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A randomized controlled comparison of NAL and DSL prescriptions for young children: Hearing-aid characteristics and performance outcomes at three years of age

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Abstract

Objective—To determine the influence of choice of prescription and other child-, family- and intervention-related factors on speech, language, and functional performance of hearing-impaired children by three years of age.

Design and study sample—A randomized controlled design was implemented as part of a population-based, longitudinal study on outcomes of children with hearing impairment (LOCHI) in Australia. Two hundred and eighteen children were randomly assigned to either the NAL or the DSL prescription for first fitting of hearing aids. Their performance outcomes were evaluated.

Results—Prescriptive targets were closely matched in children's hearing aids. There were not significant differences in children's language, speech production, or functional performance between prescriptions. Parents' ratings of children's device usage and loudness discomfort were not significantly different between prescription groups. Functional performance within the first year of fitting together with degree of hearing loss, presence of additional disabilities, and maternal education explained 44% of variation in language ability of children by three years of age.

Conclusions—There was no significant association between choice of hearing-aid prescription and variance in children's outcomes at three years of age. In contrast, additional disability, maternal educational level, and early functional performance were significant predictive factors of children's outcomes.

Keywords

Hearing-aid prescription; children; NAL-NL1; DSL v.4.1; randomized controlled trial; DSL m[i/o]; NAL-NL2; maternal education; socio-economic status; language; speech; functional performance; PEACH; PLS-4; PPVT; CDI; DEAP

The implementation of universal newborn hearing screening has made it possible for early identification of hearing loss and provision of intervention. As a crucial component of intervention, timely amplification with optimal gain-frequency responses is essential. The prescribed responses of the National Acoustic Laboratories (NAL) procedure (Byrne et al, 2001) and the Desired Sensation Level (DSL) procedure (Seewald et al, 1997; Scollie et al, 2005) are widely adopted by clinicians as targets for fitting hearing aids to children. These procedures differ in rationale. The NAL procedure aims to maximize predicted speech intelligibility while limiting total loudness to no greater than that perceived by a normal hearer listening to the same sound; whereas the DSL procedure aims to normalize loudness at different frequencies. For this reason, the prescriptions sometimes differ markedly in terms of gain-frequency responses for the same audiometric configurations (Byrne et al, 2001; Ching et al, 2010; Johnson & Dillon, 2011). Despite their worldwide adoption, the relative effectiveness of the respective prescriptions for supporting children's speech and language development is yet to be established.

Over the past decade, we have increased our understanding of the effects of choice of prescriptions for school-aged children through both independent research and collaborative research between the National Acoustic Laboratories and the University of Western Ontario. First, large differences in gain-frequency responses prescribed by the NAL and the DSL prescriptions were generally not achieved in real-life fitting of hearing aids. On average, the gain difference between the two prescriptions achieved in hearing aids was 7 dB for mid input levels (Ching et al, 2010). Second, speech perception by children in laboratory settings was similar for both prescriptions (Scollie et al, 2010). Third, loudness ratings of speech amplified with either prescription were within the range of comfortable listening. Even though the different prescriptions led to predictable differences in loudness rating at initial fitting, these differences largely disappeared with several weeks of listening experience (Jenstad et al, 1999, 2000, 2007; Scollie et al, 2010). Fourth, children preferred to listen to amplified speech in laboratory conditions at levels to which they were accustomed (Ching et al, 1996; Scollie et al, 2000, 2010). Fifth, children's preferences in everyday life were largely driven by auditory experience, although there were some variations related to real-world environments. They preferred the DSL prescription when listening to soft speech, but the NAL prescription when listening to speech in noisy environments (Scollie et al, 2010). Overall, the existing evidence suggests that the choice of prescription has little consequence in speech understanding or listening comfort for older children with largely late-identified mild to moderately severe hearing loss. However, the effects of auditory experience cannot be separated from those of electroacoustic differences resulting from application of the respective prescriptions in hearing aids (Ching et al, 2010). Such differences may be important for children's development of speech, language, and functional skills in the short and longer term when amplification is provided from the first few months of life. There were no current studies that examined the developmental impact of prescription choice on young children newly identified with hearing loss.

As with all aspects of intervention, the effectiveness of hearing-aid fitting needs to be established by evaluating and monitoring children's performance with amplification. For infants and young children, evaluation tools that rely on parent observations and reports on children's functional performance in real-world environments are widely used (Zimmerman-Phillipps et al, 1998; Weichbold et al, 2004; Ching & Hill, 2007; Coninx et al, 2009). Such tools may be used to check whether amplification characteristics may need to be altered (Byrne & Ching, 1997) or, in the more extreme case, if different management practices including cochlear implantation, alternative communication modes, and styles of early educational intervention should be considered. Furthermore, if functional performance assessed shortly after the implementation of amplification were predictive of longer term

outcomes, strategies may be designed to target children with low early functional levels. However, no prospective studies have been conducted to collect such data.

The present study was designed to address the evidence gaps by evaluating the relative effectiveness of the NAL and DSL prescriptions for infants and young children who were newly identified with hearing loss. The existence of a national hearing service network, Australian Hearing (AH), for hearing-impaired children in Australia ensures that consistent and uniform services are provided to all children. As the research arm of AH, we conducted a randomized controlled trial of prescriptions for children who first received intervention for hearing loss before three years of age. This trial is a sub-component of the population-based longitudinal study on outcomes of children with hearing impairment (LOCHI study, ACTRN12611000429954). Through the national service provision network, we invited families to participate in this study. Once informed consent was obtained, children were randomly assigned to either a NAL or DSL prescription for hearing-aid fitting. Their hearing thresholds, hearing-aid real-ear gains, and outputs were assessed and monitored via the service provision network; and their outcomes were evaluated at several time points by researchers. The outcomes measures included speech production, expressive and receptive language, social skills and real-life functional performance.

