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Maguire, C.M.

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CHAPTER 6

Follow-up Outcomes at 1 and 2 years of Infants < 32 weeks after NIDCAP Developmental Care

Celeste M. Maguire, M.S.¹ Frans J. Walther, MD, PhD¹ Paul H.T. van Zwieten, MD² Saskia Le Cessie, PhD³ Jan M. Wit, MD, PhD¹ Sylvia Veen, MD, PhD¹

Submitted

¹ Department of Pediatrics, subdivision of Neonatology, Leiden University Medical Center, Leiden

² Department of Pediatrics, subdivision of Neonatology, Haga Hospital, location Juliana Children's Hospital, The Hague

³ Department of Medical Statistics, Leiden University Medical Center The Netherlands

Abstract

Objective: Randomized controlled trial investigating the effect of NIDCAP developmental care on growth, cognitive, psychomotor and neuromotor development in infants born < 32 weeks.

Methods: Infants were randomized within 48 hours of birth to the NIDCAP group or basic developmental care C group (incubator covers or nests). At 1 and 2 years corrected age (CA) growth was measured and standardized neurological exams were administered. Mental (MDI) and psychomotor (PDI) development was assessed using the Dutch version of the Bayley Scales of Infant Development II. To obtain a total outcome measure, neurological outcome, PDI and MDI scores were combined.

Results: 168 infants were recruited (NIDCAP: 84; C: 84). Four infants (NIDCAP: 3, C: 1) were excluded because they were admitted less than or died within the first 5 days, leaving a total of 164 infants that met inclusion criteria. In-hospital mortality was 8/81 (9.9%) in the NIDCAP group and 3/83 (3.6%) in the C group. At one year 148 children (NIDCAP: 70, C: 78) and at 2 years 146 children (NIDCAP: 68, C: 78) were assessed. There was no significant difference in growth at 1 and 2 years. There was no significant difference in neurological outcome or mental and psychomotor development at 1 and 2 years found. When neurological outcome, MDI and PDI scores were combined, there still remained no significant difference.

Conclusions: NIDCAP developmental care showed no effect on growth, neurological, mental and psychomotor development at 1 and 2 years in infants born < 32 weeks. Duration of the NIDCAP intervention was not associated with neurological and developmental outcome.

Introduction

Advances in the care of preterm infants have increased their survival rates, but the chance of later developmental and/or behavioral problems remains high for a considerable percentage of these infants and may continue into young adulthood¹⁻³. Cerebral palsy rates have not fallen over the past 10 years although survival has improved and increasing survival at low gestations is associated with the highest prevalence of cerebral palsy⁴. The most common disability at two years is developmental or cognitive impairment, which assumes greater significance in the school years. Cognitive differences between ex-preterm infants and term born infants show a greater need for educational support and higher prevalence of school problems in children without severe disabilities⁵. In addition, VLBW children have an increased risk of developing attention deficit hyperactivity disorders (ADHD), generalized anxiety and symptomatic depression⁶.

With the increasing technological advances has come the awareness that the intensive care and interventions used may also play a part in developmental disabilities. Developmental care programs have focused on changing the environment and caregiving of the preterm infant while providing these necessary life saving interventions. The philosophy behind developmental care is that by reducing stress and supporting the infants' developmental in the NICU, this in turn may impact their later developmental outcome. The most comprehensive and well known program is the Newborn Individualized Developmental Care and Assessment Program (NIDCAP) developed by Als, an individual approach in which caregiving is based on the infant's behavior 7-9. Follow-up studies of the effectiveness of the NIDCAP developmental care program have shown conflicting results and are based on trials with a small sample size 10-15. A Cochrane meta analysis has therefore recommended conducting larger trials with more follow-up 15.

