expressive language part of the preschool language scale

Phonology group—auditory comprehension and expressive language scores > 1.2 SD below the mean but with an error rate of at least 40% in the production of fricative consonants (for example, f and s) and/or velar consonants (for example, “hard” c, “hard” g, and ng) and/or sounds occurring after a vowel among the 22 words included in the phonological analysis

some parents found it difficult to accept a 12 month period of monitoring.

Limitations of trial

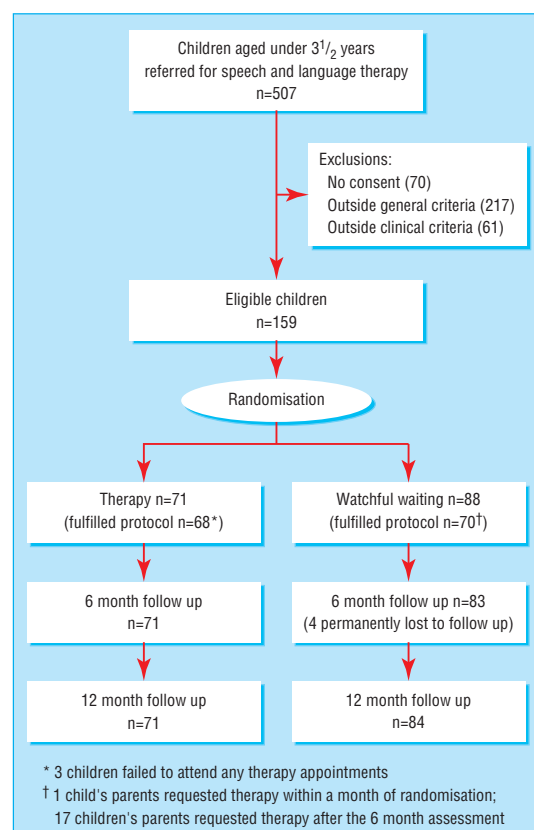
Overall, the impact of therapy in this trial was small, perhaps because of the relatively low level of therapy provided—considerably lower than levels reported in previous studies.^{3 17} On the other hand, this trial aimed to evaluate routine therapy rather than a prescribed regimen.

In line with the pragmatic design, the children included in the trial presented with a wide range of types and severity of speech and language difficulties. Although the children were stratified according to their broad entry criteria, which ensured similar groups in this respect, the sample size of the clinical groupings was too small to detect significant differential effects.

Blinding was maintained for all baseline assessments and for the language sample at follow up. Although every effort was made to retain blinding at the follow up assessments, in the presence of parents strict blinding was inevitably not always feasible for the other outcomes. The consistency of findings for the various outcomes, however, suggests that this did not seriously bias the results.

Relation to literature

Although the level of therapy in this trial was lower than in smaller scale, more explanatory trials, the present study was a relatively large and randomised trial and it had considerably longer follow up (12 months) than other studies.^{18–20}



Progress of children through trial

Table 1 Characteristics of children at baseline. Values are numbers (percentage) of children, unless stated otherwise

| | Therapy (n=71) | Watchful waiting (n=88) |
|--|----------------|-------------------------|
| Maternal education*: | | |
| No qualifications | 7 (11) | 16 (18) |
| O level or similar (CSE or technical qualification) | 53 (80) | 63 (72) |
| A level and higher | 6 (9) | 8 (9) |
| Mean (range) age in months | 34.2 (18-42) | 34.2 (24-42) |
| Male | 55 (77) | 65 (74) |
| Receiving child care | 42 (59) | 47 (53) |
| Diagnosed hearing loss | 7 (10) | 6 (7) |
| Mean (range) auditory comprehension score | 82.1 (53-118) | 83.0 (55-127) |
| Mean (range) expressive language score | 77.3 (59-135) | 76.5 (53-104) |
| Mean phonology error rate (%) | 58.1 | 60.7 |
| Mean (range) score on Bristol language development scale | 2.3 (0-8) | 2.4 (0-10) |
| Mean (range) score on Vineland adaptive behaviour scale: | | |
| Daily living skills | 89.5 (66-125) | 91.9 (67-115) |
| Motor skills | 91.5 (65-115) | 91.2 (63-115) |
| Socialisation skills | 82.1 (68-101) | 81.8 (79-114) |

*Data for some children in the therapy group were missing.

