Title: Effectiveness of domain-based intervention for language development in Japanese hearing-impaired children: a multicenter study

Abbreviated form: Domain-based language intervention for hearing-impaired children

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Abstract

Objective: Decreasing language delay in hearing-impaired children is a key issue in the maintenance of their quality of life. Language training has been presented mainly by experience-based training; effective intervention programs are crucially important for their future. The aim of this study was to confirm the efficacy of 6-month domain-based language training of school-aged, severe-to–profound hearing-impaired children.

Methods: We conducted a controlled before-after study involving 728 severe-to–profound prelingual hearing-impaired children, including an intervention group (n=60), control group (n=30), and baseline study group (n=638). Language scores of the participants and questionnaires to the caregivers/therapists were compared before-after the intervention. Average monthly increase in each language score of the control and baseline study group were compared with those of the intervention group.

Results: Language scores and the results of the questionnaire of the intervention group showed a significant improvement ($p<0.05$). The average monthly language growth of the intervention group was twice that of the control group and three to four times that of the baseline study group ($p<0.05$). The effect size was largest in communication (1.914), followed by syntax (0.931).

Conclusion: Domain-based language training improved the language development and daily communication of hearing-impaired children without any adverse effects.

Key words: language development, hearing impairment, language intervention, before-after study

Introduction

Prelingual severe-to-profound hearing impairment is one of the most frequent neurological deficits, affecting one infant per 1000 live births. Hearing impairment results in language delay and has a lifelong impact, which begins with a lack of fluent communication with preschool friends or unsatisfactory academic performance in school and expands to limited career opportunities in adulthood. Therefore, minimizing language delay is a key issue in addressing the socioeconomic problems in hearing-impaired children. Early hearing detection and intervention (EHDI) has been reported to be one of the most effective strategies for improving language development in hearing-impaired children[1)]. There have been many clinical efforts to promote EHDI, and new technologies, including digitally processed hearing aids (HA) and cochlear implants (CI), have dramatically improved the audiological experiences in children with hearing impairment. However, many reports suggest that language development in hearing-impaired children continues to lag behind compared with that in their normal-hearing peers[2)3)]. We had previously performed domain-based language assessment as part of the baseline study of the Research on Sensory and Communicative Disorders (RSCD)[4)-8)], to evaluate the characteristics of language development in Japanese hearing-impaired children.

The RSCD, a nationwide, multi-institutional epidemiological study, was conducted from April 2009 to March 2010 and supported by the Ministry of Health, Labour and Welfare of Japan. After open recruitment, we collected data on 4–12-year-old hearing-impaired children, with an average hearing level of >70 dB, with the impairment developing ≤4 years of age. The study included 638 children from 124 institutions across Japan, including 66 hospitals and clinics, 24 schools for the deaf, nine preschool training centers, seven universities, and five mainstream schools. A set of language tests (Assessment of Language Development for Japanese Children;

ALADJIN) was administered to measure communication ability, productive/comprehensive vocabulary, productive/comprehensive syntax, and academic achievements in spoken or sign language, with the children using their usual hearing devices[4)].

The major findings of this study were that early intervention, defined as the use of HAs before 6 months of age, was associated with better communication ability in school-age children and that participation in newborn hearing screening (NHS) was strongly correlated with early intervention[5)]. Many other findings of RSCD, however, revealed that school-aged, hearing-impaired children continue to have many language-development problems. For example, in comparisons of Japanese syntactic development by normal-hearing and hearing-impaired children, an apparent delay in grammatical skills was observed among hearing-impaired children, especially in the grammatical structures developed during school age[6)]. Although normal-hearing children acquired all basic grammatical structures before the age of eight, the hearing-impaired children appeared to acquire them ≥12 years of age. It is assumed that this developmental delay in grammar acquisition may readily affect academic achievement.

