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ARTICLE

A Cluster-Randomized Trial of Screening for Language Delay in Toddlers: Effects on School Performance and Language Development at Age 8

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ABSTRACT

OBJECTIVE. The goal of this study was to assess the effects of screening and early treatment of preschool children for language delay on language development and school performance at age 8.

METHODS. A cluster-randomized, controlled trial and follow-up study of 55 child health centers in 6 geographic regions were conducted from January 2002 to September 2005. A total of 9419 children who were from the general population and aged 15 months at entry were studied. School type end school progress was known for 5406 (57.4%) children. In the intervention group, a structured screening instrument was conducted twice (at ages 15/18 and 24 months), and usual care was applied in the control group. The screening instrument consisted of a uniform set of questions for the parents and test elements for the child. A positive screen result was followed by multidisciplinary assessments at speech and hearing centers and subsequent early treatment if needed. Percentages of children who attended a special school, repeated a class because of language problems, and scored low on standardized language tests, in intention-to-screen analyses, were measured.

RESULTS. At age 8, 2.7% in the intervention group and 3.7% in the control group attended a special school, 6.1% vs 4.9% had repeated a grade, 8.8% vs 9.7% had deficient oral language performance, 4.7% vs 4.7% had deficient reading, and 2.8% vs 4.2% had deficient spelling.

CONCLUSIONS. Screening toddlers for language delays reduces the number of children who require special education and leads to improved language performance at age 8. Nationwide implementation of the screening might be recommended.

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Key Words
screening, language delay, preschool children, RCT

Abbreviations
RCT—randomized, controlled trial
VTO—VroegTijdige Onderkenning Ontwikkelingsstoornissen
RR—relative risk
CI—confidence interval

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CHILDREN'S GENERAL DEVELOPMENT is crucial. In health care, there is much focus on the monitoring of developmental steps in individual young children.[1] Serious problems in cognitive and/or socioemotional development at school age or adolescence often originate from developmental disorders in childhood, of which language delays are the most prevalent.[2–5] In a large Dutch sample from the open population, the prevalence of language delays was estimated between 2.4% and 5.3% in 3-year-olds.[6] Although up to 60% of language delays at the age of 2 to 3 years probably resolve spontaneously,[5] some indicate severe and long-lasting language impairment with detrimental effects at later age.[7] Although effective treatment exists for young children with several underlying causes of language delay,[8] it is unclear whether systematic screening of language delay at an early age is effective.[9] Whether screening leads to better language performance as compared with usual practice can be investigated only in a randomized, controlled trial (RCT).

Several studies[10–14] have evaluated test characteristics of specific screening instruments to detect language delays in preschool children. Only 1 study was set up as an RCT to evaluate the accuracy of a structured test and a parent-led method for language screening among 582 3-year-old children[11]; however, none of these studies evaluated the effects of screening on language performance at later age.

In the Netherlands, on average, 85% of all 0- to 4-year-old children and their parents visit child health centers (for free) at regular times for assessing the child's general development by physicians, including language development. This article describes the effects of a specific screening instrument in a cluster-RCT among 9419 children on school performance and linguistic skills at age 8 in the Netherlands. At this age, children in Dutch schools should normally be in grade 2 of primary school, having had 1 year of reading education. If children are not capable of attending a regular primary school because of learning, behavioral, or health problems, then special education services are offered. Children with severe language delays run a high risk of being placed in special schools or having to repeat a grade.[12] We hypothesized that the screening would result in a reduction in the proportion of children who need to attend a special school, repeat a year in regular school, or have scores in the lowest percentile of several standardized language tests. We reported previously[6] that the screening did lead to more earlier diagnoses and treatments in the first 3 years of life, as compared with a control group.

METHODS

Methods of this cluster-RCT have been published before.[6] Individual randomization is the ideal design, but we used a cluster trial design to avoid biased results (induced by the alternating use of the specific screening instrument for the intervention children and standard monitoring for the control subjects by 1 physician). Child health care physicians were the units for randomization, and children were the units for analysis.

