Randomized Trial of a Population-Based, Home-Delivered Intervention for Preschool Language Delay

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**ABBREVIATIONS**
- CELF-P2—Clinical Evaluation of Language Fundamentals — Preschool, 2nd Edition
- CI—confidence interval
- LGA—local government area

**OBJECTIVE:** Population approaches to lessen the adverse impacts of preschool language delay remain elusive. We aimed to determine whether systematic ascertainment of language delay at age 4 years, followed by a 10-month, 1-on-1 intervention, improves language and related outcomes at age 5 years.

**METHODS:** A randomized trial nested within a cross-sectional ascertainment of language delay. Children with expressive and/or receptive language scores more than 1.25 SD below the mean at age 4 years entered the trial. Children randomly allocated to the intervention received 18 1-hour home-based therapy sessions. The primary outcomes were receptive and expressive language (Clinical Evaluation of Language Fundamentals — Preschool, 2nd Edition) and secondary outcomes were child phonological skills, letter awareness, pragmatic skills, behavior, and quality of life.

**RESULTS:** A total of 1464 children were assessed for language delay at age 4 years. Of 266 eligible children, 200 (13.6%) entered the trial, with 91 intervention (92% of 99) and 88 control (87% of 101) children retained at age 5 years. At age 5 years, there was weak evidence of benefit to expressive (adjusted mean difference, intervention — control, 2.0; 95% confidence interval [CI] —0.5 to 4.4; P = .12) but not receptive (0.6; 95% CI —0.9 to 2.2) language. The intervention improved phonological awareness skills (2.4; 95% CI 0.3 to 4.5; P = .03), but not other secondary outcomes.

**CONCLUSIONS:** A standardized yet flexible 18-session language intervention was successfully delivered by non-specialist staff, found to be acceptable and feasible, and has the potential to improve long-term consequences of early language delay within a public health framework. Pediatrics 2013;132:e895–e904
Children who have oral language delay at school entry are at risk for lasting difficulties. These are not restricted to children presenting clinically, and go well beyond early literacy and “school readiness” to increasingly apparent associations with emotional, behavioral, and social difficulties. Because of long-term impacts on adult literacy, mental health, and employment, effective population-level interventions could make a major contribution to society.

Therefore, it is encouraging that the last decade has seen rapid growth in trials examining treatments for children who have speech and language delays/disorders. The 2012 Cochrane review included 54 intervention trials in meta-analyses, showing positive outcomes for expressive vocabulary (effect size 0.7; 95% confidence interval [CI] 0.05–1.25; P = .04) and syntax (effect size 0.8; 95% CI 0.15–1.95; P = .01), but less clear benefits for receptive language. However, major limitations were common, including small sample sizes (often fewer than 20 in each arm), limited follow-up, lack of clear protocols or intervention detail, heterogeneity, and few replications. As most interventions were delivered by speech and language therapists in clinical settings, underlying populations were often not well characterized, and few could be construed as “effectiveness” trials with the potential for large-scale roll out. Finally, few included any economic analysis, making it impossible to establish costs versus benefits.

Recognizing these limitations, we report on a novel population-based trial targeting 4-year-olds, designed so the intervention could feasibly be rolled out in the community and address identified evidence gaps with adequate statistical power. We chose this age because toddlerhood may be too early, as most late talkers resolve spontaneously by ages 3 and 4 years (ie, low specificity) and false-negatives are also common up to at least 3 years (ie, low sensitivity). Conversely, school age may be too late, with short-term benefits not sustained to 12 months in the only rigorous, large, school-based trial to date.

Specifically, we aimed to determine whether a population-based intervention targeting children ascertained with language delay (expressive and/or receptive scores more than 1.25 SD below the mean) at their fourth birthday improves language and associated outcomes. We hypothesized that, compared with control subjects, benefits to the intervention group at 5 years would include better mean scores on:

- Standardized measures of expressive and receptive language (primary outcomes)
- Related secondary outcomes of phonological awareness skills, letter knowledge, pragmatic language skills, behavior, and health-related quality of life

We also report intervention parents’ evaluation of the program, and estimate the costs of its delivery.