Another important finding of RSCD was the distribution of language development among hearing-impaired children. Histogram-based analysis of the Test of Question–Answer Interaction Development (TQAID)[9)] revealed that the communication abilities in hearing-impaired children can be clustered into three groups: higher-scoring (43.7%), intermediate-scoring (45.9%), and lower-scoring (10.4%). Although the scores of the intermediate-scoring group in both productive/comprehensive basic vocabulary and productive/comprehensive syntax were in the midrange of the three groups, their comprehensive abstract vocabulary and academic achievement were equivalent to those of the lower-scoring group[7)]. These results suggested both the importance and difficulties in evaluating language development in hearing-impaired children.

Thus, real problems in comprehensive language skills can be easily obscured without detailed language testing since not a few children may superficially appear to speak well.

The comprehensive RSCD results appear to suggest delays in language development among some portion of hearing-impaired children. Because these delays can be diagnosed by domain-based language evaluations, the establishment of intervention protocols to minimize language delay could affect academic performance in school-aged, hearing-impaired children. Although many practical efforts have been directed to achieve this goal, most have utilized experience-based training programs without domain-based language assessments or prescribed programs. In this era of evidence-based practice, the effectiveness of language training for decreasing language delays in hearing-impaired children requires serious attention.

The study of receptive/expressive language impairments has facilitated the development and availability of well-designed clinical trials of language training[10)-15)]. On the basis of these studies in areas other than hearing impairment and the results of our RSCD, we developed a before–after clinical trial using domain-based language training that focused on the weaknesses in spoken Japanese language domains. The aim of our study was to demonstrate the effectiveness of this language training in school-aged, hearing-impaired children.

Patients and Methods

Intervention study design and participants

We used a controlled, prospective before–after study design to demonstrate the effectiveness of domain-based language training for prelingual hearing impairment in both ears of >70 dB on average. The parents of the children in the intervention study (n = 72) agreed to allow the children to receive language training. The inclusion criteria were as follows: (1) 6–12 years of age and (2) language delay of greater than −2 standard deviations (SD) in vocabulary, syntax, or communication/discourse compared with hearing peers of the same age, as determined by ALADJIN. The children were recruited from the registered institutions of this study project, and subjected to pre-intervention analysis to reveal poorly developed domains/regions. Language training was performed by therapists according to the domain-based language training guideline (hereafter referred to as the guideline) developed for this study, and videorecordings were used to monitor for biases or inconsistencies among examiners. Questionnaires were distributed to both caregivers and therapists before and after the intervention to assess changes/improvements in communication ability and behavior in daily life. The language scores and results of the questionnaires were compared before and after the intervention. A second questionnaire was distributed to caregivers for the purpose of obtaining medical and educational background information on the children as supplemental data.

In addition to the pre- and post-intervention study, average monthly growth in language scores and socioeconomic backgrounds were compared between the intervention group and the control group (Appendix study A) and the baseline study group (Appendix study B).

This study was conducted from August 2010 to December 2011. Central review board approvals from the Ethics Committee of the Associations for Technical Aids and Okayama

University Hospital were obtained before the initiation of this study, and written informed consent was obtained from the caregivers of the participants. All investigations have been conducted according to the principles expressed in the Declaration of Helsinki. This trial was registered to the Japanese clinical trial registry: UMIN000005562.

Appendix study A: intervention group versus control group (I/C study)

The control group (n = 34) consisted primarily of children awaiting intervention, who were receiving locally-supplied special education at their mainstream schools or schools for the deaf. Children who had participated in the RSCD baseline study[4)] and received a follow-up language assessment at least 6 months after the baseline study were enrolled in this group. The other inclusion criteria were the same as for the intervention group.

Appendix study B: intervention group versus baseline study group (I/B study)

Children participating in the RSCD baseline study (n = 638) constituted the baseline study group. The inclusion criteria for the baseline study group were as follows: (1) 4–12 years of age and (2) the ability to participate in several language tests[4)].

(The paragraph “Intervention” is removed after this paragraph.)