Randomization

We asked the child heath care physicians to identify low- and high-socioeconomic neighborhoods within their region. Within the identified socioeconomic strata, each physician was then allocated a number and randomly classified by rolling dice by the trial's manager as alternately intervention or control physician. Physicians in the control group performed the usual monitoring system, which is based on physicians' observation and on questioning the parents in a limited manner without clearcut referral criteria.[15] The child health center physicians in the intervention group were trained to use the specific screening instrument.

Screening and Diagnosis

The VroegTijdige Onderkenning Ontwikkelingsstoornissen (VTO; early detection of developmental disorders) Language Screening instrument consisted of questions about the language production, language reception, and interaction of children in the age group 12 to 29 months (Appendixes 1 and 2).[6,16,17] With this instrument, the child health center physician in the intervention group interviewed the parents who routinely visited the child health center with their child, which took ~5 minutes. The complete screening procedure embraced a screening interview at 15/18 months as well as at 24 months. The final score was obtained by adding the scores on both screenings, which ranged between 0 and 7. When children had a final score of ≤2, they were referred to the general practitioner for additional assessment at a speech and hearing center to confirm language delay and, if so, to assess the underlying causes.[6] This was done by a uniform protocol of multidisciplinary diagnostic procedures in all regions, which included assessment of language production, language reception, hearing, cognitive development, and socioemotional development.[6] The cutoff score of the VTO Language Screening instrument was obtained in a pilot study by using the Reynell language comprehension test as gold standard. A cutoff score of ≤2 was found to be the most optimal point, allocating 80% of the children as having either true-positive or true-negative results. More details on the validity of the VTO, which was proved to be satisfactory, have been published before.[6]

Follow-up

Follow-up was aimed at all children in both intervention and control groups who according to their date of birth should normally now have been in grade 2 of primary school, in the school years 2001–2002 and 2002–2003, respectively. In the Netherlands, there are separate spe-

cial schools for children with learning problems, for children with a visual disability, for children who are deaf and hard of hearing and for children with severe speech difficulties, for children with mental and/or physical disabilities, and for children with behavioral difficulties. In January of each school year, we informed all primary schools and special schools in the regions of the study population about the follow-up project. Then we informed the parents by mail and asked them for their written consent to obtain data on their child's linguistic abilities from the school and teacher (plus name and address details of the school and teacher). Two months later, the parents received a questionnaire and, if necessary, a reminder for the informed consent. The parents were asked a number of detailed questions about the history of language problems (age and type of problem) and related treatment. The parent questionnaire contained some questions about background characteristics (number of older brothers/sisters, foreign language spoken at home, educational level of parents, and whether the child had a physical or mental disability/illness), which are known predictors for language development.[18,19]

Schools received a list with the names of the children for which we obtained informed consent from the parents. At the end of the school year, the teachers of these children were asked to fill out a questionnaire and to supply the scores on a set of widely known specified standardized language assessment tests. In case these specified tests were not (yet) applied in a particular school, we included the relevant test material in the mail parcel and asked the teacher whether he or she was willing to administer the test(s) to the child. We also included a book for the classroom and a theater voucher as presents for all teachers (independent of the response). Reminders were sent to all parents and teachers who did not respond in the previous periods.

Participants

In 6 regions in the Netherlands, 4 regions in the south, 1 in the midsouth, and in 1 large city in the west, 55 physicians of child health centers were randomly assigned. Inclusion started in May 1995 in the 4 regions in the south, in March 1996 in the midsouth region, and in August 1996 in the city in the west. The participating children were those who were between the age of 15 to 24 months in the given inclusion period and were living within the area of the intervention physicians' health care location and those who were living within the area of the control physician ($n = 11\,440$).

Primary Outcome Measures

The primary outcome measures (at the individual level) were school performance and linguistic ability at age 8. School performance embraced school career, defined by the type of school the child was currently attending, and functioning at school, assessed by determining whether the child had repeated a grade. We assessed both oral and written linguistic abilities of the children by means of standardized assessment tests and the independent (blinded toward arms) judgment of teachers.