**METHODS**

**Study Design**

Language for Learning (ISRCTN03981121) was a randomized controlled trial nested within a cross-sectional population-based ascertainment of language delay. It was conducted in 8 of the 31 local government areas (LGAs) comprising greater Melbourne, Australia (population 4.0 million in 2011)14. Eligible children were allocated to intervention or “usual care” (control) arms in a 1:1 ratio by an independent researcher by using a computer-generated random number sequence, concealed using sealed opaque envelopes. Randomization was stratified by...
previous trial (Let's Read or Let's Learn Language) and nature of language problem (receptive, expressive, or both receptive and expressive), and blocked within each stratum using randomly permuted block sizes in a non-systematic sequence. Outcome assessors were blind to group allocation but, once allocated, participants could not be blinded.

Eligible parents were phoned to inform them about their child’s language status. Once randomized, control parents were informed of group allocation and local speech pathology services (if desired) by mail; they did not receive the intervention at any point. We recontacted intervention parents to book sessions and mail intervention information.

The intervention (see Fig 1) was designed to promote narrative skills, vocabulary and grammar, and phonological awareness and preliteracy skills, commencing within 2 months of the 4-year-old baseline assessment. We included both oral language and phonological awareness skills because the two are clearly related, with phonological awareness skills vital both to early word learning (central to the development of oral language skills) and to helping children who have spoken language impairment achieve success in literacy. The program’s development and content are detailed in the trial’s published protocol. Because language delay is clearly not homogeneous by 4 years, we designed a program that is both standardized and replicable, yet flexible enough for children with diverse cognitive and language profiles, unlike the standardized, uniform programs currently the focus of research at younger ages. We also aimed for greater intensity and duration than achieved in most clinical services, because the limited literature suggests a dose-response relationship with both duration and intensity, but it is unclear how consistent these findings are.

Weighing dose-response imperatives against cost, logistic, and workforce constraints, as well as parent priorities, led to our design of an 18-session home-based program. A trained “language assistant” visited the child and at least 1 caregiver at home for weekly 1-on-1 sessions, divided into three 6-week blocks starting every 3 months; missed sessions were rescheduled when possible. The format of each session was standardized to cover: (1) brief review of the previous week; (2) activities introduced by the language assistant directed at the child; (3) activities for parent and child together, with support from the language assistant; and (4) activities for home practice, with parents asked to practice each task daily and each activity having standardized supporting materials and manual instructions.

FIGURE 1
Pictorial diagram of Language for Learning trial.

<table>
<thead>
<tr>
<th>Time Line</th>
<th>Whole Population (N = 1464)</th>
<th>Randomization</th>
<th>Language Delay Group (N = 200)</th>
<th>Intervention</th>
<th>Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 yrs of age (ascertainment assessment)</td>
<td>a</td>
<td>b</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Randomization</td>
<td>Language Delay Group (N = 200)</td>
<td>Intervention</td>
<td>Controls</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention Block 1 (6 sessions, wk 1–6)</td>
<td>c1</td>
<td>c2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention Block 2 (6 sessions, wk 13–18)</td>
<td>c1</td>
<td>c2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention Block 3 (6 sessions, wk 25–30)</td>
<td>c1</td>
<td>c2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 yrs of age</td>
<td>d</td>
<td>e</td>
<td>f</td>
<td>d</td>
<td></td>
</tr>
</tbody>
</table>