On the basis of current knowledge, it was hypothesized that children's development at three years of age would not differ according to the prescription used for fitting. We speculated that family and intervention related factors would be important to speech, language, and functional outcomes. The primary aim of this study was to quantify the contribution of prescription method, together with other putative child, family, and intervention related factors, to explaining children's development of receptive and expressive language, speech production, and functional performance by three years of age. A secondary aim was to investigate whether functional performance assessed shortly after intervention could be a significant predictor of variability in outcomes at three years of age.

Method

Design of the study

This is a randomized controlled study. We compared outcomes of children with bilateral hearing loss according to their exposure from inception to either the NAL or the DSL procedure for hearing-aid fitting. A prospective approach was used to examine development after amplification, with measures conducted at 6 and 12 months after hearing-aid fitting, and at the chronological age of three years. This paper reports the children's performance at three years of age (children's age at evaluation ranged between 34 and 42 months, with 96% of the evaluations performed between 36 and 42 months).

Participants

All families of children with hearing loss born between 2002 and 2007 were invited to participate in the LOCHI study (Ching et al, 2010) if they: (1) were residing in the Australian states of New South Wales, Victoria, and Queensland (excluding regional Queensland), and (2) first presented for hearing services at AH paediatric centres before the children turned three years of age. The sample in this trial of hearing-aid prescription comprised the sub-group of children diagnosed with bilateral hearing loss who enrolled in the study prior to hearing-aid fitting, and who were using bilateral hearing aids by three years of age. There were 218 children, comprising 129 boys (59%) and 89 girls (41%). This sample size permits an effect size of 0.28 within-group standard deviation to be detected with a power of 80%, for an alpha level of 0.05.

Demographic characteristics

The demographic characteristics of children were solicited from parents using custom-designed questionnaires. Family socioeconomic status was determined from the Australian Census-based socio-economic indexes for areas (SEIFA) index for relative socioeconomic advantage and disadvantage (Australian Bureau of Statistics, 2008). The index defines relative socioeconomic advantage and disadvantage in terms of 'people's access to material and social resources, and their ability to participate in society' (ABS, 2008, p. 6). A lower index is associated with greater relative disadvantage. Maternal education was specified in terms of a 3-point scale: less than or equal to 12 years of school attendance, diploma or certificate, and university qualification.

Hearing-aid fitting

All children had bilateral sensorineural hearing loss. Following enrolment, individual children were randomly assigned to hearing-aid fitting with either the NAL prescription (NAL-NL1; Byrne et al, 2001) or the DSL prescription (DSL[i/o] v.4.1; Seewald et al, 1997). All children were fitted bilaterally with multi-channel hearing aids that have wide-dynamic-range compression capabilities, in accordance with the AH national paediatric amplification protocol (King, 2010). Hearing thresholds were estimated from electrophysiological measures at diagnosis or, where applicable, behavioural measures were obtained using standard audiological procedures. A real-ear-aided gain approach (Moodie et al, 1994; Seewald et al, 1999; Ching & Dillon, 2003; Bagatto et al, 2005) was used for fitting. This involved using either individual real-ear-to-coupler differences (RECD) or age-appropriate values to derive gain targets in an HA2-2cc coupler by using the NAL-NL1 or the DSL v.4.1 standalone software. Hearing aids were adjusted in an HA2-2cc coupler, using a broadband speech-weighted stimulus generated by the Aurical system to measure gain-frequency responses at low, mid, and high input levels, and a swept pure tone presented at 90 dB SPL for measuring maximum output. Verification was achieved by comparing the measured 2cc coupler gain/output to custom target values.

As an integral part of the ongoing audiological service provision, children's hearing-aid fittings were adjusted as and when there were changes in hearing thresholds and when updated versions of prescriptive procedures become available. At the time of evaluations reported in this study, the DSL group comprised 57 children fitted according to DSL m[i/o] (Scollie et al, 2005), with the remaining children fitted according to DSL v.4; and all children in the NAL group used hearing aids fitted according to NAL-NL1. Subsequent to evaluations, the hearing-aid fittings of all children have been updated, according to their assigned group, to either DSL m[i/o] or NAL-NL2 (Dillon et al, 2011). For purposes of comparing children's hearing-aid gain-frequency responses used at evaluations to current versions of each of the two prescriptive procedures, we used the standalone software to derive custom targets for individual children. These targets were compared to the measured hearing-aid gain and output values to quantify the deviation of user values from optimal gain/output based on current knowledge.

Evaluation Measures

A team of qualified speech pathologists who were blinded to children's hearing aid characteristics administered a range of age-appropriate measures directly to children at three years of age. These included the Preschool Language Scale (PLS-4; Zimmerman et al, 2002), and the Peabody Picture Vocabulary Test (PPVT; Dunn & Dunn, 1997, 2007) for assessing expressive and receptive language and vocabulary; and the Diagnostic Evaluation of Articulation and Phonology test (DEAP; Dodd et al, 2002) for assessing speech production. Also, speech pathologists provided a rating on the overall intelligibility of speech produced by children. In addition, parents completed written questionnaires. These

included checklists based on the Child Development Inventory (CDI; Ireton, 2005) for children's expressive and receptive language as well as social skills development, and the Parents' Evaluation of Aural/oral functional performance of CHildren (PEACH; Ching & Hill, 2007) for children's functional performance in real life. The PEACH also provided a measure of usage of hearing device and listening comfort in daily lives, as reported by parents.

Data analyses

To examine the effect of prescription and other factors on outcomes, three separate principal components analyses (e.g. Johnson, 1998; Strube, 2003) were used to aggregate multiple measures to represent outcomes in language, speech production, and functional performance. Multivariate linear regression was performed to estimate the contribution of respective predictor variables to the variance in each of the principal component scores. The regression coefficients for different predictors with 95% confidence intervals and p values were reported, and the coefficients of determination (R^2) for the whole models were reported to quantify explained variance. We used two-tailed tests for all analyses, and set statistical significance at $p < 0.05$. All statistical analyses were carried out using Statistica software (Statsoft Inc., Release 7.1).