Language assessments and questionnaires

Audiological assessments, including pure tone audiometry and a speech discrimination test, and several language tests were administered to the participants by an experienced therapist in a sound-attenuated chamber of their institutions in a face-to-face setting. Children underwent the language tests wearing their usual hearing devices. They received a series of ALADJIN language tests[4] including the TQAID[9], which measures communication ability/discourse; the Word Fluency Test[16] (WFT), which measures productive vocabulary; the Picture Vocabulary Test-Revised[17] (PVT-R), which measures comprehensive vocabulary; and the Syntactic Processing Test for Aphasia[18] (STA), which measures productive and comprehensive syntax. In addition, the Raven's Coloured Progressive Matrices[19] (RCPM) test was performed to screen for the presence of nonverbal intellectual delay, and the Pervasive Developmental Disorders Autism Society of Japan Rating Scale[20](PARS) was distributed to the caregivers to screen for pervasive developmental disorder-like behavior characteristics.

The questionnaires for the intervention group were distributed to both the caregivers and the trainers before and after intervention, separately. This questionnaire included questions about descriptive skills and conversational skills, friendships, and the caregiver's and trainer's impressions regarding the child, such as "Does he/she respond appropriately to the questions" and "Does he/she recognize irony?" Caregivers were asked to select one of the following four scores for each question: almost always (score 3), mostly (score 2), rarely (score 1), or never (score 0). The trainers were asked to select one of the following five scores for each question: almost always (score 4), mostly (score 3), sometimes (score 2), rarely (score 1), or never (score 0). The scores for each item and the total scores were used in the analysis.

Another questionnaire was distributed to the caregivers of all three groups, asking for the following information: birth date, birth weight, gender, participation in NHS, age at first use of a HA and/or preschool language training, type of hearing device, mode of communication, family structure, family annual income, family size, familial involvement in education, and parental education levels. The 15 questions used to assess familial involvement included the following: (1) Do you play with your child? (2) Do you talk with your child about his/her future? (3) Do you talk with your child about social concerns? and (4) Do you participate in parent–teacher association activities? Caregivers were asked to select one of four scores for each question: almost always (score 1), sometimes (score 2), rarely (score 3), or almost never (score 1). Parental educational levels were measured by asking for the final academic background of the caregivers as follows: junior high school (score 1), high school (score 2), professional training college (score 3), junior college (score 4), university (score 5), or graduate school (score 6). The total scores were used in the analysis.

Intervention

The goals of the intervention were to improve the poorly developed spoken Japanese language domains of vocabulary, syntax, and communication/discourse, as identified in the pre-intervention ALADJIN analysis. Cooperating institutions were recruited for this intervention program, and therapists were required to complete a course in the comprehension and practice of domain-based language analysis and training. The guideline was based on Boyle et al.[10], modified for Japanese hearing-impaired children. It described the interpretation of language analysis and practical training methods on the basis of the language analysis results, and introduced the use of training materials including cards and books. Before beginning intervention, the results of pre-intervention analyses were discussed by the therapists and the review board of this study project, which was composed of experienced speech–language–hearing therapists, teachers at schools for the deaf, and otolaryngologists, and an appropriate training program for each participant was selected from the guideline. The intervention was performed according to the guideline with a top-down approach.

The criteria for the intervention were as follows.

Vocabulary training: Children who met the following criteria were eligible to undergo vocabulary training: those with more than one year delay on the subscales of the TQAID entitled Riddle or Explanation of the meaning of words; those in whom a language delay of greater than −2 SD was recorded in the results of vocabulary testing using the PVT-R and WFT; those in whom less use of nouns and more use of onomatopoeia or mimetic words were observed in daily communication.

Syntactic training: Children who met the following criteria were eligible to undergo syntactic training: those with more than one year delay on the subscales of the TQAID entitled Supposition, Reason, or Explanation; those in whom a language delay of greater than −2 SD was recorded in the results of syntactic testing using the STA; those in whom syntax had developed disproportionately (according to STA score) compared with vocabulary (as indicated by PVT-R and WFT scores); those in whom grammatical errors, including misuse of the grammatical particles, were frequently observed in daily conversation.

Training of communication/discourse: Children who met the following criteria were eligible to undergo syntactic training: those in whom a language delay of greater than −2 SD was recorded in the results of the TQAID.