- **a**: Brief written questionnaires completed by parents reporting on child’s pragmatic skills, child’s health and well being, and general development.
- **b**: Language ascertainment: formal assessment of child’s expressive and receptive language. Children scoring greater than 1.25 SD below the mean on expressive and/or receptive language scores were eligible for the trial.
- **c**: Intervention administered by a trained language assistant in the family home over 18 sessions. Sessions are delivered in 3 blocks of 6 1-hour sessions over 6 weeks, with a 6-week break between each block. The format of each session is as follows:
  1. Session 1 of each block – The language assistant conducts a language screen with the child to determine the specific areas of the child’s language that need to be targeted for that block.
  2. Session 2–6 of each block – Each session consists of three main activities: a) phonological awareness/letter knowledge activity; b) specific language target activity; and c) shared book reading.
- **d**: Measurement of outcomes: Direct assessment of child’s expressive and receptive language; brief written parent questionnaires.
- **e**: Appraisal by intervention parents of Language for Learning program.
- **f**: Intervention feedback session conducted 2 weeks post-5 year assessment (beyond the scope of this paper). The language assistant visited the family to discuss the results of the child’s 5-year language assessment and provided information on further services available depending on the child’s needs.
weekly basis; phonological awareness skills were not specifically targeted for home practice. The diaries were designed not as a compliance measure, but to provide parents with guidance and reinforcement for the activities set and to aid them in discussion with the therapist at the next session.

The manual design was modeled on that of Boyle, and explained program principles and domains and documented activities and their hierarchies, and provided brief tasks to monitor the child’s progress toward their individual goals. Each activity had standardized supporting materials and manual instructions. The program was personalized by selecting harder or easier activities according to profile, severity, and progress. The 19th session (the 5-year-old language assessment) comprised the outcome measures for this report; a subsequent 20th session (not contributing to these outcomes) provided feedback on the child's progress.

**Training and Personnel**

The 10 language assistants were psychology and sociology university graduates. Their training comprised a 1-day group workshop (May 2010) followed by individual training with Dr Zens, the supervising speech pathologist (2 hours each; June 2010). Each assistant then observed Dr Zens delivering at least 2 sessions and, once they had commenced delivering sessions independently, was observed by Dr Zens on 2 occasions to ensure treatment fidelity. Two additional half-day group workshops on assessment and feedback were completed (September 2010 and May 2011). The language assistants sought ongoing guidance from Dr Zens as needed (∼0.5 hours per week, per assistant).
Measures

Table 1 shows the primary and secondary outcomes. At the 5-year follow-up visit, intervention parents also completed a short process questionnaire evaluating the program’s content, structure, and perceived resulting changes in parent and child communication.

Program Costs

Costs were estimated in 2012 Australian dollars (A$1 = US$1.02 = £0.63, October 2012), with an annual discount of 3%, using project team and provider records. As well as the cost of training therapists (see above), we estimated the costs of delivering the therapy sessions, that is, booking, rescheduling, preparing, and facilitating each of the 18 home visit sessions (~1 hour contact time and 20 minutes non-contact time per session); the 5-year assessment (12.5 hours); feedback session (30 minutes); and related travel and intervention material costs. Staff time was valued by using hourly wage rates (assistant A$39.43, supervisor A$54.76), including 27% salary on-costs to reflect leave entitlements and superannuation. Travel was valued at a standard unit cost of A$0.80 per kilometer and materials were valued at market price. Overhead costs, to reflect additional costs of building and support services used by program staff, were estimated as 22% of combined staff, travel, and materials costs. Program costs were assigned to families who received some component of the intervention.

Sample Size

We anticipated that 1500 children would be assessed at 4 years, allowing for 20% loss to follow-up. Assuming 240 (16%) would be eligible, 10% would decline participation, and 1% would be excluded, we estimated 210 children would enter the trial (105 in each arm). Ten-percent attrition would provide 94 children in each trial arm at outcome, giving 80% power to detect a difference of 0.41 SD at the 5% level of significance.

Statistical Analysis

Using the intention-to-treat principle, participants with outcome data (completers) were analyzed according to the arm to which they were randomized. We compared mean outcomes by using linear regression in unadjusted analyses and analyses adjusted for the following prognostic factors: child gender, mother’s education level, recruitment from Let’s Read or Let’s Learn Language, expressive and receptive language scores at baseline, and baseline measure of the outcome being considered when available.