The aim of this randomized controlled trial (RCT) was to explore the effectiveness of the implementation of the comprehensive NIDCAP developmental care program on growth, mental and psychomotor development and neurological outcome at 1 and 2 years CA of preterm infants born < 32 weeks gestational age. We hypothesized that an individual developmental care approach, in which the caregiving during their NICU stay was guided by the behavior of the infant, would reduce stress and promote physiological stability and in turn would positively affect their later growth and development.

Patients and Methods

The study was carried out from July 2002 to November 2006 at a tertiary NICU at 2 locations in the Netherlands: Leiden University Medical Center in Leiden and Juliana Children's Hospital in The Hague. The inclusion period was from July 2002 to August 2004 and the 1 and 2 year follow-up was from September 2003 to November 2006. Inclusion criteria were: infants born with a gestational age < 32 completed weeks. Exclusion criteria included: infants with major congenital anomalies, infants needing major surgery and infants of drug-addicted mothers. After parental informed consent was obtained by the resident or staff member on call, infants were randomized within 48 hours of birth to the NIDCAP developmental care (NIDCAP) group or the Control (C) group (basic developmental care) using sealed envelopes made in groups of 6 using a computer generated randomization allocation. According to protocol, infants in both groups who were admitted for less then 5 days were excluded from follow-up because the duration of the NIDCAP intervention was hypothesized not to be long enough to obtain an effect. A power analysis performed before the study showed that a sample size of 140 infants was needed to show a significant difference (p value < .05) with a power of 80%, based on the expected difference of half a standard deviation (7.5) on the developmental test scores at 1 and 2 years of age.

The NIDCAP intervention consisted of weekly behavioral observations of the infants by trained certified NIDCAP developmental specialists, with the first observation being done within 48 hours of birth. Individual care plans based on these observations with caregiving recommendations were discussed with parents and caregivers and were available at the infant's bedside. Parents were supported in understanding their infant's behavior and how to approach and support their infant during caregiving interactions and procedures. The infants in the NIDCAP group were primarily cared for by nurses who had received extra training and support in behavioral-based individual developmental care. If an infant was transferred to a regional hospital, a report was made with a behavioral summary and recommendations for caregiving for the parents. In addition, incubator covers and nests and positioning aids were provided to encourage flexion and containment. A NIDCAP certified developmental psychologist supervised the intervention, carried out observations and supported the parents and staff. The C group consisted of basic developmental care which included the use of incubator covers and nests and positioning aids to encourage flexion and containment. The Ethical Committees of both locations approved the study.

Measures

Infant characteristics (gestational age, birth weight, gender, small for gestational age, inborn, Apgar scores, CRIB score) and parental characteristics (age, ethnicity, educational level) were collected to compare groups (Tables 1 and 2). Severity of illness was analyzed using the CRIB (Clinical Risk Index for Babies) score which assesses initial neonatal risk. Scores are given for birth weight, gestational age, maximum and minimum fraction of inspired oxygen and maximum base excess during the first 12 hours, and the presence of congenital malformation ¹⁶.

Follow-Up

Children were assessed at 1 and 2 years of corrected age for prematurity (CA) for growth and neurodevelopment by neonatologists experienced in developmental assessments and blinded to the group assignment of the child. All mention of age hereafter is corrected age for prematurity. A standardized neurological exam according to Touwen ^{17,18} at one year and Hempel ¹⁹ at two years was administered and classified as definitely abnormal (DA) when there was definite neurological dysfunction such as cerebral palsy; mildly abnormal (MA) in the presence of mild deviations in muscle tone regulation, reflexes, fine or gross motor performance or cranial nerve function; or normal (N).

Weight was measured on a pediatric digital scale, length was measured from crown to heel on a standard measurement board and head circumference was measured around the largest area of the head, occipital-frontal circumference (OFC), using a non-stretch tape measure.