Results

Two hundred and eighteen children participated in this study. As shown in Figure 1, at three years of age there were 122 children using the NAL-NL1 prescription (NAL group) and 96 children using the DSL prescription (DSL group). The NAL group included both 115 children initially assigned to the NAL prescription and an additional seven children who were initially assigned to the DSL fitting but were subsequently refitted with a NAL-NL1 prescription at their parents' request. The 96 children in the DSL group were fitted with the DSL v.4.1 prescription, 58 of whom had their hearing aids updated with the DSL m[i/o] prescription as part of the routine services provided by AH prior to their evaluations at three years of age. Demographic characteristics for all children are summarized in Table 1.

Figure 2 shows the distribution of four-frequency-average hearing loss (4FA, averaged across octave frequencies between 0.5 and 4 kHz) for children assigned to the NAL and the DSL groups. On average, neither the audiogram slope from 0.5 to 4 kHz nor the four frequency average (4FA, averaged across octave frequencies between 0.5 and 4 kHz) hearing level was significantly different between the two groups of children (Slope: $F(1,434) = 0.29, p = 0.58$; 4FA hearing level: $F = 2.54, p = 0.11$).

Based on an audiogram averaged across all children in the study, a snapshot of the differences between the gain-frequency responses prescribed by the NAL and the DSL procedures for children is captured in Figure 3. Whereas DSL v.4 and DSL m[i/o] prescribed gain-frequency responses that were comparable, NAL-NL2 prescribed steeper response slopes than its predecessor NAL-NL1. Overall, the DSL procedures prescribed more low-frequency gain than the NAL procedures, resulting in flatter response slopes. Compared to NAL-NL1, the DSL v.4 and DSL m[i/o] prescribed more gain at low and high frequencies over a range of input levels. Consequently, the prescribed overall gain is higher for the DSL than for the NAL procedures.

Hearing-aid fitting to targets

The hearing aid gain-frequency responses used by children at their evaluations at three years of age were measured within six months of the time of evaluation. Figure 4 shows the mean gains used in hearing aids for low (50 dB SPL), mid (65 dB SPL), and high (80 dB SPL)

input levels in relation to prescriptive targets, separately for children assigned to the NAL and the DSL groups. Averaged over all children, the root-mean-square differences between achieved and target 4FA gains were less than 3 dB at low, mid, and high input levels.

Tables 2 and 3 show the mean 4FA gains and frequency responses of hearing-aids at user settings, together with targets used for fitting. Absolute deviations from targets in terms of gains and frequency response slopes are shown in Tables 4 and 5 respectively. On average, prescribed frequency response slopes from 0.5 to 4 kHz were matched within 3 dB/octave.

Effect of prescription and other factors on outcomes

Figure 5 shows the median scores for each outcomes measure, together with the quartile and range of scores. Ratings provided by parents indicated that on average, children used their hearing devices for more than 75% of their waking hours, and the incidence for loudness discomfort was very low. Separate analysis of variance revealed that there were no significant differences between the two prescription groups for usage ($F(1,117) = 0.643, p = 0.4$) and for loudness discomfort ($F = 0.013, p = 0.9$).

A primary interest in this study was to determine the influence of prescription and a range of other factors on the language, speech and functional outcomes of children at three years of age. Using principal components analysis, a Total Language component score was created, based on a linear combination of scores obtained from all measures of language (PLS-4 Auditory comprehension, PLS-4 Expressive communication, PPVT receptive vocabulary, CDI-Language comprehension, and CDI-Expressive language). In a similar manner, a speech production component score was created from three measures of speech production (Speech intelligibility rating, DEAP-vowels and DEAP-consonants); and a Functional performance component score from measures of social and functional performance (CDI-social scale, PEACH-quiet and PEACH-noise measures). Table 6 shows the factor loadings of each measure used in separate principal component analyses on each of the domains of language, speech, and functional performance. The principal components scores accounted for 68% of the variance in the total language measures (item communalities ranging from 0.68 to 0.90), 65% of the variance in speech production measures (item communalities ranging from 0.65 to 0.90), and 71% of the functional performance measures (item communalities ranging from 0.64 to 0.92).

General linear regression analysis was performed with each principal component score as a dependent variable and 10 predictors relating to child, family, and intervention characteristics as independent variables. The categorical variables included: prescription group (DSL or NAL); gender (male or female); additional disability (presence or absence); and communication mode in intervention (oral or combined mode). The six continuous variables included: age at first fitting; 4FA hearing thresholds in the better ear; maternal education; socio-economic status (SEIFA in decile); hours of educational intervention (from enrolment to three years of age); and deviation of user 4FA gains from the average of NAL-NL2 and DSL m[i/o] 4FA gains at low input level. Table 7 shows the Beta values for each component score.

In the regression analysis examining the language component score, the baseline predictors accounted for 27% of the variation in scores (Table 7). Five factors were associated with language scores at the 5% level of significance. Language component scores were higher for children who received early intervention using an oral only mode of communication than for those who used a mode that combined oral and manual methods. Scores were higher for children from higher socio-economic backgrounds than those from lower socio-economic backgrounds. Also, scores were higher for children with less severe hearing loss, and higher for children whose mothers had a university degree compared to children whose mothers

had completed 12 years of schooling. More hours of intervention were associated with lower language component scores.

In the analysis examining the speech production component score, the baseline predictors accounted for less than 1% of the total variation. A subsequent analysis added language component score as a predictor variable, based on the premise that language ability has been linked to speech production skills in previous studies (Blamey et al, 2001). The predictors accounted for 37% of the variation, with language being the only factor associated with the speech production component score at the 5% significance level.

In examining functional performance, the baseline predictors accounted for 22% of the variation in component scores. Three of the predictors were associated with functional scores at 5% significance level. Scores were higher for children who did not have additional disability than those who did; and higher for those who used oral-only mode of communication in early intervention than those who used a combination of oral and manual modes. Functional scores were also higher for those whose mothers completed university education than for those who completed 12 years or less schooling. In a subsequent analysis that included language component score as a predictor (based on the premise that language skills may be associated with functional performance in real life (Duchesne et al, 2009)), the predictors accounted for 32% of the total variation in functional scores. Language ability, presence of additional disability, and oral mode of communication were associated with functional performance scores at 5% significance level.