Participants received 40 min of individual language training for 12 sessions over 6 months at their affiliated institutions in a face-to-face setting by speech–language–hearing therapists and teachers. Repeated monitoring and discussions between the review board and the therapists were carried out, in compliance with the training program.

Data preparation

Standard scores, configured for the baseline study group (n = 638) as the parent population, were used to analyze the results of the language tests. The means and SDs of TQAID, WFT, PVT-R, and STA scores were then calculated (Table 1). The standard scores (SS = 50 + 10 × <z score>, z score = (score of the language test of each child - mean score of the language test) / SD) for the intervention and control groups were calculated using these parameters and designated TQAID(SS), WFT(SS), PVT-R(SS), and STA(SS).

We prepared four outcome measures to assess language development: the total language development (TLD) score, the vocabulary (V) score, the syntax (S) score, and the communication (C) score. Each score was calculated as described in Table 1. The monthly improvements in these four outcome measures were calculated by dividing the increase of the language scores with the test-retest intervals. Regression lines were drawn using the data from the baseline study, and the coefficient values were calculated. These values represented the average growth in language scores of hearing-impaired children, as shown in Table 2.

Statistical analysis

Intervention study

The four outcome measures, i.e., the TLD, V, S, and C scores, were compared by paired t-tests before and after intervention. In addition, the four outcome measures in the pre-intervention analysis of the dropped out participants were compared to the intervention group with a two-sample t-test.

We also used paired t-tests to separately compare the items and total questionnaire scores obtained from the caregivers and language therapists before and after intervention.

I/C and I/B studies

For I/C study, the average monthly improvements in the four outcomes for both groups were compared with two-sample t-tests. The effect sizes of the intervention were also calculated.

For I/B study, the same scores between the intervention and baseline study groups were compared using z-tests.

As supplemental data, background information on the children in the intervention group was compared with those of the control and baseline study groups. Pearson's chi-square tests were performed for gender, participation in NHS, age at first wearing a HA (≤6 or ≥7 months), use of CI or use of sign language, and familial income (<5 million yen or ≥5 million yen). Two-sample t-tests were performed for age, birth weight, standard score on RCPM, PARS score, age at beginning preschool language training, aided hearing level on pure tone audiometry, best score on speech discrimination test, familial participation, parents' education levels, and the number in the family.

The significance (p) level was set at 0.05. Analyses were performed with IBM SPSS version 19 software (IBM Corp., Armonk, NY, USA) on a Windows 7 computer.

Results

A total of 744 hearing-impaired children were enrolled in this study (Fig. 1).

In the intervention group, 12 children failed to complete the intervention for various reasons including caregiver illness (n = 3), implant failure or re-implantation (n = 2), earthquake disaster, divorce of the parents, or the need for treatment of another disease. Thus, 60 children completed the intervention and were included in the final analysis. There were seven male and five female in the dropped out group, and the age were as follows, mean: 119.9m, SD: 28.929. There were no significant difference of the baseline data of the dropped out group and the intervention group (Table 3).

Among the 34 control group subjects, four cases were eliminated because of insufficient data, resulting in a final total of 30 children in the control group. The natural language growth of the control group is shown in Table3.

Intervention study

Intervention was performed by 24 speech–language–hearing therapists at 15 registered institutions across Japan, including 10 medical institutions, four training centers, and one school for the deaf from August 2010 to December 2011. Each of the standard language scores improved significantly ($p<0.01$) by approximately 5 points after 6 months of language training (Table3). All items on the caregiver and therapist questionnaires showed significant improvement ($p<0.05$) following intervention (Table 4).

There were no protocol deviations from the study as planned, except for the child who failed to complete intervention, and there were no adverse events related to the intervention.

I/C study

The mean monthly improvements in language scores for both groups are shown in Table 5.

Language growth in the intervention group was significantly better (almost two times higher) than that in the control group ($p<0.05$). The effect size of the intervention was highest in the C score (1.914), followed by that in the S score (0.931).