In addition, children were assessed at 1 and 2 years by psychology interns supervised by a clinical psychologist, who were blinded as to whether the child was in the NIDCAP or C group. Mental and psychomotor development was assessed using the Dutch version of the Bayley Scales of Infant Development II (BSID-II) 20,21 . The mean score of the mental developmental index (MDI) and the psychomotor developmental index (PDI) is 100, with 1 standard deviation (SD) of 15 points. An MDI or PDI \geq 85 (\geq - 1 SD) is considered normal, an MDI or PDI between 70 and 84 (-2 to -1 SD) is considered mildly delayed and Index scores \leq 69 (< - 2 SD) severely delayed. The Dutch norms, which had become available during our research, were used. To obtain a single outcome measure, neurological outcome, PDI and MDI were combined. When at least 1 of these 3 outcome measures was DA, children were considered DA, and when at least 1 outcome was MA, children were considered MA.

Statistical Analysis

Data was analyzed using SPSS 12.0 for Windows. The infant and parent characteristics were compared with the Chi-square test, the Chi-square test for trend or the two-sample t-test, where appropriate. Outcome parameters were compared between the two treatment groups with the t-test, Mann-Whitney test or Chi-square test where appropriate. *P*-values < 0.05 were considered significant. Linear regression was used to evaluate the influence of the duration of the intervention on 1 and 2 year outcomes by testing if there was an interaction effect between the intervention duration and the 2 treatment groups. Linear regression was also used to evaluate the influence of postnatal steroids on growth outcomes at 1 and 2 years.

Results

In total 168 infants were recruited for the study; 84 in the NIDCAP group and 84 in the C group. Four infants (NIDCAP: 3, C: 1) were excluded according to protocol because they were admitted less than 5 days or died within the first 5 days. This left a total of 164 infants that met inclusion criteria. Of the 164 included infants, 8/81 (9.9%) in the NIDCAP group and 3/83 (3.6%) in the C group died during hospitalization, with the main cause of death being cerebral or pulmonary complications. There was no significant difference in the in-hospital mortality rate between the NIDCAP and C group (p=0.11). This left 156 infants (NIDCAP: 73, C: 80) for followup. At 1 year 148 [NIDCAP: 70/73 (95.9%), C: 78/80 (97.5%)] and at 2 years 146 children [NIDCAP: 68/73 (93.2%), C: 78/80 (97.5%)] were seen at the follow-up clinic out of a total of 153 surviving infants. At 1 year, 2 infants were lost to follow-up and the parents of 1 infant no longer wanted to participate in the NIDCAP group and 2 infants in the C group were lost to follow-up. Between the 1 and 2 year assessment two children in the NIDCAP group were lost to follow-up. There was no loss to follow-up in the C group at 2 years. The mortality rate and loss to follow-up are shown in Figure 1.

There was no significant difference in the primary infant characteristics between the NIDCAP and C groups. Despite randomization, there were significantly more surviving infants with PDA requiring medication or medication and ligation in the NIDCAP group, p=0.03 at 1 year and p=0.02 at 2 years (Table 1). Parent characteristics (age, ethnicity and educational level) were similar in both groups and are shown in Table 2.

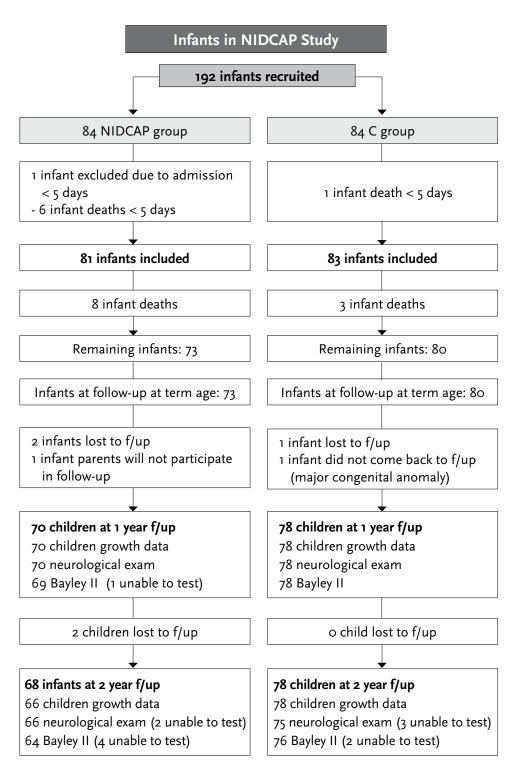


Table 1. Infant medical background variables of children seen at 1 and 2 year follow-up