School Type and Grade

Data on school type and grade were derived from the parent report on school address details. School type was determined by linking name and address details of the school to the Dutch central registry system, in which each school is allocated a unique number and categorized by school type. Children were assumed to have repeated a grade when their grade was below grade 2 (group 4 in the Netherlands) of primary school, which was the expected grade given the age of the included children.

Standardized Assessment Measures

Teachers were asked to supply the scores of the individual children with respect to receptive and productive oral and written language usage, consisting of a vocabulary test[20]; spelling[21] and reading comprehension[22] tests, which can be administered at group level; and sentence construction[23] and technical reading[24] tests, which are to be administered for each child individually. These outcomes are part of the national pupil monitoring system, which is widely used by teachers in Dutch schools to follow the school progress of individual children in primary school. Each test comprises separate units designed for specific measuring moments in the school year. Norm scores consist of 5 levels, which are based on the scores of these tests on the specified measuring moments in a national sample (A: 25% highest scores; B: 25% just above the average score; C: 25% just below the average score; D: 15% far below the average score; and E: 10% lowest scores).

Teacher and Parent Questionnaires

Apart from the standardized tests, the teacher and parent questionnaires also included questions with respect to oral and written linguistic abilities and learning. In addition, the teacher was asked about the child's future development ("Do you think that in the future the child would develop in a normal way?").

Secondary Outcome Measures

The secondary outcome measure (at the individual level) was the frequency of occurrence of (past) treatment to spur the child's language development, as reported by the parent. Interventions for language difficulties may take many forms because of the broad range of problems as well as the broad range of underlying causes.[5] To assess the number of children treated for language problems in both intervention and control

group, we therefore asked the parents the following question: "Has there ever been anything done to spur on your child's language development?" Children were identified as treated for a language problem when parents confirmed the question by answering ≥1 of the following: "Yes, treatment by speech and language therapist/ear, nose, and throat specialist/remedial teacher/physiotherapist/psychologist/social worker." In addition, parents were asked to report the age around which their child had been treated.

Sample Size

Under conditions of usual care, we estimated that ~2.5% of children would be having serious language problems at 8 years (as defined by attending special education). On the basis of the estimated treatment effect sizes from Law et al,[5] the observed proportions of different types of language delays among the children whose screening was positive at age 2, and the number of children who as a result of the screening would be treated for language delay,[6] we estimated that we could reduce the percentage of serious language delays at age 8 with 20% in the intervention arm, for a significance level of 5% (1-sided), a power of 80%, and equal allocation. For a trial with randomization of individual children to be able to detect such a reduction, a minimum of 2925 children in total would need to be recruited. Because we used cluster randomization, we required a larger sample size to compensate for this design effect. The formula $1 + [(m - 1) \times R]$, where m = the number ot children per cluster, $R = s^2b/(s^2b + s^2w)$, the intracluster correlation coefficient, is used where s^2b is the variance between clusters and s^2w is the variance within clusters.[25] On the basis of the additional assumptions of an estimated intracluster correlation coefficient of 0.005 and an average of 110 eligible and participating children in each cluster $[1 + (110 - 1) \times 0.005 = 1.55]$, we would need $1.55 \times 2925 = 4534$ children in total, which is at least 20 clusters in each trial arm.

Analyses

Comparisons were made between intervention and control groups (intention-to-screen analysis) and between children who completed the full screening procedure (screened at age 15/18 months as well as 24 months) and children who had never been screened by VTO (in this comparison, we excluded children who were screened at 1 age only). The primary outcomes were put to binary variables: regular education/special education, repeating a grade (yes/no), oral and written linguistic abilities according to standardized tests (E level/higher than E level), and normal future development (yes/no) according to the teacher. We analyzed the primary outcome variables by multilevel analysis with 2 levels (cluster and child) by using EGRET 2.0.1[26] for logistic regression with distinguishable binomial random effect. To adjust for possible regional differences, we subsequently included region in the model. Although the trial was designed with a 1-sided hypothesis,[27] we report the results for 2-sided 5% tests for the primary outcomes as well to follow statistical convention.