A secondary aim of this study was to determine whether early functional performance scores were predictive of outcomes at three years of age. PEACH data were available from parents of 82 children who completed the questionnaire between 6 and 12 months after their children received initial amplification (mean age of children: 13.5 months, SD: 5.1, Range: 6 to 25 months). The regression analysis used seven predictors, including age at fitting, 4FA hearing level, socio-economic status, maternal education, prescription for hearing-aid fitting, presence or absence of additional disability, and early PEACH score (see Table 8).

In examining language scores, the predictors accounted for 44% of the total variance. Table 8 shows that four factors, including hearing level, maternal education, additional needs, and early functional performance (early PEACH scores) were associated with language skills at the 5% level of significance. In examining speech production component scores, the predictors accounted for 10% of total variation. In examining functional performance component scores, the predictors accounted for 31% of the total variation. Higher maternal education, higher early PEACH scores, and the absence of additional disability were associated with higher functional performance component scores at three years of age at the 5% level of significance.

If early PEACH scores were the only known variable for predicting performance outcomes at three years, they accounted for 9% of the total variation in language component scores ($p = 0.004$), 5% of the variation in speech production ($p = 0.02$), and 14% of the variation in functional scores ($p = 0.003$).

Discussion

Factors affecting outcomes

On average, children's performance was slightly poorer than 1 SD below the normative mean for language, speech, and functional performance outcomes. The baseline characteristics for the 122 children who were fitted with the NAL prescription were, on average, similar to those of the 96 children who were fitted with the DSL prescription (Table

1). Analysis of the outcomes of children at three years of age did not reveal a significant difference in language, speech production, and functional performance scores favouring one prescription over the other.

The choice of prescription method, nonetheless, resulted in marked differences in real-ear-gain. Estimated loudness from the application of the DSL procedures (including DSL v4.1 and DSL m[i/o]) in hearing aids was, on average, higher than that for the NAL-NL1 procedure by a factor of 2 when the input level was medium or high (Ching et al, this issue). Even though ratings by parents on loudness discomfort or device usage in the present study did not reveal an effect of prescription, such effects may be important when children are old enough to provide subjective ratings (Ching et al, 2010) and when they function in a range of real-world environments wider than the current ones.

The impact of prescription choice on predicted speech intelligibility was also quantified by using the speech intelligibility index model (ANSI, 1997) with an allowance for hearing loss desensitization that was empirically derived (Ching et al, 2011) and adopted in the derivation of the NAL-NL2 procedure (Dillon et al, 2011). It may be expected that higher audibility can be achieved by the prescription that provides higher gains, but the effectiveness of the audible signal for speech intelligibility would be reduced by distortions arising from listening at high SPLs and the decrease of a listener's ability to extract information from an audible signal as hearing loss increases (see Ching et al, this issue). Briefly, the modelling revealed that predicted speech intelligibility was higher for DSL than for NAL at low input level, similar between prescriptions at medium input level, but higher for NAL than for DSL at high input level. Nonetheless, the overall effect size was small. Consistent with that finding, the present analysis shows that deviation of user gains from targets prescribed by the updated versions of the two prescriptions was not related to any of the measured outcomes at the 5% significance level.

The use of an aural/oral mode of communication in intervention was associated with better outcomes in language development and functional performance, but not in speech production. Because there were changes in communication mode for some children during the first few years of intervention, the use of an aural/oral mode at three years of age might be an outcome rather than a predictor.

The factors that were found to be significantly associated with language and functional performance were socio-economic status and maternal education. This finding is consistent with the literature on development of children with normal hearing. Social disadvantage has been linked to poorer expressive and receptive language in normal-hearing children at four years of age (Reilly et al, 2010), speech production at three years of age (Dollaghan et al, 1999), and academic underachievement for school-aged children (Hart & Risley, 1995). Possibly, social disadvantage and maternal educational level influence the quantity and quality of language to which children are exposed in the home environment (Bornstein et al, 1998; Hoff-Ginsburg, 1998). Maternal (parental) educational level is also linked to parents' academic competence, their attitudes toward education (Fulgini, 1997; Brody & Flor, 1998), as well as their knowledge and beliefs about child development (Benasich & Brooks-Gunn, 1996; Tamis-LeMonda et al, 1998). Although it is not possible within the scope of the present study to pinpoint the reasons for the observed effects of socio-economic status and maternal education on language development of children with hearing impairment, it may be hypothesized that maternal education may have exerted its influence on child outcomes through its association with characteristics of communicative style and child-directed language (Pine et al, 1997; Haden, 1998). Understanding the relationships among particular socio-demographic variables, especially modifiable factors, and specific measures of early

outcomes is an important area of research for children with hearing loss, and is a focus of the main LOCHI study.

Importance of early functional evaluation

Early functional level (as measured using the PEACH scale during the first year of amplification) together with degree of hearing loss, prescription method, presence or absence of additional needs, socio-economic status, and maternal education explained 44% of variation in language performance, and 31% of variation in functional performance scores for hearing-impaired children by three years of age. Early PEACH scores uniquely explained 6% of the total variation in language, 4% of the variation in speech production, and 9% of the variation in functional scores at three years; after allowing for the effects of all other predictors on component scores. If early PEACH scores were the only predictor variable, it accounted for 9% of the total variation in language, 5% of the total variation in speech production, and 14% of the variation in functional performance at three years of age. Compared to a study of normal-hearing children which revealed that maternal language level together with 10 risk factors accounted for only 4% to 7% of variation in children's language at two years of age (Reilly et al, 2007), the significance of the early PEACH scores in predicting language development by three years of age should not be underestimated. Early identification of hearing-impaired children who may be at risk for language development allows additional intervention to be implemented at an early age. Because the PEACH scale is less tied to a single socio-demographic context than is a standardized language measure, it can be used for culturally diverse populations. The PEACH scale is applicable for infants and young children, has published normative data with information on reliability and critical differences (Ching & Hill, 2007), and has been found to be significantly correlated with objective measures of audibility based on auditory evoked cortical responses in infants (Golding et al, 2007), and standardized measures of language ability in young children (Ching et al, 2010).