	NIDCAP	C	NIDCAP	C
	n (%)	n (%)	n (%)	n (%)
	1)	/ear	2 y	ears
Birth Characteristics	n=70	n=78	n=68	n=78
Gestational age mean in wks (sd) range	29.6 (1.5)	29.3 (1.6)	29.6 (1.6)	29.3 (1.6)
	25.9-31.9	25.6-31.6	25.9-31.9	25.6-31.6
Birthweight mean in g, (sd) range	1263 (311)	1247 (340)	1260.8 (314.3)	1246.6 (339.6)
	(655-1939)	(625-2060)	(655-1939)	(625-2060)
Male gender	41/70 (58.6)	40/78 (51.3)	41/68 (60.3)	40/78 (51.3)
SGA* SGA P* < 10 and P \geq 3 SGA P < 3	13/70 (18.6)	10/78 (12.8)	13/68 (19.1)	10/78 (12.8)
	2/70 (2.9)	4/78 (5.1)	2/68 (2.9)	4/78 (5.1)
Inborn	44/70 (62.9)	47/78 (60.3)	44/68 (64.7)	47/78 (60.3)
Apgar scores at 5 minutes median (range)	9.0 (4-10)	8.0 (4-10)	8.0 (4-10)	8.0 (4-10)
CRIB Score mean (sd)* Range PDA* (indomethacin and/or surgery)	2.7 (2.9)	2.9 (2.9)	2.7 (2.9)	2.9 (3.0)
	0-14	0-13	0-15	0-13
	19/70 (27.1)	10/78 (12.8) ‡	19/68 (27.9)	10/78 (12.8) †

Data shown is n (%), unless otherwise indicated

Comparisons were done using chi-square test or t-tests where appropriate

Growth

There was no significant difference between the NIDCAP and C group in growth (weight in kilograms, height and head circumference in centimeters) at 1 or 2 years. When we calculated the SDS using the Dutch growth charts²³, there was again no difference between the 2 groups. As postnatal corticosteroids may influence growth, we corrected for days of postnatal steroids and then found no significant difference in growth SDS between the 2 groups (Table 3).

^{*} SGA: small for gestational age, P: percentile, CRIB: Clinical Risk Index for Babies, PDA: patent ductus arteriosus

 $^{^\}dagger$ p value 0.03 at 1 year and 0.02 at 2 years; p value significance = < 0.05

Table 2. Parental demographic background variables

	NIDCAP	C	NIDCAP	C
	n (%)	n (%)	n (%)	n (%)
	ı year fo	ollow-up	2 year fo	ollow-up
Maternal age	n=69	n=75	n=68*	n=75*
mean in years (sd)	31.3 (5.2)	32.9 (5.1)	32.3 (5.3)	33.9 (5.1)
Paternal age	n=67	n=74	n=66	n=74
mean in years (sd)	33.5 (5.7)	35.0 (5.6)	34.4 (5.6)	36.0 (5.6)
Mother Caucasian Father Caucasian	55/69 (79.7)	65/74 (87.8)	54/68 (79.4)	65/74 (87.8)
	52/68 (76.5)	58/74 (78.4)	51/67 (76.1)	58/74 (78.4)
Education level mother † low intermediate high	23/67 (34.3) 23/67 (34.3) 21/67 (31.3)	19/74 (25.7) 25/74 (33.8) 30/74 (40.5)	22/66 (45.1) 23/66 (32.4) 21/66 (22.5)	19/74 (25.7) 25/74 (33.8) 30/74 (40.5)
Education level father† low intermediate high	16/64 (25.0) 21/64 (32.8) 27/64 (42.2)	15/73 (20.5) 31/73 (42.5) 27/73 (37.0)	15/63 (23.8) 21/63 (33.3) 27/63 (42.9)	15/73 (20.5) 31/73 (42.5) 27/73 (37.0)