RESULTS

Figure 1 shows the flow of children in clusters through the trial. In all, 28 child health center physicians were allocated to the intervention group and 27 physicians to the control group. Thirty-six physicians were not enrolled because of either the very small numbers of children in their care or their inability to meet requirements for participation. During the follow-up period, 15% of the cohort was not reachable as a result of a change of address. The parents of a total of 9419 children were asked for consent, 5424 (57.6%) of whom agreed; the parents of 5406 children supplied usable information on school type, and the teachers of 4329 children and the parents of 4281 children completed detailed questionnaires. The response (written consent) in low-socioeconomic neighborhoods was 53.7% (1447 of 2695), whereas the response in middle- and high-socioeconomic neighborhoods was 58.9% (3763 of 6388) and 63.9% (214 of 335; $P = .000$), respectively. In low-socioeconomic neighborhoods, the response in the intervention and control groups was 55.6% and 51.6% ($P = .015$), in middle-socioeconomic neighborhoods was 59.4% and 58.3% ($P = .537$), and in high-socioeconomic neighborhoods was 71.4% and 56.9% ($P = .006$), respectively. Baseline and follow-up characteristics of clusters and children were similar between arms (Table 1). Only between regions were there some differences in the number of clusters and children.

Before the age of 2 (start of screening), there were no differences in the cumulative percentages of reported treatments between the intervention and control groups (Table 2). Before age 3, 3.5% of the children in the intervention group and 2.4% in the control group had been treated to spur language development ($P = .069$). Before age 5, the percentage of children who were ever treated was significantly higher in the intervention group than in the control group: 10.8% vs 8.6% ($P = .024$). Before the age of 9, 26.5% of the children in the intervention group and 23.7% in the control group had been treated to spur language development ($P = .054$). The intention-to-treat analyses revealed that, in children who were allocated to the intervention arm, the relative risk (RR) for special school attendance was 0.71 and the RR for the lowest level of the spelling test was 0.68, calculated according to logistic regression with distinguishable binomial random effect, which takes cluster randomization into account (Table 3). After adjustments for regional differences, the RRs were 0.70 (95% confidence interval [CI]: 0.49–1.02; $P = .063$, $P = .032$ for 1-sided testing) and 0.66 (95% CI: 0.43–1.01; $P = .054$,