The strengths of the present study include its randomized controlled design that is community-based, its cohort of newly-identified children with hearing loss, its prospective measurements of a range of outcomes including language, speech, and functional performance, and its inclusion of standardized tests administered directly to participants as well as parent reports. Unlike previous studies on outcomes of children with hearing loss in which information about adequacy of hearing-aid fitting is typically lacking (Wake et al, 2004; Kennedy et al, 2006; Korver et al, 2010), the present study included comprehensive information about hearing-aid fitting and hearing threshold levels, thereby allowing for a more accurate estimation of the effects of amplification characteristics on developmental outcomes.

Summary of present findings

1. There was no significant association between choice of hearing-aid prescription and variance in children's speech production, language, and functional performance at three years of age.
2. Children's development of language and functional performance, by three years of age, is susceptible to influences of social disadvantage and maternal educational level. On average, performance was slightly poorer than 1 SD below normative mean.
3. Early functional level explained a significant proportion of variation in language, speech, and functional development by three years of age.

Our current findings cannot be generalized to children at other age groups. It remains to be seen whether relations between prescription choice and later development that were not

discernible in the study participants at three years of age might emerge at later ages. Data collection for some of the participants at five years is currently under way, and we have also begun testing at nine years of age using additional measures of literacy and related skills.

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Abbreviations

4FA	Four-frequency average, across 0.5, 1, 2, and 4 kHz
AH	Australian Hearing
CDI	Child Development Inventory
DEAP	Diagnostic Evaluation of Articulation and Phonology
DSL	Desired Sensation Level
DSL m[i/o]	Desired Sensation Level multi-stage input-output algorithm
DSL v.4.1	Desired Sensation Level procedure version 4.1
HTL	Hearing threshold level
LOCHI	Longitudinal Outcomes of Children with Hearing Impairment study
NAL	National Acoustic Laboratories
NAL-NL1	National Acoustic Laboratories' hearing aid prescription for non-linear hearing aids, version 1
NAL-NL2	National Acoustic Laboratories' hearing aid prescription for non-linear hearing aids, version 2
PEACH	Parents' Evaluation of Aural/oral performance of CHildren
PLS-4	Preschool Language Scale, 4th edition
PPVT	Peabody Picture Vocabulary Test
RECD	Real-ear-to-coupler difference
SII	Speech Intelligibility Index

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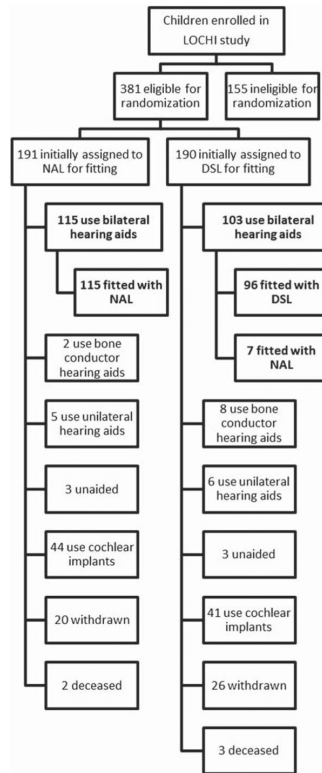


Figure 1. Enrolment and randomization of children participating in the current trial of prescription (in bold).

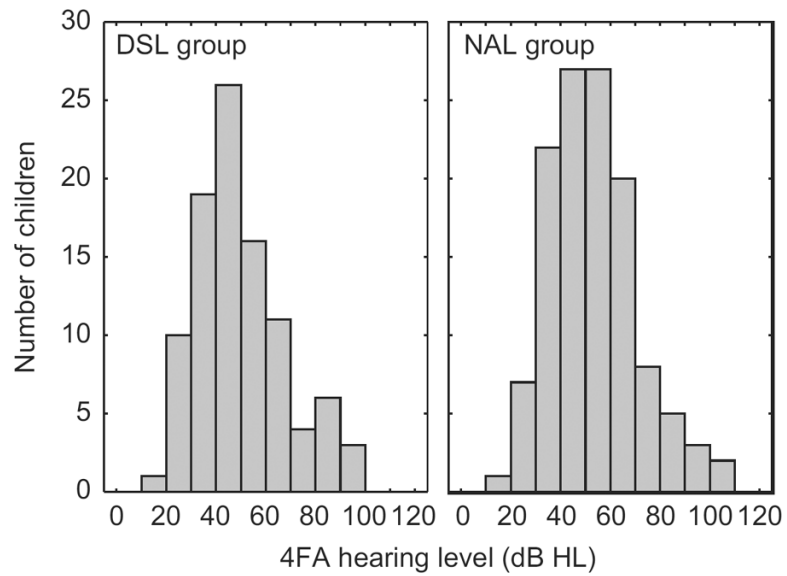


Figure 2. Distribution of four-frequency average hearing level (4FA, thresholds averaged across octave frequencies from 0.5 to 4 kHz) in the better ear for the DSL group (left panel) and the NAL group (right panel).