Data shown is n (%), unless otherwise indicated

Comparisons were done using chi-square test (for linear trend) or t-tests where appropriate

Table 3. Growth outcomes at 1 and 2 years CA

	1 year CA			2 years CA			
Growth outcomes	NIDCAP	С	p value	NIDCAP	С	p value	
Weight	n=70	n=78		n=63*	n=78		
mean in kg, sd	9.26 (1.14)	9.44 (1.45)	0.40	12.0 (1.3)	12.3 (2.1)	0.32	
SDS [†] (mean, sd)	-0.74 (1.10)	-0.59 (1.31)	0.43	-0.64 (0.98)	-0.48 (1.41)	0.42	
Head circumference	n=70	n=77		n=66	n=77*		
mean in cm, sd	46.3 (1.9)	46.7 (1.8)	0.23	48.7 (1.6)	49.0 (1.9)	0.32	
SDS† (mean, sd)	-0.26 (1.21)	0.05 (1.20)	0.13	-0.07 (0.94)	0.18 (1.18)	0.15	
Length	n=70	n=78		n=64*	n=78		
mean in cm, sd	75.2 (2.4)	75.1 (3.4)	0.82	87.9 (3.3)	87.3 (4.1)	0.33	
SDS† (mean, sd)	-0.33 (0.90)	-0.37 (1.23)	0.81	-0.19 (1.03)	-0.37 (1.19)	0.32	

Comparisons were done using t-tests

^{*} Correct n is shown in table if there are missing values

[†] Low = vocational training, intermediate = high school, high = college/university

^{*} Correct n is shown in table if there are missing values

[†] SDS (standard deviation scores) according to Fredriks et al 2000²³

Table 4. Mental and psychomotor development at 1 and 2 years CA

	NIDCAP n (%)	C n (%)		NIDCAP n (%)	C n (%)	
		ı year CA			2 years CA	
	69=u	n=78	p value	n=63 [†]	n=76	p value
Age at test in months mean (sd) range	12.2 (0.38)	12.3 (0.57)	76.0	24.2 (0.37) 23.5-25.3	24.1 (0.99) 19.3-26.0	0.41
MDI mean (sd) range	100.7 (17.8) (55-145)	100.7 (17.7) (55-133)	0.99	99.1 (15.4) (55-132)	98.7 (16.6)* (66-140)	0.90
PDI mean (sd) range	97.3 (16.7) (55-134)	95.9 (16.3) (55-126)	09.0	89.1 (14.2) (55-123)	91.2 (11.7) (58-121)	0.35
MDI classification scores [§] ≥ 85 70-84 ≤ 69	60 (87.0) 6 (8.7) 3 (4.3)	65 (83.3) 9 (11.6) 4 (5.1)	0.60	54 (85.7) 7 (11.1) 2 (3.2)	59 (78.7)* 13 (17.3) 3 (4.0)	0.35
PDI classification scores [§] ≥ 85 70-84 ≤ 69	58 (84.1) 4 (5.8) 7 (10.1)	61 (78.2) 13 (16.7) 4 (5.1)	0.93	40 (63.5) 18 (28.6) 5 (7.9)	52 (68.4) 21 (27.6) 3 (4.0)	0.38

Data shown is n (%), unless otherwise indicated

Comparisons were done using chi-square test (for linear trend) or t-tests where appropriate

* p value significance = < 0.05

† One infant in NIDCAP group had only PDI score and 1 infant in NIDCAP group had only MDI score which changed the total n from 64 to 63 at 2 years