There were no significant differences in any of the background information between the intervention and control groups, as shown in Tables 6 and 7. (supplemental data)

I/B study

The mean monthly improvements in the language scores in the intervention group were significantly (three to four times) higher than those in the baseline study group ($p<0.001$), as shown in Table 5.

There were no other differences in background factors between the two groups, expect the NHS participation rate, the use of CI, age, aided hearing level, and the best score on the speech discrimination test. ($p = 0.013$, $p = 0.001$, $p = 0.003$, $p = 0.007$, and $p = 0.010$, respectively) as shown in Table 6 and 7 (supplemental data).

Discussion

Although an appropriate study design ensures relevance for clinical practice, to our knowledge, there have been no previous clinically designed intervention studies of language development in hearing-impaired children[21)]. In this study, we enrolled a large number of school-aged children and carefully assessed their language development and demographics. We introduced an original training guideline for the purpose of administering prescribed language training for hearing-impaired children. The conversion of the language development scores into standard scores enabled us to compare children of different ages in the three groups.

After 6 months of language training, language development, as measured by five standard scores, was significantly improved in the intervention group. On the other hand, the results of the follow up analysis of the control group showed that there is a natural language growth among 6 months, and comparing the monthly language growth between each group might have been appropriate. The mean monthly language growth in the intervention group was significantly higher than that in the control group (two times) and in the baseline study group (three to four times). Calculated from these data, the language growth after 6 months of domain-based language training was equivalent to as much as 2 years of language growth without additional interventional services. This indicates that when hearing-impaired children receive well-planned, intensive language training following appropriate language assessment, language delays would be expected to decrease in a relatively short time.

The results of the effect size showed that the impact of the intervention was largest in communication (C score, 1.914), followed by syntax (S score, 0.931). In contrast, the effect of the intervention on vocabulary (V score) was relatively small (0.458), although it was still significant. Because our training protocol was primarily based on conversational interactions between the child and the therapist, communication skills may be improved at a relatively early stage of intervention. In contrast, the intervention protocol for vocabulary development included lessons in methods for guessing the meaning of the words; thus, the effects may become apparent at a later stage or even after the intervention program. Long-term outcomes assessed by follow-up study may reveal the more accurate effect sizes of this intervention.

The questionnaire results also demonstrated significant improvements after 6 months of training, as observed by both caregivers and therapists. This suggests that the effects on language development are not limited to the testing conditions but extend to daily communications.

Limitations

Our study has limitations. The first limitation of this study was that there may have been several selection biases because it was not a randomized controlled study. The children who participated in the intervention may have come from families with more concern for education, and familial communication[5)] and parental education[22)23)] are important factors for better language development. However, there were no significant differences in socioeconomic data between the intervention and control groups, suggesting that any possible biases were relatively small. Nevertheless, more children in the intervention group had undergone NHS and CI and eventually exhibited better aided-hearing levels and speech discrimination when compared with the baseline study group. Although the percentages of children who received NHS or CI did not differ between the intervention and control groups, it is possible that in the I/B study, the groups were not fully comparable in this regard.

Second, although approximately half the children in all three groups used both spoken and sign language, the preferred communication in daily life may have differed among the children in each group. Because our training guideline was based upon a study of receptive/productive language impairment using assessments of spoken Japanese, the intervention group might have included more users of daily spoken language. Therefore, there is a need for the development of Japanese sign language assessments and a corresponding intervention protocol.

Third, because the language assessment was not always performed by the same therapists, there might have been observer bias. We utilized videorecordings to minimize this.

Fourth, since the intervention period was limited to 6 months, the changes in language development and communication in daily life were assessed over a relatively short period. The long-term merit of this 6-month intervention should be evaluated to determine whether language ability continues to improve. All of the participants are now being followed to evaluate the long-term efficacy of this intervention.

The fifth limitation of this study was that the outcome measures were limited to growth in specific aspects of language, such as vocabulary, syntax, and communication/discourse. Thus, it remains to be determined whether these improvements in domain-based tests are associated with improved quality of life, including academic performance, job opportunities, or other aspects of daily life.