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**TABLE 1** Primary and Secondary Outcome Measures at Age 5 Years for the Language for Learning Trial

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Measure</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary: directly assessed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expressive and receptive language</td>
<td>CELF-P218</td>
<td>Expressive score: Word Structure, Expressive Vocabulary, Recalling Sentences, Receptive score: Sentence Structure, Concepts and Following Directions, Word Classes; both yield a standard score with normative mean 100 (SD 15)</td>
</tr>
<tr>
<td>Secondary: directly assessed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phonological awareness skills</td>
<td>Comprehensive Test of Phonological Processing40,b</td>
<td>Subtests used: Elision, Blending Words, Sound Matching; yields Phonological Awareness Composite Score, with possible range 55 (worst) to 150 (best)</td>
</tr>
<tr>
<td>Letter knowledge</td>
<td>Letter knowledge task</td>
<td>26 alphabet letters summed, with possible range 0 to 26</td>
</tr>
<tr>
<td>Secondary: parent-reported</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pragmatic skills (social language use)</td>
<td>Children’s Communication Checklist, 2nd Edition41</td>
<td>28 items on 4 subscales: Inappropriate Initiation, Stereotyped Language, Use of Context, Nonverbal Communication; summed to a single raw score, with possible range 0 (worst) to 112 (best)</td>
</tr>
<tr>
<td>Health-related quality of life</td>
<td>HUI-23PEn-15Q4b, parent-proxy</td>
<td>Proxy-completed (P), 4-wk recall (4), English language (En), 15-item (15Q) version of the broader HUI2/3 measures; we report the HUI3 score for overall utility value, calculated using multi-attribute utility function, with possible range –0.4 (worst) to 1 (best)</td>
</tr>
<tr>
<td>Pediatric Quality of Life Inventory, parent-proxy4l</td>
<td>25-item measure comprising 4 dimensions, yielding a Total Scale (also yields Physical and Psychosocial Health Summary scores, not secondary outcomes) with possible range 0 (worst) to 100 (best)</td>
<td></td>
</tr>
<tr>
<td>Behavior</td>
<td>Strengths and Difficulties questionnaire44</td>
<td>25-item measure that yields scores for total behavioral problems (0 [best] to 40 [worst]); it also measures prosocial behavior (0 [worst] to 10 [best]), which was not a secondary outcome measure</td>
</tr>
</tbody>
</table>

HUI, Health Utilities Index.
18 Baseline only: basic concepts subtest administered as part of receptive score.
19 Measured at outcome only (not baseline).
In prespecified exploratory analyses, we used tests of interaction to explore whether effects of the intervention on language differ across the following subgroups:

- Language delay subgroup (expressive versus receptive versus mixed expressive/receptive);
- Nonspecific (nonverbal IQ < 85) versus specific (nonverbal IQ ≥ 85) language delay; and
- Maternal education level (did not complete school versus completed school/tertiary degree)

### RESULTS

Figure 2 summarizes the participant flow, and Table 2 the sample characteristics. Of the 1661 children eligible, 1464 (88.1%) completed the baseline assessment; and of the 266 children who had low language, 200 (13.6% of 1464) entered the trial. Ninety-one intervention (92% of 99) and 88 control (87% of 101) children were retained at age 5 years. Of the 99 intervention families, 94%, 91%, and 85% received at least 1, 2, and 3 blocks of therapy, respectively; on average, families received 17 of the 18 intervention sessions.

### Outcomes at 5 Years

Table 3 shows that, at outcome, the adjusted analyses provided weak evidence for a small improvement in expressive language (P = .12, effect size 0.2), and little evidence for an improvement in receptive language (P = .69) in the intervention arm relative to the control arm. Of the secondary outcomes, there were sizeable benefits to phonological awareness skills (P < .001, effect size 0.6) and letter knowledge (P = .03, effect size 0.3), both explicit targets of the therapy, but not to parent-reported pragmatic aspects of language, behavior, or health-related quality of life. Of the CELF-P2 subscales, only Word Structure showed evidence of a difference between trial arms (P = .006, effect size 0.4).