† One child in the C group had only a PDI score

† One child in the C group had only a PDI score $\frac{1}{b} \ge 85 = \text{normal or above normal, } 70-84 = \text{mildly delayed, } \le 69 = \text{significantly delayed}$

Developmental outcomes

At one year of age 147 (NIDCAP: 69, C: 78) of the 148 children seen at follow-up and at 2 years of age 140 (NIDCAP: 64, C: 76) of the 146 children seen at follow-up were tested with the Bayley Scales-II-NL. There was no significant difference in the mean age of all children assessed at the 1 and 2 year follow-up. We were not able to obtain developmental scores at 1 year of age for one child in the NIDCAP group and at 2 years of age for 5 children in the NIDCAP group and 2 children in the C group because they were uncooperative. There was no difference in developmental outcomes at 1 and 2 years between the two groups (Table 4).

Neurological Outcomes and combined scores

There were 148 (NIDCAP: 70, C: 78) children assessed with a neurological exam at 1 year and 141 (NIDCAP: 66, C: 75) children at 2 years. Five children (NIDCAP: 2, C: 3) could not be tested at 2 years because they were uncooperative. There was no significant difference between the NIDCAP and C group in neuromotor development at 1 and 2 years or in the combined developmental and neurological scores (Table 5).

Table 5. Neurological outcomes and combined score of neurological outcomes, MDI and PDI at 1 and 2 years CA

	1 уеа	r CA			2 year	rs CA	
	NIDCAP n (%)	C n (%)			NIDCAP n (%)	C n (%)	
	Neurologica	l Outcome*			Neurologica	l Outcome*	
	n=70	n=78	p value		n=66	n=75	p value
- N [†] - MA - DA	52 (74·3) 12 (17.1) 6 (8.6)	53 (67.9) 19 (24.4) 6 (7.7)	0.60	- N - MA - DA	52 (78.8) 5 (7.6) 9 (13.6)	54 (72.0) 16 (21.3) 5 (6.7)	0.99
	Combined neurological score MDI and PDI				Combined n sco MDI an	ore	
	n=70	n=78			n=68	n=71	
- N [†] - MA - DA	44 (62.9) 14 (20.0) 12 (17.1)	44 (56.4) 23 (29.5) 11 (14.1)	0.78	- N - MA - DA	34 (50.0) 21 (30.9) 13 (19.1)	37 (47.4) 31 (39.7) 10 (12.8)	0.76

Comparisons were done using chi-square test (for linear trend) where appropriate

st neurological exam according to Touwen at 1 year and Hempel at 2 years

[†] N=normal, MA=mildly abnormal, DA=definitely abnormal

 $^{^{\}ddagger}$ one child from DC group and 2 children from C group's combined scores were derived from the PDI and MDI

Because there was a wide range in length of stay in the participating hospitals, we carried out a linear regression analysis to see if the number of days infants received the NIDCAP intervention influenced the neurological outcome at 1 and 2 years by testing if there was an interaction effect between the intervention duration and the 2 treatment groups. We found no significant effect on neurological outcome at 1 year (p=0.97) or 2 years (p=0.30) of age or on the combined neurological and developmental scores at 1 (p=0.27) and 2 years (p=0.73).

Discussion

In this study examining the effects of NIDCAP compared to basic developmental care on infants born < 32 weeks GA, we have been unable to show any differences in growth, neurological and developmental outcomes at 1 and 2 years of age. The percentage of lost to follow-up in this large RCT was low. The assessors were blinded to the treatment group the children participated in and the neurological outcome was assessed using a standardized neurological examination.