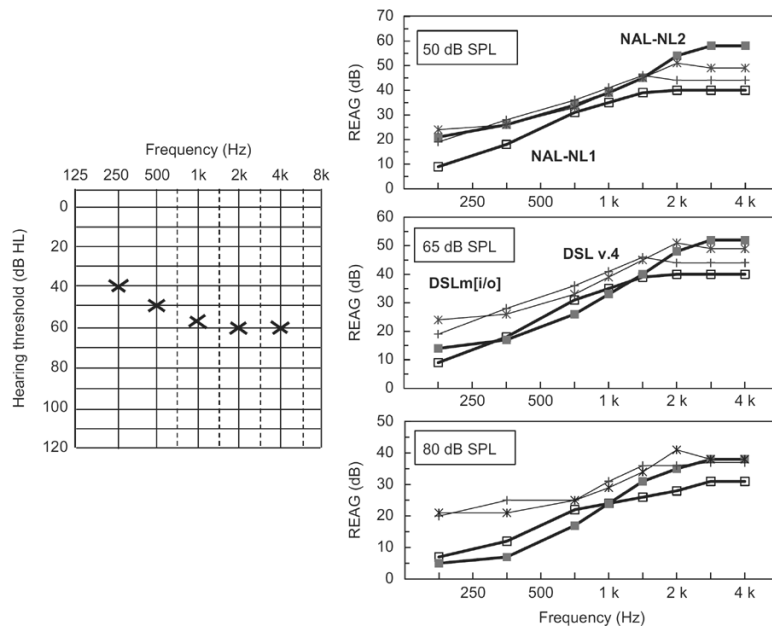


Figure 3. The left panel shows the averaged audiogram for all children in the study. The right panels show real-ear-aided gain (REAG) prescribed by NAL-NL1 (open squares), NAL-NL2 (filled squares), DSL v.4 (crosses), and DSL m[i/o] (asterisks) at low (50 dB SPL), mid (65 dB SPL) and high (80 dB SPL) input levels.

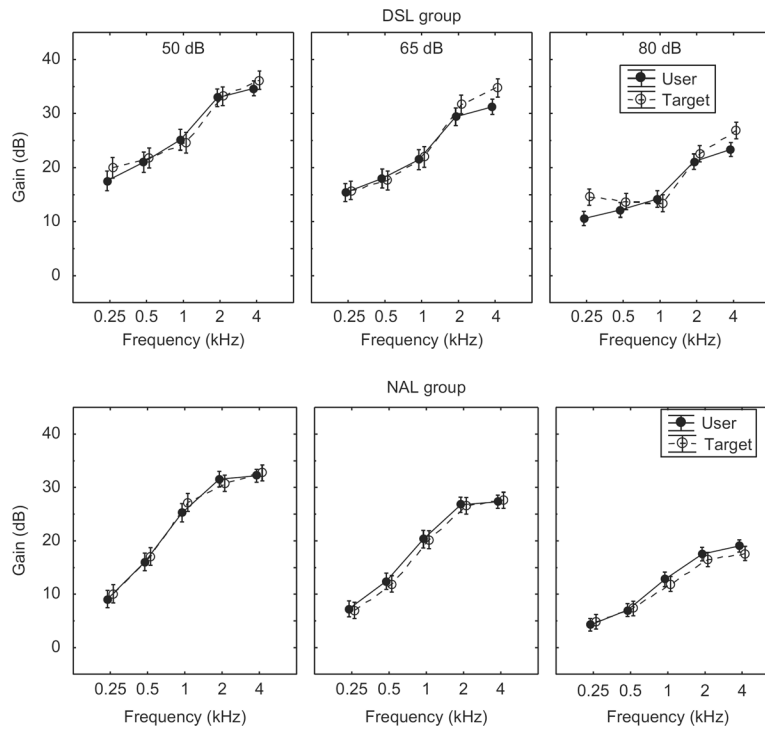


Figure 4. Mean gains for user settings (solid line with filled circles) and prescribed targets (broken line with open circles) as a function of frequency. Mean values for low input level (50 dB SPL), mid input level (65 dB SPL), and high input level (80 dB SPL) are shown. The top panels depict mean values for the DSL group, and the bottom panels depict mean values for the NAL group.

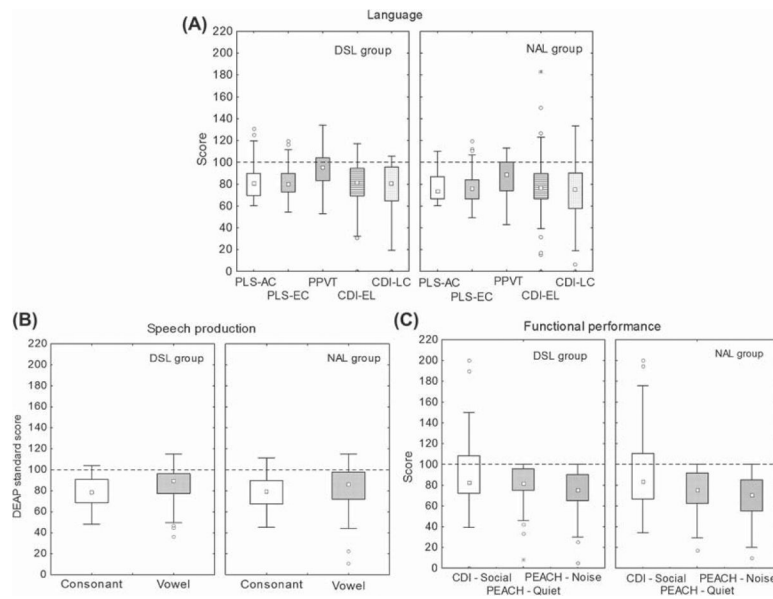


Figure 5. Scores for developmental outcomes grouped according to Language, Speech production, and Functional performance. In each group, the left panel shows scores for the DSL group, and the right panel shows scores for the NAL group. The Language scores include PLS-4 Auditory comprehension (AC) subscale, PLS-4 Expressive communication (EC) subscale, PPVT, CDI Expressive language (EL) subscale, and CDI Language comprehension (LC) subscale. The Speech production group include DEAP: Consonant score and DEAP: Vowel score. The Functional performance group include CDI: Social subscale, PEACH: Quiet subscale, and PEACH: Noise subscale. Values are expressed as the median (square in the middle of each box), with the quartiles (top and bottom of the box), and range (I bar), with out-of-range observations (i.e. > 1.5 times the interquartile range beyond the quartile) shown as circles, and extremes shown as asterisks.