Table 2 Primary outcome measures*

| | Difference or odds ratio (95% confidence interval) | P value |
|--|--|---------|
| Auditory comprehension† | 4.1 (0.5 to 7.6) | 0.025 |
| Expressive language† | 1.4 (-2.1 to 4.8) | 0.44 |
| Phonology error rate‡ | -4.4 (-12.0 to 3.3) | 0.26 |
| Bristol language development scale‡ | 0.1 (-0.4 to 0.6) | 0.73 |
| Improvement by 12 months on the clinical criterion on which child entered study§ | 1.3 (0.67 to 2.4) | 0.46 |

*Data were missing for all measures in both groups: analyses were based on 64 (therapy group) and 80 children (watchful waiting group) for auditory comprehension; 63 and 77 for expressive language; 57 and 62 for the phonology error rate; and 71 and 84 for improvement by 12 months.

†Difference in means obtained from repeated measures analysis of covariance with adjustment for baseline assessment of the outcome measure, with the difference for the therapy group minus that for watchful waiting averaged across the two follow up times.

‡Difference in means obtained from analysis of covariance for 12 month scores adjusted for baseline assessment of the outcome measure.

§Odds ratios obtained from logistic regression.

Conclusions

Most children in this study still had important clinical difficulties at 12 months, regardless of trial allocation; indeed, many remained eligible for the trial, with little evidence of “spontaneous resolution.” This study provides little evidence for the effectiveness of speech and language therapy when compared with “watchful waiting” over 12 months. In clinical terms, these findings suggest that speech and language therapy for preschool children should be reconsidered in terms of appropriateness, timing, nature, and intensity. Further research into more specific types of provision with sub-groups of children is required to identify better treatment methods.

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Contributors: The original trial design was formulated by PE and TJP, with all authors contributing to its subsequent development. The trial was implemented by SR and MG, with support and advice from TJP and PE. Data management and analysis were carried out by MG, SR, and TJP, under the overall supervision of TJP. MG produced the first draft of the paper, with substantial redrafting by TJP and SR and additional input and academic support from PE. All authors will act as guarantors for the paper.

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What is already known on this topic

A systematic review has shown short term efficacy of speech and language therapy for young children in experimental environments

Evidence is lacking on the long term effectiveness of early intervention for preschool children as provided in a service setting

What this study adds

This study provides little evidence for the effectiveness of speech and language therapy compared with "watchful waiting" over 12 months

Providers of speech and language therapy services should reconsider the therapy offered to preschool children

The low rate of resolution of difficulties suggests that further research is needed to identify effective ways of helping these children

Competing interests: None declared.

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Severity of overdose after restriction of paracetamol availability: retrospective study

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Paracetamol overdose is the commonest cause of intentional self harm in the United Kingdom, accounting for approximately 70 000 cases per year.¹ It is the commonest cause of acute liver failure,¹ although this is rare in adults if doses of <12 g are ingested.² To reduce this major health problem the government introduced legislation in September 1998 to limit the number of tablets in a single packet to 32 for packets sold in pharmacies and 16 in non-pharmacy outlets.³

This study assesses the impact of reduced availability of paracetamol on the number and severity of overdoses by comparing self poisoning cases in two periods of six months before and after the change to smaller packets.

Subjects, methods, and results

Patients presenting with acute self poisoning to five general hospitals in the Belfast area during the months January to June in 1998 and 1999 were included in the study. For each case we estimated the amount of paracetamol ingested, whether as a single agent or with other drugs. Where appropriate we recorded concentrations of serum paracetamol and liver enzymes, the international normalised ratio, and whether an antidote was given. We also recorded the numbers of patients admitted to hospital, patients transferred to a

specialist unit, and deaths related to paracetamol overdose. We used a χ^2 test to compare the numbers of patients admitted to hospital and the numbers who received an antidote during the two periods. A Mann-Whitney U test was used to compare the difference in estimated quantity of paracetamol ingested, serum concentration of paracetamol at 4-6 hours after the time of poisoning, and transaminase concentrations and the international normalised ratio at 24-48 hours.

Serum paracetamol concentrations were measured in 59% of the 590 patients who presented in the first period and 63% of 594 in the second. The estimated quantity of paracetamol ingested, the number of patients receiving the antidote, and the serum paracetamol concentration at 4-6 hours were significantly lower in the second period (table).

Two patients were transferred to a tertiary referral centre in 1998 and three in 1999. In 1998 neither patient required liver transplantation and both made a full recovery. However, in 1999 only one patient recovered completely; one died and one received a liver transplant.

Comment

Overdose behaviour changed after the introduction of smaller blister packs of paracetamol. The estimated