Clinical implications and future directions

Because we consider the ultimate goal of language intervention to be improvements in the welfare of hearing-impaired children, further study is needed to measure long-term outcomes, perhaps with the inclusion of more participants. According to the RSCD study, the most reliable prognostic factors for academic achievement are comprehensive vocabulary and comprehensive syntax[8)]. Although our study had several limitations, the improvements in these aspects appear to be promising for the improved academic achievement of hearing-impaired children. In summary, domain-based language training may contribute to the language development of school-aged, hearing-impaired children without adverse effects.

Conclusions

Domain-based, well-designed language therapy was shown to promote better language development for hearing-impaired children, and their language growth after 6 months was equivalent to 2 years of language growth in children who did not receive additional interventional services. The questionnaire results indicated a high level of satisfaction among the caregivers and language therapists. There were no adverse events related to the intervention.

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Figure Legend

Table 1: Language tests and domains comprising the outcome measures

Means and SDs were referenced data from the baseline study of the RSCD project.

Each score were calculated as follows:

TLD score =[PVT-R(SS)+ WFT(SS) + STA comprehension (SS) + STA production (SS)]/4

V score = [PVT-R(SS) + WFT(SS)]/2

S score = [STA comprehension (SS) + STA production (SS)]/2

C score = TQAID(SS)

Table 2: Regression equations for the outcome measures calculated from the baseline study

y = score, x = age in months

Significant p values (<0.05) are underlined.

Figure 1: Participant flowcharts

Flowchart of the numbers of participants in the intervention group, the control group, and the baseline study group

Table 3: Changes of the language scores of the intervention group and the control group

Upper part of the table: the intervention group, and lower part of the table: the control group. Significant p-values by two-sample t-test and paired t-tests of the intervention group; significant p-values (<0.05) are underlined.

Table 4: Caregiver and therapist questionnaire scores before and after intervention

Significant p values (<0.05) by paired t-tests are underlined.

Table 5: Comparison of the mean monthly language growth in the I/C study (t-test) and I/B study (z-test) and effect size in the I/C study

Significant p values (<0.05) are underlined.

Table 6: Pearson's χ^2 tests comparing backgrounds in the I/C and I/B studies

Significant p values (<0.05) are underlined. (Supplemental data)

Table 7: Two-sample t-tests for demographic factors in the I/C and I/B studies

Significant p values (<0.05) are underlined. (Supplemental data)

PTA: pure tone audiometry

Table 1. Language tests and domains comprising the outcome measures

	TQAID	PVT-R	WFT	STA(c)	STA(p)
Language Domain	Communication/ discourse	Vocabulary (comprehension)	(production)	Syntax (comprehension)	(production)
Mean	210.253	25.380	21.560	20.740	31.270
SD	75.262	19.710	10.666	10.872	17.458
TLD score	__	○	○	○	○
V score	__	○	○	__	__
S score	__	__	__	○	○
C score	○	__	__	__	__

Table 2. Regression equations for the outcome measures calculated from the baseline study

Outcome measures	Regression equation	R^2	p-value
TLD score	y = 0.216x + 29.190	0.448	<0.001
V score	y = 0.237x + 27.237	0.501	<0.001
S score	y = 0.200x + 30.611	0.335	<0.001
C score	y = 0.232x + 26.970	0.392	<0.001