Few studies have examined short-term neurodevelopmental outcomes of NIDCAP and the results of these studies are conflicting¹⁵. Three studies by Als et al showed an effect of NIDCAP on Bayley Developmental Index scores up to 9 months of age. The first study examined the effect of NIDCAP on 16 (E: 8, C: 8) infants born < 28 weeks GA with a birth weight < 1250 grams and found a significant difference in PDI and MDI scores at 3, 6 and 9 months in favor of the NIDCAP group as compared to the control group¹⁰. A second study of 38 infants weighing less than 1250 grams and born < 30 weeks GA also showed improved PDI and MDI scores at 9 months in the NIDCAP group²⁴. The most recent study of 30 low-risk preterm infants born between 28-33 weeks GA showed significantly better PDI and MDI developmental scores in the NIDCAP group at 9 months, however only 24 of the 30 infants returned to follow-up at 9 months¹⁴. These studies have not reported follow-up beyond 9 months of age so it is difficult to compare our results.

A few studies report follow-up at and beyond 1 year of age. Ariagno et al reported no difference at 1 and 2 years in the Bayley scores between the NIDCAP and control group, however there was a large loss to follow-up, as only 23 of the original 35 infants in the study were tested 13. Kleberg et al showed higher MDI scores in 9 infants who received NIDCAP care as compared to 11 control infants at 12 months; however the PDI scores were not significantly different 11. This study was based on an RCT of 25 infants born < 32 weeks with a need for ventilatory support 24 hours after birth 25. A second follow-up study at 3 years of age based on a non-randomized, historical design trial of 42 infants showed no difference in the developmen-

tal quotients (DQ) according to the Griffiths Developmental Scale between the NIDCAP and control group. They did show a significant difference in mother-child interaction during videotaped structured and free play¹². The preschool outcome of the RCT by Westrup showed no difference in cognition, but a possible positive impact of NIDCAP on behavior and is the only RCT to date to have published longer follow-up data²⁶. They did state that because the recruitment was less than half of the anticipated subjects, their conclusions should be interpreted with caution²⁶. All the above mentioned studies had relatively small sample sizes.

Another approach recommended would be to use qualitative research and benchmarking as well as RCT's, so that not only medical and developmental outcomes will be assessed but also additional information concerning the experience of parents and infants as well as staff when implementing a developmental care program²⁷. Previous studies as well as our study have reported that parents and the nursing team were positive about the NIDCAP approach and felt that it contributed to the wellbeing of the infant ²⁸⁻³¹.

There are a few factors to take into account in our study. The length of stay of the infants in this trial differed widely with previous NIDCAP studies as a result of the Dutch system to transfer infants to regional hospitals once stabilized. Because of this range of days of hospitalization, we examined if the number of days infants had received NIDCAP care influenced neurological and developmental outcomes at 1 and 2 years, but found no interaction effect between length of intervention and follow-up outcome.

Another consideration is the significantly higher incidence of PDA requiring medication or medication and ligation in the infants in the NIDCAP group. When we corrected for incidence of PDA, we found no significant difference in either 1 year neurological outcome (p=0.71) and combined scores (p=0.89) or 2 year neurological outcome (p=0.98) and combined scores (p=0.67).

We conclude that providing NIDCAP to preterm infants born < 32 weeks gestation in a system with regionalized NICU's and early transfer to local hospitals has no effect on their neurodevelopment or growth at 1 and 2 years of age. Perhaps follow-up studies at school age may be able to detect more subtle differences in cognition.

We had hoped that by providing parents with the tools to understand their infant's behavior and how to provide support, they would have been able to continue providing this individual approach when interacting with their infant once transferred out of the NICU, which would then have a continuing effect on their infant. It

appears, based on our results, that both infants and parents require longer periods of ongoing support in order to show any effect.

Recommendations for further research would be to continue the NIDCAP approach in the regional hospitals once infants are transferred to see if the effect would be greater. This however was beyond the scope of our present study. In addition, early intervention programs in which parents are supported once their infant is discharged home may help to build on the support and knowledge parents have received in the NICU and guide them in responding to their infants quickly changing developmental needs.

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