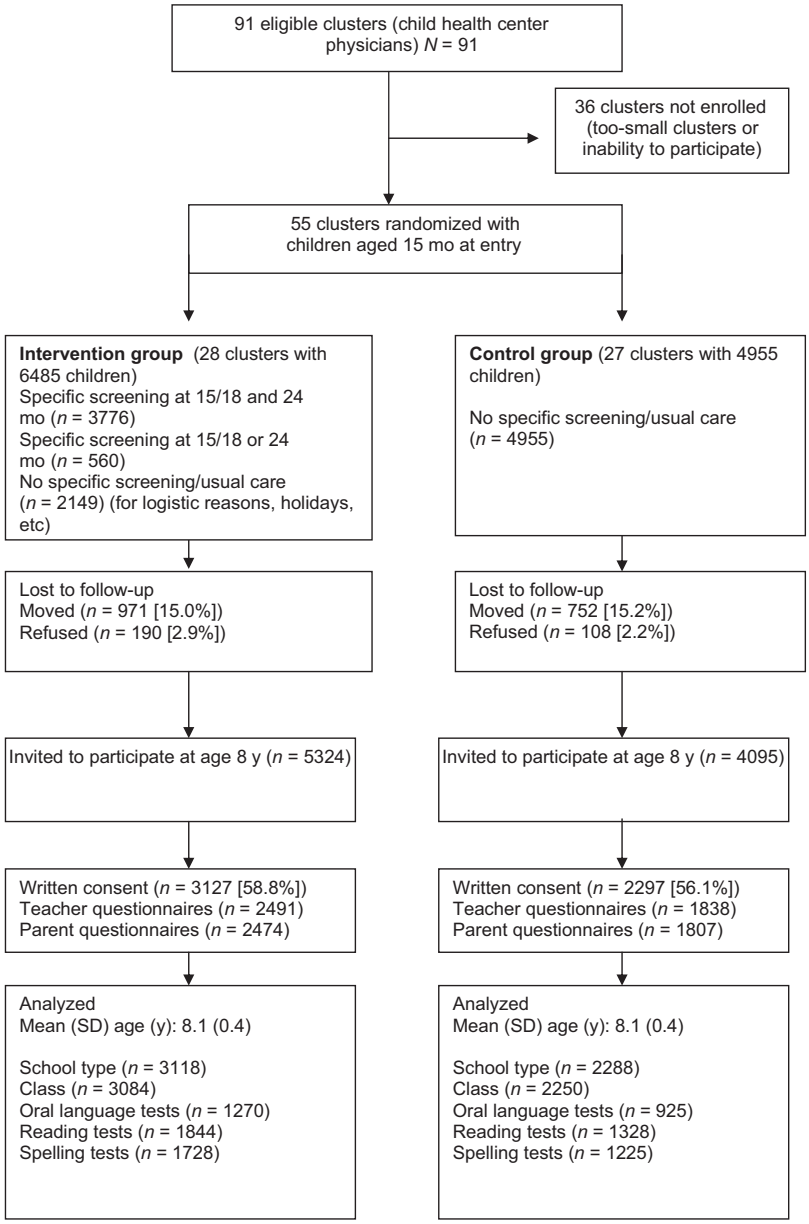

FIGURE 1
Flowchart of child health physicians (clusters) and children through the trial.

$P = .027$ for 1-sided testing), respectively. For the other outcomes, no significant differences were found. In the group of children who underwent the complete screening procedure, the RR for special school attendance was 0.75 (95% CI: 0.62–0.91; $P = .003$) and the RR for lowest level of oral language performance was 0.74 (95% CI: 0.62–0.90; $P = .002$, adjusted for regional differences; Table 4). For the other outcomes, no significant differences were found.

DISCUSSION

We have shown that early detection of language delays in toddlers at child health care centers by means of a specific screening instrument followed by early treatment can reduce the percentage of children who attend a special school at 8 years by 30%. At the same time, the number of children with spelling problems was reduced by 33%. Screened children seemed to have fewer problems with oral linguistic skills. The screening led to more treatments and support in the preschool period.

Parent report on school type and grade proved to be reliable; only <1% of the school addresses were found to be incorrect. With the help of the teachers, the children's linguistic abilities were measured by standardized tests, which were validated and proved to be reliable in previous research.[28] Only a small proportion of teachers were not familiar with the tests; however, this proportion did not differ between the intervention and control groups, so this could not have been a potential bias. Importantly, none of the teachers knew whether the child belonged to the intervention or control group. Special school attendance can be considered to be a valid

TABLE 1 **Characteristics of Child Health Care Physicians (Clusters) and Children: Initially Recruited and Follow-up at Age 8**

Characteristic	Intervention Group	Control Group	Total	*P*
Initially recruited				
Clusters				
Total No. of clusters	28	27	55	—
No. of children per cluster, mean (SD)	224 (173)	184 (133)	204 (155)	—
Region, No. of clusters (children)				
South part (south)	4 (1153)	4 (1141)	8 (2294)	—
South part (mid)	5 (1537)	4 (957)	9 (2494)	—
South part (southwest)	3 (824)	2 (466)	5 (1290)	—
South part (southeast)	3 (1166)	4 (1084)	7 (2250)	—
Midsouth	5 (1409)	8 (1210)	13 (2619)	—
Large city in west part	8 (396)	5 (97)	13 (493)	—
Socioeconomic neighborhood, No. of clusters				
Low	5	6	11	—
Middle	21	20	41	—
High	2	2	4	—
Children				
Total	6485	4755	11440	—
Male, %	50.1	52.0	50.9	.045
Follow-up age 8				
Total	3127	2297	5424	—
Age, mean (SD), y	8.1 (0.4)	8.1 (0.4)	8.1 (0.4)	.862
Male, %	49.9	50.1	50.0	.926
Parental questionnaire				
Physical disability/illness, %	6.8	7.8	7.2	.226
Maternal education, %				.196
Low	14.6	16.6	15.4	—
Intermediate	59.9	59.2	59.6	—
High	25.5	24.3	25.0	—
Paternal education, %				.921
Low	18.7	18.8	18.8	—
Intermediate	45.5	44.8	45.2	—
High	35.8	36.3	36.0	—
Foreign language in family, %	9.5	10.7	10.0	.208
Children in family, *n* (SD)	2.31 (0.84)	2.26 (0.82)	2.28 (0.83)	.053