Figure 1. Participant Flowcharts

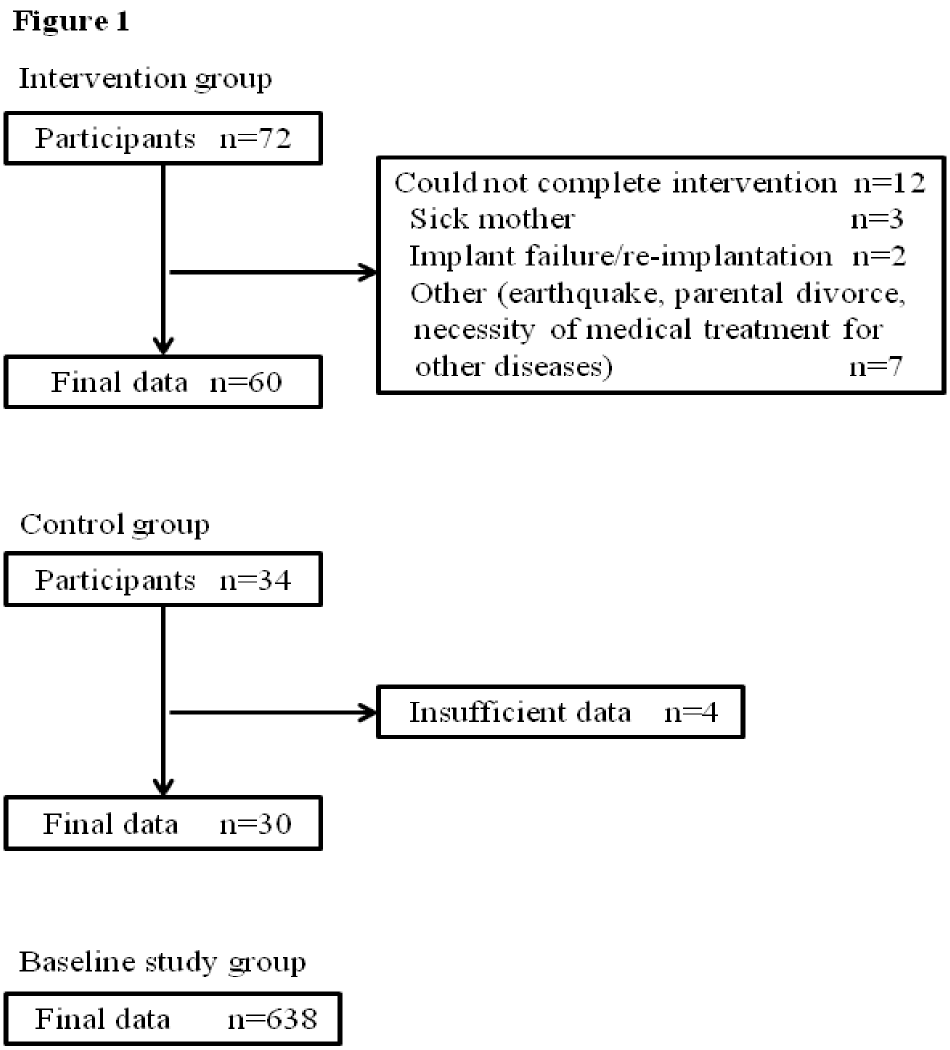

Table 3. Changes of the language scores of the intervention group and the control group

Language outcomes	Dropped out group Mean (SD)	Before intervention: Mean (SD)	After intervention Mean (SD)
TLD score	55.73(6.12)	54.30 (5.23)	59.47 (4.70)
p-value	0.413		0.001
V score	53.62(7.53)	53.69 (5.12)	58.60 (5.88)
p-value	0.997		≤0.001
S score	56.98 (6.59)	54.30 (7.31)	59.81 (5.61)
p-value	0.323		≤0.001
C score	56.29 (4.00)	52.96 (7.62)	57.03 (6.08)
p-value	0.207		≤0.001

Language outcomes	RSCD baseline study Mean (SD)	Follow up assessment Mean (SD)
TLD score	48.45 (7.26)	53.12 (6.88)
V score	48.91 (7.83)	53.32 (7.76)
S score	48.12 (7.27)	53.14 (7.27)
C score	54.31 (5.11)	56.56 (3.86)

Table 4. Caregiver and therapist questionnaire scores before and after intervention