Exploratory interaction analyses provided little evidence that the effect of the intervention on expressive and

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**TABLE 2** Participant Characteristics at Baseline

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention (N = 99)</th>
<th>Control (N = 101)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female child, %</td>
<td>32</td>
<td>36</td>
</tr>
<tr>
<td>Child age in years, mean (SD)</td>
<td>4.2 (0.1)</td>
<td>4.1 (0.1)</td>
</tr>
<tr>
<td>Mother’s education, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not complete school</td>
<td>30</td>
<td>26</td>
</tr>
<tr>
<td>Completed school</td>
<td>46</td>
<td>53</td>
</tr>
<tr>
<td>Degree/postgraduate</td>
<td>24</td>
<td>21</td>
</tr>
<tr>
<td>SEIFA disadvantage score, mean (SD)</td>
<td>1001 (61)</td>
<td>994 (61)</td>
</tr>
<tr>
<td>Original study, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Let’s Read</td>
<td>41</td>
<td>42</td>
</tr>
<tr>
<td>Let’s Learn Language</td>
<td>59</td>
<td>58</td>
</tr>
</tbody>
</table>

Baseline scores, mean (SD)a

- Expressive language (CELF-P2) 80.8 (10.0) 79.8 (10.9)
- Receptive language (CELF-P2) 78.2 (7.5) 75.5 (8.7)
- Letter knowledge (SPAT-R) 5.6 (8.3) 5.8 (9.2)
- Total behavior problems (SDQ) 10.5 (5.3) 9.4 (4.9)
- Pragmatic skills (CCC-2) 27.8 (8.8) 26.0 (9.8)
- Health-related quality of life (PedsQL) 83.7 (12.8) 83.2 (10.4)

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**TABLE 3** Outcome Comparisons at Age 5 Years

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Mean (SD) for Trial Arms</th>
<th>Unadjusted</th>
<th>Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention (I)</td>
<td>Control (C)</td>
<td>Mean Diff (I-C)</td>
</tr>
<tr>
<td>Primary outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expressive language (CELF-P2)</td>
<td>87.5 (11.4)</td>
<td>84.6 (12.8)</td>
<td>2.9</td>
</tr>
<tr>
<td>Receptive language (CELF-P2)</td>
<td>87.6 (12.3)</td>
<td>86.5 (12.1)</td>
<td>1.1</td>
</tr>
<tr>
<td>Secondary outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-literacy and language</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phonological awareness (CTOPP)</td>
<td>97.1 (11.2)</td>
<td>91.8 (8.0)</td>
<td>5.3</td>
</tr>
<tr>
<td>Letter knowledge</td>
<td>162.2 (8.8)</td>
<td>139.9 (8.4)</td>
<td>2.2</td>
</tr>
<tr>
<td>Pragmatic skills (CCC-2)</td>
<td>24.3 (11.8)</td>
<td>25.0 (11.2)</td>
<td>−0.7</td>
</tr>
<tr>
<td>Behavior</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total problems (SDQ)</td>
<td>9.3 (5.2)</td>
<td>9.3 (4.9)</td>
<td>0.1</td>
</tr>
<tr>
<td>Health-related quality of life</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total score (PedsQL)</td>
<td>76.6 (15.7)</td>
<td>76.4 (16.1)</td>
<td>0.3</td>
</tr>
<tr>
<td>Multi-attribute utility (HUI3)</td>
<td>0.9 (0.1)</td>
<td>0.9 (0.2)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Sample sizes range from 82 to 91 and 82 to 88 in the intervention and controls arms, respectively, for unadjusted analyses, and from 54 to 85 and 56 to 82 for adjusted analyses. Effect size calculated as the adjusted mean difference divided by the SD in the control arm. CCC-2, Children’s Communication Checklist, 2nd Edition; CTOPP, Comprehensive Test of Phonological Processing; HUI3, Health Utilities Index; SDQ, Strengths and Difficulties questionnaire.
receptive language was modified by modality of language delay, specific versus nonspecific language delay status, or mother’s education (P values all >0.3).