measure of school performance, because only children with severe educational problems attend such schools in the Netherlands. It should be noted, however, that problems other than language might be the only reason for special school entrance (eg, behavioral problems); therefore, we took account of possible differences in the referral policy for special education by adjusting for regional differences.

At 3 years of age, the VTO screening had been found to result in larger proportions of children with diagnosed and/or treated language problems.[6] In this study, parents in the intervention group reported significantly more

TABLE 2 **Children Being Treated Per Age (Parent Questionnaire)**

Age at Which Child Was Treated to Spur Language Development, y[a]	Intervention ($n = 2192$), Cumulative *n* (%)	Control ($n = 1601$), Cumulative *n* (%)	Total ($N = 3793$), Cumulative *n* (%)	*P*
2	26 (1.2)	20 (1.2)	46 (1.2)	.881
3	76 (3.5)	39 (2.4)	115 (3.0)	.069
4	141 (6.4)	85 (5.3)	226 (6.0)	.165
5	237 (10.8)	137 (8.6)	374 (9.9)	.024
6	331 (15.1)	214 (13.4)	545 (14.4)	.134
7	452 (20.6)	296 (18.5)	748 (19.7)	.107
8	557 (25.4)	364 (22.7)	921 (24.3)	.060
9	581 (26.5)	380 (23.7)	961 (25.3)	.054

[a] Has there ever been anything done to spur on your child's language development (by speech language therapist; ear, nose, and throat specialist, remedial teacher, physiotherapist, psychologist, or social worker)?

TABLE 3 Primary Outcome Measures at Age 8: Intervention and Control Groups (Intention-to-Screen Analysis)

	Intervention Group, *N* (*n* [%])	Control Group, *N* (*n* [%])	Total, *N* (*n* [%])	RR	95% CI	*P*		Intracluster Correlation
						2-Sided Testing	1-Sided Testing	
In special school	3118 (83 [2.7])	2288 (85 [3.7])	5406 (168 [3.1])	0.71[a]	0.48–1.04	.076	.038	0.0031
				0.70[b]	0.49–1.02	.063	.032	0.0028
Repeating a grade	3084 (443 [14.4])	2250 (318 [14.1])	5334 (761 [14.3])	0.99[a]	0.81–1.21	.905	.453	0.0000
				0.99[b]	0.81–1.22	.935	.468	0.0000
Repeating a grade because of language problems in regular primary school (parent questionnaire)	2401 (146 [6.1])	1721 (84 [4.9])	4122 (230 [5.6])	1.26[a]	0.89–1.80	.196	.098	0.0070
				1.28[b]	0.89–1.84	.189	.095	0.0072
Below 10th percentile of oral language tests	1270 (112 [8.8])	925 (90 [9.7])	2195 (202 [9.2])	0.88[a]	0.63–1.23	.464	.232	0.0043
				0.89[b]	0.64–1.24	.248	.124	0.0000
Below 10th percentile of reading tests in grade 2	1844 (86 [4.7])	1328 (62 [4.7])	3172 (148 [4.7])	1.00[a]	0.72–1.40	.994	.497	0.0000
				1.00[b]	0.71–1.40	.944	.497	0.0000
Below 10th percentile of spelling tests in grade 2	1728 (48 [2.8])	1225 (52 [4.2])	2953 (100 [3.4])	0.68[a]	0.41–1.13	.138	.069	0.0064
				0.66[b]	0.43–1.01	.054	.027	0.0000
Do you think that in the future the child would develop in a normal way (teacher "no")	1769 (201 [11.4])	1311 (175 [13.3])	3080 (376 [12.2])	0.83[a]	0.67–1.03	.096	.048	0.0000
				0.83[b]	0.67–1.03	.094	.047	0.0000