Table 1

Demographic characteristics of children and their families

Characteristics	NAL group (n = 122)	DSL group (n = 96)	Difference p value
Gender – Female no. (%)	47 (39)	42 (44)	p = 0.62
Age at fitting (months)			p = 0.06
Median	6.3	4.8	
Interquartile range	3.2 to 20.9	2.9 to 10.7	
Minimum to maximum	1.4 to 36.0	1.4 to 33.6	
Degree of hearing loss [#] – no. (%)			p = 0.22
Moderate (40–60 dB)	84 (69)	72 (75)	
Severe (61–80 dB)	28 (23)	16 (17)	
Profound (> 80 dB)	10 (8)	8 (8)	
Additional disability – no. (%)	22 (18)	18 (19)	p = 0.95
English used at home – no. (%)	109 (89)	89 (91)	p = 0.83
Socio-economic status (decile)			p = 0.17
Median	6.8	7.4	
Interquartile range	5.0 to 9.0	6.0 to 9.0	
Minimum to maximum	1.0 to 10.0	1.0 to 10.0	
Maternal education – no. (%)			p = 0.40
12 years of schooling	45 (37)	37 (39)	
Certificate or diploma	25 (21)	23 (24)	
University degree	48 (39)	32 (33)	
Intervention: Oral mode of communication – no. (%)	96 (79)	72 (75)	p = 0.71
Intervention hours			p = 0.05
Median	92	116	
Interquartile range	28 to 124	58 to 136	

[#] Averaged hearing levels across 0.5 to 4 kHz in the better ear, expressed in terms of dB HL.

Table 2

Mean, standard deviation (SD), and range of gains in user device compared to targets used for fitting (DSL or NAL prescription, depending on assigned group), as well as targets prescribed by the NAL-NL2 and DSL $m[i/o]$ formulae.

		Gain averaged between 0.5 and 4 kHz (4FA gain)				
	Level		User	Target	NAL-NL2	DSL $m[i/o]$
<i>DSL group</i>	50	Mean	28.4	28.9	26.7	29.6
		SD	11.0	11.6	10.8	10.5
		Range	5.5 to 57.5	5.5 to 64.8	7.3 to 56.5	9.5 to 59.3
	65	Mean	25.0	26.5	20.7	26.8
		SD	10.9	12.1	10.5	11.7
		Range	4.0 to 51.5	3.3 to 61.8	2.2 to 52.9	7.0 to 59.3
	80	Mean	17.6	19.1	12.9	19.6
		SD	9.0	10.4	9.0	10.3
		Range	2.0 to 40.3	1.5 to 49.0	0.7 to 43.7	4.0 to 48.8
<i>NAL group</i>	50	Mean	26.2	26.9	29.6	32.6
		SD	10.9	11.7	10.8	10.4
		Range	2.8 to 63.0	7.5 to 65.5	6.2 to 61.8	11.3 to 67.5
	65	Mean	21.7	21.5	23.4	29.9
		SD	10.5	10.8	10.7	11.8
		Range	2.0 to 59.5	4.0 to 61.3	5.3 to 59.6	8.5 to 67.5
	80	Mean	14.2	13.3	15.0	22.3
		SD	8.9	9.3	9.6	10.6
		Range	0.3 to 44.8	0.5 to 46.8	3.7 to 51.6	5.8 to 59.0

Table 3

Mean, standard deviation (SD), and range of frequency response slopes in user devices compared to targets used for fitting (DSL or NAL prescription, depending on group assignment), as well as the NAL-NL2 and DSL m[i/o] prescriptions.

		Slope between 0.5 and 4 kHz (dB/octave)				
	Level	User	Target	NAL-NL2	DSL m[i/o]	
DSL group	50	Mean	4.6	4.8	9.4	5.6
		SD	3.3	3.7	2.8	3.4
		Range	-7.7 to 12.3	-8.3 to 15.3	-3.5 to 16.2	-8.3 to 15.3
	65	Mean	4.5	5.7	9.8	6.2
		SD	3.2	3.7	2.9	3.6
		Range	-8.7 to 13.3	-8.0 to 16.7	-3.1 to 18.9	-8.0 to 16.7
	80	Mean	3.8	4.42	7.6	4.8
		SD	2.8	3.16	2.7	3.2
		Range	-7.3 to 11.7	-6.7 to 14.7	-0.7 to 18.7	-6.7 to 14.7
NAL group	50	Mean	5.4	5.2	9.2	5.0
		SD	3.5	2.9	2.6	3.1
		Range	-7.7 to 12.0	-2.7 to 11.3	-0.7 to 15.5	-5.3 to 14.3
	65	Mean	5.1	5.3	9.7	5.58
		SD	3.2	3.0	2.7	3.43
		Range	-6.3 to 11.3	-4.0 to 11.0	-1.5 to 15.6	-5.0 to 16.3
	80	Mean	4.1	3.5	7.9	4.1
		SD	2.6	2.6	2.5	3.0
		Range	-3.3 to 10.0	-6.3 to 9.7	-1.0 to 15.4	-4.0 to 13.7

Table 4

Mean deviations of user four-frequency-average gain (4FA, gains averaged over 0.5, 1, 2, 4 kHz) from prescribed gains at low (50 dB SPL), mid (65 dB SPL) and high (80 dB SPL) input levels. Mean deviation of user maximum power output (MPO) from prescribed output is shown in the last column.

		<u>User gain minus Target gain (dB)</u>			<u>User minus Target MPO</u>
		Low	Mid	High	MPO
DSL group	Mean	-0.5	-1.5	-1.4	-0.3
	SD	2.4	2.7	3.1	4.8
	CI	-0.9 to -0.2	-1.9 to -1.1	-1.9 to -1.0	-0.9 to 0.4
	Range	-10.3 to 3.5	4.5 to 2.7	-11.8 to 4.5	-16.8 to 10.3
NAL group	Mean	-0.7	0.1	0.8	-0.1
	SD	2.7	2.0	2.3	4.1
	CI	-1.0 to -0.4	0.1 to -0.1	0.5 to 1.0	-0.6 to 0.4
	Range	-11.3 to 5.3	-8.8 to 6.3	-12.3 to 6.8	-22.3 to 10.3

Table 5

Mean deviations of user frequency response slope (averaged over 0.5 to 4 kHz, expressed in terms of dB/octave) from prescribed response slopes at low (50 dB SPL), mid (65 dB SPL), and high (80 dB SPL) input levels. Also shown are standard deviation (SD), confidence interval (CI) and range.