**Process Evaluation**

Nearly 100% of parents rated the therapy structure as good/very good, with a mean score for each element, including homework, 3.6 to 3.8 out of 4. Parents felt strongly that the therapy had changed how they communicated with their child and also how their child communicated with them (mean 3.0, SD 0.8, for both). Many parents reported that these changes generalized to other communication situations, with the lowest impact reported for changing the child’s behavior (Table 4).

Program costs were A$300 514, or A $3231 per family. This comprised the cost of a speech pathologist training and supervising the language therapists (A$10 676), delivering the 18 home visit therapy sessions (A$87 675), the 5-year assessment (A$5452), the feedback session (A$2820), intervention materials (A$6131), related travel (A$135 569), and overheads costs (A$54 191).

**TABLE 4** Intervention Parents’ Evaluation of the Program, Scored From 1 (Worst) to 4 (Best)

<table>
<thead>
<tr>
<th>Program Aspect</th>
<th>Mean (SD)</th>
<th>% (N = 83)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate the therapy on...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>...the length of each therapy session</td>
<td>3.8 (0.4)</td>
<td>80 20 0 0</td>
</tr>
<tr>
<td>...the number of therapy sessions</td>
<td>3.7 (0.5)</td>
<td>75 24 1 0</td>
</tr>
<tr>
<td>...the letter games and sound matching</td>
<td>3.8 (0.4)</td>
<td>84 16 0 0</td>
</tr>
<tr>
<td>...the language targeted play activity</td>
<td>3.8 (0.4)</td>
<td>76 24 0 0</td>
</tr>
<tr>
<td>...the shared book reading activity</td>
<td>3.8 (0.4)</td>
<td>78 22 0 0</td>
</tr>
<tr>
<td>...the homework task: shared book reading</td>
<td>3.7 (0.5)</td>
<td>65 35 0 0</td>
</tr>
<tr>
<td>...the homework task: language targeted play</td>
<td>3.6 (0.5)</td>
<td>64 35 1 0</td>
</tr>
<tr>
<td>Evaluation of therapy outcomes: The therapy changed how...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>...I communicate with my child</td>
<td>3.0 (0.8)</td>
<td>30 45 24 1</td>
</tr>
<tr>
<td>...my child communicates with me</td>
<td>3.0 (0.8)</td>
<td>28 47 22 3</td>
</tr>
<tr>
<td>...my child communicates with other childrena</td>
<td>2.7 (0.9)</td>
<td>18 43 32 7</td>
</tr>
<tr>
<td>...my child communicates with other adults</td>
<td>2.7 (0.9)</td>
<td>22 32 36 10</td>
</tr>
<tr>
<td>...my child behaves with me</td>
<td>2.4 (0.9)</td>
<td>13 34 35 18</td>
</tr>
<tr>
<td>...I help my child to behave</td>
<td>2.6 (1.0)</td>
<td>17 38 28 17</td>
</tr>
<tr>
<td>...I communicate with my other childrenb</td>
<td>2.7 (0.9)</td>
<td>25 35 30 10</td>
</tr>
</tbody>
</table>

a N = 82 for this item
b N = 69 (question not applicable for 14 families with only 1 child).

**DISCUSSION**

**Principal Findings**

This is the first trial to take a population approach to systematic measurement of language delay followed by targeted intervention in 4-year-old children. We have shown that it is feasible and acceptable for staff supervised by a speech pathologist to deliver a 1-on-1, standardized yet flexible, 18-session, home based intervention program over a 10-month period to children identified with low language. The promising 5-year-old outcomes indicate benefit to phonological skills and letter knowledge: both intermediaries to subsequent literacy and probably language, and both specifically targeted by the program. However, there was little evidence of benefit to the primary outcome of receptive language, and evidence of improvements in expressive language was weak. The program delivery cost of $3231 per family seems modest for its intensity and duration, and would probably decrease were the program to be fully delivered locally, as travel was the largest cost component of the program as delivered from our tertiary referral center.