[a] Calculated according to logistic regression with distinguishable binomial random effect, which takes cluster randomization into account.

[b] Calculated according to logistic regression with distinguishable binomial random effect, which takes cluster randomization into account, adjusted for region.

treatments related to language development in their child's preschool period, in particular around the time of school entrance. Given the time period, parents might be remembering their child's being treated for language problems rather than the occurrence of (past) language problems; however, these results must be evaluated with caution, because we did not collect detailed data on language problems from specialists as we did previously.[6]

The parents of 57% of all eligible children participated in the follow-up study. Given that we addressed an open population and asked to sign for consent, the response is moderate but acceptable. The response (proportion of written consent) was only slightly lower in low-socioeconomic neighborhoods than in middle- and high-socioeconomic neighborhoods, so we think that the sample is still representative of the total population. The response of the schools and teachers was very high (82%). Although small but significant differences in response between intervention and control groups within low- and high-socioeconomic neighborhoods were found, this could not have been a potential bias of the results because we did not find any significant differences in the distribution of educational level of the parents between the intervention and control groups. In addition, there were no substantial differences in loss to follow-up and nonresponse between the study arms and hence could not have biased the observed differences in outcomes between the intervention and control groups either.

The population visiting the child health centers in the Netherlands is not a selected group: ~95% of all parents visit these centers during the first year of their child's life.[6] Only children who have severe disabilities diagnosed at birth and need specialized care during their first year are seen by pediatricians and rarely visit a child health center.

Most studies[11–14,29,30] on early detection of language problems concluded that it is possible to identify children with language problems at an early stage in the preschool period, sometimes by 2-step screening methods. These studies focused on the test characteristics of the screening instrument. Comparisons across studies are difficult because there is no generally accepted definition of language problems or gold standard, and methods of assessment differ.[5] The most valid method would be clinical examination; however, this is not feasible in population-based studies. Apart from the sensitivity and specificity of the instrument, it is important for economic reasons to consider the proportion of children who have positive screening results and require additional assessment. Previously, we[6] found that the sensitivity of the VTO instrument, resulting in 2.4% of positive screenings, was between 25% and 52%, depending on the assumed prevalence of language problems, which was based on either specialist or parent report. Some studies[31] found higher sensitivity measures at the expense of high referral rates. One RCT reported that the sensitivity of a structured test and a parent-led method was, respectively 66% and 56%[11]; however, the applica-

TABLE 4 **Primary Outcome Measures at Age 8: Screened With Specific Instrument (Completed Screens) and Never Screened With Specific Instrument**