		User minus Target slope (dB/octave)		
		Low	Mid	High
DSL group	Mean	-0.2	-1.3	-0.7
	SD	2.3	2.3	1.9
	CI	-0.6 to 0.1	-1.6 to -1.0	-0.9 to -0.4
	Range	-9.7 to 3.7	-10.0 to 2.3	-8.3 to 2.7
NAL group	Mean	0.2	-0.3	0.6
	SD	1.9	1.5	1.7
	CI	-0.1 to 0.4	-0.5 to -0.1	0.3 to 0.8
	Range	-6.3 to 8.3	-5.7 to 7.0	-5.0 to 8.0

Table 6

Factor loadings of measures used in separate principal component analyses on each of the domains of language, speech production, and functional performance.

Principle component	Measure	Factor loading
<i>Total language</i>	PLS-4 Auditory comprehension	-0.878
	PLS-4 Expressive communication	-0.902
	PPVT	-0.675
	CDI: Expressive language	-0.799
	CDI: Language comprehension	-0.841
<i>Speech</i>	Speech intelligibility rating	-0.646
	DEAP: consonants	-0.895
	DEAP: vowels	-0.851
Functional performance	CDI: Social subscale	-0.638
	PEACH: Quiet subscale	-0.935
	PEACH: Noise subscale	-0.916

Table 7

Multivariate linear regression analyses of principal component scores of Language, Speech production, and Functional performance with respect to potential predictors. The reference level of effect for 'Gender' was 'Male', 'Prescription' was 'DSL', 'Additional disability' was 'Absent', and 'Communication mode in intervention' was 'Oral'. Values significant at 5% level were marked by asterisks.

	Language		Speech production		Functional performance	
	Coefficient (95% CI [@])	p	Coefficient (95% CI)	p	Coefficient (95% CI)	p
4FA hearing level in better ear	-0.17 (-0.31 to -0.03)	0.01*	-0.02 (-0.18 to 0.14)	0.77	-0.09 (-0.23 to 0.051)	0.21
Additional disability	0.11 (-0.04 to 0.26)	0.14	-0.01 (-0.19 to 0.16)	0.87	0.35 (0.19 to 0.51)	< 0.001*
Age at fitting	-0.03 (-0.17 to 0.11)	0.69	0.07 (-0.09 to 0.23)	0.38	-0.14 (-0.28 to 0.005)	0.06
Gender	0.08 (-0.11 to 0.26)	0.42	0.05 (-0.16 to 0.27)	0.64	-0.03 (-0.23 to 0.16)	0.72
Prescription group	0.21 (-0.01 to 0.42)	0.06	-0.02 (-0.27 to 0.23)	0.88	0.14 (-0.08 to 0.36)	0.22
Maternal education	-0.23 (-0.36 to -0.09)	< 0.001*	-0.25 (-0.40 to -0.09)	0.002	-0.20 (-0.33 to -0.06)	0.005*
Socio-economic status	0.15 (0.02 to 0.28)	0.03*	0.02 (-0.13 to 0.17)	0.80	0.009 (-0.13 to 0.15)	0.90
Communication mode in intervention	0.21 (0.06 to 0.36)	0.008*	0.003 (-0.18 to 0.18)	0.97	0.29 (0.13 to 0.46)	< 0.001*
Hours of intervention	-0.17 (-0.32 to -0.03)	0.02*	0.009 (-0.16 to 0.18)	0.92	-0.13 (-0.28 to 0.02)	0.09
User 4FA gain minus Averaged NAL-NL2 and DSL m[i/o] gain at low input level	0.08 (-0.08 to 0.24)	0.31	0.11 (-0.07 to 0.29)	0.23	-0.005 (-0.17 to 0.16)	0.95
Language component score	-	-	0.70 (0.56 to 0.84)	< 0.0001*	0.38 (0.23 to 0.52)	< 0.0001*

[@] denotes confidence interval.

Table 8

Multivariate linear regression analyses of language, speech production and functional performance component scores with respect to potential baseline predictors and early functional performance status. The reference level of effect for Additional disability was 'Absent', and 'Prescription level' was 'DSL'. Values significant at 5% level are marked by asterisks.

	Language		Speech production		Functional performance	
	Coefficient (95% CI[@])	p	Coefficient (95% CI)	p	Coefficient (95% CI)	p
4FA hearing level in better ear	-0.20 (-0.37 to 0.02)	0.03*	-0.11 (-0.33 to 0.11)	0.33	-0.12 (-0.31 to 0.07)	0.22
Additional disability	0.33 (0.15 to 0.51)	< 0.001*	0.10 (-0.12 to 0.32)	0.38	0.36 (0.16 to 0.55)	< 0.001*
Age at fitting	0.10 (-0.08 to 0.27)	0.28	0.14 (-0.08 to 0.36)	0.20	0.02 (-0.18 to 0.22)	0.84
Prescription group	0.15 (-0.02 to 0.32)	0.08	0.11 (-0.10 to 0.33)	0.38	0.01 (-0.23 to 0.25)	0.93
Socio-economic status	0.18 (-0.006 to 0.37)	0.06	0.05 (-0.19 to 0.29)	0.68	-0.07 (-0.28 to 0.14)	0.49
Maternal education	-0.32 (-0.51 to 0.14)	< 0.001*	-0.18 (-0.42 to 0.06)	0.13	-0.21 (-0.41 to -0.002)	0.04*
PEACH: Early functional status	0.20 (0.02 to 0.38)	0.03*	0.22 (-0.004 to 0.45)	0.05	0.27 (0.07 to 0.47)	0.008*

[@] denotes confidence interval.