**Strengths**

The program was rated positively by parents and was not harmful. The components of therapy were not controversial; they are already widely used clinically by speech-language therapists, and a similarly flexible yet standardized approach is already known to be feasible and acceptable to parents and older children. Our innovation is in (1) the systematic identification of language delay, (2) close attention to program delivery and dose in preschool-aged children, and (3) use of non-specialist therapists. The trial responds to identified evidence gaps, has outcomes of direct relevance to families and the community, and has rigorously measured costs foreshadowing a future economic analysis.

The research design included random allocation, careful quality control of program delivery, high program attendance and overall retention rates, and blinding of all directly assessed outcomes. The manualized program meant that the intervention was tailored to children’s individual needs while following an explicit, replicable protocol. We mimicked actual practice in functioning public health screening programs by obtaining parent consent before the baseline assessment, while preserving their ability to subsequently decline the intervention. All these features indicate high internal and external validity and likely generalizability of findings.

**Limitations**

The benefits to both directly assessed secondary measures were substantial, plausible (because they reflect direct program content), and likely to flow on to subsequent literacy benefits. The fact that we saw benefits in 3 of the 4 directly assessed outcomes, but none of the parent-reported outcomes, suggests lack of parent blinding did not bias outcomes. Our findings may not
generalize to families with insufficient English to participate and very disadvantaged circumstances.

Interpretation
The most effective aspects of the intervention in the short-term appeared to be those targeting the relatively specific phonological awareness and letter knowledge skills, 2 important predictors of subsequent literacy. Thus this intervention could equip preschoolers who have language impairment (itself one of the strongest predictors of later literacy difficulties) with the necessary precursor skills to ease their start into literacy. Beyond this it is not possible to tease apart the reason for the disparity between the phonological awareness and oral language results. The bulk of the therapy activities were directed to respond to the child’s baseline CELF-P2 profile. The primary outcomes were receptive and expressive language, similar to other community-based preschool language trials.12,33 Although the CELF-P2 may be relatively “blunt” to short-term change, this reflects how societal concerns about children’s language are typically expressed (eg, the 2008 British Bercow Report34 and the 2006 US Preventive Services Task Force systematic review on preschool language delay31); one could argue that improvements in broad language domains would provide the most compelling evidence of value-for-money when scaled to the whole population. Ongoing follow-up will determine whether our results consolidate into better literacy and expressive language. The null findings for receptive language are in line with those of many other intervention studies in the field.9

This is the only trial of its type in which participants were recruited to a targeted intervention via population-ascertained language skills. Three other trials have examined service-level data, but delivered “speech and language therapy” rather than specifying a replicable, manualized intervention as in the present trial.26,28,33 A second and perhaps more important issue is the relationship between population ascertainment or screening on the 1 hand and intervention on the other, and the uncertain effectiveness of both31,35,36; as a result, policies to implement language screening have thus far seemed contraindicated. Our trial may go some way toward resolving this issue in favor of population ascertainment, in the event that an adequate screen and sufficient resources are in place. Although the program might not suffice for children who have more severe difficulties for whom other, more intensive, interventions are known to be effective,39 such children could be rapidly triaged if progress lags.

CONCLUSIONS
Given that children who have language impairment are at increased risk for developing reading problems and the robust evidence linking phonological awareness and letter knowledge with later literacy skills, these outcomes are promising. The trial provides the best evidence yet that language delay can be systematically identified and efficiently addressed before formal schooling starts. Such a well-tested intervention, delivered to children by a range of health and educational professionals, might help address inequitable distributions and perceived shortages of speech-language therapists in many English-speaking countries37–39 and thence a real and timely health services policy imperative.34

Further follow-up is ongoing. This will quantify the population outcomes of language delay in this group, determine the longer-term program impacts on children’s language, literacy, and service use, and, in turn, its overall health care and societal costs and benefits.

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