	Screened	Not Screened	Total	RR	95% CI	*P*		Intracluster Correlation
						2-Sided Testing	1-Sided Testing	
In special school	1980 (41 [2.1])	3142 (114 [3.6])	5122 (115 [3.0])	0.75[a]	0.62–0.92	.005	.003	0.0044
				0.75[b]	0.62–0.91	.003	.002	0.0024
Repeating a grade	1961 (265 [13.5])	3092 (447 [14.5])	5053 (712 [14.1])	0.95[a]	0.86–1.04	.256	.129	0.0000
				0.95[b]	0.86–1.04	.282	.141	0.0000
Repeating a grade because of language problems (in regular primary school)	1585 (92 [5.8])	2469 (142 [5.8])	4054 (234 [5.8])	0.98[a]	0.84–1.15	.821	.411	0.0051
				0.98[b]	0.84–1.15	.830	.415	0.0056
Below 10th percentile of oral language tests	817 (55 [6.7])	1271 (137 [10.8])	2088 (192 [9.2])	0.74[a]	0.62–0.90	.002	.001	0.0083
				0.74[b]	0.62–0.90	.002	.001	0.0070
Below 10th percentile of reading tests in grade 2	1188 (55 [4.6])	1829 (88 [4.8])	3017 (143 [4.7])	0.98[a]	0.82–1.16	.819	.410	0.0000
				0.98[b]	0.82–1.16	.791	.396	0.0000
Below 10th percentile of spelling tests in grade 2	1127 (30 [2.7])	1685 (65 [3.9])	2812 (95 [3.4])	0.87[a]	0.68–1.12	.287	.144	0.0099
				0.84[b]	0.66–1.08	.175	.088	0.0032
Do you think that in the future the child would develop in a normal way (answer teacher "no")	1124 (221 [12.3])	1793 (134 [11.9])	2917 (355 [12.2])	0.98[a]	0.88–1.10	.745	.373	0.0000
				0.98[b]	0.88–1.10	.770	.385	0.0000

[a] Calculated according to logistic regression with distinguishable binomial random effect, which takes cluster randomization into account.
[b] Calculated according to logistic regression with distinguishable binomial random effect, which takes cluster randomization into account, adjusted for region.

bility of these results to the general population is questionable because the sample came from a deprived area. Moreover, according to Laing et al,[11] the low uptake and high attrition rate had probably biased the results toward overestimating the performance of the screening test. Laing et al did not recommend formal screening on language problems, because they considered the sensitivity of the structured test not to be substantially higher than that of the parent-led method; however, we think that the sensitivity of the VTO screening instrument pertains to a realistic and acceptable figure, given the low referral rate and the young age of the children.[6] Most important, this is the first study to evaluate the effects of an early language screening program in an RCT, to assess whether the specific screening procedure leads to extra diagnosed and/or treated language problems and, most important, to extra "health" benefits at later age as compared with usual practice.[9] After all, the results of an RCT allow inferences about causal relationships between the screening and the effects.

CONCLUSIONS

We have shown that an early language screening program including a protocol of multidisciplinary diagnostic procedures can reduce special school entrance and linguistic problems. Nationwide implementation of the intervention as part of routine monitoring of children's general development can be recommended.

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APPENDIX 1 **Items of the VTO Language Screening Instrument[17]**

Age, mo	Items
15	1. Word production Animals, people, toys, food/drink 2. Language comprehension Going out, eating, where is the ball, put the doll to bed, get a spoon, let the doll drink 3. Understanding each other Can clearly express her/his need for food/drink, can clearly express her/his need for help 4. Playing (parent-child interaction) How often playing together, what is favorite play, can clearly express that she/he wants to play, playing alone
18	1. Word production Animals, people, toys, food/drink 2. Playing (parent-child interaction) How often playing together, what is favorite play, can clearly express that she/he wants to play, playing alone 3. Language comprehension Getting 3 objects: sock, spoon, small block
24	1. Word production Animals, people, toys, food/drink 2. Playing (parent-child interaction) How often playing together, what is favorite play, playing alone 3. Language comprehension Body parts: eyes, mouth, belly, feet, hair, hand

APPENDIX 2 **Question 1 of the Screening Instrument at 24 Months of Age[17]**

Let us start with the little sounds and words of (name of the child)
Thinking about the past period, can you tell me:
a. How does (name of the child) call people in his/her proximity?
b. What does (name of the child) say if (name of the child) wants something to eat or drink?
c. What does (name of the child) say if (name of the child) wants to play with toys?
Possible answer categories
Sentence
Word or name
Calls by sound or indicates; for instance, br = car
Daddy, mama
Pointing out with sound[a]
Pointing out without sound[a]
Not indicating anything[b]

[a] If the parent's answer is "pointing out," then ask, "Does (name of the child) make any sounds while pointing?"

[b] Does (name of the child) make little sounds? If yes, then what are these sounds like?

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