Caregivers	Before intervention: Mean (SD)	After intervention: Mean (SD)	p-value
General impression	8.07 (1.582)	8.48 (1.621)	0.021
Descriptive skills	13.62 (4.570)	16.05 (4.077)	<0.001
Conversational skills	26.57 (8.259)	31.12 (7.603)	<0.001
Friendship	22.72 (5.909)	26.32 (5.537)	<0.001
Other	11.87 (2.825)	13.27 (3.209)	<0.001
Impression regarding the child	30.83 (5.831)	33.72 (5.645)	<0.001
Total	113.67 (24.477)	128.95 (23.892)	<0.001
Therapists	**Before intervention: Mean (SD)**	**After intervention: Mean (SD)**	**p-value**
General impression	21.03 (4.614)	22.67 (3.847)	<0.001
Describing skills	17.13 (5.697)	20.67 (5.470)	<0.001
Conversational skills	48.27 (13.619)	57.45 (11.661)	<0.001
Total	86.43 (22.447)	100.78 (19.980)	<0.001

Table 5. Comparison of the mean monthly language growth in the I/C study (t-test) and I/B study (z-test) and effect size in the I/C study

	I/C study		I/B study
Language outcomes	Control group Mean (SD)	Intervention group Mean (SD)	Baseline study group Mean (SD)
TLD score	0.428 (0.504)	0.792 (0.511)	0.216(0.240)
p-value	0.003		<0.001
Effect size	0.722		
V score	0.423 (0.721)	0.753 (0.644)	0.273(0.243)
p-value	0.036		<0.001
Effect size	0.458		
S score	0.437 (0.467)	0.872 (0.739)	0.200(0.293)
p-value	0.002		<0.001
Effect size	0.931		
C score	0.183 (0.256)	0.673 (0.706)	0.232(0.283)
p-value	<0.001		<0.001
Effect size	1.914		

Supplemental data

Table 6. Pearson's χ^2 tests comparing backgrounds in the I/C and I/B studies

	I/C study		I/B study
Background	Control group (n)	Intervention group (n)	Baseline study group (n)
Gender			
Male	18	26	315
Female	12	34	312
Unknown	0	0	11
p-value	0.136		0.307
NHS participation			
Yes	12	29	199
No	17	31	414
Unknown	1	0	25
p-value	0.537		<u>0.013</u>
Age of wearing HAs			
≤6 months	9	11	144
>7 months	21	47	488
Unknown	0	2	6
p-value	0.242		0.505
Use of CI			
Yes	20	41	289
No	10	19	349
p-value	0.873		<u>0.001</u>
Use of sign language			
Yes	15	24	316
No	15	36	318
Unknown	0	0	4
p-value	0.367		0.145
Family income/year			
<5000,000	19	28	296
≥5000,000	8	14	237
Unknown	3	18	105
p-value	0.747		0.161

Supplemental data

Table 7. Two-sample t-tests for demographic factors in the I/C and I/B studies

Background	Control group (I/C study)	Intervention group (I/C study; I/B study)	Baseline study group (I/B study)
	Mean (SD)	Mean (SD)	Mean (SD)
Age (m)	108.233 (26.258)	105.517 (20.260)	96.8674 (27.241)
p-value	0.589		0.003
Birth weight (g)	3008.6 (345.5)	2878.8 (457.6)	2926.5 (548.0)
p-value	0.118		0.521
RCPM standard score	50.22 (9.584)	49.26 (9.602)	50.00 (10.01)
p-value	0.719		0.663
PARS score	5.90 (5.222)	5.55 (3.764)	5.59(4.763)
p-value	0.545		0.960
Commencement of preschool rehabilitation (m)	18.22 (12.574)	26.39 (21.665)	21.50 (16.384)
p-value	0.084		0.082
Aided hearing level of PTA (dB)	37.63 (10.22)	36.43 (11.94)	41.95 (13.83)
p-value	0.658		0.007
Best score of the speech discrimination test (%)	73.57 (19.882)	76.71 (21.604)	62.10 (31.35)
p-value	0.737		0.010
Familial participation	18.03 (2.956)	17.15 (2.841)	17.62 (3.553)
p-value	0.194		0.365
Parental education level	10.10 (4.329)	10.46 (4.528)	10.60(4.499)
p-value	0.740		0.849
Number in the family (n)	4.37 (1.273)	4.37 (1.301)	4.42(1.201)
p-value	1.000		0.733